Effective Health Care Program

Comparative Effectiveness Review
Number 41

Noncyclic Chronic Pelvic Pain Therapies for Women: Comparative Effectiveness

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Number 41

Noncyclic Chronic Pelvic Pain Therapies for Women: Comparative Effectiveness

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Noncyclic Chronic Pelvic Pain Therapies for Women: Comparative Effectiveness

Structured Abstract

Objectives. The Vanderbilt Evidence-based Practice Center systematically reviewed evidence on therapies for women age 18 and over with noncyclic chronic pelvic pain (CPP). We focused on the prevalence of conditions thought to occur commonly with CPP; changes in pain, functional status, quality of life, and patient satisfaction resulting from surgical and nonsurgical treatment approaches; harms of nonsurgical approaches; evidence for differences in surgical outcomes if an etiology for CPP is identified postsurgery; and evidence for selecting one intervention over another after an approach fails.

Data Sources. We searched MEDLINE® via PubMed, PsycInfo®, EMBASE Drugs and Pharmacology, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) databases as well as the reference lists of included studies.

Review Methods. We included studies published in English from January 1990 to May 2011. We excluded intervention studies with fewer than 50 adult women with CPP; cross-sectional studies or case series with fewer than 100 women with CPP addressing the prevalence of comorbidities; and studies lacking relevance to CPP treatment.

Results. Of 36 included studies, 18 were randomized controlled trials (RCTs) (2 good, 3 fair, and 13 poor quality); 3 were cohort studies (3 poor quality); and 15 were cross-sectional studies addressing the prevalence of comorbidities (quality varied by comorbidity). The most frequently reported comorbidities were dysmenorrhea, dyspareunia, and irritable bowel syndrome (IBS). Among studies addressing surgical interventions, there was no evidence that laparoscopic utero-sacral nerve ablation (LUNA) is more effective than simple diagnostic laparoscopy and no evidence of benefit of lysis of adhesions. Evidence was insufficient to comment on relief of pain after hysterectomy. Nine studies of nonsurgical approaches assessed hormonal therapies for endometriosis-associated CPP and reported similar effectiveness among active agents. One exception was an RCT comparing raloxifene with placebo, which reported more rapid return of pain in the raloxifene group. Few studies assessed nonhormonal medical or nonpharmacologic management; benefits were reported in single studies of a pelvic physiotherapy approach, botulinum toxin, pelvic ultrasonography, and an integrated management approach. No studies provided evidence relating to a trajectory of care. Reporting of harms data was very limited.

Conclusions. Improved characterization of the targeted condition, intervention, and population in CPP research is necessary to inform treatment choices for this commonly reported entity. A uniform definition of CPP and standardized evaluation of participants are lacking across the literature. Study populations likely vary widely, and studies may be reporting effects from treating symptoms rather than a diagnosed condition. Thus our understanding of potential treatment effects is diluted. Similarly, understanding comorbidity prevalence with CPP is difficult, as conditions may be considered part of the differential diagnosis or a concomitant condition. Among studies addressing treatment effects, little evidence demonstrates the effectiveness of surgical approaches. Studies of nonsurgical approaches typically addressed

hormonal management of endometriosis-related CPP and were not placebo controlled, thus limiting our ability to understand whether hormonal therapies would be beneficial for women with CPP without endometriosis and whether pain relief is due simply to the placebo effect. Some studies reported benefits of other nonsurgical approaches, but nonhormonal and nonpharmacologic management remain understudied.

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Executive Summary

Background

Chronic pelvic pain in women is a commonly occurring and poorly understood condition. Little consensus on the definition of the condition exists—the duration of pelvic pain considered chronic in published studies varies from 3 months to more than 6 months, and the location and pathology of the pain are largely unspecified.[1] The American College of Obstetricians and Gynecologists defines chronic pelvic pain as "noncyclical pain of at least 6 months' duration that appears in locations such as the pelvis, anterior abdominal wall, lower back, or buttocks, and that is serious enough to cause disability or lead to medical care."[2] Noncyclic chronic pelvic pain (CPP) is the focus of this review. Noncyclic CPP excludes chronic pelvic pain that is limited to dysmenorrhea (pain with menstruation), dyspareunia (pain with intercourse), dyschezia (pain with bowel movement), or dysuria (pain with urination).[3,4] Noncyclic CPP is sometimes described simply as "chronic pelvic pain" in the literature because many subdivide chronic pelvic pain into dysmenorrhea, dyspareunia, and nonmenstrual CPP.[2]

For this review, we defined noncyclic CPP as pain that has persisted for more than 3 months, is localized to the anatomic pelvis (lower abdomen below the umbilicus), and is of sufficient severity that it causes the patient to become functionally disabled or to seek medical care. The chronic pelvic pain must always have a noncyclic component; however, there could also be cyclic pain in some individuals. CPP as described throughout this review refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

The causes of CPP are not well understood and may be associated with gynecologic (e.g., endometriosis) and nongynecologic (e.g., irritable bowel syndrome [IBS]) conditions. Diagnosis of an underlying cause is complicated because the pain is rarely associated with a single underlying disorder or contributing factor;[5] Howard outlined more than 60 diseases and conditions associated with CPP.[5] Frequently diagnosed etiologies include endometriosis, adhesions, IBS, and interstitial cystitis (IC)/painful bladder syndrome (PBS);[6] however, a definitive diagnosis is often not made.

Objectives

Population. We focused this review on women age 18 and older with noncyclic or mixed cyclic/noncyclic chronic pelvic pain. Throughout this review, CPP refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

Interventions. Interventions included surgical approaches, such as hysterectomy and laparoscopy, and nonsurgical approaches, including medical management and integrative interventions.

Comparators. Comparators included no treatment, placebo, and comparative interventions or combinations of interventions.

Outcomes. Our outcomes of interest included:

- Pain status (reduction in pain, pain recurrence, subsequent intervention for unresolved or worsening pain)
- Functional status (activities of daily living, sexual functioning)

- Quality of life
- Patient satisfaction with pain management
- Harms or adverse effects of nonsurgical interventions

Key Questions

The Key Questions (KQs) were:

KQ1. Among women who have been diagnosed with noncyclic/mixed cyclic and noncyclic CPP, what is the prevalence of the following comorbidities: dysmenorrhea, major depressive disorder, anxiety disorder, temporomandibular joint pain disorder, fibromyalgia, IBS, interstitial cystitis (IC)/painful bladder syndrome (PBS), complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, and sexual dysfunction?

KQ2. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of surgical interventions on pain status, functional status, satisfaction with care, and quality of life?

KQ3. What is the evidence that surgical outcomes differ if the etiology of noncyclic/mixed cyclic and noncyclic CPP is identified after surgery?

KQ4. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of nonsurgical interventions on pain status, functional status, satisfaction with care, quality of life, and harms?

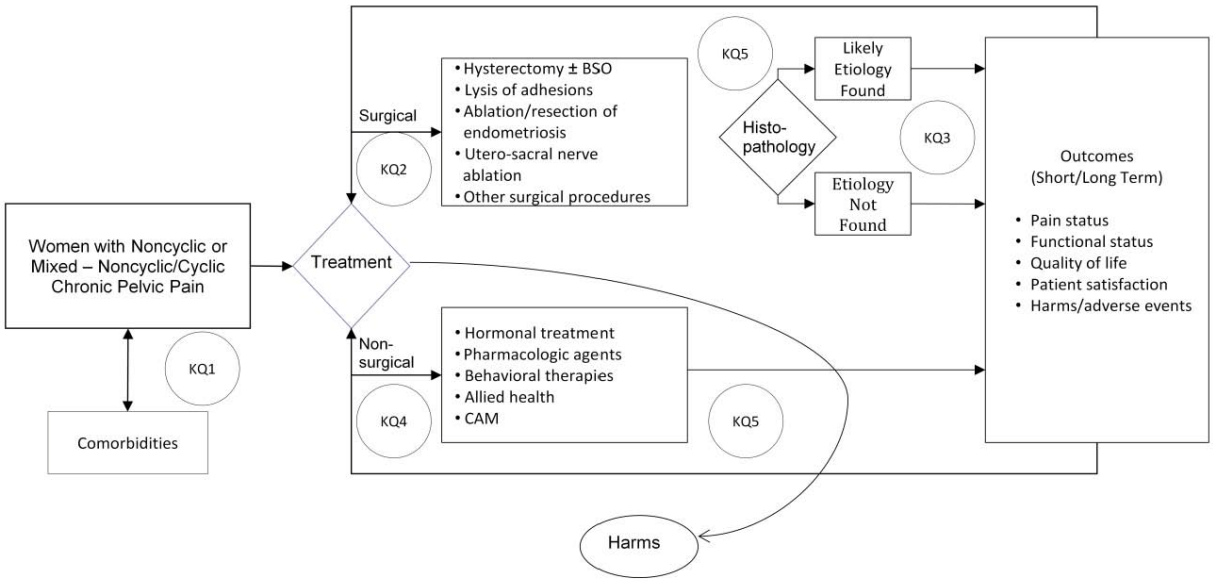
KQ5. What is the evidence for choosing one intervention over another to treat persistent or recurrent noncyclic/mixed cyclic and noncyclic CPP after an initial intervention fails to achieve target outcome(s)?

Analytic Framework

We developed the analytic framework (Figure A) based on clinical expertise and refined it with input from our Key Informants and Technical Expert Panel (TEP) members. The framework summarizes the process by which women with CPP make and modify treatment choices. Treatment choices include surgical or nonsurgical approaches and may lead to outcomes that include changes in pain status (e.g., resolution of pain, continuing pain, continued need for pain medication), patient satisfaction, quality of life, or harms/adverse effects.

Treatment choices may not provide pain relief or improvements in functional status or quality of life, and women with CPP may undergo additional interventions after a treatment approach has failed. In addition, outcomes may vary by diagnosis in those patients receiving a confirmed diagnosis for the etiology of their CPP.

Figure A. Analytic framework for therapies for women with CPP



Abbreviations: BSO = bilateral salpingo-oopherectomy; CAM = complementary and alternative medicine; KQ = key question

Methods

Input From Stakeholders

The topic was nominated in a public process. With Key Informant input, we drafted initial KQs, which the Agency for Healthcare Research and Quality (AHRQ) reviewed and posted to a public Web site for public comment. Using public input, we drafted final KQs, which AHRQ reviewed. We convened a TEP to provide input during the project on issues such as setting inclusion/exclusion criteria and assessing study quality. In addition, the draft report was peer reviewed and available for public comment.

Data Sources and Selection

Data sources. We searched four databases: MEDLINE® via the PubMed interface, PsycINFO (psychology and psychiatry literature), Embase Drugs and Pharmacology, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database. We hand searched reference lists of included articles and recent reviews for additional studies.

Inclusion and exclusion criteria. We excluded studies that:

- Did not include women age 18 and older with noncyclic CPP
- Did not report information pertinent to the KQs
- Were primarily focused on coexisting conditions, cancer pain, or pregnancy-related pain
- Were not published in English
- Were published prior to 1990
- Were not original research
- Were retrospective studies or case series (unless they included ≥100 participants and reported nonsurgical harms or comorbidity data)

We also excluded studies with fewer than 50 total participants if the studies assessed the effects of surgical or nonsurgical interventions, addressed differences in surgical outcomes by etiology, or presented evidence for selecting one intervention over another.

We accepted controlled trials and prospective cohort studies with at least 50 participants with CPP and case series and cross-sectional studies that had at least 100 participants with CPP and addressed nonsurgical harms or the prevalence of comorbidities identified in KQ1.

We did not address harms of surgical interventions in this review, as we felt that the studies meeting our inclusion criteria would necessarily provide only chance evidence of harms of surgical interventions. Most of the surgical interventions used for CPP are deployed in a broader context for other indications; a systematic review of the harms of the procedures would require a different and much larger search than the current review assignment, protocol, and KQs dictated. Reporting only the harms represented in the selected studies meeting our criteria for addressing surgical intervention for CPP would present only a partial picture of potential harms of surgery.

Screening of studies. Two reviewers separately evaluated each abstract. If one reviewer concluded that the article could be eligible, we retained it. Two reviewers independently read the full text of each included article to determine eligibility, with disagreements resolved via third-party adjudication.

Data Extraction and Quality Assessment

Data extraction. All team members entered information into the evidence tables. After initial data extraction, a second team member edited entries for accuracy, completeness, and consistency. In addition to outcomes for treatment effectiveness, we extracted data on harms/adverse effects.

Quality assessment. Two reviewers independently assessed quality, with differences resolved though discussion, review of the publications, and consensus with the team. We rated studies as good, fair, or poor quality and retained poor studies as part of the evidence base discussed in this review. More information about our quality assessment methods is in the full report.

Data Synthesis and Analysis

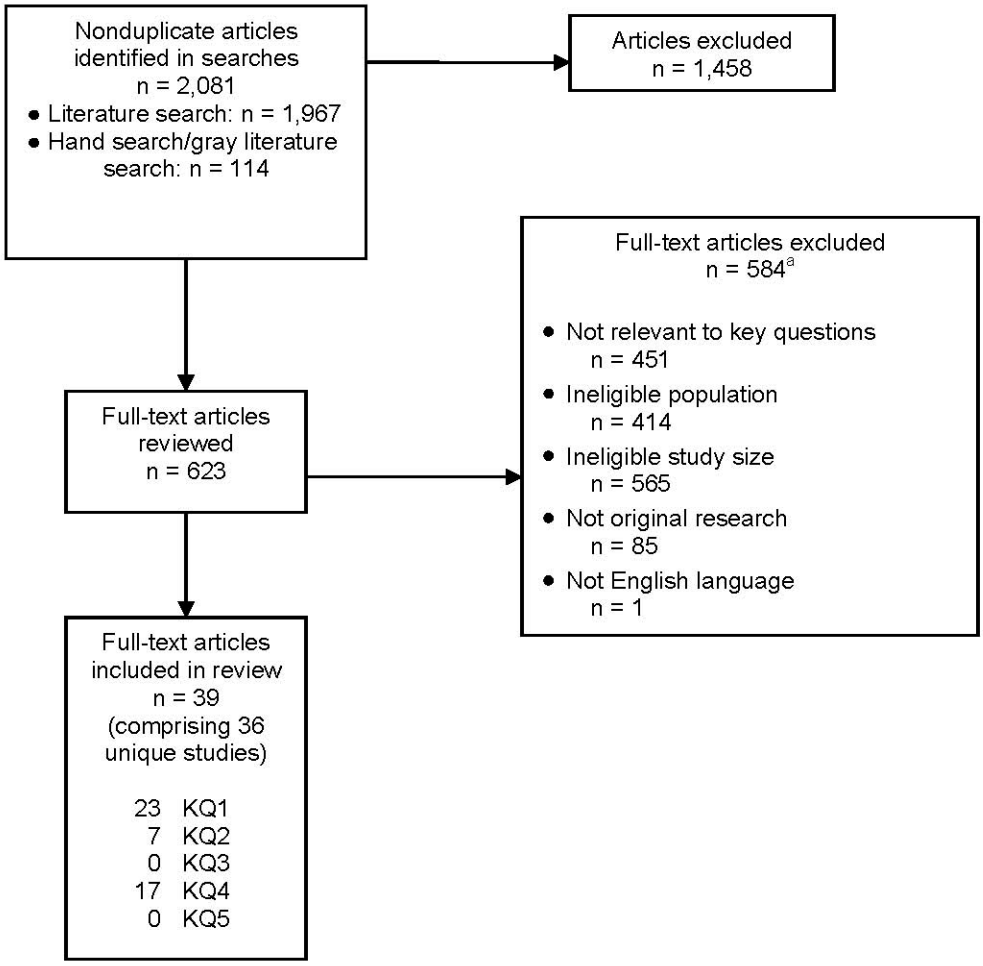
Evidence synthesis. We used summary tables to synthesize studies that included comparison groups and summarized the results qualitatively.

Strength of evidence. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence. Strength of evidence can be regarded as insufficient, low, moderate, or high. It describes the adequacy of the current research, in quantity and quality, and the degree to which the entire body of current research provides a consistent and precise estimate of effect. We established methods for assessing the strength of evidence based on AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews,[7] which is used by Evidence-based Practice Centers.

Results

Our searches retrieved 2,081 nonduplicate citations (Figure B). We reviewed the full text of 623 articles and included 39 articles, comprising 36 unique studies, in the full review. The full report details reasons for exclusion.

Figure B. Disposition of articles located for the review



[a]The total number of articles in the exclusion categories exceeds the number of articles excluded because most of the articles fit into multiple exclusion categories.
Note: KQ = Key Question; n = number.

KQ1: Prevalence of Comorbidities

We identified 23 unique studies addressing the prevalence of comorbidities of interest for this review.[8-31] Dyspareunia (11 studies), dysmenorrhea (12 studies), and IBS (10 studies) were the most frequently reported comorbidities in women with CPP, with rates ranging from 15 to 88 percent for dyspareunia, 4 to 100 percent for dysmenorrhea, and 24 to 39 percent for IBS. Rates for other comorbidities also varied widely, and studies were largely of poor quality. Studies frequently failed to use validated diagnostic criteria and may not have provided an operational definition for a given comorbidity. We did not assess the strength of evidence for studies

addressing this KQ about the prevalence of comorbidities; the strength of evidence evaluation was designed for assessing effectiveness of interventions and is thus not applicable.

KQ2: Outcomes of Surgical Interventions for CPP

We located seven unique studies addressing surgical interventions for CPP: five randomized controlled trials (RCTs)[9,13,32-34] and two prospective cohort studies.[16,35] All RCTs were conducted in Europe or New Zealand, and all prospective cohort studies were conducted in the United States. Three studies compared surgical with nonsurgical or medical approaches for CPP treatment.[13,16,35] Three studies compared an active surgical technique, either laparoscopic utero-sacral nerve ablation (LUNA) or adhesiolysis, with surgical control (diagnostic laparoscopy).[9,32,33] One study directly compared two surgical techniques (LUNA vs. utero-sacral ligament resection).[34]

One good-quality RCT evaluated laparoscopic lysis of intraabdominal adhesions[32] and reported no improvement in pain scores over diagnostic laparoscopy. Similarly, no studies reported benefit of LUNA compared with simple diagnostic laparoscopy. One poor-quality study evaluated hysterectomy for CPP pain relief compared with nonsurgical management and reported greater patient satisfaction in the hysterectomy group, although data for women with noncyclic CPP alone are difficult to isolate and participants self-selected surgical or nonsurgical intervention. We assessed the strength of evidence for all surgical interventions except LUNA and lysis of adhesions as insufficient. With two RCTs, one of fair and one of poor quality, we assessed the strength of evidence as low for the lack of efficacy of LUNA to improve pain status over diagnostic laparoscopy alone and low for the effects of adhesiolysis on pain and quality of life (one good-quality RCT).

KQ3: Evidence for Differences in Surgical Outcomes by Etiology

We did not locate any studies addressing this question.

KQ4: Outcomes of Nonsurgical Interventions for CPP

We located 17 unique studies addressing nonsurgical interventions.[8,10-16,35-44] Fourteen of these studies were RCTs, and three were prospective cohort studies. Most RCTs investigated hormone-based treatments for CPP. One evaluated antineuropathic agents, and another evaluated the neuromuscular blocking agent botulinum toxin A. Four RCTs examined nonpharmacologic therapies—pelvic floor physical therapy, photographic-enhanced counseling after surgery, pelvic ultrasonography plus counseling, and a standard versus integrated treatment approach. Cohort studies evaluated outcomes of hormone-based therapy and assessed nonsurgical compared with surgical approaches.[16,35]

Twelve of the 17 studies were performed in Europe, with the remainder conducted in the United States and Australia. Most were conducted at academic institutions. Only one study was rated as good quality,[14,15] three were fair quality,[10,36,37] and the balance were poor.[8,11-13,16,35,38-42,44]

Of the nine studies addressing hormonal treatments for endometriosis-associated CPP, all reported equal effectiveness among active agents investigated, with the exception of a placebo-controlled trial of raloxifene. This RCT reported more rapid return of pain in the raloxifene group, and the trial was stopped early.[14] The few (n = 3) placebo-controlled studies were of fair

or good quality and reported larger size of effect (60- to 70-percent range) than studies comparing two active agents. An RCT of botulinum toxin[36] reported some improvements in pain scores. An RCT of gabapentin plus amitriptyline or either agent alone[8] reported some improvements in pain scores.

Few studies addressed nonhormonal or nonpharmacologic management. One fair-quality RCT of a pelvic physiotherapy technique reported improvement in pain scores in the treatment group; one poor-quality study reported no benefit from postoperative counseling augmented with displaying operative photographs while discussing findings with participants; and two poor-quality trials reported some benefits from an integrated treatment approach and ultrasonography plus counseling. Reporting of harms data was very limited among trials; among placebo-controlled trials, harms were more frequent in the placebo arms.

We assessed the strength of evidence for all nonsurgical interventions as insufficient, with the exception of low strength of evidence for the effects of raloxifene and depot leuprolide on pain status, both assessed in good- or fair-quality placebo-controlled trials.

KQ5: Evidence for Selecting One Intervention Over Another

We did not locate any studies addressing this question.

Discussion

Key Findings

The prevalence rates for the comorbidities we examined showed significant variation. Frequently no operational definition or diagnostic criteria for comorbidities were provided. When definitions or criteria were available, they were rarely consistent across studies. Diagnostic methods varied and included patient report of symptoms, patient report that she was given the diagnosis by a health care provider, evaluation by a health care provider, and objective diagnostic criteria.

Given that many women with CPP are treated with invasive surgical procedures, remarkably little evidence exists that supports a surgical approach to the treatment of CPP. We identified and reviewed two articles comparing nonspecific surgical approaches with nonsurgical approaches,[13,16] one study addressing hysterectomy specifically,[35] one study evaluating laparoscopic adhesiolysis at the time of diagnostic laparoscopy,[32] two articles evaluating LUNA compared with diagnostic laparoscopy,[9,33] and one paper directly comparing LUNA and utero-sacral ligament resection.[34]

In none of the studies with comparison data was surgery in general or any specific surgical technique better than either nonsurgical intervention or the comparator technique in improving pain status in patients. Given the limited number of studies addressing heterogeneous surgical interventions and with so few being of good or fair quality, it is difficult to summarize the evidence for the effect of surgical interventions on any of the outcomes proposed. Although no surgical technique emerged as a superior method for surgical intervention, the evidence is insufficient to conclude that surgical intervention is either effective or ineffective for the treatment of CPP.

Studies of nonsurgical interventions were similarly subject to significant variation in study design and interventions addressed, which detracts from the ability to apply these study results to a broader population or provide concrete estimates for clinical effect. We saw this variation in

(1) definition of pelvic pain, (2) patient populations, (3) outcome measures, (4) interventions, (5) timing of outcome measures and participant followup, and (6) comparators.

Only 4 of the 17 studies included in this section had a placebo arm for comparison. All of the other studies employed active treatments as comparators. This lack of placebo comparison detracts from the active head-to-head trials because no initial validation of effect has been made. It could easily be assumed that each active intervention works simply by placebo effect, and this could explain why each hormone-based treatment seems equally effective. Many studies also included a population of patients with endometriosis; few studies include participants with CPP due to another etiology. We found the evidence insufficient to assess the effectiveness of any nonsurgical therapies for CPP.

In sum, we found that:

- Noncyclic CPP was variably defined, and diagnostic approaches were rarely reported.
- Disproportionately few studies addressed noncyclic CPP, given the prevalence of the condition.
- Comorbidities were similarly variably defined and frequently not diagnosed using standardized criteria.
- Dysmenorrhea, dyspareunia, and IBS were the most frequently reported comorbidities in the literature meeting our criteria.
- Intervention studies overall included a limited number of participants and typically included only short-term followup.
- Few studies of surgical approaches examined the same approach; none used a placebo control.
- No surgical approach was superior to a nonsurgical approach or comparative surgical approach.
- The strength of the evidence for surgical approaches overall was insufficient to low.
- Most studies of nonsurgical approaches meeting our criteria addressed hormonal approaches and included women with endometriosis-associated CPP.
- Few studies of nonsurgical interventions were placebo controlled, and few addressed nonpharmacologic approaches; strength of evidence was insufficient to low.
- Hormonal studies reported equal effectiveness among the active agents investigated, with the exception of a placebo-controlled trial of raloxifene reporting more rapid return of pain in the raloxifene group.
- Studies of nonhormonal and nonpharmacologic agents reported some positive effects on pain status.
- Few nonsurgical studies reported harms.
- No studies addressed evidence for differences in outcomes by etiology or evidence for selecting one intervention over another if an intervention failed.
- Studies overall addressed a heterogeneous group of interventions and likely had significant variability across populations.

Applicability of Evidence

We set inclusion criteria intended to identify studies with applicability to women with noncyclic or mixed chronic pelvic pain. Studies differed considerably in terms of study populations, interventions, and outcome measures. Many of the studies were noncomparative.

Lack of direct comparisons of treatment options further hinders our ability to know what findings will best extend to a specific patient or to decide about care protocols within clinics or health systems. Overall the data that are available have fair to good applicability to women with noncyclic/mixed CPP in settings within the United States, although many studies were conducted in specialty treatment centers. In the nonsurgical literature, many studies included women with endometriosis-associated CPP.

Gaps in the Evidence and Methodologic Concerns

Despite a prevalence of noncyclic CPP rivaling that of widely studied conditions such as asthma,[45] little research assessing therapies exists. While there are many publications regarding pelvic pain in general, there are relatively few addressing noncyclic CPP, and of those, few were evaluated as providing high-quality evidence. Eighteen of 36 studies meeting our criteria were RCTs; however, only 4 were placebo controlled.[10,14,36,44] Some surgical studies compared a surgical approach with diagnostic laparoscopy or compared surgical with nonsurgical management. In the nonsurgical literature, most studies compared active agents with active agents, and a number addressed hormonal therapies for endometriosis-associated CPP.

The quality of studies providing data about the prevalence of comorbidities varied by comorbidity, with the bulk of studies assessed as poor quality. Among studies reporting data on the prevalence of comorbidities, the range of prevalence estimates tended to be more narrow in studies that employed validated diagnostic criteria (e.g., Rome criteria for IBS), and studies using validated criteria were of higher quality.

The literature overall is muddled by a lack of standardized definitions for CPP and unclear diagnostic evaluation, which make it difficult to determine whether studies truly include women with CPP. Systematic reviews of the effectiveness of interventions for a symptom or syndrome are fraught with difficulty; the lack of specific diagnostic criteria results in heterogeneity within and across studies. In order to effectively treat any chronic pain, one would assume that a thorough diagnostic investigation would first take place. For many conditions, this typically follows some predetermined algorithm. However, for CPP, no such algorithm exists. Thus, in each study (and likely for each individual practitioner), the patient is approached in a variable manner, and some possible diagnoses may or may not be ruled out before treatment begins. There is no assurance that the treated condition is the causative condition. Treating a symptom means that a study group will likely have a variety of etiologies; some may be amenable to the intervention under study, others may not. Compared with an intervention trial that follows established diagnostic criteria and targets an identified condition, dilution of potential benefits and harms may occur.

Future Research

Research addressing therapies for CPP is largely composed of trials of active agents or approaches, with little placebo-controlled research and little evidence of thorough identification of patient characteristics and potential etiologies of CPP. Notably, we did not locate any studies providing evidence that surgical outcomes differ if the etiology of CPP is identified after surgery (KQ3). We did not locate any studies providing evidence for choosing one intervention over another to treat persistent or recurrent CPP after an initial intervention failed to achieve the target outcome(s) (KQ5). Future research needs include:

- Developing our understanding of the etiology of CPP, including analysis of the distribution of underlying causes (including iatrogenic causes); identification of

subgroups at risk of developing CPP; understanding of myofascial dysfunction and visceral hyperplasia in CPP; and assessing the effects of sex steroid hormone levels on pain perception
- Understanding the impact of CPP on health care costs and resource utilization
- Standardizing terminology and definitions in CPP research and research investigating related comorbidities
- Formalizing and standardizing diagnostic approaches to promote clear delineation of patient populations in CPP research
- Standardizing outcome measures
- Investigating nonsurgical and nonpharmacologic approaches to CPP treatment, including acupuncture, psychotherapy, cognitive behavioral therapy, and patient education
- Assessing nonhormonal pharmacologic therapies
- Comparing surgical and nonsurgical approaches in prospective studies
- Investigating the benefit of surgical approaches, including understanding patient populations likely to benefit, timing of intervention, and potential therapeutic benefits of diagnostic laparoscopy
- Employing placebo controls and improving methodologic rigor in studies.

Conclusions

Improved characterization of the targeted condition, intervention, and population in CPP research is necessary to inform treatment choices for this commonly reported entity. A uniform definition of CPP and standardized evaluation of participants are lacking across the literature; study populations are likely to vary widely, and studies may be reporting effects from treating symptoms rather than a diagnosed condition. Thus our understanding of potential treatment effects is diluted. Similarly, understanding comorbidity prevalence with CPP is difficult, as a condition may be considered part of the differential diagnosis or a concomitant condition.

Among studies addressing treatment effects, little evidence demonstrates the effectiveness of surgical approaches. Despite numerous surgical techniques used extensively in treating CPP, few studies included more than 50 participants, and few were considered high quality. All of the studies with comparison data failed to demonstrate that surgery in general or any specific surgical technique was more efficacious than either nonsurgical intervention or the comparator technique in improving pain status in patients. No surgical technique was superior, and the evidence to conclude that surgical intervention is either effective or ineffective for the treatment of CPP is insufficient.

Studies of nonsurgical approaches typically addressed hormonal management of endometriosis-related CPP and were not placebo controlled, thus limiting our ability to understand whether hormonal therapies would be beneficial for women with CPP without endometriosis and whether pain relief reported is due simply to the placebo effect. Some studies reported benefits of other nonsurgical approaches, but nonhormonal and nonpharmacologic management remains understudied.

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Introduction

Overview

Chronic pelvic pain is defined by the American College of Obstetrics and Gynecology as intermittent or constant pain over at least 6 months in the lower abdomen or pelvic area. Pain may occur in the lower abdomen or pelvis, including the abdominal wall at or below the umbilicus, lumbosacral back, or the buttocks. The pain is sufficiently severe that it impedes activities of daily living or causes functional disability or leads to medical care.[1-5] In practice and in current research, the diagnosis of CPP may be made as early as 3 months after onset of pain.[6]

Noncyclic chronic pelvic pain (CPP) is the focus of this review. Noncyclic CPP excludes chronic pelvic pain that is limited to dysmenorrhea (pain with menstruation), or dyspareunia (pain with intercourse), dyschezia (pain with bowel movement), or dysuria (pain with urination).[2,3] Noncyclic CPP is sometimes described simply as "chronic pelvic pain" in the literature, since many subdivide chronic pelvic pain into dysmenorrhea, dyspareunia, and nonmenstrual CPP.[1]

For this review, we defined noncyclic CPP as pain that has persisted for more than 3 months, is localized to the anatomic pelvis (lower abdomen below the umbilicus), and is of sufficient severity that it causes the patient to become functionally disabled or to seek medical care. The chronic pelvic pain must always have a noncyclic component; however, there could also be cyclic pain in some individuals. CPP as described throughout this review refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

Prevalence

Given the lack of established definitions for CPP, prevalence estimates vary. The prevalence of CPP was estimated to range from 4 percent to 43 percent in a systematic review of worldwide prevalence including 18 studies of variable quality.[7] Across 3 studies with representative samples, the prevalence range of CPP was 2 percent to 29 percent.[7] One of these studies, conducted in Australia, estimated a point prevalence of 3.8 percent in women aged 15 to 73, a prevalence comparable with that of asthma (3.7 percent) and chronic back pain (4.1 percent).[8]

Health Impact

CPP in women is common and difficult to treat.[4,9] The diagnosis of CPP is often delayed, leading to frustration and dissatisfaction for both the woman and her clinician. Treatments for CPP may often yield unsatisfactory results.[10]

CPP, both cyclic and noncyclic, accounts for about 1 in 10 outpatient gynecology visits and is the indication for an estimated 15 percent to 40 percent of laparoscopies and 12 percent of hysterectomies in the United States.[9,11] In a Gallup poll of 5,325 women in the United States, 557 indicated they had CPP within the previous month. Over half of these respondents noted that CPP interfered with mood and energy to complete daily activities and 15 percent reported work absenteeism.[10]

An estimated $1.2 billion per year is spent on outpatient management of CPP in the United States (adjusted for inflation from $880 million in 1996). In addition, the total indirect cost due to time lost from work is estimated to be $760 million per year (adjusted for inflation from $555 million in 1996).[10] CPP carries a significant quality of life burden in terms of sexual functioning, depression, fatigue, and physical limitations and disability associated with pain.[10]

An individual woman's experience of CPP is inevitably affected by a combination of physical, psychological and social factors, and the condition's impact on quality of life can be substantial. Women with CPP tend to report lower general physical health scores than women without pain.[12-15] Women with CPP describe loss, social isolation, and effects on relationships and have a high incidence of comorbidity, sleep disturbance, and fatigue. A community based study found that 41 percent of women with CPP had not seen a health care provider in the previous year,[12,13] suggesting that most women are coping outside the system.

Etiology

The causes of CPP are poorly understood, and diagnosis of an underlying cause is complicated because the pain is rarely associated with a single underlying disorder or contributing factor;[4] Howard outlined more than 60 diseases and conditions associated with CPP.[4] CPP is frequently reported in the presence of both gynecologic and nongynecologic diagnoses, including endometriosis, intra-abdominal adhesions, myofascial pain disorders, irritable bowel syndrome (IBS) and interstitial cystitis (IC)/painful bladder syndrome (PBS).[1,5,16-27]

Empirically established relationships among putative causes of CPP and CPP are variable. For example, adhesions are often thought to be a frequent cause of pelvic pain; in fact there is little difference in the prevalence of adhesions found in women with and without CPP.[22,24] It is thus unknown whether associated factors and conditions are etiologic (causal) in nature or are comorbidities with distinct etiologies from the CPP. Regardless, from the patient perspective, the presence of one or more conditions may coalesce in a common presentation of pain. For the purposes of treatment and research in this area, identifying clinical comorbidities that are in fact associated with a CPP diagnosis may affect clinical practice by guiding decisions about diagnostic and treatment processes.

Comorbidities

A number of conditions are reported along with CPP in the literature; however, understanding the prevalence of comorbidities and their contributions to overall pain is complex. Some research suggests that multiple comorbidities may intensify pain and dysfunction.[28] Research investigating comorbidities may seek to delineate more clearly the population studied or to ensure that individuals with multiple pain sites are categorized appropriately (e.g., CPP compared with fibromyalgia). Comorbidity research in CPP may also strive to define conditions that may be secondary endpoints, such as IBS, or to recognize conditions that may be important contributors to pain, such as depression. Comorbidity research is also complicated by the lack of standardized definitions or consistent diagnostic criteria for many conditions.

Comorbidities frequently associated with CPP include IBS, with studies reporting IBS prevalence of 35 to 65 percent in women with CPP.[29-31] As many as 85 percent of women with CPP meet some criteria for IC or PBS.[11,32] Prevalence estimates for endometriosis in women with CPP range from 33 to 70 percent.[33,34] Depression and sleep disorders are also commonly reported among women with CPP.[35]

CPP has also been suggested to be associated with numerous general, gynecologic, and obstetric factors including abuse (childhood physical or sexual abuse, lifetime sexual abuse); psychological morbidity (anxiety, depression, sleep disorders, hysteria, somatization, drug abuse, alcohol abuse); obstetric history (previous miscarriage, cesarean birth); gynecologic history (longer menstrual flow, presence of endometriosis, clinically suspected pelvic inflammatory

disease, pelvic adhesions).[7] Anxiety, depression, sexual problems, and sleep disorders may also be common in CPP in women.[7,35,36]

The relationships between CPP and sexual or physical abuse are complex. Many studies reporting such associations are cross-sectional and performed in settings of secondary and tertiary care.[37,38] In these selected populations, some studies reported that women with chronic pain in general are more likely to report physical or sexual abuse as children than pain-free women. Those who experienced CPP were more likely to report past sexual abuse than women with another type of chronic pain;[39-43]child sexual abuse may be a correlate of continuing abuse and concomitant development of depression, anxiety or somatization, which then predispose the individual to the development or presentation of CPP.[39,40,44]

Evaluation of CPP

Evaluation of CPP and definitive diagnosis of the cause are complex. Indeed, one retrospective study from the United Kingdom found that more than 25 percent of women with CPP never received a definitive diagnosis after nearly 4 years of follow-up.[8,45] A thorough patient evaluation including pain history and pain mapping is a critical step in determining the potential etiology and an initial therapeutic course and in establishing a rapport between the clinician and patient.[46-48] The experience of pain will inevitably be affected by physical, psychological and social factors. Thus CPP may also be viewed from a biopsychosocial perspective, which considers the contributions of organic pathology, patient beliefs, coping skills, social interactions, and overlapping conditions to the experience of pain.[49]

Surgical approaches to evaluation include laparoscopy. CPP is the reported indication for at least 40 percent of diagnostic and therapeutic laparoscopic procedures in the United States.[4,50]Endometriosis, pelvic adhesions, chronic pelvic inflammatory disease, and ovarian cysts are the diagnoses most commonly made by laparoscopy in patients with a preoperative diagnosis of CPP;[4,7,22] however, at diagnostic laparoscopy, a substantial proportion of women with CPP (24 to 55 percent) have no obvious pathological cause for their pain.[22,51] Even when pathology is found, it may not be causing the CPP, and a definitive cause and diagnosis are often not determined.

Interventions

Empirical treatment, or treatment based on clinician experience and observation as the basis for decision-making, rather than systematic logic or solid evidence, for CPP as a symptom is increasingly recommended as standard initial management.[1,52,53] For example, current guidelines from the American College of Obstetricians and Gynecologists include an empirical trial of gonadotropin releasing hormone (GnRH) agonists for women who are suspected to have CPP and endometriosis and do not desire a definitive diagnosis or wish to defer surgical investigation.[1]

A range of therapeutic interventions are used in clinical practice. Pharmacologic therapies include narcotic and nonnarcotic analgesics; antineuropathics; serotonin reuptake inhibitors; botulinum A toxin injections; and hormonal therapies such as cyclic combined hormonal contraceptives, continuous combined hormonal contraceptives, progestogens, GnRH, and aromatase inhibitors.[1] Surgical interventions, which may be performed laparoscopically or in open surgical procedures, include hysterectomy (with or without oophorectomy or salpingo-oophorectomy), utero-sacral nerve ablation, presacral neurectomy, lysis of adhesions, and utero-

sacral ligament resection. CPP (both cyclic and noncyclic) has been listed as the principal preoperative indication for 10 percent to 18 percent of hysterectomies in the United States.[9,54-61]

Other therapeutic interventions used in clinical practice include behavioral therapies such as biofeedback, psychotherapy, cognitive behavioral therapy, and support groups. Among allied health approaches, physical therapy, dietary modification, and exercise therapy have been used to treat CPP. Complementary and alternative modalities include hypnosis, herbal medicine, massage, acupuncture, meditation, and stress-reduction approaches. A recent Cochrane review of 14 RCTs of interventions for CPP (excluding studies of patients with pain "known to be caused by" endometriosis, primary dysmenorrhea [period pain with onset at menarche], pain due to active chronic pelvic inflammatory disease, or irritable bowel syndrome)[2] noted that the range of effective therapies for CPP is limited and that recommendations for their use are based largely on single studies. A recent narrative review[62] similarly concluded that few treatment modalities have demonstrated benefit for relieving CPP symptoms.

Summary

CPP is a common and broadly defined condition. Multiple interventions are used empirically in clinical practice to manage potential etiologies and to treat pain symptoms. The condition is frequently complicated by comorbidities, including depression, anxiety, IBS, and idiopathic pain disorders, and treatment must target symptoms across a spectrum of conditions. Existing literature cites a range of treatment options for women with CPP, many of which have not been tested in rigorous studies.

Scope and Key Questions

Scope of the Report

Evidence reviews of therapeutics seek to identify and systematically summarize objective information about the evidence related to factors including the:

- Effectiveness of specific, well-defined treatments
- Relative benefit of one treatment over another
- Common side effects and serious risks of a treatment.

We focused this review on therapies for women over the age of 18 with noncyclic or mixed cyclic/noncyclic chronic pelvic pain. Throughout this review, CPP refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

Key Questions

We have synthesized evidence in the published literature to address these Key Questions (KQs):

KQ1. Among women who have been diagnosed with noncyclic/mixed cyclic and noncyclic CPP, what is the prevalence of the following comorbidities: dysmenorrhea, major depressive disorder, anxiety disorder, temporomandibular joint pain disorder, fibromyalgia, IBS, IC/PBS, complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, and sexual dysfunction?

KQ2. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of surgical interventions on pain status, functional status, satisfaction with care, and quality of life?

KQ3. What is the evidence that surgical outcomes differ if the etiology of noncyclic/mixed cyclic and noncyclic CPP is identified after surgery?

KQ4. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of nonsurgical interventions on pain status, functional status, satisfaction with care, quality of life, and harms?

KQ5. What is the evidence for choosing one intervention over another to treat persistent or recurrent noncyclic/mixed cyclic and noncyclic CPP after an initial intervention fails to achieve target outcome(s)?

Organization of This Evidence Report

The Methods section describes our processes including our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and our method for extraction of data into evidence tables and compiling evidence. We also describe the approach to grading of the quality of the literature and to evaluating the strength of the body of evidence.

The Results sections presents the findings of the evidence report, synthesizing them by KQ and outcomes reported. We report the number and type of studies identified and we differentiate between total numbers of publications and unique studies. In KQ1, we discuss the prevalence of selected comorbidities. In KQs 2 and 4, we emphasize the effect of treatment on pain and functional status, quality of life, and patient satisfaction. KQs 3 and 5 describe evidence for differences in surgical outcomes when an etiology for CPP is identified after surgery and for defining a treatment trajectory or pathway once an intervention for CPP is not successful.

The final section of the report discusses key findings and expands on methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research in CPP.

The report includes a number of appendixes to provide further detail on our methods and the studies assessed. The appendixes are as follows:

- Appendix A: Search Strategy
- Appendix B: List of Excluded Studies
- Appendix C: Evidence Tables
- Appendix D: Data Extraction Forms
- Appendix E: Quality of the Literature
- Appendix F: Applicability Summary Tables
- Appendix G: Ongoing Trials of Therapies for CPP in Women.

We also include a list of abbreviations and acronyms at the end of the report.

Uses of This Report

This evidence report addresses the KQs outlined previously using methods described in the report to conduct a systematic review of published literature. We anticipate that the report will be of value to clinicians who treat women with CPP, including gynecologists and other physicians

who provide gynecologic care, nurses and advanced practice nurses, psychologists and psychiatrists, physical therapists and allied health professionals.

In addition, this review will be of use to the National Institutes of Health, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration–all of which have offices or bureaus devoted to women's health issues. This report can bring practitioners up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of therapeutic options for the management of CPP. It will be of interest to women affected by CPP and their families because of the high prevalence of CPP, significant personal costs associated with it, and the recurring need for women and their health care providers to make the best possible decisions among numerous options.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to understand best approaches to therapies for women with CPP.

Methods

Topic Development and Refinement

The topic for this report was nominated in a public process. We drafted the initial Key Questions (KQ) and analytic framework and refined them with input from key informants. After review from the Agency for Healthcare Research and Quality (AHRQ), the questions and framework were posted to a public Web site. The public was invited to comment on these questions.

After reviewing the public commentary, we drafted final KQs and submitted them to AHRQ for review. We identified technical experts on the topic of chronic pelvic pain in women in the fields of gynecology and women's health to provide assistance during the project. The Technical Expert Panel (TEP) contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included 5 members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress. TEP members participated in conference calls and discussions through e-mail to:

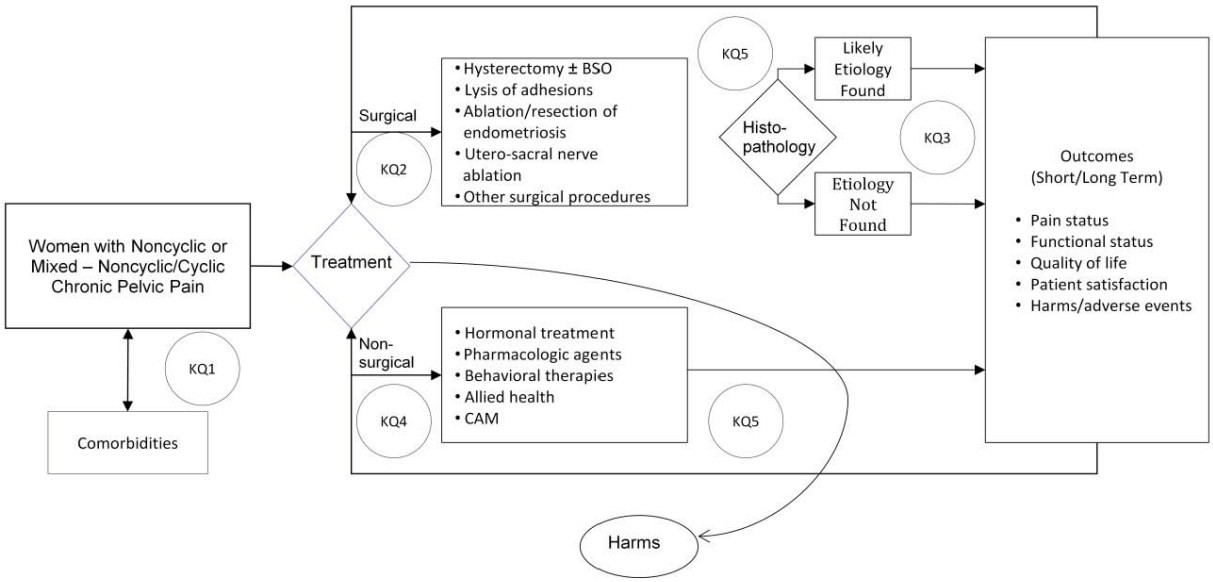
- Refine the analytic framework and KQs at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria;
- Provide input on assessing the quality of the literature.

Analytic Framework

We developed the analytic framework (Figure 1) based on clinical expertise and refined it with input from our key informants and TEP members. The framework summarizes the process by which women with noncyclic chronic pelvic pain (CPP) make and modify treatment choices. Treatment choices include surgical or nonsurgical approaches and may lead to outcomes including changes in pain status (e.g., resolution of pain, continuing pain, continued need for pain medication), patient satisfaction, quality of life, or harms/adverse effects.

Treatment choices may also not provide pain relief or improvements in functional status or quality of life, and women with CPP may undergo additional interventions after a treatment approach has failed. In addition, outcomes may vary by diagnosis in those patients receiving a confirmed diagnosis for the etiology of their CPP.

Figure 1. Analytic framework



Abbreviations: BSO = bilateral salpingo-oopherectomy; CAM = complementary and alternative medicine; KQ = key question

Literature Search Strategy

Databases

We employed search strategies provided in Appendix A to retrieve research on the treatment of CPP in women. Our primary literature search employed 4 databases: MEDLINE® via the PubMed interface, PsycINFO (psychology and psychiatry literature), EMBASE Drugs and Pharmacology, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database. Our search strategies used a combination of subject heading terms appropriate for each database and key words relevant to CPP (e.g., chronic pelvic pain, pelvic pain). We limited searches to the English language and literature published since 1990, when laparoscopic techniques became more widely used.

We also manually searched the reference lists of included studies and of recent narrative and systematic reviews and meta-analyses addressing CPP. We also invited TEP members to provide additional citations.

Grey Literature

The AHRQ Scientific Resource Center also searched for information on the following specific medications used to treat CPP. We requested grey literature information on these drugs and devices as they are either commonly used and have a number of known side effects or are beginning to be used in the CPP population and have not yet been well-reported in the published literature (e.g., aromatase inhibitors):

- Medroxyprogesterone
- Gonadotropin releasing hormone (GnRH) agonists (with or without add-back estrogen therapy including buserelin, goserelin, leuprolide, and nafarelin)

- Selective progesterone receptor modulators (SERMs) (mifepristone and ulipristal acetate);
- Selective estrogen receptor modulators (tibolone, ranitidine, clomiphene, and tamoxifen);
- Aromatase inhibitors (anastrozole and letrozole); and
- Transcutaneous electrical nerve stimulation (TENS).

The Scientific Resource Center sought grey literature in resources including the websites of the US Food and Drug Administration and Health Canada and clinical trials registries such as ClinicalTrials.gov. We also gave manufacturers of these medications and devices an opportunity to provide additional information.

Ongoing Research

To examine the direction of ongoing and recently completed research, we also searched the ClinialTrials.gov and European Union Clinical Trials Register for CPP intervention studies.

Search Terms

Controlled vocabulary terms served as the foundation of our literature search in each database, complemented by additional keyword phrases. We also employed indexing terms when possible within each of the databases to exclude undesired publication types (e.g., reviews, case reports, news), items from non-peer-reviewed journals, and items published in languages other than English.

Our literature searches were executed between September 2010 and May 2011. Appendix A provides our search terms and the yield from each database. We imported all citations into an electronic database created using EndNote. Our search for ongoing research was conducted in July 2011 using the key words “chronic pelvic pain” in each trial registry and limiting to studies in process.

Process for Study Selection

For this review, the relevant population for all KQ was adult women (≥ age 18) with noncyclic or mixed cyclic/noncyclic CPP, which we defined as pain that has persisted for more than 3 months, is localized to the anatomic pelvis (lower abdomen below the umbilicus), and is of sufficient severity that it causes the patient to become functionally disabled or to seek medical care. Pain may sometimes occur in a cyclic pattern; however, a noncyclic component is always present. CPP as described throughout this review refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

Inclusion and Exclusion Criteria

We developed criteria for inclusion and exclusion based on the patient populations, interventions, outcome measures, and types of evidence specified in the KQs and in consultation with the TEP. Table 1 summarizes criteria.

Table 1. Inclusion and exclusion criteria

Category	Criteria
Study population	Adult women (≥18 years of age) with noncyclic or mixed cyclic/noncyclic chronic pelvic pain undergoing surgical or nonsurgical treatment
Time period	1990–May 3, 2011
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs • Controlled trials, prospective cohort studies with N ≥ 50, cross-sectional studies • Case series with N ≥ 100 and harms or prevalence data relevant to the KQs Other criteria • Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results • Patient populations must include adult women (≥18 years of age) being treated for CPP; studies with a primary focus on coexisting conditions (vulvodynia, irritable bowel syndrome, etc.) or on cancer pain or pregnancy-related pain will be excluded • Studies must include at least one outcome measure of an outcome listed in the PICOTS • Studies must address one or more of the following for CPP: o Treatment modality aimed at modifying CPP symptoms o Short- and long-term outcomes (including nonsurgical harms) related to treatment for symptoms of CPP • Studies must include extractable data on relevant outcomes • Sample sizes must be appropriate for the study question addressed in the paper

Abbreviations: CPP = noncyclic chronic pelvic pain; KQ = Key Question; N = number; PICOTS = population, intervention, comparison, outcomes, timing, setting.

Study Population

Studies needed to provide adequate information to ensure that participants fell within the target age range and pain criteria. For studies with populations including women under age 18, we retained the study if we could infer that at least 80 percent of the study participants were over the age of 18. Similarly, some studies included women with cyclic chronic pelvic pain and women with noncyclic chronic pelvic pain. We retained studies with participants with both cyclic and noncyclic/mixed chronic pelvic pain if at least 80 percent of the population was composed of women with noncyclic/mixed chronic pelvic pain.

We also applied this criterion to studies including both women and men, retaining studies that included men if the study population was composed of at least 80 percent women with CPP. We attempted to extract data only on the population of interest (adult women with noncyclic/mixed CPP) where possible. We chose the figure of 80 percent as we considered studies in which a majority of participants were within our target age range (18 and older), or had noncyclic CPP, or included a low proportion of men as providing data applicable to the population of adult women with noncyclic CPP.

The inclusion in the study population of fewer than 20 percent of participants with characteristics outside our inclusion criteria of the review may introduce bias in the results, but not to such a degree that the results would not be useful. As appropriate, we note in our discussion of studies that results apply to a heterogeneous age range or pain group or include data from some male participants.

Sample Size

We excluded studies that included fewer than 50 total participants for studies addressing KQs 2 through 5. We considered the following factors in choosing this study size:

- Prevalence of noncyclic CPP (Prevalence varies by population; to maximize acceptable study size, we set prevalence at 100 percent.)
- Loss to followup (Loss varies by study; to maximize acceptable sample size, we assumed 0 percent.)
- Placebo effect (Placebo effects are known to be from 30 to 50 percent in chronic pain studies.[63-67])
- Type I error, alpha level, or p value (We set at a standard of 5 percent.)
- Desired statistical power level (We set at a standard of 0.80.)
- Statistic (We used the two-tailed z-test and the t-test for sample size.)
- Clinical effect size anticipated or clinically relevant reduction in pain (We considered 30 percent as a minimum. We selected a target of 30 percent based on published recommendations that propose that reductions in chronic pain intensity of at least 30 percent reflect moderate clinically important differences.[68])
- Sample size
    - Considering a null hypothesis of effect size of 30 percent, a study would need 176 subjects per group; a total sample size of 352 would be the smallest acceptable.
    - Considering a null hypothesis of effect size of 50 percent, a study would need 64 subjects per study group; a total sample size of 128 would be the smallest acceptable.

Therefore, a single study, with 100 percent of participants with noncyclic CPP, with no loss to follow-up, with a pain reduction in the placebo group of 30 percent, and a pain reduction of at least 60 percent in the intervention group would require a sample size of 350 patients.

Rather than choose a sample size of 350, we set a conservative lower limit for sample size at 50, to account for potential meta-analyses aggregating smaller trials at sufficient power to produce a confidence interval that excludes 1. Studies in the chronic pelvic pain realm rarely have identical patient populations or identical interventions, or identical outcome measures; hence the heterogeneity across studies would be problematic, and it would be important to have studies of sufficient size.

To examine the effects of our sample size requirement of at least 50 participants with CPP, we re-reviewed the randomized controlled trials that were excluded from the review and had fewer than 50 participants with CPP. Most studies were also excluded on another basis as well. Of those studies with an N of less than 50 that otherwise would have met the inclusion criteria at the full-text phase, none matched another in population, comparators, or interventions. None of these small studies used the same intervention; there was significant heterogeneity in the population and in the outcomes reported. Therefore, it would not have been possible to combine any two or more of these small studies and perform a meta-analysis as part of the systematic review. Moreover, these small studies, all addressing different interventions, would not have provided substantive data for the review.

We did not address harms of surgical interventions in this review as we felt that the studies meeting our inclusion criteria would necessarily provide desultory evidence of harms of surgical interventions. Most of the surgical interventions used for CPP are deployed in a broader context for other indications; a systematic review of the harms of the procedures would require a different and much larger search than the current review assignment and protocol, and KQs

dictated. Reporting only the harms represented in the select studies meeting our criteria for addressing surgical intervention for CPP would present only a partial picture of potential harms of surgery.

Study Design

We accepted study designs including controlled trials and prospective cohort studies addressing the effectiveness of surgical or nonsurgical approaches (KQ2, KQ4), outcomes if an etiology for CPP is identified (KQ3), or effectiveness of one intervention over another to treat persistent CPP (KQ5). We considered prospective cohort studies to be comparative studies, in which separate groups of participants received different interventions. Prospective cohort study designs could use contemporaneous controls or historic controls. We also accepted prospective or retrospective case series or cross- sectional studies with at least 100 participants with CPP and addressing the prevalence of comorbidities of interest (KQ1) or harms of nonsurgical therapies (KQ4).

We selected the comorbidities of interest based upon reporting in the CPP literature. We extracted data regarding a study's use of validated tools to diagnose comorbidities or the provision of an operational definition for a comorbid condition. As described below, we factored the use of a validated tool into our quality assessment of studies providing data on the selected comorbidities.

Language

To gauge the relevance of research published in other languages, we located non-English literature for the time period of interest using our MEDLINE search strategy and identified 168 citations. Twenty-nine of these citations appeared potentially relevant on a title scan. We reviewed the abstracts of 28 of these, and none met our review criteria. We believed that the one study for which we could not locate an abstract would not substantially alter the findings of the review and excluded non-English studies.

In addition, we excluded studies that:

- addressed pelvic pain related to cancer or pregnancy as the etiology of and treatment for these entities is significantly different from CPP related to other or unknown causes;
- did not report information pertinent to the KQs;
- were published prior to the year 1990 and the widespread use of laparoscopic techniques and introduction of medications such as serotonin reuptake inhibitors used to treat CPP; and
- were not original research.

Screening of Studies

Once we identified articles through the electronic database searches, review articles, and bibliographies, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated each abstract for inclusion or exclusion, using an Abstract Review Form (Appendix D). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it for full text assessment.

Two reviewers independently assessed the full text of each included study using a standardized form (Appendix D) that included questions stemming from our inclusion/exclusion criteria. Disagreements between reviewers were resolved by a third-party adjudicator. The group

of abstract and full text reviewers included expert clinicians (JA, SR, AY, FL) and health services researchers (RJ, NS).

Data Extraction and Data Management

The staff members and clinical experts who conducted this review jointly developed the evidence tables, which were used to extract data from the studies. We designed the tables to provide sufficient information to enable readers to understand the studies, including issues of study design, descriptions of the study populations (for applicability), description of the intervention, and baseline and outcome data on constructs of interest. Our outcomes of interest included:

- Pain status (reduction in pain, pain recurrence, subsequent intervention for unresolved or worsening pain);
- Functional status (activities of daily living, sexual functioning);
- Quality of life;
- Patient satisfaction with pain management; and
- Harms or adverse effects of nonsurgical interventions.

The team abstracted several articles into evidence tables and then discussed the utility of the table design as a group. We repeated this process through several iterations until we decided that the tables included the appropriate categories for gathering the information contained in the articles. All team members shared the task of initially entering information into the evidence tables. Another member of the team also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The full research team met regularly during the article extraction period and discussed global issues related to the data extraction process.

Where available, we also captured data on potential risk factors related to CPP or conditions thought to occur commonly with CPP. These data included:

- History of sexual or physical abuse;
- History of pelvic surgery;
- Pregnancy-related risk factors (e.g., history of Caesarean births, vaginal births, operative vaginal birth, genital tract trauma, pregnancy termination); and
- History of comorbidities of interest (anxiety, depression, dysmenorrhea, fibromyalgia, headache, irritable bowel syndrome (IBS), interstitial cystitis/painful bladder syndrome (IC/PBS), low back pain, and sexual dysfunction).

This list of comorbidities represents conditions thought to occur frequently with CPP and was determined in consultation with our TEP.

The final evidence tables are presented in their entirety in Appendix C. Studies are presented in the evidence tables alphabetically by the last name of the first author within each year. When possible to identify, analyses resulting from the same study were grouped into a single evidence table.

Individual Study Quality Assessment

We used a components approach to assessing the quality of individual studies, following methods outlined in the EPC's Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[69] Decision rules regarding application of the tools were developed *a priori* by the

research team. We developed separate quality assessment approaches for randomized controlled trials (RCTs), observational studies, and studies addressing the prevalence of comorbidities. Two reviewers independently assessed each study, with disagreements between assessors resolved via a third adjudicator.

We assessed each domain described below individually and integrated them for an overall quality level as described in the Determining Quality Levels section. We assessed studies as having "met" or "not met" a criterion; where relevant, criteria could also be judged as not applicable (NA) to a study. For the final integration of the assessment of quality, 3 levels were possible: good, fair, and poor.

We describe the individual quality components below and report individual quality assessments for each study in Appendix E.

RCTs

We assessed quality factors recommended in the Evidence Based Practice Centers' (EPCs) Methods Guide for Effectiveness and Comparative Effectiveness Reviews and in the Cochrane Handbook.

Sequence generation. We assessed study randomization by considering the following questions:

1. Was the assignment randomized?
2. Was the method used to generate the sequence of randomization described and was it appropriate?

We considered the following elements in determining the appropriateness of a study's randomization methods: Were random techniques like computer-generated, sequentially numbered opaque envelope used? Were technically nonrandom techniques, like alternate days of the week used?

Scoring. Studies providing a description of a truly random technique were assessed as "met" for this element.

Blinding. We considered four elements to assess blinding:

1. Was the allocation to study groups (and interventions) adequately concealed from patients/ participants?
2. Was the allocation to study groups (and interventions) adequately concealed from investigators?
3. Was the allocation to study groups (and interventions) adequately concealed from clinical providers/caregivers?
4. Was the allocation to study groups (and interventions) adequately concealed from outcome assessors?

Scoring. We defined adequate concealment as reasonable attempts (e.g., non-investigators involved in allocation, appropriate sham treatments used, etc.) by investigators to conceal intervention allocation groups. We assessed these criteria as met if the study provided such evidence of blinding.

Incomplete outcome data addressed. We considered four elements to assess the completeness of outcomes data reporting:

1. Was complete information about participant flow provided, such as CONSORT diagram or equivalent information (numbers at random assignment; numbers receiving intended intervention; numbers completing protocol; and numbers analyzed for primary outcome, drop-out, lost to followup)?
2. Was an intention-to-treat analysis (as assigned conducted and reported) performed appropriately?
3. Were incomplete/missing outcome data adequately reported?
4. Were missing outcome data managed by an accepted method?

Scoring. We considered acceptable methods of missing data management as either last observation carried forward; mean/median imputation; worst outcome imputation; or longitudinal regression imputation.

Selective outcome reporting. We assessed this domain using a single question: Was the primary outcome planned and described in the Methods section?

Scoring. Studies describing an *a priori* primary outcome determination were assessed as meeting this criterion.

Other bias. We assessed whether the study was largely free of other bias by considering the following elements: Was the trial stopped early for benefit? Was there an extreme baseline imbalance? Was there a substantive conflict of interest which posed a substantive, important threat to validity of the results?

Scoring. We scored studies as meeting this criterion if there was no evidence of such biases.

Sample size and power. We assessed this domain be determining whether an *a priori* sample size calculation was provided for the primary outcome.

Scoring. We scored studies as meeting this criterion if evidence of a sample size calculation was provided.

Statistical analysis. We considered the suitability of a study's analysis using the following questions:

1. Was statistical analysis appropriate for the study design performed?
2. Were the statistical results reliable?

Scoring. We scored studies as having "met" these criteria if our judgment was that the statistical analysis and results were appropriate and reliable for the stated study design and outcome. A glaring inconsistency or statistical error would result in a score of "not met."

Dropout proportion. We evaluated studies for this domain using the question: What proportion of enrolled participants assigned to an intervention declined to continue the assigned intervention?

Scoring. We considered studies with a dropout rate of less than or equal to 10 percent as having "met" this criteria. We assessed studies with a greater than 10 percent or unreported rate as having "not met" the criterion.

Follow-up. We assessed the adequacy of follow-up by determining what proportion of enrolled population was present or accessible at the time of the primary followup.

Scoring. We considered studies with a rate of less than or equal to 20 percent loss as having "met" this criterion. Studies with greater than 20 percent loss or not reporting the percentage were scored as having "not met" this criterion.

Observational Studies

For observational studies we considered these domains: (1) the selection of the study groups; (2) the comparability of the study groups; and (3) the ascertainment and measurement of either the exposure/intervention or outcome of interest for case-control or cohort studies respectively; (4) avoidance of detection bias; and (5) methods for limiting bias and confounding.

For example, for a cohort study, the fundamental criteria included: representativeness of cohort, selection of nonexposed cohort, ascertainment of exposure, outcome of interest, comparability of cohorts, assessment of outcome, adequate duration of follow-up, and adequate follow-up of cohort. Other sources of bias would include baseline imbalances, source of funding, early stopping for benefit, and appropriateness of crossover design.

Selection of participants in study groups. We considered three elements to evaluate a study's risk of bias in the selection of study group participants:

1. Were the characteristics of the participants/patients included in the study groups clearly described?
2. Were the inclusion and/or exclusion criteria described?
3. Were the criteria applied equally to all groups?

Scoring. We scored studies as having "met" this criterion if related data were provided.

Comparability of the study groups. We used the following questions to assess this domain:

1. Was there an assessment of baseline comparability, with regard to confounders (disease status, risk factors, prognostic factors, case-mix adjustment) for the most important factors (attempts to balance the groups by design), and did this demonstrate comparability?
2. Were concurrent controls used?

Scoring. We scored studies as having met these criteria if related data were provided.

Intervention description. We used the following questions to assess this domain:

1. Was there a clear definition of the intervention?
2. Was the measurement method of the intervention standard, valid, and reliable?

We considered the following elements in making a determination about these questions: Did all participants receive the same intervention? Were the interventions performed by the same person? Was the intervention measured equally in all study groups?

Scoring. Studies could be assessed as having "met" or "not met" these criteria. For question 2, we scored studies of pharmacologic interventions as NA.

Outcomes. We evaluated a study's measurement of outcomes using the questions:

1. Was the method of outcome assessment standard, valid, and reliable?
2. Was the follow-up duration long enough (≥12 weeks) for the outcomes to occur?

We considered whether references for measurement instruments were provided and whether authors indicated testing of an instrument in making determinations about these questions.

Scoring. Studies could be assessed as having "met" or "not met" these criteria.

Avoidance of detection bias. We used the following questions to assess avoidance of detection bias:

1. Were the outcome assessors blind to the intervention/outcome status?
2. If assessors were blinded, was concealment adequate?

Scoring. Studies could be assessed as having "met" or "not met" these criteria.

Outcome data reporting. We judged the quality of studies' outcome reporting using the two questions below.

1. Were incomplete/missing outcome data adequately reported?
2. Were the data managed by an accepted method?

We considered acceptable data management methods as last observation carried forward; mean/median imputation; worst outcome imputation; or longitudinal regression imputation.

Scoring. Studies could be assessed as having "met" or "not met" these criteria.

Selective outcome reporting. To assess this factor, we considered whether a primary outcome was planned and described in a study's methods.

Scoring. Studies could be assessed as having "met" or "not met" these criteria.

Other bias. We evaluated a study's handling of potential biases using the questions:

1. Were methods appropriate for dealing with any design-specific issues such as recall bias, interviewer bias, etc.?
2. Was there a substantive conflict of interest which posed an important threat to validity of the results?

We considered factors such as unclear reporting of findings in industry-sponsored trials and reporting interim versus final data (e.g., reporting only 6 week data in a completed 12 week study) as examples of substantive reasons for other bias.

Scoring. Studies could be assessed as having "met" or "not met" these criteria.

Sample size and power. We considered whether an *a priori* power calculation was provided for the primary outcome in assessing this element.

Scoring. We assessed studies as having "met" or "not met" these criteria.

Statistical analysis. We used the following questions to assess a study's statistical approach and scored studies as having "met" these criteria if our judgment was that the statistical analysis and results were appropriate and reliable for the stated study design and outcome. A glaring inconsistency or statistical error would result in a score of "not met."

1. Was a statistical analysis performed that was appropriate for the study design?
2. Were the statistical results reliable?

Scoring. We assessed studies as having "met" or "not met" these criteria.

Dropout proportion. We evaluated studies in this domain using the question: What proportion of enrolled participants assigned to an intervention (medication, cognitive behavioral therapy, etc.) declined to continue the assigned intervention? We considered the following factors in making this determination: Does the paper describe a comparison between dropouts and the whole group? Were the reasons for dropout or withdrawal reported? Were incomplete outcome data adequately addressed?

Scoring. We considered studies with a dropout rate of less than or equal to 10 percent as having "met" this criteria. We assessed studies with a greater than 10 percent or unreported rate as having "not met" the criterion.

Followup. We assessed the adequacy of follow-up with the question, what proportion of enrolled population was present or accessible at the time of the primary followup and evaluated the following factors in making a determination: Was loss to followup uneven across exposure groups; Did the study fail to report the number of participants available at followup; Were incomplete outcome data adequately addressed?

Scoring. We considered studies with no more than a 20 percent loss as having "met" this criterion. Studies with greater than 20 percent loss or not reporting the percentage were scored as having not "met" this criterion.

Confounding and effect modifiers. We evaluated observational studies for this domain using the following four questions:

1. For observational studies, was the approach to identifying confounding factors described?
2. Was there adequate adjustment for the potential confounding factors?
3. For observational studies, was the approach to identifying effect modifiers described?

4. Was there adequate reporting of potential effect modifiers?

We defined potentially confounding variables as having an effect on the outcome and associated with the intervention/exposure, but not on the causal pathway under study. A confounder may therefore bias the estimation of the effect of intervention/exposure on outcome if unmeasured. We considered effect modifiers to be factors that modify the effect of the putative causal factor(s) under study, by having an effect on the outcome by altering the relationship between an independent variable and a dependent variable (outcome). The effect modifier neither explains nor obscures the relationship between the causal factor of interest and the outcome—instead it alters the relationship so that under differing conditions of the effect modifier, the relationship between intervention and outcome changes in magnitude or direction.

We also considered the following elements in assessing these variables: Was the candidate variable selection discussed/noted? Was the model-building approach described? How were continuous variables handled in models? Was there restriction in design or techniques (e.g., modeling; stratified, regression, or sensitivity analyses) to correct, control, or adjust for confounding factors?

Scoring. We assessed studies as having utilized appropriate (+) or inappropriate (-) approaches.

Studies Addressing the Prevalence of Comorbidities of Interest

We assessed factors including a study's sampling method description and adequacy, sample size, response rate, specification of inclusion criteria, reporting of the age of the study population, and use of validated diagnostic criteria or operational definition of diagnosis. We assessed studies for each of the following criteria and assigned a plus if the criterion was met and a minus if not:

- **Sampling method:** The best sampling technique is random sampling, whereby a group of people are selected at random for study from a larger group (population). Each person is chosen entirely by chance, thereby reducing the likelihood of a selection bias favoring one group of people over another. Studies meeting our inclusion criteria for this question were largely intervention studies that also reported the prevalence of one or more comorbidities. If the sampling method was described, we assessed this criterion as met.
- **Sample size:** The larger the sample, the narrower will be the confidence interval around the prevalence estimate, making the results more precise. We required that studies include at least 100 participants to be assessed as having met this criterion.
- **Response rate.** Selection bias can occur if only a proportion of invited individuals participate in a survey. We set a minimum response rate of 70 percent in order for a study to be rated as having met this criterion.
- **Inclusion and exclusion criteria.** Specifying inclusion criteria allows for comparability between different prevalence data reports. Criteria should comprise information about the age range and, if appropriate, gender and ethnic group of the targeted individuals. If the inclusion and exclusion criteria were specified, then we assessed this criterion as met.

We used the above 4 criteria to establish a baseline score of zero to 4. We further considered whether a study used validated diagnostic criteria to assess comorbidities of interest or provided an operational definition for a given comorbidity:

- **Validated diagnostic criteria or operational definition.** We sought studies that addressed the prevalence of comorbidities report using validated diagnostic criteria (i.e., reference provided or discussion of testing of instrument provided), if such criteria existed when the study was conducted. If no validated criteria existed for a given comorbidity (e.g., vulvodynia, dysmenorrhea, fibromyalgia, IC/PBS, complex regional pain syndrome, functional abdominal pain syndrome, low back pain, and headache) or a validated tool was not used, we required that studies report an operational definition to meet this criterion. We considered operational definitions broadly as statements explaining how the investigators defined the comorbidity (e.g., an explanation of dysmenorrhea as painful menstrual periods). We scored each comorbidity reported in a study separately, assigning 2 points if the comorbidity was diagnosed with validated criteria, 1 point if the study provided an operational definition for the criteria, and zero points if no explanation of the criteria for the comorbid diagnosis was provided.

Determining Quality Levels

For RCTs, we considered a "good" study as one that met all criteria. We considered studies that were assessed as not meeting a factor in 3 or more domains (e.g., sequence generation, sample size and power, etc.) as poor quality. Studies not meeting criteria in one or two domains were considered fair quality.

For observational studies, we considered those meeting all criteria as good quality studies; those assessed as not meeting criteria in one to 4 domains as fair quality; and those not meeting criteria in 5 or more domains as poor quality.

For studies addressing the prevalence of comorbidities the minimum possible score was zero, and the maximum possible score was 6. In practice, the lowest score was 3 and the highest score was 6.

We considered studies achieving 6 total points as good quality; those receiving 5 points as fair quality; and those receiving 4 or fewer points as poor quality. Table 2 provides more information about study quality levels.

Table 2. Description of study quality levels

Quality level	Description
Good	Good studies are considered to have the least bias and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to treatments; has a low dropout rate; and uses appropriate means to prevent bias; measure outcomes; analyze and report results.
Fair	Fair studies are susceptible to some bias, but probably not sufficient to invalidate the results. A study may be missing information, making it difficult to assess limitations and potential problems. As the "fair quality" category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid.
Poor	Poor studies are subject to significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

Data Synthesis

There was significant heterogeneity among studies reporting therapeutic results for women with CPP, including heterogeneity of population inclusion criteria, heterogeneity of intervention,

and heterogeneity of outcome measures. Therefore, it was not appropriate to perform any meta-analysis.

Grading the Body of Evidence for Each Key Question

We evaluated the overall strength of the evidence for the primary outcomes using the approach to strength of evidence as described in the EPCs' *Methods Guide for Effectiveness and Comparative Effectiveness Reviews.*[69] We assessed the strength of evidence for key outcomes identified by the clinical investigators to be most clinically important: pain status (reduction in pain, recurrence of pain), subsequent intervention for the unresolved or worsening pain; and functional status (resolution/improvement of functioning). Secondary outcomes included: patient satisfaction with pain management; quality of life; and harms or adverse events.

We examined the following 4 major domains: risk of bias (low, medium, high), consistency (inconsistency not present, inconsistency present, unknown or not applicable), directness (direct, indirect), and precision (precise, imprecise) (Table 3).

Table 3. Domains used to assess strength of evidence[a]

Domain	Explanation
Risk of bias	Degree to which the included studies for a given outcome or comparison have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through two main elements: • Study design (e.g., RCTs or observational studies) • Aggregate quality of the studies under consideration. Information for this determination comes from the rating of quality (good/fair/poor) done for individual studies
Consistency	Degree to which reported effect sizes from included studies appear to have the same direction of effect. This can be assessed through two main elements: • Effect sizes have the same sign (that is, are on the same side of "no effect") • The range of effect sizes is narrow
Directness	Relates to whether the evidence links the interventions directly to health outcomes. For a comparison of two treatments, directness implies that head-to-head trials measure the most important health or ultimate outcomes. Evidence is indirect if: • It uses intermediate or surrogate outcomes instead of ultimate health outcomes. In this case, one body of evidence links the intervention to intermediate outcomes and another body of evidence links the intermediate to most important (health or ultimate) outcomes • It uses two or more bodies of evidence to compare interventions A and B, e.g., studies of A vs. placebo and B vs. placebo, or studies of A vs. C and B vs. C but not A vs. B. Indirectness always implies that more than one body of evidence is required to link interventions to the most important health outcomes. Directness may be contingent on the outcomes of interest.
Precision	Precision is the degree of certainty surrounding an effect estimate with respect to a given outcome (i.e., for each outcome separately). If a meta-analysis was performed, this will be the confidence interval around the summary effect size.

[a]Excerpted from Owens et al., 2010[69]

We assigned each key outcome for each comparison of interest an overall evidence grade based on the ratings for the individual domains. The overall strength of evidence could be graded as "high" (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of effect); "moderate" (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate); "low" (indicating low confidence that the evidence reflects the true effect and further research is likely

to change our confidence in the estimate of effect and is likely to change the estimate); or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect). When no studies were available for an outcome or comparison of interest, we assessed the evidence as insufficient. Two reviewers independently graded the body of evidence; disagreements were resolved through discussion or a third reviewer adjudication.

Peer Review and Public Commentary

Peer reviewers and AHRQ representatives reviewed a draft of this evidence report, and the draft report also was posted to the AHRQ Effective Health Care Web site for public comment. A document addressing the disposition of peer and public review comments we received will be posted to the AHRQ Effective Health Care web site within 3 months of posting the final report.

Results

This chapter presents the results of our systematic review of therapies for women with noncyclic chronic pelvic pain (CPP). We present findings for each Key Question (KQ) beginning with an overview of the content of the literature as a whole, including the range of study designs used, approaches assessed, and participants included. The detailed analysis of the literature provides further discussion and analysis, focusing primarily on those studies that received either a good or fair quality rating.

Studies also are described in more detailed summary tables in the relevant section of text. For information on studies not included in the summary tables, please see the evidence tables in Appendix C; for information on quality scores for each study, see Appendix E.

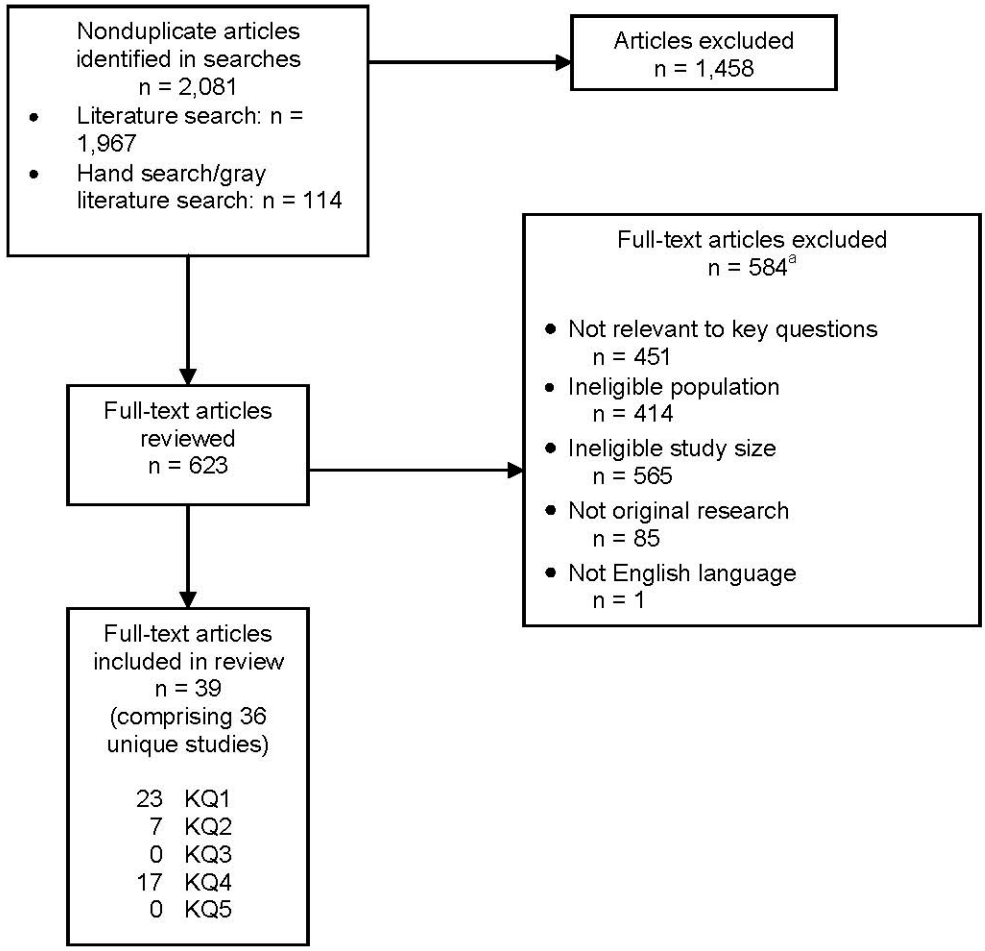
Overall, we found significant heterogeneity among studies, making it difficult to compare them; this heterogeneity was found in:

- Definitions of CPP and comorbidities of interest
- Outcome measures
- Comparators
- Duration of treatment
- Timing and length of followup
- Study populations.

Article Selection

Of the entire group of 2,081 citations, 623 required full-text review (Figure 2). Of the 623 full text articles reviewed, we retained 39 articles (comprising 36 unique studies) and excluded 584 articles. Reasons for article exclusion are listed in Appendix B.

Figure 2. Disposition of articles located for the review



[a]The total number of articles in the exclusion categories exceeds the number of articles excluded because most of the articles fit into multiple exclusion categories; KQ=Key Question

The 36 unique studies described in this review included 18 randomized controlled trials (RCTs). Table 4 provides an overview of the characteristics of the literature addressing the prevalence of comorbid conditions of interest (KQ1). We considered studies that provided data exclusively for KQ1 (and did not provide data for the other KQs) to be providing cross-sectional prevalence data, regardless of the design of the study.

Table 4. Overview of noncyclic CPP literature addressing the prevalence of comorbidities of interest

Characteristic	RCTs	Prospective cohort studies	Cross-sectional studies	Total Literature
	(n=7)	(n=1)	(n=15)	(n=23)
Comorbidities reported[a]				
Back pain	2	1	5	8
Depression	0	1	2	3
Dysmenorrhea	4	0	6	10
Dyspareunia/Sexual dysfunction	4	1	10	15
Headache	2	0	0	2
Interstitial cystitis	0	0	4	4
Irritable bowel syndrome	1	1	8	10
Vulvodynia	0	1	3	4
Study population				
United States	2	1	7	10
Europe	4	0	4	8
Other	1	0	4	5
Total N participants with noncyclic CPP at intake	620	370	5,242	6,232

[a]Studies could report multiple comorbidities. CPP = noncyclic chronic pelvic pain; N = number; RCT = randomized controlled trial.

Table 5 provides an overview of studies addressing KQs focused on outcomes of surgical and nonsurgical treatment approaches (KQ2, KQ3, KQ4) and those addressing the trajectory of care for women with CPP (KQ5).

Table 5. Overview of noncyclic CPP literature addressing treatment approaches

Characteristic	RCTs	Prospective cohort studies	Total Literature
	(n=18)	(n=3)	(n=21)
Intervention			
Antineuropathics	1	0	1
Hormonal therapies	8	1	9
Neuromuscular blocking agents	1	0	1
Adhesiolysis	1	0	1
LUNA	3	0	3
Other/combination approaches	4	2	6

Table 5. Overview of noncyclic CPP literature addressing treatment approaches (continued)

Characteristic	RCTs	Prospective cohort studies	Total Literature
Study population			
United States	2	2	4
Europe	14	1	15
Other	2	0	2
Last post-treatment outcome assessment			
<1 month	1	0	1
>1 to ≤3 months	1	0	1
>3 to ≤6 months	4	0	4
>6 to ≤12 months	8	3	11
>12 months	5	0	5
Total N participants with noncyclic CPP at intake	2,151	600	2,751

Abbreviations: CPP = noncyclic chronic pelvic pain; LUNA = laparoscopic utero-sacral nerve ablation; N = number.

Key Question 1. Among women who have been diagnosed with noncyclic/mixed cyclic and noncyclic CPP, what is the prevalence of the following comorbidities: dysmenorrhea, major depressive disorder, anxiety disorder, temporomandibular joint pain disorder, fibromyalgia, irritable bowel syndrome (IBS), interstitial cystitis (IC)/painful bladder syndrome (PBS), complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, and sexual dysfunction?

Overview of the Literature

This section presents results of 26 studies, representing 23 unique study populations, meeting our review criteria and addressing co-morbidities for CPP. Here we review co-prevalence rates for conditions associated with CPP including anxiety, back pain, depression, dysmenorrhea, dyspareunia, fibromyalgia, headache, IC/PBS, IBS, sexual dysfunction, and vulvodynia. We did not locate any articles addressing temporomandibular joint pain disorder, fibromyalgia, complex regional pain syndrome, functional abdominal pain syndrome, or anxiety disorder.

Quality assessments in this section refer to the prevalence quality for the particular co-morbidity being discussed. Therefore, an individual study may have different a level of quality for each comorbidity reported. Data regarding the comorbidities most frequently reported in the literature meeting our criteria are reported in tables 5 through 7.

Key Points

- Prevalence evidence quality for most of the studies was fair or poor.
- The majority (16/23) of studies reviewed here are observational; 7 are RCTs.
- Dyspareunia/sexual dysfunction (15 studies), dysmenorrhea (12 studies), and irritable bowel syndrome (10 studies) were the most frequently reported comorbidities.
- Dyspareunia prevalence in women with CPP ranged from 15 to 88 percent.

- Dysmenorrhea prevalence in women with CPP ranged from 4 to 100 percent.
- IBS prevalence in women with CPP ranged from 24 to 39 percent when Rome criteria were used for diagnosis.
- Understanding comorbidity prevalence in the context of a symptom-based condition like CPP is difficult; at times the same condition may be considered part of the differential diagnosis or considered to be a concomitant condition.

Detailed Analysis

Back pain. Eight studies (Table 6) reported the prevalence of back pain with rates of 1 percent to 88 percent (median 13 percent).[13,15,70-76] Studies used varied terminology, including backache, back pain, back problems, low back pain, lumbar disk disease, sacroiliac pain, and muscular back pain. Two studies provided an operational definition. One fair quality study noted magnetic resonance imaging (MRI)-verified pathology.[71] The second fair quality study defined sacroiliac pain as back pain with tenderness over either sacroiliac joint and reported 21 women with sacroiliac pain.[76] This study also reported patients with lumbar disk disease (n=7) but did not provide a specific definition or diagnostic criteria for it.[76]

All of the remaining studies were of poor quality. Three relied on patient report,[13,15,74] two on a physician diagnosis,[70,72] and one did not report how the diagnosis was made.[75] Some of the participants may overlap in two studies[70,72] conducted in the same clinic during the same time period; however, it is impossible to determine the extent of overlap.

Table 6. Prevalence of back pain in women with noncyclic chronic pelvic pain

Author, Year Country Quality	N	Study Design	Terminology	Method of Diagnosis	Prevalence
Droz et al., 2011[76] US Quality:	326	Cross-sectional	Sacroiliac pain and lumbar disk disease	Physician diagnosis on review of medical record	Sacroiliac pain=6% Lumbar disk disease=2%
Sator-Katzenschlager, 2005[71] Austria Quality: Fair	56	Cross-sectional	Low back pain	MRI-verified pathology	30%

Table 6. Prevalence of back pain in women with noncyclic chronic pelvic pain (continued)

Author, Year Country Quality	N	Study Design	Terminology	Method of Diagnosis	Prevalence
Lamvu et al., 2006[70a] US Quality: Poor	370	Prospective cohort	Muscular back pain in methods section and low back pain in results	Physician diagnosis: definite or probable	1%
Grace et al., 2004[14,15] New Zealand Quality: Poor	149	Cross-sectional	Back problems	Patient report of diagnosis by a medical practitioner	13%
Williams et al., 2004[72,73a] US Quality: Poor	987	Cross-sectional	Muscular back pain	Physician diagnosis: definite or probable	3%
Chung et al., 2003[74] Korea Quality: Poor	106	Cross-sectional	Low back pain	Patient report of symptoms	58%
Zondervan et al., 2001[13] UK Quality: Poor	237	Cross-sectional	Back pain or problems	Patient report of diagnosis by general practitioner/specialist	6%
Peters et al., 1991[75] Netherlands Quality: Poor	106	RCT	Backache	NR	88%

[a]These studies may have overlapping populations because they are from the same clinic during the same time period; however, it is impossible to determine the extent of overlap.
MRI = magnetic resonance imaging; N = number; NR = not reported; RCT = randomized controlled trial.

Depression. Three studies reported the prevalence of depression.[70,72,73,77] Prevalence rates of depression ranged from 16 percent to 64 percent.[70,72,77] Two studies[70,72] of good quality used the Beck Depression Inventory (BDI) to assess for depression. In a prospective cohort study of 370 women referred to a CPP specialty clinic who had CPP, 22 percent had moderate or severe depression defined as a BDI score of 19 or greater[70]. In a cross-sectional study of 987 women with CPP who were new patients at a pelvic pain clinic, 64 percent had a BDI score of 10 or higher.[72] The rationale for selecting the cut point of 10 is not identified. It is possible that some of the women in these 2 studies[70,72] are the same because they are from the same clinic during the same time period; however, it is impossible to determine the extent of overlap.

The third study, which was of poor quality, was a placebo-controlled RCT of raloxifene for CPP in 93 women with endometriosis, in which 41 percent of women had a history of "depression" and 16 percent had a history of "depression on hormones."[77] Definitions of depression and hormones are not provided, and no information is given about how this history was obtained.

Dysmenorrhea. Twelve studies (Table 7) reported the prevalence of dysmenorrhea with rates of 4 percent to 100 percent (unadjusted mean 75 percent, median 86 percent).[13,15,74,76,78-83] Two studies[13,76] were of fair quality. One cross-sectional postal survey reported an operational definition of dysmenorrhea and methods for calculating prevalence among women with CPP who had menstrual periods. Another chart review similarly reported a defitnion.[76] The prevalence rate was 81 percent. The other 7 studies were of poor quality.

Table 7. Prevalence of dysmenorrhea in women with noncyclic chronic pelvic pain

Author, Year Country Quality	N	Study Design	Diagnostic Criteria or Operational Definition	Method of Diagnosis	Prevalence
Droz et al., 2011[76] US Quality:Fair	326	Cross-sectional	Menstrual pain with no other discernable cause	Physician evaluated	4%
Zondervan et al., 2001[13] UK Quality: Fair	451	Cross-sectional	Pelvic pain during or shortly before or after menstrual periods; prevalence calculated by dividing the number of women who reported dysmenorrhea during the previous 3 months by the number of women who had menstrual periods	Self-reported on postal survey	81%
Montenegro et al., 2009[78] Brazil Quality: Poor	108	Cross-sectional	Pain occurring in association with menstruation	Self-reported on history form	62%
Pitts et al., 2008[79] Australia Quality: Poor	427	Cross-sectional	Pelvic pain with periods, including irregular bleeding while on the pill or HRT	Self-reported during computer-assisted telephone interview	84%
Grace et al., 2004[14,15] New Zealand Quality: Poor	214	Cross-sectional	Pelvic pain with periods, including irregular bleeding while on the pill or HRT	Self-reported on postal survey	79%
Johnson et al., 2004[80] New Zealand Quality: Poor	123	RCT	NR	NR	88%

Table 7. Prevalence of dysmenorrhea in women with noncyclic chronic pelvic pain (continued)

Author, Year Country Quality	N	Study Design	Diagnostic Criteria or Operational Definition	Method of Diagnosis	Prevalence
Chung et al., 2003[74] Korea Quality: Poor	106	Cross-sectional	NR	Self-reported	13%
Ling et al., 1999[81] US Quality: Poor	100	RCT	NR	Physician evaluated	100%
Gestrinone Study group, 1996[83] Italy Quality: Poor	55	RCT	Menstrual pain	Self-reported on VAS	100%
Vercellini et al., 1993[82] Italy Quality: Poor	57	RCT	NR	Self-reported on VAS	100%
Gestrinone Italian Study Group, 1996[83] Italy Quality: Poor	55	RCT	Menstrual pain, severity classified according to limitation of ability to work	Self-reported on questionnaire	100%
Vercellini et al., 1993[82] Italy Quality: Poor	57	RCT	NR	Self-reported on patient questionnaire	88%

HRT = hormone replacement therapy; N = number; NR = not reported; RCT = randomized controlled trial; VAS = visual analog scale.

Dyspareunia. Eleven studies (Table 8) reported the prevalence of dyspareunia.[10,13,15,72,74,75,78-81,84] Two of the studies were of fair quality and nine were poor. One fair quality study was a U.S. telephone survey that included 773 women with CPP.[10] Of the 432 of those 773 women who were sexually active, 88 percent reported pain during or after sexual intercourse some, most, or all of the time in the past month. The other fair quality study was a postal survey that reported an operational definition of dyspareunia and how prevalence was calculated among women with CPP who were sexually active. The prevalence rate was 41 percent.

One poor quality study[72] reported prevalence for three types of dyspareunia (organic, functional, and mixed) without defining the types and/or clarifying if the rates were overlapping. Excluding this study, the prevalence rates for dyspareunia among women with CPP across all studies ranged from 15 percent to 88 percent (unadjusted mean 54 percent, median 45 percent). See also sexual dysfunction below.

Table 8. Prevalence of dyspareunia in women with noncyclic chronic pelvic pain

Author, Year Country Quality	N	Study Design	Terminology and Definition	Method of Diagnosis	Prevalence
Zondervan et al., 2001[13] UK Quality: Fair	432	Cross-sectional	Dyspareunia: Pain that occurs with intercourse Prevalence calculated by dividing the number of women who reported dyspareunia during the previous 3 months by the number of women who were sexually active	Self-reported on postal survey	41%
Mathias et al., 1996[10] US Quality: Fair	432	Cross-sectional	Dyspareunia: pain during or after sexual intercourse some, most, or all of the time in the past month	Self-reported during telephone survey	88%
Montenegro et al., 2009[78] Brazil Quality: Poor	108	Cross-sectional	Dyspareunia: Pain occurring during sexual intercourse	Self-report on form	49%
Pitts et al., 2008[79] Australia Quality: Poor	427	Cross-sectional	Dyspareunia: Pelvic pain during or in the 24 hours after intercourse	Self-reported during computer-assisted telephone interview	29%
Williams et al., 2004[72] US Quality: Poor	987	Cross-sectional	Deep dyspareunia: NR	NR	Organic[a]: 37% Functional[a]: 12% Mixed[a]: 11%
Grace et al., 2004[15] New Zealand Quality: Poor	214	Cross-sectional	Dyspareunia: Pelvic pain during or in the 24 hours after sexual intercourse	Self-reported on postal survey	41%
Johnson et al., 2004[80] New Zealand Quality: Poor	123	RCT	Deep dyspareunia: pain with sexual intercourse	History	60%
Chung et al., 2003[74] Korea Quality: Poor	106	Cross-sectional	Dyspareunia: NR	Symptoms reported by patient	15%

Table 8. Prevalence of dyspareunia in women with noncyclic chronic pelvic pain (continued)

Author, Year Country	N	Study Design	Terminology and Definition	Method of Diagnosis	Prevalence
Quality					
Ling et al., 1999[81] US Quality: Poor	85	RCT	Deep dyspareunia: NR	Physician evaluated	85%
Saravelos et al., 1995[84] UK Quality: Poor	123	Cross-sectional	Dyspareunia: NR	NR	63%
Peters et al., 1991[75] Netherlands Quality: Poor	106	RCT	Dyspareunia: NR	NR	71%

[a]The authors did not define the terms organic, functional, and mixed nor did they specify if these categories overlapped.
N = number; NR = not reported; RCT = randomized controlled trial; VAS = visual analog scale.

Headache. Three studies from two unique populations reported the prevalence of headache.[75,77,85] In an RCT of surgical excision of endometriosis combined with raloxifene or placebo in 108 participants with CPP with and without endometriosis, 79 percent reported recurrent headaches[85]. Headaches were further classified using International Headache Society (IHS) Criteria. Among all of the 108 women, 67 percent had migraines (defined as four or five of the five major IHS criteria for migraines) and 12 percent had non-migraine headaches. The prevalence quality for this study was poor for headache and good for migraine.[85]

In an RCT of routine diagnostic laparoscopy versus an integrated approach without routine laparoscopy, 62 percent of 106 women with pelvic pain had headache.[75] The definition of headache and method of diagnosis were not provided for this study, which was of poor quality.[75]

Interstitial cystitis/painful bladder syndrome. Four studies reported the prevalence of IC/PBS.[76,86-88] One fair quality chart review included 326 women seeking treatment at a pelvic pain clinic. The study defined IC/PBS as "pelvic pain, pressure, or discomfort related to the bladder, associated with persistent urge to void or urinary frequency, in the absence of infection or other urinary tract disease" and reported a prevalence of 27.8 percent in this population.[76] Another fair quality study included 121 women attending a pelvic pain clinic and used response to hydrodistention as a diagnostic criterion. Twenty-one percent of participants were diagnosed with IC.[86]

In a good quality cross-sectional study of 175 consecutive women at a CPP clinic examining the nature and number of pain diagnoses, 35 percent had IC, defined as a positive response to alkalinized lidocaine bladder instillation or a previous diagnosis of IC from cystoscopy with hydrodistention.[87] In a fair quality prospective case series of 162 women with CPP who underwent laparoscopy and cystoscopy, 82 percent had IC defined as greater than 10 glomerulations per quadrant in at least 3 of 4 quadrants.[88]

Irritable bowel syndrome. Ten studies reported the prevalence of IBS.[13-15,70-73,76,86,87,89,90] Two studies with an overlapping population[14,15] are reported separately because they used different methods of determining if the women had IBS.

Six studies (Table 9) used the Rome I or II criteria for diagnosis of IBS and reported prevalence rates of 24 percent to 39 percent (unadjusted mean 34 percent, median 35 percent).[13,14,72,76,86,87,89] It is possible that some or all of the women in 2 of these studies[72,89] are the same because they are from the same clinic during the same time period; however, it is impossible to determine the extent of overlap. Four of these studies[13,72,76,87] were of good quality, and 3[14,86,89] were of fair quality.

Five studies[13,15,70,71,90] reported IBS prevalence using methods other than the Rome criteria. In 2 studies, one of good quality[13] and one of fair quality,[15] women with CPP not exclusively related to menses or sexual intercourse, who had consulted a medical practitioner, self-reported diagnoses they were given. Rates were 26 percent among 149 women who responded to a postal survey in New Zealand,[15] and 20 percent among 237 women who responded to a postal survey in the United Kingdom.[13] One of these studies[13] also reported the percentage of women who met the Rome criteria for IBS, and those results are presented in Table 9.

The remaining three studies[70,71,91] were all of poor quality. A prospective cohort study of 370 women evaluated at a pelvic pain clinic reported 37 percent of women had a clinical diagnosis of IBS, defined as the physician indicating the diagnosis was definite or probable.[70] It is possible that some of the women in this study[70] are the same as women in two of the studies that used Rome criteria[72,89] because they are from the same clinic during the same time period; however, it is impossible to determine the extent of overlap. Two studies reported prevalence rates for IBS but did not provide any information about how the diagnosis was made. One of these was an RCT of gabapentin and amitriptyline for CPP among 56 women, of whom 25 percent were reported to have IBS.[71] The other was a prospective case series of 106 women with CPP admitted for inpatient psychosomatic treatment, and 1 percent were reported to have IBS.[90]

Table 9. Prevalence of irritable bowel syndrome as diagnosed by Rome criteria in women with noncyclic chronic pelvic pain

Author, Year Country Quality	N	Study Design	Diagnostic Criteria	Prevalence
Droz et al., 2011[76] US Quality: Good	326	Cross-sectional	Rome II criteria	25%
Fenton et al., 2008[87] US Quality: Good	175	Cross-sectional	Rome II criteria	24%
Grace et al., 2006[14] New Zealand Quality: Fair	286	Cross-sectional	Rome I criteria	37%

Table 9. Prevalence of irritable bowel syndrome as diagnosed by Rome criteria in women with noncyclic chronic pelvic pain (continued)

Author, Year Country Quality	N	Study Design	Diagnostic Criteria	Prevalence
Tu et al., 2006[89a] US Quality: Fair	987	Cross-sectional	Rome I criteria	35%
Williams et al., 2004[72a] US Quality: Good	987	Cross-sectional	Rome I criteria	35%
Zondervan et al., 2001[13] UK Quality: Good	479	Cross-sectional	Rome I criteria	39%

[a]It is possible that some or all of the women in these 2 studies are the same because they are from the same clinic during the same time period; however, it is impossible to determine the extent of overlap.
N = number.

Sexual dysfunction. In addition to generalized sexual dysfunction, multiple specific forms of sexual dysfunction were reported including vaginismus, sexual pain disorder, postcoital pain, hypoactive sexual desire disorder, sexual arousal disorder, orgasmic disorder and anorgasmia, and limits on sexual activity. Five studies addressed one or more of these forms of sexual dysfunction. One of these was of fair quality.[92] The remaining four studies were all of poor quality.[15,70,72,75] See also the section on dyspareunia above.

Generalized sexual dysfunction. A cross-sectional study of fair quality about sexual dysfunction that included 112 women with CPP used the international classification of female sexual dysfunction (FSD)[92] of 4 FSD disorders to classify responses to general assessment questions designed to investigate women's sexual function. Among the 112 women, 70 percent had one or more of the 4 types of female sexual dysfunction (desire, arousal, orgasmic, and sexual pain disorders.).[92] In a prospective cohort of 370 women evaluated at a pelvic pain clinic, 76 percent had sexual dysfunction defined as "painful intercourse, decreased frequency, or decreased pleasure resulting from pain."[70] This study was of poor quality.

Hypoactive sexual desire disorder. A cross-sectional study about sexual dysfunction that included 112 women with CPP used the international classification of FSD disorders to classify responses to general assessment questions designed to investigate women's sexual function. Of the 78 women with CPP who had FSD, 54 percent had hypoactive sexual desire disorder.[92] The percentage of all of the women with CPP who had hypoactive sexual desire disorder is not reported.

Limits on sexual activity. A New Zealand postal survey about women's health included the open-ended question "Does your pelvic pain affect what you can or cannot do? If so, please describe." In response to this question, 6 percent of 286 women with CPP said they were "limited in sexual activity."[15]

Orgasmic disorder and anorgasmia. A cross-sectional study about sexual dysfunction that included 112 women with CPP used the international classification of FSD disorders to classify responses to general assessment questions designed to investigate women's sexual function. Of the 78 women with CPP who had FSD, 22 percent had orgasmic disorder.[92] The percentage of all of the women with CPP who had orgasmic disorder is not reported.

In an RCT of routine diagnostic laparoscopy versus an integrated approach without routine laparoscopy in 106 women with pelvic pain, 42 percent had anorgasmia.[75] The definition of anorgasmia (anorgasmy) and method of diagnosis were not provided.

Postcoital pain. In an RCT of routine diagnostic laparoscopy versus an integrated approach without routine laparoscopy in 106 women with pelvic pain, 27 percent had postcoital pain.[75] The method of diagnosis and parameters for how long the pain lasted were not provided.

Sexual arousal disorder. A cross-sectional study about sexual dysfunction that included 112 women with CPP used the international classification of FSD disorders to classify responses to general assessment questions designed to investigate women's sexual function. Of the 78 women with CPP who had FSD, 33 percent had sexual arousal disorder.[92] The percentage of all of the women with CPP who had sexual arousal disorder is not reported.

Sexual pain disorder. A cross-sectional study about sexual dysfunction that included 112 women with CPP used the international classification of FSD disorders to classify responses to general assessment questions designed to investigate women's sexual function. Of the 78 women with CPP who had FSD, 74 percent had sexual pain disorder.[92] The percentage of all of the women with CPP who had sexual pain disorder is not reported.

Vaginismus. Two studies, one prospective cohort and one cross-sectional, reported prevalence of vaginismus.[70,72] The studies did not define vaginismus and relied on a clinical diagnosis defined as a physician indication that vaginismus was definite or probable. The rate of vaginismus was 5 percent in both studies.

Vulvodynia. Two fair quality studies[76,86] and 2 of poor quality[70,87] reported prevalence rates of vulvodynia. A fair quality chart review reported a prevalence of 22 percent for vulvar vestibulitis, defined as vulvar pain with coitus or upon tampon/swab insertion; 2 percent for vulvodynia defined as vulvar pain upon examination; and less than 1 percent for vulvodynia (not defined).[76]A second fair quality study used a definition of vestibular tenderness to light touch and reported a rate of 19 percent among women seeking treatment at a pelvic pain clinic.[86]

In a cross-sectional study of 175 consecutive women at a CPP clinic examining the nature and number of pain diagnoses, 5 percent had vulvodynia defined as point tenderness of the vulva including the introitus.[87]In a prospective cohort study of 370 women evaluated at a pelvic pain clinic, 7 percent had a clinical diagnosis of vestibulitis.[70] Clinical diagnosis was defined as a physician indicating the diagnosis was definite or probable, and vestibulitis was not defined.

Key Question 2. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of surgical interventions on pain status, functional status, satisfaction with care, and quality of life?

This section presents the results of our literature search and findings about outcomes of surgical interventions for the treatment of CPP. The surgical approaches represented in the literature meeting our criteria included diagnostic laparoscopy and laparotomy, hysterectomy, adhesiolysis of intraabdominal and pelvic adhesions, laparoscopic utero-sacral nerve ablation (LUNA), and utero-sacral ligament resection. No studies of approaches such as presacral neurectomy met our criteria.

Overview of the Literature

We identified seven studies addressing surgical approaches; five were RCTs conducted in Europe or New Zealand, and two were prospective cohort studies conducted in the U.S. We rated one study as good[93], one as fair,[51] and 5 as poor quality.[54,70,75,80,94] Three studies compared surgical with nonsurgical or medical approaches for CPP treatment.[54,70,75] Three studies compared an active surgical technique, either LUNA or adhesiolysis, with surgical control (diagnostic laparoscopy).[51,80,93] One study directly compared two surgical techniques (LUNA vs. utero-sacral ligament resection).[94]

All studies provided definitions for CPP, although few generalizations can be drawn given the heterogeneity of definitions. All studies accepted patient self-report of pelvic pain or noncyclic pelvic pain as the principal determinant. Only one study specified a minimum degree of severity for pain as a definition component: ≥80 mm on 100 cm visual analog scale (VAS).[94] Three studies incorporated anatomic location in the definition: "midline,"[94] within or below the anterior iliac crests,[51] or abdomen below the umbilicus, pelvic organs, lower back, vulva, or vagina.[70] All but one stipulated a duration of greater than 6 months for chronicity, with one RCT allowing a duration of greater than 3 months.[75] One study limited the CPP definition to pelvic pain "unresponsive to common medical treatment."[94]

Key Points

- Of seven studies addressing KQ2, one was assessed as good, one as fair, and five as poor quality.
- While surgical and nonsurgical approaches to treating CPP both improved pain status, neither was more effective when directly compared in three studies.
- Laparoscopic lysis of adhesions (with lysis of adhesions limited to those stricturing a bowel loop and a dilated lumen during diagnostic laparoscopy) did not further improve pain scores over diagnostic laparoscopy alone.
- LUNA was no more effective in improving pain status than diagnostic laparoscopy alone or utero-sacral ligament resection.

Detailed Analysis

Surgical approaches compared with diagnostic laparoscopy. Five RCTs addressed surgical approaches (Table 10). Among studies comparing active surgical techniques to diagnostic laparoscopy, a good quality RCT evaluated laparoscopic lysis of intraabdominal adhesions and randomly assigned patients with visually confirmed abdominal adhesions to either adhesiolysis

(n = 51) or no adhesiolysis (n = 47) at the time of diagnostic laparoscopy.[93] The study included both men and women; however, over 80 percent of participants were female. The study does not present data for female participants only.

The potential effects of diagnostic laparoscopy in women with CPP have not been fully studied. Improvements following post-diagnostic laparoscopy have been reported but whether these improvements are "real" or "placebo" remains to be determined. Among studies using diagnostic laparoscopy as the comparator to an active intervention, diagnostic laparoscopy was used primarily as a diagnostic tool to try to identify potential pathologic explanations for CPP, and patients were randomized after the diagnostic laparoscopy. In these studies, patients were randomized at the time of surgery, after the diagnostic portion of laparoscopy, to receive additional treatment intervention or not.

After 12 months of followup, both the laparoscopic adhesiolysis group and the diagnostic laparoscopy group reported decreases in 100mm VAS pain scores; however, there was no difference in pain reduction between the 2 groups (p=0.63). The study was powered to measure a difference in the VAS of 35 percent between groups. The mean reduction in the VAS score was approximately 25 to 30 percent for both groups.[93] Quality of life (QOL), as assessed using the Medical Outcomes Study SF-36 instrument, improved in both groups with no significant differences between groups (p=0.84). The study did not evaluate functional status or patient satisfaction.

Two RCTs compared LUNA with diagnostic laparoscopy alone.[51,80] One of these RCTs was of fair quality study and compared 185 patients with CPP randomized to receive LUNA with 185 patients randomized to receive no additional intervention at the time of diagnostic laparoscopy.[51] Pain scores as measured on a 10cmVAS for worst pain level (mean difference in VAS (cm) = -0.02; 95 percent CI [-0.61, 0.65]) or for noncyclic pain(mean difference in VAS (cm) = 0.17; 95 percent CI [-0.4, 0.74]) were not significantly different between groups. There were also no differences in pain scores between treatment groups when analyzed according to pre-determined subsets, including parity (nulliparous, parous), pathology (none, any, endometriosis), or site of pain (central, not central). Using the EuroQOL indices of quality of life, the EQ-5D and EQ-VAS, the authors compared mean differences in scores between the 2 treatment groups and demonstrated no differences in either measure: For EQ-5D, the mean difference was 0.03 (95 percent CI, -0.03 to 0.09), and for EQ-VAS, the mean difference was −0.78 (95 percent CI, -3.9 to 5.4). The study did not assess functional status or patient satisfaction as outcomes.[51]

The second of the 2 RCTs was a poor quality study comparing LUNA with diagnostic laparoscopy.[80] Investigators randomly assigned women with CPP at diagnostic laparoscopy to receive either LUNA or no additional treatment and subclassified participants according to the presence of endometriosis. When patients with no endometriosis receiving LUNA (n= 18) were compared with those not receiving LUNA (n = 32) after 12 months of followup, there were no statistical differences in median change in 10cm VAS score for nonmenstrual pelvic pain (p=0.34) nor in numbers of patients with a greater than 50 percent reduction in VAS score (p=0.8). Similarly, in patients with endometriosis, there were no differences between patients receiving LUNA (n=26) and those not receiving LUNA (n=30) in change in VAS score for pelvic pain (p= 0.58) or numbers of patients with more than 50 percent reduction in VAS score (p= 0.78).

The authors also reported that satisfaction rates in patients with or without endometriosis that receive either LUNA or diagnostic laparoscopy alone did significantly differ; however, the paper

provided no description for how satisfaction was assessed or what measure was used. The study did not assess functional status.[80]

In the only study included in this section of the review to actively compare surgical treatments, Palomba et al. randomly assigned 80 patients with CPP to either LUNA or vaginal utero-sacral ligament resection.94 After 12 months of followup, 36 patients receiving LUNA and 38 patients receiving ligament resection were available for evaluation. Both groups reported improvements in pain severity on 100mm VAS score; however, there was no difference in pain severity between the 2 groups (p= 0.063). The study reported equivalent rates of cure (defined as complete relief of pain or residual CPP not requiring treatment) for both treatment arms (RR=0.9, 95 percent CI [0.78 to 1.33]). The study did not address functional status, patient satisfaction or quality of life as outcomes after surgery.

One poor quality study included women with CPP for whom the initial gynecologic history and physical and psychiatric evaluation did not result in a high index of suspicion for a particular etiology.[75] The women were randomized to either a "standard approach" that included laparoscopy, or an "integrated approach" that included somatic or behavioral therapies. Following the laparoscopy, the authors do not report how many of the 49 patients in this group received any subsequent interventions such as physiotherapy or behavioral therapy.

The 57 patients in the integrated approach group received physiotherapy and "equal attention was devoted to possible organic, psychological, dietary, and environmental causes of the pain," meaning they may have received medical treatments, diet and nutrition advice, or psychosocial therapy. Of the 57 patients in the integrated approach group, 5 eventually underwent a surgical intervention. In this small study population of 57 participants, of whom over 90 percent had undergone prior laparotomy for CPP, performing a laparoscopy as the next step was not as helpful for improving the "general pain experience" or the "disturbance of daily activities" as enrolling the patient in a multidisciplinary program that included physiotherapy. Improvement in general pain experience was reported by 75 percent in the integrated approach group and 41 percent in the surgical approach group. Improvement in disturbance of daily activities was reported by 68 percent in the integral approach group and 37 percent in the surgical approach group, but the authors do not report how improvements in pain experience were determined. Objective multidimensional McGill pain scores were not different between the two groups at the 1-year evaluation.[75] There were no differences between treatment arms in improvement in McGill scores after 12 months of treatment (p= 0.38), although "improvement" in McGill scores was not explicitly defined.

Two prospective cohort studies addressed surgical approaches for treating CPP; both studies were poor quality. One study involved participants from tertiary referral centers in the United States and compared medical with surgery therapy for CPP.[70] One hundred eighty-one patients receiving nonsurgical or medical therapy, including pharmaceutical therapy (with opioid and nonopioid analgesics, antidepressants, anxiolytics, antineuropathics, sedatives, hormones or anti-inflammatories), physical therapy, psychotherapy or combinations thereof, were compared with 189 patients receiving surgical therapy (including diagnostic laparoscopy, adhesiolysis, endometrial ablation, oophorectomy, hysterectomy, and utero-sacral ablation). After 12 months of followup, both groups reported significantly lower scores on the McGill Pain Questionnaire (both $p < 0.001$) from baseline, although the improvement was similar in both groups (OR = 1.2, 95 percent CI [0.8, 1.6]). There were no significant differences in change of pain status between the 2 groups, with similar numbers of patients reporting worsened pain (OR = 0.9, 95 percent CI [0.5 to 1.5]), no change (OR = 1.1, 95 percent CI [0.7 to 1.7]), improvement (OR = 0.8, 95

percent CI [0.4 to 1.6]), or resolution of pain (OR = 0.9, 95 percent CI [0.5 to 1.5]. The study did not assess functional status, patient satisfaction with care, and quality of life.

A poor quality cohort study, the Maine Women's Health Study, addressed nonsurgical management of participants with CPP who had undergone prior diagnostic laparoscopy and did not have endometriosis or any other condition that warranted a specific treatment.[54] The study reported on 12-month outcomes for 380 patients enrolled in a nonsurgical group compared with 311 patients undergoing hysterectomy in the original Maine Women's Health Study.[55] Patients included in the nonsurgical group were those with complete evaluations, including diagnostic laparoscopy, who elected nonsurgical management for leiomyomas, abnormal bleeding or CPP. Only 50 (13 percent) patients with a primary diagnosis of CPP were included in the nonsurgical group. Patients included in the hysterectomy group were those undergoing hysterectomy for non-malignant indications, including leiomyomas, abnormal bleeding, or CPP. Sixty-eight (22 percent) patients undergoing hysterectomy reported a primary diagnosis of CPP. The study also included limited data on a subset of 71 women with CPP only, (without a primary indication of fibroid or abnormal bleeding or other) who underwent nonsurgical management.

Both the surgical and nonsurgical group demonstrated significant improvement in mean number of days with pain per month as determined by structured interview after 12 months of treatment. Those in the nonsurgical group reported a mean reduction of 7 days (from 16/month to 9/month, $p < 0.001$), while those in the hysterectomy group reported a mean reduction of 18 days (from 19/month to 1/month, $p < 0.001$). The study did not report comparisons between the two groups.

Functional status, assessed with a validated Activity Index questionnaire, improved in both groups compared with baseline after 12 months of treatment (both $p < 0.001$), although comparison between the two arms was not performed. Quality of life improvements were assessed via the Mental Health Index, General Health Index, Activity Index, and assessment of positive feelings about symptom status. For all these QOL measures, hysterectomy was associated with significant improvements at 12 months compared with baseline ($p < 0.001$ for all), while nonsurgical management was only associated with significant improvements in the Activity Index and positive feelings about symptom status ($p < 0.001$ for both).

The authors report that the likelihood of positive feelings about symptoms status at 1 year of follow-up was significantly increased for participants receiving hysterectomy compared with nonsurgical management (OR=10.45, adjusted for treatment type, age, fertility, parity, education, duration of symptoms, and initial severity of discomfort). Thirty percent of the 50 women with CPP who had nonsurgical management, and who completed the 1-year followup and did not have a hysterectomy during that year, reported positive feelings about symptom relief, compared with 77 percent of 68 women with CPP who had hysterectomy. However, the decision about whether or not to have a hysterectomy was made by the woman and her physician prior to enrolment in the study. Therefore, the study reports that women who self-selected for hysterectomy as a treatment for CPP were more likely to be satisfied with their symptom status after one year than women who self-selected nonsurgical management as a treatment for CPP, with the proviso that the factors that influenced the decision about therapy were not studied.[54]

Table 10. Key outcomes of surgical interventions for noncyclic CPP

Author, Year, Country Quality	Comparison Groups, N	Outcomes
Adhesiolysis		
Swank et al., 2003[93] Netherlands Quality: Good	**G1:** Adhesiolysis at diagnostic laparoscopy, 51 **G2:** No adhesiolysis at diagnostic laparoscopy, 47	• No significant differences in 100cm VAS pain score at 12 months between either group (P = 0.63)
Hysterectomy vs. nonsurgical therapy		
Carlson et al., 1994[54] U.S. Quality: Poor	**G1:** Nonsurgical management, 50 **G2:** Hysterectomy, 68	• Significant improvement in both groups in # days with pain at 12 months: G1: 16 to 9 days, P < 0.001; G2: 19 to 1 day, P < 0.001 • Significant decreases in proportions of women with problematic pain at 12 months vs. baseline reported for both groups (P < 0.001 for both)
LUNA vs. diagnostic laparoscopy		
Daniels, 2009[51], UK Quality: Fair	**G1:** LUNA at diagnostic laparoscopy, 185 **G2:** No LUNA at diagnostic laparoscopy, 185	• No significant difference between groups in 10cm VAS for noncyclic pain level at 12 months
Johnson, 2004[80], New Zealand Quality: Poor	**G1a:** LUNA at diagnostic laparoscopy, no endometriosis, 18 **G2a:** No LUNA at diagnostic laparoscopy, no endometriosis, 32 **G1b:** LUNA at diagnostic laparoscopy, with endometriosis, 26 **G2b:** No LUNA at diagnostic laparoscopy, with endometriosis, 30	• No significant differences in change from baseline of nonmenstrual pelvic pain score on 10-point VAS at 12 months between G1a vs. G2a (p = 0.34) or G1b vs. G2b (p = 0.58) • No significant differences in > 50% reduction of pain from baseline at 12 months on 10-point VAS between G1a vs. G2a (p = 0.80) or G1b vs. G2b (p = 1.0) • No significant differences in numbers of successful treatments at 12 months between G1a vs. G2a (p = 0.85) or G1b vs. G2b (p = 0.77)
LUNA vs. utero-sacral ligament resection		
Palomba, 2006[94], Italy Quality: Poor	**G1:** LUNA, 36 **G2:** Utero-sacral ligament resection, 38	• Comparable pain severity scores on 100mm VAS at 12 months reported for both groups (p = 0.063) • Relative risk of cure rates (complete relief of pain and CPP not requiring treatment) between G1 vs. G2 = 0.90 (95% CI: 0.78 – 1.33)
Surgical vs. nonsurgical therapy		
Lamvu et al., 2006[70] U.S. Quality: Poor	**G1:** Nonsurgical therapy, 181 **G2:** Surgical therapy, 189	• MPQ scores after 12 months of therapy were significantly lower in both groups (both p < 0.001), but not significantly different from each other (p = 0.165) • Overall odds of improvement in MPQ score for surgical vs. nonsurgical treatments were similar (OR = 1.2, 95% CI [0.8, 1.6] • Comparable numbers of patients in each group with worsened pain (OR = 0.9, 95% CI [0.5, 1.5]), no change in pain (OR = 1.1, 95% CI [0.7, 1.7]), improvement in pain (OR = 0.8, 95% CI [0.4, 1.6]), and resolution of pain (OR = 0.9, 95% CI [0.5, 1.5])
Peters et al., 1991[75], Netherlands Quality: Poor	**G1:** Standard treatment approach, including routine diagnostic and/or therapeutic laparoscopy, 49 **G2:** Integrated treatment approach, without routine laparoscopy, 57	• No difference in numbers of patients with improvement in MPQ scores at 12 months between groups (p = 0.38) • Significant improvement in numbers of patients with improvement in relative disturbance of daily activities for those treated with integrated approach vs. standard approach (p < 0.01)

CPP = noncyclic chronic pelvic pain; G = group; LUNA = laparoscopic utero-sacral nerve ablation; MPQ = McGill Pain Questionnaire; OR = odds ratio; VAS = visual analog scale.

Key Question 3. What is the evidence that surgical outcomes differ if the etiology of noncyclic/mixed cyclic and noncyclic CPP is identified after surgery?

We sought evidence that surgical outcomes differed if the etiology of CPP was identified after surgical intervention. We searched for studies of surgical interventions for CPP that reported outcome measures of interest and which indentified at least two groups: those participants who had an etiology identified at the time of the surgical intervention or from surgical histopathology, and those participants who did not have an etiology identified at surgery or from pathology. Surgical approaches included in the literature meeting our criteria are described more fully in the KQ2 section of the report and included laparoscopy, laparoscopic lysis of adhesions, LUNA, and hysterectomy.

We did not identify any studies of surgical procedures in participants with CPP that reported outcomes separately for participants who had an etiology identified compared with those who did not have an etiology identified.

Key Question 4. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of nonsurgical interventions on pain status, functional status, satisfaction with care, quality of life, and harms?

Overview of the Literature

This section presents results of studies meeting our review criteria and addressing the effectiveness of nonsurgical (pharmacologic and nonpharmacologic) interventions for CPP and harms of such interventions. Seventeen studies meeting our criteria addressed nonsurgical approaches for CPP. Fourteen of these studies were RCTs, and three were prospective cohort studies (Table 11). Only one study was rated as high quality,[77,85] three were fair quality,[81,95,96] and the balance were poor.[54,70,71,75,82,83,97-103] The few placebo-controlled studies[77,81,95,103] were typically rated as higher quality.

Most RCTs investigated hormone-based treatments for CPP. One evaluated antineuropathic agents, and another the neuromuscular blocking agent, botulinum toxin A. Four RCTs examined nonpharmacologic therapies—pelvic floor physical therapy, photographic-enhanced counseling after surgery, pelvic ultrasonography plus counseling, and a standard versus integrated treatment approach. The cohort studies assessed nonsurgical compared with surgical approaches and a hormone-based therapy

Twelve of the 17 studies were performed in Europe, with the remainder conducted in the United States and Australia. Most were conducted at academic institutions. The definition of CPP varied slightly between studies, with several studies not providing a clear definition at all. Most commonly, CPP was defined as moderate to severe pelvic pain for at least 6 months duration, unrelated to menstruation. However, among these studies, the duration ranged between 3 months and 2 years. The required severity of pain varied among studies, with some studies requiring a baseline score on a specified pain index/scale while others relied on patient report only. Several studies (n=9), especially those that trialed hormone-based therapies, also required patients to have a diagnosis of endometriosis. Other than those requiring a diagnosis of endometriosis, studies addressing KQ4 reported no consistent screening for other pain conditions or co-morbidities. A full gynecologic and obstetric history was also rarely reported.

Key Points

- Only one study met criteria for good quality; this study demonstrated that a selective estrogen receptor modulator (SERM), raloxifene, was associated with a faster return of endometriosis-associated pelvic pain.
- The majority of studies reviewed here are RCTs, most of which investigate hormone-based therapies.
- More often, studies compared active versus active interventions; thus is it difficult to determine whether or not both arms are actually demonstrating placebo effect versus treatment effect.
- Reporting of a systematic evaluation of participants prior to randomization to ascertain the etiology of pelvic pain prior to treatment was limited.
- Reporting of harms data was very limited among trials; among the placebo-controlled trials, harms were more frequent in the placebo arms.

Detailed Analysis

Hormonal therapies. Hormonal treatments for pelvic pain, with or without an underlying diagnosis of endometriosis, were the most common treatment studied. We identified nine RCTs[77,81-83,85,98-100,103] and one prospective cohort study[97] involving hormone-based therapies (Table 11). Seven were conducted in Europe[82,83,97-100,103] and 2 in the United States[77,81,85] with 887 total participants. Three of these used placebo as the control,[77,81,103] while the remainder compared two or more active interventions. These included combined estrogen/progesterone contraceptive agents, gonadotropin releasing hormone (GnRH)-analogues, a SERM, and progesterone injection.

Pain reduction was the primary pain-based outcome measured in all studies; however, many tools used to measure this outcome varied. Six studies used a 0–10 point VAS.[77,81,82,97,98,100] One study[83] utilized a 10 cm VAS and two used a 100mm VAS.[99,103] In addition to a VAS, several studies evaluated participants with other pain scales including the McGill Pain Questionnaire, Biberoglu and Behrman scale, and SF-12 or 36. The lack of consistent outcome measures limited our ability to compare outcomes across studies.

One good quality study, one of the few to employ a placebo, evaluated a SERM, raloxifene, looking at its effect on pelvic pain in participants with biopsy-proven endometriosis.[77] Compared with placebo, those participants who received raloxifene experienced a return of pain significantly sooner after laparoscopy (OR, 2.81; 95 percent CI,1.41 to 6.19). The effect was so pronounced that the trial was stopped early.

Four studies investigated the effects of the GnRH-analogue leuprolide acetate on pelvic pain. In one fair quality, placebo-controlled study,[81] participants randomized to depot leuprolide had significantly greater improvement in pelvic pain scores at the end of 12 weeks of treatment, compared with those randomized to placebo ($p<0.001$). These participants all had clinically suspected endometriosis. The other three studies were poor quality and compared leuprolide acetate with another active treatment. When compared with gestrinone, a similar GnRH-analogue with mild progestogenic and androgenic effects, both treatment groups experienced significant reduction in pain scores during the treatment period.[83] However, the gestrinone group showed overall lower pain scores at the end of followup, compared with leuprolide recipients. The third study evaluated add-back therapy in participants receiving leuprolide acetate for the treatment of endometriosis-associated pain.[98] Participants were randomized to leuprolide alone,

leuprolide plus daily estradiol and norethindrone, or a daily estroprogestin alone. Participants treated with leuprolide (either with or without add-back therapy) had significantly greater reduction in pain scores compared with those treated with the estroprogestin alone ($p<0.01$). Those with add-back therapy reported better quality-of-life. The fourth study compared treatment with estroprogestin alone for 12 months with treatment with a GnRH agonist for 4 months followed by with estroprogestin for 8 months for the treatment of endometriosis-associated pain.[100] While both arms were effective in the treatment of pain, there was no difference between arms.

Two poor quality studies evaluated monophasic oral contraceptive pills (OCP), both for the treatment of pain associated with endometriosis. The first study[99] randomized participants to depot medroxyprogesterone or OCP plus low dose danazol. Both groups reported significant improvement in pain scores, compared with baseline, with no significant between-group difference. In the second study, OCPs were compared with goserelin, another GnRH-analogue.[82] During the treatment period, both groups experienced similar reduction of pain, but then had similar return to baseline pain levels once treatment was stopped. There was no significant between-group difference.

One poor quality study evaluated depot medroxyprogesterone and a placebo injection for the treatment of CPP in women with a prior negative laparoscopy[103] and reported no significant between group difference. The final hormonal intervention study, also of poor quality, compared two contraceptive delivery methods—the contraceptive vaginal ring (ethinyl estradiol/etonogestrel) and the transdermal patch (ethinyl estradiol/norelgestromin)—for the treatment of endometriosis-associated pain.[97] In this cohort study, participants chose their preferred delivery method. The primary outcome of this study was treatment satisfaction, and the study reported no difference between groups in satisfaction with treatment. The study did not report data for the secondary outcome of nonmenstrual pain.

Table 11. Key outcomes of hormonal therapies for noncyclic CPP

Author, Year, Country Quality	Intervention, N at Enrollment (N at Followup)	Last Outcome Assessment Post Treatment Day 1	Key Findings
Vercellini et al., 2010,[97] Italy Quality: Poor	**G1**: Vaginal ring (15 mcg ethinyl E and 120 mcg etonogestrel/day), 72 (32) **G2**: Transdermal patch (20 mcg ethinyl E and 150 mcg norelgestromin/day), 23 (19)	At end of 12 months of treatment	• Pain symptoms reduced significantly in both groups, with no significant difference between groups • No differences in pain outcomes in those with or without rectovaginal lesions. Patients who chose patch were more likely to drop out of the study compared with those who chose ring (RR, 1.7; 95% CI, 1.27 to 2.28) • Irregular bleeding was a common side effect in both groups in those who attempted continuous use (ring 46%, patch 42%) • Ring users were more likely to be satisfied with treatment
Stratton et al., 2008,[77] US Quality: Good	**G1:** Raloxifene, 180 mg/day, 47 (38) **G2:** Placebo, 46 (35)	12 months after patient completed 6 months of treatment	• Raloxifene group experienced quicker return of pain (p=0.03) and required repeat surgery sooner than placebo group (p=0.016) • Presence of biopsy-proven endometriosis was not significantly associated with return of pain • Study terminated early due to negative effect

Table 11. Key outcomes of hormonal therapies for noncyclic CPP (continued)

Author, Year, Country Quality	Intervention, N at Enrollment (N at Followup)	Last Outcome Assessment Post Treatment Day 1	Key Findings
Zupi, et al., 2004,[98] Italy Quality: Poor	**G1:** GnRH-analogue (leuprolide acetate 11.25 mg IM every 3 months), 46 (NR) **G2:** GnRH-analogue (leuprolide acetate 11.25 mg IM every 3 months) and transdermal E2 25 mcg/day + norethindrone 5 mg/day, 44 (NR) **G3:** Estroprogestin alone (ethinyl E2 30 mcg/day + gestodene 0.75 mg/day), 43 (NR)	6 months after patient completed 12 months of treatment	• Patients treated with GnRH-analogue (either with or without add-back therapy) had significantly greater reduction in pain scores compared with those treated with oral contraceptive therapy (p<0.01) • Significant loss of bone mineral density noted in both GnRH-analogue groups, but less so in the group given add-back therapy • Patients treated with GnRH-analogue plus add-back therapy reported overall better quality of life than those in the other 2 groups
Parazzini et al., 2000[100] Italy Quality: Poor	**G1:** Estroprogestin (gestodene/ethinyl estradiol) 0.75 mg/0.03 mg daily for 12 months, 46 (NR) **G2:** GnRH agonist (triptorelin) 3.75 mg IM for 4 months, followed by estroprogestin daily for 8 months, 49 (NR)	12 months	• Significant improvement in pain scores over 12 months of treatment in both groups • No statistically significant difference between groups in overall pain improvement • Endometriosis stage had no significant effect on pain status
Ling et al., 1999,[81] US Quality: Fair	**G1:** Depot leuprolide, 3.75 mg IM every 4 weeks, 50 (49) **G2:** Placebo, 50 (46)	At end of 12 weeks of treatment	• Leuprolide group had significant reduction in all pain scores compared with placebo (p<0.001) • Majority of patients in both groups had laparoscopically-confirmed endometriosis after 12 weeks of treatment (leuprolide 78%, placebo 87%) • Most commonly-reported statistically significant harms in the treatment group were hot flushes (80%), insomnia (40%), and enlarged abdomen (percentage not reported) (p ≤ 0.50)

Table 11. Key outcomes of hormonal therapies for noncyclic CPP (continued)

Author, Year, Country Quality	Intervention, N at Enrollment (N at Followup)	Last Outcome Assessment Post Treatment Day 1	Key Findings
Gestrinone Italian Study Group, 1996,[83] Italy Quality: Poor	**G1:** Gestrinone, 2.5 mg/2x week, 27 (17) **G2:** Leuprolide acetate, 3.75 mg IM every 4 weeks, 28 (17)	6 months after patient completed 6 months of treatment	• Both groups experienced significant reduction in pain during the treatment period • Gestrinone group showed overall lower pain scores at the end of followup, compared with the leuprolide group • Recurrence of moderate-severe pain observed less frequently in the gestrinone group, compared with the leuprolide group (OR, 0.12; 95% CI, 0.02 to 0.69) • Nonsignificant increase in bone mineral density in the gestrinone group and a statistically significant decrease (-3.04% ± 4.77%) in the leuprolide group
Vercellini et al., 1996,[99] Italy Quality: Poor	**G1:** Depot medroxy-progesterone acetate, 150 mg IM every 90 days, 36 (36) **G2:** Monophasic OCPs (ethinyl estradiol 0.02 mg/desogestrel 0.15 mg) with danazol 50 mg), 32 (32)	At the end of 12 months of treatment.	• Significant improvements in pain scores noted in both treatment groups without significant between-group difference • 72.5% of depot medroxyprogesterone patients were either satisfied or very satisfied with treatment, compared with 57.5% of OCP users • Larger proportion of depot medroxyprogesterone patients experienced side effects during the treatment period
Vercellini et al., 1993,[82] Italy Quality: Poor	**G1:** Goserelin, 3.6 mg every 28 days, 29 (26) **G2:** Monophasic OCP with ethinyl estradiol 0.02 mg/day, 28 (24)	6 months after patient completed 6 months of treatment	• Both groups experienced improvement in pain during treatment without significant differences between groups • At end of followup, both groups experienced similar return to baseline pain levels • Symptoms recurred in most patients 6 months after treatment end
Walton et al., 1992,[103] UK Quality: Poor	**G1:** Medroxyprogesterone acetate, 50 mg/day for 4 mos, 107 (68) **G2:** Placebo, 58 (33)	At the end of 4 months of treatment	• 30/68 G1 participants and 9/34 G2 participants experienced 50% reduction in pain scores (100mm VAS) • No statistically significant between group differences • Discontinuation reasons included noncompliance, pregnancy, adverse events, and lack of efficacy

Abbreviations: CI = confidence interval; CPP = noncyclic chronic pelvic pain; G = group; GnRH = gonadotropin releasing hormone; IM = by mouth; mg = milligram; OCP = oral contraceptive pills; OR = odds ratio; N = number; NR = not reported; RR = relative risk.

Other pharmacologic therapies. The nonhormonal treatments evaluated include the neuromuscular-blocking agent botulinum toxin A[95] and antineuropathic agents gabapentin and amitriptyline.[71] In a fair quality, placebo-controlled study, women with 2 years of pelvic pain due to pelvic floor spasm were randomized to injection of the pelvic floor muscles with botulinum toxin A or saline.[95] Pain scores, followed for 6 months after injection, were significantly improved in the botulinum group compared with placebo (p=0.009). However, both groups had significantly decreased pelvic floor pressures after 6 months with no significant between-group difference.

In a poor quality anti-neuropathic study,[71] participants were randomized to one of three arms: gabapentin daily, amitriptyline daily, or gabapentin plus amitriptyline daily. Each group demonstrated significant improvement in pain from baseline scores; however, pain reduction was significantly greater in participants who received gabapentin (either with or without amitriptyline). Table 12 summarizes key outcomes for these nonhormonal therapies.

Table 12. Key outcomes of nonhormonal pharmacologic treatments for noncyclic CPP

Author, Year, Country Quality	Intervention, N at Enrollment (N at Followup)	Last Outcome Assessment Post Treatment Day 1	Key Findings
Abbot et al., 2006,[95] Australia Quality: Fair	**G1:** Botulinum toxin type A, 80 units, 30 (29) **G2:** Placebo (saline), 30 (28)	6 months after injection	• Botulinum toxin treatment group showed significant improvement in nonmenstrual pelvic pain scores (p=0.009); the placebo group did not • Significantly decreased pelvic floor pressures from baseline in both treatment groups (p<0.001, p=0.003) • Notable events/serious complications occurred in 4 women in the botulinum toxin group
Sator-Katzenschlager et al., 2005,[71] Austria Quality: Poor	**G1:** Gabapentin, maximum 3600 mg/day, 20 (17) **G2:** Amitriptyline, maximum 150 mg/day, 20 (17) **G3:** Gabapentin + amitriptyline, 16 (15)	At the end of 24 months of treatment	• All patients experienced significant pain relief during treatment and at the end of treatment, compared with baseline scores • Between groups, pain reduction was significantly greater in those who received gabapentin alone or gabapentin/amitriptyline combination compared with those who received amitriptyline alone • Incidence of dose-limiting side effects was lower in the gabapentin group, compared with the other 2 groups • No significant difference between groups in the incidence of severe side effects (those requiring discontinuation of treatment)

Abbreviations: CPP = noncyclic chronic pelvic pain; G = group; mg = milligram; N = number.

Nonpharmacologic therapies. Four trials addressed nonpharmacologic treatments for CPP (Table 13). The first of these was the only one to evaluate pelvic floor physical therapy, described as "distension of painful pelvic structures" as a treatment for pelvic pain.[96] In this fair quality study the control group received counseling only. Participants were evaluated at baseline and 2 to 3 weeks after treatment. Those randomized to pelvic floor distention showed significant improvement in pain scores compared with controls (OR, 18.37; 95 percent CI 3.39 to 99.64).

Two studies, both of poor quality, addressed practice-based treatment approaches and their effectiveness for overall pain outcomes. The first looked at post-operative counseling after diagnostic laparoscopy, and the effect of showing operative photos from the surgery while discussing findings.[101] The addition of photos to counseling had no effect on overall pain scores.

The second study[75]sought to determine if an integrated treatment approach to pelvic pain (promoting equal attention to organic, psychologic, dietary, and environmental causes of pain) was more effective than the standard approach (excluding organic causes before looking elsewhere) in patients in whom the initial gynecologic history and physical and psychiatric evaluation at the specialty clinic did not result in a high index of suspicion for a particular etiology for CPP. Participants randomized to the integrated approach showed greater improvement in scores in 3 areas: "general pain experience" (p<0.01), "disturbance of daily activities" (p<0.01), and "associated symptoms" (p<0.01). However, there was no significant difference in improvement in McGill pain scores between the integrated and standard approaches.

A fourth poor quality study randomized 100 patients with CPP after a negative laparoscopy to a session of ultrasound and counseling or a "wait and see" approach.[102] Participants had similar pain duration, McGill pain scores, and Hospital Anxiety and Depression scale scores at baseline. The study reported that performing an interactive pelvic and transvaginal ultrasound with demonstration, education, reassurance that the findings were normal, and counseling

resulted in resolution of pain for 12/46 patients, compared with 4/44 patients in the "wait and see" group.

Table 13. Key outcomes of nonpharmacologic treatments for noncyclic CPP

Author, Year, Country Quality	Intervention, N at Enrollment (N at Followup)	Last Outcome Assessment Post Treatment Day 1	Key Findings
Heyman et al., 2006,[96] Sweden Quality: Fair	**G1:** Distension of the pelvic floor muscles and joint between the coccyx and rectum, 25 (22) **G2:** Counseling, 25 (22)	2-3 weeks after treatment	• Pelvic floor treatment group showed significant improvement in pain scores compared with the counseling group (OR, 18.37; 95% CI, 3.39 to 99.64)
Onwude et al., 2004,[101] UK Quality: Poor	**G1:** Photographic reinforcement , 109 (53) **G2:** No reinforcement, 124 (62)	6 months after treatment	• No significant difference in changes in pain scores between groups
Ghaly, 1994[102] Scotland Quality: Poor	**G1:** Pelvic ultrasonography plus counseling, 50 (46) **G2:** Expectant management, 50 (44)	4-9 months	• Greater improvement in pain scores in the ultrasound group (P<0.01) • Pain reported as resolved in 12/46 participants in ultrasonography group and 1/44 in the expectant management group
Peters et al., 1991,[75] Netherlands Quality: Poor	**G1:** Standard treatment (exclusion of organic causes of pain and routine laparoscopy before attention devoted to treating other causes, 49 (49) **G2:** Integrated approach (equal attention devoted to organic, psychological, dietary, and environmental causes of pain, including consultation with physiotherapist; laparoscopy not routinely performed, 57 (57)	Approximately 12 months after patient completed treatment	• Integrated approach significantly associated with pain improvement in 3 areas: general pain experience (p<0.01), disturbance of daily activities (p<0.01), and associated symptoms (p<0.01) • No significant between-group difference in McGill scores

CI = confidence interval; G = group; N = number; OR = odds ratio.

Medical versus surgical management. Two poor quality prospective cohort studies addressed nonsurgical approaches (Table 14).[54,70] In one study, 370 patients in a pelvic pain clinic were followed for a year after treatment either by medical or surgical intervention.[70] The choice of treatment was provider-based and solely derived by clinical interaction. Participants were asked to complete baseline questionnaires regarding general medical information, history of abuse, depression screening, and pain assessment. The pain and depression assessments were repeated after one year. Groups were divided into those who received surgical treatment (with or without medical treatment) and medical treatment alone. Though the patient populations and treatment algorithms were highly varied, baseline characteristics were fairly evenly distributed. At the end of one year, improvement in pain was similar in both groups (OR 1.2, 95 percent CI 0.8 to 1.6).

In the Maine Women's Health Study,[54] patients with leiomyomas, abnormal bleeding, or pelvic pain were recruited from private obstetrics and gynecology practices to determine improvement in these conditions when treated with either medical options or hysterectomy. Over the course of their treatment, 118 patients were followed by questionnaire administered at

baseline, 3, 6, and 12 months, and included demographic information as well as indices for quality-of-life, functionality, and pain severity. While both treatment groups experienced improvement in pain severity and quality of life, the hysterectomy group showed an even greater degree of change.

Table 14. Key outcomes of studies comparing nonsurgical with surgical treatment of CPP

Author, Year, Country Quality	Intervention, N at Enrollment (N at Followup)	Last Outcome Assessment Post Treatment Day 1	Key Findings
Lamvu, et al., 2006[70] US Quality: Poor	**G1:** Medical treatment, NR (181) **G2:** Surgical treatment, NR (189)	At end of 12 months of treatment	• Improvement in pain scores was similar in both groups • The odds of improvement in both groups was 1.2 (95% CI 0.8 to 1.6) • Improvement in depression scores was also similar in both groups after one year
Carlson, et al., 1994[54] US Quality: Poor	**G1:** Nonsurgical management, (N not clearly reported) **G2:** Hysterectomy, (N not clearly reported)	1 year after initiation of treatment	• A substantial proportion (25%) of patients treated medically for abnormal bleeding or pelvic pain will later choose hysterectomy • The odds of positive feelings about pelvic pain symptoms at 1 year were 10.45 (p=0.0001) for hysterectomy compared with nonsurgical management

CI = confidence interval; CPP = noncyclic chronic pelvic pain; N = number; NR = not reported; OR = odds ratio.

Harms of nonsurgical interventions. Among the few placebo-controlled studies addressing nonsurgical approaches to treating CPP,[77,81,95] reported harms included depression, amenorrhea, sleep changes, hot flushes, and headache (Table 15). Harms were more frequent in placebo arms compared with either active GnRH agonist or the SERM raloxifene. The numbers of adverse events reported in a placebo (saline) versus botulinum toxin group were roughly equivalent.[95]

Additional harms reported in non-placebo controlled studies included spotting/breakthrough bleeding, changes in libido, vaginal dryness, mood changes, breast tenderness, weight gain, nausea and vomiting, dizziness, skin manifestations, and joint pain.

Table 15. Nonsurgical harms[a] reported in placebo-controlled studies

Reported Event	Placebo	GnRH Agonists	SERM	Medroxyprogesterone[b]
	Range of % of participants with adverse event (number of studies reporting event)			
Amenorrhea	4 (1)	98 (1)	NR	NR
Depression	22 (1)	NR	NR	NR
Headache	20-22 (2)	NR	21 (1)	NR
Hot flushes	26 (1)	80 (1)	NR	NR
Ovarian cyst	11 (1)	NR	17 (1)	NR
Reduction/discontinuation of drug	44-49 (2)	NR	32 (1)	37 (1)
Sleep changes	NR	40 (1)	NR	NR
Leg color change	NR	NR	NR	0.9 (1)
Benign breast lump	NR	NR	NR	0.9 (1)
Sheath accident	NR	NR	NR	0.9 (1)

GnRH = gonadotropin releasing hormone; NR = not reported; SERM = selective estrogen receptor modulator.
[a]Studies report harms for all participants only (vs. only those participants with noncyclic pain)
[b]Study notes that women in the treatment group experienced headache, nausea, vomiting, hot flushes, bloating, and mood changes and women in the placebo group experienced headache, bloating, weight gain, hot flushes, mastalgia, nausea, and vomiting, but numbers experiencing each event are not reported.
NOTE: An RCT of botulinum toxin A compared with placebo[95] did not allow for calculation of percentages but reported total events per group (botulinum toxin/placebo): headache (20/20), cold/flu symptoms (33/42), pelvic/back pain (26/30), gastroenterological symptoms (11/8).

Key Question 5. What is the evidence for choosing one intervention over another to treat persistent or recurrent noncyclic/mixed cyclic and noncyclic CPP after an initial intervention fails to achieve target outcome(s)?

We sought evidence for choosing one intervention over another to treat persistent or recurrent CPP after an initial intervention failed to achieve the target outcome(s). We did not identify any comparative studies of interventions explicitly noting prior failed interventions and addressing this question.

Ongoing Research

As noted, we also searched U.S. and European trial registries to understand trends in ongoing and recently completed research. We located 8 ongoing or recently completed studies examining interventions including hormonal therapies including GnRh agonists and OCPs, physical therapy techniques, transcutaneous electrical nerve stimulation, acupuncture, and botulinum toxin injection. These studies represent some interventions described in the literature meeting our criteria and also address some interventions not represented. Appendix G contains additional study details.

Summary and Discussion

In this section, we summarize our findings about therapies for women with noncyclic chronic pelvic pain (CPP). We provide an overview of the state of the literature and outcomes for each Key Question (KQ), detail the strength of evidence for the impact of each major intervention on relevant outcomes, and describe major issues and gaps in the current body of evidence.

State of the Literature

Despite a high reported prevalence for noncyclic CPP,[8] little research assessing therapies exists. While there are many publications regarding pelvic pain, there are relatively few addressing noncyclic CPP, and of those, few were high quality. Eighteen of 36 studies meeting our criteria were randomized controlled trials (RCTs); however, only 4 were placebo controlled.[77,81,95,103] This lack of placebo comparison detracts from the active head-to-head trials because no initial validation of effect has been made.

Some surgical studies compared a surgical approach with diagnostic laparoscopy or compared surgical with nonsurgical management. In the nonsurgical literature, most studies compared active agents with active agents, and a number addressed hormonal therapies for endometriosis-associated CPP. We did not locate any studies of other potentially effective nonsurgical modalities (relaxation, yoga, cognitive-behavioral therapy, etc.).

The quality of those studies providing data about the prevalence of comorbidities varied by comorbidity, with the bulk of studies assessed as poor quality for a given condition (Appendix E). Among studies reporting data on the prevalence of comorbidities, the range of prevalence estimates tended to be more narrow in those studies that employed validated diagnostic criteria (e.g., Rome criteria for irritable bowel syndrome [IBS]), and studies using validated criteria were of higher quality.

Few intervention studies were rated as good[77,93] or fair[51,81,95]quality. The higher quality evidence tended to demonstrate a lack of benefit: lysis of adhesions showed no benefit,[93] a selective estrogen receptor modulator (SERM) had a negative effect on pain and the trial was stopped early.[77,85] Some higher quality studies also suggested benefit of some approaches including depot leuprolide for endometriosis-associated CPP[81] and botulinum toxin for myofascial-related CPP.[95]

The literature overall is muddled by a lack of standardized definitions for CPP and unclear diagnostic evaluation that make it difficult to determine whether studies are truly including women with CPP. Systematic reviews of effectiveness of interventions for a symptom or syndrome are fraught with difficulty; the lack of specific diagnostic criteria results in heterogeneity within and across studies. In order to effectively treat any chronic pain, one would assume that a thorough diagnostic investigation would first take place. For many conditions, this typically follows some pre-determined algorithm. However, for CPP, no such algorithm exists. Thus, in each study (and likely for each private practitioner), the patient is approached in a variable manner, and some possible diagnoses may or may not be ruled out before treatment begins. There is no assurance that the treated condition is the causative condition. Treating a symptom means that a study group will likely have a variety of etiologies—some may be amenable to the intervention under study, others may not. Compared with an intervention trial that follows established diagnostic criteria and targets an identified condition, dilution of potential benefits and harms may be occurring.

Summary of Outcomes by Key Question

KQ1. Prevalence of comorbidities. We located 26 studies [10,13-15,70-90,92] comprising 23 unique study populations addressing the prevalence of our comorbidities of interest. The prevalence rates for the co-morbidities we examined showed significant variation. Frequently no operational definition or diagnostic criteria were provided. When definitions or criteria were available, they were rarely consistent across studies. Methods of making diagnoses varied and included patient report of symptoms, patient report that they were given the diagnosis by a health care provider, evaluation by a health care provider, and objective diagnostic criteria. Undoubtedly these inconsistencies in defining the comorbidities and making the diagnoses contributed to the variation.

KQ2. Effectiveness of surgical approaches. Seven unique studies addressed surgical interventions for CPP in women.[51,54,70,75,80,93,94] Given that many women with CPP are treated with invasive surgical procedures, remarkably little evidence exists that supports a surgical approach to the treatment of CPP. We identified and reviewed two studies comparing nonspecific surgical approach to nonsurgical approach for CPP therapy,[70,75] one study addressing hysterectomy specifically,[54] one study evaluating laparoscopic adhesiolysis at the time of diagnostic laparoscopy,[93] two studies evaluating laparoscopic utero-sacral nerve ablation (LUNA) comparing to diagnostic laparoscopy,[51,80] and one paper directly comparing LUNA and utero-sacral ligament resection.[94]

In none of the studies with comparison data was surgery in general or any specific surgical technique better than either nonsurgical intervention or the comparator technique in improving pain status in patients. Given the limited number of studies addressing heterogeneous surgical interventions and so few of good or fair quality, it is impossible to summarize the evidence for the effect for surgical interventions on any of the outcomes proposed. The most common surgical technique used as control in comparison trials was diagnostic laparoscopy; however, the direct therapeutic benefit of this procedure is poorly understood, and its role as a standalone surgical intervention for the treatment of CPP remains to be determined. The evidence is insufficient to conclude that surgical intervention is either effective or ineffective for the treatment of CPP.

KQ3. Evidence for differences in treatment outcomes by etiology. We did not locate studies addressing whether surgical outcomes differ if an etiology for CPP is identified after surgery.

KQ4. Effectiveness of nonsurgical approaches. We located 18 articles[54,70,71,75,77,81-83,85,95-103] comprising 17 unique studies addressing nonsurgical approaches for CPP. Overall, little good quality data was available. This was usually due to a lack of reporting or significant bias, either for lack of blinding or failure to analyze by intent-to-treat.

Within our included studies, there was significant variation in study design that did not allow us to synthesize results or perform a meta-analysis. This significantly detracts from the ability to apply these study results to a broader population or provide concrete estimates for clinical effect. We saw this variation in definition of pelvic pain, patient populations, outcome measures, interventions, timing of outcome measures and participant followup, and comparators.

Only 4 of the 17 studies utilized a placebo arm for comparison. All of the other studies employed active treatments as comparators. As noted earlier, this lack of placebo comparison detracts from the active head-to-head trials because no initial validation of effect has been made.

It could easily be assumed that each active intervention works simply by placebo effect, and this could explain why each hormone-based treatment seems equally effective in our review.

Nine of 17 studies evaluated hormone-based therapies for the treatment of pelvic pain. This is likely a result of most participant populations being recruited from endometriosis-based pain centers. However, it is well known that endometriosis is only one of many etiologies for pelvic pain, and hormone therapies one of many pain treatments.

The majority of the available literature focuses on hormone-based medical treatments, thus indirectly assuming that the majority of pelvic pain is gynecologic and/or endometriosis-driven. This bias toward gynecologic-based pain diagnoses is reflected in the absence of a true diagnostic work-up in most of these studies.

KQ5. Evidence for choosing intervention approaches. We did not identify any comparative studies of interventions for CPP in participants who had a prior intervention that failed to achieve the target outcome(s).

Strength of the Evidence for Effectiveness of Therapies

Overview

We assessed the literature by considering both the observed effectiveness of interventions and the confidence that we have in the stability of those effects in the face of future research. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence and can be insufficient, low, moderate or high. Strength of evidence describes the adequacy of the current research, both quantity and quality, and whether the entire body of current research provides a consistent and precise estimate of effect. Interventions that have shown significant benefit in a small number of studies but have not yet been replicated using rigorous study designs will have insufficient or low strength of evidence, despite potentially offering clinically important benefits. Future research may find that the intervention is either effective or ineffective.

Methods for applying strength of evidence assessments are established in the Evidence-based Practice Centers' (EPCs) Methods Guide for Effectiveness and Comparative Effectiveness Reviews[69] and are based on consideration of four domains: risk of bias, consistency in direction of the effect, directness in measuring intended outcomes, and precision of effect. We determined the strength of evidence for effectiveness outcomes (KQ 2–5) and assessed the body of literature deriving from studies that included comparison groups.

Tables 16 and 18 provide summaries of results, including strength of evidence, for each category of intervention addressing each KQ. Tables 17 and 19 document the strength of evidence for each domain of the major intervention-outcome combinations.

Strength of the Evidence by Key Question

KQ1. Prevalence of comorbidities. We did not assess the strength of evidence for studies addressing this KQ as we were interested in data regarding the prevalence of comorbid conditions and not effectiveness of interventions.

KQ2. Effectiveness of surgical approaches. We rated the strength of evidence for the effect of surgery on improving pain status as low or insufficient overall (Table 16). The strength of

evidence was insufficient specifically for the comparison between a general surgical approach to CPP treatment as compared with nonsurgical approach. There were two studies in this area, one poor quality RCT[75] and one poor quality prospective cohort,[70] which were at high risk of bias, but did demonstrate consistent estimates of effects. With 2 RCTs, one of fair[51] and one of poor quality,[80] we considered the strength of evidence to be low for the lack of efficacy of LUNA to improve pain status over diagnostic laparoscopy alone. Both studies were consistent in the findings, with direct comparisons and precise measures, but were also subjected to potentially high levels of bias. The evidence was insufficient due lack of comparison studies to measure the effect of hysterectomy and utero-sacral ligament resection on improvement of pain status. The strength of evidence for the effect of adhesiolysis on pain status was low based on one good quality RCT.[93]

The evidence was insufficient to evaluate the effects of surgical treatment on any of the other prescribed outcome measures, i.e., improving functional status, satisfaction with care or quality of life, because lack of comparison studies, multiple studies and studies with significant risk of bias.

Table 16. Summary of results and strength of evidence of studies assessing surgical interventions

Intervention	Study Design/Quality	Study Results and Overall Strength of Evidence
Surgical vs. nonsurgical therapy	1 RCT / 1 poor[75] 1 prospective cohort / 1 poor[70]	• Equivalent improvements for both surgical and nonsurgical therapy in pain status • Nonsurgical therapy with an integrated treatment approach without routine diagnostic laparoscopy improved functional status over surgical therapy with routine diagnostic laparoscopy in 1 study • Strength of evidence for lack of difference in improving pain status is insufficient • Strength of evidence for improving functional status is insufficient with only one RCT of poor quality
Hysterectomy vs. nonsurgical therapy	1 prospective cohort / 1 poor[54]	• Improvement in pain status for both groups, but no group comparison • Strength of evidence for improving pain status is insufficient with 1 prospective cohort of poor quality
Laparoscopic adhesiolysis vs. diagnostic laparoscopy	1 RCT / 1 good[93]	• No significant difference on improvement of pain status • No significant difference between the groups in quality of life scores • Strength of evidence for lack of difference in improving pain status is low, with 1 RCT of good quality • Strength of evidence for improving quality of life is low with 1 RCT of good quality
LUNA vs. diagnostic laparoscopy	2 RCT / 1 fair,[51] 1 poor[80]	• No significant difference on improvement in pain status • No difference on improvement in quality of life between groups in one study • Strength of evidence for lack of difference in improving pain status is low • Strength of evidence for improving quality of life is insufficient with 1 RCT of poor quality
LUNA vs. utero-sacral ligament resection	1 RCT / 1 poor[94]	• No significant difference on improvement of pain status • Strength of evidence of improving pain status is insufficient with 1 RCT of poor quality

Abbreviations: LUNA = laparoscopic utero-sacral nerve ablation; RCT = randomized controlled trial.

Table 17 summarizes assessments in each domain comprising strength of evidence for studies of surgical approaches.

Table 17. Strength of evidence domains for studies assessing surgical approaches to CPP

Study	No. of Studies (N participants)	Risk of Bias	Consistency	Directness	Precision	SOE	Magnitude of Effect
Pain Status: Reduction in Pain							
Surgery vs. nonsurgical therapy							
Peters et al.[75], Lamvu et al.[70]	2 (476)	High	Consistent	Direct	Imprecise	Insufficient	No difference between treatment groups
Hysterectomy vs. nonsurgical therapy							
Carlson et al.[54]	1 (118)	High	Unknown	Direct	Precise	Insufficient	Improvement in both treatment groups; no comparison
Laparoscopic adhesiolysis vs. diagnostic laparoscopy							
Swank et al.[93]	1 (98)	Low	Unknown	Direct	Imprecise	Low	No statistically significant intergroup difference in pain scale measures
LUNA vs. diagnostic laparoscopy							
Daniels et al.[51], Johnson et al.[80]	2 (466)	High	Consistent	Direct	Precise	Low	No difference between treatment groups
Pain Status: Reduction in Pain							
LUNA vs. utero-sacral ligament resection							
Palomba et al.[94]	1 (74)	High	Unknown	Direct	Imprecise	Insufficient	No difference between treatment groups
Pain Status: Activities of Daily Living							
Surgery vs. nonsurgical therapy							
Peters et al.[75]	1 (106)	High	Unknown	Direct	Imprecise	Insufficient	Improvement in ADL: Integrated 39/57; Standard 18/49
Functional Status							
Surgery vs. nonsurgical therapy							
Peters et al.[75]	1 (106)	High	Unknown	Direct	Precise	Insufficient	Improved in integrated, nonsurgical group vs. surgical group
Patient Satisfaction with Pain Management							
Hysterectomy vs. nonsurgical therapy							
Carlson et al.[54]	1 (146)	High	Unknown	Direct	Imprecise	Insufficient	Hysterectomy 68/75; Nonsurgical 50/71

Table 17. Strength of evidence domains for studies assessing surgical approaches to CPP

Study	No. of Studies (N participants)	Risk of Bias	Consistency	Directness	Precision	SOE	Magnitude of Effect
Quality of Life							
Laparoscopic adhesiolysis vs. diagnostic laparoscopy							
Swank et al.[93]	1 (98)	Low	Unknown	Direct	Imprecise	Low	No statistically significant intergroup difference in pain scale measures
Johnson et al.[80]	1 (153)	High	Unknown	Direct	Imprecise	Insufficient	No difference between treatment groups

Abbreviations: ADL = activities of daily living; LUNA = laparoscopic utero-sacral nerve ablation; N = number; SOE = strength of evidence.

KQ3. Evidence for differences in treatment outcomes by etiology. We did not locate studies addressing whether surgical outcomes differ if an etiology for CPP is identified after surgery.

KQ4. Effectiveness of nonsurgical approaches. We found few studies addressing nonsurgical therapies. In two of the five categories (antineuropathic agents and neuromuscular blocking agents), we found only one study, so evidence in this area is insufficient to evaluate effects on outcomes assessed as there are no comparison studies. Among hormonal therapies and nonpharmacologic interventions, none of the 11 studies used the same intervention or comparator (Table 18). Thus we have insufficient evidence to evaluate effects for outcomes for most of these as well, with the exception of low strength of evidence for the effects of raloxifene and depot leuprolide on pain stauts, assessed in one good and one fair quality placebo-controlled RCT, respectively.

For the primary outcomes and for secondary outcomes of patient satisfaction, quality of life, and functional status, nonsurgical interventions were evaluated to have insufficient strength of evidence, often because of single study. Studies generally had high risk of bias and frequent imprecision, and the studies examined diverse interventions and outcome measures (Table 18).

Table 18. Summary of results and strength of evidence for studies assessing nonsurgical treatments for CPP

Intervention	Study Design/ Quality	Study Results and Overall Strength of Evidence
Hormonal therapies	8 RCTs / 1 good,[77,85] 1 fair,[81] 6 poor[82,83,98-100,103] 1 prospective cohort study / 1 poor[97]	• Multiple interventions among studies, most without a placebo as comparator • Many were not blinded to participant • Overall, most hormone therapies show clinically significant improvement in pain, but unable to rate one as superior to another • Insufficient evidence to determine effectiveness with the exception of low strength of evidence for raloxifene and depot leuprolide vs. placebo
Antineuropathic agents	1 RCT / 1 poor[71]	• All 3 arms experience clinically significant reduction in pain • Insufficient evidence to determine effectiveness
Neuromuscular blocking agents	1 RCT / 1 fair[95]	• Clinically significant reduction in pain with intervention group compared with placebo • Insufficient evidence to determine effectiveness
Nonpharmacologic therapies	4 RCTs / 1 fair,[104] 3 poor[75,101,102]	• Integrated treatment approach, pelvic ultrasonography plus counseling, and pelvic floor muscle therapy showed clinically significant reduction in pain • Photographic-enhanced post-operative counseling showed no benefit • Insufficient evidence to determine effectiveness
Surgical vs. Nonsurgical approaches	2 prospective cohort studies/ 2 poor[54,70]	• Equivalent improvements for both varied surgical and nonsurgical therapy in pain status • Improvement in pain status for individuals electing hysterectomy vs. nonsurgical management, but no group comparison • Strength of evidence is insufficient with 2 poor quality cohort studies

Abbreviations: CPP = noncyclic chronic pelvic pain; RCT = randomized controlled trial.

Table 19 summarizes domain scores for each of the domains comprising strength of effectiveness (risk of bias, consistency, directness, and precision).

Table 19. Strength of evidence domains for studies assessing nonsurgical approaches to CPP

Study	Number of Studies (N participants)	Domains Pertaining to Strength of Evidence:				SOE
		Risk of Bias	Consistency	Directness	Precision	Overall SOE and Magnitude of Effect
Pain Status: Time to return of pain						
Raloxifene vs. Placebo						
Stratton et al.[77,85]	1 (93)	Low	Unknown	Direct	Imprecise	Low: quicker return to pain with raloxifene (OR 2.81, 95%CI 1.41–6.19)
Pain Status: Reduction in Pain						
GnRH analogue vs. GnRH analogue + E2/norethindrone vs. Estroprogestin						
Zupi et al.[98]	1 (133)	High	Unknown	Direct	Precise	Insufficient: improvement in both treatment groups, greater in GnRH (52% vs. 6%)
Depot leuprolide vs. Placebo						
Ling et al.[81]	1 (86)	Medium	Unknown	Direct	Precise	Low: greater reduction in pain with treatment (81% vs. 36%)
Gestrinone vs. Depot leuprolide						
Gestrinone Study Group[83]	1 (55)	High	Unknown	Direct	Imprecise	Insufficient: no statistically significant intergroup differences.
Goserelin vs. Monophasic OCP + E2						
Vercellini et al.[82]	1 (57)	High	Unknown	Direct	Imprecise	Insufficient: no statistically significant intergroup differences.
Medroxyprogesterone vs. placebo						
Walton et al.[103]	1 (165)	High	Unknown	Direct	Imprecise	Insufficient: no statistically significant intergroup differences.
Estroprogestin vs. GnRH agonist + estroprogestin						
Parazzini et al.[100]	1 (97)	High	Unknown	Direct	Imprecise	Insufficient: no statistically significant intergroup differences.
Botulinum toxin vs. Placebo						
Abbott et al.[95]	1 (60)	Medium	Unknown	Direct	Imprecise	Insufficient: no statistically significant intergroup differences.
Gabapentin vs. Amitryptyline vs. Gabapentin + Amitryptyline						
Sator-Katzenschlager et al.[71]	1 (56)	High	Unknown	Direct	Imprecise	Insufficient: groups with gabapentin showed greater improvement at 12mo: pain score 1.5/10 ± 0.9 vs. 2.2/10 ± 1.6

Table 19. Strength of evidence domains for studies assessing nonsurgical approaches to CPP (continued)

Study	Number of Studies (N participants)	Domains Pertaining to Strength of Evidence:				SOE
		Risk of Bias	Consistency	Directness	Precision	Overall SOE and Magnitude of Effect
Pain Status: Reduction in Pain						
Distention of pelvic floor muscles vs. counseling						
Heyward et al.[96]	1 (50)	High	Unknown	Direct	Imprecise	Insufficient: Improvement in treatment group VAS (35/100 vs. 0/100)
Photographic post-operative counseling vs. without photos						
Onwude et al.[101]	1 (233)	High	Unknown	Indirect	Imprecise	Insufficient: no difference in groups
Standard treatment for pelvic pain vs. integrated approach						
Peters et al.[75]	1 (112)	High	Unknown	Direct	Imprecise	Insufficient: No difference in McGill Pain Score
Pelvic ultrasonography vs. expectant management						
Ghaly[102]	1 (100)	High	Unknown	Direct	Imprecise	Insufficient: Greater reduction of pain with intervention (26% vs. 9%)
Hysterectomy vs. nonsurgical therapy						
Carlson et al.[54]	1 (118)	High	Unknown	Direct	Precise	Insufficient: Improvement in both treatment groups; no comparison
Surgical vs. nonsurgical therapy						
Lamvu et al.[70]	1 (370)	High	Consistent	Direct	Imprecise	Insufficient No difference between treatment groups
Pain Status: Activities of Daily Living						
Standard treatment for pelvic pain vs. integrated approach						
Peters et al.[75]	1 (112)	High	Unknown	Direct	Imprecise	Insufficient: Improvement in ADL: Integrated 39/57; Standard 18/49

Table 19. Strength of evidence domains for studies assessing nonsurgical approaches to CPP (continued)

Study	Number of Studies (N participants)	Domains Pertaining to Strength of Evidence:				SOE
		Risk of Bias	Consistency	Directness	Precision	Overall SOE and Magnitude of Effect
Patient Satisfaction with Treatment						
Depot medroxy-progesterone vs. Monophasic OCPs + Danazol						
Vercellini et al.[99]	1 (80)	High	Unknown	Direct	Precise	Insufficient: no statistically significant intergroup differences.
Vaginal ring vs. Transdermal patch						
Vercellini et al.[97]	1 (207)	High	Unknown	Direct	Imprecise	Insufficient: More satisfied with ring (RR, 1.50; 95% CI, 1.17–1.93), pain reduced in both groups
Hysterectomy vs. nonsurgical therapy						
Carlson et al.[54]	1 (146)	High	Unknown	Direct	Imprecise	Insufficient: Hysterectomy 68/75; Nonsurgical 50/71

Abbreviations: ADL = activities of daily living; CPP = noncyclic chronic pelvic pain; E2 = estradiol; GnRH = gonadotropin releasing hormone; OCP = oral contraceptive pill; OR = odds ratio; RR = relative risk; SOE = strength of evidence; VAS = visual analog scale.

KQ5: Evidence for choosing intervention approaches. We did not identify any comparative studies of interventions for CPP in participants who had a prior intervention that failed to achieve the target outcome(s).

Applicability

We set inclusion criteria intended to identify studies with applicability to women with noncyclic or mixed CPP. Studies differed considerably in terms of study populations, interventions, and outcome measures (Table 20). Many of the studies were noncomparative.

Table 20. Summary of outcome measures

Study, year	0-10 point VAS	0-100 point VAS	10 cm VAS	100 mm VAS	140 mm VAS	Activity Index	Andersch and Milson Verbal Pain Scale	Biberoglu and Behrman scale	Beck Depression Inventory	EQ-VAS	EuroQOL EQ-5D	General and Mental Health Indices	McGill Pain Questionnaire	Medication Quantification Scale	MOS SF 12 or 36	Pain diary	Pain interview	Sexual Activity Questionnaire	Social Readjustment Rating Scale	Symptoms interview	Verbal Pain Rating Scale	Other pain or symptoms duration scale	Other QOL scale	Other pain rating scale
RCTs																								
Daniels et al., 2009[51]			✓							✓	✓													
Stratton et al., 2008[77]	✓																							✓
Palomba et al., 2006[94]	✓			✓																				
Heyman et al., 2006[96]		✓																				✓		
Abbott et al., 2006[95]		✓									✓				✓			✓						
Sator-Katzen-schlager et al., 2005[71]	✓																							
Johnson et al., 2004[80]	✓																							
Onwude et al., 2004[101]					✓								✓				✓							
Zupi et al., 2004[98]	✓														✓									
Swank et al., 2003[93]		✓												✓	✓						✓			
Ling et al., 1999[81]	✓							✓					✓			✓								
Gestri-none Study Group, 1996[83]			✓					✓																
Vercellini et al., 1996[99]	✓							✓																
Ghaly, 1994[102]													✓											

Table 20. Summary of outcome measures

Study, year	0-10 point VAS	0-100 point VAS	10 cm VAS	100 mm VAS	140 mm VAS	Activity Index	Andersch and Milson Verbal Pain Scale	Biberoglu and Behrman scale	Beck Depression Inventory	EQ-VAS	EuroQOL EQ-5D	General and Mental Health Indices	McGill Pain Questionnaire	Medication Quantification Scale	MOS SF 12 or 36	Pain diary	Pain interview	Sexual Activity Questionnaire	Social Readjustment Rating Scale	Symptoms interview	Verbal Pain Rating Scale	Other pain or symptoms duration scale	Other QOL scale	Other pain rating scale
Vercellini et al., 1993[82]	✓						✓	✓																
Walton et al., 1992[103]				✓																				
Peters et al., 1991[75]													✓			✓				✓				
Prospective cohort studies																								
Vercellini et al., 2010[97]				✓				✓																
Lamvu et al., 2006[70]									✓				✓											
Carlson et al., 1994[54]						✓						✓								✓			✓	✓

Abbreviations: QOL = quality of life; RCT = randomized controlled trial; VAS = visual analog scale.

Lack of direct comparisons of treatment options further hinders our ability to know what findings will best extend to a specific patient or to decisions about care protocols within clinics or health systems. Overall the data that are available have fair to good applicability to women with noncyclic/mixed CPP populations in specialist or secondary care settings within the United States. Table 21 summarizes applicability of the evidence across the studies included in this review; Appendix F contains applicability tables for individual KQs.

Table 21. Applicability of noncyclic CPP evidence reviewed

Domain	Description of Applicability of Evidence
Population	The study populations represented by the reviewed studies consist of either highly selected women with CPP presenting to high-level referral centers specializing in CPP care or broader groups of women recruited from general gynecologic practices without CPP specialization. The patients referred to or attracted to this type of care are often different than the types of patients who present to a primary care physician or local gynecologist for the treatment of pelvic pain. Some of the findings, may not be generally applicable to larger populations. Specific intervention comparator studies generally were single institution studies, which may not be applicable to general populations. Participants were almost exclusively recruited from academic centers. Considering this, the participants in the included studies may not represent the typical pelvic pain patient—they could easily have a more refractory illness or complicating factors that precipitate referral. Patients in primary care practices and general obstetrics and gynecology practices may experience more improvement with the same treatments than the study populations. A preponderance of studies focused primarily on endometriosis-based CPP; for patients without endometriosis or with milder disease, these studies' findings cannot be applied.
Intervention	Interventions described as integrative care, involving multiple disciplines would be difficult to duplicate outside of specialty centers. Several of the hormonal therapies required complex or multi-disciplinary algorithms and close follow-up. Some of the interventions may not be applicable to general population of women with CPP. Laparoscopic lysis of abdominal adhesions, for example, is only applicable to a subset of women with CPP who undergo diagnostic laparoscopy and have visible adhesions.
Comparators	Most of the studies compared one treatment paradigm with another, which is appropriate to clinical practice. The lack of placebo-controlled trails in the studies, while detrimental to overall study strength, improves applicability.
Outcomes	Only 2 studies reported reduction of pain by 30% or 50%, which are the outcome measures deemed to be of clinical significance in the pain literature. Many patients are limited in activities of daily living or quality of life; reports of these outcomes are applicable to most of the patients with noncyclic CPP. Few studies assessed outcome variables such as functional status, quality of life or satisfaction with care. The outcomes measured mostly included a form of the VAS. While helpful to measure improvement in pain ratings, most patients clinically desire not only improvement in pain, but in day-to-day functionality and quality-of-life. Similarly, few studies looked at overall treatment satisfaction which, in practice, typically drives the selection of certain treatments over others.
Setting	The settings in which studies were conducted was highly diverse, which limits general applicability of any findings. When specified, all surgical procedures were performed at facilities with operating rooms, but the various levels of specialty and referral care were quite disparate. Most of the studies were set in large academic centers; many of these were European.

Abbreviations: CPP = noncyclic chronic pelvic pain; VAS = visual analog scale.

Applicability of the Evidence for Surgical Approaches

The study populations represented by the reviewed studies consist of either highly selected women with CPP presenting to high-level referral centers specializing in CPP care or broader groups of women recruited from general gynecologic practices without CPP specialization. Some of the findings, therefore, may be generally applicable to larger populations, while some may not be applicable. Specific intervention comparator studies generally were single institution studies, which may not be applicable to general populations.

Several interventions are represented in the reviewed studies, some of which may not be applicable to general population of women with CPP. Laparoscopic lysis of abdominal adhesions, for example, is only applicable to a subset of women with CPP who undergo diagnostic laparoscopy and have visible adhesions.

Most studies compared surgical (nonspecific) interventions with nonsurgical interventions or specific surgical techniques to diagnostic laparoscopy alone. One study compared two active interventions, LUNA to utero-sacral ligament resection. The outcomes assessed by the various studies were not uniform. All studies measured the effect of interventions of pain status, but the measurement techniques and definitions for improvement or comparison were generally not uniform. Few studies assessed other outcome variables, such as functional status, quality of life, or satisfaction with care.

The settings in which studies were conducted was highly diverse, which limits general applicability of any findings. When specified, all surgical procedures were performed at facilities with operating rooms, but the various levels of specialty and referral care were quite disparate. Comparisons across studies are also complicated by variability among surgeons' training and skills.

Applicability of the Evidence for Nonsurgical Approaches

Within studies addressing surgical approaches, participants were recruited from academic centers (17/17), and of those, 12/17 were European and one was conducted in Australia. The patients referred to or attracted to this type of care may be different than the types of patients who present to a primary care physician or local gynecologist for the treatment of pelvic pain. Considering this, the participants in the included studies may not represent the typical pelvic pain patient—they could easily have a more refractory illness or complicating factors that precipitate referral. Patients in primary care practices and general obstetrics and gynecology practices may experience more improvement with the same treatments than the study populations. Another factor which may contribute to this is the preponderance of endometriosis-based CPP within the included articles. Eight of 17 studies focused primarily on endometriosis-associated pain. Thus, for patients without endometriosis or with milder disease, these studies' findings cannot be applied.

The interventions employed are highly variable. There was a large focus on hormone therapies, which are a common first-line therapy in many gynecology practices. However, because many of these studies took place in Europe, the same drugs may not be available in the United States and other countries. Thus, the results may not directly translate. Also, being located in academic centers, often the intervention is more than just a medication but also includes a significant interaction with the treatment team and multidisciplinary therapies. For most primary care and gynecology practices, this type of treatment algorithm may be difficult to replicate; thus, similar results may not be possible.

These interventions were often compared with other active treatments, which is common in practice. Many patients often switch between therapies when one becomes ineffective or intolerable. The lack of placebos, while detrimental to overall study strength, improves applicability.

The outcomes measured mostly included a form of the visual analogue scale (VAS). While helpful to measure improvement in pain ratings, most patients clinically desire not only improvement in pain, but in day-to-day functionality and quality of life. These were not often assessed. Similarly, few studies looked at overall treatment satisfaction which, in practice, typically drives the selection of certain treatments over others.

Future Research

Gaps in Areas of Research

Research addressing therapies for CPP is largely composed of trials of active agents or approaches with little placebo-controlled research and little evidence of thorough identification of patient characteristics and potential etiologies for CPP. Notably, we did not locate any studies providing evidence that surgical outcomes differ if the etiology of CPP is identified after surgery (KQ3). We did not locate any studies providing evidence for choosing one intervention over another to treat persistent or recurrent CPP after an initial intervention failed to achieve the target outcome(s) (KQ5). The following sections outline gaps in the literature and future research needs.

Etiology. The causes of CPP are not well understood and may be associated with gynecologic (e.g. endometriosis) and nongynecologic (e.g., irritable bowel syndrome [IBS]) conditions. Diagnosis of an underlying cause is complicated because the pain is rarely associated with a single underlying disorder or contributing factor. Future research needs include:

- Analysis of distribution of the underlying causes of CPP
- Systematic assessment of the relationship between pain and disease, using approaches such as translational research (animal to clinical models)
- Longitudinal studies to identify subgroups at risk of developing CPP. Once these populations are identified, preventive strategies can then be investigated
- Developing understanding of the role of pelvic floor myofascial dysfunction in CPP
- Developing understanding of the role of visceral hyperalgesia in CPP
- Assessment of the effects of variations in sex steroid hormone levels on pain perception in both pain-free women and those with CPP.

Iatrogenic pain. Iatrogenic pain (pain resulting from a procedure or complication of a procedure performed by a clinician) is another understudied etiologic factor for CPP. Emerging causes of iatrogenic pain include use of permanent mesh (post-mesh pain syndrome), tubal ligation/occlusion (post-tubal syndrome), and endometrial ablation (post-ablative pain syndrome). Because these women are often not followed for long periods of time and no formal reporting system for complications exists, the prevalence of chronic pain in these women is likely underappreciated.

It is imperative that, in addition to studying chronic pain that emerges de novo, practitioners look inward at how the medical community may be contributing to the CPP problem. Prevention of iatrogenic pain may be the key to saving many CPP patients from years of treatment and decreased quality of life. Future research needs related to iatrogenic causes of CPP include:

- Understanding benefits and harms of interventions for newer procedures to treat pelvic organ prolapse and uterine bleeding
- Assessing chronic postoperative incisional pain as factor contributing to CPP
- Understanding connections between surgical approaches and nervous system changes that may perpetuate pain (e.g., damage to pelvic nerves from thermal energy)
- Understanding the role of repeat surgeries in the same location with declining benefit as a pain source

- Raising awareness of the importance of identifying an etiology for pain prior to hysterectomy with or without castration in young women.

Impact and resource utilization. CPP accounts for an estimated 1 in 10 outpatient gynecology visits, and an estimated $1.2 billion per year is spent on outpatient management of CPP in the United States (adjusted for inflation from $880 million in 1996).[10] To understand better how to manage CPP care, future research needs include:

- Assessment of the impact of CPP on the use of health services
- Economic analysis to determine most cost effective diagnosis and management strategies.

Standardized definitions and diagnostic criteria. As noted in this review and previous studies,[105] definitions of CPP vary across the literature and may conflate noncyclic and cyclic pain; Table 22 outlines definitions of CPP used in the studies comprising this review. Employing standardized definitions of CPP is a critical need in future research to establish clearly the condition under study and the effects of specific therapies. The lack of a standardized conception of CPP likely leads to a dilution of treatment effects that may be present, and clarifying our understanding of patient populations can help to bring treatment outcomes into focus. Similarly, few studies reporting comorbidity data used validated tools to diagnose comorbidities, and may relied on patient self-report. Future research needs related to defining and diagnosing CPP and comorbid conditions include:

- Widespread use of accepted definitions of CPP across studies
- Standard use of validated tools in studies to inform our understanding of the true prevalence of conditions reported to co-occur with CPP.
- Larger, prospective studies examining the extent to which comorbidities modify treatment approaches and outcomes in CPP.

Table 22. Descriptions/definitions of CPP in studies assessed

Study	CPP Description/Definition
Droz et al., 2011[76]	Nonmenstrual pelvic pain of 6 or more months' duration that is severe enough to cause functional disability or require medical or surgical treatment
Fenton et al., 2011[86]	May involve organ system diagnoses including gynecologic pain, interstitial cystitis or painful bladder syndrome, irritable bowel syndrome, vulvodynia, pelvic floor tension myalgia, and abdominal and pelvic myofascial pain
Vercellini et al., 2010[97]	Persistent pelvic pain (dysmenorrhea, dyspareunia, nonmenstrual pelvic pain) of more than 6 months' duration
Daniels et al., 2009[51]	Noncyclical pain, dysmenorrhea, or dyspareunia lasting longer than 6 months, located within and below the anterior iliac crests
Montenegro et al., 2009[78]	Continuous or recurrent pain in the lower abdomen or pelvis lasting at least 6 months, not related to pregnancy, and sufficiently severe to interfere with habitual activities; CPP excludes pain occurring exclusively in association with menstruation or during sexual intercourse
Pitts et al., 2008[79]	Any type of pain in the pelvic region including dysmenorrhea, dyspareunia, and pelvic pain not occurring with periods of intercourse, either on and off or constantly
Stratton et al., 2008[77,85]	Pelvic pain for at least 3 months
Fenton et al., 2007[87]	NR
Paulson et al., 2007[88]	Constant or intermittent pain of greater than 6-month duration is present in the pelvic area and lower abdomen
Abbott et al., 2006[95]	Chronic pelvic pain (dysmenorrhea, dyspareunia, dyschezia, and nonmenstrual pelvic pain) causing disruption to daily activities
Grace et al., 2006[14,15]	Pain in the lower abdomen of at least 6 months duration that is not associated with menstruation or sexual activity

Table 22. Descriptions/definitions of CPP in studies assessed (continued)

Study	CPP Description/Definition
Heyman et al., 2006[96]	Acyclic pain of at least 6-months duration; pain is typically dull, with diffuse aching throughout the lower abdomen or localized at the iliac fossa. Pain may increase pre- and paramenstrually. Upon rectal palpation, the findings in CPP consist of tenderness of the following structures: the musculature of the pelvic floor and possibly the coccygeal vertebrae and/ or the sacrotuberous/spinal ligaments
Lamvu et al., 2006[70]	Noncyclic pain of at least 6 months duration, localized to the pelvis, anterior abdominal wall, at or below the umbilicus and lower back and buttocks
Verit et al., 2006[92]	Pain longer than 6 month's duration, not exclusively associated with menstrual periods or sexual intercourse
Tu et al., 2006[89]	NR
Palomba et al., 2006[94]	Severe midline pelvic pain persisting for more than 6 months and unresponsive to common medical treatment
Sator-Katzenschlager et al., 2005[71]	Chronic pelvic pain persisting longer than 6 months
Williams et al., 2005[72,73]	Extended duration of pain in the pelvis; pain may originate from any organ system or pathology and may have multiple contributing factors
Zupi et al., 2004[98]	NR
Johnson et al., 2004[80]	Pelvic pain present as dysmenorrhea (primary or secondary), nonmenstrual pain, deep dyspareunia (pain with sexual intercourse) or dyschezia (defecatory pain) from more than 6 months
Onwude et al., 2004[101]	NR
Chung et al., 2003[74]	Noncyclic abdominal and pelvic pain lasting at least 6 months
Swank et al., 2003[93]	Continuous or intermittent abdominal pain of at least 6 months' duration
Zondervan et al., 2001[13]	Constant or intermittent pelvic pain of ≥6 months' duration, not exclusively associated with menstrual periods or sexual intercourse
Parazinni et al., 2000[100]	Pelvic pain lasting 3–12 months after laparoscopy or laparotomy
Bodden-Heidrich et al., 1999[90]	Chronic pain in the lower abdomen lasting longer than 6 months
Ling et al., 1999[81]	Chronic pelvic pain for at least 6 months unrelated to menstruation
Vercellini et al., 1996[99]	NR
Matthias et al., 1996[10]	Pain below the belly button or in the female organs for at least 6 months
Gestrinone Italian Study Group, 1996[83]	NR
Saravelos et al., 1995[84]	Pain in the pelvis persisting for ≥ 6 months
Carlson et al., 1994[54]	Pain of at least 6 months duration
Ghaly, 1994[102]	Pain of at least 6 months duration
Vercellini et al., 1993[82]	NR
Walton et al., 1992[103]	NR
Peters et al., 1991[75]	Chronic pelvic pain for at least 3 months

Abbreviation: CPP = noncyclic chronic pelvic pain.

Diagnostic approaches. Standardized, thorough diagnostic approaches are an important area for future study as the literature currently lacks clear delineation of patient populations. Moreover, standardized evaluations can be help to ensure that clinicians are treating the actual cause(s) of CPP versus pain symptoms. The International Pelvic Pain Society has published a clinical assessment document which could be utilized to standardize the initial evaluation of potential participants.[48] Research needs in this area include:

- Estimation of the accuracy of individual and combinations of diagnostic tests for CPP
- Assessing the role of magnetic resonance imaging (MRI) and positron emission tomography (PET)-scan in narrowing the differential diagnosis of CPP
- Development and validation of a new pain assessment tool to capture the multidimensional experience of pelvic pain.

Standardized outcome measures. Studies used numerous outcomes measures to assess pain, quality of life, and patient satisfaction. While studies typically used a VAS measure for pain, VAS scales varied widely (Table 20), making comparisons across studies difficult. Similarly, quality of life measures varied, and patient satisfaction was typically reported using unvalidated instruments. Future research needs should address:

- Use of standardized outcome measures such as those recommended by the IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) consensus conference.[68]

Nonsurgical and nonpharmacologic management. The research meeting our criteria largely assessed surgical and pharmacologic, especially hormonal, management of CPP, despite research suggesting the need to consider psychological and sociodemographic factors in understanding and treating chronic pain.[106-110] The few studies to address nonsurgical or nonpharmacologic approaches were generally of poor quality but reported some benefit from a pelvic physiotherapy technique,[96] ultrasonography plus counseling,[102] and an integrated treatment approach[75] emphasizing psychological, dietary, environmental, and physiotherapeutic treatment factors. One study reported no benefit of photographic display of pelvic findings at laparoscopy.[101]

Given the importance of a holistic approach to CPP, a better understanding of the potential effects of allied health, integrative medicine, and psychological and behavioral approaches is imperative, and research needs include:

- Studies of nonpharmacologic/nonsurgical interventions for CPP including acupuncture, transcutaneous electrical nerve stimulation (TENS), physiotherapy, cognitive behavioral therapy, advice and communication about pain, and education
- Studies of health care settings and consultation styles and their effects on the impact of the treatments for CPP
- High quality assessments of multidimensional treatment packages, including psychological therapies.

Pharmacologic approaches. Much of the literature addressing pharmacologic interventions for CPP investigated hormonal therapies in women with endometriosis-associated CPP, and few studies were placebo controlled. Future research needs include:

- Studies of nonhormonal agents such as tanezumab (a monoclonal antibody against nerve growth factor)
- Placebo-controlled studies.

Surgical compared with nonsurgical approaches. The literature also lacks studies comparing surgical and nonsurgical approaches, and future research in this area is important. Two poor quality cohort studies comparing surgical and nonsurgical approaches reported similar effects on pain status between modalities[54,70] and greater patient satisfaction with hysterectomy compared with nonsurgical management in one study.[54] One study comparing a standard laparoscopic

approach to an integrated approach emphasizing psychological and other treatments reported no differences in pain scores between approaches and improvements in "general pain experience" in the integrated approach arm.[75] Research needs include:

- Prospective, comparative studies addressing commonly employed surgical and medical treatment approaches for CPP.

Benefits of surgical treatment. Another important area for research lies in establishing whether surgical approaches are of benefit for CPP treatment, and if so, which approaches are superior. On study comparing LUNA with diagnostic laparoscopy alone (sham LUNA) reported similar outcomes between approaches.[51,80] One study reported no benefit of lysis of adhesions compared with laparoscopy alone,[93] and one comparing active approaches (LUNA vs. utero-sacral ligament resection)[94] reported no differences in pain outcomes between groups. Future research needs in this area include:

- Larger, rigorously conducted studies to help determine surgical outcomes, which patients are likely to benefit from surgery, and the optimal timing of intervention
- Study design that plans to use operative findings and histopathology to categorize patients after the surgical intervention, according to pathology identified (by type) or no pathology identified; then performing planned subgroup analysis to determine if efficacy of the surgical intervention varies according to identified diagnosis.
- Research to classify the therapeutic benefit of diagnostic laparoscopy, often used as a standard control arm in surgical studies.
- Multicenter studies using standardized approaches to enhance comparability across studies.

Study designs that enhance applicability of findings. Most women with CPP will undergo numerous interventions to try to diagnose and remedy their pain. Study designs typically employed in most CPP research do not provide a clear method for providing an alternate intervention if an initial intervention fails, which may diminish the applicability of findings to the larger population. We did not locate any studies assessing the trajectory of care when an initial intervention is not successful (KQ5). Research to address this issue could include:

- Developing study design methodology that plans for sequential alternate interventions if an initial intervention fails
- Standardizing patient history taking to ensure that relevant information about prior pain history and interventions attempted is adequately captured

Methodologic Issues

While 18 of the studies identified for this review were RCTs, few adhered to standard study design and reporting conventions as reflected in the generally poor quality of studies. In particular, few trials adequately concealed treatment assignments from participants, investigators, and outcome assessors, and just under half reported an intention-to-treat-analysis (7/18). Eight studies had dropout rates exceeding 10 percent, and in 7 out of 18 trials, more than 20 percent of participants were lost to followup. Most trials (n=13/18) did report an *a priori* primary outcome of interest and sample size calculation. Seven reported missing or incomplete outcome data adequately.

Among cohort studies (n=3), none employed blinded outcome assessors, and 1 provided an *a priori* sample size calculation. All studies had significant drop-out rates (> 10 percent). Attention

to study design and conduct in future research should aid researchers in drawing conclusions about outcomes of CPP treatment.

As noted, definitions of CPP varied across studies. Among studies reporting definitions for CPP, most (n=25) reported a pain duration (typically 6 months), and 5 specified an anatomic location for pain that was more specific than "lower abdomen or pelvis." Five studies included dysmenorrhea or dyspareunia along with noncyclic pain in their definition, and 8 of 36 studies reported no definition for CPP.

Outcome measures similarly varied across studies. While many studies used a VAS scale to assess pain, few studies used the same scale. Quality of life measures used were typically validated tools (e.g., SF 36) but varied among studies. Measures of patient satisfaction were typically not validated. Ideally, future research will better characterize CPP study populations.

Studies were typically of 6 to 12 months' duration with few providing long-term followup data after the cessation of an intervention. Future studies should extend the followup period to assess the degree to which outcomes are durable, especially as many women with CPP fail to adequate pain relief despite multiple interventions. RCTs in this literature also typically included fewer than 150 women with CPP, despite the high reported prevalence of CPP. Future research including larger sample sizes should yield greater confidence in treatment effects.

A thorough diagnostic investigation is necessary to treat any chronic pain effectively. For many conditions, this investigation typically follows a pre-determined algorithm, but no such algorithm exists for CPP. Thus, in each study of CPP interventions (and likely for each private practitioner), the patient is approached in a variable manner, and some possible diagnoses may or may not be ruled out before treatment begins. There is no assurance that the treated condition is the causative condition, which certainly influences overall treatment success. We recommend that future studies outline and report the diagnostic process for participants. Pelvic pain researchers would improve the overall quality of literature if an established diagnostic algorithm was developed and put forward for use. A standardized assessment of potential study participants and standardized inclusion criteria would permit systematic analysis of data from multiple trials.

Only four trials included here were placebo-controlled; the bulk of nonsurgical studies compared active agents, and no surgical studies used a placebo. A major source of both false positive and false negative results in trials of treatment for pain is the placebo effect, which in analgesic trials is often substantial and may have a duration of weeks or months.[63] The frequency of placebo effects varies among analgesic studies from zero to 100 percent.[63-65] In large double-blind randomized placebo-controlled medication trials, the total percentage of patients receiving placebo reporting a clinically significant effect from the placebo intervention for neuropathic pain or functional pain syndromes is 22 percent.[65] Placebo responses have also been large across a number of clinical trials for treatment of women's sexual dysfunction.[111]

Placebo-controlled trials of any surgical interventions are exceedingly rare. A challenge in interpreting observation trials of surgery, or randomized trials of surgical versus nonsurgical therapy, is that patients could not reasonably be blinded to the intervention,[65] which may be responsible for some overestimation of surgical benefits for pain relief,[112] as surgery can be associated with important placebo effects.[113] Operations that later proved to be useless, including gastric freezing for duodenal ulcers, internal mammary artery ligation for angina pectoris, and knee arthroscopy were initially reported to improve or eliminate the pain of 60 to100 percent of patients for a year after surgery.[63,114] Based upon the very small number of placebo-controlled randomized trials, the magnitude of the placebo effect of surgery for pain is about 35 percent.[114]

To understand the true effects of therapies for CPP, future research of interventions for relief of CPP should be placebo-controlled, with the exception of small pilot studies to evaluate the potential of a new intervention to be utilized in a future placebo-controlled trial.

Conclusions

The literature addressing therapies for CPP in women is of largely poor quality and inconclusive. While half of the literature comprised RCTs, only two were good quality[77,93] and three were fair.[51,81,95] Studies providing cross-sectional data about the prevalence of comorbidities varied in quality but were largely poor. Nonetheless, some conclusions can be drawn.

Among studies reporting data on the prevalence of comorbidities, prevalence estimates tended to be more tightly clustered in those studies that employed validated diagnostic criteria (e.g., Rome criteria for IBS), and studies using validated criteria were of higher quality. Studies of nonsurgical approaches typically addressed hormonal management of endometriosis-related CPP and were not placebo-controlled, thus limiting our ability to understand whether hormonal therapies would be beneficial for women with CPP without endometriosis and whether pain relief reported is due simply to the placebo effect. Some studies reported benefits of other nonsurgical approaches, but nonhormonal and nonpharmacologic management remain understudied.

Across the literature, higher quality intervention studies tended to demonstrate a lack of benefit: lysis of adhesions showed no benefit,[93] a SERM had a negative effect on pain.[77,85] Some studies suggest benefit of some approaches including depot leuprolide for endometriosis-associated CPP.[81]

Aside from the lack of benefit reported for adhesiolysis,[93] little evidence demonstrates the effectiveness of surgical approaches. Studies typically reported no differences in improvements in pain scores between groups in studies comparing surgical interventions with diagnostic laparoscopy alone or active surgical interventions. Studies comparing hysterectomy and nonsurgical management[54,70] reported similar improvements in pain scores between groups and greater patient satisfaction among women undergoing hysterectomy in a sample of women electing hysterectomy.[54] Despite numerous surgical techniques used extensively in treating CPP, few studies included more than 50 participants, and few were considered high quality. All of the studies with comparison data failed to demonstrate that surgery in general or any specific surgical technique was more efficacious than either nonsurgical intervention or the comparator technique in improving pain status in patients. No surgical technique was superior, and the evidence to conclude that surgical intervention is either effective or ineffective for the treatment of CPP is insufficient.

Indeed, the strength of evidence for effectiveness across interventions ranges from insufficient to low with few studies comparing the same intervention and variable patient populations. The literature lacks placebo-controlled studies, studies of nonhormonal interventions, studies of nonpharmacologic interventions, and studies comparing medical and surgical management. Studies establishing the benefit of surgery as a treatment option for CPP are also lacking.

Despite a prevalence for CPP rivaling that of widely studied conditions such as asthma,[8] little research assessing therapies exists. While there are many publications regarding pelvic pain, there are relatively few addressing noncyclic CPP, and of those, we evaluated few as providing high quality evidence. In sum, the literature overall is muddled by a lack of standardized

definitions for CPP and unclear diagnostic evaluation that make it difficult to determine whether studies are truly including women with CPP. Similarly, understanding comorbidity prevalence with CPP is difficult as conditions may be considered part of the differential diagnosis or a concomitant condition.

Improved characterization of the targeted condition, intervention, and population in CPP research is necessary to inform treatment choices for this commonly reported entity. A uniform definition of CPP and standardized evaluation of participants are lacking across the literature; study populations likely vary widely, and studies may be reporting effects from treating symptoms rather than a diagnosed condition. Thus our understanding of potential treatment effects is diluted.

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Acronyms and Abbreviations

ADL	Activities of daily living
AHRQ	Agency for Healthcare Research and Quality
BDI	Beck Depression Inventory
CI	Confidence interval
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CPP	Noncyclic chronic pelvic pain
EPC	Evidence based Practice Center
EQ VAS	EuroQol Visual Analog Scale
EQ-5D	EuroQol-5D
FSD	Female sexual dysfunction
g,G	Group
GnRH	Gonadotropin releasing hormone
IBS	Irritable bowel syndrome
IHS	International Headache Society
IC	Interstitial cystitis
IC/PBS	Interstitial cystitis/Painful bladder syndrome
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
KQ	Key question
LUNA	Laparoscopic utero-sacral nerve ablation
MPQ	McGill Pain Questionnaire
MRI	Magnetic resonance imaging
n, N	Number
NR	Not reported
OCP	Oral contraceptive pills
OR	Odds ratio
PBS	Painful bladder syndrome
PET	Positron Emission Tomography
QOL	Quality of life
RCT	Randomized controlled trial
RR	Relative risk
SERM	Selective estrogen receptor modulator
SOE	Strength of evidence
TENS	Transcutaneous Electrical Nerve Stimulation
TEP	Technical Expert Panel
VAS	Visual analog scale

Appendix A. Search Strategies

Last updated May 3, 2011

Table A1. PubMed search results

Search terms		Preliminary search results
#1	"chronic pelvic pain"	1932
#2	chronic OR recurrent OR recurring OR chronic disease[mh] OR noncyclic OR non-cyclic OR mixed	1141198
#3	"pelvic pain" OR pelvic pain[mh]	8305
#4	(musculoskeletal diseases[mh] OR myofascial[tiab]) AND (pelvic[tiab] OR pelvis[tiab] OR pelvis[mh] OR pelvic pain[tiab])	7333
#5	#1 OR (#2 AND (#3 OR #4)) AND eng[la] AND humans[mh] AND 1990:2011[dp]	2337
#6	#5 AND case reports[pt]	396
#7	#5 AND letter[pt]	52
#8	#5 AND comment[pt]	61
#9	#5 AND editorial[pt]	29
#10	#5 AND review[pt]	609
#11	#5 AND meta-analysis[pt]	13
#12	#5 AND practice guideline[pt]	14
#13	#5 NOT (#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12)	1280

Key: [mh] Medical Subject Heading; [la] language; [pt] publication type; [dp] publication date; [tiab] title/abstract word

*32 new items in May 2011 update

Table A2. CINAHL search results

Search terms		Preliminary search results
#1	((MH "Chronic Pain") OR (MH "Chronic Disease") OR chronic OR recurrent OR recurring OR noncyclic OR non-cyclic OR mixed) AND (pelvic pain OR (MH "Pelvic Pain")), limited to English language, human, research articles, and citations published since 1990; MEDLINE records excluded	23
#2	((MH "Musculoskeletal Diseases+") OR myofascial) AND (pelvic OR pelvis), limited to English language, human, research studies, and citations published since 1990; MEDLINE records excluded	59
#3	#1 OR #2	79
#4	#3 AND PT doctoral dissertation	7
#5	#3 AND PT systematic review	5
#6	#3 NOT (#4 OR #5)	67

Key: MH medical subject word; PT publication type

*7 new items in May 2011 update

Table A3. PsycINFO results (CSA interface)

Search terms		Preliminary search results
#1	KW=(chronic or recurrent or recurring) or DE=("chronic illness" or "chronic pain")	92687
#2	KW=(pelvic pain)	309
#3	KW=(pelvic or pelvis) and (DE=("musculoskeletal disorders" or "myofascial pain") or KW=(myofascial))	7
#4	#1 AND (#2 OR #3), limited to English language, human, peer-reviewed journals, and items published between 1990 and 2011	149
#5	#4 and PT=(letter)	2
#6	#4 and PT=(comment/reply)	7
#7	#4 and PT=(editorial)	1
#8	#4 and PT=(book)	1
#9	#4 and PT=(abstract collection)	1
#10	#4 not (#5 OR #6 OR #7 OR #8 OR #9)	136

Key: PT publication type; DE descriptor/subject term
Note: No new items retrieved in May 2011 update

Table A4. EMBASE results (1988–2011 file)

Search terms		Preliminary search results
#1	(chronic or recurrent or recurring or noncyclic or non-cyclic or mixed or chronic disease/ or chronic illness/ or chronic pain/)	1087381
#2	pelvic pain.mp. or pelvic pain syndrome/	8390
#3	(musculoskeletal disease/ or musculoskeletal pain/ or myofascial pain/) and (pelvis/ or pelvic.mp.)	241
#4	#1 AND (#2 OR #3), limited to English language; human; items published between 1990 and 2011; database source=EMBASE	2312
#5	#4 and conference paper.pt.	120
#6	#4 and review.pt	571
#7	#4 and short survey.pt	31
#8	#4 and book.pt	5
#9	#4 and editorial.pt	34
#10	#4 and letter.pt	57
#11	#4 and note.pt	49
#12	#4 and case report/	287
#13	#4 and practice guideline/	54
#14	#4 and “systematic review”/	31
#15	#4 and meta analysis/	15
#16	#4 not (#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 OR #13 OR #14 OR #15)	1161

Key: .pt publication type; .mp keyword
Note: With May 2011 update, changed from EMBASE Drugs and Pharmacology to full EMBASE database; 738 new items retrieved in May 2011. After eliminating 498 citations duplicated by the other database retrieval sets, 240 unique items were included in the update.

Appendix B. Excluded Studies

Exclusion Reasons:
X-1: Not original research
X-2: Population not applicable
X-3: Ineligible study size
X-4: Does not address key questions
X-5: Does not include relevant outcomes
X-6: Not published in English

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9. Abercrombie, P., Providing holistic care for women with chronic pelvic pain. Beginnings, 2010. 30(1): p. 20-1. X-1, X-2, X-3, X-4
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14. Roman, J.D., Surgical treatment of endometriosis in private practice: cohort study with mean follow-up of 3 years. J Minim Invasive Gynecol, 2010. 17(1): p. 42-6. X-2, X-3

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16. McGowan, L., et al., Is chronic pelvic pain a comfortable diagnosis for primary care practitioners: a qualitative study. BMC Fam Pract, 2010. 11: p. 7. X-1, X-2, X-3, X-4, X-5

17. Ansari, N.N., et al., Low back pain during pregnancy in Iranian women: Prevalence and risk factors. Physiother Theory Pract, 2010. 26(1): p. 40-8. X-2, X-3, X-4, X-5

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Appendix C. Evidence Tables

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Droz et al., 2011 **Country:** US **Enrollment period:** January 2005 to June 2007 **Intervention setting:** Clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Cross-sectional	**Operational definition of CPP:** Nonmenstrual pelvic pain of ≥ 6 months' duration that is severe enough to cause functional disability or require medical or surgical treatment. **Inclusion criteria:** • Seen in clinic for CPP • Completed MPQ **Exclusion criteria:** • Inadequate MPQ Data **Assessments:** 15-Point Short Form McGill Pain Questionnaire (0-3) **Groups:** **G1:** Women with CPP **N with non-cyclic CPP at enrollment:** **G1:** 326 **N with non-cyclic CPP at follow-up:** **G1:** 326 **Groups: Age, yrs, mean (range):** **G1:** 36 (15-82) **BMI, mean ± SD:** **G1:** NR **Parity, median (range):** **G1:** 1 (0-8) **Duration of pelvic pain, mean years (range):** **G1:** 8 (0.5 -55) **Intake diagnoses within CPP/ Indications for treatment, n (%):** Endometriosis: **G1:** 108 (32.6) IC/PBS: **G1:** 92 (27.8) IBS: **G1:** 83 (25.1) Vulvar vestibulitis: **G1:** 73 (22.1) Myofascial pain syndrome: **G1:** 64 (19.3) Pelvic adhesive disease: **G1:** 55 (16.6) Pelvic floor tension myalgia: **G1:** 33 (10.0) Sacroiliac pain: **G1:** 21 (6.3)	**Pain status, n endorsing (%), mean score ± SD [% of total MPQ Score]:** Sensory descriptors: Sharp: **G1:** 256 (77), 1.9 ± 1.2 [11.0] Cramping: **G1:** 248 (75), 1.8 ± 1.2 [10.8] Tender: **G1:** 253 (76), 1.7 ± 1.1 [10.0] Stabbing: **G1:** 227 (69), 1.7 ± 1.3 [8.9] Aching: **G1:** 255 (77), 1.6 ± 1.1 [9.7] Shooting: **G1:** 204 (62), 1.4 ± 1.2 [6.8] Throbbing: **G1:** 202 (61), 1.2 ± 1.1 [6.1] Heavy: **G1:** 165 (50), 1.1 ± 1.2 [5.1] Hot-burning: **G1:** 121 (37), 0.8 ± 1.1 [4.7] Gnawing: **G1:** 118 (36), 0.7 ± 1.0 [3.5] Splitting: **G1:** 91 (28), 0.5 ± 0.9 [2.2] Affective descriptors: Tiring-exhausting: **G1:** 222 (67), 1.5 ± 1.2 [7.7] Sickening: **G1:** 199 (60), 1.2 ± 1.2 [6.0] Fearful: **G1:** 147 (44), 0.9 ± 1.2 [4.0] Punishing-cruel: **G1:** 132 (40), 0.9 ± 1.2 [3.9] **Functional status:** **G1:** NR **Satisfaction with care:** **G1:** NR **Quality of life:** **G1:** NR	Anxiety: **G1:** NR Clinical depression: **G1:** NR Dysmenorrhea: **G1:** 12* Fibromyalgia: **G1:** NR Headache: **G1:** NR IBS: **G1:** 83 (25.1) IC/PBS: **G1:** 92 (27.8) Low back pain: Sacroiliac pain + concomitant diagnoses, n (%): **G1:** 21 (6.3) Sacroiliac pain alone, n (%): **G1:** 1 (5) Lumbar disk disease, n: **G1:** 7 Sexual dysfunction: **G1:** NR Vulvodynia: Vulvar vestibulitis syndrome + concomitant diagnoses: **G1:** 73 (22.1) Vulvar vestibulitis syndrome alone, n: **G1:** 5 Vulvodynia, n: **G1:** 3

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Droz et al., continued	Ilioinguinal neuralgia: **G1:** 17 Pelvic congestion syndrome: **G1:** 15 Adenomyosis: **G1:** 12 Ovarian remnant syndrome: **G1:** 9 Pudendal neuralgia: **G1:** 8 Primary dysmenorrhea neuralgia: **G1:** 7 Lumbar disk disease: **G1:** 7 Vaginal apex pain: **G1:** 6 Short leg syndrome: **G1:** 4 Post-pelvic inflammatory disease: **G1:** 3 Sciatic hernia: **G1:** 3 Inguinal hernia: **G1:** 3 Abdominal wall hernia: **G1:** 3 Vulvodynia: **G1:** 3 Endosalpingitis: **G1:** 2 Leiomyomata uteri: **G1:** 2 Vaginal atrophy: **G1:** 2 Inflammatory bowel disease: **G1:** 2 Erosive lichen planus: **G1:** 2 Coccygodynia: **G1:** 1 Premenstrual syndrome: **G1:** 1 Chronic appendiceal syndrome: **G1:** 1 Abdominal migraine: **G1:** 1 Pubic symphysis separation: **G1:** 1 **History of menstrual problems:** **G1:** NR **History of menstrual problems:** **G1:** NR **History of pelvic surgery:** **G1:** NR **History of sexual/physical abuse:** **G1:** NR **Other risk factors:**		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
	Pregnancy: **G1:** NR C-section: **G1:** NR Operative vaginal delivery: **G1:** NR Vaginal birth: **G1:** NR Genital tract trauma: **G1:** NR Pregnancy termination: **G1:** NR		

Comments: additional 5 patients with no pelvic pain-related diagnosis also reported in the paper
*Reported as adenomyosis in study

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, %:
Author: Fenton et al., 2011 **Country:** US **Enrollment period:** 2008 to 2010 **Intervention setting:** Clinic **Funding:** Summa Foundation **Author industry relationship disclosures:** NR **Design:** Retrospective Case Series	**Operational definition of CPP:** As reported/NR **Inclusion criteria:** • Multidisciplinary evaluation, including detailed history and physical exam as proposed by the IPPS • Completion of short form PROMIS questionnaire **Exclusion criteria:** • See inclusion criteria **Assessments:** PROMIS questionnaire converted to T scores, scaled to a mean (SD) of 50 (10). **Groups:** **G1:** Women with CPP **N with non-cyclic CPP at enrollment:** **G1:** 149 **N with non-cyclic CPP at follow-up:** **G1:** 149 **Groups: Age, median yrs:** **G1:** 32 **BMI, mean ± SD:** **G1:** NR **Parity, median:** **G1:** 1 **Duration of pelvic pain, median months:** **G1:** 30 **Intake diagnoses within CPP/ Indications for treatment, %:** Gynecologic pain: **G1:** 66 Interstitial cystitis: **G1:** 21 Irritable bowel syndrome: **G1:** 38 Vulvodynia: **G1:** 19 **History of menstrual problems, n (%):** **G1:** NR **History of pelvic surgery, %:** Laparoscopy: **G1:** 57 Tubal ligation: **G1:** 31 Hysterectomy: **G1:** 27 **History of sexual/physical abuse, n (%):** **G1:** NR	**Pain status:** **G1:** NR **Functional status:** **G1:** NR **Satisfaction with care:** **G1:** NR **Quality of life mean T score (SD):** Global Physical: **G1:** 38 (7)* Global Mental: **G1:** 45 (10)***** Anger: **G1:** 52 (11) Anxiety: **G1:** 53 (11) Depression: **G1:** 51 (12) Fatigue: **G1:** 56 (8)* Pain Behavior: **G1:** 60 (6)* Pain Impact: **G1:** 63 (8)* Physical Function: **G1:** 43 (7)* Social Satisfaction, Discretion: **G1:** 45 (9)* Social Satisfaction, Roles: **G1:** 44 (10)* Sleep Disturbance: **G1:** 59 (10)*	Anxiety: **G1:** NR Clinical depression: **G1:** NR Dysmenorrhea: **G1:** NR Fibromyalgia: **G1:** NR Headache: **G1:** NR IBS: **G1:** 38 IC/PBS: **G1:** 21 Low back pain: **G1:** NR Sexual dysfunction: **G1:** NR Vulvodynia: **G1:** 19

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, %:
Fenton et al., continued	**Other risk factors, n (%):** Pregnancy: **G1:** NR C-section: **G1:** NR Operative vaginal delivery: **G1:** NR Vaginal birth: **G1:** NR Genital tract trauma: **G1:** NR Pregnancy termination: **G1:** NR		

Comments: *Represent PROMIS T scores that are significantly different ($p<.05$) when corrected for multiple comparisons from the reference population mean of 50 (10). Fenton, p. 191

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Vercellini et al., 2010 **Country:** Italy **Enrollment period:** 2004 to 2007 **Intervention setting:** Endometriosis outpatient clinic **Funding:** University of Milan **Author industry relationship disclosures:** None **Design:** Prospective cohort (subject allowed to choose interven-tion group) **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Intervention:** Ethinyl estradiol via vaginal ring (15 mcg ethinyl estradiol + 120 mcg etonogestrel/day) or patch (0.60 mg ethinyl estradiol + 6.0 mg 17-deacetyl-norgestimate) for 21 days, followed by 7 days off; however, women were allowed to use either continuously **Assessments:** At baseline: pain questionnaire to assess severity and presence of dysmenorrhea, dyspareunia, and nonmenstrual pain on a 0-3 point Biberoglu and Behrman verbal rating scale; 100 mm VAS for the severity of each; lab work for serum chemistries and lipids Every 3 months: pelvic exam, US, lab work, pain questionnaire At 12 months: likert scale for overall treat-ment satisfaction **Groups:** **G1:** vaginal ring **G2:** patch **Ga:** rectovaginal endometriosis **Gb:** no rectovaginal endometriosis **N with noncyclic CPP at enrollment:** **G1a:** 23 **G1b:** 49 **G2a:** 7 **G2b:** 16 **N with noncyclic CPP at follow-up:** **G1a:** 11 **G1b:** 21 **G2a:** 6 **G2b:** 13 **Duration of treatment:** 12 months **Length of follow-up post-treatment day 1:**	**Operational definition of CPP:** Pelvic pain > 6 months duration (and not occurring during a bleeding episode) **Inclusion criteria:** • 18-40 years old • Regular menses • Not wanting pregnancy • BMI 18-27 kg/m^2 • Previous laparoscopy or laparotomy for stage I-IV symptomatic endometri-osis in prior 12 months • Persistent pain > 6 months • Unwilling to undergo another surgery • At least one moderate to severe pain symptom • Normal baseline lab **Exclusion criteria:** • Obstructive uropathy or bowel stenosis • Complex adnexal cysts/endometrioma greater than 3 cm • Treatments for endo-metriosis other than NSAIDS for prior 3 months (6 months for GnRH agonist) • Contraindications to estrogen/progestogen • Use of drugs that interfere with study drug metabolism • Allergy to study meds or NSAIDS • Abnormal breast findings • Active skin disease • Abnormal pap smear • STD/vaginal infection • Genital prolapsed • STD & vaginal infections • PID • Genital malformation • Pelvic varices • Genital malformations at previous surgery • GI/urologic/orthopedic diseases • Psychiatric illness • History of drug or alcohol abuse • Unwillingness to tolerate	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** Absent: **G1a:** 5 **G1b:** 12 **G2a:** 4 **G2b:** 6 Mild: **G1a:** 14 **G1b:** 23 **G2a:** 5 **G2b:** 7 Moderate: **G1a:** 7 **G1b:** 12 **G2a:** 2 **G2b:** 6 Severe: **G1a:** 2 **G1b:** 4 **G2a:** 0 **G2b:** 3 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment:** NA **Pain status:** 12 months: Absent: **G1a:** 17 **G1b:** 30 **G2a:** 5 **G2b:** 9 Mild: **G1a:** 11 **G1b:** 18 **G2a:** 6 **G2b:** 11 Moderate: **G1a:** 0 **G1b:** 3 **G2a:** 0 **G2b:** 2 Severe: 0 in all groups **Functional status:** NR **Satisfaction with care:** Overall very satisfied or satisfied, %:* **G1:** 71 **G2:** 48 **G1/G2:** *P* < 0.001 RR = 1.50 (95% CI: 1.17-1.93) **Quality of life:** NR **Non-surgical harms, n (%):**** Weight gain: **G1:** 8 (6) **G2:** 4 (5) **G1/G2:** *P* = 0.82 Headache: **G1:** 7 (6) **G2:** 15 (18) **G1/G2:** *P* = 0.01 Vomiting: **G1:** 0 (0) **G2:** 2 (2) **G1/G2:** *P* = 0.31 Nausea: **G1:** 3 (2) **G2:** 7 (8) **G1/G2:** *P* = 0.10

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Vercellini et al., continued	12 months **Treatment adherence reported:** Yes **Concomitant therapies, %:** Naproxen 550 mg bid: **G1:** 100 **G2:** 100 **Concomitant therapies held stable during treatment:** NR	menstrual changes **Age:** NR **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		Depression: **G1:** 7 (6) **G2:** 4 (5) **G1/G2:** *P* = 0.76 Decreased libido: **G1:** 5 (4) **G2:** 4 (5) **G1/G2:** *P* = 0.80 Breast tenderness: **G1:** 6 (5) **G2:** 7 (8) **G1/G2:** *P* = 0.47 Skin reaction: **G1:** 0 (0) **G2:** 4 (5) **G1/G2:** *P* = 0.05 Bloating/swelling: **G1:** 12 (10) **G2:** 3 (3) **G1/G2:** *P* = 0.15 Vaginal discomfort: **G1:** 8 (7) **G2:** 0 (0) **G1/G2:** *P* = 0.04 Vaginal dryness: **G1:** 0 (0) **G2:** 2 (2) **G1/G2:** *P* = 0.31 Other: **G1:** 4 (3) **G2:** 5 (6) **G1/G2:** *P* = 0.55 **Confounders:** Age, previous pregnancies, BMI, ASRM stage, endometriomas, RV lesions, pain severity, type of delivery system (intervention), NSAID use considered **Effect modifiers:** NR

Comments: * ITT analysis of all subjects, not only those with noncyclic pain ** harms reported for all participants, not only those with noncyclic pain

Evidence tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities:
Author: Montenegro et al., 2009 **Country:** Brazil **Enrollment period:** NR **Intervention setting:** Academic medical center **Funding:** NR **Author industry relationship disclosures:** None **Design:** Cross sectional	**Operational definition of CPP:** Lower abdominal pain lasting at least 6 months, occurring continuously or intermittently and not associated exclusively with menstruation or intercourse **Inclusion criteria:** • Consecutive women with CPP of > 6 months duration **Exclusion criteria:** • See inclusion criteria **Assessments:** Nature of pain, personal history, BDI, VAS, MPI, physical exam and postural assessment by 2 physical therapists, blind to all clinical data **Groups:** **G1:** CPP **N with noncyclic CPP at enrollment:** **G1:** 108 **N with noncyclic CPP at follow-up:** **G1:** 108 **Age, yrs, mean ± SD:** **G1:** 35.3 ± 8.6 **BMI, mean ± SD:** **G1:** 26.0 ± 4.8 **Parity, median (range):** **G1:** 2 (0-6) **Duration of pelvic pain, months, mean ± SD:** **G1:** 60.9 ± 6.4 **Intake diagnoses within CPP/ Indications for treatment:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section, n (%): **G1:** 38 (35.2) Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination, n (%): **G1:** 22/106 (20.7)	**Pain status, mean ± SD:** VAS: 66.8 ± 2.1 MPI: 28.7 ± 2 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea, n (%): **G1:** 67 (62) Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction, n (%): Dyspareunia (mild, moderate, and intense symptoms): 82 (76) Dyspareunia (moderate and intense symptoms only): 53 (49) Vulvodynia: NR

Comments: Postural changes in women with CPP are the main study focus. Musculoskeletal changes were associated with CPP in 34% of women.

Evidence Tables. Therapies for Women with Noncyclic Chronic Pelvic Pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Daniels et al., 2009 **Country:** UK **Enrollment period:** February 1998 to December 2005 **Intervention setting:** Multicenter UK hospitals **Funding:** Wellbeing for Women, Birmingham Women's Foundation, UK Department of Health **Author industry relationship disclosures:** None **Design:** RCT **Blinding of:** Subjects: Yes, except for 13 women Clinicians: No Investigators: NR Outcome assessors: NR	**Intervention:** LUNA (laparoscopic uterosacral nerve ablation) **Assessments:** Pain (10 cm VAS); EuroQoL EQ-5D; EQ-VAS **Groups:** **G1:** LUNA **G2:** no LUNA **N with noncyclic CPP at enrollment:** **G1:** 219 **G2:** 228 **N with noncyclic CPP at follow-up:** 6 months: **G1:** 181 **G2:** 189 12 months: **G1:** 185 **G2:** 185 60 months: **G1:** 96 **G2:** 104 **Duration of treatment:** 1 day **Length of follow-up post-treatment day 1:** 12 months – 5 years **Treatment adherence reported:** Yes **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** Noncyclic pain, dysmenorrhea, or dyspareunia, > 6 months, within or below anterior iliac crests **Inclusion criteria:** • CPP • Planned to undergo diagnostic laparoscopy **Exclusion criteria:** • Previous LUNA or hysterectomy • Previous therapeutic procedures for endometriosis or PID • Previous diagnosis of endometriosis or PID **Age:** NR **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Noncyclic pain: **G1:** 159/243 (65) **G2:** 153/244 (63) Dysmenorrhea, dyspareunia, and noncyclic pain: **G1:** 89/243 (37) **G2:** 79/244 (32) **Pain status, VAS score, cm:** Overall worst pain level:* **G1:** NR** **G2:** NR** Noncyclic pain: NR Dysmenorrhea: NR Dyspareunia: NR **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment:** NR for participants with noncyclic pain only **Pain status, 12 months, VAS score, cm, treatment effect (95% CI):** Overall worst pain level:* **G1/G2:** -0.02 (-0.61, 0.65) Noncyclic pain: **G1/G2:** 0.17 (-0.4, 0.74) **Pain status, 12 months, VAS score, cm, treatment effect (95% CI), last observation carried forward analysis:** Overall worst pain level:* **G1/G2:** NR Noncyclic pain: **G1/G2:** 0.35 (-0.19, 0.88) **Functional status:** NR **Satisfaction with care:** NR **Quality of life, 12 months, treatment effect (95% CI):** EuroQoL EQ-5D: **G1/G2:** 0.03 (-0.03, 0.09) *P* = 0.30 EQ-VAS: **G1/G2:** -0.78 (-3.9, 5.4) *P* = 0.30 **Non-surgical harms:** NR **Confounders:** NR

Evidence Tables. Therapies for Women with Noncyclic Chronic Pelvic Pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Daniels et al., continued				**Effect modifiers, treatment effect (95% CI):** Noncyclic pain: Parity: Nulliparous: **G1/G2:** -0.02 (-0.41, 0.37) Parous: **G1/G2:** -0.12 (-0.47, 0.20) *P* = 0.60 Pathology: None **G1/G2:** -0.08 (-0.34, 0.18) Any minimal **G1/G2:** 0.64 (-0.68, 1.39) *P* = 0.20 Site of pain: Central: **G1/G2:** -0.15 (-0.46, 0.16) Not central: **G1/G2:** 0.01 (-0.50, 0.51) *P* = 0.30 Worst pain level:* Parity: Nulliparous: **G1/G2:** 0.34 (-0.06, 0.74) Parous: **G1/G2:** -0.08 (-0.41, 0.24) *P* = 0.50 Pathology: None: **G1/G2:** 0.10 (-0.16, 0.36) Any minimal: **G1/G2:** 0.19 (-0.81, 1.18) *P* = 0.20 Site of pain: Central: **G1/G2:** -0.03 (0.31‡, 0.30) Not central: **G1/G2:** 0.10 (-0.49, 0.49) *P* = 0.20

Comments: * indicates worst pain level experienced from any of the 3 types of pain analyzed—noncyclic pain, dysmenorrhea, dyspareunia ** data only illustrated graphically in Figure 2

‡ appears to be missing a negative sign as reported in the study

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Stratton et al., 2008, 2010 **Country:** US **Enrollment period:** January 1999 to December 2004 **Intervention setting:** Clinic **Funding:** NIH **Author industry relationship disclosures:** None **Design:** Randomized, placebo controlled clinical trial **Blinding of:** Subjects: Yes Clinicians: Yes Investigators: Yes Outcome assessors: Yes	**Intervention:** Raloxifene, 180 mg daily for 6 months versus placebo **Assessments:** QOL questionnaires and pelvic pain (VAS 0, no pain, to 10, worst) questionnaires every 3 months. Pain assessed (with VAS) for dysmenorrhea, dyspareunia and non-menstrual pelvic pain Subjective verbal ratings for: *Nonmenstrual pain* (Mild = occasional, Moderate = most of time, Severe = daily); *Dysmenorrhea* (Minimal = patients able to work with reduced efficiency, Moderate = patients in bed or could not work part of 1 day, Severe = patients in bed > 1 day or incapacitated); *Dyspareunia* (Mild = discomfort tolerated during intercourse, Moderate = intercourse interrupted by pain, Severe = intercourse avoided because of pain). Headache severity by Visual Analog scale (0-10); headache classified using International Headache Society criteria Standardized questionnaires on pelvic pain, headache, depression and quality of life Complete blood count, serum lipids, liver function test, blood urea nitrogen, creatinine, electrolytes, glucose, thyroid panel,	**Operational definition of CPP:** 3 months of pelvic pain **Inclusion criteria:** • Age 18-45 • 3-month history of pelvic pain • Biopsy-proven endometriosis at laparoscopy • Postoperative significant pelvic pain reduction **Exclusion criteria:** • CPP resulting from: infectious, gastrointestinal, musculoskeletal, neurologic, or psychiatric causes • Significant abnormalities in physical or laboratory examination • Hormonal contraception, selective estrogen receptor modulators, progestins, estrogens, steroids or ovulation induction in prior 3 months to enrollment • Medical or surgical treatment for endometriosis in prior 6 months • History of venous thrombosis events, stroke, transient ischemic attack, manic depressive illness, or untreated major depression • Hysterectomy, BSO, pregnant or lactating **Age, yrs, mean (SE):** **G1:** 31.1 (1.1) **G2:** 32.0 (1.1) **G3a:** 31.2 ± 0.8 SEM **G3b:** 31.5 ± 1.4 SEM **BMI, mean (SE):** **G1:** 25.3 (0.7) **G2:** 25.3 (0.9) **G3a:** 25.1 ± 0.6 SEM **G3b:** 28.4 ± 1.2 SEM (G3a/G3b p=.01) **Parity, mean (SE):** **G1:** 1.0 (0.3) **G2:** 1.0 (0.2) **G3a:** 0.9 ± 0.2 SEM **G3b:** 1.3 ± 0.4 SEM (G3a/G3b p=ns) **Duration of pelvic pain, mean years (SE) (range):**	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** **G1, G2:** NR* Non-menstrual pain severity, mean ± SEM: **G3a+b:** 5.2 ± 0.2 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** Pain, mean ± SEM: **G1:** NR **G2:** NR **G3a**: 61.5 ± 4.1 **G3b**: 63.0 ± 6.3 (p=ns) Disability, mean ± SEM: **G1:** NR **G2:** NR **G3a**: 18.0 ± 2.9 **G3b**: 22.2 ± 6.2 (p=ns) General health, mean ± SEM: **G1:** NR **G2:** NR **G3a**: 71.2 ± 1.8 **G3b**: 62.9 ± 3.4 (p=.02) Depression, mean ± SEM: **G1:** NR **G2:** NR **G3a**: 27.1 ± 2.1 **G3b**: 34.2 ± 4.0 (p=ns)	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** Return of pelvic pain, n (%):** **G1:** 14 (30) **G2:** 11 (24.4) **G1/G2:** *P* = 0.64 Time to return of pelvic pain, mean: **G1:** NR* **G2:** NR* **G1/G2:** *P* = 0.03 Biopsy proven endometriosis at secondary laparoscopy, n: **G1:** 16/23 **G2:** 13/17 **G1/G2:** *P* = 0.52 Time to second surgery, days, mean (SE): **G1:** 530 (48) **G2:** 682 (46) **G1/G2:** *P* = 0.016 Recurrence of pain, controlling for second surgery, odds ratio (95% CI): **G1/G2:** OR = 1.71 (1.10, 2.71) *P* = 0.02 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** Mental health status, mean change: **G1:** -5.3 **G2:** 5.8 **G1/G2:** *P* < 0.05 **Non-surgical harms, n (%):** Ovarian cyst: **G1:** 8 (17) **G2:** 5 (11.1) **G1/G2:** *P* = NS Headaches:

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Stratton et al., continued	antinuclear antibody, rheumatoid factor, erythrocyte antisedimentation rate, and creatinine kinase. Bone densitometry at baseline, 6 and 12 months. Histological exam of excised tissue following laparoscopic exam to establish or exclude endometriosis **Groups:** **G1:** raloxifene **G2:** placebo **G3a**[‡]**:** CPP + Endometriosis **G3b:** CPP + No Endometriosis **N with noncyclic CPP at enrollment:** **G1:** 47 **G2:** 46 **G3a:**81 **G3b:**27 **N with noncyclic CPP at follow-up:** **G1:** 38 **G2:** 35 **G3a:**81 **G3b:**27 **Duration of treatment:** 6 months **Length of follow-up post-treatment day 1:** 18 months **Treatment adherence reported:** NR **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	**G1:** 10.6 (0.9) (0.75-32) **G2:** 10.8 (1.3) (1-28) **G3a+b:** 10.3 ± 0.7 SEM **History of menstrual problems:** NR **History of pelvic surgery, n (%):** Prior laparoscopies for endometriosis: 1: **G1:** 22 (46.8) **G2:** 22 (47.8) ≥ 2: **G1:** 15 (31.9) **G2:** 14 (30.4) History of laparotomy **G1:** 7 (14.9) **G2:** 4 (8.7) **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		**G1:** 10 (21.3) **G2:** 9 (20) **G1/G2:** *P* = NS Migraines: **G1:** 6 (12.8) **G2:** 8 (17.8) **G1/G2:** *P* = NS Depression: **G1:** 8 (17) **G2:** 4 (8.9) **G1/G2:** *P* = NS Pregnant: **G1:** 1 (2.1) **G2:** 3 (6.7) **G1/G2:** *P* = NS Number reduced or stopped study drug: **G1:** 15 (31.9) **G2:** 22 (48.9) **G1/G2:** *P* = 0.09 Reasons drug stopped: Pelvic pain: **G1:** 8 (17) **G2:** 7 (15.6) **G1/G2:** *P* = 0.23 Ovarian cyst: **G1:** 4 (8.5) **G2:** 4 (8.9) **G1/G2:** *P* = 0.53 Headaches:*** **G1:** 4 (8.5) **G2:** 6 (13.3) **G1/G2:** *P* = 0.58 Migraines: **G1:** 3 (6.4) **G2:** 5 (11.1) **G1/G2:** *P* = 0.6 Depression: **G1:** 3 (6.4) **G2:** 2 (4.4) **G1/G2:** *P* = 0.43 **Confounder(s):** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: **G1:** 17 (36.2) **G2:** 21 (45.7) **G3a+b:** With migraine: 33%

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Stratton et al., continued				**G3a+b:** Non-migraine headaches: 23% Without headaches: 17%) (p=ns) Clinical "depression on hormones": **G1:** 9 (19.2) **G2:** 6 (13.0) Dysmenorrhea: NR Fibromyalgia: NR Headaches, n (%): **G1:** 32 (68.1) **G2:** 39 (84.8) Headaches on hormones, n (%): **G1:** 3 (6.4) **G2:** 9 (19.6) **G3a:** NR **G3b:** NR Migraines, n (%): **G1:** 25 (53.2) **G2:** 34 (73.9) **G3a**: 54 (66.7) **G3b**: 18 (66.7) Non-migraine, n (%): **G1:** NR **G2:** NR **G3a**: 11 (13.6) **G3b**: 2 (7.4) No headache, n (%) **G1:** NR **G2:** NR **G3a**: 16 (19.8) **G3b**: 7 (25.9) IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction: NR Vulvodynia: NR

Comments: * Data only illustrated graphically in Figures 2 and 3; ** Primary end point defined as return of pelvic pain, defined as 2 consecutive months of pelvic pain equal to or more severe than that at study entry; ‡Data for G3a and G3b from Karp 2010

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities:
Author: Pitts et al., 2008 **Country:** Australia **Enrollment period:** 2004 to 2005 **Intervention setting:** Population based **Funding:** National Health & Medical Research Council **Author industry relationship disclosures:** NR **Design:** Cross-sectional	**Operational definition of CPP:** Any type of pain in the lower part of belly not occurring with periods or intercourse either on and off or constantly **Inclusion criteria:** • Ages 16-49 years • Reported menstruating in the last 12 months • Sexually active **Exclusion criteria:** • Women aged ≥ 50 years • Currently pregnant or who had been pregnant in the previous 12 months **Groups:** **G1:** women with CPP not due to periods/during sex **N at enrollment (%):** **G1:** 427/1,983 (21.5) **Assessment:** Self-report **Age, yrs, %:*** 16-19 : **G1:** 8.0** 20-29: **G1:** 23.1** 30-39: **G1:** 33.6** 40-49: **G1:** 35.3** **BMI:** NR **Parity, %:*** 0: **G1:** 37.8** 1: **G1:** 10.9** 2: **G1:** 30.6** ≥ 3: **G1:** 20.2** **Duration of pelvic pain:** NR **Intake diagnoses within CPP/Indications for treatment:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors, %:*** C-section: NR	**Pain status:** Severe Pain, % (95% CI): **G1:** 20 (16.1, 24.6) Slight/mild pain, %: **G1:** 38.3 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea, n (%): **G1:** 357/427 (83.6) Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction, % OR (95% CI): Were anxious about sex: **G1:** 16.0*** OR = 1.46 (1.05, 2.01) Unable to orgasm: **G1:** 20.3*** OR = 1.31 (0.98, 1.75) Were quick to orgasm: **G1:** 7.0*** OR = 1.44 (0.91, 2.28) Had physical pain during sex: **G1:** 15.0*** OR = 1.86(1.30, 2.66) Had vaginal dryness: **G1:** 12.9*** OR = 1.46 (1.02, 2.07) Dyspareunia, n (%): **G1:** 124/427 (29) Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities:
Pitts et al., continued	Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy terminations: 0: **G1:** 85.2** 1: **G1:** 10.9** 2: **G1:** 3.5** ≥ 3: **G1:** 0.6**		

Comments: * n = total weighted N, weighted for sex & household size
** Computed from data in Tables 2 and 4 on incidence of other CPP in demographic categories.
*** Computed from data in Tables 3 on incidence of other CPP and sexual difficulty correlates.

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities:
Author: Fenton et al., 2008 **Country:** USA **Enrollment period:** September 2005 to January 2007 **Intervention setting:** Clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Cross-sectional	**Operational definition of CPP:** NR **Inclusion criteria:** • Consecutive patients seen at a chronic pelvic pain center during the enrollment period **Exclusion criteria:** • See inclusion criteria **Groups:** **G1:** CPP **Assessment:** VAS assessing total pain, pelvic pain, back pain, and migraine pain and duration of symptoms; 11-item pain disability score modified from the Roland-Morris back pain disability scale; interstitial cystitis symptom index (ICSI); five minor irritable bowel syndrome (IBS) criteria (Rome II); assessment of history of abuse; personality ratings for neuroticism, fear, and self-examination based on the inter-national personality item pool; number of pain-generating regions of the body (maximum of 27) **N with noncyclic CPP at enrollment:** **G1:** 175 **N with noncyclic CPP at follow-up:** **G1:** 175 **Age, yrs, mean:** **G1:** 36 **BMI:** NR **Parity, mean:** **G1:** 2 **Duration of pelvic pain, months, mean ± SD:** **G1:** 54.8 ± 60.7 **Intake diagnoses within CPP/Indications for treatment:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse, %:** **G1:** 55 **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Pain status:** Pelvic pain, VAS score, mean ± SD: **G1:** 7.4 ± 2.3 **Functional status:** Disability scale score, mean ± SD: **G1:** 5.7 ± 3.6 **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS, %: **G1:** 24 IC/PBS, %: **G1:** 35 Low back pain: NR Sexual dysfunction: NR Vulvodynia, %: **G1:** 5

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Paulson et al., 2007 **Country:** US **Enrollment period:** August 2002 to December 2005 **Intervention setting:** Clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Cross-sectional **Blinding of:** Subjects: NR Clinicians: NR Investigators: NR Outcome assessors: NR	Operational definition of CPP: NR **Inclusion criteria:** • Consecutive nonpostmeno-pausal women with CPP **Exclusion criteria:** • Musculoskeletal, gastrointestinal conditions • Other nongynecological & urological conditions **Assessments:** Pain Urgency and Frequency questionnaire, visual analog pain indices (0-10 scale), physical exam. Pain levels assessed before, immediately after treatment & after 3,6,12 months **Groups:** **G1:** CPP **N with noncyclic CPP at enrollment:** **G1:** 162 **N with noncyclic CPP at follow-up:** **G1:** 162 **Age < 18 yrs, n:** **G1:** 8 **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **Intake diagnoses within CPP/ Indications for treatment, n:** Endometriosis: **G1:** 16 Other intake diagnoses: NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Pain status, mean:** Pain Urgency and Frequency score: 21.2 VAS: Initial pain: 5.4 Dyspareunia: 7.3 Dysmenorrhea: 8.1 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: All IC: **G1:** 133 (82) IC only/no endometriosis: **G1:** 26 (16) IC and endometriosis: **G1:** 107 (66) Low back pain: NR Sexual dysfunction: NR Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Verit et al., 2006 **Country:** Turkey **Enrollment period:** NR **Intervention setting:** Academic outpatient clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Cross-sectional	**Operational definition of CPP:** Chronic pelvic pain > 6 months duration, not exclusively associated with menstrual periods or sexual intercourse **Inclusion criteria:** • Premenopausal women • Age 18-52 years • Married **Exclusion criteria:** • Pregnancy • Having surgery, labor, or delivery in < 3 months period • History of traumatic deliveries • Chronic inflammatory bowel disease • Mental diseases • Pain due to malignancy • Treated elsewhere for pain condition • Taking any medication that had potential both to impair and enhance sexual function (e.g., analgesics, psychotropic drugs) **Assessments:** Female Sexual Function Index (FSFI); unstructured interview for psychological history; general assessment questions for female sexual dysfunction (FSD; complaints categorized based on international classification of FSD proposed by International Consensus Development Conference; also divided by DSM-IV and ICD-10) **Groups:** **G1:** CPP **G1a:** CPP with sexual dysfunction **G1b:** CPP without sexual dysfunction **N at enrollment:** **G1:** 112 **G1a:** 78 **G1b:** 34 **N at follow-up:** NA **Age, yrs, mean ± SD (range):** **G1:** 34.73 ± 8.07 (18-50) **Age, yrs, range, n (%):** < 30: **G1:** 38 (33.9) **G1a:** 21 (26.9) **G1b:** 17 (50.0) 30-39: **G1:** 37 (33.0) **G1a:** 25 (32.1) **G1b:** 12 (35.3)	**Pain status:** VAS score, mean ± SD: **G1:** 5.72 ± 2.18 **G1a:** 6.62 ± 2.03 **G1b:** 4.64 ± 1.63 **G1a/G1b:** *P* < 0.001 **Functional status:** FSFI score, mean ± SD: Desire scale: **G1:** 3.31 ± 1.38 Arousal scale: **G1:** 3.58 ± 1.29 Lubrication scale: **G1:** 4.20 ± 1.52 Orgasm scale: **G1:** 3.70 ± 1.62 Satisfaction scale: **G1:** 3.80 ± 1.46 Pain scale: **G1:** 2.75 ± 1.39 Full scale: **G1:** 21.35 ± 7.74 **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction: **G1:** 78 (69.6) Hypoactive sexual disorder: **G1a:** 42 (53.8) Sexual arousal disorder: **G1a:** 26 (33.3) Orgasmic disorder: **G1a:** 17 (21.7) Sexual pain disorder: **G1a:** 58 (74.3) Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Verit et al., continued	40-49: **G1:** 36 (32.1) **G1a:** 31 (39.7) **G1b:** 5 (14.7) > 50: **G1:** 1 (0.9) **G1a:** 1 (1.3) **G1b:** 0 (0) **G1a/G1b:** *P* = NS **BMI:** NR **Parity, n (%):** 0: **G1:** 9 (8) **G1a:** 5 (6.4) **G1b:** 4 (11.8) 1-2: **G1:** 32 (28.6) **G1a:** 22 (28.2) **G1b:** 10 (29.4) ≥ 3: **G1:** 71 (63.4) **G1a:** 51 (65.4) **G1b:** 20 (58.8) **G1a/G1b:** *P* = NS **Pelvic pain, cumulative duration in last 12 in months, hrs, mean ± SD (range):** **G1:** 381.31 ± NR (4-1460) **G1a:** 571.73 ± 485.01 (NR) **G1b:** 71.85 ± 105.40 (NR) **G1a/G1b:** *P* < 0.0001 **Pelvic pain, first onset, n (%)** 6 months - 1 year: **G1:** 33 (29.5) **G1a:** 16 (20.5) **G1b:** 17 (50.0) > 1-5 years: **G1:** 49 (43.8) **G1a:** 38 (48.7) **G1b:** 11 (32.4) > 5 years: **G1:** 26 (23.2) **G1a:** 20 (25.6) **G1b:** 6 (17.6) Unable to recall: **G1:** 4 (3.6) **G1a:** 4 (5.1) **G1b:** 0 (0) **G1a/G1b:** *P* < 0.05 **Intake diagnoses within CPP/ Indications for treatment:** NR **History of menstrual problems:** NR		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Verit et al., continued	**History of pelvic surgery:** NR **History of sexual/physical abuse, n (%):** **G1:** 0 **Other risk factors, n (%):** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination, number of abortions: 0: **G1:** 66 (58.9) **G1a:** 43 (55.1) **G1b:** 23 (67.6) 1-2: **G1:** 31 (27.7) **G1a:** 23 (29.5) **G1b:** 8 (23.5) ≥ 3: **G1:** 15 (13.4) **G1a:** 12 (15.4) **G1b:** 3 (8.8) **G1a/G1b:** *P* = NS		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Tu et al., 2006 **Country:** US **Enrollment period:** 1993 to 2000 **Intervention setting:** University-based chronic pelvic pain clinic **Funding:** NR **Author industry relationship disclosures:** None **Design:** Cross-sectional See related studies, Williams et al., 2004 and Lamvu et al., 2006	**Operational definition of CPP:** NR **Inclusion criteria:** • New female patients seen at the gynecologic chronic pelvic pain clinic between 1993-2000 **Exclusion criteria:** • See inclusion criteria **Assessments:** Patient-completed medical history questionnaire (pain characteristics, including Rome I criteria to screen for IBS; Beck Depression Inventory; McGill Pain Index). Clinician-assessed pain via physical examination (0-10 point scale) **Groups:** **G1:** all women **G1a:** women with levator ani tenderness **G1b:** women without levator ani tenderness **G1c:** women with pyriformis tenderness **G1d:** women without pyriformis tenderness **N with noncyclic CPP at enrollment:** **G1:** 987 **G1a:** 212 **G1b:** 743 **G1c:** 127 **G1d:** 815 **N with noncyclic CPP at follow-up:** NA **Age, yrs, mean ± SD:** **G1:** 33.2 ± 10.1 **G1a:** 32.3 ± 10.0 **G1c:** 33.7 ± 9.3 **BMI:** NR **Parity:** NR **Duration of pelvic pain, yrs, mean ± SD:** **G1:** 4.5 ± 5.4 **G1a:** 4.9 ± 5.9 **G1b:** 4.3 ± 5.2 **G1c:** 4.8 ± 6.2 **G1d:** 4.4 ± 5.3 **Intake diagnoses within CPP/ Indications for treatment, n (%):** Endometriosis, related to pain: **G1:** 129/926 (14) **G1a:** 26/129 (20)	**Pain status:** Number of pain sites reported, mean ± SD: **G1:** 3.9 ± 1.8 **G1a:** 4.6 ± 1.8 **G1b:** 3.7 ± 1.8 **G1c:** 4.6 ± 1.9 **G1d:** 3.8 ± 1.8 Pain increased with bowel movements, n (%): **G1:** 372 (39) **G1a:** 106 (51) **G1b:** 261 (36) **G1c:** 62 (50) **G1d:** 299 (37) McGill Pain Index, mean ± SD: **G1:** 31.5 ± 15.5 **G1a:** 35.5 ± 14.8 **G1b:** 30.4 ± 15.4 **G1c:** 34.2 ± 13.8 **G1d:** 31.0 ± 15.6 **G1a/G1b:** $P < 0.001$ **G1c/G1d:** $P < 0.05$ **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression**: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS (Rome criteria), related to pain: **G1:** 331/955 (35) **G1a:** 71/331 (21) **G1c:** 47/326 (14) IBS (Rome criteria), unrelated to pain: **G1:** 624/955 (65) **G1a:** 141/624 (23) **G1c:** 81/617 (13) IC/PBS: NR Low back pain: NR Sexual dysfunction: dyspareunia, %: **G1:** NR **G1a:** 64 **G1b:** 67 **G1c:** NR **G1d:** NR Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Tu et al., continued	**G1c:** 20/129 (16) Endometriosis, unrelated to pain: **G1:** 86 (797/926) **G1a:** 176/797 (22) **G1c:** 102/786 (13) IBS (Rome criteria), related to pain: **G1:** 331/955 (35) **G1a:** 71/331 (21) **G1c:** 47/326 (14) IBS (Rome criteria), unrelated to pain: **G1:** 624/955 (65) **G1a:** 141/624 (23) **G1c:** 81/617 (13) Intraabdominal adhesions, related to pain: **G1:** 210/926 (23) **G1a:** 51/210 (24) **G1c:** 29/205 (14) Intraabdominal adhesions, unrelated to pain: **G1:** 716/926 (77) **G1a:** 151/716 (21) **G1c:** 93/710 (13) **History of menstrual problems:** NR **History of pelvic surgery, n (%):** Previous surgeries for pain:* None: **G1:** 274 (28) **G1a:** 48 (23) **G1b:** 218 (30) **G1c:** 27 (21) **G1d:** 238 (30) 1-3: **G1:** 585 (60) **G1a:** 128 (61) **G1b:** 440 (60) **G1c:** 80 (63) **G1d:** 478 (59) > 3: **G1:** 112 (12) **G1a:** 35 (17) **G1b:** 74 (10) **G1c:** 19 (15) **G1d:** 88 (11) **History of sexual/physical abuse, %:** **G1:** NR **G1a:** 49 **G1b:** 42 **G1c:** NR **G1d:** NR **Other risk factors:** C-section: NR		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Tu et al., continued	Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		

Comments: * Types of surgeries not reported ** Reports mean Beck Depression Inventory scores but not N with depression

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Palomba et al., 2006 **Country:** Italy **Enrollment period:** October 2001 to January 2003 **Intervention setting:** Hospital **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT, block randomization **Blinding of:*** Subjects: No Clinicians: No Investigators: No Outcome assessors: Yes	**Intervention:** Minimally invasive pelvic denervation, one time **Assessments:** Pain evaluated post-operatively every 2 hours for the first 12 hours, 24 hours, and at discharge using a 10 point VAS Symptom severity of CPP and deep dyspareunia evaluated with 100mm VAS ("least possible pain" to "worst possible pain") at baseline, and at 6 and 12 months post-intervention **Groups:** **G1:** laparoscopic uterine nerve ablation (LUNA) **G2:** vaginal uterosacral ligament resection **N with noncyclic CPP at enrollment:** **G1:** 40 **G2:** 40 **N with noncyclic CPP at follow-up:** **G1:** 36 **G2:** 38 **Duration of treatment:** <1 day **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** NR **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** Severe midline pelvic pain (VAS ≥ 80) persisting for more than 6 months and unresponsive to common medical treatment **Inclusion criteria:** • Postmenopausal (FSH > 40 U/L, E_2 < 20 pg/ml) women • Severe pelvic pain (VAS ≥ 80) persisting more than 6 months **Exclusion criteria:** • Major medical diseases • Psychological/psychiatric disorders • Neurological alterations of lumbar-sacral tract • Previous pelvic surgery • History of severe abdominal or pelvic infections • History of infertility • Presence of other gynecological pathologies • Previous or current use of HRT • Unable to complete the daily diary • History of alcohol or drug abuse • History of physical/sexual abuse **Age, yrs, mean ± SD:** **G1:** 55.2 ± 3.2 **G2:** 54.2 ± 3.7 **BMI, mean ± SD:** **G1:** 27.9 ± 2.1 **G2:** 28.5 ± 2.3 **Parity, median (range):** **G1:** 2 (0-4) **G2:** 2 (0-5) **Duration of pelvic pain, months, mean ± SD:** **G1:** 9.2 ± 4.6 **G2:** 10.7 ± 3.4 **History of menstrual problems:** NR **History of pelvic surgery, n (%):** **G1:** 0 **G2:** 0 **History of sexual/physical**	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Deep dyspareunia: **G1:** 38 (95) **G2:** 36 (90) **Pain status, mean ± SD:** Pain severity (100 mm VAS): **G1:** 86.1 ± 4.4 **G2:** 84.5 ± 3.1 **G2/G1:** *P* = 0.055	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** Pain severity (100 mm VAS), mean ± SD: **G1:** 50.5 ± 3.5 **G2:** 48.5 ± 3.2 **G2/G1:** *P* = 0.063 Complete pain relief at 12 months, %: **G1:** 19 **G2:** 22 CPP not requiring medical treatment at 12 months, %: **G1:** 19 **G2:** 23 Cure rate (complete relief + CPP not requiring treatment), n (%): **G1:** 27 (75) **G2:** 28 (74) **G2/G1:** RR = 0.90** (CI: 0.78-1.33) **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction, dyspareunia:

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Palomba et al., continued		**abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		**G1:** 38 (95) **G2:** 36 (90) Vulvodynia: NR

Comments: * Random allocation sequence was concealed until intervention was assigned.
** Though the comparison between the two groups for pain outcomes is not significant, the reported RR for 6 and 12 month follow-up cure rate is not clear. For the 12 month follow-up, the RR is reported as 0.90; however, it seems that the RR should be 1.02.
As cost was the primary outcome, it is unclear if the study is sufficiently powered to detect a difference in pain outcomes.

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Lamvu et al., 2006 **Country:** US **Enrollment period:** June 1993 to December 2000 **Intervention setting:** Pelvic pain clinic **Funding:** NR **Author industry relationship disclosures:** 1 of 7 Glaxo SmithKline (1) **Design:** Prospective cohort **Blinding of:** Subjects: NA Clinicians: NA Investigators: NA Outcome assessors: NA See related studies, Williams et al., 2004 and Tu et al., 2006	**Intervention:** Medical treatments: analgesics (opioid and nonopioid), antidepressants, anti-anxiety/ sedative-hypnotic/ anticonvulsant, estrogens, progestins, combination estrogens and progestins, injectable progestins, gonadotropin releasing hormone agonists, nonsteroidal anti-inflammatory drugs, trigger point injections, physical therapy, psychotherapy, or combinations thereof Surgical treatments: minimally diagnostic laparoscopy, lysis of adhesions, excision or ablation of endometriosis, unilateral or bilateral oopherectomy, ovarian cystectomy, pain mapping, uterine suspension, uterosacral ablation and hysterictomy. Laparotomy, vaginal or vulvar surgery (54 hysterectomies, 136 other procedures without hysterectomy). **Assessments:** Beck Depression Inventory; McGill Pain Questionnaire **Groups:** **G1:** Women treated primarily with medical interventions **G2:** Women treated primarily with surgical interventions **N with noncyclic CPP at enrollment:** **G1:** 181 **G2:** 189 **N with noncyclic CPP at follow-up:** **G1:** 181 **G2:** 189 **Duration of treatment:** ≤ 1 year	**Operational definition of CPP:** Self-reported pelvic pain lasting ≥ 6 months, usually localized to 1 or more of the following anatomic areas: abdomen (below the umbilicus), pelvic organs, lower back, vulva, or vagina **Inclusion criteria:** • Women with pelvic pain lasting ≥ 6 months **Exclusion criteria:** • See inclusion criteria **Age, yrs, mean ± SD (range) (95% CI):** **G1:** 34.8 ± 11.6 (15-70) (33.1, 36.5) **G2:** 31.9 ± 8.0 (14-59) (30.8, 33.0) **Total:** 33.3 ± 10.0 (14-70) (32.3, 34.3) **BMI:** NR **Parity:** NR **Duration of pelvic pain, yrs, mean ± SD (range) (95% CI):** **G1:** 4.9 ± 6.3 (0.1-34) (4.0, 5.8) **G2:** 4.4 ± 4.4 (0.1-20) (3.8, 5.0) **Total:** 4.6 ± 5.4 (0.1-34) (4.0, 5.2) **History of menstrual problems:** NR **Previous surgical treatment, n (%) (95% CI):** **G1:** 163 (90) (85, 94) **G2:** 182 (96) (93, 99) **Total:** 345 (93) (90, 96) **History of sexual abuse, n (%) (95% CI):** **G1:** 68 (38) (31, 45) **G2:** 65 (34) (28, 42) **Total:** 133 (36) (31, 41) **History of physical abuse, n (%, 95% CI):** **G1:** 44 (29) (18, 31) **G2:** 48 (32) (19, 32) **Total:** 92 (30) (21, 30) **Other risk factors, n (%):** C-section: NR Operative vaginal delivery: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%) (95% CI):** IBS: **G1:** 68 (38) (31, 45) **G2:** 67 (36) (29, 43) **Total:** 135 (37) (32, 42) Adhesions: **G1:** 25 (14) (9, 20) **G2:** 60 (32) (25, 39) **Total:** 85 (23) (19, 28) Pelvic floor tension: **G1:** 51 (28) (22, 35) **G2:** 33 (18) (12, 24) **Total:** 84 (23) (19, 27) Myofascial pain-vaginal: **G1:** 33 (18) (13, 25) **G2:** 25 (13) (9, 19) **Total:** 58 (16) (12, 20) Endometriosis: **G1:** 20 (11) (7, 17) **G2:** 37 (20) (14, 26) **Total:** 57 (16) (12, 20) Pyriformis pain: **G1:** 29 (16) (11, 22) **G2:** 21 (11) (7, 17) **Total:** 50 (14) (10, 17) Vestibulitis: **G1:** 16 (9) (5, 14) **G2:** 10 (5) (3, 10) **Total:** 26 (7) (5, 10) Vaginismus: **G1:** 10 (6) (3, 10) **G2:** 7 (4) (2, 8) **Total:** 17 (5) (3, 7) Pelvic congestion: **G1:** 7 (4) (2, 8) **G2:** 5 (3) (1, 6) **Total:** 12 (3) (2, 6) Adenomyosis: **G1:** 5 (3) (1, 6) **G2:** 2 (1) (0, 4) **Total:** 7 (2) (1, 4) Fibroids: **G1:** 4 (2) (1, 6) **G2:** 2 (1) (0, 4) **Total:** 6 (2) (1, 4) Pelvic relaxation:	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** Pain levels, 12 months, n (%) (95% CI) No/minimal pain: **G1:** 77 (43) (35, 50) **G2:** 98 (52) (45, 59) **Total:** 175 (47) (42, 53) Mild: **G1:** 38 (21) (15, 28) **G2:** 33 (18) (12, 24) **Total:** 71 (19) (15, 24) Moderate: **G1:** 13 (7) (4, 12) **G2:** 13 (7) (4, 12) **Total:** 26 (7) (5, 10) Severe/very severe: **G1:** 53 (29) (23, 37) **G2:** 45 (24) (18, 31) **Total:** 98 (27) (22, 31) Missing: **G1:** 0 (0) (0, 2) **G2:** 0 (0) (0, 2) **Total:** 0 (0) (0, 1) Pain, 12 months, change, n (%) (95% CI): Worsened: **G1:** 34 (19) (13, 25) **G2:** 31 (16) (11, 23) **Total:** 65 (18) (14, 22) **G1/G2:** OR = 0.9 (95% CI: 0.5, 1.5) No change: **G1:** 65 (36) (29, 43) **G2:** 71 (38) (31, 45)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Lamvu et al., continued	**Length of follow-up post-treatment day 1:** 1 year **Treatment adherence reported:** No **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**G1:** 3 (2) (0, 5) **G2:** 3 (2) (0, 5) **Total:** 6 (2) (1, 4) Urethral syndrome: **G1:** 2 (1) (0, 4) **G2:** 4 (2) (1, 5) **Total:** 6 (2) (1, 4) Low back pain: **G1:** 4 (2) (1, 6) **G2:** 1 (1) (0, 3) **Total:** 5 (1) (0, 3) Nerve entrapment: **G1:** 1 (1) (0, 3) **G2:** 0 (0) (0, 2) **Total:** 1 (0) (0, 2) **Pain status:** Number of pain sites, mean ± SD (range) (95% CI) **G1:** 3.6 ± 1.8 (1-8) (3.4, 3.9) **G2:** 3.9 ± 1.9 (1-8) (3.6, 4.2) **Total:** 3.8 ± 1.9 (1-8) (3.6, 4.0) Pain levels, n (%) (95% CI): No/minimal pain: **G1:** 39 (22) (16, 28) **G2:** 47 (25) (19, 32) **Total:** 86 (23) (19, 28) Mild: **G1:** 54 (30) (23, 37) **G2:** 50 (27) (20, 33) **Total:** 104 (28) (24, 33) Moderate: **G1:** 18 (10) (6, 15) **G2:** 19 (10) (6, 15) **Total:** 37 (10) (7, 14) Severe/very severe: **G1:** 70 (39) (32, 47) **G2:** 73 (39) (32, 46) **Total:** 143 (39) (34, 44) Missing: **G1:** 0 (0) (0, 2) **G2:** 0 (0) (0, 2) **Total:** 0 (0) (0, 14) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Total:** 136 (37) (32, 42) **G1/G2:** OR = 1.1 (95% CI: 0.7, 1.7) Improved: **G1:** 24 (13) (9, 19) **G2:** 21 (11) (7, 17) **Total:** 45 (12) (9, 16) **G1/G2:** OR = 0.8 (95% CI: 0.4, 1.6) Resolved: **G1:** 58 (32) (25, 39) **G2:** 66 (35) (28, 42) **Total:** 124 (34) (29, 39) **G1/G2:** OR = 0.9 (95% CI: 0.5, 1.5) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Depression, 12 months, n (%) (95% CI): Mild: **G1:** 50 (28) (21, 35) **G2:** 48 (26) (19, 32) **Total:** 98 (27) (22, 31) Moderate: **G1:** 32 (18) (12, 24) **G2:** 29 (16) (11, 21)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Lamvu et al., continued				**Total:** 61 (17) (13, 21) Severe/very severe: **G1:** 10 (6) (3, 10) **G2:** 12 (6) (3, 11) **Total:** 22 (6) (4, 9) Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: **G1:** 68 (38) (31, 45) **G2:** 67 (36) (29, 43) **Total:** 135 (37) (32, 42) IC/PBS: NR Low back pain: **G1:** 4 (2) (1, 6) **G2:** 1 (1) (0, 3) **Total:** 5 (1) (0, 3) Sexual dysfunction: **G1:**129 (71) (64, 78) **G2:** 154 (82) (75, 87) **Total:** 283 (77) (72, 81) Sexual dysfunction, vaginismus: **G1:** 10 (6) (3, 10) **G2**: 7 (4) (2, 8) **Total:** 17 (5) (3, 7) Vulvodynia, vestibulitis: **G1:** 16 (9) (5, 14) **G2:** 10 (5) (3, 10)

Comments: McGill pain scores significantly lower after 1 year of treatment in both groups (both $P < 0.000$); improvement similar in both groups ($P = 0.165$)
Odds of improvement in MPQ score, surgical vs. medical (OR = 1.2; 95% CI: 0.8,1.6)
Multivariable analysis of association between surgical treatment and pain improvement showed that women who received medical treatment were as likely to improve as those receiving surgery (OR = 0.9, 95% CI: 0.6, 1.3)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Heyman et al., 2006 **Country:** Sweden **Enrollment period:** NR **Intervention setting:** Primary health care center **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Open-label RCT **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Intervention:** Distension of the pelvic floor muscles and joint between the coccyx and rectum, with a rectal finger, for 60 seconds, repeated after 2-3 weeks **Assessments:** Questionnaire which included: background variables, VAS (100 point) to assess pain and QOL, 5 point scale for frequency of pain episodes, duration of symptoms **Groups:** **G1:** pelvic muscle distention **G2:** counseling only **N with noncyclic CPP at enrollment:** **G1:** 25 **G2:** 25 **N with noncyclic CPP at follow-up:** **G1:** 22 **G2:** 22 **Duration of treatment:** < 1 day **Length of follow-up post-treatment day 1:** 2-3 weeks **Treatment adherence reported:** Yes **Concomitant therapies, n (%):** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** 6 months of continuous or intermittent pelvic pain 2 days/week **Inclusion criteria:** • Pelvic pain > 6 months • Age > 19 • Continuous or intermittent pain at least 2 days/week • Pain reproduced with pressure by examiner on pelvic floor structures **Exclusion criteria:** • Known diseases of abdomen or pelvis • Pregnancy • STD • Mental illness • Substance abuse • Previous treatment with distention for pelvic floor pain • Infertility **Age, yrs, median (range):** **G1:** 31 (19-54) **G2:** 36 (20-51) **BMI:** NR **Parity:** NR **Duration of pelvic pain, months, median (range):** **G1:** 36 (6-264) **G2:** 21 (6-156) **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse, n (%):** **G1:** 0 **G2:** 2 (8) **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status, mean ± SD:** 100 point VAS: **G1:** 64 ± 22 **G2:** 71 ± 17 **Functional status:** NR **Satisfaction with care:** NR **Quality of life, mean ± SD:** Sleep quality, 100 point VAS: **G1:** 43 ± 35 **G2:** 48 ± 31	**Post-operative diagnoses within CPP/Indications for treatment:** NA **Pain status, mean ± SD:** 100 point VAS: **G1:** 29 ± 28 **G2:** 71 ± 18 **G2/G1**: OR = 18.37 (CI: 3.39-99.64) **Functional status:** NR **Satisfaction with care:** NR **Quality of life mean ± SD:** Sleep quality, 100 point VAS: **G1:** 32 ± 33 **G2:** 52 ± 29 **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** NR

Comments: Depression and low back pain were assessed at baseline and follow-up, but only as an outcome and not as a percentage of the treatment/control population.

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Abbott et al., 2006 **Country:** Australia **Enrollment period:** January 2004 to November 2004 **Intervention setting:** Hospital **Funding:** Allergan Australia **Author industry relationship disclosures:** 2 of 5 Allergan Australia (2) **Design:** RCT **Blinding of:** Subjects: Yes Clinicians: Yes Investigators: Yes Outcome assessors: NR	**Intervention**: 80 units of botulinum toxin type A (4 injections total at 20 units/ml each administered at two sites bilaterally within the puborectalis and pubococcygeus muscles) or saline injection (placebo) **Assessments:** Follow-up via telephone 2-3 days post-injection. VAS for pain, bowel, and bladder questionnaires and physical findings at 2, 4, 8, 12, 16, 20, and 26 weeks post-injection. Quality of life and sexual activity questionnaires at 4, 12, and 26 weeks post-injection: EuroQOL-5D (EQ-5D), Short Form 12 Health Survey (SF-12), Sexual Activity Questionnaires (*pleasure:* higher score = more sexual pleasure; *habit:* higher score = greater frequency of intercourse; *discomfort:* higher score = more pain) **Groups:** **G1:** botulinum toxin type A injections **G2:** saline injections **N with noncyclic CPP at enrollment:** **G1:** 30 **G2:** 30 **N with noncyclic CPP at follow-up:** **G1:** 29 **G2:** 28 **Duration of treatment:** ≤ 1 day **Length of follow-up post-treatment day 1:** 6 months **Treatment adherence reported:** NA **Concomitant therapies:**	**Operational definition of CPP:** NR **Inclusion criteria:** • Women aged 18-55 years • > 2 years CPP that disrupted daily activities • Objective evidence of pelvic floor myalgia (contracted painful muscles on palpation and delevated resting pressures (> 40 mm H_20) by vaginal manometry) **Exclusion criteria:** • Women living outside the Sydney metropolitan area • Pain other than female pelvic pain • Known untreated endometriosis • Breastfeeding, pregnant, or desiring pregnancy • Unwilling to use contraception during the study period • Previous use of botulinum toxin type A injections in the pelvic floor • Palpable pelvic pathology • Current use of aminoglycoside antibiotics • History of neurologic or bleeding disorders • Known sensitivity to the formulation of botulinum toxin type A **Age, yrs, mean ± SD:** **G1:** 30.6 ± 8.1 **G2:** 30.5 ± 7.5 **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery, n (%):** Previous laparoscopy: **G1:** 26 (87) **G2:** 27 (90) Previous abdominal surgery: **G1:** 28 (93)	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** Nonmenstrual pelvic pain, VAS score, median: **G1:** 51 **G2:** NR* **Functional status:** Dyspareunia, VAS score, median: **G1:** 66 **G2:** 64 **Satisfaction with care:** NR **Quality of life:** EQ-5D index score, median (IQR): **G1:** 0.62 (0.16-0.73) **G2:** 0.65 (0.23-0.70) EQ-5D VAS score, median (IQR): **G1:** 52 (49-70) **G2:** 51 (45-66) SF-12 compoment score, median (IQR): Physical: **G1:** 38.44 (31.65-46.64) **G2:** 37.19 (30.21-40.59) Mental: **G1:** 41.03 (34.02-53.02) **G2:** 42.08 (33.44-51.77) Sexual Activity Questionnaire score, median (IQR): Pleasure: **G1:** 9 (5.5-13) **G2:** 8 (7-11) Habit: **G1:** 1 (0–1) **G2:** 1 (0–1) Discomfort: **G1:** 3 (2.5–4.5) **G2:** 5 (3–6)	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** Nonmenstrual pelvic pain, post-injection, VAS score, median: **G1:** 22 **G2:** NR* **G1/BL:** *P* = 0.009 **G2/BL:** *P* = NS **G1/G2:** *P* = NS **Functional status:** Dyspareunia, post-injection, VAS score, median: **G1:** 12 **G2:** 27 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = 0.043 **G1/G2:** *P* = NS **Satisfaction with care:** NR **Quality of life:** EQ-5D index score, 26 weeks post-injection, median (IQR): **G1**: 0.78 (0.69-1.00) **G2**: 0.69 (0.25-0.81) **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.01 **G1/G2:** *P* = 0.03 EQ-5D VAS score, 26 weeks post-injection, median (IQR): **G1**: 70 (51-80) **G2**: 70 (40-80) **G1/BL:** *P* = 0.01 **G2/BL:** *P* = 0.14 **G1/G2:** *P* = 0.67 SF-12 component score, 26 weeks post-injection, median (IQR): Physical: **G1**: 46.20 (37.55-

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Abbott et al., continued	NR **Concomitant therapies held stable during treatment:** Women suppressing menstruation with oral contraceptives or progesterone were asked to continue those medications; changes in medication assessed at each visit (data NR)	**G2:** 27 (90) **History of sexual/physical abuse, n (%):** **G1:** 9 (30) **G2:** 6 (20) **Other risk factors, n (%):** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Previous delivery: **G1:** 8 (27) **G2:** 6 (20) Genital tract trauma: NR Pregnancy termination: NR		54.09) **G2**: 44.83 (37.08-54.16) **G1/BL:** *P* = 0.49 **G2/BL:** *P* = 0.03 **G1/G2:** *P* = 0.62 Mental: **G1**: 49.75 (36.77-56.45) **G2**: 44.88 (30.46-56.67) **G1/BL:** *P* = 0.93 **G2/BL:** *P* = 0.21 **G1/G2:** *P* = 0.37 Sexual Activity Questionnaire score, 26 weeks post-injection, median (IQR): Pleasure: **G1**: 11.5 (7.2-13.7) **G2**: 10 (8.5-13) **G1/BL:** *P* = 0.54 **G2/BL:** *P* = 0.68 **G1/G2:** *P* = 0.52 Habit: **G1**: 1 (1-1.75) **G2**: 1 (0-1) **G1/BL:** *P* = 0.28 **G2/BL:** *P* = 0.95 **G1/G2:** *P* = 0.025 Discomfort: **G1**: 2 (1-4) **G2**: 2 (1-4) **G1/BL:** *P* = 0.32 **G2/BL:** *P* = 0.08 **G1/G2:** *P* = 0.78 **Harm(s), n:** Cold/flu-like illness: **G1:** 33 **G2:** 42 Gastroentero-logical: **G1:** 11 **G2:** 8 Headache/neuro-logical: **G1:** 20 **G2:** 20 Pelvic/back pain: **G1:** 26 **G2:** 30 Non-study-related or non-significant:

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Abbott et al., continued				**G1:** 25 **G2:** 29 Pregnancy during study period: **G1:** 2 **G2:** 0 Urinary stress incontinence: **G1:** 1 **G2:** 0 Urge/stress urinary incontinence, flatus, and fecal incontinence: **G1:** 1 **G2:** 0 Request for laparoscopy due to severe ongoing pain during study: **G1:** 0 **G2:** 2 **Confounders:** NR **Effect modifiers:** NR

Comments: Timing for dyspareunia and nonmenstrual pelvic pain VAS scores not reported
* Data only illustrated graphically in Figure 2

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Williams et al., 2004 Williams et al., 2005 **Country:** US **Enrollment period:** June 1993 to December 2000 **Intervention setting:** Clinic **Funding:** GlaxoSmithKline; Sunshine Lady Foundation **Author industry relationship disclosures:** NR **Design:** Cross-sectional See related studies Lamvu et al., 2006 and Tu et al., 2006	**Operational definition of CPP:** Extended duration of pain in the pelvis **Inclusion criteria:** • New patients of a pelvic pain clinic during the enrollment period • Self-reported pelvic pain for ≥6 months **Exclusion criteria:** • See inclusion criteria **Assessments:** Beck Depression Inventory; Symptom Checklist-90 (SCL-90); McGill Pain Questionnaire; clinic-specific general information form; life experiences survey **Groups:** **G1:** women with IBS **G2:** women without IBS **N with noncyclic CPP at enrollment:** **G1:** 341 **G2:** 646 **N with noncyclic CPP at follow-up:** **G1:** 341 **G2:** 646 **Age, yrs, n (%):** < 20 years: **G1:** 12 (3.5) **G2:** 27 (4.2) 20-29 years: **G1:** 97 (28.4) **G2:** 253 (39.5) 30-39 years: **G1:** 134 (39.3) **G2:** 237 (37.0) 40-49 years: **G1:** 75 (22.0) **G2:** 90 (14.1) ≥ 50 years: **G1:** 23 (6.7) **G2:** 33 (5.2) **BMI:** NR **Parity:** NR **Duration of pelvic pain, n (%):** Duration of pain ≥ 5 years: **G1:** 114 (34.8) **G2:** 151 (25.0) **Intake diagnoses within CPP/ Indications for treatment, n (%):** Muscular back pain: **G1:** 19 (5.7) **G2:** 11 (1.8) Endometriosis:	**Pain status, n (%):** 6-8 pain sites: **G1:** 85 (25.0) **G2:** 98 (15.5) Chronic pain syndrome: **G1:** 227 (67.4) **G2:** 353 (56.7) McGill total score ≥ 43: **G1:** 102 (29.9) **G2:** 136 (21.4) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: Beck Depression Inventory ≥ 10: **G1:** 250 (74.6) **G2:** 362 (58.8) SCL-90 Global Index Score ≥ 50: **G1:** 69 (30.1) **G2:** 80 (18.5) Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: **Total:** 341 (34.5) IC/PBS: NR Low back pain: NR Sexual dysfunction, vaginismus: 43 (4.8) Deep dyspareunia: Organic: **G1:** 113 (37.5) **G2:** 209 (37.1) Functional: **G1:** 36 (11.8) **G2:** 64 (11.4) Mixed: **G1:** 39 (12.7) **G2:** 55 (8.7) Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Williams et al., continued	**G1:** 61 (18.1) **G2:** 71 (11.4) Pelvic floor tension myalgia, tender on exam: **G1:** 88 (26.2) **G2:** 128 (20.7) Pyriformis syndrome: Tender pyriformis: **G1:** 58 (17.3) **G2:** 80 (13.0) Positive thigh rotation test: **G1:** 40 (11.9) **G2:** 67 (10.9) Ventral hernia: **G1:** 3 (0.9) **G2:** 1 (0.2) Rectus tendon: **G1:** 4 (1.2) **G2:** 2 (0.3) Nerve entrapment: **G1:** 4 (1.2) **G2:** 2 (0.3) Fibroids: **G1:** 8 (2.4) **G2:** 10 (1.6) Vaginismus: **G1:** 16 (5.1) **G2:** 27 (4.7) Myofascial syndrome: **G1:** 64 (19.0) **G2:** 106 (17.1) Adhesions: **G1:** 82 (24.3) **G2:** 138 (22.3) Deep dyspareunia: Organic: **G1:** 113 (37.5) **G2:** 209 (37.1) Functional: **G1:** 36 (11.8) **G2:** 64 (11.4) Mixed: **G1:** 39 (12.7) **G2:** 55 (8.7) Pelvic congestion syndrome: Late day aching: **G1:** 7 (2.1) **G2:** 17 (2.8) Luteal increase: **G1:** 5 (1.5) **G2:** 11 (1.8) Broad ligament tenderness: **G1:** 5 (1.5) **G2:** 10 (1.6) Adenomyosis: **G1:** 3 (0.9) **G2:** 16 (2.6)		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Williams et al., continued	**History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse, n (%):** Adult sexual abuse: **G1:** 48 (22.0) **G2:** 54 (13.2) Adult physical abuse: **G1:** 93 (41.7) **G2:** 124 (30.2) Rape at any age: **G1:** 71 (32.1) **G2:** 97 (23.4) Child sexual abuse: **G1:** 84 (38.4) **G2:** 144 (34.8) Physical discipline in childhood: **G1:** 153 (68.0) **G2:** 286 (68.1) **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		

Comments: Study reporting on this group of 987 participants and published in 2005 reports 336 women with IBS and 634 without IBS and 193 with IBS and depression, 359 without IBS and depression. Data extracted here from 2004 study.

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Sator-Katzenschlager et al., 2005 **Country:** Austria **Enrollment period:** October 2000 to October 2002 **Intervention setting:** Medical university hospital's out-patient pain clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Open-label randomized trial with 3 arms **Blinding of:** Subjects: No Clinicians: No Investigators: NR Outcome assessors: NR	**Intervention:** Gabapentin (titrated up from 300 mg/day to max of 3600 mg/day in 300 mg increments each week), amytrip-tyline (titrated up from 25 mg/day to max of 150 mg/day in 25mg increments each week) or a combination of both. Doses were adjusted for side effects and pain control. **Assessments:** Intensity and quality of pain (10 point VAS), side effects at weekly/ monthly visits **Groups:** **G1:** gabapentin **G2:** amytriptyline **G3:** gabapentin and amytriptyline **N with noncyclic CPP at enrollment:** **G1:** 20 **G2:** 20 **G3:** 16 **N with noncyclic CPP at follow-up:** **G1:** 17 **G2:** 17 **G3:** 15 **Duration of treatment:** 24 months **Length of follow-up post-treatment day 1:** 24 months **Treatment adherence reported:** Yes **Concomitant therapies, n (%):** All patients: active and passive physiotherapy and psychotherapy TENS: **G1:** 16 (80) **G2:** 16 (80) **G3:** 13 (81.3) Acupuncture: **G1:** 6 (30) **G2:** 6 (30) **G3:** 3 (18.75) Psychotherapy, prior to	**Operational definition of CPP:** NR **Inclusion criteria:** • Pelvic pain not relieved with 2 weeks of daily opioid therapy (metamizol 1000 mg four times daily, plus tramadol 100 mg twice daily, plus rescue tramadol 50 mg up to six times daily) • Pain had neuropathic qualities or combination of nociceptive and neuropathic qualities • Pain intensity at least VAS 5 at the end of the second opioid week **Exclusion criteria:** • Renal, hepatic, cardiovascular, or psychiatric diagnoses • Concomitant administration of strong opioids, NSAIDS, benzodiazapines, capsaicin, or muscle relaxants **Age, yrs, mean ± SD:** **G1:** 40.4 ± 12.9 **G2:** 36.7 ±11.0 **G3:** 49.6 ±15.3 **BMI:** NR **Parity, n (%):** 1: **G1:** 5 (25) **G2:** 6 (30) **G3:** 6 (38) 2: **G1:** 4 (20) **G2:** 1 (5) **G3:** 3 (19) 3: **G1:** 1 (5) **G2:** 2 (10) **G3:** 1 (6) **Duration of pelvic pain, yrs, mean ± SD:** **Total:** 5.9 ± 2.4 **History of menstrual problems:** NR **History of pelvic surgery, n (%):** Prior surgery (not defined):	**Pain status:** VAS score, ≥ 5, N participants: **G1 + G2:** 56	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** VAS score, 24 months, mean ± SD: **G1:** 3.4 ± 0.9 **G2:** 1.9 ± 0.9 **G3:** 2.3 ± 0.9 **G1/G2:** *P* ≤ 0.05 **G1/G3:** *P* = NS **G2/G3:** *P* ≤ 0.05 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** Dropped out due to severe side effects: **G1:** 2 **G2:** 2 **G3:** 1 Dropped out for insufficient pain reduction: **G1:** 0 **G2:** 1 **G3:** 0 **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: **G1:** 3 (15) **G2:** 6 (30) **G3:** 5 (31.3)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Sator-Katzenschlager et al., continued	treatment: **G1:** 5 (25) **G2:** 1 (5) **G3:** 1 (6.25) Psychotherapy, after 12 months: **G1:** 16 (100) **G2:** 17 (100) **G3:** 15 (100) Psychotherapy, after 24 months: **G1:** 10 (62.5) **G2:** 10 (58.82) **G3:** 9 (60) **Concomitant therapies held stable during treatment:** NR	**G1:**16 (80) **G2:**16 (80) **G3:** 10 (63) Number of prior surgeries: 1: **G1:** 6 (30) **G2:** 8 (40) **G3:** 2 (12.5) 2: **G1:** 5 (25*) **G2:** 2 (10) **G3:** 1 (6.25) ≥ 3: **G1:** 5 (25) **G2:** 6 (30) **G3:** 7 (43.75) **History of sexual/physical abuse, n (%):** Cause of pain given as sexual abuse: **G1:** 3 (15) **G2:** 1 (5) **G3:** 2 (12.5) **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		IC/PBS: NR Low back pain (with MRI-verified pathology): **G1:** 5 (25) **G2:** 7 (36) **G3:** 5 (31.3) Sexual dysfunction: NR Vulvodynia: NR

Comments: * reported as 10%

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Zupi et al., 2004 **Country:** Italy **Enrollment period:** March 2000 to February 2003 **Intervention setting:** University hospital **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT **Blinding of:** Subjects: No Clinicians: No Investigators: Yes Outcome assessors: No	**Intervention:** GnRH-analogue (leuprolide acetate 11.25 mg IM q 3 months for 12 months) with or without add-back therapy (trans-dermal E2 25 mcg and daily oral norethindrone 5 mg) or estroprogestin alone (oral ethinyl E2 30 mcg plus gestodene 0.75 mg daily for 12 months) **Assessments:** At baseline: complete medical, gynecologic, and drug history; clinical exam with pap smear, ultrasound, hysteroscopy, endo-metrial biopsy, and blood chemistries; SF36 questionnaire; pain questionnaire (VAS) for pelvic pain, dysmenorrhea, and dyspareunia; BMD At follow-up visits (6, 12 and 18 months): SF 36, pain question-naire, BMD **Groups:** **G1:** GnRH-a with add-back therapy **G2:** GnRH-a alone **G3:** estroprogestin **N with noncyclic CPP at enrollment:** **G1:** 46 **G2:** 44 **G3:** 43 **N with noncyclic CPP at follow-up:** NR **Duration of treatment:** 12 months **Length of follow-up post-treatment day 1:** 18 months **Treatment adherence reported:** No **Concomitant therapies:** NR	**Operational definition of CPP:** NR **Inclusion criteria:** • Age 20-43 • Regular menses • History of symptomatic endometriosis diagnosed surgically • Recurrence of pelvic pain, dysmenorrhea, and dyspareunia **Exclusion criteria:** • See inclusion criteria **Age, yrs, mean ± SD:** **G1:** 35.8 ± 5.1 **G2:** 35.1 ± 4.8 **G3:** 36.1 ± 5.3 **BMI, mean ± SD:** **G1:** 26.9 ± 3.2 **G2:** 25.8 ± 3.3 **G3:** 26.4 ± 2.9 **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Endometriosis: Stage III: **G1:** 26 (56.5) **G2:** 25 (56.8) **G3:** 22 (55.1) Stage IV: **G1:** 20 (43.5) **G2:** 19 (43.2) **G3:** 21 (44.9) **Pain status:** VAS score, mean ± SD: **G1:** 6.9 ± 1.4 **G2:** 6.7 ± 1.2 **G3:** 6.3 ± 1.6 **G1/G2/G3:** *P* = NS **Functional status:** Dyspareunia, VAS score, mean ± SD: **G1:** 5.8 ± 1.6 **G2:** 5.9 ± 1.5 **G3:** 5.6 ± 1.2 **G1/G2/G3:** *P* = NS **Satisfaction with care:** NR **Quality of life:** SF36 score, mean ± SD: General health: **G1:** 47.9 ± 12.7 **G2:** 49.4 ± 14.2 **G3:** 48.1 ± 12.1 Physical function: **G1:** 52.6 ± 14.4 **G2:** 51.6 ± 13.2 **G3:** 52.8 ± 10.9 Physical role: **G1:** 58.3 ± 13.0 **G2:** 59.2 ± 15.4 **G3:** 57.1 ± 13.9 Emotional role: **G1:** 60.8 ± 12.0 **G2:** 60.5 ± 11.9 **G3:** 60.1 ± 15.2 Mental health: **G1:** 58.1 ± 12.3 **G2:** 59.8 ± 12.9 **G3:** 60.2 ± 13.6 Social function: **G1:** 56.4 ± 11.0 **G2:** 55.6 ± 9.7 **G3:** 58.5 ± 11.5	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** VAS score, 6 month follow-up, mean ± SD **G1:** 3.7 ± 2.7 **G2:** 3.2 ± 2.6 **G3:** 5.9 ± 2.5 **G1/G3:** *P* < 0.01 **G2/G3:** *P* < 0.01 **Functional status:** Dyspareunia, VAS score, 6 month follow-up, mean ± SD **G1:** 2.7 ± 1.5 **G2:** 2.2 ± 1.1 **G3:** 3.9 ± 1.4 **G1/G3:** *P* < 0.01 **G2/G3:** *P* < 0.01 **Satisfaction with care:** NR **Quality of life:** SF36 score, end of follow-up, mean ± SD: General health: **G1:** 54.1 ± 12.1 **G2:** 51.6 ± 13.7 **G3:** 51.3 ± 13.0 Physical function: **G1:** 60.8 ± 10.9 **G2:** 55.4 ± 15.1 **G3:** 54.2 ± 14.8 Physical role: **G1:** 56.3 ± 13.8 **G2:** 55.2 ± 13.4 **G3:** 54.2 ± 14.4 Emotional role: **G1:** 62.2 ± 14.4 **G2:** 60.8 ± 11.9 **G3:** 60.5 ± 14.8 Mental health: **G1:** 59.2 ± 14.4 **G2:** 59.7 ± 12.9 **G3:** 59.3 ± 12.2 Social function: **G1:** 60.2 ± 12.4 **G2:** 53.6 ± 9.7 **G3:** 57.0 ± 12.8

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Zupi et al., continued	**Concomitant therapies held stable during treatment:** NR		Vitality: **G1:** 52.7 ± 11.0 **G2:** 53.4 ± 10.3 **G3:** 52.3 ± 11.3 Pain: **G1:** 47.1 ± 19.2 **G2:** 46.4 ± 18.5 **G3:** 50.1 ± 14.0 Bone mineral density, mean ± SD: **G1:** 1.040 ± 0.111 **G2:** 1.050 ± 0.120 **G3:** 1.035 ± 0.112	Vitality: **G1:** 64.2 ± 14.4 **G2:** 56.3 ± 10.3 **G3:** 55.6 ± 17.0 Pain: **G1:** 57.2 ± 11.4 **G2:** 58.4 ± 18.1 **G3:** 50.4 ± 18.5 **Non-surgical harms, n (%):** Hot flashes: **G1:** 12 (26.1) **G2:** 34 (77.3) **G3:** 0 (0) Emotional changes: **G1:** 5 (10.8) **G2:** 16 (36.4) **G3:** 3 (6.9) Abnormal uterine bleeding: **G1:** 3 (6.5) **G2:** 1 (2.3) **G3:** 7 (16.2) Bone mineral density, 6 month follow-up, mean ± SD: **G1:** 1.010 ± 0.09 **G2:** 0.995 ± 0.11 **G3:** 1.052 ± 0.13 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.03 **Confounders:** NR **Effect modifiers:** NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Onwude et al., 2004 **Country:** UK **Enrollment period:** NR **Intervention setting:** Hospital **Funding:** Birthright **Author industry relationship disclosures:** NR **Design:** RCT **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Intervention:** Photographic reinforcement, once following surgery **Assessments:** Pain severity and beliefs prior to surgery and at 3 and 6 months postoperatively using the VAS, a short McGill questionnaire and a pain beliefs and perceptions inventory. VAS: 140 mm line, left end marked "no pain" and right end marked "worst possible pain" McGill questionnaire: *Sensory*: responses "none," "mild," "moderate," and "severe" scored 0-3 to rate 11 different words (maximum score 33) *Pain affect*: responses "none," "mild," "moderate," and "severe" scored 0-3 to rate four different words (maximum score 12) *Pain intensity*: select one of the following expressions "no pain", "mild", "discomforting", "distressing", "horrible", "excruciating" to rate pain from 0-5 Pain perceptions and belief inventory: response of "strongly disagree", "disagree", "agree", "strongly agree" for eight questions with four composite scales (constancy, self-blame, mysteriousness, and permanence) **Groups:** **G1:** photographic reinforcement **G2:** control **N with non-cyclic CPP at enrollment n:** **G1:** 109 **G2:** 124 **N with non-cyclic CPP**	**Operational definition of CPP:** NR **Inclusion criteria:** • Women undergoing diagnostic laparoscopy for sterilization, infertility or pelvic pain of > 3 months duration **Exclusion criteria:** • See inclusion criteria **Age, yrs, mean ± SD:** **G1:** 31.7 ± 7.7 (n=109) **G2:** 33.2 ± 7.9 (n=123) **BMI:** NR **Parity, ≥ 1 live births, n (%):** **G1:** 71 (65) **G2:** 88 (71) **Duration of pelvic pain, n:** < 1 year: **G1:** 42 **G2:** 41 > 1 year: **G1:** 53 **G2:** 53 **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors, n (%):** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: Spontaneous: **G1:** 19 (17) **G2:** 17 (14) Induced: **G1:** 17 (16) **G2:** 19 (15)	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** VAS score, mean ± SD: **G1:** 96 ± 38 (n=67) **G2:** 80 ± 32 (n=71) McGill sensory score, mean ± SD: **G1:** 9.4 ± 7.1 (n=100) **G2:** 7.4 ± 5.2 (n= 99) McGill present pain intensity score, mean ± SD: **G1:** 3.3 ± 1.3 (n=97) **G2:** 2.9 ± 1.6 (n=96) McGill affect score, mean ± SD: **G1:** 2.3 ± 3.0 (n=100) **G2:** 1.7 ± 2.6 (n=98) Pain perceptions and belief inventory scale score, mean ± SD: Constancy: **G1:** 5.0 ± 0.5 (n=89) **G2:** 4.9 ± 0.5 (n=89) Mysteriousness: **G1:** 5.8 ± 1.3 (n=88) **G2:** 5.6 ± 1.3 (n=86) Permanence: **G1:** 5.8 ± 0.9 (n=85) **G1:** 5.7 ± 0.8 (n=80) Self-blame: **G1:** 3.2 ± 1.2 (n=88) **G2:** 3.4 ± 1.1 (n=90) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** VAS score, 6 months, mean ± SD: **G1:** 52.6 ± 49 (n=45) **G2:** 45.1 ± 45 (n=57) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** 7.5 (-10.9, 25.9) Adjusted: **G1/G2:** 10.9 (-10.1, 31.9) McGill sensory score, 6 months, mean ± SD: **G1:** 6.3 ± 7.6 (n=53) **G2:** 5.2 ± 7.0 (n=62) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** 0.53 (-1.1, 2.1) Adjusted: **G1/G2:** 0.10 (-1.6, 1.8) McGill present pain intensity score, mean ± SD: **G1:** 1.9 ± 1.6 (n=46) **G2:** 1.8 ± 1.7 (n=61) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** 0.08 (-0.55, 0.72) Adjusted: **G1/G2:** 0.40 (-0.37, 1.2) McGill affect

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Onwude et al., continued	**at follow-up:** 3 months: **G1:** 69 **G2:** 71 6 months: **G1:** 53 **G2:** 62 **Duration of treatment:** < 1 day **Length of follow-up post-treatment day 1:** 6 months **Treatment adherence reported:** No **Concomitant therapies, n (%):*** Contraceptive use: **G1:** 58 (53) **G2:** 68 (55) **Concomitant therapies held stable during treatment:** NR			score, 6 months, mean ± SD: **G1:** 2.1 ± 3.1 (n=50) **G2:** 1.3 ± 2.4 (n=62) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** 0.80 (-0.23, 1.83) Adjusted: **G1/G2:** 0.82 (-0.46, 2.10) Pain perceptions and belief inventory scale score, 6 months, mean ± SD: Constancy: **G1:** 5.1 ± 0.47 (n=37) **G2:** 5.0 ± 0.49 (n=43) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** 0.05 (-0.16, 0.27) Adjusted: **G1/G2:** 0.07 (-0.21, 0.35) Mysteriousness: **G1:** 5.8 ± 1.8 (n=38) **G2:** 5.8 ± 1.4 (n=44) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** -0.002 (-0.71, 0.71) Adjusted: **G1/G2:** -0.30 (-1.1, 0.53) Permanence: **G1:** 5.9 ± 1.2 (n=34) **G2:** 5.5 ± 0.95 (n=41) Estimated mean difference (95% CI):

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Onwude et al., continued				Unadjusted: **G1/G2:** 0.42 (-0.06, 0.91) Adjusted: **G1/G2:** 0.44 (-0.21, 1.10) Self-blame: **G1:** 3.3 ± 1.3 n=37 **G2:** 3.4 ± 1.1 (n=45) Estimated mean difference (95% CI): Unadjusted: **G1/G2:** -0.08 (-0.59, 0.44) Adjusted: **G1/G2:** 0.06 (-0.57, 0.69) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** Comparisons adjusted for length of pain, age, marital status, previous spontaneous or induced abortion, previous live birth, history of oral contraceptive use, and presence of pelvic pathology

Comments: * Specific concomitant therapies other than OCP use were not reported; article states that "As far as possible all other medical or surgical treatment was the same in both groups."

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Johnson et al., 2004 **Country:** New Zealand **Enrollment period:** April 1997 to December 2001 **Intervention setting:** Hospital **Funding:** Princess of Wales Memorial Trust and Johnson & Johnson (NZ) **Author industry relationship disclosures:** NR **Design:** RCT, unblocked randomization **Blinding of:** Subjects: Yes Clinicians: No Investigators: No Outcome assessors: Yes	**Intervention:** Laparoscopic Uterine Nerve Ablation (LUNA) at time of diagnostic laparoscopy ± endometriosis ablation/excision in patients with or without endometriosis **Assessments:** Patient-completed 10 point VAS (0, no pain to 10, worst pain) for 4 pain domains (non-menstrual pelvic pain, dysmenorrhea, deep dyspareunia, dyschezia) at baseline, 1 day, 3 and 12 months postoperatively; satisfaction; requirement of further surgery within follow-up 12 months; institution of new medical treatment within 12 month followup; occurrence of prolapse or surgery-related complications **Groups:** **G1:** LUNA **G2:** no LUNA **Ga:** no endometriosis **Gb:** endometriosis **N with noncyclic CPP at enrollment:** **G1a:** 22 **G2a:** 34 **G1b:** 32 **G2b:** 35 **N with noncyclic CPP at follow-up:** **G1a:** 18 **G2a:** 32 **G1b:** 26 **G2b:** 30 **Duration of treatment:** < 1 day **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** Yes **Concomitant therapies:** NR	**Operational definition of CPP:** Dysmenorrhea, non-menstrual pelvic pain, dyschezia, or deep dyspareunia > 6 months **Inclusion criteria:** • Age 18-45 • CPP • No change in medications for 3 months prior to enrollment **Exclusion criteria:** • Previous hysterectomy, pelvic malignancy or LUNA • Known ovarian cysts • Plan for pregnancy in 12 months • Intention to change other medical treatment with study period • Laparoscopic findings prohibiting LUNA performance • Necessity of transection of one or both uretero-sacral ligaments for endometriosis resection • Pelvic adhesions not related to endometriosis **Age, yrs, mean ± SD:** **G1a:** 29 ± 5.83 **G2a:** 29 ± 6.49 **G1b:** 30 ± 6.71 **G2b:** 29 ± 5.31 **BMI:** NR **Parity, n (%):** Nulliparous: **G1a:** 8 (36) **G2a:** 15 (44) **G1b:** 22 (69) **G2b:** 26 (74) Parous: **G1a:** 14 (64) **G2a:** 19 (56) **G1b:** 10 (31) **G2b:** 9 (26) **Duration of pelvic pain, median, months (IQR):** **G1a:** 33 (17, 87) **G2a:** 42 (20, 78) **G1b:** 60 (24, 108) **G2b:** 37 (13, 108) **History of menstrual problems:**	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Non-menstrual pelvic pain: **G1a:** 21 (95) **G2a:** 32 (94) **G1b:** 28 (88) **G2b:** 35 (100) Dysmenorrhea: **G1a:** 19 (86) **G2a:** 28 (82) **G1b:** 30 (94) **G2b:** 31 (89) Deep dyspareunia: **G1a:** 14 (64) **G2a:** 20 (59) **G1b:** 19 (59) **G2b:** 21 (60) **Pain status:** Non-menstrual pelvic pain, VAS score, median (IQR): **G1a:** 6 (4, 8) **G2a:** 6 (4, 8) **G1b:** 6 (3, 7) **G2b:** 6 (5, 9) **Functional status:** Deep dyspareunia, VAS score, median (IQR): **G1a:** 4 (1, 7) **G2a:** 8 (7, 10) **G1b:** 6 (1, 7) **G2b:** 8 (4, 9) **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** Non-menstrual pelvic pain, 12 months: VAS score, median change (IQR):* **G1a:** -4 (-6, 0) **G2a:** -1 (-5, 1.3) **G1b:** -2 (-6, 0) **G2b:** -3.5 (-5.8, -1) **G1a/G2a:** *P* = 0.34 **G1b/G2b:** *P* = 0.58 VAS score, > 50% reduction, n (%):* **G1a:** 8/17 (47) **G2a:** 13/30 (44) **G1b:** 11/22 (50) **G2b:** 15/30 (50) **G1a/G2a:** *P* = 0.805 **G1b/G2b:** *P* = 1.0 Successful treatment, ITT analysis, n (%):** **G1a:** 8/21 (38.1) **G2a:** 13/32 (40.6) **G1b:** 11/28 (39.3) **G2b:** 15/35 (42.9) **G1a/G2a:** *P* = 0.854 **G1b/G2b:** *P* = 0.775 **Functional status:** Deep dyspareu-nia, 12 months:^ VAS score, median change (IQR):* **G1a:** -3 (-4, 0) **G2a:** -2 (-5.5, 0) **G1b:** 0 (-5, 0) **G2b:** -2 (-6, 0.5) **G1a/G2a:** *P* = 0.74 **G1b/G2b:** *P* = 0.497 VAS score, > 50%

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Johnson et al., continued	**Concomitant therapies held stable during treatment:** NR	NR **History of pelvic surgery, n (%):** Previous laparoscopy: **G1a:** 12 (55) **G2a:** 20 (59) **G1b:** 21 (55) **G2b:** 25 (71) Previous laparotomy: **G1a:** 2 (9) **G2a:** 8 (24) **G1b:** 4 (13) **G2b:** 8 (23) **Other risk factors, n (%):** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		reduction, n (%):* **G1a:** 7/9 (78) **G2a:** 8/14 (57) **G1b:** 6/10 (60) **G2b:** 8/16 (50) **G1a/G2a:** *P* = 0.40 **G1b/G2b:** *P* = 0.70 Successful treatment, ITT analysis, n (%):** **G1a:** 7/14 (50) **G2a:** 8/20 (40) **G1b:** 6/19 (31.6) **G2b:** 8/21 (38.1) **G1a/G2a:** *P* = 0.410 **G1b/G2b:** *P* = 0.666 **Satisfaction with care, 12 months, n (%):** **G1a:** 15/18 (83) **G2a:** 22/32 (69) **G1b:** 18/26 (69) **G2b:** 24/30 (80) **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: NR Dysmenorrhea: **G1a:** 19 (86) **G1b:** 30 (94) **G2a:** 28 (82) **G2b:** 31 (89) Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction, dyspareunia:

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Johnson et al., continued				**G1a:** 14 (64) **G1b:** 19 (59) **G2a:** 20 (59) **G2b:** 26 (74) Vulvodynia: NR

Comments:

* Available data analysis, excluding patients lost to follow-up or with missing data. In addition, > 50% reduction of VAS includes women undergoing additional surgery for symptoms; VAS change from baseline excludes patients who underwent additional surgery.

** Intention to treat analysis: women lost to follow up or with missing data considered unsuccessful treatment. Treatment success considered > 50% reduction in VAS pain score in the absence of further surgery for pelvic pain or loss to follow up .

^ Among those with CPP

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities:
Author: Grace et al., 2004, 2006† **Country:** New Zealand **Enrollment period:** 2001 **Intervention setting:** NA **Funding:** Health Research Council, NZ **Author industry relationship disclosures:** NR **Design:** Cross-sectional	**Operational definition of CPP:** Recurrent or constant pain in the lower abdomen of ≥ 6 months duration, unrelated to menstruation, intercourse or pregnancy. CPP case defined as a woman with CPP in the previous 3 months **Inclusion criteria:** • Women 18-50 years of age randomly selected from the electoral roll **Exclusion criteria (exclusion from analysis):** • Pregnancy in the last 12 months • Contradictory pelvic pain data **Assessments:** Verbal pain rating scale (none, mild, moderate, severe); VAS (10 cm, least possible pain to worst possible pain); IBS defined according to Rome criteria (1992); SF-36 **Groups:** **G1:** CPP **N at enrollment:** **G1:** 286 **Age, yrs range, n:** 18-25: 35 26-30: 41 31-35: 53 36-40: 64 41-45: 56 46-50: 35 **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **Intake diagnoses within CPP/ Indications for treatment:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Pain status:** Pain severity VRS, n (%): Mild: 148 (51.9) Moderate/severe: 137 (48.1) VAS, mean ± SD: **G1:** 4.3 ± 2.6 VAS by category, n (%): 0-4.5: 159 (55.6) 4.6-10: 127 (44.4) **Functional status, n (%):**† General lethargy/fatigue: 26 (9.1) Requires rest/painkillers for any activity: 35 (12.2) Limited in housework activities: 23 (8.0) Limited in doing exercise: 17 (5.9) Posture problems, standing/ sitting: 26 (9.1) Concentration problems: 12 (4.2) Limited in mobility, moving/ walking: 41 (14.3) Limited in social activities: 6 (2.1) Other restrictions: 12 (4.2) **Satisfaction with care:** NR **Quality of life:**† SF-36 PCS, mean ± SD: **G1:** 47.3 ± 9.2 (n=248) SF-36 MCS, mean ± SD: **G1:** 45.2 ± 12 (n=248) Sleep quality, n (%): Pain affects sleep quality: 7 (2.4) Difficulty falling asleep: 40 (14.1) Frequent awakenings: 94 (33.2) Non regenerative sleep: 104 (36.7)	**Comorbidities of interest:** Dysmenorrhea, n: **G1:** 91/214* IBS, n (%): **G1:** 39/149** (26.2) Sexual dysfunction (limited in sexual activity), n (%): **G1:** 5.9 (17) Dyspareunia: 10/214* Anxiety: NR Clinical depression: NR Fibromyalgia: NR Headache: NR IC/PBS: NR Low back pain: NR Vulvodynia: NR

Comments: Postal questionnaire survey

* Among those who had periods and were sexually active in the past 3 months

** Among 149 women with CPP who had consulted a medical practitioner at any time

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Swank et al., 2003 **Country:** Netherlands **Enrollment period:** August 1997 to January 2001 **Intervention setting:** Academic and community hospitals **Funding:** NR **Author industry relationship disclosures:** None **Design:** RCT **Blinding of:** Subjects: Yes Clinicians: Yes Investigators: Yes Outcome assessors: Yes	**Intervention:** Patients randomly assigned to laparoscopic adhesiolysis or no treatment after adhesions confirmed during diagnostic laparoscopy **Assessments:** VAS; verbal rating pain change scale (VRCS); medication quantification scale (MQS); MOS SF-36 to assess quality of life; standardized physical exams at 3, 6, and 12 months post-surgery **Groups:** **G1:** laparoscopic adhesiolysis **G2:** control (no treatment) **N with noncyclic CPP at enrollment:** **G1:** 52 **G2:** 48 **N with noncyclic CPP at follow-up:** **G1:** 51 **G2:** 47 **Duration of treatment:** ≤ 1 day **Length of follow-up post-treatment day 1:** 1 year **Treatment adherence reported:** NA **Concomitant therapies:** NR	**Operational definition of CPP:** Chronic abdominal pain: continuous or intermittent abdominal pain ≥ 6 months duration **Inclusion criteria:** • Chronic abdominal pain **Exclusion criteria:** • Age < 18 years • Treatment by psychologist or psychiatrist • Use of laxatives, sedatives, morphine, antipsychotics, antidepressants, or drugs that stimulate the central nervous system • Abnormal concentrations of serum alanine amino transferase, aspartate aminotransferase, bilirubin, amylase, urea, or creatinine • Abnormal results of lactose tolerance tests, H_2 respiration tests, analysis of feces for worms and worm eggs, ultrasonography or CT scan of abdomen, radiography of small and large bowel, or colonoscopy **Age, yrs, mean ± SD:** **G1:** 45.4 ± 14.5 **G2:** 47.8 ± 12.3 **Female, n (%):** **G1:** 45 (87) **G2:** 42 (88) **BMI, median (range):** **G1:** 24.2 (17-37) **G2:** 24.2 (19-29) **Parity:** NR **Duration of abdominal pain, months, median (range):** **G1:** 30 (6-240) **G2:** 18 (6-180) **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Adhesions: **G1:** 52 (100) **G2:** 48 (100) **Pain status:** VAS score, mean ± SD: **G1:** 57.2 ± 17.9 **G2:** 56.0 ± 18.0 MQS score, median (range): **G1:** 1.0 (0-6) **G2:** 2.0 (0-19) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** MOS SF-36 score, mean ± SD: **G1:** 35.1 ± 16.9 **G2:** 33.8 ± 15.4	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** VAS score, 12 months, mean ± SD: **G1:** 38.9 ± 3.4 **G2:** 40.5 ± 3.7 **G1/G2:** *P* = 0.63 Free of pain or much improved, 12 months, n (%): **G1:** 14 (27) **G2:** 13 (27) No change or worsened pain, 12 months, %: **G1:** 43 **G2:** NR MQS score, 12 months, mean: **G1:** 0.8 (n=49) **G2:** 1.8 **G1/G2:** *P* = 0.53 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** MOS SF-36 score, 12 months, mean ± SD: **G1:** 51.0 ± 3.3 **G2:** 49.7 ± 3.2 **G1/G2:** *P* = 0.84 **Confounders:** NR **Effect modifiers:** NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Swank et al., continued		**Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR History of appendectomy, %: **G1:** 27 **G2:** 27 History of gynecological procedures, %: **G1:** 46 **G2:** 55 History of bowel resection, %: **G1:** 7 **G2:** 17 Number of previous abdominal operations, mean ± SD: **G1:** 2.8 ± 1.5 **G2:** 2.7 ± 1.5		

Comments: Data is not separated by gender, but > 80% of participants are female.
After the 12 months of follow-up, 17 patients from G2 elected to undergo the adhesiolysis; follow-up scores (VAS, MQS, and MOS-SF-36) at 12 months were not significantly different from preoperative baseline

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Chung et al., 2003 **Country:** Korea **Enrollment period:** November 1998 to December 2002 **Intervention setting:** Clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Cross-sectional **Blinding of:** Subjects: NR Clinicians: NR Investigators: NR Outcome assessors: NR	**Intervention:** Ovarian vein embolization, hysterectomy with BSO and hormone replacement therapy, or hysterectomy with USO **Assessments:** Pain intensity assessed with 10 point VAS (0, no pain to 10, unbearable pain) at baseline, 3, 6, 12 months Stress scores assessed with social readjustment rating scale (SRRS) **Groups:** **G1:** ovarian vein embolization **G2:** hysterectomy with BSO and HRT **G3:** hysterectomy with USO **Ga:** SRRS 100-199 (typical stress level) **Gb:** SRRS 200-299 (moderate stress level) **Gc:** SRSS > 300 (very high stress level) **N with noncyclic CPP at enrollment:** **G1:** 52 **G2:** 32 **G3**: 34 **N with noncyclic CPP at follow-up:** **G1:** 52 **G1a:** 27 **G1b:** 18 **G1c:** 7 **G2:** 27 **G2a:** 15 **G2b:** 7 **G2c:** 5 **G3**: 27 **G3a:** 16 **G3b:** 6 **G3c:** 5 **Duration of treatment:** <1 day for surgical intervention **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** No	**Operational definition of CPP:** Noncyclic abdominal and pelvic pain lasting at least 6 months* **Inclusion criteria:** • Pelvic pain • Pelvic congestion syndrome, confirmed by laparoscopy and ovarian/ internal iliac venography • Failed treatment with medroxyprogesterone acetate for 4-6 months **Exclusion criteria:** • Associated pathologies (i.e., adhesions, myoma, endometriosis) **Age, yrs, mean ± SD:** **G1:** 40.1 ± 4.9 **G2:** 45.5 ± 3.8 **G3**: 44.1 ± 3.9 **BMI:** NR **Parity, mean ± SD:** **G1:** 2.4 ± 1.1 **G2:** 2.3 ± 1.0 **G3**: 2.4 ± 0.9 **Duration of pelvic pain, months, mean ± SD:** **G1:** 32.9 ± 21.6 **G2:** 34.2 ± 22.6 **G3**: 34.1 ± 21.4 **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** VAS score, mean ± SD: **G1:** 7.8 ± 1.2 **G2:** 7.7 ± 1.3 **G3**: 7.8 ± 1.2 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** SRRS score, mean ± SD: **G1a:** 141.3 ± 23.1 **G1b:** 238.1 ± 19.5 **G1c:** 312.0 ± 18.7 **G2a:** 138.6 ± 24.3 **G2b:** 245.0 ± 21.5 **G2c:** 307.4 ± 19.8 **G3a:** 139.6 ± 23.8 **G3b:** 141.2 ± 19.9 **G3c:** 312.9 ± 20.2	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** VAS score, 12 months, mean ± SD: **G1:** 3.2 ± 0.9 **G2:** 4.6 ± 1.1 **G3**: 5.6 ± 0.8 **G1/BL:** $P \leq 0.05$** VAS score, 12 months, mean % decrease ± SD: **G1:** 59.0 ± 4.2 **G2:** 40.3 ± 4.7 **G3**: 28.2 ± 4.1 **G1/BL:** $P \leq 0.05$** **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** VAS score, 12 months, mean % decrease ± SD: **G1a:** 61.5 ± 5.1 **G1b:** 56.4 ± 4.6 **G1c:** 40.2 ± 4.6 **G2a:** 46.5 ± 3.5 **G2b:** 45.6 ± 2.9 **G2c:** 39.5 ± 4.6 **G3a:** 34.6 ± 3.8 **G3b:** 33.3 ± 4.4 **G3c:** 33.4 ± 4.8 **G1a/BL:** $P \leq 0.05$ **G1b/BL:** $P \leq 0.05$ **G1c/BL:** P = NS **Prevalence of comorbidities of interest, %:** Anxiety: NR Clinical depression: NR Dysmenorrhea: **Total:** 12.8

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Chung et al., continued	**Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR			Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: **Total:** 57.6 Sexual dysfunction, Dyspareunia: **Total:** 15.0 Vulvodynia: NR

Comments: * definition from Introduction

** decreases in mean VAS pain score were significantly different for groups 1 and 2 ($P < 0.05$) according to the text, but in table 1, only group 1 is represented as having a significance

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Zondervan et al., 2001 **Country:** UK **Enrollment period:** NA **Intervention setting:** General population (survey) **Funding:** BUPA Foundation **Author industry relationship disclosures:** NR **Design:** Cross-sectional	**Operational definition of CPP:** Recurrent or constant pelvic pain of ≥ 6 months' duration, unrelated to periods, intercourse or pregnancy **Inclusion criteria:** • Women ages 18-49 years • Randomly selected from Oxfordshire Health Authority register of persons under care of a general practitioner **Exclusion criteria:** • Practice objected to participation by patients • Mental illness • Participation in the study pilot **Assessments:** Survey questionnaire (via mail) with questions assessing duration of pain, severity (categorical scale: none, mild, moderate, severe; and 10 cm VAS ranging from least possible pain to worst possible pain), and frequency **Groups:** **G1:** All CPP **G1a:** CPP only **G1b:** CPP + IBS only **G1c:** CPP + genitourinary symptoms only **G1d:** CPP + IBS + genitourinary symptoms **N with noncyclic CPP at enrollment:** **G1:** 483 **G1a:** 249 **G1b:** 114 **G1c:** 44 **G1d:** 72 **N with noncyclic CPP at follow-up:** **G1:** 483 **G1a:** 249 **G1b:** 114 **G1c:** 44 **G1d:** 72 **Age, yrs, mean ± SD:** **G1:** 35.4 ± 8.6 **G1a:** 36.1 ± 8.5 **G1b:** 34.4 ± 8.1 **G1c:** 35.4 ± 9.9 **G1d:** 34.4 ± 8.9 **BMI:** NR **Parity:** NR **Duration of pelvic pain, n (%):** First onset of pain, n (%):	**Pain status:** Typical CPP severity, moderate or severe, n (%): **G1:** 246 (50.9) **G1a:** 106 (42.6) **G1b:** 66 (57.9) **G1c:** 21 (47.7) **G1d:** 51 (70.8) VAS score, mean ± SD: **G1:** 4.2 ± 2.6 **G1a:** 3.8 ± 2.6 **G1b:** 4.3 ± 2.5 **G1c:** 3.9 ± 2.6 **G1d:** 5.4 ± 2.3 **Functional status:** Prevalence of dyspareunia, n (%) **G1:** 178/432 (41.2) **G1a:** 78/218 (35.8) **G1b:** 46/104 (44.2) **G1c:** 20/42 (47.6) **G1d:** 32/64 (50) Typical severity of dyspareunia during intercourse, VAS score, mean ± SD: **G1:** 4.0 ± 2.3 **G1a:** 3.8 ± 2.2 **G1b:** 4.2 ± 2.2 **G1c:** 3.0 ± 1.7 **G1d:** 4.8 ± 2.5 Typical severity of dyspareunia after intercourse, VAS score, mean ± SD: **G1:** 3.8 ± 2.3 **G1a:** 3.4 ± 2.3 **G1b:** 3.9 ± 2.4 **G1c:** 3.4 ± 2.3 **G1d:** 4.6 ± 2.1 **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea: **G1:** 364/451 (80.7) **G1a:** 193/239 (80.8) **G1b:** 88/11 (79.3) **G1c:** 28/37 (75.7) **G1d:** 53/60 (88.3) Fibromyalgia: NR Headache: NR IBS: **G1:** 94/475 (19.8)* **G1a:** 27/244 (11.1) **G1b:** 37/113 (32.7) **G1c:** 5/43 (11.6) **G1d:** 24/71 (33.8) IC/PBS: NR Back pain or problems: **G1:** 27/475 (5.7) **G1a:** 11/244 (4.5) **G1b:** 4/113 (4.5) **G1c:** 1/43 (2.3) **G1d:** 11/71 (15.5) Sexual dysfunction (dyspareunia): **G1:** 178/432 (41.2) **G1a:** 78/218 (35.8) **G1b:** 46/104 (44.2) **G1c:** 20/42 (47.6) **G1d:** 32/64 (50) Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Zondervan et al., continued	6 months to 1 year earlier: **G1:** 92 (19) **G1a:** 43 (17.3) **G1b:** 18 (15.8) **G1c:** 13 (29.5) **G1d:** 18 (25.4) > 1-5 years earlier: **G1:** 151 (31.3) **G1a:** 81 (32.5) **G1b:** 39 (34.2) **G1c:** 14 (31.8) **G1d:** 16 (22.5) > 5 years earlier: **G1:** 159 (32.9) **G1a:** 74 (29.7) **G1b:** 41 (36) **G1c:** 14 (31.8) **G1d:** 27 (38) Unable to recall year of onset: **G1:** 81 (16.8) **G1a:** 51 (20.5) **G1b:** 16 (14) **G1c:** 3 (6.8) **G1d:** 10 (14.1) **Self-reported intake diagnoses within CPP/ Indications for treatment, n (%):** IBS: **G1:** 94/475 (19.8)* **G1a:** 27/244 (11.1) **G1b:** 37/113 (32.7) **G1c:** 5/43 (11.6) **G1d:** 24/71 (33.8) Stress: **G1:** 45/475 (9.5) **G1a:** 18/244 (7.4) **G1b:** 8/113 (7.1) **G1c:** 5/43 (11.6) **G1d:** 14/71 (19.7) Ovarian cyst: **G1:** 40/475 (8.4) **G1a:** 20/244 (8.2) **G1b:** 9/113 (8) **G1c:** 3/43 (7) **G1d:** 8/71 (11.3) Endometriosis: **G1:** 35/475 (7.4) **G1a:** 16/244 (6.6) **G1b:** 10/113 (8.8) **G1c:** 1/43 (2.3) **G1d:** 8/71 (11.3) Cystitis: **G1:** 34/475 (7.2) **G1a:** 11/244 (4.5) **G1b:** 5/113 (4.4) **G1c:** 8/43 (18.6) **G1d:** 9/71 (12.7)		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Zondervan et al., continued	PID: **G1:** 31/475 (6.5) **G1a:** 13/244 (5.3) **G1b:** 10/113 (8.8) **G1c:** 2/43 (4.7) **G1d:** 6/71 (8.5) Constipation: **G1:** 31/475 (6.5) **G1a:** 7/244 (2.9) **G1b:** 11/113 (9.7) **G1c:** 1/43 (2.3) **G1d:** 12/71 (16.9) Back pain or problems: **G1:** 27/475 (5.7) **G1a:** 11/244 (4.5) **G1b:** 4/113 (3.5) **G1c:** 1/43 (2.3) **G1d:** 11/71 (15.5) Uterine fibroids: **G1:** 24/475 (5.1) **G1a:** 8/244 (3.3) **G1b:** 7/113 (6.2) **G1c:** 2/43 (4.7) **G1d:** 7/71 (9.9) Adhesions: **G1:** 22/475 (4.6) **G1a:** 9/244 (3.7) **G1b:** 4/113 (3.5) **G1c:** 2/43 (4.7) **G1d:** 6/71 (8.5) Appendicitis: **G1:** 12/475 (2.5) **G1a:** 5/244 (2) **G1b:** 3/113 (2.7) **G1c:** 3/43 (7) **G1d:** 1/71 (1.4) Inflammatory bowel disease: **G1:** 10/475 (2.1) **G1a:** 6/244 (2.5) **G1b:** 1/113 (0.9) **G1c:** 0 (0) **G1d:** 3/71 (4.2) Other: **G1:** 58/475 (12.2) **G1a:** 35/244 (14.3) **G1b:** 9/113 (8) **G1c:** 6/43 (14) **G1d:** 8/71 (11.3) **History of menstrual problems:** NR **History of pelvic surgery, n (%):** Laparoscopy or laparotomy: **G1:** 53 /475 (11.2) **G1a:** 24/ 244 (9.8) **G1b:** 10/113 (8.8) **G1c:** 3/43 (7) **G1d:** 15/71 (21.1)		

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Zondervan et al., continued	**History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		

Comments: All diagnoses are self-reported and not confirmed

* 65% (n=61/94) met Rome I criteria; study also groups women with CPP and IBS (G1b), reported n=114

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Parazzini et al., 2000 **Country:** Italy **Enrollment period:** 1995 to 1996 **Intervention setting:** Multicenter—clinics **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Intervention:** Gestoden 0.75 mg/ ethynlestradiol 0.03 mg for 12 months or tryptorelin 3.75 mg slow release for 4 months followed by gestoden /ethynlestradiol for 8 months **Assessments:** Verbal pain rating (modified Andersch and Milsom scale) and 0-10 point VAS (0=no pain, 10=unbearable pain) at baseline, 6 months, and 12 months **Groups:** **G1:** Estroprogestin (gestoden /ethynlestradiol) **G2:** GnRH agonist (tryptorelin followed by gestoden/ ethynlestradiol) **N with non-cyclic CPP at enrollment:** **G1:** 46 **G2:** 49 **N with non-cyclic CPP at follow-up:** 12 months: **G1:** 15 **G2:** 17 **Duration of treatment:** 12 months **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** Yes **Concomitant therapies:** Naproxen allowed per clinician's and participant's judgment **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** NR **Inclusion criteria:** • Laparoscopically confirmed endometriosis • Pelvic pain of 3-12 months duration post laparoscopy or laparotomy • Score of ≥3 for the multidimensional scale & or ≥5 for the analog scale for dysmenorrhea and/or non-menstrual pelvic pain **Exclusion criteria:** • Pregnancy or interest in pregnancy **Age, yrs, mean ± SD*:** **G1:** 31 ± 7.1 **G2:** 30 ± 6.7 **BMI, mean ± SD:** **G1:** NR **G2:** NR **Parity, n (%)*:** 0: **G1:** 31 **(**66.0) **G2:** 41 (74.5) ≥ 1: **G1:** 16 (34.0) **G2:** 14 (25.5) **Duration of pelvic pain, mean, months ± SD:** **G1:** NR **G2:** NR **History of menstrual problems, n (%):** **G1:** NR **G2:** NR **History of pelvic surgery, n (%)*:** Laparoscopy: **G1:** 36 (76.6) **G2:** 47 (85.4) Laparotomy: **G1:** 11 (23.4) **G2:** 8 (14.5) **History of sexual/physical abuse, n (%):** **G1:** NR **G2:** NR **Other risk factors, n (%):** C-section: **G1:** NR **G2:** NR Operative vaginal delivery: **G1:** NR	**Intake diagnoses within CPP/ Indications for treatment, n (%)*:** Endometriosis, stage I-II: **G1:** 26 (57.8) **G2:** 27 (51.9) Endometriosis, stage III-IV: **G1:** 19 (42.2) **G2:** 25 (48.1 **Pain status:** Non-menstrual pain present, n (%): **G1:** 46 (97.9) **G2:** 49 (89.1) Multidimensional pain score, median (range): **G1:** 3 (0-5) **G2:** 2 (0-5) VAS, median (range): **G1:** 5 (2-7) **G2:** 6 (2-9) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment, n (%):** NA **Pain status:** Non-menstrual pain present, n (%): **G1:** 15 (31.9) **G2:** 17 (30.9) Multidimensional pain score, median (range): **G1:** 0 (0-4) **G2:** 0 (0-5) VAS, median (range): **G1:** 4 (2-5) **G2:** 6 (2-8) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** Endometriosis stage had no significant effect on pain status **Effect modifiers:** NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Parazzini et al., continued		**G2:** NR Vaginal birth: **G1:** NR **G2:** NR Genital tract trauma: **G1:** NR **G2:** NR Pregnancy termination: **G1:** NR **G2:** NR		

Comments: *Data reported for entire sample, 93% (95/102) of whom had noncyclic/mixed chronic pelvic pain

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Ling et al., 1999 **Country:** US **Enrollment period:** June 1995 to January 1997 **Intervention setting:** 12 sites, mostly academic **Funding:** Grant from TAP Holdings, Inc. (distributes Depo Lupron) **Author industry relationship disclosures:** NR **Design:** Double-blind RCT **Blinding of:** Subjects: Yes Clinicians: Yes Investigators: Yes Outcome assessors: Yes	**Intervention:** Depot leuprolide 3.75 mg IM or placebo (given 3 times at 4 week intervals: day 0, during weeks 4 & 8) **Assessments:** Questionnaire on dysmenorrhea, dyspareunia, and nonmenstrual pain using the 4-point Biberoglu and Behrman scale (1=none to 4= severe), and pelvic exam for tenderness and induration; both done at baseline and 12 weeks. Women also assessed severity of pain using an 11-point VAS (0=none to 10=worst possible) and the McGill Pain Inventory at baseline, weeks 4, 8, and 12. **Groups:** **G1:** depot leuprolide **G2:** placebo **Ga:** laproscopic finding of endometriosis **Gb:** laproscopic finding of no endometriosis **N with noncyclic CPP at enrollment:** **G1:** 50 **G2:** 50 **N with noncyclic CPP at follow-up:** **G1:** 49 **G1a:** 38 **G1b:** 11 **G2:** 46 **G2a:** 40 **G2b:** 6 **Duration of treatment:** 12 weeks **Length of follow-up post-treatment day 1:** 12 weeks **Treatment adherence reported:** Yes **Concomitant therapies:** NR **Concomitant**	**Operational definition of CPP:** Pelvic pain unrelated to menses, not relieved with NSAIDS, present for ≥ 6 months **Inclusion criteria:** • Age 18-45 • Moderate to severe pelvic pain for ≥ 6 months • Clinically suspected endometriosis • Regular menstrual cycles for ≥ 3 months before enrollment • Agreed to use barrier contraception if not sterilized **Exclusion criteria:** • Previous diagnosis of endometriosis confirmed by surgery or histology • Used OCs in the 3 months before study • Used GnRH agonist in the 6 months before study • Surgical treatment for endometriosis • Pelvic pain related to GU or GI cause • History of alcohol, tranquilizer, illicit drug use **Age, yrs, mean:** **G1:** 32.3 **G2:** 29.4 **BMI:** NR **Parity:** NR **Duration of pelvic pain:** See inclusion criteria. **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** Clinician-evaluated pain, 4 point scale score, mean: **G1:** 3.2 **G2:** 3.1 Patient-evaluated pain, VAS score, mean: **G1:** 7.5 **G2:** 6.5 McGill pain score, mean: **G1:** 31.3 **G2:** 35.8 **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment, n (%) (90% CI):** Post-treatment laparoscopy, positive for endometriosis: **G1:** 38/49 (78) (66, 87) **G2:** 40/46 (87) (76, 94) **Pain status:** Clinician-evaluated pain scores, 4 point scale score, mean: **G1:** 1.9 **G2:** 2.9 **G1/G2:** $P < 0.001$ Patient-evaluated pain, VAS score, mean: **G1:** 2.2 **G2:** 6.6 **G1/G2:** $P < 0.001$ McGill pain scores, mean: **G1:** 9.5 **G2:** 28.3 **G1/G2:** $P < 0.001$ Pain relief, 12 weeks, n (%): **G1a:** 27/33 (82) **G1b:** 8/11 (73) **G2a:**15/38 (39) **G2b:** 1/6 (17) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** Hot flushes, n (%): **G1:** 40/50 (80) **G2:** 13/50 (26) Severe adverse events: n: **G1:** 1 **G2:** 5

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Ling et al., continued	**therapies held stable during treatment:** NR			No menses until end of treatment, n (%): **G1:** 48/49 (98) **G2:** 2/46 (4) Insomnia, n (%): **G1:** 20/50 (40) **G2:** NR* Enlarged abdomen, n: **G1:** NR **G2:** NR **G1/G2:** *P* ≤ 0.05 Headache, n (%): **G1:** NR* **G2:** 11/50 (22) Depression, n (%): **G1:** NR* **G2:** 11/50 (22) **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n:** Anxiety: NR Clinical depression: NR Dysmenorrhea, %: **G1+G2:** 100 Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction, n (%): Dyspareunia: 76/89 sexually active (85) Vulvodynia: NR

Comments: * Only the potentially treatment-related adverse events experienced by the largest number of women in each group were reported.

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities:
Author: Bodden-Heidrich et al., 1999 **Country:** Germany **Enrollment period:** NR **Intervention setting:** Clinic and hospital **Funding:** NR **Author industry relationship disclosures:** None **Design:** Cross-sectional	**Operational definition of CPP:** NR; general description in the introduction **Inclusion criteria:** • Patients with chronic pain in the lower abdomen (CPPS) that lasted longer than 6 months; treated as outpatients and later admitted for inpatient psychosomatic treatment **Exclusion criteria:** • See inclusion criteria **Assessments:** Freiburg Personality Inventory, GieBen test **Groups:** **G1:** chronic pain in the lower abdomen (CPPS) **N with noncyclic CPP at enrollment:** **G1:** 106 **N with noncyclic CPP at follow-up:** **G1:** 106 **Age, yrs, mean:** **G1:** 34 **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **Intake diagnoses within CPP/ Indications for treatment, n (%):** Without organ diagnosis: 40 (38) Endometriosis: 28 (26) Adhesions: 21 (20) Cysts: 12 (11) Pelvic inflammatory disease: 2 (2) Cysts and adhesions: 2 (2) Irritable bowel syndrome: 1 (1) **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse, n (%):** **G1:** 23 (22) **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Pain status:** NR **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS, n (%): **G1:** 1 (1) IC/PBS: NR Low back pain: NR Sexual dysfunction: NR Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Vercellini, 1996 **Country:** Italy **Enrollment period:** NR **Intervention setting:** Academic department **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Open-label, parallel group RCT **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Intervention:** Depot medroxy-progesterone acetate 150 mg IM q 90 days, or cyclic monophasic OCPs (ethinyl estradiol 0.02 mg/desogestrel 0.15 mg) with danazol 50 mg po for 21 days of each 28 day cycle **Assessments:** Pain questionnaire: severity of dysmenor-rhea, dyspareunia, and pelvic pain with the Biberoglu and Behrman scale, 10 cm VAS (0=absence of pain to 10=unbearable pain). Completed at baseline, 6 months, and end of treatment. Blood work done at these time points for serum lipids and estrogen. Clinical exam for side effects done every 3 months. Satisfaction evaluation (likert scale) at 12 months. **Groups:** **G1:** depot medroxy-progesterone acetate **G2:** cyclic monophasic OCPs plus danazol **N with noncyclic CPP at enrollment:** **G1:** 36 **G2:** 32 **N with noncyclic CPP at follow-up:** **G1:** 36 **G2:** 32 **Duration of treatment:** 12 months **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** Yes **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:**	**Operational definition of CPP:** NR **Inclusion criteria:** • 18-40 years old • First diagnosis of endometriosis at laparoscopy with no treatment of disease • Pelvic pain: at least one moderate to severe symptom on both pain assessment scales **Exclusion criteria:** • Treatment for endometriosis other than NSAIDS in the 3 months prior to study • Contraindications to estrogens, progestins, or danazol • Unwillingness to tolerate menstrual changes • Wish to conceive in the following 2 years **Age, yrs, n (%):*** < 30 years: **G1:** 15 (37) **G2:** 17 (42) ≥ 30 years: **G1:** 25 (63) **G2:** 23 (58) **BMI:** NR **Parity, ≥ 1 previous pregnancy, n (%):*** **G1:** 16 (40) **G2:** 14 (35) **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Endometriosis:* Stage I: **G1:** 8 (20) **G2:** 6 (15) Stage II: **G1:** 14 (35) **G2:** 16 (40) Stage III: **G1:** 10 (25) **G2:** 11 (27) Stage IV: **G1:** 8 (20) **G2:** 7 (18) **Pain status:** VAS score, median (IQR): **G1:** 4 (0-7.5) **G2:** 4.1 (1-7.3) **Functional status:** Verbal rating, median (IQR): **G1:** 1 (0-2) **G2:** 1 (0-2) **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** VAS score, month 12, median (IQR): **G1:** 0 (0-1) **G2:** 0 (0-0.5) **Functional status:** Verbal rating, month 12, median (IQR): **G1:** 0 (0-0) **G2:** 0 (0-0) **Satisfaction with care:** Pleased with care, n (%):* **G1:** 31 (72.5) **G2:** 23 (57.5) **Quality of life:** NR **Non-surgical harms, n (%):*** Amenorrhea: **G1:** 8 (20) **G2:** 0 (0) Breakthrough bleeding: **G1:** 6 (15) **G2:** 0 (0) Spotting: **G1:** 26 (65) **G2:** 4 (10) Bloating: **G1:** 25 (63) **G2:** 11 (28) Weight gain: **G1:** 21 (53) **G2:** 12 (30) Nausea: **G1:** 12 (30) **G2:** 4 (10) Headache: **G1:** 11 (28) **G2:** 9 (23) Acne-Seborrhea: **G1:** 8 (20) **G2:** 2 (5) Depression **G1:** 8 (20) **G2:** 7 (18) Breast pain-tension:

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Vercellini et al., continued	NR			**G1:** 6 (15) **G2:** 5 (13) Hot flushes: **G1:** 2 (5) **G2:** 1 (3) Peripheral edema: **G1:** 2 (5) **G2:** 1 (3) Asthenia: **G1:** 1 (3) **G2:** 1 (3) Dizziness: **G1:** 1 (3) **G2:** 0 (0) **Confounders:** NR **Effect modifiers:** NR

Comments: * Data reported for the entire sample

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Gestrinone study group, 1996 **Country:** Italy **Enrollment period:** NR **Intervention setting:** 6 academic departments **Funding:** Poli Industria Chimica **Author industry relationship disclosures:** NR **Design:** Double blind RCT **Blinding of:** Subjects: Yes Clinicians: Yes Investigators: Yes Outcome assessors: Yes	**Intervention:** Gestrinone (oral) 2.5 mg twice a week or leuprolide acetate (intramuscular) 3.75 mg q 4 weeks **Assessments:** Questionnaire: dysmenorrhea, dyspareunia, and nonmenstrual pain; each assessed with a verbal rating scale (Biberoglu and Behrman). Participants also rated each category of pain on a 10-cm VAS. (Both at baseline, 3, and 6 months) Bone mineral density of lumbar spine (baseline and 6 months) Plasma lipids and lipoproteins (fasting) (baseline, 1, and 6 months) **Groups:** **G1:** gestrinone **G2:** leuprolide acetate **N with noncyclic CPP at enrollment:** **G1:** 27 **G2:** 28 **N with noncyclic CPP at follow-up:** **G1:** 17 **G2:** 17 **Duration of treatment:** 6 months **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** Yes **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** NR **Inclusion criteria:** • CPP associated with enodmetriosis • Age 18-40 • Not desiring pregnancy in the immediate future • Diagnostic laparoscopy within the 3 months prior to study with no treatment of endometriosis • At least one moderate-severe pain symptom **Exclusion criteria:** • Prior treatment (other than DSAIDS) for endometriosis in the 6 months before study • Concomitant disorders that may cause gynecologic pain • Contraindications for the treatments • Abnormal bone density • Refusal to use barrier contraception **Age, yrs, mean ± SD:** **G1:** 31.9 ± 5.4 **G2:** 28.6 ± 6.2 **BMI, mean ± SD:** **G1:** 20.9 ± 2.1 **G2:** 21.4 ± 3.1 **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems, n (%):** **G1:** 27 (49) **G2:** 28 (51) **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Endometriosis: **G1:** 27 (49) **G2:** 28 (51) **Pain status:** VAS score, mean ± SD: **G1:** 4.07 ± 2.86 **G2:** 4.67 ± 2.87 **Functional status:** Verbal rating scale score, mean ± SD: **G1:** 1.22 ± 0.93 **G2:** 1.68 ± 0.90 **Satisfaction with care:** NR **Quality of life:** NR **Other:** HDL cholesterol, mg/dL, mean ± SD: **G1:** 54.0 ± 10.9 **G2:** 50.0 ± 10.0 **G1/G2:** *P* = NS Lipoprotein(a) mg/dL, mean ± SD: **G1:** 12.5 ± 8.3 **G2:** 8.4 ± 7.2 **G1/G2:** *P* < 0.05	**Post-operative diagnoses within CPP/Indications for treatment:** NA **Pain status:** VAS score, mean ± SD: **G1:** 1.11 ± 1.54 **G2:** 3.41 ± 3.45 **G1/BL:** *P* < 0.01 **G1/BL:** *P* = NS **G1/G2:** *P* < 0.05 Recurrence of severe/moderate pain, n (%): **G1:** 2/17 (11.8) **G2:** 9/17 (52.9) **G1/G2:** OR = 0.12 (95% CI: 0.02, 0.69) **Functional status:** Verbal rating scale score, mean ± SD: **G1:** 0.29 ± 0.47 **G2:** 1.12 ± 0.99 **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:*** Weight, mean change ± SD: **G1:** 0.9 ± 4.6 **G2:** -0.4 ± 2.6 Any side effects, n (%): **G1:** 15/27 (56) **G2:** 19/28 (68) Hot flushes: **G1:** 8 (29.6) **G2:** 19 (67.8) Headache: **G1:** 2 (7.4) **G2:** 5 (17.8) Asthenia: **G1:** 4 (14.8) **G2:** 1 (3.6) Mood change: **G1:** 2 (7.4) **G2:** 3 (10.7) Dermatitis: **G1:** 3 (11.1)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Gestrinone study group, continued				**G2:** 0 Dizziness: **G1:** 2 (7.4) **G2:** 1(3.6) Joint pain: **G1:** 2 (7.4) **G2:** 1(3.6) Drowsiness: **G1:** 2 (7.4) **G2:** 1(3.6) Swelling: **G1:** 2 (7.4) **G2:** 0 Nausea: **G1:** 1 (3.7) **G2:** 1 (3.6) Tachycardia: **G1:** 1 (3.7) **G2:** 1(3.6) Vaginal dryness: **G1:** 0 **G2:** 2 (7.1) Insomnia: **G1:** 1 (3.7) **G2:** 0 Hypertrichosis: **G1:** 1 (3.7) **G2:** 0 Seborrhea: **G1:** 1 (3.7) **G2:** 0 Skin rash: **G1:** 1 (3.7) **G2:** 0 Constipation: **G1:** 1 (3.7) **G2:** 0 Itching: **G1:** 0 **G2:** 1 (3.6) Vaginal discharge: **G1:** 0 **G2:** 1 (3.6) Paresthesia: **G1:** 0 **G2:** 1 (3.6) Cramps: **G1:** 0 **G2:**1 (3.6) Bone mineral density, mean % change ± SD: 6 months: **G1:** 0.88 ± 2.12 **G2:** -3.04 ± 4.77

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Gestrinone study group, continued				**G1/BL:** *P* = NS **G2/BL:** *P* = 0.01 **G1/G2:** *P* < 0.01 12 months (6 month follow-up): **G1:** 2.06 ± 2.51 **G2:** -1.08 ± 3.26 HDL cholesterol, mg/dL, 6 months, mean ± SD: **G1:** 35.6 ± 10.7 **G2:** 52.3 ± 11.3 **G1/BL:** *P* < 0.05 **G1/BL:** *P* = NS **G1/G2:** *P* < 0.01 Lipoprotein(a), mg/dL, 6 months, mean ± SD: **G1:** 5.8 ± 3.6 **G2:** 10.2 ± 10.3 **G1/BL:** *P* < 0.05 **G1/BL:** *P* = NS **G1/G2:** *P* < 0.01 Uterine bleeding at the end of treatment, n (%): **G1:** 12/23 (52.2%) had no bleeding **G2:** 25/26 (96.1 %) had amenorrhea **Confounders:** NR **Effect modifiers:** No significant interaction between treatment & endometriosis stage **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: NR Dysmenorrhea, n (%): **G1:** 27 (100) **G2:** 28 (100) Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Gestrinone study group, continued				Sexual dysfunction, Dyspareunia: **G1:** 26 (96) **G2:** 26 (93) Vulvodynia: NR

Comments: * harms reported for all 55 participants

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Mathias et al., 1996 **Country:** US **Enrollment period:** April 1994 to May 1994 **Intervention setting:** NA **Funding:** TAP Holdings, Inc. **Author industry relationship disclosures:** NR **Design:** Cross-sectional study	**Operational definition of CPP:** Intermittent or constant pain below the navel or in the female organs for at least 6 months, including pain during the past 3 months **Inclusion criteria:** • Pelvic pain at least 6 months including pain during the past 3 months • Age 18-50 **Exclusion criteria:** • Pregnancy • Postmenopausal • Menstrual cycle-related diagnoses **Assessments:** Pelvic pain-related questions (pain index = frequency of pelvic pain multiplied by average severity on scale of 0-10) and quality of life related questions addressed to women indicating pelvic pain in the past month (0-100 scale with higher scores indicating more of attribute, e.g., more pain or more energy) **Groups:** **G1:** women with CPP **Ga:** no underlying diagnosis determined **Gb:** gynecologic diagnoses not related to menstrual cycle **Gc:** endometriosis **Gd:** non-gynecologic diagnoses **Ge:** unclassifiable/forgotten diagnoses **N with non-cyclic CPP at enrollment:** **G1:** 773 **G1a:** 472 **G1b:** 149 **G1c:** 74 **G1d:** 31 **G1e:** 47 **N with non-cyclic CPP at follow-up:** **G1:** 773 **G1a:** 472 **G1b:** 149 **G1c:** 74 **G1d:** 31 **G1e:** 47 **Age, yrs, mean ± SD:** **G1:** 35.7 ± 8.6 **BMI:** NR **Parity:** NR	**Pain status:** Pain in past month, n (%): **G1:** 557 (72) Pain index score, mean ± SD: **G1a:** 1.9 ± 0.1 **G1b:** 2.4 ± 0.2 **G1c:** 3.1 ± 0.2 **G1d:** 3.0 ± 0.4 **G1a/G1b:** *P* < 0.05 **G1a/G1c:** *P* < 0.05 **G1a/G1d:** *P* < 0.05 **G1c/G1b:** *P* < 0.05 **Functional status:** Interference with activities scale score, mean ± SD: **G1a:** 21.9 ± 1.4 **G1b:** 28.5 ± 2.2 **G1c:** 30.5 ± 3.0 **G1d:** 29.4 ± 4.5 **G1a/G1b:** *P* < 0.05 **G1a/G1c:** *P* < 0.05 Energy scale score, mean ± SD: **G1a:** 54.9 ± 1.4 **G1b:** 45.5 ± 2.3 **G1c:** 53.3 ± 3.1 **G1d:** 45.4 ± 4.6 **G1a/G1b:** *P* < 0.05 **G1a/G1d:** *P* < 0.05 **G1c/G1b:** *P* < 0.05 Pain during or after inter-course scale score, mean ± SD: **G1a:** 21.6 ± 2.1 **G1b:** 30.1 ± 3.5 **G1c:** 35.9 ± 4.7 **G1d:** 29.1 ± 6.8 **G1a/G1b:** *P* < 0.05 **G1a/G1c:** *P* < 0.05 Stayed in bed more than half the day, n (%): **G1:** 144/557 (26) Reduced activities on ≥ 1 days in past month, n (%): **G1:** 323/557 (58) Bed days/month, participants reporting pelvic pain in past month, mean ± SD: **G1:** 2.6 ± 2.4 (n=557) Missed ≥ 1 hours of work, employed participants, n (%): **G1:** 82/548 (15) **Satisfaction with care:** NR **Quality of life:** General health scale score, mean ± SD:	**Comorbidities of interest:** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction (dyspareunia), participants reporting sexual activity: **G1:** 380/432 (88) Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Mathias et al., continued	**Duration of pelvic pain:** NR **Intake diagnoses within CPP/ Indications for treatment, n (%):** No underlying diagnosis determined: **G1a:** 472 (61) Gynecologic diagnoses not related to menstrual cycle: **G1b:** 149 (49) Endometriosis: **G1c:** 74 (25) Non-gynecologic diagnoses: **G1d:** 31 (10) Unclassifiable/forgotten diagnoses: **G1e:** 47 (16) **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**G1a:** 73.6 ± 1.4 **G1b:** 64.8 ± 2.2 **G1c:** 70.7 ± 3.1 **G1d:** 62.4 ± 4.4 **G1a/G1b:** *P* < 0.05 **G1a/G1d:** *P* < 0.05 Mental health scale score, mean ± SD: **G1a:** 64.0 ± 1.3 **G1b:** 58.1 ± 2.1 **G1c:** 63.0 ± 2.8 **G1d:** 54.3 ± 4.2 **G1a/G1b:** *P* < 0.05 **G1a/G1d:** *P* < 0.05 Health distress scale score, mean ± SD: **G1a:** 28.7 ± 1.7 **G1b:** 40.1 ± 2.8 **G1c:** 45.7 ± 3.6 **G1d:** 42.6 ± 5.5 **G1a/G1b:** *P* < 0.05 **G1a/G1c:** *P* < 0.05 **G1a/G1d:** *P* < 0.05 Pain interferes with mood, n (%): **G1:** 310/557 (56) Feeling downhearted or blue, n (%): **G1:** 261/557 (47) Having energy to do things, n (%): **G1:** 456/557 (82)	

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Inclusion/Exclusion Criteria & Population	Baseline Measures	Prevalence of Comorbidities, n (%):
Author: Saravelos et al., 1995 **Country:** UK **Enrollment period:** January 1987 to January 1994 **Intervention setting:** Hospital **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Retrospective case series **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Operational definition of CPP:** Pain in the pelvis persisting for ≥ 6 months **Inclusion criteria:** • Women presenting for adhesiolysis for chronic pelvic pain **Exclusion criteria:** • Presence of significant gynecological, gastrointestinal, urological, musculoskeletal, or neurological pathology • Presence or history of malignancy or psychiatric disease **Groups:** **G1:** Microsurgery **G2:** Laparoscopy **Age, yrs, mean (range):** **G1:** 32.5 (19-60) **G2:** 31.4 (18-61) **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery, n (%):** Previous surgery for CPP: **G1:** 25 (35) **G2:** 18 (35) History of laparotomy: **G1:** 47 (65) **G2:** 29 (57) **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** NR **Pain status:** NR **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction (dyspareunia): **G1:** 43 (60) **G2:** 34 (67) Vulvodynia: NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Carlson et al., 1994 **Country:** US **Enrollment period:** June 1989 to January 1991 **Intervention setting:** Acute care hospital **Funding:** Agency for Health Care Policy and Research **Author industry relationship disclosures:** NR **Design:** Prospective cohort **Blinding of:** Subjects: NR Clinicians: NR Investigators: NR Outcome assessors: NR	**Intervention:** Hysterectomy or non-surgical management consisting of non-steroidal agents alone (15%), other analgesics (47%), hormone therapy (22%), or observation (16%). **Assessments:** Personal interview at study entry and 3 months; telephone interviews at 6 and 12 months; self-administered questionnaire at entry, 3, 6 and 12 months; Mental Health Index; General Health Index; Activity Index (index scores transformed to 1-100 scale where 100 is positive); physician questionnaire for each patient on physical exam findings, diagnostic procedures, and planned treatment. **Groups:** **G1:** nonsurgical management **G2:** hysterectomy **N with noncyclic CPP at enrollment:** **G1:** 50 **G2:** 68 **N with noncyclic CPP at follow-up:** **G1:** 50 **G2:** 68 **Duration of treatment:** ≥ 12 months **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** No **Concomitant therapies, n (%):** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** Pain of at least 6 months duration **Inclusion criteria:** • Ages 25-50 years • Chronic pelvic pain ≥ 6 months duration • Laparoscopy to rule out endometriosis, malignancy, and other conditions requiring specific treatment) • Any medical therapy **Exclusion criteria:** • Patients who crossed over from nonsurgical treatment to hysterectomy during the 12-month follow-up period were excluded from analysis of treatment outcomes **Age:** NR* **BMI:** NR **Parity:** NR **Duration of pelvic pain:** NR **History of menstrual problems:** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** Pain, days, mean: **G1:** 16 **G2:** 19 Pain a problem, %: **G1:** 84 **G2:** 95 **Functional status:** Bleeding, days, mean: **G1:** 7 **G2:** 8 Bleeding a problem, %: **G1:** 30 **G2:** 61 Fatigue a problem, %: **G1:** 55 **G2:** 75 **Satisfaction with care:** Positive feelings about symptom status, %: **G1:** 7 **G2:** 0 **Quality of life:** Mental Health Index, mean: **G1:** 63 **G2:** 50 General Health Index, mean: **G1:** 54 **G2:** 45 Activity Index, mean: **G1:** 54 **G2:** 42	**Post-operative diagnoses within CPP/Indications for treatment:** NR **Pain status:** Pain, 12 months, days, mean: **G1:** 9 **G2:** 1 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 Pain a problem, 12 months, %: **G1:** 49 **G2:** 3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Functional status:** Bleeding, 12 months, days, mean: **G1:** 6 **G2:** 0 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.001 Bleeding a problem, 12 months, %: **G1:** 28 **G2:** 0 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.001 Fatigue a problem, 12 months, %: **G1:** 59 **G2:** 22 **Satisfaction with care:** Positive feelings about symptom status, 12 months, %: **G1:** 30 **G2:** 77 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Quality of life:** Mental Health Index, 12 months, mean: **G1:** 60 **G2:** 71 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.001

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Carlson et al., continued				General Health Index, mean: **G1:** 61 **G2:** 77 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.001 Activity Index, mean: **G1:** 67 **G2:** 77 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** Hysterectomy (vs. nonsurgical management): OR = 10.45** *P* = 0.0001 Education > 12 years (vs. ≤ 12 years): OR = 2.73** *P* = 0.033

Comments:
* Mean age for nonsurgical pelvic pain, leiomyomas and abnormal bleeding combined was 41 years (380 subjects).
** Adjusted likelihood (for treatment type, age, fertility, parity, education, duration of symptoms, and initial severity of discomfort) of positive feelings about symptom status at 1 year in patients with CPP

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Ghaly, 1994 **Country:** Scotland **Enrollment period:** NR **Intervention setting:** Gynecologic clinic **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT **Blinding of:** Subjects: no Clinicians: no Investigators: no Outcome assessors: yes	**Intervention:** Pelvic ultrasonography plus counseling (demonstrations of the normality of pelvic organs, education, counseling and reassurance) **Assessments:** McGill Pain Score, HADS prior to randomization and 4-9 months post-intervention **Groups:** **G1:** pelvic ultrasonography plus counseling **G2:** expectant management **N with non-cyclic CPP at enrollment:** **G1:** 50 **G2:** 50 **N with non-cyclic CPP at follow-up:** **G1:** 46 **G2:** 44 **Duration of treatment:** 1 day **Length of follow-up post-treatment day 1:** 4-9 months **Treatment adherence reported:** NA **Concomitant therapies, n (%):** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** Pain of at least 6 months duration **Inclusion criteria:** • CPP of at least 6 months duration • Negative laparoscopic findings **Exclusion criteria:** • Previous malignancy • Medical treatment for CPP at prior clinic visit • Mental retardation • Prior psychiatric treatment • Suspicion of malignant disease at pelvic exam • Abnormal laparoscopic findings that could be cause of CPP and required medical or surgical intervention **Age, yrs, mean (range):** **G1:** 32.2 (21-55) **G2:** 32.5 (22-54) **BMI, mean ± SD:** NR **Parity, mean (range):** **G1:** 1.6 (0-4), 10 nulliparous **G2:** 1.5 (0-5), 8 nulliparous **Duration of pelvic pain, median, months (range):** **G1:** 42 (6-370) **G2:** 37 (9-320) **History of menstrual problems, n (%):** NR **History of pelvic surgery, n (%):** NR **History of sexual/physical abuse, n (%):** NR **Other risk factors, n (%):** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Diagnosis(es): NR **Pain status:** McGill pain score, median (range): **G1:** 29 (19-36) **G2:** 30 (17-38) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment, n (%):** Diagnosis(es): NR **Pain status:** McGill pain score: **G1:** 13/46 had "significant improvement" **G2:** 4/44 showed "significant improvement" (p<0.01) Resolution of pain: **G1:** 12/46 **G2:** 1/44 (p<0.01) **Functional status:** NR **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** NR

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Vercellini et al., 1993 **Country:** Italy **Enrollment period:** NR **Intervention setting:** University hospital **Funding:** Italian National Research Council **Author industry relationship disclosures:** NR **Design:** Open label RCT **Blinding of:** Subjects: No Clinicians: No Investigators: No Outcome assessors: No	**Intervention:** Goserelin 3.6 mg subq q 28 days or cyclic low dose monophasic OC with ethinyl estradiol 0.02 mg and desogestrel 0.15 mg (could switch to EE 0.03 mg/desogestrel 0.15 mg if breakthrough bleeding) **Assessments:** Questionnaire: severity of dysmenorrhea, dyspareunia, and nonmenstrual pain with a verbal rating scale and 10 point linear analog scale. Given at baseline, end of treatment, and end of follow-up. **Groups:** **G1:** goserelin **G2:** oral contraceptive **N with noncyclic CPP at enrollment:** **G1:** 29 **G2:** 28 **N with noncyclic CPP at follow-up:** **G1:** 26 **G2:** 24 **Duration of treatment:** 6 months **Length of follow-up post-treatment day 1:** 12 months **Treatment adherence reported:** Yes **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** NR **Inclusion criteria:** • Moderate to severe pelvic pain • Laparoscopically diagnosed endometriosis within 3 months of study with no surgical treatment of endometriosis • 18-35 years old **Exclusion criteria:** • Treatment (excepting NSAID use) for endometriosis in the 3 months prior to study • Contraindications to oral contraceptives **Age, yrs, mean ± SD:** **G1:** 28 ± 5 **G2:** 27 ± 5 **BMI:** NR **Parity, parous, n (%):** **G1:** 8 (28) **G2:** 7 (25) **Duration of pelvic pain:** NR **History of menstrual problems, n (%):** NR **History of pelvic surgery:** NR **History of sexual/physical abuse:** NR **Other risk factors:** C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Endometriosis stage: I: **G1:** 12 (41) **G2:** 14 (50) II: **G1:** 10 (35) **G2:** 9 (32) III: **G1:** 5 (17) **G2:** 4 (14) IV: **G1:** 2 (7) **G2:** 1 (4) **Pain status:** Linear analog scale, overall mean ± SD: **G1:** 4.4 ± 3.2 **G2:** 4.2 ± 3.0 Linear analog scale, %:* Absent: **G1:** 19 **G2:** 17 Mild: **G1:** 31 **G2:** 42 Moderate: **G1:** 27 **G2:** 24 Severe: **G1:** 23 **G2:** 17 **Functional status:**: Verbal rating scale, overall mean ± SD **G1:** 3.0 ± 1.9 **G2:** 2.9 ± 2.1 Verbal rating scale, %:* Absent: **G1:** 19 **G2:** 17 Mild: **G1:** 35 **G2:** 42 Moderate: **G1:** 42 **G2:** 33 Severe: **G1:** 4 **G2:** 8 **Satisfaction with care:** NR **Quality of life:**	**Post-operative diagnoses within CPP/Indications for treatment:** NA **Pain status:** Linear analog scale, overall mean ± SD: **G1:** 3.9 ± 3.0 **G2:** 3.6 ± 2.6 Linear analog scale, %: Absent: **G1:** 19 **G2:** 17 Mild: **G1:** 54 **G2:** 67 Moderate: **G1:** 12 **G2:** 8 Severe: **G1:** 15 **G2:** 8 **Functional status:** Verbal rating scale, overall mean ± SD: **G1:** 2.6 ± 1.9 **G2:** 2.6 ± 2.0 Verbal rating scale, %: Absent: **G1:** 19 **G2:** 17 Mild: **G1:** 54 **G2:** 50 Moderate: **G1:** 19 **G2:** 25 Severe: **G1:** 8 **G2:** 8 **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms, n (%):**** Hot flushes: **G1:** 24 (83) **G2:** 1 (4) Insomnia: **G1:** 7 (24)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria & Population	Baseline Measures	Outcomes
Vercellini et al., continued			NR	**G2:** 0 Spotting: **G1:** 6 (21) **G2:** 7 (25) Decreased libido: **G1:** 5 (17) **G2:** 0 Vaginal dryness: **G1:** 5 (17) **G2:** 5 (18) Mood changes: **G1:** 4 (14) **G2:** 6 (21) Headache: **G1:** 3 (10) **G2:** 1 (4) Paresthesias: **G1:** 3 (10) **G2:** 5 (18) Breast tenderness: **G1:** 2 (7) **G2:** 4 (14) Weight gain: **G1:** 1 (3) **G2:** 1 (4) Peripheral edema: **G1:** 1 (3) **G2:** 0 **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n:** Anxiety: NR Clinical depression: NR Dysmenorrhea: **G1:** 26 **G2:** 24 Fibromyalgia: NR Headache: NR IBS: NR IC/PBS: NR Low back pain: NR Sexual dysfunction (dyspareunia)[‡]: **G1:** NR **G2:** NR Vulvodynia: NR

Comments: * G1: n=26; G2: n=24, ** Numbers not provided for non cyclic patient only; harms reported for whole population
[‡]Dyspareunia reported in a group of patients but denominator not clear

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Walton et al., 1992 **Country:** UK **Enrollment period:** NR **Intervention setting:** Multisite (hospital) **Funding:** Upjohn Laboratories-Europe **Author industry relationship disclosures:** NR **Design:** RCT **Blinding of:** Subjects:Yes Clinicians:No Investigators:No Outcome assessors:NA	**Intervention:** Medroxyprogesterone acetate, 50mg daily by mouth for 4 months **Assessments:** Patient-completed pelvic pain diary and patient-completed 100mm VAS (no pain at all to unbearable pain) **Groups:** **G1:** Medroxyprogesterone acetate **G2:** Placebo **N with non-cyclic CPP at enrollment:** **G1:** 107 **G2:** 58 **N with non-cyclic CPP at follow-up:** **G1:** 68 **G2:** 33 **Duration of treatment:** 4 months **Length of follow-up post-treatment day 1:** Immediately post-treatment **Treatment adherence reported:** Yes **Concomitant therapies, n (%):** NR Therapy name(s): NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** Women with pelvic pain lasting ≥ 6 months, including dyspareunia, postcoital ache, pain exercising, and ovarian point tenderness. **Inclusion criteria:** • Women with pelvic pain lasting ≥ 6 months • Negative laparoscopy ≥ 6 weeks prior to study **Exclusion criteria:** • See inclusion criteria **Age, yrs, mean ± SD:** **G1:** NR **G2:** NR **BMI, mean ± SD:** **G1:** NR **G2:** NR **Parity:** **G1:** NR **G2:** NR **Duration of pelvic pain, mean, months ± SD:** **G1:** NR **G2:** NR **History of menstrual problems, n (%):** **G1:** NR **G2:** NR **History of pelvic surgery, n (%):** NR **History of sexual/physical abuse, n (%):** **G1:** NR **G2:** NR **Other risk factors, n (%):** Pregnancy: **G1:** NR **G2:** NR C-section: **G1:** NR **G2:** NR Operative vaginal delivery: **G1:** NR **G2:** NR Vaginal birth: **G1:** NR **G2:** NR Genital tract trauma: **G1:** NR **G2:** NR Pregnancy termination: **G1:** NR **G2:** NR	**Intake diagnoses within CPP/ Indications for treatment, n (%):** Diagnosis(es): **G1:** NR **G2:** NR **Pain status:** 100mm VAS: **G1:** 72.1 **G2:** 78.4 **Functional status:** **G1:** NR **G2:** NR **Satisfaction with care:** **G1:** NR **G2:** NR **Quality of life:** **G1:** NR **G2:** NR	**Post-operative diagnoses within CPP/Indications for treatment, n (%):** Diagnosis(es): **G1:** NR **G2:** NR **Pain status:** 100mm VAS: **G1:** 46.2 **G2:** 68.8 P=NS Mean change in VAS, baseline to last follow-up: **G1:** -25.9 **G2:** -19.7 P=NS Treatment success (≥ 50% reduction in pain score), n: **G1:** 30/68 **G2:** 9/34 P=NS Participant rating of improvement at 5 months, % noting improvement: **G1:** 57 **G2:** 41 P=NS **Functional status:** **G1:** NR **G2:** NR **Satisfaction with care:** **G1:** NR **G2:** NR **Quality of life:** **G1:** NR **G2:** NR **Non-surgical harms:** Serious events leading to study withdrawal: Leg color changes: **G1:** 1 **G2:** 0

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Walton et al., 1992 (continued)				Benign breast lumps: **G1:** 1 **G2:** 0 Sheath accident: **G1:** 1 **G2:** 0 Headache, bloating, weight gain, hot flushes, mastalgia, nausea, and vomiting (data NR): G1 vs. G2: P=NS **Confounders:** NR **Effect modifiers:** NR

Comments:
Discrepancy between reported serious medical events recorded in Table I and the text.
* "Three patients given medroxyprogesterone acetate reported serious medical events which led to their withdrawal from the study. These included leg colour changes, benign breast lumps, and a sheath accident." (Walton, S51)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Author: Peters et al., 1991 **Country:** The Netherlands **Enrollment period:** January 1983 to January 1987 **Intervention setting:** University medical center **Funding:** Praeventie Fonds **Author industry relationship disclosures:** NR **Design:** RCT **Blinding of:** Subjects: No Clinicians: No Investigators: Yes Outcome assessors: No	**Intervention:** Standard treatment (exclusion of organic causes of pain, laparoscopy, before attention devoted to treating other causes, i.e., psychological) or integrated approach (equal attention devoted to organic, psychological, dietary, and environmental causes of pain) including consultation with physiotherapist; laparoscopy not routinely performed **Assessments:** At baseline and 12 months after finishing treatment: pain history, review of associated symptoms, pain calendar, pain questionnaire similar to McGill (score 10-40) **Groups:** **G1:** standard treatment **G2:** integrated approach **N with noncyclic CPP at enrollment:** **G1:** 49 **G2:** 57 **N with noncyclic CPP at follow-up:** **G1:** 49 **G2:** 57 **Duration of treatment:** Varies, but close to 6 months **Length of follow-up post-treatment day 1:** Varies, but close to 18 months **Treatment adherence reported:** No **Concomitant therapies:** NR **Concomitant therapies held stable during treatment:** NR	**Operational definition of CPP:** Chronic pelvic pain for at least 3 months **Inclusion criteria:** • Chronic pelvic pain for at least 3 months • No suspicion of malignancy or GYN disease requiring prompt attention • No history of psychiatric treatment for abdominal pain in prior 2 years • No elaborate medical analysis for abdominal pain in prior 2 years • No ongoing treatment for pelvic pain elsewhere • No problem with Dutch language • No mental retardation **Exclusion criteria:** • See inclusion criteria **Age, yrs, mean (range):** **G1:** 35.7 (16-56) **G2:** 35.5 (21-58) **BMI:** NR **Parity:** NR **Duration of pelvic pain, months, mean (range):** **G1:** 36 (5-240) **G2:** 48 (3-350) **History of menstrual problems:** NR **History of pelvic surgery, %:** Appendectomy: **Total:** 61 Hysterectomy: **Total:** 13 Adhesiolysis: **Total:** 15 Antefixation for retroverted uterus: **Total:** 9 **History of sexual/physical abuse, %:** Childhood sexual abuse or rape: **Total:** 20 **Other risk factors:**	**Intake diagnoses within CPP/ Indications for treatment:** NR **Pain status:** McGill score, mean (range): **G1:** 24.9 (14-40) **G2:** 26.4 (15-36) **Functional status:** Disturbance of daily activities, n (%): **G1:** 33 (67) **G2:** 55 (96) **Satisfaction with care:** NR **Quality of life:** NR	**Post-operative diagnoses within CPP/Indications for treatment, n:** Endometriosis: **G1:** 4 **G2:** NR Adhesions: **G1:** 9 **G2:** NR **Pain status:** McGill score, improvement, n (%): **G1:** 25 (51) **G2:** 35 (61) **G1/G2:** $P = 0.38$ **Functional status:** Disturbance of daily activities, improvement, n (%): **G1:** 18 (37) **G2:** 39 (68) **G1/G2:** $P < 0.01$ **Satisfaction with care:** NR **Quality of life:** NR **Non-surgical harms:** NR **Confounders:** NR **Effect modifiers:** NR **Prevalence of comorbidities of interest, n (%):** Anxiety: NR Clinical depression: NR Dysmenorrhea: NR Fibromyalgia:NR Headache: **G1:** 26 (53) **G2:** 40 (70) IBS: NR IC/PBS: NR Low back pain: **G1:** 39 (79) **G2:** 54 (94)

Evidence Tables. Therapies for women with noncyclic chronic pelvic pain (continued)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Baseline Measures	Outcomes
Peters et al., continued		C-section: NR Operative vaginal delivery: NR Vaginal birth: NR Genital tract trauma: NR Pregnancy termination: NR		Sexual dysfunction, %: Dyspareunia: **Total:** 71 Anorgasmy: **Total:** 42 Postcoital pain: **Total:** 27 Vulvodynia: NR

Appendix D. Data Extraction Forms

Therapies for Women with Chronic Pelvic Pain
Abstract Review Form

First Author, Year: _____ Reference #_____ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria			
1. Original research (exclude editorials, commentaries, letters, etc)	Yes	No	Cannot Determine
2. Study includes **(check applicable)**: - Women: ___ Yes ___ No ___ Cannot Determine - ≥ 18 years of age ___ Yes ___ No ___ Cannot Determine - with CPP (excluding cyclic pain associated with menstruation) ___ Yes ___ No ___ Cannot Determine **If combination of "Yes" or "Cannot Determine" selected, indicate Yes in final criteria box; if any "no" selected, indicate No**	Yes	No	---
3. Eligible study size (N≥ 50 women with CPP) **N=**_____	Yes	No	Cannot Determine
4. Addresses *either*: __a. CPP in women **AND** one of the following co-morbidities (**circle applicable)**: depression, anxiety, fibromyalgia, temporomandibular joint pain disorder, IBS, IC/PBS, complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, sexual dysfunction ***OR*** __b. Surgical or non-surgical therapies for women with CPP	Yes	No	Cannot Determine

Retain for: _____BACKGROUND/DISCUSSION _____REVIEW OF REFERENCES _____Other

Reason for Other: _____

Therapies for Women with CPP CER

Full Text Review Form

First Author, Year: _____ Reference ID #: _____ Abstractor Initials: ___ ___ ___

1. Original research (exclude editorials, commentaries, letters, reviews, etc.)	Yes	No
2. Includes women ≥ 18 yrs **with non-cyclic or mixed cyclic/non-cyclic chronic pelvic pain** (Record participants' age range: _____)	Yes	No
2a. Majority of patients defined as having non-cyclic/mixed CPP (NOT cancer OR pregnancy OR associated comorbidities such as IBS, IC/PBS)	Yes	No
3. Eligible study size and design ___Is the study an RCT/controlled trial or prospective cohort (two or more groups of patients that received different interventions) with N ≥ 50 **TOTAL** women with non-cyclic/mixed CPP **OR** ___Is the study a case series with N ≥ 100 women with non-cyclic/mixed CPP and discussing prevalence of co-morbidities **OR** ___Is the study a case series with N ≥ 100 women with non-cyclic/mixed CPP and discussing harms **If at least one of the above is checked, circle Yes.** If No, record N with non-cyclic/mixed CPP:____	Yes	No
4. Study addresses one or more of the following questions (check applicable KQ below):	Yes	No
__KQ1: Among women who present for treatment for a diagnosis of Chronic Pelvic Pain (CPP), what is the prevalence of the following co-morbidities **(CIRCLE APPLICABLE)**: dysmenorrhea, major depressive disorder, anxiety disorder, temporomandibular joint pain disorder, fibromyalgia, irritable bowel syndrome, interstitial cystitis/painful bladder syndrome, complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, and sexual dysfunction? __KQ2: Among women with CPP, what is the effect of surgical interventions on pain status, functional status, satisfaction with care, and quality of life? __KQ3: What is the evidence that surgical outcomes differ by whether an etiology for CPP is identified after surgery? __KQ4: Among women with CPP, what is the effect of non-surgical interventions on pain status, functional status, satisfaction with care, quality of life, and harms? __KQ5: What is the evidence for choosing one intervention over another for treating persistent or recurrent CPP after initial intervention (which failed to achieve target outcome(s))?		
5. Study includes at least one outcome measure related to any of the following **(CIRCLE APPLICABLE):** pain status (includes reduction, recurrence, subsequent intervention); functional status (includes ADL, sexual functioning); patient satisfaction; QOL; or harms **OR** addresses prevalence of comorbidities	Yes	No
6. Study published in English	Yes	No

EXCLUDE IF AN ITEM IN A GRAY BOX IS SELECTED

7. Review the reference list (included papers only) and list author name/year for EPC to verify if included in database:

_____

_____

8. **If included**, does the study assess association(s) between any of the following patient history factors: pregnancy, cesarean birth, operative vaginal delivery (forceps or vacuum extraction), vaginal birth, genital tract trauma related to childbirth, pelvic or abdominal surgery, termination of pregnancy AND CPP-related outcomes? ___Yes ___No

9. If excluded, retain for ____Background/Discussion ___Review of references ___
Other:_____

Appendix E. Quality of the Literature

Randomized Trials

Table E1. Quality of randomized controlled trials

Author, Year	Random assignment	Blinding--participants	Blinding--investigators	Blinding--providers	Blinding--assessors	Participant flow described	ITT analysis	Missing data adequately reported	Missing data managed acceptably	Primary outcome planned a priori	Free from bias	Sample size calculation provided	Appropriate statistical analysis	Statistical results reliable	< 10% drop-out rate	< 20% loss to follow-up	Final rating
Daniels 2009[1]	+	+	-	-	-	+	+	+	+	+	+	+	+	+	+	-	Fair
Stratton 2008[2,3]	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	Good
Heyman 2006[4]	+	-	-	-	-	+	-	-	-	+	+	+	+	+	-	+	Poor
Palomba 2006 [5]	+	-	-	-	-	+	-	-	-	-	+	+	+	+	+	+	Poor
Abbott 2006[6]	+	+	+	-	-	+	-	+	-	+	+	+	+	+	+	+	Fair
Sator-Katzenschlager 2005[7]	-	-	-	-	-	+	-	-	-	-	+	-	+	+	-	+	Poor
Onwude 2004[8]	-	-	-	-	-	-	+	+	-	+	+	+	+	-	NA	-	Poor
Johnson 2004[9]	-	+	-	-	-	+	+	-	-	+	+	+	+	+	+	+	Poor
Zupi 2004[10]	+	-	-	-	-	-	NA	-	-	+	+	+	+	+	-	-	Poor
Swank 2003[11]	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	Good
Parazzini 2000[12]	+	-	-	-	-	-	+	+	-	+	+	-	+	+	-	-	Poor
Ling 1999[13]	+	+	+	+	+	+	-	-	-	+	-	+	+	+	+	+	Fair
Vercellini 1996[14]	+	-	-	-	-	+	+	-	-	+	+	+	+	+	-	-	Poor
Gestrinone Study Group1996[15]	+	+	+	+	+	+	-	-	-	-	+	-	+	+	-	-	Poor
Ghaly 1994[16]	-	-	-	-	+	-	-	-	-	+	+	-	-	-	+	+	Poor
Vercellini 1993[17]	-	-	-	-	-	+	-	-	-	+	+	+	+	+	-	+	Poor
Walton 1992[18]	-	-	-	-	-	+	-	+	-	-	-	+	-	-	-	-	Poor
Peters 1991[19]	+	-	+	-	-	-	-	-	-	-	+	-	-	-	+	+	Poor

Cohort Studies

Table E2. Quality of cohort studies

Author, Year	Participant characteristics described	Inclusion/exclusion criteria described	Criteria equally applied	Baseline comparability	Concurrent controls	Intervention clearly defined	Reliable measurement of intervention	Assessors blinded to intervention status	Avoidance of detection bias	Reliable outcome assessment methods	≥ 12 weeks follow-up duration	Missing data adequately reported	Missed data managed adequately	Primary outcome planned a priori	Bias handling adequate	Substantive conflict of interest	Sample size calculation provided	Appropriate statistical analysis	Reliable statistical results	< 10% drop-out rate	< 20% loss to follow-up	Approach to contounders described	Adjustment for confounders adequate	Approach to effect modifiers described	Adequate adjustment for effect modifiers	Final Score
Vercellini 2010[20]	+	+	+	+	+	+	NA	-	NA	+	+	+	-	+	+	+	+	+	+	-	-	+	+	-	-	Poor
Lamvu 2006[21]	+	+	+	+	+	+	-	-	NA	+	+	+	NA	+	+	+	-	+	+	-	-	+	+	+	+	Poor
Carlson 1994[22]	+	+	+	-	+	-	-	-	NA	-	+	-	-	+	-	-	-	-	-	-	-	+	+	+	+	Poor

Studies Addressing Prevalence of Comorbidities of Interest

Table E3. Quality of studies addressing prevalence of comorbidities of interest

Author, Year	Sampling method adequate	Sample size > 100	Response rate > 70%	Inclusion/exclusion criteria specified	Validated diagnostic criteria for comorbidity	Operational definition provided	Final Score
Back Pain							
Droz 2011[23]	+	+	NA	+	-	+	Fair
Lamvu 2006[21]	+	+	NA	+	-	-	Poor
Grace 2005[24,25]	+	+	-	+	-	-	Poor
Sator-Katzenschlager 2005[7]	+	-	NA	+	+	NA	Fair
Williams 2004[26,27]	+	+	+	+	-	-	Poor
Chung 2003[28]	+	+	NA	+	-	-	Poor
Zondervan 2001[29]	+	+	+	+	-	-	Poor
Peters 1991[19]	+	+	NA	+	-	-	Poor
Depression							
Stratton 2008[2,3]	+	+	NA	+	-	-	Poor
Lamvu 2006[21]	+	+	NA	+	+	NA	Good
Williams 2004[26,27]	+	+	+	+	+	NA	Good
Dysmenorrhea							
Droz 2011[23]	+	+	NA	+	-	+	Fair
Montenegro 2009[30]	-	+	+	+	-	+	Poor
Pitts 2008[31]	+	+	-	+	-	+	Poor
Grace 2005[24,25]	+	+	-	+	-	+	Poor
Johnson 2004[9]	+	+	NA	+	-	+	Poor
Chung 2003[28]	+	+	NA	+	-	-	Poor
Zondervan 2001[29]	+	+	+	+	-	+	Fair
Ling 1999[13]	+	+	NA	+	-	-	Poor
Gestrinone Study Group 1996[15]	+	-	NA	+	-	+	Poor
Vercellini 1993[17]	-	-	NA	+	-	+	Poor
Dyspareunia							
Montenegro 2009[30]	-	+	+	+	-	+	Poor
Pitts 2008[31]	+	+	-	+	-	+	Poor
Grace 2005[24,25]	+	+	-	+	-	+	Poor
Johnson 2004[9]	+	+	NA	+	-	+	Poor
Williams 2004[26,27]	+	+	+	+	-	-	Poor
Chung 2003[28]	+	+	NA	+	-	-	Poor
Zondervan 2001[29]	+	+	+	+	-	+	Fair
Matthias 1996[32]	+	+	+	+	-	+	Fair
Ling 1999[13]	+	+	NA	+	-	-	Poor
Gestrinone Study Group 1996[15]	+	-	NA	+	-	+	Poor
Saravelos 1995[33]	-	+	NA	+	-	-	Poor
Peters 1991[19]	+	+	NA	+	-	-	Poor
Headache							
Stratton 2008[2,3]	+	+	NA	+	-	-	Poor
Peters 1991[19]	+	+	NA	+	-	-	Poor
Interstitial cystitis							
Droz 2011[23]	+	+	NA	+	-	+	Fair
Fenton 2011[34]	+	+	NA	+	-	+	Fair

Author, Year	Sampling method adequate	Sample size > 100	Response rate > 70%	Inclusion/exclusion criteria specified	Validated diagnostic criteria for comorbidity	Operational definition provided	Final Score
Paulson 2007[35]	+	+	NA	+	-	+	Fair
Fenton 2008[36]	+	+	NA	+	+	-	Good
Irritable bowel syndrome							
Droz 2011[23]	+	+	NA	+	+	NA	Good
Fenton 2011[34]	+	+	NA	+	-	+	Fair
Fenton 2008[36]	+	+	NA	+	+	NA	Good
Lamvu 2006[21]	+	+	NA	+	-	-	Poor
Tu 2006[37]	-	+	NA	+	+	NA	Fair
Grace 2005[24,25]	+	+	-	+	+	NA	Fair
Sator-Katzenschlager 2005[7]	+	-	NA	+	-	-	Poor
Williams 2004[26,27]	+	+	+	+	+	NA	Good
Zondervan 2001[29]	+	+	+	+	+	NA	Good
Bodden-Heidrich 1999[38]	-	+	NA	+	-	-	Poor
Migraine							
Stratton 2008[2,3]	+	+	NA	+	+	NA	Good
Sexual dysfunction							
Lamvu 2006[21]	+	+	NA	+	-	-	Poor
Verit 2006[39]	-	+	+	+	+	NA	Fair
Grace 2005[24,25]	+	+	-	+	-	-	Poor
Williams 2004[26,27]	+	+	+	+	-	-	Poor
Peters 1991[19]	+	+	NA	+	-	-	Poor
Vulvodynia							
Droz 2011[23]	+	+	NA	+	-	+	Fair
Fenton 2011[34]	+	+	NA	+	-	+	Fair
Fenton 2008[36]	+	+	NA	+	-	+	Poor
Lamvu 2006[21]	+	+	NA	+	-	-	Poor

Appendix E References

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Appendix F. Applicability Tables

Table F1. Applicability of evidence for LUNA

Population	The populations from studies examining the efficacy of LUNA represent highly selected populations within RCT protocols. Patients were generally recruited from tertiary care or academic centers, many with specialty pain clinics. Even between the three RCTs, the populations differed considerably based on different selection processes, with varying age restrictions, menopausal status, concomitant medical conditions (e.g., endometriosis) and thoroughness of preoperative analysis. Almost all randomized patients intraoperatively at the time of surgery, so these patients represent a specific group of women undergoing surgery for CPP. These findings may not be applicable to broader populations of women with CPP.
Intervention	LUNA is a common procedure for treatment of CPP, and its use may be applicable to many women with CPP
Comparators	The two comparators evaluated, diagnostic laparoscopy and uterosacral ligament resection, are both commonly performed procedures for diagnosis and treatment of CPP. Diagnostic laparoscopy is often a standard component of the evaluation process for CPP and its use is broadly applicable to the population at large.
Outcomes	The primary outcomes measured for all three studies were fairly consistent in the analysis of pain status recorded by VAS. However, interpretation and categorization of pain scores based on VAS was variable for studies. While VAS is a widely used measure of pain, the specific levels of measure may not be widely applicable to other populations of women with CPP.
Setting	All studies were performed at hospital settings that provide surgical expertise for laparoscopic procedures. Many of these were academic or referral centers specializing in CPP therapy. Generalization of these study findings to other settings may be limited.

Abbreviations: CPP = noncyclic chronic pelvic pain; LUNA = laparoscopic utero-sacral nerve ablation; RCT = randomized controlled trial; VAS = visual analog scale.

Table F2. Applicability of evidence for adhesiolysis

Population	The population recruited for the single study assessing the effectiveness of laparoscopic adhesiolysis was necessarily limited by the protocol for RCT, but was still fairly unrestricted in terms of age and associated medical conditions. The participants were limited to those thought to have adhesions from a previous abdominal surgery causing CPP, which was confirmed at the time of diagnostic laparoscopy. This specificity limits applicable to the broader population of women with CPP.
Intervention	The intervention studies, laparoscopic adhesiolysis, is a common procedure for the treatment of CPP and broadly applicable.
Comparators	The comparator procedure was diagnostic laparoscopy alone. This is a common procedure for the evaluation and treatment of women with CPP.
Outcomes	The primary outcome measured was change on VAS pain score, which is a common measure to quantify pain severity in women with CPP. Additionally, QOL was measured with the SF-36, which has been validated in and applied to many populations.
Setting	The surgical procedures were all performed at surgical facilities, but encompassed a range of settings, including teaching, non-teaching and university hospitals.

Abbreviations: CPP = noncyclic chronic pelvic pain; QOL = quality of life; RCT = randomized controlled trial; VAS = visual analog scale.

Table F3. Applicability of evidence for hysterectomy

Population	One study assessing the effect of hysterectomy on CPP recruited a broad population of women undergoing either hysterectomy or medical management for multiple reasons, including CPP. While the analysis focuses specifically on the subgroup of CPP patients, these patients likely represent a fairly non-selective cohort of women with CPP.
Intervention	Hysterectomy is a common procedure performed in women with or without CPP and would be applicable to a wide range of women with CPP.
Comparators	Medical therapy is a common approach to treating women with CPP and would be applicable to many women.
Outcomes	Measures used by the study to assess for change in pain status were not standard instruments, thus lacking validation. This may limit the applicability of the outcomes to other women with CPP undergoing hysterectomy or medical therapy.
Setting	The study was conducted in a wide variety of clinical settings, which would be applicable to many women with CPP.

Abbreviation: CPP = noncyclic chronic pelvic pain.

Table F4. Applicability of evidence for nonsurgical compared with surgical interventions

Population	In studies evaluating general surgical interventions comparing to non-surgical interventions for CPP, the populations are quite selected. One study examined a general cohort of women treated for CPP at a specialized referral clinic for CPP. The other enrolled women under an RCT protocol also after referral to specialized center. These populations are likely different from most women with CPP.
Intervention	Surgical intervention was broadly categorized in these studies, and included many different surgical techniques employed for the treatment of CPP.
Comparators	Non-surgical interventions included as comparators for the studies were varied. In one study, all patients treated with non-surgical approaches were grouped together, representing a heterogeneous group. In the other study, patients were administered a highly specific, intensive therapy which is not a mainstream approach to CPP treatment.
Outcomes	Outcomes for pain status were measured using the MPQ in both studies, which is a common tool for quantifying pain. However, interpretation and categorization of MPQ values were different for each trial and specific outcomes may not be broadly applicable.
Setting	The settings in which the studies were conducted ranged from community-based practices to university medical centers. This may allow for broad application of the findings.

Abbreviations: CPP = chronic pelvic pain; MPQ = McGill Pain Questionnaire; RCT = randomized controlled trial.

Table F5. Applicability of evidence for nonsurgical approaches

Population	Populations were largely from academic centers, and a majority of studies were conducted in Europe. Many studies included women with endometriosis-associated CPP.
Intervention	Many (8/15) studies focused on hormonal therapies; many require complex or multidisciplinary algorithms and close follow-up. Medication options across countries represented in the literature were inconsistent.
Comparators	Few studies were placebo-controlled; most assessed 2 or more active treatments.
Outcomes	Pain-related outcomes were typically assessed using a VAS. Few studies assessed quality of life or functionality.
Setting	The majority of studies were conducted in large academic centers with support systems, typically in Europe.

Abbreviations: CPP = noncyclic chronic pelvic pain; VAS = visual analog scale.

Appendix G. Ongoing and Recently Completed Intervention Studies

Table G1. Ongoing and recently completed CPP intervention studies

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
Role Of Paroxetine As Add-On Therapy To GnRH Agonist In The Treatment Of Endometriosis-Related Chronic Pelvic Pain, Italy, EudraCT Number: **2008-008722-73**	**Principal inclusion criteria:** • Age between 30 and 45 years old • Caucasian • Diagnosis of endometriosis associated chronic pelvic pain made by a ginecologist at the Endometriosis Center in S. Chiara Hospital. The endometriosis diagnosis confirmation includes specific bioptic report performed after surgical operation. • Disease phase on the basis of III-IV endometriosis classification proposed by American Fertility Society. The disease phase definition performed during previous surgical operation. • Entering treatment with GnRH agonist (leuproreline) to reduce pain symptoms • VAS score =>3 before treatment • HAM-A and HAM-D =>7 before treatment. All participants will sign a written informed consent; at any time they could decide to discontinue the treatment.Women on antidepressants, psychostimulants, sedative-hypnotics or narcotic	Experimental Group: Paroxetine: 1 mg Controlled Group: Leuprorelin: 3.75 mg	Azienda Ospedaliera Pisana	April 2009 —	40

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
	analgesic require to remain off of them for at least two weeks before entry into the study and for the duration of the study. **Principal exclusion criteria:** • Pregnancy • Feeding • Use of oral contraceptives • Alcohol or illicit drug use (according to DSM-IV criteria) HIV/HCV positivity • Experimental drugs and excipients hypersensitivity reactions • Withdraw of written consent during the study				
Female Chronic Pelvic Pain (Female CPP), Denmark, **NCT01255345**	**Inclusion Criteria:** • Women ≥ 18 years • Living in Copenhagen Country (Region H) • Capable of reading, writing and speaking Danish **Exclusion Criteria:** • Pain limited solely to the perineal skin or introitus (vulvodynia) • Pregnancy, cancer, active pelvic inflammatory disease • Operation in the pelvic during the last 6 months • Cognitively impaired individuals	A physioterapeutic examination of abnormal muscular findings, i.e. tonus, elasticity and strength, in the pelvic area connected to female CPP.	Copenhagen University Hospital at Herlev	January 2011 — December 2012	2500
Transcranial Direct Stimulation in Chronic Pelvic Pain, United States, **NCT01143636**	**Inclusion Criteria:** • Providing informed consent to participate in the study • 18 to 64 years old • Having symptoms of pelvic pain for more than 6 months	Transcranial Direct Current Stimulation	Spaulding Rehabilitation Hospital	April 2010 — April 2012	68

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
	with an average of 3 on a 0-10 VAS scale (for pelvic pain subjects only) • No history of or current genitourinary tuberculosis as self reported • No history of urethral cancer as self reported • No history or current bladder malignancy, high grade dysplasia or carcinoma in situ as self reported • No occurrence of ovarian, vaginal or cervical cancer in the previous 3 years as self reported • No current vaginal infection as self reported • No active herpes in previous 3 months as self reported • No antimicrobials for urinary tract infections in previous 3 months as self reported • Never treated with cyclophosphamide as self reported • No radiation cystitis as self reported • No neurogenic bladder dysfunction (due to a spinal cord injury, stroke, Parkinson's disease, multiple sclerosis, spina bifida or diabetic cystopathy) as self reported • Absence of bladder, ureteral or urethral calculi for previous 3 months as self reported • No urethritis for previous 3				

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
	months as self reported • No urethral dilatation, cystometrogram, bladder cystoscopy with full anesthesia or bladder biopsy in previous 3 months as self reported • Must not be pregnant • Eligible to MRI according to MRI screening checklist • No contraindications to Transcranial Direct Stimulation: • No history of alcohol or drug abuse within the past 6 months as self reported • No use of carbamazepine as self reported • Does not have severe depression (with a score of >30 in the Beck Depression Inventory) • No history of neurological disorders as self reported • No history of unexplained fainting spells as self reported, • No history of head injury resulting in more than a momentary loss of consciousness as self reported • Have had no neurosurgery as self reported • No history of psychological disorders as self reported • Must have the ability to feel pain as self reported				
Efficacy of Acupuncture on	**Inclusion Criteria:** • Patients diagnosed	Active: acupuncture treatment Placebo: Sham acupuncture	East West Neo Medical Center	December 2010 —	30

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
Chronic Pelvic Pain in Women With Endometriosis or Adenomyosis, Korea, Republic of, **NCT01259180**	pathologically of Endometriosis or Adenomyosis among those who had undergone laparoscopic surgery due to pelvic pain • Patients who have been on GnRH agonist treatment for 6 months after being diagnosed Endometriosis or Adenomyosis • Patients who agreed a written consent by their own will • Patients' compliance and geographical adjacency appropriate for proper follow up survey • Continuous pelvic pain over VAS 5 during past 1 week on screening visit(after 6 weeks of surgery) (0='no pain', '10=most severe') **Exclusion Criteria:** • Those who had taken hormones or drugs that can affect diagnosis of endometriosis or adenomyosis for past 1 year • Patients found to have malignant tumor of uterus and adenexa, PID or pregnancy during surgery • Allergies to metal or contraindications for acupuncture treatment (ex: coagulopathy, epilepsy) • Unable to participate in clinical trial by doctor's			September 2011	

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
	judgment • Irritable bowel syndrome				
EMG Guided Botulinum Toxin Type A Injections for Refractory High Tone Pelvic Floor Dysfunction (BTXA EMG), United States, **NCT01323829**	**Inclusion Criteria:** • Participant must be diagnosed with High Tone Pelvic Floor Dysfunction(HTPMFD). • Participant must have tried and failed at least one other conventional mode of therapy for HTPMFD. • Participant must be a female at least 18 years of age. • Participant must give written informed consent to participate in this study. • Participant must be able to make decisions for herself. • Participant must not be undergoing another procedure at the time of BTX A injection. **Exclusion Criteria:** • Participant is male. • Patient has a history of past BTX A use • Patient has had pelvic organ prolapse repair • Participant is pregnant or intends to get pregnant during the study period or is breastfeeding. • Participant is unwilling or unable (because of long distance from office) to follow-up. • Participant has a neuro-modulator device implanted.	Other: EMG Guidance of Injection The use of the EMG guidance is the experimental part of the study. We will perform EMG Needle testing in order to pin-point the best location for the patients Botox injections.	Pelvic and Sexual Health Institute; Allergan	November 2010 —	20

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
	• Participant has a known bleeding disorder or is on anticoagulation. • Participant has a known hypersensitivity to BTX A. • Participant has a pre-existing neuromuscular disorder such as amytrophic lateral sclerosis, motor neuropathy, myasthenia gravis or Lambert-Eaton syndrome. • Participant with skin infection at the perineum at the site of injection.				
Medical Treatment of Endometriosis-Associated Pelvic Pain, United States, **NCT00229996**	**Inclusion Criteria:** • Age greater than 18 and pre-menopausal. • Pelvic pain of at least 3 months duration. • Diagnosis of endometriosis by laparoscopy or laparotomy within three years of entry. The diagnosis of endometriosis will require either histology consistent with endometriosis or operative records indicating visual evidence of lesions consistent with endometriosis. • Moderate to severe pelvic pain preoperatively attributable to endometriosis (average Numerical Rating Scale of 5 or more for three or more months). • Willingness to comply with visit schedule and protocol.	Drug: Oral Contraceptive Drug: Depot-Leuprolide/Norethindrone Intervention Model: Parallel Assignment Masking: Double-Blind	Eunice Kennedy Shriver National Institute of Child Health and Human Development	July 2004 —	194

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
	Exclusion Criteria: • Use of oral contraceptives within one month of the surgery. • Dose of Lupron within three months if given monthly or within five months if given 3-month injection. • Any disorder that represents a contraindication to the use of oral contraceptives (e.g. insulin-dependent diabetes mellitus, history of thrombophlebitis, hypertension, history of cardiovascular disease, smoker at 35 or more years of age) or GnRH analogs (e.g., history of osteopenia). • History of hysterectomy and bilateral salpingoophorectomy. • Positive pregnancy test at first postoperative (i.e, intake visit). • Significant mental or chronic systemic illness that might confound pain assessment or the inability to complete the study.				

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
Addition of Pudendal Blocks to Pelvic Floor Physical Therapy for the Treatment of Pelvic Floor Tension Myalgia, United States, **NCT00928564**	**Inclusion Criteria:** • Non-pregnant women over the age of 18 with the diagnosis of pelvic floor tension myalgia that are naive to pelvic floor physical therapy. • Able to provide informed consent. • Subjects must be willing to accept randomization. **Exclusion Criteria:** • Previously treated with physical therapy. • An allergy to any component within the pudendal block. • Bleeding disorders. • Active vaginal infection. • Inability to complete the questionnaires. • Inability to read English (validated questionnaires are available in English only). • Inability to complete the follow-up visits.	Intervention Model: Crossover Assignment Masking: Double Blind (Subject, Outcomes Assessor) Active: Drug: Pudendal block: 8ml of 0.5% bupivicaine, 1ml of 10mg/ml triamcinolone, 1ml of 8.4% sodium bicarbonate for a total volume of 10ml. Five ml will be used at each block site. Placebo: 5ml of saline at each block site.	University of California, Irvine	April 2009 — June 2011	140

Study Name, Location, Trial#	Inclusion/Exclusion Criteria	Interventions	Sponsor	Start Date ~ Anticipated Completion Date	Estimated Enrollment
Cortical Plasticity in a Complex Intervention for Endometriosis, Germany, **NCT01321840**	**Inclusion Criteria:** • age > 18 years old • clinically or histologically ensured diagnosis of Endometriosis • preoperative and postoperative recurring ailments related to Endometriosis • no hormone therapy (GnRH analogues, contraceptives) • sufficient understanding of the German or English language • persisting pain during menstruation (also in between) • voluntary participation after information on the possible benefits and risks of the examination and intervention • written informed consent **Exclusion Criteria:** • alcohol addiction, drug addiction • pregnancy • diseases and other criteria, preventing an MRI examination: • pacemaker • neurostimulator or drug pump • metal parts in the body (implants, splinters, etc.) • claustrophobia	Intervention Model: Parallel Assignment Masking: Single Blind (Outcomes Assessor) Treatment: Experimental. Specific Autoregulation Therapy Complex intervention involving acupuncture and hypnotherapeutic techniques after an extensive diagnosis using Chinese medical concepts. Patients will receive a maximum of 10 treatments, which are delivered weekly. No treatment: No Intervention: This group will not be treated with Specific Autoregulation Therapy but will regularly be examined by a gynecologist to detect sudden aggravation of the disease.	University of Jena Technische Universität München	March 2010 — December 2011	60

Abbreviations: BTXA = Botulinum Toxin Type A; CPP = chronic pelvic pain; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Fourth edition; EMG = electromyogram; GnRH = gonadotropin releasing hormone; HAM-A = Hamilton anxiety Scale; HAM D = Hamilton depression Scale; HCV = hepatitis C; HTPMFD = High Tone Pelvic Floor Dysfunction; MRI = magnetic resonance imaging; PID = pelvic inflammatory disease; VAS = visual analog scale.