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SYNTHETIC MESH SLINGS: SAFETY AND RISK/BENEFIT CONSIDERATIONS

Hypothesis / aims of study

Safety is defined as “freedom from risk…not causing injury, damage or loss.” Safety describes the probability of an adverse event while risk describes the range of adverse events. While it is easy to demonstrate risk, assessing safety is much more difficult. Any known adverse event is a risk, no matter how infrequently it has been reported or observed – even a single case report establishes risk, but without knowing the denominator it is impossible to accurately assess safety. The problem, simply stated, is that no well controlled, long term safety studies have been reported, nor are there any good registries. In lieu of this we performed a literature review with the intent of evaluating the minimum major risks associated with synthetic midurethral sling (SMUS) surgery and the minimum risk of failure of the SMUS surgery to improve stress incontinence.

Study design, materials and methods

A systematic review of the English language literature was performed in August 2014 to investigate the complications of SMUS. Using the Medline database, the search used a complex search strategy including both medical subject heading (MeSH) and free-text protocols. The MeSH search was limited to humans combining the following terms: mid urethral sling, suburethral sling, midurethral sling, urethral sling, mid urethral slings, midurethral slings, suburethral slings, urethral slings, and follow-up study. Multiple free-text searches were also performed, searching for the following terms individually in the fields title and abstract of the records: Urinar*incont*, TVT, tension-free vaginal tape*, Tension-free vaginal sling*, Transobturator tape*, Transobturator sling*, TVT-obturator, TVT-O, TVT secure, miniarc, abbrevio, TOT, suprapubic arc sling*, SPARC sling*, intravaginal slingplasty, IVS sling, Raz sling, Uratape, ObTAPE, Prepubic sling*, Prepubic TVT, Prepubic tape*, PelviLace, Ureter, Aris, In-Fast, Monarc, I-Stop, urethral reconstruction, urethrovaginal fistula, Obtape, gortex sling, silastic sling, mersilene sling, marlex sling, vesicovaginal fistula, BioArc. The authors reviewed the abstracts to select the papers relevant to the review topic. Discrepancies were solved by open discussion. Once the citations were accrued and the full text papers read, the bibliographies were cross checked for any relevant citations that were missed by the digital search. Only articles published since 2007 were included in the reporting of complications to update and expand upon previously published reviews of SMUS.

Serious complications were defined as those that required further surgery (urethral obstruction, vaginal, bladder & urethral erosion, urinary fistulas, bowel injury and serious infections) and those that were refractory to treatment (chronic pain and *de novo* OAB). Surgical failure, with respect to treatment of stress incontinence, was defined by whatever methods the authors chose.

To accurately report on incidence of complications, the following scheme was repeated for each complication: The total number of patients included in all of the case series that reported a specific complication was tabulated. Then, the total number of patients presenting with that complication was tabulated. The incidence was calculated by dividing the total number of patients with the complication by the total number of patients in those series

Results

A total of 995 records were retrieved from Medline and 746 were excluded for lack of relevance leaving 249. Another 88 were added after reviewing references from the reviewed papers, so 337 papers formed the basis of this review. With respect to assessing safety and complications, the overall quality of the studies was deemed very poor. Only a handful of studies even recorded adverse events contemporaneously and none of those had a follow-up longer than two years. Results are shown in the table below.

Interpretation of results

The incidence of adverse events reported herein were calculated from the total number of reported divided by the number of patients at risk in the case series so it represents the absolute minimum estimate of serious complications; the actual risks could be considerably higher.

Concluding message

Because of the limitations inherent to the evaluation of risk and safety alluded to above, we can estimate that, based on the available literature, a minimum of 15.3% of women who undergo mesh sling surgery suffer a significant adverse outcome and/or surgical failure to cure or improve stress incontinence.

Table:

Complication	% Calculated Incidence (Estimated Incidence)
Requiring surgery	
Urethral obstruction	3.2
Erosion/extrusion/exposure	2.0
Fistulas	0.3
Bowel injury, infection	0.1
Life style altering	
Chronic pain	4.3 (0.5)*
Refractory (*de novo*) OAB	11 (3.9)*
Recurrent/persistent SUI	5.3
TOTAL Incidence of serious complications and/or sling failure with respect to incontinence	15.3

*These numbers are not mutually exclusive. For example, a patient who underwent mesh excision for exposure may develop refractory pain. To avoid counting the same patient twice, the numbers in parenthesis refer to those who did not have prior surgery and only those were included in the total.

Disclosures
Funding: Funded by: Institute for Bladder and Prostate Research **Clinical Trial:** No **Subjects:** NONE