



Research Article

Unilateral Sacrospinous Ligament Fixation for the Treatment of Stage 3-4 Utero-Vaginal Prolapse: Single-Centre Experiences

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Abstract

Pelvic organ prolapse (POP) is becoming a major health problem, especially in older women. This study aimed to explore the efficacy, safety and potential risk factors for the recurrence of unilateral sacrospinous fixation (SSLF) for the management of severe prolapse. From January 2010-March 2015, 43 patients who underwent unilateral SSFL for stage 3-4 prolapses were retrospectively investigated. A total 43 patients were included in the study. The mean follow-up period was 30.69±17.4 months. Three (6.9%) patients showed recurrent apical prolapse. In addition, 15 patients (34.8%) had asymptomatic cystocele. Eleven patients (25.5%) complained of gluteal or lower back pain that resolved spontaneously after 12 weeks. There was no relationship observed between the POP recurrence and patient's age, duration or stage of POP, duration of menopause status ($p=0.05$).

Obesity was significantly associate with POP recurrence after SSFL ($p=0.002$). SSLF technique is safe and effective for the treatment of apical prolapse. Obesity seems to be a risk factor for POP recurrence.

Impact statement

What is already known on this subject?

Pelvic organ prolapse is a common health problem and has a significant negative influence on quality of life. Because the majority of women with POP are in old age, and most of them have concomitant systemic disease, so the preferred surgical technique should have a satisfactory success rate and less surgical morbidity. SSLF a method for restoring vaginal support in women with vault prolapse.

What do the results of this study add?

There was no relationship observed between the POP recurrence and patient's age, duration or stage of POP, duration of menopause status. Obesity was significantly associate with POP recurrence after SSFL. Despite the relatively high asymptomatic cystocele recurrence rate, SSFL is a simple, effective and low morbidity procedure for the surgical treatment of cases of stage 3-4 POP and can be performed along with vaginal hysterectomy and vault prolapse.

What are the implications of these findings for clinical practice and/or further research?

Obese patients, especially those with a BMI ≥ 30 kg/m², have a higher risk of recurrence, so appropriate patient counselling regarding the risks and benefits of different options is especially important for obese patients prior to the operation.

Keywords: Prolapse, pelvic organ, sacrospinous ligament fixation, recurrence

Introduction

Pelvic organ prolapse is a common health problem affecting 41% of parous women between 50 and 79 years old [1]. Although not a life-threatening condition, women with POP often complain of pelvic discomfort, urinary or anal incontinence and sexual dysfunction. Therefore, POP has a significant negative influence on quality of life. The prevalence of POP is known to increase with increasing age. The life-time risk for women to undergo surgery for the management of POP is approximately 11%, and 30% of these women will need additional surgery because of prolapse recurrence [2]. Risk factors for POP include age, menopause, obesity, obstetrical trauma, vaginal delivery, connective tissue disorders and family history [3].

The sacrospinous ligaments extend from the ischial spines on each side to the lower portions of the sacrum and coccyx. Sedera was the first to describe the sacrospinous ligament as a secure point of attachment for patients with vaginal vault and uterine prolapse, a report that occurred as early as 1958 [4], and since then it has become a favoured method for restoring vaginal support in women with vault prolapse in Europe and the USA [5].

Sacrospinous ligament fixation keeps the vaginal axis in the midline and enables adjustment of the vaginal length.

As a vaginal procedure, sacrospinous ligament suspension allows concurrent management of anterior and posterior vaginal wall prolapse, which is present in at least two-thirds of cases with total prolapse [6].

Other advantages of SSFL include the avoidance of laparotomy, which results in fewer complications and less postoperative pain, greater cost effectiveness [7], a shorter hospital stay, decreased blood loss, and the preservation of coital function.

This strong ligament has been used successfully for apical support procedures for many decades.

The aim of this study was to evaluate the long-term results of sacrospinous ligament fixation in patients with stage 3-4 uterovaginal and vault prolapse in our clinic during the last 5 years.

Materials and Methods

The study period was from January 2010 to January 2015 and it was carried out at the Erciyes University Medical School, Obstetrics and Gynaecology Department. The research protocol was approved by the Institutional Review Boards of the hospitals (Date 18.11.2016 Resolution No: 2016/597). A total of 43 patients with stage 3-4 uterovaginal or vault prolapse were included in the study. The patients' data were analysed retrospectively. Inclusion criteria were POP-Q stage 3 or 4 uterine or vaginal vault prolapse, with an operation only by two surgeon (EMA or SZU). Exclusion criteria were recurrent prolapse, stage 1-2 (POP-Q) prolapse and any serious medical condition not allowing convenient anaesthesia.

Pelvic organ prolapse was defined and staged according to the International Continence Society Pelvic Organ Quantification (ICS POP-Q) staging system. Our primary aim was to achieve anatomical success defined as a (POP-Q) apical prolapse stage of ≤ 1 .

The steps of the operative procedure are as follows. Patients underwent the operation under general or spinal anaesthesia in the lithotomy position. At the beginning of the operation, all patients intravenously received 2 mg of second generation cephalosporin for antibacterial chemoprophylaxis. With the exception of three patients, all of the patients with uterovaginal prolapses underwent vaginal hysterectomies and the peritoneum was closed as the initial step. We used a posterior approach for sacrospinous fixation. First a longitudinal incision was made in the posterior vaginal wall to the vaginal cuff level to expose the rectovaginal space. The epithelium was then dissected laterally and the pararectal space opened on the right side. The suspension is most often performed on the patient's right side because of the position of the rectum. Blunt dissection was used to further remove tissue from this area, and a window was created between the rectovaginal space and the ischial spine. A long retractor was placed medially to mobilize and protect the rectum. We used a Deschamps ligature carrier for the SSFL.

Non-absorbable 2 polypropylene sutures were placed approximately 2 cm medial to the ischial spine and 0.5 cm below the superior edge of the sacrospinous ligament to avoid damaged to the neurovascular bundle. Rectal examination was performed routinely to ensure that inadvertent rectal injury did not occurred.

For post-operative haemostasis, a sterile sponge was placed into the vagina and was removed after 12 hours. In three patients, we performed sacrospinous ligament hysteropexy techniques without a hysterectomy. In this procedure, an extraperitoneal dissection was performed until the right sacrospinous ligament was identified and the posterior cervix was attached to the sacrospinous ligament with non-absorbable sutures using a Deschamps ligature carrier.

The characteristics of these patients and their sixth month and long-term post-operative outcomes were recorded.

Intra- and post-operative complications and the length of the post-operative hospital stay were recorded. Patients' characteristics were summarized using descriptive statistics for continuous variables and presented with means and standard deviations. The relationship between categorical variables was analysed by a chi-square test. $P < 0.05$ was considered statistically significant.

Results

A total of 47 patients underwent apical sling surgery during the study period. Four of them did not have follow-ups, so 43 patients were included in the study. Twenty-one of these patients (48.8%) had stage 3 and 22 (51.2%) had stage 4 POP. Thirty-one patients (72.1%) had utero vaginal prolapse and 12 (27.9%) had vaginal vault prolapse following previous hysterectomies. In the preoperative period, 12/43 patients (27.9%) had pyelectasis on one or both sides, complaints of flank pain and difficulty with urination.

Two of the patients with uterine prolapse did not undergo vaginal hysterectomy, which kept the operation time short due to their medical condition, and one patient was not accepted for hysterectomy. Table 1 shows baseline demographics.

Characteristics	Results
Mean Age (years) mean(SD)	64.06±7.95
BMI (kg/m ²) mean(SD)	28.8±3.04
Postmenopausal n (%)	40(93)

Macrosomic fetus n(%)	8(18.6)
Prior hysterectomy n (%)	12(27.9)
Mean parity	4.04± 1.09
Duration of POP(years) mean(SD)	4.48±3.23
Diabetes Mellitus n (%)	12(27.9)
Arterial hypertension n (%)	20(46.5)
Hearth disease n (%)	4(9.3)

Table 1: Demographic characteristics of the 43 patients BMI: Body Mass Index.

The mean age was 64.06±7.95 years and the mean operation time was 87.79±18.9 minutes. Concomitant procedures included an anterior and posterior colporrhaphy for all patients, placement of an anti-incontinence device (TVT or pubo-vaginal sling) due to occult stress urinary incontinence in 8 patients (18.6%) and 5 patients (11.6%) underwent enterocele repair. Urinary catheters were left in place for 12 hours post-operatively. There were no major haemorrhages and no need for erythrocyte replacement. There were no intraoperative or early post-operative complications. The mean hospitalization time was 2.55±0.73 days and the average expense was \$434.35±133.

A patient with a history of venous thromboembolism who had been using anticoagulant therapy (clopidogrel hydrogen sulphate tablets/Plavix), and had complaints of right buttock pain and defecation difficulties one week after sacrospinous ligament hysteropexy was diagnosed with a 6 cm para-rectal hematoma. It resolved spontaneously in eight weeks.

The mean follow-up period was 30.69±17.4 months. The objective cure rate was (POP Q apical prolapse stage ≤1) 36 (83.7%). The subjective cure rate was 34 (80%) (Cured or greatly improved). Table 2 shows objective and subjective cure rates of the patients. The first follow-up was at six weeks after the operation. All of the recurrences occurred within the first 6 months. Patients with recurrences stated that they had to do heavy physical work; except for one, all the patients with recurrences were obese and had BMIs that were greater than 30 kg/m² ($p=0.002$). We observed no effects of patient age, number of vaginal deliveries, duration or stage of POP, duration of menopause, or diabetes status on POP recurrence ($p>0.05$).

	Preoperative	Postoperative
POP-Q stage n(%)		
Stage-0	-	
Stage-1	-	36(83.7)
Stage-2	-	5(11.6)
Stage-3	21(48.8)	2(4.65)
Stage-4	22(51.2)	-
Primary objective cure rate%(n/total)	-	36(83.7)
Patients self assesment of symptoms,n(%)		
Cured	-	13(30.2)
Greatly Improved	-	21(48.8)
Somewhat Improved	-	7(16.3)
Not Improved	-	2(4.7)
Worsened	-	-
Subjective Cure Rate %(n/total)	-	34(80)

Table 2: Objective and subjective cure rates of the patients (POP-Q) pelvic organ quantification.

Abdominal sacrocolpopexy was performed in 2 patients with recurrences. Nine (20.9%) patients were diagnosed with stage 1 and 6 (14%) patients with stage-2 non-symptomatic anterior prolapse and none of these needed surgical repair. The main complaints of patients were: 4 (9.3%) patients had new onset stress urinary incontinence, 6 (13.9%) had urge urinary incontinence, 3 (6.9%) patients felt vaginal prolapse but their POP-Qs were normal. Eleven (25.5%) patients suffered from gluteal or lower back pain that resolved spontaneously in 12 weeks, 4 (9.6%) of the patient's partners complained of non-absorbable sutures in the vagina during intercourse and two of these women suffered from dyspareunia. Despite local oestrogen therapy for six week, patients experienced de novo dyspareunia, which resolved in these two cases after stitch removal (Figure 1).

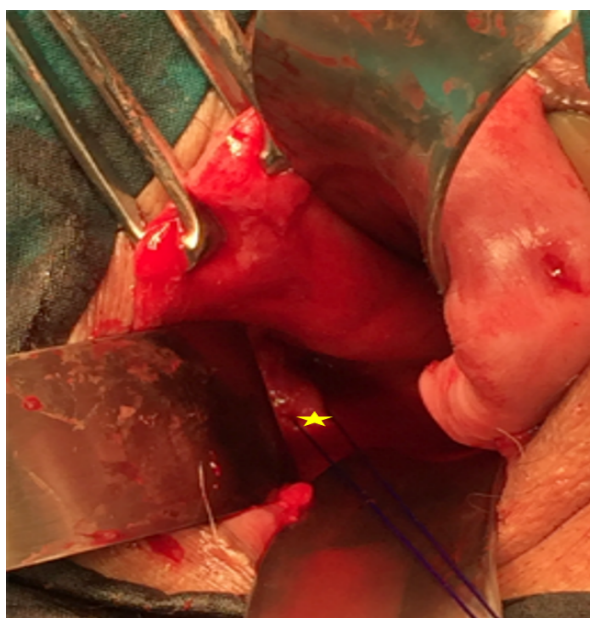


Figure 1: Yellow star show sacro-spinous ligament.

Discussion

POP is a common disorder in women and its incidence increases after menopause. Patients with advanced POP have significant symptoms, such as pelvic pain, urinary retention, voiding dysfunction, sexual dysfunction, urinary incontinence, and back pain, which decrease quality of life. Approximately 4.1% of these patients are over 80 years old [8]. It is estimated that 11.1% of women will undergo at least one surgery for POP repair or stress urinary incontinence (SUI) by 80 years of age [2]. Because the majority of women with POP are in old age, and most of them have concomitant systemic disease, so the preferred surgical technique should have a satisfactory success rate and less surgical morbidity. In this context, objective cure rates using SSFL have been reported to be between 67% and 97%, and subjective cure rates between 70% and 98%. Alas AN et al. also reported that the objective cure rate was 100% using the mesh sling technique six months after the operation [9]. In present study, the mean follow-up period was 30.69 ± 17.4 months, the objective cure rate was 83.7% and the subjective cure rate was 80%. Our patients' long-term outcomes seemed to be satisfactory. We performed anterior and posterior colporrhaphy for all patients. The anterior segment failure rate was 34.8% and for the apical segment was 6.9% in our series. In the literature, cystocele was reported as the most frequent recurrence (21.3%), while apical prolapse recurrence occurred at 7.2% [10], so our results were similar to the literature. An apical prolapse is more likely to be associated with a larger prolapse, and 50% of the size of a cystocele is explained by the descent of apical support. The goal of a sacrospinous ligament suspension is to restore level I vaginal support. However, after SSFL, the posterior shift of the vaginal axis leaves the anterior compartment more susceptible to larger intra-abdominal pressure and to a cystocele [11]. In patients with an apical prolapse, when performed in addition to SSFL, an anterior colporrhaphy does not seem to prevent the recurrence of a cystocele. In some studies, the anterior wall failure rate after SSFL was reported to be above 55% despite the addition of an anterior colporrhaphy.

After SSFL, a cystocele failure rate of 58% was reported in the colporrhaphy group and a failure rate of 18% was reported in the synthetic mesh group [12]. Despite the anatomical superiority of synthetic mesh for cystocele recurrence [13], mesh extrusion was the most frequently reported adverse incident and the U.S. Food and Drug Administration (FDA) published warnings related to the risks associated with the use of synthetic materials.

The re-operation rate after SSSL ranges from 1.3% to 37%, with all but two series reporting less than 9% [14]. Our re-operation rate was 4.7% due to symptomatic apical segment failure. None of the patients with cystocele recurrences required re-operation. All of the recurrences occurred within the first 6 months in our series.

Peng P et al. reported that recurrences usually occurred within six months post operatively after SSFL [15].

The de novo stress urinary incontinence rate was 9.3% and the de novo urge was 13.9% in our series. Miedel A et al. reported a de novo stress incontinence rate of 6%, a de novo urge rate of 22.6%, a re-operation rate of 9.7% and a 63.3% anatomical recurrence diagnosed within the 1-year follow-up [16]. These results are similar to ours.

The recurrence of POP is an undesirable situation after an SSFL operation. There are risk factors that are associated with recurrence that are indicated in the literature. Hu CD et al. reported the severe degree of POP, an anterior compartment defect of the pelvic floor and high risk factors for POP recurrence in the early days of performing pelvic floor reconstruction surgeries [17]. Nieminen K et al. reported a re-operation rate of 5% and that postoperative vaginal cuff infection was an independent and the most important risk factor for recurrence [18]. However, they did not use preoperative antibacterial chemoprophylaxis for most of the patients and they used different types of surgical suture materials. No cuff infections occurred in our series and we routinely use preoperative antibacterial chemoprophylaxis, and our suture materials and surgical techniques were identical in all our cases.

Although having a higher BMI was a significant risk factor for primary POP [19], according to some studies it was not a significant risk factor for POP recurrence [20]. In our series, aside from one case, all the patients with recurrences were obese and their BMIs were greater than 30 kg/m². Diez-Itza I et al. reported that younger women and those with a higher body weight are more likely to experience recurrent prolapse after vaginal repair [21]. Kawasaki A et al. showed that obesity is associated with increased odds of an anatomical recurrence of anterior vaginal wall prolapse. Obese subjects (BMI ≥ 30.0) generated significantly more abdominal pressure than did normal-weight subjects (BMI 18.5-24.9), especially during activity [22].

On the other hand, advanced POP (stage 3-4) and being younger in age (<60 years old) were associated with an increase in the risk for both anatomical and functional recurrence [21], [23]. Being younger was a risk factor for recurrence such that the lower the age at the time of the prolapse, the weaker the tissues and the greater nerve, muscle or fascia injury [18]. In our series, all the patients had a POP-Q stage of 3 or 4 and there was no differences between these two groups in regards to their recurrence rate. We did not find any significant associations or relationship between age and recurrence risk. Similar to our results, some studies found no significant associations between age and POP recurrence [24],[25]. Studies have also showed a trend toward a positive association between menopausal status and primary POP [19],

but, similar to our results, menopausal status was not significantly associated with POP recurrence [23]. Parity, vaginal delivery and diabetes mellitus were frequently investigated and shown to be risk factors for primary POP 3, 4. We observed no relationship between recurrence of POP after SSFL and parity, number of vaginal deliveries or diabetes mellitus status. The premature resumption of physical exertion, such as heavy lifting, can increase the risk of recurrence [26].

Our patients who had prolapse recurrences after SSFL engaged in heavy lifting within the six-month post-operative period. Increased intra-abdominal pressure in obese patients leads to POP recurrence, so the premature resumption of physical exertion may have implications for postoperative restrictions in patients with POP.

After SSFL, damage to the femoral and sciatic nerves were reported in 1.8% of patients, while gluteal pain bladder pain and non-classified pain were reported in 0.8% of cases [27]. None of our patients had any neuro-vascular injuries, but the gluteal or lower back pain rate was higher in our series, occurring in 11 (25.5%) of our patients, but these issues resolved spontaneously within 12 weeks. In their series of patients with stage 3–4 POP, Gupta P et al. reported no sciatic nerve injuries and also reported that two patients had non-specific gluteal pain that resolved spontaneously. Two women complained of dyspareunia at 8 months, but in the following visit at 24 months, there were no further complaints in their study group [28]. Interestingly 4 women's partners complained about the non-absorbable sutures in the vagina during intercourse. There may have been extrusion of the rigid non-absorbable monofilament suture material into the vaginal mucosa that could have delayed epithelization because of a hypoestrogenic state. Two of these patients were treated with local oestrogen therapy for six weeks. Two patients, despite receiving local oestrogen therapy for six weeks, still suffer from dyspareunia and partner complaints at 10 months, but these resolved after stitch removal. It is particularly important in post-menopausal patients with atrophic vaginal mucosa, to consider the use of delayed absorbable or silk suture materials instead of non-absorbable monofilament suture material to prevent this situation.

Conclusion

Despite the relatively high asymptomatic cystocele recurrence rate, SSFL is a simple, effective and low morbidity procedure for the surgical treatment of cases of stage 3-4 POP and can be performed along with vaginal hysterectomy and vault prolapse. Obese patients, especially those with a BMI ≥ 30 kg/m², have a higher risk of recurrence, so appropriate patient counselling regarding the risks and benefits of different options is especially important for obese patients prior to the operation.

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