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SAFETY, EFFICACY AND THE IMPACT ON VOIDING FUNCTION OF THE TVM PROCEDURE.

Hypothesis / aims of study

To evaluate the efficacy and safety of a tension-free vaginal mesh (TVM) procedure and its impact on urinary function in patients with symptomatic pelvic organ prolapse (POP).

Study design, materials and methods

We retrospectively reviewed the medical records of 153 patients with POP ≥ stage 3 (ICS classification) who underwent TVM procedure with polypropylene mesh between June 2006 and November 2009 at our institute. The uroflowmetry data before and 3 months after the operation were compared with the Liverpool nomogram [1] to determine centile values (5th, 10th, 25th, 50th, 75th, 90th and 95th centile) for the maximum flow rate in each patient. Urinary symptoms were evaluated at baseline and 3 months post operatively by using International Prostate Symptom Score (IPSS), Overactive Bladder Symptom Score (OABSS) and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF).

Results

The mean age of the patients was 67.8 years (range, 50 – 88) with the mean body mass index of 24.3 ± 3.2 (range, 18.5 – 33.0). 41 patients (26.8%) had undergone hysterectomies. 49 patients (32.0%) underwent an isolated cystocele repair. The mean follow-up period was 10.1 ± 7.2 months (range, 1 - 33). Bladder injury in one patient (0.7%) was the only intraoperative complication. The POP relapse rate was 4.1 % and 6.1 % at 6 months and 12 months, respectively (Fig.1). Late complications included 9 mesh exposures (5.9%), 8 de novo stress urinary incontinences (5.2%), 1 persistent pelvic pain (0.7%) and 1 rectovaginal fistula (0.7%). While the majority of POP recurrence (87.5%) occurred within 6 months, 66.7% of mesh exposures developed after 6 months (Fig.2).

The uroflowmetry results showed that 43.1% of the patients had an impaired peak flow rate (≤ 10th centile in the Liverpool nomogram) at baseline. This number significantly reduced to 16.2% at 3 month post operatively (Fig.3).

All the individual questions in IPSS except for question 7 (number of nocturia) significantly improved after the operation (Fig. 4). The IPSS-QOL score significantly improved from 4.3 to 1.9 ($p<0.001$). OABSS questions 1 (diurnal urinary frequency) and 3 (urgency) also significantly improved (Fig. 5), on the other hand, questions 2 and 4 and all the ICIQ-SF individual scores did not change significantly.

Figure 1

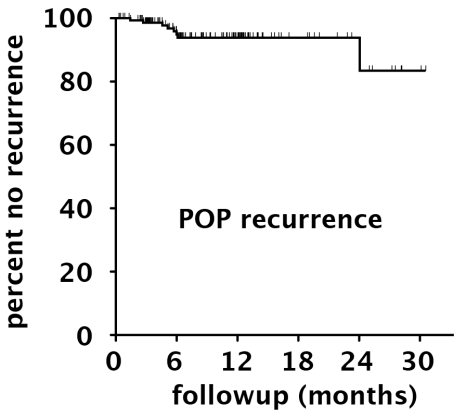


Figure 2

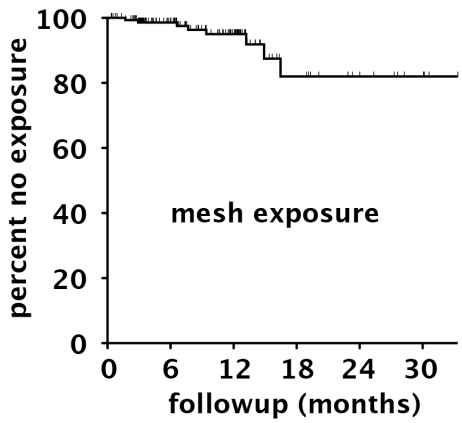


Figure 3 Uroflowmetry results. Proportion of the patient with each centile value of peak flow rate according to the Liverpool nomogram before and 3 months after the operation.

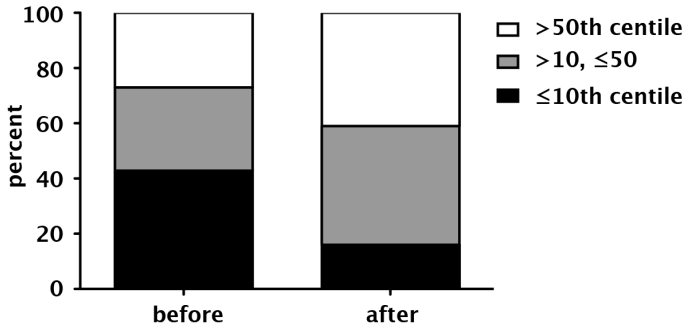


Figure 4

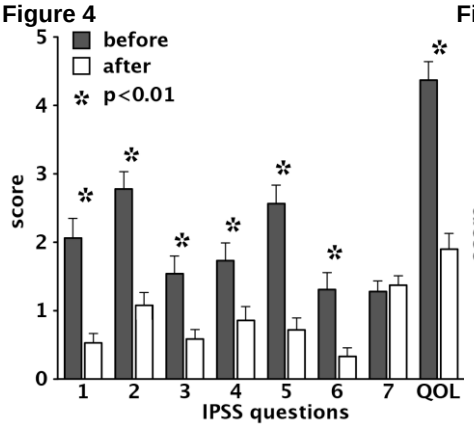
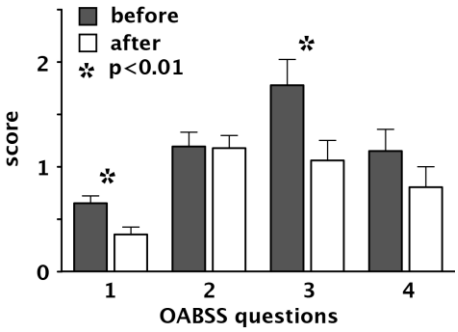


Figure 5



Interpretation of results

The rates of anatomical success and mesh exposures are comparable to other reports. There was one severe mesh-related complication (rectovaginal fistula). More than 40% of the patients had abnormally low urinary flow rate preoperatively. The voiding function and symptoms significantly improved after the operation.

Concluding message

Transvaginal mesh repair of POP is effective and can be carried out with a low incidence of peri- and post-operative morbidity. Subjective and objective improvement of urinary symptoms and voiding difficulties were also achieved. Nevertheless, the possibility of developing a rare but potentially severe mesh-related complication such as rectovaginal fistula should be emphasized.

References

1. Haylen BT, Ashby D, Sutherst JR, Frazer MI, West CR: Maximum and average urine flow rate in normal male and female populations - the Liverpool nomograms. Br J Urol 1989; 64: 30-38

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**retrospective review of a normal clinical practice**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**