Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial

Jeremy Fairbank, Helen Frost, James Wilson-MacDonald, Ly-Mee Yu, Karen Barker, Rory Collins and for the Spine Stabilisation Trial Group

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Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial

Jeremy Fairbank, Helen Frost, James Wilson-MacDonald, Ly-Mee Yu, Karen Barker, Rory Collins for the Spine Stabilisation Trial Group

Abstract

Objectives To assess the clinical effectiveness of surgical stabilisation (spinal fusion) compared with intensive rehabilitation for patients with chronic low back pain.

Design Multicentre randomised controlled trial.

Setting 15 secondary care orthopaedic and rehabilitation centres across the United Kingdom.

Participants 349 participants aged 18–55 with chronic low back pain of at least one year's duration who were considered candidates for spinal fusion.

Intervention Lumbar spine fusion or an intensive rehabilitation programme based on principles of cognitive behaviour therapy.

Main outcome measure The primary outcomes were the Oswestry disability index and the shuttle walking test measured at baseline and two years after randomisation. The SF-36 instrument was used as a secondary outcome measure.

Results 176 participants were assigned to surgery and 173 to rehabilitation. 284 (81%) provided follow-up data at 24 months. The mean Oswestry disability index changed favourably from 46.5 (SD 14.6) to 34.0 (SD 21.1) in the surgery group and from 44.8 (SD 14.8) to 36.1 (SD 20.6) in the rehabilitation group. The estimated mean difference between the groups was −4.1 (95% confidence interval −8.1 to −0.1, P = 0.045) in favour of surgery. No significant differences between the treatment groups were observed in the shuttle walking test or any of the other outcome measures.

Conclusions Both groups reported reductions in disability during two years of follow-up, possibly unrelated to the interventions. The statistical difference between treatment groups in one of the two primary outcome measures was marginal and only just reached the predefined minimal clinical difference, and the potential risk and additional cost of surgery also need to be considered. No clear evidence emerged that primary spinal fusion surgery was any more beneficial than intensive rehabilitation.

Introduction

Chronic low back pain is a common cause of distress and results in considerable personal and public financial consequences. Management is mostly non-operative, but spinal fusion has been used for nearly 90 years. Spinal fusion rates vary between and within countries. In England about 1000 lumbar fusions are performed per year. An almost direct relation exists between the numbers of operations performed each year and of orthopaedic and neurosurgeons per head of population. In the United States, spinal fusions for “degenerative changes” rose sharply from around 11 000 operations per year in 1996 to 37 000/year in 2001 (a 336% increase). Both the rationale and the techniques used to fuse the spine have been questioned. Multi-disciplinary rehabilitation programmes that focus on physical, psychological, social, and occupational factors have been advocated for patients with chronic pain of the low back.

This trial was conceived in response to the identification of weak evidence for surgery as a priority by the NHS standing group on health technology in 1994. The pragmatic trial was designed to compare two treatment strategies (spinal stabilisation surgery or intensive rehabilitation) for patients considered by surgeons to be candidates for surgical stabilisation of the lumbar spine.

Methods

This multicentre, randomised trial was set in 15 hospitals in the United Kingdom. Only consultant surgeons with training and expertise in performing spinal fusions participated. We approached an additional 39 centres where either the surgeon was unwilling to recruit patients or implementation of the intensive rehabilitation programme was impossible.

Eligibility criteria

We used the uncertainty of outcome principle to define our entry criteria and therefore depended on the current practice of many experienced spine surgeons and their patients. Patients who were candidates for surgical stabilisation of the spine were eligible if the clinician and patient were uncertain which of the study treatment strategies was best. Patients had to be aged between 18 and 55, with more than a 12 month history of chronic low back pain (with or without referred pain) and irrespective of whether they had had previous root decompression or discectomy.

Patients were ineligible if the surgeon considered that any medical or other reasons made one of the trial interventions unsuitable. These included infection or other comorbidities (inflammatory disease, tumours, fractures), psychiatric disease, inability or unwillingness to complete the trial questionnaires, or...
Papers

pregnancy. If patients had had previous surgical stabilisation surgery of the spine they were also excluded.

**Objectives**
The aim was to determine whether surgical stabilisation of the spine (by fusion or flexible stabilisation) was more or less effective at achieving worthwhile relief of symptoms over a two year period than an intensive rehabilitation programme based on principles of cognitive behaviour therapy.

**Outcome measures**
We assessed outcomes at baseline and 6, 12, and 24 months from randomisation by a trial research therapist in each centre. If the patient was unable to attend the follow-up appointments we mailed the questionnaire. We approached non-responders by phone, through their family doctor, and via national databases.

Primary outcome
The two primary measures at 24 months included a back pain specific questionnaire and a standardised walking test. The Oswestry low back pain disability index is scored from 0% (no disability) to 100% (totally disabled or bedridden) and designed to assess limitations of various activities of daily living. The shuttle walking test is a standardised, progressive, maximal test of walking speed and endurance.

Secondary outcomes
The short form 36 general health questionnaire (SF-36) includes 35 items summarised in two measures related to physical and mental health. Each scale ranges from 0 (worst health state) to 100 (best health state). The summary measures are transformed to give a population mean of 50 (SD 10). The SF-36 is recommended as an outcome assessment for spinal disorders because it provides strong psychometric support and extensive normative data.

Psychological assessment—We used the distress and risk assessment method (DRAM), which includes the modified Zung depression index and somatic perception questionnaire, to assess anxiety and depression.

Complications—We recorded the intraoperative use of anaesthetic agents, implants, and radiological investigations; complications of surgery and any adverse effects of rehabilitation; postoperative complications, implant failure and repeat surgery; and personal items and devices purchased by the patient because of lower back pain. Work status was monitored. We recorded “obvious pseudoarthrosis” only where it was clear to the treating surgeon that fusion had failed and that this was a problem to the patient.

Sample size
We used the Oswestry disability index to determine the sample size. The trial was designed to be able to detect a difference in mean score between the intervention groups of as little as 4 points. We estimated that 133 subjects would be required in each group to detect such a difference at the α = 0.05 level with 80% power. We initially planned to recruit at least this number of patients in each of three separate clinical groups to allow reliable subgroup analysis, but most of the patients were recruited in one clinical category.

Interventions
Spinal stabilisation surgery—The particular technique used for spinal fusion was left to the discretion of the operating surgeon. This allowed choice of the most appropriate surgical approach, implant (if any), interbody cages, and bone graft material for that patient. A small number of surgeons used flexible stabilisation of the spine (the Graf or Global technique). This was recorded for each patient before randomisation.

Intensive rehabilitation programme—Each centre was modelled on a daily outpatient programme of education and exercise running on five days per week for three weeks continuously. Further details of the programme are reported elsewhere. Most centres offered 75 hours of intervention (range 60-110 hours), with one day of follow-up sessions at one, three, six, or 12 months after treatment. The rehabilitation programmes were led by physiotherapists but included clinical psychologists in all but one centre, as well as medical support. The daily exercises were individually tailored and paced to increase repetitions and duration, aiming to build on the participants’ baseline ability. They included stretching of major muscle groups, spinal flexibility exercises, general muscle strengthening, spine stabilisation exercises, and cardiovascular endurance exercise using any mode of aerobic exercise (treadmill walking, step-ups, cycling, rowing). All but one centre included daily sessions of hydrotherapy. We used principles of cognitive behaviour therapy to identify and overcome fears and unhelpful beliefs that many patients develop when in pain.

Treatment allocation and recruitment
Surgeons approached patients who were candidates for spinal fusion. Each centre employed a trial research therapist to organise the trial locally, recruit patients, book treatment appointments, and carry out assessments. Patients were given verbal, written, and videotape (OMI, Oxford) explanations of the background and nature of the trial. The trial research therapists obtained written consent and carried out baseline assessments before randomisation.

Randomisation was generated centrally by computer program, with minimisation for various potential confounding factors: age, smoking, litigation, Oswestry score, clinical classification, and planned use of the Graf procedure.

Statistical methods
We carried out an intention to treat analysis. We used analysis of covariance (ANCOVA) to analyse quantitative outcomes at 24 months, with corresponding baseline values and treatment group as covariates.

We used multiple imputation to handle missing data. To impute the missing data we constructed multiple regression models including variables potentially related to the fact that the data were missing and also variables correlated with that outcome. We used Stata (StataCorp, College Station, Texas, USA) and PROC MI in SAS (SAS Institute, Cary, NC, USA) to obtain similar answers, and only the former are presented.

Results
A total of 349 patients were randomised between June 1996 and February 2002 from 15 centres in the UK (176 allocated to surgery and 173 to rehabilitation). The figure shows the progression through the trial. Table 1 shows the baseline characteristics of patients who entered the trial.

Compliance with treatment and follow-up
Table 2 shows data on participants’ compliance with their treatment and follow-up. Forty eight (28%) patients randomised to rehabilitation had surgery by two years. Seven (4%) patients randomised to surgery had rehabilitation instead of surgery.

Complications
Intraoperative complications occurred in 19 surgical cases (table 3). Eleven patients required further operations on their lumbar...
spine during the two year follow-up. We did not identify any specif-
cific complications of the rehabilitation programmes.

Clinical outcomes

Oswestry scores improved slightly more in favour of surgery
(−4.1, 95% confidence interval −8.1 to −0.1, P = 0.045). After
imputation for missing follow-up data the mean difference was
−4.5 (−8.2 to −0.8, P = 0.02) (tables 4 and 5). No significant
heterogeneity in the effect on the Oswestry score was observed
between the predefined groups of patient (table 6). No other dif-
fERENCE between the groups was observed. The Oswestry
scores improved significantly more in patients allocated to
surgery than in those allocated to rehabilitation. Although this
difference just exceeds the 4 points specified in the sample size
calculation, clinically this difference is small considering the
potential risks and additional costs of surgery. Analyses adjusting
for baseline variations or per protocol analysis do not change
this interpretation (data not shown). Overall, since the other pri-
mary outcome of the shuttle walking test and the other measures
did not differ (even after imputation for missing values), the small
difference observed in Oswestry scores should be interpreted
cautiously. Furthermore, the confidence intervals can be used to
rule out differences in Oswestry scores of more than 10 points in
favour of surgery and of more than 2 points in favour of
rehabilitation. Consequently, they narrow substantially the range
of plausible estimates for any benefit of surgery.

Discussion

Patients with low back pain who are considered by surgeons to
be candidates for spinal fusion may obtain similar benefits from
an intensive rehabilitation programme as they do from surgery.
Our large randomised controlled trial of spinal fusion surgery
compared with intensive rehabilitation was limited by recruit-
ment difficulties, some crossover between intervention groups,
and incomplete follow-up at 24 months, but the results should
help clinicians and service providers make decisions about the
management of chronic low back pain. Both groups improved
over time, but this effect may reflect a natural resolution of
chronic low back pain or regression to the mean. The Oswestry
scores improved significantly more in patients allocated to
surgery than in those allocated to rehabilitation. Although this
difference just exceeds the 4 points specified in the sample size
calculation, clinically this difference is small considering the
potential risks and additional costs of surgery. Analyses adjusting
for baseline variations or per protocol analysis do not change
this interpretation (data not shown). Overall, since the other pri-
mary outcome of the shuttle walking test and the other measures
did not differ (even after imputation for missing values), the small
difference observed in Oswestry scores should be interpreted
cautiously. Furthermore, the confidence intervals can be used to
rule out differences in Oswestry scores of more than 10 points in
favour of surgery and of more than 2 points in favour of
rehabilitation. Consequently, they narrow substantially the range
of plausible estimates for any benefit of surgery.

### Table 1: Baseline characteristics of patients and clinical details at trial entry.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Surgery (n=176)</th>
<th>Rehabilitation (n=173)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30 years</td>
<td>24 (13.6)</td>
<td>20 (11.6)</td>
</tr>
<tr>
<td>30-39 years</td>
<td>63 (35.6)</td>
<td>67 (38.7)</td>
</tr>
<tr>
<td>≥40 years</td>
<td>56 (31.8)</td>
<td>66 (38.1)</td>
</tr>
<tr>
<td><strong>Centre</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>55 (31.3)</td>
<td>54 (31.2)</td>
</tr>
<tr>
<td>B</td>
<td>28 (15.9)</td>
<td>27 (15.6)</td>
</tr>
<tr>
<td>C</td>
<td>45 (25.6)</td>
<td>43 (24.8)</td>
</tr>
<tr>
<td>D</td>
<td>48 (27.3)</td>
<td>49 (28.3)</td>
</tr>
<tr>
<td><strong>Mean duration of back pain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>years (range) in years</td>
<td>8 (1-35)</td>
<td>8 (1-35)</td>
</tr>
<tr>
<td><strong>Current smokers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>76 (43.2)</td>
<td>74 (42.8)</td>
</tr>
<tr>
<td><strong>Ligation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 (14.2)</td>
<td>21 (12.1)</td>
</tr>
<tr>
<td><strong>Currently in paid employment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>88 (50.4)</td>
<td>94 (54.3)</td>
</tr>
<tr>
<td><strong>Back pain interfered patient’s ability to work</strong></td>
<td>149 (84.7)</td>
<td>149 (86.1)</td>
</tr>
<tr>
<td><strong>Had to give up job</strong></td>
<td>65 (38.6)</td>
<td>67 (45.0)</td>
</tr>
<tr>
<td><strong>Had to change job</strong></td>
<td>19 (12.7)</td>
<td>10 (6.7)</td>
</tr>
<tr>
<td><strong>Had to reduce hours</strong></td>
<td>17 (11.4)</td>
<td>12 (8.0)</td>
</tr>
<tr>
<td><strong>Had to take sick leave</strong></td>
<td>93 (53.6)</td>
<td>68 (46.3)</td>
</tr>
<tr>
<td><strong>Clinical details</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Surgical indication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>20 (11.4)</td>
<td>18 (10.6)</td>
</tr>
<tr>
<td>Post-laminectomy</td>
<td>14 (8.0)</td>
<td>14 (8.1)</td>
</tr>
<tr>
<td>Chronic low back pain</td>
<td>142 (80.6)</td>
<td>141 (81.5)</td>
</tr>
<tr>
<td>Planned surgery type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nancy</td>
<td>149 (84.7)</td>
<td>144 (83.2)</td>
</tr>
<tr>
<td>Fusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td><strong>Planned fused level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single level</td>
<td>100 (56.8)</td>
<td>109 (63.0)</td>
</tr>
<tr>
<td>&gt;1 level</td>
<td>70 (39.6)</td>
<td>62 (35.8)</td>
</tr>
<tr>
<td>Missing</td>
<td>6 (3.4)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td><strong>Mean score (0-50)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oswestry disability index</td>
<td>46.5 (14.6)</td>
<td>44.8 (14.8)</td>
</tr>
<tr>
<td>Shuttle walking test in metres</td>
<td>254 (209)</td>
<td>247 (186)</td>
</tr>
<tr>
<td>SF-36 physical component score</td>
<td>19.4 (8.8)</td>
<td>20.9 (7.1)</td>
</tr>
<tr>
<td>SF-36 mental component score</td>
<td>43.2 (10.9)</td>
<td>44.2 (12.6)</td>
</tr>
<tr>
<td>Modified somatic perception questionnaire</td>
<td>9.0 (6.4)</td>
<td>7.7 (5.7)</td>
</tr>
<tr>
<td>Zung self rating depression scale</td>
<td>31.8 (10.4)</td>
<td>31.2 (11.8)</td>
</tr>
</tbody>
</table>

**Distress and risk assessment method**

| Normal                          | 14 (8.0)        | 14 (8.1)             |
| At risk                         | 65 (36.9)       | 85 (49.1)            |
| Distressed depressive           | 87 (49.4)       | 69 (39.9)            |
| Distressed somatic              | 9 (5.1)         | 2 (1.2)              |
| Missing                         | 1 (0.6)         | 3 (1.7)              |

*Refers to the three largest recruiting centres and a pool of the remaining centres.
The patients randomised to an exercise programme. With 77 patients randomised to different forms of surgery and 34 randomised controlled trials have been reported subsequently. *Rehabilitation only.

Complication due to surgery (each subject could have more than one complication)

<table>
<thead>
<tr>
<th>Complication</th>
<th>No of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>At treatment site:</td>
<td></td>
</tr>
<tr>
<td>Dural tear</td>
<td>5</td>
</tr>
<tr>
<td>Excessive bleeding</td>
<td>3</td>
</tr>
<tr>
<td>Implant problems</td>
<td>5</td>
</tr>
<tr>
<td>Bone fracture</td>
<td>1</td>
</tr>
<tr>
<td>Vascular injury</td>
<td>1</td>
</tr>
<tr>
<td>Loss of purchase or fixation</td>
<td>3</td>
</tr>
<tr>
<td>Associated with surgical approach:</td>
<td></td>
</tr>
<tr>
<td>Vascular injury</td>
<td>1</td>
</tr>
<tr>
<td>Other (loss of swab, peritoneal tear)</td>
<td>3</td>
</tr>
<tr>
<td>Systemic</td>
<td></td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>1</td>
</tr>
<tr>
<td>Further surgery (up to 2 years follow-up)</td>
<td>11</td>
</tr>
</tbody>
</table>

A total of 19 patients had complications as a result of surgery.

Strengths and limitations of the study

The uncertainty principle had initially been expected to aid trial accrual by bringing the process of informed consent closer to standard medical practice. However, recruitment was slow and numbers enrolled smaller than planned. Eligibility was based on the uncertainty of outcome principle, but uncertainty does not come easily to surgeons when patients are demanding clear direction and advice. Factors influencing recruitment will be presented elsewhere. This pragmatic trial reflects current practice across the UK of experienced spine surgeons selecting patients for fusion. Surgeons may argue that we excluded the best candidates for surgery through "certainty" of outcome, but this certainty varied between surgeons. Evidence from the Swedish trial shows that patients with low neuroticism, narrow discs, and low back compared with usual care or non-multidisciplinary treatment. This type of treatment was difficult to implement in the trial and, although recommended in recent European guidelines, is not routinely available in the NHS.

Surgical issues

Surgeons were allowed their own choice of operation to improve the chance of clinical success. The Swedish trial showed no difference between three surgical techniques of fusion. These results call into question what lumbar fusion is actually doing to patients with chronic back pain. Elucidation of this question was not the objective of this study. The results are highly relevant to spinal fusion surgery, as well as the new techniques of flexible stabilisation and disc replacement that are being applied to this group of patients.

Loss to follow-up

Loss to follow-up at 24 months (20%) limits the internal validity of the trial. We used multiple imputation as a sensitivity analysis to tackle potential bias resulting from the poor response rate. Overall estimates of the treatment effect were very similar with all methods of statistical analysis.

Blinding

The pre-randomisation outcomes were scored by the trial research therapists and later checked by computer. All subsequent outcomes were scored centrally. We were not able to...
blind the trial research therapists to patient allocation after the baseline assessment.

**Limitation of outcomes**

The available outcome measures are blunt instruments for assessing a complex condition. The minimum clinically important change in the Oswestry scores has been estimated by different observers as being somewhere between 4 and 17. Debate continues among back pain experts over what represents a clinically important change. Functional measures are difficult to apply in a multicentre setting, and although the use of muscle measurement techniques may be useful, it was not possible to use them in this trial because of financial limitations. Walking capacity was chosen as it is simple and cheap to measure and often a limitation for people with chronic low back pain.

**Compliance with treatment protocol**

The 48 (28%) patients who were randomised to rehabilitation and then had additional surgery by two years should be considered as an additional outcome of the trial and taken into account in the interpretation of the results. Although some patients and surgeons were clearly not satisfied with the results of rehabilitation, many more seem to have benefited and avoided surgical intervention.

**Conclusion**

Nearly three quarters of those patients allocated to rehabilitation avoided surgery by two years. Rehabilitation including a cognitive behaviour approach is not routinely or widely available to patients with chronic pain of the low back, and this trial implies that it should be. Rehabilitation programmes require

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Mean(SD) outcome values at 24 months, and differences in changes from baseline to 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Surgery (n=176)</td>
</tr>
<tr>
<td>Oswestry disability index</td>
<td>34.0 (21.1)</td>
</tr>
<tr>
<td>Shuttle walking test</td>
<td>352 (244)</td>
</tr>
<tr>
<td>SF-36 physical component score</td>
<td>28.8 (14.9)</td>
</tr>
<tr>
<td>SF-36 mental component score</td>
<td>47.4 (12.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Summary of results from available cases and from multiple imputation analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>Available cases</td>
</tr>
<tr>
<td></td>
<td>Estimated difference (95% CI)</td>
</tr>
<tr>
<td>Oswestry disability index</td>
<td>-4.1 (-8.1 to -0.1)</td>
</tr>
<tr>
<td>Shuttle walking test</td>
<td>34 (-8 to 77)</td>
</tr>
<tr>
<td>SF-36 (physical component score)</td>
<td>2.0 (-1.2 to 5.3)</td>
</tr>
<tr>
<td>SF-36 (mental component score)</td>
<td>-0.2 (-2.9 to 2.6)</td>
</tr>
</tbody>
</table>

*Adjusted for baseline measures. Rehabilitation group is the reference group. P value: Analysis of covariance adjusted for baseline measure.
finance, space, and training, but above all they need the strong support of all clinicians involved in the care of these patients.

We thank the patients, who permitted a difficult decision to be made for them; referees, physiotherapists, and surgeons, inside and outside the trial (www.ndos.ox.ac.uk/SST), who helped develop the protocol; the Medical Research Council for supporting the study; NHS R&D (especially Richard Lilford) for supporting and promoting the study. We thank the patients, who permitted a difficult decision to be made for them. We thank the patients, who permitted a difficult decision to be made for them. Research Council for supporting the study; NHS R&D (especially Richard Lilford) for supporting and promoting the study. We thank the patients, who permitted a difficult decision to be made for them.

Competing interests: JF and JWM have received funding from Synthes for a trial injury. A prospective study with comparison group and one year follow up. Spine 1995;20:788-838.


Contributors: JF was responsible for the overall study design, the organisation of the study and economic analysis. Nicolas Mantaras was responsible for economic data collection and analysis. Kate Johnston, Helen Campbell, and Oliver Rivero were responsible for economic analysis. Patricia Carver was responsible for data collection and analysis. I. Morgan was responsible for data collection and database design. Kate Stevens, Victoria Erlander, Rebecca Bale collected and entered data. Peter Smith developed and maintained the database.

Funding: The Medical Research Council supported the trial financially and provided the database.


menopausal soon after hysterectomy. We were therefore unable to carry out separate analyses using menopausal status.

Previous studies have looked at risk of specific cancers after hysterectomy, rather than all cancer mortality. The reduced risk of ovarian cancer after hysterectomy found in one study may have been due to a screening effect, as surgery provides an opportunity to detect abnormal ovaries. Such effects would persist for as long as it takes visible premalignant abnormalities to reduce women's risk of death later in life. Instead, patients should be reassured that hysterectomy will not put their lives at risk later on.

We thank Val Angus for extracting the data, the doctors who have contributed to the oral contraception study, and the Chief Scientist Office, Scottish Executive, who funded LI as part of a research training fellowship to complete the masters degree of which this study was a component.

Contributors: See bmj.com

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Competing interests: None declared.

Ethical approval: The study was part of a masters degree submission and received approval from the ethics committee of the London School of Hygiene and Tropical Medicine.


Corrections and clarifications

Recent developments in inhaled therapy in stable chronic obstructive pulmonary disease

In the second paragraph of the section “Long acting inhaled bronchodilators” in this Clinical Review by C B Cooper and D P Tashkin (BMJ 2005;330:1233-9, 28 May), the final sentence should have said that tiotropium increases (not reduces) the time to first exacerbation compared with placebo (Figure 2 in the article confirms this statement.)

Management of pregnancies with RMD alloimmunisation

We mixed up images and captions in this Clinical Review by Sailesh Kumar and Fiona Regan (BMJ 2005;330:1255-8, 28 May). The caption published with figure 1 should have appeared with figure 2, and the caption for figure 1 should have read: “Ultrasound image showing features of hydrops (skin oedema, hepatomegaly, and ascites).” In the text, these two figures should have been referenced in the Pathophysiology section (the third sentence from the end (fig 1)) and in the seventh sentence of the second paragraph of the Monitoring section (fig 2).

Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial

An oversight in the editorial process of this paper by J Fairbank and colleagues led to the omission of the international trial number (BMJ 2005;330:1233-9, 28 May). The number is ISRCTN88854663.