



The resurrection of sacrospinous fixation: unilateral apical sling hysteropexy

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Abstract

Introduction and hypothesis The apical compartment is a keystone in POP treatment. Sacrospinous fixation, suggested half a century ago, today is still one of the most popular and efficient methods of colpo-hysteropexy. However, it has specific side effects: chronic pain syndrome, dyspareunia and a high rate of cystocele de novo. We aimed to evaluate the efficacy and safety of unilateral sacrospinous hysteropexy with a synthetic apical sling combined with anterior subfascial colporrhaphy.

Methods Following the suggested technique, 174 women with anterior-apical prolapse underwent surgery. The follow-up period took 12 months. Pre- and postoperative examination included: urogynecological examination (POP-Q), uroflowmetry, ultrasound of the bladder and filling in of validated questionnaires (PFDI-20, PISQ-12).

Results The mean surgery time was 26 ± 7.84 min. No cases of damage of the bladder or rectum or of intraoperative clinically significant bleeding were noted. At the 12-month follow-up, the recurrence rate in the apical compartment was 0.7% (1/147) and in the anterior compartment 7.4% (11/147). The efficacy of the surgery reached 96.5%. During 12 months of follow-up, no cases of mesh exposure or chronic pelvic pain syndrome were detected. The incidence of dyspareunia de novo was observed in just one patient.

Conclusions A unilateral sacrospinous fixation with a synthetic mesh (apical sling) combined with anterior subfascial colporrhaphy enhances the anatomical efficacy of surgery. It also helps to avoid specific side effects of traditional sacrospinous fixation.

Keywords Pelvic organ prolapse · Unilateral sacrospinous fixation · Subfascial colporrhaphy · Apical sling

Introduction

Pelvic organ prolapse (POP) during a gynecological examination is detected in > 40% of women [1]. In almost half the cases, the pelvic floor disorder is represented by the cystocele. It is known that the loss of apical support contributes to the prolapse of the anterior wall of the vagina beyond the hymen [2]. Today, the absolute majority of specialists agree that the uterus, with its uterosacral-cardinal ligament complex, is a key element of reliable support of the pelvic floor [2, 3]. Traditionally, more than 80% of all POP surgeries are performed vaginally [4]. In the middle of the twentieth century, the sacrospinous fixation technique was proposed, which is currently one of the most studied and widely used colpo-hysteropexy techniques. The effectiveness of this approach in the apical compartment during an observation period of up to 84 months is up to 96% [5, 6]. The appearance of the Miya hook and then more advanced suture devices (Caspary, Endostitch, I-stitch and Capio) allowed minimizing tissue

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dissection with simplified and increased vaginal vault fixing safety [7]. In contrast to abdominal approaches, this technique is devoid of the risks associated with manipulations inside the abdominal cavity and provides a shorter duration of the surgery. One of the described method limitations is the high risk of cystocele *de novo*, which reaches 20–33% and is probably the result of the vaginal axis shift in the direction of the fixation point [8, 9]. Another significant problem was buttock pain and dyspareunia, the risk of which reaches 36% according to several studies [10]. Possible reasons for these complications are: irritation of the nervous structures adjacent to sacrospinous ligament, excessive tension of the sutures and displacement of the vagina in the direction of fixation. It was the specific complications of the described method that led many surgeons to switch to a comparable in effectiveness, but much more traumatic, expensive and technically difficult sacrocolpopexy.

The aim of this study was to evaluate the efficacy and safety of unilateral sacrospinous fixation with a modern monofilament synthetic mesh combined with the reconstruction of the second level of pelvic floor support according to DeLancey using an original technique—subfascial colporrhaphy.

Materials and methods

This prospective non-randomized study was conducted on the basis of the Department of Urology of Saint Petersburg State University Clinic of Advanced Medical Technologies n.a. Nikolay I. Pirogov. It involved women with anterior-apical prolapse stage III–IV according to the POP Quantification (POP-Q) system. All enrolled patients underwent a unilateral hybrid surgical reconstruction using a synthetic mesh in accordance with the proposed technique in the period of November 2016 to November 2017. Exclusion criteria were: history of gynecological cancer, the presence of an atypical Pap test, endometrial hyperplasia, concomitant stress urinary incontinence and chronic pelvic pain. All patients admitted for treatment were provided with information about the procedure, its technique, risks and possible complications. All the patients signed an informed consent. The study was registered and approved by the Ethics Committee of the Clinic.

Preoperative examination included: collection of complaints, demographic data, medical and personal history; urogynecological examination with mandatory palpation of the sacrospinous ligament area on both sides, urodynamic tests and ultrasound measurement of post-voiding residual volume (PVR). Prolapse staging was recorded according to the POP-Q system. Patients completed questionnaires translated and validated in Russia: Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Repeated examinations after

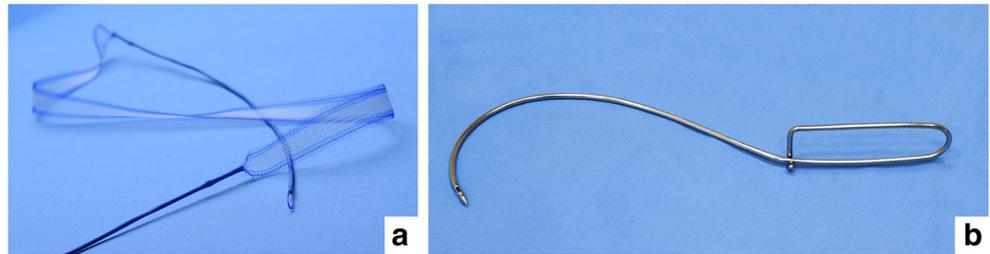
surgical treatment were carried out at 1, 6 and 12 months and then annually. The postoperative examination was similar to the preoperative one and was performed by physicians of the outpatient center of the urology department (non-surgeons). Anatomical success was defined as the absence of symptomatic (complaints of bulge symptoms) prolapse \geq stage 2 POP-Q in the operated compartment. To assess the level of patient's satisfaction, the scale with the question "Are you satisfied with the results of the surgery?" and five points from "extremely dissatisfied" to "extremely satisfied" was used. Also, a satisfaction criterion was the answer to the question: "Would you recommend the procedures to friends?"

The technique involved the use of a synthetic monofilament polypropylene woven macroporous (volume porosity 72%) mesh (Urosling-1; LLC Lintex, St. Petersburg), which was developed specifically for apical prolapse repair. The size of the tape was 1.5 cm \times 45 cm with a surface density of 60 g/m² and atraumatic edges (Fig. 1a). The sling was inserted using the reusable metal Urofix PL guide needle (Fig. 1b).

Surgical technique

All surgical procedures were performed by two staff urologists experienced in this technique. Patients received intravenous antibiotics (amoxicillin clavulanate according to weight) within an hour before the operation. Surgery was performed under general anesthesia (endotracheal or intravenous). The features of subfascial surgical access to the sacrospinous ligament were described in detail earlier [11]. The differences in the described technique included: unilateral insertion of the mesh and the use of a guide tool, which implies an "inside-out" technique (Fig. 1b). The choice of the sacrospinous ligament for mesh placement was made at both the preoperative (taking into account the previous fractures of the pelvis, injuries and presence of pain syndrome during palpation of sacrospinous areas) and intraoperative stages (taking into account the flexibility of the paravaginal tissues and bleeding during blunt dissection). After the identification of the sacrospinous ligament, its perforation was performed not $<$ 2 cm medially from the ischial spine. Then, the instrument was carried from the inside to outside in the direction of the gluteal region. The tip of the instrument was removed through a previously made incision on the skin of the buttock. Then, a ligature was passed through the hole on the distal end of the guide. One of the ends of the ligature was secured by the fingers, and subsequently the instrument with the remaining thread was pulled out back through the vaginal incision. After that, the distal end of the tape was tied to the end of the ligature removed from the vaginal wound. By the traction of the free end of the ligature, the tape was conducted through the sacrospinous ligament and withdrawn in the gluteal area incision. (Fig. 2a). Then, half of the sling was cut off, and the remainder was fixed to the cervix

Fig. 1 **a** Apical sling, UroSling-1; **b** Urofix PL instrument needle, modification 3 ("hook")



with three stitches using a non-absorbable braided polyester thread with a fluoropolymer coating (Ftorex USP1 HR 45). Afterwards, a Halsted suture (PGA USP2 HR 35) was applied on the internal surface of the pubocervical fascia. At the end the thread was tied to one of the ligatures that fixed the mesh to the cervix (Fig. 2b). An important feature of subfascial colporrhaphy was its implementation by the so-called "ultralateral" technique, i.e., the stitches were laid as far as possible from the median line of the vaginal incision. This technique allows restoring the maximum area of the defect of the pubocervical fascia. The vagina was closed by continuous USP 2/0 PGA suture. After that, the sling was pulled up at its distal end. Due to the traction of the apical region with a subfascial suture fixed to it, both levels I and II of support (according to DeLancey) were restored. Then, the rectum lumen was checked to be sure there was no obstruction by the apical sling. If necessary, the tape tension was decreased. The distal end of the mesh was cut subcutaneously, and the wound of the gluteal region was sutured (PGA USP 2/0). Vaginal packing and a urethral catheter were placed and removed within 24 h.

Statistical analysis

The obtained clinical results were analyzed using the STATISTICA for Windows software system (version 10). Quantitative data were described in terms of mean, standard deviation, 95% confidence interval, minimum and maximum values, medians and quartiles. The processing of the QOL scale and POP-Q system was carried out by comparing the initial data and values obtained during the observation

process; they were compared using signs and Wilcoxon paired criteria. Statistical hypotheses were tested at a significance level (alpha error) of 0.05.

Results

The study included 174 patients with an average age of 61 ± 8.69 years. The patients' demographics are tabulated in Table 1. Thirty-one women had a history of pelvic organ surgery. More than half of the patients at the preoperative stage were identified with overactive bladder (OAB). This condition was determined by a combination of positive answers to questions 15 and 16 of the PFDI-20 questionnaire with the specific complaints. Unilateral pain in the area of the sacrospinous ligament before the surgery was observed in 11 patients, who were consulted by a neurologist. In two (18.2%) patients, sciatic nerve neuropathy was recognized as the cause of this syndrome, in three (27.3%) the previous fracture of pelvic bones. The pain of the remaining six (54.5%) patients was regarded as a manifestation of degenerative spine disease (Table 1).

The mean surgery time was 26 ± 7.84 min (15–62); the average volume of intraoperative blood loss was 20.63 ± 9.47 ml (10–100). In 128 (73.6%) cases, the tape was installed on the left side and in 46 (26.4%) on the right side. Fourteen (8.1%) patients had cervicopexy due to previous supravaginal uterine amputation; the other 160 (91.9%) had hysteropexy. No cases of intraoperative bladder or rectum damage, or clinically significant bleeding requiring blood transfusion, were recorded. The average duration of bladder drainage was 1.06 ± 0.38 days (1–5); the average hospital stay was 2 ± 0.43 days (2–5).

Fig. 2 Main steps of the surgery: **a** the position of the sling: (a) the sling, fixed to the cervix; (b) the sacrospinous ligament; (c) distal part of the sling, conducted through the incision in the gluteal area. **b** Subfascial colporrhaphy: (a) the suture laid on the internal surface of the fascia; (b) the suture is tied with the ligature, fixing the sling to the cervix

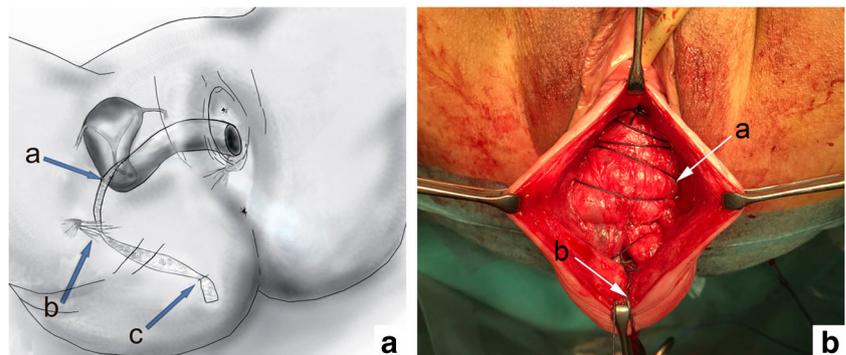


Table 1 Patient characteristics

Parameters	<i>n</i> = 174
*Age, years	61 ± 8.69
*BMI, kg/m ²	27.86 ± 4.13
*Number of childbirth	1.94 ± 0.69
	<i>n</i> , (%)
Postmenopause	165 (94.8%)
Sexually active women	82 (47.1%)
Scarpinal area pain syndrome	11 (6.3%)
Sciatic nerve neuropathy	2 (18.2%)
Previous fracture of the pelvic bones	3 (27.3%)
Degenerative spine diseases	6 (54.4%)
Overactive bladder	98 (56.3%)
Previous surgeries	
Supravaginal uterine amputation	14 (8%)
Mid-urethral sling operation	2 (1.1%)
Anterior/posterior colporrhaphy	13 (7.4%)
Prosthetic treatment	2 (1.1%)

*Data presented by the mean values ± SD

Follow-up data for ≥ 12 months were obtained for 147 (84.4%) patients. Among women who did not come for a 12-month appointment, 21 (14.3%) had no prolapse and no complaints at the previous examination (6 month). Of the 174 operated patients, 6 (3.4%) refused to participate further in the study.

When analyzing the POP-Q points, the overwhelming majority of the patients in the postoperative period showed an improvement in the anterior and apical compartments while maintaining the total length of the vagina (TVL). During 12 months of follow-up, anatomical recurrence in the apical compartment was detected only in one woman (0.7%), in the anterior compartment in ten patients (6.8%). However, the vaginal wall descended ≥ 3 cm beyond the hymen in only three cases. In 57 (38.7%) patients asymptomatic prolapse of the anterior vaginal wall at the level of Ba-1 POP-Q was observed. It should be mentioned that at the beginning of the technique development, subfascial colporrhaphy was not ultralateral (in the first 15 patients). At the 12-month appointment, four cases of ten recurrences were observed in those patients (40.0%). Also interesting is the fact that all the patients with a postoperative defect in the anterior compartment initially showed a severe stage of the cystocele (Ba +3 or more) in combination with signs of vaginal laxity and/or early stage of rectocele.

When comparing pre- and postoperative urination parameters, a statistically significant ($p < 0.001$) increase in the maximum flow rate (Q max) and a decrease in post-voiding residual urine volume (PVR) were detected. Of the 98 patients with OAB preoperatively, 73 came for follow-up examination

12 months after the intervention. Among them, 65.7% (48/73) noted the disappearance or reduction of the severity of symptoms (Table 2).

The main postoperative complications are presented in Table 3. No cases of mesh erosion were observed during 12 months of follow-up. In case of the development of urgency de novo, M-cholinolytics were prescribed with a positive effect in most patients. Stress urinary incontinence (SUI) de novo was observed in 6.8% (10/147) of patients. Within 6 months after the surgery, a suburethral sling was performed in seven of them. Three women refused the proposed surgical treatment because of mild symptoms. In the early postoperative period, atony of the bladder developed in five (2.9%) patients, resolving in 2–5 days because of the intermittent catheterization and drug therapy (anticholinesterase drugs). Moderate buttock pain was present in 49 operated women. For most patients, the pain did not interfere with their everyday life (sitting, walking, driving and doing housework) and was completely gone by the 2nd week after the surgery. Functional disorders of the rectum (constipation/incontinence) in the postoperative observation period were not identified.

Most of the patients showed a significant improvement in the quality of life after the treatment (Table 4). The quality of sexual life was assessed according to PISQ-12 data and also improved after surgery. Sixty-five patients filled in this questionnaire before the surgery and 12 months after. Dyspareunia (defined as the answer “always” or “usually” to question 5 of PISQ-12, “Do you feel pain during intercourse?”) before the surgery was observed in 11 (16.9%) patients, regressing in 7 (63.6%) postoperatively. In addition, nine women who were not sexually active before the surgery returned to sexual life within a year after the treatment.

The satisfaction rating of 147 patients showed: 89.1% (131/147) were “extremely satisfied” and 7.4% (11/147) “satisfied.” In general, 96.5% (142/147) of the patients answered that they could recommend such an intervention to friends who need it.

Table 2 POP-Q and uroflowmetry assessment before and 12 months after the surgery (*n* = 147)

POP-Q	Before	12 months follow-up	<i>p</i>
Aa	−0.22 ± 1.24	−1.93 ± 0.82	<0.01
Ba	2.95 ± 1.07	−1.53 ± 0.82	<0.001
C	1.73 ± 1.54	−8.38 ± 0.87	<0.001
Ap	−2.15 ± 0.96	−2.06 ± 0.93	>0.05
Bp	−2.52 ± 0.54	−2.42 ± 0.5	>0.05
TVL	8.63 ± 0.63	8.78 ± 0.57	>0.05
Uroflowmetry			
PVR (ml)	30.61 ± 35.4	4.6 ± 13.67	<0.001
Q max (ml/s)	15.83 ± 6.14	23.78 ± 4.76	<0.001

Values are presented as mean (cm) ± SD

Table 3 Postoperative complications

Complications, amount	1 month (<i>n</i> = 174)	6 month (<i>n</i> = 168)	12 month (<i>n</i> = 147)
Hematoma in the surgical area (> 50 ml)	1 (0.57%)	0	0
Urinary retention (PVR > 100 ml)	2 (1.14%)	0	0
Overactive bladder de novo	7 (4.02%)	2 (1.19%)	2 (1.36%)
SUI de novo	10 (5.74%)	3 (1.78%)	3 (2.04%)
Dyspareunia de novo	–	1 (0.59%)	1 (0.68%)
Pain in gluteal/sacrococcygeal area	6 (3.44%)	0	0

Discussion

Sederl first described sacrospinous fixation for vault prolapse in 1958. The technique began to spread actively in Europe and the US because of the works of Richter [9]. Thirty years later, Richardson published the results of the first case series of patients who underwent sacrospinous hysteropexy for uterovaginal prolapse [12]. According to a recent review conducted under the guidance of the International Urogynecological Association (IUGA), > 60% of surgeons prefer transvaginal reconstruction of the apical compartment, with sacrospinous fixation being the most popular procedure [13, 14]. Moreover, the International Federation of Gynecology and Obstetrics (FIGO) recommends this technique as highly effective (level 1a) and safe (level 1b), and the level of evidence corresponds to that of sacrocolpopexy [15]. The clinical practice guidelines of the Society of Gynecologic Surgeons (SGS) regarding the use of uterine preservation support the opinion that sacrospinous hysteropexy should be widely recommended among other uterus-sparing techniques (level 2a) [16]. All the authors highlight the following main advantages of sacrospinous fixation: cost effectiveness, technical simplicity, short duration of the surgery, low postoperative morbidity and allowing simultaneous correction of several compartments.

According to a recent meta-analysis including two RTCs and four cohort studies on sacrospinous hysteropexy, the failure rate in the apical compartment was 8.5% (0–21), in the anterior compartment 34.9% (5.4–51%) [17]. The data are comparable to those of a published paper that included > 3500 patients who underwent sacrospinous fixation for vault

prolapse, where the recurrence in the anterior compartment was 18.3% (0–42%) and in the apical 5.3% (0–14%) [18]. A simultaneous correction of the pubocervical fascia by colporrhaphy was proposed to reduce the risk of cystocele recurrence after sacrospinous fixation. However, according to the research data, the performance of anterior colporrhaphy with sacrospinous fixation, in case of uterine preservation or hysterectomy, either had no effect on the results or improved them slightly with a still high rate of cystocele [19–21]. Unfortunately, this approach did not solve the main problem of sacrospinous fixation—displacement of the axis of the vagina and the “opening” of the anterior compartment. In our study, to minimize the retroflexion effect, we used a sling as a “bridge” between the fixation points. We also performed a subfascial colporrhaphy ultralaterally, which allowed closing most of the defect of the pubocervical fascia. Due to these technical solutions, it was possible to reduce the cystocele recurrence rate to 7.4% with a follow-up period of 12 months. Only 25% (3/12) of patients with recurrence were symptomatic. The efficiency of the surgery at the apical compartment exceeded 99%.

The use of the sacrospinous ligament for fixation of the apical compartment is always carries the risk of developing intraoperative bleeding and pain syndrome after the surgery. According to the published studies, the rate of these complications is 0–4.1% and 0–4.4%, respectively [6, 21–23]. The proposed method allowed us to use a minimal dissection from the most convenient side and only for one finger. The perforation point of the sacrospinous ligament in the “safe zone” dramatically reduced the likelihood of damage to large vessels. During the study, there were no cases of severe bleeding and only one case of postoperative hematoma of > 50 ml. Pain syndrome may be associated with multiple (≥ 3 sutures) sutures laid on the sacrospinous ligament and a rigid fixation of the vagina to the ligament. Unfortunately, even the use of modern stitching devices did not allow us to eliminate postoperative pain [7, 24]. Preoperative examination of the sacrospinous area made it possible to avoid implantation of the sling in the side compromised by the existing neurological pathology, which may provoke a chronic pain syndrome. Besides, pulling the mesh through the sacrospinous ligament minimized the possibility of ischemia of the nerve endings

Table 4 Pre- and postoperative quality-of-life data

Questionnaire	Before <i>n</i> = 147	After <i>n</i> = 147	<i>p</i>
PFDI-20	75.22 ± 38.2	17.85 ± 24.77	<0.001
POPDI-6	42.6 ± 24.11	14.97 ± 14.89	<0.001
CRADI-8	14.57 ± 16.4	15.21 ± 15.67	<0.01
UDI-6	17.57 ± 10.55	4.37 ± 7.67	<0.001
	<i>n</i> = 65	<i>n</i> = 74	
PISQ-12	20.42 ± 4.44	30.74 ± 3.36	<0.001

Values are presented as mean score ± SD

surrounding the surface of the ligament in the area of the fixation zone. None of the patients in our study complained of severe pain or chronic pain syndrome during the follow-up. We believe that this result was achieved by a preoperative assessment of the sacrospinous ligament area and the use of the trocar, allowing us to perform a tunnel in the ligament, pushing its fiber apart, and to minimize the fixation zone ($< 0.5 \text{ cm}^2$).

Another common postoperative complication of sacrospinous fixation is dyspareunia. According to research data, dyspareunia developed in 2–36% of women after the surgery, and in some of them it resolved only after the sutures were removed [25]. One of its causes is the non-physiological anatomical vaginal position. Not by accident, the outcomes of bilateral sacrospinous fixation showed a decrease of this side effect [26]. In our study, the use of the sling allowed preserving vaginal mobility and its natural position because of the separation of the fixation points. Dyspareunia de novo disturbed one patient and only in a certain sexual position. Moreover, after the treatment, some women returned to sexual activity.

The most popular system for bilateral mesh-augmented sacrospinous hysteropexy is UpHold (Boston Scientific). Vu et al. reported an approximately 1.89% recurrence rate and mesh exposure in 1.9% [27]. Jirschele et al. published a success rate of approximately 97% for the apical and anterior compartment after the surgery; nevertheless, the extrusion and reoperation rates were 6.52% and 7.53%, respectively [28]. A serious limitation of the studies mentioned above is the absence of data about operation time and intraoperative complications. A similar success rate for the apical (94%) but only 71% for the anterior compartment was reported by the Nordic TVM group; the overall rate of serious complications was 4.3% [29]. The authors mentioned about three cases of bladder perforation, one case of hemorrhage $> 1000 \text{ ml}$ and seven $> 500 \text{ ml}$, and five mesh removals because of pain or mesh exposure. Interesting data were presented in a recent review on uterine-preserving techniques for the treatment of pelvic organ prolapse [30]. The average recurrence rate for vaginal mesh hysteropexy was 9.5% (2–33%) and for repeat POP surgery was 4.5% (3–29%). One of the most common complications was sexual dysfunction [8.7% (0–48%)] and mesh exposure [5.4% (0–19%)]. Also the operating time was 112 min (58–171 min), intraoperative blood loss was 117 ml (49–161 ml), and hospital stay was 3.4 days (1–6 days). In our study there were no bowel or bladder damage accidents and no severe hemorrhages (intraoperative blood loss was just $20.63 \pm 9.47 \text{ ml}$). The operating time was $26 \pm 7.84 \text{ min}$, and the average hospital stay was $2 \pm 0.43 \text{ days}$. In the described unilateral sacrospinous fixation method, minimal mesh was used: just a $1.5 \times 20 \text{ cm}$ sling. Implantation of the tape in the subfascial space allowed preserving the blood supply of the vaginal wall and also, in combination with subfascial

colporrhaphy, isolating the mesh from the vaginal mucosa. We believe that these basic steps may minimize the risk of mesh exposure. In our study, there were no cases of exposure during the year of postoperative follow-up period. Moreover, the minimal dissection and unilateral approach allowed reducing the operation time, blood loss and rehabilitation time.

The results of the use of the proposed technique seem to be promising, but a short follow-up period (1 year) is a limitation of this study. However, the repeatedly confirmed high efficiency of traditional sacrospinous fixation and the proposed solutions for the reduction of its main complications make it possible to predict the success of the described technique.

Conclusion

Unilateral sacrospinous fixation using an apical sling in combination with reconstruction of the pubocervical fascia (subfascial colporrhaphy) provides high efficiency, while ensuring a low frequency of specific complications. It is universal and can be successfully used in patients with anterior-apical prolapse.

Compliance with ethical standards

Financial disclaimer/conflict of interest D.D. Shkarupa and N.D. Kubin are consultants (LlcLintex); other authors claim no conflict of interest.

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