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GENERAL GYNECOLOGY

Transobturator adjustable tape (TOA) in female stress urinary incontinence associated with low maximal urethral closure pressure

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Abstract
Purpose To determine the success rate of transobturator adjustable tape (TOA, Agency for Medical Innovations, A.M.I., Austria) in stress urinary incontinent patients with maximal urethral closure pressure (MUCP) $\leq$20 cm H_2O compared to those with MUCP >20 cm H_2O.
Materials and methods In this retrospective study, all female patients with a diagnosis of stress urinary incontinence underwent TOA, from September 2005 to August 2007. All patients had preoperative multichannel urodynamic tests (cystometry, urethral profile and uroflowmetry). During September 2008, patients were contacted by telephone and the validated short forms of the Urogenital Distress Inventory (UDI-6) questionnaire and the Incontinence Impact Questionnaire (IIQ-7) were administered.
Results The chart review identified 146 patients (125 with MUCP >20 cm H_2O and 21 with MUCP $\leq$20 cm H_2O) who had undergone TOA and who met the inclusion criteria. Of these, 121 patients (82.9%) were contacted by telephone. Results showed a very good quality of life (score 0–7 in the IIQ-7) in 95.9% of patients. Only two (1.6%) patients had persistent significant urine leakage related to physical activity. In the MUCP $\leq$20 cm H_2O group, 90% of patients could be considered as being very satisfied, with a very good quality of life.
Conclusion With the TOA procedure, the obturator route could be used to treat patients with urinary incontinence and also with low MUCP.

Keywords Stress urinary incontinence · Transobturator tape · Adjustable tape · Intrinsic sphincter deficiency

Introduction

Stress urinary incontinence is caused by abnormalities of the urethra, such as loss of anatomic support (hypermobility) or impaired sphincter functioning due to loss of elasticity and coaptation [1].

Incontinence caused by insufficient functioning of the intrinsic sphincter is called intrinsic sphincter deficiency (ISD) [2]. ISD was first described in 1992 by the Urinary Incontinence Guideline Panel [3], and has been defined by urethral closure pressure, leak point pressure or an open bladder neck at rest in the absence of a bladder contraction on videourodynamics.

Some authors have demonstrated that leakage pressure during Valsalva maneuver (Valsalva leak point pressure) is a reliable method for evaluation of the urethral sphincteric mechanism and, therefore, for diagnosis of intrinsic urethral sphincteric deficiency [1].

Another form of sphincter evaluation is through urethral pressure profile, in which some parameters, such as maximal urethral closure pressure (MUCP), functional length and abdominal transmission pressure to the urethra, are obtained. Maximum urethral closure pressure is the highest pressure generated along the length of the urethra above

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baseline intravesical pressure, and has been used to represent the urethra's ability to resist leakage. Several authors have demonstrated that values of <20 cm H_2O of MUCP would be suggestive of sphincteric defect [4, 5].

Women with low urethral closure pressure have been associated with an increased failure of surgical procedures to correct urinary stress incontinence [6, 7].

Some authors have proposed adjustable slings in women with intrinsic urethral sphincteric deficiency. In 2006, Romero et al. [8] presented a new suburethral transobturator sling (TOA, Agency for Medical Innovations, A.M.I., Austria) that allows tension adjustment up to several days after surgery, thus facilitating the correction of defects or excesses incurred during the operation.

The aim of this study was to determine the success rate of TOA in stress urinary incontinent patients with MUCP $\leq$20 cm H_2O compared to those with MUCP >20 cm H_2O.

Materials and methods

In this retrospective study, we included all female patients with a diagnosis of stress urinary incontinence who underwent TOA, from September 2005 to August 2007.

The inclusion criteria were:

- mentally competent patients (able to understand all study requirements);
- agreeing to be available for the follow-up examinations required by protocol;
- persistent incontinence for >6 months before surgery;
- preoperative negative urine culture;
- standard preoperative evaluation consisting of history, physical examination and multichannel urodynamic tests (cystometry, urethral profile and uroflowmetry);
- urethral hypermobility >30° (confirmed by perineal ultrasound evaluation).

Operative technique

The TOA procedure uses a special tape, made of a type I non-absorbable monofilament polypropylene. The tape inserts two groups of polypropylene threads. The first group comprises two threads located laterally at 1.5 cm from the mesh midline. These are exteriorized through the anterior vaginal surface and used to reduce tension. The second group in turn consists of three threads in each branch of the mesh, located at a distance from the midline. These are exteriorized when the mesh emerges to the exterior and allow increased tension of the mesh.

The other specific item of equipment is a reusable helicoidal stainless steel tunneler. The helicoidal tunnelers are paired instruments, specific to the left and right sides.

Surgical technique

The anterior vaginal wall was suspended with two Allis clamps on either side of the midline, 0.5 cm proximally to the urethral meatus. A vertical midline incision of the vaginal wall was performed. Using scissors, dissection of the para-urethral space was made bilaterally. The external tunneler entry point was made in the genito-femoral fold and the helicoidal tunneler was introduced. Once the tunneler passed through the obturator membrane, it reached the fingertip inserted in the para-urethral space. The tape was then connected to the tunneler. Next, with a rotating wrist motion, the tape was guided through the tunnel and exited the skin incision. The same procedure was carried out on the contralateral side. Then the two threads per side, located laterally at 1.5 cm from the mesh midline, were crossed and exteriorized through the anterior vaginal surface, while the three threads in each branch of the mesh were exteriorized through the cutaneous incisions.

Postoperative evaluation

On the day after surgery, or later if required by the patient's condition, we assessed the mictional situation as follows:

1. The bladder was filled with 250 ml of saline solution.
2. The patient was instructed to cough in decubitus, in the standing position and while walking.

In the event of leakage, we tightened the suprapubic threads by about 0.5 cm. The exploration was then repeated until continence was confirmed in all three situations (decubitus, standing and walking).

3. Then the postvoiding residue was measured. In the presence of residue >100 ml, the mesh was loosened by pulling approximately 0.5 cm upon one of the vaginal threads. Continence was then checked and residue measurement was repeated.

When the patient was continent in all the situations and no residue was observed, the threads were sectioned and extracted and the patient was discharged.

Outcomes

The following variables were assessed for each group: intra and postoperative complications (hemorrhages, episodes of dysfunctional voiding, urinary tract or wound infections), time of catheter removal and length of hospital stay.

At 3 months postsurgery, patients had a follow-up visit, including a detailed interview by the surgeon and a clinical examination. Outcomes considered were postoperative complications, such as vaginal erosion and infections.

Do you experience, and if so, how much are you bothered by:

1. Frequent urination?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
2. Urine leakage related to physical activity, coughing, or sneezing?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
3. Small amounts of urine leakage (drops)?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
4. Difficulty emptying your bladder?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
5. Pain or discomfort in the lower abdominal or genital area?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly

6. Quality of life due to urinary problems

If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?

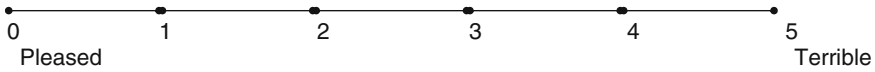

Fig. 1 Short form of the Urogenital Distress Inventory (UDI-6) questionnaire (English version)

During September 2008, patients were contacted by a single gynecologist. At this telephone follow-up, the validated short forms of the Urogenital Distress Inventory (UDI-6) questionnaire (Fig. 1) and Incontinence Impact Questionnaire (IIQ-7) (Fig. 2) [9] were administered by telephone.

Cure was defined as the absence of involuntary urine loss, requiring a score of 0 in the second question of the UDI-6 and an associated 0 score in the third questions of the UDI-6 (no urine leakage related to urgency and no urine leakage related to physical activity).

Failure was defined as a score of 2–3 in the second question of the UDI-6 and an associated score of 2–3 in the third questions of the UDI-6.

Statistical analysis

Data were analyzed by using the Student's *t* test and the Fisher's exact test. All calculations were performed using the SPSS software package (release 10.0.5, SPSS Inc., Chicago, IL, USA). A *p* value of less than 0.05 was considered to be statistically significant.

Results

The chart review identified 146 consecutive female patients with a diagnosis of stress urinary incontinence who had undergone TOA (AMI) and who met the inclusion criteria.

Evaluation of preoperative urodynamic tests identified two patient subsets: patients with MUCP >20 cm H_2O ($n = 21$) and patients with MUCP ≤20 cm H_2O ($n = 125$).

The characteristics of the two groups are shown in Table 1. As much as 26 (20.8%) of the 125 patients in the MUCP >20 cm H_2O group versus 11 (52.4%) of the 21 patients in the MUCP ≤20 cm H_2O group had already undergone pelvic surgery, as shown in Table 1. Most of the previous pelvic surgeries were hysterectomies, either transvaginal or transabdominal, with or without a concomitant anti-incontinence procedure (usually anterior repair with Kelly's plication or Burch colposuspension) performed at the same time.

Types of anesthesia used during surgery are presented in Table 2.

1. Over the past month, has urinary incontinence and/or pelvic prolapse affected your ability to do household chores (cooking, housecleaning, laundry, etc.)?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
2. Over the past month, has urinary incontinence and/or pelvic prolapse affected your physical recreation such as walking, swimming, or other activities?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
3. Over the past month, has urinary incontinence and/or pelvic prolapse affected your ability to attend entertainment activities (movies, concerts, etc.)?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
4. Over the past month, has urinary incontinence and/or pelvic prolapse affected your ability to travel by car more than 30 minutes from home?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
5. Over the past month, has urinary incontinence and/or pelvic prolapse affected your participation in social activities outside your home?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
6. Over the past month, has urinary incontinence and/or pelvic prolapse affected your emotional health (nervousness, depression, etc.)?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly
7. Over the past month, how many times has urinary incontinence and/or pelvic prolapse made you feel frustrated?	❑ (0)Not at all ❑ (1)Slightly ❑ (2)Moderately ❑ (3)Greatly

Fig. 2 Short form of the Incontinence Impact Questionnaire (IIQ-7) (English version)

Table 1 Patients characteristics

	MUCP >20 cm H_2O	MUCP ≤20 cm H_2O	Total
Number of patients	125	21	146
Age	57.8 (36–76)	62.7 (43–80)	59.6 (36–80)
Parity	2.2 (0–4)	2.2 (0–3)	2.2 (0–4)
MUCP	54.8 (23–155)	18.7 (10–20)	50.4 (10–155)
Previous urinary and/or gynecological surgery:	26 (20.8%)	11 (52.4%)	37 (25.3%)
Hysterectomy	20	7	27
Burch	1	3	4
TVT	1	0	1
Others	4	1	5

MUCP Maximal urethral closure pressure

Table 2 Types of anesthesia

	MUCP >20 cm H_2O (n = 125)	MUCP ≤20 cm H_2O (n = 21)	Total (n = 146)
Spinal anesthesia	67	14	81
Sedation + local anesthesia	58	7	65

Intraoperative complications are shown in Table 3. There were two cases of hemorrhage with loss of ≤300 ml. No transfusions were required. All hemorrhages were classically treated simply by tamponade. There was one case of bladder lesion during needle passage. In this case, we only removed the sling, and 5 days later removed the catheter, without consequences. No lesions of the obturator nerves or vessels occurred. No patient needed to practise self-catheterization after being discharged. No tape excisions were necessary.

Depending on postoperative evaluation, we had to tighten the suprapubic threads in five patients (4 in the MUCP ≤20 cm H_2O group and 1 in the MUCP >20 cm H_2O group) who were still incontinent, and loosen the mesh by pulling the vaginal threads in 12 patients (8 in the

Table 3 Intraoperative complications, catheter time and length of hospitalization

	MUCP >20 cm H_2O (n = 125)	MUCP ≤20 cm H_2O (n = 21)	Total (n = 146)
Bladder lesions	1	0	1
Obturator nerves or vessels lesions	0	0	0
Intraoperative hemorrhage with loss <300 ml	2	0	2
Catheter time (days)	1.4	1.4	1.4
Length of hospitalization (days)	1.8	1.9	1.8

MUCP ≤20 cm H_2O group and 4 in the MUCP >20 cm H_2O group) with a residue >100 ml.

At 3 months after surgery, 132 patients (90.4%) had a follow-up visit, including detailed interviews by the surgeon plus clinical examinations. There were two cases of extrusion, treated with local antibiotics and estradiol, but no tape excisions were required. None of the patients developed fistula.

A total of 121 patients (82.9%) were contacted by telephone for a second follow-up (average 19 months, range: 13–36 months), using the validated short forms of the UDI-6 and IIQ-7 questionnaires. Results showed a very good quality of life (score 0–7 in the IIQ-7) in 95.9% of patients (Table 4): 97.0% of patients in MUCP >20 cm H_2O group and 90% of patients in MUCP ≤20 cm H_2O group (p = 0.628).

Eight patients reported significant urine leakage related to urgency [3 (2.9%) patients in the MUCP >20 cm H_2O group and 5 (25%) patients in MUCP ≤20 cm H_2O group (Table 5)], but there was no significant difference between these two groups. More patients in the MUCP >20 cm H_2O group were urge incontinence free (score 0 at the UDI-6 second questions) compared to women in the MUCP ≤20 cm H_2O group (p = 0.009). In addition, women in the MUCP ≤20 cm H_2O group had more symptoms of frequent urination compared to those in the MUCP >20 cm H_2O group (p = 0.007).

Only two (1.6%) patients had persistent significant urine leakage related to physical activity at the time of the telephone follow-up (Table 6).

Severe voiding dysfunction occurred in only two patients (Table 7). Of these patients, one was in the MUCP >20 cm H_2O group and one in the MUCP ≤20 cm H_2O group, with no statistical significance.

Table 4 Follow-up at 19 months (13–36 months): the global results of the UDI-6 and of the IIQ-7 questionnaires

	MUCP >20 cm H_2O	MUCP ≤20 cm H_2O	p value	Total
No. of patients who answered the questionnaire (n)	101/125 (80.8%)	20/21 (95.2%)	0.218	121/146 (82.9%)
QoL score (IIQ-7)				
0–7	98 (97.0%)	18 (90.0%)	0.628	116 (95.9%)
8–14	2 (2.0%)	2 (10.0%)	0.764	4 (3.3%)
15–21	1 (1.0%)	0		1 (0.8%)

Table 5 Follow-up at 19 months (13–36 months): urgency symptoms and urge incontinence

	MUCP >20 cm H_2O	MUCP ≤20 cm H_2O	p value	Total
No. of patients who answered the questionnaire (n)	101/125 (80.8%)	20/21 (95.2%)	0.218	121/146 (82.9%)
Frequent urination (UDI-6 first question)				
0	50 (49.5%)	3 (15.0%)	**0.003**	53 (43.8%)
1	49 (48.5%)	11 (55.0%)	0.134	60 (49.6%)
2–3	2 (2.0%)	6 (30.0%)	**0.007**	8 (6.6%)
Urine leakage related to urgency (UDI-6 second question)				
0	73 (72.3%)	9 (45.0%)	**0.009**	82 (67.8%)
1	25 (24.8%)	6 (30.0%)	0.128	31 (25.6%)
2–3	3 (2.9%)	5 (25.0%)	0.061	8 (6.6%)

Significant p values < 0.05 are indicated in bold characters

Table 6 Follow-up at 19 months (13–36 months): stress incontinence

	MUCP >20 cm H_2O	MUCP ≤20 cm H_2O	*p* value	Total
No. of patients who answered the questionnaire (*n*)	101/125 (80.8%)	20/21 (95.2%)	0.218	121/146 (82.9%)
Urine leakage related to physical activity (UDI-6 third question)				
0	97 (96.0%)	16 (80.0%)	0.085	113 (93.4%)
1	3 (3.0%)	3 (15.0%)	0.096	6 (5.0%)
2–3	1 (1.0%)	1 (5.0%)	0.214	2 (1.6%)

Table 7 Follow-up at 19 months (13–36 months): voiding dysfunction

	MUCP >20 cm H_2O	MUCP ≤20 cm H_2O	*p* value	Total
No. of patients who answered the questionnaire (*n*)	101/125 (80.8%)	20/21 (95.2%)	0.218	121/146 (82.9%)
Difficulty in emptying the bladder (UDI-6 fifth question)				
0	85 (84.2%)	16 (80.0%)	0.628	101 (83.5%)
1	15 (14.8%)	3 (15.0%)	0.731	18 (14.9%)
2–3	1 (1.0%)	1 (5.0%)	0.852	2 (1.7%)

Discussion

The primary goal of the present study was to assess the success rate of the new suburethral transobturator sling TOA for treatment of stress urinary incontinence in patients with low maximal urethral closure pressure (MUCP ≤20 cm H_2O) compared to those with MUCP >20 cm H_2O.

Intrinsic sphincteric deficiency is considered as a significant risk factor for surgical success [10]. Blaivas and Jacobs [11] and McGuire et al. [12] have reported success rates of 80–85% in women undergoing a pubovaginal sling procedure for ISD. Rezapour et al. [13] reported 74% cure rate in women with an MUCP at rest of <20 cm H_2O treated with TVT.

The transobturator route technique was put forward by Delorme [14] as a useful alternative to the retropubic route to limit the risks of vesical, bowel and vascular wounds. A recent review of literature confirms the safety and efficacy of transobturator urethral slings in the treatment of stress urinary incontinence [15]. In our series, we were able to observe three cases of surgical morbidity (one bladder lesion and two hemorrhages) and only two (1.4%) vaginal erosions. In literature, the frequency of vaginal erosion after suburethral sling is variable, dependant on the tape material. Spinosa and Dubuis [16] had recently reported a 2.5% of tape erosion using a non-woven 5% polypropylene tape. In our series, we used TOA tape, made of non-absorbable monofilament polypropylene, the same material as the TVT. The quality and longevity of this material may explain the low percentage of erosion observed.

Surgical outcome is usually defined subjectively, depending on the presence, frequency or number of episodes of stress incontinence [17]; others also include those with urge incontinence as failures [11]. We chose to assess patients subjectively by asking them to express their satisfaction level via two validated questionnaires: the UDI-6 and the IIQ-7 [9]. Lemack and Zimmern [18] published the results of their study on the predictability of urodynamic findings based on UDI-6, and concluded that the UDI-6 provides predictive information regarding urodynamic findings in women. Blanc et al. [19] in 1999 assessed the contributions of the UDI-6 and IIQ-7 questionnaires in the evaluation of surgical SUI patients. Their results showed that the two questionnaires allowed greater accuracy in assessing the patient's postoperative state.

Regarding the UDI-6 questionnaire results, we divided the questions in relation to urinary symptoms:

- The first and second questions discuss urgency symptoms and urge incontinence, respectively; we have collected these results in Table 7. In our series, women with ISD had more frequent urination than those with MUCP >20 cm H_2O. Moran et al. [20] reported a 3–15% incidence of de novo urge incontinence for the TVT. We investigated urinary leakage related to urgency with the UDI-6 second question and found eight women (6.6%) who reported having significant urge incontinence, and there were no significant differences between the MUCP >20 cm H_2O and the MUCP ≤20 cm H_2O groups. Our results encompass urge incontinence in general, not only

de novo urge incontinence, since no UDI-6 questionnaire results were obtained pre-operatively.

- The third question is about stress incontinence (Table 6). We found only one woman who had significant leakage of urine during physical activity. Segal et al. [21], in their recent publication, defined "cure" as the subjective resolution of SUI without development of voiding dysfunction or de novo urge incontinence. They reported a 77.3% cure rate in women with ISD without urethral hypermobility and 81.3% cure rate in women with ISD and urethral hypermobility. Ghezzi et al. [22] recently reported a 91.4% objective cure rate for stress incontinence in a study involving 35 patients with both low closure pressure and leak point pressure. If we consider only persistent severe stress incontinence as failure, we have only 5% of failed women in the ISD group and, consequently, 95% of cured–improved women.
- The fourth question inquires about small amounts of urinary leakage, but in our experience the women did not understand this question, and their answers were more closely related to questions 2 and 3. Because of patient confusion, we did not report these results.
- The fifth question is about voiding dysfunction (Table 7). Recently, Barry et al. [23] conducted a prospective study involving 83 women with urodynamic stress incontinence who underwent insertion of the Monarc transobturator tape. Postoperatively, four women (4.8%) had objective voiding dysfunction, but the authors concluded that this value was not statistically significant from the pre-operative ones. Ghezzi et al. [22] reported postoperative urinary voiding difficulties in 25.7% of women with ISD treated with TVT. In the present study, only one patient in the MUCP $\leq$20 cm H_2O group had voiding dysfunction with long-term follow-up.
- The sixth question is about pain, but in our results no women reported pain at the long-term follow-up.

The IIQ-7 questionnaire evaluates the quality of life in women with urinary incontinence. This QoL questionnaire involves seven questions, which can be answered on a scale between 0 (incontinence does not influence quality of life) and 3 (incontinence greatly influences quality of life); the global score is between 0 (very good quality of life) and 21 (bad quality of life). We divided the global score into three groups:

- 0–7, very good quality of life; the patient is considered to be very satisfied;
- 8–14, selective quality of life improvement; the patient is considered to be satisfied;
- 15–21, bad quality of life; the patient is considered to be dissatisfied.

In our series, 90% of patients in MUCP $\leq$20 cm H_2O group could be considered as being very satisfied, with a very good quality of life.

This study has a number of limitations. It is a retrospective study and there were a relatively small number of subjects who met the criteria for the MUCP $\leq$20 cm H_2O group. Our series has not been objectively assessed, since postoperative evaluation was based only on subjective telephone questionnaires. The questionnaires were administered only at the postoperative follow-up and had no preoperative comparison scores. However, the two questionnaires provide information for long-term follow-up; they analyze urgency, urinary incontinence, voiding dysfunction, pain and quality of life.

In conclusion, our results show that there is a low percentage of failure in women with low maximal urethral closure pressure treated with the TOA procedure. With this adjustable sling, the obturator route could be an excellent, reliable method of treating patients with urinary incontinence due to MUCP $\leq$20 cm H_2O.

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