Re: Association Between the Amount of Vaginal Mesh Used with Mesh Erosions and Repeated Surgery After Repairing Pelvic Organ Prolapse and Stress Urinary Incontinence

Chughtai B, Barber MD, Jialin Mao J, et al

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Experts' summary:

The authors report results from an observational cohort study that included 41 604 women to evaluate the occurrence of mesh complications and repeat surgery within 1 yr after initial mesh implantation for pelvic organ prolapse (POP) and/or a suburethral sling for stress urinary incontinence (SUI) [1]. The population was divided into four groups according to the intervention performed: transvaginal POP repair with mesh and concurrent sling (vaginal mesh plus sling group), transvaginal POP repair with mesh and no concurrent sling (vaginal mesh group), transvaginal POP repair without mesh but with concurrent sling (POP plus sling group), and sling only (sling group). The highest risk of erosion (2.72%; 95% CI, 2.31%-3.21%) and repeat surgery with concomitant erosion (5.64%; 95% CI, 5.04%-6.31%) was found in the vaginal mesh plus sling group. The lowest risk of erosion was found in the sling group (1.57% for erosion and 1.16% for repeat surgery with concomitant erosion). The authors concluded there is evidence for a dose-response relationship between the amount of mesh used and subsequent mesh erosions, complications and invasive repeat interventions.

Experts' comments:

We all live and practice in the same evolving society, but it seems that being a surgeon is a "serious" job that requires sensible and balanced opinions.

Those who have been around for a while will certainly remember the first attempts to use small size meshes to improve the outcomes for urinary incontinence and prolapse surgery. It was a small world with a careful indication for and use of implants, with relatively good outcomes and minimal complications.

At some point the medical industry glimpsed the potential for big business by taking our small mesh business to a higher, industrial level. Most surgeons expressed words of caution about the possible risks inherent to more widespread use of implants, their increasingly larger sizes, and the associated complications. The industry rapidly approached a large target of potential users with the promise of a new area of treatment blessed by an easy surgical technique with high success rates.

Some 10 yr ago, regulatory bodies started to express concerns about the possible risks associated with the use of mesh for prolapse surgery. And 30 yr later it is hard to determine whether we should blame the industry or ourselves for letting things go the way they did, for not controlling the borders of our profession, and for letting the promise of easy surgery fool us and, more importantly, our patients.

To fully understand the problem, let us consider the different points of view of the parties involved: the patients, the surgeons, the industry, and the scientific societies/government bodies.

The paper by Chugthai and co-workers reports the incidence of complications after mesh surgery for POP and SUI from the New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) longitudinal database. The authors report an incidence of secondary surgery to address complications that varies between 5.6% for the combined use of POP and SUI meshes and 2.5% for patients receiving mesh for SUI only. How do these data compare to what has been published previously and how can we interpret them?

Looking at the peer-reviewed evidence, a standardised review of complications after mesh surgery for POP reported 10% incidence of graft erosions [2], double the risk reported by Chugtai et al. Looking at slings for SUI, randomised trials report a risk of repeat surgery for erosion/extrusion of 2.9% [3], while analysis of large databases identified a risk of $<$4% for sling revision/removal at 9 yr [4].

These data need to be put into perspective. Following the Hippocratic oath "first do no harm", the risk of erosions caused by the implanted mesh is of importance, although not all erosions are equal; vaginal erosions are annoying, but erosions into the female urethra are more difficult to repair. We also have to consider that there is no surgery without complications. The concept of an informed decision by our patients implies an understanding of the balance between the risks and benefits of which our patients should be clearly informed.

To fully appreciate the data provided by Chugthai and co-workers we have to consider that although equally effective alternative procedures exist for surgical repair of SUI (European Association of Urology guidelines) the same is not necessarily true for POP repair. In 2014 the Therapeutic Goods Administration of Australia banned the use of mesh for POP surgical repair, and a similar warning has been issued by the National Institute for Health and Care Excellence in the UK. More recently (2017), New Zealand banned the use of mesh for both POP and SUI, asking the industry to stop marketing their products until proof of product safety.

Changing perspective, the medical industry that manufactures and sells mesh for POP repair and SUI surgery is facing lengthy and costly litigations from both individual and class actions that may easily wipe out the entire income of this business area, forcing an industry exit. Whether this is good or not is not for us to say. The world of SUI surgery is probably ready to offer alternative techniques requiring no mesh implants or the use of autologous materials, but surgery for POP moved to the use of mesh because of the rather poor outcomes for fascial procedures, so it is doubtful whether the cure for the current problem is going to be better than the "disease" we want to treat.

To finish on a lighter note, the paper by Chugtai et al does confirm that sometimes "size matters".

Conflicts of interest: The authors have nothing to disclose.

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Re: Clinical Outcomes of the Upper Urinary Tract after Ureteral Clipping for Treatment of Low Functioning or Nonfunctioning Renal Moieties

Lopes RI, Fernandez N, Koyle MA, et al

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Expert's summary:

The authors report on indications and outcomes for a promising innovative methodology to treat poorly or nonfunctioning renal moieties. They introduced clipping of ureters in 35 children and divided them into four categories. A duplex system with an ectopic ureter represents the majority (46%), followed by a duplex system with a large ureterocele (11%), a duplex system with progressive dilatation (9%), and a single system with low or nonfunctioning kidneys (34%). Of the patients, 91% underwent laparoscopic clipping. All were followed for clinical outcomes and sonographic assessment of hydronephrosis up to maximum follow-up of 34.6 mo. There were complications in two patients (5.7%) due to febrile urinary tract infections, with a need for nephrectomy in one.

The authors conclude that this methodology of "simple" ureteral clipping is safe and effective in managing such renal moieties. The complication rate is low and the procedure itself is less demanding, simpler, and quicker than extirpative or reconstructive options.

Expert's comments:

Traditionally there is no perfect approach but several options for treating poorly or nonfunctioning renal moieties. Careful observation, heminephrectomy, ureteroureterostomy, and common sheath reimplantation, usually with a need for tapering, comprise a few. Apart from the first one, these represent rather invasive procedures with a risk of bleeding, urinary leakage, and functional loss of the healthy parts of duplex kidneys in up to 7% of cases [1]. In addition, some of these reconstructive procedures can become reasonably demanding [2]. There are many controversies and no consensus on the best treatment option among experts or in the corresponding guidelines [3]. Consequently, such a novel alternative [4] seems to be promising, even though hydronephrosis persisted in their series. However, since there is a need to treat clinical symptoms rather than morphological signs, a minimally invasive procedure with a low complication rate is desirable, although it has to stand the test of time in the long run. In addition, ruling out subsets of patients who might not benefit is essential. This is only possible by frequently revising outcomes to better define indications and patient selection. It is true that there is no surgical innovation without evaluation, and therefore such studies are mandatory and important for further improvement of our therapeutic strategies.

Conflicts of interest: The author has nothing to disclose.

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