European Journal of Obstetrics & Gynecology and Reproductive Biology 161 (2012) 105–108

Contents lists available at SciVerse ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Three-year outcome of transvaginal mesh repair for the treatment of pelvic organ prolapse

Cheng-Yu Long [a,b], Chun-Shuo Hsu [c,*], Chin-Hu Wu [d], Cheng-Min Liu [a], Chiu-Lin Wang [b], Eing-Mei Tsai [a,d]

[a] Graduate Institute of Medicine, Center of Excellence for Environmental Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan
[b] Department of Obstetrics and Gynecology, Kaohsiung Municipal Hsiao-Kang Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan
[c] Department of Obstetrics and Gynecology, Buddhist Dalin Tzu Chi General Hospital, Chiayi, Taiwan
[d] Department of Obstetrics and Gynecology, Kaohsiung Medical University Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan

ARTICLE INFO

Article history:
Received 19 July 2011
Received in revised form 13 November 2011
Accepted 6 December 2011

Keywords:
Detrusor overactivity
Pelvic organ prolapse
Transvaginal mesh repair
Urodynamic study
Vaginal erosion

ABSTRACT

Objective: To evaluate the clinical and urodynamic outcomes of transvaginal mesh repair (TVM) for the treatment of pelvic organ prolapse (POP).
Study design: One hundred and twenty-four women with POP stage II to IV were scheduled for a TVM procedure. Preoperative and postoperative assessments included pelvic examination, urodynamic testing, and a personal interview about urinary symptoms using a standard questionnaire.
Results: We found a significant improvement at points Aa, Ba, C, Ap, and Bp ($P < 0.001$) except for total vaginal length ($P = 0.08$), and the overall success rate was 93.5% (116/124). Various urinary symptoms improved significantly following TVM ($P < 0.01$). In addition, residual urine, functional urethral length, and the rate of detrusor overactivity, improved significantly after surgery ($P < 0.05$). Apart from vaginal erosion (14/124; 11.3%), the rates of other surgical complications were acceptably low.
Conclusion: TVM is an effective procedure for the treatment of POP and urinary symptoms, this being possibly related to postoperative release of urethral obstruction. Vaginal erosion is less likely to occur beyond the learning curve.

1. Introduction

Nearly 11% of all women need some type of operation for pelvic organ prolapse (POP) or urinary incontinence in their lifetime, with 29% needing a second operation for recurrence within five years [1]. Surgery with placement of mesh or graft materials has therefore become increasingly popular over the last decade due to the excellent short-term cure rate [2–4]. However, the use of transvaginal meshes (TVM) for POP repair is not yet definitively validated. Abdominal or laparoscopic sacro-colpopexy remains the "gold standard" technique with a higher satisfaction rate and objective success rate than TVM surgery [5].

Recently a number of mesh materials and devices have been designed by different companies. Perigee/Apogee® (AMS, Inc., Minnetonka, MN, USA) and the Prolift® system (Gynecare Prolift, Ethicon, Inc., Piscataway, NJ, USA) are examples of synthetic mesh kits recently developed and adopted in pelvic reconstruction. These non-absorbable meshes allow surgeons to reinforce the pubocervical and the rectovaginal fascia via minimally invasive approaches. There are more and more studies to evaluate the changes in clinical and urodynamic parameters following these graft-reinforced POP surgeries.

Estrogen deficiency in the menopause decreases urogenital vascularization [6,7], which causes various symptoms in the lower urinary tract. Over 75% women undergoing POP repair fall into this age group [3]. Change in urinary symptoms following POP surgery remains a critical issue that should be discussed with patients. Reviewing the literature, few papers have studied both surgical efficacy and functional results. Lack of standardized surgical techniques further complicates interpretation of the literature. We therefore selected the two most popular commercial kits (Perigee/Apogee® and Prolift® system) in this study, and evaluated their clinical outcomes.

2. Materials and methods

Between June 2004 and January 2010, one hundred and sixty-two women with POP stage II to IV (stage II, $n = 25$; stage III, $n = 78$; stage IV, $n = 21$) defined by the POP quantification (POP-Q) staging system [8], were referred for TVM procedures using the Perigee and/or Apogee devices ($n = 83$) or Prolift devices ($n = 79$) at our hospitals. Concomitant midurethral sling operations were performed in

* Corresponding author at: Department of Obstetrics and Gynecology, Buddhist Dalin Tzu Chi General Hospital, 2 Min-Sheng Road, Dalin Town, Chiayi, Taiwan. Tel.: +886 7 803 6783x3450; fax: +886 7 806 5068.
E-mail address: 0830263@kmhk.kmu.edu.tw (C.-S. Hsu).

0301-2115/$ – see front matter.
doi:10.1016/j.ejogrb.2011.12.007

women with current or occult urodynamic stress incontinence (USI), unless they did not desire additional surgery. These midurethral sling procedures included tension-free vaginal tape (TVT) (Gynecare TVT, Ethicon, Inc., Piscataway, NJ), TVT-O (Gynecare TVT-Obturator System, Ethicon, Inc., Somerville, NJ), and Monarc (AMS, Inc., Minnetonka, MN, USA). Thirty-eight patients were excluded due to various reasons, including incomplete medical records ($n = 28$), and current use of anticholinergic drugs ($n = 10$). Finally, the remaining 124 women were included for analysis in this study (69 Perigee and/or Apogee; 55 Prolift devices).

Clinical assessments before and 6 months after surgery included multichannel urodynamic study, and a personal interview to identify urinary symptoms with a standardized questionnaire taking into account the 2002 ICS definitions [9]. Urodynamic studies, including non-instrumented uroflowmetry, filling and voiding cystometry, and urethral pressure profilometry, were performed according to the recommendations by the International Continence Society [10] with a 6-channel urodynamic monitor (MMS; UD2000, Enschede, The Netherlands). Any uninhibited detrusor contraction during filling cystometry was deemed positive for idiopathic detrusor overactivity (DO). USI was diagnosed by involuntary urinary leakage with cough in the absence of detrusor contraction during cystometry. The diagnosis of occult USI was made by the occurrence of urine leakage during the reduction of POP.

Perigee–Apogee and Prolift systems are similar with only subtle differences in the posterior procedure involved. In the Prolift procedure for apical and posterior prolapse, the trocar is inserted 3 cm lateral and inferior to the anus. The needle is designed to pass through the sacrospinous ligament at a level 2 cm posterior and medial to the ischial spine. The Apogee system uses the same insertion location, but with a more helical trocar that pierces the ileococcygeus muscle rather than the sacrospinous ligament at the level of the ischial spine [11].

Postoperative follow-up with the POP-Q system was at 1, 2, 3 and 6 months and then semiannually beyond 6 months. Recurrence was defined as the most distal portion of POP stage II or greater. The Clavien–Dindo grading and the International Urogynecological Association (IUGA)/International Continence Society (ICS) scale were used for the classification of the mesh-related complications [12,13]. Ethics approval by the Institutional Review Board of our hospitals had been obtained for retrospective data analysis. Statistical analysis was performed using the paired t-test or Wilcoxon signed rank test for continuous variables, and the McNemar's test for categorical variables. A difference was considered statistically significant when $P < 0.05$.

Table 1
Demographic data ($n = 124$) are given as mean ± standard deviation or n (%).

Mean age (years)	58.4 ± 11.3
Mean parity	3.3 ± 1.4
Mean BMI (kg/m2)	24.9 ± 3.4
Menopause	94 (75.8)
Current smokers	3 (2.4)
Diabetes Mellitus	17 (13.7)
Hypertension	43 (34.7)
History of hysterectomy	18 (14.5)
Procedures in this study	
Anterior mesh repair	67 (54.0)
Anterior and posterior mesh repair	57 (46.0)
Posterior repair	4 (3.2)
Vaginal hysterectomy	8 (6.5)
Suburethral sling	72 (58.1)
Follow-up (months)	36.4 ± 12.8

BMI, body mass index; POP, pelvic organ prolapse; SUI, stress urinary incontinence; Sx, surgery.

3. Results

The demographic data of the enrolled 124 women are shown in Table 1. The ages of participants ranged from 35 to 80 years, with an average of 58 years, and parity ranged from 1 to 10, with a mean of 3.3. Ninety-four (75.8%) patients were postmenopausal and 18 (14.5%) had a previous history of hysterectomy. Concomitant vaginal hysterectomy with the TVM surgery was performed in eight (6.5%) women at their request; two of them with uterine fibroids. Concomitant mid-urethral slings were done in 72 women, and 63 of them (87.5%) were free of stress incontinence postoperatively. Five of 40 (12.5%) preoperative continent women developed de novo USI. Twelve women with preoperative USI undergoing TVM alone remained incontinent postoperatively. After a mean follow-up time of 36 months (range: 25–72 months) there was a significant improvement at points Aa, Ba, C, Ap, and Bp ($P < 0.001$; Wilcoxon signed rank test) except for total vaginal length ($P = 0.08$) (Table 2). The rate of TVM recurrence was 6.5% (8/124) (Table 2).

The prevalence of urinary symptoms, including urinary frequency, stress incontinence, urge incontinence, incomplete bladder emptying, urinary hesitancy, and nocturia was found to be significantly lower six months after TVM repair ($P < 0.01$; McNemar's test) (Table 3). In addition, the rate of DO and residual urine decreased, and functional urethral length increased in a significant manner postoperatively ($P < 0.05$; Table 4). However, other urodynamic parameters, including maximum flow rate, maximum cystometric capacity, maximum urethral closure pressure and urethral closure area revealed that analogous parameters were not significantly different following the TVM procedures ($P > 0.05$; paired t-test) (Table 4).

In regard to intra-operative complications including bladder injury, rectal injury, and transfusion, none was suspected and confirmed by cystoscopic and rectal examination. Postoperative complications included urinary tract infection in 17 women (13.7%), voiding dysfunction in five (4%), and pelvic hematoma in two (1.6%). We did not find any woman with bladder erosion. Of the 14 (14/124; 11.3%) women with vaginal erosion (Table 5), twelve occurred for the first 50 cases; other two erosions occurring in the 53rd and 65th cases.

Table 2
Pelvic organ prolapse quantification (POP-Q) values before and 36 months (mean) after surgery. Data are given as median (range) or n [%].

POP-Q parameters (cm)	Pre-op ($n = 124$)	Post-op ($n = 124$)	P values*
Aa	2 (−2 to 3)	−2 (−3 to 0)	<.001
Ba	3 (−2 to 6)	−2 (−5 to 0)	<.001
C	0 (−4 to 7)	−6 (−7 to −3)	<.001
Ap	−1 (−3 to 3)	−2 (−3 to 0)	<.001
Bp	−1 (−3 to 5)	−2 (−5 to 0)	<.001
Tvl	7 (5–11)	7 (5–9)	0.08
Recurrent POP		8 [6.5]	

Pre-op, preoperative; Post-op, postoperative; Tvl, total vaginal length.
* Wilcoxon signed rank test.

Table 3
Urinary symptoms before and 6 months after surgery. Data are given as n (%).

Symptoms	Pre-op ($n = 124$)	Post-op ($n = 124$)	P value*
Urinary frequency	86(69.4)	39(31.5)	<.001
Stress urinary incontinence	84(67.7)	26(21.0)	<.001
Urge incontinence	51(41.1)	30(24.2)	0.001
Incomplete bladder emptying	88(71.0)	8(6.5)	<.001
Urinary hesitancy	63(50.8)	3(2.4)	<.001
Nocturia	63(50.8)	41(33.1)	0.007

* McNemar's test.