U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

News & Events

FDA NEWS RELEASE

For Immediate Release: July 13, 2011
Media Inquiries: Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA: Surgical placement of mesh to repair pelvic organ prolapse poses risks
Agency says other options may expose women to less risk than transvaginal procedure

The U.S. Food and Drug Administration today issued an updated safety communication warning health care providers and patients that surgical placement of mesh through the vagina to repair pelvic organ prolapse may expose patients to greater risk than other surgical options.

The safety communication also says that with the exposure to greater risk comes no evidence of greater clinical benefit such as improved quality of life.

Pelvic Organ Prolapse (POP) occurs when the internal structures that support the pelvic organs such as the bladder, uterus and bowel, become so weak or stretched that the organs drop from their normal position and bulge or prolapse into the vagina. While not a life-threatening condition, women with POP often experience pelvic discomfort, disruption of their sexual, urinary, and defecatory functions, and an overall reduction in their quality of life.

Surgery to repair POP can be performed through the abdomen or transvaginally, through the vagina, using stitches, or with th addition of surgical mesh to reinforce the repair and correct the anatomy.

"There are clear risks associated with the transvaginal placement of mesh to treat POP," said William Maisel, M.D., M.P.H., deputy director and chief scientist of the FDA's Center for Devices and Radiological Health. "The FDA is asking surgeons to carefully consider all other treatment options and to make sure that their patients are fully informed of potential complications from surgical mesh. Mesh is a permanent implant -- complete removal may not be possible and may not result in complete resolution of complications."

In 2010, there were at least 100,000 POP repairs that used surgical mesh. About 75,000 of these were transvaginal procedures.

The FDA issued a safety communication in 2008 due to increasing concerns about adverse events associated with the transvaginal placement of mesh. Since then, the number of adverse events has continued to climb. From 2008 to 2010, the FDA received 1503 adverse event reports associated with mesh used for POP repair, five times as many as the agency received from 2005 to 2007. The reports don't always differentiate between transvaginal and abdominal procedures.

The most frequently reported complications from surgical mesh used to repair POP include mesh becoming exposed or protruding out of the vaginal tissue (erosion), pain, infection, bleeding, pain during sexual intercourse, organ perforation from surgical tools used in the mesh placement procedure, and urinary problems. Some reports cited the need for additional surgeries or hospitalization to treat complications or to remove the mesh.

The FDA also conducted a review of scientific literature published between 1996 and 2010 comparing mesh surgeries to non-mesh surgeries. The agency review suggests that many patients who undergo transvaginal POP repair with mesh are exposed to additional risks, compared to patients who undergo POP repair with stitches alone. While mesh often corrected anatomy, there was no evidence that mesh provided any greater clinical benefit than non-mesh surgeries.

FDA recommends that health care providers:

- Recognize that in most cases, POP can be treated successfully without mesh;
- Know that surgical mesh is a permanent implant that can make any future surgical repairs more challenging and can put the patient at risk for additional complications and surgeries;
- Consider that mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh; and
- Be sure that patients are aware of the risks and benefits of transvaginal POP repair with mesh, and inform patients if mesh is being used.

The FDA recommends that patients:

- Ask the surgeon before surgery about all POP treatment options, including those that do not involve mesh, and understand why the surgeon may be recommending treatment of POP with mesh;

• Continue with routine check-ups and follow-up care after surgery. Notify the surgeon if complications develop (persistent vaginal bleeding or discharge, pelvic or groin pain during sex); and
• Those who have had POP surgery but don't know if the surgeon used mesh should find out if mesh was used during their next scheduled visit with their health care provider.

The FDA also announced that an outside panel of experts in obstetrics and gynecology will meet on Sept. 8-9, 2011, to discuss the safety and effectiveness of surgical mesh used to treat POP and stress urinary incontinence (SUI), a leakage of urine during physical activity. The panel will discuss the risk of transvaginal POP repair, clinical studies that may be necessar to address risks and benefits of this type of surgery, and the FDA's interim recommendations for health care professionals an patients.

"Input from the clinicians, manufacturers and other experts will help the FDA better understand the safety and effectiveness of surgical mesh for POP and SUI repair, including any changes that would improve our oversight," Maisel said.

Today's safety communication is limited to the transvaginal placement of mesh to repair POP. It does not address the safety and effectiveness of mesh used to treat SUI or mesh implanted abdominally.

For more information:

FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse
[1]

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

#

Visit the FDA on Facebook[2]

RSS Feed for FDA News Releases[3] [what is RSS?[4]]

Links on this page:

1. /MedicalDevices/Safety/AlertsandNotices/ucm262435.htm
2. http://www.facebook.com/FDA
3. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml
4. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm