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ORIGINAL ARTICLE

Quality of life of gastric cancer patients after radical surgery depending on the status of the duodenal passage

O. M. Asipovich^{1,2}, I. B. Uvarov^{1,2™}, V. A. Porkhanov¹

□ uvarovivan@yandex.ru

ABSTRACT

Purpose of the study. To assess the impact of preservation of the duodenal passage on the quality of life (QOL) after total gastrectomy (TGE) in patients with gastric cancer (GC).

Patients and methods. The study included 55 patients with GC who underwent TGE: group I (n = 29) included patients with preservation of the duodenal passage (PDP) using the double tract reconstruction method; Group II (n = 26) included those with standard Roux-en-Y reconstruction. QOL was assessed using the EORTC QLQ-C30 questionnaire with the QLQ-STO22 module for GC patients.

Results. Changes in QOL in patients 3 months after TGE were expressed in a statistically significant decrease in scores of all functional scales (QL, PF, RF, EF, CF and SF), and an increase in the scores of symptom scales (FA, NV, PA, DY, SL, AL, CO, DI, FI), to the same extent for both groups. After 6 months, an increase in the scores of functional scales was noted; statistically significant differences between the groups were identified on the QL, RF, CF and SF scales in favor of the group with PDP. In the group with PDP, a more significant decrease in the level of most symptomatic scales was also noted. After 12 months, a statistically significant advantage remained on functional and symptomatic scales for patients in the group with PDP. Assessment of QOL using the scales of the QLQ-STO22 module showed similar trends: after a sharp increase in symptom values at 3 months after surgery, equally pronounced in both groups, there was a decrease at 6 months, more pronounced in the group with PDP. At 12 months postoperatively, the overall trend towards an advantage in the PDP group continued.

Conclusion. The dynamics of QOL recovery in patients with GC after surgical treatment depends on the status of the duodenal passage: in the group of patients with PDP, faster positive dynamics are observed on all scales of functioning and symptoms than in patients without duodenal passage. Preservation of duodenal passage during surgical treatment of GC has a positive effect on the dynamics of recovery of the QOL of patients with GC, providing a positive contribution to improving the results of antitumor treatment.

Keywords: gastric cancer, total gastrectomy, quality of life, duodenal passage

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For correspondence: Ivan B. Uvarov – Dr. Sci. (Med.), Associate Professor, Professor of the Department of Surgery No. 2 of the FPC and Teaching Staff, Kuban State Medical University, Krasnodar, Russian Federation; Head of the Department of Abdominal Oncology and X-ray Surgical Methods of Diagnosis and Treatment, Clinical Oncological Dispensary No. 1, Krasnodar, Russian Federation

Address: 4 Mitrofan Sedina str., Krasnodar 350063, Russian Federation Address: 146 Dimitrova St., Krasnodar, 350040, Russian Federation

E-mail: uvarovivan@yandex.ru

ORCID: https://orcid.org/0000-0002-2725-3281

SPIN: 6871-1440, AuthorID: 456706 ResearcherID: AAB-5295-2022 Scopus Author ID: 57188736991

Compliance with ethical standards: this research has been carried out in compliance with the ethical principles set forth by the World Medical Association Declaration of Helsinki, 1964, ed. 2013. The study was approved by the Committee on Ethics at the Kuban State Medical University (extract from the protocol of the meeting No. 107 dated 28/01/2022). Informed consents were received from all the participants of the study

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¹ Kuban State Medical University, Krasnodar, Russian Federation

² Regional Oncological Center No. 1, Krasnodar, Russian Federation

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3.1.6. Онкология, лучевая терапия

ОРИГИНАЛЬНАЯ СТАТЬЯ

Качество жизни больных раком желудка после радикального хирургического лечения в зависимости от статуса восстановления дуоденального пассажа

О. М. Асипович^{1, 2}, И. Б. Уваров^{1, 2™}, В. А. Порханов¹

□ uvarovivan@yandex.ru

РЕЗЮМЕ

Цель исследования. Оценка влияния на качество жизни (КЖ) сохранения дуоденального пассажа в хирургическом лечении больных раком желудка (РЖ).

Пациенты и методы. В исследование включены 55 больных РЖ, которым выполнена гастрэктомия (ГЭ): І группа (n = 29) — с сохранением дуоденального пассажа (СДП) методом реконструкции «двойной тракт»; ІІ группа (n = 26) — со стандартной реконструкцией по Ру. Оценка КЖ проводилось с помощью опросника EORTC QLQ-C30 с модулем для РЖ QLQ-STO22.

Результаты. Изменения КЖ у пациентов через 3 месяца после ГЭ выражались в статистически значимом снижении показателей всех функциональных шкал (QL, PF, RF, EF, CF и SF), и повышении значений шкал симптомов (FA, NV, PA, DY, SL, AP, CO, DI, FI), в одинаковой степени для обеих групп. Через 6 месяцев отмечено повышение значений функциональных шкал, статистически значимые различия между группами выявлены по шкалам QL, RF, CF и SF в пользу группы с СДП. В группе с СДП отмечено также более значительное снижение уровня большинства симптоматических шкал. Через 12 месяцев сохранилось статистически значимое преимущество пациентов группы с СДП по функциональным и симптоматическим шкалам. Оценка КЖ по шкалам модуля QLQ-STO22 показала аналогичные тенденции: после резкого роста значений симптомов в сроки 3 месяца после операции, одинаково выраженного в обеих группах, отмечалось их понижение к сроку 6 месяцев, более выраженное в группе с СДП. Через 12 месяцев после операции общая тенденция к преимуществу группы с СДП сохранялась.

Заключение. Динамика восстановления КЖ у больных РЖ после хирургического лечения зависит от статуса дуоденального пассажа: в группе пациентов с СДП отмечается более быстрая позитивная динамика по всем шкалам функционирования и симптомов, чем у пациентов без включения двенадцатиперстной кишки (ДПК). Сохранение дуоденального пассажа при хирургическом лечении РЖ положительно влияет на динамику восстановления КЖ пациентов после радикального хирургического лечения РЖ, обеспечивая позитивный вклад в улучшение результатов противоопухолевого лечения.

Ключевые слова: рак желудка, гастрэктомия, качество жизни, дуоденальный пассаж

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Для корреспонденции: Уваров Иван Борисович – д.м.н., доцент, профессор кафедры хирургии № 2 ФПК и ППС, ФГБОУ ВО «Кубанский государственный медицинский университет» Министерства здравоохранения Российской Федерации, г. Краснодар, Российская Федерация; заведующий отделением абдоминальной онкологии и рентгенхирургических методов диагностики и лечения, ГБУЗ «Клинический онкологический диспансер № 1» Министерства здравоохранения Краснодарского края, г. Краснодар, Российская Федерация

Адрес: 350063, Российская Федерация, г. Краснодар, ул. Митрофана Седина, д. 4 Адрес: 350040, Российская Федерация, г. Краснодар, ул. Димитрова, д. 146

E-mail: uvarovivan@yandex.ru

ORCID: https://orcid.org/0000-0002-2725-3281

SPIN: 6871-1440, AuthorID: 456706 ResearcherID: AAB-5295-2022 Scopus Author ID: 57188736991

Соблюдение этических стандартов: в работе соблюдались этические принципы, предъявляемые Хельсинкской декларацией Всемирной медицинской ассоциации (World Medical Association Declaration of Helsinki, 1964, ред. 2013). Исследование одобрено Независимым этическим комитетом ФГБОУ ВО «Кубанский государственный медицинский университет» Министерства здравоохранения Российской Федерации (протокол № 107 от 28.01.2022 года). Информированное согласие получено от всех участников исследования

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¹ ФГБОУ ВО «Кубанский государственный медицинский университет» Министерства здравоохранения Российской Федерации,

г. Краснодар, Российская Федерация

²ГБУЗ «Клинический онкологический диспансер № 1» Министерства здравоохранения Краснодарского края, г. Краснодар, Российская Федерация

INTRODUCTION

Quality of life (QOL) assessment is an important component for determining optimal therapy in both radical and palliative care programs for patients with cancer, including gastric cancer [1-5]. It is important that QOL is a patient-oriented variable reflecting the functional impact of the disease and its treatment process on the patient in the system of his goals, expectations, standards and problems [6-8]. At the same time, as emphasized by B. Alkhaffaf et al. (2020), the patient's priorities regarding treatment outcomes may differ and be broader than traditional oncological criteria and priorities of oncologists [9]. At the present stage, there is an increasing demand for functional treatment outcomes, including surgical ones, both from oncologists and patients. This determines the search for functionally optimal methods of reconstructing the digestive tract in the surgical treatment of GC, one of the options of which is the restoration of the duodenal passage [10-13]. The importance of QOL assessment in oncology is outlined by the randomized clinical trial R. van Amelsfoort et al. (2022), which showed that a decrease in QOL was associated with worse event-free and overall survival in patients with GC [14]. In this regard, the introduction of new or improved treatment methods into clinical practice should be accompanied by a thorough and objective study of their effects on QOL.

The purpose of the study was to evaluate the effect on quality of life (QOL) of maintaining the duodenal passage in the surgical treatment of patients with gastric cancer (GC).

PATIENTS AND METHODS

The study included 55 patients with histologically verified gastric cancer who underwent gastrectomy (GE) surgery. The study was prospective in nature, patients were randomized into 2 groups according to the study design: group I (29 patients) included patients with GE performed with restoration of the duodenal passage using the "double tract" reconstruction method (DT); II group was presented by 26 patients with GE performed with standard reconstruction according to Roux-en-Y (Fig. 1). The examination was conducted in 3, 6, and 12 months after surgery. The study was performed on the basis of the Clinical Oncological Dispensary in Krasnodar in

the period from 2020 to 2024. The work followed the ethical principles set forth in the Helsinki Declaration of the World Medical Association (1964, ed. 2013), the study was approved by the Independent Ethics Committee of the Kuban State Medical University (Protocol No. 107 dated 01/28/2022). Informed consent was obtained from all participants in the study. Inclusion criteria: age over 18, GE surgery, obtained written informed consent to participate. Exclusion criteria: stage IV of GC cancer (with distant metastases), presence of decompensated chronic and acute concomitant diseases, refusal to participate. There were no statistically significant differences between the groups in terms of the main clinical characteristics (Table 1).

Surgical treatment was performed in accordance with the clinical recommendations of the Ministry of Health of the Russian Federation for the diagnosis and treatment of patients with gastric cancer. In patients with stage IB and higher, diagnostic laparoscopy with cytological examination of peritoneal flushes for the presence of free tumor cells was performed before planning treatment. Patients with positive (Cyt+) flushes were classified as having M1 and excluded from the study. Perioperative chemotherapy, according to the "Clinical guidelines for the treatment of gastric cancer", was performed in 37 patients with tumors of stages II and III (37/44. 84 % of the total number, the differences between the groups are statistically unreliable). The preferred regimen was the FLOT regimen:

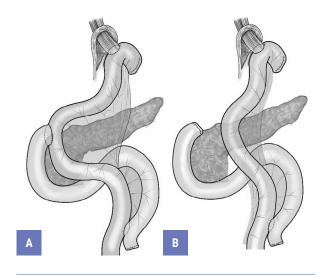


Fig. 1. The scheme of the operation: A-GE with the reconstruction of the double tract (DT); B-GE with the Roux-en-Y reconstruction

4 courses preoperatively, 4-6 weeks after surgery, 4-8 weeks after surgery - 4 more courses in the FLOT regimen, regardless of the therapeutic pathomorphosis of the tumor. In somatically burdened patients, FOLFOX (4 + 4 cycles), XELOX (3 + 3 cycles), cisplatin and fluorouracil (3 + 3 cycles) combinations were used with the onset of the postoperative stage 4-6 weeks after surgery. There were no statistically significant differences in access, volume of organ removal, and volume of lymph dissection in both groups. Laparotomy access was used in 27 (93.1 %) patients of group I and in 23 (88.5 %) of group II (p = 0.550). In 2 cases (6.9 %) in group I and 3 (11.5 %) in group II, abdominalmediastinal access was used to resect the abdominal esophagus and form an esophageal-intestinal anastomosis in the lower mediastinum. The volume of lymph dissection corresponded to the volume of D2: lymph nodes of groups No. 1-7, 8a, 9, 10, 11p, 11d and 12a were removed, with the spread above the cardia, lymph dissection expanded at the expense of groups No. 19, 20, 110 and No. 111 (according to the classification of the Japanese Association for the Study of Gastric Cancer). There were no deaths after surgery in both groups. The length of hospital stay was similar for patients of both groups: 7.4 ± 1.2 days for GE with DT reconstruction vs 7.6 ± 1.9 days for GE according to Roux-en-Y (p = 0.632). Postoperative complications were noted in 2 patients of group I and 2 in group II. In group II, a surgical complication was registered, which led to re-operation (perforation of the stump of the loop). In other cases, the development of pneumonia was diagnosed, and in 2 of them, pneumonia had a viral etiology (COVID-19).

We used a Quality of Life Questionnairy – Core 30, EORTC QLQ-C30 to assess the quality of life [15, 16], which includes 30 questions and consists of multiposition scales and individual indicators. The estimated indicators include: 1) Global health/quality of life scale (quality of life, QOL); 2) five functional scales – physical functioning (PF), role function-

Table 1. Characteristics of operated patients who underwent GE with DT reconstruction (group I) and Roux-en-Y (group II)			
Parameter	I group (n = 29)	II group (<i>n</i> = 26)	р
Age, years	61.21 (9.42)	57.4 (11.4)	0.191
Body mass, kg; ave. (SD)	71.0 (11.1)	74.4 (17.6)	0.244
BMI, ave. (SD)	24.3 (3.61)	26.2 (4.8)	0.464
Sex, n (%)			
М	18 (62.1)	16 (61.4)	0.968
F	11 (37.9)	10 (38.5)	
TNM staging, n (%)			
IA	3 (10.3)	4 (15.3)	0.978
IB	2 (6.9)	2 (7.7)	
IIA	4 (13.8)	3 (11.5)	
IIB	3 (10.3)	3 (11.5)	
IIIA	9 (31.0)	6 (23.1)	
IIIB	4 (13.8)	4 (15.4)	
IIIC	4 (13.8)	4 (15.4)	
Tumor localization, n (%)			
Cardia, fundus	8 (27.6)	5 (19.2)	0.685
Body	17 (58.6)	16 (61.5)	
Antrum	1 (3.4)	1 (3.8)	
A lesion that spread beyond one location	3 (10.3)	4 (15.3)	

ing (RF), emotional functioning (EF), cognitive functioning (CF) and social functioning (SF) functioning; 3) three scales of symptoms – fatigue (FA), nausea and vomiting (NV), pain (PA); 4) six separate items dyspnea (dyspnea, DY), sleep disorder (SL), loss of appetite (AP), constipation (CO), diarrhea (DI), financial difficulties (FI). In addition to the main questionnaire, the QLQ-STO22 module was also used, a validated QOL assessment tool specific to patients with GC [17], consisting of 22 items and mainly focused on symptoms specific to GC: pain, dysphagia, reflux and early satiety, as well as addressing emotional problems (including body image changes, weight loss and the patient's thoughts about his illness). The scale scores were calculated based on the official EORTC QLQ-C30 Scoring Manual [16]. As a result of the calculation procedure, all scales and measures for individual items ranged from 0 to 100 points.

Statistical analysis

The statistical analysis was carried out using the following methods: analysis of four-field and multipole arbitrary conjugacy tables using the Pearson chi-square (χ^2) criterion, the Kruskal-Wallis H-test, the t-test for independent samples, and the t-test for paired samples. The threshold criterion for statistical significance is p < 0.05. For statistical analysis, the IBM® SPSS Statistics 23.0 software package for statistical data processing for Windows (IBM, USA) was used.

STUDY RESULTS AND DISCUSSION

Changes in QOL parameters in patients after GE in the early stages after surgery (3 months) were expressed in a statistically significant decrease in all six functional scales (QL, PF, RF, EF, CF, and SF), and an increase in the values of the symptom scales (FA, NV, PA) and individual questionnaire items (DY, SL, AP, CO, DI, FI). These changes affected patients of both groups to the same extent, and there were no statistically significant differences between them in any of the indicators during this period (Fig. 2).

By the time of 6 months after surgery, the QOL parameters were transformed towards their improvement, with an increase in the values of all functional scales, statistically significant differences were noted between the groups on the functional scales QL (p < 0.001), RF (p = 0.028), CF (p = 0.009),

SF (p < 0.001), in In favor of the group with PDP, there was no statistically significant difference on the PF and EF scales. In the group of patients with PDP, there was also a more pronounced decrease in the values of the symptomatic scales compared to the Roux-en-Y group: FA (p = 0.001), NV (p = 0.003), PA (p = 0.010), DY (p = 0.001), SL (p < 0.001), CO (p = 0.001), DI (p = 0.004), FI (p < 0.001), the difference was statistically insignificant only in the symptom of loss of appetite (AL) (p = 0.092) (Fig. 3).

When evaluated after 12 months in both groups, the indicators on the scales of the EORTC QLQ-C30 questionnaire did not change significantly, and the statistically significant advantage of patients with PDP remained in such parameters as the functional scales QL (p < 0.001), PF (p < 0.001), RF (p < 0.001), EF (p < 0.001), CF (p < 0.001), SF (p < 0.001), symptomatic scales FA (p < 0.001), NV (p < 0.001), PA (p < 0.001), DY (p < 0.001), SL (p < 0.001), CO (p = 0.002), DI (p = 0.010). There was no statistically significant difference in the symptoms of AL and the FI issue (Fig. 4).

The assessment of QOL dynamics on the scales of the QLQ-STO22 module showed similar trends.

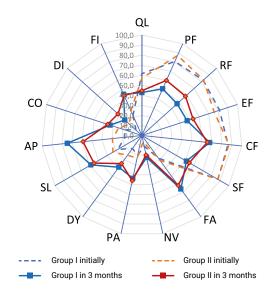


Fig. 2. Dynamics of quality of life according to the scales of the EORTC QLQ-C30 questionnaire in patients after GE, depending on the method of reconstruction 3 months after surgery. Group I – with preservation of the duodenal passage, group II – with reconstruction according to Roux-en- Y. QL – global state of health / quality of life; PF – physical functioning; RF – role functioning; EF – emotional functioning; CF – cognitive functioning; SF – social functioning; FA – fatigue; NV – nausea and vomiting; PA – pain; DY – dyspnea; SL – sleep disorders; AL – appetite loss; CO – constipation; DI – diarrhea; FI – financial difficulties

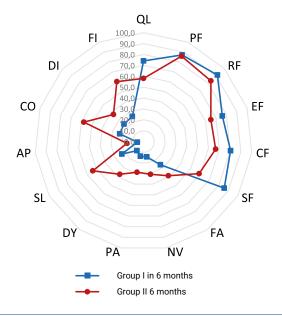


Fig. 3. Dynamics of quality of life according to the scales of the EORTC QLQ-C30 questionary in patients after GE, depending on the method of reconstruction 6 months after surgery. Group I – with preservation of the duodenal passage, group II – with reconstruction according to Roux-en- Y. QL – global state of health / quality of life; PF – physical functioning; RF – role functioning; EF – emotional functioning; CF – cognitive functioning; SF – social functioning; FA – fatigue; NV – nausea and vomiting; PA – pain; DY – dyspnea; SL – sleep disorders; AL – appetite loss; CO – constipation; DI – diarrhea; FI – financial difficulties

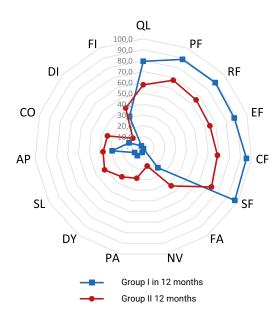


Fig. 4. Dynamics of quality of life according to the scales of the EORTC QLQ-C30 questionnaire in patients after GE, depending on the method of reconstruction 12 months after surgery. Group I – with preservation of the duodenal passage, group II – with reconstruction according to Roux-en- Y. QL – global state of health / quality of life; PF – physical functioning; RF – role functioning; EF – emotional functioning; CF – cognitive functioning; SF – social functioning; FA – fatigue; NV – nausea and vomiting; PA – pain; DY – dyspnea; SL – sleep disorders; AL –appetite loss; CO – constipation; DI – diarrhea; FI – financial difficulties

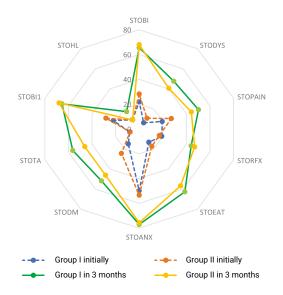


Fig. 5. Dynamics of QL values according to the scales of the QLQ-ST022 module in patients after GE, depending on the method of reconstruction 3 months after surgery. Group I – with preservation of the duodenal passage, group II – with reconstruction according to Roux-en-Y. STOBI – change in appearance; STODYS – dysphagia; STOPAIN – pain; STORFX– reflux symptoms; STOEAT – dietary restrictions; STOANX – anxiety; STODM– dry mouth; STOTA– taste change; STOHL – hair loss

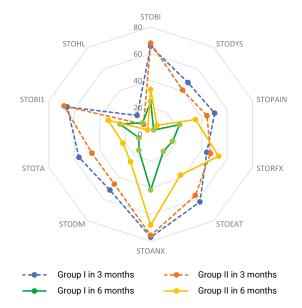


Fig. 6. Dynamics of QL values according to the scales of the QLQ-STO22 module in patients after GE, depending on the method of reconstruction 6 months after surgery. Group I – with preservation of the duodenal passage, group II – with reconstruction according to Roux-en- Y. STOBI – change in appearance; STODYS – dysphagia; STOPAIN – pain; STORFX– reflux symptoms; STOEAT – dietary restrictions; STOANX – anxiety; STODM– dry mouth; STOTA– taste change; STOHL – hair loss

After a sharp increase in the scales of symptoms within 3 months after surgery, which was equally pronounced in both groups of patients (Fig. 5), there was a decrease in the severity of symptoms by the time of 6 months, and this decrease was more pronounced in the group of patients after GE with PDP.

Statistically significant differences between the groups were noted on the scales of STODYS (p = 0.007), STOPAIN (p = 0.038), STORFX (p < 0.001), STOEAT (p < 0.001), STOANX (p < 0.001), STODM (p = 0.045), STOTA (p = 0.004). The differences were unreliable on the scales of STABI (p = 0.135) and STAHL (p = 0.149) (Fig. 6).

12 months after surgery, the general trend towards the advantage of the duodenal passage restoration group persisted. Statistically significant differences between the groups were noted on the scales of STO-DYS (p=0.007), STOPAIN (p=0.038), STORFX,000 STOEAT (p<0.001), STOANX (p<0.001), STODM (p=0.045), STOTA (p=0.004). The differences were not significant on the STOBI (p=0.135) and STOHL (p=0.149) scales. The differences on the STOBI scale reached the limits of statistical significance (p<0.001), and the statistically significant advantage of the PDP group remained in terms of STODYS, STOPAIN, STORFX, STOEAT, STOANX, and STOTA. The differences in symptoms of STODM and STOHL were not significant (Fig. 7).

CONCLUSION

The dynamics of quality of life on the EORTC QLQ-C30 scale with the STO22 module in patients with GC in the early stages after surgery (3 months) is characterized by a sharp decrease in total QOL and all scales of functioning and an increase in values on the scales of symptoms, later (6 and 12 months after surgery), the QOL parameters transform towards their improvements.

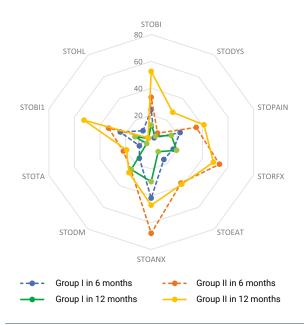


Fig. 7. Dynamics of QL values according to the scales of the QLQ-ST022 module in patients after GE, depending on the method of reconstruction 12 months after surgery. Group I – with preservation of the duodenal passage, group II – with reconstruction according to Roux-en- Y. STOBI – change in appearance; STODYS – dysphagia; STOPAIN – pain; STORFX– reflux symptoms; STOEAT – dietary restrictions; STOANX – anxiety; STODM – dry mouth; STOTA – taste change; STOHL – hair loss

The dynamics of recovery of QOL parameters in patients with GC after surgical treatment depends on the status of the duodenal passage: in the group of patients with duodenal passage preservation, there is a faster positive dynamic of recovery of indicators on the scales of functioning and reduction of symptomatic scales than in patients without duodenal passage. Thus, the preservation of the duodenal passage during surgical treatment of GC has a positive effect on the dynamics of restoring the quality of life of patients, providing a positive contribution to the quality and results of antitumor treatment.

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Information about authors:

Olesia M. Asipovich – PhD student of the Department of Oncology with a course in thoracic Surgery of the FPC and Teaching Staff, Kuban State Medical University, Krasnodar, Russian Federation; oncologist at the Department of Antitumor Drug Therapy No. 2 of the Clinical Oncology Dispensary No. 1, Krasnodar, Russian Federation

ORCID: https://orcid.org/0000-0001-9278-6335

Ivan B. Uvarov 🖂 – Dr. Sci. (Med.), Associate Professor, Professor of the Department of Surgery No. 2 of the FPC and Teaching Staff, Kuban State Medical University, Krasnodar, Russian Federation; Head of the Department of Abdominal Oncology and X-ray Surgical Methods of Diagnosis and Treatment, Clinical Oncological Dispensary No. 1, Krasnodar, Russian Federation

ORCID: https://orcid.org/0000-0002-2725-3281, SPIN: 6871-1440, AuthorID: 456706, ResearcherID: AAB-5295-2022, Scopus Author ID: 57188736991

Vladimir A. Porkhanov – Academician of the Russian Academy of Sciences, Dr. Sci. (Med.), Professor, Head of the Department of Oncology with a course in Thoracic Surgery and Faculty of Surgery, Kuban State Medical University, Krasnodar, Russian Federation ORCID: https://orcid.org/0000-0003-0572-1395, SPIN: 2446-5933, AuthorID: 682896

Асипович О. М., Уваров И. Б.[⊠], Порханов В. А. Качество жизни больных раком желудка после радикального хирургического лечения в зависимости от статуса восстановления дуоденального пассажа

Contribution of the authors:

Asipovich O. M. - performed development of the research design, data collection, analysis and interpretation, writing the draft;

Uvarov I. B. – performed development of the research design, analysis of the obtained data, writing the draft, critical revision with the introduction of valuable intellectual content;

Porkhanov V. A. – performed development of the research design, critical revision with the introduction of valuable intellectual content, final approval of the published version of the manuscript.