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Intracorporeal ileotransverse anastomosis in laparoscopic right colectomy. Results of randomized clinical trial

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ABSTRACT *AIM: to assess the postoperative complications rate in the groups with intra- and extracorporeal ileotransverse anastomosis in laparoscopic right colectomy.*
PATIENTS AND METHODS: a single-center, randomized, non-inferiority trial was conducted with intention-to-treat data analysis. There were two groups of patients in whom performed laparoscopic right colectomy using a standardized technique. In the main group (n = 39) intracorporeal ileotransverse anastomosis (IA) was formed, in the comparison group — extracorporeal anastomosis (EA) (n = 40).
RESULTS: the operation time in the IA group was 192.4 ± 62.3, and in the EA group — 144.1 ± 41.3 minutes (p = 0.0002). The time of anastomosis formation was also significantly different: 53 (35; 71) minutes in intracorporeal and 30 (26; 35) minutes inn extracorporeal methods (p < 0.0001). The morbidity rate was not significantly different (25.6% vs 27.5%; p = 0.95). In the main group it was 25.6%, and in the control group 27.5% (p = 0.95). Postoperative hospital stay in the main group was significantly less — 5 vs 7.3 days in the comparison group (p < 0.001).
CONCLUSION: the randomized trial demonstrated that IA is safe and comparable to EA in terms of the morbidity rate, despite its longer operation time. At the same time, in the IA group, patients achieved discharge criteria earlier, which reduced postoperative hospital stay.

KEYWORDS: *laparoscopic right hemicolectomy, intracorporeal anastomosis, colon cancer*

CONFLICT OF INTEREST: *the authors declare no conflict of interest*

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INTRODUCTION

In recent years, there has been a trend towards an increase in the incidence of colorectal cancer. So, in comparison with 2012, when there were 116.7 patients per 100,000 people, in 2022 this figure was 165.4. At the same time, in 63.1% of patients with malignant neoplasms of the colon, the surgical method was used as the main type of treatment [1].

It is worth noting that the choice of access during surgery — laparoscopic or open — does not affect oncological parameters, but the former allows you to improve the immediate results of treatment. Thus, in patients operated with minimally invasive technologies, the restoration of the gut function and the ability to self-care occurs earlier, as well as the postoperative hospital stay is shortened [2–4].

The intracorporeal anastomosis in laparoscopic surgery can further reduce its trauma by reducing the size of the mini-laparotomy wound, and this is due to the fact that in such surgeries access is used only for specimen extraction. In addition, the surgeon becomes freer in choice of a place for the incision taking into account the Langer

tension lines, the presence of scars on the anterior abdominal wall and other individual characteristics of the patient. All together, it potentially reduces the risk of postoperative ventral hernias and increases the cosmetic effect of the surgery [5,6].

However, recently, there is no consensus on whether an intracorporeal or extracorporeal ileotransversal anastomosis in laparoscopic right hemicolectomy should be used right colon cancer [7]. There are few randomized controlled trials (RCTs) devoted to this issue in the world literature, and their endpoints do not allow us to conclude about the safety and applicability of intracorporeal ileotransverse anastomosis in routine surgical practice. In this regard, we initiated this work, the purpose of which was to assess the safety of this technique.

PATIENTS AND METHODS

In the period from September 2021 to December 2023, a single-center, randomized 'non-inferiority' study with the analysis of 'intention-to-treat' data was done. It included adult patients with colon-cancer, who signed a voluntary informed consent to participate in the study, who were scheduled to undergo laparoscopic right hemicolectomy with ileotransverse anastomosis. The criteria for non-inclusion were the local advanced and disseminated cancer.

Patients were excluded if anastomosis was not formed, or with intraoperative detection of carcinomatosis or local advanced cancer, as well as patients who refused to participate at any stage of the study.

Based on the assumption of comparability in terms of safety of intra- and extracorporeal variants of ileotransverse anastomosis during right hemicolectomy, the postoperative morbidity rate was the endpoint in this study. The secondary points of the study were the nature of postoperative morbidity, the severity of postoperative pain syndrome, the time of activation of patients and the post-op hospital stay.

Taking into account the permissible difference in effect (postoperative morbidity rate) of no more than 10%, the estimated study capacity of 80% and the significance level for the endpoint $p = 0.025$, as well as taking into account the possible loss of data of 10% of patients in the postoperative period, the sample size was 80 people.

After signing the voluntary informed consent form, the patients were randomized into two groups. In both groups, enema bowel cleansing with oral antibiotics was done. In the main group, after standard laparoscopic right hemicolectomy, intracorporeal isoperistaltic ileotransverse anastomosis of the 'side-to-side' type was formed using the Covidien Endo GIAU ltra 12 mm endoscopic stitching device. The 'technological windows' formed in the anastomosed segments of the iliac and transverse colon to create an interstitial junction, after stitching with the device, was sutured with two-row 3–0 absorbable polyfilament. After the formation of the ileotransverse anastomosis, the surgical specimen was extracted through a transverse minilaparotomy access in the hypogastrium (Fig. 1).

In the control group, after the laparoscopic stage, a median mini-laparotomy was performed to form an anastomosis. Anastomosing parts of the bowel were removed out of peritoneum, and hand-sewn 'end-to-end' ileotransverse anastomosis was done. The inner row was continuous, the outer row is made up of single sutures with a 3–0 absorbable polyfilament (Fig. 2).

According to the study protocol, the postoperative management of patients in the control and main groups was of the same type. Complications were assessed using the Clavien-Dindo scale [8]. The intensity of the pain syndrome was assessed by a visual analog scale (VAS). Patient activation and achievement of discharge criteria were assessed using the Bartel index [9]. All patients underwent regular comprehensive checkup after surgery according to clinical guidelines. A year after surgery, they were consulted; and the results of computed tomography (CT) of the chest, abdominal cavity, and pelvis were evaluated, among

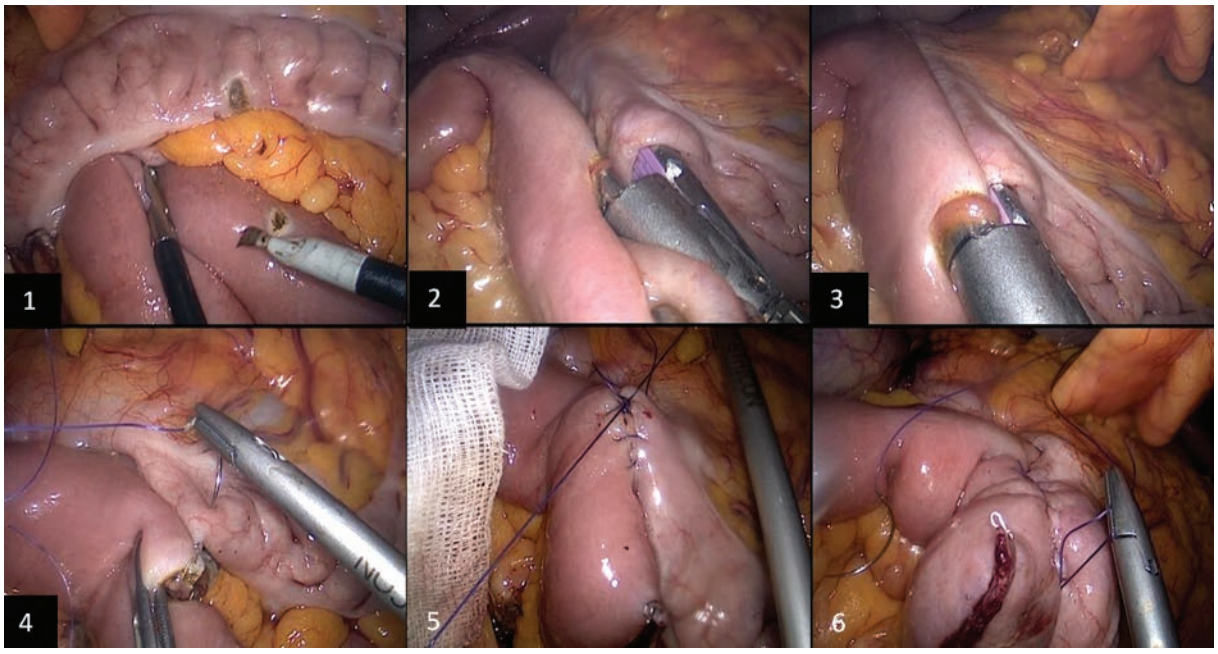

Figure 1. *Intraoperative photo. Laparoscopically assisted right colectomy. Operation stage: formation of intracorporeal ileotransverse anastomosis (1 — formation of "technological windows"; 2 — carrying out the stapler; 3 — formation of a "side-to-side" anastomosis using a mechanical suture; 4–6 — suturing of "technological windows")*

other things, for the detection and verification of postoperative ventral hernias. Computed tomograms were interpreted together with a radiologist using Philips Intelli Space Portal 10 software. Statistical data processing was carried out in the GraphPad Prism 9 resource. The normal distribution was estimated using the D'Agostino-Pearson test. With a normal distribution of the sign, continuous data were described using averages and standard deviations. In the case of an asymmetric distribution, variables were represented through medians and quartiles (25%; 75%). Parametric data were compared using the Student's t-test, nonparametric data were compared using the Mann-Whitney U-test, frequency characteristics were compared using χ^2 (with Yates correction for tables 2 × 2) and the two-sided Fisher accurate criterion.

Within the specified time frame, 80 patients who met the inclusion criteria were included in the study: 40 each in the main group and the control group. A simple randomization method of random number generation was used. One patient was excluded from the main group due to intraoperative detection of a locally advanced tumor with peritoneal carcinomatosis (Fig. 3).

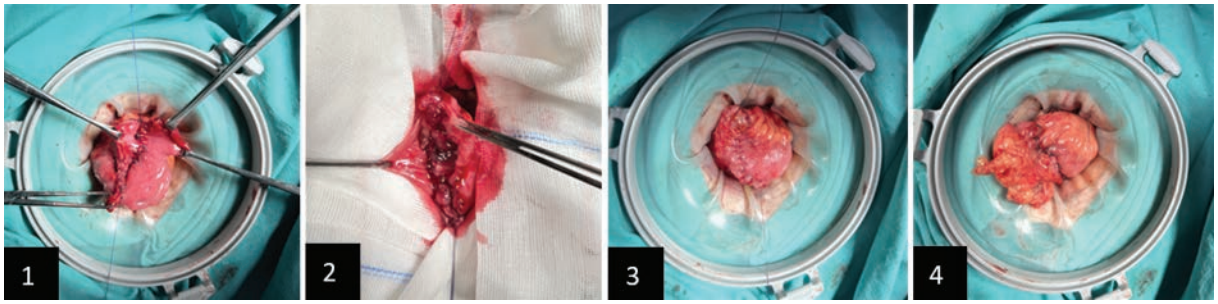

Figure 2. *Intraoperative photo. Laparoscopically assisted right colectomy. Operation stage: formation of extracorporeal ileotransverse anastomosis (1 — application of separate external sutures; 2 — the beginning of the formation of an internal continuous wrapping suture; 3 — completion of the formation of an internal continuous wrapping suture; 4 — completion of application of separate external sutures)*

Table 1. *Characteristics of patients in groups*

Parameter	Intracorporeal anastomosis (*n* = 39)	Extracorporeal anastomosis (*n* = 40)	*p*
Gender, *n* (%) Male Female	 21 (53.8%) 18 (46.2%)	 25 (62.5%) 15 (37.5%)	0.581***
Age, years	64.6 ± 12.1	67.3 ± 9.5	0.33**
BMI, kg/m²	25.3 ± 3.5	27.37 ± 3.4	0.13**
Classification by scale ASA, *n* (%) ASA I ASA II ASA III	 20 (51%) 15 (38%) 4 (11%)	 20 (50%) 15 (37.5%) 5 (12.5%)	0.95*
Comorbidities	25 (65%)	28 (72%)	0.75***

*Note: * χ^2; ** t-test; *** χ^2 adjusted by Yates*

Table 2. *Short-term results of operations in groups*

Parameters	Intracorporeal anastomosis (*n* = 39)	Extracorporeal anastomosis (*n* = 40)	*p*
Operation time, min.	192.4 ± 62.3	144.1 ± 41.3	0.0002*
Time of formation of the anastomosis, min.	53 (35;71)	30 (26;35)	< 0.0001*
Incision length, cm	5.7 ± 1.1	6.7 ± 1.3	0.001**
Postoperative hospital stay	5 ± 0.8	7.3 ± 1.05	< 0.001**
The first gases, day	1 (1;1)	1 (1;1)	1*
The first stool, day	2 (2;3)	4 (2;4.75)	< 0.0001*

*Note: * U-test; ** t-test*

Both groups were homogeneous in gender, age, body mass index (BMI), ASA and comorbidities (Table 1).

RESULTS

When analyzing the data obtained during the study, attention is drawn to the significant difference in intraoperative chronometry. The operation time in the main group was 192.4 ± 62.3 minutes, and in the comparison group it was almost 50 minutes less — 144.1 ± 41.3 minutes (p = 0.0002). The time of formation of the anastomosis was also significantly different: 53 (35;71) minutes with intracorporeal and 30 (26;35) minutes with extracorporeal methods (p < 0.0001).

It is worth noting that in the group with intracorporeal anastomosis, the size of the postoperative wound was significantly less — 5.7 versus 6.7 cm (p < 0.001).

The post-op hospital stay in main group was 5/0 ± 0.8 days, while in the control group patients were discharged 2 days later(p < 0.001).

In both groups gases were released on the first day after surgery. However, the first defecation after surgery occurred earlier in the group with intracorporeal anastomosis — already on the 2nd day, whereas in the comparison group the first stool was recorded only on the 4th day (p < 0.0001) (Table 2).

When analyzing the rate of recovery of the ability to self-care using the Bartel index in the

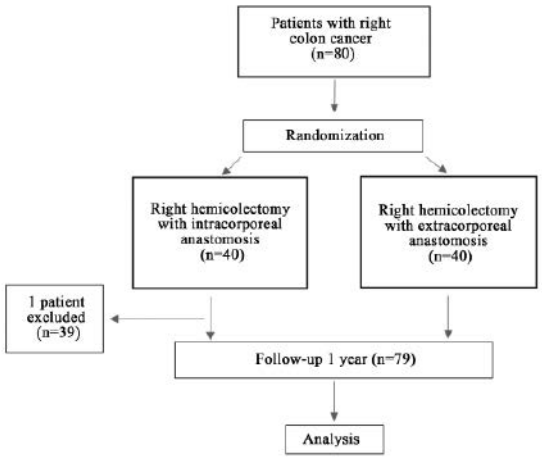

Figure 3. *Research scheme*

postoperative period, there were no significant differences in the compared groups (Fig. 4). It was evaluated from the first to the fifth postoperative day, since the majority of patients from the main group were discharged during this time.

From the first day, patients of the main group noted a lower pain compared to the control group. Thus, the intensity of pain measured by VAS on the first day in the IA group was less than in EA — 2.4 versus 3.3 points, respectively ($p < 0.0001$) (Fig. 5).

The overall morbidity rate was 10 (25.6%) and 11 (27.5%) in the main and control groups, respectively, there were no significant differences ($p = 0.95$). In the IA group, grade I complications developed in 6 (15.4%) patients, mainly as postoperative fever vs 4 (10%) patients with a similar complication in the EA group ($p = 0.52$). Hematoma in the surgical area was detected in the main group — in 2 (5.1%) patients, and in the comparison group — in 3 (7.5%) patients ($p = 1$). Grade II complications are represented by 1 (2.6%) and 2 (5%) cases of post-op ileus in groups IA and EA, respectively ($p = 1$). Suppuration of the postoperative wound developed in 2 (5%) cases in the control group. There was 1 (2.6%) case of anastomosis failure in the main group (grade III according to the Clavien-Dindo scale) ($p = 0.49$) (Table 3).

A comparative analysis of the morphological characteristics of surgical specimens revealed that the average length of the removed segments of the large and small intestine in the group with intracorporeal anastomosis was, on average, 4 cm longer than in the control group and amounted to 28.7 ± 8.7 and 24.2 ± 5.3 cm, respectively ($p = 0.068$). At the same time, the differences in this parameter only tended to be statistically significant. The median number of lymph nodes harvested in the IA and EA groups also did not differ significantly and amounted to 29 (22;35) and 25.5 (18.7; 34), respectively ($p = 0.39$). Thus, the samples formed did not have significant differences in the main morphological characteristics of the removed specimens. The vast majority of the removed tumors, 71 (90%), were represented by adenocarcinoma, more often of moderate differentiation (Table 4). In addition, 5 neoplasms had the structure of an adenoma with epithelial dysplasia, 2 — a neuroendocrine tumor and 1 — lymphoma.

In a year after the surgery, the patients were invited for a checkup. The median time of follow-up was 14 (12;20) months. The number of patients followed up for more than one year was 38 (97.4%) in the main group and 38 (95%) in the control group ($p = 1$).

Three (7.9%) cases of disease progression (liver metastases) were detected in the main group, in 1 (2.6%) case this led to the death of the patient. In the comparison group, no cases of progression were detected, but 1 (2.5%) fatal outcome

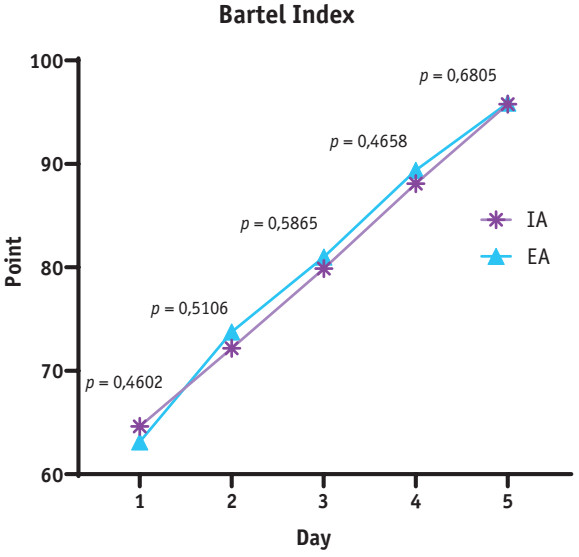

Figure 4. *Postoperative Barthel index in groups*

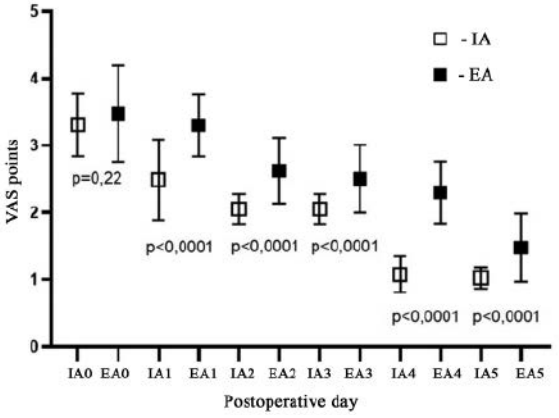

Figure 5. *Postoperative pain in groups*

Table 3. *Postoperative complications according to the Clavien-Dindo scale*

Clavien-Dindo	Complications	IA (*n* = 39)	EA (*n* = 40)	*p**
Grade I	Fever	6 (15.4%)	4 (10%)	0.52
	Hematoma in the area of the postoperative wound	2 (5.1%)	3 (7,5%)	1.0
Grade II	Suppuration of a postoperative wound	0	2 (5%)	0.25
	Gastrointestinal paresis	1 (2.6%)	2 (5%)	1.0
Grade III	Anastomosis leakage	1 (2.6%)	0	0.49
Grade IV		0	0	1
Grade V		0	0	1

*Note: * Two-sided Fisher test*

Table 4. *The results of the pathomorphological*

Parameters		Intracorporeal anastomosis (*n* = 39)	Extracorporeal anastomosis (*n* = 40)	*p*
The length of the removed segment of the intestine, cm		28.7 ± 8.7	24.2 ± 5.3	0.068*
The number of lymph nodes in the specimen, pcs.		29.0 (22;35)	25.5 (18.7; 34)	0.39**
The margins of resection	Proximal, cm	11 (7; 16.2)	12.5 (8.2; 15.7)	0.67**
	Distal, cm	12 (9; 16.2)	13 (10;19.7)	0.48**
Histological structure of the tumor	Adenocarcinoma G1	7 (17.9%)	5 (12.5%)	0,6***
	Adenocarcinoma G2	21 (53.8%)	23 (57.5%)	
	Adenocarcinoma G3	6 (15.3%)	9 (22.5%)	
	Adenoma	2 (5.1%)	3 (7.5%)	
	Neuroendocrine tumor	2 (5.1%)	0	
	Lymphoma	1 (2.5%)	0	

*Note: * t-test; ** U-test; *** Accurate Fisher criterion*

Table 5. *Long-term outcomes in groups*

	Intracorporeal anastomosis (*n* = 38)	Extracorporeal anastomosis (*n* = 38)	*p**
Progression, *n* (%)	3 (7.9%)	0	0.24
One-year overall survival rate, *n* (%)	37 (97.4%)	37 (97.4%)	1
Postoperative hernia, *n* (%)	0	3 (8.3%)	0.24

*Note: * Two-sided accurate exact Fisher test*

was recorded, associated with decompensation of concomitant diseases ($p = 1.0$). There were no significant differences between the groups in overall and disease-free survival (Table 5).

Checkup in 1 year after surgery, none of the patients complained of the presence of protrusion in the area of postoperative scars, whereas during a physical examination, postoperative ventral hernias were detected in 3 (8.3%) cases in the control group. It is worth noting that in none of the patients in whom Pfannenstiel access was chosen as the method for extracting the specimen, postoperative hernias were not detected. CT scans were performed in patients for the presence of postoperative ventral hernias of the anterior abdominal wall. At the same time, the CT data correlated with the results of the physical examination. Nevertheless, when processing the results, there were no differences in the rate of formation of postoperative ventral hernias between the groups (Table 5).

DISCUSSION

Laparoscopic right hemicolectomy is considered the standard treatment right colon cancer [10]. After performing mobilization and lymphodissection, there are two ways to form anbowel anastomosis. However, the question of choosing a method remains challenging. The technique of performing extracorporeal anastomosis requires the removal of a segment of the bowel to the

anterior abdominal wall by means of a mini-laparotomy, which is usually located along the median line in the navel area. In patients with excessive development of subcutaneous adipose tissue and/or visceral fat, exteriorization of the anastomosed partof the intestine is technically more difficult and can lead to excessive traction, mesentery ruptures and bleeding, as well as cause an increase in the length of the incision. Another argument in favor of the IA may be the fact that there is no need to remove the anastomosed segments of the intestine into the wound, thereby eliminating the need for greater mobilization of them, as in the case of EA. In the study, this statement was proved: there was a trend to a longer length of the removed segment of the intestine in the main group than in the control group — 28.7 ± 8.7 and 24.2 ± 5.3 cm, respectively. With the extracorporeal method of anastomosis, tension of the anastomosed segments of the intestine is created, which in turn can be realized during a longer period of gut function restoration, increase the activation time of the patient, which is not occurred in case of intracorporeal anastomosis [11].

Most likely, the opening of the intestinal lumen in the area of the minilaparotomic wound was the cause of its suppuration in 2 (5%) patients of the control group. There were no complications in the wound area in the main group.

In addition, the use of IA does not limit the surgeon in choosing the location and size of the mini-laparotomy access. The removed specimen can be extracted through a small incision on the anterior abdominal wall, and the hypogastric region is preferable, since the rate of postoperative hernias at the site of this incision does not exceed 4%, while with median access reaches 29% [12–15]. The meta-analysis in 2019 by Emile, S., et al. demonstrated that in patients with EA, the probability of postoperative hernias was significantly higher (OR 3.14 (95% CI 1.85–5.33) $p < 0.001$) [16]. As part of our study, postoperative hernias were detected in 3 patients in the group where the anastomosis was done extracorporeally, and the access was a mid-median mini-laparotomy, whereas in the Pfannenstiel access area, they were not detected in patients. Speaking about the prospects for further development of this area of surgery, it should be mentioned that the surgical specimen can be extracted through natural openings, which will further reduce the invasiveness [17]. However, intracorporeal anastomosis is more difficult, since it requires advanced laparoscopic skills, training, and takes longer time [18–20]. It is also impossible to ignore the fact that the material costs for intracorporeal anastomosis are higher than for extracorporeal, which is due to the additional use of cutting and stitching staplers for laparoscopic procedures [21]. Thus, the choice between intracorporeal and extracorporeal options for anastomosis in laparoscopic right hemicolectomy is ultimately dictated by the preferences, as well as the experience of the operating surgeon and the individual characteristics of the patient.

The results of the presented randomized study demonstrated that intracorporeal anastomosis is comparable in safety with extracorporeal, the morbidity rate was 25.6% in the IA group and 27.5% in the EA group ($p = 0.82$). At the same time, the gut activity occurred faster, the first stool was registered earlier by 2 days. Similar data were obtained in the meta–analysis by Zhang, H. et al, published in 2021, involving 559 patients from five RCTs, where in the IA group there was a reduction in the time to gas discharge (mean difference — 0.71 (95% CI, from –1.12 to –0.31) $p = 0.0005$), and the first stool (the average difference is 0.53 (95% CI, from –0.69 to –0.37) $p < 0.00001$) [22].

Further follow-up and analysis of long–term results showed that the choice of surgery did not have a significant effect on oncological results, such as disease progression — 3 cases in the IA group, none in the EA group ($p = 0.24$) and one-year overall survival of 37 (97.4%) people in both groups ($p = 1$).

CONCLUSION

A randomized clinical trial has confirmed that intracorporeal anastomosis is safe, comparable to

EA in terms of the postoperative morbidity rate. When using it, patients demonstrated faster recovery — the first defecation after surgery occurred on day 2, less intense pain syndrome from the first day — 2 points. In addition, discharge criteria were achieved faster, and patients were discharged on average on the 5th day after surgery. However, due to the longer time of the operation, as well as taking into account the need for special skills of the surgeon, the issue of routine use of this technique remains controversial.

AUTHORS CONTRIBUTION

Concept and design of the study: *Sergey I. Achkasov, Oleg I. Sushkov, Dmitry G. Shakhmatov*
Collection and processing of the material: *Ekaterina M. Romanova, Egor M. Shunin*
Statistical processing: *Airat F. Mingazov, Evgeniy S. Surovegin*
Writing of the text: *Ekaterina M. Romanova, Evgeniy S. Surovegin*
Editing: *Sergey I. Achkasov, Oleg I. Sushkov, Denis V. Aleshin, Dmitry G. Shakhmatov*

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