

IS THERE AN ASSOCIATION BETWEEN POLYPROPYLENE MIDURETHRAL SLINGS AND MALIGNANCY?

Hypothesis / aims of study

Stress urinary incontinence (SUI) is a prevalent condition affecting up to 38% of women. Per the recent AUGS/SUFU position statement on mesh midurethral slings, "Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI." Furthermore, the FDA has stated that "the safety and effectiveness of (*mesh*) multi-incision slings is well established." A recently published study demonstrated objective cure rates of over 90% with 17 years of follow-up. [1]

Despite long term studies supporting the efficacy and safety of macroporous, monofilament polypropylene slings for the treatment of SUI, there have been concerns regarding the general risks of using mesh in transvaginal surgery. While these concerns often relate to mesh used for prolapse repair, some have voiced apprehension regarding mesh slings as well.

Recently some have raised concerns about synthetic midurethral slings and a possible link with malignancy. [2] Experiments done in mice have demonstrated a high rate of sarcoma formation after implantation of polypropylene. However, further investigation suggests that the risk of malignancy may be related to surface area and morphology of the implanted material more than the material composition itself. [3]

The objective of this study is to examine any association between polypropylene mesh used in midurethral slings and malignancy in humans.

Study design, materials and methods

A retrospective review was performed for all slings performed at our institution from 2004 to 2013, using the CPT code for this procedure. From within this group, the ICD codes for urethral cancer, vaginal cancer and bladder cancer were reviewed. Then each case associated with malignancy was further examined.

Results

From 2004-2013, 2545 cases were performed. Mean age of the patients at the time of surgery was 59.4 (\pm 13.1) years old, and average follow up was 42.5 (\pm 34.1) months with follow up extending up to 122.3 months. Of the total cases, there were 12 cases of bladder cancer and one case of vaginal cancer. After reviewing the records further, 11 of the 12 cases of bladder cancer were diagnosed before the sling was placed. Therefore, the rate of bladder cancer after sling procedure was 1/2546 (0.0%) with the same rate of vaginal cancer. There were no sarcomas noted.

The patient diagnosed with bladder cancer was diagnosed 4 years after a transobturator polypropylene sling was placed. She presented in acute renal failure with bilateral hydronephrosis secondary to high grade, invasive urothelial carcinoma. Her disease was aggressive, and she was transitioned to hospice care within one year from diagnosis.

The patient diagnosed with vaginal cancer had undergone a hysterectomy, approximately forty years earlier for unknown indications. Two years after placement of a TVT-O sling, she was found to have a low grade squamous intraepithelial lesion with the presence of HPV on a surveillance pap smear of the vaginal cuff. Vaginal biopsy showed CIS. She underwent laser vaporization at the apex of the vagina as well as concomitant placement of a retropubic TVT sling for recurrent stress incontinence.

Interpretation of results

Overall, the rate of malignancy after polypropylene mesh midurethral sling placement is 0.0%. In addition, based on the location and cell type, the connection between the sling material and the potential development of malignancy is highly unlikely. The most common type of bladder cancer associated with the presence of a foreign body is squamous cell carcinoma. The patient in our series with bladder cancer had urothelial carcinoma. The patient who developed CIS at the vaginal apex had disease far from the site of the sling, and the more likely association is the presence of HPV and CIS.

Concluding message

Based on these findings, with a mean follow-up of almost four years, our series does not support an association between polypropylene mesh used for midurethral slings and the development of malignancy in humans.

References

1. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J* 2013; 24: 1265-1269.
2. Wideman, N. (n.d.) The Toxic Connection: Nonylphenol. Retrieved from <http://www.tvtno.org/the-toxic-connection-nonylphenol>.
3. McGregor, D.B., et al., Evaluation of the carcinogenic risks to humans associated with surgical implants and other foreign bodies - a report of an IARC Monographs Programme Meeting. International Agency for Research on Cancer. *Eur J Cancer*, 2000. 36(3): p. 307-13.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Cleveland Clinic IRB **Helsinki:** Yes **Informed Consent:** No