

## TRANSOBTURATOR SLINGPLASTY USING MULTIFILAMENT MESH IS A RISK FACTOR FOR INCREASED DAYTIME FREQUENCY

### Hypothesis / aims of study

Since 2005, the Anterior IVS (Tyco Healthcare LP, Norwalk, CT), a macroporous, multifilament midurethral sling with a trans-obturator approach, has been the procedure of choice for the treatment of women with stress urinary incontinence in our Department (1). In 2006, following reports on complications of multifilament meshes in POP surgery, Tyco Healthcare changed the tape in their surgical kits into a monofilament mesh and removed all multifilament kits from the shelves of operative theatres in our country (2). We used the kit when it included a multifilament tape, and continued to use it after the manufacturer switched to a monofilament mesh.

The primary objective of this study was to evaluate the incidence and type of late postoperative complications related to Anterior IVS in our patients and to compare multifilament to monofilament mesh in this regard. We expected to detect a difference in incidence and type of complications between the two types of mesh.

As a secondary outcome measure, we compared the two groups as regards objective and subjective outcome for SUI, post-operative quality of life (QoL) and appearance and location of the tape on trans-perineal 3D sonography.

### Study design, materials and methods

Our study had a retrospective design. Since January 2005 until December 2007, 110 patients underwent Anterior IVS in our Department. Patients were contacted and given an appointment for a follow-up visit. Three gynecologists blinded to the date of surgery (and therefore to the type of mesh) interviewed the patients and carried out a urogynecological examination. The interview included general and urogynecological history (except for the date of surgery) and a structured symptom questionnaire regarding lower urinary tract symptoms, vaginal complaints such as foul discharge, dyspareunia or any other change in sexual function. Physical examination included inspection of vulva and groins for abnormal masses; speculum inspection of the vagina for granulation tissue, mesh erosion or abnormal discharge from sinus opening; pelvic examination for detection of pelvic masses (possible abscesses). A cough stress test with a comfortably full bladder (200-400 cc), Q-tip test for urethral hypermobility and POP-Q staging of prolapse degree were carried out.

Post-operative QoL was assessed using the UDI-6 and IIQ-7 questionnaires.

Two gynecologists with specialty in ultrasound, blinded to tape allocation, performed transperineal 3D sonography. The relation of the tape with the bladder neck and the urethra was assessed. 3D-volume analysis was carried out on a computer with the help of proprietary software (GE Kretz 4D View).

According to manufacturer's information, on the 1<sup>st</sup> of April 2006 all multifilament kits were removed from our shelves and replaced by monofilament kits. Patients were thus allocated into 2 groups (group 1: multifilament tape, group 2: monofilament tape) according to the date of surgery. Additional information on pre-operative assessment and on the surgery was obtained from each patient's medical record. Descriptive statistics were mean  $\pm$  standard deviation for parametric continuous variables, median (minimum-maximum) for nonparametric continuous variables and frequency for categorical variables. The Student's t-test was used for comparison of continuous variables between groups. Fisher's Exact test or Chi-square test were used as appropriate for comparison of categorical variables between groups. We considered  $p < 0.05$  to be statistically significant.

### Results

Fifty-nine out of 110 patients (54%) were recruited for this study. Group 1 included 27 patients and group 2 included 32 patients. Mean follow-up was 42.7 months for group 1 and 28.5 months for group 2. No significant difference was found between groups in demographic data, menstrual status, risk factors for SUI recurrence, previous POP surgery, additional procedures done at the time of Anterior IVS, intraoperative and early postoperative complications. The pre-operative prevalence of storage symptoms other than SUI was found to be similar between groups. Pre-operative urodynamic diagnosis was SUI in 76.3% of sample and mixed urinary incontinence (MUI) in 23.7% of patients, with no significant difference between study groups. As regards post-operative symptoms, significantly more patients complained of increased daytime frequency in group 1 (44.4% vs 18.8%,  $p=0.048$ ). Furthermore, we detected a higher rate of post-operative resolution of increased daytime frequency in group 2 (22.2% vs 37.5%,  $p=0.049$ ) and a higher rate of post-operative de-novo frequency in group 1 (29.6% vs 6.3%,  $p=0.049$ ). No difference was detected between groups in any other storage or voiding symptom, nor in the rate of vaginal symptoms, sexual dysfunction or de-novo dyspareunia. One patient in each study group complained about long-lasting anorgasmia following surgery. We observed one case of tape erosion in a patient with a multifilament tape. A trend toward a higher incidence of urethral hypermobility was observed in group 1, but this did not reach statistical significance. Subjective cure or improvement for SUI was observed in 81.5% of group 1 and in 71.9% of group 2. The objective cure rate was 81.5% in group 1 and 78.1% in group 2. We observed no significant difference in outcome between groups. Seventeen patients in group 1 (63%) and 17 patients in group 2 (53%) completed QoL questionnaires. No significant difference was observed between groups in any QoL domain. Twenty-three out of 59 patients (40%) underwent transperineal 3D sonography, 8 patients in group 1 and 15 patients in group 2. No difference was detected between groups in tape to bladder neck and tape to urethra distances at rest, maximum Valsalva or contraction. A small fluid collection in the anterior vaginal wall was observed in 2 cases, one in each study group.

### Interpretation of results

We observed a higher incidence of increased daytime frequency following Anterior IVS using a multifilament as compared to a monofilament tape. Furthermore, in a larger proportion of patients with multifilament tape this symptom appeared de novo and in

more patients with monofilament tape this symptom improved after surgery. Although we did not observe differences in other storage symptoms between groups, we suppose this finding may indicate a greater tendency to overactive bladder following the use of multifilament meshes. Animal studies have shown Amid- type 3, multifilament meshes, such as IVS, to cause significantly more foreign body reaction than monofilament meshes (3). The correlation of such histological findings with defective healing, mesh extrusion and erosion has been widely discussed in the literature. Our findings suggest that post-operative overactive bladder as well may be related to a marked inflammatory reaction in the peri-urethral area.

Concluding message

Multifilament mid-urethral tapes are related to a higher incidence of increased daytime frequency and possibly to de-novo overactive bladder, as compared to monofilament slings. Additional data on a larger sample of patients is required for a definite conclusion.

References

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<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Helsinki Ethics Committee, Assaf Harofe Medical Center</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>