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Endoscopic mucosal resection with a circumferential incision in the removal of colorectal neoplasms (preliminary results of the prospective randomized study)

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ABSTRACT *AIM: to assess the early results in patients with benign epithelial colorectal neoplasms which underwent endoscopic mucosal resection with a circumferential incision (C-EMR).*

PATIENTS AND METHODS: a prospective randomized trial included 50 patients who underwent endoscopic removal of benign epithelial colorectal neoplasms sized 20–30 mm (November 2020 — January 2022). The main group included 26 patients which underwent C-EMR. The control group included 24 patients which underwent endoscopic submucosal dissection (ESD).

RESULTS: postoperative complications developed in the C-EMR group in 5 (19.2%), and in the ESD group — in 7 (29.2%) cases ($p = 0.51$). The operative time in the C-EMR group was significantly less than in the ESD group — 30 vs 60 min., respectively ($p < 0.001$). In all cases in both groups, tumors were removed en bloc. There R0 resection were performed in 22 (84.6%) and in 23 (95.8%) cases in the main and control groups, respectively ($p = 0.3$). Two (8.3%) procedures in the control group were converted to the C-EMR procedure.

CONCLUSION: endoscopic mucosal resection with a circumferential incision is an effective and safe method for removing benign epithelial neoplasms sized 20–30 mm, as well as submucosal dissection. The removal of the tumor by the C-EMR method reduces operative time by half compared with ESD method.

KEYWORDS: circular incision, epithelial neoplasms, EMR, ESD, C-EMR

CONFLICTS OF INTEREST: The authors declare no conflicts of interest

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INTRODUCTION

Standard endoscopic mucosal resection (EMR) is considered the main method of removal of epithelial colorectal tumors worldwide [1]. When removing neoplasms of the size exceeding 20 mm by EMR, it is often necessary to resort to its fragmentation, i.e. piecemeal endoscopic mucosal resection (P-EMR), which eventually translates into a high rate of local recurrences [2, 4]. In addition, the correct histological assessment of the fragments of the removed neoplasm and the resection margins becomes an almost unsolvable task

for pathologists. Taking this into account, currently endoscopic submucosal dissection, (ESD) is increasingly used to remove colorectal tumors, which makes it possible to overcome the disadvantages of mucosectomy [3]. As it is known, ESD was developed to remove large epithelial neoplasms of the upper gastrointestinal tract, while providing better early and late results compared to other methods, regardless of the size of the neoplasm [5]. However, this technique also has a number of disadvantages: a long learning curve, a long operative time, a high rate of perforation of the bowel wall [6].

Table 1. General characteristics of patients and removed neoplasms in the study groups

Parameter	C-EMR (n = 26)	ESD (n = 24)	p
Age, years	64 (42-78)	60 (45-78)	0.16*
Gender			
Male	10 (38.5%)	13 (54.2%)	0.26***
Female	16 (61.5%)	11 (45.8%)	
Localization of the tumor in the colon			
Caecum	3 (11.5%)	5 (20.8%)	0.45**
Ascending colon	10 (38.5%)	7 (29.2%)	0.55**
Transverse colon	8 (30.8%)	8 (33.3%)	1.0**
Descending colon	1 (3.8%)	0	0.33***
Sigmoid colon	4 (15.4%)	4 (16.7%)	1.0**
Median tumor size, quartiles mm	25 (21-25)	25 (23-30)	0.12****

p* — unpaired t-test; p** — Fisher's exact test; p*** — χ^2 -test; p**** — Mann Whitney's test

Table 2. Characteristics of colon polyps according to endoscopic classifications in the groups

Parameter	C-EMR (n = 26)	ESD (n = 24)	p
Parisian Classification			
0-Is	5 (19.2%)	1 (4.2%)	0.19*
0-IIa	21 (80.8%)	23 (95.8%)	0.19*
Pragmatic classification			
LST-GH	12 (46.2%)	9 (37.5%)	0.54**
LST-GM	0	3 (12.5%)	0.1*
LST-NG-FE	9 (34.6%)	11 (45.8%)	0.56*
Pit pattern (Kudo, S., Kimura, T.'s classifications)			
IIIs	5 (19.2%)	5 (20.8%)	1.0*
IIIL	13 (50.0%)	7 (29.2%)	0.15*
IIIL+IV	1 (3.8%)	2 (8.3%)	0.46*
II-O	7 (26.9%)	10 (41.7%)	0.37*
Capillary pattern (Sano, Y.'s classification)			
I	6 (23.1%)	9 (37.5%)	0.35*
II	20 (76.9%)	15 (62.5%)	

p* — Fisher's exact test; p** — χ^2 -test

In order to increase the *en bloc* resection of epithelial neoplasms of the esophagus and stomach, Japanese colleagues in 1988 for the first time proposed a new method for their removal using a circumferential mucosal incision (CMI) and subsequent loop excision. This technology was especially useful in the removal of flat neoplasms, when the capture of the formation by the endoscopic loop was complicated [7]. According to literature data, in the case of endoscopic procedures for epithelial neoplasms of the stomach, the effectiveness of the C-EMR method is comparable with ESD in terms of achieving negative resection margins [8, 9].

In some comparative Japanese and Korean studies, it is reported that the rate of removal of large

colorectal neoplasms *en bloc* using C-EMR and ESD does not significantly differ [10, 11]. Other authors have demonstrated a higher morbidity rate and a lower incidence of *en bloc* removal of the specimen using the C-EMR method compared with ESD in the case of colorectal tumors larger than 20 mm [12, 13].

Given the lack of results of randomized trials, the question of the effectiveness and safety of using C-EMR in the removal of large epithelial benign colorectal neoplasms remains poorly understood at the moment.

That is why it is a need for a prospective randomized study comparing the C-EMR for the removal of benign epithelial colorectal neoplasms with a size of 20 to 30 mm.

PATIENTS AND METHODS

In November 2020, a single-center prospective randomized comparative study started, which has

so far included 50 patients with benign epithelial neoplasms of the colon ranging 20–30 mm. The study protocol was approved by the local ethics committee. All the patients signed an informed

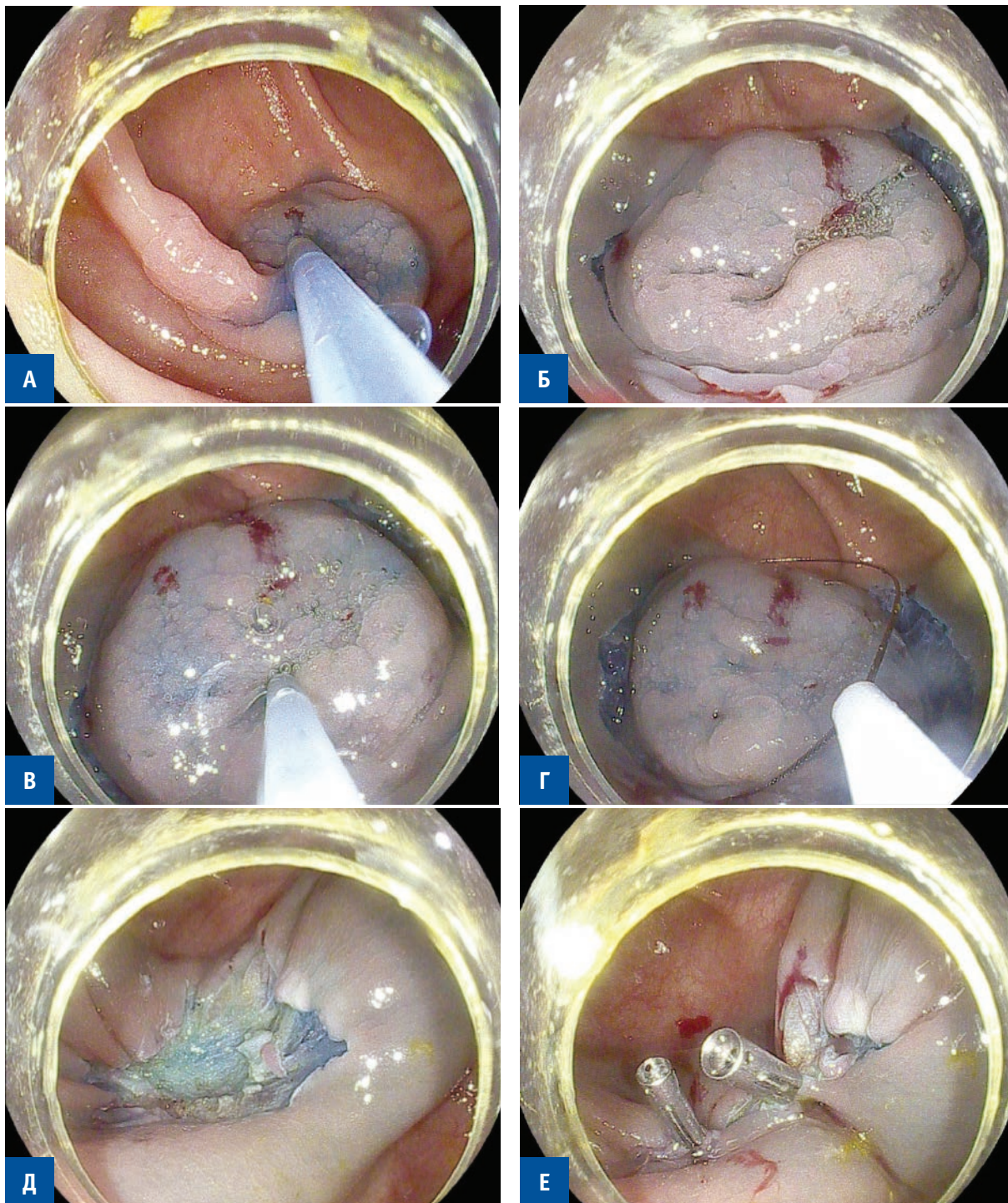


Figure 1. Endophoto of the main stages of endoscopic resection with a circular incision of the epithelial neoplasm of the caecum (C-EMR): А — creation of a liquid submucosal cushion; Б — making a circular incision around the tumor with an indent of 2–3 mm; В — additional injection of a solution into the base of the tumor; Г — installation of an endoscopic loop 33 mm in the zone of a circular incision; Д — visual assessment of the postoperative defect; Е — clipping of the wound surface.

consent to participate in it. The inclusion criteria were: benign epithelial neoplasms of the colon without the presence of endoscopic signs of malignancy (pit pattern corresponding to types IIIs, IIIL, IV according to the Kudo S. classification, and type II-O according to the classification of Kimura T., vascular pattern — type I and II according to Sano Y.); age over 18 years; informed consent of the patient. The non-inclusion criteria included: epithelial neoplasms with endoscopic signs of malignancy (Vi-Vn types according to Kudo S. and IIIa-IIIb types according to Sano Y.); familial adenomatous polyposis; recurrent colorectal neoplasms; refusal of the patient to participate in the study at any stage. The exclusion criterion was incomplete lifting of the tumor or its absence.

The distribution of the patients into groups was carried out using a random number generator on the website *randomizer.org*. The main group, which used the technique of endoscopic mucosal resection with a circumferential incision, included 26 patients. The control group, where removal of tumors was carried out using endoscopic submucosal dissection, included 24 patients. In the both groups, procedures were performed under intravenous sedation. During the endoscopy, first of all, the location and size of the epithelial neoplasm were evaluated.

There were no significant differences between the groups by age, gender, tumor site and its size (Table 1).

The macroscopic structure of the tumor was evaluated according to the Parisian and Pragmatic classifications [14, 15]. The pit and microvascular patterns were interpreted according to Kudo, S. and Sano, Y.'s classifications [16, 17]. With regard to the characteristics of dentate formations, the classification of Kimura, T. was used [18]. The characteristics of neoplasms, according to endoscopic classifications, are presented in Table 2.

In the macroscopic evaluation of the removed specimens in the main group, in 21 (80.8%) cases epithelial tumors were predominantly flat (0-IIa type according to the Parisian classification), in 5 (19.2%) cases — on a wide basis (0-Is type according to the Parisian classification). In the control group, 0-IIa type tumors were detected in 23

(95.8%) cases, and 0-Is type — in 1 (4.2%) case. According to the Pragmatic classification, in the C-EMR group, the largest number of cases were granular homogeneous laterally spreading neoplasms (LST-GH) — 12 (46.2%) cases, and in the ESD group — non-granular flat-raised (LST-NG-FE) — 11 (45.8%). However, there were no statistically significant differences between the groups when assessing neoplasms using the Parisian and Pragmatic classifications.

The first stage in performing endoscopic submucosal dissection was to create a “cushion” in the submucosal layer of the intestinal wall using an injection needle and Gelofusine® stained with 0.4% indigocarmine.

Lifting was evaluated using Kato H.'s classification [19]. In the presence of a complete lifting (the 1,2 types according to Kato H.), in the case of ESD, a semilunar incision of the mucosa 2–3 mm from the distal pole of the neoplasm was performed with an endoscopic knife. The next step was the dissection of the submucosal layer.

During the procedure, for a longer preservation of the “cushion” of the submucosal layer, an additional injection of solution was repeatedly performed. After complete separation of the tumor, the postoperative surface was evaluated in accordance with the Sydney Classification to determine the depth of damage to the intestinal wall [20]. The remaining perforant vessels in the formed defect were treated with a coagulation grasper, and, if necessary, clipping of the intestinal wall defect was performed. Upon completion of the dissection, the removed neoplasm was extracted and fixed on a foam plate for a correct assessment of the resection margins.

When removing the neoplasm using the C-EMR technique, after lifting, a circumferential incision was made around the tumor with an indentation of 2–3 mm to achieve negative lateral resection margins. Then, without fail, repeated injection of gelofuzine solution with indigocarmine into the base of the neoplasm was carried out, which reduced the risk of thermal damage to the deep layers of the intestinal wall. Then, an endoscopic loop was installed directly into the incision area, and electroexcision of the tumor was performed. After removal of the neoplasm, visual control of the formed defect of the intestinal wall was carried



Video 1. Endoscopic mucosal resection with a circumferential incision in the removal of colon neoplasms

out and, if necessary, its clipping was performed (Fig. 1, Video 1).

The systematization and accumulation of initial information about patients was carried out in a spreadsheet Microsoft Office Excel 2018. The statistical analysis was carried out using the IBM SPSS Statistics v. 26 program.

The research materials were subjected to statistical processing using parametric and nonparametric analysis methods.

Quantitative indicators were evaluated for compliance with the normal distribution, for this purpose Shapiro-Wilk's test was used. In the case of describing quantitative indicators with a normal distribution, the data obtained were combined into variational series in which arithmetic averages (M) and standard deviations (SD), the limits of the 95% coincidence interval (95% CI) were calculated. Aggregates of quantitative indicators whose distribution differed from normal were described using median values (Me) and lower and upper quartiles (Q1-Q3).

Nominal data were described with absolute values and percentages. When comparing average values in normally distributed sets of quantitative data, Student's t-test was calculated.

Mann-Whitney's U-test was used to compare independent aggregates in cases where there were no signs of normal data distribution.

For the analysis of qualitative variables, the χ^2 test and the exact Fisher's test were used.

RESULTS

When analyzing the operation time, we took into account the time spent on intubation of the colon to the tumor location zone, determining its size,

assessing the dimple and vascular patterns of the neoplasm, removing the tumor and extracting it. The median operative time in the main group was 30 (25–35) minutes, which turned out to be significantly less than half the operative time in the ESD group — 60 (60–90) minutes ($p < 0.001$) (Table 3). There were no intraoperative complications during the removal of neoplasms by C-EMR and ESD methods. The assessment of the incidence and nature of postoperative complications was carried out within 30 days in accordance with Clavien-Dindo's classification.

Postoperative complications after endoscopic procedure in the main and control groups developed in 5 (19.2%) and 7 (29.2%) patients, respectively ($p = 0.5$).

Postcoagulation syndrome (PS) in the postoperative period was diagnosed in the presence of pain during palpation of the abdomen in the surgery site, subfebrile hyperthermia, an increase in the level of C-reactive protein (CRP) above normal values and occurred in 5 (19.2%) and 6 (25.0%) patients of the main and control groups, respectively ($p = 0.7$). This complication corresponded to grade I according to Clavien-Dindo's classification, and was cured conservatively.

In the ESD group, 1 (4.2%) patient developed postoperative bleeding, which corresponded to grade III according to Clavien-Dindo's classification. It required a colonoscopy and clipping of a bleeding vessel.

There was no conversion to abdominal surgery in any of the groups. However, in 2/24 (8.3%) cases in the group of endoscopic submucosal dissection, conversion to C-EMR was carried out (Table 3). The reason for the conversion was the tumor site inconvenient for performing ESD (behind the "upper lip" of the ileocecal valve) in one case, and intestinal spasm against the background of abdominal breathing — in another one.

It should be emphasized that no fragmentation of the tumor occurred in any observation in the two groups, all neoplasms were resected *en bloc* (Table 4).

In one case in the main group, due to the deformation of the lateral edge of the resection of the specimen by thermal action, it was difficult to clearly assess the resection margins. In addition, in 3 (11.6%) and 1 (4.2%) cases in the main and

Table 3. Characteristics of endoscopic removal of neoplasms in groups

Parameter	C-EMR (n = 26)	ESD (n = 24)	p
Median operative time, quartiles min.	30 (25–35)	60 (60–90)	0.001**
Postoperative complications	5 (19.2%)	7 (29.2%)	0.5*
Postcoagulationsyndrome, n (%)	5 (19.2%)	6 (25.0%)	0.7*
Bleeding, n (%)	0	1 (4.2%)	0.48*
Conversion rate, n (%)	0	2 (8.3%)	0.2*
Lifting of neoplasms, H. Kato			
1 type	25 (96.2%)	22 (91.7%)	0.6*
2 type	0	2 (8.3%)	0.2*
3 type	1 (3.8%)	0	1.0*

p* — Fisher's exact test; p** — Mann-Whitney's U-test

Table 4. Results of the pathomorphological study of specimens in the groups

Parameter	C-EMR (n = 26)	ESD (n = 24)	p
En bloc, %	26 (100%)	24 (100%)	–
Resection margins, %			
R0	22 (84.6%)	23 (95.8%)	0.3
R1	3 (11.6%)	1 (4.2%)	0.6
Rx	1 (3.8%)	0	1.0
Histological structure of neoplasms			
Tubular adenoma	8 (30.8%)	8 (33.3%)	1.0
Tubular villous adenoma	12 (46.2%)	7 (29.2%)	0.25
Dentate tumor	6 (23.1%)	9 (37.5%)	0.35
Grade of epithelial dysplasia			
Dentate neoplasm without dysplasia	3 (11.5%)	5 (25.0%)	0.3
Adenomas			
Low grade	19 (73.1%)	14 (58.3%)	0.4
High grade	4 (15.4%)	4 (16.7%)	1.0

p* — Fisher's exact test

control groups, respectively, the resection margins were regarded as R1 (Table 4). The results of histology of the removed specimens showed that the majority of tumors in the main group were represented by tubular-villous adenomas, and in the ESD group tubular adenomas, tubular-villous adenomas and dentate neoplasms were found with approximately the same frequency.

DISCUSSION

The development of endoscopic methods for removing colorectal neoplasms increasingly allows us to reject intestinal resection in favor of minimally invasive techniques. To date, a personalized approach to choosing the most appropriate treatment method in each case allows achieving the

best early and late results with a minimal morbidity rate.

Currently, the “gold standard” of endoscopic procedure for the removal of large benign neoplasms of the colon is *en bloc* resection, which allows pathologists to make a correct histology of the specimen. Taking into account the fact that the fragmentation of the tumor increases the recurrence rate, the removal of tumor *en bloc* should help to reduce it. A large meta-analysis devoted to the results of removal of colorectal tumors by mucosectomy showed that the recurrence rate was significantly lower after resection with a single fragment than after fragmentary resection — 3% and 20% of cases, respectively ($p < 0.0001$) [21]. That is why we consider it important that in this study, the C-EMR method was able to demonstrate a very high rate of *en bloc* resection, as well as the

method of classical submucosal dissection: in all patients, tumors were removed *en bloc*.

Almost 25 years have passed since the introduction of the ESD method, which is characterized by a higher rate of *en bloc* resection compared to mucosectomy, regardless of the size or shape of the tumor being removed. However, this method has not yet been widely used as a routine one, due to the long learning curve, as well as technical difficulties, especially in the case of removal of large colorectal neoplasms. In this regard, according to a number of authors, C-EMR can serve as a transitional stage in the development of the ESD method by young specialists [10–12].

The analysis of the results of this randomized study showed that it took twice less time to remove colon neoplasms by C-EMR than using classical submucosal dissection, which corresponds with the results of previous studies [11, 13].

The incidence of perforation of the intestinal wall in the case of using the C-EMR method largely depends on the size, site of neoplasm and the experience of an endoscopist and can reach 4.5% [11]. In this study, not a single such complication was registered, which we associate with strict compliance with the criteria for inclusion in the study. It is important to emphasize that patients with tumors with endoscopic signs of invasion into the intestinal wall, as well as whose size exceeded 30 mm, were not included in this study. Such selection of patients for this surgery, in our opinion, is extremely important, since the development of such a formidable complication as intestinal perforation can significantly worsen the prognosis of patients, compromise the method itself, which, of course, needs clarification of indications.

The analysis of the results of histology of the removed specimens showed that C-EMR allows to provide a negative resection boundary with approximately the same rate as the ESD method. Thus, during a pathomorphological study, it was found that in both groups, in most specimens, the resection margins were estimated as R0 — in 84.6% of cases in the C-EMR group and in 95.8% of cases in the ESD group. This circumstance allows us to state that the method of endoscopic mucosal resection with a circumferential incision can be an alternative to the method of

dissection in the submucosal layer in the case of removal of neoplasms with the size between 20 and 30 mm. With such a tumor size, the method of mucosectomy can no longer provide a high rate of *en bloc* resection, and the method of classical submucosal dissection is not advisable to use due to the high morbidity rate and longer operative time.

Thus, at present it can be stated that the C-EMR method demonstrates early results comparable to the submucosal dissection method. However, in order to make a final judgment, it is necessary to evaluate another important component, namely, the local recurrences rate.

CONCLUSION

The C-EMR method has demonstrated efficiency and safety comparable to the ESD method in the removal of epithelial benign neoplasms ranging in size from 20 to 30 mm. At the same time, the operative time in the group of endoscopic resections with a circumferential incision was twice less than in the group of classical submucosal dissection. It is necessary to continue the study, including to assess such an important criterion of effectiveness as the recurrence rate.

AUTHORS CONTRIBUTION

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