Aris® Transobturator Sling: Three Years Follow-Up

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Abstract

Objective & Background: The lack of long-term outcome data of the Trans-Obturator Tape (TOT) procedure in the literature reflects the novelty of the technique. We report the results of three years follow up of the outcome and adverse events associated with the TOT procedure in the treatment of female patients with stress urinary incontinence (SUI). Methods: Two hundred and thirty four consecutive patients were prospectively evaluated with history, pads/day (PPD), physical exam, Incontinence Impact Questionnaire (IIQ), Urogenital Distress Inventory (UDI), analog global satisfaction scale (GSS), and urodynamic studies. All patients had the TOT procedure using the Aris® polypropylene sling (COLOPLAST A/S). Pelvic prolapse repair was done as indicated by the preoperative findings. Postoperatively patients were evaluated with history, PPD, physical exam, IIQ, UDI, and GSS. The paired t-test was used for statistical analysis. Results: Two hundred and thirty four patients (mean age 59.59 years) who have completed a minimum follow up of 12 months are the subjects of this report. Preoperatively, SUI was reported by 93.8%, and 66.2% reported urge incontinence (UI). PPD use was 2.22 (0-10). The mean scores on the IIQ were 11.05 (range 0-35), UDI 10.46 (range 0-18), and GSS 2.78 (range 0-10). Urodynamics demonstrated detrusor overactivity in 25.8%, mean valsalva leak point pressure of 74.21 cm H20 (range 3-157). Detrusor pressure at maximum flow rate (Pdet max) was 25.82 cm H20, and the maximum flow rate (Qmax) was 16.26 ml/sec. All patients underwent the TOT procedure using the Aris® sling (COLOPLAST A/S). Cystocele repair was done in 57.75% (N=134), enterocele repair in 4.31% (N=10), rectocele repair in 21.98% (N=51), hysterectomy in 12.93% (N=30), and vaginal vault suspension in 9.05% (N=21). The mean hospital stay was 0.46 days (rage 0-4 days) and 65.51% (N=152) were done as an outpatient procedure. The mean duration of catheter was 0.53 days (range 0-6 days), and 64.65% (N=150) did not require a catheter postoperatively. The mean follow up is 23.34 months (range 12-36 months), and 41% (N=98) of patients have follow up more than 24 months. SUI resolution was reported in 90.41% (P<0.0001), 61.04% reported resolution of UI (P< 0.0001), and 2 (2.5%) reported de novo urge symptoms. PPD use declined to 0.30 (P<0.0001). The mean scores on the IIQ declined to 1.64 (P<0.0001), UDI 3.80 (P<0.0001), and GSS increased to 8.0 (P<0.0001). Three (1.3%) patients had vaginal extrusion of the sling, 2 (0.9%) had urinary tract infection, and 2 (0.9%) developed urinary obstruction which required sling to be released. No patient sustained bladder injury, bowel injury, vascular injury, or nerve injury.

Conclusions: This prospective series of patients with SUI demonstrates the success of the TOT in resolving the symptoms of incontinence. The safety, functional efficacy and patient satisfaction with the procedure are sustained at intermediate follow up. The rate of vaginal extrusion using the Aris® sling is low. The procedure can be done as an outpatient procedure in the majority of patients, and the majority of patients do not require catheterization post-operatively. The lower incidence of de novo urge symptoms in this series is consistent with other series reported in the literature, and is an important advantage for the TOT over existing techniques.

Background

Stress urinary incontinence is the most common form of urinary incontinence and is estimated to affect more than 13 million adult women in the United States[1]. Two minimally invasive sling procedures for the surgical treatment of stress urinary incontinence have been developed in the past decade. In 1996, Ulmsten introduced the tension free vaginal tape (TVT) procedure[2]. In an attempt to minimize the complications associated with the TVT technique, Delorme devised and first described the Transobturator tape (TOT) technique in 2001[3, 4].

The TOT is a mid-urethral sling. It reproduces the natural suspension of the urethra while preserving the retropubic space. The TOT is a tension free sling as the resting urethral angle is not changed by the procedure, nor is it necessary to correct urethral hypermobility[5]. The anatomical course of the transobturator sling avoids any major neurovascular structures, and the anatomical structures crossed by the sling are muscles and fascia. It avoids femoral and obturator vessels in the thigh and pudendal vessels in the perineum[6]. Because of the nature of the procedure, major hemorrhage and bowel perforation are not reported in the TOT procedure[7, 8]. This approach is more anatomically correct and poses no significant impact on voiding function[9]. Several studies in the literature have confirmed the feasibility, safety and efficacy of this operation[7, 10-14].

In this series, we report the results of our 3 years experience with the TOT procedure using Aris® polypropylene sling (Coloplast A/S) in female patients with stress urinary incontinence.

Methods

Two hundred and thirty four consecutive patients with SUI who have completed a minimum follow up of 12 months were included in this study. All patients were prospectively evaluated with history including pads use/day, physical examination including pelvic examination, urinalysis, quality of life questionnaire including Incontinence Impact Questionnaire, Urogenital Distress Inventory, and analog global satisfaction scale, and urodynamic studies. Urodynamic studies included filling cystometry, pressure-flow studies, and Valsalva Leak Point Pressure (VLPP). The VLPP was recorded via a 9F urethral catheter, and both valsalva maneuver and coughing was used to provoke SUI. The intra-vesical pressure (PVes) was used to calculate the VLPP starting at 250 ml bladder volume and subsequently at increments of 50 ml until SUI was demonstrated or perceived by the patient. The history of SUI or the demonstration of SUI during urodynamic studies constituted the indication for the sling procedure. All patients had the TOT procedure using the Aris® polypropylene sling (Coloplast A/S). Patients with concomitant pelvic organ prolapse had prolapse repair and/or hysterectomy as indicated by the preoperative findings. All patients had cystoscopy as part of the procedure. Postoperatively all patients were evaluated with history including PPD, physical examination, IIQ, UDI, and GSS. The patient continence status was recorded based on the history reported by the patient. All patients were carefully examined postoperatively for any evidence of vaginal sling extrusion, erosion, or infection. The functional results and patient satisfaction were assessed using the quality of life questionnaire. Completion of the quality of life questionnaire was done by telephone interview of the patient by an independent third person. Urodynamics were done only in patients who had unexplained voiding dysfunction. The paired t-test was used for statistical analysis.

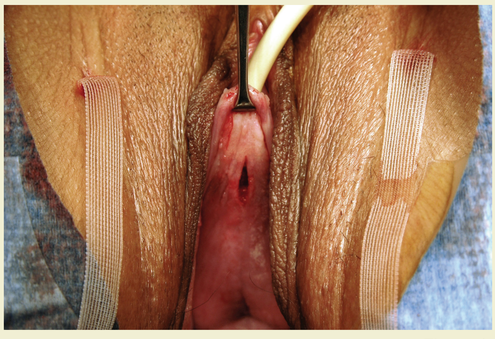

Figure 1.
Aris®® Sling (Coloplast A/S)

Results

Two hundred and thirty four patients with a mean age 59.59 years (range 29-91) completed a minimum follow up of 12 months. Preoperatively, SUI was reported in 219 patients (93.8%), and 154 patients (66.2%) reported urge incontinence. PPD use was 2.22 (0-10). The mean scores on the IIQ were 11.05 (range 0-28), UDI 10.46 (range 0-18), and GSS 2.78 (range 0-10). One hundred and thirty eight patients had cystocele (grade 2-4), 30 patients had uterine prolapse, 10 patients had an enterocele, 21 patients had vault prolapse (post-hysterectomy), and 51 patients had a rectocele.

Urodynamics demonstrated detrusor overactivity in 25.8%, and mean VLPP was 74.21 cm H20 (range 3-157). Detrusor pressure at maximum flow rate (Pdet max) was 25.82 cm H20 (range 0-96), and the maximum flow rate (Qmax) was 16.26 ml/sec (range 1-53). All patients underwent the TOT procedure using the Aris® sling (Coloplast A/S). Cystocele repair was done in 134 patients (57.75%), enterocele repair in 10 patients (4.31%), rectocele repair in 51 patients (21.98%), hysterectomy in 30 patients (12.93%), and vaginal vault suspension in 21 patients (9.05%). The mean hospital stay was 0.46 days (rage 0-4 days) and in 152 patients (65.51%) the procedure was done as an outpatient procedure. The mean duration of catheter was 0.53 days (range 0-6 days); and 150 patients (64.65%) did not require a catheter postoperatively. The mean follow up is 23.34 months (range 12-36), and 98 patients (41%) have follow up more than 24 months.

In the absence of urodynamic studies postoperatively, the only indicator for the presence or absence of SUI postoperatively is the patient history. Thus, only data from patients who did have history of SUI preoperatively were used in the calculation of the rate of success or failure of the procedure. A similar principle was applied in patients who had history of urge incontinence. SUI resolution was reported in 90.41% (P<0.0001), 61.04% reported resolution of UI (P< 0.0001), and 2.5% (N=2) reported de novo urge symptoms. PPD use declined 86.49% to 0.30 pads/day (P<0.0001).

The mean scores on the IIQ declined to 1.64 (range 0-25) {P<0.0001}, UDI declined 3.80 (range 0-15) {P<0.0001}, and GSS increased to 8.0 (0-10) {P<0.0001}.

Three (1.3%) patients had vaginal extrusion of the sling. Vaginal discharge was the presenting symptom, and all were diagnosed on pelvic examination. No patient demonstrated clinical evidence of infection at the site of extrusion vaginally or elsewhere. Excision of the extruded portion of the vaginal sling with primary closure of the vaginal wall resulted in complete healing. A culture of the extruded sling resulted in growth of a variety of microorganisms with no specific pattern. All patients maintained their continence status after sling excision or removal, and none required further intervention. Two patients (0.9%) had urinary tract infection, and 2 patients (0.9%) developed urethral obstruction that required sling to be released. No patient sustained bladder injury, urethral injury, bowel injury, vascular injury, or nerve injury.

	Pre-Op	Post-Op	% Change	P-Value
SUI	219	21	90.41	<0.0001
UI	154	60	61.04	<0.0001
PPD	2.22	0.3	86.49	<0.0001
IIQ	11.05	1.64	85.15	<0.0001
UDI	10.46	3.8	63.67	<0.0001
GSS	2.78	8	72.29	<0.0001

Table 1.
Pre- and Post-operative results

Conclusions

This prospective series of patients with urodynamic demonstrated stress incontinence is the largest series of patients who had the TOT procedure using the Aris® polypropylene sling (Coloplast A/S) reported in the literature. Using the quality of life assessment questionnaire concerning urinary incontinence, we demonstrated the functional efficacy and patient satisfaction with the procedure in patients with stress urinary incontinence.

One of the important and not well-recognized advantages of the TOT as compared to other mid urethral sling procedures is the lower rate of de novo urge/urge incontinence. The low incidence of de novo urge/urge incontinence observed in our series is consistent with what has been reported in the literature.

The TVT mid urethral sling is associated with serious though rare complications including intestinal perforation, vascular injury, obturator nerve injury, and even death. The transobturator sling procedure spares the retropubic space and thus eliminates the risk of major bowel, neural and vascular complications. No patient in our series had bladder, urethral, vascular, neural, or bowel injury, and the rate of vaginal extrusion with the Aris® sling (Coloplast A/S) is rare.

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