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Surgical Outcomes Within 1 Year After Native-Tissue Apical Suspension for Pelvic Organ Prolapse: Sacrospinous Ligament Fixation Versus Uterosacral Ligament Suspension

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ABSTRACT

Background & Objective: Pelvic organ prolapse (POP) is the herniation of the pelvic organs to or beyond the vaginal wall. Patients with POP may present with specific symptoms like vaginal bulge or pressure or associated symptoms including urinary, defecatory or sexual dysfunction, which could negatively affect the quality of life in these patients. This study aimed to assess the surgical outcomes of native-tissue apical suspension by sacrospinous ligament fixation (SSLF) versus uterosacral ligament suspension (ULS).

Materials & Methods: This prospective cohort study was conducted to evaluate the outcomes of native-tissue apical suspension for pelvic organ prolapse within one year after the surgery from March 2017 to July 2019 at Imam Khomeini hospital, an academic hospital of Tehran University of Medical Sciences, Tehran, Iran. Inclusion criteria were patients with uterine prolapse at Stage 2 or 3 according to the Pelvic Organ Prolapse Quantification System (POP–Q) who planned for total vaginal hysterectomy and apical suspension using uterosacral ligament suspension (ULS) or sacrospinous ligament fixation (SSLF) with no history of pelvic organ prolapse surgery. The main outcome was surgical consequences within 1 year after surgery.

Results: There was no significant difference between the two groups in terms of relapse of anterior, posterior, or apical compartment prolapse. According to the clinical recurrence, although vaginal bulging and pressure were more common in sacrospinous ligament fixation (SSLF) group, the difference was not significant. The number of patients with severe buttock and pelvic pain was significantly higher in the sacrospinous ligament fixation (SSLF) group.

Conclusion: sacrospinous ligament fixation (SSLF) and uterosacral ligament suspension (ULS) are both optimal procedures with the same complications and similar surgical outcomes; however, uterosacral ligament suspension (ULS) had lower post-operative pelvic pain, and also the number of retreatments was lower in this group.

Keywords: Pelvic organ prolapse, Ligament, Outcomes, Pelvic pain, Complication, Recurrence

Introduction

Pelvic organ prolapse (POP) is defined as the descent of one or more of the anterior vaginal walls, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy) **(1)**. It is a common clinical problem that may bother 50% of parous women 50 years or older **(2)**. These women usually complain of symptoms like vaginal bulge or pressure or associated symptoms including urinary, defecatory or sexual dysfunction, which could negatively affect the quality of life **(1)**.

For asymptomatic women, at the time of other pelvic surgery, it is a reasonable option to repair any defect or

compartment prolapse in cases with severe prolapse (stages 3 or 4) **(3-5)**.

Reconstructive surgery corrects the prolapsed organs and aims to reconstruct normal anatomy, on the other hand, obliterative surgery corrects prolapse by removing and/or closing off all or a portion of the vaginal canal (i.e., colpocleisis or colpectomy) to help the viscera back into the pelvis. Another difference between these two types of surgery is that reconstructive procedures can be performed using a vaginal or abdominal approach; while all obliterative surgeries are performed on the vaginal route **(6-9)**.

The most common anatomic location for prolapse is an anterior vaginal wall; however, approximately 50% of anterior prolapse can be related to apical prolapse **(10, 11)**. Therefore, the risk of reoperation for prolapse increases in the absence of a concomitant apical support procedure.

Since the apical support from the uterosacral cardinal ligament complex is generally considered as the cornerstone of any good prolapse repair, every effort should be made to restore the apical compartment **(12)**. Given the minimally invasive nature of transvaginal surgery and the ability to repair all three compartments more efficiently through this route, this is the most common approach for POP repair **(13)**. Currently, there is a growing interest in trans vaginal native-tissue apical repair (using sacrospinous or uterosacral ligaments) because of lower cost and lack of mesh-related complications compared with abdominal sacral colpopexy **(10, 11)**.

Correction of symptomatic apical compartment prolapse usually requires concomitant hysterectomy. In abdominal sacral colpopexy and transvaginal sacrospinous ligament suspension, hysterectomy is performed because the apex is suspended by fixing the vaginal cuff to a support structure (e.g., the sacrospinous ligament or the anterior longitudinal ligament of the sacrum). At least one trial has reported similar 36-month recurrence outcomes for transvaginal mesh hysteropexy compared with traditional vaginal hysterectomy with uterosacral ligament suspension **(14)**.

There are some studies that evaluated the surgical outcomes of sacrospinous ligament fixation (SSLF) versus uterosacral ligament suspension (ULS) **(15, 16)**. Considering the importance of restoring apical suspension as the most important stage of any compartment repair, also the device availability and cost, this study was performed to assess the surgical consequences of apical suspension by using natural tissue including sacrospinous ligament fixation versus high uterosacral ligament suspension. To the best of our knowledge, there is no similar study in the Iranian women population in this field.

Methods

This prospective cohort study was designed for women who were candidates for total vaginal hysterectomy) TVH)and concomitant apical compartment suspension by either uterosacral ligament suspension or sacrospinous ligament fixation. This study was performed from March 2017 to July 2019 at Imam Khomeini hospital, an academic hospital of Tehran University of Medical Sciences, Tehran, Iran.

The institutional Ethics Committee approval was obtained with code number of IR.TUMS.IKHC.REC.1397.334.

Detailed written informed consent was obtained from the patients and one of their closed family members.

Inclusion criteria consisted of women who diagnosed as the second or third stage of symptomatic uterine prolapse that total vaginal hysterectomy and apical suspension by ULS or SSLF were designed for them. Exclusion criteria included: patient's refusal for regular follow-up after surgery, history of connective tissue disorders, diabetes, chronic cough and known malignancy. All patients in both groups underwent vaginal hysterectomy and then apical suspension by either SSLF or ULS was done, concomitant repair of anterior or posterior vaginal prolapse (colporrhaphy) and concomitant anti incontinence surgery was performed if indicated. The main outcomes were anatomical and clinical recurrence of any compartment prolapse. Anatomical recurrence was defined as a recurrent prolapse beyond the hymenal ring and clinical recurrence was evaluated by the bothersome bulge symptoms (vaginal mass protrusion or vaginal pressure). Secondary outcomes were intraoperative and postoperative complications and need for pop retreatment.

Experimental

To accomplish the same standard technique among the surgeons, a detailed surgical protocol was provided as follows:

Sacrospinous ligament fixation was performed unilaterally to the right sacrospinous ligament: The posterior vaginal wall was incised and the right pararectal space was dissected and sacrospinous ligament exposed. Two non-absorbable sutures (polyester 0-Dematech- USA) were fixed at the middle portion of the ligament by Capio suturing device (Boston Scientific-USA). The both sutures' ends were fixed in to the right and left uterosacral ligaments. Anterior and posterior compartment repair or anti incontinence surgery was performed if required. The posterior vaginal wall was closed by running lock method using absorbable sutures (Vicryl; 2-0-Ethicon).

For ULS suspension in this study, each uterosacral ligament was attached to the vaginal vault with two

delayed absorbable sutures (Vicryl 1.0, Ethicon). Both sutures were placed at the proximal part of each ligament, which was at the level of the ischial spine. Additional anterior or posterior compartment repair or anti-incontinence surgery was done if indicated.

After hospital discharge, all patients were followed by regular postoperative visits 3, 6, and 12 months after surgery.

Data were extracted from the patient's file and were recorded in the checklist containing demographic data, POP-Q (pelvic organ prolapse quantification system) preoperative examination and then 3, 6 and 12 months after the surgery.

The main outcomes were the anatomical and clinical recurrence; prolapse of any vaginal compartment beyond the hymenal ring was considered as anatomical recurrence which evaluated by POP-Q examination. Complaint of vaginal pressure, bulging or mass protrusion were considered as the subjective or clinical recurrence. Secondary outcomes were intraoperative complications including urologic and bowel injuries, intraoperative hemorrhage (≥1000 cc), blood transfusion and postoperative complications consist of severe pelvic and buttock pain, suture erosion, vaginal discharge, dyspareunia, vaginal stenosis and retreatment.

A Paired t-test was used to compare mean continuous data within the groups. Statistical analysis was performed by using Fisher exact test and Mann-Whitney U test to compare proportions and continuous variables between two groups. SPSS software version 24 was used for statistical analysis. P<0.05 was considered statistically significant.

Results

A total of 125 patients enrolled in this study and were followed-up for one year (97 cases in SSLF group, 28 cases in HULS group). Baseline characteristics of the patients were not significantly different between the two groups (Table 1).

Table 1. Baseline characteristics of the patients with apical prolapse

	SSLF	HULS	P-value*
Anatomical recurrence:			
Anterior	20 (20.6%)	4 (14.3%)	0.32
Posterior	4 (4%)	1 (3.6%)	0.68
Apical	9 (9.3%)	2 (7.1%)	0.53
Clinical recurrence:			
Mass protrusion	14 (14.4%)	3 (10.7%)	0.44
Pelvic pressure	15 (15.5%)	4 (14.3%)	0.57
Retreatment:			
Pessary insertion	7 (7.2%)	0 (0%)	0.161
Reoperation	8 (8.2%)	3 (10.7%)	0.465

*Fisher Exact test

According to the POP-Q staging system, all cases had stage 2 and 3 of apical compartment prolapse. Total vaginal hysterectomy (TVH) was performed for all patients in both groups.

No significant difference was found between the two groups in terms of the anatomical points which related to the recurrence of anterior, posterior, or apical compartment prolapse (Ba, Bp, c points, respectively) 12 months after the surgery (P>0.05) (Table 2).

In terms of clinical relapse, although vaginal bulging and pressure were more common in SSLF group, no significant difference was observed between the two groups (P>0.05).

As shown in Table 2, retreatment for recurrence of prolapse symptoms; including pessary insertion or repeat surgery were applied in 15.4% of SSLF group and 10.7% of ULS group; no significant difference was seen between the two groups (P=0.1).

Intraoperative complications were observed only in 4 patients of ULS group that including one case of ureteral ligation, 2 cases of massive bleeding, and 3 cases of blood transfusion. Suture erosion was only observed in 4 cases of the SSLF. The rate of severe buttock and pelvic pain were significantly higher in the SSLF group (Table 3).

No significant difference was found between the two groups in terms of vaginal discharge and dyspareunia after the surgery (p>0.05). Dyspareunia due to vaginal stenosis was observed only in 3 cases of SSLF group.

Table 2. Anatomical and clinical recurrence within one year after SSLF and HULS

	ULS (n=28)	SSLF (n=97)	P-value*
Age, Mean±SD (year)	51.27 (10/194)	50 (9.114)	0.511
Number of deliveries	Vaginal 4.3 (2.2)	3.1 (1.8)	0.129
Mean±SD	Cesarean 0.5 (0.5)	0.5 (0.5)	
BMI, Mean±SD	27.2 (27.6)	26.8 (2.15)	0.817
POPQ stage			
Stage 2	N=8 (28.57%)	N=40 (41.23%)	0.116
Stage 3	N=20 (71.42%)	N=57 (58.76%)	

*Fisher Exact test

Table 3. Intra-operative and post-operative complications in HULS and SSLF groups

Complications	SSLF	HULS	P-value*
Intra operative complication:			
Bowel injury	0 (0%)	0 (0%)	
Ureteral injury	0 (0%)	1 (3.6%)	
Bladder injury	0 (0%)	0 (0%)	
Severe hemorrhage	0 (0%)	2 (7.1%)	0.49
Blood transfusion	1 (1%)	3 (10.7%)	0.39
Postoperative complications:			
Severe pelvic or buttock pain	34 (35.1%)	2 (7.1%)	0.02
Dyspareunia due to:			
Vaginal stenosis	3 (3.1%)	0 (0%)	0.46
Vaginal shortening	1 (1%)	0 (0%)	0.77
Suture erosion	4 (4.1%)	0 (0%)	0.36

*Fisher Exact test

Discussion

According to the results of the current study, transvaginal native-tissue procedures for apical prolapse suspension (ULS and SSLF) are safe procedures with minimal intraoperative and postoperative complications with comparable surgical outcomes within 1 year after surgery. The rate of perioperative adverse events was not significantly different between the two groups, although there was a higher number of buttocks and pelvic pain after SSLF which was consistent with the results of previous studies **(15, 17)**.

Anatomical and clinical symptoms didn't show significant difference between the SSFL and ULS groups within one year after the surgery, which was the same as the results of a previous study **(17)**. Maybe longer follow-up would declare the significant difference in this field, but some previous studies again demonstrated that with longer follow-up (after 5 years), although the surgical outcomes were significantly deteriorated over time, but the anatomical and clinical status of participants were not significantly different between the SSLF and ULS at 5 years **(15, 17)**. Another study which compared sacrospinous hysteropexy versus total vaginal hysterectomy and uterosacral ligament suspension showed the significant higher rate of objective and subjective (anatomical and symptomatic) failure especially apical prolapse in the TVH group **(18)**.

Another study that evaluated the effect of uterine preservation on long-term subjective outcomes showed that sacrospinous ligament fixation with or without uterine preservation had no significant difference in long-term (more than 5 years) follow-up **(19)**. The differences on this issue maybe mainly due to patient's selection and elimination of the confounding factors which could affect the outcomes; for example, patients who undergone TVH and uterosacral suspension may have a higher stage of apical prolapse than others which their apical prolapse was corrected only by SSLF. However, another study showed the high success rate of SSLF in treatment of higher stages of apical prolapse **(20)**.

In terms of postoperative complication; participants in sacrospinous group reported significantly more buttock and pelvic pain, which is one of the major complications of this method.

A large multicenter surgical trial found that 12.4% of patients in the SSLF group had postoperative buttock pain requiring intervention, with 4.3% persisting up to 6 weeks **(15)**. While the majority of studies showed pain resolution within 6 weeks after the surgery without intervention, pain that is severe, persistent and intractable with radiation down the leg or associated with muscle weakness should prompt suture removal within the first 2 weeks **(13)**.

In the current study, reoperation for suture removal due to this severe complication needed only in one case of the SSLF group and other cases were transient and resolved by conservative treatment (baclofen and warm pack).

In terms of retreatment by conservative procedure (pessary placement) or surgical correction one year after primary surgery; although both treatments were applied more common in the SSLF group, but there is no significant difference between the two groups. These results are in contrast with the results of a previous study **(21)**. The different results may be justified by different populations and health care systems and also larger sample size and study design. Transvaginal native-tissue prolapse surgery had lower efficacy than abdominal repair with mesh (sacral colposcopy), however it was associated with decreased morbidity that led to many women considering it as the procedure of choice **(22, 23)**. The synthetic mesh used to reinforce transvaginal apical prolapse repair improved some anatomical outcomes, but it was associated with greater morbidity **(23, 24)**.

Regarding the comparable surgical outcomes of these two methods and significantly lower pelvic pain after ULS; it might be prudent to recommend ULS as a procedure of choice especially in the situation where the expensive suturing devices for SSLF are not available or affordable.

One of the strengths of the current study was precise anatomical and clinical evaluation of POP recurrence up to 1 year after transvaginal native-tissue apical prolapse suspension that to the best of our knowledge, this is the first study which evaluated both subjective and objective outcomes of native-tissue apical suspension by these two methods in the Iranian women population.

One of the limitations of this study was the observational approach with no randomization and lack of longer follow-up. Performing the surgeries by different surgeons was another limitation; however, by using the standard protocol of the surgical methods, we tried to overcome this shortage.

Conclusion

Native-tissue apical suspension by performing either SSLF or ULS are both safe and effective procedures with comparable perioperative complications, anatomical and clinical outcomes; however postoperative pelvic pain and the number of retreatments was lower in ULS group.

Ethical Approval and Consent to Participate

The study was approved by the Ethics Committee of Tehran University of Medical Sciences, Iran.

Human and Animal Rights

No animals were used in the study that is the basis of this research. The case study was done on a woman in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013 (http://www.wma.net/en/20activities/10ethics/10helsinki/).

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Consent for Publication

Written and informed consent has been obtained from the patients.

Availability of Data and Materials

Care guideline is used for this study.

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Conflict of Interest

The authors declare no conflict of interests, financial or otherwise.

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