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# Comparative analysis of methods of surgical correction of post-hysterectomy pelvic organ prolapse

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ABSTRACT

***BACKGROUND:*** The incidence of prolapse after hysterectomy requiring surgical intervention is estimated at 36 cases per 10,000 women. A universal surgical treatment method for post-hysterectomy pelvic organ prolapse is lacking, prompting the need for new approaches.

***AIM:*** To comparatively analyze the results of laparoscopic sacrocolpopexy, sacrospinous fixation, and the developed new method of surgical correction of pelvic organ prolapse after hysterectomy.

***MATERIAL AND METHODS:*** This prospective non-randomized study included 57 patients with stage II, III, or IV symptomatic post-hysterectomy prolapse of the pelvic organs who were admitted at the clinical hospital RZD-Medicine in Tula, Russia, between August 2019 and September 2023. The first group ($n$=18) consisted of women who underwent surgical correction of post-hysterectomy pelvic organ prolapse in a newly developed method; the second group ($n$=19) included women who underwent laparoscopic promontofixation according to the conventional technique; and the third group ($n$=20) involved patients who underwent installation of an apical sling using a UroSling-1 mesh endoprosthesis (Lintex LLC, St. Petersburg). The patients' quality of life was assessed using specialized validated questionnaires: Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. Patients were asked to complete questionnaires before surgery and 12 and 24 months after surgical correction of PGP. The patients were invited for a follow-up examination after 1, 6, 12, and 24 months.

***RESULTS:*** The duration of the operation in the second group significantly exceeded the indicators of the first and third groups. The average duration of hospital stay of patients was 4.4±0.6 (95% CI: 4.1–4.7) bed days in the first group, 4.9±1.1 (95% CI: 4.6–5.3) in the second, and 4.6±0.6 (95% CI: 4.3–4.9) in the third. The differences were insignificant ($p^{1-2}$=0.437; $p^{1-3}$=0.137; $p^{2-3}$=0.235). The anatomical results after 24 months at points Aa and Ba showed significant differences. At point Aa, $p^{1-3}$=0.007 and $p^{2-3}$=0.004, and at point Ba, $p^{1-3}$=0.032 and $p^{2-3}$=0.041. A comparative assessment of the questionnaire data before surgery and 12 and 24 months after surgery showed a significant improvement in the quality of life of patients in the three groups.

***CONCLUSION:*** The proposed method of correction of post-hysterectomy pelvic organ prolapse provides high anatomical and functional results and reduces the posibility of repeated surgical intervention for recurrence.

**Keywords:** post-hysterectomy prolapse; hysterectomy; laparoscopy; laparoscopic sacrocolpopexy; sacrospinous fixation.

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# Сравнительный анализ методов хирургической коррекции постгистерэктомического пролапса тазовых органов

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АННОТАЦИЯ

**Обоснование.** Частота пролапса после гистерэктомии, требующего хирургического вмешательства, оценивается в 36 случаев на 10 000 женщин. Отсутствие универсальной методики хирургического лечения постгистерэктомического пролапса тазовых органов приводит к необходимости поиска новых подходов.

**Цель**. Сравнительный анализ результатов лапароскопической сакровагинопексии, крестцово-остистой фиксации и разработанного нового метода хирургической коррекции пролапса тазовых органов после субтотальной гистерэктомии.

**Материал и методы**. В проспективное нерандомизированное исследование вошли 57 пациенток с симптоматическим постгистерэктомическим пролапсом тазовых органов II, III, IV стадий, обратившихся в Клиническую больницу «РЖД-Медицина» (Тула) с августа 2019 по сентябрь 2023 г. Основная (1-я) группа ($n$=18) — женщины, которым хирургическую коррекцию постгистерэктомического пролапса тазовых органов выполняли новым разработанным способом; 2-я группа ($n$=19) — женщины, которым выполняли лапароскопическую промонтофиксацию по классической методике; 3-я группа ($n$=20) — женщины, которым выполняли установку апикального слинга с использованием сетчатого эндопротеза «УроСлинг-1» (ООО «Линтекс», Санкт-Петербург). Качество жизни пациенток оценивали при помощи специализированных валидированных опросников Pelvic Floor Distress Inventory (PFDI-20) и Pelvic Floor Impact Questionnaire (PFIQ-7). Пациенткам предлагалось заполнить опросники до операции, а также через 12 и 24 мес. после хирургической коррекции постгистерэктомического пролапса. На контрольный осмотр пациентки приглашались через 1, 6, 12 и 24 мес.

**Результаты**. Длительность операции во 2-й группе статистически значимо превышает показатели 1-й и 3-й групп. Средняя длительность пребывания в стационаре составила у пациенток 1-й группы 4,4±0,6 (95% ДИ 4,1–4,7) койкодня, 2-й группы — 4,9±1,1 (95% ДИ 4,6–5,3), 3-й группы — 4,6±0,6 (95% ДИ 4,3–4,9); различия статистически незначимы ($p^{1-2}$=0,437, $p^{1-3}$=0,137, $p^{2-3}$=0,235). Анатомические результаты через 24 мес. по точкам Aa и Ba показали статистически значимые различия. По точке Aa: $p^{1-3}$=0,007, $p^{2-3}$=0,004, по точке Ba: $p^{1-3}$=0,032, $p^{2-3}$=0,041. Сравнительная оценка данных опросников до операции, через 12 и 24 мес. после операции показала значительное улучшение качества жизни пациенток трёх групп.

**Заключение**. Предложенная методика коррекции постгистерэктомического пролапса тазовых органов обеспечивает высокие анатомические и функциональные результаты, а также уменьшает вероятность повторного хирургического вмешательства по поводу рецидива заболевания.

**Ключевые слова**: постгистерэктомический пролапс; гистерэктомия; лапароскопия; лапароскопическая сакровагинопексия; крестцово-остистая фиксация.

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# 子宫切除术后盆腔器官脱垂手术矫正方法的比较分析

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摘要

**论证。**据估计，子宫切除术后需要手术干预的脱垂发生率为每万名妇女中有 36 例。子宫切除术后盆腔器官脱垂缺乏通用的手术治疗方法，因此需要寻找新的方法。

**目的。**比较分析腹腔镜骶阴道成形术、骶髂固定术和新开发的子宫次全切除术后盆腔脏器脱垂手术矫正方法的效果。

**材料和方法。**这项前瞻性非随机研究纳入了2019年8月至2023年9月期间在 “RZD-Medicine”临床医院（图拉）就诊的57名症状性子宫切除术后盆腔器官脱垂II、III、IV期患者。主要（第1）组（n=18）包括以新开发的方法对子宫切除术后盆腔器官脱垂进行手术矫正的女性。第 2 组（n=19）包括根据经典方法接受腹腔镜原位固定术的妇女。第 3 组（n=20）包括使用网状内支架 “UroSling-1”（Lintex LLC，圣彼得堡）进行顶端吊带置入术的妇女。患者的生活质量通过专门的验证问卷 Pelvic Floor Distress Inventory (PFDI-20) 和 Pelvic Floor Impact Questionnaire (PFIQ-7) 进行评估。患者被要求在手术前以及12个月和24个月后填写问卷。邀请患者在 1、6、12 和 24 个月时进行随访检查。

**结果。**据统计，第2组的手术持续时间在统计学上显著超过第1组和第3组。第1组患者的平均住院时间为4.4±0.6（95% CI 4.1-4.7）天，第2组为4.9±1.1（95% CI 4.6-5.3）天，第3组为4.6±0.6（95% CI 4.3-4.9）天；差异无统计学意义（$p^{1-2}$=0.437，$p^{1-3}$=0.137，$p^{2-3}$=0.235）。24 个月后，Aa 点和 Ba 点的解剖结果显示出显著的统计学差异。Aa点：$p^{1-3}$=0.007，$p^{2-3}$=0.004；Ba点：$p^{1-3}$=0.032，$p^{2-3}$=0.041。对手术前、手术后 12 个月和 24 个月的问卷数据进行的比较评估显示，三组患者的生活质量均有明显改善。

**结论。**所提出的矫正子宫切除术后盆腔器官脱垂的技术提供了很高的解剖学和功能结果，并降低了因疾病复发而反复进行手术治疗的概率。

关键词： 子宫切除术后脱垂；子宫切除术；腹腔镜；腹腔镜骶阴道成形术；骶髂固定术。

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## INTRODUCTION

Genital prolapse occurs in 67% of females after hysterectomy [1]. The incidence of post-hysterectomy prolapse requiring surgery is estimated to be 36 per 10,000 women [2]. Indications for surgery include symptoms associated with pelvic organ prolapse after hysterectomy prolapse [3], such as pelvic pressure, foreign body sensation inside and outside the vagina, back pain, and bladder, bowel, and sexual issues [4]. These symptoms have a significant impact on women's quality of life after hysterectomy, leading not only to physical and emotional distress, but also to partial or complete disability [5].

The literature shows that 12% of women undergoing hysterectomy had surgery for pelvic organ prolapse [6].

There are abdominal, laparoscopic, and vaginal surgical procedures for post-hysterectomy prolapse using autologous, alloplastic, and synthetic materials [7]. The most common surgical treatment options for post-hysterectomy prolapse include laparoscopic sacral vaginopexy [8] and sacrospinous fixation [9], including apical sling with an UroSling-1 mesh endoprosthesis [10]. In some studies, laparoscopic sacral vaginopexy is considered the optimal treatment for vaginal vault prolapse [11] and is associated with a high success rate and low recurrence rate due to the supportive role of vaginal mesh [12]. However, this procedure can be complicated by an extended operation time and hospital stay [13]. Some authors consider sacrospinous fixation to be the preferred option because this technique is free of risks associated with intraperitoneal manipulation and ensures a shorter duration of surgery [14]. A significant issue with this type of treatment is buttock pain and dyspareunia, which may be caused by irritation of the nerve structures adjacent to the sacrospinous ligament, excessive tension of the sutures, and displacement of the vagina toward fixation [15]. There are conflicting results and recommendations for the use of these surgical procedures. Each of these surgical techniques has a number of limitations that prevent its use as a one-size-fits-all option [16], requiring search for new approaches to the treatment of post-hysterectomy prolapse [17].

## AIM

The aim of the study was to compare outcomes of laparoscopic sacral vaginopexy, sacrospinous fixation, and the proposed new surgical technique in treatment of post-hysterectomy prolapse after subtotal hysterectomy.

## MATERIALS AND METHODS

The prospective, non-randomized study included 57 patients with post-hysterectomy prolapse who presented to the RZD-Medicine Clinical Hospital (Tula, Russia) from August 2019 to September 2023. All patients provided signed informed consent to participate in the study. The study was approved by the Ethics Committee of the Medical Institute of the Tula State University (Protocol No. 2 of 15 February 2021).

The study group was formed using continuous topic sampling.

*Eligibility Criteria* included history of subtotal hysterectomy for benign neoplasm; stage II, III, IV symptomatic pelvic organ prolapse after hysterectomy; consent for propylene implant placement.

*Exclusion criteria* included cancer, hysterectomy for other indications, cervical and vaginal disease, severe medical conditions contraindicating surgery, and massive pelvic adhesions.

All patients were divided into three groups. The first (main) group ($n$ = 18) included women who received surgical treatment of post-hysterectomy prolapse using a new two-step surgical technique [18], and the first stage included anterior and posterior subfascial colporrhaphy in 94.4% of cases ($n$ = 17). The second group ($n$ = 19) included women who underwent laparoscopic sacrocolpopexy using the classical technique [19]. The third group ($n$ = 20) included women who underwent apical sling according to the published technique [20] using the UroSling-1 mesh endoprosthesis (Lintex LLC, St. Petersburg, Russia). In 95% ($n$ = 19) of the cases, both the anterior and posterior parts of the pelvic floor were treated.

The study included gynecologists who had previously performed at least 20 study procedures, excluding procedures using the new technique. The surgical technique was chosen by a surgeon and discussed with a patient.

Patients were evaluated according to the standard of care for pelvic prolapse.

Complaints and medical history were assessed and a physical examination was performed. The scope of previous hysterectomy was considered. The quality of life of patients was assessed. The gynecologic examination included assessment of the vaginal mucosa, the degree of anterior and posterior vaginal wall prolapses at rest and on exertion, the status and degree of cervical prolapse, if present, and cough stress test and straining test. Digital rectal examination was performed to detect rectocele or enterocele.

Standard laboratory tests, smear tests, and cytology were performed. All patients underwent pelvic ultrasound and, if dysuria was present, urinary tract and renal ultrasound and uroflowmetry were performed, and residual urine volume was determined. Patients with urinary tract symptoms were referred to a urologist.

The Pelvic Organ Prolapse Quantification System (POP-Q) was used to determine the severity of prolapse after hysterectomy.

The Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Impact Questionnaire (PFIQ-7) were used to assess quality of life. Patients were asked to complete questionnaires before and at 12 and 24 months after surgical treatment of post-hysterectomy prolapse. Patients were asked to return for follow-up visits at 1, 6, 12, and 24 months.

Statistical analysis was performed using StatTech v. 2.8.8 (StatTech LLC, Russia). Quantitative parameters were tested for normality of distribution using the Shapiro-Wilk test or the Kolmogorov–Smirnov test. Quantitative parameters with a normal distribution were presented as arithmetic means (M) and standard deviations (SD) with 95% confidence intervals (95% CI), and categorical data were presented as absolute values and percentages. Three groups were compared for quantitative parameters with normal distribution using one-way analysis of variance, with post hoc comparisons using Tukey's test. One-way repeated measures analysis of variance was used to compare three groups for a normally distributed quantitative parameter. Statistical significance of parameter changes over time was assessed using Pillai's trace, and post hoc analysis was performed using paired Student's *t*-test with Holm correction.

### Surgical technique

The first step of the surgery was performed through a vaginal access. A patient was placed in the lithotomy position. A 14–16 Fr Foley urethral catheter with an inflatable cuff and urine collector was placed. After aquadissection of the anterior vaginal wall with 0.9% saline, an incision was made in the most prolapsed part of the vaginal wall down to the subfascial space of 4–5 cm. The edges of the vaginal mucosa were grasped using Allis clamps. Subfascial dissection of the paravaginal tissues was performed using a blunt technique toward the pelvic peritoneum, exposing as much of the cervix as possible and isolating the vaginal walls laterally to the pelvic peritoneum. A 15 mm wide and 120–140 mm long endoprosthetic band was cut from a polypropylene mesh. At one end of the tape, a loop approximately 20 mm in diameter was sewn with Prolene thread. The tape was secured along the cervix with 3 to 5 interrupted sutures using non-absorbable Bioinert thread, and the free end with a loop was placed directly on the peritoneum after being rolled into a cuff. Subfascial colporrhaphy was then performed using a non-absorbable Bioinert thread with a Halsted suture, capturing a fixed portion of the mesh in the suture. If a rectocele was present, a posterior subfascial colporrhaphy was performed (Figure 1).

After the vaginal step of surgery was completed, the second, laparoscopical, step was performed. First, a classical laparoscopic abdominal access was formed. The peritoneum was opened above the cervical stump and an endoprosthesis tape was inserted into the abdomen. The peritoneum above the promontorium was opened. Tissue was dissected under the peritoneum with an endoscopic flexible blunt-ended dissector down to the cervical stump involving the polypropylene endoprosthesis tape loop. The tape was passed under the peritoneum and secured to the anterior longitudinal ligament of the spine with a non-absorbable suture. The loop was cut off. Peritoneal defects were sutured with absorbable sutures (Figure 2).

## FINDINGS

Before surgery, all patients complained of discomfort, a foreign body sensation in the vagina, which increased after exercise and at the end of the day. Patients reported pulling pain in the lower abdomen after exercise in 12 (21.1%) cases. Urinary difficulty was reported by 47 (82.5%) patients, constipation by 22 (38.4%), and dyspareunia by 28 (49.1%). Stress urinary incontinence was diagnosed in 4 (7.0%) cases. Table 1 shows the clinical characteristics of the group.

No statistically significant differences were found between three groups according to the data presented.

In group 1, the above surgical technique was used. In group 2, a laparoscopic sacral vaginopexy was performed. In group 3, a sacrospinous fixation with the UroSling-1

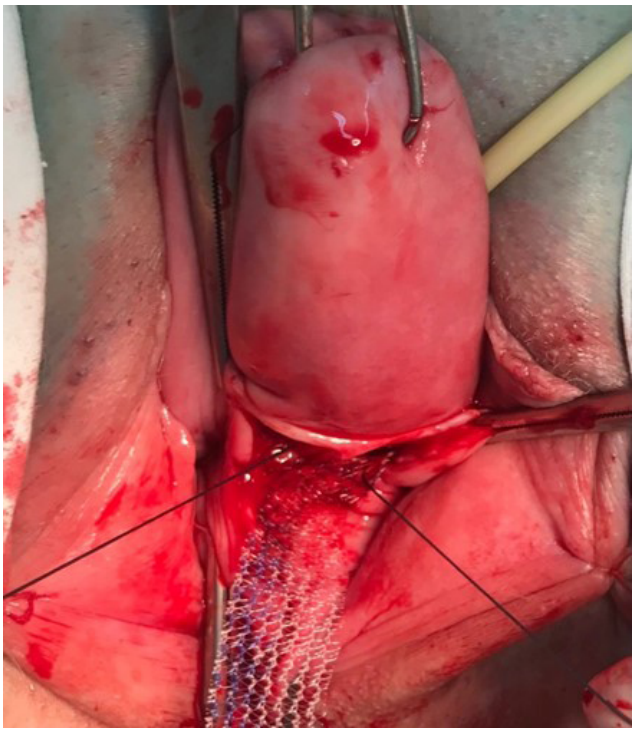

**Fig. 1.** Vaginal stage of fixation of the endoprosthesis.

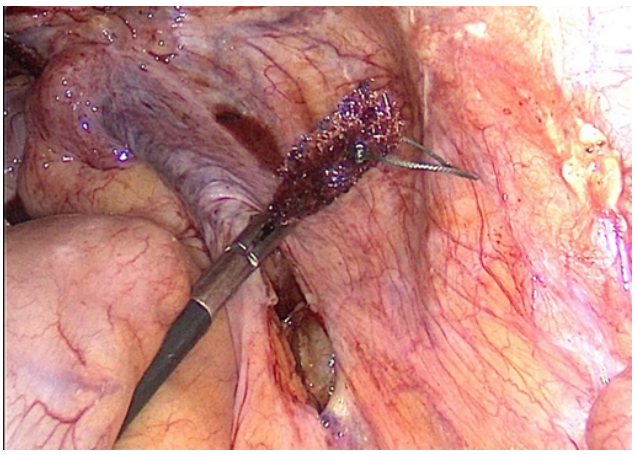

**Fig. 2.** Stage of the peritoneal endoprosthesis to the promontory.

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**Table 1.** General clinical characteristics of patient groups

| Indicator | 1st group (*n*=18) | | 2nd group (*n*=19) | | 3rd group (*n*=20) | | *p* |
|---|---|---|---|---|---|---|---|
| | M±SD | 95% CI | M±SD | 95% CI | M±SD | 95% CI | |
| Age, years (M±SD) | 61.4±4.1 | 59.2–63.3 | 60.7±8.2 | 56.6–63.8 | 62.5±10.1 | 58.7–67.2 | 0.561 |
| BMI (M±SD) | 30.2±4.3 | 29.2–31.6 | 30.7±4.2 | 28.5–32.7 | 31.8±3.2 | 29.2–32.4 | 0.667 |
| POP-Q | 2.7±0.6 | 2.4–3.0 | 2.7±0.7 | 2.3–3.0 | 3.1±0.6 | 2.9–3.4 | 0.050 |
| *Anatomical parameters before surgery (M±SD)* | | | | | | | |
| Aa | 0.7±1.8 | -0.2–1.6 | 0.6±1.7 | -0.2–1.5 | 0.4±1.9 | -0.5–1.3 | 0.851 |
| Ba | 1.6±1.9 | 0.6–2.5 | 1.4±1.8 | 0.5–2.2 | 0.8±2.5 | -0.3–2.0 | 0.566 |
| Ap | 0.2±1.6 | -0.6–1.0 | -0.1±1.4 | -2.7±0.6 | 0.9±1.7 | 0.1–1.7 | 0.137 |
| Bp | 0.8±1.8 | -0.1–1.7 | 0.1±2.1 | -1.0–1.1 | 1.6±2.2 | 0.6–2.7 | 0.062 |
| C | 0.5±2.7 | -0.9–1.9 | 0.7±2.2 | -0.3–1.8 | 1.1±3.4 | -0.6–2.7 | 0.837 |

*Note.* BMI, body mass index; *p*, level of statistical significance; *n*, quantity; M, median value; SD, standard deviation, POP-Q, Pelvic Organ Prolapse Quantification; Aa and Ba, distal and proximal parts of the anterior vaginal wall; Ap and Bp, distal and proximal parts of the posterior vaginal wall; C, distal edge of the cervix.

mesh endoprosthesis was performed. Table 2 shows the characteristics of surgical treatment.

The data obtained showed that surgery duration in group 2 was statistically significantly longer than in groups 2 and 3. Blood loss in group 2 was statistically significantly less than in groups 2 and 3, but blood loss did not exceed 50 mL in all groups.

No intraoperative or postoperative complications were reported in any group. The mean length of hospital stay was 4.4 ± 0.6 (95% CI: 4.1, 4.7) bed-days in group 1, 4.9 ± 1.1 (95% CI: 4.6, 5.3) in group 2, 4.6 ± 0.6 (95% CI: 4.3, 4.9) in group 3; differences were not significant ($p^{1-2}$ = 0.437, $p^{1-3}$ = 0.137, $p^{2-3}$ = 0.235).

Simultaneous TVT-O sling surgery for stress urinary incontinence due to severe symptoms was performed in 2 patients (11.1%) in group 1, 1 patient (5.2%) in group 2, and 1 patient (5.0%) in group 3.

In group 1, one patient developed symptoms of stress urinary incontinence 1 month after surgery; TVT-O sling surgery was performed 3 months later with a positive outcome. No vaginal mucosal erosion or mesh extrusion occurred in any group.

Analysis of POP-Q scores in three groups showed statistically significant improvement at 12 and 24 months after surgery. However, the anatomical evaluation at 24 months showed statistically significant differences at points Aa and Ba (for point Aa: $p^{1-3}$ = 0.007, $p^{2-3}$ = 0.004 (Figure 3); for point Ba: $p^{1-3}$ = 0.032, $p^{2-3}$ = 0.041 (Figure 4)).

Comparison of questionnaire scores before surgery and at 12 and 24 months after surgery showed a significant improvement in the patients' quality of life in three groups. No statistically significant differences between groups were found according to FIQ-7 scores (Figure 5) and PEDI-20 scores (Figure 6).

## DISCUSSION

Our study showed that symptoms of post-hysterectomy prolapse were significantly reduced in all three groups. A study by Köleli et al. [14] showed that operative time and

**Table 2.** Characteristics of surgical treatment

| Indicator | 1st group (*n*=18) | | 2nd group (*n*=19) | | 3rd group (*n*=20) | | *p* |
|---|---|---|---|---|---|---|---|
| | M±SD | 95% CI | M±SD | 95% CI | M±SD | 95% CI | |
| Duration of the operation (min) | 92.2±23.1 | 81.2–104.1 | 163.3±39.3 | 145.3–182.4 | 86.7±17.2 | 78.5–94.2 | $p^{1-2-3}$ <0.001*<br>$p^{1-2}$ <0.001*<br>$p^{1-3}$ <0.685<br>$p^{2-3}$ <0.001* |
| Blood loss (ml) | 35.0±10.2 | 30.0–40.2 | 22.5±14.7 | 15.5–28.7 | 39.1±19.4 | 30.2–48.8 | $p^{1-2-3}$ <0.001*<br>$p^{1-2}$ <0.020*<br>$p^{1-3}$ <0.785<br>$p^{2-3}$ <0.002* |

*Note*. * The differences are statistically significant ($p$ < 0,05); $p^{1-2-3}$, comparison of three groups: first, second, and third; $p^{1-2}$, comparison of the first and second groups; $p^{1-3}$, comparison of the first and third; $p^{2-3}$, comparison of the second and third; *n*, quantity; M, median value; SD, standard deviation.

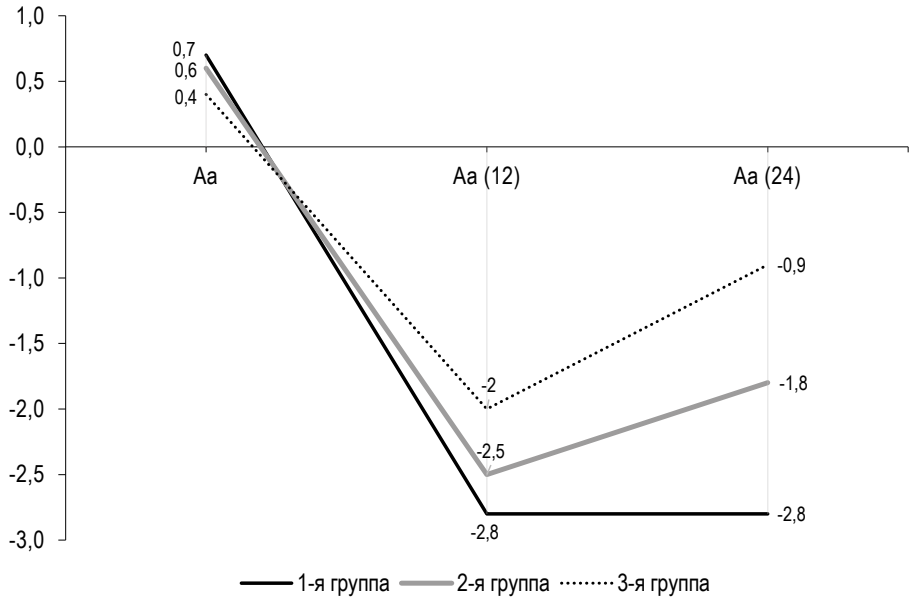


**Fig. 3.** Dynamics of the Aa indicator after 12 and 24 months.

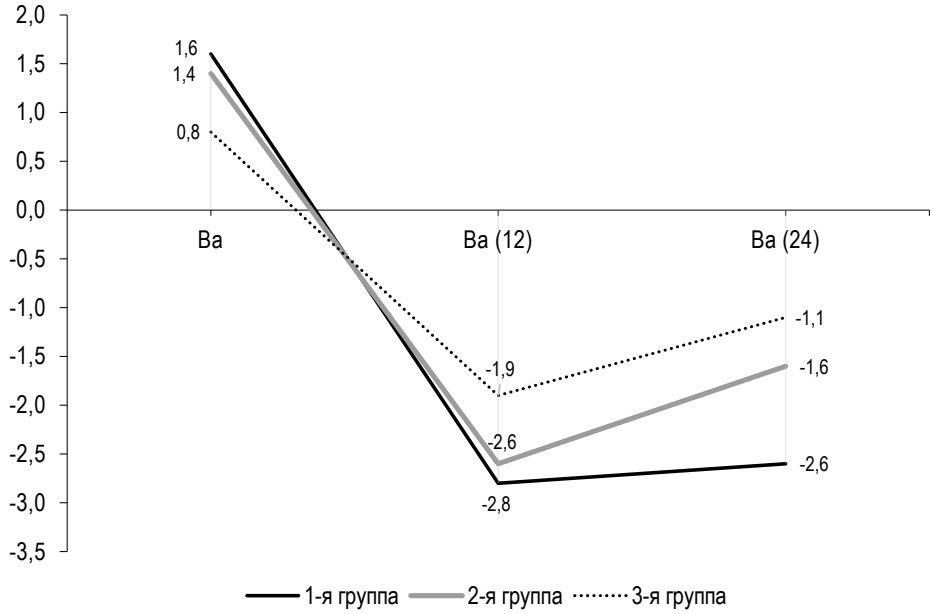


**Fig. 4.** Dynamics of the Ba indicator after 12 and 24 months.

hospital stay were shorter in the sacrospinous fixation group compared to the laparoscopic sacral vaginopexy group. Our results showed no statistically significant differences in the length of hospital stay between three groups, which was consistent with the mean length of stay in the study by Bastani et al. [12], where patients were admitted the day before surgery and discharged after 4 days. Bastani et al. [16] showed that the blood loss rate in sacrospinous fixation was higher than that in laparoscopic sacral vaginopexy which is associated with tissue dissection in the actively perfused area for sacrospinous fixation. Our study confirms these data. However, Köleli et al. [14] and Marcickiewicz et al. [21] showed similar intraoperative blood loss with laparoscopic sacral vaginopexy and sacrospinous fixation. Intraoperative blood loss rates in treatment of post-hysterectomy prolapse with the new surgical technique were similar to that in sacrospinous fixation.

Baghdadi et al. [22] showed that laparoscopic sacral vaginopexy was more effective in the treatment of post-hysterectomy prolapse, especially in advanced stages. The recurrence rate of post-hysterectomy prolapse was lower after laparoscopic sacral vaginopexy than after sacrospinous fixation. However, retrospective studies by Köleli et al. [14] and Marcickiewicz et al. [21] showed the same anatomical outcomes of both techniques, which was not confirmed by our data. Our study showed comparable anatomical

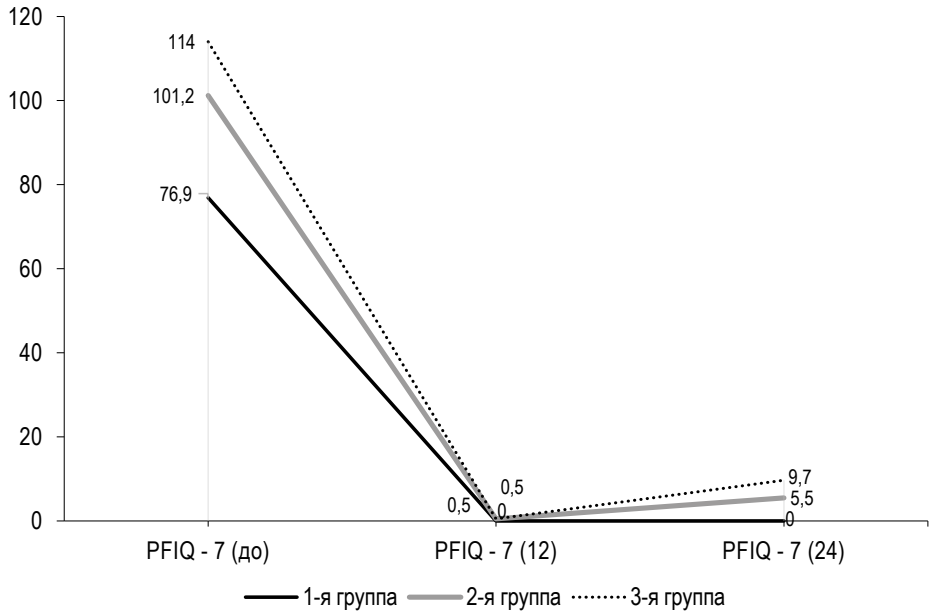


**Fig. 5.** Dynamics of PFIQ-7 indicators depending on the type of surgical intervention.

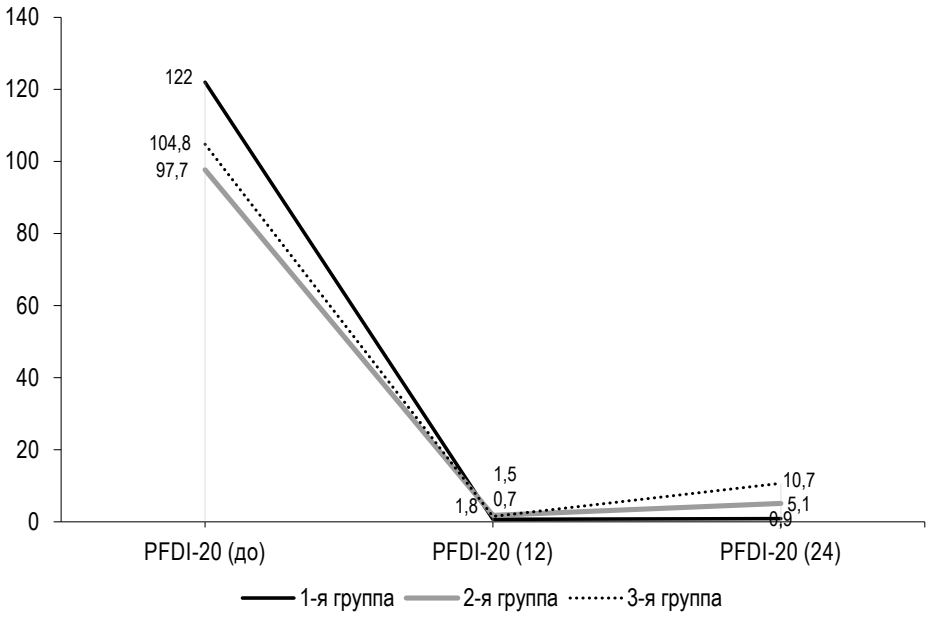


**Fig. 6.** Dynamics of PFDI-20 indicators depending on the type of surgical intervention.

outcomes 12 months after laparoscopic sacral vaginopexy, sacrospinous fixation, and the new proposed technique at all points, but statistically significant differences were obtained at 24 months: status at points Aa and Ba after sacrospinous fixation was worse than after laparoscopic sacral vaginopexy and surgery with our new technique.

The present study showed that preoperative PFDI-20 and PFIQ-7 scores were similar in three groups. In three groups, PFDI-20 and PFIQ-7 scores decreased significantly at 12 and 24 months after surgery compared to preoperative scores. Overall, three types of surgery reduced the major symptoms of post-hysterectomy prolapse during the follow-up period, although no statistically significant difference was observed.

## CONCLUSION

Post-hysterectomy prolapse is a difficult-to-treat condition that often requires surgery due to severity of symptoms and failure of non-surgical treatment. The proposed technique provides high anatomic and functional outcomes, allows visual guidance through all steps of the procedure compared to sacrospinous fixation, reduces operative time compared to laparoscopic sacral vaginopexy, and also reduces the likelihood of repeat surgery due to recurrence. Surgeons performing procedures for post-hysterectomy prolapse should evaluate the patient's condition, stage of prolapse, and their own experience to achieve a satisfactory outcome.

## ADDITIONAL INFO

**Authors' contribution**. V.G. Volkov, O.V. Soloveva — the concept and design of the study; O.V. Soloveva, K.Yu. Sorokoletov — collection and processing of the material; O.V. Soloveva — statistical data processing; O.V. Soloveva — writing a text; V.G. Volkov — editing. All authors confirm that their authorship meets the international ICMJE criteria (all authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work).

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**Competing interests**. The authors declares that there are no obvious and potential conflicts of interest associated with the publication of this article.

**Consent for publication**. The patients who participated in the study signed an informed consent to participate in the study and publish medical data.

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