Thieme

Residual adenoma after cold snare polypectomy for small colorectal adenomas: a prospective clinical study

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ABSTRACT

Background Endoscopic resection of all colonic adenomas prevents the occurrence of colon cancer and death. The European Society of Gastrointestinal Endoscopy Clinical Guideline recommends resection of all polyps predicted to be adenomas and cold snare polypectomy (CSP) for removal of adenomas ≤ 9 mm on the basis of safety; however, it also states that this recommendation lacks adequate evidence of efficacy. The residual adenoma rate after resection is an important indicator of efficacy, but there have been no reports showing this prospectively. Therefore, we aimed to investigate the residual adenoma rate after CSP of small colonic polyps.

Methods Between March 2015 and April 2017, patients who were endoscopically diagnosed with colorectal adenomas < 9 mm underwent CSP, the site being marked with endoscopic clips. Patients with pathologically confirmed adenomas underwent follow-up colonoscopy 3 weeks after CSP and any post-CSP scars were biopsied. The primary endpoint was the presence of pathological residual adenoma 3 weeks after CSP.

Results Overall, 126 lesions in 39 patients were removed and 125 (99.2 %) were resected en bloc using CSP. Pathologically, 111 lesions (88.1 %) were confirmed as adenomas (4.2 ± 1.5 mm), with 36 of these (32.4 %) determined to be R0 resections. No complications were observed. All 37 patients with pathologically confirmed adenomas underwent follow-up colonoscopy, and 102 of 111 scars were detected in 33 patients. One pathological residual adenoma (0.98 %, 95 % confidence interval 0.02 % – 5.3 %) was identified.

Conclusions CSP appears to be an effective treatment for diminutive and small colorectal adenomas, with a low residual adenoma rate.

University Hospital Medical Network Clinical Trials Registry UMIN000016824
TRIAL REGISTRATION: Single-Center, Single-Arm, prospective trial UMIN000016824 at http://www.umin.ac.jp.

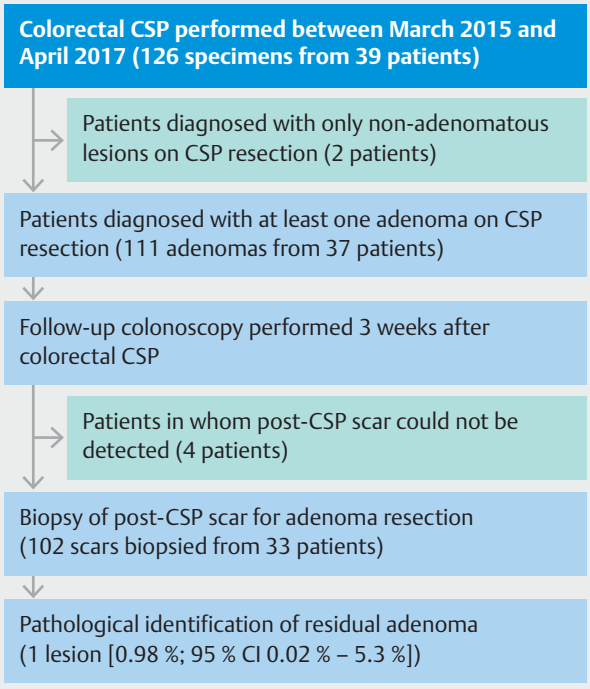
Introduction

Endoscopic detection and resection of colorectal adenomas is a well-established strategy for preventing colorectal carcinoma, because carcinomas can develop from colorectal adenomas through the adenoma – carcinoma sequence, in addition to developing as de novo carcinoma [1, 2]. Resection of all adenomas and carcinomas of the colon has been shown to prevent the occurrence of colon cancer and death [3]. The European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline strongly recommends, with high quality evidence, that all polyps be resected, except for diminutive rectal and rectosigmoid polyps

that are predicted with high confidence to be hyperplastic [4]. Endoscopic resection of small adenomas, even of diminutive lesions, is increasingly being recommended worldwide. Additionally, over the last few years, the use of cold snare polypectomy (CSP) for the therapy of diminutive and small colorectal polyps has increased greatly owing to its excellent safety [1, 5–13], good efficacy [5–8, 14–18], and time-saving qualities [9, 10, 14, 19, 20].

The ESGE Clinical Guideline recommends CSP for the removal of colorectal polyps of ≤ 9 mm because of its superior safety profile; however, it also states that this recommendation lacks adequate evidence pertaining to the efficacy of CSP [4]. Complete histological resection rates based on pathological analysis (R0 resection rate) of specimens resected using CSP for diminutive and small colorectal polyps range from 32.9 % to 84.3 % [5–8, 15–17]. Other authors have achieved complete histological resection rates of 93.2 % [14] and 96.1 %–96.6 % [16, 18] with CSP for colorectal adenomas based on either additional biopsies obtained from the base and edges of the ulcers [14] or on additional endoscopic mucosal resection (EMR) performed at the resection site immediately after CSP [16, 18]. Only one retrospective study has investigated the actual residual/recurrence rate after CSP for colorectal adenomas; the authors reported that there were no residual/recurrent adenomas, on the basis of a lack of scars in the vicinity of any newly found polyps on follow-up colonoscopy within 3 years of the original CSP [21].

To accurately assess post-resection residual/recurrent adenomas, it is necessary to identify the precise location of surgical scars and to perform histopathological examination of biopsy specimens obtained from these sites; however, no previous reports have demonstrated the histological efficacy of CSP using this approach. Therefore, in this prospective study, we aimed to investigate the presence of pathological residual adenomas 3 weeks after CSP for diminutive and small colorectal adenomas.



▶ **Fig. 1** Flow chart for patients undergoing cold snare polypectomy (CSP) and study follow-up for those with an adenoma resected. CI, confidence interval.

Methods

Study design and patients

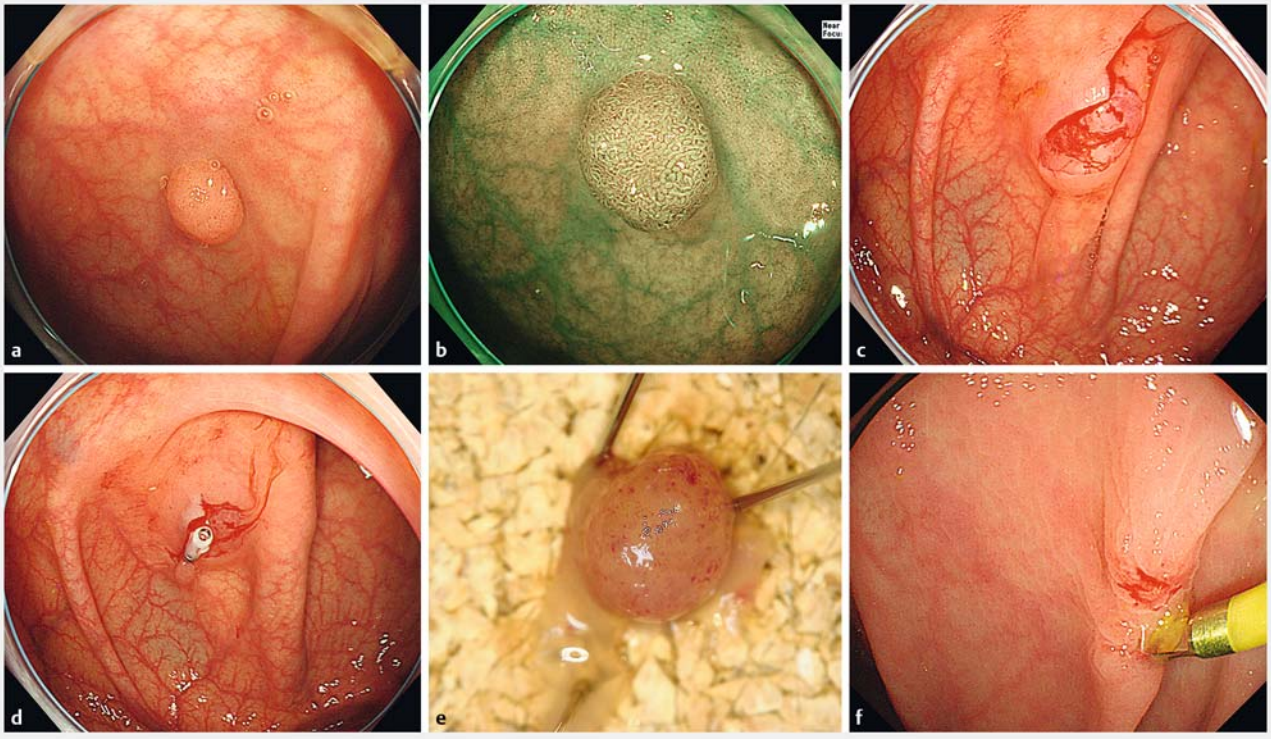
Patients diagnosed with at least one colorectal adenoma measuring < 9 mm on colonoscopy were enrolled in this study. Colorectal lesions were resected via CSP. The patients then underwent repeat endoscopy 3 weeks later to morphologically and pathologically assess the presence of any residual tumor (▶ **Fig. 1**).

Patients diagnosed with colorectal adenomas and treated with CSP at a single center (Department of Gastroenterology, Chiba University Hospital) between March 2015 and April 2017 were recruited for this prospective, single-arm, observational study. Inclusion criteria were: (i) age over 20 years; and (ii) provision of informed consent. Exclusion criteria were: (i) polyposis syndromes, such as familial adenomatous polyposis; (ii) inflammatory bowel disease; (iii) coagulation abnormalities; (iv) antithrombotic drug therapy; (v) hemodialysis with a tendency to bleed; (vi) severe hepatic or renal disorders; and (vii) pregnancy. Lesions biopsied before inclusion were excluded because undergoing biopsies for diminutive or small polyps without resection was not justifiable from a clinical point of view.

The study protocol, including follow-up endoscopy and biopsy 3 weeks after CSP, was clearly explained and written informed consent was obtained from all patients prior to their enrolment. This study was approved by the Medical Ethics Board of the Graduate School of Medicine, Chiba University (registration number: 2007), in accordance with the Declaration of Helsinki, and was registered with the University Hospital Medical Information Network (clinical trial registration number: UMIN000016824; https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000019530. Accessed: 5 December 2017).

All patients were prepped the day before colonoscopy with a low-residue diet and were administered 10 mL sodium picosulfate. Patients drank a highly concentrated polyethylene glycol solution (MoviPrep; Ajinomoto Pharma Co. Ltd., Tokyo, Japan) with ≥ 0.5 L water on the morning of the colonoscopy for bowel preparation.

The colonoscope was first inserted into the cecum using the conventional white-light mode. The location, macroscopic appearance [22, 23], and size of each lesion were then evaluated using a magnifying colonoscope (CF-HQ290ZI, CF-HQ290I, CF-H260AZI, PCF-H290ZI, or PCF-Q260AZI; Olympus Corp., Tokyo, Japan) with a light source (EVIS LUCERA ELITE CLV-290SL; Olympus) and video processor (EVIS LUCERA ELITE CV-290; Olympus). Polyp size was estimated by visual comparison with an open biopsy forceps with an open mouth diameter of 7.58 mm



▶ **Fig. 2** Cold snare polypectomy (CSP) of a colonic polyp. **a** White-light endoscopic image showing a type Isp colonic polyp (5-mm diameter) in the ascending colon. **b** The lesion under magnifying endoscopy with narrow-band imaging (NBI) showing what was diagnosed as being a non-carcinomatous adenoma. **c** The ulcer and surrounding mucosa after en bloc resection of the lesion using a round snare via CSP, followed by application of a water jet to the area. **d** A marking clip placed near the ulcer immediately after resection to allow the scar to be detected at follow-up endoscopy; the ulcer was not closed by clips. **e** The resected specimen stretched and pinned flat on a cork board, which was diagnosed pathologically as a low grade tubular adenoma with non-R0 resection. **f** Image during follow-up colonoscopy 3 weeks after CSP showing a biopsy being taken from a post-CSP scar near a marking clip; no residual tumor was found morphologically or pathologically.

(Captura Biopsy Forceps; Wilson-Cook Medical Inc., Limerick, Ireland). Magnifying endoscopy with narrow-band imaging (NBI) was used to examine all lesions before resection and only morphologically non-carcinomatous lesions were enrolled [24].

Cold snare polypectomy for colorectal lesions

All procedures were performed by four experienced endoscopists who had each conducted more than 1000 colorectal polypectomies (D.M., H.I., K.O., and T.M.). CSP was performed using a conventional single-channel endoscope (CF-HQ290ZI, CF-HQ290I, PCF-Q260AZI, or PCF-Q260JI; Olympus). Lesions were resected endoscopically using an electrosurgical round snare (Captivator II Polypectomy Snare; 10 mm; Boston Scientific, Natick, Massachusetts, USA) without electrocautery for CSP (▶ **Fig. 2**; ▶ **Video 1**). Submucosal injection was not performed.

Snaring of the polyp including normal surrounding mucosa was attempted to maintain a non-neoplastic mucosal margin around the lesion. When the lesion could not be resected by snaring, the snare device was pulled into the working channel while snaring the lesion. Specimens resected via CSP were retrieved via suction through the colonoscope working channel and trapped in separate bottles that were attached to the suction tube. Following this, the area was thoroughly rinsed with a water jet to check for residual tumor in the surrounding mucosa

Video 1 Cold snare polypectomy (CSP) being performed for colorectal polyps. Each lesion was resected via en bloc CSP and marking clips were placed near to each ulcer immediately after resection to allow detection of the scars during follow-up endoscopy.
Online content viewable at:
https://doi.org/10.1055/s-0043-124869

and in the mucosal defect. If tumor was present, an additional resection was performed until macroscopic eradication was achieved. Marking clips were placed in the area surrounding the ulcers immediately after resection using endoscopic clips (EZClip; Olympus) to enable the detection of scars during follow-up endoscopy 3 weeks later (▶ **Fig. 2**). Ulcers were not closed with endoscopic clips.

The resected specimens were stretched, pinned flat on a cork board, and placed in a 10 % formalin container. All tissue samples were sent separately for histologic analysis using standard hematoxylin and eosin (H&E) staining and were evaluated by gastrointestinal pathologists blinded to the clinical information, according to the Japanese classification of colorectal carcinomas [25]. If the vertical and lateral margins were free of tumor, specimens were defined as being "R0 resection specimens." Specimens with positive or indeterminate tumor margins and lesions that were resected piecemeal were defined as "non-R0 resection specimens."

Endoscopy 3 weeks after cold snare polypectomy

All patients with a histopathological diagnosis of adenoma underwent colonoscopy 3 weeks after CSP (▶ **Fig. 1**). CSP scars were examined morphologically using white-light imaging with chromoendoscopy, using 0.08 % indigo carmine spray, as well as with magnifying endoscopy with NBI (▶ **Fig. 2**). Because the absence of a macroscopic residual adenoma does not completely rule out the possibility of a histopathological residual adenoma [26], either one or a few biopsy specimens were obtained from all scars using Captura Biopsy Forceps (Wilson-Cook Medical). If only a clear scar was present, one biopsy specimen was taken from the center of the scar; if however there was a protruded or reddish area, additional biopsies were taken, not only from the center of the scar but also from the other affected areas.

Study endpoints

The primary study endpoint was the presence of pathological residual adenoma 3 weeks after CSP. Secondary outcomes included: the R0 resection, complete retrieval, and complication rates, including post-polypectomy syndrome, intraprocedural or delayed bleeding, and perforation. Intraprocedural bleeding was defined as spurting of blood continuing for more than 1 minute following resection that needed to be stopped with endoscopic clips. Delayed bleeding was defined as hematemesis, melena, or a decrease in hemoglobin concentration of > 2 g/dL. Post-polypectomy syndrome was defined as abdominal pain, fever, leukocytosis, and peritoneal inflammation in the absence of frank perforation after polypectomy.

Statistical analysis

Data are presented as means ± standard deviations or medians and ranges. The R0 resection, complication, and residual adenoma rates are presented as proportions with 95 % confidence intervals (CIs). All statistical analyses were performed using SPSS Statistics, version 23 (SPSS Inc., IBM Corp. Armonk, NY, USA).

Results

Characteristics of the patients and lesions

During the study period, 126 lesions in 39 patients were removed via CSP (3.2 ± 3.0 lesions/patient; median 2; range 1 – 12). All 39 patients underwent complete total colonoscopy. None of the patients qualified for the Amsterdam I or II criteria for Lynch syndrome. The characteristics of these 39 patients (29 men, 10 women) are summarized in ▶ **Table 1**. There were also 18 patients who refused to undergo the procedures evaluated in the present study who were not enrolled in this clinical trial. They were treated with conventional hot snare polypectomy (HSP), EMR, or CSP, and did not undergo follow-up colonoscopy and biopsy 3 weeks after resection.

The characteristics of the adenomas resected via CSP are summarized in ▶ **Table 2**. Of the 111 adenomas, 56 (50.5 %) were located in the right side of the colon (the cecum, ascending colon, and transverse colon), 43 (38.7 %) in the left side of the colon (the descending colon and sigmoid colon), and the other 12 (10.8 %) in the rectum. CSP was performed for adenomas of 2 – 8 mm in size; 92 (82.9 %) were diminutive (≤ 5 mm) and 19 (17.1 %) were small adenomas (6 – 8 mm). Depressed lesions were not included.

Outcomes of cold snare polypectomy

All 126 lesions were completely resected in a single endoscopy session without requiring electrocautery. En bloc removal was achieved using CSP for 125 lesions (99.2 %). One lesion was removed piecemeal, requiring two cuts (two pieces), and was found to be a low grade tubular adenoma. The complete retrieval rate of all specimens resected via CSP was 98.4 % (124 of 126).

▶ **Table 1** Characteristics of the 39 patients who underwent cold snare polypectomy (CSP) for a clinical small colorectal adenoma.

	Overall	Adenoma identified from CSP specimen	Scar successfully biopsied 3 weeks after CSP
Number of patients	39	37	33
Mean age ± SD, years	70.5 ± 10.0	70.2 ± 10.2	71.6 ± 9.3
Median age (range), years	71 (49 – 87)	68 (49 – 87)	71 (49 – 87)

SD, standard deviation.

▶ **Table 2** Characteristics of the adenomas resected via cold snare polypectomy.

	All adenomas (n = 111)	**Adenomas with successfully biopsied scar at follow-up (n = 102)**
Location, n (%)		
▪ Cecum	4 (3.6)	4 (3.9)
▪ Ascending colon	23 (20.7)	23 (22.5)
▪ Transverse colon	29 (26.1)	26 (25.5)
▪ Descending colon	13 (11.7)	12 (11.8)
▪ Sigmoid colon	30 (27.0)	27 (26.5)
▪ Rectum	12 (10.8)	10 (9.8)
Size		
▪ Mean ± SD, mm	4.2 ± 1.5	4.2 ± 1.5
▪ Median (range), mm	4 (2 – 8)	4 (2 – 8)
Diminutive / small polyps, n (%)	92/19 (82.9/17.1)	84/18 (82.4/17.6)
Macroscopic appearance (Paris endoscopic classification), n (%)		
▪ Ip	2 (1.8)	2 (2.0)
▪ Isp	25 (22.5)	20 (19.6)
▪ Is	43 (38.7)	42 (41.2)
▪ IIa	41 (36.9)	38 (37.3)
Pattern of resection, n (%)		
▪ En bloc	110 (99.1)	101 (99.0)
▪ Piecemeal	1 (0.9)	1 (1.0)
Histopathological diagnosis, n (%)		
▪ Low grade tubular adenoma	104 (93.7)	95 (93.1)
▪ High grade tubular adenoma	3 (2.7)	3 (2.9)
▪ Low grade tubulovillous adenoma	1 (0.9)	1 (1.0)
▪ High grade tubulovillous adenoma	2 (1.8)	2 (2.0)
▪ Low grade traditional serrated adenoma	1 (0.9)	1 (1.0)
R0/non-R0 resection, n	36/75	33/69
R0 resection rate (95 %CI), %	32.4 (23.9 – 42.0)	32.4 (23.4 – 42.3)
Complications, n	0	0
Complication rate (95 %CI), %	0 (0 – 3.3)	0 (0 – 3.6)
Marking clip, Yes / No, n	105 / 6	99 / 3
Scar detected, Yes / No, n	102/9	–
Residual adenoma, Yes / No, n	1/110	1/101
Residual adenoma rate (95 %CI), %	0.90 (0.02 – 4.9)	0.98 (0.02 – 5.3)

SD, standard deviation; CI, confidence interval.

Pathologically, 111 lesions (88.1 %) were diagnosed as being adenomas, of which 104 (82.5 %) were low grade tubular adenomas, three (2.4 %) were high grade tubular adenomas, one (0.8 %) was a low grade tubulovillous adenoma, two (1.6 %) were high grade tubulovillous adenomas, and one (0.8 %) was a low grade traditional serrated adenoma. None of the lesions were diagnosed as carcinomas. Of the 111 adenomatous lesions, 36 (32.4 %) had an R0 resection margin (▶ **Table 2**). There were 13 lesions resected via CSP that were found not to be tumors: 11 were hyperplastic polyps, one was inflamed colonic mucosa, and the remaining one was a juvenile polyp.

All intraprocedural bleeding observed immediately after treatment was limited to oozing that largely resolved spontaneously or through compression by the scope within 1 minute. None of the ulcers were managed with endoscopic clip closures. Marking clips were placed in the area surrounding the ulcer immediately after resection in 120 of 126 ulcers (95.2 %). No cases of post-polypectomy syndrome, delayed bleeding, or intraprocedural or delayed perforation were observed.

Residual adenomas after cold snare polypectomy

All 37 patients with a histopathological diagnosis of adenoma underwent colonoscopy 3 weeks after CSP (▶ **Fig. 1**). Of 111 post-CSP scars for histological adenomas, 102 (91.9 %) were identified in 33 patients. None of the patients exhibited signs of residual tumor on morphological findings. All scars were biopsied, taking one or a few specimens from the scars using forceps, and one residual adenoma was identified pathologically (0.98 %, 95 %CI 0.02 %–5.3 %) (▶ **Table 2**; ▶ **Fig. 1**). The one case of residual adenoma followed an en bloc, non-R0 resection of a low grade tubular adenoma of 7 mm in diameter (type Isp tumor). In line with the patient's wishes, follow-up colonoscopy was performed 6 months later; the further biopsy specimens revealed no morphological or pathological residual tumor at follow-up colonoscopy 7 months after CSP.

Discussion

This is the first study to investigate the histological efficacy of CSP for treating colorectal adenomas by prospective histopathological assessment for residual adenoma on biopsies taken at follow-up colonoscopy. We were able during these subsequent colonoscopies to identify post-CSP scars in the immediate vicinity of either the marking clips or the scars created by these clips, allowing us to assess for residual adenomas after CSP. By adopting this approach, we were able to identify 91.9 % of post-CSP scars (102 of 111) to assess for residual adenoma, and the residual adenoma rate after CSP for colorectal adenomas < 9 mm was 0.98 %.

This result is similar to the recurrence rate after HSP (including EMR) reported in Japan (0.87 %) [27]. Furthermore, in the CARE study [28], the incomplete resection rate associated with HSP for small colorectal neoplastic polyps (5–9 mm) was 6.8 %, a rate that was not lower than that associated with CSP [14, 16, 18]. The en bloc resection rate with cold forceps polypectomy (CFP) for colorectal polyps was low in the case of polyps ≥ 4 mm [29], and the R0 resection rate with CFP for colorectal adenomas ≥ 4 mm was lower than that with CSP [14, 30]. In a retrospective study, the recurrence rate after CFP for diminutive colorectal polyps, as detected by follow-up colonoscopy over a mean follow-up period of 59.7 months, was 17 % (definite recurrence 4 %; probable recurrence 13 %) [31], which seems to be higher than the main outcome of the present study. Therefore, the current study suggests that the efficacy of CSP for diminutive and small colorectal adenomas is superior to that of CFP and similar to that of HSP or EMR.

Moreover, there were no complications in the current study, emphasizing the safety of CSP, which was no worse than that reported in previous studies. In addition, all lesions were successfully resected via CSP without the need to resort to electrocautery. When the lesion could not be resected by snaring, we pulled the snare device into the working channel while snaring the lesion and some lesions were successfully resected using this method. The success rate of resection was 100 %, the en bloc resection rate was 99.2 %, and there were no complications in the present study.

In this study, the R0 resection rate was 32.4 %, which is similar to or slightly lower than that reported in previous studies [5–8, 15–17]. However, the actual residual adenoma rate after CSP was very low at 0.98 %. We conducted this study because the actual residual adenoma rate after resection is arguably the most important indicator of the efficacy of a resection method. Because there was discrepancy between the rates for residual adenoma and R0 resection, it can be concluded that the R0 resection rate cannot assess the efficacy of resection methods. Matsuura et al. [16] reported that one possible explanation for low R0 resection rates is damage to specimens retrieved via suction through the colonoscope working channel; the R0 resection rate for colorectal adenomas in their study was 32.9 %, which is similar to that in the present study.

We previously investigated the efficacy of CSP for diminutive and small non-ampullary duodenal adenomas and reported an R0 resection rate of 68.0 % [32]. The duodenum represents one of the most challenging areas for endoscopic resection because of the difficulty in controlling a conventional endoscope [33]. In fact, we experienced greater difficulty in snaring the polyps with a rim of normal surrounding mucosa to maintain a perilesional non-neoplastic mucosal margin during duodenal CSP than we experienced during colorectal CSP. Therefore, the R0 resection rate in colorectal CSP was expected to be higher than that in duodenal CSP; however, the actual outcome was the opposite of this.

We believe this surprising outcome can be attributed to the different retrieval methods used in these studies. Because specimens resected via duodenal CSP were retrieved endoscopically using alligator forceps (extraction of the endoscope from patients with forceps grasping the specimens) instead of suction, the condition of specimens was better in our previous study. On the other hand, in the present study, specimens retrieved by suctioning through the colonoscope working channel were occasionally cracked or split, and the retrieved specimens were stretched and pinned on a cork board without re-formation of cracks. In addition, specimens were more commonly retrieved using controlled suction rather than maximum suction. Speci-

mens resected via CSP were soft and liable to be damaged by suctioning through the working channel because of the absence of the heat-coagulated proteins on the resected surface that are typically associated with the use of electrocautery. Further improvement with respect to these points might have helped improve the R0 resection rate in the current study.

There were certain limitations to the present study. First, the sample size was not sufficiently large. The present study was designed with at least two colonoscopies per patient so as to allow examination of the post-CSP scars and accurate detection of residual adenomas. As this is inherently time-consuming, the sample size was not large. However, the residual adenoma rate after CSP was low, even if the estimated upper limit of the 95 % CI (5.3 %) is used. Factors associated with residual adenoma after CSP were not identified because only one case of residual adenoma was detected.

Second, the follow-up period in our study was necessarily short because it is not feasible to detect post-CSP scars in the long-term using the marking clip method. One possible method to identify post-CSP scars during long-term follow-up would involve creating endoscopic tattoos near the ulcers immediately after CSP. However, this would require great care and would be irreversible; there might also be problems using the tattoo method on patients with small benign colorectal adenomas.

Third, because the current study was not a randomized clinical trial (RCT), the residual adenoma rate for CSP was not directly compared with the rates for other procedures, such as hot biopsy forceps, HSP, or EMR.

Fourth, this study was conducted at a single institution and all procedures were performed by four experienced endoscopists, which is associated with known risks of bias.

Fifth, we used a dual-purpose snare in the present study, which can be used for both CSP and HSP (including EMR). Some studies have employed a dedicated snare for CSP, which results more often in R0 resection than was achieved using our dual-purpose snare [6, 15]. If we had used a dedicated snare for CSP, the R0 resection rate might have been slightly higher.

In conclusion, CSP for diminutive and small colorectal adenomas appears to be effective. In this study, CSP was associated with a low rate of residual adenoma by pathological diagnosis on biopsy specimens obtained from the post-CSP scars at 3-week follow-up. We believe that further multicenter RCTs examining the efficacy of CSP vs. HSP (including EMR), involving larger sample sizes, are needed to verify the efficacy of CSP.

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Competing interests

None.

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