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Effects of uterine preservation on long-term subjective outcomes of sacrospinous ligament fixation for the treatment of pelvic organ prolapse

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ABSTRACT

Objective: To evaluate the long-term subjective outcomes in women who underwent sacrospinous ligament fixation with and without uterine preservation for treatment of uterovaginal prolapse.
Study design: Two hundred and ten women with POP-Q≥stage III uterovaginal prolapse, who underwent sacrospinous ligament fixation from January 1994 to December 2007 were included. Patient Global Impression of Improvement was used to assess the surgical outcome in July 2016. Primary outcome measures were subjective success rate and current satisfaction. Kaplan-Meier method and Cox proportional hazard model were used for analysis.
Results: The mean follow-up was 13.3 years (range 8.5–22.6 years). One hundred and thirty-nine patients were successfully interviewed and analyzed. The cumulative subjective success rate was 88.5% and current satisfaction was 77.7%. The repeat surgery rate was 2.9%. There were no significant differences in subjective success (89% vs. 88%) or current satisfaction (78.1% vs. 77.3%) between uterine preservation (n = 64) and concomitant hysterectomy (n = 75). Kaplan-Meier analysis showed that sacrospinous ligament fixation with uterine preservation had a better subjective outcome at mid-term follow-up but was not significantly different compared with concomitant hysterectomy after long-term follow-up (P = 0.63). The adjusted HR of uterine preservation was 0.75 (95%CI: 0.22–2.12, P = 0.59).
Conclusion: Sacrospinous ligament fixation with or without uterine preservation in the treatment of women with uterovaginal prolapse has no significant difference in long-term subjective outcomes and patient satisfaction.

Introduction

Treating pelvic organ prolapse (POP) has become more challenging due to a growing senior population and increased life expectancy. Artificial mesh augmentation for treating POP was once considerably popular but now it is only recommended in complex cases with recurrent prolapse [1,2]. However, the higher recurrence rate of POP after transvaginal native tissue repair has raised concerns [3]. It is necessary to evaluate the long-term outcome of transvaginal native tissue repair in treating POP or other treatment modalities need to be developed in the future.

Recently, a trend of uterine preservation in treating uterovaginal prolapse has drawn attention [4]. Uterine-preserving prolapse surgeries may improve operating time, blood loss, and risk of mesh exposure and do not significantly affect their short-term outcomes [5]. However, uterine preservation or hysterectomy in the treatment of uterovaginal prolapse is a complex issue. Patient goals, treatment preferences and values need to be acknowledged and considered in modern practice as well as choice of POP surgery. Decision making might be influenced by patient wishes or autonomy, surgeon preference, hospital policy and literature-based recommendations [6]. In addition, most literature regarding POP surgeries have follow-up intervals of less than three years and the long-term risk of uterine pathology after uterine preservation is also lacking [5].

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The anatomical outcome might not correlate with the patients' perception of overall improvement after the operations because of an inconsistency between functional and anatomical outcomes of POP surgeries. The success rate of POP surgery is affected by the definition of success [7]. A recent study revealed the post-operative objective recurrence rate (POP≧2) was 25.2%, but the subjective recurrence rate was 5.4% and only 2.7% of patients required re-intervention after a mean follow-up of 24.5 months [8]. Subjective outcomes such as patient satisfaction should be used for assessing surgical outcomes in women who have undergone POP surgery.

The aims of our study were to evaluate the long-term postoperative subjective outcome and satisfaction in women who underwent sacrospinous ligament fixation (SSLF) with or without uterine preservation for apical suspension due to POP. We also explored the risk factors associated with subjective failure.

Materials and methods

Two hundred and ten consecutive patients who had POP stage III or IV and underwent transvaginal SSLF with or without uterine preservation by the same surgeon (GDC) from January 1994 to December 2007 were recruited in this observational cohort study. The study subjects were identified through a treatment code set up by the National Health Insurance (NHI) in Taiwan. Patients who had a previous hysterectomy, recurrent POP or vaginal hysterectomy due to other surgical indications such as abnormal uterine bleeding or suspected endometrial pathology were excluded. Uterine preservation or concomitant hysterectomy was an option for women who underwent SSLF. This patient cohort was analyzed for surgical outcomes. We reviewed the preoperative and postoperative chart records including basic characteristics, clinical data of pelvic examinations, early postoperative complications, and adverse effects related to these procedures.For subjective outcome measurement, telephone interviews were carried out by a nursing coordinator in July 2016. The study protocol was approved by the Institutional Review Board of Chung Shan Medical University Hospital (CSMUH No:CS12207).

Operation procedures

The SSLF was performed as follows: The apex of the vaginal vault (for patients with concomitant hysterectomy) or cervix was grasped with two Allis clamps, and downward traction was applied to determine the extent of prolapse. The upper part of the posterior vaginal wall was incised (about 3 cm in length) and the perirectal space was entered. Blunt dissection was used to break through the fibroareolar tissue. The ischial spine was identified by palpation and retractors were used to expose the SSL complex. Under direct visualization, a single non-absorbable suture (Ethibond) was placed through the middle portion at the right side (unilateral) of the SSL (about 2–3 cm medial to the ischial spine) and then to the posterior lateral of vaginal vault or cervix without passing through the vaginal epithelium. The suspension sutures were tied to allow the vaginal apex or cervix to attach to the SSL. Transanal examination by index finger was used to ensure the vaginal apex or cervix was attached to the SSL. Concomitant anterior-posterior colporrhaphy was performed according to the prolapse status of the vaginal walls. The vaginal mucosa and fibromuscular tissue were closed using delayed absorbable sutures while performing concomitant anterior and posterior colporrhaphy. Autologous pubo-vaginal sling or Kelly plication was performed to treat associated stress urinary incontinence. Those procedures are described elsewhere [9].

Outcome measurement

Patient Global Impression of improvement (PGI-I) was used to assess the outcome of surgical treatment [10]. The primary outcome measures were subjective success rate and current satisfaction. For subjective surgical outcome, if the patients' responses were "very much better" and "much better", the surgery was considered successful. If they responded "a little better", it was grouped as improved. Other perceptions were considered as failures of surgical treatment. In this study, subjective success rate was defined as the percentage of patients that perceived the surgical outcome as successful or improved. If the patient's perceived outcome was failure, the trained nurse coordinator asked: "When did the condition start?" For current satisfaction, the following questions were asked: "Compare your present symptoms with that before the operation, do you feel satisfied with your current condition?" And if not, "When did your dissatisfaction begin and what are the symptoms that bother you?" "Do you feel or see a bulging mass at the vaginal introitus?"Secondary outcome measures were subjective perception of recurrent prolapse, receiving a repeat prolapse surgery and post-operative lower urinary tract symptoms (LUTS). Patients were asked about any repeat operation for recurrent prolapse during the telephone interview. For the current post-operative LUTS, the UDI-6 questionnaire [11] was used for further evaluation at the same time.

Statistical methods

SPSS software version 18.0 (SPSS Inc., Chicago, IL, USA) was used for the data analysis.Student's *t*-test was used to compare the means of continuous variables between uterine preservation and hysterectomy. Chi square test was used for nominal or ordinal data analysis. Kaplan-Meier analysis was used to demonstrate the length of time patients remained in an improved state after the operation.Cox proportional hazard model was used to evaluate the associated factors related to surgical failure. A P value of less than 0.05 was considered to be a statistically significant difference.

Table 1
Baseline characteristics of patients enrolled and comparison between patients who underwent SSLF with uterine preservation and concomitant hysterectomy.

Characteristic	Overall (n = 139)	Hysterectomy (n = 75)	Uterine preservation (n = 64)	p-value
Age (years)	54.0 ± 12.4	57.6 ± 10.6	49.9 ± 13.2	<0.001*
BMI (kg/m^2)	24.8 ± 3.5	24.8 ± 4.1	24.8 ± 2.7	0.97
Parity (median, range)	3(1-8)	3(1-8)	3(1-6)	0.81
Menopause	77(57.0)	53(71.6)	24(39.3)	<0.001*
Previous Urogynecology surgery	15(10.8)	11(14.7)	4(6.3)	0.11
Concomitant anti-incontinence surgery	66(49.6)	36(49.3)	30(50)	0.94

Data presented as n (%) or mean ± SD.
Denominators differ due to missing data.
* Statistically significant difference; P < 0.05.

Results

The mean follow-up was 13.3 years (range 8.5–22.6 years). One hundred and thirty-nine (66.2%) patients returned the written informed consent by mail. These patients were interviewed by telephone and the data was analyzed. Seventy-five (54%) patients had SSLF with a concomitant hysterectomy. Sixty-four (46%) patients received SSLF with uterine preservation. The characteristics of the study subjects at time of surgery are shown in Table 1. There were demographic differences between the uterine preservation and concomitant hysterectomy groups. The mean age of the patients was 54 (range, 27–79) years old, and patients who had undergone concomitant hysterectomy were older compared with patients who underwent uterine preservation (57.6 vs. 49.9, $P < 0.001$). Overall, 57% (n = 77) of the women had experienced menopause.For the patients who had undergone a hysterectomy, 71.6% (n = 53) had experienced menopause compared to 39.3% in the uterine preservation group ($p < 0.001$).There was no statistically significant difference between the two groups, regarding other procedures (i.e. anti-incontinence surgery and colporrhaphy) that performed concomitantly during the operation.

The overall cumulative subjective success rate was 88.5% (Fig. 1). Sixteen (11.5%) patients reported that the operation was a failure, 53(38.1%) reported the operation caused improvement and 70(50.4%) reported that the surgery was successful. Twenty-five patients were successfully followed up for at least 17 years. Only one patient reporting a failed operation and dissatisfaction with the current condition compared to her pre-operative condition. For patients that underwent SSLF with uterine preservation, 7(11%) reported failure; 23(35.9%) reported improvement and 34(53.1%) reported success. For patients that underwent SSLF with concomitant hysterectomy, 9(12%) reported failure; 30(40%) reported improvement and, 36(48%) reported success. There was no statistically significant difference in the subjective success rate between women who underwent SSLF with uterine preservation and concomitant hysterectomy (89% vs. 88%, $P > 0.05$). The Kaplan-Meier analysis of the cumulative subjective success rate for these two groups is presented in Fig. 2.The trend for patients who underwent SSLF with uterine preservation was a better subjective outcome at the mid-term follow-up, but there was no significant difference between these two groups at the long-term follow-up ($P = 0.63$). The overall current satisfaction of the patients was 77.7% (n = 108), and there was no statistically significant difference between the SSLF with uterine preservation and SSLF with concomitant hysterectomy (78.1% vs.77.3%, $P > 0.05$). Overall, 4 patients (2.9%) received a second operation for recurrent prolapse. Three patients (2.2%) experienced exposed non-absorbable suture through vaginal epithelium that need further removal.Nine patients (6.5%) reported that they felt or saw a bulging mass at the vaginal introitus.

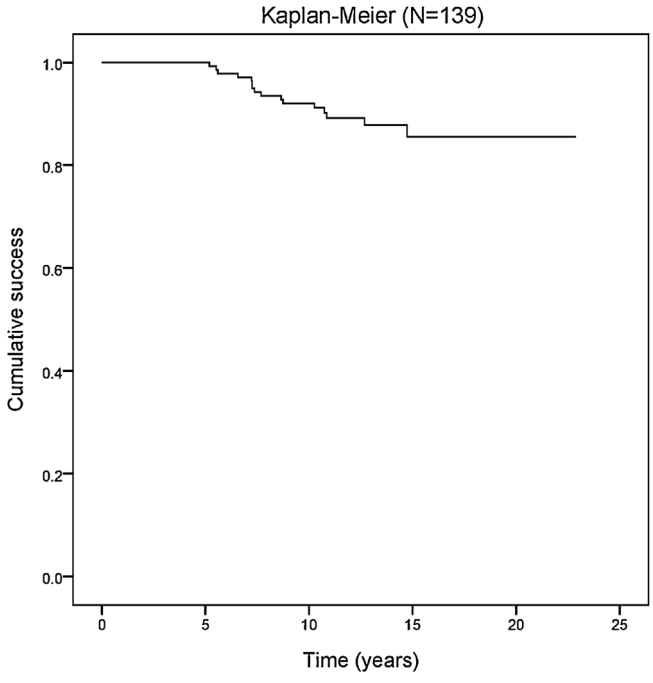

Fig. 1. Kaplan-Meier survival analysis of the cumulative subjective success rate after sacrospinous ligament fixation; mean follow-up of 13.3 years.

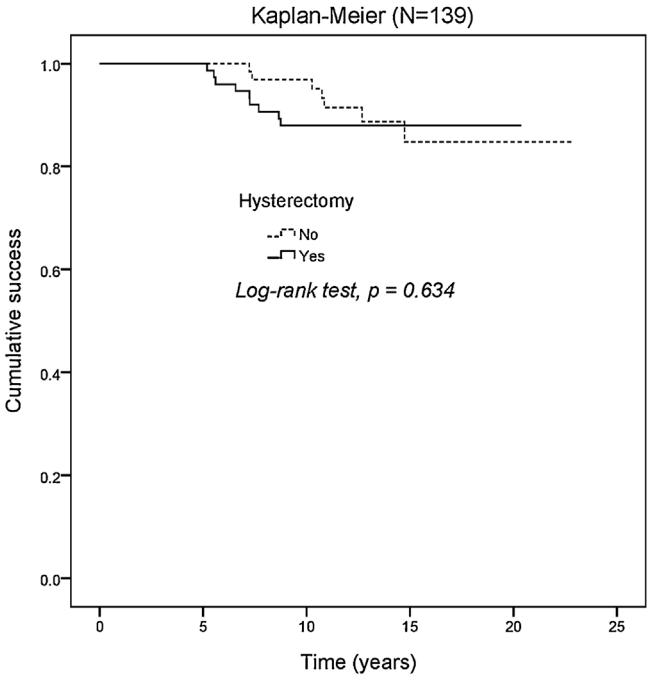

Fig. 2. Kaplan-Meier survival analysis of the cumulative subjective success rate after sacrospinous ligament fixation with and without uterine preservation.

The post-operative lower urinary tract symptoms analyzed by the UDI-6 questionnaire are summarized in Table 2. Seventy-four patients (53.2%) reported at least one symptom.The most common reported lower urinary tract symptoms were slight to moderate urinary frequency (45.8%) and urgency urinary incontinence (27.7%). There was no statistically significant difference between women who underwent SSLF with uterine preservation or concomitant hysterectomy for all symptoms. The adjusted Hazard Ratio (HR) of independent risk factors associated with subjective surgical failure are shown in Table 3. Adjusted HR of uterine preservation was 0.75 (95%CI: 0.22–2.12, P = 0.59) after controlling for age, BMI, parity and menopausal status.

Comment

There was no significant difference in the subjective success rate and patient satisfaction between women who underwent SSLF with uterine preservation and concomitant hysterectomy after a mean follow-up of 13.3 years (8.5 to 22.6 years). The patient's self-perception of improvement after operation was high. The surgical outcome was perceived as successful or improved in 88.5% of patients in this study. Nearly 78% of our patients reported being satisfied with their current condition compared to their preoperative state. Subjective outcomes in our study were comparable with previous studies. Some studies have revealed that the subjective success rates for SSLF range from 84%–99% after a median

Table 2
Patients' self–reported lower urinary tract symptoms evaluated by UDI-6 questionnaire after mean follow up of 13.3 years.

UDI-6	Overall (n = 139)	Hysterectomy (n = 75)	Uterine preservation (n = 64)	p-value
Urinary frequency				0.21
0	75(54.7)	41(56.2)	34(53.1)	
1	44(32.1)	26(35.6)	18(28.1)	
2	16(11.7)	6(8.2)	10(15.6)	
3	2(1.5)	0(0)	2(3.1)	
Urge urinary incontinence				0.11
0	99(72.3)	57(78.1)	42(65.6)	
1	31(22.6)	15(20.5)	16(25)	
2	6(4.4)	1(1.4)	5(7.8)	
3	1(0.7)	0(0)	1(1.6)	
Stress urinary incontinence				0.68
0	119(86.9)	65(89)	54(84.4)	
1	14(10.2)	7(9.6)	7(10.9)	
2	3(2.2)	1(1.4)	2(3.1)	
3	1(0.7)	0(0)	1(1.6)	
Small amount of urine leakage				0.59
0	114(83.2)	63(86.3)	51(79.7)	
1	19(13.9)	9(12.3)	10(15.6)	
2	3(2.2)	1(1.4)	2(3.1)	
3	1(0.7)	0(0)	1(1.6)	
Voiding difficulty				0.12
0	119(86.9)	67(91.8)	52(81.3)	
1	9(6.6)	3(4.1)	6(9.4)	
2	8(5.8)	2(2.7)	6(9.4)	
3	1(0.7)	1(1.4)	0(0)	
Perineal pain				0.05
0	129(94.2)	71(97.3)	58(90.6)	
1	3(2.2)	2(2.7)	1(1.6)	
2	4(2.9)	0(0)	4(6.3)	
3	1(0.7)	0(0)	1(1.6)	

Data presented as n (%).
Denominators differ due to missing data.
UDI-6 scores: 0="not at all", 1= "slightly", 2= "moderately" and 3= "greatly".

Table 3
Cox proportional hazards model predicting independent risk factors for subjective surgical failure after SSLF.

	Adjusted HR	95% CI	p-value
Age≧60	1.39	0.27-7.29	0.69
BMI≧24	1.19	0.41-3.47	0.75
Parity>2	0.72	0.18-2.88	0.64
Menopause	0.73	0.14-3.85	0.71
Uterine preservation	0.75	0.22-2.12	0.59

Statistically significant difference if $P < 0.05$.

follow-up of 5 years (6 months-15 years) [12,13,14]. Aigmueller et al. used PGI-I to evaluate surgical outcomes of SSLF operations and reported that the "sensation of descent" was better in 92.7% of patients after a mean follow-up of 7 years [14].

A recent systematic review article revealed that uterine-preserving prolapse surgeries do not significantly change short-term outcomes compared with hysterectomy after pelvic reconstruction surgery [5]. Maher et al. conducted a study to compare success rates of sacrospinous colpopexy and sacrospinous hysteropexy. They found that the subjective success rate of SSLF with concomitant hysterectomy was 86% after a mean follow-up of 33 months and 78% in the SSLF with uterine preservation group after a mean follow-up of 26 months [15]. A sub-analysis result from a relatively long-term follow-up (median: 86 months) group revealed no difference in objective and subjective success rates between SSLF with and without uterine preservation [16]. Our study has comparable results; there were no statistically significant differences in subjective success (88% vs.89%) and current satisfaction (77.3% vs. 78.1%) between women who had SSLF with uterine preservation and concomitant hysterectomy. Our results seem to support that uterine preservation is an option for treating POPs. Korbly et al. conducted a study to evaluate patient preferences for uterine preservation or hysterectomy in women with POP symptoms assuming outcomes were equal between uterine preservation and hysterectomy [17]. They found that a higher proportion of women preferred uterine preservation (36%), compared with hysterectomy (20%), and 44% of the women had no strong preference. Cvach et al. reported 22% of the women in their abdominal sacral hysteropexy cohort had subsequent uterine pathology such as abnormal bleeding [18]. Thus, uterine preservation during pelvic reconstruction surgery raised concerns for the risk of uterine abnormalities such as presence of uterine leiomyoma or adenomyosis, possibility of occult malignancy, or subsequent malignancy. However, until now there has not been subsequent uterine pathology in our SSLF with uterine preservation cohort.

The strength of our study is a long-term follow-up of more than10 years after the SSLF procedure. All patients were treated by the same surgeon to avoid surgeon bias such as training background, physician preference, or patient selection. This study has some limitations. This is not a randomized controlled trial and several other procedures (i.e. anti-incontinence surgery and colporrhaphy) were done concomitantly. Although 139 patients were successfully interviewed, the loss of follow-up rate was 34%. However, this is one of the problems encountered with long-term follow-ups after surgery. Many of our patients are elderly with poor ambulation or those with poor access, were unwilling to attend the hospital for further follow -up. We were unable to compare the subjective outcome with the objective anatomical outcome in our present study. Most importantly, recall bias may have occurred during the telephone interview. For the evaluation of LUTS, new medical illnesses or comorbidities might develop and

could affect the bladder function and the symptoms might not related to the pelvic reconstruction surgery.

In conclusion, our study shows that SSLF with and without uterine preservation for treating uterovaginal prolapse offers beneficial long-term subjective success and patient satisfaction. The overall re-operation rate for recurrent prolapse was low. The adjusted hazard ratio for uterine preservation did not increase after long- term follow-up.

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