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Complications of surgical mesh for pelvic organ prolapse and stress incontinence

FDA notifications worth heeding

Numerous reports from surgical mesh manufacturers describe adverse events associated with their devices.

On 20 October 2008, the United States Food and Drug Administration released two public health notifications about serious complications associated with transvaginal placement of surgical mesh in the repair of pelvic organ prolapse and stress urinary incontinence. One notification was directed to health care professionals, the other to consumers. In the release to health care professionals, the FDA noted that over the previous 3 years they had received more than 1000 reports from nine surgical mesh manufacturers of complications associated with these devices used to repair pelvic organ prolapse and urinary stress incontinence. Various complications were discussed, including erosion, infection, and pain; bowel, bladder, or blood vessel perforation; and failure of the procedure. Also discussed was vaginal scarring, which leads to decrease in quality of life due to pelvic discomfort, chronic pain, and dyspareunia.

Based on these results, the FDA recommended that physicians should attain specialized training for the various mesh procedures, should watch for complications, and, most important, should inform patients of the possible complications and explain that the implantation of surgical mesh is permanent and some of the complications may require additional surgery, which may or may not resolve the problem.

The release to consumers was similar, and included a recommendation to interview the surgeon in advance and find out about the pros and cons of using surgical mesh, and the experience of the surgeon with the surgery. Consumers were also encouraged to ask about possible complications and the likelihood of being able to remove the mesh if there are complications, and if the surgical repair could be successfully performed without using mesh.

In November 2007, my colleagues and I published an article in the *BC Medical Journal* about the various complications noted by the FDA that we had observed.[1] We also made a number of recommendations, including the proper training of surgeons performing the procedure, the use of cystoscopy during the procedure to be certain there is no perforation, and the avoidance of surgery in certain patients, including those with urethral syndrome, interstitial cystitis, chronic pain, or obstructive uropathy. We also recommended that patients be advised of the success rates and complications of the various surgical procedures available to treat incontinence and prolapse.

We expressed our belief that the success rates are quite similar for the various procedures now available to surgeons to treat prolapse and incontinence. However, we were concerned about the serious complications noted with the use of mesh and the difficulty of treating them. The release of two notifications by the FDA confirms our opinion.

Physicians in British Columbia should be aware of the FDA recommendations, including the need to fully inform patients of the nature of these procedures and the potential complications. Patients should be advised that there are alternate non-mesh procedures available with similar success rates.

The absolute numbers of incontinence and prolapse procedures performed is not monitored, and therefore we cannot calculate the rate of complications. There have been a

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number of reports over the last 10 years that describe these complications, but they are described as uncommon.[2-7] As a surgeon who is seeing increasing numbers of the complications, my personal experience and the experience recounted by fellow health care professionals suggest to me that these complications are more common than have been reported. In addition, these complications, especially pelvic pain and discomfort, can be very difficult to treat successfully.

The FDA notifications can be reviewed online at www.fda.gov/cdrh/safety/102008-surgicalmesh.html.

Competing interests

None declared.

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Putting the FDA notifications in perspective

A frank discussion with a patient about the anticipated outcomes and the potential complications of a reinforced repair is essential.

We fully support notifying physicians who are unaware of the releases described in Dr Fenster's article and welcome the opportunity to open a dialogue that will put these notifications in perspective. The U.S. Food and Drug Administration is a conservative organization that does not publish such notifications lightly or without considerable supporting evidence. In this case, the warnings about surgical mesh use for pelvic organ prolapse and stress incontinence highlight a longstanding controversy among female reconstructive pelvic surgeons.

The use of surgical mesh is not new to reconstructive pelvic surgery. The sacral colpopexy is well established as the gold standard for the repair of vaginal vault prolapse, yet this procedure, which is more than 50 years old, is generally done with surgical mesh.[1] However, the FDA release does not address the sacral colpopexy, but is directed at procedures that place surgical mesh vaginally. The surgeons who developed these transvaginal mesh procedures for prolapse were no doubt unhappy with the poor long-term success rates for traditional repairs of pelvic organ prolapse. They were inspired by the success of the sacral colpopexy as well as by level I evidence supporting the value of mesh in hernia surgery. This group of reconstructive pelvic surgeons worked to develop minimally invasive approaches using mesh to reinforce vaginal repairs of pelvic organ prolapse. Such surgical innovation is not new, but

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these procedures are unique in that much of the development was funded by the surgical device industry. Regrettably, while considerable resources were marshaled to develop these devices, minimal corporate funds were dedicated to proving clinical efficacy. In fact, these devices have been heavily marketed with minimal evidence for safety or efficacy, which is a primary concern of many of the opponents of these procedures. One exception to this trend is the midurethral sling. The initial retropubic midurethral sling, the tension-free vaginal tape (TVT) device, was developed by Ulmsten as a treatment for stress urinary incontinence.[2] By the time Johnson & Johnson began marketing the device nearly 10 years ago, there was already considerable prospective evidence of its efficacy and safety. Subsequent randomized clinical trials comparing it to the gold standard, the retropubic urethropexy, demonstrated equivalent efficacy.[3,4] Complications with the TVT, while different from those following retropubic urethropexy, were not more common, and TVT had clear advantages over retropubic urethropexy in terms of patient recovery.[5] In fact, a Cochrane review concluded that TVT placement was followed by lower risk of reoperation compared with Burch retropubic urethropexy.[6] The success of TVT use rapidly led to new approaches to the midurethral sling, with level I data supporting equivalent efficacy with comparable complications rates for the transobturator midurethral slings.[7,8] While surgical complications are attributable to the use of mesh, the low incidence of these complications is outweighed by the long-term success rates of 90% for curing stress urinary incontinence. The risk-benefit ratio of surgery in general is an important consideration. All surgeries have a risk-benefit ratio that is influenced by both the potential for beneficial outcomes and the risk of complications. This ratio is different for all surgical procedures and, as highlighted in the FDA notifications, explaining this is an essential component of the informed consent process. As part of the conversation with the patient that the process requires, the surgeon must explain that the risk-benefit ratio for any given procedure is not necessarily the same for all patients. For example, a vigorous, sexually active 40-year-old with stage III prolapse and no risks for recurrence might find the possible increased efficacy of a transvaginal prolapse repair reinforced with mesh does not outweigh the risk of mesh erosion, pelvic pain, or dysparunia. In contrast, a sedentary, abstinent 80-year-old with two previous failed repairs that did not use mesh might find the prospect of a more durable repair does outweigh the potential risk. What makes these discussions difficult is the paucity of data comparing nonreinforced with reinforced repairs, a concern considered in an article about ethical issues and new surgical devices in the *Journal of Obstetrics and Gynaecologists Canada.*[9]

A Cochrane review concluded that TVT placement was followed by lower risk of reoperation compared with Burch retropubic urethropexy.

We agree with the recommendations proposed in the FDA notifications. Clearly, physicians intending to perform these procedures should seek training that not only includes the surgical technique but also an understanding of potential complications and how to manage them. Moreover, as with any surgical procedure, a frank discussion with a patient about the anticipated outcomes and the potential complications for that patient in particular is an essential component of the informed consent process for reinforced repairs. This discussion is simplified in patients considering a midurethral sling for stress urinary incontinence, as there is ample evidence that the procedure has a favorable outcome in the majority of patients. When it comes to transvaginal reinforced repairs for

prolapse, there is less evidence. We believe that manufacturers marketing these surgical devices have a responsibility to fund research that not only clarifies the efficacy of their products but also establishes their complication rates and safety. These data will identify subpopulations for whom the transvaginal reinforced mesh repairs have favorable risk-benefit ratios.

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Competing interests

In 2005 Dr Cundiff received fees for organizing continuing education for BARD Urologic, a company that makes surgical mesh kits.

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