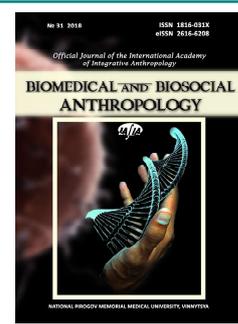




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## Quality of life of patients with cancer of the esophagus and cardioesophageal cancer

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*The urgency of the study is due to the aggressiveness of esophageal cancer and cardioesophageal cancer, low survival rate of patients, the need for further development aimed at improving the consequences of surgical intervention, the effectiveness of which can be evaluated with the help of determining the quality of life of these patients. The aim of the work is to assess the quality of life of patients with esophagus cancer and cardioesophageal cancer after radical surgery, depending on the variant of the formed esophagogastroanastomosis based on the analysis of indicators of the general condition of patients and the severity of esophageal-gastric symptoms at different stages of observation. 60 patients with cancer of the esophagus and cardioesophageal cancer after proximal gastrectomy with resection of the esophagus accesses of Lewis or Osawa Garlock were subject to questioning. The patients were divided into two groups: the study group consisted of 30 patients who had developed the mechanical invagination of the esophagogastro-anastomosis developed and protected by the Ukrainian patent, the comparison group made up 30 patients who had the end-to-side mechanical esophagogastroanastomosis formed. Quality of life was assessed before surgery and at 3, 6, and 12 months after surgery. The EORTC QLQ-C30 V.3 questionnaire was used to assess the general condition of the patients, and the EORTC QLQ-OG25 questionnaire was used to assess the presence of specific gastrointestinal symptoms. Statistical analyses were performed using EZR v. 1.35 software (Saitama Medical Center, Jichi Medical University, Saitama, Japan, 2017), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). To analyze the dynamics of the indicators, the Friedman criterion was used for repeated measurements, pairwise comparisons were performed according to the Conover criterion. To verify the validity of the differences between dependent samples, the non-parametric W-criterion of Wilcoxon was used. It was established that the general condition of the patients after surgery, assessed by the EORTC QLQ-C30 V.3 scales, did not depend on the method of formation of esophagogastroanastomosis. The results of the study of the quality of life of patients after surgery with various ways of forming esophagogastroanastomosis modulo EORTC QLQ-OG25 showed significantly lower frequency rate of symptoms such as reflux, pain and discomfort in the stomach, nutritional problems in front of other people and a sense of physical unattractiveness in the group of patients for which formation of a mechanical invagination esophagogastroanastomosis was applied.*

**Keywords:** quality of life, EORTC QLQ-C30 V.3 questionnaire, EORTC QLQ-OG25 questionnaire, esophageal cancer, cardioesophageal cancer, proximal gastrectomy with esophageal resection, Lewis or Osawa-Garlock accesses, esophagogastroanastomosis.

### Introduction

For a long time survival and absence of recurrence in patients of oncologic profile were considered as one of the most important parameters for assessing the outcome of the treatment. However, given the aggressiveness of

oncological diseases, especially esophageal and stomach cancers, where survival of up to 5 years after the diagnosis is critically low [23], and the 5-year survival rate of patients with esophageal cancer, both operated and not operated,

is roughly the same levels [11], there was a need to apply another indicator of the effectiveness of treatment, aimed at assessing the state of health of the patient. For this reason, the concept of quality of life related to health (HRQoL - Health-Related Quality of Life) is currently being used. The essence of the term "quality of life" (HRQoL) consists in perceiving patients the positive and negative aspects of their lives associated with the disease and its treatment [9]. The development of the HRQoL assessment was initiated by the European Organization for the Study and Cure of Cancer (EORTC) in 1980. The overall clinical questionnaire EORTC QLQ-C30 V.3 has been developed as a result of international large-scale clinical cancer research, which provides an opportunity to assess the general condition of oncologic profile patients [1] and a number of specific questionnaires, including the EORTC QLQ-OG25, an add-on module that allows assessing the quality of life in patients with esophageal cancer and cardioesophageal cancer by indicating the presence of specific esophagus-gastric symptoms [16].

Modern world standards for treating cancer of the esophagus, including preoperative chemo- and chemoradiation therapy, severe and extensive radical surgery and post-operative therapy aimed at improving survival rates and survival time without relapses, can compete with the deterioration of quality of life, which manifests itself in a difficult general condition. patients after treatment, native problems, low level of emotional and social status of patients [14]. At the same time, the overwhelming majority of patients with esophageal or stomach cancer, aware of the severity of their disease, indicate that improving the quality of life is their main goal of treatment [13, 20]. In view of this, HRQL is a fundamental part of the treatment of surgical oncology, especially in esophageal and stomach cancer [7]. Therefore, we consider it necessary to find out whether the option of treatment can influence the quality of life of patients with esophageal cancer and cardioesophageal cancer.

The *purpose* of the work - based on the analysis of indicators of the general condition of patients and the severity of the esophageal-gastric symptoms at different stages of observation, assess the quality of life of patients with esophageal cancer and cardioesophageal cancer, depending on the variant of the formed esophagogastroanastomosis.

### Materials and methods

The research was based on the materials of surgical treatment and clinical examination of 60 patients with esophageal cancer and cardioesophageal cancer who were on the examination and in-patient treatment in the department of surgery of the gastrointestinal tract of the O.O. Shalimov National Institute of Surgery and Transplantology for the period from 2015 to 2018 and survival of which was not less than a year. All patients performed proximal resection of the stomach with resection of the esophagus by accesses of Lewis, or Osawa Garlock.

By blind randomization method, the patients were divided into two groups depending on the chosen method of forming the esophagogastroanastomosis. The study group included 30 patients who undertook the formation of a mechanical invagination esophagogastroanastomosis developed at the institute and protected by the patent of Ukraine [22]. The comparison group also included 30 patients who performed the formation of a mechanical circular esophagogastroanastomosis end-to-side. Taking into account the fact that the period from two to four weeks is not enough to observe significant changes in the quality of life in such patients [21], we estimated the quality of life of the patients of both groups under study for surgery and at 3, 6 and 12 months after surgery. For this purpose, questionnaires were used: EORTC QLQ-C30 V.3 - to assess the general condition of patients [1] and EORTC QLQ-OG25 - to assess the presence of specific gastrointestinal symptoms [16]. For this study, the most important are the following indicators: global health status, physical, emotional and social functioning, fatigue, dysphagia, reflux, pain when swallowing, pain and discomfort in the stomach area.

To calculate responses, a linear transformation of the standard pre-calculation is used, forming ranges from 0 to 100 [10]. The indicators of quality of life and the severity of the symptoms we received were interpreted as follows: for functional scales and the scale of the global status of life, a higher rate corresponded to a higher quality of life, while for symptomatic scales, higher rates showed more pronounced symptoms of the disease.

Statistical data processing was carried out in the package EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan, 2017), representing a graphical interface to R (The R Foundation for Statistical Computing, Vienna, Austria). To analyze the dynamics of the indicators used Friedman criterion for repeated measurements [12], paired comparisons were conducted according to the Conover criterion [3]. To verify the validity of the differences between dependent samples, the non-parametric W-criterion of Wilcoxon was used.

The formed groups that were compared comparable to the frequency distribution of patients by age, sex, histological type of tumors, stage of the disease and the localization of the malignant process. All patients, according to NCCN recommendations, passed the standard neoadjuvant therapy courses: for squamous cell carcinoma - radiotherapy of TFD 45 Gy, RAB 1.8 Gy. and polychemotherapy Cisplatin 75-100 mg/m<sup>2</sup> at 1 and 29 day and 5-fluorouracil 750-1000 mg/m<sup>2</sup> at 1-4 and 29-32 days; for adenocarcinoma - oxaliplatin 75-100 mg/m<sup>2</sup> at 1 and 29 day and 5-fluorouracil 750-1000 mg/m<sup>2</sup> at 1-4 and 29-32 days [2].

### Results

The results of the assessment of the quality of life in the dynamics based on the indicators of the *general condition* of patients whom was formed the end-to-end mechanical circulatory esophagogastroanastomosis (the comparison

group) are given in Table 1.

During the analysis of the *global health status*, its change was detected for 12 month of follow-up ( $p < 0.001$  for the Friedman criterion for repeated sampling). On 3 month surveillance index of global health status has decreased ( $p < 0.05$  by Conover criterion), on 6 month there is an increase in it compared with the indicator before surgery and a value on 3 month ( $p < 0.05$  in both cases). On 12 month, the indicator had the highest value ( $p < 0.05$ ) for all measurement points (see Table 1).

In analyzing the *physical functioning* of patients, a decrease in this indicator on 3 month after surgery was noted as compared to the corresponding indicator before surgery ( $p < 0.05$ ), with that starting on 6 month after surgery, this figure increased and was higher than the rate on 3 month of evaluation ( $p < 0.05$ ), however, it did not significantly differ from the patient evaluation score before surgery ( $p > 0.05$ ). On 12 month the indicator remained constant and had no statistical difference from the 6-month indicator and before surgery ( $p > 0.05$ ) (see Table 1).

When analyzing the indicator of *emotional functioning* at the time of evaluation before surgery and on 3 month after surgery, the level of the indicator is low and has no statistically significant difference ( $p > 0.05$ ). However, since 6 month after surgery, there is an increase in this indicator ( $p < 0.001$ ) compared with the indicators before the operation and on 3 month. On 12 month after operative treatment, this indicator is the highest ( $p < 0.05$ ) (see Table 1).

The indicator of *social functioning* was the lowest on 3 month after surgical treatment ( $p < 0.05$ ). However, it has been growing since 6 month and became the highest for all 12-month evaluation periods after surgical intervention ( $p < 0.05$ ) (see Table 1).

When evaluating *fatigue*, the highest severity of this symptom was detected on 3 month after surgical intervention in comparison with all stages of the assessment of the indicator ( $p < 0.05$ ). At the same time, there was a decrease in this indicator on 6 month in comparison with the indicator before operative intervention and the indicator on 3 month ( $p < 0.05$ ). For all periods of evaluation, the fatigue index was the lowest on 12 month of observation of patients ( $p < 0.05$ ) (see Table 1).

The results of the assessment of the quality of life in the dynamics on the indicators of the *general condition* of patients who were formed invagination esophagogastric anastomosis (study group) are given in Table 2.

The change in the *global health status* of patients in the study group during the 12-month follow-up ( $p < 0.001$  by Friedman's criterion for re-sampling) was found. On 3 month of surveillance global health status has decreased ( $p < 0.05$  by Conover criterion), on 6 month this indicator has increased in comparison with the indicator before the surgical intervention and the value on 3 month ( $p < 0.05$  in both cases). On 12 month the indicator had the highest value ( $p < 0.05$  for all measuring points) (see Table 2). When

**Table 1.** Dynamics of indicators of the questionnaire EORTC QLQ-C30 V.3 in the comparison group.

Indicator	Me (Q <sub>I</sub> - Q <sub>III</sub> ), (n=30)				p
	Before	3 months	6 months	12 months	
GHS/QI Global health status (questions 29, 30)	42 (33-50) <sup>#&amp;§</sup>	33 (33-42) <sup>*&amp;§</sup>	49 (42-50) <sup>**§</sup>	67 (58-67) <sup>**&amp;</sup>	<0.001
1. PF2 Physical functioning (questions 1-5)	60 (47-73) <sup>#</sup>	50 (47-53) <sup>*&amp;§</sup>	67 (53-67) <sup>#</sup>	67 (67-67) <sup>#</sup>	<0.001
2. RF2 Role functioning (questions 6, 7)	58,5 (50-67) <sup>#</sup>	33 (33-50) <sup>*&amp;§</sup>	67 (50-67) <sup>#</sup>	67 (50-67) <sup>#</sup>	<0.001
3. EF Emotional functioning (questions 21-24)	58 (42-67) <sup>&amp;§</sup>	50 (42-67) <sup>&amp;§</sup>	67 (50-67) <sup>**§</sup>	75 (67-83) <sup>**&amp;</sup>	<0.001
4. CF Cognitive functioning (questions 20, 25)	75 (67-83) <sup>&amp;§</sup>	67 (67-83) <sup>&amp;§</sup>	83 (67-83) <sup>**</sup>	83 (83-100) <sup>**</sup>	<0.001
5. SF Social functioning (questions 26, 27)	67 (50-67) <sup>#&amp;§</sup>	33 (33-33) <sup>*&amp;§</sup>	67 (50-83) <sup>**§</sup>	67 (67-83) <sup>**&amp;</sup>	<0.001
1. FA Fatigue (questions 10, 12, 18)	67 (56-78) <sup>#&amp;§</sup>	83,5 (67-100) <sup>*&amp;§</sup>	33 (33-44) <sup>**§</sup>	33 (0-33) <sup>**&amp;</sup>	<0.001
2. NV Nausea and vomiting (questions 14, 15)	17 (0-50) <sup>&amp;§</sup>	17 (0-17) <sup>&amp;§</sup>	0 (0-17) <sup>**</sup>	0 (0-0) <sup>**</sup>	<0.001
3. PA Pain (questions 9, 19)	50 (33-50) <sup>#&amp;§</sup>	33 (17-33) <sup>*&amp;§</sup>	8,5 (0-17) <sup>**</sup>	0 (0-0) <sup>**</sup>	<0.001
1. DY Dyspnea (question 8)	33 (33-67) <sup>&amp;§</sup>	33 (33-67) <sup>&amp;§</sup>	0 (0-33) <sup>**</sup>	0 (0-33) <sup>**</sup>	<0.001
2. SL Insomnia (question 11)	33 (33-67) <sup>&amp;§</sup>	33 (33-67) <sup>&amp;§</sup>	33 (0-33) <sup>**</sup>	0 (0-33) <sup>**</sup>	<0.001
3. AP Loss of appetite (question 13)	67 (67-67) <sup>#&amp;§</sup>	33 (33-33) <sup>*&amp;§</sup>	0 (0-33) <sup>**</sup>	0 (0-0) <sup>**</sup>	<0.001
4. CO Constipation (question 16)	33 (0-33) <sup>#&amp;§</sup>	16,5 (0-33) <sup>*&amp;§</sup>	0 (0-0) <sup>**</sup>	0 (0-0) <sup>**</sup>	<0.001
5. DI Diarrhea (question 17)	0 (0-0) <sup>#</sup>	33 (0-33) <sup>*&amp;§</sup>	0 (0-0) <sup>#</sup>	0 (0-0) <sup>#</sup>	<0.001
6. FI Involvement (question 28)	33 (0-33) <sup>#&amp;§</sup>	100 (67-100) <sup>*§</sup>	100 (67-100) <sup>*</sup>	100 (67-100) <sup>**</sup>	<0.001

**Notes:** here and thereafter, median value (Me), values of the first and third quartiles (Q<sub>I</sub>-Q<sub>III</sub>) were calculated for data presentation; for analyzing the dynamics of the indicators, the Friedman criterion was used for repeated measurements, the pair comparisons were conducted according to the Conover criterion (Conover, 1999): \* - the difference from the indicator before the treatment is statistically significant ( $p < 0,05$ ), # - the difference from the indicator on the 3 month is statistically significant, & - the difference from the indicator on the 6 month is statistically significant, § - the difference from the indicator on the 12 month is statistically significant.

**Table 2.** The dynamics of the EORTC QLQ-C30 V.3 questionnaire for the study group.

Indicator	Me (Q <sub>1</sub> - Q <sub>3</sub> ), (n=30)				p
	Before	3 months	6 months	12 months	
GHS/QI Global health status (questions 29, 30)	42 (33-50) <sup>#&amp;§</sup>	33 (33-42) <sup>*&amp;§</sup>	50 (48-50) <sup>**§</sup>	62,5 (58-67) <sup>**&amp;§</sup>	<0.001
1. PF2 Physical functioning (questions 1-5)	53 (47-73) <sup>#&amp;§</sup>	47 (47-53) <sup>*&amp;§</sup>	67 (67-67) <sup>**</sup>	67 (67-67) <sup>**</sup>	<0.001
2. RF2 Role functioning (questions 6, 7)	67 (50-67) <sup>#</sup>	33 (17-33) <sup>*&amp;§</sup>	67 (50-67) <sup>#</sup>	67 (50-67) <sup>#</sup>	<0.001
3. EF Emotional functioning (questions 21-24)	58 (42-58) <sup>&amp;§</sup>	50 (42-50) <sup>&amp;§</sup>	67 (50-75) <sup>**</sup>	75 (75-83) <sup>**</sup>	<0.001
4. CF Cognitive functioning (questions 20, 25)	67 (67-83) <sup>&amp;§</sup>	67 (50-67) <sup>&amp;§</sup>	83 (67-83) <sup>**</sup>	83 (67-83) <sup>**</sup>	<0.001
5. SF Social functioning (questions 26, 27)	67 (50-67) <sup>#&amp;§</sup>	33 (33-50) <sup>*&amp;§</sup>	67 (50-83) <sup>#</sup>	67 (67-83) <sup>**</sup>	<0.001
1. FA Fatigue (questions 10, 12, 18)	78 (56-89) <sup>#&amp;§</sup>	100 (78-100) <sup>*&amp;§</sup>	38,5 (33-44) <sup>**§</sup>	33 (0-33) <sup>**&amp;§</sup>	<0.001
2. NV Nausea and vomiting (questions 14, 15)	41,5 (33-50) <sup>#&amp;§</sup>	17 (0-17) <sup>*&amp;§</sup>	0 (0-17) <sup>**</sup>	0 (0-17) <sup>**</sup>	<0.001
3. PA Pain (questions 9, 19)	41,5 (33-50) <sup>#&amp;§</sup>	17 (17-33) <sup>*&amp;§</sup>	0 (0-17) <sup>**</sup>	0 (0-17) <sup>**</sup>	<0.001
1. DY Dyspnea (question 8)	33 (33-67) <sup>&amp;§</sup>	33 (33-33) <sup>&amp;§</sup>	0 (0-0) <sup>**</sup>	0 (0-0) <sup>**</sup>	<0.001
2. SL Insomnia (question 11)	33 (33-33) <sup>&amp;§</sup>	33 (33-33) <sup>&amp;§</sup>	33 (0-33) <sup>**</sup>	0 (0-33) <sup>**</sup>	<0.001
3. AP Loss of appetite (question 13)	67 (67-67) <sup>#&amp;§</sup>	33 (33-33) <sup>*&amp;§</sup>	0 (0-33) <sup>**</sup>	0 (0-33) <sup>**</sup>	<0.001
4. CO Constipation (question 16)	33 (0-33) <sup>#&amp;§</sup>	0 (0-33) <sup>*</sup>	0 (0-0) <sup>*</sup>	0 (0-0) <sup>*</sup>	<0.001
5. DI Diarrhea (question 17)	0 (0-0) <sup>#</sup>	33 (33-33) <sup>*&amp;§</sup>	0 (0-0) <sup>#</sup>	0 (0-0) <sup>#</sup>	<0.001
6. FI Involvement (question 28)	33 (33-33) <sup>#&amp;§</sup>	100 (67-100) <sup>*</sup>	100 (67-100) <sup>*</sup>	100 (67-100) <sup>*</sup>	<0.001

comparing the global health status of the study group and the comparison group at the time before the surgery, 3, 6 and 12 month after a surgical intervention, no statistically significant differences were found ( $p=0.50$ ,  $p=0.90$ ,  $p=0.80$ ,  $p=0.70$ , respectively, according to the W-Wilcoxon criterion for dependent samples) (see Table 1, 2 )

In analyzing the *physical functioning* of patients, a decrease in this indicator on 3 month after surgery was noted ( $p<0.05$ ), with the increase starting from 6 month after surgery, which was higher than the rate on 3 month of evaluation and measure before surgical intervention ( $p<0.05$ ). On 12 month, the indicator remained constant and did not have a statistical difference from 6 month and an indicator before surgical intervention ( $p>0.05$ ) (see Table 2). When comparing the indicators of the study group and the comparison there were no true difference between the indicators before the surgery, and after 3, 6 and 12 month of estimates ( $p=0.50$ ,  $p=0.20$ ,  $p=0.97$ ,  $p=0.50$ , respectively) (see Table 1, 2).

When analyzing the indicator of *emotional functioning* at the time of evaluation before surgery and on 3 month after surgery, its value is low, but it has no statistical difference ( $p>0.05$ ). However, since 6 month after surgery, there is an increase in this indicator ( $p<0.05$ ) compared with the indicators before the operation and on 3 month. On 12 month after operative treatment the indicator is the highest ( $p<0.05$ ) (see Table 2). Comparing the indices of the study group and the control group, there was no difference between the indicators before the surgery, after 3, 6 and 12 months ( $p=0.40$ ,  $p=0.97$ ,  $p=0.40$ ,  $p=0.40$ , respectively) (see Table 1, 2).

The indicator of *social functioning* was the lowest on 3 month after surgical treatment ( $p<0.05$ ). However, it has

been growing since 6 month and also remained stable for 12 month after surgical intervention ( $p>0.05$ ) (see Table 2). Comparing the indicator of social functioning of the research group and the comparison group in the period prior to surgery, there was no statistically significant difference between the indices ( $p=0.50$ ). However, when comparing the indicator on 3 month it was lower in the comparison group ( $p=0.04$ ). However, in the assessment periods on 6 and 12 month after a surgical intervention statistically significant difference between the indicators was not observed again ( $p=0.70$ ,  $p=0.50$ , respectively) (see Table 1, 2).

When estimating *fatigue* rate, the greatest fever of this symptom was observed on 3 month after surgery and was more pronounced in comparison with all stages of assessment of patients ( $p<0.05$ ). At the same time, there was a decrease in this indicator on 6 month in comparison with the indicator before operative intervention and an indicator of 3 month ( $p<0.05$ ). The lowest fatigue rating for all periods was on 12 month of patients observation ( $p<0.05$ ) (see Table 2). When comparing the indicators of the study group and the comparison there was no true difference between the indicators before the surgery, after 3, 6 and 12 months ( $p=0.09$ ,  $p=0.10$ ,  $p=0.70$ ,  $p=0.40$  respectively) (see Table 1, 2).

Thus, the analysis of the EORTC QLQ-C30 V.3 questionnaire indicators shows a decline in the functional scales immediately after surgery and their gradual increase during the 12 months of follow-up, as well as the highest severity of symptoms prior to surgical treatment and their gradual reduction to 12 month of following-up symptomatic scales in both groups of comparison.

We have also analyzed the specific aspect of the quality

**Table 3.** Dynamic of indicator EORTC QLQ-OG25 for the comparison group.

Indicator	Me (Q <sub>1</sub> - Q <sub>3</sub> ), (n=30)				p
	Before	3 months	6 months	12 months	
1. Dysphagia (three questions) (questions 1, 2, 3)	56 (44 - 67) <sup>#&amp;§</sup>	11 (0 - 17) <sup>&amp;§</sup>	11 (0 - 11) <sup>##</sup>	11 (0 - 11) <sup>##</sup>	<0.001
2. Restricting food intake (four questions) (question 4, 5, 6, 7)	58 (42 - 67) <sup>#&amp;§</sup>	25 (17 - 33) <sup>&amp;§</sup>	17 (0 - 25) <sup>##</sup>	12,5 (0-17) <sup>##</sup>	<0.001
3. Reflux (questions 8, 9)	0 (0 - 17) <sup>#&amp;§</sup>	50 (50 - 67) <sup>*</sup>	50 (50 - 67) <sup>*</sup>	50 (50 - 67) <sup>*</sup>	<0.001
4. Odynophagia (questions 10, 11)	67 (50 - 83) <sup>#&amp;§</sup>	17 (17 - 17) <sup>&amp;§</sup>	8,5 (0 - 17) <sup>##</sup>	0 (0 - 17) <sup>##</sup>	<0.001
5. Pain and discomfort in the stomach (questions 12, 13)	33 (33 - 33) <sup>#&amp;§</sup>	17 (0 - 17) <sup>*</sup>	17 (0 - 17) <sup>*</sup>	17 (0 - 17) <sup>*</sup>	<0.001
6. Anxiety and worry (questions 14, 15)	33 (33 - 50) <sup>#&amp;§</sup>	50 (33 - 67) <sup>&amp;§</sup>	33 (0 - 33) <sup>##</sup>	17 (0 - 33) <sup>##</sup>	<0.001
Problems with food to other people (question 16)	0 (0 - 33) <sup>§</sup>	0 (0 - 33) <sup>§</sup>	0 (0 - 33) <sup>§</sup>	0 (0 - 0) <sup>##&amp;</sup>	<0.02
Dry mouth (question 17)	33 (0 - 33) <sup>#&amp;§</sup>	0 (0 - 33) <sup>&amp;§</sup>	0 (0 - 0) <sup>*</sup>	0 (0 - 0) <sup>##</sup>	<0.001
Problems with a taste of food (question 18)	0 (0 - 33) <sup>&amp;§</sup>	0 (0 - 33) <sup>&amp;§</sup>	0 (0 - 0) <sup>##</sup>	0 (0 - 0) <sup>##</sup>	<0.001
Feelings of physical unattractiveness (question 19)	33 (33 - 67) <sup>§</sup>	33 (33 - 67) <sup>&amp;§</sup>	33 (33 - 33) <sup>#</sup>	33 (0 - 33) <sup>##</sup>	<0.001
Complicated dipping of saliva (question 20)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	>0.99
Shortness of breath while swallowing (question 21)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	>0.99
Coughing (question 22)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	=0.90
Problems with the ability to speak (question 23)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	>0.99
Weight loss (question 24)	67 (33 - 67) <sup>&amp;§</sup>	67 (33 - 67) <sup>&amp;§</sup>	33 (0 - 33) <sup>##</sup>	33 (0 - 33) <sup>##</sup>	<0.001

**Table 4.** Dynamic of indicator EORTC QLQ-OG25 for the comparison group.

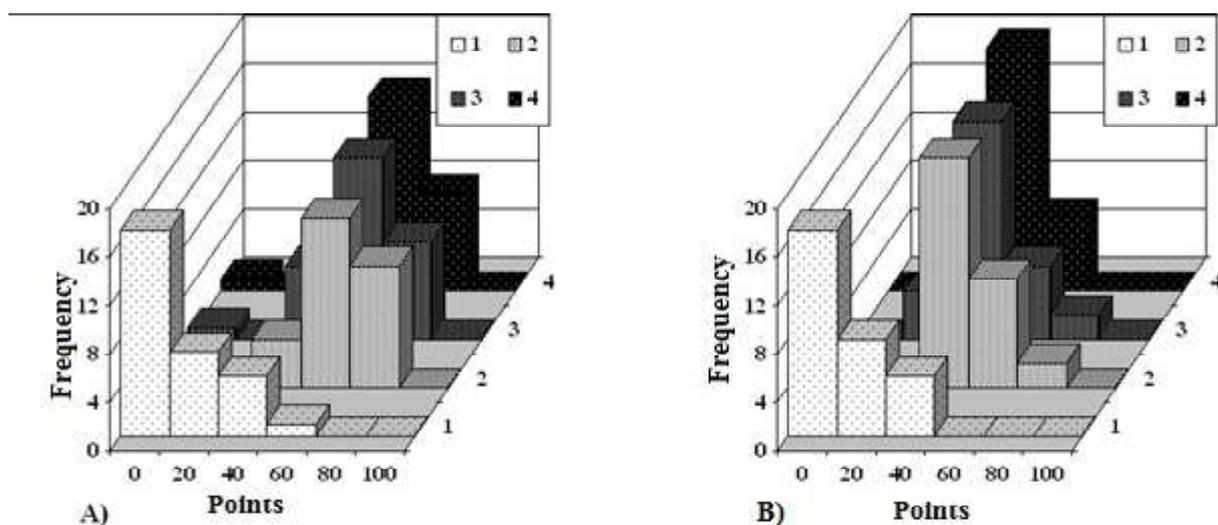
Indicator	Me (Q <sub>1</sub> - Q <sub>3</sub> ), (n=30)				p
	Before	3 months	6 months	12 months	
1. Dysphagia (three questions) (questions 1, 2, 3)	50 (44 - 67) <sup>#&amp;§</sup>	11 (0 - 11) <sup>*</sup>	11 (0 - 11) <sup>*</sup>	11 (0 - 11) <sup>*</sup>	<0.001
2. Restricting food intake (four questions) (question 4, 5, 6, 7)	54 (33 - 67) <sup>#&amp;§</sup>	21 (17 - 25) <sup>&amp;§</sup>	17 (8 - 17) <sup>##</sup>	17 (0 - 17) <sup>##</sup>	<0.001
3. Reflux (questions 8, 9)	0 (0 - 17) <sup>#&amp;§</sup>	33 (33 - 50) <sup>&amp;§</sup>	33 (33 - 50) <sup>##</sup>	33 (33 - 33) <sup>##</sup>	<0.001
4. Odynophagia (questions 10, 11)	67 (50 - 83) <sup>#&amp;§</sup>	17 (17 - 17) <sup>&amp;§</sup>	0 (0 - 17) <sup>##</sup>	0 (0 - 17) <sup>##</sup>	<0.001
5. Pain and discomfort in the stomach (questions 12, 13)	33 (33 - 33) <sup>#&amp;§</sup>	0 (0 - 17) <sup>*</sup>	0 (0 - 17) <sup>*</sup>	0 (0 - 17) <sup>*</sup>	<0.001
6. Anxiety and worry (questions 14, 15)	33 (33 - 50) <sup>#&amp;§</sup>	50 (33 - 50) <sup>&amp;§</sup>	17 (0 - 33) <sup>##</sup>	17 (0 - 33) <sup>##</sup>	<0.001
Problems with food to other people (question 16)	0 (0 - 0)	0 (0 - 33)	0 (0 - 0)	0 (0 - 0)	=0.06
Dry mouth (question 17)	33 (0 - 33) <sup>#&amp;§</sup>	0 (0 - 0) <sup>*</sup>	0 (0 - 0) <sup>*</sup>	0 (0 - 0) <sup>*</sup>	<0.001
Problems with a taste of food (question 18)	0 (0 - 0) <sup>#&amp;§</sup>	0 (0 - 33) <sup>&amp;§</sup>	0 (0 - 0) <sup>##</sup>	0 (0 - 0) <sup>##</sup>	<0.001
Feelings of physical unattractiveness (question 19)	33 (33 - 67) <sup>&amp;§</sup>	33 (33 - 33) <sup>§</sup>	33 (0 - 33) <sup>*</sup>	33 (0 - 33) <sup>##</sup>	<0.004
Complicated dipping of saliva (question 20)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	>0.99
Shortness of breath while swallowing (question 21)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	>0.99
Coughing (question 22)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	=0.90
Problems with the ability to speak (question 23)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	>0.99
Weight loss (question 24)	67 (33 - 67) <sup>&amp;§</sup>	67 (33 - 67) <sup>&amp;§</sup>	33 (0 - 33) <sup>##</sup>	33 (0 - 33) <sup>##</sup>	<0.001

of life of patients after esophagectomy. The results of the assessment of the quality of life in the dynamics based on the indicators of the presence of *specific esophageal-gastric symptoms* in patients whom were formed the end-to-side mechanical circulatory esophagogastric anastomosis (comparison group) are shown in Table 3.

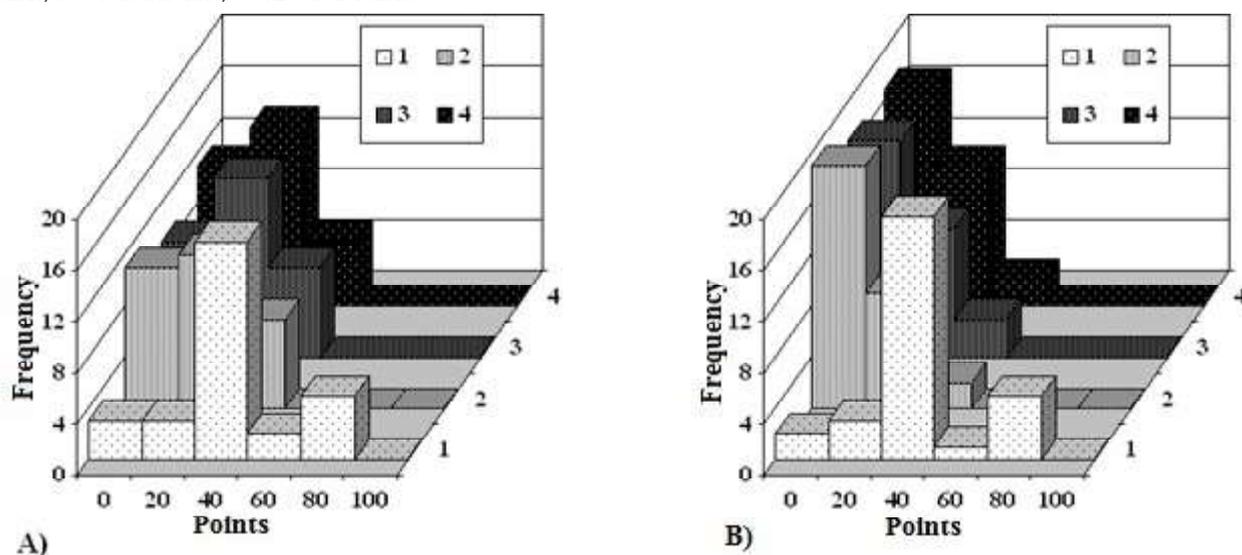
Analysis of data of *specific esophageal-gastric symptoms* of patients in the comparison group shows that during the 12 months of the observation there is a change in the severity of the symptom of *dysphagia* (p<0.001). The

most pronounced symptom of dysphagia was observed at the assessment stage prior to surgical treatment. On 3 month of the observation, it has significantly decreased (p<0.05) and continued its decline on 6 month of observation. On 12 month the assessment rate has not changed compared to 6 month of estimates (p>0.05) (see Table 3).

The evaluation of the symptom of *reflux* showed its lowest severity at the stage prior to surgical intervention. Starting from 3 month the assessment of this indicator



**Fig. 1.** Histograms of value distribution rate of reflux in the comparison group (A) and study group (B): 1 - before treatment, 2 - 3 months later, 3 - 6 months later, 4 - 12 months later.



**Fig. 2.** Histograms for the distribution of values of the pain and discomfort index in the stomach area in the comparison group (A) and the study group (B): 1 - before treatment, 2 - 3 months later, 3 - 6 months later, 4 - 12 months later.

has become significantly higher ( $p < 0.05$ ). It remained at the same high level for 6 and 12 month of estimates ( $p > 0.05$ ) (see Table 3).

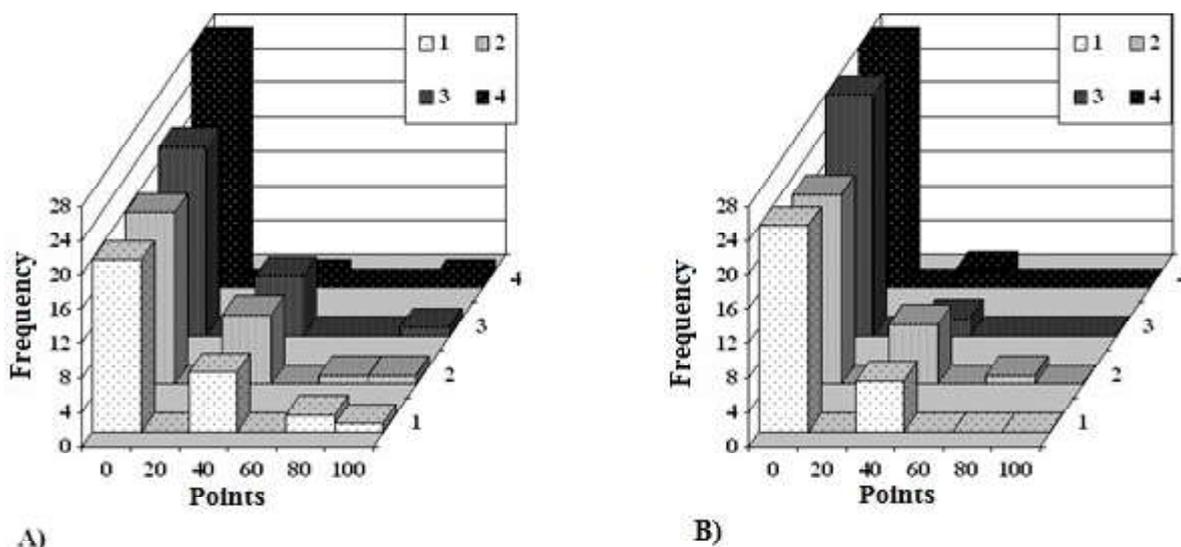
*Pain when swallowing* was also most pronounced in patients before surgery and began to decrease from 3 month of estimates ( $p < 0.05$ ). On 6 month the score shows an even lower value ( $p < 0.05$ ). However, on 12 month of the assessment remains constant and does not differ from the assessment on 6 month after surgical intervention ( $p > 0.05$ ) (see Table 3).

When evaluating *pain and discomfort* in the stomach area, the highest severity of the symptom was also observed at the stage prior to surgery and decreased from 3 month of estimates ( $p < 0.05$ ). In the subsequent assessment periods (6 and 12 month) no change was found (see Table 3).

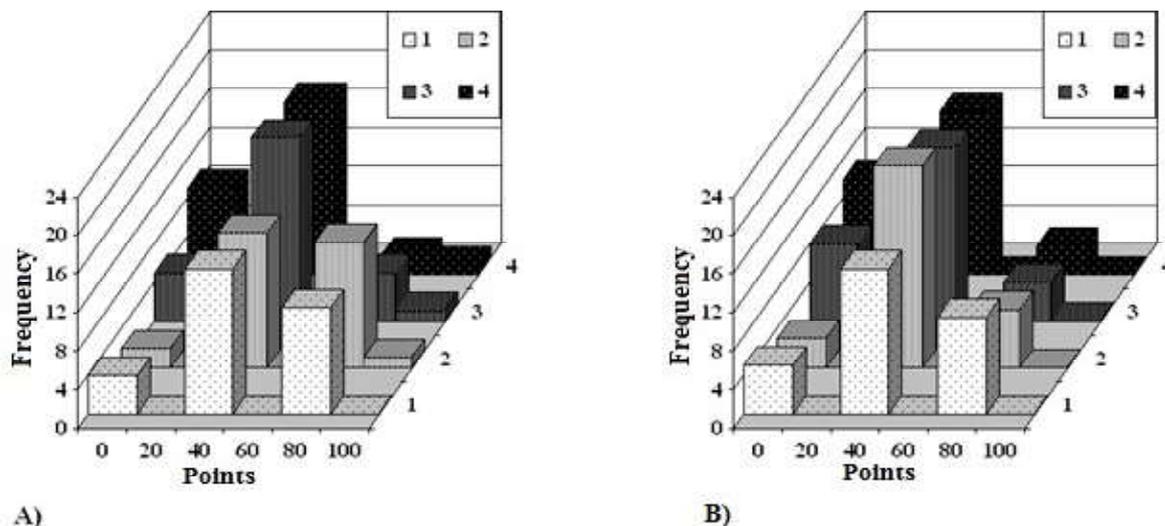
The results of the assessment of the quality of life in the dynamics of the indicators of the presence of *specific esophageal-gastric symptoms* in patients whom were formed invagination esophagogastric anastomosis (study group) are shown in Table 4.

Analysis of data from the EORTC QLQ-OG25 patient group in the study group indicated that the severity of the *dysphagia* symptom was the highest in the assessment stage prior to the surgical treatment. On 3 month of the observation rate decreased ( $p < 0.05$ ). On the 6 and 12 month of the assessment, the rate has not changed compared with 3 month of estimates ( $p > 0.05$ ) (see Table 4).

When comparing the *dysphagia* of the study group and the comparison group at the time before the surgery, and 3, 6 and 12 month after surgery, no statistically significant difference was found ( $p = 0.80$ ,  $p = 0.10$ ,  $p = 0.70$ ,  $p = 0.90$ ,



**Fig. 3.** Histograms of the distribution of values of the problems with food to other people in the comparison group (A) and study group (B): 1 - before treatment, 2 - 3 months later, 3 - 6 months later, 4 - 12 months later.



**Fig. 4.** Histogram of the distribution of the values of the physical unattractiveness in the comparison group (A) and the study group (B): 1 - before treatment, 2 - 3 months later, 3 - 6 months later, 4 - 12 months later.

respectively, according to the W-Wilcoxon criterion for dependent samples) (see Table 3, 4).

The evaluation of the symptom of *reflux* showed its lowest severity at the stage prior to surgical intervention. Starting from 3 month the assessment of this indicator has been significantly higher ( $p < 0.05$ ) and remained at the same level at 6 and 12 month of estimates ( $p > 0.05$ ) (see Table 4).

When comparing the reflux indexes of the study group and the comparison group at the time prior to the surgery, no statistically significant difference was detected ( $p = 0.90$ ). However, 3, 6 and 12 month after surgery, the reflux symptom in the study group was significantly lower in comparison with the comparison group ( $p = 0.05$ ,  $p < 0.05$ ,  $p < 0.05$ ) (see Fig. 1, Table 3, 4).

*Pain when swallowing* was also most pronounced in patients before surgery and began to decrease from 3

month of estimates ( $p < 0.05$ ). On 6 month the score shows an even lower value ( $p < 0.05$ ). However, on 12 month the assessment remains constant and does not differ from the assessment on 6 month after surgical intervention ( $p > 0.05$ ) (see Table 4).

When comparing pain when swallowing indices of the study group and the control group at the time before surgery, 3, 6 and 12 month after surgery, there was no statistically significant difference ( $p = 0.70$ ,  $p = 0.40$ ,  $p = 0.30$ ,  $p = 0.80$ ) (see Table 3, 4).

When evaluating *pain and discomfort* in the stomach area, the highest severity of the symptom was also observed at the stage prior to surgery and decreased from 3 month of estimates ( $p < 0.05$ ). In evaluation periods 3, 6 and 12 month there were no changes in the indicator (see Table 4).

Comparison of pain and discomfort in the stomach area of the study group and the control group at the time before surgery did not reveal a statistically significant difference ( $p=1.0$ ). However, 3, 6 month after surgery, the symptom of pain and discomfort in the stomach area in the study group was significantly lower in comparison with the control group ( $p=0.025$ ,  $p=0.033$ ). On 12 month of observation there is no difference between the assessment of patients and the control group ( $p=0.1$ ) (see Fig. 2, Table 3, 4).

Indicators of *nutritional problems with other people* in the study group did not differ during all assessment periods ( $p=0.06$ ) (see Table 4).

When comparing the indicator of the nutrition problem with other people in the study group and the comparison group at the time before the surgery, 3 and 12 month after the surgical intervention, no statistically significant difference was detected ( $p=0.20$ ,  $p=0.50$ ,  $p=1.0$ , respectively). However, 6 months after a surgical intervention, the indicator of the *nutrition problem with other people* in the study group was significantly lower than in the comparison group ( $p=0.04$ ) (see Fig. 3, Table 3 and 4), which may be due to higher level of postoperative complications from the side of esophago-gastroanastomosis in the comparison group.

Feeling of *physical unattractiveness* has changed little throughout the observation period. At the stage of assessment to surgery, the rate was significantly higher than 6 and 12 months grades ( $p<0.05$ ), however, did not differ from the 3 months of evaluation ( $p>0.05$ ). On 3 month the score is higher than 12 month ( $p<0.05$ ) (see Table 4).

When comparing the index of physical unattractiveness of the study group and the comparison group at the time before the surgery and on 6 and 12 month after surgical intervention, no statistically significant difference was detected ( $p=0.70$ ,  $p=0.30$ ,  $p=0.80$ ). However, 3 months after surgery, the physical unattractiveness score in the study group was significantly lower in comparison with the control group ( $p=0.04$ ) (see Fig. 4, Table 3, 4).

## Discussion

The study presents the results of assessing the quality of life of patients with esophageal cancer and cardioesophageal cancer before and after radical surgery in the annual dynamics and clarified effect of the variant of the formed esophagogastroanastomosis on the quality of life of these patients with the help of the EORTC-QLQ-C30 and QLQ-OG25 tools.

According to the results of the questionnaire EORTC QLQ-C30 V.3, functional scales were reduced in patients immediately after surgery and gradually increased during the 12 months of observation, regardless of the applied variant of the formation of esophagogastroanastomosis. The obtained data indicate a significant traumatic effect of surgical interventions in malignant diseases of the esophagus and cardio-esophageal transition, and that the formed groups that were compared were comparable in

terms of their general condition and oncology status. The assessment of quality of life on symptomatic scales shows the highest severity of symptoms before surgery and their gradual reduction to 12 month of follow up of patients, indicating the severity of general oncological symptoms in such patients. In this case, patients equally bear significant financial losses throughout the postoperative period of observation. Several authors [4, 8, 15, 17] emphasize significant disruption of most aspects of the quality of life, both in functional and symptomatic scales, during the first few months after surgery, regardless of the surgical technique used. On the positive dynamics of improvement of functional indicators (role, emotional, cognitive and social functions) according to our data and data of P. Lagergren et al. [15], should be expected on 6-12 month after surgery. In the short-term postoperative perspective, a series of messages [4, 8, 15, 17], confirmed by our data, improves the emotional state of patients. M. Scarpa et al. [18] believe that improving the emotional function of patients undergoing successful surgery may be due to the impression that they have experienced a nearly fatal experience, and P. Lagergren et al. [15] emphasize that the improvement of emotional function can be explained by the release of patients from depression that they experienced at the stage of announcement of the diagnosis.

According to the results of the questionnaire EORTC QLQ-OG25 we also analyzed the specific aspect of the quality of life of patients after esophagectomy. Our data demonstrate the advantages of a mechanical invagination method for the formation of anastomosis over a mechanical circular in reducing the frequency of the reflux symptom, pain and discomfort in the stomach, nutritional problems in presence of people, and a feeling of physical unattractiveness, thereby providing a better quality of life for patients after esophagectomy. The results of the quality of life assessment on the indicators of the presence of specific gastrointestinal symptoms suggest that the variant of the formation of esophagogastroanastomosis may affect the quality of life of patients with esophageal cancer and cardio-esophageal cancer. Such a conclusion is supported in the study of D. Dorcaratto et al. [9] who believe that the type of anastomosis and the type of reconstruction used to restore gastrointestinal tract continuity and its location can have a significant impact on the quality of life.

In general, it should be noted that the deterioration in some of the quality of life indicators in patients undergoing treatment of esophageal or stomach cancer is long-lasting. According to A. Schandl et al. [19] 10 years after the operation, compared with the control population, lower quality of life indicators is observed for the global health status, role and social functioning, with the preservation of a number of symptoms - reflux, nutritional difficulties, diarrhea and food intake. According to P. Lagergren et al. [15], estimates of physical function, global quality of life, shortness of breath, reflux, diarrhea, although improved during the first postoperative year, 3 years after the operation

did not return to baseline levels. T. Djarv et al. [8] and E.F. Courrech Staal et al. [5] indicate a greater number of problems with fatigue, diarrhea, loss of appetite, nausea and vomiting in patients 3 years after the operation compared with the control population. The long-term adverse effects of esophagectomy include a violation of the physical function, which may include either the respiratory system or the digestive tract [18]. Violations in the respiratory system are the result of both the actual thoracotomy and its complications. A number of authors associate persistent dyspnea with a decrease in the volume of lungs due to the presence of the intra-thorax stomach [15]. Disturbances in the digestive tract are due to functional complications and accelerated transit. Thus, diarrhea is associated with surgical vagotomy, and reflux with excision of the mechanism of the lower sphincter of the esophagus. In general, patients who survive for three years or more after esophagectomy can expect a satisfactory quality of life [15].

The availability of HRQoL data, as an integrative indicator of patient health, is extremely important for both the clinician and the patient. They help the physician and patient to make a joint decision on choosing an optimal treatment option [9], contributing to surgical decisions [17], providing information on the short- and long-term effects of surgical intervention [18]. At the same time, the recovery of indicators of global quality of life, physical and social functioning for 6 months after surgery can be predictive indicators of survival of patients [6]. An overview of existing prognostic models for esophageal and stomach cancer suggests that the overwhelming majority of them are aimed at predicting survival, none of them suggests both the benefits and the negative effects of certain types of treatment, and none of the studies predict HRQoL [23]. Today, there is an urgent need to develop such prognostic models that would not only potentially increase life

expectancy, but primarily focus on a personalized assessment of the possible negative effects of treatment and the impact of treatment on HRQoL in a patient. There is also a need to develop information guidance for patients about clinical expectations: short- and long-term effects of esophagectomy, which in general will determine their further quality of life associated with health. The basis for such development may be the data we received. In the future, research aimed at identifying predictors of short- and long-term decline in postoperative quality of life: the stage and localization of the tumor, concomitant diseases, the volume of surgical intervention, the nature of postoperative complications, age, sex, body weight, etc. are promising.

### Conclusions

1. It was established that the proximal resection of the stomach with resection of the esophagus, regardless of the method of formation of esophagogastric anastomosis, temporarily significantly impairs the quality of life of patients in the immediate postoperative period on the functional and symptomatic scales, which is associated with a high traumatic surgical intervention. In the annual perspective, most of the parameters of the quality of life, gradually improving, recover to preoperative level, or surpass it, demonstrating a satisfactory quality of life.

2. The improvement of a number of specific gastrointestinal symptoms, which was manifested by a decrease in the frequency of reflux symptoms, pain and discomfort in the stomach area, as well as the problems of eating before other people and a feeling of physical unattractiveness, provided a better quality of life for patients after esophagectomy and demonstrated better efficacy of our developed mechanical invagination method for the formation of esophagogastric anastomosis.

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## ЯКІСТЬ ЖИТТЯ ХВОРИХ НА РАК СТРАВОХОДУ ТА КАРДІОЕЗОФАГАЛЬНИЙ РАК

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Актуальність дослідження зумовлена агресивністю раку стравоходу та кардіоезофагального раку, низькою виживаністю хворих, необхідністю подальших розробок, направлених на поліпшення наслідків оперативного втручання, ефективність яких може бути оцінена при допомозі визначення якості життя таких хворих. Мета роботи - оцінити якість життя хворих на рак стравоходу та кардіоезофагальний рак після радикального оперативного втручання залежно від варіанту сформованого езофагогастроанастомозу на основі аналізу показників загального стану пацієнтів і вираженості стравохідно-шлункових симптомів на різних етапах спостереження. Анкетуванню підлягали 60 хворих на рак стравоходу та кардіоезофагальний рак після проксимальної резекції шлунку з резекцією стравоходу доступами Льюїса, або Осава-Гарлока. Хворі були поділені на дві групи: група дослідження становила 30 хворих, яким було сформовано розроблений і захищений патентом України механічний інвагінаційний езофагогастроанастомоз, група порівняння становила 30 хворих, яким було сформовано механічний циркулярний езофагогастроанастомоз кінцею в бік. Якість життя оцінена до оперативного втручання та на 3, 6 і 12 місяць після оперативного втручання. Для оцінки загального стану пацієнтів використовували опитувальник EORTC QLQ-C30 V.3, а для оцінки наявності специфічних стравохідно-шлункових симптомів - опитувальник EORTC QLQ-OG25. Статистична обробка даних проведена у пакеті EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan, 2017), графічний інтерфейс до R (The R Foundation for Statistical Computing, Vienna, Austria). Для аналізу динаміки показників використаний критерій Фрідмана для повторних вимірювань, парні порівняння проводили за критерієм Коновера. Для перевірки достовірності відмінності між залежними вибірками застосовували непараметричний W-критерій Вілкоксона. Встановлено, що загальний стан пацієнтів після оперативного втручання, оцінений за шкалами EORTC QLQ-C30 V.3, не залежав від способу формування езофагогастроанастомозу. Результати дослідження якості життя хворих після оперативного втручання з різними способами формування езофагогастроанастомозу за модулем EORTC QLQ-OG25 продемонстрували достовірно нижчу вираженість симптомів: рефлюксу, болю та дискомфорту в ділянці шлунку, проблем харчування перед іншими людьми та відчуття фізичної непривабливості у групі хворих, яким було застосовано формування механічного інвагінаційного езофагогастроанастомозу.

**Ключові слова:** якість життя, опитувальник EORTC QLQ-C30 V.3, опитувальник EORTC QLQ-OG25, рак стравоходу, кардіоезофагальний рак, проксимальна резекція шлунку з резекцією стравоходу, доступи Льюїса або Осава-Гарлока, езофагогастроанастомоз.

## КАЧЕСТВО ЖИЗНИ БОЛЬНЫХ РАКОМ ПИЩЕВОДА И КАРДИОЕЗОФАГАЛЬНЫМ РАКОМ

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Актуальность исследования обусловлена агрессивностью рака пищевода и кардиоэзофагального рака, низкой

выживаемостью больных, необходимостью дальнейших разработок, направленных на улучшение последствий оперативного вмешательства, эффективность которых может быть оценена при помощи определения качества жизни таких больных. Цель работы - оценить качество жизни больных раком пищевода и кардиоэзофагеальным раком после радикального оперативного вмешательства в зависимости от варианта сформированного эзофагогастроанастомоза на основании анализа показателей общего состояния пациентов и выраженности пищеводно-желудочных симптомов на разных этапах наблюдения. Анкетированию подлежали 60 больных раком пищевода и кардиоэзофагеальным раком после проксимальной резекции желудка с резекцией пищевода доступами Льюиса, или Осава-Гарлока. Больные были разделены на две группы: группа исследования составила 30 больных, которым был сформирован разработанный и защищенный патентом Украины механический инвагинационный эзофагогастроанастомоз, группа сравнения составила 30 больных, которым был сформирован механический циркулярный эзофагогастроанастомоз конец в бок. Качество жизни оценено до оперативного вмешательства и на 3, 6 и 12 месяц после оперативного вмешательства. Для оценки общего состояния пациентов использовали опросник EORTC QLQ-C30 V.3, а для оценки наличия специфических пищеводно-желудочных симптомов использовали опросник EORTC QLQ-OG25. Статистическая обработка данных проведена в пакете EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan, 2017), графический интерфейс R (The R Foundation for Statistical Computing, Vienna, Austria). Для анализа динамики показателей использован критерий Фридмана для повторных измерений, парные сравнения проводили по критерию Коновера. Для проверки достоверности различий между зависимыми выборками применяли непараметрический W-критерий Вилкоксона. Установлено, что общее состояние пациентов после оперативного вмешательства, оцененное по шкалам EORTC QLQ-C30 V.3, не зависело от способа формирования эзофагогастроанастомоза. Результаты исследования качества жизни больных после оперативного вмешательства с различными способами формирования эзофагогастроанастомоза по модулю EORTC QLQ-OG25 продемонстрировали достоверно более низкую выраженность симптомов: рефлюкса, боли и дискомфорта в области желудка, проблемам питания перед другими людьми и ощущения физической непривлекательности в группе больных, которым было применено формирование механического инвагинационного эзофагогастроанастомоза.

**Ключевые слова:** качество жизни, опросник EORTC QLQ-C30 V.3, опросник EORTC QLQ-OG25, рак пищевода, кардиоэзофагеальный рак, проксимальная резекция желудка с резекцией пищевода, доступы Льюиса или Осава-Гарлока, эзофагогастроанастомоз.

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