FDA: Surgical Placement of Mesh to Repair Pelvic Organ Prolapse Poses Risks

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SILVER SPRING, Md., July 13, 2011 /PRNewswire-USNewswire/ -- 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.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO [1])

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 the 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
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SOURCE [2]

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