Comparison of prophylactic clip and endoloop application for the prevention of postpolypectomy bleeding in pedunculated colonic polyps: a prospective, randomized, multicenter study

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Background and study aims: The effectiveness of the prophylactic clip for the prevention of postpolypectomy bleeding in pedunculated colonic polyps has not been confirmed. The aim of this prospective, randomized study was to compare the efficacy of prophylactic clip and endoloop application in the prevention of postpolypectomy bleeding in large pedunculated polyps.

Patients and methods: A total of 195 patients who had pedunculated colorectal polyps, with heads ≥10 mm and stalks ≥5 mm in diameter, were included in the study between July 2010 and January 2013. Polyps were randomized to receive either clips or endoloops. Both devices were applied to the base of the stalk before conventional snare polypectomy. Bleeding complications were analyzed with a noninferiority margin of 5%.

Results: A total of 203 polyps were included in the study (98 in the clip group and 105 in the endoloop group). Bleeding occurred after five polypectomies in the clip group (5.1%) and after six in the endoloop group (5.7%) (P=0.847). Noninferiority of the prophylactic clip to the endoloop could not be confirmed (absolute bleeding rate difference –0.6%, 95% confidence interval –5.6% to 6.8%) due to small sample size. Immediate bleeding episodes occurred in 4/5 polyps in the clip group and 5/6 polyps in the endoloop group. Delayed bleeding occurred in one polyp in each group.

Conclusions: These results suggest that the application of a prophylactic clip is as effective and safe as an endoloop in the prevention of postpolypectomy bleeding in large pedunculated colonic polyps.

Introduction

Endoscopic polypectomy has become a standard procedure for removing polyps, and is effective in reducing the incidence of colorectal cancer [1–3]. The procedure is associated with complications such as bleeding, perforation, and postpolypectomy coagulation syndrome [4]. Postpolypectomy bleeding is the most common complication of colonoscopic polypectomy, with an incidence ranging from 0.3% to 6.1% [5].

The risk of bleeding is higher after the resection of pedunculated polyps, due to the presence of a large artery in the stalk [6]. When large pedunculated polyps were resected without taking any precautions to prevent bleeding, the bleeding rates were reported to be approximately 10%–15.1% [7–9]. Several preventive methods, such as injection of epinephrine into the stalk and application of an endoloop (detachable snare), have been developed for the management of postpolypectomy bleeding [7–11].

The efficacy of the prophylactic clip has not been confirmed. No randomized trials have been conducted to assess the effectiveness of the prophylactic clip for the prevention of postpolypectomy bleeding for large pedunculated colonic polyps. The aim of the current prospective, randomized, noninferiority study was to compare the efficacy and safety of the prophylactic clip and endoloop in the prevention of postpolypectomy bleeding.

Patients and methods

Study design and patient population

This was a prospective, randomized, multicenter, noninferiority study conducted at the following six hospitals of the Catholic University of Korea: Incheon St. Mary's Hospital, St. Vincent's Hospital, Daejeon St. Mary's Hospital, Bucheon St. Mary's Hospital, Uijeongbu St. Mary's Hospital, and Seoul St. Mary's Hospital. The study protocol and participation in the study were approved by the institutional review board. Written informed consent

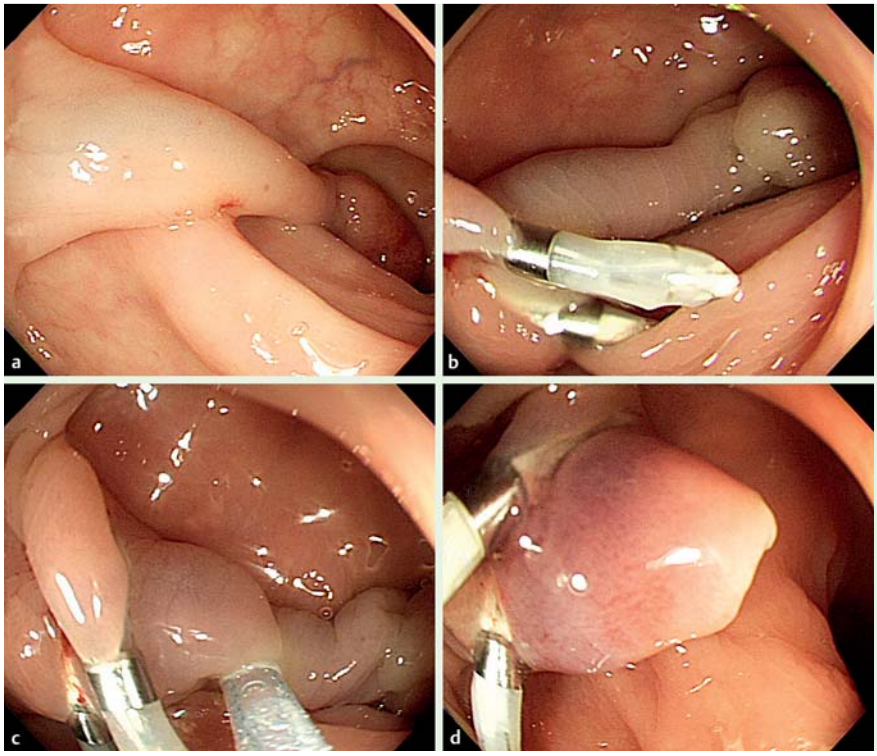

Fig. 1 Endoscopic procedure for prophylactic clip application. **a** A pedunculated polyp with a thick stalk was detected. **b** Two hemoclips were applied to the base of the stalk. **c** Conventional snare polypectomy was performed. **d** There was no immediate postpolypectomy bleeding.

was obtained from all patients. The study was registered at ClinicalTrials.gov (NCT01406379).

Patients with at least one pedunculated colorectal polyp who were 18 years or older were included. Polyps had the following characteristics: heads ≥ 10 mm, stalks ≥ 5 mm in diameter, and stalk lengths ≥ 10 mm. For patients with more than one pedunculated polyp suitable for inclusion in the study, each polyp was randomized separately.

The exclusion criteria were as follows: 1) patients with severe coagulopathy (a platelet count of < 50 000 /mm^3 or prothrombin time of > 30 % above the control value) or patients for whom anticoagulant or antiplatelet therapy could not be suspended; 2) patients with inadequate bowel preparation; and 3) patients who were unable or refused to provide informed consent.

The patients undergoing anticoagulant or antiplatelet therapy for noncritical problems were instructed to discontinue the use of these drugs at least 5 days before the endoscopic procedure. They were instructed to restart anticoagulant or antiplatelet therapy on the day after polypectomy if there was no hematochezia.

Endoscopic procedure

All patients underwent bowel preparation by ingesting 4 L of polyethylene glycol solution. A total of 17 endoscopists (7 attending staff and 10 fellows) participated in the study. Colonoscopic polypectomy was performed using standard colonoscopes (CF 240 L or 260 L; Olympus Ltd., Tokyo, Japan). The procedures were performed with patients under conscious sedation using intravenously administered midazolam with or without meperidine. The monitoring during colonoscopy and polypectomy included pulse oximetry.

The pedunculated polyps were randomly allocated to the clip group or the endoloop group using computer-generated random numbers. Treatment allocation concealment was achieved by sealed opaque envelopes, which were consecutively numbered and contained a label reporting the assigned treatment. The sealed envelope was opened by a nurse at the endoscopy center when requested by the endoscopist, following identification of a polyp that could be included in the study.

In the clip group, prophylactic hemoclips (HX-610 – 090L; Olympus) were applied to the base of the stalk, followed by conventional snare polypectomy (**Fig. 1**). In the endoloop group, an endoloop (MAJ-340 or MAJ-254; Olympus) was positioned at the base of the stalk, followed by conventional snare polypectomy (**Fig. 2**). The resection was performed using a combination of an Endocut-Q (effect 2, duration 2, interval 6) and forced coagulation (effect 2, 40 W) current (VIO 300 D; ERBE Elektromedizin GmbH, Tübingen, Germany). Electrocoagulation was applied initially as forced coagulation and then in Endocut mode.

The size of each polyp was measured immediately after removal or by visual comparison with open biopsy forceps of predetermined width. Each removed polyp was sent to a pathologist at each hospital for histopathological examination.

Complications

Immediate bleeding was defined as bleeding occurring immediately after polypectomy (lasting 30 seconds or more) during the endoscopic procedure [12]. Immediate bleeding was graded on a scale from 1 to 4 (Grade 1, spontaneous hemostasis within 60 seconds; Grade 2, continuous but decreased oozing over 60 seconds; Grade 3, continuous oozing over 60 seconds that requires endoscopic treatment; Grade 4, active spurting) [12].

Delayed bleeding was defined by the presence of two of the following parameters after an endoscopic procedure: 1) hematochezia, 2) drop in hemoglobin of 2 g/dL, and 3) blood pressure decrease > 20 mmHg or a pulse rate increase > 20 % of the baseline. Delayed bleeding was defined as either early (< 24 hours after polypectomy) or late (≥ 24 hours – 30 days after polypectomy).

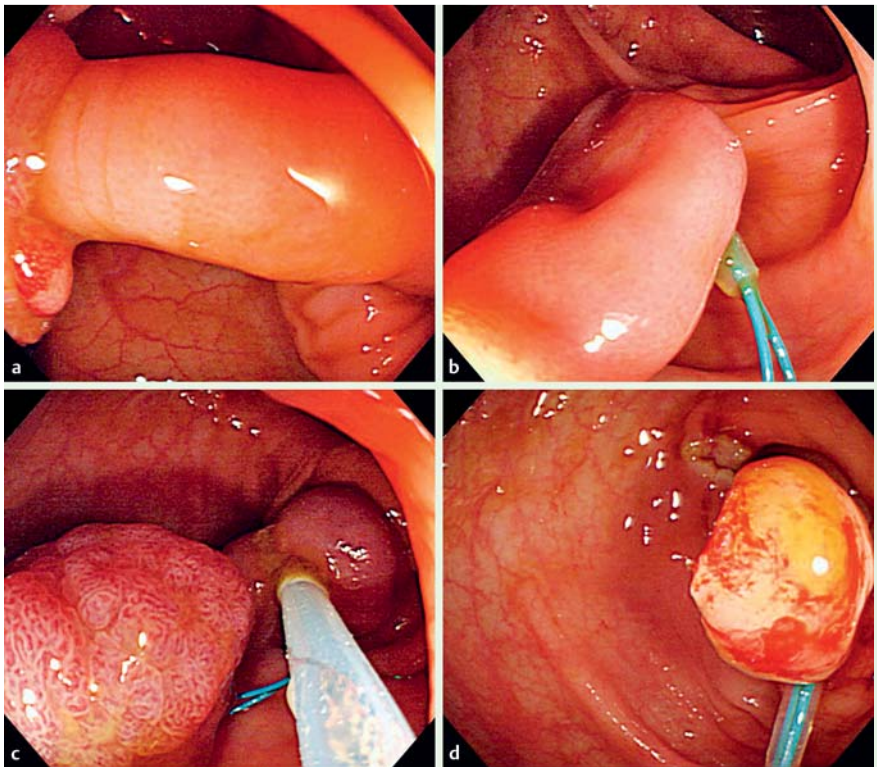

Fig. 2 Endoscopic procedure for prophylactic endoloop application. **a** A pedunculated polyp with a thick stalk was detected. **b** An endoloop was positioned at the base of the stalk. **c** Conventional snare polypectomy was performed. **d** There was no immediate postpolypectomy complication.

Study outcomes

Postpolypectomy bleeding was the main outcome variable. Other parameters evaluated were age, sex, size of head, size of stalk, polyp location, procedure time, number of clips and loops used, procedural complications, volume of blood transfused, and histological type. Procedure time was defined as the time required to apply the clip or endoloop to the polyp stalk and to perform polypectomy. The mortality and morbidity associated with the colonoscopic polypectomy were evaluated until 30 days after the procedure. Patients returned to the hospital a week after polypectomy to receive the pathology result. Patients were contacted by telephone 1 month after the procedure to check for postpolypectomy bleeding.

Patients were instructed to return to the hospital if they experienced hematochezia. In cases of bleeding episodes after the end of the endoscopy, a follow-up endoscopy was performed to locate the site of bleeding, evaluate the severity, and perform endoscopic hemostatic therapy if required.

Statistical analysis

The SPSS ver. 16.0 software package was used for the statistical analysis (SPSS Inc., Chicago, Illinois, USA). Continuous data were compared using unpaired Student's *t* test. The categorical variables were tested using corrected chi-squared or two-tailed Fisher's exact tests. The correlation between the variables was assessed by Pearson's correlation coefficient. A *P* value of ≤0.05 was considered statistically significant.

The sample size calculation was based on a noninferiority margin of 5% and an assumed postpolypectomy bleeding rate of 3% in the clip group and 0.6% in the endoloop group. A total of 178 polyps were required to detect noninferiority with at least 80% power and one-sided type I error of 0.05. Considering a 10% loss to follow-up, a total of 196 polyps were aimed for inclusion. All analyses were based on the intention-to-treat principle. A per-protocol analysis was also performed for the primary end point.

Results

Between July 2010 and January 2013, 210 polyps from 195 patients were assessed for eligibility (**Fig. 3**). Seven polyps were excluded, due to coagulopathy, failure to provide consent, and poor bowel preparation. Finally, 98 polyps were randomized to receive clips and 105 were randomized to receive endoloops.

The demographic data of the patients and characteristics of the polyps are presented in **Table 1**. The mean (±SD) polyp head sizes were 17.2±7.8 and 18.4±7.0 mm in the clip and endoloop groups, respectively (*P*=0.24). The mean stalk diameter was 8.2±2.7 mm in the clip group and 8.5±2.5 mm in the endoloop group (*P*=0.34). There was no difference in the stalk length between the groups.

The assessment of the outcomes and complications in both groups are presented in **Table 2**. Clip application was possible in all cases in the clip group. In seven cases in the endoloop group, endoloop placement failed (6.7%). The causes of the technical failures included slippage of the loop after polypectomy (n=4), polyp entrapment (n=1), pedicle resection (n=1), and a narrow sigmoid colon lumen (n=1). A short polyp stalk (≤15 mm) was a more significant cause of slippage of the loop after polypectomy compared with a long polyp stalk (>15 mm) (*P*=0.014).

The average time required for the procedure was significantly shorter in the clip group (5.3±4.9 minutes) than in the endoloop group (6.9±4.0 minutes) (*P*=0.017).

Overall bleeding complications occurred in 11/203 polyps (5.4%; 5 in the clip group [5.1%] and 6 in the endoloop group [5.7%]; *P* = 0.847). However, noninferiority of the prophylactic clip to the endoloop could not be confirmed (absolute bleeding rate difference –0.6%, 95% confidence interval [CI] –5.6% to 6.8%).

A per-protocol analysis of the primary end point produced a similar result to the intention-to-treat analysis. The bleeding rate was 5.1% (n=5) in the clip group. In the cases in which the endoloop placement was successful, four cases of bleeding (4.1%) were

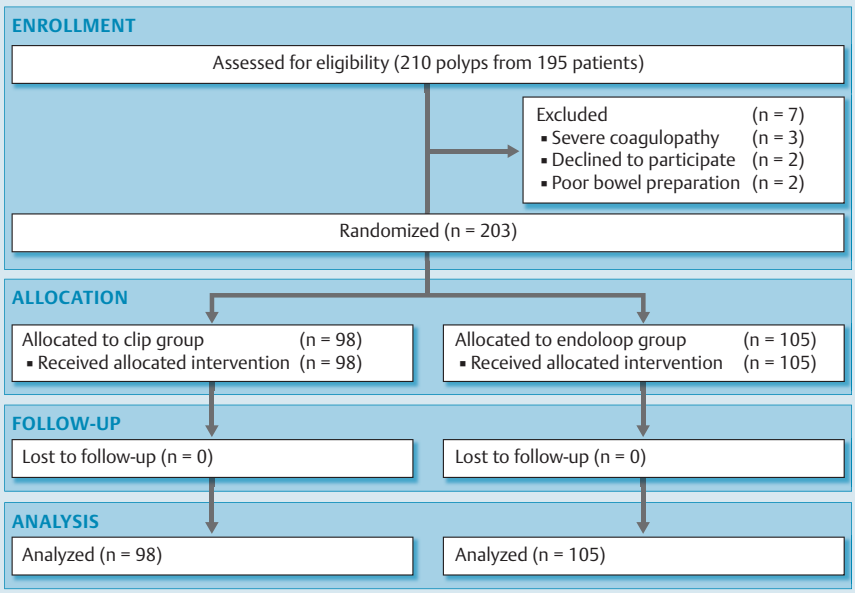

Fig. 3 Flow diagram of the study.

	Clip	Endoloop	*P* value
Patients, n	92	96	
Polyps, n	98	105	
Age, mean ± SD, years	57.4 ± 11.1	57.2 ± 11.4	0.87
Sex, male/female, n	77/15	84/12	0.46
Expert endoscopist (> 2 years' experience). n (%)	75 (76.5)	90 (85.7)	0.094
Size of head, mean ± SD, mm	17.2 ± 7.8	18.4 ± 7.0	0.24
Stalk diameter, mean ± SD, mm	8.2 ± 2.7	8.5 ± 2.5	0.34
Stalk length, mean ± SD, mm	20.0 ± 9.0	20.4 ± 8.3	0.73
Other resected polyps, mean ± SD, n	3.8 ± 4.7	4.0 ± 4.3	0.76
Location			
Rectum	3	2	
Sigmoid colon	54	77	
Descending colon	6	11	
Transverse colon	10	9	
Ascending colon	24	5	
Cecum	1	1	
Histopathology, n			
Tubular adenoma	63	60	
Tubulovillous adenoma	14	12	
Villous adenoma	0	9	
Serrated adenoma	3	5	
Hyperplastic	8	5	
Inflammatory	4	0	
Hamartoma	1	3	
Juvenile	0	3	
Cancer	5	8	

Table 1 Patient and polyp characteristics.

observed (*P* = 0.999). Noninferiority of the prophylactic clip to the endoloop could not be confirmed (absolute bleeding rate difference 1.0 %, 95 %CI – 4.8 % to 6.8 %).

Of the five bleeding cases in the clip group, four were immediate bleeding episodes. There were five cases of immediate bleeding in the endoloop group, three of which occurred in cases of successful endoloop placement. Grade 3 and 4 immediate bleeding episodes in both groups were successfully treated with clips or argon plasma coagulation. Three patients who had immediate bleeding were taking anticoagulant or antiplatelet therapy prior to colonoscopy. They were instructed to restart these drugs if there was no hematochezia for 24 hours after polypectomy.

One case of delayed bleeding was observed in each group. Both cases were late bleeding episodes (31 hours and 24 hours after polypectomy in the clip and endoloop groups, respectively) (▶ **Table 2**). Follow-up colonoscopy of the late bleeding in the clip group showed only blood clot in the lumen, and no additional therapy was required. The histopathology of the polyp showed a hamartoma. In the endoloop group, an adherent clot was observed on the polypectomy site, and an additional hemoclip was placed. Surgery or angiography was not necessary for any of the patients, and none of the patients required blood transfusion.

The mean number of clips used was 1.5 ± 0.7 and was related to the size of the head of the polyp (Pearson's correlation coefficient

Table 2 Outcomes and complications of prophylactic clip and endoloop application.

	Clip	Endoloop		*P* value
		All cases	Successful placement of endoloop	
Polyps, n	98	105	98	
Success of procedure, n (%)	98 (100)	98 (93.3)		0.014
No. of clips or loops, mean ± SD, n	1.5 ± 0.7		1.0 ± 0.2	< 0.001
Procedure time, mean ± SD, minutes	5.3 ± 4.9		6.9 ± 4.0	0.017
Overall bleeding, n (%)	5 (5.1)	6 (5.7)	4 (4.1)	0.847
Immediate bleeding, n	4	5	3	0.999
Grade 1	1	1	1	
Grade 2	0	1	0	
Grade 3	2	3	2	
Grade 4	1	0	0	
Endoscopic therapy, n				
Clip	3	2	1	
APC	0	1	1	
Delayed bleeding	1	1	1	0.999
Early (< 24 hours)	0	0	0	
Late (≥ 24 hours – 30 days)	1	1	1	
Colonoscopic finding, n				
Spurting	0	0	0	
Visible vessel	0	0	0	
Adherent clot	0	1	1	
Blood clot in the lumen	1	0	0	
Endoscopic therapy				
Clip	0	1	1	
No therapy	1	0	0	
Transfusion	0	0	0	
Perforation	0	0	0	

APC, argon plasma coagulation.

Table 3 Characteristics of bleeding polyps.

	Bleeding polyps (n = 11)	Nonbleeding polyps (n = 192)	*P* value
Patients, n	11	177	
Age, mean ± SD, years	56.1 ± 12.0	57.4 ± 11.2	0.717
Sex, male/female, n	11/0	150/27	0.366
Size of head, mean ± SD, mm	19.3 ± 8.9	17.7 ± 7.3	0.495
Diameter of stalk, mean ± SD, mm	10.5 ± 2.5	8.2 ± 2.6	0.006
Length of stalk, mean ± SD, mm	18.6 ± 8.7	20.1 ± 8.8	0.561
Other resected polyps, mean ± SD, n	6.2 ± 5.2	3.8 ± 4.4	0.100
Location, n (%)			0.754
Left colon	7 (63.6)	129 (67.2)	
Right colon	4 (36.4)	63 (32.8)	
Cancer	2 (18.2)	11 (5.7)	0.131
Failed preventive procedure, n (%)	2 (18.2)	5 (2.6)	0.048
Procedure time, mean ± SD, minutes	8.4 ± 4.1	6.0 ± 4.6	0.104
Expert endoscopist (> 2 years' experience), n (%)	10 (90.9)	155 (80.7)	0.693

$r = 0.377$, $P < 0.001$) and the polyp stalk diameter (Pearson's correlation coefficient $r = 0.457$, $P < 0.001$). No other complications, including perforation or postpolypectomy syndrome, occurred.

Table 3 shows the characteristics of the bleeding polyps. A thick stalk and failed preventive procedure were related to a greater risk of postpolypectomy bleeding ($P = 0.006$ and $P = 0.048$, respectively). The size of the polyp head showed no significant relationship to postpolypectomy bleeding ($P = 0.495$). A stalk larger than 10 mm in diameter was a significant risk factor for postpolypectomy bleeding (odds ratio 8.57, 95 %CI 2.36 – 31.07) (**Table 4**).

Discussion

Postpolypectomy bleeding is the most common complication of colonoscopic polypectomy. Large pedunculated colonic polyps have a greater risk of immediate and delayed postpolypectomy bleeding due to the presence of a large blood vessel within the stalk [13]. Several endoscopic techniques have been proposed to prevent postpolypectomy bleeding, such as injection therapy and mechanical maneuvering. Injection of an epinephrine solution into the polyp stalk reduces the blood flow and promotes vasoconstriction and compression [7, 8, 14]. Epinephrine injection is the most commonly used method of preventing bleeding in pedunculated polyps because it is less difficult and less expensive to use.

Table 4 Bleeding risk according to stalk diameter.

	Bleeding polyps (n = 11)	Nonbleeding polyps (n = 192)	Odds ratio	95 %CI
Stalk diameter ≤ 1.0 mm, n (%)	6 (54.5)	175 (91.1)	1.00	
Stalk diameter > 1.0 mm, n (%)	5 (45.5)	17 (8.9)	8.57	2.36 – 31.07

CI, confidence interval.

The endoloop procedure was originally developed by Hachisu [15] and consists of the tightening of a loop of nylon thread around the polyp stalk. When successfully applied, this device completely stops the blood flow in the stalk [16]. An alternative method is to apply clips on the stalk before resection to stop the blood flow in the stalk [17, 18]. However, the effectiveness of the prophylactic clip has not been confirmed.

One study compared the outcomes of applying the prophylactic clip in patients with large pedunculated colorectal polyps with historical control patients who were treated with endoloop-assisted polypectomy [19]. The study included a small number of patients and was not randomized. The results suggested that the prophylactic clip could be a safe alternative to an endoloop in cases in which endoloop placement was difficult.

To the best of our knowledge, the current study is the first prospective, randomized study to compare the efficacy of the prophylactic clip and the endoloop in the prevention of postpolypectomy bleeding in large pedunculated polyps. In the clip group, bleeding occurred after 5.1 % of polypectomies, which was similar to the rate reported in the study by Luigiano et al. [19]. In the endoloop group, the rate of bleeding was 5.7 %. Of the cases in which the endoloop placement was successful, 4.1 % of the polyps bled, which was slightly higher than the rate reported in previous studies [7, 10, 19, 20].

Application of the endoloop requires experience. Because the current study was a multicenter study, the skill levels of the endoscopists and assistants differed by hospital. It was hypothesized that bleeding was related to the learning curve of the endoloop technique. In both groups, there was one case of delayed bleeding. Both cases were late bleeding episodes. In all patients with postpolypectomy bleeding, endoscopic treatment (clips or argon plasma coagulation) was successfully performed, without the need for surgery or angiography. There were no other complications, including perforation or postpolypectomy syndrome.

There are some limitations to the study. First, the study was underpowered due to the small sample size. As a result, noninferiority of the prophylactic clip to the endoloop could not be confirmed. Second, no control group was included in the study. Therefore, we do not know how effective the prophylactic clip is compared with no prophylactic treatment.

In the current study, it was possible to apply prophylactic clips to all of the polyps in the clip group. In the endoloop group, endoloop placement failed in 6.7 %. The causes of the technical failures included slippage of the loop after polypectomy, polyp entrapment, pedicle resection, and narrow colon lumen. A short stalk (≤ 15 mm) was a significant cause of slippage of the loop after polypectomy. The satisfactory position of the endoloop is low on the stalk, to allow room to place the electrocautery snare between the endoloop and the polyp head [4]. Endoloop placement is also difficult in narrow colon lumens [21]. An endoloop has limited stiffness and an expansible force because of its thin nylon composition [19], and therefore it could be a challenge to position in locations with limited space available for the complete opening of the loop. It was hypothesized that a prophylactic clip may be preferred in cases with a short stalk (≤ 15 mm) and narrow colon lumen. Another advantage of the application of the prophylactic clip is that the average time required for the procedure is significantly shorter than that for endoloop positioning.

In this study, a thick stalk and failed preventive procedure were significant risk factors for postpolypectomy bleeding. Polypectomy should be performed with caution under these conditions. A stalk larger than 10 mm in diameter was related to a greater risk of postpolypectomy bleeding. The mean number of clips required in the clip group increased in proportion with the diameter of the stalk. Larger clips than the model applied in the current study are available and, particularly for pedunculated polyps with a thick stalk, these larger clips might be desirable.

In conclusion, the current data suggest that the prophylactic clip is as effective and safe, with a similarly low complication rate, as the endoloop for the prevention of postpolypectomy bleeding in large pedunculated colonic polyps. A large scale, randomized, controlled clinical study is needed to confirm the efficacy of prophylactic clips.

Competing interests: None

Institutions

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