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Research Article

Assessment of the Quality of Life of Patients Undergoing Pelvic Evisceration with Locally Advanced Pelvic Tumors

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Abstract

The purpose of pelvic evisceration is not only to ensure a long period of general and non-recurring survival of patients with locally-common primary and resistive tumors of the pelvic organs, but also, ultimately, as soon as possible achieving the most complete medical and social rehabilitation of patients. At the moment, one of the important criteria for the result of modern surgical treatment of cancer patients is the assessment of quality of life.

Keywords: *Locally Advanced Tumor; Pelvic Evisceration; Quality of Life*

Introduction

Recently, much attention has been paid to evaluating the results of surgical treatment in patients with locally distributed pelvic tumors, relying not only on the long-term results of overall and relapse-free survival as the main treatment indicators, but also on assessing the quality of life [15]. The expected decline in the quality of life is the main reason for the refusal to conduct pelvic evisceration in locally advanced and recurrent pelvic tumors [6,9]. Depending on the type of pelvic evisceration and the volume of surgical intervention, patients often acquire urostomy and/or colostomy drainage for life [23]. Permanent functioning stomas require daily careful care, constant use of urine and colostomy, otherwise recurring infectious and inflammatory processes of the intestines and kidneys will provide a critically low level of quality of life [11,12]. It should also be noted that on the problem of assessing the quality of life of patients undergoing pelvic evisceration, a small number of studies have been conducted [3,24]. However, all the studies conducted are summarized by the fact of improving the quality of life of patients without deteriorating the oncological results of treatment when performing reconstruction of the distal urinary tract, digestive tract and pelvic floor restoration [1,17,18].

The significant prevalence of locally common pelvic tumors, the complexity and persistence of impaired urination and defecation, accompanied by complete disability, put the problem of rehabilitation and the quality of life of patients on the list of most important medical and social problems [7,19]. At present, the quality of life of women with cancer profile is one of the main criteria for evaluating the effectiveness of treatment along with immediate and long-term results of treatment and five-year survival [13,21].

The use of standardized international questionnaires is the most effective criterion for assessing the quality of life of women with cancer profile [2,8,22]. Currently, among the available literature, you can find a small number of publications devoted to the analysis of the quality of life of patients who underwent pelvic evisceration [10,14,16].

Pelvic evisceration is becoming more widespread in the treatment of locally advanced pelvic tumors. According to the literature review, conclusive evidence has been obtained that performing pelvic evisceration improves the oncological results of treating patients with locally advanced pelvic tumors [4,15].

Thus, the implementation of the surgical stage as part of the complex treatment of patients with locally advanced pelvic tumors remains relevant, since the use of all possible options for simultaneous reconstruction, including closing of perineal defects, allows us to judge the speed of functional and social rehabilitation of patients whose life expectancy is minimal [1,5,23,24].

Methodology

The study assessed the quality of life in patients who underwent total supralevatory eviscerations of the small pelvis and patients who underwent infralevatory eviscerations of the small pelvis with simultaneous pelvic floor reconstruction with a displaced skin-muscle-fascial flap based on the thin muscle of the thigh.

In the course of the work performed, an analysis was made of the impact of total pelvic eviscerations on the quality of life of patients using the MOS SF-36 questionnaire (Medical Outcomes Study 36-item Short Form Health Survey, author - J.E. Ware, 1992). SF-36 refers to non-specific frequently used questionnaires for assessing the quality of life, the use of which is widespread in developed countries when conducting studies of quality of life.

The selected questionnaire is designed to meet the minimum psychometric standards required for comparisons. This questionnaire measures overall health, based on indicators of assessing the level of quality of life, which are non-specific for age groups, certain diseases and treatment programs.

The analysis of physical and mental health concepts obtained on the basis of these concepts represents the main characteristics of patient health, including function and dysfunction of organs, induced stress and well-being, objective and subjective assessment of satisfaction with treatment, positive or negative assessment of the patient's overall health.

To fill out the questionnaire, patients needed 5 - 10 minutes, elderly patients were given up to 15 minutes, which is undoubtedly a positive feature of the chosen questionnaire in terms of the speed of the study. All 36 questions in the SF-36 questionnaire, grouped into 8 scales, were quantified.

The results of each scale vary in the range from 0 to 100 points, where 100 is full mental and physical health. The results were presented in the form of ratings, expressed in points on 8 scales, compiled according to the principle: a higher score indicated a higher level of quality of life.

The following indicators were quantified:

1. Physical functioning (PF) reflects the patient's physical condition after surgery and the degree of restriction in physical activity (self-care, walking, climbing stairs, carrying heavy loads, etc.). Low indicators in this scale indicate a significant limitation in the physical activity of the patient due to health status.
2. Role-based functioning due to a physical state (role-physical functioning - RP) - the influence of a physical state on daily activities (the performance of daily activities). Low indicators on this scale indicate that the patient's daily activities are significantly limited by her physical condition.

3. The intensity of pain (bodily pain - BP) and its effect on daily activity, including the need for pain medication. High indicators of this scale indicate that pain syndrome limits the patient's activity to a large extent.
4. General health (GH) - a subjective assessment of the patient's state of health, both at the current time and in the future. The lower the score on this scale, the lower the health score.
5. Vitality (VT) - a subjective assessment of well-being. A low score indicates a decrease in the patient's vital activity, fatigue.
6. Social functioning (SF) - assessment of the impact of a physical or emotional state on a patient's social communication. A low score of this scale demonstrates the degree of restriction of social contacts, a decrease in communication with society with a deterioration in physical and emotional state.
7. Role-based functioning due to the emotional state (role-emotional - RE) involves assessing the impact of the emotional state on everyday activities (including increasing the time spent, reducing the amount of activity, reducing the quality of work, etc.). Low scores of this scale express the degree of restriction in the sphere of everyday activities that are associated with a deterioration in the patient's emotional state.
8. Mental health (mental health - MH) shows a change in mood, the appearance of depressive disorders, anxiety. A low indicator characterizes the mental state of the patient after surgery.

The results obtained for each of the above scales were grouped into two indicators: "physical component of health" and "psychological component of health". The components of the scale of the physical health component (Physical health - PH): physical functioning, role functioning due to physical condition, intensity of pain, general state of health. The components of the scale are the psychological component of health (Mental Health - MH): mental health, role-based functioning, due to emotional state, social functioning, vital activity.

The questions of the SF-36 questionnaire were independently answered by 11 patients with a locally advanced pelvic tumor who underwent pelvic eviscerations. Survey and collection of patient data was carried out immediately before the operation, before discharge of patients from the hospital and then every 3 months after discharge within one year. It should be noted that all patients underwent a routine examination every 3 months, including routine laboratory tests, ultrasound examination of the abdominal cavity and magnetic resonance imaging of the small pelvis.

Statistical analysis of the results was carried out using Microsoft Excel 2016 software for Windows 10, using the STATISTICA version 9 program. The significance of differences in the quantitative results of the study was evaluated using the Wilcoxon-Mann-Whitney statistical test for independent variables. Differences were considered statistically significant at $p < 0.05$.

Results and Findings

The study involved 11 women. The main step in the complex treatment of locally advanced pelvic tumors in this category of patients was the radical surgical treatment of locally distributed pelvic tumors in the volume of total pelvic evisceration. Most patients - 8, were in the age group of 50 - 69 years.

The study is prospective - all patients are traced from the beginning of antitumor treatment to the end of the observation period. There were no women who had dropped out of surveillance. The selection of the clinical material of the study was carried out by an open cohort method - inclusion in the study as patients treated the patients were included in the study when consulting a doctor at the oncology department. The study group did not include patients with distant metastases identified during examination, with somatic diseases in the stage of decompensation, as well as patients who did not have a local tumor spread to neighboring organs.

All patients underwent combined treatment depending on the histological variant of the tumor in accordance with the available treatment protocols.

The study was conducted in accordance with the Helsinki Declaration of the World Medical Association "Ethical Principles for Medical Research with the Participation of a Person" (1964, with subsequent amendments and additions), as well as ethical principles presented in the National Standard of the Russian Federation "Good Clinical Practice" Federal Standard P 52379 - 2005, ICH GCP principles and actual regulatory requirements.

When carrying out the study, federal standards for the provision of medical care to patients with malignant neoplasms limited to the small pelvis, including measures of the prehospital and inpatient phase of complex treatment, were observed and dynamic monitoring was performed at the end of the antitumor treatment.

When conducting the study, we were guided by the International classification of malignant tumors according to the TNM 7 system, revised in 2010, in accordance with the primary localization of the primary tumor. The distribution of patients by tumor location and stage of the tumor process is presented in table 1.

Tumor location	Primary tumor		Relapse or continued tumor growth	Total
	$T_3N_{0-1}M_0$	$T_{3-4}N_{0-3}M_0$		
Bladder	3	2	6	11
Uterus	2	1	5	8
Cervix	2	1	3	6
Vagina	-	-	2	2
Ovaries	-	1	-	1
	7	5	19	36
	9			

Table 1: *Distribution of patients by tumor location and stage of the tumor process.*

High rates of localization of the primary tumor lesion in the bladder are due to the fact that most of the patients in our study went to the urology department of the Clinic of the Federal State Budgetary Educational Institution of Higher Education "Bashkir state medical University" of the Ministry of Health of the Russian Federation, where they were diagnosed with a locally common process.

Based on this information, all patients of the present study at the time of hospitalization with the aim of performing pelvic evisceration had either the primary locally widespread tumor process.

A significant number of patients with local tumor recurrence indicates insufficient attention to the surgical method for the treatment of pelvic malignant neoplasms and an overestimation of the value of chemoradiotherapy, leading to disease progression, especially in the case of resistance to anticancer treatment.

It should be noted that the choice of the method of surgical treatment, especially the resection stage, was not significantly affected by either age or the presence of concomitant pathology. The volume of surgical intervention was determined by the degree of spread of the tumor process and the radicalism of the operation.

The ultimate goal of any surgical treatment, including the treatment of patients with locally advanced pelvic tumors, is to achieve a better quality of life for patients, along with maintaining the possibility of self-care and satisfactory psychological well-being. The study of changes in the quality of life indicators of patients who underwent total pelvic evisceration allows an in-depth analysis of the physical, psychological, emotional and social difficulties that arise in the postoperative period.

Quality of life is an objective indicator based on the subjective perception of patients, which characterizes the difference between the patient's expectations and the results obtained. Differences that remain at a minimum level indicate a higher quality of life for the patient.

In this work, there is no comparative analysis of the quality of life indicators of healthy individuals and patients who underwent total pelvic evisceration, since a low level of quality of life in patients with locally advanced pelvic tumors is beyond doubt.

In the process of the work, the effects of performing total pelvic eviscerations on changes in the quality of life of patients over time when the survey was conducted are analyzed. The obtained indicators of quality of life are presented in table 2.

Indicator	Polling time period					
	Before surgery	At discharge	3 months	6 months	9 months	12 months
PF[1]	76 ± 1,72	70 ± 4,36*	71 ± 2,31*	73 ± 1,34	74 ± 2,17	77 ± 1,56
RP[2]	43 ± 6,67	33 ± 7,05*	38 ± 3,16*	38 ± 3,87	40 ± 4,16	45 ± 2,37
BP[3]	57 ± 4,07	53 ± 4,21*	55 ± 2,45*	57 ± 3,16	58 ± 4,78	61 ± 4,65
GH[4]	20 ± 3,17	14 ± 2,62*	16 ± 2,27*	17 ± 3,34	20 ± 4,12	21 ± 3,28
VT[5]	37 ± 2,35	30 ± 3,49*	34 ± 2,44*	35 ± 3,12	37 ± 1,74	41 ± 2,13
SF[6]	58 ± 3,61	54 ± 4,21*	55 ± 3,76*	58 ± 3,12	60 ± 4,13	61 ± 2,86
RE[7]	43 ± 6,36	42 ± 4,89*	47 ± 3,17*	50 ± 2,75	51 ± 4,16	51 ± 1,14
MH[8]	32 ± 2,52	33 ± 2,97*	38 ± 1,52*	40 ± 2,14	43 ± 3,61	45 ± 2,54

Table 2: *Changes in the quality of life of patients for 1 year.*

[1]PF: Physical Functioning; [2]RP: Role Functioning; [3]BP: Pain Intensity; [4]GH: General Health Status; [5]VT: Vital Activity; [6]SF: Social Functioning; [7] RE: Role Functioning; 8 MH: Mental Health.

*Note * - statistically significant differences (p < 0.05).*

The quality of life indicators in the majority of patients in this study significantly differed from the initial ones during the first 3 months compared with the results of a survey conducted in the prehospital phase. After this time, the results on all scales did not have statistically significant differences compared with the values obtained during the survey in the preoperative period.

Low values in the "Physical Functioning" scale indicate the degree of traumatic effect of total pelvic eviscerations, leading to a prolonged disturbance in the physical activity of patients. The decrease in the "Role-based functioning" scale clearly demonstrates how radical surgical treatment of a locally advanced pelvic tumor leads to a number of physiological disorders, which in turn limit the daily activities of patients.

The most significant discrepancy was noted in the scales of "Role functioning due to physical state" and "Role functioning due to emotional state". The above scales relate to the characteristic of constant activity and to the daily lifestyle of patients. Undoubtedly, all patients, without exception, who underwent total pelvic evisceration, noted changes in the daily routine, especially during the first 3 months after surgery. A decrease in the values of the indicators in the scale indicates the degree of emotional disorders that impede the implementation of ordinary daily activities.

The data obtained once again prove that performing total pelvic evisceration is a serious crippling surgical intervention that leads not only to physical, but also to psychological disorders.

In our opinion, the patient's mental health status is significantly affected by the patient's fear for the risk of recurrence of the disease, increased irritability, sleep problems, adjuvant chemotherapy or chemoradiotherapy. In the social aspect, the situation is often aggravated due to the appearance in patients of constant stomas on the anterior abdominal wall that impede the patient's social communication, which is confirmed by the results in the "Social functioning" scale.

Despite the results described above, in the period from 6 to 12 months, all indicators of quality of life improved significantly and continued to increase, after which they were comparable with preoperative values. On average, patients returned to the preoperative results of assessing the quality of life within 6 months after surgery, however, there were no statistically significant differences in the indicators of assessing the quality of life.

Based on the presented statistical data, a schedule was constructed for the change in the average indicators of the quality of life of patients over time (Figure 1).

Figure	Period of time of the survey					
	Before surgery	At an extract	3 months	6 months	9 months	12 months
PF[1]	76 ± 1,72	70 ± 4,36*	71 ± 2,31*	73 ± 1,34	74 ± 2,17	77 ± 1,56
RP[2]	43 ± 6,67	33 ± 7,05*	38 ± 3,16*	38 ± 3,87	40 ± 4,16	45 ± 2,37
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MH[8]	32 ± 2,52	33 ± 2,97*	38 ± 1,52*	40 ± 2,14	43 ± 3,61	45 ± 2,54

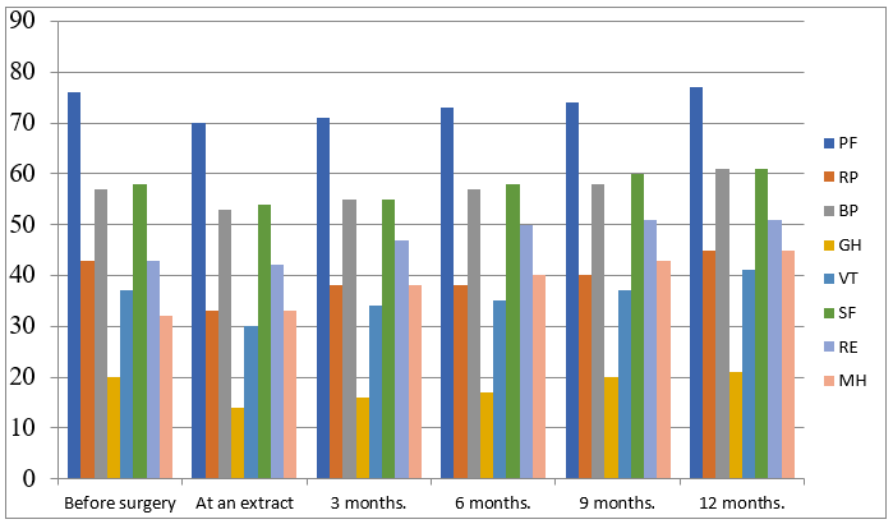

Figure 1: *Averaged profile of the quality of life of patients at different time periods according to the scales of the SF-36 questionnaire. PF: Physical Functioning; RP: Role Functioning; BP: Pain Intensity; GH: General State of Health; VT: Vital Activity; SF: Social Functioning; RE: Role Functioning; MH: Mental Health.*

The data obtained from the survey were grouped into two main indicators characterizing the change in the parameters for assessing the quality of life of patients: the physical component of health and the psychological component of health.

The components of the scale "Physical health component" are: physical functioning, role-based functioning due to physical condition, intensity of pain, general state of health. The schedule for changing the psychological component of health was built from the following scales: mental health, role-based functioning, due to emotional state, social functioning, life activity.

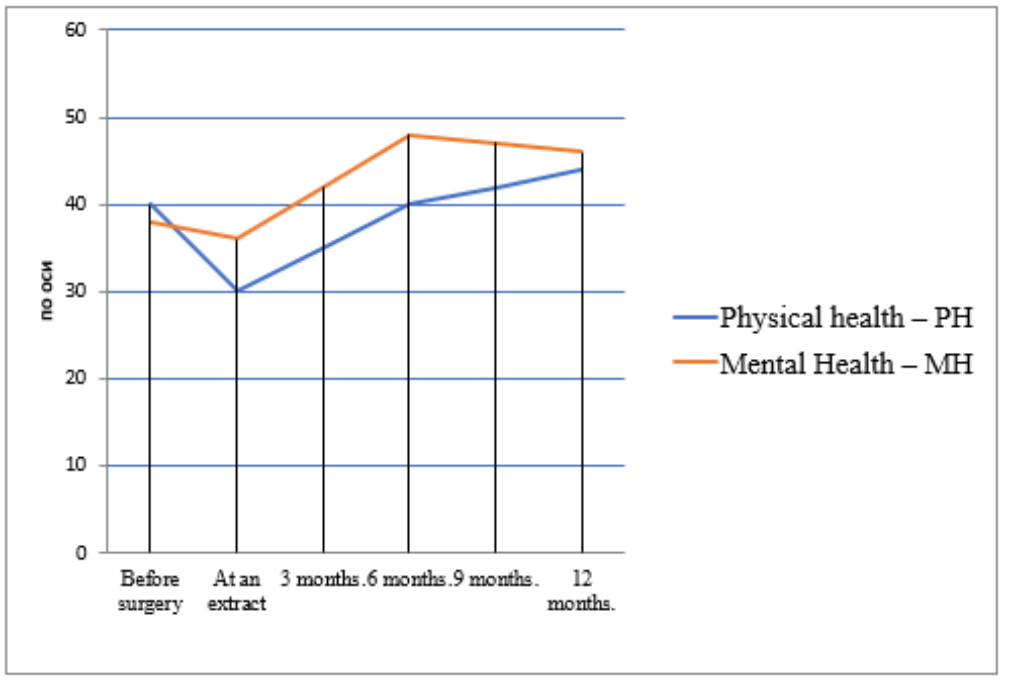

Figure 2: *Total summary estimates of indicators of the physical and mental components of women's health.*

At the initial stage of the postoperative period, there was a decrease in both the physical and mental components of the patients' health.

The physical component of health at the time the patient was admitted for surgical treatment ranged from 38.45 to 43.12 (average 41.6 ± 1.13). This health indicator in patients after total pelvic evisceration significantly worsened by 22.5% ($p < 0.05$.) in the first days after total pelvic evisceration and was at the lowest level of assessment at the stage of discharge of patients from the hospital.

Within six months after the operation, this indicator was characterized by a relatively fast recovery rate and turned out to be comparable with the preoperative value when interviewing patients after 6 months. Over the next 6 months, the indicator of the physical component of health continued to grow and at the time of the last survey, an increase of this indicator by 7.5% was confirmed ($p > 0.05$).

The value of the psychological component of health in the preoperative period ranged from 37.45 to 43.12 (average value 39.6 ± 1.24), which naturally differed from that in healthy patients.

The psychological component of patient health at the time of discharge from the hospital deteriorated by 5.2% ($p > 0.05$), which indicates a statistically insignificant difference compared with preoperative values. However, indicators of mental health components quickly returned within 1 month of surgery and reached levels above baseline within 3 months after surgery. The maximum values of psychological health indicators were recorded after 6 months, when their value exceeded the preoperative level by 26.3% ($p < 0.05$).

In this study, we examined the issue of changing quality of life over time and were able to identify improvements in most functional scales. Slow postoperative recovery and rehabilitation are obvious reasons for lowering the quality of life of patients, since performing pelvic total eviscerations is associated with a high level of postoperative complications, physical limitations and emotional stress.

Discussion

The results of a study of quality of life showed that in the early postoperative period, patients who underwent total pelvic evisceration had a lower level of quality of life than before surgery. 12 months following the surgery, all the studied indicators of quality of life improved. The most significant improvement was noted in the indicators of the mental component of health. Undoubtedly, relieving patients from volumetric education and correcting the consequences of its treatment with providing good functional results from the distal urinary and digestive systems can compensate for the damage caused by the operation and, importantly, increase the quality of life of patients.

Conclusion

The indicators of the physical component of the patient's health after undergoing total pelvic eviscerations significantly worsen by 22.5% ($p < 0.05$.) but are restored within 6 months to the level of initial values before surgery. The values of psychological health indicators are restored within one month, exceeding the level of preoperative values by 26.3% ($p < 0.05$.) within 6 months after the surgery.

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