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Efficacy and Safety of Cold Snare Polypectomy of Colorectal Polyps 10–15 mm with a Hybrid Snare: A Prospective Observational Pilot Study

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Keywords
Colorectal adenoma · Cold snare polypectomy · Colonoscopy · Prospective observational study

Abstract
Introduction: Cold snare polypectomy (CSP) is a safe and effective procedure for small colorectal polyps ≤9 mm. There are only limited data regarding CSP of larger neoplastic lesions. This study evaluated the efficacy and safety of CSP for polyps between 10 and 15 mm in size. ***Methods:*** In this prospective single-arm observational pilot study, patients with a least one polyp 10–15 mm were included. These polyps were preferably removed by CSP using a dedicated hybrid snare. The primary outcome was the histological complete resection rate (CRR) determined by pathologically negative margins of the specimen and no neoplastic tissue obtained from biopsies of the resection site margin. Secondary outcomes were en bloc resection rate, failure of CSP, and incidence of adverse events. ***Results:*** A total of 61 neoplastic polyps were removed from 39 patients. Overall CRR was 80.3% (49/61). CSP was feasible in 78.7% (48/61) of polyps and the CRR in this group was 85.4% (41/48). When CSP failed (13/61; 21.3%), lesions were successfully resected by immediate HSP using the same snare with a CRR of 61.5% (8/13) in this group. One patient presented delayed hemorrhage after HSP of a polyp but successful hemostasis was achieved with two hemoclips. No other adverse events occurred. No recurrence was seen on follow-up colonoscopy in cases with incomplete resected polyps. ***Conclusion:*** CSP seems to be efficient and safe in removing colorectal polyps up to 15 mm. A hybrid snare seems to be particularly advantageous for these polyps as it allows immediate conversion to HSP if CSP might fail in larger polyps. This trial is registered at ClinicalTrials.gov (NCT04464837).

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Introduction

Colorectal cancer (CRC) is one of the leading causes of cancer-related deaths worldwide [1]. Endoscopic screening for CRC with resection of adenomas and sessile serrated lesions (SSL), which are CRC precursors, has been shown to reduce CRC incidence and mortality [2–4]. However, the success of colonoscopy as prevention for CRC highly depends on the detection and complete resection of adenomas and SSL [5–7]. Different polypectomy techniques may lead to differences in complete resection rates (CRRs) and procedure-related adverse events [8, 9].

For many years hot snare polypectomy (HSP) has been the standard of care for the removal of lesions ≥5 mm. However, the use of electrocautery is related with adverse events such as delayed bleeding, perforation, and deep thermal injury potentially causing post-polypectomy coagulation syndrome [10]. Thus, cold snare polypectomy (CSP) has been growing in popularity because, at least for subcentimeter lesions, CSP shows short procedure time and low risk of adverse events without compromising efficacy in terms of complete resection and en bloc resection [10–12].

However, CSP is not performed for lesions ≥10 mm because potential incomplete resection and/or lower en bloc resection rate have been suggested [13]. Thus, HSP (with or without prior submucosal injection) has still been suggested as the standard approach for flat or sessile lesions 10–19 mm [14].

In the last few years, development of dedicated cold snares pushed boundaries toward bigger lesions feasible for safe and efficient en bloc and piecemeal resection with CSP [15–18]. This prospective single-center feasibility trial evaluated the efficacy and safety of CSP with a hybrid snare in polyps (adenomas and SSL) with a size of 10–15 mm.

Materials and Methods

This prospective single-arm observational pilot study was conducted between July 2020 and February 2021 at a tertiary university hospital in Germany.

Study Population

Patients older than 18 years and with any indication for colonoscopy were prospectively invited to participate in this study. Exclusion criteria were an American Society of Anesthesiologists (ASA) class IV or higher, pregnancy, active inflammatory bowel disease, and contraindication for polypectomy (e.g., necessity to continue anticoagulant or antiplatelet medication [except aspirin or clopidogrel as a mono therapy], uncorrected blood coagulation disorder, and/or thrombopenia). According to current guidelines, in patients with anticoagulant therapy, medication was paused. Antiplatelet monotherapy was continued in all patients [19].

Patients who were found to have one or more polyp sized 10–15 mm were eligible and enrolled for the study. To include only flat and sessile adenomatous polyps and SSL, an endoscopic diagnosis was made based on macroscopic appearance using the Paris classification (Paris Is, Isp, IIa) [20] and findings in narrow-band imaging (Narrow-band Imaging International Colorectal Endoscopic [NICE] classification 1 and 2) [21]. When lesions were classified NICE 1, they were only included if Workgroup serrAted polypS and Polyposis (WASP) classification was positive [22].

After enrollment, polyps failed in retrieval or presenting hyperplastic mucosa in histological analysis were further excluded. When other polyps <10 mm or >15 mm were found they were treated preferably in the same session according to the clinical standard.

Endoscopic Procedure

All colonoscopies were performed by board certified gastroenterologists or surgeons with minimum experience of 200 colonoscopies and 50 polypectomies per year, using high-definition colonoscopes (CF-HQ190, Olympus medical systems, Japan) with a high-definition screen (OEV261H, Olympus medical systems, Japan) and processor (Evis Excera III, Olympus medical systems, Japan).

Patients were prepared according to usual clinical practice. As in our clinical routine, all procedures were performed under conscious sedation using propofol.

After a target lesion was identified, eligibility was assessed based on abovementioned endoscopic features. The size was estimated using the opened snare as a reference. Once eligibility was confirmed, the polyp was removed, preferably by CSP with a dedicated hybrid snare (SnareMaster® Plus 15 mm, Olympus medical systems, Japan) and the aim of en bloc resection. Submucosal injection was not permitted. When a lesion could not be removed by CSP, the use of high-frequency current was permitted with the same snare using an electrocoagulation unit in EndoCut mode (VIO 300, Erbe Elektromedizin, Tübingen, Germany).

After resection, the mucosal defect was rinsed thoroughly with saline solution and the resection margin was carefully inspected. When residual polyp tissue was recognized, additional snaring with the same snare and technique was allowed. When absence of residual polyp tissue was confirmed, biopsies (large capacity Radial Jaw® 4, Boston Scientific, Marlborough, USA) of all quadrants (upper-lower-left-right) of the marginal mucosa of the resection site were obtained (see Fig. 1).

The resected specimen was retrieved by suction into a trap or by using a retrieval forceps. All biopsy specimens were placed in separate containers. Endoscopic hemostasis was performed when active hemorrhage continued ≥30 s after polypectomy. Prophylactic hemostasis or preventive closure of the resection site was not allowed. All patients were followed up in our outpatient clinic or by telephone call to identify postprocedure adverse events (delayed bleeding, abdominal pain, late perforation) within 30 days after the resection.

In patients with incompletely resected polyps, a follow-up colonoscopy was performed within 12 months and the former resection site was carefully inspected. If the mucosa appeared suspicious for neoplastic tissue, biopsies were taken.

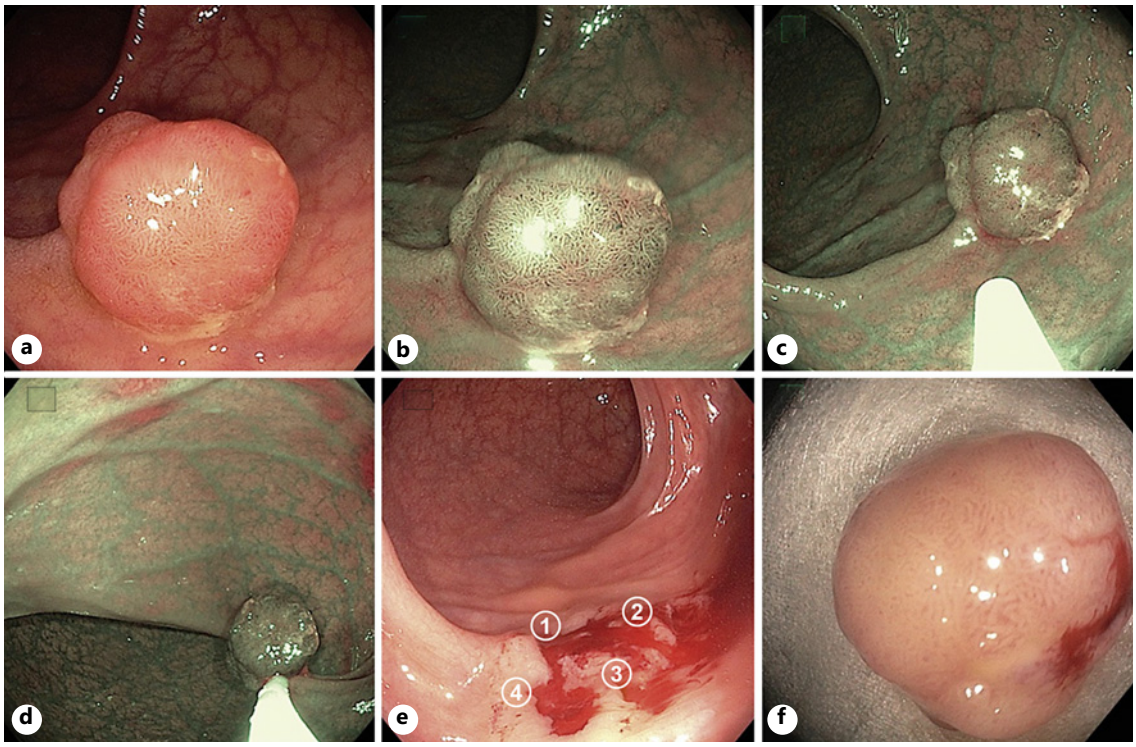

Fig. 1. Study procedure. **a** Sessile polyp detected in the sigmoid colon. **b** Polyp was diagnosed Paris Is, NICE 2. **c** The polyp size was estimated using the snare. **d** Polyp was ensnared and CSP was performed. **e** Biopsies were obtained from 4 quadrants of the resection site margin. **f** Resected specimen was retrieved and sent to histopathological examination.

Histological Analysis

All specimens and biopsies were evaluated under supervision of an experienced gastrointestinal pathologist (MJ) after fixation in formalin solution and staining with hematoxylin and eosin according to our usual clinical practice.

Outcomes

The primary outcome was the histological CRR, which was defined as pathologically negative margins of the specimen and absence of neoplastic tissue in four biopsies obtained from the margin of the resection site after polypectomy. Secondary outcomes were the en bloc resection rate, number of additional resections (snare/biopsy), impossible resection with CSP, time required for resection, immediate bleeding, performed hemostasis and incidence of adverse events such as delayed bleeding, perforation, and abdominal pain. Furthermore, in case of incomplete resection, recurrence within 6 months was evaluated by follow-up colonoscopy. An impossible CSP resection was defined as a procedure that needed electrocautery and thus was converted to HSP. Resection time was measured from the opening of the snare to completion of polyp resection by an assistant using a stopwatch. Immediate bleeding was defined as continuous bleeding ≥30 s after resection. Delayed bleeding was defined as bloody stools with necessity of medical consultation regarding this matter within 28 days after the procedure.

Statistics

As recommended by Billingham et al. [23] for pilot studies, we included 39 patients (considering potential drop outs) for this feasibility study. To determine the relationship between clinical or histopathologic features with complete resection, en bloc resection, and successful CSP, comparisons were performed using Fisher's exact test for categorical variables and binary logistic regression analysis for quantitative variables. All statistical tests were performed two-sided using a significance level of $\alpha = 5\%$. Results from multiple polyps within the same patient were assumed to be independent. The statistical analysis was carried out using SPSS (IBM SPSS® Statistics 28).

Results

A total number of 275 patients were recruited and underwent colonoscopy. As shown in Figure 2, 218 of these patients were excluded because they did not have polyps sized 10–15 mm. From 57 patients, 18 patients with 25 polyps were excluded because histopathological analysis of the eligible polyps in these patients turned out to be hyperplastic polyps (n = 19), due to loss of biopsies

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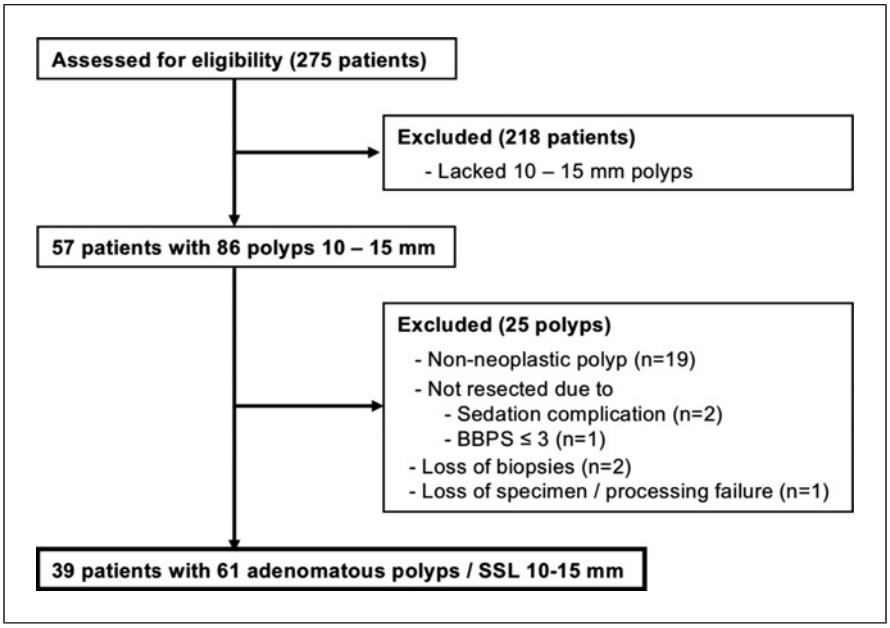

Fig. 2. Study flowchart.

(n = 2), and loss of specimen (n = 1). Furthermore, two polyps could not be resected due to insufficiency of sedation and one due to poor bowel preparation. Finally, 39 patients with 61 adenomatous polyps or SSL were included.

Patient and Polyp Characteristics

The median patient age was 74 years (IQR: 58–80), 22 (56.4%) were men and 9 patients (23.1%) took antithrombotic or antiplatelet medication. Patient background characteristics are shown in Table 1.

The polyp characteristics are summarized in Table 2. The mean polyp size was 11.8 mm (SD: 1.9). The most lesions were located in the right colon (73.8%), 70.5% had sessile morphology (Paris 0–Is), 65.6% were histologically diagnosed low-grade adenoma.

Outcome Measures

Overall CRR was 80.3% (49/61). CSP was feasible in 78.7% (48/61) of polyps and the CRR in this group was 85.4% (41/48). When CSP failed (13/61; 21.3%), lesions were successfully resected using immediate HSP with the same snare with a CRR of 61.5% (8/13) in this group (Table 3). En bloc resection rate by CSP was 81.3% (39/48) and 69.2% (9/13) for HSP, respectively. The overall en bloc resection rate was 78.7% (48/61).

In 13 cases (21.3%) where en bloc resection was not possible, piecemeal resection was performed. In the majority of cases (9/13) there was one additional resection necessary. Three polyps required two, and one case required three additional resections. There was no significant difference in CRR or adverse events between the different numbers of additional resections.

Table 1. Patient characteristics

Age, years, median (IQR)	74 (58–80)
Male sex, *n* (%)	22 (56.4%)
ASA classification, median (IQR)	2 (0)
Antithrombotic treatment, *n* (%)	9 (23.1%)
Rivaroxaban	2 (5.1%)
Enoxaparin	1 (2.6%)
ASA	3 (7.7%)
ASA + Enoxaparin	1 (2.6%)
ASA + Edoxaban	1 (2.6%)
ASA + Clopidogrel	1 (2.6%)
Colonoscopy duration, median (IQR), min	47 (36–67)

When en bloc resection was performed, the CRR was 81.3% (39/48) and 76.9% (10/13) for piecemeal resection, respectively. This difference was not statically significant (p = 0.707). After en bloc CSP the CRR was 82.1% (32/39) and 100% (9/9) after piecemeal resection, respectively. This also turned out to be not significant (p = 0.320).

In all cases when CSP failed and conversion to HSP was necessary, this was due to the large amount of tissue impossible to cut with the snare without electrocautery. Follow-up colonoscopy was performed in patients with incomplete resected polyps (12/61) within a median of 8 months ([IQR] 5–11). In all these cases no recurrence was seen.

Table 2. Characteristics of 61 resected polyps

Location, *n* (%)	
Cecum	12 (19.7)
Ascending colon	23 (37.7)
Transverse colon	10 (16.4)
Descending colon	5 (8.2)
Sigmoid	6 (9.8)
Rectum	5 (8.2)
Size, mean (SD), mm	11.8 (1.9)
Size, *n* (%)	
10 mm	21 (34.4)
11 mm	10 (16.4)
12 mm	16 (26.2)
13 mm	0
14 mm	2 (3.3)
15 mm	12 (19.7)
Morphology, *n* (%)	
0–Is	43 (70.5)
0–Isp	5 (8.2)
0–IIa	13 (21.3)
Histology, *n* (%)	
Low-grade adenoma	40 (65.6)
High-grade adenoma	9 (14.8)
SSL	11 (18.0)
Carcinoma	1 (1.6)

Table 3. Procedure-related outcomes

Complete resection, *n* (%)	49 (80.3)
CSP, *n* (%)	41 (85.4)
After conversion to HSP, *n* (%)	8 (61.5)
En bloc resection, *n* (%)	48 (78.7)
CSP, *n* (%)	39 (81.3)
After conversion to HSP, *n* (%)	9 (69.2)
Immediate bleeding (>30 s), *n* (%)	28 (45.9)
CSP, *n* (%)	19 (39.6)
After conversion, *n* (%)	9 (84.6)
Delayed bleeding	1 (1.6)
CSP, *n* (%)	0 (0)
HSP, *n* (%)	1 (7.7)
Applied hemoclips, mean (SD), *n*	2.4 (1.3)

CSP, cold snare polypectomy; HSP, hot snare polypectomy.

In univariate analysis, CRR was not associated with histopathological diagnosis of adenoma compared to SSL ([OR] 2.56; [CI] 0.60–10.80; $p = 0.166$). In logistic regression analysis, complete resection of smaller polyps was more likely compared to larger lesions, although this was not statistically significant ([OR] 0.77; [CI] 0.55–1.06; $p = 0.111$). Higher probability for en bloc resection was observed for smaller polyp sizes ([OR] 0.69; [CI] 0.50–0.96; $p = 0.014$), as was probability for successful CSP without conversion to HSP ([OR] 0.48; [CI] 0.33–0.72; $p < 0.001$) (Table 4).

One lesion (1.6%) with submucosal cancer invasion in a 15 mm polyp (Paris 0–Is, NICE 2) was resected after conversion to HSP. Obtained biopsies of the resection margin did not show neoplastic tissue, but complete resection of the vertical margin of the specimen could not be confirmed histopathologically. The submucosal cancer invasion was stated 2,000 µm, no lymphatic or vessel infiltration was observed and the tumor was moderately differentiated (T1 Nx Mx G2 L0 V0 Rx). After discussion in the multidisciplinary tumor board, the patient underwent surgery with hemicolectomy with lymphadenectomy. No cancer or adenoma was found in the specimen. The average time for the resection with CSP was 34.2 s (SD: 20.2), and 67.4 s (SD: 39.4) when using high-frequency electric current (conversion to HSP).

Adverse Events

After CSP immediate bleeding ≥30 s occurred in 19 lesions (39.6%) in 16 patients. Four of these patients (25%) were on antiplatelet mono therapy. After conversion to HSP immediate bleeding occurred in 9 lesions (69.2%). None of these patients were on antiplatelet therapy. In all cases successful hemostasis was obtained with 2.1 (SD: 1.1) and 3.0 (SD: 1.7) hemoclips in the CSP group and after conversion to HSP, respectively.

One patient presented delayed hemorrhage at 48 h after HSP of a polyp (12 mm SSL) and required hospitalization. In an urgently performed colonoscopy successful hemostasis was achieved with two hemoclips. No other adverse events such as postprocedural abdominal pain or perforation occurred.

Discussion

Our prospective observational trial demonstrated that CSP for polyps with a size of 10–15 mm was safe and efficient with a CRR of 85.4%. However, in 13 cases (21.3%) CSP failed and the use of high-frequency electric current was necessary to successfully resect the lesion which resulted in an overall CRR and en bloc rate of 80.3% and 78.7%, respectively.

CRR demonstrated in our analysis were consistent with previously published data. The prospective observational CARE study reported a CRR for HSP of 86.6% and 76.7% in lesions 10–14 mm and 15–20 mm, respectively [8]. Most recently published data from Yabuuchi et al. [17] with cold

Table 4. Clinical and histopathological features associated with complete resection, piecemeal resection, and successful CSP

			Univariate analysis	
Complete resection	R0, *n* (%)	R1, *n* (%)	OR (95% CI)	*p* value
Histological diagnosis*				
Adenoma	42 (85.7)	7 (14.3)	2.56 (060–10.80)	0.166
SSL	7 (63.6)	4 (36.4)		
Size of polyp				
10 mm	20 (95.2)	1 (4.8)	0.77 (0.55–1.06)	0.111
11 mm	7 (70.0)	3 (30.0)		
12 mm	12 (75.0)	4 (25.0)		
14 mm	2 (100.0)	0 (0.0)		
15 mm	8 (66.7)	4 (33.3)		
En bloc resection	En bloc, *n* (%)	Piecemeal, *n* (%)		
Size of polyp				
10 mm	19 (90.5)	2 (9.5)	0.69 (0.50–0.96)	0.028
11 mm	7 (70.0)	3 (30.0)		
12 mm	14 (87.5)	2 (12.5)		
14 mm	2 (100.0)	0 (0.0)		
15 mm	6 (50.0)	6 (50.0)		
Successful CSP	HSP, *n* (%)	CSP, *n* (%)		
Size of polyp				
10 mm	1 (4.8)	20 (95.2)	0.48 (0.33–0.72)	<0.001
11 mm	0 (0.0)	10 (100.0)		
12 mm	4 (25.0)	12 (75.0)		
14 mm	0 (0.0)	2 (100.0)		
15 mm	8 (66.7)	4 (33.3)		

CSP, cold snare polypectomy; HSP, hot snare polypectomy; SSL, sessile serrated lesion; OR, odds ratio; CI, confidence interval. *Carcinoma (*n* = 1) was not included in analysis.

snare-EMR in polyps 10–14 mm revealed a CRR of 63.8%. This was mainly due to failure of CS-EMR and a difference in the definition of histological complete resection, which was defined as en bloc resection with negative vertical margins and negative biopsies obtained from 4 quadrants of the mucosal defect margin in their study. Of note is also that they did not include SSL in the analysis.

In another current study, Ma et al. [16] reported a CRR of 96.55% for polyps and SSL. This might be a result of using a dedicated cold snare and snaring technique, although there are contradictory data regarding the effect of this matter [24, 25].

The main reason CSP failed was the inability to cut through the ensnared tissue, although a dedicated snare was used as well [25]. To aim for en bloc resection, a larger amount of tissue must be captured, which may lead to resection failure with CSP, as previously reported by Yabuuchi et al. [17]. In our study, in univariate logistic regression analysis, conversion to HSP was more likely associated with larger polyps, which also supports this assumption. After conversion to HSP the CRR dropped to 61.5%. This low CRR (in comparison to studies reporting on primary HSP) could be due to tissue alterations caused by previous CSR attempts. When piecemeal resection was necessary in this group, we did not notice any significant difference compared to en bloc resection with regard to CRR and adverse events. This was also true for the number of additional resections and is consistent with previous studies [9, 11, 26].

To determine histopathologically complete resection, we obtained biopsies of the resection margin as reported before, which seems a reasonable and accurate method for intramucosal lesions not suspicious for submucosal invasion [8, 11, 12, 27]. Surveillance colonoscopy was conducted in the case of histopathologically positive margin of the specimen and/or positive biopsies, taking

into account that there is a relevant risk of recurrence in this constellation. Murakami et al. [28] showed a recurrence rate of 60% in polyps ≥10 mm with positive margins in a surveillance colonoscopy after 10–24 months. With positive or unclear margins of the specimen, other studies reported recurrence rates of 4.7% and 6.3% in SSL 10–14 mm and 15–20 mm, respectively, in a mean follow-up period of 18 months [15]. In our study we performed followed-up colonoscopy in these cases within 8 months ([IQR] 5–11) and did not find any recurrence. This period is rather short, so results should be interpreted with caution, although a 6-month follow-up period has been previously reported by Ma et al. [16].

In our study we observed 1 patient (1.6%) with delayed bleeding. This only applied to a lesion were CSP failed and HSP was performed. Most previous reports present delayed bleeding rates for CSP under 1% supporting our findings [28–30], whereas for HSP delayed bleeding rates range from 2.9% to 7.8% [18, 31, 32]. This may be explained by the fact that these studies evaluated larger lesions, where bleeding risk is higher [33]. Compared to the literature, we observed relatively high rates of intraprocedural bleeding for CSP (39.6%) and HSP (69.2%). This might be explained by the fact, that per protocol "immediate bleeding" was defined as an occurrence of bleeding within a relatively short period (30 s) after polypectomy, as well as by the greater polyp size compared to other studies. Furthermore, polypectomy was performed without submucosal injection. By contrast, Kawamura et al. [11] reported an immediate bleeding rate for CSP and HSP of small polyps 4–9 mm of 7.1% and 3.5%, respectively. Other studies extend the period after resection to 60 s, thus showing even lower incidence of immediate bleeding from 0.8% to 5.8% for polyps <10 mm [12, 18, 33]. Yabuuchi et al. [17] did not observe any immediate bleeding after CS-EMR of large polyps 10–15 mm with prior submucosal injection. With regard to the diverging immediate bleeding rates it is noteworthy that, especially in retrospective studies, immediate bleedings are often only reported when endoscopic hemostasis is required, resulting in low intraprocedural bleeding rates [18, 33]. If bleeding persists, clipping is a highly effective method for endoscopic hemostasis and it probably also prevents delayed bleeding. In our study, endoscopic hemostasis by clipping was successful in all cases. Taking this into account, it should be reconsidered if it is still appropriate to regard immediate bleedings after polypectomy as an adverse event, especially in large polyps. Most recent studies show that liberal application of hemoclips seems to be both beneficial for the patient and cost effective [34, 35].

The study presented here offers a number of strengths. First, we kept it as close as possible to real life practice. Polypectomies were performed by different endoscopists with varying experience and with the same snare we use regularly for large polyps. The advantage of this strategy was that the same snare could be used to resect smaller polyps not eligible for the study in the same session. Second, our study included all types of neoplastic lesions (SSL and adenomas), although SSL are more likely to be associated with incomplete resection [11, 17]. Third, in contrast to many other studies, we performed surveillance endoscopies when incomplete resection was confirmed. Thus, we were able to show that incomplete resection not necessarily leads to recurrence of the lesion. This may contribute to the discussion about the clinical significance of residual or incompletely resected polyps previously published [9, 36].

Nevertheless, this study has certain limitations that should be acknowledged. First, we obtained biopsies from the resection margins, as has been done in previous studies [8, 9, 11, 12]. However, this methodology has not been thoroughly validated. Because we did not perform biopsy from the base of the mucosal defect, the possibility of residual neoplastic tissue could not be ruled out.

Therefore, CRR in our case does not essentially represent the clinically more significant recurrence rate, which should be evaluated by surveillance colonoscopy after 3 years (according to European and US guidelines). We only performed surveillance endoscopy after incomplete resection within 12 months, potentially missing out on later cases of recurrence. Second, the resection rate of large polyps sized 10–15 mm was not directly compared with the rates of other procedures as cold snare-EMR, HSP, or hot snare-EMR, due to the fact that this was not a randomized controlled clinical trial. Third, to measure the polyp size, we used the opened snare, which may lead to inaccurate measurements [37]. Fourth, this was a single-center study, which is associated with known potential bias.

Nevertheless, our study provides valuable insights regarding CSP of large polyps and demonstrates that CSP can be an effective and safe technique for the resection of polyps up to 15 mm. The use of a hybrid snare seems to be particularly advantageous, as it allows immediate conversion to HSP if CSP fails. These findings have to be further clarified by prospective randomized controlled trials.

Statement of Ethics

This study protocol was reviewed and approved by the Ethics Committee of the Technical University Munich with the approval number 550/19 S and registered at ClinicalTrials.gov (NCT04464837). All patients provided written informed consent.

Conflict of Interest Statement

C.S. has received speaker fees by Olympus. All other authors declare no conflict of interest.

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Author Contributions

Jörg D. Ulrich: study concept and design, analysis and interpretation of data, performing endoscopic procedures, and drafting of the manuscript. Paul Rechberger and Bernhard Haller: analysis and interpretation of data and critical revision of the manuscript. Jeannine Bachmann, Alexander Herner, Guido von Figura, Ulrich Mayr, and Mohamed Abdelhafez: performing endoscopic procedures. Tobias Lahmer and Veit Phillip: performing endoscopic procedures and critical revision of the manuscript. Moritz Jesinghaus: evaluating the specimens. Roland M. Schmid: final approval of the manuscript. Christoph Schlag: study concept and design, analysis and interpretation of data, performing endoscopic procedures, and final approval of the manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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