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Editorial

The Food and Drug Administration's 2011 Warning Regarding Adverse Effects Related to Mesh Implants for Pelvic Floor Reconstruction—Personal Perspectives

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The Food and Drug Administration (FDA), acting as public health guardians, recently released a continuation to the 2008 warning regarding the adverse effects of mesh implants used for reinforcement of the female pelvic floor during surgical reconstruction. This is based on medical device reports accumulated from manufacturers and a user device experience database, as well as a review of the literature. The FDA concluded that serious adverse events are not rare and that use of mesh does not conclusively improve the clinical outcome [1].

It is evident that pelvic organ prolapse (POP) occurs when the supporting pelvic floor becomes weakened or stretched, usually caused by childbirth, leading to descent of the pelvic organs to the vagina and beyond. This contributes to the impairment of pelvic organ function and a deterioration of patient quality of life. POP is estimated to severely affect approximately 11% of the female population [2].

Patients with symptomatic POP might benefit from conservative management, such as the use of physiotherapy or vaginal pessaries. However, advanced POP necessitates surgical reconstruction. This might be achieved by the abdominal approach as an open operation, by laparoscopy, or by the vaginal approach. Synthetic permanent or absorbable meshes or biologic grafts or any combination of these might be used for reinforcement of the weakened pelvic floor structures that led to POP.

The FDA warning letter cites 1503 POP mesh adverse events, arising from an estimated 75 000 POP mesh operations performed from January 2008 through December 2010. Most of the adverse events are related to mesh exposure, which is regarded as a minor complication, and which can be treated easily with no morbid sequelae. Some cases of chronic pain are reported, and 3 fatalities were directly attributed to bowel perforation or hemorrhage, which was likely caused by the surgery itself rather than from the mesh.

Because there is no database for the non-mesh surgical alternatives, the FDA could analyze only mesh-related operations. However, it is evident that the non-mesh operation, such as vaginal hysterectomy, which is commonly performed whenever the uterus is prolapsed, is associated with operation-related complications. Vaginal hysterectomy might be related to bladder, ureteral, and bowel iatrogenic injuries, as well as to operative bleeding and postoperative infection, chronic pain, vaginal shortening, and various psychological impacts. This is the case as well with each and every other non-mesh POP reconstructive procedure, such as vaginal sacrocolpopexy and abdominal sacrocolpopexy.

The American Urogynecologic Society, Society of Female Urology and Urodynamics, and American Congress of Obstetricians and Gynecologists have all responded to the FDA alarm [3–5]. The importance of the FDA warning is appreciated, but at the same time accurate weight is given by the aforementioned agencies both to the actual and true modest severity and occurrence rate of the POP-mesh complications, as well as to the well-reported severe and rather frequent complications attributed by the non-mesh POP reconstruction operations.

These societies emphasize the importance of obtaining specialized thorough and rigorous training before implementing mesh augmentation for POP, maintaining good skills by keeping large-volume expertise, being vigilant for potential adverse effects, watching for complications carefully, informing patients properly, and considering non-mesh POP reconstruction when appropriate.

The need for reinforcement of the weakened fascia for achieving a long-lasting cure of herniation processes is unquestionable. Given that the underlying disease leading to

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POP is actually just a hernia of the pelvic floor, one must admit that the very same surgical principles used for any hernia repair are applicable for POP.

The distinction between abdominal hernia and POP repair is that the intrinsic differences between the anterior and inferior abdominal wall need to be addressed properly. This includes the need to take into account 2 important factors: (1) POP is about horizontal repair and the pelvic floor is not surrounded by "healthy fascia," meaning the apical and peripheral support is needed; and (2) the width of the vaginal wall covering the mesh implant is rather thin, and therefore meticulous surgical measures are required to reduce mesh exposure.

The vagina is definitely the best natural orifice for POP surgery, providing both convenient access to the desired surgical field and the easiest recovery and rehabilitation for the patient. There is no doubt that supportive pelvic side wall solid ligaments, such as the arcus tendineus fascia pelvis and the sacrospinous ligaments, are accessible via vaginal approach and that the uterine cervix or the vaginal apex might be anchored to these ligaments.

Most of the adverse effects mentioned in the FDA announcement are likely related to excessive implanted mesh mass, inappropriate mesh placement, which applies exaggerated tension forces on the implants, and native pelvic tissues and lack of appropriate training and sufficient skills maintenance.

A careful reading of the literature leads one to the notion that non-mesh POP reconstruction drawbacks have unacceptably high recurrence rates (as high as 40%), which necessitates further large-scale operations with limited success rates and inherited specific severe adverse events [6].

The FDA must be applauded for taking a stand on behalf of the public and for pointing out the hazards of mesh usage with POP reconstruction. Mesh manufacturers and users must pay careful attention to this and take necessary precautions. However, mesh implants for POP reconstruction provide true and valuable benefits and therefore should not be abandoned, especially because non-mesh POP reconstruction alternatives frequently do not deliver the long-lasting and complication-free outcome desired by patients and physicians.

The FDA recommendations for improving mesh implant usage should be embraced and meticulously implemented. The FDA warning letter and the complications noted as being mesh-related should challenge mesh manufacturers and users to achieve better outcomes. Potential routes for reducing the complication rates and improving clinical outcomes should be looked for, such as improving the minimal invasiveness of the procedure, reducing tissue damage during dissection and placement, standardizing the surgical steps and improving surgical reproducibility, and avoiding iatrogenic injuries and morbid consequences. These guidelines can lead to greater usage of mesh repair for the benefit of our patients.

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