UROGYNECOLOGY

Use of vaginal mesh in the face of recent FDA warnings and litigation

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Choosing to use mesh in vaginal reconstructive surgery for pelvic organ prolapse or stress urinary incontinence is perplexing in the face of recent US Food and Drug Administration (FDA) warnings. In October 2008, the FDA alerted practitioners to complications associated with transvaginal placement of surgical mesh. Litigation is another concern. A Google search of "transvaginal mesh" results in numerous hits for plaintiff attorneys seeking patients with complications related to use of mesh. In light of a recent decision by the US Supreme Court and strategies by manufactures of medical devices to escape liability, it is imperative that gynecologic surgeons using transvaginal mesh document proper informed consent in the medical records. The purpose of this commentary is not to deter gynecologic surgeons from using transvaginal mesh when appropriate, but to provide an overview of current medical-legal controversies and stress the importance of documenting informed consent.

Key words: informed consent, lawsuit, mesh, pelvic organ prolapse, stress urinary incontinence

Cite this article as: Mucowski SJ, Jurnalov C, Phelps JY, et al. Use of vaginal mesh in the face of recent FDA warnings and litigation. Am J Obstet Gynecol 2010;203:103.e1-4.

The advent of midurethral mesh slings has revolutionized treatment for stress urinary incontinence (SUI), and transvaginal mesh procedures seek to do the same for pelvic organ prolapse (POP). With an increasing number of women undergoing surgery for SUI and POP annually, the number of complications reported to the US Food and Drug Administration (FDA) can be expected to increase as well.[1] The FDA has recently issued a public health notification regarding these complications associated with surgical correction of POP and SUI with transvaginal mesh. This warning stated that "the most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence" and later suggested that physicians "report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting."[2] Many gynecologists may be hesitant to continue offering vaginal mesh procedures secondary to recent FDA warnings and the many advertisements from plaintiff attorneys seeking patients who have experienced complications from their mesh placements.

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Received July 14, 2009; revised Oct. 8, 2009; accepted Jan. 20, 2010.

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0002-9378/$36.00

doi: 10.1016/j.ajog.2010.01.060

Complications of transvaginal mesh and overview of available data

Since 2005, the FDA has received >1000 reports from 9 surgical mesh manufacturers of serious complications associated with mesh use in repair of POP and SUI.[2] A review of the last 301 Manufacturer and User Facility Device Experience Database complications shows that 119 have resulted from using vaginal mesh placement procedures and 64 from midurethral slings.[3] This is a 3:1 ratio for vaginal mesh compared to slings. The potential complications of using transvaginal mesh are wide ranging, from mild to life threatening. The most common complications, as reported in the FDA Public Health Notification, include mesh erosion through the vagina, infection, pain, urinary problems, recurrence of prolapse or incontinence, dyspareunia, and perforation of the bowel, bladder, vessels, or nerves during insertion.[2]

As with any surgery, complications are a known risk, and it is the physician's duty to inform the patient of all potential adverse outcomes at the time of consent. The use of transvaginal mesh for repair of POP has increased tremendously in the past few years. Only recently have systematic reviews and clinical practice guidelines been available to guide the physician in the science of vaginal mesh implantation.[4,5] Although the research is in its early stages, it is possible that there may be a subgroup of patients who could benefit from these new techniques. Similarly, the vaginal compartments where these meshes should be placed will be better delineated, as will the most efficient methods of their placement. Presently, there is limited evidence from randomized controlled trials to guide decisions as to when and how to use graft materials.[4] However, the United Kingdom has published several guidelines on the use of vaginal meshes by their National Institute for Health and Clinical Excellence (NICE).[6] Although helpful, it is important for physicians in the United States to realize that the NICE guidelines may not meet the legal standards applied to show a breach in the US standard of care. Therefore, it remains difficult for providers to find consistent data that can be used when counseling patients about the long-term follow-up and complications regarding the use of mesh.

Learned intermediary doctrine and preemption

The concept of learned intermediary doctrine should be understood by gynecologists using products that are the subject of ongoing litigation, such as transvaginal mesh. The learned intermediary doctrine shifts the liability of harm caused by a medication or medical device away from the manufacturer and onto the physician prescribing or using the product. Overall, under learned intermediary doctrine, if a manufacturer adequately warns a physician of a product's potential complications and risks, then they do not possess the legal duty to warn patients of possible dangers associated with their product. Instead, the duty to warn falls on the physician prescribing the product.

This legal doctrine is frequently used by manufacturers as a legal shield to shift liability for warning patients away from manufacturers and onto physicians. For example, in *Linsley v C.R. Bard Inc*,[7] the manufacturer of Marlex mesh used the learned intermediary doctrine to shift liability of the duty to warn patients of potential complications onto physicians. This suit stated that mesh "was and is a prescription medical device, which requires that it be used only upon order of a qualified physician, thus the warning required is not to the general public or to the patient, but to the prescribing physician."[7] Therefore, C.R. Bard Inc. (Murray Hill, NJ), as the manufacturer of the mesh, only has a legal duty to warn physicians, not patients, of the risks associated with the use of their product. As a result, physicians are left with the responsibility of warning patients of potential complications of a product used in surgery.

Johnson & Johnson (New Brunswick, NJ), the parent company of Ethicon (Somerville, NJ), a manufacturer of mesh used in tension-free midurethral tape procedures, has used the learned intermediary doctrine to shift liability away from itself in suits involving its pharmaceutical product, the Ortho Evra Patch.[8] Whether Johnson & Johnson will choose to use the learned intermediary doctrine to shift liability onto physicians that use their transvaginal tape remains unclear in the early stages of litigation. Manufacturers that use the learned intermediary doctrine to shift responsibility onto physicians risk alienating them and losing the trust of the physicians who prescribe or use their products in surgical procedures. If physicians become aware of a manufacturer's legal tactic to shift responsibility to the physicians, they may decide to no longer prescribe or use that product. In the long run, this may be more financially detrimental to a manufacturer than defending itself in a lawsuit. However, this would depend on physicians' understanding the learned intermediary doctrine and becoming aware of a manufacturer's use of the learned intermediary doctrine in court. Physicians in busy clinical practices are unlikely to be familiar with this tactic or to be aware of which manufacturers are using the learned intermediary doctrine to shift responsibility onto physicians. This may explain why manufacturers frequently choose to use the learned intermediary doctrine when confronted with litigation pertaining to their products prescribed or used by physicians.

If the learned intermediary doctrine is used by a company in suits involving transvaginal mesh, gynecologists can attempt to redirect responsibility to the manufacturer by showing that they did not receive adequate warning of risks associated with the use of their product.[7] However, with the recent FDA warnings, it will be difficult for gynecologists to successfully argue they were not aware of the potential complications involving the use of mesh in vaginal reconstructive surgery. Alternatively, a better choice for gynecologists defending themselves from liability is to assure there is documentation in the medical record that the patient was properly informed of the potential complications that may be encountered with mesh use in vaginal reconstructive surgery.

Another recent development that significantly impacts existing and deters future lawsuits against manufacturers of medical devices is the 2008 US Supreme Court case *Riegel v Medtronic Inc*.[9] In this case, the US Supreme Court held that the preemption clause enacted in the Medical Device Amendments, 21 USC §360k (1976), bars claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA.[9] As a result, patients injured by a medical device previously approved by the FDA have little recourse other than to sue their physicians. This recent US Supreme Court decision makes it imperative that physicians document proper informed consent in the medical records to protect themselves from lawsuits stemming from their use of a medical device such as transvaginal mesh.

The concept of informed consent has been applied in court against physicians since 1972, when *Canterbury v Spence*[10] determined that the average patient must be assumed to have little or no understanding of medicine as an art, so all risks must be disclosed to patients when obtaining their consent for procedures. When there is documentation in the medical record of obtaining consent, the presumption is in the physician's favor that proper informed consent was given to the patient. However, this is a rebuttable presumption that the injured patient may have an opportunity to refute. Nevertheless, the legal presumption is in the physician's favor, and it would be difficult for the patient to prevail in a claim for lack of informed consent when such documentation is in the medical record. For instance in 2006, *Polcari v Dottino*,[11] the plaintiff's lack of informed consent claim against her gynecologist was dismissed on the grounds that there was documentation illustrating that the physician "fully explained the benefits, risks and possible complications, as well as the possible alternatives to the proposed treatment," in addition to the patient's signature on the consent form, further demonstrating that informed consent was obtained from the patient prior to the procedure. As a result, it cannot be stressed enough that documenting informed consent is critical before attempting any gynecologic procedure. Gynecologists should be particularly mindful of informed consent when offering a procedure with a known multitude of potential complications as reported in an FDA Public Health