

Uterine-preserving pelvic organ prolapse surgery using the UPHOLD LITE vaginal support system

The outcomes of 291 patients

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Abstract

This article aims to evaluate the safety and outcome of women with pelvic organ prolapse (POP) treated by a minimally invasive bilateral sacrospinous hysteropexy (UPHOLD LITE Vaginal Support System, Boston Scientific) without concomitant anti-incontinence surgery.

This retrospective study was conducted between 2014 and 2016. Evaluated items included surgical parameter and postoperative outcome.

Three hundred thirteen women with POP were eligible and 22 were excluded because of history of either or more following situations, such as hysterectomy, mesh augmentation, previous anti-incontinence procedures, and radical pelvic surgery before. With a median follow-up of 26 months, surgery-related morbidity rate was 23.7% (69/291), 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. The difference of pelvic organ prolapse quantification (POP-Q) stage before and after surgery showed a statistical significance (anterior portion from 1.36 ± 2.60 to -2.69 ± 0.26 , posterior portion from -1.29 ± 2.08 to -2.46 ± 0.62 , and cervix portion from 2.03 ± 4.80 to -6.98 ± 2.26 , all $P < .001$). At the end of August 2018, re-intervention rate for POP recurrence was 2.1% ($n = 6$), including abdominal sacrocolpopexy ($n = 1$), anterior repair ($n = 1$), vaginal total hysterectomy and uterine-sacral ligament suspension ($n = 1$), vaginal total hysterectomy and LeFort ($n = 1$), LeFort ($n = 1$), and pessary support ($n = 1$).

Because some women developed postoperative lower urinary tract symptom, preoperative evaluation, including careful and detailed history taking, and urodynamic evaluation is suggested. After adequate counseling, uterine-preserving sacrospinal ligament suspension by UPHOLD LITE Vaginal Support System surgery could be considered in the management of women with POP, because of its high successful rate (97.9%) and low morbidity rate.

Abbreviations: CI = confidence interval, LUTS = lower urinary tract symptom, OAB = overactive urinary bladder, POP = pelvic organ prolapse, POPDI-6 = pelvic organ prolapse distress inventory 6, POP-Q = pelvic organ prolapse quantification, RR = relative risk, SUI = stress urinary incontinence, UTI = urinary tract infection.

Keywords: pelvic organ prolapse, sacrospinous hysteropexy, uterine preservation

1. Introduction

Pelvic organ prolapse (POP) is a major burden for the public health system, affecting up to 30% of all women during their lifetime.^[1,2] Although hysterectomy is often considered during POP surgery, there is a growing belief that this strategy may, for some women, offer no specific benefit when compared to newer minimally invasive alternatives accompanied with uterine-

preserving procedures.^[3–6] Vaginal mesh insertion was associated with significantly lower failure rates although its use is still controversial, because of the potential risk and mesh-related complications such as pain, dyspareunia, mesh contraction and exposure.^[7–10] In addition, a recent large population-based cohort study did not recommend the use mesh procedure for anterior and posterior mesh procedures for anterior and posterior

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compartment prolapse.^[11] Because the design of the UPHOLD LITE Vaginal Support System with the Capio SLIM Suture Capturing Device (Boston Scientific, Marlborough, MA, USA) significantly decreases the size of mesh (only one-fourth of the traditional trans-vaginal mesh in size) and only 2 arms for bilateral sacrospinous suspension (only one-half or one-third of the number of arms from the traditional methods) with less paravesical dissection and no distal anchorage, all reported to decrease the risk of mesh exposure and also decrease the opportunity of soft tissue trauma and chronic pain after surgery.^[12–15] There are a few studies which have shown the safety and efficacy outcomes and subjective relief of condition specific symptoms in a relatively new technique (the UPHOLD LITE Vaginal Support System) for women with uterine-preserving POP surgery.^[12–15] However, these studies are limited to the small population.^[12–15] Therefore, in the present study we conducted a largest case series to investigate the safety and effectiveness in women with POP who underwent the uterine-preserving POP surgery by UPHOLD LITE Vaginal Support System.

2. Methods

Between 2014 and 2016, 313 women with POP treated with uterine-preserving POP surgery by UPHOLD LITE Vaginal Support System with the Capio SLIM Suture Capturing Device (Boston Scientific, Marlborough, MA, USA) without concomitant anti-incontinence surgery were retrospectively reviewed. These women did not have significant stress urinary incontinence (SUI). All procedures were performed by 2 experienced urogynecologists at a single center. The current study was approved by the institutional review board (IRB 2014–08–006CC). The data included the baseline characteristics, pre- and post-operation POP-Q stage, surgery-related morbidity, further surgery and recurrence rate. Recurrence was defined as objective pelvic organ prolapse quantification (POP-Q) stage \geq stage II at the anterior/apical vaginal wall or subjective recurrence with positive clinical symptoms and negative feedback to Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6). One-sided significance tests were used, and *P* values $< .05$ were considered to indicate statistical significance.

3. Results

Among 313 women, 22 patients who had either or more following situations, such as hysterectomy, mesh augmentation, previous anti-incontinence procedures, and radical pelvic surgery before were excluded. The characteristics of 291 patients were shown in the Table 1. The mean age of women in the current study was 63.9 years. The difference of POP-Q stage before and after surgery showed statistical significant improvement, especially for cervix location (Table 2). The surgery-related morbidity, including immediate (during operation and within 1 week postoperatively) and delayed types occurred in 69 patients

Table 1
Characteristics of the patients (n=291).

Variables	Mean	Standard deviation
Age (years of age)	63.9	± 10.1
Parity	3.0	± 1.2
Blood loss (ml)	69.1	± 58.1
Days of hospitalization (days)	4.8	± 0.8

Table 2

The anatomic Pelvic Organ Prolapse Quantification (POP-Q) stage preoperatively and postoperatively (n=291).

	Pre-operation (cm)	Post-operation (cm)	Mean difference (cm)	<i>P</i> value
Anterior compartment	1.36 ± 2.60	-2.69 ± 0.26	-3.99 ± 1.70	$< .001$
Posterior compartment	-1.29 ± 2.08	-2.46 ± 0.62	-1.21 ± 1.44	$< .001$
Cervix	2.03 ± 4.80	-6.98 ± 2.26	-9.01 ± 2.62	$< .001$

Table 3

Immediate and delayed surgery-related morbidity (n=69).

Morbidity	Number
Bladder injury	1 (0.3%)
Hematoma	2 (0.7%)
Urinary tract infection	8 (2.8%)
Voiding dysfunction	48 (16.5%)
Mesh problems	10 (3.4%)

(23.7%). Immediate postoperative complications included bladder injury (n=1, 0.3%), urinary tract infection (UTI) (n=8, 2.8%), hematoma (n=2, 0.7%), and voiding dysfunction (n=48, 16.5%), as shown in Table 3. Lower urinary tract symptoms (LUTS) included the occurrence of de novo SUI (8.6%, n=25) and overactive urinary bladder (OAB) (7.9%, n=23), although some of them were complicated with combined symptoms. Urinary tract problems, such as voiding dysfunction (16.5%, n=48) and UTI (2.8%, n=8) were the key problems in women after uterine-preserving POP surgery (Table 3). However, only 6 (60%, 6/10) patients needed further surgical correction for mesh problems and 3 patients (12%, 3/25) needed anti-incontinence surgery (Tables 3 and 4). In overall, 12 patients (4.1%) needed surgical intervention for the surgery-related morbidity (Table 4). At the end of August 2018, a total of 6 patients were reported to be recurrent (recurrence rate: 2.1%) (Table 5). One patient was treated with abdominal sacrocolpopexy (n=1); 1 with anterior repair (n=1); 1 with total hysterectomy and uterine-sacral ligament suspension (n=1); 1 with total hysterectomy and LeFort procedure (n=1), and 1 with LeFort procedure (n=1).

Table 4

Surgical intervention for immediate and delayed surgery-related morbidity (n=12).

Mesh problems (n=6)
Bladder repair (n=1)
Hematoma incision and drainage (n=2)
Anti-incontinence surgery (n=3)

Table 5

Recurrence of patients after uterine-preserving pelvic organ prolapse surgery (n=6).

Abdominal sacrocolpopexy (n=1)
Anterior repair (n=1)
Total vaginal hysterectomy and uterine-sacral ligament Suspension (n=1)
Total vaginal hysterectomy and LeFort (n=1)
LeFort (n=1)
Follow-up (n=1)

4. Discussion

Psychologically, the uterus has been regarded as the regulator and controller of important physiological functions, a source of energy and vitality, and a maintainer of youth and attractiveness, contributing to consideration of organ-preserving strategy in the management of various kinds of obstetrics and gynecology-related problems.^[16–18] In Taiwan, the trend of uterus preservation becomes more and more popular. An 11-year population-based nationwide descriptive study showed a trend of uterine suspension with uterine preservation during the latter years,^[19] and the uterus preservation is always considered when there is no pathological finding of uterus.^[20] In 2014, this minimally invasive procedure of UPHOLD LITE Vaginal Support System with the Capiro SLIM Suture Capturing Device (Boston Scientific, Marlborough, MA, USA) has been used in our hospital. More than 500 patients have been treated with this procedure so far.

In the current study, the successful rate was near 98% during the median follow-up period of 26 months, which was significantly better than those from the previous studies.^[12,15] Dr. Lo and colleagues enrolled 95 patients treated with UPHOLD procedures and the objective and subjective cure rate for prolapse was 95.5% and 94.3%, respectively.^[12] Dr. Altman and colleagues investigated 207 patients treated with UPHOLD, regardless of accompanied with anterior colporrhaphy and found that the successful rate of POP-Q stage ≤ 1 and subjective symptom relief was 94% and 91%, respectively.^[15]

The most common surgery-related morbidity was the occurrence of LUTS, with an incidence rate of 16.5% in the current study. Lower urinary tract symptom was also common in the previous studies.^[12,15] One study was 9.7%,^[15] and the other study was 20%.^[12] However, both studies commented that LUTS was a minor complication,^[15] which was not bothersome enough to require further surgery.^[12] Our study found that the de novo SUI occurred less than 10%, and there were a total of 25 women (8.6%) who had this morbidity and only 3 patients needed a further surgical intervention (1%).

Since POP is frequently associated with LUTS, the impact on postoperative LUTS, including SUI, frequency, urgency, urgent incontinence, OAB, etc., should be always kept in mind.^[21] Among these LUTS, SUI might be most important, either with or without evidence by urodynamic study. It is reported that women with POP often coexist with SUI and the incidence rate might be up to 20%.^[22] In addition, de novo SUI after POP surgery occurred frequently with the range between 10% and 35%.^[23,24] That is to say after surgical correction of POP, persistent and occult or new LUTS can be present.^[25] Therefore, for those patients who are arranged for POP surgery, the postoperative LUTS should be taken care of. There are some tools to predict, counsel, and subsequently handle postoperative LUTS. Due to its impact on the success of POP surgery, there are many articles available to address this issue.^[25–32] The main findings include

1. POP is much more severe, and obstructive symptom is much more significant positive, but other LUTS is not;
2. urodynamic evaluation is valuable in patients with prolapse reduction but its importance might be limited on certain population, because of absence of correlation between POP surgery and other LUTS, such as OAB, detrusor underactivity, detrusor overactivity, and others;
3. a thorough history evaluation is of most importance;
4. patients need adequate counseling about postoperative LUTS when they are arranged for POP surgery.^[25–32]

Based on our study, it is highly possible that these 25 women might have a coexistence of SUI before surgery. Because we did not perform the urodynamic study in women with POP preoperatively in all patients, and these patients in the current study did not receive anti-incontinence surgery during the uterine-preserving POP surgery, we did not know where these patients did have a coexistence of de novo SUI or have a subsequent development of de novo SUI.

The overall rate of serious complications was 3.1% (9 out of 291 patients), including 1 patient with bladder perforation, 2 patients with hematoma, and 6 patients who had undergone reoperations either with complete mesh removal or with tape down because of pain or mesh exposure. Compared with previous study, the complication rate was reported ranged from 0% (66 patients),^[12] 1% (95 patients)^[13] to 4.3% (207 patients),^[15] suggesting that this minimally invasive procedure of UPHOLD LITE Vaginal Support System with the Capiro SLIM Suture Capturing Device is safe and acceptable in the management of women with POP who need uterine-preserving POP surgery.

The strength of the current study included the followings. First, the study population is relatively homogeneous and all procedures were standardly performed by 2 experienced urogynecologists. Second, the current study enrolled the largest number of the patients. Third, the follow-up was longer enough (with a mean follow-up period of 26 months). However, some limitations should be claimed. In the current study, we did not analyze the sexual function in these patients, and this should be emphasized in the current practice.^[33] However, the subsequent analysis of quality of life after UPHOLD LITE Vaginal Support System for POP has been done. In addition, we did not provide preoperative and postoperative urodynamic examinations in all patients, contributing to the uncertain of co-existence or subsequent occurrence of de novo SUI in the current study. However, a recent systematic review and meta-analysis was conducted to compare efficacy and safety surgery with and without incontinence surgery and the results showed that women with preoperative SUI symptoms or occult SUI had a significant lower risk to receive subsequent anti-incontinence surgery for postoperative SUI after POP surgery with a simultaneous midurethral sling surgery than those with POP surgery did only: 0 vs 40% (relative risk [RR] 0.0, 95% confidence interval [CI] 0.0–0.2) and 1 vs 15% (RR 0.1; 95% CI 0.0–0.6).^[34] However, severe adverse events were significantly increased after POP surgery with midurethral sling procedure (14% vs 8%; RR 1.7, 95% CI 1.1–2.7).^[34] It is interesting to find that there was no significant difference in continent women not tested for occult SUI or without occult SUI.^[34] Due to above findings, the recent trend seemed to favor the strategy to postpone the anti-incontinence surgery during POP surgery and perform a delayed (two-stage) continence procedure, if required.^[24,25,27,31,34,35]

Based on the current study, we suggested that the use of UPHOLD LITE Vaginal Support System with the Capiro SLIM Suture Capturing Device could be considered in women with POP who need uterine-preserving POP surgery. Because some women may have LUTS after POP surgery, preoperative evaluation and counseling to identify risk factors of LUTS may be important.^[25,31,32] This counseling should contain a discussion about persistent LUTS and the development of new LUTS. More studies are welcome to provide the better care of women with POP.

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