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Laparoscopic right colectomy with intracorporeal ileotransverse anastomosis (results of the pilot study)

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ABSTRACT *AIM: to evaluate the safety of intra- and extracorporeal ileotransverse anastomosis in laparoscopic right hemicolectomy.*

PATIENTS AND METHODS: a pilot «case-control» study included two groups of patients, who underwent laparoscopic right colectomy according to a standardized technique. An intracorporeal anastomosis (IA) was formed in the main group (n = 20), in the control group — extracorporeal anastomosis (EA) (n = 18).

RESULTS: in main group the postoperative complications rate was 20%, in the control group — 28% (p = 0.71). The postoperative hospital stay in the main group was significantly less than in control (5.0 vs 7.3 days) (p < 0.001).

CONCLUSION: the postoperative complications rate in both groups was not significant, but postoperative hospital stay was shorter in IA group. A randomized controlled trial is required.

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

CONFLICTS OF INTERESTS: *The authors declare no conflicts of interest.*

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INTRODUCTION

The surgery is the main approach for colon cancer.

In recent years, clinical trials and new protocols for the management of patients after elective colon resections are being developed and edited in order to shorten the rehabilitation period [1].

Taking into account the development of technologies and the experience accumulated in world practice, when choosing the method of surgery, preference is currently given to the minimal invasive and traumatic methods. Within the framework of this concept, laparoscopic access is the 'gold standard' in the treatment of localized colorectal cancer (CRC) [2]. It is worth noting that the technique of laparoscopic surgery, including the method of forming an anastomosis, is continuously modified. The formation of an intracorporeal anastomosis allows the surgeon to choose the method of the specimen extraction [3].

To date, there are quite a large number of articles in the world literature devoted to the study of the advantages and disadvantages of intracorporeal ileotransverse anastomosis (ITA) in laparoscopic right hemicolectomy (LRH).

However, papers on pubmed.ncbi.nlm.nih.gov, overwhelmingly represent a series of clinical cases.

Along with this, on clinicaltrials.gov only 6 randomized controlled trials (RCTs) have been registered; all of them are at various stages.

In addition, in the available literature, we found two meta-analyses.

In one of them, published by Emile, S. et al. (2019), intracorporeal ITA (iITA) performed in 2,123 patients with LRH was compared with extracorporeal (eITA), which was formed in 2,327 cases.

The advantages of iITA over eITA were demonstrated, consisting in a significant decrease in the incidence of the surgical site infection — OR = 1.69, 95% CI 1.4–2.6, $p = 0.002$, anastomosis leakage — OR = 1.95, 95% CI 1.4–2.7, $p = 0.003$, as well as the rate of postoperative hernias — OR = 3.14, 95% CI 1.85–5.33, $p < 0.001$ [4].

A year later, in 2020, Selve M. et al. published a meta-analysis that included 3,699 patients and 24 publications. It was shown that along with a decrease in the rate of in the surgical site infection — OR = 0.526 ($p = 0.006$), there was a faster recovery of gastrointestinal tract function, early gas discharge — OR = –0.46 ($p = 0.02$); stool — OR = –0.48 ($p < 0.001$), as well as a reduction in the time of the patient's hospital stay — OR = –0.35 ($p < 0.001$) [5].

It is worth noting that both meta-analyses turned out to be comparable not only in terms of results, but also in terms of the quality of the included data. However, each meta-analysis included only one RCT while the rest of the studies were retrospective series of cases. Therefore, there was a high probability of a bias.

Taking into account the limited number and quality of studies, we initiated a pilot study focused on the safety of intra- and extracorporeal ITA after LRH.

PATIENTS AND METHODS

The pilot study was a prospective 'case-control' type.

It included adult patients who gave their consent to participate in the study, who were scheduled for LRH for right colon cancer.

The study did not include patients with locally advanced cancer and carcinomatosis at the stage of preoperative check-up.

Patients whose carcinomatosis was detected intraoperatively were excluded as well, or a decision was made avoid ITA. Patients who refused to participate in the study at any of its stages were also excluded.

All the patients underwent standard LRH, taking into account the site of the primary tumor and oncological principles.

In the main group, after removal of the right colon, iITA of the 'side-to-side' type was done. To form an anastomosis, 3 cassettes for the endoscopic staplers were used. With their help, the crossing of the intestine was carried out within the designated borders. The next stage was ileo- and colostomy.

A stapler was inserted through the holes into the lumen and anastomosis was created. After that, the 'technological' hole was intracorporeally sutured with absorbable double-row suture. An additional nodal reinforcing suture was applied to the corner of the stapler line. The macro-specimen was extracted through Pfannenstiel incision.

In the control group patients, eITA was formed according to the hand-sewn 'end-to-end' type using a double-row suture. This type of anastomosis is performed most often in the Center and is accepted here as the standard for LRH. The macro-specimen was extracted from the abdominal cavity through paraumbilical minilaparotomy.

As part of the study, iITA was performed by five surgeons with sufficient experience in laparoscopic surgery for colorectal cancer.

Statistical processing of the data obtained was carried out using GraphPad Prism 9 software.

The parametric data were compared using the Student t-test, while nonparametric data were compared using the Mann-Whitney U-test; and the rate characteristics were compared using χ^2 with Yates correction.

From September 2020 to February 2021, 38 patients meeting the selection criteria were included in the study.

The main group with iITA included 20 patients; and the control group with eITA included 18 patients. Both groups were homogenous in gender, age, body mass index (BMI), ASA status and the comorbidities (Table 1).

Table 1. *Characteristics of patient*

Parameter	Intracorporeal Anastomosis (*n* = 20)	Extracorporeal Anastomosis (*n* = 18)	*p*
Gender (m/f)	5/15	4/14	0.59*
Age (years)	67 ± 12.1	68.4 ± 9.5	0.68**
BMI (kg/m²)	25.3 ± 3.5	27.3 ± 3.4	0.07**
ASA I/II/III	10/8/2	12/5/1	0.57***
Comorbidities, %	65%	72%	0.64*

** U-test; ** t-test; *** χ^2 с поправкой Yates *** χ^2 adjusted by Yates*

Table 2. *The incidence of postoperative complications in the groups according to the Clavien–Dindo scale*

Clavien–Dindo	Intracorporeal Anastomosis (*n* = 20)	Extracorporeal Anastomosis (*n* = 18)	*p*
Degree I	1 (5%)	1 (5.5%)	
Degree II	2 (10%)	3 (17%)	
Degree III	1 (5%)	1 (5.5%)	
Degree IV	0	0	
Degree V	0	0	
TOTAL	4 (20%)	5 (28%)	*p* = 0.71*

** χ^2 adjusted by Yates*

Table 3. *Operation time, creation of anastomosis and postoperative hospital stay*

Duration	Intracorporeal Anastomosis (*n* = 20)	Extracorporeal Anastomosis (*n* = 18)	p
Operative time, minutes	225 ± 60	166 ± 32	0.0007**
Anastomosis formation, min.	50 (45; 70)	45 (40; 60)	0.06*
Postoperative hospital stay	5 ± 0.8	7.3 ± 1.05	*p* < 0.001**

** U-test; ** t-test*

RESULTS

Analyzing the iITA and eITA groups by the rate of complications, no significant differences were obtained. So, in the main group they occurred in 20%; in controls — in 28% of cases ($p = 0.71$). It is important to note that there was no leakage in both groups (Table 2).

We evaluated the hospital stay after surgery. The patients left the clinic after their condition met the discharge criteria (80 or more points on the Bartel scale; the severity of pain syndrome was less than 3 points by VAS) [6].

It turned out that in the main group, the hospital stay was significantly less — 5.0 versus 7.3 days ($p < 0.001$).

LRH with iITA was significantly longer than eITA — 225 vs 166 minutes ($p = 0.0007$). The time spent for iITA, was 5 minutes longer than eITA. However, these differences are not significant ($p = 0.06$) (Table 3).

DISCUSSION

Despite the large number of studies devoted to the iITA in LRH, the question of its advantages and disadvantages remains open. The reason for

Table 4. *Incidence of incisional ventral hernia*

Study	Incisional hernias, % (number of patients)		Observation period	*p*
	Pfannenstiel	Median minilaparotomy		
DeSouza A., 2011 (*n* = 512)	0 (*n* = 119)	23.2 (*n* = 56)	17.5 months	< 0.0001
Lee L., 2012 (*n* = 99)	0 (*n* = 24)	29 (*n* = 68)	28.2 months	0.02
Samia H., 2013 (*n* = 480)	3.8 (*n* = 26)	8.9 (*n* = 305)	3.5 years	< 0.01
Lee L., 2017 (*n* = 5447)	0 0.9 (*n* = 956)	10.6 (*n* = 3177)	17.3–42 months	< 0.001
Widmar M., 2020 (*n* = 164)	3 (*n* = 67)	19 (*n* = 97)	14 months	0.007

this is the insufficient number of RCTs, which does not allow to approve the issue, to determine the place of iITA in colorectal surgery.

One of the main disadvantages of the intracorporeal anastomosis, in comparison with extracorporeal one, is the high 'cost'. Thus, the need to use at least 3 cassettes for laparoscopic stapler in routine practice, at first glance, does not seem fully justified, given the existing possibility of forming an extracorporeal anastomosis hand-sewn.

On the other hand, it should be borne in mind that the cost of cassettes for the device is not the only component of the total cost of the treatment. So, in addition to the cost of consumables used directly for the surgery, at least the costs associated with a longer stay of the patient in the hospital after surgery are included in the latter [7].

Another aspect that should be considered when describing the advantages and disadvantages of iITA is the method of extracting a specimen.

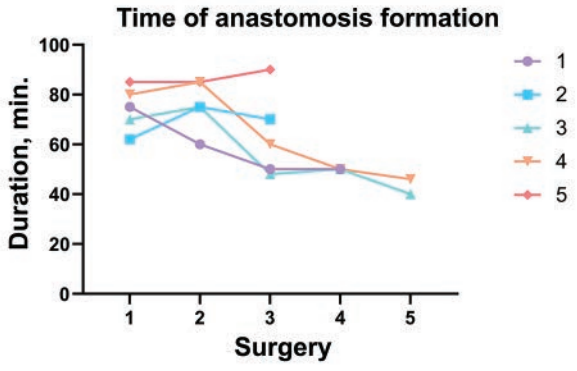

Figure 1. *Time of anastomosis formation. 1,2,3,4,5 — the number of the surgeon who performed the IA*

Thus, during the eITA formation the limited mobility of the transverse colon dictates the need for the minilaparotomic incision in the paraumbilical area or higher.

On the contrary, performing the anastomosis intracorporeally makes it possible to extract the specimen through a transverse Pfannenstiel incision in the hypogastric area, which, according to a number of studies, is associated with a decrease in the rate of post-op ventral hernias [8–12] (Table 4).

Thus, the absence of the need for patients to subsequently seek medical help in order to perform hernioplasty, potentially also reduces the cost of treatment, and in general the burden on the healthcare system.

Discussing the potential advantages of using the iITA technique, it is worth mentioning the NOSE (Natural Orifice Specimen Extraction) technology, in which the macro-specimen is removed through natural openings, which provides maximal cosmetic effect. Most often, the extraction of the specimen is carried out through the colpotomy opening [13]; and there are fewer reports of a transanal method [14].

Referring to this study, it can be noticed that with each subsequent procedure, surgeons reduce the time spent on the intracorporeal anastomosis. The small number of cases does not allow to state this categorically. Nevertheless, it is possible to trace the trend to accelerate this stage as experience accumulates (Fig. 1). A similar pattern is noted by other authors who have extensive experience in the iITA [15].

The potential disadvantages of the intracorporeal technique for the formation of ITA can also include the need to work on the opened lumen of the intestine in the conditions of pneumoperitoneum. However, we found no differences in the rate of surgical site infection during the iITA formation in comparison with eITA — 4 (20.0%) and 5 (28.0%) cases (p = 0.71), which correlates with the literature data [4, 5].

Thus, it is obvious that there is a need for RCT, the purpose of which would be to compare iITA and eITA in terms of safety, the quality of life, and economic efficiency. This study was initiated in the Center and registered on the portal ClinicalTrials.gov (Identification number: NCT05026268).

CONCLUSIONS

The results of the pilot study demonstrated that the iITA is not associated with an increase in the postoperative complications. However, it reduces the post-op hospital stay.

The less injury of the mini-laparotomy incision in the hypogastrium, in comparison with the traditional paraumbilical access, apparently causes a better recovery and early discharge from the hospital.

Nevertheless, to confirm the results previously obtained in the pilot study, a randomized clinical trial is required for a more balanced approach to choosing the method of ITA during LRH.

AUTHORS CONTRIBUTION

Concept and design of the study: *Oleg I. Sushkov, Evgeniy S. Surovegin*

Processing of the material: *Ekaterina M. Romanova*

Writing of the text and statistical data processing: *Ekaterina M. Romanova, Evgeniy S. Surovegin*

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