

Original Article

Is transobturator suburethral sling effective for treating female urodynamic stress incontinence with low maximal urethral closure pressure?

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Abstract

Objective: To assess retrospectively the efficacy and safety of MONARC (American Medical Systems) transobturator suburethral slings in the treatment of female urodynamic stress incontinence with and without low maximal urethral closure pressure (MUCP).

Materials and Methods: Seventy-three women with urodynamic stress incontinence, fitted with the transobturator suburethral sling at a medical center in central Taiwan, participated in the study. Objective postoperative evaluations, including a 1-hour pad test, cough stress test, uroflowmetry, and residual urine volume, were conducted 6 months after operation. Subjective outcomes were evaluated by telephone interview. Charts were reviewed for perioperative complications, urinary retention, and requirements for postoperative medication for symptoms of urgency. The mean follow-up was 48 months.

Results: Objective cure rate was 80.8% (dry pad test and negative stress test), 82.4% for MUCP less than 30 cmH₂O, and 80.4% for MUCP greater than 30 cmH₂O ($p = 1.000$). Mean pad weight gain changed from 25.8 g preoperatively to 1.8 g postoperatively ($p < 0.05$). There was no significant change in urinary flow rate or residual volume. Subjectively, 98.6% of subjects experienced complete improvement; only one patient found no improvement. Very few perioperative complications occurred. Immediate postoperative difficulty in voiding occurred in 6.8% of patients. Postoperative *de novo* urgency was 2.7%.

Conclusions: The MONARC transobturator suburethral sling is a safe and highly effective treatment for stress urinary incontinence even in women with low MUCP at a mean follow-up of 48 months. Evaluation of the outcomes after a longer follow-up period is necessary.

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Keywords: Female stress urinary incontinence; Maximal urethral closure pressure; Transobturator suburethral sling; Urodynamic stress incontinence

Introduction

The surgical treatment of urodynamic stress incontinence (USI) because of urethral hypermobility has changed radically since the introduction of the tension-free vaginal tape (TVT) procedure first described by Ulmsten and Petros [1] in 1995. Although TVT is effective, with success rates ranging from 84% to 95% [2–5], the retropubic placement of suburethral slings has been associated with a variety of intra- and

postoperative complications, including major blood vessel injuries and perforations of the bladder, bowel and urethra [5]. In addition, postoperative voiding difficulties are fairly common, with transient urine retention rates of between 8% and 17% [6–8]. Urgency also developed in 5–15% of subjects [7–10]. These complications appear to be related to the passage of metallic sling trocars through the retropubic space. In 2001, a new surgical approach was described by Delorme [11], where the needle passers run the sling through the obturator foramen. The retropubic space is avoided, and a V-shaped hammock of support is created for the urethra, rather than the U-shaped urethral suspension of TVT. Ninety percent of Delorme's patients were cured, without perioperative complications and postoperative voiding difficulties. To date, very few articles

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have reported the outcome of transobturator suburethral sling for intrinsic sphincter deficiency. Patients with intrinsic sphincter deficiency are often more difficult to cure by surgery; the cure rates of 74% obtained using the TVT procedure appear to be equivalent to those achieved through traditional incontinence operations [11]. The aim of this study is to evaluate and report on the safety and efficacy of the transobturator suburethral approach using the MONARC transobturator suburethral sling for the treatment of USI; additionally, because the grades of intrinsic urethral sphincter deficiency were determined by maximal urethral closure pressure (MUCP) values in our hospital, we would like to know if patients with low MUCP (<30 cm H₂O) would suffer a worse outcome.

Materials and methods

From March 2004 to August 2005, 80 consecutive patients with USI underwent the transobturator suburethral sling technique (MONARC, American Medical Systems). All of the women who were confirmed with USI were candidates for inclusion. Patients with predominant urge incontinence, urodynamic detrusor overactivity, previous failed incontinence surgery, or loss of follow-up were excluded. All patients included had been indicated for surgical treatment of their USI with or without a concomitant reconstructive procedure. Patients with MUCP less than 20 cm H₂O were diagnosed with intrinsic urethral sphincter deficiency or USI Type III according to International Continence Society. However, very few patients had MUCP less than 20 cmH₂O, so we adopted the method of de Tayrac et al [12], who also grouped patients with a cut off value of MUCP less than 30 cmH₂O for special occasions. Although this grouping does not follow the International Continence Society standard, the observations of the grouped patients remain valuable.

The preoperative evaluation included a medical history, urogynecologic examination (pelvic examination and genital prolapse examination), Q-tip test, cough provocation stress test, 1-hour pad test, a voiding diary kept for at least 2 weeks, and urodynamics. An assessment of postoperative efficacy and safety was conducted at 1, 6, and 12 months. Postoperative uroflowmetry, residual urine, urine sediment analysis, the 1-hour pad test, and cough provocation stress test were performed 6 months postoperatively. Subjective cure evaluations were all performed in August 2008 simultaneously (the mean postoperative time for the telephone interview was 48 months, ranging from 42.1 months to 60.6 months) by telephone interview and a cure was defined as the absence of any subjective complaint of urine leakage; patients were considered to have improved when the number of their stress incontinence episodes were said to have been reduced by half. Patients who still had a subjective complaint of leakage were considered failures. We defined “objectively cured” as a patient who had a negative stress test and dry pad test. Postoperative voiding difficulty was defined as residual urine of more than 100 mL, any experience of hesitancy in voiding, weak stream or a discontinuous flow, or an amount of postvoid residual more than two-thirds of that from self-voiding. All of the patients were also asked to assess

their own postoperative voiding function through the use of a voiding diary.

Patients were also asked to rate their overall satisfaction with the surgical outcome as being: very satisfied, moderately satisfied, not very satisfied, or not at all satisfied.

All of the patients were operated on according to the MONARC technique described by Dargent et al [10]. All of the procedures were carried out under general anesthesia in the lithotomy position. A Foley catheter was inserted to empty the bladder completely, and a 2-cm incision was made along the anterior vaginal mucosa and 0.5 cm below the urethral meatus. For the concomitant reconstructive procedure, the MONARC procedure was performed after the vaginal hysterectomy and anterior vaginal repair. Cystoscopy was performed in the initial 10 cases but was thereafter abandoned because there were never any signs of bladder injury during follow-up. Forceps were placed between the mesh and the urethra to adjust the mesh tension, leaving a gap of approximately 3–5 mm between the urethra and the mesh. The excess tape was cut off at the skin incision. The vaginal incision was closed with interrupted sutures of gradually absorbable thread.

A urinary catheter was inserted before the MONARC implant and removed on the day following surgery. The postvoid residual was then measured before the patient was discharged from the hospital. In cases of voiding difficulty (i.e. >100 mL residual urine), hospitalization was prolonged until a postvoid residual less than 100 mL was obtained. Statistical analysis was based on the student *t* test for parametric, and the Wilcoxon signed Ranks test or McNemar test for nonparametric continuous variable categorical variables. A *p* value less than 0.05 were considered to denote a significant difference.

Results

Seventy-three patients were included in this study and 7 were excluded because of loss of follow-up data. The basic background of the study subjects is shown in Table 1. Fourteen patients (19.2%) underwent the MONARC sling operation alone, whereas 51 (69.9%) underwent at least one concomitant reconstructive procedure at the time of implant. The mean operative time taken to implant the MONARC sling for the patients who underwent the MONARC alone was 15.2 ± 5.0 minutes. There

Table 1
Patients' characteristics ($n = 73$)

Patients' characteristics	Value
Age (yr)	54.3 ± 11.6
Parity	3.5 ± 1.2
Body mass index	25.4 ± 3.7
Intrinsic sphincter deficiency (MUCP < 30 cm H ₂ O)	17 (23.3)
Hormone replacement therapy	3 (4.1)
Menopausal status	38 (52.1)
Prior hysterectomy	11 (15.1)
Previous surgery for prolapse	6 (8.2)

Data are presented as *n* (%) or mean \pm standard deviation.
MUCP = maximal urethral closure pressure.

Table 2
Operative and postoperative complications of MONARC ($n = 73$)

Complication	n (%)
Bladder perforation	0 (0)
Hemorrhage or hematoma	0 (0)
Postoperative urinary retention (RU > 100 cc)	5 (6.8)
Voiding difficulty on postoperative visit (3–6 mo)	14 (19.2)
Voiding difficulty on telephone interview (13 mo)	1 (1.4)
Fever (>38°C)	0 (0)
Urinary tract infection	17 (23.3)
<i>De novo</i> urgency/frequency	2 (2.7)
<i>De novo</i> urgency/frequency at postoperative visit	6 (8.2)
<i>De novo</i> urgency/frequency at telephone interview	1 (1.4)
Vaginal or urethral erosion	0 (0)

RU = residual urine.

were very few perioperative complications (Table 2). Immediate postoperative voiding difficulty was reported in five (6.8%) patients and all recovered a normal voiding function (residue urine less than 100 mL) within a week after prolonged indwelling catheter and drug medication; although the postoperative subjective response at 6 months showed 19.2% voiding difficulty. Postoperative evaluations at 6 months (Table 3) showed a cure rate of 80.8% (patients dry on both the 1-hour pad test and cough stress test). The cure rate among patients with a lower MUCP (<30 cm H₂O) was 82.4% (14/17). Among all patients, the mean pad weight gain changed from 25.9 g preoperatively to 1.7 g postoperatively ($p < 0.05$); for the low MUCP patients, the change was from 39.0 to 0.9 g ($p = 0.05$). The uroflowmetry and residual urine showed no significant change at the 6 months follow-up visit. As of the last follow-up visit, there were no urethral, bladder, bowel, or neurovascular injuries and no vaginal or urethral erosions. Postoperative *de novo* urgency was reported by two (2.7%) patients.

Subjective outcome and satisfaction were evaluated during the most recent postoperative telephone interviews, with an average follow-up of 48 months. Seventy-two of 73 patients (98.6%) were cured, no patient (0%) improved, and one patient (1.4%) failed. Most patients were satisfied: 59 of 73 (80.8%) were very satisfied, 9 of 73 (2.3%) were moderately satisfied, 4 of 73 (5.5%) were not very satisfied, and 1 of 73 (1.4%) was dissatisfied.

The preoperative and postoperative uroflowmetry evaluation for the MONARC did not reveal a statistically significant difference (Table 4).

Table 4
Preoperative and postoperative urodynamic parameter

Urodynamic parameters	Preoperative	Postoperative	p^a
Q maximum (mL/s)	19.1 ± 9.3	19.7 ± 8.7	0.576
Q average (mL/s)	10.1 ± 5.2	11.5 ± 13.9	0.829
Residual urine (mL)	32.5 ± 75.5	40.3 ± 85.1	0.806

^a By Wilcoxon signed Ranks test.

Discussion

TVT procedure is the first of a new generation of minimally invasive operations for the treatment of female USI [13]. Systemic prospective clinical trials have proved that the TVT procedure is effective and safe in curing stress incontinence [14]. Through assessment by strict objective and subjective outcome measures, cure rates of 85% have been reported, with another 5–10% showing significant improvement [13], and preliminary analysis of the 7-year results of Nilsson [14] indicates a cure rate of 81%. Because TVT is a simple minimally invasive procedure that can be performed under local anesthesia with high cure rates, it is the most preferred surgical treatment for female USI in some countries [15]. However, because the TVT trocar is directed from the vagina to the retropubic area in an essentially blind manner, it can cause bladder injuries and rare but life-threatening injuries to the bowels or large vessels [15,16]. Because most of these complications seem to be related to the penetration of the retropubic space, a new surgical procedure that retains the same midurethra position as that of TVT while maintaining or even improving efficacy by reducing or eliminating the complications related to the penetration of the retropubic space has been invented. The original description of this new technique was published by Delorme [11] in 2001, whereby he placed the tape between the two obturator foramen, creating a hammock-like support for the urethra instead of urethral suspension, as with TVT [17]. Delorme [11,18] has reported in two articles that MONARC is a safe and effective surgical procedure for the treatment of female USI, with an 83% cure rate and a 5.4% improvement at 6 months follow-up. Two recent comparative studies of MONARC versus TVT [12,19] reported no difference in terms of efficacy. MONARC represents an easily performed and reproducible procedure. A study by Costa et al [17] confirmed the hypothesis that MONARC may dramatically reduce intraoperative complications by avoiding the retropubic space, indicating an overall complication rate of 2.2% (bladder perforation, urethral perforations, and number of vaginal lateral

Table 3
Objective surgical outcome of MONARC based on stress test and 1-hour pad test at 6-month postoperation

Surgical outcome	MUCP < 30 cmH ₂ O ($n = 17$)	MUCP > 30 cmH ₂ O ($n = 56$)	Total ($n = 73$)	p
Cure rate, n (%)	14 (82.4)	45 (80.4)	59 (80.8)	1.000
Cure—negative stress test and dry pad test				
Pad test				
Preoperative (g)	39.0 ± 35.0	22.1 ± 38.5	25.9 ± 38.2	0.043
Postoperative (g)	0.9 ± 3.2	2.0 ± 6.2	1.7 ± 5.7	
Change (g)	38.0 ± 33.3	20.1 ± 38.0	24.1 ± 37.5	

MUCP = maximal urethral closure pressure.

perforations). This rate is far lower than that reported with TVT, which can be up to 15% [20]. After incorporating the use of the index finger into the vaginal incision to protect the urethra, no urethral injury has been reported [17]. In this study, there were no intraoperative complications and no urethral, bladder, bowel, or vascular injuries. Voiding difficulties with retention problems and *de novo* urge symptoms are the other complications that are most frequently associated with anti-incontinence operations, whereas the traditional incontinence operation had an incidence rate of more than 30% [13]. TVT has shown postoperative voiding difficulties of transient urine retention in 8–17% [6–8] and urgency in 5–15% [7–9] of patients. Delorme [11] reported no postoperative voiding difficulties in his research into using the transobturator approach. de Tayrac et al [12] prospectively compared TVT and MONARC for the surgical treatment of USI in women. The rate of postoperative urinary retention was 25% in the TVT group versus 13.3% in the MONARC group ($p > 0.05$) [12]. In this study, 6.8% of patients experienced transient voiding difficulties. It has been hypothesized that, with the retropubic approach, the U-shaped sling kinks the urethra, whereas with the obturator approach, the sling is positioned more horizontally, reestablishing more natural lateral support [15] and so decreasing the risk of postoperative voiding difficulties. Although serious complications appear to be reduced and early studies have shown promise, the long-term efficacy of the transobturator suburethral approach has not yet been established and thus requires long-term observation. There was no significant difference in the incidence of postoperative *de novo* urgency between the use of the MONARC (6.7%) and TVT (6.5%) [12], whereas in the study by Deval et al [21], SPARC showed a *de novo* urgency symptom incidence of 11.5%. In our study of MONARC, there was only a 2.7% incidence of *de novo* urgency. This lower incidence of postoperative *de novo* urgency may be because of the less-invasive surgical procedure and less tension around the urethra.

Hemorrhagic complications can occur intraoperatively during needle insertion. There was about a 2–4% rate in the five studies of TVT [22]. The transobturator suburethral approach has been introduced to minimize the risk of complications arising from the retropubic passage of the needle. No significant bleeding or hematoma complication has been reported [23]. In this study, there were no symptomatic hemorrhagic complications, although we did not perform routine postoperative ultrasound scans.

Patients with intrinsic sphincter deficiency are often more difficult to cure by surgery; the cure rates of 74% obtained through the TVT procedure seem to be equivalent to those achieved by traditional incontinence operations [11]. Delorme et al [18] reported a 100% cure rate for preoperative maximum urethral closure pressure less than 20 cmH₂O. Guerette et al [24] reported that a transobturator slings should be used with caution in women with impaired urethral function (Valsalva leak-point pressure less than 60 cmH₂O and MUCP less than 40 cmH₂O) [24]. In our study, there were 17 cases of low MUCP (<30 cmH₂O), with an 82.4% objective cure rate. We recognize that this outcome would vary with different surgeons, and that the results for patients with low MUCP appear to differ from the

past researches related to MONARC. This may be because of the small sample size, and patients with low MUCP will need a longer follow-up period and more powerful evaluation in the future.

In conclusion, this is a rare study of the use of MONARC and USI in Asia, which may provide a useful reference. The MONARC transobturator suburethral sling results in a high continence rate and has the advantage of avoiding many of the risks normally associated with the retropubic approach, potentially reducing the incidence of serious potential complications. The medium-term results presented here show that the transobturator suburethral sling is a safe, simple, and effective treatment for women with USI, even for those with low MUCP. An evaluation of the outcome after a longer follow-up period is required to validate this procedure for the long term.

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