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Comparison of cold snare endoscopic mucosal resection and hot snare endoscopic mucosal resection for small colorectal polyps: a randomized controlled trial

Chang Kyo Oh^{1,5}, Young Wook Cho^{2,5}, Jiyeon Jung³, Hee Yeon Lee⁴, Jin Bae Kim¹ & Young-Seok Cho²

Incomplete resection rates vary among endoscopists performing cold snare polypectomy. Cold snare endoscopic mucosal resection (CS-EMR) is the technique of cold resection after submucosal injection to reduce incomplete resection. This study aimed to evaluate the efficacy and safety of CS-EMR for small colorectal polyps compared to hot snare endoscopic mucosal resection (HS-EMR). Preplanned sample size required 70 polyps to CS-EMR group or HS-EMR group, respectively. Patients with polyps sized 6–9 mm were randomly allocated to either the CS-EMR or the HS-EMR group. The primary outcome was residual or recurrent adenoma (RAA) rate. A total of 70 and 68 polyps were resected using CS-EMR and HS-EMR, respectively. In the intention-to-treat population, the RAA rate was 0% in the CS-EMR group and 1.5% in the HS-EMR group (risk difference [RD], –1.47; 95% confidence interval [CI] –4.34 to 1.39). *En bloc* resection rate was 98.6% and 98.5% (RD, –0.04; 95% CI –4.12 to 4.02); the R0 resection rate was 55.7% and 82.4% (RD, –27.80; 95% CI –42.50 to –13.10). The total procedure time was 172 s (IQR, 158–189) in the CS-EMR group and 186 s (IQR, 147–216) in the HS-EMR group (median difference, –14; 95% CI –32 to 2). Delayed bleeding was 2.9% vs 1.5% (RD, 1.37; 95% CI –3.47 to 6.21) in both groups, respectively. CS-EMR was non-inferior to HS-EMR for the treatment of small colorectal polyps. CS-EMR can be considered one of the standard methods for the removal of colorectal polyps sized 6–9 mm.

Keywords Small colorectal polyp, Cold snare endoscopic mucosal resection, Hot snare endoscopic mucosal resection, Residual or recurrent adenoma

Colonoscopy is pivotal in effectively reducing morbidity and mortality associated with colorectal cancer (CRC). However, post-polypectomy CRC still occurs in 2–9% of all CRC cases^{1–3}. Considering that incomplete resection accounts for 20–30% of post-polypectomy CRC, it is crucial to achieve the complete resection of colorectal lesions^{4,5}.

Cold snare polypectomy (CSP) is the preferred method for the resection of small non-pedunculated colorectal lesions. It offers higher safety by not requiring the use of an electrosurgical unit (ESU) and has been shown to be non-inferior to hot snare endoscopic mucosal resection (HS-EMR) in achieving complete resection of colorectal lesions. However, several randomized controlled trials have reported that incomplete resection rates (IRRs)

¹Division of Gastroenterology, Department of Internal Medicine, Hallym University Kangnam Sacred Heart Hospital, Hallym University of Korea, 1 Singil-ro, Yeongdeungpo-gu, Seoul 07441, South Korea. ²Division of Gastroenterology, Department of Internal Medicine, Seoul St. Mary's Hospital, The Catholic University of Korea, Seoul, South Korea. ³Departments of Pathology, Hallym University Kangnam Sacred Heart Hospital, Hallym University of Korea, Seoul, South Korea. ⁴Departments of Biostatistics, Soonchunhyang University Hospital Seoul, Soonchunhyang University of Korea, Seoul, South Korea. ⁵These authors contributed equally: Chang Kyo Oh and Young Wook Cho. ✉email: ckdryekd@gmail.com

via margin biopsy of CSP varies 0–10.7% for small sized non-pedunculated polyp^{6–13}. Considering this, there appears to be a significant disparity in the IRRs in CSP compared to HS-EMR (0–4.5%) among endoscopists^{12–16}.

Cold snare EMR (CS-EMR) is a polypectomy method that conducts a submucosal injection process similar to HS-EMR. However, it does not require the use of ESU like CSP. Although there have been studies on CS-EMR for small non-pedunculated colorectal polyps^{12,16} evidence is still limited, and there have been no studies on residual or recurrent adenoma (RRA) via surveillance colonoscopy comparing CS-EMR and HS-EMR.

This study was aimed to evaluate the RRA, other resection-related factors, and safety of CS-EMR compared to HS-EMR for the small colorectal polyps (6–9 mm).

Methods

Study design

This was a multicenter, prospective, non-inferiority, randomized, controlled trial conducted at Kangnam Sacred Heart Hospital, Hallym university of Korea, and Seoul St. Mary's Hospital, Catholic University of Korea. Small polyps (6–9 mm) detected during colonoscopy were randomly allocated to CS-EMR or HS-EMR groups. The study followed the principles outlined in the Declaration of Helsinki, and the study protocol was approved by the Institutional Review Board of Hallym university Knangnam Sacred Heart Hospital and Seoul St. Mary's Hospital (approval no. HKS 2022-03-010 and KC22EIDI0183). Written informed consent was obtained from all participants. The study adhered to the CONSORT guidelines and was registered with the International Clinical Trials Registry Platform (KCT0007181) on 13 April 2022.

Study participants

Participants were prospectively enrolled between April 2022 and January 2023. The inclusion criteria were patients over the age of 19 years who underwent endoscopic resection for one or more small polyps ranging in diameter from 6 to 9 mm. The exclusion criteria were as follows: (1) patients with known or suspected malignant polyps, previously incompletely resected polyps, or subepithelial lesions; (2) patients with inflammatory bowel disease; (3) patients continuously using antithrombotic drugs; and (4) patients with coagulation disorders.

The baseline characteristics of the eligible participants including demographic data and indications for colonoscopy (abdominal symptoms, scheduled polypectomy, colorectal cancer screening, and post-polypectomy surveillance) were collected.

Interventions

All procedures were performed by two expert endoscopists who had conducted more than 2000 HS-EMR procedures and two trainee endoscopists who had conducted more than 30 HS-EMR procedure independently. Bowel preparations were conducted with oral sulfate solution or 1 L of polyethylene glycol plus ascorbic acid solution. Colonoscopy was performed using a high-definition endoscopy system (CV-290; Olympus, Tokyo, Japan) and a high-definition colonoscope with a magnification function (CF-HQ290L, CF-HQ290I; Olympus). Upon polyp identification, eligibility was assessed based on endoscopic findings, and eligibility for the study was confirmed. Once the resection technique (CS-EMR or HS-EMR) was assigned to the patient, all eligible polyps were removed using the same technique.

The submucosal injection used normal saline with a few drops of an indigo carmine solution. A 10 or 15 mm oval snare (SnareMaster Plus; Olympus) was used for CS-EMR or HS-EMR. The forced Coagulation current of the ESU setting (VIO300D; Erbe Elektromedizin GmbH, Tübingen, Germany) was used for the HS-EMR. Polyp size was assessed by comparing it to the size of the deployed snare. *En bloc* resection was attempted in all the cases.

The CS-EMR procedure comprises the following steps: (1) submucosal injection; (2) snaring of the polyp along with the surrounding normal mucosa (> 2 mm); and (3) resection without the use of electrocautery (Fig. 1). After resection, the polypectomy site was washed with a waterjet and the resection margin was carefully examined using white-light, narrow-band imaging (NBI), and magnifying NBI endoscopy to detect any residual lesions. If magnifying NBI endoscopy was inconclusive, magnifying chromoendoscopy with indigo carmine was performed to further investigate the residual lesions. Additional snaring was performed when residual lesions were suspected on endoscopy.

Endoscopic closure was performed in cases of blood spurting, continuous oozing for more than 30 s, visible vessels, or deep mural injury. The morphology of colorectal polyps was categorized as sessile (Is), flat (IIa), or pedunculated (Ip). The colorectal polyp locations were categorized as the right colon (from the cecum to the splenic flexure), the left colon (from the splenic flexure to the sigmoid colon), and the rectum. Ineligible polyps were managed according to the standard clinical practice of each institution.

Post-polypectomy management

All patients were required to visit the outpatient clinic within 2 weeks after polypectomy to check for any adverse events, histological diagnosis, and establish a plan for surveillance colonoscopy. They were checked for tarry stools, hematochezia, abdominal pain, and/or dizziness and underwent a brief physical examination. All patients underwent surveillance colonoscopy 6 months after polypectomy to confirm the presence of RRA. Previously recorded areas were meticulously observed to identify RRA during surveillance colonoscopy. If RRA was suspected, it was resected according to the endoscopist's preferred technique, and when a polypectomy scar was identified, a biopsy was performed to confirm RRA. When a scar or new lesion was not visible despite careful evaluation of the previously recorded area, we determined that the RRA was absent.

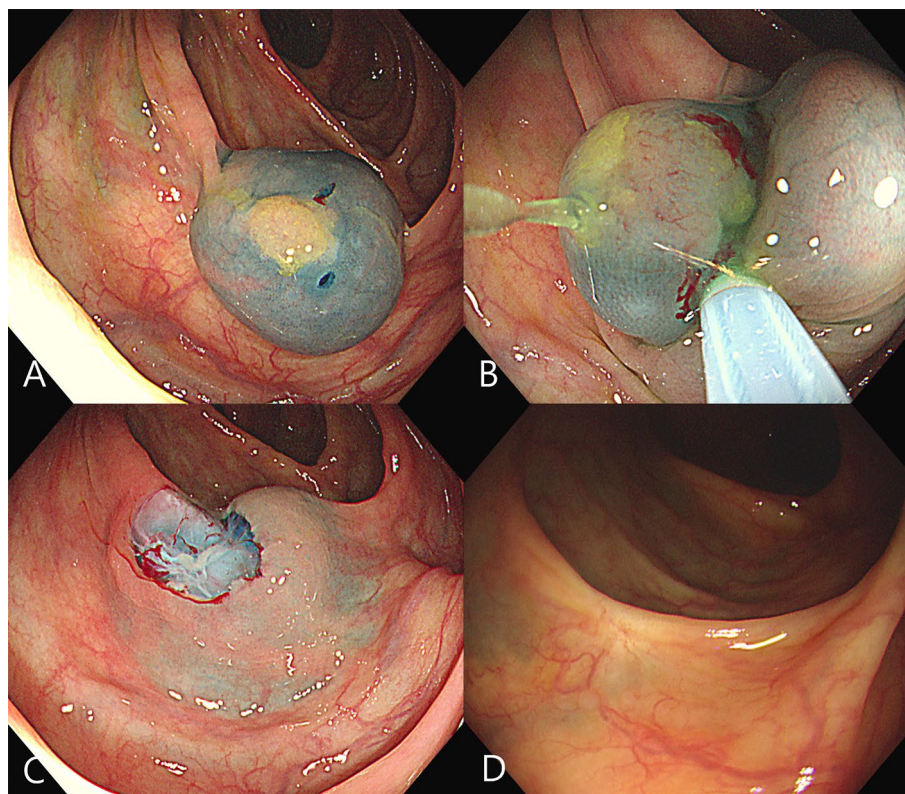


Fig. 1. CS-EMR procedure. (A) Submucosal injection. (B) Snaring the polyp including the surrounding normal mucosa. (C) Resection and inspection meticulously resection margin. (D) Post polypectomy scar on surveillance colonoscopy.

Histological examination

All polypectomy specimens were initially evaluated by attending pathologists according to the standard protocol of each institution and reviewed by an experienced gastrointestinal pathologist at each institution. All specimens with histological discrepancies were reviewed again and discussed by the attending and gastrointestinal pathologist.

Outcome parameters

The primary outcome was efficacy of resection, which was defined as the RRA rate between the CS-EMR and HS-EMR groups. RRA was defined as histological lesions confirmed to be equal to those of the previous polypectomy histology at the polypectomy site on surveillance colonoscopy performed 6 months after polypectomy.

Secondary outcomes included *en bloc* resection rate, R0 resection rate, total procedure time, and incidence of adverse events. R0 resection was defined as *en bloc* resection with a negative margin on the resected specimen. R1 resection was defined as the presence of neoplastic tissue at specimen margins. Rx resection was defined as a specimen margin that could not be assessed because of tangential tissue sectioning, fragmentation, and crushing. The total procedure time was defined as the time from submucosal injection to complete removal of the polyp.

Immediate bleeding was defined as blood spurting or continuous oozing for more than 30 s that needed to be managed by endoscopic hemostatic procedures. Delayed bleeding was defined as bleeding within 14 days of polypectomy, requiring a separate endoscopic hemostatic procedure at the polypectomy site. Perforation was defined as a colonic wall defect requiring immediate endoscopic or surgical intervention.

Sample size calculation

We hypothesized the RRA rate for small colorectal polyps based on previous studies. Previous studies reported that the RRA rate of HS-EMR for small sized colorectal polyps were 0.93–1.4%, respectively^{17,18}. Combining our preliminary experience with CS-EMR and HS-EMR for small colorectal polyps, we speculated that the RRA rates of CS-EMR and HS-EMR would be approximately 1%. Thus, the required sample size was 70 polyps for each group with a two-sided α -value of 0.05, a power of 80%, a non-inferiority margin of 5%, and a 10% dropout rate.

Randomization and monitoring

A stratified permuted block randomization method was used in this study. The research assistant who did not participate in clinical practice created the random allocation sequence, and the information was concealed until the treatment method was assigned at the time of polypectomy. Patients were unaware of their assigned treatment methods before and during polypectomy.

Statistics

The primary outcome was analyzed using intention-to-treat (ITT) analysis. Continuous variables are described using the median difference with a 95% confidence interval (CI). Categorical variables are described using risk differences with a 95% CI. Given the potential presence of multiple polyps in each patient, generalized estimating equations (GEE) were used to control for within-patient correlations. Statistical significance was set at $P < 0.05$. Statistical analyses were performed using R Statistical Software (version 4.3.1; R Core Team, 2023).

Results

Patients and polyp characteristics

A total of 99 patients were included in this trials, 51 patients with 70 eligible polyps and 48 patients with 70 eligible polyps were randomly allocated into the CS-EMR or the HS-EMR group, respectively (Fig. 2). An eligible polyp in one patient, who was initially allocated to the HS-EMR group, was finally treated using the CS-EMR technique because resection was completed without ESU and was excluded from the per-protocol analysis. All patients visited the outpatient clinics to confirm adverse events, histological diagnosis, or surveillance colonoscopy plans. However, two patients did not undergo surveillance colonoscopy.

The baseline characteristics of the patients and polyps are summarized in Table 1. The median size of the polyps was 7 mm in the CS-EMR and HS-EMR groups. Polyps were found in the right colon in 64.3% and 58.8% of cases in the CS-EMR and HS-EMR groups, respectively. Morphology was represented as flat in 62.9% and 50.0% of the CS-EMR and HS-EMR groups, respectively.

Primary and secondary outcomes

In the intention-to-treat population, the RRA rate was 0% in the CS-EMR group and 1.5% in the HS-EMR group (risk difference [RD], -1.47 ; 95% CI -4.34 to 1.39 ; $P = 0.313$) (Fig. 3). *En bloc* resection rates for the CS-EMR and HS-EMR group were 98.5% vs 98.4% (RD, -0.04 ; 95% CI -4.12 to 4.02 ; $P = 0.981$), and the R0 resection rates were 55.7% vs 82.4% (RD, -27.80 ; 95% CI -42.50 to -13.10 ; $P < 0.001$) (Table 2). One RRA occurred in trainee who performed HS-EMR.

The median procedure time was shorter in the CS-EMR group compared to the HS-EMR group (172 s [IQR: 158–189] vs 186 s [147–216 s]; median difference, -14 ; 95% CI -32 to 2 ; $P = 0.400$).

Immediate bleeding was observed in 11.4% in the CS-EMR group and 7.4% in the HS-EMR group (RD, 3.16 ; 95% CI -6.68 to 13.00 ; $P = 0.529$). Delayed bleeding occurred in 2.9% vs 1.5% (RD, 1.37 ; 95% CI -3.47 to 6.21 ; $P = 0.578$) in the CS-EMR and HS-EMR groups. One post-polypectomy syndrome occurred in the HS-EMR group (Table 2).

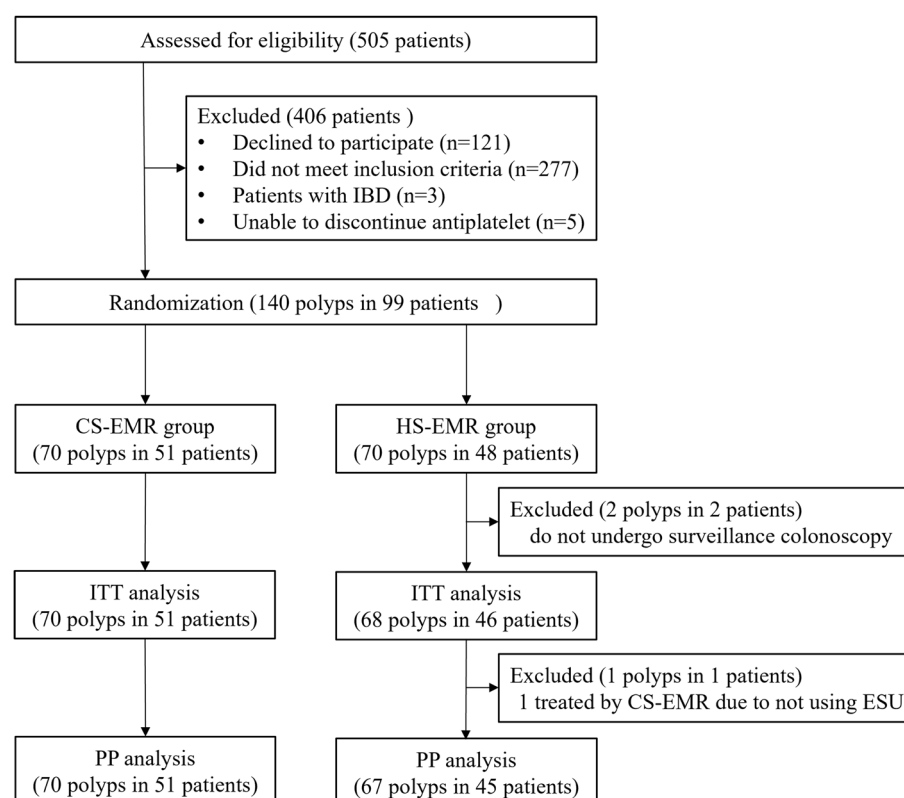


Fig. 2. A flow diagram of the study. CS-EMR cold snare endoscopic mucosal resection, HS-EMR hot snare endoscopic mucosal resection, ITT intention-to-treat, PP per-protocol.

Patients	CS-EMR (n = 51)	HS-EMR (n = 46)	P
Age, median (IQR), years	65 (58–73)	62 (55–71)	0.394
Sex, Male, n (%)	30 (58.8)	30 (65.2)	0.517
Indication, n (%)			
Symptoms	24 (47.1)	16 (34.8)	0.376
Polypectomy	12 (23.5)	14 (30.4)	
Surveillance	6 (11.8)	10 (21.7)	
Cancer screening	9 (17.6)	6 (13.0)	
Hemodialysis, n (%)	11 (21.6)	9 (19.6)	0.808
Antithrombotics, n (%)			
Antiplatelets	7 (13.7)	6 (13.0)	0.922
Anticoagulants	0	0	
Follow-up, (IQR), months	6 (6–7)	6 (6–7)	0.620
Polyps	CS-EMR (n = 70)	HS-EMR (n = 68)	
Size, median (IQR), mm	7 (6–8)	7 (6–8)	0.314
Size, n (%)			
6–7 mm	44 (62.9)	38 (55.9)	0.509
8–9 mm	26 (37.1)	30 (44.1)	
Morphology, n (%)			
Sessile	22 (31.4)	26 (38.2)	0.232
Flat	44 (62.9)	34 (50.0)	
Pedunculated	4 (5.7)	8 (11.8)	
Location, n (%)			
Right colon	45 (64.3)	40 (58.8)	0.760
Left colon	23 (32.9)	25 (36.8)	
Rectum	2 (2.9)	3 (4.4)	
Histology, n (%)			
Low grade adenoma	63 (90.0)	63 (92.3)	0.168
High grade adenoma	0	2 (2.9)	
Sessile serrated lesion	7 (10.0)	3 (4.4)	
Endoscopists, n (%)			
Expert	64 (91.4)	55 (80.9)	0.121
Trainee	6 (8.6)	13 (19.1)	

Table 1. Baseline characteristics of the patients and polyps. *CS-EMR* cold snare endoscopic mucosal resection, *HS-EMR* hot snare endoscopic mucosal resection, *IQR* interquartile range.

Population

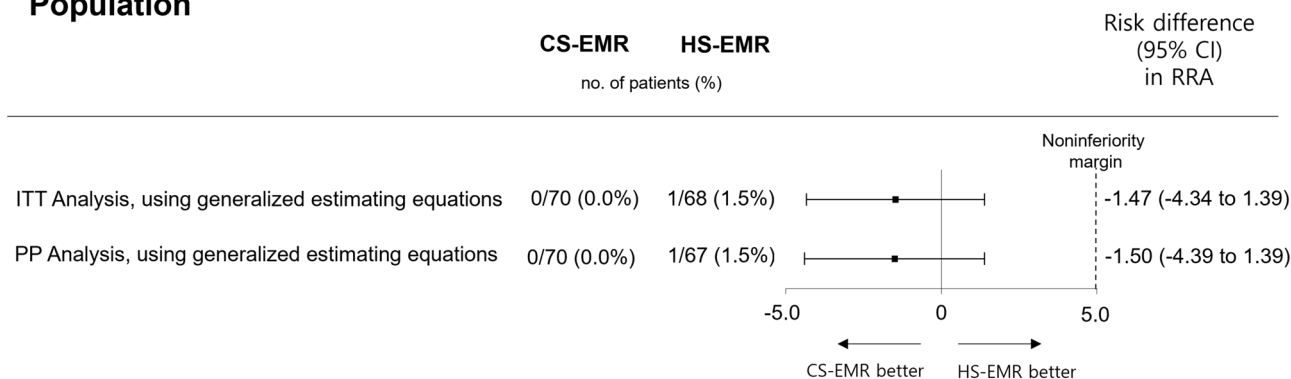


Fig. 3. Results of primary outcome for intention-to-treat and per-protocol analysis. *CS-EMR* cold snare endoscopic mucosal resection, *HS-EMR* hot snare endoscopic mucosal resection, *CI* confidence interval, *RRA* residual or recurrent adenoma, *ITT* intention-to-treat, *PP* per-protocol.

	CS-EMR (n = 70)	HS-EMR (n = 68)	Risk difference* (95% CI)	P*
RRA, n (%)	0	1 (1.5)	-1.47 (-4.34-1.39)	0.313
<i>En bloc</i> resection, n (%)	69 (98.6)	67 (98.5)	-0.04 (-4.12-4.02)	0.981
R0 resection, n (%)	39 (55.7)	56 (82.4)	-27.80 (-42.50- -13.10)	<0.001
Total procedure time, median (IQR), seconds	172 (158-189)	186 (147-216)	-14 (-32-2)†	0.400
Prophylactic clip use, n (%)	1 (1.4)	2 (2.9)	-1.51 (-6.40-3.37)	0.400
Adverse event, n (%)				
Immediate bleeding	8 (11.4)	5 (7.4)	3.16 (-6.68-13.00)	0.529
Delayed bleeding	2 (2.9)	1 (1.5)	1.37 (-3.47-6.21)	0.578
Perforation	0	0	0	1.000
PPS	0	1 (1.5)	-1.49 (-4.37-1.39)	0.310

Table 2. Study outcomes for the intention-to-treat population. *Risk difference, median difference, and *P* value were calculated by generalized estimating equations. †Median difference. *CS-EMR* cold snare endoscopic mucosal resection, *HS-EMR* hot snare endoscopic mucosal resection, *CI* confidential interval, *RRA* recurrent and residual adenoma, *IQR* interquartile range, *PPS* post-polypectomy syndrome.

In the per-protocol population, the RRA rate was 0% in the CS-EMR group and 1.5% in the HS-EMR group (RD, -1.50; 95% CI -4.39 to 1.39; *P* = 0.308) (Fig. 3). *En bloc* resection rate for the CS-EMR and HS-EMR group was 98.6% and 98.5% (RD, -0.02; 95% CI -4.12 to 4.06; *P* = 0.989) and R0 resection rate was 55.7% vs 83.6% (RD, -29.10; 95% CI -43.70 to -14.60; *P* < 0.001), respectively (Table 3).

Discussion

There are few studies on RRA for small colorectal polyps. In contrast, relatively many studies on IRR have been reported, and in these studies, IRR was defined as a residual lesion confirmed by performing random biopsies of at least two or four locations of the resection margin. Although this method is useful, it cannot represent all cases of RRAs. Therefore, it is important to study RRA incidence conducting surveillance colonoscopy.

In the present study, we clearly showed that the RRA rate of the CS-EMR group was similar to that of the HS-EMR group for small colorectal polyps (0% vs 1.5%; 95% CI -4.34-1.39; *P* = 0.313). This is similar to the recently reported Japanese retrospective study on RRAs where HS-EMR was used (98%)¹⁷. In CSP, where relatively several RRA studies were conducted in small colorectal polyps, it has been reported that the RRA rate varies from 0.9 to 6.3%¹⁷⁻¹⁹. It is well-known that there is a wide range of incomplete resection differences among endoscopists^{7,20}. Several studies reported that the acquisition of a free margin (> 2 mm) including normal mucosa and a meticulous inspection of the resection margin are important for improving RRA or IRR^{11,21-24}. Submucosal injection can help in achieving the complete resection of the colorectal polyp by clearly demarcating its margins and contribute to easier polypectomy by enabling the endoscopist to manipulate the shape of the colorectal polyp according to their intended form^{16,25}. Furthermore, using submucosal injection in cold resection can be more helpful for examination of the resection site, as there is no cautery effect, which might make residual lesions more visible. These benefits can be maximized particularly when piecemeal resection occurred. In our study, RRA occurred in piecemeal resection case of HS-EMR, which likely occurred because the cautery effect made it difficult for the endoscopist to identify residual lesions. Considering these, CS-EMR can speculate helpful for improving the complete resection rate of endoscopists with high RRA or IRR. We presume that our study reflected these points well, resulting in low RRA results.

	CS-EMR (n = 70)	HS-EMR (n = 67)	Risk difference* (95% CI)	P*
RRA, n (%)	0	1 (1.5)	-1.50 (-4.39-1.39)	0.308
<i>En bloc</i> resection, n (%)	69 (98.6)	66 (98.5)	-0.02 (-4.12-4.06)	0.989
R0 resection, n (%)	39 (55.7)	56 (83.6)	-29.10 (-43.70- -14.60)	<0.001
Total procedure time, median (IQR), seconds	172 (158-189)	184 (147-213)	-12 (-30-4)†	0.500
Prophylactic clip use, n (%)	1 (1.4)	2 (3.0)	-1.56 (-6.47-3.35)	0.534
Adverse event, n (%)				
Immediate bleeding	8 (11.4)	5 (7.5)	3.10 (-6.75-12.9)	0.537
Delayed bleeding	2 (2.9)	1 (1.5)	1.35 (-3.50-6.20)	0.586
Perforation	0	0	0	1.000
PPS	0	1 (1.5)	-1.51 (-4.41-1.39)	0.307

Table 3. Study outcomes for the per-protocol population. *Risk difference, median difference, and *P* value were calculated by generalized estimating equations. †Median difference. *CS-EMR* cold snare endoscopic mucosal resection, *HS-EMR* hot snare endoscopic mucosal resection, *CI* confidential interval, *RRA* recurrent and residual adenoma, *IQR* interquartile range, *PPS* post-polypectomy syndrome.

Current study showed differences in R0 resection rates between the CS-EMR and HS-EMR groups (55.7% vs. 82.4%; $P=0.001$). Conversely, the Rx resection rate in the CS-EMR group was higher than that in the HS-EMR (40.0% vs. 13.2%; $P=0.001$). However, these differences did not translate into disparities in the RRA rates. This is thought to represent the difficulty of histological evaluation in cold resection, in which fragmentation or crushing of specimens is often observed in histological examination²⁶. In the case of R1 resection, it was shown that the two groups were similar. However, this may also be due to the fragmentation or crushing effect of the specimen on CS-EMR. Ultimately, these points make it difficult to identify incomplete resection or residual lesions through the histological evaluation of specimens and can confuse endoscopists in the post-polypectomy surveillance process. Moreover, in the clinical setting, it is not easy to generalize margin biopsy to confirm incomplete resection, therefore it is important for endoscopists to lower the RRA rate in cold resection.

The safety of CS-EMR was similar to that of HS-EMR for small colorectal polyps in this study. Immediate and delayed bleeding rates were higher than those reported in previous studies^{6–8,12}. It might be related to pedunculated polyps and hemodialysis patients. Excluding the bleeding that occurred in these patients, similar bleeding rates were observed as in previous studies. Several studies have reported that immediate and delayed bleeding can occur frequently in pedunculated polyps and hemodialysis patients^{27–29}. All cases of immediate and delayed bleeding were easily treated with an endoscopic hemoclip.

In the present study, pedunculated polyps were also included. Although there have been some studies on CSP for small pedunculated colorectal polyps, the evidence is still limited, and no studies have conducted this in CS-EMR^{7,30–33}. Cold resection has not been frequently conducted for pedunculated polyps because of concerns about immediate bleeding rather than RRA and IRR. Immediate bleeding occurred in most pedunculated polyps in the CS-EMR group (three cases, 75%) but was safely treated with an endoscopic hemoclip. Furthermore, as immediate bleeding did not occur, one delayed bleeding cases occurred in the CS-EMR group, in which endoscopic hemoclip was not used. Even if immediate bleeding does not occur, it appears safe to use a prophylactic clip during CS-EMR of pedunculated polyps to prevent delayed bleeding.

De Benito Sanz Marina et al. reported that endoscopist performance is a strong risk factor for incomplete resection⁷. Our study included trainee endoscopists who were predicted to have a high RRA rate owing to relatively less experience. Nonetheless, only one RRA occurred among trainee endoscopists. Recently, Kaltenbach et al. reported that trainee endoscopists have a long learning curve to reach competence in CSP³⁴. Based on our findings and theoretical background, CS-EMR is expected to be of great help to trainee endoscopists.

Our study has several limitations. First, pedunculated polyps were included, but there were small sample sizes. It seems that large-scale studies are needed to confirm the safety of CS-EMR for pedunculated polyps. Second, most surveillance colonoscopies were performed 6 months after polypectomy, and delayed recurrence could not be determined after the polyp recurrence rate was not evaluated by follow-up colonoscopy. Third, trainee endoscopists predicted to have a high RRA were included, but it is necessary to compare CS-EMR with CSP through further studies to confirm whether submucosal injection is really helpful in improving RRA in trainee endoscopists.

In conclusion, the RRA is similar in CS-EMR and HS-EMR for small colorectal polyps. CS-EMR can be recommended as a standard method for resection of small colorectal polyps.

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Author contributions

CKO conceived the idea presented in this study, and revised the study design. CKO and YWC processed the data acquisition for this study. JJ and HYL processed the data analysis and interpretation for this study. CKO, YWC, JBK, YSC developed the theory. CKO and YWC wrote the main manuscript text. All authors discussed the results and contributed to the final manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare no competing interests.

Additional information

Correspondence and requests for materials should be addressed to C.K.O.

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