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Hybrid laparo-endoscopic surgery for colon tumors (results of pilot study)

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ABSTRACT *AIM: to assess the early results of hybrid laparoscopic endoscopic procedures for colon tumors.*
PATIENTS AND METHODS: a pilot "case-control" study included two groups of patients, who underwent surgery for endoscopic irremovable colon adenomas. Hybrid laparo-endoscopic procedures were done in the main group (n = 31), in the control group — laparoscopic resections of the colon (n = 20).
RESULTS: no significant differences obtained in rate of postoperative complications: 9.7% in the main group vs 20.0% of cases in the control (p = 0.41). The postoperative hospital stay in the main group was significantly less than in control group — 5 versus 7 days (p < 0.0001).
CONCLUSION: the hybrid laparoscopic endoscopic surgery does not associate with the increased risk of postoperative complications. Moreover, this procedure decreases postoperative hospital stay. However, a randomized controlled trial is required.

KEYWORDS: *hybrid operations, combined laparo-endoscopic surgery, colon tumors*

CONFLICT OF INTEREST: *The authors declare no conflicts of interest*

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INTRODUCTION

Colorectal cancer takes one of the first places in the structure of cancer incidence in developed countries. Since adenomatous polyps in the colon have the potential for malignancy, their timely removal is an effective method of preventing the development of cancer of this site.

The "gold standard" in the treatment of colorectal adenomas is their endoscopic removal by mucosectomy (EMR) or dissection in the submucosal layer (ESD) [1–3]. However, up to 15% of such neoplasms cannot be removed using these techniques due to their large size, site, for example, in the area of the mouth of the diverticulum or the vermiform process, as well as the presence of fibrosis in the submucosal layer. Traditionally, in such cases, open or laparoscopic resection of the bowel is performed [3,4]. These procedures, along with obvious oncological advantages, are not without drawbacks, such as trauma (patients lose a segment of the intestine).

Moreover, the surgeon and the patient are forced to accept the risks associated with the need to form an intestinal anastomosis.

Hybrid laparoscopic and endoscopic procedures can be considered as an alternative to resection. Their use makes it possible to avoid segmental resection of the bowel, thereby preserving its natural anatomy, reducing the patient's hospital stay, reducing the rate of postoperative complications, while providing a comparable level of radicality [4–6].

Summarizing the data available in the literature, hybrid surgeries can be divided into two main groups: laparoscopically-assisted endoscopic

Table 1. *Characteristics of the groups*

Parameter		Main Group (n = 31)	Control Group (n = 20)	p
Gender (m/f)		15/16	7/13	p = 0.39
Age, years		67.8 ± 0.96	66.8 ± 1.16	p = 0.91
BMI, kg/m²		28.3 ± 0.96	28.1 ± 0.55	p = 0.97
ASA Grade I/II/III		4/21/6	5/10/5	p = 0.40
Comorbidities, (%)		90.3%	90.5%	p = 0.78
The size of the neoplasm Me (quartile), mm		40.0 (35;55)	40.0 (27.5;50)	p = 0.15
Site of the tumor in the colon	Left colon	5 (16.2%)	8 (40.0%)	p = 0.15
	Right colon	20 (64.5%)	10 (50.0%)	
	Transverse colon	6 (19.3%)	2 (10.0%)	

resections and endoscopically-assisted laparoscopic resections.

In the first, the main role belongs to endoscopists. They perform tumor detection and, using elements of dissection technique in the submucosal layer, remove it.

Surgeons in this situation play an assistant role, which, as a rule, consists in creating an optimal exposure for endoscopic removal, and, in case of lesionon the intestinal wall, suture the defect from the peritoneal side.

In the group of endoscopically assisted laparoscopic resections, the abdominal team performs a full-layer excision of the intestine with adequate margins and, subsequently, eliminates the defect of the intestinal wall by applying a manual or stapler suture. At the same time, endoscopists mark the tumor, navigate and control the lateral margins of resection, as well as control the tightness of the sutures and the lumen of the bowel in the operative area. In addition, they can extract the specimen through the bowellumen [7,8].

Along with the advantages, hybrid laparoscopic procedures also have disadvantages: they require the simultaneous participation of two surgical teams at once and are undoubtedly hard to organize. If, according to the pathomorphology of removed specimen, adenocarcinoma with an invasion depth of over pT1sm1 is detected, bowel resection is required in compliance with oncological principles.

Thus, a number of the listed issues served as a reason for a study, the purpose of which was to assess the safety of laparoscopic procedures and the possibility of radical removal of colon tumors.

PATIENTS AND METHODS

From August 2019 to September 2020, a prospective pilot case-control study was conducted, which included patients, aged over 18 years, with endoscopically non-removable colon adenomas.

The patients were divided into 2 groups: the main one, in which hybrid laparoscopic endoscopic procedures were performed (n = 31), and the control group, in which laparoscopic colon resections were performed (n = 20). The criteria for non-inclusion in the study were: regional lymph nodes involvement according to computed tomography, familial adenomatosis, the intestinal stoma, ASA > III, inflammatory bowel diseases.

Table 2. *Data of pathomorphological examination in patients of the compared groups*

Parameter	Main Group (*n* = 31)	Control Group (*n* = 20)	*p*
Resection margin – positive (R1) – negative (R0)	 3 (9.7%) 28 (90.3%)	 0 (0%) 20 (100.0%)	*p* = 0.64
The tumor structure – adenocarcinoma – tubulo-villous adenoma	 5 (16.1%) 26 (83.8%)	 6 (30.0%) 14 (70.0%)	*p* = 0.30
Grade of adenoma dysplasia – low-grade – high-grade	 19 (73.0%) 7 (27.0%)	 8 (57.1%) 6 (42.9%)	*p* = 0.48
Degree of adenocarcinoma invasion (T) – T1sm1 – T1sm2 – T1sm3	 2 (40.0%) 2 (40.0%) 1 (20.0%)	 3 (50.0%) 2 (33.3%) 1 (16.7%)	*p* = 0.54

Based on previous studies, the following were identified as risk factors for endoscopic failure of non-removable tumors [9,10]:

1. the size of the neoplasm over 50 mm in diameter;
2. lifting is less than 3 mm;
3. severe fibrosis at the tumor base;
4. IIIa type of capillary relief according to the Sano Y. classification;
5. Vi type of pit pattern according to the Kudo S. classification;
6. Type III superficial tumor lesionsaccording to the Paris classification.

The groups did not differ significantly in basic characteristics, such as gender, age, body mass index, ASA scale, site of neoplasm in the colon, as well as its size (Table 1).

The decision to perform this or that procedure was made intraoperatively, together with endoscopists, based on the endoscopic picture, taking into account the site, mobility of the neoplasm, as well as the technical capabilities of its removal.

Of the 31 hybrid procedures performed in the main group, there were 15 laparoscopically-assisted endoscopic removals of colon tumors and 16 endoscopically-assisted laparoscopic resections of its wall.

In the laparoscopic resection group, 10 right hemicolectomies, 2 resections of the transverse colon, 3 segmental resections of the left side of the colon hemicolectomies, 3 distal resections of the sigmoid colon and 2 left-sided hemicolectomies were performed.

RESULTS

The mean time of the procedure in both groups was the same (158.0 ± 12.9 minutes in the main and 157.0 ± 10.7 minutes in controls, p = 0.96).

The postoperative hospital stay in the main group was 5 (4;5) days versus 7 (6;9) ($p < 0.0001$) in the control group.

Postoperative complications in the hybrid surgery group developed in 3 (9.7%) patients, while all of them had grade I according to the Clavien-Dindo classification. In the group of laparoscopic resections, 4 (20.0%) complications related to the I and II grades by Clavien-Dindo developed. There were no significant differences in the rateof complications between the groups (p = 0.41). All complications were cured conservatively. Re-operations were not required. No mortality occurred in both groups.

A positive resection margin (R1) in the main group was detected in 3 (9.7%) cases, while, according to the results of a pathomorphological study, the removed neoplasms were benign and did not require re-operation. A control

colonoscopy within 5.5 (3;8) months showed no recurrence.

In the control group, no positive resection margin (R1) was obtained.

In 19 (61.2%) patients in the main group and 8 (40.0%) patients in the control,the tumors were tubulo-villous adenomas with low-grade epithelial dysplasia.

Tubulo-villous adenomas with high-grade epithelial dysplasia were detected in 7 (22.6%) patients of the main and 6 (28.6%) patients of the control group ($p = 0.48$).

In 5 (16.1%) patients in the main group and in 6 (30.0%) patients in the control one, adenocarcinoma pT1 was detected. In each group there were 2 cases with the invasion into the submucosal layer of sm2 and 1 case with invasion into the submucosal layer of sm3, according to the Kikuchi classification ($p = 0.30$).

Thus, out of 51 observations in both groups, adenocarcinomas were detected by morphology in 11 (21.5%) removed specimens. At the same time, invasion of the pT1sm2 level and deeper was registered in 6 (11.7%) cases. In other words, only in these 6 (11.7%) patients it was justified to perform colon resection in compliance with oncological principles.

Taking into account the results of histology, 3 (9.7%) patients of the main group underwent colon resection with removal of the mesentery with regional lymph nodes (Table 2).

Metastatic lesion of the lymph nodes was detected in 1 out of 3 patients of the main group who underwent re-operation. In the control group, no metastases to regional lymph nodes were detected in the removed specimens.

DISCUSSION

The widespread use of diagnostic and screening colonoscopy has led to an increase in the detection of colorectal polyps, including those whose endoscopic removal is impossible.

In this situation, colorectal resection is most often performed in patients.

In 2020, a team from the USA published the results of a cohort study that included 280,815 patients who underwent colorectal resections for tumors. More than a third of the patients (81,937) had benign neoplasms. At the same time, postoperative complications of III-IV on the Clavien-Dindo scale developed in 17% of the patients [11], which is significantly higher than after hybrid procedures (3.5%). The mortality rate was 1.5% [11], which is higher than in hybrid approach (0.7%) [12–14]. It should be emphasized that the results of hybrid procedures differ significantly, which indicates that this trend is insufficiently developed.

In addition to the safety of these operations, the question of their radicality remains open.

In an attempt to answer it, Arezzo, A. in 2015 published a systematic review of the literature with meta-analysis, which included 11 single-center non-randomized studies. The total number of patients was 621, in whom 707 neoplasms were detected. All patients underwent one or another type of hybrid procedure. The mean postoperative hospital stay was 3 days.

Re-operations for oncological radicality were required in 7.9%, for postoperative complications — in 3.5%. The recurrence rate of colorectal neoplasms was 3.4% with a mean follow-up of 35.5 months [12]. The resection margins were not analyzed. The authors concluded that hybrid surgeries are quite radical and safe. It should be noted that this paperhas some drawbacks: it is based on the data of retrospective, incomparable studies, which limits its value.

The results of this study have demonstrated that the hybrid laparoscopic approach for colon neoplasms allowed to achieve negative resection margins in 90.3% of cases, while no complications requiring re-operations developed. Positive resection margins were obtained only in three cases in the main group at the initial stage of the study during the implementation of the technique. In the future, in all cases, it was possible to achieve radical removal of neoplasms.

It should be emphasized that only 6 (11.7%) patients included in the study had adenocarcinoma with invasion of pT1sm2 and deeper, which, according to current clinical guidelines, is an indication for colon resection according to oncological principles.

In most patients, local excision of the tumor could be an adequate approach.
Taking into account the lack of literature data, a randomized study has been initiated, the purpose of which is to improve the results of treatment of colon neoplasms that are not subject to endoscopic removal. This study is registered on the website clinicaltrials.gov No. NCT04801355.

CONCLUSION

Hybrid laparoscopic-endoscopic procedures may be offered as an alternative to colorectal resection in the patients with adenomas that are not subject to endoscopic removal.
This approach, in comparison with resection, do not increase the rate of postoperative morbidity, and make it possible to decrease postoperative hospital stay.
The significance of the results obtained in the pilot study is limited by a small number of the cohort, as well as the design.
Therefore, a prospective randomized trial is required to objectify the data.

AUTHORS CONTRIBUTION
Concept and design of the study: *Oleg I. Sushkov, Evgeniy S. Surovegin, Aleksey A. Likutov*
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