449

Lee K[1], Lee Y[1], Seo J T[2], Lee J G[3], Lee J Z[4], Kim H Y[5], Park W H[6], Chung J Y[7], Lee S E[8], Kim H G[9], Choo M S[10]
1. *Sungkyunkwan University School of Medicine,* ***2.*** *Kwandong University College of Medicine,* ***3.*** *Korea University College of Medicine,* ***4.*** *Pusan National University College of Medicine,* ***5.*** *Hallym University School of Medicine,* ***6.*** *Inha University College of Medicine,* ***7.*** *Inje University College of Medicine,* ***8.*** *Seoul National University Bundang Hospital,* ***9.*** *Konkuk University College of Medicine,* ***10.*** *University of Ulsan College of Medicine*

EVALUATION OF THE EFFICACY AND SAFETY OF PELVIC ORGAN PROLAPSE REPAIR USING PROLIFT® TRANSVAGINAL MESH SYSTEM

Hypothesis / aims of study

Pelvic organ prolapse (POP) is a disorder that may have significant impact on pelvic organ function and quality of life. Though various surgical techniques and modifications have been proposed, surgical treatment of POP has yet been exposed to failure and re-operations. The use of synthetic implant materials in pelvic reconstructive surgery has increased considerably in recent years. These novel procedures are presumed to decrease in surgical failures, commonly associated with traditional repairs. However, clinical efficacy and safety remains uncertain. The objective of the study was to evaluate the efficacy and safety of POP repair using the Prolift® transvaginal mesh system.

Study design, materials and methods

A prospective study was conducted in three institutions. Between April 2005 and March 2007, a total of 47 women with symptoms attributed to POP and the condition-specific POP quantification stage (POP-Q)≥II, underwent surgical repair using Prolift® (Ethicon, Somerville, NJ,USA) transvaginal mesh system. The surgical technique was the same as described by the TVM Group in 2004.(1) Primary endpoint was objective cure rate after 12 months of operation based on POP-Q system. Other outcome measures were urodynamic parameters, symptom questionnaire of Pelvic Floor Distress Inventory (PFDI) (2), and patients' satisfaction. An objective cure was defined as POP-Q stage 0, improvement as stage I. Failure was defined as stage II or greater. Adverse events during follow-up were also evaluated.

Results

Median age was 63.5 (range 47-76), median parity 3.0 (range 1-8), mean body mass index 25.1±3.0. Median follow-up period was 12.0 (12-16) months. Total mesh was used in 6 patients (20.0%), an isolated anterior mesh in 21 patients (70.0%) and an isolated posterior mesh in 1 patient (3.3%). Concomitant procedures were midurethral sling in 14 women, posterior colporrhaphy in 2, and hysterectomy in 1. Pre- and post-operative POPQ were shown in table 1. There were significant changes in all points but point Pb and Tvl. Approximately 90% of the anterior vaginal wall prolapse, 78% of the posterior vaginal wall prolapse, and 67% of the apical prolapse were cured (Table 2). There were significant improvements in the UDI (urinary distress inventory) and POPDI (pelvic organ prolapse distress inventory) (Table 3). Pre- and post-operative maximum flow rate and post-void residual were not different. About 95.5% of the women were satisfied with the operation. There was no bladder or rectal perforation during the procedure. During the follow-up period, mesh exposure was found in one patient about 7 months after anterior vaginal wall repair. About 0.5cm of exposed portion was excised on an ambulatory basis.

Interpretation of results

Cure rates of the anterior, posterior and apical vaginal wall prolapse were about 90%, 78% and 67% using Prolift® system with the median follow up of 12 months. The UDI and POPDI were significantly improved. About 95% of the women were satisfied with the treatment. No intra-operative complications were noticed. One patient had tape exposure that was removed successfully at the outpatient clinic.

Concluding message

The POP repair using the Prolift® transvaginal mesh system is an effective in terms of objective and subjective assessments with no significant complications. The adverse event attributed to the polypropylene mesh need to be evaluated on long-term in vivo biocompatibility.

References

1. J Gynecol Ostet Biol Reprod (2004) 33:577–87
2. Qual Life Res (1994) 3:291–306

Table 1. Preoperative and postoperative POPQ (Pelvic Organ Prolapse Quantification)

	Preoperation (mean±SD)	Postoperation (mean±SD)	p-value*
Point Aa	1.26±1.375	-2.47±0.883	0.000
Point Ba	1.70±1.486	-2.41±0.939	0.000
Point C	-1.95±4.372	-5.53±2.462	0.000
Point gh	5.06±1.174	4.79±0.848	0.002
Point Pb	2.74±0.870	2.59±0.833	0.630
Point Tvl	7.50±1.313	7.30±1.192	0.531
Point Ap	-0.23±2.280	-1.97±1.111	0.000
Point Bp	-0.18±2.508	-1.94±1.123	0.000
Point D	-3.60±4.112	-5.92±3.187	0.003

*Wilcoxon signed rank test

Table 2. Postoperative changes in the POP-Q stage (n, %)

	Anterior (n=29)		Posterior (n=9)		Apical (n=6)	
	Pre-operatively	Post-operatively	Pre-operatively	Post-operatively	Pre-operatively	Post-operatively
Stage 0	0	26 (89.7%)	1 (11.1%)	7(77.8%)	0	4 (66.7%)
Stage Ⅰ	0	2 (6.9%)	3 (33.3%)	2 (22.2%)	2 (33.3%)	2 (33.3%)
Stage Ⅱ	15 (51.7%)	1 (3.4%)	1(11.1%)	0	1 (16.6%)	0
Stage Ⅲ	11 (37.9%)	0	4 (44.4%)	0	0	0
Stage Ⅳ	3 (10.3%)	0	0	0	3 (50.0%)	0

Table 3. Pre-and Post-operative scores of the Pelvic Floor Distress Inventory (PFDI)

Symptom scales	Pelvic Floor Distress Inventory		
	Preoperative	Postoperative	*p*-value
Mean UDI	107.2±52.6	58.9±40.4	0.001
Mean POPDI	110.4±60.5	71.0±50.2	0.003
Mean CRADI	77.9±62.3	58.7±53.7	0.199

UDI (urinary distress inventory), POPDI (pelvic organ prolapse distress inventory), CRADI (colo-rectal-anal distress inventory)

Specify source of funding or grant	**No**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**Prolift® transvaginal mesh system is a practical treatment for pelvic organ prolapse.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**