

# Effects of unilateral apical sling and laparoscopic sacrocolpopexy on the outcome in women with apical prolapse: randomised trial

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## ABSTRACT

**Objectives:** The purpose of this study was to compare the use of unilateral apical sling versus laparoscopic sacrocolpopexy in the treatment of the apical form of pelvic organ prolapse in women.

**Material and methods:** A prospective, single-center randomized trial included 100 patients who were alternately assigned to treatment. Each patient had a ≥ III stage of apical or anterior-apical prolapse determined by the POP-Q system. 45 accepted for unilateral apical sling (UAS) and 55 accepted for laparoscopic sacrocolpopexy (LS). Data were compared by the One-way ANOVA test using IBM SPSS stats 19.

**Results:** Mean operating time was significantly greater in the LS group versus UAS group, 194.6 vs 42.4 minutes, respectively ( $p < 0.05$ ). The amount of intraoperative bleeding was significantly higher in the UAS group, compared to the LS group ( $p = 0.01$ ). Within the follow-up period, 2 patients in UAS group and 3 patients in LS group (4.4% vs 5.4%, respectively;  $p = 0.9$ ) had recurrent cystocele. HRQoL and sexual outcomes did not differ significantly between the two treatment groups.

**Conclusions:** Our data demonstrate the non-superiority one on each other of the two different approaches, except in terms of shorter operating time and higher intraoperative bleeding when UAS used. These findings raise questions about the need for long-term results of quality of life outcomes for women with genital prolapse, especially in resource-limited settings similar to Kazakhstan.

**Key words:** apical prolapse; health-related quality of life; unilateral apical sling; mesh surgery

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## INTRODUCTION

The apical form of pelvic organ prolapse (POP) is probably the most complex form of genital prolapse [1]. The lifetime risk for POP surgery correlates among 12–19% [2]. It is known that the uterus, with its uterosacral-cardinal ligament complex, is a clue component of reliable support of the pelvic floor [3, 4]. Patients with apical prolapse might have pelvic pain associated with vaginal symptoms (vaginal “bulge” or “something coming down”), urinary tract symptoms (stress incontinence, urgency incontinence, voiding difficulties), bowel and sexual dysfunctions [5].

With the improvement of quality of life (QoL) and growing interest in maintaining the capacity for sexual activity

among the female population, the need for reconstructive surgery is increased. Prolapse of the vaginal apex can be treated using multiple surgical approaches depending on the severity of bothersome symptoms, sexual activity, comorbidities, and previous pelvic floor surgery.

Based on long-term results, laparoscopic sacrocolpopexy (LS) is considered the most durable surgical approach for apical form of genital prolapse and is associated with lower rates of recurrence than vaginal approaches [12]. However, anesthesia, pneumoperitoneum and long duration of operation in the Trendelenburg position increases risk of complications in elderly patients with medical disorders [13].

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Vaginal reconstructive surgery is more commonly used [8, 9] as it is associated with shorter operative time, fewer complications, less pain, and faster convalescence [10]. In the early 1950s, sacrospinous colpopexy was first proposed in patients with genital prolapse. Currently, this approach is one of the most studied and widely used colpohysteropexy techniques [11–13].

The main advantage of vaginal approaches is their less-invasive nature and the possibility of the concomitant repair of other vaginal compartments [14]. The unilateral apical sling (UAS) — surgical modification in which the apical sling was fixed by the monofilament synthetic mesh to the sacrospinous ligaments unilaterally by making a single construction — is one of the novel methods with vaginal approach used to treat apical prolapse [15]. However, there are limited data on outcomes after POP reconstructive surgery among Asian women [16].

The literature regarding UAS is sparse and devoid of comparative studies. The present clinical comparative study aimed to evaluate the effect of treatment with UAS. To the best of our knowledge, this study is the first randomized trial in Kazakhstan to evaluate the effect of treatment with UAS in patients with apical prolapse.

## MATERIAL AND METHODS

The patients who participated in this clinical comparative study were referred to a Clinical Academic Department of Women's Health, University Medical Center in Astana, Kazakhstan between January 2019 and May 2022, with a history of the apical form of genital prolapse according to the POP quantification (POP-Q) system [17]. Exclusion criteria were: history of gynecological cancer, the presence of an atypical Pap test, endometrial hyperplasia, concomitant stress urinary incontinence and chronic pelvic pain.

The study was a prospective, single-center trial approved by the ethics committee of JSC "Astana Medical University" and all patients provided informed consent.

In total, 119 patients were investigated and randomized into two groups. Of these, 19 patients were lost to follow-up after six months, and ultimately 100 patients were analyzed. Of the 100 patients, 45 accepted the UAS surgery, and 55 accepted the LS surgery.

Preoperative examination included: age, parity, normal vaginal delivery, body mass index (BMI), menopause status, previous pelvic surgery, chronic pulmonary disease, diabetes mellitus, smoking. Maximum prolapse was demonstrated and identified by asking the patient to cough and to perform a Valsalva maneuver while each vaginal wall was individually exposed. The staging of prolapse was determined by the POP-Q system.

UAS was described in detail earlier [18]. Procedure was performed by one surgical team with the use of spinal anes-

thesia. After the deep hydrodissection the incision was made at least 3 cm away from the external orifice of the urethra and 2 cm from the cervical canal. The paravaginal avascular space was entered. Blunt subfascial dissection was continued unilaterally. After the identification of the sacrospinous ligament by the surgeon, its perforation was performed not < 2 cm medially from the ischial spine. The tip of the reusable metal Urofix PL guide needle was removed through a previously made incision on the skin of the buttock and the 15 × 1.5 cm monofilament synthetic mesh (Esfil® light) was fixed to the cervix with four stitches using a non-absorbable thread (Ethibond 0). Fascia was closed according to the Halsted technique (running inverting suture, which is placed through the subcutaneous fascia and runs parallel to the wound, USP2). Thus, the apical sling was fixed to the sacrospinous ligament unilaterally. No additional surgery was performed through the vaginal route other than posterior vaginal wall colporrhaphy when concomitant rectocele was present.

Laparoscopic sacrocolpopexy was performed in ten steps as previously described [19]:

- Step 1: Exposition of the operating field;
- Step 2: Dissection of the promontory;
- Step 3: Pararectal dissection;
- Step 4: Rectovaginal dissection;
- Step 5: Vesicovaginal dissection;
- Step 6: Supracervical hysterectomy;
- Step 7: Fixation of the monofilament synthetic mesh (Esfil® light) to the cervix;
- Step 8: Peritonization;
- Step 9: Fixing the prosthesis to the promontory;
- Step 10: Uterine morcellation.

All the patients were operated on under general anesthesia and in the specific lithotomy position.

An estimation of operative blood loss was based on the amount of blood that had collected in the perineal pouch and the difference in weight of all swabs that had been used for the removal of blood from the surgical field. All patients received antibiotic prophylaxis.

Postoperative examination and data on postoperative complications was collected by physicians of the Department. All patients visited hospital after surgery at six months. The patient reported QoL and sexual outcomes evaluated by validated questionnaires [20, 21]. These questionnaires were completed in two stages: before surgery and six months after.

Statistical analysis was performed using IBM SPSS stats 19. Variables were analyzed using the One-way ANOVA test.  $P < 0.05$  was considered significant.

## RESULTS

Patient characteristics: Out of 119 candidates for POP reconstructive surgery, 51 and 68 patients underwent UAS

**Table 1. Baseline patient's demographics**

Demographic	UAS (n = 45)	LS (n = 55)	p value
Mean (SD) age [years]	59.80 ± 6.86	52.93 ± 10.39	> 0.05
Mean (SD) BMI [kg/m <sup>2</sup> ]	28.79 ± 3.58	28.86 ± 4.79	0.153
Median (range) parity	2 (0 – 7)	3 (1 – 6)	NS
Normal vaginal delivery	30 (66.6)	42 (76.3)	0.923
Cesarean section	2 (4.4)	1 (1.8)	0.420
Subtotal hysterectomy	6 (13.3)	5 (9.1)	0.998
History of anti-incontinence surgery	0 (0)	1 (1.8)	0.612
History of previous pelvic surgery	3 (6.7)	7 (12.7)	0.728
Stress urinary incontinence	4 (8.8)	8 (14.5)	0.607
Menopause	37 (82.2)	31 (56.4)	0.919
Sexually active women	35 (77.8)	47 (85.5)	0.480

Data are presented as n (%) or mean (range) or mean ± SD; UAS — unilateral apical sling; LS — laparoscopic sacrocolpopexy; SD — standard deviation; BMI — body mass index; NS — not significant

**Table 2. Comparison of different perioperative clinical characteristics of the study population**

Characteristics	UAS (n = 45)	LS (n = 55)	p value
Mean operating time [min]	41.78 ± 14.40	194.66 ± 40.06	< 0.05
Mean operative blood loss [mL]	103.40 ± 73.34	40 ± 10.69	0.01
Duration of hospitalization	6.3 ± 1.6	6.5 ± 1.3	0.165

Data are presented as mean ± standard deviation; UAS — unilateral apical sling; LS — laparoscopic sacrocolpopexy

and LS, respectively. Consequently, the data of 45 patients in UAS group and 55 patients in LS group were analyzed. The main cause of the lack of follow-up in each group was the COVID-19 pandemic. There was no statistically significant difference between both groups with regard to mean age, parity and previous surgeries (Tab. 1). Four patients in UAS group and eight patients in LS group had a history of stress urinary incontinence (SUI). TVT procedure was performed three months after the main surgery among these patients: two cases in UAS group and five cases in LS group. There were no significant differences between groups.

**Perioperative characteristics:** Mean operating time was significantly shorter in the UAS group versus LS group, 42.4 ± 13.9 vs 194.6 ± 40.0 minutes, respectively ( $p < 0.05$ ). However, the amount of intraoperative bleeding was significantly higher in the UAS group compared to the LS group, 103.40 ± 73.34 mL vs 40 ± 10.69 mL ( $p = 0.01$ ). Most of the patients were referred from other cities and regions. These patients were admitted the day before surgery and were not discharged to ensure their condition. Moreover, all patients were prescribed low molecular weight heparin for at least five postoperative days. For this reason, hospital stay duration results were longer in both groups. The duration of hospitalization was 6.3 ± 1.6 days in the UAS group and 6.5 ± 1.3 days in the LS group ( $p = 0.16$ ) (Tab. 2).

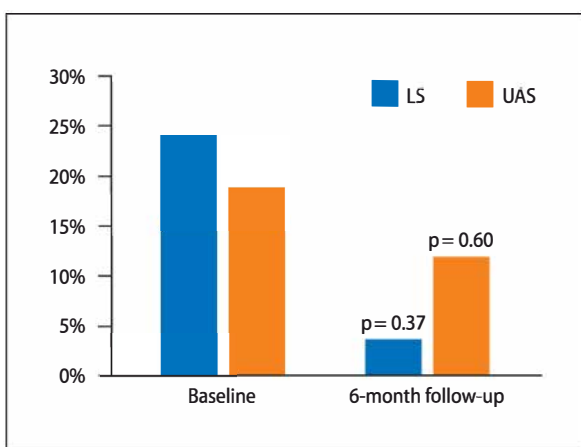
**Intraoperative complications:** No intraoperative complications, such as vesical, rectal, or ureteric injuries, were observed in any of the patients and none of the patients required intraoperative blood transfusion. Hematoma, pelvic abscess, embolism and death were not observed in any of the patients in the two groups.

**Composite outcomes:** The term anatomical success was defined as the absence of symptoms, with the cervix and/or vaginal apex remaining well supported > 3 cm above the hymenal ring level, while the patient performed Valsalva's maneuver and the vagina admitted two fingers without discomfort. All cases of surgical failure occurred in the anterior compartment. Two patients in UAS group and three patients in LS group (4.4% vs 5.4%, respectively;  $p = 0.9$ ) had recurrent cystocele during follow-up but did not need surgery because the cystocele was < 2 stage by POP-Q and asymptomatic (Tab. 3).

No cases of mesh erosion and re-operations were observed during six months of follow-up. Finally, dyspareunia was analyzed separately, comparing LS to UAS pre- and postoperatively (Fig. 1). Preoperative dyspareunia was significantly reduced after LS but not after UAS. SUI *de novo* was observed in 1 (2.2%) and 2 (3.6%) patients in UAS and LS groups, respectively. Within five months after the surgery, a TVT procedure was performed in one of them from LS group. Two women refused the proposed surgical treatment because of mild symptoms.

POP-Q stages	UAS (n = 45)	LS (n = 55)	p value
Before the surgery			0.5
Second-degree uterine prolapse	24 (53.4)	12 (21.8)	
Third-degree uterine prolapse*	15 (33.3)	27 (49.1)	
Fourth-degree uterine prolapse*	6 (13.3)	16 (29.1)	
After the surgery			0.780
Stage < 1	43 (95.6)	52 (94.6)	
Stage < 2	2 (4.4)	3 (5.4)	

Data are presented as n (%); UAS — unilateral apical sling; LS — laparoscopic sacrocolpopexy



**Figure 1.** Comparison of dyspareunia rates by laparoscopic sacrocolpopexy (LS) and unilateral apical sling (UAS) at baseline and at 6-months follow-up

Patient reported QoL and sexual outcomes: Most of the patients showed a significant improvement in the QoL after the treatment. Outcomes, assessed by comparing the preoperative and postoperative scores of validated questionnaires are also summarized (Tab. 4).

There was no difference between preoperative PFDI-20 and P-QOL scores in the two groups ( $p=0.81$ , and  $p=0.57$ , respectively). The PFDI-20 and P-QOL scores decreased significantly after treatment in both groups ( $p < 0.01$ ).

Five patients (11.2%) from UAS group and two patients from LS group (3.6%) noted the presence of anxiety about the resumption of sexual activity. The results of the Female Sexual Function Inventory (FSFI) questionnaire increased significantly after both surgery ( $p < 0.01$ ).

## DISCUSSION

Symptomatic POP is considered a challenging issue for females, particularly among sexually active women. It is important that reconstructive surgery fights not only for the restoration of the normal position of the pelvic organs, but also for the return of their function. In accordance with a review conducted under the guidance of the International

Urogynecological Association (IUGA), more than sixty per cent of surgeons prefer vaginal surgery for the treatment of apical prolapse, with sacrospinous fixation being the most popular procedure [22, 23]. This approach is able to fulfill the main task of treatment - restoring the quality of life of the patient. Most surgeons especially note the main advantages of sacrospinous ligament fixation as technical simplicity, short duration of the surgery and low postoperative morbidity.

The FDA previously communicated about serious complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and SUI [24]. However, currently, transvaginal placements of synthetic mid-urethral slings and vaginal meshes have largely superseded traditional tissue repairs [25]. Shkarupa et al. [26] in original research also demonstrate improvement of QoL after 12 months follow-up and 99% efficiency of UAS surgery at the apical compartment.

When analyzing efficacy, our data show that the two different approaches are not superior to each other, except in terms of operating time and blood loss. There were no statistically significant differences in patient-reported QoL and sexual outcomes data. It is also one of the first studies among Kazakh women to assess the outcome of genital prolapse operation with the use of an objective standardized tool.

Interesting data is presented by the Swedish Pregnancy, Obesity and Pelvic floor (SWEPOP) project: with each unit exceeding the normal value of the body mass index (BMI), the risk of developing symptomatic POP increases by 3% [27]. Currently, obesity also is one of the main problems in our country [28]. In this study, all the patients were overweight as a risk factor for POP, which is consistent with the results of previous studies [29].

Unfortunately, due to the stigma associated with mentality, symptomatic women rarely self-report these symptoms to their providers. The major strength of this study is that the surgeries' effectiveness was evaluated among Kazakh women with validated PFDI-20, P-QOL and FSFI scores. Our results showed that both approaches are

**Table 4. Effect of unilateral apical sling (UAS) and laparoscopic sacrocolpopexy (LS) on quality of life and sexual outcomes**

Questionnaires	Before surgery		12-month follow-up		p value	
	UAS (n = 45)	LS (n = 55)	UAS (n = 45)	LS (n = 55)	Within group (UAS/LS)	Between group (before/after surgery)
PFDI-20	109 ± 53	107 ± 48	43 ± 31	38 ± 35	< 0.01 / < 0.01	< 0.81 / < 0.17
POPDI-6	46 ± 21	48 ± 23	11 ± 15	9 ± 8	< 0.01 / < 0.01	< 0.78 / < 0.21
CRADI-8	12 ± 11	10 ± 15	9 ± 18	13 ± 15	< 0.21 / < 0.47	< 0.16 / < 0.24
UDI-6	51 ± 27	49 ± 22	23 ± 18	15 ± 11	< 0.01 / < 0.01	< 0.42 / < 0.01
P-QOL	67 ± 2.6	70 ± 2.7	11 ± 2.3	13 ± 2.6	< 0.01 / < 0.01	< 0.57 / < 0.15
FSFI	17.1 ± 1.58	17.6 ± 1.15	23.1 ± 3.3	27.1 ± 3.2	< 0.01 / < 0.01	< 0.87 / < 0.51

Data are presented as mean ± standard deviation; PFDI-20 — pelvic floor disability index; POPDI-6 — pelvic organ prolapse distress inventory-6; UDI-6 — urinary distress inventory-6; CRADI-8 — colorectal-anal distress inventory-8; P-QOL — prolapse quality of life; FSFI — female sexual function index

effective for patients with apical prolapse. Shortcoming of our study was the COVID-19 pandemic making it difficult for patients to return to follow-up.

In addition, few studies are comparing the results of UAS and LS in the literature. Early and intermediate outcomes showed satisfactory restoration of vaginal topography and symptom relief. However, the lack of randomized controlled trials, makes it difficult to decide, which technique is superior. Admittedly, longer follow-ups are required to assess complications [30].

Despite limitations, this study is one of few prospective studies comparing UAS with LS approaches. Furthermore, random allocation of patients in study groups was impossible. Further prospective randomized clinical trials are recommended in future studies.

## CONCLUSIONS

This trial is small, but its results raise questions about the need for reconstructive surgeries such as unilateral apical sling and laparoscopic sacrocolpopexy for women with apical prolapse in resource-limited settings similar to Kazakhstan.

The short-term results of the current study are promising and show a high success rate for UAS for apical prolapse. Although UAS and LS have comparable composite outcomes, UAS appears to be superior to LS regarding shorter operating time. Large-scale, high-quality RCTs, and further investigation are needed to identify quality of life outcomes with long-term results.

## Article informations and declarations

### Conflict of interest

All authors declare no conflict of interest.

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