Editorial

Living with the FDA 2011 warning regarding adverse effects related to mesh implants for pelvic floor reconstruction

The FDA, acting as public health guardian, released in 2011 a follow up to the previous 2008 warning regarding the adverse effects of mesh implants used for reinforcement of female pelvic floor upon surgical reconstruction. This was 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 not mild and the 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 more than a tenth of the female population.

Advanced POP necessitates a surgical reconstruction that might be achieved via abdominal approach by an open operation, by laparoscopy, by robotic surgery, or via vaginal approach. A non mesh operation entails a rather high incidence of recurrence,[2] *which is understandable as POP is a herniation phenomenon, and mesh reinforcement reduces the rate of recurrence. Synthetic permanent or absorbable meshes or biological grafts, or any synthesis of these may be used for reinforcement of the weakened pelvic floor structures that led to POP. The field of vaginal mesh operations was significantly studied regarding relevant adverse effects, whereas other surgical options have been criticized much less.*[3]

The FDA warning, referring just to the vaginal mesh augmentation operations, quotes about 3.000 urinary anti-incontinence sling and POP mesh adverse events, arising from an estimated total of 300.000 sling and 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, which can be easily treated 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. Yet, the announcement declares that the mesh related complications are not rare and not mild.

As there are no database for the non-mesh or abdominal approach surgical alternatives, the FDA could only analyze vaginal mesh operations. However it is evident that the non-vaginal mesh operation, such as vaginal hysterectomy and open, laparoscopic and robotic abdominal colpo-sacro-pexy which are occasionally performed whenever the uterus is prolapsed, are definitely associated with operation related complications. Vaginal hysterectomy might be related to bladder, ureteral and bowel iatrogenic injuries as well as to operative bleeding and post-operative 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 colpo-sacrospinous-pexy, abdominal colpo-sacro-pexy and laparoscopic or robotic pelvic floor reconstruction. The nature, occurrence and severity of these operation related complications were never defined properly.

The AUGS (American Urogynecologic Society), SUFU (Society of Female Urology and Urodynamics) and ACOG (American Congress of Obstetricians and Gynecologists) as well as some editorials have all responded to the FDA alarm.[4-6] *The importance of the FDA warning is appreciated, but at the same time the accurate weight is given both to the actual and true modest severity and occurrence rate of the POP vaginal mesh reconstruction complications as well as to the reported severe and rather frequent complications attributed to the non-vaginal mesh POP reconstruction operations.*

These articles emphasize the importance of obtaining specialized thorough and rigorous training prior to 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 mesh reinforcement of the weakened fascia for achieving a long lasting cure of herniation processes is unquestionable. Given that the underlying pathology leading to 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 inherited differences between the anterior and inferior abdominal wall need to be addressed properly. This includes the need to take into account two 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 in order 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 Tendineous Fascia Pelvis and the Sacro-Spinous 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 with the FDA announcement are likely related to excessive implanted mesh mass, inappropriate mesh placement, applying exaggerated tension forces on the implants and native pelvic tissues and lack of appropriate training and sufficient skills maintenance.

Reading carefully the literature leads one to the notion that non-mesh POP reconstruction drawbacks have unacceptably high recurrence rates (as high as 45%), which necessitate further large-scale operations with limited success rates and inherited specific sever adverse effects.[2]

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 since non-mesh POP reconstruction alternatives do not deliver the long lasting and complication free outcome desired by patients and physicians.

The FDA recommendations for improving the mesh implant usage should be embraced and meticulously implemented. The FDA warning 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, avoiding iatrogenic injuries and morbid consequences. These guidelines can lead to greater usage of mesh repair for the benefit of our patients.

Both, industry and pelvic floor surgeons were discouraged of further using the vaginal mesh augmentation for the cure of POP. Yet, one must always bear in mind the draw-backs of surgical modalities other than vaginal mesh operations when being driven to elect these for his patient. Although vaginal meshes carry potential hazards, so do all operative modalities. Thus, the question is not whether a certain operation is totally safe, because none is. The issue is choosing the best operation for the specific patient, in terms of safety, ease of rehabilitation and long standing therapeutic results. This will lead frequently toward vaginal mesh POP reconstruction.[7-9] Surgical good training and expertise, combined with thorough theoretical knowledge, proper patient selection and transparent patient information providence and counselling are the keys for successful operative treatment.

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