

# Relapse Prophylaxis and Early Recognition of Pelvic Organ Prolapse in Primary Medical Care Organizations - Randomized Controlled Trial

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**Abstract Background:** Due to the high incidence of genital prolapse surgery in women, the relapse rate, and the lack of clear recommendations for postoperative management, the approach of pelvic floor rehabilitation has had to be developed. **Material and methods:** A randomized controlled trial has enrolled sixty patients with grade II anterior and posterior vaginal prolapse and grade III stress urinary incontinence. The patients of both groups have undergone surgical treatment in the form of anterior and posterior colpotomy, colporrhaphy with perineolevatoroplasty. In the main group, thirty patients underwent a 6-month course of pelvic floor training in 2 months after surgery to assess the effect of this regimen on muscle contractile strength and a muscle strength thresholding to predict recurrence in primary care organizations; furthermore, all patients followed the general recommendations. Thirty patients in the control group had only surgical treatment and general recommendations. **Results:** At 8 months after surgery, the

strength of the pelvic floor muscles and early manifestations of prolapse were statistically different between the groups. Statistically significant inverse correlations between pelvic floor muscle strength and prolapse symptoms were established. The threshold value of pelvic floor muscle strength at the cut-off point totals up to 62.5 mm Hg. **Conclusions:** The regular training of the pelvic floor muscles after surgery resulted in a significant increase in pelvic floor muscle strength, which served a protective function in preventing relapse. The threshold value of pelvic floor muscle strength can be employed in clinical practice to assess the risk of prolapse recurrence in women after surgery.

**Keywords** Stress Urinary Incontinence, Relapse Prevention, Pelvic Floor Muscle Training, Genital Prolapse, Pelvic Floor Rehabilitation

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## 1. Introduction

An important step in any surgery is the rehabilitation process, especially for highly recurrent diseases, such as genital prolapse. Relapse in this condition may range from 5% to 30% [1]. Genital prolapse is one of the leading factors of surgical interventions in gynecology [1-3]. This disease is not life threatening; however, it significantly impairs the quality of life, reduces performance, affects interpersonal relationships, and leads to self-isolation [4-6]. Thus, adherence to the multidisciplinary approach to patient management is quite appropriate and justified.

There are no accurate data on the prevalence of prolapse. According to various researchers, the prevalence ranges from 3% to 70% [1-3]. The researchers state that the prevalence could increase by 46% in America by 2050, which they attribute to both the growing obesity “pandemic” and increased life expectancy [7]. The number of surgical interventions for prolapse is increasing near the age of 80 [1-3]. All this places an increased burden on health care.

The function of pelvic floor muscle strength and training is undoubtedly proven in protecting the connective tissue structures of the pelvic floor, unfortunately the long-term perspective is unclear and doubtful [3,8-16]. Regarding postoperative management of patients, we did not identify a convincing body of literature on the prevention of postoperative complications. There are several references to pelvic floor muscle exercises after surgery in the early and late Cochrane reviews [13, 14].

Maher C et al. [8] believe that there is a pressing issue of pelvic floor rehabilitation approach, since we often observe in clinical practice a tendency to relapse several months after surgery without the application of mesh prostheses, and, in rare cases, complete relapse in the first year after surgery. The increasing decline in support for the mesh prosthesis application in gynecologic transvaginal surgery, notably in young women, emphasizes this concern.

Our study has been conducted to compare the strength of the pelvic floor muscles after traditional anterior and posterior colpotomy, colporrhaphy with perineolevatoroplasty combined with training two months after surgery and without it. Undoubtedly, after such surgery, the tone of the walls of the vagina increases, due to the narrowing of its lumen and the juxtaposition of the pelvic floor muscles; nevertheless, the surgery has no effect on the strength of the pelvic floor muscles. Therefore, we believe it is critical to incorporate exercises into the pelvic floor rehabilitation program in order to reduce the risk of recurrence. This study is designed so that the subjects have a high commitment to practice exercises. We had to assess the impact of consistent, no-miss training, with increasing numbers of repetitions, on increasing muscle contraction strength, to determine the threshold value of muscle contraction strength to predict the possible progression of a relapse.

## 2. Materials and Methods

Sixty patients diagnosed with pelvic floor dysfunction have been admitted to the study. Clinical study site: Gynecology Department of the multidisciplinary clinic “LS Clinic”. The study had been conducted from October 2021 to July 2022 in compliance with the Helsinki Declaration recommendations and with the approval of the local bioethics committee of the Kazakh Medical University “Higher School of Public Health”. The study protocol was registered by the local bioethics committee in the research database of the Kazakh Medical University “Higher School of Public Health”, which complies with the requirements for conducting clinical trials in the Republic of Kazakhstan. Registration number: 132/4, registration date: January 28, 2021, entered in the ISRCTN registry under registration number ISRCTN23741622. Project title: “Optimization of Surgical Treatment of Genital Prolapse”. All participants signed an informed consent prior to admission to the study.

### 2.1. Participants

The authors randomized the participants into two groups. Each participant picked up an envelope with the number of her group. The Principal Investigator knew about the allocation of the study groups, while the study participants did not. Twenty-three people were dropped out of the study, nine of them did not meet all eligibility criteria, three were visitors and could not confirm the possibility to appear for the examination at the appointed time, five patients had contraindications for the surgical intervention, and the rest were withdrawn by the computer to the number of sixty people. Sixty participants who met the eligibility criteria were assigned to the main and control groups of thirty each (Fig. 1). All patients completed the study program and attended follow-up examinations. Adherence to the exercises was constantly monitored online by the gynecologists. The exercises were not grueling and were possible to perform in the course of daily work.

The patients were admitted to the study based on specific eligibility criteria: 1. Patients with grade II anterior and posterior vaginal wall prolapse according to the POP-Q classification (Appendix 1) [18] and grade III stress urinary incontinence, which was defined according to the classification of D.V. Kahn (1978) (Appendix 2) [19]; 2. under the age of 45 years; 3. two or more births in the anamnesis; 4. no consent to conservative treatment; 5. no consent to the use of vaginal synthetic prostheses, including uroslings; 6. no history of conservative prolapse treatment, including pelvic floor muscle training; 7. no history of diseases accompanied by metabolic disorders (diabetes mellitus, obesity, metabolic syndrome, thyroid disease, calcium-phosphorus metabolism disorders).

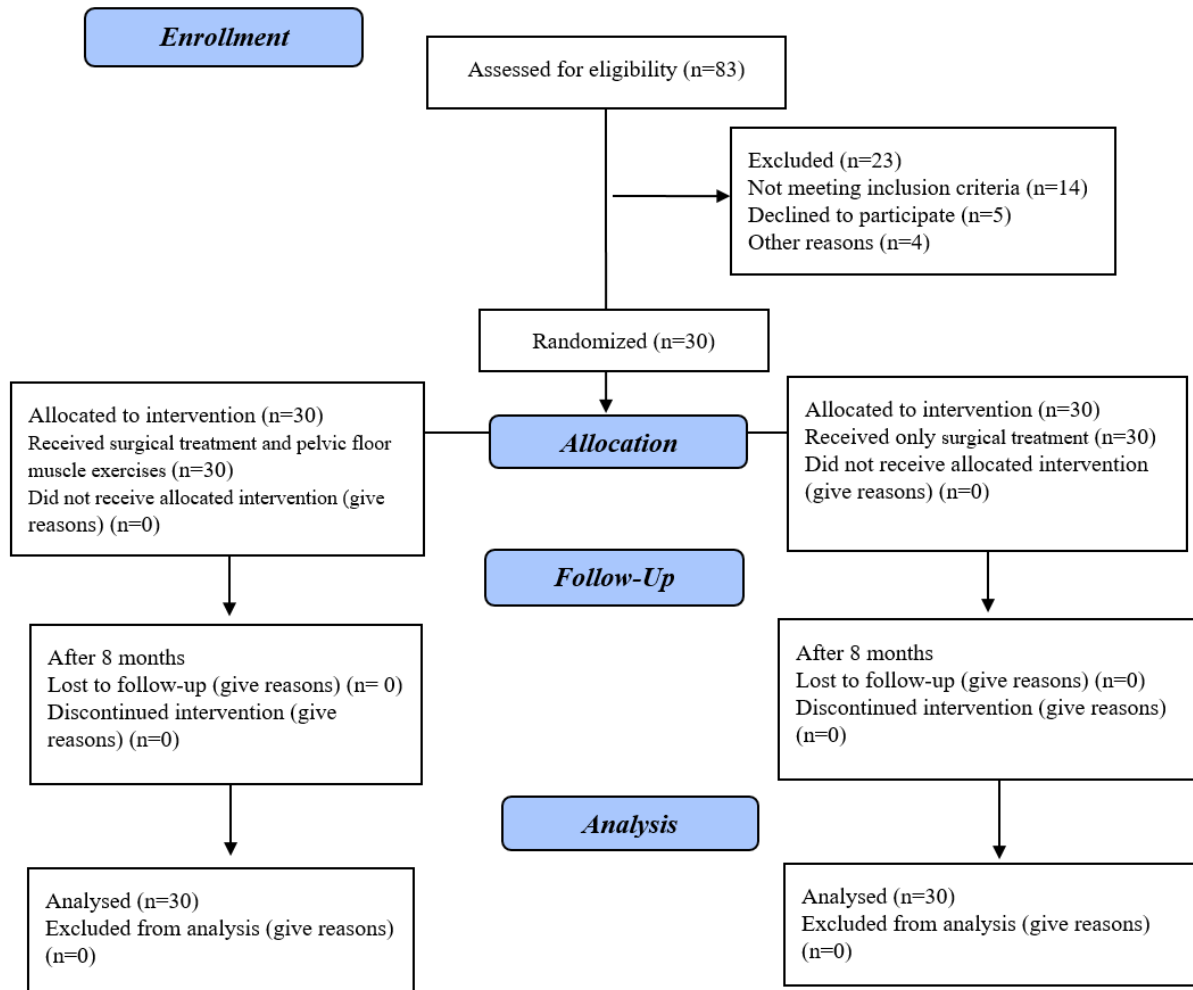


Figure 1. CONSORT flow diagram

#### Withdrawal criteria:

Urgent or mixed urinary incontinence, contraindications to surgical treatment and anesthesia (endotracheal anesthesia, regional anesthesia: spinal, epidural): acute or chronic inflammatory and infectious diseases in the period of exacerbation, malignant neoplasms, anemia, benign ovarian and/or uterine neoplasms, pregnancy, stage 3 or 4 hemorrhoids, uncompensated chronic somatic diseases, thrombosis; polyvalent allergies.

#### 2.2. Procedure

Female patients of both groups underwent surgical treatment in the volume of anterior and posterior colpotomy, colporrhaphy with perineolevatoroplasty. These surgical methods are included in the Kazakhstani Diagnosis and Management Care Path of female genital prolapse (Protocol №16 dated November 20, 2015). Female patients in the main group started exercising the pelvic floor muscles for 6 months after surgery with Kegel exercises modified according to Borello-France et al., [20-21] in accordance with our scheme, and also followed the generally accepted recommendations [22-28]. The patients in the control group followed only general

recommendations after surgery [22-28]. 2 months (6-8 weeks) is the required period when the sutures (Vicryl) are completely resorbed, pelvic pain disappears and the patients' well-being is completely normalized [29-30]. We do not recommend any physical activity until complete healing (6-8 weeks), which can cause pain or interfere with the healing process [29-30]. Before training, all patients were instructed on the structure of the pelvic floor muscles, their functions, the importance of training and training techniques, and which muscles we work on during training. All patients were taught pelvic floor muscle exercises during their visit to the gynecologist.

#### 2.3. Compliance with General Recommendations

Certificate of authorship № 31497 dated December 30, 2022: Guidelines for Genital Prolapse for Women (posted on our website: <https://www.prolaps-monitoring.com/>)

1. weight control;
2. nutrition supporting collagen synthesis: sufficient protein; products or supplements containing lysine, carnitine, vitamins C, E, B group, trace elements (silicon, magnesium, copper, zinc, manganese, selenium), iron (with control of hemoglobin and

ferritin blood levels, if low - consultation and treatment of a therapist!), calcium and vitamin D3 (with blood monitoring, if low - consultation and treatment by a general practitioner!); - reduce or eliminate easily digestible carbohydrates;

3. Exclude weight lifting and/or carrying more than 5 kg for more than 2 hours;
4. Prophylaxis of constipation: diet containing fiber (if necessary, normalization of intestinal microflora with probiotics);
5. Prevention of diseases accompanied by a prolonged cough;
6. Check-up with attending or operating physician 2 weeks after treatment, then in 1 month, 3 months, and 6 months.

### 2.4. Training Program

First week: Three sets of 10 contractions of the pelvic floor muscles (holding for 3 seconds) and three sets of five contractions (holding for 12 seconds) per session, twice a day every other day.

From the second week to the 12th week: 3 sets of 20 contractions of the pelvic floor muscles (holding for 3 seconds) and 3 sets of 10 contractions (holding for 12 seconds) per session, twice a day every other day.

From week 13 to week 24: 3 sets of 20 contractions of the pelvic floor muscles (holding for 3 seconds) and 3 sets of 10 contractions (holding for 12 seconds) per session, twice a day every day.

All patients were assigned to 6 gynecologists at PHC organizations, monitoring clear adherence to recommendations or exercises through online monitoring using public messengers.

Rationale for the exercise scheme.

We chose pelvic floor muscle training as rehabilitation so that patients could perform these activities at home, in the course of daily activities. We formed a focus group of women (9 people) who did not participate in the follow-up study before the study began. We were interested in the number of repetitions of the exercises that were most comfortable for patients to perform regularly. Our main goal was to ensure a high adherence to regularity of performance. Together, we determined that the Borello-France scheme was the most appropriate for this purpose [20, 21]. We took it as a ground and made some modifications. In the first week, we gave a small number of repetitions in order to avoid overloading the muscles after the break, as in the process of 2 months we completely banned physical activity [29, 30]. Then we increased the number of repetitions and sets, adhering to the principle of overload [21]. Both exercises are aimed at increasing the tone and endurance of the pelvic floor muscles [31]. Faster contractions (3 seconds) strengthen the slow fibers. Static exercises with a contractile hold (12 seconds) also strengthen the slow contractile fibers and strengthen the tendon center of the perineum, the supporting role of which

is not well covered in the literature [32].

### 2.5. Outcome Measures

The international POP-Q scale (Appendix 1) was used to assess the stage of prolapse [18]. Prolapse stage was determined by gynecological examination before and 8 months after surgery.

The adapted specialized questionnaire for women with genital prolapse of Kazakhstan P-QoL in Russian and Kazakh languages (Certificate of authorship #23609 dated February 15, 2022) was used to assess the quality of life in women. Patients filled out the questionnaire before treatment and 8 months after treatment.

Pelvic floor muscle strength before treatment and 8 months after treatment was assessed by the following methods: vaginal palpation with visual assessment according to the Oxford Scale and objective determination using a pneumatic perineometer [17].

### 2.6. Assessment of the Strength of Pelvic Floor Muscles

Oxford scale score is recorded during vaginal palpation during a gynecological chair examination. One finger is inserted into the lower third of the vagina and the patient is asked to contract the pelvic floor muscles; if no contractions are felt, another finger is inserted, and so on. The patient should be asked to contract the muscles and keep them contracted for 10 seconds with an interval of 30 seconds three times, and the results should be assessed (Table 1) [17].

Table 1. Pelvimetry parameters relative to the Oxford scale.

Oxford score, points	Average pressure recorded by perineometer sensor, mm Hg /points	Characteristics of the force of contraction muscles
0	55 (initial) - 0	Absent
1	56-60 / 1-2	Very low
2	61-65 / 3-4	Low
3	66-75 / 5-6	Moderate
4	76-85 / 7-8	Good
5	86-100 / 9-10	Strong

The examination was performed during examination in a gynecological chair, and a pneumatic perineometer was inserted into the vagina. The device consists of a silicone part with a manometer and a hand pump. Muscle strength was recorded on the manometer at maximum contraction of the pelvic floor muscles for 10 seconds. The measurement was taken three times at 30-second intervals during one study, and the result was taken as the mean value with a score according to Table 1 [17].

The authors analyzed the collected data in the SPSS-statistic 26 program. The Shapiro-Wilk test was employed to check for normality of the distribution of the measured variables. Quantitative data were analyzed by the Mann-

Whitney U-test and t Student's test, for nominal data the Fisher exact test was utilized. The results in the dynamics before and after treatment were evaluated in both groups by Wilcoxon test, McNemar's test. Spearman's rank correlation coefficient was applied to assess the correlation between pelvic floor muscle strength and clinical manifestations of prolapse; the closeness of correlation was established according to the Chaddock scale. To predict the risk of pelvic organ prolapse formation in relation to pelvic floor muscle strength, the authors performed Roc-analysis, and established a cut-off point threshold with determination of sensitivity and specificity. The level of statistical significance was defined as  $p < 0.05$ .

### 3. Results

The groups were comparable in age, parity, and BMI (Tables 2; 3). The mean age in the groups was: Group 1 - 39.50 ( $\pm 3.246$ ) years; Group 2 - 39.70 ( $\pm 3.544$ ) years, ( $p = 0.820$ ). The median and IQR (interquartile range) values of pregnancy history by group were: Group 1 - 4.00 (Q1-Q3:1); Group 2 - 3.00 (Q1-Q3:2), ( $p = 0.934$ ). The median and IQR values of birth history were: Group 1 -

2.00 (Q1-Q3:1); Group 2 - 2.00 (Q1-Q3:1) ( $p = 0.419$ ). Mean BMI in the groups was: Group 1 - 23.9100 ( $\pm 1.338$ ) kg; Group 2 - 24.22 ( $\pm 1.559$ ) kg, ( $p = 0.820$ ) (Table 2). The groups were comparable in mean anatomic positions before treatment according to the POP-Q classification (Aa, Ba, Ar, Bp, C, D, tvl, gh, pb) (Table 3).

There were no statistically significant differences when comparing anatomic positions according to the POP-Q classification before treatment. When these parameters were evaluated before treatment and after treatment in dynamics by group using the Wilcoxon test, there were statistically significant differences for all points. After treatment, statistically significant differences were found when comparing points on the anterior vaginal wall (Aa and Ba,  $p = 0.005$ ); and the gh index ( $p < 0.001$ ), (Tab. 3).

In the main group after treatment, we did not find the presence of prolapse and symptoms of stress urinary incontinence objectively. In the control group, 7 patients had grade 1 (23.3%) and 1 (3.3%) had grade 2 prolapse, differences were statistically significant ( $p < 0.001$ ), 8 patients (26.7%) had rare episodes of coughing and sneezing urinary incontinence, differences were statistically significant ( $p < 0.001$ ), (Table 4).

**Table 2.** Past medical history

Studied parameter	Treatment group		Control group		
	M ( $\pm$ SD)	Me ( Q1-Q3)	M ( $\pm$ SD)	Me (Q1-Q3)	p-value
Age (years)	39.50 ( $\pm 3.246$ )	39.00(5)	39.70 ( $\pm 3.544$ )	40.00 (7)	0.820**
Pregnancies (n)	3.70 ( $\pm 1.264$ )	4.00(1)	3.40 ( $\pm 1.102$ )	3.00 (2)	0.934*
Childbirths(n)	2.60 ( $\pm 0.724$ )	2.00 (1)	2.60 ( $\pm 0.770$ )	2.00 (1)	0.419*
BMI (kg)	23.91 ( $\pm 1.338$ )	23.500 (2.05)	24.22 ( $\pm 1.559$ )	24 (1.88)	0.412*

M - mean, Me - median, SD - standard deviation, CI - confidence interval, Q1-Q3 - interquartile range,\* Mann-Whitney U-test,\*\* t Student's test, BMI - body mass index

**Table 3.** Quantitative evaluation of pelvic prolapse, according to POP-Q classification.

POP-Q	Treatment group			Control group			
	Me (Q1-Q3)	M (±SD)	p-value *	Me(Q1-Q3)	M (±SD)	p-value**	p-value*
Aa (b)	0.000 (0.0)	0.007 (±0.3016)	<0,001**	0.000 (0.0)	(-)0.10 (±0.3418)	0.966*	<0,001**
Aa (a)	(-)3.000 (0.5)	(-)2.843 (±0.2661)		(-)2.500 (2.0)	(-)2.227 (±0.8788)	0.005*	
Ap (b)	0.000 (0.0)	(-)0.093 (±0.2180)	<0,001**	0.000 (0.0)	(-)0.103 (±0.2428)	0.955*	<0,001**
Ap (a)	(-)3.000 (0.0)	(-)2.967 (±0.1373)		(-)3.000 (1.0)	(-)2.617 (±0.6254)	0.020*	
C(b)	(-)5.000 (1.5)	(-)4.883 (±0.8579)	<0,001**	(-)4.500 (1.5)	(-)4.733 (±0.7849)	0.524*	<0,001**
C (a)	(-)7.000 (1.0)	(-)6.873 (±0.5483)		(-)6.500 (2.0)	(-)6.417 (±1.1528)	0.239*	
Ba (b)	0.00 (0)	0.00 (±0.000)	<0,001**	0.00 (0)	0.3 (±0.183)	0.317*	<0,001**
Ba (a)	(-)6.000 (0.5)	(-)5.800 (±0.3851)		(-)5.500 (2.5)	(-)4.900 (±1.3287)	0.003*	
Bp (b)	0.000 (0.0)	(-)0.283 (±0.7154)	<0,001**	0.000 (0.0)	(-)0.067 (±0.6530)	0.169*	<0,001**
Bp (a)	(-)5.500 (0.5)	(-)5.740 (±0.2634)		(-)6.000 (1.6)	(-)5.400 (±0.9685)	0.792*	
D (b)	(-)6.000 (1.0)	(-) 6.876 (±2.5248)	<0,001**	(-)6.000 (0.5)	(-)6.267 (±0.5208)	0.712*	<0,001**
D (a)	(-)8.500 (1.0)	(-)8.567 (±0.5040)		(-)8.500 (2.5)	(-)8.150 (±1.4029)	0.802*	
tv1 (b)	6.000 (1.0)	6.403 (±0.6547)	<0,001**	6.000 (0.5)	6.267 (±0.528)	0.417*	<0,001**
tv1 (a)	8.750 (0.6)	8.667 (±0.4795)		8.500 (2.6)	7.700 (±3.0218)	0.435*	
gh (b)	5.000 (0.6)	5.233 (±0.5979)	<0,001**	5.000 (1.0)	5.067 (±0.4498)	0.267*	<0,001**
gh (a)	2.000 (0.0)	2.000 (±0.000)		2.000 (0.5)	2.317 (±0.4450)	<0,001*	
pb (b)	2.000 (0.6)	2.050 (±0.4224)	<0,001**	2.000 (0.1)	2.133 (±0.3198)	0.346*	<0,001**
pb (a)	4.500 (0.0)	4.617 (±0.3395)		5.000 (2.0)	4.880 (±0.8892)	0.477*	

Aa (A anterior) the distance from the genital slit to the bladder neck is normally 3 cm; Ba (B anterior) the distance from the genital slit to the most prominent part of the anterior vaginal wall is normally not less than 3 cm; “Ap” (A posterior) distance from the genital slit to the projection of M. Levator ani to the posterior wall of the vagina is normally at least 3 cm; “Bp” (B posterior) distance from the genital slit to the most protruding point of the posterior wall of the vagina above the level of M. Levator ani, normally at least 3 cm; “C” distance to the most distal (i.e., descending) part of the cervix or the top of the dome (the scar after hysterectomy), normally at least 7 cm; “D” point in the posterior fornix (Douglas cavity) in women who have a cervix of at least 9 cm is normal. “tv1” is the maximum length of the vagina, expressed in centimeters; the perineal body “pb” is measured from the genital slit to the middle of the anal opening and is expressed in centimeters. M - mean, Me - median, SD - standard deviation, CI - confidence interval, Q1-Q3 - interquartile range,\* Mann-Whitney U-test,\*\* Wilcoxon test, before- (b), after- (a), p-value \* - comparison before and after, p-value\*\* - comparison between groups

**Table 4.** Prolapse and degrees of stress urinary incontinence

POP before and after treatment		Treatment group					p-value*	Control group					p-value**	p-value*
		Degree (POP-Q) n (%)						Degree (POP-Q) n (%)						
		0	1	2	3	4		0	1	2	3	4		
before	Prolapse n(%)	0	0	30 (100%)	0	0	<0,001**	0	0	30 (100%)	0	0	-	<0,001**
after	Prolapse n(%)	0	0	0	0	0		0	7(23,3%)	1(3.3%)	0	0	0,005*	
SUI before and after treatment		SUI degree n (%)			p-value*	SUI degree			p-value**	p-value*				
		1	2	3		1	2	3						
		before	SUI n(%)	30(100%)		<0,001**	30 (100%)				-	<0,001**		
after	SUI n(%)	0	0	0	8(26,7%)		0	0	0,005*					

\*Fisher exact test, \*\*McNemar's test, SUI- stress urinary incontinence, POP-pelvic organ prolapse, POP-Q - Pelvic Organ Prolapse Quantification System, p-value \* - comparison before and after, p-value\*\* - comparison between groups

**Table 5.** Pelvic floor muscle strength values and quality of life

Measured parameter	Treatment group			p-value*	Control group			p-value*
	M (±SD)	Me (Q1-Q3)			M (SD)	Me (Q1-Q3)	p-value**	
Oxford scale (b)	0.83 (±0.461)	1.00 (0)	<0,001**	0.73 (±0.640)	1.00 (1)	0.392*	<0,001**	
Oxford scale (a)	4.73 (±0.450)	5.00 (1)		2.27 (±0.740)	2.00 (1)	<0,001*		
Perineometry (b), mmHg.	57.37 (±2.025)	57.00 (2)	<0,001**	57.47 (±2.776)	57.00 (4)	<0,001*	<0,001**	
Perineometry (a), mmHg.	87.80 (±5.436)	88.50 (7)		64.83 (±5.528)	63.50 (9)	<0,001***		
P-QOL (b)	71.23 (±11.793)	67.00 (19)	<0,001**	68.47 (±14.014)	64.50 (20)	0.242*	<0,001**	
P-QOL (a)	0.701 (±368)	0.00 (1)		2.33 (±4.071)	0.00 (6)	0.543*		

M - mean, Me - median, SD - standard deviation, Q1-Q-3 - interquartile range,\* Mann-Whitney U-test, \*\* Wilcoxon test, \*\*\* t Student's test, before- (b), after- (a), p-value \* - comparison before and after, p-value\*\* - comparison between groups

Vaginal wall tone, which we measured using the Oxford scale and perineometry, increased statistically significantly due to narrowing of the vaginal lumen and plasticity of the muscle raising the anus in the group without training ( $p < 0.001$ ), but the strength of contraction corresponded to low and moderate, whereas in the main group it was good and strong, ( $p < 0.001$ ) (Table 1, Table 5). There were no statistically significant differences in post-treatment quality of life scores between the groups ( $p = 0.543$ ) (Table 5).

There were statistically significant inverse correlations of marked closeness on the Chaddock scale between pelvic floor muscle strength as assessed by Oxford with the degree of prolapse ( $r_{xy} = (-) 0.607$ ,  $p < 0.001$ ) and with the degree of stress incontinence ( $r_{xy} = (-) 0.607$ ,  $p < 0.001$ ), as well as statistically significant inverse correlations of moderate closeness on the Chaddock scale between pelvic floor muscle strength established by perineometry with the

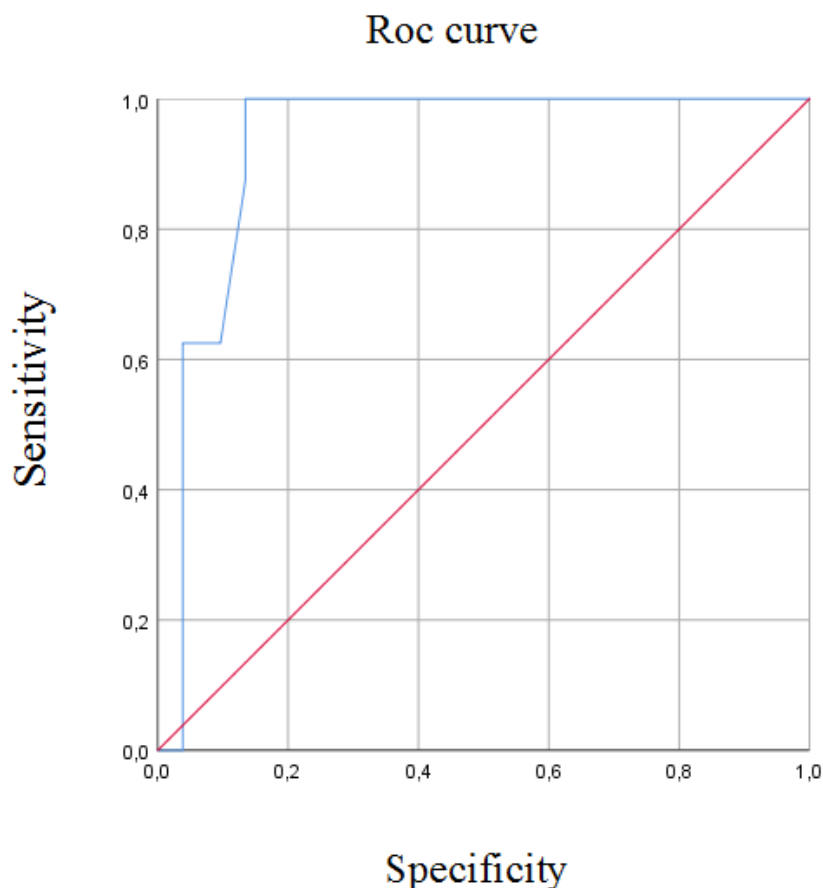
degree of prolapse ( $r_{xy} = (-) 0.493$ ,  $p < 0.001$ ) and with the degree of stress incontinence ( $r_{xy} = (-) 0.493$ ,  $p < 0.001$ ) (Table 6).

The area under the ROC-curve corresponding to the relationship between the prediction of pelvic floor muscle strength and prolapse symptoms was  $0.930 \pm 0.033$  with 95% CI: 0.865-0.996 (Figure 2). The obtained model was statistically significant ( $p < 0.001$ ).

**Table 6.** Correlation between prolapse symptoms and pelvic floor muscle strength

	PFMS (Oxford scale)	PFMS (Pelvimetry)	p-value
Prolapse after	-0.607	-0.493	0.000*
SUI after	-0.607	-0.493	0.000*

\*Spearman's rank correlation coefficient, SUI - stress urinary incontinence, PFMS - Pelvic floor muscle strength



**Figure 2.** Roc curve

The threshold value of pelvic floor muscle strength at the cut-off point is equal to 62.5 mmHg, which corresponds to a score of 2 on the Oxford scale. The risk of pelvic organ prolapse was predicted for equal or inferior muscle contractions. The sensitivity corresponding to the proportion of cases of pelvic organ prolapse at pressures equal to or lower than 62.5 mmHg was 87%; the specificity corresponding to the proportion of cases without pelvic organ prolapse at pressures above 62.5 mmHg was 75%.

#### 4. Discussion

The results of our study proved a statistically significant increase in pelvic floor muscle strength when combined with surgical treatment and training compared with the surgical treatment group alone. Statistically significant inverse correlations between pelvic floor muscle strength and prolapse symptoms were established. The stronger was the objectively established strength of the pelvic floor muscles, the less was the early manifestation of pelvic prolapse. However, clinically these changes did not bother the patients and did not limit their daily activities. We found no convincing recommendations on postoperative management of women with prolapse and pelvic floor muscle training in the available sources. The 2018 Cochrane Review reported only the results of several

studies that evaluated perioperative exercise training of the pelvic floor muscles [13]. In patients who exercised 2 weeks before surgery and 2, 4, 6, 8, and 12 weeks after surgery, no differences were found between symptoms of prolapse, but muscle function improved significantly in the exercise group in one of these studies [33]. Although the authors did not report any adverse events [33], we are concerned that early exercise may cause pain or interfere with the healing process, since full tissue recovery after surgery occurs within 6-8 weeks [29-30]. McClurg D et al. [34] reported a significant difference in prolapse symptoms after 12 months in the postoperative exercise group compared with the control group [mean difference 3.94; 95% confidence interval (CI) 1.35-6.75;  $m = 3.24$ ,  $p = 0.006$ ], but they reported the risk of systematic error. In this study, each patient received an individualized exercise plan in 6 weeks after surgery [34]. The patients were in constant contact with their physician and were informed about the risks of recurrence and preventive measures, as in our study [34]. While a 2 x 2 multicenter factor randomized trial with 374 women showed no significant difference in prolapse symptoms between the groups 2 years after surgery, perioperative training with pelvic floor muscle training was also used in the main group [35].

It has been reported that irregular exercise of the pelvic floor muscles was the reason for the ineffectiveness of



physical exercise treatment for prolapse [16]. Self-efficacy assessment is considered an important component of increasing adherence [37]. Sacomori C, Berghmans B et al. [36] presented the results of an RCT where discussion of achievement and goals, video feedback, and exercise reminders did not increase exercise adherence and effectiveness more than exercise mastery. Nevertheless, high adherence was achieved due to regular feedback in both our study and the McClurg D et al. [34]. As reported in a more recent meta-analysis, supervision by healthcare professionals and the use of online applications improved outcomes with pelvic floor muscle exercises [16].

We do not have exact recommendations after surgery for genital prolapse in the Kazakhstani Diagnosis and Management Care Path of female genital prolapse (dated November 20, 2015, protocol #16). There are currently no conclusive long-term studies on the effectiveness of pelvic floor muscle training. Glazener CM et al. [38] published the results of a 12-year randomized controlled trial comparing nurse-led interventions (pelvic floor and detrusor training) at 5, 7, and 9 months after delivery with standard care demonstrated that the presence of pelvic organ prolapse and its symptoms did not differ between groups. However, some results seem encouraging [9-16, 34, 36-42]. Hagen S et al. [39] evaluated a more intensive exercise program (individualized physical therapy, supportive Pilates, and annual individual checkups). The results of the study showed that training the pelvic floor muscles resulted in a small, but probably significant reduction in the symptoms of prolapse. Bø K et al. [40] stated that pelvic floor muscle training is more effective than electrical stimulation and vaginal cones in treating stress urinary incontinence. Pelvic floor muscle training is recommended as a first-line treatment for urinary incontinence in the 2018 Cochrane review, but further studies with long-term prognosis are needed [41]. Pregnant women who performed an intensive exercise program during pregnancy were less likely to report urinary incontinence up to 6 months postpartum (hazard ratio (RR) 0.71, 95% CI 0.54-0.95) [41]. Females with urinary incontinence who performed postpartum exercises were less likely to report urinary incontinence in 12 months after delivery (RR 0.60, 95% CI 0.35-1.03) [41].

We can assume that regular training is the prevention of relapse, because in the group without training, the initial manifestations of prolapse were noted in 8 months after surgery in our study. Changes in the anatomical points on the anterior vaginal wall (Aa; Wa) and dilation of the virgin ring (gh) confirm this. However, it is possible that not all patients with initial signs of prolapse will have further progression of the disease; longer studies are needed to confirm.

This is the first study in which we proposed the use of pelvic floor muscle strength to predict recurrence of pelvic prolapse after surgery. We suggest that this index can be used by clinicians to assess the risk of prolapse in

asymptomatic patients using simple noninvasive methods: both a pneumatic perineometer and vaginal palpation with an Oxford score. In any case, performing exercises as a recommendation does not require financial costs, it is a simple way to prevent prolapse and possible complications in childbirth without the risk of harm to health [9-16, 34, 36-42].

The authors acknowledge certain shortcomings of the analysis. A larger number of subjects and a longer period of observation are needed for objective conclusions. In addition, compliance with nutritional recommendations and the influence of other factors that can increase intra-abdominal pressure (patient's body weight, prolonged cough, and constipation) were not taken into account. We did not use specialized applications; the control was carried out through available messengers. We concluded that online monitoring increased adherence to regular physical activity, as pelvic floor muscle strength was statistically significantly higher in the experimental group. We believe that this was sufficient for a simple exercise scheme. However, it was not possible to assess objectively how correctly the exercises were performed. All this should be taken into account in future studies.

## 5. Conclusions

- The method of a continuous course of exercises on a simplified scheme, as one of the elements of health rehabilitation, is able to create conditions that allow to preserve the maximum therapeutic effect after surgical treatment without invasive intervention.
- What particularly distinguishes this model from previously known other models is the integration of the hospital, PHC and patient, online monitoring, determination of muscle contractile strength threshold to predict recurrence; and the speed, simplicity and accessibility of this model for healthcare professionals of any level, the financial liberality of the method can be useful for health and recommended for implementation in existing protocols, and as a recommendation for pelvic prolapse and medical institutions.

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This study has not received external funding.

## Conflicts of Interest

The authors state that none of the parts of this article has been published in the open press and is not under consideration by other publishers.

## Appendix

### Web Appendix 1. Pelvic Organ Prolapse Quantification (POP-Q) [18]:

- Aa (A anterior) the distance from the genital slit to the bladder neck is normally 3 cm;
- Ba (B anterior) the distance from the genital slit to the most prominent part of the anterior vaginal wall is normally not less than 3 cm;
- “Ap” (A posterior) distance from the genital slit to the projection of M. Levator ani to the posterior wall of the vagina is normally at least 3 cm;
- “Bp” (B posterior) distance from the genital slit to the most protruding point of the posterior wall of the vagina above the level of M. Levator ani, normally at least 3 cm;
- “C” distance to the most distal (i.e., descending) part of the cervix or the top of the dome (the scar after hysterectomy), normally at least 7 cm;
- “D” point in the posterior fornix (Douglas cavity) in women who have a cervix of at least 9 cm is normal.
- “tvI” is the maximum length of the vagina, expressed in centimeters;
- the perineal body “pb” is measured from the genital slit to the middle of the anal opening and is expressed in centimeters.

Stage I. The most prolapsed part of the prolapse does not reach the hymen by 1 centimeter.

Stage II. The most distal part of the prolapse  $\leq 1$  cm proximal or distal to the hymen (Value  $\geq -1$  cm, but  $\leq +1$  cm).

Stage III. The most prolapsed point  $>1$  cm distal to the hymenal plane, but no more than TVL - 2 cm (Value  $\geq -1$  cm, but  $\leq +1$  cm).

Stage IV. Complete prolapse. The most distal part of the prolapse protrudes more than TVL - 2 cm.

### Web Appendix 2. Classification of stress urinary incontinence, according to D.V. Kan (1978) [19].

1. Mild degree - involuntary urine (a few drops) occurs only when there is a sudden and sharp increase in intra-abdominal pressure: when coughing strongly, walking quickly;
2. Medium degree - involuntary discharge of urine during a quiet walk, with light physical activity, etc.
3. Severe degree - patients completely or almost completely lose urine even when they change their body position.

We apply in practical health care the classification of D.V. Kahn (1978) because of its simplicity. To determine the degree of stress urinary incontinence, the patient's complaints were taken into account. We asked patients to fill their bladder before the examination. A cough test was performed during the gynecological examination. Urine

was involuntarily excreted in drops when coughing violently; this corresponded to a mild degree. If a stream of urine was excreted during a weak cough, it corresponded to a medium degree. The loss of urine occurred when the body position was changed during a gynecological examination in severe cases.

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