

TRANS-PERINEAL PELVIC ORGAN PROLAPSE REPAIR: PRELIMINARY RESULTS WITH SYNTHETIC MESH

Hypothesis / aims of study

The new "tension-free" concept acquired by general surgeons in treating abdominal hernia, and the revolution in the treatment of female Stress Urinary Incontinence (SUI) by the Tension-free Vaginal Tape (TVT) has been translated into Pelvic Organ Prolapse (POP) repair. Recent innovative approaches using prosthetic materials without tension via strips placed through the obturator foramen and the ischioanal fossa with a special device have been introduced. The primary objective of this study is to evaluate the anatomical efficacy and the safety of a new transobturator technique for the correction of medium/high stage POP: the Trans-vaginal Mesh Repair (TVM®). The secondary objective is to define the impact of this procedure on anorectal function, sexuality and Quality of Life (QoL).

Study design, materials and methods

Female patients with POP grade ≥ 2 were enrolled in this study. The pre-operative work up included: history, clinical examination with vaginal profile using POP-Q System, Q-Tip test for urethral hypermobility, conventional urodynamic studies and completion of questionnaires (King's Health Questionnaire, Wexner score for anal incontinence and constipation, and a Sexuality score).

All the patients underwent TVM®: it uses one reusable long curved needle to deliver Prolene® soft (Gynemesh®) anchored by a tension-free velcro effect in the vesico-vaginal, Retzius and para-vesical spaces. There are also two posterior arms positioned apical and distal to the arcus tendineus fascia pelvis(ATFP). In this way it is possible to correct the anterior, apical and posterior segments. 10 patients underwent concomitant vaginal hysterectomy.

The results were analyzed using two statistical tests: T-test and McNemar Chi-squared test.

Results

27 patients were available for this study. The mean age was 59.6 years (range 35-80), median parity was 2 (range 1-5); Body Mass Index (BMI) ranged from 20.03 to 31.25 (mean 24.7; SD 3.27). 20 patients (74.1%) were post-menopausal. 4 patients complained of a recurrent prolapse. 7 patients had undergone previous abdominal hysterectomy and 3 women a previous vaginal hysterectomy. Follow up ranged from 3 to 13 months (mean 9.2 months).

Pre and post-operative symptoms are reported in Table 1.

Table 1 – Pre and post-operative symptoms

Symptoms	Pre-op # (%)	Post-op # (%)	P*
Increased Daytime frequency	9 (33.3)	5 (18.5)	0.34
Urgency	13 (48.1)	5 (18.5)	0.04
Urge Urinary Incontinence	12 (44.4)	4 (14.8)	0.02
Nocturia	4 (14.8)	3 (11.1)	1
Hesitancy	12 (44.4)	3 (11.1)	0.02
Slow stream	17 (62.9)	2 (7.4)	0.0013
Feeling of Incomplete emptying	10 (37.1)	2 (7.4)	0.02
Stress Urinary Incontinence	6 (22.2)	11 (40.7)	0.13
Pelvic pain	4 (14.8)	1 (3.7)	0.24
Dyspareunia	7 (25.9)	5 (18.5)	0.72
Constipation	7 (25.9)	3 (11.1)	0.22
Heaviness	25 (92.6)	3 (11.1)	0.00001

* McNemar Chi-square test

In Table 2 the pre and post-operative vaginal profiles are reported.

Table 2 – Pre and post-operative vaginal profile according to POP-Q system

	Pre-op (%)	Post-op (%)	P*
Aa	18 (66.7)	7 (25.9)	0.009
Ba	25 (92.6)	5 (18.5)	0.00001
C	23 (85.2)	2 (7.4)	0.00001
Ap	19 (70.4)	5 (18.5)	0.0012

* McNemar Chi-square test

Urodynamic data are reported in Table 3

Table 3 – Pre and post-operative urodynamic data

	Pre-op	Post-op	P
First desire to void	30-333 (mean 166.5)	73-379 (mean 166.7)	0.98*

	SD 69.2	SD 70.7)	
Maximum Bladder capacity	100-639 (mean 379.5 SD 93.3)	150-480 (mean 366.5 SD 69.5)	0.61*
Detrusor overactivity	5 (18.5%)	1 (3.7%)	0.22**
Pressure at Maximum flow	15-69 (mean 36.3 SD 13.4)	8-53 (mean 27.4 SD 12.7)	0.01*
Maximum flow	4-36 (mean 11.7 SD 6.9)	3-36 (mean 13.7 SD 9.5)	0.43*
Urodynamic SUI	1 (3.7%)	7 (25.9%)	0.07**

* T-test

** McNemar Chi-square test

Quality of life was significantly improved in almost all domains according to the King's Health Questionnaire, with the exception of Role Limitation, Physical Limitation and Personal Relationships.

The post-operative complications were: vaginal erosion in 9 cases (33.3%), pelvic hematoma in 2 patients (7.4%) and cuff infection in 2 cases (7.4%).

Interpretation of results

The analysis of the results shows a statistically significant anatomical correction of POP in all vaginal segments, with a statistically significant improvement of the storage, voiding and prolapse-related symptoms and a good impact on the Quality of Life. Moreover there were no statistically significant variations in sexuality and or anorectal function. The rate of vaginal erosions is still too high but in 6 of the 10 patients in which this complication appeared, a vaginal hysterectomy was associated.

Concluding message

The study demonstrates that this procedure is effective in the correction of medium/high stage POP, both anatomically and functionally, with a good impact on the quality of life. Our study confirms, as reported elsewhere, that the preservation of the uterus is an important element in reducing the incidence of vaginal erosions, the most important side-effect related to prosthetic mesh placement, without interfering with the anatomical results of this operation.

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HUMAN SUBJECTS: This study did not need ethical approval because the technique has already been approved and is commercially available but followed the Declaration of Helsinki Informed consent was obtained from the patients.