

COMPLICATIONS AND LONG-TERM RESULTS OF TWO DIFFERENT TRANS-OBTURATOR TECHNIQUES FOR SURGICAL TREATMENT OF WOMEN WITH URINARY INCONTINENCE: A RANDOMIZED STUDY FOLLOW-UP

Hypothesis / aims of study

In 2007, we conducted a randomized study in which we analysed peri-operative complications and short-term results of two different trans-obturator techniques for surgical treatment of women with stress (SUI) or mixed urinary incontinence (MUI): the inside-out trans-obturator vaginal tape (TVT-O) and the outside-in (Monarc) approach. Study included 120 women who were operated between January 2005 and June 2007 and treatment results were evaluated 3 months after the procedure. Although both procedures were equally successful, we found out that the inside-out procedure was associated with more pain and longer duration of pain after the procedure [1]. However, the study only included the short-term results of both approaches. The aim of our follow-up study was to evaluate the long-term results and patients' satisfaction with the procedure, and to compare the successfulness of both trans-obturator techniques for SUI treatment.

Study design, materials and methods

Women (N=120) who participated in our randomized study from 2007 were included in this follow-up study. They were invited to a check-up via regular mail and also received a voiding diary, incontinence impact questionnaire (IIQ) and urogenital distress inventory (UDI), which they filled out. In each patient, a detailed history, basic gynaecological examination, pelvic organ prolapse (POP) evaluation using POP quantification system (POP-Q), gynaecological ultrasound, Q-tip test, pad test, and uroflowmetry were performed.

Statistical analysis was performed using SPSS Statistics Programme 21.0. Descriptive statistics were calculated on basic patients' characteristics. Non-parametric Mann-Whitney U test and Wilcoxon signed ranks test were used for comparisons between and within groups, respectively. Pearson's Chi square was used to compare categorical data between groups. Statistical significance was set at $p < 0.05$.

Results

We examined 38 out of 120 women (31.6%), 25 of them underwent Monarc and 13 TVT-O procedure. Their average age at the time of the operation was 51.3 ± 7.9 years (range 34-70 years) and 62.1 ± 7.9 years (range 45-80 years) at the time of the check-up. Their average body mass index (BMI) was 28.8 kg/m^2 (range 20.3-40.4 kg/m^2). 89.2% were menopausal and 78.9% had accompanying medical issues, most commonly arterial hypertension, diabetes mellitus, hyperlipidaemia and lumbalgia. 31.6% had a history of another gynaecological operation, hysterectomy being the most common. Only one patient needed another continence procedure (mini sling approximately 9 years after the original operation). None of the patients used local hormone therapy and 7.9% used some form of hormone replacement therapy in the past. 39.5% had another urogynaecological issues after the procedure, most commonly overactive bladder disorder and recurrent bladder infections. Average time from the procedure was 3932.1 ± 102.7 days (10.7 years) (range 3746-4084 days). There were no statistically significant differences in these parameters between the Monarc and TVT-O group (tables 1 and 2).

Table 1: Comparison of some numerical clinical parameters between groups

Parameter	Monarc	TVT-O	p-value
Average age at the time of the procedure [years]	50.4 ± 7.1	53.1 ± 9.3	0.329
Average age at the time of the check-up [years]	61.1 ± 7.2	63.9 ± 9.2	0.286
Average time from the procedure [days]	3931.7 ± 108.8	3932.9 ± 94.2	1.000
Average BMI [kg/m^2]	29.2 ± 4.9	27.9 ± 4.7	0.627

Table 2: Comparison of some categorical clinical parameters between groups

Parameter	Monarc		TVT-O		p-value
	Yes	No	Yes	No	
Menopause	92.0%	8.0%	83.3%	16.7%	0.819
Accompanying medical issues	84.0%	16.0%	69.2%	30.8%	0.522
Another gynaecological procedure	32.0%	68.0%	30.8%	69.2%	1.000
Local hormone therapy	0.0%	100.0%	0.0%	100.0%	1.000
Hormone replacement therapy	12.0%	88.0%	0.0%	100.0%	0.505
Another urogynaecological issues after the procedure	40.0%	60.0%	38.5%	61.5%	1.000

Patients evaluated success of the treatment on a scale from 0% (no improvement) to 100% (complete satisfaction with the results). Average satisfaction rate 3 months after the procedure in the original study was $90.1 \pm 17.8\%$ (range 35-100%) and $83.7 \pm 28.9\%$ (range 0-100%) at the second check-up. For Monarc, satisfaction rates were $89.0 \pm 19.6\%$ and $85.7 \pm 28.4\%$, and for TVT-O $92.3 \pm 13.4\%$ and $79.8 \pm 30.7\%$, respectively. There were no statistically significant differences between average satisfaction scores on the first and second check-up overall (p -value=0.141) or for each procedure (p -value 0.684 for Monarc and 0.051 for TVT-O), or satisfaction scores between Monarc and TVT-O at the first and second check-up (p -values 0.671 and 0.361, respectively).

Of all women, 69.4% still had sexual intercourses and only one in Monarc group reported dyspareunia. 69.7% of all women did not need to use any pads; the average number of used pads per day was 0.8 ± 1.6 . Average number of daytime voids was 6.5 ± 2.6 and 1.6 ± 1.2 for night voids. Average stress pad test value was 3.1 ± 13.7 grams and 89.5% of women had negative stress pad test. Average Q-tip angle during Valsalva manoeuvre was $36.7^\circ \pm 22.2^\circ$, average mean and maximal flow during uroflowmetry $9.3 \text{ mL} \pm 3 \text{ mL}$ and $19.0 \text{ mL} \pm 9.7 \text{ mL}$, respectively, and average post-voiding residual volume $15.3 \pm 22.8 \text{ mL}$. There was no statistically significant difference between groups for these parameters as there was no significant difference in prevalence of unrecognised bladder infection defined by positive urine culture between groups. There was no vaginal erosions found during clinical examination.

Interpretation of results

Surgical treatment of SUI using different types of slings has become a subject of debate and controversy in the last couple of years. This is why the aim of our study was to evaluate the success of this kind of treatment and to compare the results of two different trans-obturator techniques for SUI treatment.

According to our results, both procedures seem to be equally successful. 71.7% of all patients evaluated the success of the treatment approximately 10 years after the procedure as 85% or higher. Some cases of lower success rate seem to be the consequence of the fact that patients might misinterpret symptoms of overactive bladder and urgency or unrecognised bladder infection as a failure of the procedure. The latter was also one of the most common reasons for dissatisfaction at the check-up and was appropriately treated after the diagnosis.

There was only one case of dyspareunia, no cases of vaginal erosions found and vast majority of women had negative stress PAD test. This suggests that both techniques represent an effective method of SUI treatment.

However, so far we have managed to examine only 31.6% of all patients. By the time of the presentation, we plan to achieve the response rate of at least 80%, which will enable us to present more accurate and reliable results. Then we will also be able to add IIQ and UDI results and to identify possible independent prognosticators for failure of the procedure. Results of the procedure regarding the ultrasonic position of the sling compared to total urethral length will also be presented.

Concluding message

According to our preliminary results, both trans-obturator techniques for SUI and MUI treatment had high success and low complication rate. Further inclusion of the rest of the patients will confirm whether these findings can be applied to the whole cohort. At the end, this will be to our knowledge a randomized controlled study with one of the longest follow-up periods performed so far, and we believe that it will be of great contribution to further urogynaecological practice.

References

1. But I, Faganelj M. Complications and short-term results of two different transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:857-61.

Disclosures

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