

Prospective multicenter study of the efficacy and safety of cold forceps polypectomy for ≤ 6 -mm non-ampullary duodenal low-grade adenomas




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ABSTRACT

Background and study aims Because the endoscopic treatment for non-ampullary duodenal adenoma (NADA) has a non-negligible risk of adverse events (AEs), a safe and easy treatment for NADA is desirable. This was a multicenter prospective trial evaluating the efficacy and safety of cold forceps polypectomy (CFP) for diminutive NADAs.

Patients and methods This study was prospectively conducted at six general hospitals and one university hospital. The inclusion criteria were histologic and endoscopic diagnosis of low-grade NADA measuring ≤ 6 mm. A second endoscopy was scheduled for 1 month after CFP. After confirmation of the success of CFP, 6-month and 12-month surveillance endoscopies were scheduled. The primary endpoint was the endoscopic and histologic disease disappearance rates at the 12-month endoscopy.

Results Thirty-nine lesions from 38 patients were prospectively included. Median tumor size at enrollment was 5 mm (range 3–6 mm). There were four cases of remnant lesions at the second endoscopy, and the lesion disappearance rate of single CFP was 89.7% (35/39; 95% confidence interval (CI), 76.9%–97.9%). In three cases, complete removal of the lesion was achieved with a single re-CFP, but one case required four repeat CFPs. The lesion disappearance rate at 12-month endoscopy was 97.4% (38/39; 95%CI, 86.8%–99.5%). During the follow-up period, no AEs related to CFP were observed.

Conclusions CFP for NADA ≤ 6 mm was safe and effective in this study. This common endoscopic method to remove lesions may be an option for treatment of diminutive NADAs.

Introduction

Although non-ampullary duodenal adenoma (NADA) is a rare disease, it is sometimes found incidentally on screening gastro-duodenoscopy (EGD) in patients who are asymptomatic [1]. It is considered a precancerous lesion, similar to colonic adenoma, which is proven to be in the adenoma-carcinoma sequence. Therefore, the treatment strategy at initial diagnosis is mainly resection with an endoscopic procedure such as endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD). However, EMR for NADA has a non-negligible rate of adverse events (AEs), especially perforation and delayed perforation [2–8]. The reasons for these AEs may be related to the thin duodenal wall, interaction of various digestive juices, and poor operability of the endoscope. Perforation of the duodenum sometimes results in severe complications, and treatment of them imposes a heavy burden [8]. Therefore, a safe endoscopic resection method is needed.

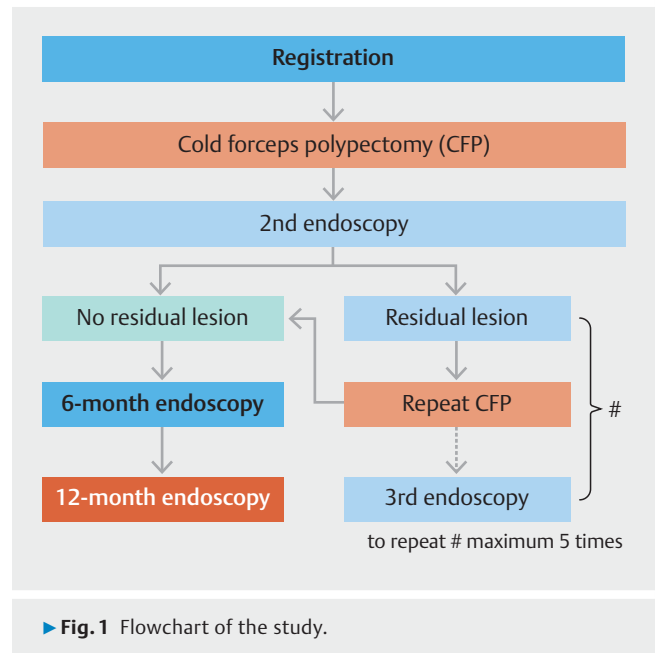
There have been some reports about the efficacy and safety of cold forceps polypectomy (CFP) and cold snare polypectomy (CSP) for diminutive colorectal polyps [9–14]. A single study revealed the safety and effectiveness of cold polypectomy for NADA [15]; however, most of the patients in that study underwent CSP, and there are no clear data about CFP. Because forceps biopsy is the strategy that general endoscopists most commonly use to remove gastrointestinal tissue, CFP might be a safe and easy method to treat small lesions, not only in the colon but also in the duodenum.

Because it is difficult to identify the lateral and vertical margins from specimens taken during cold polypectomy, it is typically used in the colon for non-cancerous lesions that are mainly diagnosed by endoscopic findings. However, endoscopic diagnosis of cancer or adenoma has not been firmly established in duodenal epithelial lesions. Moreover, it is difficult to distinguish high-grade adenoma or carcinoma in the duodenum, even for expert histologists [16]. Therefore, the adoption of cold polypectomy for NADA should be limited to low-grade adenomas. We previously presented a multicenter, retrospective, observational study of NADA. Therein, diminutive NADA (≤ 6 mm) tended to disappear after follow-up with cold forceps biopsy [17]. Based on these results, we hypothesized that NADA measuring ≤ 6 mm might be safely treated with CFP. Therefore, we conducted a multicenter prospective study to assess the feasibility of CFP for low-grade NADA measuring ≤ 6 mm.

Patients and methods

Study design

The standard treatment method for resecting small NADA is EMR or underwater EMR, and the disease control rate with EMR is expected to be approximately 100% for such lesions. CFP may have the same rates of efficacy and safety and a lower patient burden. Because NADA is a rare disease and the efficacy of EMR and CFP may be almost the same, a randomized controlled trial with EMR is difficult to perform. This study was designed as a single-arm, prospective, multicenter trial to explore the possibility of using CFP to treat diminutive NADAs. The par-



► Fig. 1 Flowchart of the study.

ticipating facilities were seven hospitals, including one university hospital belonging to the Okayama Gut study group. The estimated number of cases was 35, to be chosen from among cases collected at participating facilities during the study period from a previous retrospective, multicenter cohort study [17]. The study protocol was approved by the Ethics Committee of each facility and was registered in the University Hospital Medical Network Clinical Trials Registry (number UMIN 000025913) before recruitment; we adhered to the ethical code of the Declaration of Helsinki.

Patients

Inclusion criteria were as follows: 1) NAD located in the duodenum and no continuation with ampulla of Vater; 2) histologically diagnosed as adenoma according to biopsy specimens before the registration; 3) lesion ≤ 6 mm according to endoscopic findings; 4) no other NADA > 7 mm; 5) age > 20 years; and 6) informed consent from the patient. Patients were excluded if they: 1) had lesions that could not be ruled out by histologic or endoscopic findings as high-grade adenoma or cancer; 2) were taking two or more anticoagulant agents that could not be discontinued during the procedure period; 3) were pregnant or nursing; 4) had a life expectancy < 1 year; or 5) an investigator judged the case inappropriate. Written informed consent was obtained from all patients prior to enrollment.

The schedule of CFP and follow-up is shown in ► Fig. 1. The second endoscopy was scheduled 1 month after CFP. At the second endoscopy, observation at the site of CFP and at least one biopsy were required. If a residual tumor was detected, repeat CFP was performed at that time, a third follow-up endoscopy was scheduled after 1 month. Endoscopy with repeated CFP was permitted five times. With the confirmation of no residual tumor by endoscopic and histological evaluation, the protocol transitioned to surveillance endoscopy 6 and 12 months after the endoscopy that had confirmed the disappearance of

the lesion. The method used for endoscopic and histological evaluation performed during the surveillance endoscopies was the same as that used during the second endoscopy. In cases in which no adenomatous lesion was seen at the first CFP and the lesion might have been removed during biopsy before registration, the second endoscopy could be skipped by investigator choice and the patient placed on a surveillance endoscopy protocol.

The following patient and lesion factors were investigated: age, sex, comorbidity of familial adenomatous polyposis, use of anticoagulant agents and antacids, and tumor location and size. Data on the following CFP-related factors also were collected: inpatient or outpatient care, sedation, number of biopsy procedures in CFP, number of biopsy specimens with adenomatous lesion, procedure time, endoscopic clip use after CFP, AEs, histological evaluation, and residual tumors found during follow-up endoscopy.

The main outcome was the rate of endoscopic and histological disease disappearance at 12-month endoscopy. Secondary outcomes were as follows: any AEs, total number of EGDs with CFP required for a lesion to disappear, total number of biopsy procedures during the first CFP, and procedure time, which was defined as being from the start of the first bite of CFP to hemostasis as determined by the endoscopist. Factors associated with residual lesions, which were defined as residual lesions found at second, 6-month or 12-month endoscopy, also were analyzed.

CFP method (with video)

The type of endoscope and system used in this study were dependent on the institutions, but the biopsy forceps used for this CFP method were restricted to the radial jaw 4 (Boston Scientific, Boston, Massachusetts, United States), which are generally used for biopsy procedures in clinical settings (► Fig. 2). The endoscopies were performed by endoscopists certified by the Japan Gastroenterological Endoscopy Society. After inserting the endoscope into the duodenum, the lesions were identified by referring to endoscopic images obtained before registration. Multiple biopsy procedures were permitted until the lesions were no longer visible on endoscopy (► Video 1). The procedure was complete when bleeding ceased. If bleeding continued, the endoscopist could use any method to achieve hemostasis. Use of endoscopic closure by clipping was not required and its use depended on endoscopist preference.

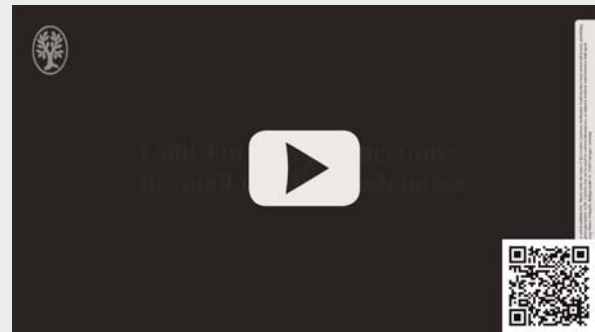
Histological evaluation

All tissues were fixed in formalin and embedded in paraffin. After thin sectioning, hematoxylin and eosin staining was performed. Histological diagnosis was performed by a pathologist at each institution. A histological central review was performed after the follow-up period in all cases that were completed. The specimens from CFP and 12-month endoscopy were reviewed by a certified pathologist (HT) who was blinded to the clinical information. He made the histological diagnosis and determined whether the tumor was present or no longer visible. If the histological diagnosis differed between an institution and the central reviewer, another pathologist who was blinded to



► **Fig. 2** Biopsy forceps of radial jaw four that was used for cold forceps polypectomy (CFP) in this study (Boston Scientific, Boston, Massachusetts, United States).

► VIDEO



► **Video 1** A 6-mm superficial elevated lesion is located on the descending part of the duodenum. Cold forceps polypectomy was performed for the lesion with three bites. Endoscopy confirmed that the resection was complete. The histological diagnosis was low-grade adenoma and there was no residual lesion at 12-month endoscopy.

the results of the histological evaluation evaluated the cases, and the majority result was the final diagnosis. If the histological diagnosis at the first CFP was not adenoma on both institutional and central reviews, meaning that the lesion had been removed by biopsy before registration, biopsy specimens obtained prior to enrollment were reviewed by a central pathologist to confirm the diagnosis of adenomatous lesions.

Statistics

All statistical analyses were performed using statistical software (JMP PRO, version 12; SAS Institute Inc., Cary, North Carolina, United States). All continuous variables are listed as medians. The 95% confidence intervals (CIs) were calculated for the rate at which lesions were no longer visible on the second and 12-month endoscopies. Univariate analysis of the association

with residual lesions during the study period was performed using Yates X² test for comparisons of variables.

Results

A total of 39 lesions included in the study in 38 patients prospectively enrolled between July 2017 and October 2018, as shown in ► **Table 1**. There were 30 men with a median age of 70.5 years (range, 36–83). Oral antithrombotic drugs were administered to nine patients (9/39, 23%). Eight patients underwent CFP with continuing antithrombotic drugs, five with low-dose aspirin, and three with warfarin. One patient stopped using apixaban only the day before the procedure. The median tumor diameter at enrollment was 5 mm (range, 3–6), and the sites of the lesions were the first portion, oral side of Vater on the second portion, and anal side of Vater on the second portion in one, 20, and 18 cases, respectively. The morphology was protruded, superficial elevated, and superficial depressed in seven, 19, and 13 cases, respectively.

Data on CFP are presented in ► **Table 2**. The procedure was performed in all cases on an outpatient basis. The median number of biopsy procedures was five (range, 1–17) for CFP, whereas the median number of specimens including adenomatous lesions was two (range, 0–11). The median time required for CFP was 363 seconds (range, 60–1620), and no AEs were observed. The pathological assessment based on central review by the protocol included 31 cases of low-grade adenoma and no tumor in eight cases. Following the protocol, specimens from biopsies performed before patient enrollment were reviewed by the central pathologist in these eight cases. Moreover, all specimens were confirmed to be low-grade adenomas.

The flow of all cases is shown in ► **Fig. 3**. The second endoscopy was performed in 36 cases, except for three cases in which no adenomatous lesion was observed at CFP. At the second endoscopy, remnant lesions were observed in four cases, which indicated the rate at which lesions were no longer visible on a single CFP was 89.7% (35/39; 95%CI, 76.9%–90.9%). For the remnant lesions, a second CFP was performed at that time. In three cases, lesion disappearance was confirmed on the third endoscopy. However, one case required a total of four CFP procedures to confirm the disappearance of a lesion endoscopically and histologically. A 6-month endoscopy was performed, except in one patient who could not come to the institution for personal reasons, and no residual lesion was observed in the other 38 cases. A 12-month endoscopy was performed in all cases, and one patient had endoscopic and histological residual lesions. The case was a 5-mm protruded-type lesion at enrollment, and CFP was performed in four sessions. The second and 6-month endoscopies revealed no residual tumor, either endoscopically and histologically. At the 12-month endoscopy, a 3-mm protruding lesion was revealed at the site of CFP, and the biopsy specimen showed a low-grade adenoma. CFP was performed on the lesion after histological diagnosis of low-grade adenoma. The rate at which lesions were no longer visible on 12-month endoscopy was 97.4% (38/39; 95%CI, 86.8%–99.5%). Histological central review was performed on all specimens taken during the 12-month endoscopies and con-

► **Table 1** Characteristics of patients and lesions.

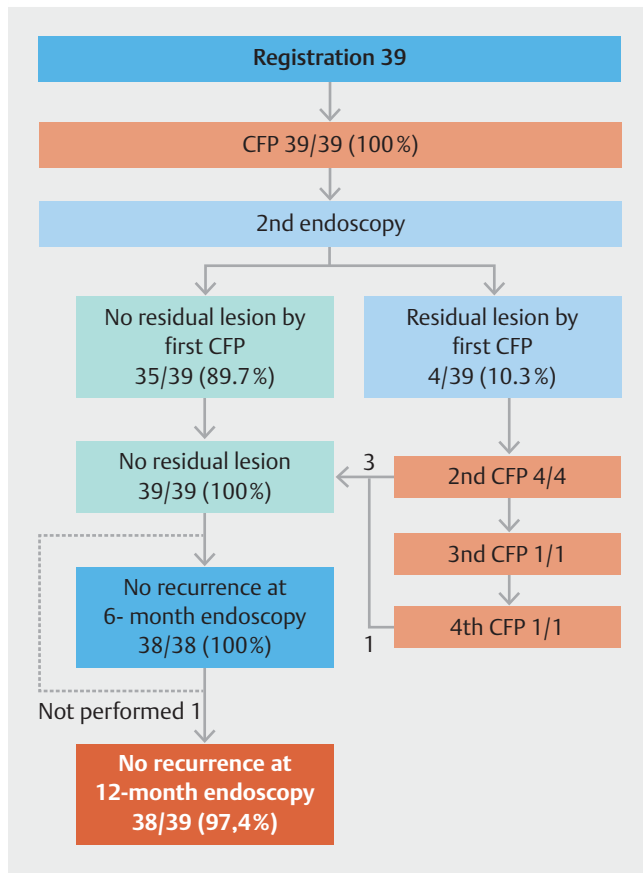
Patients	38
Male/female	30/8
Median age (range)	70.5 (36–83)
Comorbidity of familial adenomatous polyposis	0
Any use of antithrombotic agents	
▪ Yes/no	9/29
▪ Low-dose aspirin	5
▪ Warfarin	3
▪ Apixaban	1
Lesions	39
Median tumor size at the registration (range, mm)	5 (3–6)
Location	
▪ First portion/oral side of Vater on the second portion/anal side of Vater on the second portion	1/20/18
Morphology	
▪ Protruded/superficial elevated/superficial depressed	7/19/13

► **Table 2** Short-term data on cold forceps polypectomy.

Cold forceps polypectomy (CFP)	
Inpatient/outpatient	0/39
Sedation (%)	20 (51%)
Median number of biopsy procedures (range)	5 (1–17)
Median number of specimens including adenomatous lesion (range)	2 (0–11)
Median procedure time (range, s)	363 (60–1620)
Endoscopic closure by clip (%)	1 (3%)
Adverse event	0
Histological evaluation by central review protocol	
Low-grade adenoma/high-grade adenoma/no adenomatous lesion	31/0/8*

* Following the protocol, biopsy specimens before the enrolment were reviewed by the central pathologist in these eight cases. Moreover, all specimens were confirmed low-grade adenoma.

firmed one case of low-grade adenoma. The factors associated with residual lesions during the study period are shown in ► **Table 3**. Lesions size ≤ 4 mm was significantly associated with having no residual lesions ($P=0.02$). During the follow-up period, no AEs related to CFP were observed.



► **Fig. 3** Flow of all registered cases.

► **Table 3** Factors related with the residual lesion during the study period

	residual lesion (n=5)	no residual lesion (n= 34)	P-value
Lesion size			
▪ 4mm or less	0	15	0.02
▪ over 5mm	5	19	
Location			
▪ Oral side of Vater	4	17	0.19
▪ Anal side of Vater	1	17	
Morphology			
▪ Protruded or superficial elevated	3	23	0.74
▪ Superficial depressed	2	11	

Discussion

To the best of our knowledge, this is the first prospective study of the efficacy and safety of CFP for NADA. In this study, rate at which lesions ≤ 6 mm were no longer visible 12 months after

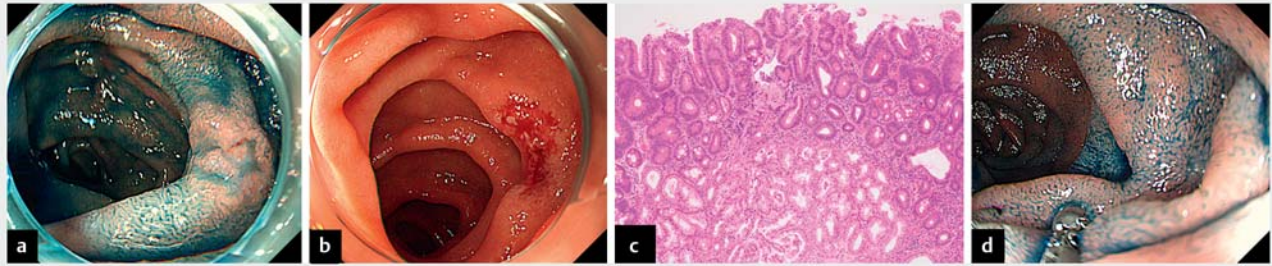
CFP for NADA was 97.4%, and the AE rate was 0%. This study design was not sufficient to prove the efficacy and safety of CFP. However, there were no AEs, and the procedure could be safely performed regardless of lesion site or morphology. The digestive tract of the duodenum is narrow and has the anatomy is difficult to navigate when performing endoscopic procedures. Cold biopsy, the tissue excision method most commonly used by general endoscopists, may be easy to use to treat diminutive NADAs. CFP may be an option for such lesions.

In this study, there were eight cases in which the lesion was not found at the time of CFP. A histological diagnosis of adenoma was required before enrollment. Therefore, all patients underwent biopsy at least once. Complete removal of lesions might have occurred during biopsy before enrollment. These cases were treated as CFP successes with no residual lesions on 12-month endoscopy. Based on these results, a diminutive lesion may be removed completely with a single biopsy, whether the goal is resection or just sampling.

The European Society of Gastrointestinal Endoscopy and American Gastroenterological Association guidelines do not recommend CFP for diminutive colonic polyps because of high recurrence rates [18, 19]; however, CFP can be considered it a lesions is difficult to snare. Four of our patients did have residual adenomas on second endoscopy, resulting in an 89.7% rate of complete lesion removal. However, in all of these cases, repeat CFP was performed, and after 12 months, as many as 97.4% of lesions were no longer visible. In the duodenum, use of endoscopic techniques is severely limited because of the anatomy. Diminutive polyps in the duodenum are considered targets for CFP. In particular, lesions ≤ 4 mm are a promising indication for CFP, based on analysis of factors related to residual lesions during the study period.

Post-biopsy fibrosis is a problem when performing endoscopic resection [20]. The efficacy of CFP after multiple biopsies suggests that CFP is effective not only for diminutive polyps but also for small recurrent or residual lesions after endoscopic resection, which are considered to be difficult to snare due to fibrosis of the submucosal layer. Furthermore, 13 patients with depressed lesions were included in this study. Because snaring depressed lesions without submucosal injection is generally difficult, these cases may be good indications for CFP (► **Fig. 4**).

The median treatment time for CFP was approximately 6 minutes, but some cases take much longer. During multiple biopsies of CFP, visibility of lesions worsened due to bleeding. Therefore, the median number of biopsies was five, but there only two patients had tumors, indicating that unnecessary biopsies were performed due to poor visibility. To avoid these issues, jumbo biopsy forceps may be effective in removing enough tissue in one bite. In this study, we used standard-size forceps to assess the risk of duodenal perforation. However, data on outcomes with CFP for colorectal adenoma using jumbo forceps are favorable [9] suggest that perforation of the digestive tract may not be a consideration with use of large forceps. However, the efficacy of use of jumbo biopsy forceps should be verified, given the potential to further shorten procedure time and number of biopsies.



► **Fig. 4** A case of cold forceps polypectomy (CFP) for a depressed lesion. **a** Chromoendoscopy with indigo-carmin reveals a 6-mm depressed-type lesion located on the oral side of Vater on the second portion. **b** CFP is completed with eight bites. **c** Histological evaluation of the lesion showed that it was a low-grade adenoma. **d** There was no residual lesion endoscopically and histologically at endoscopy 12 months later.

Cold polypectomy is not recommended for carcinoma because evaluation of the lateral and vertical margins is difficult using tissue from cold polypectomy [21, 22]. For the indication of cold polypectomy, the lesion should be confirmed as non-cancerous before treatment. From this perspective, histological confirmation was required in this study. However, there has been a report of a discrepancy between biopsy specimens and resected specimens [20]. Diagnosis based on a single biopsy specimen might not be completely reliable. Moreover, pre-biopsy scar did not affect the CFP procedure, but if the lesion required EMR or ESD, such a scar might disturb the procedure due to submucosal fibrosis. Unnecessary biopsies should be avoided as much as possible. The incidence of carcinoma in small lesions was expected to be low, but there have been some reports of submucosal carcinomas in lesions <10 mm [23]. In terms of morphology, a depressed lesion is related to carcinoma in colorectal epithelial tumor [24]; however, in this and a previous study, many patients had depressed-type low-grade NADAs [25]. Studies also have been published on the efficacy of magnifying endoscopy for diagnosis of duodenal epithelial tumors [26, 27]. Although the efficacy of endoscopic diagnosis has not been fully established, given advances in endoscopic diagnosis, it should replace histological diagnosis to avoid submucosal fibrosis, which makes future treatment difficult. Moreover, a reliable endoscopic diagnosis may allow direct cold polypectomy at the initial diagnosis, as in colorectal tumors.

The purpose of excision of adenomatous lesions is to suppress the development of adenocarcinoma in the future, but the risk of progression to cancer of small low-grade adenomas has not been clarified. Endoscopic resection for NADAs should be performed if it is safe and simple, as well as for colorectal treatment. However, if the AEs resulting from the treatment cannot be ignored, we should consider a minimally invasive and safe treatment method. In recent years, the usefulness of underwater EMR for NADAs measuring 10 to 20 mm NADA has been proven by a multicenter trial [28]. Moreover, for small adenomas, the development of cold polypectomy is progressing as a safe and minimally invasive treatment. The safety and effectiveness of CSP for NADAs have been reported [15], and a large-scale trial is being conducted in Japan (UMIN000030876).

Positive results are expected from these studies; however, we believe our study provides evidence of the benefit for NADAs measuring ≤ 6 mm because the biopsy method is commonly used, easy, and simple for endoscopists to perform.

There were several limitations of this study. First, it was a single-arm, prospective, small-scale study. Therefore, the safety and effectiveness of the technique were not statistically proven. However, our results showing promise for clinical benefit and support for large-scale trials or use of the technique as an alternative to treat diminutive NADAs. Second, there were no data from the follow-up period with which to evaluate the recurrence of NADA. In this study, there was one recurrence found at 12-month endoscopy in a tumor that was not visible at either the second or 6-month endoscopies. Thus, a 12-month follow-up period was considered sufficient. However, if there is recurrence at the site of the CFP, severe fibrosis may obstruct EMR or ESD. Follow-up endoscopy should be done after CFP for early detection so that, if necessary, treatment can be performed without being hampered by fibrosis.

Conclusions

In conclusion, CFP for NADAs ≤ 6 mm was safe and effective in this study. This common endoscopic method for remove lesions may be an option for treatment of diminutive NADAs.

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Competing interests

The authors declare that they have no conflict of interest.

Clinical trial

UMIN-CTR
UMIN000025913
TRIAL REGISTRATION: Multi-Center, Single arm, prospective trial at
<https://upload.umin.ac.jp>

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CORRECTION

Prospective multicenter study of the efficacy and safety of cold forceps polypectomy for ≤ 6 -mm non-ampullary duodenal low-grade adenomas

Hiroimitsu Kanzaki, Joichiro Horii, Ryuta Takenaka et al.
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In the above-mentioned article the accepted date was corrected to 20.12.2021.

This was corrected in the online version on 13 July 2022.