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Evaluation the efficacy and complications of uphold system for total organ pelvic prolapse repair

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ABSTRACT

Objective: The aim of present study was to use an uphold system (Boston Scientific) for restoration of total organ pelvic prolapse. *Materials and methods*: Between 2014 and 2019 years, This retrospective study was conducted on forty-three women with pelvic organ prolapse stage 4, underwent pelvic repair surgery with transvaginal mesh. Pre and postoperative Pelvic Organ Prolapse Quantification (POP-Q) stage, Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), urodynamic parameters, peri- and postoperative complications were evaluated. *Results*: forty-Three female patients were followed-up for 48 month. The result showed that there were statistically significant differences between POP-Q parameters, UDI-6 and IIQ-7 before and after surgery (p value < 0.05). Complications included seven cases (16.3%) of urinary tract infection, one cases (2.7%) of mesh exposure, three cases (7%) of recurrent prolapse, and 4 cases (9.3%) of objective stress urinary incontinence. No bladder and tract perforation occurred during surgery. *Conclusions*: total organ pelvic reconstructive surgery that done with transvaginal mesh of the Uphold System assign satisfactory anatomical and outcomes of urinary function in a median 60 months of follow-up.

Keywords: pelvic organ prolapse, transvaginal uphold mesh, complications

1. INTRODUCTION

Downward displacement of components that are normally adjacent to the vaginal apex is defined as pelvic organ prolapse (POP), which is a problem of pelvic floor muscle relaxation (Obstetricians and Gynecologists, 2019; Jelovsek et al., 2007). In addition to pelvic organ prolapse, pelvic floor muscle relaxation causes pelvic organ dysfunction, painful intercourse or dyspareunia, low back pain, sexual dysfunction, and sexual dissatisfaction (Turner et al., 2015). Pelvic floor disorders cause urinary and intestinal incontinence (feces, gas) and uterine-vaginal prolapse (Uustal Fornell et al., 2004). Among all types of pelvic disorders, POP is common and affects a large percentage of women and has a direct effect on the function of the urinary tract and sexual function (Barber et al., 2002; Rogers et al., 2006). According to the results of current studies, about 50% of women have some degree of

prolapse after childbirth, but only 10-20% of them have a clear symptom (MacLennan et al., 2000; Dumoulin et al., 2016).

The incidence of POP is directly related to the number of pregnancy and childbirth, age and race (Kepenekci et al., 2011). Although, several abdominal or vaginal surgical methods are used for treating of POP, but in the last few years surgery with placement of mesh has become more popular because of the excellent short-term treatment rate (Feiner et al., 2009; Rahkola-Soisalo et al., 2019). In addition, the use of synthetic mesh improves anatomical results as well as decrease the risk of relapse prolapse (Long et al., 2012; Ker et al., 2018). However, the usage of vaginal mesh have a more complications like mesh erosion, pain, infection, bleeding and dyspareunia (Rahkola-Soisalo et al., 2019; Ker et al., 2018). It should be noted that, depending on the surgical procedure as well as the nature of the mesh, the complications may be increased. However, finding an alternative surgical method and reducing the biomaterials burden has become a priority (Allegre et al., 2019; Vu et al., 2012). In this study, the uphold system (Boston Scientific, Natick, MA, USA) was used. We use this system for women with stage 4 POP at our hospital. The purpose of this study was to achieve this goal the clinical outcomes, evaluation the efficacy and complications of uphold system for total organ pelvic prolapse repair.

2. MATERIALS AND METHODS

Between 2014 and 2019, 103 women patients with POP symptoms (stage 1- 4) were treated with transvaginal surgery with pop mesh surgery at our hospital. We peruseded the charts of patients with stage 4 Pelvic Organ Prolapse Quantification (POP-Q) who received the uphold mesh for repair. Finally, 47 patients were identified from medical records, all of which followed up from a minimum of 12 months to a maximum of 60 months. Patients with pop stage 4 who were treated with other methods such as laparoscopic sacrocolpopexy or transvaginal sacrospinous ligament suspension or another mesh kit, were excluded from this study.Due to follow up period less than 12 months and inadequate data, 4 patients were excluded. Ethical approval was obtained from the relevant organization of the hospital for retrospective data analysis (ID-number: 1398.941 IR.kums.R2C). Pre- and post-operative assessments included urogenital distress inventory-6 (udi-6), incontinence impact questionnaire-7 (II Q-7), pelvic examination, pop Q staging, measurement of PVR, Qmax and cough stress test after repositioning of prolapse compartment. Pre-operative pop-q values were measured in the outpatient clinic and Post-operative POP-Q values were measured in follow up visits. All patients were aware of the potential risks of transvaginal mesh (including the FDA warning). We informed patients of serious complications including bladder or rectal injury, mesh erosion, bleeding and chronic pelvic pain.

Surgical procedure

All patients were operated on by an experienced female urology surgeon (F.Sh) and all were treated with pop stage 4 with an uphold mesh system. The surgical procedure involved incision on the anterior wall of the vagina from the neck to the cervix (in patients with uterus) or to the vaginal apex (post hysterectomy). In patients with uterus, the upper edge of the mesh was fixed beneath the neck of the bladder and the lower edge was affixed to the paracervical ring. After fixation of the mesh, vaginal fascia was drawn. Intra-operative, cystoscopy and DRE were performed routinely to rule out bladder and colorectal injuries and to check bilateral ureteral opening. All patients received prophylactic antibiotic (1 g intravenous cefazolin) half an hour prior to surgery.

Data collection and analysis

Pre –and post-operative information including urinalysis, Hemoglobin 24 hour before and after surgery, operation time, estimated blood loss, days with indwelling catheter, number of days hospitalized and complications during surgery such as bladder neck perforation, urethral perforation or rectum, was collected. Postoperative follow up was performed in the first week, months 1, 3, 6 and 12 and then annually. Postoperative information included urinary tract infection (UTI), urinary abnormal symptoms including dysuria, urinary incontinence, and SUI, fever more than 3 days, discharge with catheter, wound infection, hip pain, vaginal hematoma and pelvic hematoma, were recorded and investigated. PVR and Q max measurements were performed about 1 month after surgery. Mesh extrusion was considered in pelvic examinations follow up, and recurrence was defined as stage 2 or more based on the most distal portion with the pop -q system. All data were analyzed using SPSS software version 20. P value < 0.05 was shown to be a significant difference between the variables.

3. RESULTS

The demographics of 43 patients including age, parity, weight, operating time, menopause status and etc., are shown in Table 1. In this study the mean age of women at surgery was 66 (SD ± 7) years and mean parity was 4 (SD ± 2). Forty oneof women (95.3%) were menopausal and 9.3 % had a thyroid dysfunction. Ten patients (23.3%) had a history of diabetes and 23 patients had a

previously undergone hysterectomy. Eight patients (18.6%) had previous floor pelvic surgery. Preoperative and postoperative POP-Q values were listed in Table 2. For this purpose, the data were analyzed by pair t-test and Wilcoxon for normal and abnormal data, respectively. Statistical analysis showed that there is a significant difference between the pre and postoperative POP-Q values (p value < 0.05). In addition, the relationship between age, hysterectomy history, parity numbers, as well as previous pelvic floor surgery history with changes in POP-Q values were evaluated.

Table 1 Patients demographics (n=43).

Variables	Mean	Standard deviation or n (%)
Age (years of age)	66	±7
Parity	4	±2
Weight (kg)	67	±10
num NVD	4	±2
num CUR	2	4.6%
num CS	3	7%
Menopause	41	95.3%
Smokers	1	2.3%
CVD	3	7%
Thyroid dysfunction	4	9.3%
Asthma	0	0
Diabetes	10	23.3%
Fibromyalgia	0	0
Hysterectomy	23	53.5%
Any previous pelvic floor surgery	8	18.6%
Operating time (min)	67	±11
Bleeding (ml)	0	0
Hospital stay (days)	1	2.3%

Table 2 Preoperative and postoperative POP-Q values (n= 43).

POP-Q variables (cm)	Mean ± SD		p-value
	Preoperatively	Postoperatively	
Aa	3.0 ± 0.3	-2.9 ± 0.3	<0.001
Ba	6.1 ± 0.5	-2.9 ± 0.3	<0.001
BP	6.1 ± 0.3	-2.9 ± 0.3	<0.001
C	6.1 ± 0.5	-7.0 ± 1.2	<0.001[a]
Ap	3.0 ± 0.4	-2.9 ± 0.3	<0.001
TVL	7.0 ± 0.3	-7.5 ± 0.3	<0.001
Qmax	15 ± 0.3	24.0 ± 2.6	<0.001
PVR	110 ± 4	45 ± 3	<0.001
UDI-6	5 ± 1	2 ± 1	<0.001[a]
IIQ-7	6 ± 1	3 ± 1	<0.001[a]

a: Wilcoxon, the others are paired t test.

For quantitative variables (age and parity number), relationship was assessed with Spearman correlation coefficient and for qualitative variables, independent t-test, Mann-Whitney (hysterectomy) and Kruskal-Wallis (pelvic surgery history) tests were used. The results showed that there was no significant correlation between the variables (age and parity) with POP-Q values (p value > 0.05). Also, there was not significant relationship between hysterectomy and pelvic surgery history with POP-Q values (p

value > 0.05) except II Q in pelvic surgery history (p value < 0.05). In the other words, increasing the age or number of parities as well as having hysterectomy history or previous pelvic surgery has no effect on these parameters. The intra and post-operative complications are shown in Table 3. During surgery, intra-operative complications such as bladder perforation, tract perforation and bleeding were not observed. The most post complications included seven cases (16.3%) of urinary tract infection, one case (2.7%) of mesh exposure, four cases (9.3%) of objective stress urinary incontinence, three cases (7%) of recurrent prolapse, and ten cases (23%) urge urinary incontinence. The relationship between the surgery result and the hysterectomy, history of previous pelvic surgery, parity number, and age is presented in Tables 4–6. As the results show, there was not statistically significant correlation between hysterectomy and previous surgical history with anterior and posterior POP (Chart 1 and 2). Also, as the correlation coefficient results show, there is no significant relationship between age and parity with anterior and posterior POP.

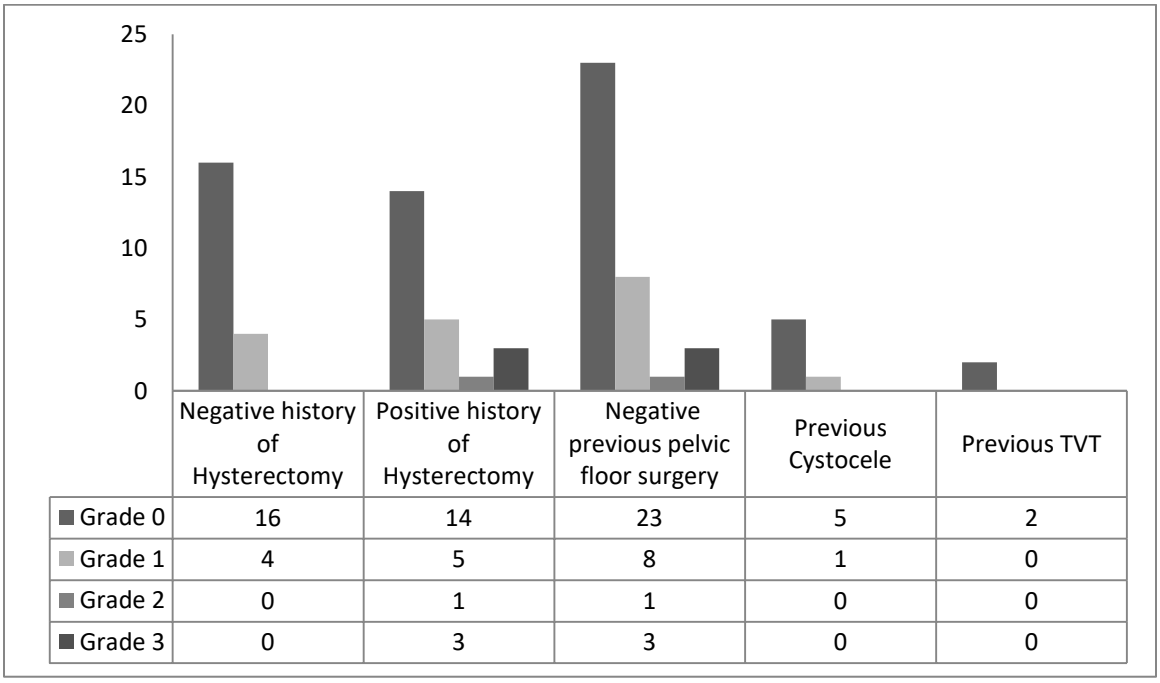
Table 3 Intra and Post-operative complications after Uphold mesh kit surgery.

Complications	N (%)
Intra-operative	
Bladder perforation	0
Tract perforation	0
Bleeding more than 50 ml	0
Post-operative (6 month)	
Urinary tract infection	7 (16.3%)
Bladder-emptying difficulties	0
Catheter after hospital stay	0
Fever (≥3 days)	0
Wound infection	3 (7%)
Groin pain	14 (32.6%)
Dyspareunia	4 (9.3%)
Vaginal hematoma	0
Pelvic hematoma	0
Stress urinary incontinence (SUI)	5 (11.6%)
Re-operation / mesh removal	0
Mesh exposure	1 (2.3%)
After one year	
Recurrence prolapse (anterior-posterior)	6 (14%)
Mesh exposure	2 (4.7%)
Stable pain	2 (4.7%)
SUI	9 (20.9%)
UUI	10 (23.3%)
Mesh extrusion	1 (2.3%)
Recurrent prolapse/need operation	3 (7%)

Table 6 Investigation of relationship between age and parity with anterior and posterior POP with Spearman correlation coefficient.

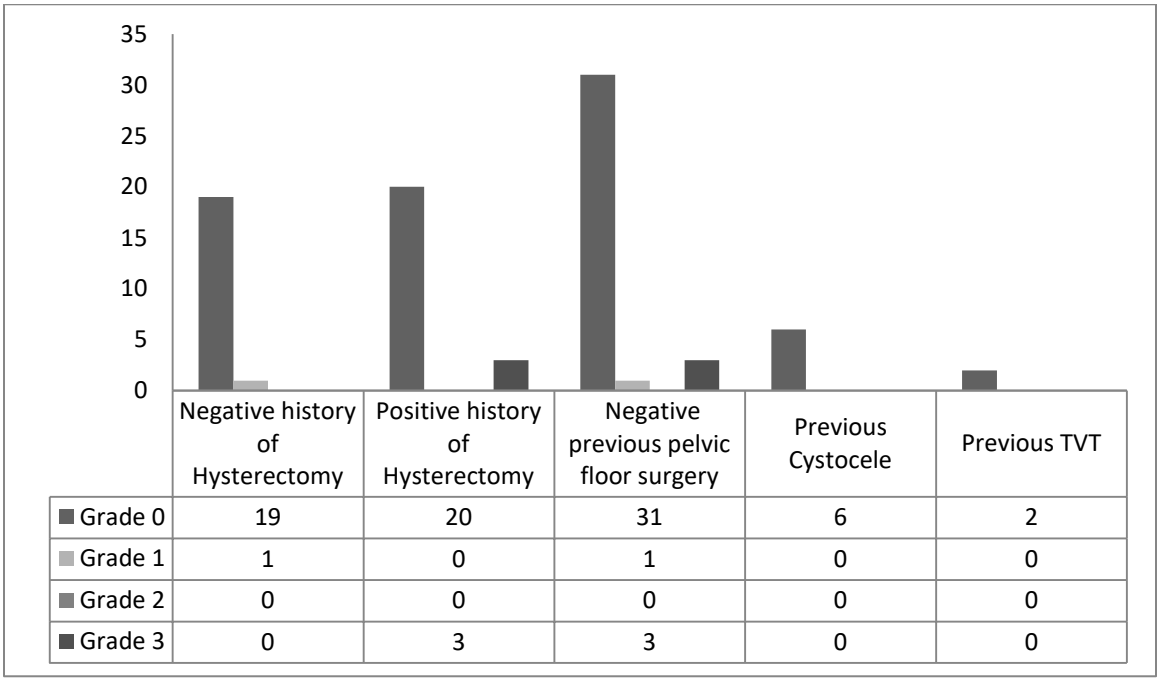
Correlations			age	parity	POP anterior	POP posterior
Spearman's rho	age	Correlation Coefficient	1.000	.174	.096	.141
		Sig. (2-tailed)	.	.264	.541	.368
		N	43	43	43	43
	parity	Correlation Coefficient	.174	1.000	.197	.244
		Sig. (2-tailed)	.264	.	.206	.114
		N	43	43	43	43

POP anterior	Correlation Coefficient	.096	.197	1.000	.442**
	Sig. (2-tailed)	.541	.206	.	.003
	N	43	43	43	43
POP posterior	Correlation Coefficient	.141	.244	.442**	1.000
	Sig. (2-tailed)	.368	.114	.003	.
	N	43	43	43	43



	Negative history of Hysterectomy	Positive history of Hysterectomy	Negative previous pelvic floor surgery	Previous Cystocele	Previous TVT
Grade 0	16	14	23	5	2
Grade 1	4	5	8	1	0
Grade 2	0	1	1	0	0
Grade 3	0	3	3	0	0

Chart 1 Investigation of relationship between hysterectomy and previous surgical history with anterior POP



	Negative history of Hysterectomy	Positive history of Hysterectomy	Negative previous pelvic floor surgery	Previous Cystocele	Previous TVT
Grade 0	19	20	31	6	2
Grade 1	1	0	1	0	0
Grade 2	0	0	0	0	0
Grade 3	0	3	3	0	0

Chart 2 Investigation of relationship between hysterectomy and previous surgical history with posterior POP.

4. DISCUSSION

Over the past decade, the use of synthetic meshes (in particular the Boston scientific mesh) has been increasing in the pelvic organ prolapse repair. Based on the results of previous researches, surgical operations with this method associated with a high success rate. But along with the many benefits, this type of surgery has different complications such as mesh erosion, urinary tract infection, dyspareunia, and voiding dysfunction (Altman et al., 2011; Da Silveira et al., 2015). Chang et al., (2015 and 2017), investigated 111 patients with pelvic organ prolapse stage 3 and 4. After 2 years fallow up, the anatomical success percentage was 97.3% and mesh related complication such as mesh exposure was obtained 1.8%. Also, the recurrence rate of prolapse was reported to be 3.9% (Chang et al., 2019). In another study, letouzeyet et al., (2015), Using the uphold mesh kits, treated 115 patients with stage 2 or higher prolapse. After 23 months follow-up, the percentage of success rate, mesh exposure rate and erosion rate was reported 93, 3.4 and 2.7%, respectively. Chang et al., (2019), treated 291 patients with pelvic organ prolapse by a minimally invasive bilateral sacrospinous hysteropexy (Uphold Lite Vaginal Support System). After 26 months of follow-up, they reported that 69 patients (23.7%) had surgery-related complications, including 1 with bladder injury (0.3%), 2 with hematoma (0.7%), 8 with urinary tract infection (2.8%), 48 with voiding dysfunction (16.5%) and 10 with mesh problems (3.4%). Among these morbidities, 12 patients (4.1%) needed surgical intervention, including 6 for mesh problems, 1 for bladder injury, 2 for hematoma, and 3 for anti-incontinence surgery. Also, recurrence rate of prolapse in the studied patients was reported to be 2.1%. In additions, Altman et al., (2016), studied patients that had pelvic organ prolapse greater than stage 2. The patients underwent surgery with uphold mesh kits and follow-up for more than a one year. The objective success rate was reported 94%.

In comparison to the above studies, the anatomical success rate in the present study was 93% and the mesh exposure rate were 2.7% and 4.3% after a median 6 and 12 months of follow-up. These obtained values are compatible with the results of above-mentioned previous studies. As well, the mesh exposure rate is lower than that in the use of the Perigee/Apogee and Prolift systems (Chu et al., 2012; Huang et al., 2015) . One of the interesting finding of this study is that intra-operative complications like bladder perforation, tract perforation and bleeding which is reported in previous studies, was not incident in the patients. Furthermore, some of the post-complications such as bladder-emptying difficulties, urinary retention and use of urethral catheterization after hospital stay, fever (≥3 days), vaginal hematoma, pelvic hematoma and re-operation / mesh removal not observed. The SUI value in this study appears to be similar to the results of previous studies. Nine patients in this study reported SUI, but only 4 of them were objective identified as having SUI. As for other postoperative complications, ten patients (23.3%) had urge incontinence. A limitation of this study is the low number of the patients.

5. CONCLUSION

In conclusion, it should be noted that the use of the uphold mesh kits can be very helpful and valuable in the repair and treatment of pelvic organ prolapse, although further studies on the consequences and complications of this system are inevitable.

Author's contribution

Sharifiaghdas F: Project development and Manuscript writing
Esmaeili R: Data collection and Manuscript writing and editing
Bartani Z: Data collection and Manuscript writing and editing

Consent to publish

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

Conflicts of interest

The authors have no conflict of interest

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Data and materials availability

All data associated with this study are present in the paper.

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