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EDITORIAL

What to do?

Over 200 operations for the treatment of stress incontinence were described before the recent onslaught of synthetic slings in the mid 1990s. Since then, another 30 or so have been added to our repertoire. This, despite the fact that there is little in the peer review literature to distinguish one from another. Of course, anterior repairs and transvaginal needle suspensions (the darlings of the late 80's and 90's) were discredited by the AUA Guidelines panel of 1997, and are not done nearly as often any longer. But they were discredited by studies so flawed by lack of credible outcome data that one can only surmise the reasons why. In that same report, retropubic operations and autologous fascial pubovaginal slings were found to have the highest success and a low complication rate. Insofar as retropubic procedures were mostly done for uncomplicated and pubovagnial slings for complicated stress incontinence, it was only logical that pubovaginal sling became the unofficial gold standard.

That paved the way for the synthetic slings of the 21st century. It seems reasonably clear (based on a plethora of new somewhat improved studies) that, with respect to treatment of stress incontinence, the doctors and patients believe that the new generation of synthetic slings fare at least as well as those that came before. The widespread appeal of these new techniques is that they are truly minimally invasive. Most of these are outpatient surgeries that can be performed in 30 min or less, most patients void immediately afterwards and can return to their usual activities within days. Complications are said to be low and urinary retention, the bane of anti-incontinence surgery, can be managed by simple sling incision without jeopardizing the outcome of surgery.

Or so they say. Most of what you have just read comes not from unassailable studies in the peer review literature, but from a few good studies supplemented by the rumor mill and conversations I have had with a large number of well respected surgeons who regularly perform these operations.

In fact, there are a few reasonably well done studies that document medium term success rates that are as good as the autologous fascial sling. The success rate may even be better in the long term. Further, these operations are much easier to learn and require much less surgical skill.

So far, there is not much here for an editorial. Here's the rub. During the evolution of these surgical techniques, there were a number of deaths worldwide due to inadvertent and unrecognized vascular and bowel injuries. Although some were reported to governmental agencies (between 10–20 worldwide), none of the deaths appeared in the peer review literature. Urethral erosions of slings have been reported in about 1% or less and vaginal extrusion has been reported in to occur in single digit percentages, but the impact of both of these complications might be being downplayed. Most authorities agree that most extrusions are easily treated with minor out patient surgical procedures and that most erosions can be treated by removal of the tape and repair of the urethra, but caution that a secondary procedure for incontinence may be necessary.

Unfortunately all of this expert opinion and all of the peer review literature is based on very short followup; only a few studies go out to 4 years. Moreover, the surgical technique and the composition of the slings themselves continue to be changing at such a rapid pace, that it does not seem possible that the true consequences of these complications could possibly be known at this early stage of the evolution of the procedure.

I and some of my peers have already seen a number of women who suffered significant, difficult to treat complications of synthetic slings including: (1) urethral erosions with urethrovaginal and vesicovaginal fistula that, even after successful reconstruction, proved refractory to anti-incontinence procedures, (2) vaginal extrusions of the sling causing recurrent granulomas with persistent draining sinuses and dyspaeruinia that defied multiple attempts at surgical excision and repair. And, do not forget the deaths.

It has been estimated that over 1 million of these synthetic slings have been performed worldwide; the denominator is very big, the numerator very small. Small, but real, and the followup is short; the numerator may grow over time. None of these complications occur with autologous tissue, nor with allografts and zenografts (but they may have their own set of complications).

I have little doubt that a synthetic will be developed (or may have already been developed) that will mitigate these concerns. I have little doubt that a synthetic will become the new gold standard for sling surgery, but for the present, there are too many women with sling complications that cannot be readily fixed.

It leaves me asking, when it comes to my own patients, what to do?

Jerry G. Blaivas
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