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THE COMPARISON OF LIFE'S QUALITY OF PATIENTS WITH CONCOMITANT GENITAL PROLAPSE BEFORE AND AFTER COMPLEX AND STAGED SURGICAL TREATMENT. NON-RANDOMIZED CONTROLLED TRIAL.

Mariya Laktionova [1], https://orcid.org/0000-0002-9435-8841
Arsen Askerov[3], Maksut Kulzhanov[1],
Altyn Aringazina[2], https://orcid.org/0000-0002-9056-2394
Mairash Baimuratova[1], Sabina Zhaganova[1], https://orcid.org/0000-0003-1164-3821
Zauresh Barmanasheva[1], Irina Smagina[4]

[1] Kazakhstan's Medical University «Kazakhstan School of Public Health», Almaty, the Republic of Kazakhstan;
[2] Caspian International School of Medicine, Almaty, the Republic of Kazakhstan;
[3] Kyrgyz-Russian Slavic University named of B.N. Yeltsin, Bishkek, Kyrgyz Republic;
[4] Kazakh Research Institute of Oncology and Radiology, Almaty, the Republic of Kazakhstan.

Abstract

Introduction. Nowadays, there is an unresolved issue for public health of surgical treatment of concomitant genital prolapse and the importance of complex surgical approach.

Objective. Assessment the level of quality of life in patients before and 6 months after surgical treatment with a comprehensive approach and staged treatment, by using the validated life questionnaire P-QOL foe patients with genital prolapse.

Materials and Methods. There are 76 patients over 45 years of age with stages III and IV concomitant prolapse (anterior apical prolapse accompanied by stress urinary incontinence and rectocele) took part in the non-randomized controlled trial. All sections' prolapse and functional disorders were eliminated at once in the main group (n=39), only one section's prolapse was eliminated in the control group (n=37). The quality of life was assessed by specialized questionnaire P-QOL. Statistical analysis was done using SPSS-statistic 26 program.

Results. The quality of life's measures were statistically significant before (Me:71; Q1-Q-3: 14) and after treatment (Me:2; Q1-Q-3: 7)(Wilcoxon criterion, $p<0.05$) in the main group, and it was statistically significant before (M:66.00; SD± 10.593)and after treatment (M:47.92; SD± 19.323)(Paired Student's t-criterion, $p<0.05$) in the control group. We got statistically significant differences post-treatment quality of life measures between main (Me:2; Q1-Q-3: 7) and control (Me:48.00; Q1-Q-3: 28) groups, (U-test, $p<0.05$). There were also statistically significant differences in the number of repeated hospitalizations for prolapse symptoms (5 -12.8% vs. 37-100%) (Fisher's exact test,$p<0.05$). We note a strong relationship between the compared features (Cramer's V 1 =0.880;. Cramer's V 2 =0.876, $p<0.05$).

Conclusion. Comprehensive approach of surgical treatment in comparison with staged treatment statistically significantly improves quality of life index.

Key words: *combined genital prolapse, complex treatment, quality of life, P-QOL questionnaire, promontofixation, urosling, mandatory health insurance.*

Резюме

ОЦЕНКА КАЧЕСТВА ЖИЗНИ ПАЦИЕНТОВ С СОЧЕТАННЫМ ГЕНИТАЛЬНЫМ ПРОЛАПСОМ ДО И ПОСЛЕ ХИРУРГИЧЕСКОГО ЛЕЧЕНИЯ ПРИ КОМПЛЕКСНОМ И ЭТАПНОМ ЛЕЧЕНИИ В СРАВНИТЕЛЬНОМ АСПЕКТЕ. НЕРАНДОМИЗИРОВАННОЕ КОНТРОЛИРУЕМОЕ ИССЛЕДОВАНИЕ

Мария В. Лактионова[1], https://orcid.org/0000-0002-9435-8841
Арсен А. Аскеров[3], Максут К. Кульжанов[1],
Алтын М. Арингазина[2], https://orcid.org/0000-0002-9056-2394
Майраш А. Баймуратова[1],
Сабина А. Жаганова[1], https://orcid.org/0000-0003-1164-3821
Зауреш Е. Барманашева[1], Ирина М. Смагина[4]

[1] Казахстанский медицинский университет «Высшая школа общественного здравоохранения», г. Алматы, Республика Казахстан;

[2] УО «Каспийский общественный университет», г. Алматы, Республика Казахстан;
[3] Кыргызско-Российский Славянский университет им. Б.Н. Ельцина, г.Бишкек, Республика Кыргызстан;
[4] Казахский Научно-исследовательский институт онкологии и радиологии, г. Алматы, Республика Казахстан.

Введение. На сегодняшний день существует нерешенный вопрос для здравоохранения в организации хирургического лечения сочетанного генитального пролапса и обоснования комплексного хирургического подхода в его решении.

Цель. Оценить уровень качества жизни у пациентов до и через 6 месяцев после хирургического лечения при комплексном подходе и этапном лечении, с помощью валидного опросника качества жизни при генитальном пролапсе P-QOL.

Материалы и методы. В этом нерандомизированном контролируемом исследовании приняло участие 76 пациентов с III и IV стадией сочетанного пролапса (переднеапикальный пролапс, сопровождаемый стрессовым недержанием мочи и ректоцеле) в возрасте старше 45 лет. В основной группе (n=39), комплексного лечения, одномоментно был устранен пролапс всех отделов и функциональные нарушения, в контрольной группе (n=37) устранен пролапс только одного отдела, качество жизни оценено с помощью специализированного опросника P-QOL.Статистический анализ выполнен в программе SPSS-statistic 26.

Результаты. В основной группе до (Me:71; Q1-Q-3: 14) и после лечения (Me:2; Q1-Q-3: 7) (Критерий Уилкоксона, $p< 0,05$), и в контрольной группе до (M:66,00; SD± 10,593)и после лечения (M:47,92; SD± 19,323) (Парный t-критерий Стьюдента, $p< 0,05$) показатели качества жизни были статистически значимы. При сравнении показателей качества жизни после лечения в основной (Me:2; Q1-Q-3: 7) и контрольной (Me:48,00; Q1-Q-3: 28),(U-критерий, $p< 0,05$) группах были статистически значимые различия. Также статистически значимо отличались количество повторных госпитализаций по поводу симптомов пролапса (5 -12,8% против 37-100%) (Точный критерий Фишера,$p< 0,05$), между сопоставляемыми признаками мы отмечаем сильную связь (V Крамера 1 =0,880;. V Крамера 2 =0,876, $p< 0,05$).

Вывод. Комплексный подход хирургического лечения статистически значимо улучшает показатель качества жизни по сравнению с этапным лечением.

Ключевые слова: *сочетанный генитальный пролапс, комплексное лечение, качество жизни, опросник P-QOL, промонтофиксация, урослинг, обязательное медицинское страхование.*

Түйіндеме

КҮРДЕЛІ ЖӘНЕ ҮЗІЛІССІЗ ЕМДЕУ, РАНДОМИЗАЦИЯЛАНБАҒАН БАҚЫЛАУ ЖАҒДАЙЫНДА ОПЕРАЦИЯҒА ДЕЙІН ЖӘНЕ ОДАН КЕЙІНГІ АРАЛАС ЖЫНЫСТЫҚ БҰЛШЫҚЕТ ПРОЛАПСЫ БАР НАУҚАСТАРДЫҢ ӨМІР САПАСЫН БАҒАЛАУ.

Мария В. Лактионова[1], https://orcid.org/0000-0002-9435-8841
Арсен А. Аскеров[3], Максут К. Кульжанов[1],
Алтын М. Арингазина[2], https://orcid.org/0000-0002-9056-2394
Майраш А. Баймуратова[1],
Сабина А. Жаганова[1], https://orcid.org/0000-0003-1164-3821
Зауреш Е. Барманашева[1], Ирина М. Смагина[4]

[1] Қазақстандық медицина университеті «Қоғамдық денсаулық сақтау жоғары мектебі», Алматы қ., Қазақстан Республикасы;
[2] «Каспий қоғамдық университеті», Алматы қ., Қазақстан Республикасы;
[3] Б.Н. Ельцин атындағы Қырғыз-Ресей Славян Университеті, Бишкек қ., Қырғызстан Республикасы;
[4] Қазақ онкология және радиология зерттеу институты, Алматы қ., Қазақстан Республикасы.

Кіріспе. Бүгінгі күні біріктірілген жыныс пролапсын хирургиялық емдеуді ұйымдастыруда және оны шешуде кешенді хирургиялық тәсілді негіздеуде Денсаулық сақтау үшін шешілмеген мәселе бар.

Мақсаты. P-QOL жыныс пролапсы кезінде өмір сапасының валидті сауалнамасының көмегімен кешенді тәсілмен және кезеңдік емдеумен хирургиялық емдеуге дейін және одан кейін 6 айдан кейін пациенттердегі өмір сапасының деңгейін бағалау.

Материалдар мен әдістер. Бұл рандомизацияланбаған бақыланатын зерттеуге 45 жастан асқан бірлескен пролапстың III және IV сатысы бар 76 пациент қатысты (алдыңғы апикальды пролапс, стрессті зәр ұстамау және ректоцеле). Кешенді емдеудің негізгі тобында (n=39) барлық бөлімдердің пролапсы және функционалдық бұзылулар бір уақытта жойылды, бақылау тобында (n=37) тек бір бөлімнің пролапсы жойылды, өмір сапасы P-QOL мамандандырылған сауалнамасының көмегімен бағаланды. Статистикалық талдау SPSS-statistic 26 бағдарламасында орындалды.

Нәтижелері. Негізгі тобындаемдеуге дейін (Me:71; Q1-Q-3: 14) және емдеуден кейін (Me:2; Q1-Q-3: 7) (Уилкоксон критерийі, p<0,05) және бақылау тобында емдеуге дейін(M:66,00; SD± 10,593)және емдеуден кейін (M:47,92; SD± 19,323) (жұптық Т-Стьюдент критерийі, p<0,05) өмір сапасының көрсеткіштері статистикалық маңызды болды. Емдеуден кейінгі өмір сапасының көрсеткіштерін салыстыру кезінде негізгі (Me:2; Q1-Q-3: 7) және бақылау (Me:48,00; Q1-Q-3: 28),(U-критерий, p<0,05) топтарда статистикалық маңызды айырмашылықтар болды. Сондай-ақ,пролапс белгілері бойынша қайта ауруханаға жатқызу саны статистикалық тұрғыдан айтарлықтай ерекшеленді (37-100% қарсы 5 -12,8%) (Фишердің нақты өлшемі, p<0,05), салыстырылатын белгілер арасында Біз күшті байланысты атап өтеміз (V Крамера 1 =0,880;. V Крамер 2 =0,876, p<0,05).

Қорытынды. Хирургиялық емдеудің кешенді тәсілі кезеңді емдеумен салыстырғанда өмір сүру сапасының көрсеткішін статистикалық тұрғыдан айтарлықтай жақсартады**.**

Түйінді сөздер: *біріктірілген жыныс пролапсы, кешенді емдеу, өмір сапасы, P-QOL сауалнамасы, промонтофиксация, уроспинг, міндетті медициналық сақтандыру.*

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Introduction

Nowadays, there is an unresolved issue for public health of surgical treatment of concomitant genital prolapse and the importance of complex surgical approach.

Currently, there is still no standardized approach to assess the success of surgical treatment of women with pelvic floor dysfunction [6]. In recent years, a large number of studies on the quality of life in genital prolapse have been conducted [9,5,3,7]. The international associations dealing with prolapse recommended taking into account quality of life indicators as the initial points of surgical treatment evaluation [8]. We have carried out the cultural-linguistic adaptation of the Kazakhstan genital prolapse questionnaire P-QOL that is specialized for this pathology (copyright №23609 from 15.02.2022) to create a tool for assessing the quality of medical care for women with pelvic floor dysfunction.

It is known that pelvic fascia defect can occur at several levels, according to the three-level concept of pelvic structure, resulting in the prolapse of several departments at once with possible functional disorders of the organs of these departments [8]. For example: anterior apical prolapse accompanied by stress urinary incontinence. It is reasonable to assume that a defect at all levels simultaneously from several points of view should be eliminated in this situation. Firstly: one surgical procedure may not eliminate all clinical manifestations of prolapse, and on the other hand, the remaining pelvic fascia defect, as we observe in clinical practice, may enlarge, which will worsen the surgical results. Thirdly, operation risks are not associated only with the surgery itself and anesthesia, but also a long period of preparation, rehabilitation and decreased ability to work greatly affect the quality of life. Now long-absorbing suture materials are used in surgical treatment, which resolve on average 100 days. It solves well the condition of the perinea sutures. But every 4 or 5 can get alloinflammatory reactions, and its affects the quality of life in the postoperative period. Thus, surgery in several stages will affect to the emotional, social, economic and family well-being, especially if there was no significant improvement after the first surgery.

The health care burden is also increasing. Since the state is forced to fund repeated surgical treatment, it is associated with both an increase in direct costs (costs for drugs, medical services, laboratory and diagnostic tests, consumables, hospital stays, etc.) and indirect costs (loss of ability to work, payment of disability certificates, etc.). Currently, quite a few studies are devoted to this issue and the results are contradictory; however, quite a few data show better clinical outcomes when the defect is eliminated at all levels one-stage, if any [4,1,2,]. The results of our earlier studies we also indicate better significantly clinical outcomes with a comprehensive approach.

Payment for the surgical treatment of genital prolapse can be made through the compulsory health insurance fund. But only one operation will be paid from the health insurance fund. So a patient with concomitant genital prolapse will get help in several steps if she wants to use her insurance benefits. In the context of the mentioned problem, we decided to evaluate the level of quality of life in patients with the same anatomical situation, who were operated on using complex and staged approaches. The P-

QOL questionnaire for the population of Kazakhstan, which has been adapted and validated by us, was used.

Objective. Assessment the level of quality of life in patients before and 6 months after surgical treatment with a comprehensive approach and staged treatment, by using the validated life questionnaire P-QOL foe patients with genital prolapse.

Materials and Methods. We conducted a non-randomized controlled trial involving 76 patients from 2020-2021. Inclusion criteria were: III and IV degrees of pelvic organ prolapse in accordance with POP-Q classification, combined prolapse (anterior apical prolapse accompanied by stress urinary incontinence and rectocele), age over 45 years, patients who signed an informed voluntary consent to participate in the study.

Exclusion criteria: I-II stages of prolapse, isolated defect, age less than 45 years, obesity, diabetes mellitus, polyvalent allergy, patients who declined to participate in the study. Laparoscopic promontofixation with a mesh prosthesis, transobturator urethropexy, posterior colpoperineoleuroplasty were used in a one-step approach in the main group with complex treatment. Only laparoscopic promontofixation was used in the control group. Polypropylene mesh prosthesis was used in both groups. The main group included 37 people; the control group included 39 people.

The patients were not randomly distributed into groups based on the type of payment for treatment. The main group included patients who received treatment on the basis of the contract for paid services, according to the established price list; the control group included patients who received treatment from the compulsory health insurance funds.

The degree of prolapse and anatomical recurrence were assessed according to the POP-Q international classification.

The presence of functional abnormalities was determined during the gynecological examination with the help of functional tests (stop test, finger elevation test, cough test, residual urine test).

The P-QOL questionnaire, adapted for the population of Kazakhstan and specialized for genital prolapse, was used to assess the quality of life. Patients were interviewed for the first time before surgical treatment, then 6 months after.

Wilcoxon's criterion and paired Student's t-criterion were used to assess statistically significant differences in quality of life in the dynamics. To assess statistically significant differences in quality of life after treatment between the groups, Student's test and Mann-Whitney U-criterion were applied. For qualitative data, statistical significance of differences was determined using Fisher's exact test. P-value <0.05 was taken as critical.

Statistical analysis was performed using SPSS-statistic 26.

Results

The respondents' answers to the P-QOL quality of life questionnaire specialized for genital prolapse were assessed in the main and control groups before and after treatment. The are differences between the sum of scores before (M:71.84; Me:71; Q1-Q-3: 14) and 6 months after treatment (M:8.51; Me:2; Q1-Q-3: 7) were statistically significant (Wilcoxon criterion, p<0.05) in the main group. The statistically significant decrease in scores, indicating the effect of comprehensive treatment on improving quality of life (Table 1). The are scores before (M:66.00; SD± 10.593)and after treatment (M:47.92; SD± 19.323) were also statistically significantly different (Paired Student's t-criterion, p<0.05) in the control group. The staged treatment also showed improvement in quality of life, but the sum of the mean scores still remained high (M:47.92; SD± 19.323) (Table 1). The sum of the points was lower than 10 and there was a good clinical effect in the main group. Prolapse symptoms persisted after treatment in the control group. The results after treatment were statistically significant in the main group (M:8,51; Me:2; Q1-Q-3: 7), and the control group (M:47,92; Me:48,00; Q1-Q-3: 28) (U-test, p<0,05) (Table 2).

Table 1.

Assessment of results before and after treatment by group.

	Group	n	M	Me	SD±	CI %	Q1-Q-3	Criterion	p
before	1.	37	71,84	71	10,049	95	14	-5,304c*	,000
after	1.	37	8,51	2,00	14,185	95	7		
before	2.	39	66,00	66,00	10,593	95	14	9,547**	,000
after	2.	39	50,51	48,00	16,114	95	27		

M - mean, Me - median, SD - standard deviation, CI - confidence interval, Q1-Q-3 - interquartile range,
* - Wilcoxon test, ** paired Student's t-criterion

Table 2.

Differences between groups before and after treatment.

	Group	n	M	Me	SD±	CI %	Q1-Q-3	Criterion	p
before	1.	37	71,84	71	10,049	95	14	2,462*	0,016
	2.	39	66,00	66,00	10,593	95	14		
after	1.	37	8,51	2,00	14,185	95	7	134,000	,000
	2.	39	50,51	48,00	16,114	95	27		

M - mean, Me - median, SD - standard deviation, CI - confidence interval, Q1-Q-3 - interquartile range,
*t Student's test,** Mann-Whitney U-test

Domain № 10, which we developed to assess the level of anxiety in patients with genital prolapse associated with reoperation, was removed from the final version of the questionnaire. Due to the fact that the domain is specific only for concomitant prolapse. This domain cannot be applied to assess quality of life for all women with prolapse. In our study,

we interviewed patients with staged treatment using domain № 10. It appeared that the majority of patients 31(83.8%) were concerned about having another surgery, 30(81.1%) felt anxious that their condition had not improved after the first surgery, and 28 (75.7%) of those interviewed indicated that if only one surgical treatment was available, anxiety would be greatly reduced (Table 3).

Table 3.

Level of anxiety associated with the need for repeated operations.

Anxiety about having to operate again	Not at all	Slightly	Moderately	A lot
1. Are you experiencing tension, anxiety related to what you have suffered or are you facing more than one surgical intervention	0	1 (2,7%)	5 (13,5%)	31(83,8%)
2. If it were possible to reschedule just one surgery, how much would that ease your emotional stress	1 (2,7%)	3(8,1%)	5(13,5%)	28 (75,7%)
3. Evaluate your level of tension, anxiety, or upset that your condition remained the same after the first surgical intervention, got worse, or improved slightly	1 (2,7%)	2(5,4%)	4(10,8%)	30(81,1%)

The rates of prolapse recurrence (Group 1: 8 people (23,07%); Group 2: 37 people (100%) Me:3,0; Q1-Q-3:1) and functional disorders of pelvic organs (Group 1: 9 people (23,07%); Group 2: 37 people (100%) in both groups were also statistically significantly different (p<0,05) (Table 4), taking into account the fact that in the main group the initial stages of prolapse (2-5.1% versus 37 - 100%) and functional disorders (5 -12.8% versus 37-100%), not requiring further correction by surgery, prevailed, while in the control group more advanced stages requiring surgical treatment, which was statistically significant (U-criterion,p<0.05)), we note a strong relationship between the compared signs (Cramer's V 1 = 0.880; Cramer's V 2 =0.876, p<0.05) (Table 4).

Table 4.

Recurrences and Re-hospitalizations.

	n	1 Group	2 Group	Criterion	p
Anatomical recurrence	1 degree	3 (7,7%)	0	,880* 67,535***	,000
	2 degree	3 (7,7%)	14(37,8%)		
	3 degree	2 (5,1%)	18(48,6%)		
	4 degree	0	5(13,5%)		
	In total	8(20,5%)	37(100%)		
	Reoperation	2 (5,1%)	37 (100%)	1406,000**	,000
Pelvic organ dysfunction	1 degree	4 (10,3%)	1(2,7%)	,876* 70,270***	,000
	2 degree	4 (10,3%)	8(21,6%)		
	3 degree	1(2,6%)	28(75,7%)		
	In total	9(23,07%)	37(100%)		
	Reoperation	5 (12,%)	37(100%)	1350,500**	,000
***Fisher exact test, **Mann-Whitney U-test, *Cramer V-score					

Conclusions

Comprehensive surgical treatment of concomitant prolapse statistically significantly improved quality of life (; Me:2; Q1-Q-3: 7) compared with staged treatment (Me:48,00; Q1-Q-3: 28),(U-criterion,p<0,05).

The number of repeated hospitalizations for prolapse symptoms was also statistically significantly different (5 - 12.8% versus 37-100%)(Fisher's exact test,p<0.05),), we note a strong relationship between the compared features (Cramer's V 1 = 0.880;. Cramer's V 2 = 0.876, p<0.05).

Many patients in the staged treatment group were stressed, anxious about having to have another surgery 31(83.8%), most were also concerned that there was no significant improvement after the first surgery 30(81.1%). Twenty-eight women (75.7%) indicated that if only one surgical intervention had been possible, emotional stress would have been significantly lower.

The results of our study demonstrate the effectiveness of quality of life assessment as a baseline for determining the effectiveness of treatment for prolapse. Which may justify the necessity of reconsidering payment at the expense of compulsory health insurance for the treatment of combined prolapse with several surgeries. The staged treatment not only fail to improve clinical outcomes, but it also affects patients' emotional, social, and economic well-being. Which are generally health criteria as defined by the World Health Organization. After all, even one surgical intervention is stressful, the collection of tests, instrumental studies, examinations by specialists, risks associated with surgical manipulation and anesthesia, a long rehabilitation period, temporary disability, and the fact that after the first surgery the patient did not experience significant improvement of his condition. The burden on Healthcare also increases due to the need to finance repeated hospitalizations for surgical treatment at the expense of direct and indirect costs. To date, we have not found studies in the literature devoted to the clinical and economic analysis of this issue. In our opinion, further research is needed for larger sample volume using methods of clinical and economic analysis, such as cost-benefit and cost-effectiveness.

Conclusion. The comprehensive approach of surgical treatment statistically significantly improves the index of quality of life in comparison with staged treatment.

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Контактная информация:
Лактионова Мария Владимировна - докторант 1 года обучения, специальность «Общественное здравоохранение», Казахстанский медицинский университет «Высшая школа общественного здравоохранения», г.Алматы, Республика Казахстан;
Почтовый адрес: Республика Казахстан, 050000, г. Алматы, ул. Утепова 19А.
E-mail: rigel1992@mail.u
Телефон: +7**-**705-758-02-36.