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Vaginal mesh – the controversy

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Abstract

Pelvic organ prolapse is a condition that can cause significant symptoms that affect a woman's quality of life. It is the result of defects in the supporting structures of the vagina and, depending on the location and size, can alter the functions of the organs contained within the female pelvis. Approximately 11% of women will undergo surgical intervention for their prolapse or for incontinence in their lifetime. Unfortunately, one third of these will require reoperation for failed procedures. Pelvic floor surgeons have sought to improve these outcomes. Based largely on the success of midurethral slings (MUS), transvaginal mesh has been implanted, and commercial kits developed with the intent of improving these outcomes. In 2008, the Food and Drug Administration (FDA) issued a Public Health Notification in response to possible increased adverse events associated with the use of mesh compared to traditional repairs. The 2011 update required that further study be conducted for the use of transvaginal mesh. In this article, we wish to discuss the background of mesh use and the evolution of the public health warnings, and focus on future prospects.

Introduction

Pelvic organ prolapse is a complex condition resulting from defects in the supporting structures of the vagina. Women are estimated to have a 30%-50% risk of pelvic organ prolapse, with 2% having symptoms [1]. In the United States, an estimated 11% of women will undergo surgery for pelvic organ prolapse and stress urinary incontinence in their lifetimes [2]. In response to concerns regarding inherent tissue defects in women with prolapse, and high rates of recurrence, interposition grafts and mesh have been used to improve outcomes. Numerous studies have been performed using vaginal mesh, but there is no compelling evidence to support its routine use [3-6]. In 2008, the FDA issued a Public Health Notification [7] and followed with an update in 2011 [8] regarding concerns for an increased rate of complications associated with the use of vaginal mesh for prolapse. We will briefly discuss the background, rationale for use, complications and appropriate patient counseling.

Recent developments

Numerous approaches that reapproximate native tissue have long been utilized for the repair of pelvic organ prolapse [9]. However, owing to high recurrence rates, particularly in the anterior compartment, surgeons continue to search for ways to improve outcomes for the repair of pelvic organ prolapse. There are several challenges. It is difficult to recruit patients for head-to-head studies comparing surgical techniques. Because patients with multiple compartment defects commonly require correction, comparing specific procedures for a single compartment is challenging. Compounding the problem is the general lack of a standardized definition of success. It seems increasingly clear that patient satisfaction is predicated on the relief of symptoms as well as anatomic correction. As such, some women report high satisfaction rates in spite of recurrence of the pelvic organ prolapse [10]. As a result of these issues, much of the data is from uncontrolled, retrospective case series of single techniques.

Using surgical mesh is intended to increase the longevity of the repair, restore anatomy, and prevent recurrence. Mesh can be hand tailored or pre-formed as found in kits. Vaginal mesh classification is based on the classification used for treating inguinal hernias [11]. The type of mesh that is presently used in the treatment of pelvic organ prolapse is a Type I monofilament, large-pore polypropylene mesh. Theoretically, this promotes a host-graft response that ultimately results in tissue ingrowth, and facilitates immune cells to fight bacterial invasion [12,13]. A number of surgeons began adopting mesh as an interposition graft, owing to the inherently weak tissue of the prolapsed pelvic floor. Since 2000, the FDA approved over 60 mesh procedures for use in pelvic organ prolapse under a 510 K exemption process with the index device being hernia mesh [14]. This exemption facilitates devices going to market without the rigorous pre-market data required of entirely new devices or Class III devices. Initially, transvaginal mesh "kits" were developed utilizing trocar placement via the obturator approach, which many surgeons adopted for placement of MUS. Newer anchor-based or suture-based systems have since been developed. These procedures are distinctly different from established procedures using transabdominal mesh, which had been used for support of the vaginal vault with success rates of 80-90% [15,16]. Use of synthetic mesh is an integral part of an abdominal approach to vaginal repair (abdominal sacral colpopexy) and has been demonstrated to be superior to biologic grafts [17].

As the use of mesh materials in the transvaginal correction of pelvic organ prolapse became more common, a number of complications were observed. Through voluntary reporting, complications such as mesh exposure erosion into the urinary tract began to be identified with an apparent increased frequency [18]. Despite data that demonstrated objective anatomic improvements in anterior compartment outcomes after using mesh, concerns over increasing complications led the FDA to issue a Public Health Notification informing clinicians and patients of adverse events related to transvaginal mesh and to provide recommendations on how to decrease risks and counsel patients [7]. The original notification included mesh for slings and transvaginal prolapse surgery. Over continued concerns of increasing complications, an update was issued in 2011 in which the FDA concluded that "serious adverse events associated with mesh use are not rare" and that "transvaginal mesh placement in pelvic organ prolapse repair does not conclusively improve clinical outcomes over traditional non-mesh repair" [8]. In addition, the FDA concluded that adverse events associated with transvaginal mesh can be life altering for some women and pain may persist despite mesh removal. It must be noted that the 2011 FDA update only pertained to mesh for prolapse repair and not MUS. As a result of this action, public hearings followed that led the FDA to ultimately issue the following recommendations: reclassification of transvaginal mesh devices for the correction of pelvic organ prolapse to class III devices, and 522 post-market study orders for all transvaginal mesh device procedures and second generation single incision slings on the market. The Class III application to transvaginal mesh procedures means that any new device or significant alteration of current devices will require pre-clinical testing. Participating companies from the industry were required to submit study designs to the FDA for currently utilized products by the Spring of 2012 [19]. It should be mentioned that devices currently on the market will be available for use as long as there is compliance with the 522 order. While it is hopeful that these trials will answer many much needed questions in this area, the current "state" of transvaginal mesh placement is an item of debate—particularly regarding the FDA conclusions.

To date, there are a number of established facts that warrant discussion. First, there are a large number of transvaginal mesh procedures being performed, many of them safely. Second, there are a number of experienced pelvic surgeons who are reporting improved anatomic correction, shorter operative times and a shorter recovery period using mesh [20]. Third, few would argue that a woman without any sequelae from a transvaginal mesh procedure should not have the mesh routinely removed without clinical indication. Fourth, the lack of control of voluntary reporting of complications following transvaginal mesh, through a device website, raises a number of concerns: there is no way to compare the complications to tissue repairs (which are not reported on a device website) and the increase observed might be a consequence of the increasing numbers of transvaginal mesh procedures overall. An estimate of overall incidence of complications utilizing a ratio of the number of adverse reports compared to a projection of the total number of procedures performed is roughly 0.67%, [20]. Lastly, there is compelling evidence that the use of mesh does improve objective anatomic outcomes in the anterior compartment [21]. Although the general consensus is that this is not associated with improved patient satisfaction, most surgeons would undoubtedly prefer objective success in a satisfied patient versus satisfaction alone.

However, there are legitimate sequelae that are unique complications of transvaginal mesh procedures. Extrusion of mesh in the vagina, erosion into the urinary tract, bleeding and infectious complications that differ from traditional repairs have been reported [22]. Additionally, the rate of reoperation as a result of these complications

appears to be higher within a two year timeframe when compared with tissue repairs. Generalized pelvic pain and sexual pain may occur following tissue repair, and these conditions may be associated with mesh precipitating vaginal extrusion, nerve entrapment or mesh contraction eliciting a secondary pelvic floor dysfunction [23]. Although the incidence of these complications may actually be low (incidence is not truly defined), these complications associated with mesh appear to be more severe and require reoperation more often. Diwadkar *et al.*, in a meta analysis comparing complication and reoperation rates between vaginal repairs, abdominal repair and vaginal mesh kits, noted that reoperation rates were highest with transvaginal mesh kits [24]. However, they also found that the abdominal approach for uterine/vaginal vault prolapse had a relatively low reoperation rate for recurrence but at the expense of a high complication rate.

Summary and future directions

In light of these issues, surgeons (and patients) are asking the question "does vaginal mesh have a place in vaginal prolapse repairs?". In reviewing this issue, the answers are not clear. It does seem clear that routine mesh placement in all patients is probably not necessary, and not good practice. Additionally, the lack of data does not support mesh placement in the posterior compartment. But, what about in the middle and anterior compartments? Is there a role for mesh in patients who have recurred or are at risk for recurrence? When trying to answer these important questions it becomes imminently clear that our current methods of accumulating data and answering these important questions are woefully inadequate. Hopefully, the FDA studies and registries in development will help us answer these important questions.

In summary, one thing is clear. As in most of our quality of life procedures, patient communication and informed consent are of paramount importance when considering transvaginal mesh procedures. Patients should be told why mesh may be better for them and that there are non-mesh alternatives available. Patients should be informed of the complications that may occur following prolapse repairs, in general, and those that are unique to mesh. They should be informed that mesh is permanent and that more than one operation may be required to correct the complication, should it occur. After this discussion, it is inevitable that many women will choose not to have a transvaginal mesh procedure. However, a woman who has had a recurrent pelvic organ prolapse or is at risk of recurrence, may choose to do so—and there is no definitive or controlled data to suggest that she shouldn't. Randomized and controlled trials such as PROSPECT will hopefully allow women to make a more informed choice in future.

Abbreviations

FDA, U.S. Food and Drug Administration; MUS, midurethral slings.

Competing interests

The authors declare that they have no competing interests.

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