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POSTOPERATIVE ANASTOMOTIC COMPLICATIONS IN PATIENTS WITH MALIGNANT TUMORS OF THE ESOPHAGUS AND ESOPHAGEAL GASTRIC JUNCTION CANCER

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Formation of esophagogastric anastomosis after esophagectomy, despite apparent progress, is still accompanied by the development of complications associated with anastomosis. However, information about the impact of the method of forming esophagogastric anastomosis on the effects after the esophagectomy remains controversial. The aim of the study – to provide a comparative characteristic of postoperative complications in patients after esophagectomy, depending on the method of forming the mechanical esophagogastric anastomosis. The study included 30 patients who were formed by developed and protected by the Ukrainian patents invagination mechanical esophagogastric anastomosis (study group) and 30 patients who had formed circular mechanical esophagogastric anastomosis end-to-side (comparison group) after esophagectomy. Evaluated the rate of anastomotic leakage, the frequency of benign strictures, the frequency and severity of reflux esophagitis. In the dynamics all patients performed esophagogastroduodenoscopy, the severity of the reflux esophagitis was evaluated according to the modified Los Angeles classification. Statistical analysis of data was carried out using the statistical analysis package EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), Graphic interface to R (The R Foundation for Statistical Computing, Vienna, Austria). In the conditions of the formation of invagination mechanical esophagogastric anastomosis, the results revealed a statistically significant reduction in benign strictures ($p=0,047$) (17% (95% CI 5,4% – 32,6%), vs 43% (95% CI 25,7% – 61,9%), $RF=0,4$ (95% CI 0,2 – 0,9), as well as the frequency of postreaction reflux esophagitis (43% vs 68%; $p=0,02$) in comparison with the circular mechanical esophagogastric anastomosis end-to-side. However, there were no significant differences between the two groups regarding the anastomotic leakage (0% vs 7%, $p=0,49$). It should be noted that in the conditions of the formation of invagination mechanical esophagogastric anastomosis cases of its leakage were not revealed. The method of formation of the invagination mechanical esophagogastric anastomosis contributes to the reduction of the frequency of benign strictures of anastomosis and reflux esophagitis, anastomotic leakage was not observed.

Keywords: mechanical anastomosis, invagination, circulatory, anastomotic leakage, benign stricture, reflux esophagitis.

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Esophageal cancer, being a multifaceted and complex disease, which puts increasing social and financial burdens on global health systems [14], is marked by aggressiveness [9], low survival rate of patients [7, 22], high mortality and postoperative complications after the esophagectomy [8] and requires further development aimed at improving the consequences of operational intervention [8].

The standard of treating resectable esophageal cancer and some benign illnesses of the esophagus is neoadjuvant chemotherapy or chemoradiotherapy with an open, transthoracic esophagectomy [14]. The success of esophagectomy, besides the experience of a surgeon [1], is largely determined by the reliability of the created esophagogastric anastomosis [12]. Despite the presence of a large number of variants of esophagogastric anastomosis in the location, the way of formation and the peculiarities of the technique of execution, the search for "ideal" esophagogastric anastomosis continues to this day. Almost all known methods of anastomosis technique have their specialized advantages and disadvantages, and such important major complications after esophagectomy as the anastomotic leakage, the formation of benign strictures and gastroesophageal reflux disease can endanger the quality of life of patients and even be directly hazardous to life [15]. Scientific discussions focus on questions about the observed contribution of each method to the frequency of the above complications and the results of at least 3-month mortality. Creation of functionally complete anastomosis with a minimal amount of postoperative complications by this time remains one of the most important issues of esophageal surgery [3]. According to Law D. E. [11], the key to success is the development of new methods aimed at improving the quality of intrathoracic anastomosis after esophagectomy, and clinical studies to compare the different ways of forming EGA in terms of reducing the level of development of late complications from the anastomosis [12].

An analysis of the literature from the above-mentioned problems suggests that most surgeons around the world use mechanical techniques to form a thoracic anastomosis [1, 12, 14]. The development and implementation of surgical suturing devices in the clinical practice has become an important contribution to esophageal surgery, as the time for their implementation was reduced, the accuracy of the crosslinked tissue, aseptic, durability and tightness of the seam, the reliability of the formation of the esophagointestinal and gastroesophageal anastomoses was increased. All this greatly improved the results of esophagoectomy and esophagoplasty [1]. Due to the introduction of a mechanical (staple) method for the formation of esophagogastric anastomosis, the frequency of anastomotic leakage has decreased

compared to the manual method of formation. However, the mechanical (staple) method of forming the esophagogastric anastomosis end-to-back increases the risk of the formation of anastomotic benign strictures [10]. Consequently, along with convincing advantages, the use of stapler devices somewhat impairs the functional results of operations due to the high level of development of late complications from anastomoses: inflammatory complications (anastomosisitis, reflux esophagitis) and benign strictures [7, 10]. We did not find any studies to compare different ways of forming mechanical anastomosis.

The purpose of the study was to provide comparative description of postoperative complications associated with anastomosis in patients after esophagectomy depending on the method of forming a mechanical esophagogastric anastomosis.

Table 1

Clinical and demographic profile of patients

Characteristic	Groups				Total, n=60		p
	research, n=30		comparison, n=30				
	abs.	%	abs.	%	abs.	%	
Age							
41 – 50	4	13	5	16	9	15	0,19
51 – 60	12	40	11	36	23	38	
61 – 70	14	46	10	33	24	40	
more than 70	0	–	4	13	4	7	
Sex							
Female	5	17	3	10	8	13	0,45
Male	25	83	27	90	52	87	
Histologic type of tumors							
Adenocarcinoma	15	50	15	50	30	50	>0,99
Squamous cell carcinoma	15	50	15	50	30	50	
Localization							
Middle third of the esophagus	13	43	12	40	25	42	0,89
lower third of the esophagus	2	7	3	10	5	8	
Esophagogastric junction	15	50	15	50	30	50	
Distribution of patients according to Siewert`s classification							
Type I	2	12	3	17	5	14	0,95
Type II	15	88	15	83	30	86	
Type III	0	–	0	–	0	–	
Distribution of patients by TNM classification							
T1	0	–	0	–	0	–	0,54
T2	1	3	2	7	3	5	
T3	14	47	17	57	31	52	
T4	15	50	11	37	26	43	
N0	14	47	14	47	28	47	0,91
N1	12	40	12	40	24	40	
N2	2	7	3	10	5	8	
N3	2	7	1	3	3	5	>0,99
M0	28	93	28	93	56	93	
M1	2	7	2	7	4	7	
Stage of the disease							
I st. (IA, IB)	–	–	1	3	1	2	0,95
II st. (IIA, IIB)	12	40	10	33	22	37	
III st. (IIIA, IIIB, IIIC)	16	53	17	57	33	55	
IV st.	2	7	2	7	4	6	
Access options							
Ivor Lewis	14	47	15	50	29	48	0,8
Osawa-Garlock	16	53	15	50	31	52	
Chemoradiotherapy	15	50	15	50	30	50	>0,99
Chemotherapy	15	50	15	50	30	50	
Comorbidity							
CHD. Angina pectoris II-III FC. HF IIA–B st.	5	17	7	23	12	20,0	>0,05
CHD. Postinfarction cardiosclerosis. HF IIA–B st.	4	13	3	10	7	12	
CHD. Atherosclerotic cardiosclerosis. HF IIA–B st.	13	43	15	50	28	47	
CHD. Extrasystolic arrhythmia and atrial fibrillation. HF IIA–B st.	7	23	5	17	12	20	
Arterial hypertension II–III st.	24	80	22	73	46	77	
COPD Respiratory Insufficiency I–II st.	19	63	18	60	37	62	

Materials and methods. The study included 60 patients operated in Shalimov`s National Institute of Surgery and Transplantology with regard to malignant tumors of the esophagus and esophagogastric junction, which have undergone radical surgical intervention (Proximal gastric resection with esophagectomy by Ivor Lewis and Osawa-Garlock accesses). The diagnosis of cancer has been verified morphologically before surgery. On the basis of analysis of medical cards and protocols of surgical procedures, results of endoscopic and histological examination, information on the characteristics of tumors, surgical interventions and complications are collected.

The study included 30 patients who were formed by developed and protected by the Ukrainian patents [4] and implemented in a clinical practice by a team of employees of Shalimov`s National Institute of Surgery and Transplantology invagination mechanical esophagogastric anastomosis (IM EGA) [4]. The comparison group also included 30 patients who developed end-to-side circular mechanical esophagogastric anastomosis after the esophagectomy (CM EGA). The oncology process was exposed using the international classification of malignant tumors "TNM" 7 edition for malignant tumors of the esophagus and esophagogastric junction.

We have analyzed the clinical and demographic profile of the patients being studied, since in the scientific literature from time to time there are publications about the risk factors of complications after esophagectomys, both in general [13], and related directly to anastomosis in order to determine the comparability of the studied groups (table 1).

Since we wanted to detect anastomosis-related complications that could potentially affect the postoperative period in a clinically meaningful way, we only evaluated the incidence of esophagogastric anastomosis leakage, the frequency of benign strictures, the frequency and severity of reflux esophagitis. The fact of esophagogastric anastomosis leakage was fixed by X-ray examination, esophagogastric duodenoscopy (EGDS) and clinical manifestations. EGDS is performed for all patients in the dynamics of 3, 6 and 12 months of observation. Endoscopic examination of the presence of postoperative benign strictures of esophagogastric anastomosis and endoscopic manifestations of reflux esophagitis was performed by video gastroscope Olympus GIF-H180. In dubious cases of reflux esophagitis diagnostics, virtual chromoscopy NBI was used. The endoscopic severity of reflux esophagitis was evaluated according to the modified Los Angeles classification. The study was conducted in compliance with the principles of bioethics. *Data Processing.* Statistical analysis of data was carried out using the statistical analysis package EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), Graphic interface to R (The R Foundation for Statistical Computing, Vienna, Austria). To test the distribution of indicators for normality, the criterion of Shapiro-Wilk was used. To analyze the differences between groups of quantitative (and rank characteristics), the Mann-Whitney criterion was used. For the analysis of the differences in qualitative characteristics, the χ^2 criterion or Fisher's exact criterion is used for tables 2x2. To analyze the dynamics of the indicators, Friedman's criterion was used for repeated measurements; pair comparisons were conducted according to the Conover criterion. To analyze the dynamics of complications, we used the method of constructing survival curves (Kaplan-Meier survival analysis) [6].

Table 2

Clinical and laboratory profile of patients

Characteristic	Groups		p
	research, n=30	comparison, n=30	
BMI	23,0 (22,2–24,9)	21,8 (19,6–24,7)	0,20
Total protein g/l	65,2 (62,9–74,1)	67,0 (64,4–70,3)	0,94
Albumin g/l	39,6 (37,6–42,6)	39,4 (37,6–41,6)	0,34
Operation time	4,3 (4,2–5,2)	4,4 (4,2–5,3)	0,38

Notes: Median Me value and Interquartile swing (QI-QIII) are presented.

Results of the study and their discussion. A detailed analysis of patients' clinical and demographic, clinical and laboratory profile (table 1, 2) was conducted with one purpose - to achieve the maximum objectivity and comparability of estimated post-resection results associated with anastomosis, which is achieved under the condition of homogeneity of the comparable groups of patients at risk factors. The etiology of the development of anastomotic leakage and the formation of benign stricture is due, according to the literature, by many factors. Thus, the formation of strictures is associated with excessive effects of gastric acid, subclinical leakage, pressure levels and local anastomosis ischemia [15]. The factors contributing to the leakage of anastomosis include the personality factors of the patient [4, 14]; technical factors [4, 14] and postoperative factors [19]. Since most of the above factors were taken into account and

no reliable differences were found between the comparable groups of patients, we obtained a statistically well-founded argument in favor of the fact that the differences between the groups for the complications associated with anastomosis will be conditioned solely with the used methods of formation of esophagogastric anastomosis.

Results of the reflux esophagitis manifestation in the dynamics are shown in table 3.

Table 3

Endoscopic manifestations of reflux esophagitis

Severity of reflux esophagitis	Research group, abs. (%), (n=30)				Comparison group, abs. (%), (n=30)				P
	Absent	LA-A	LA-B	LA-C	Absent	LA-A	LA-B	LA-C	
3 moth.	12 (40)	10 (33)	8 (27)	0 (0)	5 (17)	11 (37)	12 (40)	2 (7)	0,03
6 moth.	12 (40)	13 (43)	5 (17)	0 (0)	5 (17)	16 (53)	8 (27)	1 (3)	0,046
12 moth.	17 (57)*#	10 (33)	3 (10)	0 (0)	7 (23)*#	18 (60)	5 (17)	0 (0)	0,02
p	0,001				0,002				

Notes: Mann-Whitney's criterion was used to analyze the differences between the groups. To analyze the dynamics of the indicators, Friedman's criterion was used for repeated measurements; pair comparisons were performed according to the Conover criterion (Conover, 1999); * - the difference from the indicator at the time of 3 months is statistically significant ($p < 0,05$); # - the difference from the indicator at the time of 6 months is statistically significant ($p < 0,05$).

On the 3rd ($p=0,03$) and the 6th ($p=0,046$) months, estimates for the presence / absence of reflux esophagitis were different: in 40% of the patients in the study group and only in 17% of the patients in the comparison group, reflux esophagitis was not found out. Accordingly, the frequency of reflux esophagitis was significantly higher in the group of patients, which was formed by CM EGA compared with the MI EGA (60% vs. 83%). In this case, severe reflux esophagitis (LA-C) was not observed in the study group, while in the comparison group, 2 cases of severe reflux esophagitis (Table 3) were observed.

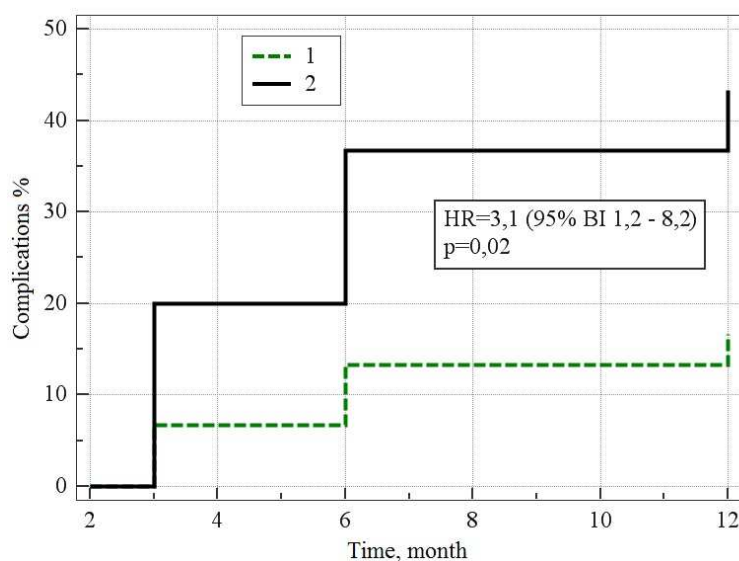


Fig. 1. Evaluation of the risk of developing benign strictures.

vs. 23%). In the total number of patients with reflux esophagitis, the best results were obtained in the study group compared to the comparison group (43% vs. 68%; $p=0,02$). At the same time, for the 12th month, compared with the 6th month, the reflux-esophagitis LA-A was registered 10% less in the study group, while in the comparator group, the tendency towards its growth continues to grow (more than 7%). There was a steady tendency to reduce the more severe manifestations of reflux esophagitis, as reflux esophagitis LA-B in the study group decreased by 7%, and in the comparison group – by 10%, cases of reflux esophagitis LA-C were not registered. Thus, in assessing the dynamics of distribution of patients in terms of severity of reflux esophagitis both in the study group ($p=0,001$) and in the comparison group ($p=0,002$), there was a decrease in its severity throughout the evaluation period. In both groups, the degree of severity of reflux esophagitis was lowest at 12 months of follow-up (Table 3). The comparative analysis of the distribution of values according to severity of reflux esophagitis between the study group and the comparison group by the Mann-Whitney criterion showed significantly lower values in the group of patients who formed an invagination mechanical

On the 6th month of the assessment, compared to the 3rd month, both groups showed an increase in the number of patients with reflux esophagitis LA-A degree (10% more in the study group and 20% in the comparison group) and their decrease with more severe degrees of reflux esophagitis (LA-B) (10% in the study group and 13% in the comparison group). There were no cases of reflux esophagitis LA-C in the study group, with a reduction in the reflux-esophagitis LA-C of 3% in the comparison group. At the 12th month of observation, the number of patients without reflux esophagitis was higher in the study group (57%

esophagogastroanastomosis during the entire assessment period ($p=0,03$, $p=0,046$, $p=0,02$) (Table 3). We believe that such a decrease in the severity of manifestations of reflux esophagitis is associated with the administration of proton pump inhibitors.

One of the known complications of esophageal cancer surgery is the formation of benign strictures. The total number of postoperative benign strictures during the year of follow-up in the study group was lower ($p=0,047$) and amounted to 5 (17%) (95% CI 5,4% - 32,6%), and in the comparison group – 13 (43%) (95% CI 25,7% - 61,9%), RF=0,4 (95% CI 0,2-0,9). To analyze the dynamics of postoperative benign strictures, we used the method of constructing Kaplan-Meyer's survival curves [16]. At the same time, when comparing the Lorgang criterion, the risk of development of benign strictures was significantly higher in the comparison group ($p=0,02$), HR=3,1 (95% CI 1,2-8,2) (Fig. 1).

An increase in the number of cases of benign strictures of esophagogastroanastomosis in patients with CM EGA was associated with a more severe reflux esophagitis in these patients, which causes a persistent inflammatory process in the region of esophagogastroanastomosis and leads to the formation of benign strictures. All cases of benign strictures were corrected by endoscopic balloon hydrodilation.

Esophagogastroanastomosis leakage is one of the most formidable postoperative complications in patients after esophagectomy, and according to Birkmeyer J. D. et al. [1], the 5-year survival rate of patients may be reduced by 20%. During the analysis of the number of cases of anastomotic leakage, no statistically significant difference was found between the two groups of patients, however, in the study group, anastomotic leakage was not fixed (0% vs. 7%, $p = 0,49$). According to the literature, the average anastomotic leakage is 6-21% [3, 11]. In conclusion, this study demonstrates that anastomosis-related complications, such as reflux esophagitis and benign strictures, are a direct consequence of the formation of a mechanical EGA.

Conclusions

1. Invagination mechanical esophagogastroanastomosis in comparison with circular mechanical esophagogastroanastomosis end-to-back is more effective with respect to a significant decrease in the number of postoperative complications such as post-resection reflux esophagitis and benign strictures in patients after esophagectomy. It is reliable because anastomotic leakage was not observed.

2. Since complications after esophagectomy as a whole and related to anastomosis are those factors that increase the use of resources and costs in the surgical treatment of esophageal cancer, affect the quality of life of patients and the very life, we consider it necessary to inform the medical community about the effectiveness of the proposed a method for the formation of invagination mechanical EGA.

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Реферат

ПІСЛЯОПЕРАЦІЙНІ УСКЛАДНЕННЯ З БОКУ АНАСТОМОЗУ У ХВОРИХ ЗІ ЗЛОЯКІСНИМИ НОВОУТВОРЕННЯМИ СТРАВОХОДУ ТА КАРДИОЕЗОФАГІАЛЬНОГО ПЕРЕХОДУ

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Формування стравохідно-шлункових анастомозів після езофагектомії, не дивлячись на явний прогрес, все ще супроводжується розвитком у пацієнтів ускладнень, пов'язаних з анастомозом. Однак інформація щодо впливу способу формування езофагогастроанастомозу на наслідки після езофагектомії залишається суперечливою. Мета роботи – надати порівняльну характеристику пост-операційних ускладнень у хворих після резекції стравоходу залежно від способу формування механічного езофагогастроанастомозу. У дослідження включені 30 пацієнтів, яким було сформовано розроблений і захищений патентом України інвагінаційний механічний езофагогастроанастомоз (група дослідження) і 30 хворих, яким було сформовано циркулярний механічний езофагогастроанастомоз кінцев-в-бік (група порівняння) після езофагектомії. Оцінювали частоту неспроможності езофагогастроанастомозу, частоту рубцевих стриктур, частоту та вираженість рефлюкс-езофагіту. У динаміці усім хворим проведена фіброезофагогастро-дуоденоскопія, ендоскопічне дослідження, вираженість рефлюкс-езофагіту оцінювали відповідно до модифікованої Лос-Анджелеської класифікації. Статистичний аналіз даних проведений з використанням пакету статистичного аналізу EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), графічний інтерфейс до R (The R Foundation for Statistical Computing, Vienna, Austria). В умовах формування інвагінаційного механічного езофагогастроанастомозу результати виявили статистично значуще зниження стриктур анастомозу ($p=0,047$) (17% (95% ВІ 5,4% – 32,6%), проти 43% (95% ВІ 25,7% – 61,9%), $VP=0,4$ (95% ВІ 0,2 – 0,9), а також частоту пострезекційного рефлюкс-езофагіту (43% проти 68%; $p=0,02$) порівняно з циркулярним механічним езофагогастроанастомозом кінцев-в-бік. Однак між двома групами не було виявлено істотних відмінностей щодо неспроможності анастомозу. Зазначимо, що в умовах формування інвагінаційного механічного езофагогастроанастомозу випадків його неспроможності не було виявлено (0% проти 7%, $p=0,49$). Спосіб формування інвагінаційного механічного езофагогастроанастомозу сприяє зниженню частоти стриктур анастомозу та рефлюкс-езофагіту, неспроможність анастомозу не спостерігали.

Ключові слова: механічний анастомоз, інвагінаційний, циркулярний, недостатність анастомозу, стриктури, рефлюкс-езофагіт.

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ПОСЛЕОПЕРАЦИОННЫЕ ОСЛОЖНЕНИЯ СО СТОРОНЫ АНАСТОМОЗА У БОЛЬНЫХ СО ЗЛОКАЧЕСТВЕННЫМИ НОВООБРАЗОВАНИЯМИ ПИЩЕВОДА И КАРДИОЕЗОФАГЕАЛЬНОГО ПЕРЕХОДА

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Формирование пищеводно-желудочных анастомозов после эзофагектомии, несмотря на явный прогресс, все еще сопровождается развитием у пациентов осложнений, связанных с анастомозом. Однако информация о влиянии способа формирования эзофагогастроанастомоза на последствия после эзофагектомии остается противоречивой. Цель работы – предоставить сравнительную характеристику послеоперационных осложнений у больных после резекции пищевода в зависимости от способа формирования механического эзофагогастроанастомоза. В исследование включены 30 пациентов, которым был сформирован разработанный и защищенный патентом Украины инвагинационный механический эзофагогастроанастомоз (группа исследования) и 30 больных, которым был сформирован циркулярный механический эзофагогастроанастомоз конец-в-бок (группа сравнения) после эзофагектомии. Оценивали частоту несостоятельности эзофагогастроанастомоза, частоту рубцовых стриктур, частоту и выраженность рефлюкс-езофагита. В динамике всем больным проведена фиброэзофагогастро-дуоденоскопия, выраженность рефлюкс-езофагита оценивали в соответствии с модифицированной Лос-Анджелесской классификацией. Статистический анализ данных проведен с использованием пакета статистического анализа EZR v. 1.35 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), графический интерфейс к R (The R Foundation for Statistical Computing, Vienna, Austria). В условиях формирования инвагинационного механического эзофагогастроанастомоза результаты выявили статистически значимое снижение количества стриктур анастомоза ($p = 0,047$) (17% (95% ВІ 5,4% - 32,6%), против 43% (95% ВІ 25,7% - 61,9%), $OP = 0,4$ (95% ВІ 0,2 - 0,9), а также частоту пост-резекционного рефлюкс-езофагита (43% против 68%; $p = 0,02$) по сравнению с циркулярным механическим эзофагогастроанастомозом конец-в-бок. Однако между двумя группами не было выявлено существенных различий по несостоятельности анастомоза. Отметим, что в условиях формирования инвагинационного механического эзофагогастроанастомоза его несостоятельности не было обнаружено (0% против 7%, $p = 0,49$). Способ формирования инвагинационного механического эзофагогастроанастомоза способствует снижению частоты рубцовых стриктур анастомоза и рефлюкс-езофагита, несостоятельности анастомоза не наблюдали.

Ключевые слова: механический анастомоз, инвагинационный, циркулярный, недостаточность анастомоза, стриктуры, рефлюкс-езофагит.

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