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LAPAROSCOPIC PROMONTOFIXATION IN APICAL FORMS OF PELVIC ORGAN PROLAPSE: ANATOMIC, FUNCTIONAL AND PATIENT-REPORTED QUALITY OF LIFE OUTCOMES

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Abstract

Introduction. Pelvic organ prolapse (POP) has been increasing in recent years for both developed and developing countries.

Objective. To evaluate anatomic, functional and patient-reported quality of life outcomes of laparoscopic promontofixation for apical forms of POP.

Methods. This was a single-center observational study conducted at the Clinical Academic Department of Women's Health, University Medical Center between January 2019 and August 2021. A cohort of 55 patients receiving laparoscopic promontofixation following a diagnosis of apical or anterior-apical prolapses with grade III–IV. The anatomic and functional cure characteristics, also subjective patient's evaluation were included in this study. Primary outcomes were anatomic, functional, and subjective cures, that were measured pre- and postoperatively using the POP-Q system values and validated questionnaires. Secondary outcome measures included data on surgical complications. Data analysis was performed with descriptive statistics, Wilcoxon tests, and Mann–Whitney U-tests.

Results. A total of 55 patients underwent laparoscopic promontofixation. An objective anatomic cure was reported for 94.6% of patients, and significant improvement of all prolapse symptoms was observed following surgery. Only three patients (5.4%) experienced postoperative dyspareunia de novo. Analysis of validated questionnaires` results showed significant improvement of quality of life and sexual activity after surgical treatment ($p < 0.001$). No other complications requiring medical or surgical interventions were reported.

Conclusion. Laparoscopic promontofixation was associated with excellent anatomic, functional, and subjective results at follow-up. These findings raise questions about the need for long-term results of quality-of-life outcomes after surgical treatment.

Key words: *pelvic organ prolapse, laparoscopic promontofixation, reconstructive surgery, quality of life.*

Резюме

ЛАПАРОСКОПИЧЕСКАЯ ПРОМОНТОФИКСАЦИЯ ПРИ АПИКАЛЬНЫХ ФОРМАХ ПРОЛАПСА ТАЗОВЫХ ОРГАНОВ: АНАТОМИЧЕСКИЕ, ФУНКЦИОНАЛЬНЫЕ И ПАЦИЕНТ-ОРИЕНТИРОВАННЫЕ ИСХОДЫ

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Введение. Частота пролапса тазовых органов ежегодно увеличивается как в развитых, так и в развивающихся странах.

Цель. Оценить анатомические, функциональные и пациент-ориентированные исходы лапароскопической промонтофиксации при апикальных формах ПТО.

Методы. Проведено одноцентровое обсервационное исследование в условиях клинического академического департамента женских болезней, Университетского Медицинского Центра в период с января 2019 по август 2021 года. В исследование включены 55 пациентов, получивших оперативное лечение в объеме лапароскопической промонтофиксации по поводу апикального или передне-апикального пролапса III–IV степени. Были проанализированы анатомические и функциональные характеристики лечения, а также субъективная оценка пациентов. Первичными исходами были анатомические, функциональные и субъективные результаты лечения, которые были измерены до и после операции с использованием значений системы POP-Q и валидированных опросников. Вторичные показатели исхода включали данные о хирургических осложнениях. Анализ данных проводился с помощью описательной статистики, тестов Уилкоксона и U-тестов Манна–Уитни.

Результаты. В общей сложности 55 пациентам была проведена лапароскопическая промонтофиксация. Объективное анатомическое улучшение продемонстрировано в 94,6% случаев, также после операции наблюдалось значительное улучшение всех симптомов пролапса. У трех пациентов (5,4%) в послеоперационном периоде возникла диспареуния de novo. Анализ результатов опросников показал значительное улучшение качества жизни и сексуальной активности после хирургического лечения (p <0,001). Никаких других осложнений, требующих медицинского или хирургического вмешательства, зарегистрировано не было.

Заключение. Метод лапароскопической промонтофиксации на сроках наблюдения 12 месяцев и более показывает высокую анатомическую, функциональную и субъективную эффективность. Данные результаты требуют дальнейшего подтверждения в долгосрочных исследованиях качества жизни после хирургического лечения.

Ключевые слова: *пролапс тазовых органов, лапароскопическая промонтофиксация, реконструктивная хирургия, качество жизни.*

Түйіндеме

ЛАПАРОСКОПИЯЛЫҚ ПРОМОНТОФИКСАЦИЯ ЖАМБАС АҒЗАЛАРЫ ПРОЛАПСЫНЫҢ АПИКАЛДЫ ТҮРІНДЕ: АНАТОМИЯЛЫҚ, ҚЫЗМЕТТІК ЖӘНЕ ПАЦИЕНТКЕ-БАҒДАРЛАНҒАН НӘТИЖЕЛЕРІ

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Кіріспе. Дамыған елдерде де, дамушы елдерде де жамбас ағзалары пролапсының жиілігі жыл сайын артып келеді.

Мақсат. Жамбас ағзалары пролапсының апикалды түрінде жүргізілген лапароскопиялық промонтофиксацияның анатомиялық, қызметтік және пациентке-бағдарланған нәтижелерін бағалау.

Әдістері. Бірорталықты обсервациялық зерттеу жұмысы әйелдер аурулары клиникалық академиялық департаменті, Университеттік Медициналық Орталық аясында 2019 жылдың қаңтар айы мен 2021жылдың тамыз айы аралығында жүргізілді. Зерттеуге III–IV дәрежелі апикалды немесе алдыңғы-апикалды пролапс бойынша лапароскопиялық промонтофиксация көлемінде оперативті ем жүргізілген 55 пациент енгізілді. Емшараның анатомиялық және функционалды сипаттамалары, сонымен қатар пациенттердің субъективті бағасы талқыланды. Бастапқы нәтижелер ретінде қабылданған емшараның анатомиялық, қызметтік және субъективті нәтижелері операцияға дейін және кейін POP-Q жүйесін және арнйы сауалнамаларды қолдану аясында алынды. Қорытынды көрсеткіштер аясында хирургиялық асқынулар жайындағы ақпарат талқыланды. Деректерді талдау сипаттамалық статистика, Уилкоксон сынақтары және Манн-Уитни U сынақтары арқылы жүргізілді.

Нәтижелер. Барлығы 55 пациентке лапароскопическая промонтофиксация операциясы жүргізілді. Объективті анатомиялық жақсару 94,6% жағдайда байқалды, сонымен қатар операциядан кейін пролапспен байланысты симптомдарының барлығының біршама жақсарғандығы анықталды. Үш пациентте (5,4%) диспареуния de novo операциядан кейінгі мерзімде пайда болды. Сауалнамаладың нәтижесін талдау барысында операциядан кейін өмір сапасы мен жыныстық белсенділіктің айтарлықтай жақсарғандығы дәлелденді (p < 0,001). Медициналық және хирургиялық көмекті қажет ететін асқынулар жайында ешбір ақпарат тіркелмеді.

Қорытынды. Лапароскопиялық промонтофиксация әдісі бақылаудың 12 айында жоғары анатомиялық, қызметтік және субъективті оң нәтиже көрсетті. Алынған нәтижелер хирургиялық емшарадан кейінгі өмір сапасын бағалаудың ұзақмерзімді зерттеулер негізінде растауды қажет етеді.

Түйінді сөздер: *жамбас ағзалары пролапсы, лапароскопиялық промонтофиксация, реконструктивті хирургия, өмір сапасы.*

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Introduction

Pelvic organ prolapse (POP) is a common, benign condition in women. The proportion of women with one or complex dysfunction of the pelvic floor is 6.3% at the age of 20–29, 31.6% at the age of 50–59, and 52.7% in women over 60 [5]. POP is defined as the descent of any or all of the following: anterior vaginal wall, posterior vaginal wall, and vaginal apex. Damaged parametrium, cardinal and uterosacral ligaments are responsible for the development of apical prolapse [4]. The incidence of POP surgery is 1.5–1.8 surgeries per 1,000 women years [21, 22]. In terms of surgical treatment, the apical prolapse is more complex form of POP [9].

The approach must be tailored depending on the surgeon's experience, the patient's history and anatomical considerations. Based on the fact, that POP is not a life-threatening condition, most urogynecologists define the goals of POP surgery as symptom relief, restoration of anatomy, and preservation of sexual function [17].

The weak connective tissue problems became a cause of the vaginal mesh implants development. There are few studies about the anatomic results achieved after vaginal mesh surgery. Although challenges as recurrent POP and weak connective tissue make limitations in use of mesh surgery in some cases, outcomes show more effectiveness compared to surgery using native tissues [2, 13]. In an exhaustive review of more than twenty randomized controlled trials, the authors concluded that the abdominal approach was associated with a lower recurrence rate and dyspareunia than the vaginal approach [15].

Laparoscopic promontofixation is based on treatment of POP in three compartment defects by DeLancey [10, 11]. The main advantages of the method are less invasiveness, easier access to the pelvis, magnification of the surgical field, less blood loss and a shorter convalescence [8, 16, 20, 23, 24].

Although genital prolapse is not a life-threatening condition, it can be extremely distressing and alter the health-related quality of life (HRQoL) of patients. Therefore, **the objective** of this study was to evaluate laparoscopic promontofixation method in three domains – objective anatomic and functional cure, as well as subjective cure – in patients with three-compartment defects.

Material and methods

This was a single-center observational study conducted at the Clinical Academic Department of Women's Health, University Medical Center between January 2019 - August 2021. Institutional local ethics committee approval was obtained, and all patients gave written informed consent. All had symptoms of genital prolapse, which included vaginal "bulge", the need for a manual procedure for emptying, changing the position of the body to urinating, urinary retention, dyspareunia, embarrassment due to altered body image. Inclusion criteria were: all patients with stage III and IV apical or combined prolapse types. Exclusion criteria were: patients with POP stage <III, history of postmenopausal bleeding, abnormal cervical smears, cervical elongation and ulceration. A cohort of 55 patients receiving modified unilateral apical sling following a diagnosis of grade III–IV pelvic organ prolapse and defects of three pelvic compartments. The post-surgical follow-up period was 12 months. The three characteristics of cure in functional surgery – anatomy, function, and subjective patient's judgement – were evaluated in this study. Primary outcomes were anatomic, functional, and subjective cures, that were measured pre- and postoperatively using the POP Quantification System (POP-Q) values [7] and validated questionnaires (Pelvic Floor Disability Index (PFDI-20), Prolapse Quality-of-Life (P-QOL), Female Sexual Function Index (FSFI)) [6, 19]. These questionnaires were completed in two stages: before surgery and 12 months after. Secondary outcome measures included data on surgical complications. Data analysis was performed with descriptive statistics, Wilcoxon tests, and Mann–Whitney U-tests.

Clinical examination

Pre-operatively, all patients underwent a thorough clinical examination. Minimum demographics 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.

Surgical technique

Laparoscopic promontofixation was performed in 10 steps as previously described [1]: 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 prosthesis, 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. All patients received antibiotic prophylaxis and were prescribed low molecular weight heparin for at least 5 postoperative days.

Results

Patient characteristics: Sixty-eight women were successfully operated. However, after 12 months thirteen

patients did not return to the hospital for a medical examination. Consequently, the data of 55 patients after laparoscopic promontofixation were analyzed (Figure 1). The main cause of the lack of follow-up in each group was the COVID-19 pandemic. Eight (14.5%) patients had a history of stress urinary incontinence (SUI). TVT procedure was performed 3 months after the main surgery in 5 (9.1%) cases.

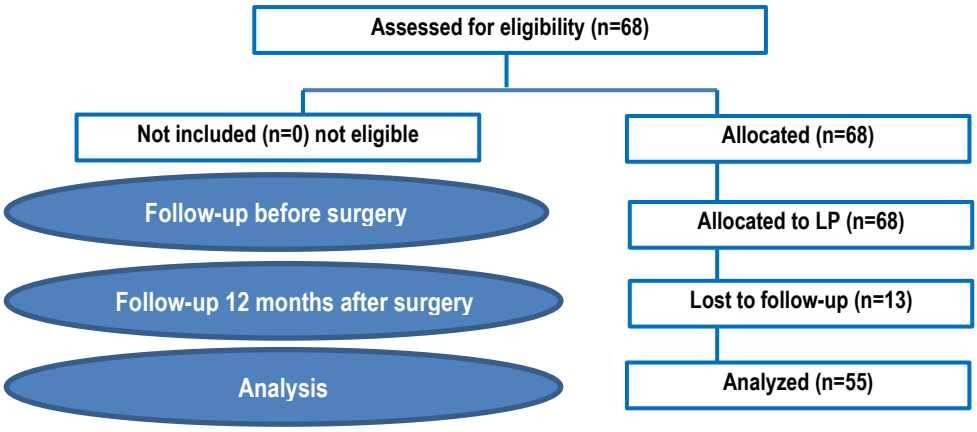

Figure 1. Flow chart of the study

Table 1.

Baseline patient's demographics.

Demographic	n=55
Mean (SD) age, years	52.93 ± 10.39
Mean (SD) BMI, kg/m2	28.86 ± 4.79
Median (range) parity	3 (1 – 6)
Normal vaginal delivery	42 (76.3)
Cesarean section	1 (1.8)
Subtotal hysterectomy	5 (9.1)
History of anti-incontinence surgery	1 (1.8)
History of previous pelvic surgery	7 (12.7)
Stress urinary incontinence	8 (14.5)
Menopause	31 (56.4)

Data are presented as n (%) or mean (range) or mean ± SD.
LP: laparoscopic promontofixation;
BMI: Body mass index; NS: Not significant.

Perioperative characteristics: Mean surgery duration was 194.6±40.0 min (range 150–270); mean volume of intraoperative bleeding was 40±10.69 ml (range 20–60). The average duration of bladder drainage was 1.07 ± 0.69 days (maximum 4). 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 5 postoperative days. For this reason, duration of hospital stay was 6.5±1.3 days (maximum 9) (Table 2).

Table 2.

Perioperative clinical characteristics.

Detail	n=55
Mean operating time, min	194.66±40.06
Mean operative blood loss, mL	40±10.69
Duration of hospitalization	6.5 ± 1.3

Data are presented as mean ± standard deviation

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.

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. Significant improvements were seen in POP-Q points Aa, Ba, and C, with no significant change seen in total vaginal length (TVL). The mean Ba score changed from 2.3 ± 1.6 at baseline to −2.9 ± 0.9 at the 12-month follow-up ($p < .001$). The mean C score changed from 3.5 ± 2.7 at baseline to −5.9 ± 0.5 at follow-up ($p < .001$; Table 3). Three patients (5.4%) had recurrent cystocele during follow-up but did not need surgery because the cystocele was <2 stage by POP-Q and asymptomatic. No cases of mesh erosion and re-operations were observed during 12 months of follow-up.

Table 3.

Anatomic results according to POP-Q.

	Before surgery	12-month follow-up
POP-Q measurements		
Aa	0.5 ± 1.1	-2.6 ± 0.8**
Ba	2.3 ± 1.6	-2.9 ± 0.9**
Ap	-2.5 ± 0.9	-2.5 ± 0.6
Bp	-2.2 ± 1.7	-2.7 ± 0.8
C	3.5 ± 2.7	-5.9 ± 0.5**
D	0.9 ± 2.7	-7.8 ± 0.7**
TVL	8.1 ± 0.8	8.4 ± 0.7

Data are presented as mean ± standard deviation.
*p < 0.01, **p < 0.001 (statistically significant differences)
TVL: Total Vaginal Length

Patient reported quality of life and sexual outcomes: Outcomes, assessed by comparing the preoperative and postoperative PFDI-20 and P-QOL scores are also summarized (Table 4). The PFDI-20 and P-QOL scores decreased significantly after LP procedure (p< 0.01). Only

three patients (5.4%) reported dyspareunia de novo. Two patients (4.2%) noted the presence of anxiety about the resumption of sexual activity. PRQoL and sexual outcomes assessed according to PFDI-20, P-QOL and FSFI scores were significantly improved after surgery (p< 0.001).

Table 4.

Health-Related Quality of Life and sexual outcomes.

Questionnaires	Before surgery	12-month follow-up
PFDI-20	107 ± 48	32 ± 35*
POPDI-6	48 ± 23	9 ± 8*
CRADI-8	10 ± 15	8 ± 15*
UDI-6	49 ± 22	15 ± 11*
P-QOL	70 ± 2.7	13 ± 2.6*
FSFI	17.6±1.15	27.1±3.2**

Data are presented as mean ± standard deviation.
*p < 0.01, **p < 0.001 (statistically significant differences)
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.

Discussion

Females with genital prolapse symptoms demonstrate clinically significant declines in physical performance and quality of life over time. 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. This approach is able to fulfill the main task of treatment - restoring the quality of life of the patient.

POP as a common problem among women can occur at any age. According to the latest studies, no more than 15% of women experience retreatments for POP in their lifetime [18]. Our results demonstrated that women's illnesses still rank low among other priorities, particularly when the condition is not life-threatening.

The FDA previously communicated about serious complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and SUI [12]. However, currently, transvaginal placements of synthetic mid-urethral slings and vaginal meshes have largely superseded traditional tissue repairs [14].

When analyzing efficacy, our data show statistically significant improvements in patient-reported QoL and sexual outcomes after laparoscopic promontofixation after 12 months follow-up. It is also one of the first observational studies in Kazakhstan to assess the outcome of reconstructive surgery with the use of a standardized tools as a POP-Q system, PFDI-20, P-QOL and FSFI questionnaires. Shortcoming of our study was the COVID-19 pandemic making it difficult for patients to return to follow-up. Admittedly, follow-ups more than 5 years are required to assess complications [3].

Pelvic reconstructive surgery not only focuses on anatomy, but also on function and satisfaction of the patient. For this reason, scientific classification of mesh and sling impacts according to the size, location and patient-reported outcomes is required to eliminate complications conjugated with mesh-surgery. Also, further prospective research based on long-time results are recommended in future studies.

Conclusion

Laparoscopic promontofixation was associated with excellent anatomic, functional, and subjective results at follow-up. These findings raise questions about the need for long-term results of quality-of-life outcomes after surgical treatment.

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