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Endoscopic submucosal dissection for early colon cancer. Early results

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ABSTRACT *AIM: to identify risk factors for perforation during colorectal ESD for early colon cancer.*
PATIENTS AND METHODS: the study included 61 patients with early colon cancer who underwent ESD in 2018–2023. Perforation was defined as a deep muscular layer defect down to serosa with its preservation without connection with free peritoneal cavity. Clinical risk factors for perforation during ESD, including age, gender, tumor morphology, tumor size, tumor location, procedure time, were analyzed.
RESULTS: the mean ESD specimen size was 20.0 (1.50–2.80) mm. The overall en bloc resection rate was 81.7%. Perforations occurred during ESD in 6 of 61 patients (9.9%). All perforations were successfully treated with endoscopic closure using hemoclips and nonsurgical management. No emergency surgery occurred. On univariate analysis, tumor size ⩾ 2.0 cm (p = 0.04), localization in the right colon (p = 0.04), 2B-high type\JNET classification (p = 0.0004), negative lifting (p = 0.04) were the factors most significantly associated with perforation.
CONCLUSION: tumor size ⩾ 2.0 cm, tumor site in the right colon, 2B-high type (JNET), negative lifting are risk factors for perforation during ESD in early colon cancer.

KEYWORDS: *endoscopic submucosal dissection, early colon cancer, colon perforation*

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

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BACKGROUND

Recently, the main method for colon cancer is surgery. Regarding early colon cancer, surgeons have a wide variety of treatment methods in their arsenal, starting with endoscopic local removal and ending with various types of open, laparoscopic, and robotic colon resections [1]. Endoscopic submucosal dissection (ESD)is a safe method of local removal of benign neoplasms of the colon for many years [2].

At the same time, the issue of the use of ESD in early cancer remains quite controversial. One of the main limitations for this is the presence of negative prognosis factors related to the tumor itself (deep invasion into the submucosa, G3 differentiation of adenocarcinoma, lymphovascular and venous invasion, tumor budding). In such situations, local removal of early colon cancer is non-radical and requires performing a “rescue surgery” in the form of resection [3,4]. Another negative aspect of endoscopic dissection in early cancer is the technical side of the technique, which is the appearance of problems with lifting the neoplasm and searching for a layer during the procedure, due to the presence of an invasive tumor, as a result of which the muscle layers are damaged, while intraoperative complications (bleeding, perforation) develop, which worsen the immediate results and oncological effectiveness (an increase in the rate of R1 resections) of dissections in the submucosal layer [4].

AIM

To demonstrate of the possibilities of endoscopic submucosal dissection in patients with early colon cancer. Patients with early cancer with invasion limited to the submucosal layer were selected and systematized. The analysis of the early results and the rate of intraoperative complications associated with deep lesion of the intestinal wall up to perforation were performed, significant and independent risk factors were identified.

PATIENTS AND METHODS

The study was single-center and retrospective. In the period of 2018–2023, 1,100 endoscopic submucosal dissections for colon adenomas and adenocarcinomas were performed. Based on the data from the pathomorphologyof removed specimens, 61/1,100 (5.5%) patients with colon cancer with invasion into the submucosa were selected for further analysis. Before dissection, all patients underwent diagnostic colonoscopy on expert-class endoscopic devices. A modified JNET classification was used to evaluate the surface pattern of the tumor in order to predict the depth of invasion [5]. To exclude metastases to the regional lymph nodes, all patients underwent computed tomography or abdominal ultrasound. A biopsy was not performed due to the associated high risk of submucosal fibrosis. The tumor lifting was evaluated in accordance with Kato H. classification [6].

To prepare the bowel before surgery, schemes using drugs based on polyethylene glycol were used. Endoscopic submucosal dissection was performed according to the classical method; tunnel and ligature methods were not used. During dissection, Olympus expert-class video endoscopic equipment was used — colonoscopes with a double focus function, and gastroscopes combined with an EVIS EXERA III video processor and an ERBE 300D electrosurgical unit were used to locate the neoplasm in the rectum. Clavien-Dindo's classification was used to analyze the severity of postoperative complications [7].

During the dissection process, technical difficulties arose, the presence of which could lead to the development of intra- or postoperative complications. They were combined by us for subsequent inclusion in the analysis of risk factors: inconvenient location of the tumor (location on the fold, lack of removal of the optimal angle of attack of the endoscope), increased intestinal motility, the presence of large vessels in the submucosa.

In some cases, if it was difficult to identify the layer during dissection, an endoscopic loop was used to permanently remove the neoplasm. After performing the dissection, an endoscopist assessed the lesion of the intestinal wall. The Sydney classification of wall lesion after endoscopic mucosectomy, adapted for the presented article, was used. It was proposed in 2016 by Burgess N.G. et al. [8], according to which 6 types of endoscopic pattern of postoperative wall defect were identified (Fig. 1):

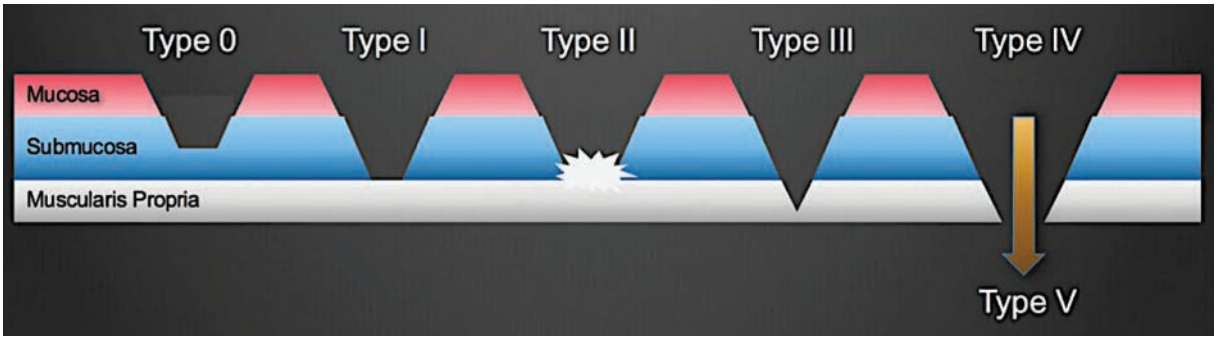

Figure 1. *Sydney classification of intestinal wall damage after endoscopic removal of tumors (mucosectomy, submucosal dissection)*

Type 0. Only the submucosal layer of the intestinal wall is visualized;
Type I. The submucosal and muscular layers are visualized, without signs of lesion of the latter;
Type II. The muscle layer is visualized over a larger area of the defect, and areas of lesion are noted;
Type III. There is marked lesion of the muscle layer of the wall, and there is a "target" symptom in the form of a rounded coagulation ring of the resected muscle layer left on the surgical specimen or in the area of the defect bottom;
Type IV. Perforation of the intestinal wall without contamination of the abdominal cavity;
Type V. Perforation of the intestinal wall with contamination of the abdominal cavity with intestinal contents.
When a defect with a lesion depth corresponding to types 0–II was detected, as a rule, it did not need to be closed, in the presence of a defect of types III–V, the intervention was completed by clipping, in type V with abdominal cavity contamination, surgeons were consulted to resolve the issue of revision and rehabilitation of the abdominal cavity.
Removed specimens after dissection were subjected to a total pathomorphological examination. The 8th edition of the TNM classification was used to stage adenocarcinoma, and Kikuchi's subclassification was used to determine the depth of invasion of the submucosal layer [9].
In the case of adenocarcinoma with deep invasion into the submucosal layer or negative prognosis factors identified during pathomorphological examination, patients were recommended to undergo resection of the large intestine.

RESULTS

The study included 61/1,100 (5.5%) patients with colon adenocarcinomas. By gender, 33/61 (54%) women predominated. The average age (M ± SD) was 66 ± 10.2 years. The distribution of patients by demographics, localization, and endoscopic imaging data is shown in Table 1.

Table 1. *Characteristics of neoplasms*

Parameter		n = 61 (100%)
Age, years (M ± SD min-max)		66 ± 10.2
Gender Male Female		28 (46%) 33 (54%)
Diameter, cm (Me, min-max)		2.0 (1.5–2.8)
Localization	Sigmoid	34 (55.7%)
	Descending	3 (4.9%)
	Transverse	11 (18.0%)
	Ascending	9 (14.8%)
	Caecum	4 (6.6%)
The type of surface pattern according to the JNET classification	2a	7 (11.5%)
	2B-low	45 (73.8%)
	2B-high	5 (8.2%)
	3	4 (6.5%)

Table 2. *Tumor lifting in accordance with the classification of Kato H. [6]*

Tumor lifting	Type	n = 61 (100%)
Type as per Kato H.'s classification [6]	1 type	23 (37.7%)
	2 type	27 (44.3%)
	3 type	10 (16.4%)
	4 type	1 (1.6%)

For subsequent analysis, the tumors were divided by localization in the right and left colon (the middle third of the transverse colon was considered the conditional border). The majority of tumors, 37/61 (60.6%), were localized in the left colon. The median dissection time (Me, max–min) was 60 (45–94) minutes. When evaluating tumor lifting, it turned out that almost every fifth patient had an inadequate lifting of 11/61 (18%), corresponding to type 3–4 according to Kato, H.'s classification, which indirectly indicated the presence of invasion into the submucosal layer.

Intraoperative and Postoperative Complications

There was no conversion to another type of endoscopic intervention or to resection in any case. Intraoperative complications during dissection occurred in 7/61 (11.5%) cases. Bleeding during surgery developed in 1/61 patient (1.6%) with neoplasm localization in the cecum (type III lesion according to the Sydney classification). In this case, incomplete tumor lifting corresponded to type 3 according to Kato H.'s classification [6]. During dissection, difficulties arose in separating

the submucosal layer from the muscular layer with injury to the latter, bleeding developed from the vessel of the muscular layer, which was stopped by applying a clip. The most serious intraoperative complication, deep lesion to the intestinal wall up to perforation, developed in 6/61 (9.9%) patients (type IV according to the Sydney Classification): 3 patients with tumor localization in the cecum, one — in the ascending colon, and two patients — in the descending colon. It should be noted that no type V defects were noted in any case. In all cases, the complication was eliminated endoscopically using clips and closing the defect endoluminally. As in the case of bleeding, lifting was inadequate, while in 1/6 case it corresponded to type 4 according to Kato, N.'s classification [6].

Depending on the lesion depth to the muscle layer during dissection, we conditionally divided patients into a group with superficial lesion (types 0–I according to the Sydney Classification) and deep lesion on the intestinal wall (types II–IV). Risk factors that could cause lesion on the intestinal wall of various depths and as a result of perforation were analyzed: localization of the tumor (right and left colon, size of the neoplasm (< 2 cm or ⩾ 2 cm), the presence of inadequate lifting (type 3–4 according to Kato, N.), duration of dissection (< 60 min. or ³60 min.), the presence of signs of deep tumor invasion (type 2B-high type according to JNET), the use of loop excision to remove the specimen, fragmentation of the surgical specimen, technical difficulties during dissection (Fig. 2).

Based on the univariate analysis, it turned out that the tumor size ⩾ 2.0 cm, localization in the right colon, type 2B-high according to JNET classification and lifting 3–4 according to Kato, H., are significant factors associated with the risk of intraoperative deep lesion up to perforation. Given the small number of intraoperative perforations in this sample of patients, multivariate analysis was not advisable.

There was no mortality after endoscopic dissections. There were also no postoperative complications requiring re-operations or hospitalization. In 12/61 (19.6%) patients, the phenomena of postcoagulation syndrome were noted, which was stopped in all cases by conservative measures: the administration of intraluminal or systemic antibacterial drugs (grade I as per Clavien-Dindo's classification).

Pathomorphological Examination of Surgical Specimens

During the pathomorphological examination of removed specimens, it was noted that in 50/61 (81.7%) patients, *en bloc* removal of the neoplasm was noted (Table 3). However, only in half of the cases, 31/61 (50.8%), a negative resection border (R-0) was noted.

All neoplasms were structurally adenocarcinomas of varying degrees of differentiation: in most cases, 32/61 (52.5%) adenocarcinomas were highly

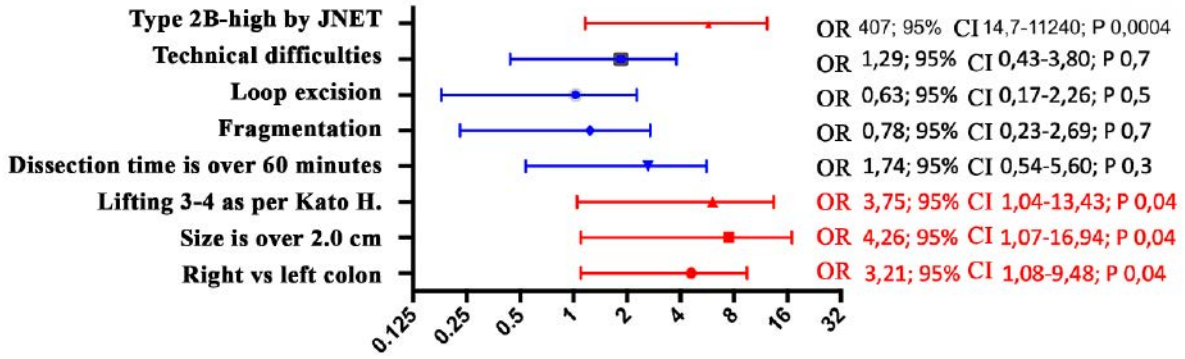

Figure 2. *A tree-like graph of the results of a univariate analysis of risk factors for deep damage to the intestinal wall during endoscopic dissection*

Table 3. *Results of pathomorphological examination of surgical preparations after endoscopic dissection*

Parameter	n = 61 (100%)
Resection *en bloc*	50/61 (81.7%)
ResectionR0	31/61 (50.8%)
Resection R1 (< 1mm)	18/61 (29.5%)
The mean lateral margin of resection is M ± SD (min-max), mm	2.0 ± 0.3 (0-4)
The mean deep resection margin is M ± SD (min-max), mm	1.2 ± 0.2 (0-2)

Table 4. *Distribution of tumors depending on the depth of invasion, structure, differentiation, and presence of lymphovascular invasion*

The tumor structure	n = 61 (100%)
AdenocarcinomaT1 sm1 sm2 sm3	34/61 (55.7%) 11/61 (18.0%) 16/61 (26.3%)
HDA (G1)	32/61 (52.5%)
MDA (G2)	25/61 (41%)
LGA (G3)	4/61 (6.5%)
Lymphovascular invasion	23/61 (37.7%)

differentiated (Table 4). It is worth noting that more than half of the patients had superficial invasion of the submucosal base pT1sm1 –n = 34/61 (55.7%).

According to the data of the pathomorphological examination after dissection, the majority of 42/61 (68.8%) patients showed signs of a negative tumor prognosis in the form of R1 resection, G3 differentiation, deep invasion of the submucosal base — sm3 and/or the presence of lymphovascular invasion. In accordance with the national clinical guidelines for the treatment of colon cancer, patients were offered surgical treatment in the form of intestinal resection, a "rescue surgery". Nevertheless, 26/42 (62%) patients agreed to transabdominal procedure, which, depending on the location of the removed lesion during dissection, was performed: 13/26 — right hemicolectomy, 2/26 — transverse colon resection, 6/26 — sigmoid colon resection, 5/26 — left hemicolectomy (Fig. 3). It is important to emphasize that the residual tumor in the area of endoscopic resection was detected in 2/26 (7%) cases. Tumors were located in one patient in the distal third of the transverse colon, in the other case in the descending colon and corresponded to pT1sm3. Based on the data of the pathomorphological examination, the stage of pT1sm3N0 (0/9)M0 was found in the first patient, and pT1sm3N2a(5/25) M0L1 in the second one. Also, after performing

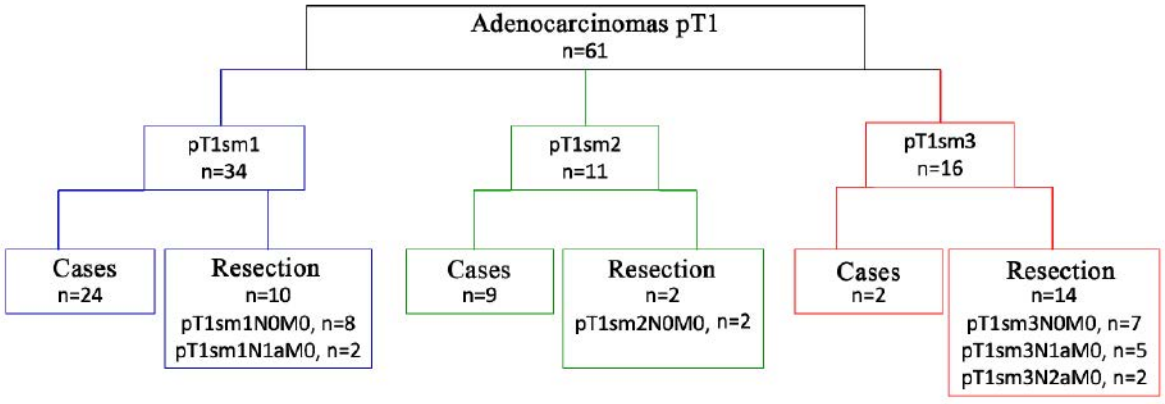

Figure 3. *Results of endoscopic dissections and "rescue operations" in patients with early colon cancer*

a “rescue resection”, 9/26 (34%) patients had affected regional lymph nodes: 5/9 patients had stage pT1sm3N1a, 2/9 patients had pT1sm1N1aL1, and 2/9 patients had pT1sm3N2aL1.

In all cases, patients underwent adjuvant polychemotherapy according to the XELOX and FOLFOX regimen. Recently, 38/61 (62.3%) patients have been followed up. The median follow-up (Me, min-max) is 31 (2–46) months, there were no signs of locoregional recurrence.

DISCUSSION

Endoscopic submucosal dissection is an attractive alternative to resection methods for colon tumors. In recent years, there has been a stereotype that endoscopic dissection is the main organ-preserving technology in patients with colon adenomas. ESD is a safe method with a rate of post-operative complications not exceeding 2–3%, while the probability tumor fragmentation is less than 15% [3, 10]. In relation to patients with early colon cancer, the approach to local removal is more restrained. Already at the stage of diagnostic colonoscopy, a possible tumor invasion into the submucosa is identified based on endoscopic classifications (2B-low/2B-high/3 type according to JNET) and a connection with inadequate tumor lifting is traced, which in turn is the main factors for making a decision in favor of dissection or resection. The selection of patients for ESD should be careful, as there is a direct relationship between the endoscopic picture of a malignant adenoma with an invasive cancer focus, unsatisfactory tumor lifting and lesion of the colon wall during dissection deeper than the submucosa. In the presented work, we found a high incidence of intraoperative complications — 11.5% during ESD, and the most common, which developed in one of ten (9.9%) patients, was deep lesion on the intestinal wall. It should be noted that during transanal endomicrosurgery (TEM) for early colorectal cancer, many authors [11, 12] do not describe any complications during the procedure at all. The reason for this is the anatomical feature of the rectum with its surrounding fiber, when full-thickness excision with suturing of the defect eliminates most septic complications. On the contrary, deep lesion of the colon wall during dissection, up to perforation, is a significant complication, since it is technically difficult and sometimes impossible to stop it, especially in the absence of devices for an endoluminal suture. Therefore, it is an important task to predict this complication and identify risk factors. So, Burgess N.G. et al. [8] proposed The Sydney Classification of wall lesion after endoscopic mucosectomy.

The authors showed in their work that deep lesion is noted only in 3.0% of cases, and significant factors are the tumor size of more than 25 mm, localization in the transverse colon, *en bloc* resection and the presence of invasion into the submucosal layer. In this study, a higher incidence of perforations was noted — 9.9%. However, in all cases these were patients with invasive early colon cancer, and in our opinion, these are fairly acceptable indicators of the development of this intraoperative complication. The univariate analysis showed that significant factors that can lead to deep lesion on the wall are endoscopic signs of deep invasion, reflected as type 2B-high according to the JNET classification, the tumor size exceeding 2.0 cm, localization in the right colon, and this is associated with a thinner intestinal wall, the presence of inadequate lifting — 3/4 type according to Kato H.

The low rate of R0 resection (50.8%) and *en bloc* resection (81.7%) is also noteworthy in the group we analyzed. At the same time, in a number of publications comparing endoscopic submucosal dissection with resection methods, the rate of R0 interventions exceeds 91% [14–16]. However, these studies consider the results of ESD, performed mainly for benign neoplasms, and not for early cancer, where no more than 5–10% is allocated to the proportion of adenocarcinomas. It is important to emphasize that according to our data, in two cases after the performed “rescue resections” for oncological indications, signs of a residual tumor were revealed. Also, Sun, Y.M. et al., analyzed

the results of "rescue resections" after endoscopic removal of early colon cancer. In 5.4% of cases, a residual tumor was found in the dissection area [16]. This circumstance highlights the complexity of the technique of dissection in the colon, namely, for a tumor with invasion of the submucosal layer. There are studies proving that the rate of "rescue resections" for oncological indications after TEM with full-wall removal of the tumor is significantly lower than the rate of resections in similar situations after dissections — 2.9% and 8.4%, respectively, $p = 0.001$ [17]. Thus, Khomyakov E.A. et al. [18] showed that for 600 surgical procedures performed in the volume of TEM, pathomorphological examination of removed specimens in no case revealed a residual tumor in the area of local removal. Therefore, the improvement of endoscopic techniques with full-thickness removal of early colon cancer and endoluminal suture is currently a promising area in the treatment of this complex category of patients.

CONCLUSION

Endoscopic submucosal dissection in early colorectal cancer may be a promising intervention in a selected cohort of patients. Tumor size ⩾ 2.0 cm, localization in the right colon, type 2B-high according to the JNET classification and lifting 3–4 according to Kato H., are significant factors associated with the risk of intraoperative deep lesion on the intestinal wall up to perforation.

AUTHORS CONTRUBUTION

Concept and design of the study: *Dmitriy A. Mtvralashvili, Alexey A. Likutov*
Processing of the material: *Dmitriy A. Mtvralashvili, Oleg M. Yugai*
Writing of the text and statistical data processing: *Mikhail A. Tarasov, Stanislav V. Chernyshov*
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