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Outcome and efficacy of transobturator polypropylene mesh kit in treatment of anterior pelvic organ prolapse

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Synopsis: The repair of anterior pelvic organ prolapse with transobturator mesh is effective treatment even in a population with previously hysterectomy or traditional anterior colporrhaphy.

Key words: Anterior prolapse; Hysterectomy; Mesh complications; Perigee®; Polypropylene mesh; Transobturator route

Word count: 2445

Abstract

Objective: To report the efficacy and complications of anterior pelvic organ prolapse (POP) repair with mesh trough transobturator route.

Methods: Totally, 198 woman with anterior POP ≥ II grade according to the POP-Q system were treated by Perigee® procedure. The primary outcome was defined as anterior POP ≤ stage I at 12 months follow-up. The secondary outcomes included the incidence of perioperative, mesh, short and long-term postoperative complications.

Results: The overall cure rate was 92.9 %, and in population with previously hysterectomy or traditional anterior colporrhaphy was 90.6%. Postoperative mean POP-Q Aa and Ba points were significantly improved (Aa 2.2 [0-3.1] cm versus -2.1 [-1.2- -3] cm and Ba -2.4 [-1.6 – -5.5] cm versus 2.5 [-1 – 4.2] cm, $p < 0.001$ Wilcoxon signed rank test). Vaginal or bladder erosions had observed in three patients. The other short and long term complications were low and not significant.

Conclusion: The Perigee® procedure is effective treatment of anterior POP without serious complications even in a population with previously hysterectomy or traditional anterior colporrhaphy.

Introduction

It has been estimated that over the next 30 years, the demand for the treatment of pelvic organ prolapse (POP) will increase for 45% [1]. According to the Women's Health Initiative study anterior POP was the most frequent type and had observed in 34.2% of women [2]. Approximately 10% of them will have a surgical intervention (hysterectomy or correction procedure) for this condition during their lifetime, and 30% of these women will undergo repeat operation for prolapse recurrence in a 5 years period [3-5]. Due to the limitations and high recurrence rate after traditional surgery various synthetic implants have been developed in the last couple of years [6-8]. There are numerous types of mesh and graft materials available, which vary according to type and structure of material and physical properties such as absorbability and pore size [8].

The Perigee® system (Perigee system, AMS, Minnetonka, MN) was designed and first used in Townsville, Australia, and it appears to be valuable and time-efficient approach for all types of anterior vaginal wall defects with high cure rate and minimal complications [9-15]. It contains four specific, helical needles designed for each anatomic pass through the obturator space to attach a graft to the pelvic sidewall distally at the level of the bladder neck, and apically near the ischial spines and reinforce the pubocervical fascia with minimally invasive approach [9-11]. The results of recent studies have shown high anatomic success rate and low incidence of complications [9-15]. Moreover, subpopulation of patients with previous hysterectomy and traditional anterior colporrhapy has been considered as risk group for lower cure rate with reoperation [16]. The major concerns with this method have been related to mesh complications including erosion of the vagina or bladder and formation of the vesicovaginal fistula [9-15, 17].

The purpose of our study was to evaluate the efficacy and safety together with short and long term outcomes of anterior vaginal wall repair using tension-free polypropylene mesh.

Materials and methods

Between May 1. 2007 and September 30. 2009, 198 women with anterior POP ≥ grade II underwent anterior colporrhaphy using Perigee® system at University hospital KBC Zagreb, Croatia. Local and national ethical committee approved the study protocol, and all patients included in the study gave their informed written consent.

The exclusion criteria for enrollment were: previous placement of an anterior wall graft; predominant urge incontinence diagnosed by urodynamics; pelvic infection or systemic infection; inguinal or vulvar abscesses; pregnancy; urinary tract obstruction or renal insufficiency; pelvic pain (unrelated to prolapse); vaginal bleeding unknown etiology; blood coagulation disorders; pelvic malignancy or previously radiation of pelvic area; vaginal erosion or severe vaginal atrophy; vaginal or urethral fistula; and known allergy to mesh material.

Preoperative evaluation was consisted of a complete history and gynecologic examination. Prolapse severity was assessed using the pelvic organ prolapse quantification (POP-Q) system adopted by the International Continence Society [18]. Urinary incontinence was diagnosed clinically and with urodynamic studies. Appropriate local estrogen replacement (Vagifem, Novo Nordisk, Denmark) were applied to all patients at least in 8 weeks period before the procedure and it was continued after it. All urogynecologists participating in the study have been experienced surgeons, had pre-trial hands-on training and were performed at least 50 procedures before the beginning of this study. The patients were followed-up at 7 days, 6-8 weeks and 12 months postoperatively.

The primary endpoint of this study and treatment success was defined as ≤ stage I of anterior POP according to the POP-Q system at 12-month follow-up. The secondary outcomes included the incidence of intraoperative (hemorrhage, infection), short term postoperative (nerve, vessel, and bladder or bowel injury) and long term postoperative complications

(erosion, rejection, *de-novo* incontinence, urinary retention, constipation and dyspareunia). Residual urine was measured by the catheterization with cut off point at 50 ml of urine. We also measured operating time, intraoperative blood loss and hospital stay. Follow-up was obtained by gynecologic examination and survey using a questionnaire from a study of Shah et al [19].

Perigee® system consists of polypropylene mesh for repairing central defects and four self-attached arms for correction of lateral vaginal detachments. Following a vertical incision from the bladder neck, around 4 cm from the apex of vagina the dissection is similar to that of the anterior colporaphy. Structure of the needle provides fixation of the mesh at the white line of arcus tendineus so there was no need for deep lateral sutures. After orientation about inferior needle pathway, lateral dissection toward the white line of the arcus tendineus may be done. Plication sutures in the midline were placed to reduce the anterior POP but also to prevent the bladder perforation when the inferior needles pass by. Superior bilateral incisions were made in the genitofemoral folds at the base of the adductor longus tendon at the level of clitoris. The inferior incisions are made 2 cm lateral and 3 cm inferior to the superior. Narrow-diameter superior helical needles are guided at 45 degrees to patient's midline and perforate the obturator membrane laterally to the ischiopubic ramus under the finger guidance to avoid the bladder perforation. The inferior helical needles are inserted with the handle at 90 degrees and are driven under finger control directly to ischial spines in straightforward direction. After penetrating the levators they exit along white line at about 1.5-2 cm below the spines. It is extremely important to direct the needle tips proximally towards spines before rotation throughout the levator muscles. The mesh was subsequently adjusted to vaginal wall extent in a tension-free manner and the proximal tail was drowning to the lower-most portion of the cystocele. The distal arms were than adjusted with slight tension beneath the bladder neck, to return the anterior vaginal wall back to its natural anatomical position. Further step was the

fixation of the apical edge of the graft to the pericervical ring by the sutures in order to fasten the attachment. The redundant tail of the mesh was additionally removed. After rolling over the mesh only a small portion (less than 25%) of surplus vaginal wall was excided. Vaginal incision was closed, avoiding the superposition of the mesh and its exposure or infection. The outer plastic sheets were cut at the level of skin incision. After the positioning of the mesh cistoscopy was obligate to eliminate the bladder injury and verify potency of both ureters. The Foley catheter was inserted in the bladder for 24 hours. We have practiced one day perioperative antibiotic prophylaxis and analgetic therapy if necessary. Patients were recommended to avoid heavy lifting, exercise, and sexual activity for at least 4 weeks.

As a part of the study design, a sample size calculation was performed (Sample size calculator, MaCorr Inc., Toronto, Ontario, Canada). Based on the previously results the calculation was designed to detect at least 85 % success rate at 12 months follow-up. Confidence interval was determined using the confidence level (CL) of 95%. The program has calculated that confidence interval is 7.0%. Using CL of 95% and confidence interval of 7.0 % the program has calculated that for our population the sample size needed to be 196.

Data were analyzed using SPSS version 15.0 (SPSS Inc., Chicago IL, USA). For comparison of categorical data before and 12 months after procedure we calculated likelihood ratio with 95% confidence interval. The Wilcoxon signed-rank test was used in comparison the POP-Q measurements before and after procedure. Two-tailed p values are reported throughout and statistical significance was defined as $p \leq 0.05$.

Results

Totally, 243 patients with anterior POP $\geq$ II stage were consented to participate in the study. We excluded 41 patients (10 had dominantly urge incontinence; 5 had previously placement of mash for anterior wall prolapse; 4 had chronic renal insufficiency; 4 had previously radiation of pelvic area due to the gynecologic malignancy; 3 had acute pelvic infection; 2 had severe forms of vonWillebrand disease, 2 had cervical carcinoma, 2 had severe vaginal atrophy despite of local estrogen therapy; 1 had endometrial carcinoma and finally 8 patients refused to participate in the study). Of the remaining 202 patients the 12 month follow up data was obtained for 198 (98%) patients, and our results were based on their analysis. The baseline data of our patients are shown in Table 1.

Median time for operation was 25 minutes [range 13-75]. The average hospital stay was 6 days [range 5 - 11 days]. Average time to void was 2.2 days [range 1–10 days].

Intraoperative, early postoperative and mesh related complications are presented in Table 2. Moderate levator pain and groin discomfort at 12 patients (6.1%) was the most prominent short-term postoperative problem but have disappeared 2 months with analgetic therapy.

Median blood loss was 50 ml [range 5-300 ml], and three patients received blood transfusion (two of them because of heavy bleeding during the procedure, and one because of formation of hematoma under the anterior wall after initial closure).

Regarding the complications related to mesh only two patients had vaginal erosion, and one had erosion of the bladder. The median days-to-onset of mesh complications were 62 days [range 14 – 98]. A patient with bladder erosions required surgical correction that involved excision of the exposed mesh, secondary closure of the vaginal defect, and subsequently application of vaginal estrogen cream. Vaginal erosions were resolved with vaginal estrogen cream only.

Preoperative versus postoperative POP-Q measurements were shown in Table 3. Due to the primary outcome the objective cure rate 12 months after procedure was 92.9 % (184/198). The failure rate was 7.1 % (14/198), 10 patients had anterior POP-Q II and 4 had III stage prolapse 12 months after the procedure.

The co-occurrence of posterior vaginal prolapse in our study population was 13.1% (26/198). In 17/198 the correction procedure was made with Apogee system whereas in remaining patients traditionally procedure (posterior colporraphy and levatoroplasty) was performed. Since posterior prolapse was not the objective of this study we did not analyze the short and long term outcomes regarding the posterior correction procedure in this subpopulation of patients.

In a population of patients with previously traditional anterior colporrhapy 28/198 (14.1%) or hysterectomy 25/198 (12.6 %) the objective cure rate 12 month after the procedure were high 48/53 (90.6%) and did not different from patients without these procedures 136/145 (92.4 %).

Comparison of urinary and other symptoms before and 12 months after Perigee® procedure was presented in Table 4. There were three cases of mild *de novo* stress urinary incontinence which have manifested by occasional leak, one case of *de novo* mixed incontinence, and in two patients *de novo* urinary retention developed immediately after releasing from the hospital and has been managed promptly by recateterisation and antibiotic therapy. The other long term symptoms were unchanged 12 months after procedure.

Discussion

Unacceptably high failure rate of traditional anterior POP repair triggered the attempts in pelvic floor reconstructive surgery for innovative vaginal approaches and evolution of new graft augmentation techniques [3-5]. Few years ago Rane et al. invented a technique to utilize the obturator space to attach the graft not only at the bladder neck but also more apically by the ischial spine utilizing needles passed through the obturator space in order to repair all types of anterior vaginal wall defects [9]. Bilateral superior and inferior needles allow the surgeon minimal lateral dissection and therefore reduce the blood loss and other healing abnormalities [9-11]. The inferior helical needles provide the positioning of the proximal part of the mesh adjacent to the ischial spines which is fundamental route for the reattachment of the vaginal wall to its normal position at the level of the white line. It seems that lateral detachments of white line have usually been unrecognized, neglected and maltreated with traditional approaches. Consequently, it could be the strongest explanation for high success rate after the Perigee® procedure [9-15].

Results of our study have shown favorable results of transvaginal mesh surgery with anatomic success rate of 92.9 % 12 months after the procedure. Comparisons of our results with previously published trials using Perigee mesh are shown in Table 5. The anatomic success rate of our study was high (92.9 % versus 88.5-96.3%) and comparable with previously published trials [11-15]. Additionally, this technique did not short the vaginal length which is very common with traditional procedures.

Recently, concerns over complications with vaginal mesh have been raised and the erosion of the vagina or bladder seems to be the most common complication seen with the use of synthetic mesh graft [8-13]. Comparison of our results regarding the formation of erosion of vagina or bladder after the procedure is lower in comparison to the others (1.5 % versus 3.1-

10 %). This difference could be connected with the use of long term local estrogen therapy before procedure. Long term estrogen therapy improves the status of the vaginal mucosa and subsequently decreased the formation of erosion [20]. All participants in our study had long term (at least 8 weeks before procedure) estrogen therapy. Furthermore, our lower incidence of formation of erosion could be connected with the final step of the procedure. When the mesh was embedded in its anatomical position we excised only a small part of surplus anterior vaginal wall tissue. The excessive excision of anterior vaginal wall could compress the mesh to the bladder or vagina and leads to the formation of erosion or even vesicovaginal fistula. Additionally, this complication could be reduced with newer techniques which we did not use in our study such as hydro dissection and the use of lighter, softer, and less dense type of mesh [11]. The overall rates of other intraoperative and early postoperative complications seem very low in our study and the results are comparable with previously published trials [9-15].

In our study 12.6 % patients had previously hysterectomy and 14.1 % had previous repair of the anterior POP with traditionally anterior colporraphy. This population could be considered as risk group for developed complications and lower cure rate [16]. However, the results in this subgroup are very encouraging and showed that their cure rate was consistent with patients without these procedures.

Regarding the long term urinary symptoms occasional leak of urine and *de novo* mild stress incontinence manifested in three cases and suggesting that Perigee® interposition does not interfere with continence mechanism. Loss of sharp vesico-urethral angle after anterior POP repair was probably the only mechanism of *de novo* urinary stress incontinence, so the effort should be focused on preservation of vesico-urethral junction.

In conclusion, our results confirm that this procedure is minimally invasive, reproducible, and efficient. It has low morbidity and is well tolerated by the patients and seems to be an

satisfactory procedure for definitive repair of anterior POP even in a population of patients with previously hysterectomy or traditionally anterior colporraphy.

Conflict of interest

None

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Table 1

Demographic characteristic

N = 198

Age (years) median, (IQR), [range]	62 (55-69) [42-86]
BMI (kg/m2) median, (IQR), [range]	26.5 (24.3-28.2) [20.3-35.4]
Number of deliveries median, (IQR), [range]	2 (2-3) [0-9]
Postmenopausal (number, %)	176 (88.9%)
Prior hysterectomy (number, %)	25 (12.6%)
Prior anterior colporraphy (number, %)	28 (14.1%)

Abbreviation; N –number, IQR – interquartile range; BMI – body mass index

Table 2

Intraoperative, early postoperative and mesh related complications

N = 198	Number (%)
Intraoperative complications	
Blood transfusion	3 (1.5%)
Bladder injury	1 (0.5%)
Bowel injury	0
Early postoperative complications	
Hematoma	1 (0.5%)
Urinary infection	7 (3.5%)
Pain	12 (6.1 %)
Mesh complications	
Vaginal erosion	2 (1%)
Bladder erosion	1 (0.5%)
Vesico vaginal fistula	0

Table 3

Preoperative versus postoperative POP-Q measurements (mean [range]).

	Preoperative	12 months postoperative	p value
Aa (cm) anterior wall	2.2 [0 – 3]	-2.1 [-1.2 - -3]	< 0.001*
Ba (cm) anterior wall	2.5 [-1 – 4.2]	-2.2 [-1 – - 5.5]	< 0.001*
C (cm) cervix or vaginal vault	-1.7[-3 – 5.1]	-6.5 [-5.1 - -8.3]	< 0.001*
Ap (cm) posterior wall	-1.5 [-2 – 3]	-1.8 [-2.5 – 0]	0.24*
Bp (cm) posterior wall	-1.9 [-2.5-4.2]	- 2.2 [- 5.5 – 1]	0.38*
Tvl (cm) total vaginal length	8.4 [4.8-9.2]	7.9 [6.1 – 9.2]	0.47*

*Wilcoxon signed rank test

Table 4

Comparison of urinary and other symptoms before and 12 months after Perigee® procedure

Symptom	Before procedure (N, (%)	12 months after procedure (N, (%)	LR (95%CI)
Anterior POP ≥ grade II	198 (100)	14 (7.1)	NA
de novo stress incontinence	-	3 (1.5)	NA
de novo mixed incontinence	-	1 (0.5)	NA
Stress incontinence	16 (8.1)	13 (6.6)	0.89 [0.59-1.35]
Retention	12 (6.1)	9 (4.5)	0.85 [0.51-1.41]
Mixed incontinence	9 (4.5)	10 (5.1)	1.06[0.68-1.64]
Constipation	10 (5.1)	7 (3.5)	0.82 [0.46-1.45]
Dyspareunia	14 (7.1)	12 (6.1)	0.92 [0.60-1.41]

Abbreviations: N – number, LR – likelihood ratio, CI – confidence interval, POP – pelvic organ prolapse

Table 5

Previously published studies of Perigee® system use in repair of anterior pelvic organ prolapse

Author	Year	N	Mesh	Follow up(m)	ASC (%)	VE (%)
Long [15]	2010	60	Perigee	20	96.3	10
Moore [11]	2010	114	Perigee	24	88.5	7
Moore [12]	2009	77	Perigee	36	93	6.5
Rane [9]	2008	70	Perigee	18	95.3	7.1
Nguyen [14]	2008	38	Perigee	12	89	5
Gauruder-Burmeister [13]	2007	72	Perigee	12	93	5.6

Abbreviations: N- number, m – months, ASC – anatomic sucess rate, VE – vagianl erosion