



Words of Wisdom

Re: Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women with Stress Urinary Incontinence

Guroł-Urganci I, Geary RS, Mamza JB, et al

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Experts' summary:

Guroł-Urganci and colleagues retrospectively analyzed data for nearly 100 000 women who underwent surgery with a midurethral tape for stress urinary incontinence (SUI) for the first time. All the procedures were carried out in National Health Service (NHS) hospitals in England between 2006 and 2015. The focus was on complications, especially removal of the tape and reoperation because of SUI. The 9-yr removal rate was 3.3%. The reoperation rate for SUI was 4.5 at 9 yr. A total of 7% of the women had undergone surgery for either of these reasons by 9 yr.

Experts' comments:

This is an important publication in the discussion on how to deal with implants in health care. In urology the dispute is about the use of artificial material, mainly polypropylene, for benign disorders such as pelvic organ prolapse and SUI in women. Tension-free midurethral tapes, mostly made of polypropylene, were introduced in 1995 by Ulmsten and Petros [1]. The procedure they described and results reported for tapes dramatically changed the treatment for female SUI. Since the introduction of midurethral tapes, made from artificial material, the number of surgical procedures for SUI increased exponentially. The reasons for this explosion in the use of tapes are that the procedure is minimally invasive, can be done in a daycare setting, and has quick recovery rates and good results with few complications. Therefore, both patients and surgeons prefer this solution.

The classic alternative surgical solutions for SUI such as the pubovaginal sling, Burch colposuspension, and bulk material have another profile. Slings and Burch operations are perhaps equally effective, but the procedure is more extensive and involves a longer recovery time compared to that for midurethral tapes. Bulk material is simply less effective. This means that patients and surgeons are more selective and critical in choosing the classic options. Therefore, the number of women undergoing surgery for SUI with one of the classic options is far less than those

opting for midurethral tapes. One could also state that women suffering from SUI were surgically undertreated until the introduction of midurethral tapes. Another valid statement is that since it is so easy to put in a tape, this could be done for dubious indications and perhaps by less skilled surgeons with all the possible negative consequences.

Midurethral tapes are being heavily scrutinized at present because they are made of polypropylene, the same material that was used for pelvic organ prolapse repair and caused many severe complications. After the US Food and Drug Administration (FDA) warnings in 2011 [2] a cascade of actions followed. For instance, in 2018 the NHS boards in Scotland were told to stop using mesh for pelvic organ prolapse and for SUI [3]. The most recent milestone was on April 16, 2019, when the FDA ordered manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling and distributing these products [4]. For mesh used to treat pelvic organ prolapse this decision can be justified since many disasters with this material have been described. The question however is whether the complications and drawbacks for SUI repair are so numerous or severe that midurethral polypropylene tapes should be banned as well. There are good publications comparing the results and complications for midurethral tapes to the alternatives. One of the latest meta-analyses was published in 2017 in *European Urology* and included 28 randomized controlled trials with 15 855 patients [5]. For patients undergoing midurethral tape surgery the overall and objective cure rates were higher than for Burch colposuspension. The cure rates and complication rates for midurethral tapes were similar to those for pubovaginal slings, but the reoperation rate tended to be higher in the pubovaginal sling group. In this review the Burch colposuspension and pubovaginal sling groups comprised only 1168 patients, which is only 7% of the total cohort.

It seems that midurethral tapes made from polypropylene used for SUI treatment are good, quick, and safe. The publication by Guroł-Urganci et al underlines this important finding. Analysis of data for nearly 100,000 women with 9 year follow-up revealed that only 3% underwent partial or complete removal. Data for large series such as this one rather than sentiment should guide the discussion on the use or abandonment of medical devices in our practice.

Conflicts of interest: The author has nothing to disclose.

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Re: Use of Prostate Systematic and Targeted Biopsy on the Basis of Multiparametric MRI in Biopsy-naïve Patients (MRI-FIRST): A Prospective, Multicentre, Paired Diagnostic Study

Rouvière O, Puech P, Renard-Penna R, et al

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Experts’ summary:

Multiparametric magnetic resonance imaging (mpMRI) before prostate biopsy has become increasingly common with the growing scientific evidence that it increases the likelihood of finding clinically significant prostate cancer [1–3]. However, whether a negative mpMRI scan obviates the need for systematic biopsy in biopsy-naïve men is controversial. Most studies in support of this concept have been conducted in specialized centers with expertise in the interpretation of mpMRI and/or in performing mpMRI-targeted prostate biopsy. Rouvière and colleagues [3] conducted a well-designed, prospective, real-world study (MRI-FIRST) across 16 centers in France and compared the sensitivity of systematic versus targeted biopsy in patients with a clinical suspicion of prostate cancer undergoing mpMRI. Combining both techniques improved the detection of clinically significant prostate cancer and omitting systematic biopsy reduced the detection of indolent disease (from 19.5% to 5.6%). However, for every three additional clinically significant prostate cancers detected by adding targeted biopsy, two were missed by omitting systematic biopsy.

Experts’ comments:

Avoiding unnecessary prostate biopsy is crucial. Complications from prostate biopsy are not trivial (especially infectious complications if biopsy is performed using a transrectal approach) and systematic biopsy clearly drives overdiagnosis. Overtreatment is a concern and some men drop out of active surveillance because of anxiety. Identification of a diagnostic pathway that can accurately stratify risk and avoid the need for prostate biopsy in men with a low risk of harboring clinically significant prostate

cancer is urgently needed. Undoubtedly, a pathway that includes mpMRI followed by targeted biopsy in the case of positive mpMRI improves risk stratification and increases the detection of clinically significant disease. However, the MRI-FIRST trial adds to the body of literature [4] indicating that a negative mpMRI scan does not preclude the need for systematic biopsy owing to the high miss rate for clinically significant cancer: the negative predictive value in the PROMIS trial was 76% [1]. To be successful, prebiopsy mpMRI requires access to high-quality mpMRI studies, a robust training program for radiologists to mitigate interobserver variability, and access to high-quality mpMRI-targeted biopsy, which has a learning curve. One way forward to combining the advantages of mpMRI and targeted biopsy (ie, detecting more clinically significant prostate cancer while reducing the number of biopsies and overdiagnosis) could be to perform systematic biopsy only in men in whom the clinical suspicion is high. Prostate-specific antigen (PSA) testing alone has proven inadequate in selecting men for prostate biopsy. While the “best” approach has yet to be defined, a multistep, multivariable approach is logical: risk assessment (age, family history, race); repeating measurement of PSA for men with elevated levels; clinical examination (digital rectal examination, prostate volume assessment/PSA density); and likely additional biomarker testing such as percentage free/total PSA, 4Kscore, Prostate Health Index, or SelectMDx. Should this assessment result in a recommendation for a prostate biopsy, then mpMRI should be performed, followed by systematic biopsy plus targeted biopsy should the mpMRI identify a lesion [5].

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