#### **ANNOTATION**

Of dissertation work of Botagoz M. Aibayeva on the topic: «Оптимизация коррекции пролапса тазовых органов» submitted for the degree of Doctor of Philosophy (PhD) in the specialty 8D10102 - "Medicine"

#### Relevance

Pelvic organ prolapse (POP) is a syndrome involving the descent of the pelvic floor and organs within the small pelvis, either in isolation or in combination. It is one of the most relevant and widespread issues in modern gynecology. Increased life expectancy, lifestyle changes, and the growing demand for high-quality living among women necessitate a global consideration of POP-related problems.

According to the majority of researchers, the prevalence of POP in gynecological pathologies ranges from 3% to 50% in various populations, depending on assessment criteria (Nygaard I. et al., 2008). Furthermore, this figure is rapidly increasing, negatively impacting not only the quality of life for patients but also significantly reducing their productivity (Veit-Rubin N. et al., 2016, DeLancey JOL. 2017, Pushkar D. Yu. et al., 2017).

According to the Women's Health Initiative program, the annual incidence in the United States ranges from 1.5 to 9.3 cases per 100 women, depending on the pelvic floor compartment (Handa V.L. et al., 2004, Maher C. et al., 2023).

Despite the diversity of surgical methods, the risk of recurrence remains significant, leading to repeat surgeries and creating serious economic challenges (Boyles S.H. et al., 2003, Brown J.S. et al., 2002). As further research into the complex multifactorial etiopathogenesis of POP continues, the need for new studies in this field remains relevant.

The prospects for the development of female pelvic medicine and reconstructive surgery are continuously linked to finding ways to achieve an anatomically "optimal" state, minimizing recurrences, reducing postoperative complications, and ensuring high-quality life indicators for patients in the long term (Kubin N.D. et al., 2017).

It is essential to note the lack of anatomical assessment systems for POP that take into account symptoms. As asymptomatic descent of pelvic organs is not an indication for surgical intervention, subjective aspects of this condition must be considered (Handa V.L. et al., 2004). In light of this, it is necessary to consider the subjective aspects of this condition (Mahajan S.T. et al., 2005, Kowalski J.T., 2023).

According to global research, the expert opinion regarding reconstructive surgeries for POP emphasizes the need to minimize interventions on the pelvic floor. Thus, the current "niche" in scientific research involves identifying strict criteria for selecting patients for surgical treatment and improving conservative management methods for patients with symptomatic genital prolapse. Patient education and involvement in decision-making are crucial for selecting the most appropriate treatment option.

Previously, validated Russian-language questionnaires were used to assess the quality of life of women in Kazakhstan. However, considering that more than half of the female population (69.4%) speaks Kazakh, most of these women could not participate in surveys due to the language barrier. Currently, there is a lack of data in

Kazakhstan regarding the availability of specific validated questionnaires in Kazakh for assessing the quality of life in patients with genital prolapse and sexual dysfunction.

Given the need to analyze the impact of pelvic organ prolapse symptoms on health and quality of life, there is a growing interest in the use of specialized validated tools (Radzimińska A, et al., 2018, Ptak M, 2019). Moreover, the effectiveness of assessing indications for surgery and determining its success significantly increases with the use of specialized questionnaires that take into account the characteristics of specific diseases (Belayneh T, et al., 2021).

# Purpose of the study

Optimizing the outcomes of diagnosis and treatment for symptomatic pelvic organ prolapse.

# **Object of study:**

The research was conducted in three stages: Stage 1: A total of 126 and 150 patients were selected according to inclusion/exclusion criteria for the Kazakhlanguage validation of the Prolapse Quality of Life (P-QOL) and Female Sexual Function Index (Kz-FSFI) questionnaires, respectively. Stage 2: The study included 119 patients with anterior-apical pelvic organ prolapse (POP) (DeLancey levels I-II) who underwent either hybrid pelvic floor reconstruction with unilateral sacrospinous fixation (main group) or laparoscopic promontofixation with mesh (control group). Stage 3: Involved 76 patients with symptomatic POP (DeLancey levels II-III) who underwent a comparative analysis of surgical treatment with native tissues combined with preoperative conservative correction (behavioral therapy and pessary) versus standard surgical treatment of POP with native tissues without conservative correction.

## **Research objectives:**

- 1. Compare the effectiveness of surgical treatment methods for pelvic organ prolapse using mesh prosthetics (hybrid pelvic floor reconstruction with unilateral sacrospinous ligament fixation, laparoscopic mesh promontofixation).
- 2. Evaluate the efficacy of surgical treatment methods using native tissues with preoperative conservative correction (behavioral therapy, pessary) in comparison to standard surgical treatment for pelvic organ prolapse with native tissues, excluding conservative correction.
- 3. Optimize the management approach based on the quality of life of patients with symptomatic Pelvic Organ Prolapse (POP), utilizing results from P-QOL and FSFI in conjunction with the verification of POP stage using the Pelvic Organ Prolapse Quantification (POP-Q) system.
- 4. Validate specific questionnaires, Prolapse Quality of Life (P-QOL) and Female Sexual Function Index (FSFI), in the Kazakh language for assessing the quality of life in patients with genital prolapse and sexual dysfunctions.

#### Research methods

- 1. Definition of the key parameters of anatomical success and subjective effectiveness in conservative correction methods and surgical treatment of pelvic organ prolapse (POP).
- 2. Conducting a comparative analysis of the effectiveness of hybrid pelvic floor reconstruction with unilateral sacrospinous ligament fixation (main group) and laparoscopic mesh promontofixation (control group) involving patients with anteriorapical POP (DeLancey levels I-II) using mesh implants.

- 3. Conducting a comparative analysis of surgical treatment using native tissues with preoperative conservative correction (behavioral therapy, pessary) compared to standard surgical treatment for pelvic organ prolapse using native tissues without conservative correction (DeLancey levels II-III).
- 4. Determination of quality-of-life levels based on validated P-QOL and FSFI questionnaires and their comparison depending on the identified stage of genital prolapse according to the Pelvic Organ Prolapse Quantification (POP-Q) system.
- 5. Implementation of the validation procedure for the Kazakh language of the Prolapse Quality of Life (P-QOL) and Female Sexual Function Index (FSFI) questionnaires following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) protocol.
- 6. Statistical data processing.

# Scientific novelty of the research results

The findings of this study justify the feasibility of implementing a new strategy in optimizing the diagnosis and treatment of symptomatic pelvic organ prolapse.

## **Practical significance**

The results of this study will enable obstetricians-gynecologists and urologists to better address quality of life improvements for patients with symptomatic pelvic organ prolapse (POP). Based on these findings, the developed unified structured algorithm is aimed at enhancing diagnostic methods, reducing the need for surgical intervention by improving pelvic organ functionality, and decreasing recurrence rates, which will clearly improve outcomes for patients with symptomatic POP.

## Main provisions submitted for defense:

- 1. Hybrid pelvic floor reconstruction with unilateral sacrospinous fixation and laparoscopic promontofixation in patients with apical pelvic organ prolapse (DeLancey levels I-II) increases anatomical success and significantly improves the quality of life for patients.
- 2. Conservative treatment of symptomatic prolapse (DeLancey levels II-III) in the early stages significantly improve outcomes for patients with pelvic organ prolapse.
- 3. Implementing a standardized diagnostic algorithm for patients with pelvic organ prolapse is essential to reduce the risk of recurrent genital prolapse following surgical treatment.

#### **Approbation of the dissertation**

The main results of the dissertation work were reported at an extended departmental meeting of obstetrics and gynecology №2 of the NJSC "Astana Medical University", June 29, 2023. Based on the results of the dissertation research, 4 printed works were published (2 articles in publications recommended by the Committee for Quality Assurance in Education and Science of the Ministry of Education and Science of the Republic of Kazakhstan, 2 articles in international peer-reviewed publications included in the Scopus citation database and Web of Science), 1 act of implementation, 2 copyright certificates (№25241 «19» April 2022 year «Жамбас ағзаларының симптомды пролапсы бар пациенттердің өмір сапасын бағалау сауалнамасы»; №32181 «01» February 2023 year «Әйелдердегі жыныстық қызметті бағалау шкаласы (KZ-FSFI)»).

### **Conclusions:**

- 1. The results of a randomized study indicate that the hybrid pelvic floor reconstruction method with unilateral sacrospinous ligament fixation reduces the duration of surgical intervention by 4.6 times. The average duration of the operation in the hybrid reconstruction group was  $42.4 \pm 13.9$  minutes, whereas in the laparoscopic promontofixation group, it was  $194.6 \pm 40.0$  minutes (p < 0.05).
- 2. Anatomical success in the short term (6 months) for the hybrid pelvic floor reconstruction group with unilateral sacrospinous ligament fixation reached 95.6%, compared to 94.6% in the laparoscopic promontofixation group.
- 3. Subjective effectiveness, as per the validated P-QOL questionnaire, at 6 and 12 months in the hybrid pelvic floor reconstruction group, was 89% and 90%, respectively. In the laparoscopic promontofixation group, these figures were 87% and 89%, indicating a significant improvement in the quality of life for patients in both groups (p < 0.001).
- 4. Female Sexual Activity Index scores from the FSFI questionnaire, both before surgical treatment and after 6 months, revealed a higher satisfaction index among patients (p < 0.01). The maximum satisfaction threshold according to the FSFI questionnaire was 26.6 points in the hybrid pelvic floor reconstruction group and 28.3 points in the laparoscopic promontofixation group, 12 months after surgical treatment.
- 5. The effectiveness of surgical treatment using native tissues, coupled with preoperative conservative correction (behavioral therapy, pessary), compared to standard surgical treatment of pelvic organ prolapse (POP) using native tissues without conservative correction, showed subjective effectiveness at 3 months reaching 84.2% in the experimental group and remaining within 74.3% in the control group (p < 0.001).
- 6. Female Sexual Activity Index scores from the FSFI questionnaire in the group undergoing surgical treatment with native tissues, along with preoperative conservative correction (behavioral therapy, pessary), compared to the group with standard surgical treatment of POP using native tissues without conservative correction, at the initial stage and 3 months postoperatively, were not statistically significant (p = 0.652 and p = 0.581, respectively).
- 7. In the group of patients continuing conservative correction, subjective effectiveness scores from the P-QOL questionnaire at the initial stage and after three months of conservative correction were not statistically significant (p = 0.481). However, participants reported a positive trend in improving quality of life, leading to a refusal of surgical intervention.
- 8. The validated P-QOL questionnaire in the Kazakh language confirmed acceptable internal consistency with a Cronbach's alpha coefficient exceeding 0.7, indicating high reliability. Highly significant test-retest reliability correlations (p < 0.001) demonstrated the stability of questionnaire results upon repeated measurements. The Cronbach's alpha coefficient for the entire Kz-FSFI questionnaire was 0.92, signifying high internal consistency. Coefficients for each of the six domains (ranging from 0.78 to 0.95) also indicated acceptable reliability in evaluating corresponding aspects of female sexual function.

### **Practical recommendations:**

- 1. The use of the hybrid pelvic floor reconstruction method with unilateral sacrospinous ligament fixation is recommended as the preferred surgical treatment option for pelvic organ prolapse (DeLancey levels I-II). This method reduces operative time and ensures high anatomical success, significantly enhancing pelvic floor restoration efficiency.
- 2. Active integration of preoperative conservative correction, such as behavioral therapy and pessary use, is recommended at the initial stages of pelvic organ prolapse (POP) as part of the overall treatment plan. This strategy reduces the number of premature surgical interventions and significantly improves subjective effectiveness, contributing to the enhancement of patient quality of life (DeLancey levels II-III).
- 3. For a more complete assessment of the effectiveness of the treatment and to reduce the risk of recurrence of genital prolapse after surgical treatment, it is recommended to use a unified structured diagnostic algorithm (POP-Q system, validated questionnaires P-QOL and FSFI) among patients with pelvic organ prolapse.

### **Doctoral student's contribution**

The selection of patients in the study groups was carried out, participated in the collection of anamnestic data, data from clinical and laboratory instrumental studies. The doctoral student participated in a total of 155 operations in patients of the study groups (67 operations were performed personally, 88 as an assistant). All patients of the study groups were monitored during the postoperative period, including questionnaires, interviews, examinations and laboratory and instrumental examination of these patients. A number of scientific papers have been published based on the results of the study.

# Scope and structure of the dissertation

The dissertation includes an introduction, literature review, sections of own research, conclusion, conclusions and recommendations. The volume of the dissertation is 118 pages, there are 39 figures and 17 tables. 172 sources were analyzed.