Anchoring endoscopic mucosal resection versus conventional endoscopic mucosal resection for large nonpedunculated colorectal polyps: a randomized controlled trial

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ABSTRACT

Background Colorectal polyps >10 mm in size are often incompletely resected. Anchoring-endoscopic mucosal resection (A-EMR) is the technique of making a small incision at the oral side of the polyp using a snare tip after submucosal injection to avoid slippage during ensnaring. This study was performed to evaluate whether A-EMR could increase the complete resection rate for large colorectal polyps compared with conventional endoscopic mucosal resection (C-EMR).

Methods Polyps with sizes of 10–25 mm were randomly allocated to either the A-EMR or the C-EMR groups.

Results 105 and 106 polyps were resected using A-EMR and C-EMR, respectively. In the intention-to-treat population, the complete resection rate was 89.5 % in the A-EMR group and 74.5 % in the C-EMR group (relative risk [RR] 1.20, 95 %CI 1.04 to 1.38; $P=0.01$). The en bloc resection rates for the A-EMR and C-EMR groups were 92.4 % vs. 76.4 % (RR 1.21, 95 %CI 1.06 to 1.37; $P=0.005$) and R0 resection rates were 77.1 % vs. 64.2 % (RR 1.18, 95 %CI 0.98 to 1.42; $P=0.07$), respectively. The median (interquartile range [IQR]) total procedure time was 3.2 (2.6–4.1) minutes in the A-EMR group and 3.0 (2.2–4.6) minutes in the C-EMR group (median difference 0.2 minutes, 95 %CI −0.22 to 0.73; $P=0.25$). There was one episode of delayed bleeding and one perforation in the C-EMR group.

Conclusions A-EMR was superior to C-EMR for the complete resection of large colorectal polyps. A-EMR can be considered one of the standard methods for the removal of colorectal polyps of 10 mm or more in size.

Introduction

Colonoscopy reduces the incidence and mortality of colorectal cancer (CRC) by detecting and removing premalignant polyps. However, post-colonoscopy CRCs account for 9 % of all CRCs, and 20 %–30 % of post-colonoscopy CRCs are likely related to incomplete resection [1, 2].

Conventional endoscopic mucosal resection (C-EMR) is the preferred method for the resection of large nonpedunculated

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polyps because the submucosal injection is expected to reduce the risk of deep mural injuries from electrocautery and increase the complete resection rate by securing a clear margin of normal tissue [3–5]. However, the incomplete resection and local recurrence rates of EMR for polyps > 10 mm in size have been reported to be as high as 20 % and 15 %, respectively [6–8].

Anchoring-EMR (A-EMR) or "tip-in EMR" is a method for the complete resection of large-sized colorectal polyps [9–16]. The only difference between A-EMR and C-EMR is the process of making a small mucosal incision at the oral side of the lesion, which is helpful for deploying the snare in a wider area laterally and avoiding slippage during ensnaring by anchoring the snare tip into the submucosal layer. To date, however, only a small-sized randomized study has been conducted to compare A-EMR and C-EMR for large nonpedunculated colorectal polyps [16]. Therefore, this study was performed to evaluate the efficacy and safety of A-EMR compared with C-EMR for the endoscopic removal of nonpedunculated polyps of 10–25 mm in size.

Methods

Study design

This was a prospective, randomized, controlled, parallel, superiority, single-center trial. The study was conducted at Seoul St. Mary's Hospital, The Catholic University of Korea, Seoul, South Korea. Nonpedunculated polyps with sizes of 10–25 mm detected during colonoscopy were randomly allocated to the A-EMR or C-EMR groups.

All procedures were conducted in accordance with the Declaration of Helsinki and the study protocol was approved by the Institutional Review Board (KC20EISE0171). All patients provided their written informed consent before participating in the study. The study was reported according to the CONSORT guidelines.

Study participants

The participants were prospectively enrolled between April 2020 and January 2021. We included patients aged 19–85 years undergoing endoscopic resection for one or more nonpedunculated polyps that were 10–25 mm in diameter. The exclusion criteria were: (i) having a known or suspected malignant polyp, a previously incompletely resected polyp, a subepithelial lesion, or a pedunculated polyp; (ii) inflammatory bowel disease; (iii) the uninterrupted use of antithrombotic drugs; and (iv) presence of a coagulopathy.

The baseline characteristics of the eligible participants including their demographic data and the indications for colonoscopy (polypectomy, positive fecal occult blood test, colorectal cancer screening or surveillance, and abdominal symptoms) were collected.

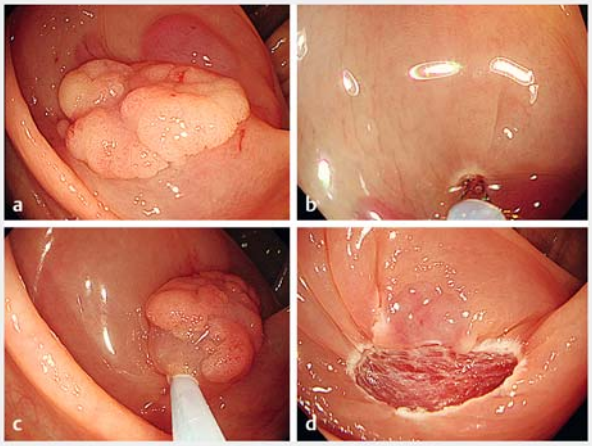
Interventions

All patients were prepared with 1 L of polyethylene glycol plus ascorbic acid solution (Taejoon Pharm, Seoul, South Korea) or 4 L of polyethylene glycol solution (Taejoon Pharm). The procedures were performed by two experienced endoscopists with over 10 000 colonoscopy cases (L.B.I and C.Y.S.) and one less experienced endoscopist with fewer than 1000 colonoscopy cases (O.C.K.). All endoscopists had a self-learning of at least 20 A-EMRs with reference to Japanese and European video sources before the trial was started [10, 16].

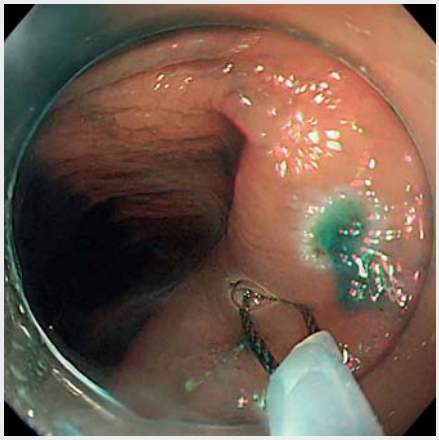
All the procedures were carried out with a high definition RGB sequential video-endoscopy system (CV-290; Olympus Co., Tokyo, Japan). A high definition colonoscope with magnification function (CF-HQ290I or PCF-260AZI; Olympus) was used for all procedures. Once a polyp was identified, eligibility was assessed by the endoscopic findings, and eligibility for the study was confirmed. Because the resection technique (A-EMR or C-EMR) was allocated for the patient, multiple eligible polyps in each patient were resected using the same resection technique.

Normal saline with or without a few drops of an indigo carmine solution was used for submucosal injection. A 25- or 15-mm oval snare (Olympus or Taewoong Medical, Gimpo, Korea) with Endocut Q/I or the forced coagulation current of the electrosurgical unit (VIO300D; Erbe Elektromedizin GmbH, Tübingen, Germany) was used for resection. The polyp size was measured by comparison with the size of the deployed snare. En bloc resection at the initial snaring was attempted in all cases.

The A-EMR procedure included the following: (i) submucosal injection; (ii) a small mucosal incision being made at the oral side of the polyp with a snare tip using cut current; (iii) the polyp including the surrounding normal mucosa being snared, while keeping the snare tip in the submucosal layer; and (iv) resection using electrocautery (▶ **Fig. 1**; ▶ **Video 1**). A mucosal incision at the oral side was omitted in the C-EMR procedure. After resection, the mucosal defect was washed with a waterjet and the resection margin was meticulously observed with white-light, narrow-band imaging (NBI), and magnifying NBI endoscopy to identify any residual polyp tissue. Magnifying



▶ **Fig. 1** Endoscopic images showing the steps in the anchoring endoscopic mucosal resection (A-EMR) procedure, which include: **a** submucosal injection; **b** a small mucosal incision being made at the oral side of the polyp with a snare tip using cut current; **c** the polyp including the surrounding normal mucosa being snared, while keeping the snare tip in the submucosal layer; **d** resection using electrocautery.



Video 1 A video demonstrating the anchoring endoscopic mucosal resection (A-EMR) procedure.
Online content viewable at:
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chromoendoscopy with indigo carmine was additionally performed for residual histologic examination when the appearance with magnifying NBI endoscopy was uncertain.

When the optical decision was not clear because of cautery artifacts, distorted pit/microvascular patterns, tearing of the resection margin, and continuous oozing, among other reasons, a forceps biopsy was performed where residual polyp tissue was most likely to be present. When residual tissue was apparent endoscopically, additional snaring was performed. Endoscopic closure was performed where there was blood spurting, continuous oozing for more than 30 seconds, a visible vessel, or deep mural injury. Protruded and superficial polyps were categorized as Paris classification type I and type II, respectively [17]. The location of colorectal polyps was classified 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 treated according to the usual clinical practice of our department.

Histological examination

Each resected specimen was initially examined by the pathologists in charge according to the routine procedure of our institution and reviewed again by the experienced gastrointestinal pathologist (L.S.H.), who was blinded to the clinical information. Any specimens with a histologic discrepancy were reviewed and discussed by the pathologist in charge and the gastrointestinal pathologist. Histological classification was conducted based on the World Health Organization classifications.

Outcome parameters

The primary outcome of this study was the difference in complete resection rates between the A-EMR and C-EMR groups. En bloc resection was classified as the resection of the polyp in one piece. Complete resection was defined as en bloc resection and the absence of residual polyp with endoscopic confidence, or en bloc resection and negative forceps biopsy for a suspicious resection margin.

Secondary outcomes included the en bloc resection rate, R0 resection rate, total procedure time, procedure time until the completion of the first snaring, and the incidence of adverse events. R0 resection was defined as a histologic examination showing the absence of polyp tissue at the margin of the resected specimen, while R1 resection was the presence of neoplastic tissue at the margin. Rx resection was recorded when the involvement of the resection margin could not be determined because of electrocautery effects or a tangential tissue section.

The total procedure time was measured as the time from the submucosal injection to complete removal of the polyp, and the procedure time until the completion of the first snaring was the time from the submucosal injection to the completion of the first snare resection.

Perforation was defined as a full-layered defect of the colonic wall that needed immediate endoscopic or surgical intervention. Immediate bleeding was not regarded as an adverse event when it was managed immediately by endoscopic hemostatic procedures. Delayed bleeding was defined as overt bleeding within 7 days after the colonoscopic procedure that required a separate endoscopic hemostatic procedure. All patients were supposed to visit our outpatient clinic within 2 weeks to be checked for any adverse events after polypectomy and to receive their histologic diagnosis and post-polypectomy colonoscopy surveillance plan. They were also asked whether they had experienced abdominal pain, tarry stool, hematochezia, and/or dizziness, and they underwent a brief physical examination.

Sample size calculation

We hypothesized that the complete resection rate for nonpedunculated polyps of 10–25 mm would be between the en bloc resection rate and the R0 resection rate. Previous studies have reported that the en bloc and R0 resection rates of C-EMR for colorectal polyps of 10–20 mm were 75.0 %–85.7 % and 50.0 %–67.3 %, respectively [18, 19]. Pioche et al. [10] reported that the en bloc resection rate and R0 resection rate of A-EMR for colorectal polyps of 8–20 mm were 92.0 % and 82.8 %, respectively. Therefore, combining our preliminary experience with C-EMR and A-EMR for colorectal polyps of 10–25 mm, we estimated that the complete resection rate of C-EMR and A-EMR for such colorectal polyps would be approximately 72 % and 88 %, respectively. Thus, the required sample size was 105 polyps for each group with a two-sided α-value of 0.05, a power of 80 %, and a 10 % dropout rate.

Randomization and monitoring

A stratified permuted block randomization method was employed. A research assistant who was not involved in clinical practice generated the random allocation sequence, and the contents were concealed until the intervention group was assigned at the time of polyp resection. The patients were blinded to the allocated treatment method before and during the endoscopic procedures.

Statistics

The primary outcome was analyzed by intention-to-treat (ITT) analysis. Categorical outcomes were represented by the relative risk (RR) with 95 %CI. Continuous outcomes were represented by the median difference with 95 %CI. As each patient could have more than one polyp, the generalized estimating equations (GEE) were used to control for within-patient correlations. We also performed pre-planned subgroup analyses based on the size, morphology, and the location of lesions using GEE. $P < 0.05$ was considered to indicate significance. All statistical analyses were carried out using R Statistical Software (version 4.2.0; R Core Team, 2021).

Results

Patients and polyp characteristics

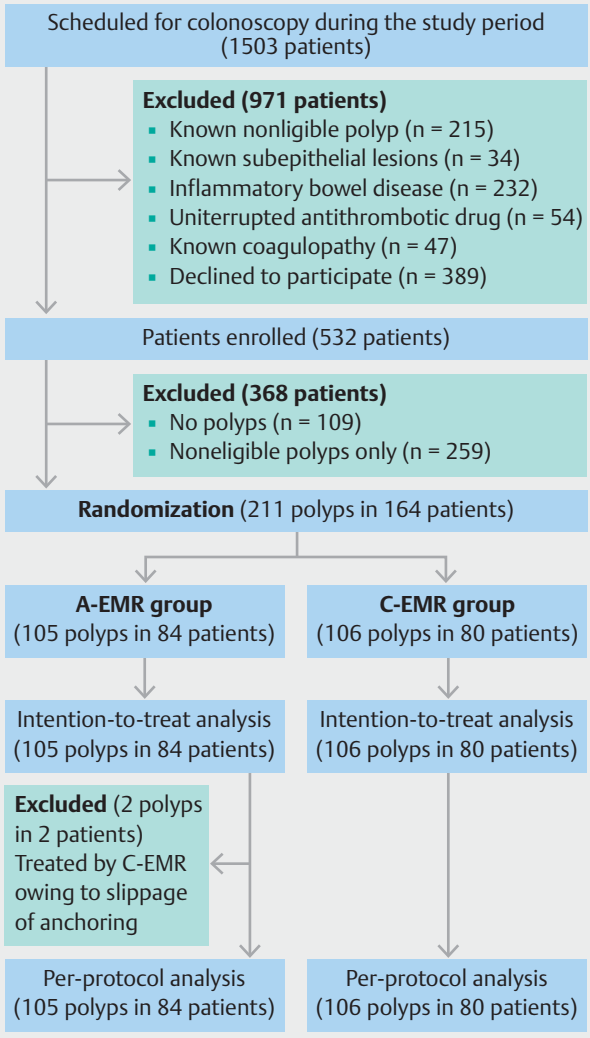
A total of 532 patients were enrolled in the study between April 2020 and January 2021 (▶ **Fig. 2**). Among them, 368 patients were excluded because they did not have any eligible polyps during colonoscopy (no polyp; n = 109), had only a pedunculated polyp (n = 7), only polyps < 10 mm (n = 245), only polyps > 25 mm (n = 4), or only endoscopically malignant polyps (n = 3). Finally, 84 patients with 105 eligible polyps and 80 patients with 106 eligible polyps were randomly allocated into the A-EMR and C-EMR groups, respectively. An eligible polyp in each of two patients who were initially allocated into the A-EMR group was finally treated by the C-EMR technique because of repetitive slippage of the snare tip from the small mucosal incision on the oral side; these two patients were excluded from the per-protocol analysis. There was no follow-up loss through patients not visiting to confirm their adverse events, and receive their histological diagnosis and post-polypectomy colonoscopy surveillance plan.

▶ **Table 1** shows the baseline characteristics of the patients and their polyps in the A-EMR and C-EMR groups. The median size of the polyps was 14 mm in both the A-EMR and C-EMR groups. The polyp was located in the right colon in 72.4 % and 81.1 % of cases in the A-EMR and C-EMR groups, respectively. The morphology was classified as type II in 81.0 % and 76.4 % of the A-EMR and C-EMR group, respectively.

Primary and secondary outcomes

In the intention-to-treat population, the complete resection rate was 89.5 % in the A-EMR group and 74.5 % in the C-EMR group (RR 1.20, 95 %CI 1.04 to 1.38; $P = 0.01$) (▶ **Table 2**). The en bloc resection rates for the A-EMR and C-EMR groups were 92.4 % vs. 76.4 % (RR 1.21, 95 %CI 1.06 to 1.37; $P = 0.005$) and the R0 resection rates were 77.1 % vs. 64.2 % (RR 1.18, 95 %CI 0.98 to 1.42; $P = 0.07$), respectively.

The median (IQR) procedure time until the completion of the first snaring was longer in the A-EMR group compared with the C-EMR group (3.2 [2.6–3.9] vs. 2.7 [2.1–4.0] minutes; median difference 0.5 minutes, 95 %CI 0.07 to 0.75; $P = 0.03$). However, the total procedure time was not significantly different between the two groups (3.2 [2.6–4.1] vs. 3.0 [2.2–4.6] minutes; median difference 0.2 minutes, 95 %CI −0.22 to 0.73; $P = 0.25$).



▶ **Fig. 2** A flow diagram of the study.
A-EMR, anchoring-endoscopic mucosal resection; C-EMR, conventional-endoscopic mucosal resection.

There was no immediate bleeding. One patient in the C-EMR group had delayed bleeding, which was managed successfully by endoscopic clipping, and one perforation occurred in the C-EMR group (▶ **Table 2**).

In the per-protocol population, the complete resection rate was 90.3 % in the A-EMR group and 74.5 % in the C-EMR group (RR 1.21, 95 %CI 1.05 to 1.39; $P = 0.008$) (**Table 1 s**, see online-only Supplementary material). The en bloc resection rates for the A-EMR and C-EMR group were 93.2 % vs. 76.4 % (RR 1.21, 95 %CI 1.06 to 1.38; $P = 0.003$) and R0 resection rates were 78.6 % vs. 64.2 % (RR 1.20, 95 %CI 1.00 to 1.44; $P = 0.049$), respectively.

▶ **Table 1** Baseline characteristics of the 164 patients and their 211 polyps.

	A-EMR	C-EMR
Patient characteristics	(n = 84)	(n = 80)
Age, median (IQR), years	61 (53–71)	60 (50–70)
Sex, male, n (%)	43 (51.2)	39 (48.8)
Indication, n (%)		
▪ Polypectomy	62 (73.8)	54 (67.5)
▪ Surveillance	11 (13.1)	14 (17.5)
▪ Symptoms	8 (9.5)	7 (8.8)
▪ Cancer screening	1 (1.2)	4 (5.0)
▪ Positive occult blood test	2 (2.4)	1 (1.2)
Antithrombotic agent use, n (%)		
▪ Antiplatelets	9 (10.7)	9 (11.3)
▪ Anticoagulants	2 (2.4)	1 (1.3)
▪ Combination	0	0
Polyp characteristics	(n = 105)	(n = 106)
Size, median (IQR), mm	14 (11–19)	14 (12–18)
Size, n (%), mm		
▪ 10–14	56 (53.3)	57 (53.8)
▪ 15–25	49 (46.7)	49 (46.2)
Morphology, n (%)		
▪ Type I	20 (19.0)	25 (23.6)
▪ Type II	85 (81.0)	81 (76.4)
Location, n (%)		
▪ Right colon	76 (72.4)	86 (81.1)
▪ Left colon	22 (21.0)	19 (17.9)
▪ Rectum	7 (6.7)	1 (0.9)
Histology, n (%)		
▪ Low grade adenoma	43 (41.0)	48 (45.3)
▪ High grade adenoma	7 (6.7)	4 (3.8)
▪ Sessile serrated lesion	50 (47.6)	48 (45.3)
▪ Hyperplastic polyp	4 (3.8)	6 (5.7)
▪ Intramucosal carcinoma	1 (1.0)	0
Submucosal injection with indigo carmine mixed solution, n (%)	51 (48.6)	55 (51.9)
Use of distal transparent cap, n (%)	11 (10.5)	13 (12.3)

A-EMR, anchoring-endoscopic mucosal resection; C-EMR, conventional endoscopic mucosal resection; IQR, interquartile range.

Subgroup analysis

Subgroup analysis is shown in ▶ **Fig. 3**. A-EMR was better for complete resection of colorectal lesions over 15 mm and lesions located in the right colon. A-EMR was superior to C-EMR for complete resection of both flat and protruded lesions.

Discussion

In the present study, we clearly showed that the complete resection and en bloc resection rates of A-EMR were higher than those of C-EMR for nonpedunculated polyps of 10–25 mm. The incomplete resection rate of polyps of 10–20 mm has been reported to be as high as 17.3 %–20.8 % in previous studies [6, 20, 21]. Moreover, lesions ≥ 20 mm frequently require piecemeal resection, whereas most lesions < 20 mm typically can be removed en bloc by the EMR technique [3]. It is well known that piecemeal EMR is associated with higher rates of post-polypectomy recurrence [22]. In our study, the incomplete resection rate of A-EMR for nonpedunculated polyps of 10–25 mm was only 10.5 %.

Endoscopic submucosal resection is an effective technique for the en bloc resection of large colorectal lesions; however, the application of the technique is limited to lesions with superficial submucosal invasion or submucosal fibrosis because of the perforation risk, prolonged procedure time, and technical difficulty. A circumferential submucosal incision prior to EMR, a so-called "precut-EMR," is less time-consuming and technically easier, but our retrospective analyses with propensity score matching have shown that the technique does not increase the complete resection or en bloc resection rates compared with conventional EMR [5].

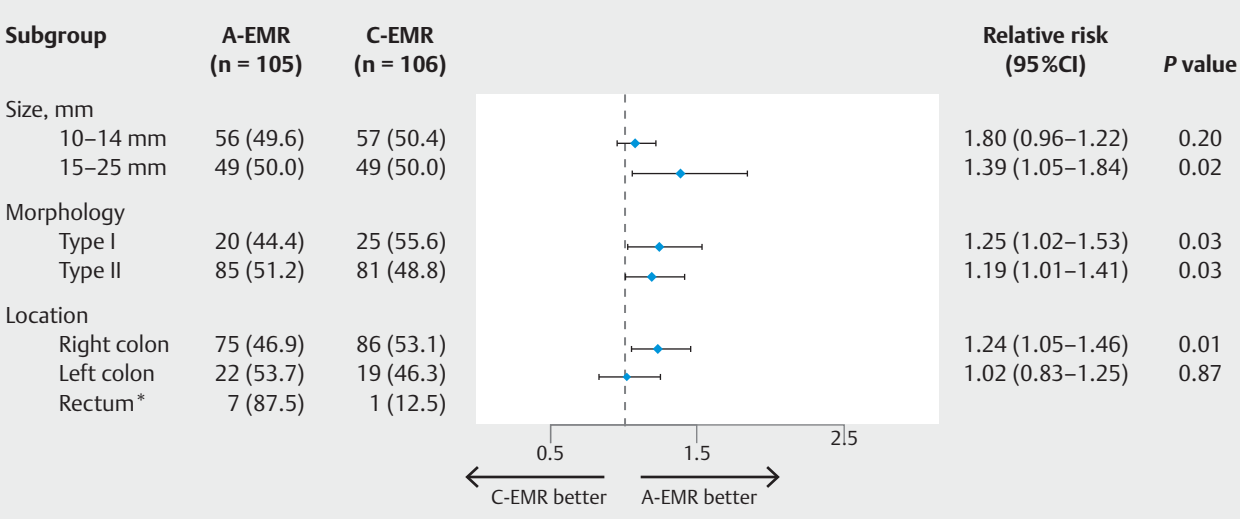
In our study, the procedure time until the completion of the first snaring was longer in the A-EMR group (3.2 vs. 2.7 minutes; median difference 0.5 minutes, 95 %CI 0.07 to 0.75 minutes; $P = 0.03$) because the technique required time for anchoring of the snare tip. However, the median difference in the total procedure times between the A-EMR and C-EMR groups was only 0.2 minutes (95 %CI −0.22 to 0.73; $P = 0.25$), despite the achievement of higher complete resection, en bloc resection, and R0 resection rates. This was because the en bloc resection rate in the A-EMR group was higher than that of the C-EMR group, which resulted in fewer snarings being performed in the A-EMR group. Therefore, A-EMR appears to be an excellent method for the resection of nonpedunculated polyps of 10–25 mm in terms of achieving complete resection and also presenting lower technical difficulty.

A previous Japanese study also showed that A-EMR significantly improved the en bloc resection rate for nonpedunculated lesions of 15–25 mm compared with C-EMR (90.2 % vs. 73.1 %; $P = 0.04$) [16]; however, there was no statistical difference in the R0 resection rate between their A-EMR and C-EMR groups (73.2 % vs. 58.5 %; $P = 0.19$), which might have been caused by the relatively small number of study patients (n = 41 in each group). The definition of en bloc resection in the Japanese study was compatible with that of complete resection in our study, and our subgroup analysis also revealed that the

▶ **Table 2** Study outcomes for the intention-to-treat population.

	A-EMR (n = 105)	C-EMR (n = 106)	Relative risk* (95 %CI)	Median difference* (95 %CI)	*P**
Complete resection, n (%)	94 (89.5)	79 (74.5)	1.20 (1.04 to 1.38)	–	0.01
En bloc resection, n (%)	97 (92.4)	81 (76.4)	1.21 (1.06 to 1.37)	–	0.005
R0 resection, n (%)	81 (77.1)	68 (64.2)	1.18 (0.98 to 1.42)	–	0.07
Procedure time until the completion of the first snaring, median (IQR), minutes	3.2 (2.6–3.9)	2.7 (2.1–4.0)	–	0.5 (0.07 to 0.75)	0.03
Total procedure time, median (IQR), minutes	3.2 (2.6–4.1)	3.0 (2.2–4.6)	–	0.2 (−0.22 to 0.73)	0.25
Forceps biopsy for suspicious resection margin, n (%)	28 (26.7)	21 (19.8)	1.35 (0.81–2.22)	–	0.25
Prophylactic clip use, n (%)	18 (17.1)	37 (34.9)	0.48 (0.29–0.80)	–	0.005
Adverse events, n (%)					
Delayed bleeding	0 (0.0)	1 (0.9)	–		
Perforation	0 (0.0)	1 (0.9)	–		

A-EMR, anchoring-endoscopic mucosal resection; C-EMR, conventional endoscopic mucosal resection; IQR, interquartile range.
* Relative risk, median difference, and *P* value were calculated by generalized estimating equations.



▶ **Fig. 3** Subgroup analyses for complete resection of polyps by anchoring-endoscopic mucosal resection (A-EMR) or conventional endoscopic mucosal resection (C-EMR).
† No relative risk owing to small sample size.

complete resection rate in the A-EMR group was higher than that in the C-EMR group, especially when the polyp was ≥ 15 mm (RR 1.39, 95 %CI 1.05 to 1.84).

In the present study, the complete resection rate in the A-EMR group was also higher than that in the C-EMR group when the polyp was located at the right colon. It is assumed that the snare was more likely to slip during ensnaring in the right colon because of the higher transverse folds compared with the left colon. The greatest virtue of A-EMR is that the snare can avoid spillage during ensnaring because its tip is fixed in the incised submucosal layer. This technique enables the snare to capture more of the lesion because it can be deployed in a wider area laterally by pushing the sheath to the oral side. It also prevents the snare tip from lifting when the lesion is located on a convex surface. One of the most important points for successful EMR was anchoring the snare tip in the best position, where the snare could cover the entire lesion with enough normal margin and avoid torque during ensnaring.

In the present study, prophylactic clip use in the C-EMR group was also higher than that in the A-EMR group. We believe

that deeper resection occurred more frequently with C-EMR as a wider normal margin needs to be secured, although the depth of resection was not measured prospectively.

A retrospective French study reported that A-EMR was related to a considerable transmural perforation rate (3/125 patients; 2.1 %) and all the perforations occurred when en bloc resection was attempted for a lesion of > 2 cm in size [10]. However, in our study, there were no episodes of perforation or bleeding in the 105 patients in the A-EMR group.

This study had several limitations. First, it was performed in a single center. Second, the polyp recurrence rate was not evaluated by follow-up colonoscopy. Third, the endoscopists could not be blinded to the allocations.

In conclusion, A-EMR was better than C-EMR for complete resection of nonpedunculated polyps of 10–25 mm and can be recommended as a standard method for the resection of large colorectal polyps.

Acknowledgments

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Competing interests

The authors declare that they have no conflict of interest.

Clinical trial

Trial Registration: Clinical Research Information Service, Republic of Korea (https://cris.nih.go.kr) | Registration number (trial ID): KCT0004942 | Type of study: A randomized controlled trial

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