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Translation of the article

"Cold" polypectomy for colorectal polyps: prospective randomized trial

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ABSTRACT *BACKGROUND: endoscopic electroexcision is the standard technique for the removal of colorectal polyps. However, it is associated with the postoperative morbidity. In order to reduce the incidence of complications, "cold" excision seems to be an alternative option.*
AIM: to improve the results of endoscopic treatment for patients with colorectal polyps.
PATIENTS AND METHODS: from September 2019 to September 2020, 160 patients ⩾ 18 years old (80 in each group), who underwent endoscopic removal of colorectal polyps ⩽ 10 mm in size by cold excision (132 lesions) and traditional polypectomy (129 lesions), were included in a prospective randomized trial. All removed specimens were studied histologically with an assessment of the resection margins (R0/R1). The analysis of the postoperative complications after endoscopic polypectomy and the incidence of Rx resection after removal of polyps by both techniques was done.
RESULTS: the compared groups were homogenous in the number of patients, gender, age, and comobridities. There were no significant differences in the number of removed polyps, their site and the type according to endoscopic classifications. The operation time was significantly higher in the conventional polypectomy group compared with the "cold" one (p = 0.0001). There were no significant differences in the intraoperative complications rate between the two groups (p = 0.06). There were no postoperative complications in the "cold" group. In the control group postoperative complications occurred after 12 out of 129 polyps removal (p = 0.001). The univariate analysis showed that a risk factor for the development of postoperative complications after conventional polypectomy is the lack of submucosal lifting (OR: 15.3, 95% CI: 1.9-125.6, p = 0.01). Histopathology of the removed specimens showed that in both groups most of the procedures were considered as R0 resections (54% in the main group, 56.4% in the control group, p = 0.8). The polyp size ⩽ 4 mm identified as a risk factor for R1, Rx resection (OR: 2.4, 95% CI: 1.3–4.7, p = 0.007).
CONCLUSION: "cold" polypectomy is an effective and safe method and may be recommended as an alternative technique for the removal of non-pedunculated colorectal polyps ⩽ 10 mm.

KEYWORDS: *small colorectal polyps, colonoscopy, cold and hot snare polypectomy, resection rate, postpolypectomy symptoms*

CONFLICT OF INTEREST: *The authors declare no conflict of interest.*

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INTRODUCTION

The classic path of carcinogenesis is a malignant transformation of adenoma, the so-called mechanism of adenoma-carcinoma. Up to 85% of colorectal cancer cases develop in this way [1–3]. Despite the fact that epithelial lesions of the bowel with a size of less than 10 mm carry a low risk of severe dysplasia and malignant transformation, their timely endoscopic removal can

Table 1. *Characteristics of polyps according to endoscopic classifications*

Parameter	Cold snare polypectomy (*n* = 132)	Hot snare polypectomy (*n* = 129)	*p*
NICE			
1	14 (10.6%)	28 (21.7%)	0.02
2	118 (89.4%)	101 (78.3%)	0.02
Paris Classification			
0-Is	91 (68.9%)	86 (66.7%)	0.8
0-IIa	41 (31.1%)	42 (33.3%)	0.9
Pit pattern as per Kudo S., Kimura T.			
IIIs	44 (33.3%)	22 (17.1%)	0.04
IIIL	74 (56.1%)	77 (60.5%)	0.6
IV	–	1 (0.8%)	0.9
II-O	13 (9.8%)	19 (14.7%)	0.3
Capillaries in the form of curved lines	1 (0.8%)	9 (6.9%)	0.02
Capillary pattern as per Sano Y.			
I	14 (10.6%)	29 (22.5%)	0.02
II	118 (89.4%)	99 (77.5%)	0.007

Table 2. *Prophylactic hemostasis during polypectomy in both groups*

Parameter	Cold snare polypectomy (*n* = 132)	Hot snare polypectomy (*n* = 129)	*p*
Clipping	5/132 (3.8%)	26/129 (20.1%)	0.001
Number of clips	5/132 (3.8%)	33/129 (25.6%)	0.001
Coagulation	–	2/129 (1.6%)	0.06

prevent the development of colorectal cancer and reduce mortality rate caused by this disease [4,5].

Endoscopic polypectomy using electrocoagulation, which is widely used in practice, is a standard method for removing detected epithelial lesions of the bowel.

However, "hot" polypectomy, as well as the other types of minimally invasive removal of colorectal adenomas (submucosal dissection, transanal endomicrosurgery) can be associated with various postoperative complications [6–8].

In this regard, an interesting method of removing epithelial lesions is the "cold"polypectomy, in which the polyps are removed without using electrocoagulation. According to the results of foreign studies, this option is effective and safe [9–11].

However, despite the available results of the studies on this topic, a number of questions remain unsolved regarding the technical aspects of the cold polypectomy, the need for lifting before excision, as well as the prevention of bleeding. Moreover, the question of the need to extract the removed epithelial lesions with their subsequent morphological study and assessment of the resection margins remains debatable. In this regard the prospective study aimed at finding the optimal method for removing colorectal epithelial lesions was done.

PATIENTS AND METHODS

From September 2019 to September 2020, a prospective randomized comparative clinical trial was done and was approved by the local ethics committee and registered in the international research database on the ClinicalTrials.gov (A prospective randomized controlled trial of cold snare polypectomy vs. Conventional polypectomy for non-pedunculated colorectal adenomas, NCT03859479).

The criteria for inclusion in the study were as follows: patients aged 18 years and older, with flat colorectal epithelial lesions (adenomas, dentate adenomas), up to 10 mm in size, who signed an informed consent. The criteria for non-inclusion were as follows: the presence in patients of disorders of the blood clotting system, familial adenomatosis, inflammatory bowel diseases, comorbidities in the decompensation stage. The exclusion criteria were endoscopic signs of malignancy of the neoplasm.

The study included 160 patients (87 women and 73 men) aged between 26 and 88 years old. The

Table 3. *Characteristics and severity of postpolypectomy adverse events in both groups*

The nature of complications	Severity of complications (as perClavien-Dindo)	Cold Snare Polypectomy (n = 132)	Hot Snare Polypectomy (n = 129)	*p*
Postpolypectomy syndrome	I	–	9/129 (7%)	0.003
Bleeding	IIIa-IIIb	–	2/129 (1.5%)	0.2
Perforation	IIIb	–	1/129 (0.8%)	0.3
Total:		–	12/129 (9.3%)	0.001

distribution of the groups was done using a random number generator on the www.castlots.org site.

The analysis of the results was done as "per protocol". The patients were randomized into two groups depending on the method of removal of benign colorectal epithelial lesions: cold snare polypectomy (the main group), hot snare polypectomy (the control group), with 80 patients in each group. At the same time, 132 polyps were removed in the cold snare polypectomy group, and 129 lesions were removed in the hot snare polypectomy group.

All the patients underwent a standard preoperative checkup: digital rectal examination, rectoscopy, esophagogastroduodenoscopy, video colonoscopy.

To perform diagnostic colonoscopy and subsequent removal of identified colorectal epithelial lesions, EVIS EXERA III video endoscopic systems (Olympus, Japan) were used, equipped with conventional colonoscopes, pediatric colonoscopes and expert-class colonoscopes. Pentax — EPK-i7000 video endoscopic systems with conventional colonoscopes, pediatric colonoscopes, and colonoscopes with optical magnification were also used. If necessary, the mucosa was washed using an Olympus AFU-100 water pump or an EIP 2 water pump built into the ERBE 300D electrosurgical unit.

During the diagnostic colonoscopy, the size and site of epithelial lesions, their macroscopic structure according to the Paris classification

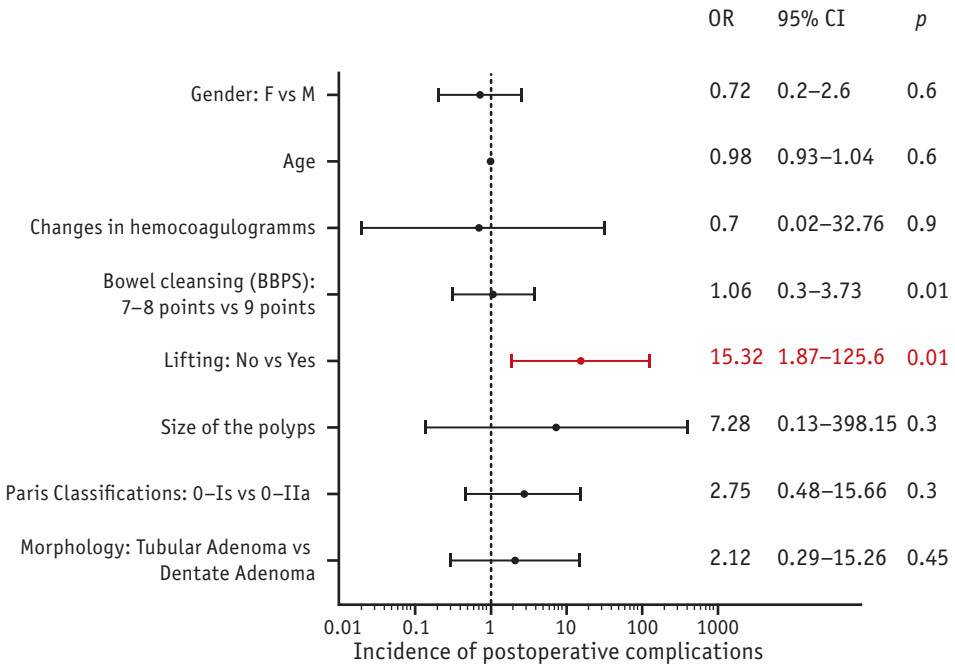

Figure 1. *Forest plot of univariate analysis of risk factors for postpolypectomy complications*

Table 4. *Results of the pathomorphology in both groups*

Parameter	Cold Snare Polypectomy (*n* = 132)	Hot Snare Polypectomy (*n* = 129)	*p*
Number of extracted polyps	126 (95.5%)	117 (90.7%)	0.2
Histological structure of polyps			
Tubular adenoma with mild dysplasia	108 (85.7%)	77 (65.8%)	0.1
Tubular adenoma with moderate dysplasia	2 (1.6%)	7 (6%)	0.1
Tubular adenoma with mild and focal moderate dysplasia	0	1 (0.85%)	0.9
Tubulo-villous adenoma with mild dysplasia	4 (3.2%)	3 (2.6%)	0.9
Tubulo-villous adenoma with moderate dysplasia	2 (1.6%)	1 (0.85%)	0.9
Tubular adenoma + dentate adenoma with mild dysplasia (mixed polyp)	0	1 (0.85%)	0.9
Dentate adenoma	10 (7.9%)	25 (21.4%)	0.005
Mucosal adenocarcinoma on the background of tubulo-villous adenoma	0	1 (0.85%)	0.9
G2 adenocarcinoma on the background of tubular adenoma (pT1 Rx)	0	1 (0.85%)	0.9

were taken into account. The assessment of the pit and microvascular patterns was carried out according to the Kudo S. and Sano Y. classifications [13–15]. To characterize the microrelief of dentate lesions, the Kimura T. classification was used [16]. The characteristics of the polyps according to the endoscopic classification are presented in Table 1.

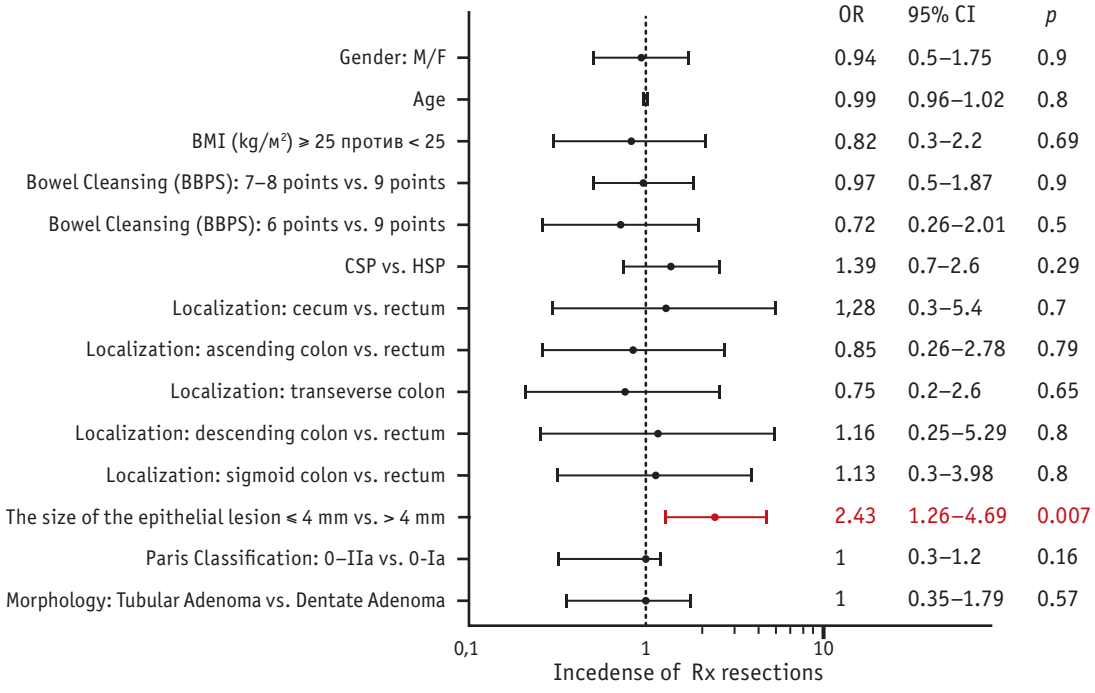

Figure 2. *Forest plot of univariate analysis of risk factors for Rx resection after polypectomy*

When removing polyps by the cold snare polypectomy, polyfilament loops made by the MTW, Boston Scientific, and Endoflex were used. The opening diameter of the loops is 11–15 mm. Electrosurgical units ERBEVIO-300D, Olympus ESG-100, Olympus PSD-60 with the use of cutting and coagulation modes were used for loop hot snare polypectomy.

If it was necessary to create a lifting of the removed lesion, a preliminary submucosal injection of a gelatin/sodium chloride solution with 0.4% indigocarmine was done into its base using endoscopic injectors by Olympus and MTW. The decision to do the lifting was made by the endoscopist performing the polypectomy. Thus, in the group where hot snare polypectomy was performed, submucosal injection was done significantly more often than in the group of cold snare polypectomy: 61/129 (47.3%) and 10/132 (7.8%), respectively, $p = 0.001$.

With extensive defects of the mucosa or with the appearance of intraoperative bleeding after the removal of the lesions, clipping or irrigation of the wound surface with hemostatic solutions for preventive or treatment purposes was performed on the basis of the endoscopist's decision (Table 2).

All the specimens were extracted by aspiration through the endoscope canal into a preinstalled gauze trap. With a large polyp size, it was extracted by a loop. Each extracted lesion was fixed on a foam plate and transported to the Pathomorphology and Immunohistochemical Study unit.

The data analysis was done using the Statistica 13 TIBCO, USA program. The Mann-Whitney test was used to compare the medians. To compare the mean values, an unpaired t-test was used. For the analysis of qualitative variables, the exact Fisher test or the $\chi 2$ criterion was used. To assess the risk factors, the odds ratio (OR) was calculated. Possible risk factors for the treatment were identified using simple linear regression and simple logistic regression. $P < 0.05$ was considered statistically significant. The cut-off points were determined using ROC analysis with the construction of a ROC curve (Receiver Operating Characteristic).

RESULTS

The study included 160 patients (80 people in the cold snare polypectomy group and 80 people in the hot snare polypectomy group). When comparing the two groups, there were no significant differences in the age of the patients ($p = 0.9$). The median age (Me, min-max) of the patients in the cold snare polypectomy (CSP) group was 62.1 (56–70) years old, in the hot snare polypectomy (HSP) group was 63 (56–70) years old.

According to the number of removed lesions, the groups were comparable: 132 polyps were removed by a cold loop and 129 polyps — by HSP, $p = 0.9$. In the CSP group, the two — stage (55/80 (69%), rather than the one — stage (25/80 (31%) scheme of bowel cleansing was more often followed. In the HSP group, these indicators were 49/80 (62%) and 31/80 (38%), respectively, $p = 0.4$. In both groups, in most cases: 72/80 (90%) of CSP, 75/80 (93.7%) of HSP, the procedures were performed without anesthesia, $p = 0.6$.

The mean size (M ± SD) of the polyps in the CSP group was 6 ± 3 mm, in the HSP groupwas 8 ± 2 mm, $p = 0.08$. According to the macroscopic structure in the CSP group 91/132 (68.9%), the lesion was flattened (0-Is type according to the

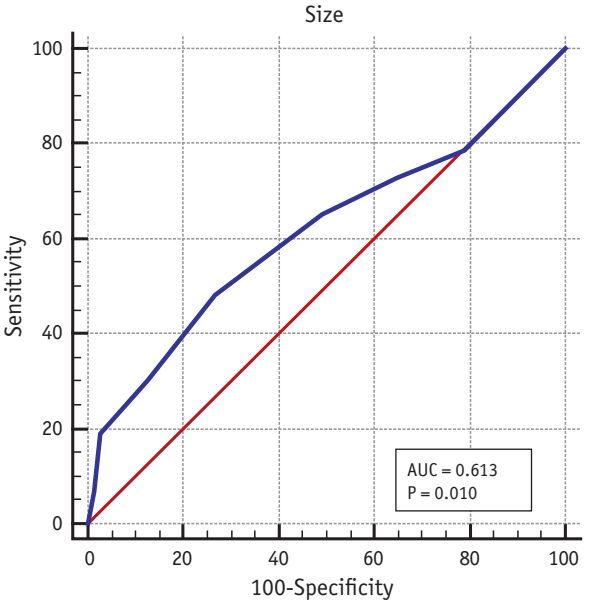

Figure 3. *ROC-curve of the correlation between the size of polyps and the incidence of Rx resection. Area under the curve 0.61. Cut-off point 4 mm*

Paris classification), 41/132 (31.1%) was flat (0-IIa type according to the Paris classification. In the HSP group-0-Is type of lesions was found in 86/129 (66.7%) cases, 0-IIa type — in 43/129 (33.3%) cases.

The time spent for the removal of epithelial lesions by HSP (Me = 3.0 min.) appeared to be significantly longer than the time for the CSP (Me = 1.2 min.), $p = 0.0001$.

The total number of removed lesions was 261 (132 lesions in the CSP group and 129 — in the HSP group), $p = 0.9$. Mainly, epithelial lesions were detected in the proximal parts of the large intestine: 78/132 (59.1%) lesions in the CSP group and 79/129 (61.2%) — in the HSP group, $p = 0.9$.

When analyzing intraoperative complications during endoscopic polypectomy by both methods, it was found that in the both groups, the complications were represented by bleeding.

In the CSP group, intraoperative bleeding developed after removal of 2/132 (1.5%) polyps in two patients, while in the HSP group, the bleeding developed after removal of 4/129 (3.1%) polyps in four patients. There were no significant differences, $p = 0.06$. In both groups, the endoscopic hemostasis was performed because of the intraoperative bleeding: two patients in the CSP group were irrigated with a hemostatic Hemoblock solution. Clipping (in three cases) and coagulation (in one patient) of the bleeding vessel were performed only with endoscopic HSP of epithelial lesions.

The assessment of postoperative complications in each group was done within 30 days in accordance with the Clavien-Dindo classification [25]. It should be noted that the complications were calculated for the number of polypectomies. After the removal of the polyps by the CSP, no postoperative complications were registered in any of the cases. On the contrary, in the HSP group after the removal of 12/129 (9.3%) polyps, postoperative complications were noted in 12 patients. Thus, the complication rate in the patients was 12/80 (15%) (Table 3).

The most common complication — postpolypectomy syndrome occurred in 9 patients after removal of 9 polyps. In all the cases, this complication was cured conservatively and was found in the patients who had the removal of polyps performed only by hot snare polypectomy.

To identify risk factors for postoperative complications after the HSP, we performed a univariate analysis. It was found that the failure to lift the lesion during polypectomy is a significant risk factor (OR: 15.3, 95% CI: 1.9–125.6; $p = 0.01$) (Figure 1).

Factors associated with the patient (gender, age, changes in laboratory parameters of the hemocoagulogram), as well as the quality of the bowel cleansing and the characteristics of polyps (size, type, morphological structure) did not have a significant effect on the incidence of postoperative complications after the hot snare polypectomy.

The success rate of extraction of surgical specimens prevailed in the CSP group and was 126/132 (95.5%) versus 117/129 (90.7%) in the HSP group, but the differences were insignificant, $p = 0.2$.

According to the histology, in most cases, epithelial lesions were represented by tubular adenomas with various degrees of epithelial dysplasia: in the CSP group — 110/126 (87.3%), in the HSP group — 85/117 (72.6%) (Table 4).

In the pathomorphological study of the removed specimens, it was noted that in the CSP group, a greater number of 68/126 (54%) specimens were assessed as R0, and in the HSP group — 66/117 (56.4%); the differences are insignificant, $p = 0.8$.

It should be noted that in 33/126 (26.2%) cases after the removal with a cold loop and in 38/117 (32.5%) cases after endoscopic HSP, it was impossible to assess the resection margins (Rx). In order to study the risk factors for obtaining R1 and Rx resection, we performed a univariate analysis, according to which, a significant risk factor was found to be the lesion size of ⩽ 4 mm (OR: 2.4, 95% CI: 1.3–4.7; $p = 0.007$) (Fig. 2).

Gender, age, and BMI of the patients did not significantly affect the incidence of R1 and Rx resection, $p = 0.5$. Moreover, the chosen method of removing epithelial lesions, the quality of bowel cleansing, the site of polyps, their type

and morphological structure also did not significantly affect it as well.

In order to determine the cut-off point in the size of the removed polyps, we performed a ROC analysis (Receiver Operating Characteristic). The area under the curve (AUC) was 0.61 (p = 0.01), which is typical for the average quality of the data analysis model (Fig. 3). When constructing the ROC curve, the cut-off point of the size of the epithelial lesions was found to be 4 mm.

Thus, the chance of obtaining R1 and Rx resection when removing epithelial lesions in size of ⩽ 4 mm is 2.43 times higher than when removing lesions in size of > 4 mm (OR: 2.43; 95% CI: 1.26–4.69, p = 0.007).

DISCUSSION

Recently, there are several options for removing colorectal polyps. Each of them has both advantages and disadvantages. The presented study showed that the removal of polyps by the cold snare polypectomy takes less time in comparison with endoscopic hot snare polypectomy (p = 0.0001), which is similar to the results of the previous studies [12,17–19,24].

The results of our randomized study showed that lifting of epithelial lesions was significantly more often performed with the removal of polyps by hot snare polypectomy — 61/129 (47.3%), than by cold snare polypectomy — 10/132 (7.8%), p = 0.001. A number of authors note that the lifting of lesions provides a safer removal of them due to less thermal damage to the muscle layer, which justifies the expediency of its implementation when using the hot snare polypectomy technique [20–22]. However, it should be noted that in the presented study, the lifting was not the inclusion criterion, but was performed only under the decision by the endoscopist performing the polypectomy.

The cold snare polypectomy is comparable to the hot snare polypectomy technique used for removing colorectal polyps. Thus, there were no significant differences in the incidence of intraoperative bleeding (p = 0.06), which also correlates with the results of foreign studies [17,24].

The intraoperative bleeding, which required its endoscopic control, developed after removal of 2/132 lesions (1.5%) in the CSP group, and in the HSP group — 4/129 polyps (3.1%).

It should be noted that it was in the patients after the removal of polyps with a cold loop that postoperative complications did not develop. This fact is confirmed by the data of a number of studies [12,17–19,24] and, apparently, depends on the absence of a damaging effect of electric current on the intestinal wall and vessels of the submucosal layer. Whereas, after the hot snare polypectomy, according to our data, in 7% of cases, postpolypectomy syndrome develops. And we can state that the use of coagulation during polypectomy significantly increases the risk of developing post-polypectomy syndrome, postoperative bleeding, and perforation of the intestinal wall in the postoperative period.

Analyzing the results of the pathomorphological study of removed specimens, we can say that the hot snare polypectomy technique is not superior in efficiency to cold snare polypectomy in removing epithelial lesions in size of ⩽ 10 mm. Thus, during the final histological study, it was revealed that in the both groups, most specimens (68/126–54% — in the CSP group and 66/117–56.4% — in the HSP group) were assessed as R0, p = 0.8. The advantage of the CSP is the possibility of examining the margins of the resulting defect, which cannot be done with standard polypectomy due to the resulting coagulation scab.

The factor analysis illustrates that obtaining R1 and Rx resections is associated with the size (⩽ 4 mm) of the removed epithelial lesions, which may reflect the technical aspect of endoscopic polypectomy, manifested in the complexity of adequately capturing the polyp with a loop due to the polyp's small size.

CONCLUSION

Cold snare polypectomy is an effective safe technique and not worse than hot one. Thus, it can be the method of choice for epithelial colorectal lesions in size of ⩽ 10 mm.

AUTHORS CONTRIBUTION

Concept and design of the study: *Stanislav V. Chernyshov, Olga S. Toporkova, Viktor V. Veselov*

Collection and processing of the material: *Olga S. Toporkova, Stanislav V. Chernyshov, Olga A. Majnovskaya, Yuri E. Vaganov*
Statistical processing: *Marat A. Nagudov, Olga S. Toporkova, Stanislav V. Chernyshov*
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