Safety and efficacy of cold polypectomy compared to endoscopic mucosal resection and hot biopsy polypectomy

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Abstract

Backgrounds Recently, several studies have demonstrated the usefulness of cold polypectomy (CP), a safe and simple method for removal of small polyps. We investigated the safety and efficacy of CP compared to that of endoscopic mucosal resection (EMR) and hot biopsy polypectomy (HB).

Methods We retrospectively examined 1713 colorectal polyps (size 1–9 mm) in 731 patients. CP, EMR, and HB were performed on 476, 997, and 240 lesions, respectively. We compared the region, size, morphology, presence of delayed bleeding as overt bleeding 24 h after operation, number of clips, pathology, presence of antithrombotic therapy, procedure time from detection of a polyp to resection and hemostasis, device cost including device and clips, and polyp remnants.

Results The delayed bleeding in the CP group (0/476) was significantly lower compared to that in the HB group (3/240) and EMR group (7/997). There were no cases of perforations. The procedure time was significantly shorter in the CP group than in the EMR group (91.3sec vs 290.1sec, $P < 0.0001$). The CP group had a significantly lower device cost than the HB and EMR groups (49.2USD vs 58.0USD vs 91.3USD, $P < 0.0001$) was not inferior in terms of polyp remnants to the EMR and HB groups. (1.4% vs 0.6% vs 6.1%, $P = 0.1599$)

Conclusions CP is a safe treatment that achieves less delayed bleeding. Moreover, CP is not inferior to other groups in terms of polyp remnants and offers a cost benefit. CP can be considered useful for colonic polypectomy.

Keyword: colon polyp, cold polypectomy, hot biopsy, endoscopic mucosal resection, delayed

bleeding

Introduction

Vogelstein et al. proposed the hypothesis that colorectal cancer develops from the normal mucosa via colonic adenoma in a multi-step manner [1]. This hypothesis has been widely accepted as the adenoma-carcinoma sequence [2]. The National Polyp Study has demonstrated that a clean colon condition achieved by the removal of all colonic adenomatous polyps leads to a 76%–90% reduction in the incidence of colorectal cancer and a 53% reduction in the colorectal cancer mortality; therefore, endoscopic resection of colonic adenoma has been recommended in Japan [3, 4]. The choice of endoscopic procedure is determined by considering the tumor morphology and diameter. Polypectomy is indicated for pedunculated and sub-pedunculated polyps. Endoscopic mucosal resection (EMR) is a good indication for sessile lesions suspected to be non-cancerous or sub-pedunculated and superficial lesions [5].

Recently, cold polypectomy (CP) is becoming a common method for resecting small or diminutive polyps without using submucosal injections or electrocautery and is widely used in Western countries [6]. There were two method in CPs, including cold forceps polypectomy (CFP) using biopsy forceps and cold snare polypectomy (CSP) using a snare. CSP was first reported by Tappero et al. as a safe excision technique for small polyps in 1992 [7]. Although to our knowledge, there were no reports for some time thereafter, Deenadayalu et al. supported its safety and efficacy

against small polyps in 2005 [8]. Recently, several studies have demonstrated the usefulness of CSP, a safe and simple method for the removal of small polyps [6, 9, 10]. CSP is recommended for small polyps ≤ 5mm and suggested for sessile polyps 6-9 mm by the European Society of Gastrointestinal Endoscopy [11]. CP did not cause late-onset mucosal disorder by thermocoagulation; therefore, it had a lower risk of delayed bleeding. Thus, CP was considered more beneficial than EMR, as shown in a recent studies [12].

However, to our knowledge, there is no report that has compared the safety and efficacy of CP with that of EMR and hot biopsy polypectomy (HB) in small polyps (1–9 mm). In the present study, we compared the safety and efficacy of the following three methods: CP (CSP and CFP), EMR, and HB.

Materials and Methods

Patient samples

We retrospectively examined 1713 colorectal polyps (size 1–9 mm) in 731 patients; these polyps were resected in our hospital from April 2015 to July 2016. They were classified into the following three groups: CP group (476 lesions), EMR group (997 lesions), and HB group (240 lesions). The CP group comprised 288 CFP lesions and 188 CSP lesions. These lesions were compared with respect to the region, size, morphology, presence of delayed bleeding, postoperative pathology, presence of antithrombotic therapy (antiplatelet or anticoagulant), and polyp remnants.

Delayed bleeding was defined as overt bleeding including melena or hematochezia, 24 h after operation. Procedure time was defined as the total time from detection of a polyp to resection and hemostasis. Antithrombotic drugs were discontinued or changed based on the guidelines established by the Japanese Gastroenterological Endoscopy Society. Briefly, we performed endoscopic treatment under taking aspirin and cilostazol. Thienopyridine was changed to aspirin or cilostazol 3-5 days prior to treatment. Other antiplatelet drugs were withdrawn from the day before endoscopic treatment. Direct oral anticoagulants such as rivaroxaban and dabigatran was discontinued only on the day of treatment. These antithrombotic drugs are resumed from the next day. All antithrombotic drugs were resumed from the day after treatment. This study was approved by Fukuoka City Medical Association Hospital ethics committee (approval data: Feb 7, 2018).

Endoscopic procedures

Endoscopic resection was performed by total nine gastrointestinal physicians, five of whom were well-trained specialists of the Japan Gastroenterological Endoscopy Society (JGES). The other non-specialists underwent endoscopic resection under the supervision of experienced specialists. Radial Jaw JUMBO that has a relatively large jaw outer diameter of 2.8 mm and maximum opening of 8.8 mm (Boston Scientific, Natick, MA, USA) was used for CFP, and a Rotatable Snare small 13 mm (Boston Scientific) was used for CSP and EMR. Radial Jaw HOT that has a jaw outer diameter of 2.2 mm and a maximum opening of 7.1 mm (Boston Scientific) was used for the HB group. For

the EMR group, Sure LIFTER 3 mm 25 G (Boston Scientific) for local injection needle, glycerol solution (consisted of concentrated glycerin, fructose and sodium chloride, Nipro Co., Osaka, Japan) for local injection fluid, and long clip or short clip (Olympus Co., Tokyo, Japan) for clipping was used. The choice of the endoscopic procedure was decided by each endoscopist. HB was chosen commonly when the polyp was difficult to observe, such as in flexure section and excessive peristalsis of the intestine. Total 476 lesions using CP without electrocautery, 997 lesions using EMR with electrocautery and snare, and 240 lesions using HB with electrocautery and hot biopsy forceps were performed. In this study, clipping was not performed in the CP group and the HB group in most cases; however, clipping was performed on the resection region of the polyps where hemostasis after resection could not be sufficiently confirmed.

Statistical analyses

The data were analyzed using JMP statistics software for Windows version 9 (SAA Institute, Cary, NC, USA). Chi-square, Student's t-test, and Mann–Whitney U test were used to determine the statistical difference between the two groups. Analysis of variance (ANOVA) and Kruskal-Wallis test were used to determine the statistical differences among the three groups. $P < 0.05$ was considered statistically significant.

Results

Characteristics of patients in each treatment group

Characteristics of patients in each treatment group are shown in Table 1. The mean age of those in the HB group was higher than that of those in the other groups (P = 0.0296). There were no significant differences in the regions of polyps among all the groups. In polyp morphology, 0-Ip type polyps were selected for EMR in many cases. In the CP group, there were fewer patients who were taking antithrombotics (30/476, 6.3%). The complication of delayed bleeding was observed in 0 lesions in the CP group, 7 lesions in the EMR group, and 3 lesions in the HB group. This result indicated a low risk of delayed bleeding in the CP groups as compared to that in the EMR group (7/997, 0.72%) and HB group (3/240, 1.3%). No case of postoperative perforation was observed. The mean number of clips used per lesion in the CP group (0.42) was significantly lower than those in the EMR group (1.41) (P < 0.0001). Histopathological examination revealed high-grade dysplasia only in the EMR group and only in 10/997 (1.0%). Invasive cancer was not detected in any polyp. Histopathology in the HP group was not fully evaluated because of the low retrieval rate of polyp after resection (216/249, 90%).

The complication of delayed bleeding was observed in the EMR and HB groups

Table 2 shows the characteristics of 10 patients with delayed bleeding (7 in the EMR group and 3 in the HB group). Among 7 lesions of the EMR group, all lesions were clipped after snare resection. Four lesions (4/7, 57.1%) were under antithrombotic therapy. In the EMR group, the

incident rate of delayed bleeding under antithrombotic therapy (4/161, 2.48%) was significantly higher than that without antithrombotic therapy (3/836, 0.36%). In the HB group, all 3 lesions with delayed bleeding (3/3, 100%) were under antithrombotic therapy. In the HB group, the incident rate of delayed bleeding under antithrombotic therapy (3/63, 4.76%) was highest among that in all treatment groups. Furthermore, our results showed that delayed bleeding in the HB group occurred in even smaller polyps compared to those in the EMR (mean 5.57 mm) group because the mean polyp size of these lesions was 3 mm.

There were no significant differences in the polyp remnants after endoscopic procedure in the CP, EMR, and HB groups

The pathological evaluation for the complete removal of polyps was performed in 84.4% of cases (1446/1713); therefore, the presence of polyp remnants was evaluated in patients who underwent follow-up endoscopy. Of the total 1713 lesions, follow-up endoscopy was performed for 267 lesions within 6 months in the patients diagnosed high-grade dysplasia and more than 1 year in the other patients after endoscopic procedure. Among them, obvious polyp remnants were observed in 1 of 71 lesions (1.4%) in the CP group, 1 of 163 lesions (0.6%) in the EMR group, and 2 of 33 lesions (6.1%) in the HB group, indicating that the CP group was not significantly inferior in terms of the complete resection rate of polyps from the EMR and HB groups. (Table 3)

A comparison of the three groups for 1–4 mm polyps and 5–9-mm polyps

Polyp size was significantly larger in the EMR group; therefore, the subgroups of lesions wherein the polyp size was l–4 mm were analyzed. Table 4 showed the characteristics of patients with a polyp size of l–4 mm. With respect to the region of polyps, polyps in the ascending colon were selected for HB (P = 0.0005). There was no significant difference in the number of pedunculated polyps in all the groups. More patients on antithrombotic drug were selected the HP treatment compared to other treatments in this study. Delayed bleeding occurred in 0 patients of the CP group, 3 of those in the EMR group, and 3 of those in the HB group; the incident rate of delayed bleeding in the CP group was significantly lower than that in the EMR and HB groups (P = 0.0175). Histopathological examination showed no high-grade dysplasia ≤ 4 mm in each group.

Table 5 shows the cases of patients with 5–9-mm polyp in each group. The number of patients treated with CP and HB was significantly lower than that of those treated with EMR. There was no significant sex-based difference in each group; however, age was significantly higher in the HB group (P = 0.0390). There was no significant difference in the region and morphology in the 3 groups, and the number of patients undergoing antithrombotic therapy in the CP group was significantly lower as compared to those in the other groups (P = 0.0111). Delayed bleeding was observed in 4 cases in the EMR group; however, no delayed bleeding occurred in the CP and HB groups. Histological examination showed 10 cases of high-grade dysplasia in the adenomas in the EMR group, but none in the CP and HB groups.

A comparison of the procedure time and the medical costs in the three groups

We compared the procedure time to resect one polyp and the medical costs for the device. Table 6 shows the procedure time and device cost in the CP, EMR, and HB groups. The procedure time using HB was the shortest ($P < 0.0001$); further, the procedure time in the CP group was significantly shorter than that in the EMR group ($P < 0.0001$). Moreover, the device cost to resect one polyp was calculated. The device cost of Radial Jaw JUMBO 3.2 mm for CFP and Rotatable Snare small 13 mm for CSP and EMR was approximately 50 USD. Radial Jaw HOT was approximately 100 USD, and clip cost was approximately 10 USD. The CP group could be excised at the lowest cost, and the highest cost was that for the HB group ($P < 0.0001$).

Discussion

The two main complications of colonic polypectomy are hemorrhage and perforation [13, 14]. A prospective study has reported only one case (0.17%) of bleeding in 573 patients resected with CFP [15]. A meta-analysis that included 1665 patients with 3195 polyps also showed that the delayed bleeding rate in the CSP group was less than that in the EMR group [12]. Perforation was not reported in any study. Thus, majority of the studies suggest that CP causes less delayed bleeding in case of smaller polyps; however, there is no significant difference in case of larger polyps. In our study, delayed bleeding was less in the CP group for both, 1–4-mm size polyps and 5–9-mm size

polyps.

Delayed bleeding was observed in 0.72% (7/977) of the lesions in EMR group, similar to that in previous studies [12]. Although all 7 lesions used clips after polyp resection, delayed bleeding occurred. Several studies have also indicated that clipping after EMR had no effect on the prevention of delayed bleeding [16, 17]. Thus, the usefulness of the clip remains questionable. Further research is necessary to determine whether clip implementation is useful in preventing delayed bleeding.

In endoscopic treatment, patients on antithrombotic drugs had a higher incidence of bleeding after endoscopic treatment than those not on antithrombotic drugs [18, 19]. In fact, the delayed bleeding rate (7/254, 2.8%) in patients on antithrombotic drugs was higher than that in those not on them (3/1459, 0.2%), indicating more delayed bleeding with antithrombotic therapy. Horiuchi et al. compared the incidence of delayed bleeding between CSP and EMR in patients on antithrombotic drugs [20]. They found that CSP was suitable for polypectomy with the use of antithrombotic drugs because there was no case of bleeding. In our study, there was no bleeding case in the CP group, irrespective of whether an antithrombotic drug was administered. Although to our knowledge, no report has shown an association between delayed bleeding and antithrombotic drug use after HB treatment, our study revealed that all 3 lesions in the 3 delayed bleeding lesions (100%) were in patients on antithrombotic therapy in the HB group. Compared to the EMR group with a hemorrhaged polyp size of 5.57 mm, bleeding was observed around small polyps (3 mm) in the HB group. Therefore, CP was preferred over HB in the treatment with antithrombotic drugs.

Several studies have demonstrated no significant differences between the CP and EMR groups regarding polyp remnants and recurrence within a 3-year follow-up period [9, 21]. Komeda et al. compared CP and HB in polyp treatment for polyps with a size of 3–5 mm and reported no significant difference in the complications, such as bleeding and perforation. However, CP had a high rate of complete resection compared to HB [22]. Hasegawa et al. demonstrated that the complete resection rate of CFP was significantly higher in polyps with size < 3 mm [15]. The complete resection rate with endoscopic therapy in each group has not been evaluated. However, our studies showed no significant difference in the polyp remnants between the CP group and other groups. The CP group was not inferior to other groups with regard to the risk of polyp remnants.

Few studies have compared the medical costs of CP, EMR, and HB treatment. In Japan, the medical cost for removing a polyp ≤ 2 cm, using CP, EMR, or HB is 500 USD. In terms of device cost, Radial Jaw JUMBO 3.2 mm for CFP and Rotatable Snare small 13 mm for CSP and EMR groups were available at the same price (50 USD). Since the device cost also reflected the number of clips used after resection, it in CP group, which does not require clipping, was significantly cheaper than it in EMR group. Furthermore, Radial Jaw HOT costs twice as much as Radial Jaw JUMBO and Rotatable Snare; therefore, the device cost in the HB group was high. The procedure time of EMR was significantly longer owing to the use of electrification treatment and clipping [23]. We also proved that the procedure duration of HB and CP was significantly lower than that of EMR; further, CP could be treated at a lower cost than HB.

In conclusion, CP methods, such as CFP and CSP, are highly safe treatment methods with an extremely low incidence rate of delayed bleeding. No significant difference in CP and other groups was observed in gross polyp remnants. Furthermore, CP appears to be a method of choice from the viewpoint of medical economics. This study has several limitations. Since, our study was conducted retrospective study at a single center, it is necessary to perform a prospective study of patients across multicenter in the future.

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Disclosure of interest

The authors have no conflict of interest to declare.

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Table1. Characteristics of patients with 1713 colon polyps

	CP	EMR	HB	p
Number of polyps	476	997	240	
Mean age in years (range)	68.2 (34–90)	68.8 (34–91)	70.4 (28–94)	P = 0.0296
Sex (male/female)	311/165	686/311	173/67	P = 0.1618
Location				P = 0.0005
Ileocecal valve	1	4	0	
Cecum	42	57	18	
Ascending colon	111	215	79	
Transverse colon	113	189	47	
Descending colon	39	76	21	
Sigmoid colon	129	347	57	
Rectum	41	109	18	
Form				P < 0.0001
0-Is	298	661	178	
0-Isp	55	159	37	
0-Ip	2	36	3	
0-IIa	121	141	22	
Size				P < 0.0001
1–4	401	214	200	
5–9	75	783	40	
Usage of antithrombotic drugs	30 (6.3%)	161 (16.2%)	63 (26.3%)	P < 0.0001
Frequency of bleeding	0 (0%)	7 (0.7%)	3 (1.3%)	P = 0.0276
Number of clips (mean ± SD)	0.42 ± 0.71	1.41 ± 0.91	0.04 ± 0.19	P < 0.0001
Histopathology				P < 0.0001
Inflammatory polyps	1 (0.2%)	2 (0.2%)	0 (0%)	
Hyperplastic polyp	43 (9.0%)	79 (7.9%)	3 (1.3%)	
Adenoma	396 (83.2%)	871 (87.4%)	21 (8.8%)	
high-grade dysplasia	0 (0%)	10 (1.0%)	0 (0%)	
Not submitted	36 (7.6%)	35 (3.5%)	216 (90.0%)	

Table2. Characteristics of 10 patients with delayed bleeding

No.	Age	Sex	Location	Size	Form	Number of clipping	Histo-pathology	Antithrombotic drugs coagulant	Number of days to bleeding
EMR group									
1.	73	M	T	6	0-Is	2	adenoma	-	5
2.	75	M	S	3	0-Is	1	adenoma	aspirin	3
3.	71	M	S	4	0-Is	3	adenoma	-	2
4.	79	M	S	5	0-IIa	2	adenoma	aspirin	1
5.	86	M	A	4	0-Isp	1	hyperplastic	rivaroxaban	1
6.	60	M	S	9	0-Ip	2	adenoma	aspirin	2
7.	60	M	A	8	0-Is	1	adenoma	-	7
HB group									
1.	74	M	S	2	0-Is	1	adenoma	aspirin	2
2.	88	F	S	4	0-Is	0	unknown	rivaroxaban	11
3.	71	F	C	3	0-Is	0	unknown	dabigatran	7

Table3. Comparison of polyp remnants after the resection

	CP	EMR	HB	p
Number of polyps	71	163	33	
Remnants (%)	1 (1.4%)	1 (0.6%)	3 (6.1%)	P = 0.1599

Table4. Characteristics of 432 patients with 815 colon polyps (size 1–4 mm)

	CP	EMR	HB	p
Number of polyps	401	214	200	
Mean age in years (range)	68.3 (34–90)	67.8 (40–86)	69.8 (28–93)	P = 0.1336
Sex (male/female)	252/149	145/69	143/57	P = 0.0397
Location				P = 0.0005
Ileocecal valve	1	1	0	
Cecum	35	19	16	
Ascending colon	98	38	67	
Transverse colon	100	47	40	
Descending colon	32	10	19	
Sigmoid colon	103	71	43	
Rectum	32	28	16	
Form				P < 0.0001
0-Is	258	159	165	
0-Isp	37	14	19	
0-Ip	2	2	0	
0-IIa	104	39	16	
Usage of antithrombotic drugs	26 (6.5%)	36 (16.8%)	53 (26.5%)	P < 0.0001
Frequency of bleeding	0 (0%)	3 (1.4%)	3 (1.5%)	P = 0.0175
Number of clips (mean ± SD)	0.34 ± 0.62	1.20 ± 1.75	0.03 ± 0.17	P < 0.0001
Histopathology				P < 0.0001
Inflammatory polyps	1(0.3%)	0 (0%)	0 (0%)	
Hyperplastic polyp	35 (8.7%)	22 (10.3%)	3 (1.5%)	
Adenoma	329 (82.1%)	175 (81.8%)	19 (9.5%)	
High-grade dysplasia	0 (0%)	0 (0%)	0 (0%)	
Not submitted	36 (9.0%)	17 (7.9%)	178 (89.0%)	

Table5. Characteristics of 556 patients with 898 colon polyps (size 5–9 mm)

	CP	EMR	HB	p
Number of polyps	75	783	40	
Mean age in years (range)	67.5 (37–87)	69.1 (34–91)	73.6 (47–94)	P = 0.0390
Sex (male/female)	59/16	541/242	30/10	P = 0.0841
Location				P = 0.8639
Ileocecal valve	0	3	0	
Cecum	7	38	3	
Ascending colon	13	177	12	
Transverse colon	13	142	7	
Descending colon	7	66	2	
Sigmoid colon	26	276	14	
Rectum	9	81	2	
Form				P < 0.0001
0-Is	40	502	13	
0-Isp	18	145	18	
0-Ip	0	34	3	
0-IIa	17	102	6	
Usage of antithrombotic drugs	4 (5.3%)	125 (15.7%)	10 (25.0%)	P = 0.0111
Frequency of bleeding	0 (0%)	4 (0.5%)	0 (0%)	P = 0.3917
Number of clips (mean ± SD)	0.81 ± 0.97	1.47 ± 0.94	0.10 ± 0.30	P < 0.0001
Histopathology				P = 0.0028
Inflammatory polyps	0 (0.0%)	2 (0.3%)	0 (0%)	
Hyperplastic polyp	8 (10.7%)	57 (7.3%)	0 (0%)	
Adenoma	67 (89.3%)	696 (88.9%)	2 (5.0%)	
high-grade dysplasia	0 (0%)	10 (1.3%)	0 (0%)	

Table6. Comparison of the procedure time and the device cost in the CP, EMR, and HB groups

	CP	EMR	HB	p
Number of polyps	476	997	240	
Time (range) (seconds)	91.3 (23–472)	290.1 (45–1658)	66.6 (23–528)	P < 0.0001
Cost (range)	49.2 (45.5–80.9)	58.0 (45.5–125.2)	91.3 (90.9–99.8)	P < 0.0001