Int Urol Nephrol (2015) 47:1611–1617
DOI 10.1007/s11255-015-1085-y

UROLOGY - ORIGINAL ARTICLE

Double-sling procedure for the surgical management of stress urinary incontinence with concomitant anterior vaginal wall prolapse

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Received: 8 July 2015 / Accepted: 8 August 2015 / Published online: 2 September 2015

Abstract
Purpose To assess the safety, efficacy of double-sling procedure (DS) for the surgical management of stress urinary incontinence (SUI) with concomitant anterior wall prolapse (AVWP) and to identify if less synthetic material implantation will decrease the complication rates without decreasing the high cure rates.
Methods We reviewed the women who underwent DS in two institutions from January 2009 to December 2013. In DS, there are two transobturator tapes inserted from two different routes for the surgical management of SUI with concomitant AVWP. POP-Q was used for anatomical evaluation of prolapse. SUI was assessed by cough stress test and ICIQ-SF questionnaire. We accepted that the patient was satisfied if the visual analog scale score was ≥80. The severity of urinary incontinence was classified by ICIQ-SF. The women were evaluated at the 3 and 12 months and annually.
Results A total of 74 women met the requirements for inclusion and had sufficient records for analysis. The mean follow-up period was 35.4 months (range 12–60). Operative time was 33.2 ± 6.2. The objective cure and subjective success rates of SUI were 87.8 and 93.2 %, respectively. The satisfaction from the surgery was also high with 86.5 % rate. The anatomical success in our series was rather high with 96 % rate. Our overall complication rate was 12.2 %. Mesh extrusion rate was 0 %.
Conclusions Double-sling procedure is feasible, efficient, and safe. Reducing the mesh size did not have a detrimental effect on the outcomes of SUI treatment and simultaneous AVWP repair.

Keywords Surgical technique · Stress urinary incontinence · Prolapse · Transvaginal mesh · Cystocele · Transobturator tape

Introduction

Urinary incontinence (UI) is a very common, distressing medical disorder that affects approximately 50 % of women with medical, social, and economic burdens, and among these women, 15–80 % have a component of stress urinary incontinence (SUI) [1]. Anterior vaginal wall prolapse (AVWP) is the most commonly diagnosed pelvic organ prolapse in women [2]. Olsen et al. [3] estimated that one in nine women will undergo at least one surgery for POP or UI by the age of 80 and 30 % of those will undergo at least one additional surgery. Prolapse repair and anti-incontinence surgeries have been increasingly performed transvaginally. Midurethral slings (MUS) became the most effective and popular techniques for the surgical treatment of SUI [4]. Anterior colporrhaphy (AC) is the most common operation performed alone or concomitantly with sling procedures for AVWP repair [5]. Traditional AC utilizing the patient's own tissue is a procedure that utilizes weakened and damaged tissue with failure rates in the range of 40–60 % [6, 7]. AVWP repair by the vaginal route is one of the most challenging aspects of pelvic reconstructive surgery in terms of achieving a durable anatomical support. A new Cochrane review has confirmed that mesh use in the anterior compartment has

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a lower anatomical failure rate when compared with traditional native tissue repairs [5].

There has been an increasing interest in the use of mesh for prolapse repair recently. As the use of synthetic materials in POP surgery has increased, the complications have also increased. A wide spectrum of potential complications exists with the use of transvaginal mesh in POP surgery [8]. Rare, but severe complications, including death, fistula formation, and mesh erosion into adjacent organs, have been reported in the Manufacturer and User Device Experience database (MAUDE). Finally, in October 2008, the FDA released a warning about complications associated with mesh devices used to repair POP and SUI [8].

After the FDA warning, we reduced the mesh size used for transvaginal repair of SUI with concomitant AVWP to minimize the complications associated with mesh. Our aim in this study is to assess the safety, efficacy of double sling (DS) in the management of SUI with concomitant AVWP and to discuss with the literature if less synthetic material implantation will decrease the complication rates without decreasing the high cure rates.

Materials and methods

We analyzed 187 consecutive women who underwent the TOT procedure for SUI with concomitant anterior wall prolapse repair in two institutions from January 2009 to December 2013. Only women who completed at least 12-month follow-up were reviewed. We documented the patient characteristics, surgical techniques, operative reports, postoperative visits, and complications from electronic medical records. The tape was type 1, macropore monofilament polypropylene mesh. Two tapes were used in each operation.

Patient selection

Eligible women were at least 21 years old and had documented SUI [shown by urodynamic studies (UDS)] with symptomatic recurrent stage 2 or stage 3 (primary or recurrent) AVWP. Women with apical prolapse repair, previous transvaginal mesh surgery (TMS), predominant urgency urinary incontinence (UUI), and preexisting neurological disease were excluded. All the surgeries were performed by the experienced surgeon (TY), very familiar with the female prolapse repair surgery.

Informed consent was obtained from all patients, and the study was approved by the local ethics committee.

Double-sling procedure

With the patient in the lithotomy position, we made a 2-cm vertical anterior wall incision starting proximal to the urethral meatus. The upper skin punctures are made at the medial border of the obturator foramen at the level of the clitoris, and approximately 1.5 cm below the insertion of the adductor longus tendon, dissection was performed as in the classical TOT procedure and tape was inserted via outside-in transobturator route and was not adjusted but left loosely. Then, the second vaginal incision was made starting 1 cm under the first incision and extending to the 2 cm (according to the grade of AVWP) proximal to cervix or vaginal cuff. The vaginal epithelium was then grasped and then dissected off the bladder and out laterally to the pelvic sidewalls up to the level of the ischial spines bilaterally. Apically and in the midline, the bladder was dissected all the way up and off the cuff of the vagina or the cervix if the uterus was in place. We made the dissection deeper than we would for standard anterior colporrhaphy and leave pubocervical fascia on the vaginal epithelium in order to reduce the risk of mesh extrusion. The inferior needles were passed as in the technique described in previous studies [9, 10]. The inferior skin incisions were made 3 cm inferior and 2 cm lateral to the superior incisions bilaterally. We passed the inferior needles through the groin incisions, obturator space, and brought with direct finger guidance through the sidewalls at the level of the bladder neck and approximately 1.5 cm distal to the ischial spine apically. The inferior needles pass through adductor magnus, adductor brevis, obturator externus, obturator membrane, obturator internus, levator ani, and endopelvic fascia and exit through the vaginal incision [11]. A standard tape used in TOT procedure was attached to the needles, and they were pulled back out of the groin incisions. The tape was attached from lower edge to the pericervical ring or the cuff of the vagina with absorbable sutures. The tape was adjusted and tightened in a tension-free fashion which created a hammock effect under the bladder and elevated the bladder back into its normal anatomical position (Fig. 1). Minimal or no vaginal epithelium was excised (according to the grade of cystocele) and the incision closed with a running, locked 2-0 polyglactin suture. Afterward, the TOT tape (upper tape) was adjusted in a tension-free fashion. We prefer to adjust the MUS after cystocele repair in order to tighten the tape when the bladder and urethra are in their normal anatomical position. The superior incision also closed with a running, locked 2-0 polyglactin suture. The inferior needles were also the standard needles used in TOT procedure.

Cystoscopy was performed at the end of the case. Postoperatively, vaginal packing and Foley catheter were left in for 24 h. If stable, women were discharged home on postoperative day one after voiding without residual urine and antibiotics were given for 5 days postoperatively. Vaginal estrogen cream was started 1 week after surgery and was given every other day for 3 months in postmenopausal women.

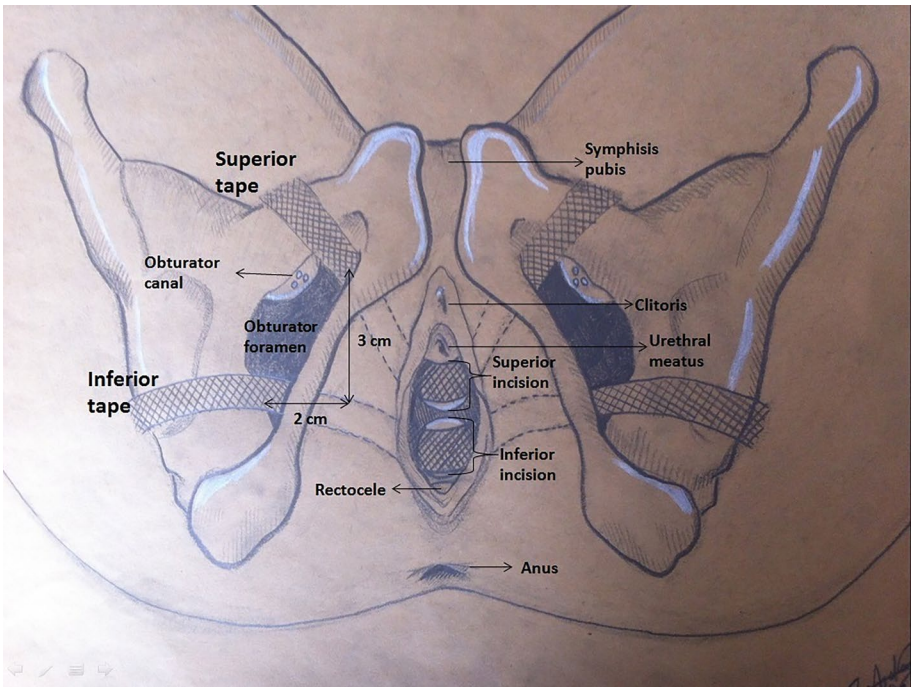

Fig. 1 Double-sling procedure

The women were evaluated by history, pelvic examination in the lithotomy position, urinary system ultrasound with the measurement of post-void residual urine volume (PVR), ICIQ-SF questionnaire, and the cough stress test (CST). POP was described during a maximal Valsalva maneuver using the POP-Q system. Postoperative patient satisfaction was assessed using a visual analog scale (VAS) where 0 represents very dissatisfied/unbearable urinary complaints and 100 very satisfied/no urinary problems [6]. We accepted that the patient was satisfied if the VAS score was $\geq$80.

The women were evaluated on the fifteenth postoperative day with urine culture and were questioned for early postoperative complaints. They were re-evaluated at the 3 and 12 months and annually with pelvic examination including the CST and the ICIQ-SF. UDS, according to standardized protocols, were performed before surgery in accordance with International Continence Society guidelines. Postoperative additional UDS were performed only in the case of de novo urgency symptoms. The severity of urinary incontinence was classified by ICIQ-SF: slight (1–5), moderate (6–12), severe (13–18), and very severe (19–21). The data presented in this study were collected at the last control of the women.

We analyzed considering seven postoperative parameters: objective cure, subjective cure, subjective improvement, anatomical success, patient satisfaction, resolution of UUI, and complications. Criteria for objective cure were a negative CST, no need for pads, and no re-operation for SUI. Subjective cure was defined by a score of 0 points from the ICIQ-SF questionnaire and no need for pads. Subjective improvement defined as no need for additional treatment for SUI, an ICIQ-SF score $\leq$12 (slight or moderate symptoms), and satisfaction with surgery (VAS $\geq$ 80). The sum of subjective cured and improved women was defined as subjective success. Resolution of UUI was defined by subjective patient reporting on the questionnaire and no need for antimuscarinic medication. Also, the results of pelvic examination with POP-Q were documented, and anatomical success was defined by anterior wall POP-Q stage $\leq$1.

Statistical analysis

Data were analyzed using SPSS version 21 (SPSS, Chicago, IL). Categorical variables were presented as numbers and percentages, and continuous variables were presented as means and standard deviations. Preoperative and postoperative ICIQ-SF values were compared with paired sample *t* test. Statistical significance was set at a *p* value of 0.05.

Results

Among the 187 women, 106 women underwent TOT procedure with concomitant different types of prolapse repair surgery (anterior colporrhaphy, various types of transvaginal mesh surgery) and 81 women underwent DS procedure. Of the 81 women, 74 women met the requirements for inclusion and had sufficient records for analysis. Surgery was performed under spinal and general anesthesia in 66 and eight women, respectively. The patient characteristics are shown in

Table 1 Patients' characteristics and perioperative findings

n	74
Age, years Mean ± SD (range)	52.4 ± 9.3 (29–72)
Follow-up time, month Mean ± SD (range)	35.4 ± 16.6 (12–60)
Parity Mean ± SD (range)	2.8 ± 1.15 (1–5)
Menopausal state, *n* (%)	49 (66.2)
BMI, kg/m^2 Mean ± SD (range)	29.1 ± 2.7 (22–36)
SUI, *n* (%)/MUI, *n* (%)	43 (58.1)/31 (41.9)
Preoperative DO, *n* (%)	3 (4.05)
Primary/recurrent AVWP, *n* (%)	68/6 (8.1/91.9)
Cystocele + rectocele, *n* (%)/cystocele *n* (%)	14 (18.9)/60 (81.1)
Incontinence severity*, *n* (%)	
Slight	0
Moderate	6 (8.1)
Severe	46 (62.2)
Very severe	22 (29.7)
Operative time (minutes) (range)	33.2 ± 6.2 (25–52)
Hospital stay (range)	1.1 ± 0.2 (1–2)

Results are given as mean ± SD, standard deviation

SUI stress urinary incontinence, *MUI* mixed urinary incontinence, *DO* detrusor overactivity, *BMI* body mass index

* Incontinence severity according to ICIQ-SF score: slight (1–5), moderate (6–12), severe (13–18), and very severe (19–21)

Table 1. The mean follow-up period was 35.4 months (range 12–60). Average blood loss was 57 cc (range 20–400 cc). None of the women required a blood transfusion. The previous surgery of the six patients with recurrent AVWP was AC. The outcomes of the procedure are shown in Tables 2 and 3. Seventy-four women with SUI and concomitant symptomatic stage 2 or 3 AVWP underwent DS procedure. Postoperatively, anatomical success was achieved in 71 women (POP-Q stage $\leq$1). Anatomical failure was seen in three women (POP-Q stage $\geq$2), but all of them were asymptomatic and no women required repeat surgery for prolapse (Fig. 2). Our overall complication rate was 12.2 %. No major complication was documented intraoperatively in any woman. Postoperatively, two woman had de novo UUI, but UDS was normal. De novo dyspareunia was seen in two postmenopausal women and improved with estrogen cream treatment. Mesh extrusion was not documented in any woman.

Discussion

The high recurrence rate of traditional AC has led to the development of multiple surgical techniques and the use of various meshes [12–14]. Prior to mesh use becoming the standard repair in the anterior compartment, it is very important to see the improved anatomical outcomes being accompanied by superior patient-determined outcomes. One of the major concerns associated with mesh use is the complications as the transobturator meshes are associated with 10 % rate of mesh complications and higher blood loss [5]. Pelvic pain and dyspareunia were also reported frequently after TMS and may seriously affect the quality of life [15].

The use of a synthetic mesh in vaginal surgery was first introduced by Julian in 1996 [16]. de Tayrac [14], in an attempt to simplify the technique of graft placement and attachment, was one of the first to utilize the transobturator route for partial attachment of a mesh graft in the anterior compartment. In 2004, Rane introduced the Perigee transobturator cystocele repair system (AMS) for the management of cystocele and concluded that this kit was an effective, minimally invasive, with minimum morbidity in the medium term [17]. In our study, we thought that instead of using a larger size four corner mesh, two separate narrow tapes passing through the obturator foramen would provide adequate support for the repair of both SUI and AVWP.

There is an ongoing query about the type of graft to be used in POP repair surgery. The use of biological graft materials was suggested to be associated with lower complication but higher recurrence rates compared with synthetic materials. Mahdy et al. [18] evaluated the anatomical success and complications of Perigee with porcine dermis graft in the management of AVWP and found 69.6 % success rate with minimal graft-related complications. In a recent meta-analysis, Jia et al. [19] reviewed systematically the efficacy and safety of mesh/graft for posterior or AVWP surgery. When they compared the different types of procedures, procedures not using mesh/graft for AVWP repair were found to have the highest failure rate (29 %), followed by procedures with absorbable synthetic mesh (23 %), biological graft (18 %), and nonabsorbable synthetic mesh (9 %). When we had planned to modify the Perigee system, our biggest concern was the distance between the two tapes which might cause a recurrent prolapse. Actually, the average vaginal length in young women population is approximately 6–7 cm across the anterior wall [20]. When we pass the two tapes, upper one from 1 cm below the urethral meatus and the lower one 2 cm proximal to the cervix (according to the grade of AVWP), then only approximately 3 cm distance is left between the tapes (Fig. 1). The overall anatomical success in our series was rather high with 96 % rate in medium-term follow-up. There was not significant bulging from the space between the tapes postoperatively. These good results are comparable to the other studies that reported average 90 % anatomical success rates with polypropylene mesh using the same transobturator approach for graft support [21]. In the literature, anatomical success rate

Table 2 Outcomes of double-sling procedure at medium-term follow-up (range 12–60)

n	74
Objective cure	65 (87.8)
Subjective success	69 (93.2)
Subjective cure	59 (79.7)
Subjective improvement	10 (13.5)
Anatomical success	71 (95.9)
Patient satisfaction	64 (86.5)
Resolution of UUI	12 (38.7)*
De novo UUI	2 (2.7)
De novo dyspareunia	2 (2.7)
Severe groin and/or leg pain	3 (4)
Urinary tract infection	2 (2.7)
Mesh extrusion	0

Results are given as *n* (%)

Subjective cure; patients with postoperative ICIQ-SF = 0

Subjective improvement; ICIQ-SF score ≤12 and visual analog scale (VAS) score ≥90

Subjective success; subjective cure and improvement

Objective cure; patients with negative cough stress test (CST)

Patient satisfaction; VAS score ≥80

Anatomical success; anterior vaginal wall prolapse ≤1 postoperatively

UUI urgency urinary incontinence

* Out of 31 women, 13 with preoperative mixed urinary incontinence

of TVMS for cystocele repair is greater than 90 % (range 75–100) [13]. In our study, women with anatomical failure had no symptoms and none of them underwent re-operation. Exclusion of the women with an AVWP stage 4 may have increased our success rates. The functional results were satisfactory and similar with the previous studies [6, 22]. The objective cure and subjective success rates of SUI were 87.8 and 93.2 %, respectively. The satisfaction from the surgery was also high with 86.5 % rate.

Previous studies showed that nonabsorbable synthetic mesh use in AVWP surgery is the most effective procedure and decreases the reoperation rates. However when it comes to the safety, the procedures with nonabsorbable synthetic mesh have the worst complication rates compared with all other procedures. Among these complications, mesh erosion is the most common one (10.2 %) [23]. In an international multicentre prospective study, Palma et al. assessed the efficiency and safety of a monoprosthesis with combined prepubic and transobturator arms (NAZCA TC) for AVWP repair and simultaneous SUI treatment. At a 12-month follow-up, they concluded that monoprosthesis demonstrated both anatomical and functional high success rates with an almost 6 % vaginal mesh exposure. The mean operative time was 64.3 ± 32.9 min. Four women (3.8 %) developed acute urinary retention after catheter removal, and two additional women (1.9 %) had significant PVR [24]. Mesh erosion rates up to 20 %

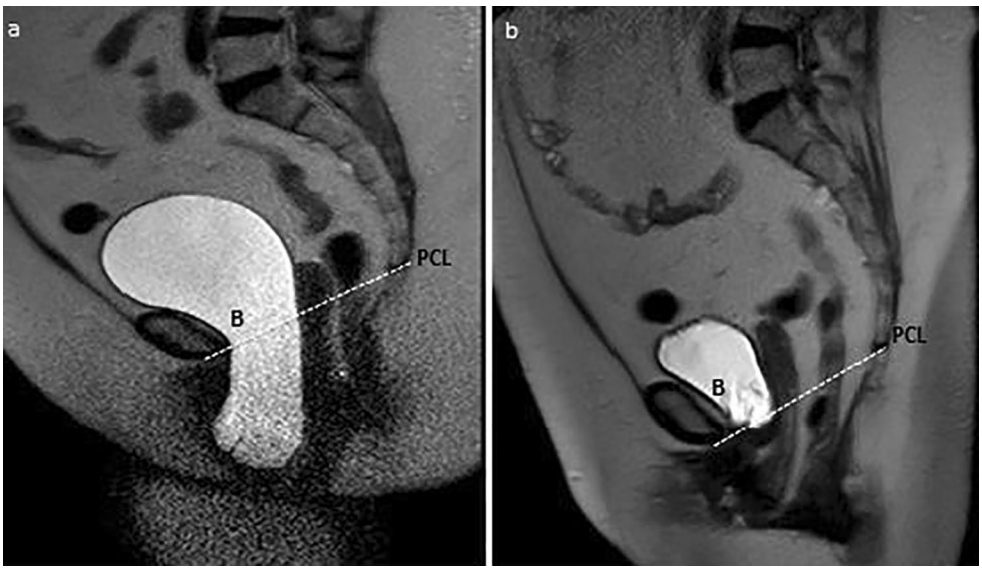

Fig. 2 **a** Preoperative MRI at maximum strain showed severe cystocele. **b** No significant cystocele at 24 months postoperatively. *B* bladder, *PCL* pubococcygeal line

Table 3 Preoperative and postoperative ICIQ-SF scores and POP-Q stratification for anterior wall prolapse

	Preoperative	Postoperative
ICIQ-SF (mean ± SD)	16.2 ± 3.1*	1.9 ± 1.4*
AVWP, *n* (%)		
Stage 0	0	9 (12.2)†
Stage 1	0	62 (83.8)†
Stage 2	32 (43)	3 (4.0)‡
Stage 3	42 (57)	0

* $p < 0.001$ (paired sample *t* test)

† Anatomical success 96 % (stage 0 + stage 1, 71 women)

‡ Anatomical failure

SD standard deviation, *ICIQ-SF* International Consultation on Incontinence Questionnaire Short Form, *AVWP* anterior vaginal wall prolapse

were reported in a retrospective cohort of women who underwent anterior repair augmented with polypropylene mesh [23]. Eboue et al. evaluated the outcomes of cystocele repair by transobturator four-arm handmade mesh in 123 women. Voiding dysfunction was seen in nine women, and mesh extrusion was seen in eight women [25]. Ballert et al. reported 8.5 % sling takedown secondary to obstruction after a MUS placement at transvaginal POP repair. When compared with previous studies, voiding dysfunction was very low in our study [22, 25]. None of our women had acute urinary retention or incomplete voiding after catheter removal. De novo UUI was seen in one woman. It seems that prepubic arms in NAZCA procedure caused voiding dysfunction symptoms. In addition, we did not see any major bleeding or hematoma perioperatively. Our operative time was comparable with other TVMSs (33.2 ± 6.2) [21, 24]. According to these data, reducing the mesh size seems to decrease the mesh-related complications and shortens the operative time of the procedure. In addition, small mesh size and short operative time presumably may decrease the risk of contamination. Also, the relatively low exposure/extrusion rate might be due to a deeper dissection into the proper true pelvic spaces. We do recommend randomized controlled trials with longer-term follow-up for the further evaluation of this innovative technique.

Conclusions

Double-sling procedure is feasible, efficient, and safe. Reducing the mesh size did not have a detrimental effect on the outcomes of SUI treatment and simultaneous AVWP repair. On the contrary, the rate of mesh extrusion, the most common complication of transvaginal mesh surgery, was not seen. We hope this new technique would encourage the innovative surgeons for reducing the mesh size in many other surgeries.

Author contributions T Yonguc developed the project, collected and managed data, and wrote/edited manuscript; I H Bozkurt wrote/edited manuscript; V Sen analyzed data; O Aydogdu edited manuscript; G N Yonguc edited manuscript/drew illustration; B Gunlusoy edited manuscript/managed data.

Compliance with ethical standard

Conflict of interest None.

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