

Anatomical outcome and patient satisfaction after two-stitch utero-sacral ligament suspension

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Summary

Purpose of Investigation: High uterosacral ligament suspension (USLS) performed after vaginal hysterectomy is a popular technique for apical vaginal suspension. This technique was originally described using three stitches on each ligament. The aim of this study was to determine anatomical and clinical cure rates, as well as patient satisfaction after transvaginal hysterectomy and two-stitch uterosacral ligament suspension. **Materials and Methods:** A retrospective cohort study including all patients who underwent transvaginal hysterectomy and two-stitch USLS between January 2012 and December 2014. Preoperative as well as postoperative clinical data was gathered including POP-Q measurements of prolapse. Primary outcomes were anatomical cure defined as no POP-Q point above stage 1 and clinical cure defined as a composite of no prolapse symptoms, no prolapse beyond the hymen, and no need for treatment of prolapse. Patient satisfaction was evaluated using the Patient Global Impression of Improvement (PGI-I) questionnaire validated in the Hebrew language for this study. Statistical analyses included univariate and logistic regression methods. **Results:** Eighty-two women underwent vaginal hysterectomy and USLS during the study period. Follow up data were available for 66 women. At a median follow-up of 14.5 months, all relevant POP-Q measures were significantly improved compared to preoperatively. Anatomical cure was 87.8% and clinical cure rate was 95.4%. Patient satisfaction was high at 100%, stating that their prolapse symptoms were much better or exceptionally better postoperatively. **Conclusion:** Transvaginal hysterectomy and two-stitch uterosacral ligament suspension has high cure and patient satisfaction rates.

Key words: Pelvic organ prolapse (POP); Pelvic reconstructive surgery; Urogynecology.

Introduction

Pelvic organ prolapse (POP) affects up to 50% of women in the United States and varies widely among different ethnic populations around the world, with ranges from 30% to 93% [1-3]. These numbers are expected to rise as population ages [4]. This problem leads to surgery in 11% of women during their life time. Almost one-third of these women will also have a second procedure [5-7]. According to the US National Center for Health Statistics, POP is one of the three most common reasons for hysterectomy [6].

Apical (level I) support has a vital role in any prolapse repair. It has been shown, that there is an association between loss of apical support and a high stage anterior wall prolapse. It has also been established that achievement of apical support had led to improved outcome of both anterior and posterior prolapse repair, with significantly lower reoperation rates [4].

Along with sacrospinous ligament fixation, uterosacral ligament suspension (USLS) is one of the two most commonly reported transvaginal, native-tissue, apical prolapse repair procedures [8]. Several clinical studies have shown the effectiveness and long-term anatomical outcome of this procedure [8]. In a recent meta-analysis, the pooled cure

rate for apical suspension approached 98.3%, with over 80% anatomical cure in the anterior wall [8]. USLS is classically performed with three sutures on each ligament [1]. In an attempt to reduce the risk for ureteral injury or kinking, the authors used only two stitches; one proximal – at the cervical portion of the uterosacral ligament, and one distal at its sacral portion. The authors chose these locations because the middle portion of the uterosacral ligament is closer to the ureter with an average distance of 2.3 cm versus 4.1 cm in the proximal sacral portion [9].

The aim of this study was to describe anatomical cure and patient satisfaction after transvaginal hysterectomy and two-stitch uterosacral ligament suspension.

Materials and Methods

This was a retrospective cohort study of all patients who underwent transvaginal hysterectomy and two-stitch USLS between January 2012 and December 2014 at the division of Female Pelvic Medicine and Reconstructive Surgery at Hadassah Medical Center, Ein Kerem, Jerusalem, Israel. The study was approved by the Institutional ethics Review Board.

Patient demographics and clinical data were obtained using electronic medical records.

Preoperative evaluation included a detailed history and physical

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exam while POP was evaluated using the Pelvic Organ Prolapse Quantification (POP-Q) system. Each patient had multichannel urodynamic testing and pelvic ultrasound prior to surgery.

The surgical procedure performed is a two-stitch modification of the technique, originally described by Shull *et al.* in 2000 [1]. After conduction of either regional or general anesthesia, the patient is placed in the dorsal lithotomy position. Upon completion of vaginal hysterectomy, both uterosacral ligaments are grasped by a Kocher clamp. The bowel is pushed away from the surgical field with packing and the proximal part of each ligament is identified and grasped by a long Allis clamp. A CV-2 Gore-Tex suture is placed at the proximal-sacral portion of each ligament and a 1-0 Vicryl stitch is placed at the distal-cervical part of each ligament. The sutures are held under tension and cystoscopy is performed to ensure the integrity of both ureters and of the bladder. If necessary, anterior and/or posterior colporrhaphies are performed afterwards. All stitches are then connected to the vaginal cuff and tied, suspending the vaginal cuff to the ligaments.

Patients were seen in the present clinic three weeks and three months postoperatively, as well as at 12 months and each year afterwards. On each visit, both a pelvic exam and a full POP-Q [10] evaluation were performed.

Patient satisfaction was determined using Patient Global Impression of Improvement (PGI-I) [11]. It is a transition scale that is a single question asking the patient to rate their urinary tract condition now, as compared with how it was prior to beginning treatment on a scale from 1 = very much better, to 7 = very much worse. For the purpose of using this tool in this population, validation of the PGI-I questionnaire in Hebrew, for patients with POP was performed.

For statistical analysis, a *p* value of 0.05 or less was considered statistically significant. All tests were two-tailed, establishing a relationship between the variables, but without reference to directionality. The paired *t*-test was used for testing the significance of change for quantitative variables, i.e. the POP-Q points before and after the procedures. The Wilcoxon signed ranks test was used for testing the significance of change for categorical variables. For the validation process, the Spearman correlation coefficient was used. Comparison of the "success" and "failure" groups was carried out using Fisher's exact test. The Mann-Whitney test was used for comparison of quantitative variables between the "success" and "failure" groups, instead of the *t*-test, due to the fact that the "failure" group turned out to be very small.

Results

Eighty-two women underwent vaginal hysterectomy and USLS at Hadassah Ein-Kerem Medical Center during the study period. Follow-up data were available for 66 women. Patients' demographic data are presented in Table 1. Mean age was 64 years and mean parity 4. Eighty-eight percent were menopausal and 63% were sexually active. Preoperative prolapse stage was 3 or 4 in 95.5% of the patients. All patients had undergone vaginal hysterectomy and two-stitch USLS. Most patients had concomitant procedures. Table 2 summarizes surgical parameters and concomitant procedures. Of note, 100% of patients had an anterior colporrhaphy and 51% had a concomitant mid-urethral sling. There were no intraoperative complications – no cystotomy or enterotomy. All women had their catheter removed before being discharged from the hospital.

Table 1. — Patient demographics and baseline characteristics

Mean Age (range±SD)	63.48 (46.05-83.58; ±8.51)
Parity [mean (SD)]	4.44 (±2.89)
Maximal birth weight [Mean (SD) in gr]	3595.21 (±508.1)
Menopausal (%)	88
Prior prolapse surgery (%)	1
Prior incontinence surgery (%)	3
Sexually active (%)	63
Smoker (%)	5
Pre-op POP-Q Stage (%)	II 4.5 III 80.3 IV 15.2
Mean Ba point pre-op (cm)	3.07 (±0.38)
Mean C point pre-op (cm)	2.49 (±1.09)
Mean Bp point pre-op (cm)	1.83 (±0.93)

Table 2. — Surgical parameters.

Mean OR time (min)	150.2
Concomitant sling (TVT-O) (%)	51
Concomitant anterior repair (%)	100
Concomitant posterior repair (%)	94
Concomitant BSO (%)	7.5

OR = operation room; TVT-O = tension free vaginal tape-obturator; BSO = bilateral salpingo-oophorectomy.

Table 3. — Anatomical outcomes.

Reference POP-Q point (cm)	Pre-op (mean)	Last Post-op (mean)	<i>p</i> value*
Aa	2.5	-1.64	< 0.001
Ba	4.49	-1.64	< 0.001
C	2.57	-7.75	< 0.001
GH	5.42	4	< 0.001
PB	3.49	3.65	NS
TVL	9.80	9.11	< 0.001
Ap	-0.78	-2.08	< 0.001
Bp	-0.2	-2.08	< 0.001
D	-4.19	X	

Aa = point A anterior; Ap = point A posterior; Ba = point B anterior; Bp = point B posterior; C = cervix or vaginal cuff; D = posterior fornix (if cervix is present); GH = genital hiatus; PB = perineal body; TVL = total vaginal length.

** Between pre-op and last POP-Q.

Table 4. — Prolapse cure rates and patient satisfaction.

Definition of cure	No (%)
Anatomical cure: National Institutes of Health optimal prolapse by POP-Q stage 0-1	58 (87.8)
Clinical cure*	63 (95.4)
PGI-I frequencies:	(42)
Very much better	36 (85.7)
Much better	6 (14.3)
A little better	0 (0)
No change	0 (0)
A little worse	0 (0)
Much worse	0 (0)
Very much worse	0 (0)
PGI-I success (or subjective cure): defined as answers 1 or 2	42 (100%)

*Clinical cure is defined as the lack of prolapse greater than point 0 (outside the hymen) or >-(TVL/2) for point C or any complaint of prolapse symptoms or need for retreatment for recurrent prolapse.

Table 5. — Postoperative complications.

Early complication	n. (%)	Dindo grade	Remarks
UTI	4 (6.1)	I	
Infected pelvic hematoma	5 (7.5)	III	Four of the five required draining. All patients were treated with antibiotics.
Urinary retention > 3 d	0 (0)	N/A	
Anesthetic complications	3 (4.55)	I	
Bleeding	2 (3.03)	I+IIIa	One patient required blood transfusion, the other had cuff bleeding that required suturing in the office
Late complication	n. (%)	Dindo grade	Remarks
UTI	4 (6.1)	I	
Pelvic pain – mild	3 (4.5)	I	
Suture erosion	4 (6.1)	IIIa	One patient required removal of granulation tissue in the OR

Anatomical outcomes are presented in Table 3. At a median follow-up of 14.5 (range 1-50) months, significant improvement was noted in the three most important points (Ba, C, and Bp). Cure rates are summarized in Table 4. Anatomical cure, defined as no POP-Q point above stage 0-1, was 87.8%. Clinical cure rate was 95.4%. Postoperative complications are presented in Table 5. Early complications were defined as complications diagnosed up to three weeks postoperatively. There were no serious complications. One patient required one unit of blood transfusion and another had cuff bleeding when the vaginal pack was removed, requiring suturing in the office. Infected cuff hematoma was diagnosed in five (7.5%) patients. All five patients presented with a spike of fever. In four of them, the hematoma was drained, either vaginally or in the office (two cases) or under CT/ultrasound guidance (one case each). The authors attributed the relatively high prevalence of cuff hematoma to a diagnostic bias, due to their policy of having every woman perform an ultrasound scan, one or two days postoperatively to check the post-void residual volume.

Forty-two patients answered the PGI-I questionnaire, that was used as a measure for satisfaction – subjective cure. As seen in Table 4, 100% of patients stated that they felt much better or very much better postoperatively. The mean time between surgery and the PGI-I questionnaire was 17.2 months.

In order to further understand factors influencing cure rates and patient satisfaction, the authors examined the relationships between selected variables and success or failure in the study outcomes. Initially, the relations between the anatomical, clinical, and subjective cures were examined. Then each variable was examined for significant differences between the two compared groups for several parameters: age, maximal birth weight, parity, vaginal deliveries, instrumental deliveries, cesarean deliveries, post-op hospital stay, marital status, place of birth, menopause, smoking, sexual activity, concomitant midurethral sling (TVTO) operation, early post-op complications, and late post-op complications. The present analysis was unable to find statistically significant ties between success and failure for these variables, probably due to the small sample size of the failure group.

Discussion

In this study the authors described anatomical cure and patient satisfaction after transvaginal hysterectomy and two-stitch uterosacral ligament suspension. Clear anatomical, as well as clinical improvement, were noted after surgery and during follow up. Patient satisfaction following this procedure was very high. Recurrence rate and recurrence location were in agreement with previously published data, mostly occurring in the anterior vaginal wall [12]. Operating time was somewhat long, reflecting the involvement of residents and fellows in surgery.

When evaluating success rates of a surgical procedure, traditionally, mainly anatomical cure was determined; however, there is a growing interest in subjective outcome measures of POP repair surgery. Previous studies have shown a lack of correlation between anatomical and subjective outcome after prolapse surgery [13]. Recently Barber *et al.* have challenged the traditional definition of success in POP surgery calling for adoption of a combined approach to success that takes into account both anatomical and subjective outcome measures [14].

Patient satisfaction after POP surgery can be assessed using the Patient Global Impression of Improvement (PGI-I) [11]. It is a simple, direct, and easy to use scale that is intuitively understandable to patients and clinicians [11]. Although originally designed for women with stress urinary incontinence, it has widely been used in the evaluation of patients' satisfaction following POP repair and was recently validated in this population [15-17].

In the present study group, two-stitch uterosacral ligament suspension technique was used as opposed to the more acceptable three-stitch technique. In their anatomic cadaver study, comparing two versus three suspension sutures for vaginal apex support in USLS, Montoya *et al.* presented evidence showing that the three-stitch technique appears to provide greater vaginal apical support [18]. Although statistically significant, the differences recorded were small and the clinical significance of these findings is unclear. The present results further support the hypothesis that the two-stitch technique is not inferior to the three-stitch technique from the standpoint of clinical outcome

and may have a higher safety profile. Future randomized control studies are needed in order to address the question of safety regarding these two surgical techniques.

The present study has a few important strengths. The authors conducted a single center study using standardized clinical techniques for the assessment of anatomical, as well as clinical outcomes. The number of cases in this series is considered relatively large compared to previous data published.

In addition to its retrospective design, there are some clear limitations to this study. Preoperatively, no validated questionnaires were used for POP symptoms or quality of life. This of course hampers the ability to accurately assess clinical improvement after surgical treatment. The present cohort was comprised of mostly Caucasian both Jews and Arab ethnic origin women, which may limit generalizability of the results to other populations.

Conclusion

In this study transvaginal hysterectomy and two-stitch uterosacral ligament suspension were shown to encompass high anatomical, as well as clinical cure rates. Patient satisfaction evaluated using the PGI-I questionnaire was high as well. Larger randomized control studies are needed in order to answer questions still pending regarding superiority of one surgical technique over the other and for better understanding of the long-term impact of such procedures.

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