JGH Open An open access journal of gastroenterology and hepatology
Open Access
JGHF Journal of Gastroenterology and Hepatology Foundation
doi:10.1002/jgh3.13052

ORIGINAL ARTICLE

Hot avulsion *versus* argon plasma coagulation for the management of the non-ensnarable polyp: A multicenter, randomized controlled trial

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Key words
argon plasma coagulation, hot avulsion, polypectomy.

Accepted for publication 24 February 2024.

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Abstract

Background and Aim: Snare resection of nonlifting colonic lesions often requires supplemental techniques. We compared the success rates of neoplasia eradication using hot avulsion and argon plasma coagulation in colonic polyps when complete snare polypectomy had failed.

Methods: Polyps that were not completely resectable by snare polypectomy were randomized to argon plasma coagulation or hot avulsion for completion of resection. Argon plasma coagulation was delivered using a forward shooting catheter, using a nontouch technique (flow 1.2 L, 35 watts). Hot avulsion was performed by grasping the neoplastic tissue with hot biopsy forceps and applying traction away from the bowel wall while using EndoCut I or soft coagulation for avulsion. Surveillance colonoscopies were performed at 6, 12, and 18 months.

Results: From November 2013 to July 2017, 59 patients were randomized to argon plasma coagulation (28) or hot avulsion (31). The median age was 69 (60–75), with 46% being female. The median residual tissue size was 10 mm (6–12). The residual adenoma rate at 6 months (hot avulsion 6% *vs* argon plasma coagulation 21% $P = 0.09$) and 18 months was not different between the groups (6.6% *vs* 3.6% $P = 0.25$). One patient in the argon plasma coagulation arm was diagnosed with metastatic cancer of likely colorectal origin despite benign histology in the original polypectomy specimen, supporting the importance of tissue acquisition.

Conclusion: Both hot avulsion and argon plasma coagulation are effective and safe modalities to complete resection of non-ensnarable colonic polyps.

Introduction

Endoscopic removal of large colonic polyps via snare technique is a common and accepted alternative to surgery.[1,2] However, polyps in awkward positions or non-lifting lesions most often due to submucosal fibrosis are less likely to be removed completely by snare resection alone.[3–5] As such supplemental techniques are usually employed. The techniques most often used in this situation are tissue ablation (using argon plasma coagulation [APC] or snare tip coagulation), cold avulsion snare tip (CAST), or surgery.[3,6] APC results in an inconsistent depth of tissue injury, often confined to superficial layers while deeper layers are intact. Furthermore, APC results in the destruction of tissue samples preventing histopathological analysis.[7] APC at the time of polypectomy has also been identified as a predictor of residual adenoma at subsequent colonoscopies.[1,7,8] A prospective study using the CAST technique reported high residual adenoma rates at 6 months in naïve (27.5%) and previously attempted nonlifting lesions (15.2%).[3]

Hot avulsion (HA) is a likely safer variation of the well-described hot biopsy (HB) technique for polyp removal.[9–12] It entails the avulsion of neoplastic tissue using HB forceps and thermal energy. Unlike HB, HA is performed using a cutting or soft coagulation current, which results in less thermal injury to deeper layers of the colon.[9,12] HA has the benefit of removal rather than ablation of neoplastic tissue. In a prospective pilot trial, HA has been shown to be both a highly effective and safe technique for nonlifting polyps.[13] Recent retrospective studies have found that HA decreases adenoma recurrence rate without significantly increasing the risk of the procedure compared with APC.[14]

The primary outcome of the study is the rate of macroscopic and histologic neoplasia eradication at the 6-month follow-up colonoscopy of non-ensnarable colonic polyps, comparing standard therapy of APC with HA. Secondary outcomes included immediate and delayed complication rates and adenoma eradications rates at 12 months post no residual polyp.

Methods

This is a multicenter prospective, parallel nonblinded randomized control study with a 1:1: allocation ratio. All endoscopic mucosal resections (EMR) were performed by senior interventional endoscopists with extensive experience in large polyp removal (over 500 EMR). Each endoscopist was trained in high-volume tertiary centers in Australia, New Zealand, and overseas. This includes training in the technique of HA.

Written informed consent for snare polypectomy and both APC and HA was obtained by a trained research assistant for all patients prior to colonoscopy and attempt at polyp resection. Random allocation sequence occurred at the time of failed polypectomy in block sizes of six patients using a computer-generated random number system. Depending on the assignment, the patient received either APC or HA.

To meet entrance criteria for the study, the patient needed to be referred for resection of a 20 mm or larger polyp or for an incompletely resected polyp. Patients were included in the study if polypectomy failed with snare resection, the residual polyp was not amenable to snare resection, and there were no endoscopic features of submucosal invasion. All enrolled patients had a single biopsy of the residual tissue prior to treatment, which was reviewed by specialist gastrointestinal pathologists to confirm neoplastic tissue.

Patients were excluded from the study if they were under the age of 18, had a bleeding susceptibility, or the presence of medical conditions that precluded the patient from having a colonoscopy. Bleeding susceptibility included the use of warfarin, ticagrelor, or clopidogrel in the last 7 days, direct acting anticoagulant within 2 days, low-molecular weight heparin within 12 h, therapeutic unfractionated heparin within 6 h, coagulopathy (INR > 2), or thrombocytopenia (platelet count <50 000/L).

In preparation for the colonoscopy, all patients received bowel preparation in accordance with standard established practice. Intravenous sedation was administered either by an anesthetist using deep sedation or by the endoscopist using conscious sedation.

Colonoscopy was performed using a high-definition colonoscope (e.g. Olympus 180 or 190 series high-definition variable-stiffness colonoscopes [180/190 PCF/CF; Olympus, Tokyo, Japan]) with distal cap attachment. Carbon dioxide was used for insufflation in all colonoscopies.

Once the polyp was identified, resection was attempted using a snare technique in line with the current standard of care using varied snares and injectate solutions at the discretion of the endoscopist.

APC was delivered using an Erbe or equivalent forward shooting catheter, using a nontouch technique. Initial Erbe settings were a flow of 1.2 L/min and 35 watts. Ablation was continued until all macroscopic neoplastic tissue had been successfully ablated.

HA was performed by grasping the neoplastic tissue (Image 1) with HB forceps (Boston Scientific or Olympus) and applying traction away from the bowel wall while using EndoCut I (Erbe VIO 200/300, effect 2, timing 2, other 3) delivered using a tapping technique for avulsion. If neoplastic tissue did not avulse with the application of current, gentle mechanical traction was applied away from the bowel wall. This process was repeated until all neoplastic tissue had been removed (Image 2). All specimens avulsed using this technique were sent for histopathological assessment. A link to the video demonstrating this technique has been previously published at https://www.youtube.com/watch?v=p-vi-a3JhZI.[15]

All patients had a repeat colonoscopy at 6 months. If no residual polyp was seen, the scar was biopsied to confirm histopathological clearance. For patients with no residual polyp, a repeat colonoscopy was performed 12 months later. If this was

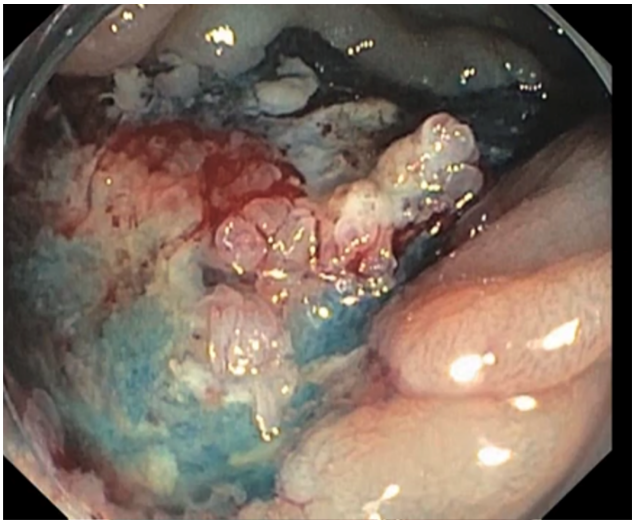

Image 1 Non-ensnarable residual colonic polyp.

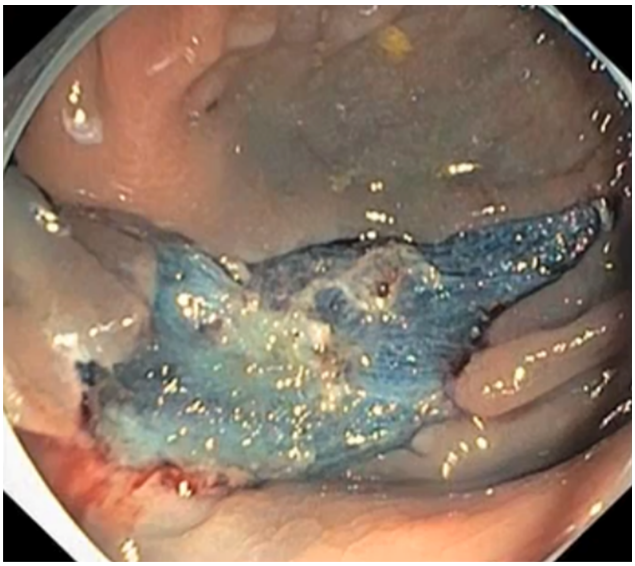

Image 2 Polypectomy site after hot avulsion.

clear, the patient was discharged from the study and commenced surveillance as per national guidelines.

If residual adenoma was detected, patients underwent repeat intervention as per their randomized treatment arm (APC or HA). A repeat colonoscopy was performed at 6 months. At this colonoscopy if residual tissue remained, the patient crossed over treatment arms or was referred for surgical management as determined by the treating Gastroenterologist. This was considered as failed therapy for that arm.

After each colonoscopy, all patients were observed and had a clinical review 4 h after procedure. If well, the patient was discharged and commenced on a clear fluid diet until the following morning. At 14 days after therapeutic colonoscopy, a research assistant completed a phone interview of each patient to assess for any post-procedure complications. Patients were followed until treatment failure was confirmed as above or for 12 months after complete polyp destruction.

Basic demographics of the patients were recorded including indication for colonoscopy. Data recorded from the procedures included polyp location, the size of the polyp or residual neoplastic tissue (as estimated by a fully opened snare or biopsy forceps), reason for nonlifting polyp/failed polypectomy, any treatment-related complications (including hospitalization), endoscopy techniques, and equipment used.

The primary outcome sample size calculation was extrapolated from published literature.[1,2,6,13] According to standard binomial sample size calculation formulas, the study required 80 patients per group, assuming an incidence of polyp residual of 40% in the APC group and 20% in the HA group (proportional difference = 20%, alpha = 0.05, beta = 0.20, two-tailed).[1,2,6,13] The sample size achieved ($n = 59$) has 80% power to detect a higher (35%) proportional difference (G*Power 3.1.9.7).

Data were summarized using frequency distributions for categorical data and medians (Mdn) and inter-quartile range (IQR) for continuous data that were not normally distributed. Nominal data were analyzed using χ^2 or Fisher's exact tests, as appropriate depending on group size. While ordinal data were compared using nonparametric Mann–Whitney *U* tests. Stata version 17.0 (StataCorp, College Station, TX) was used for analysis.

Ethics approval was obtained from relevant hospital HREC and conducted in agreement with the Declaration of Helsinki. No funding was received and there are no conflicts to declare. The study was registered with the Australian New Zealand Clinical Trials Registry, trial number: ACTRN12613000720718, registered on the 1 July 2013.

Results

From 2013 to 2017, a total of 59 patients were randomized into the APC (28) or HA arm (31). The demographics of the HA and APC arms were similar (Table 1). The median age of the cohort was 69 (60–75), with 46% of patients being female. Two thirds of the cohort had at least one previous attempt at EMR prior to the index colonoscopy. The median residual tissue size was 10 mm (6–12). The polyp location and reason for incomplete snare resection are listed below in Tables 2 and 3, respectively.

The rate of residual adenoma at 6 months was lower in the HA arm (6% *vs* 21%), but it did not reach statistical significance ($P = 0.09$.) The six patients from the APC cohort with residual polyp were non-ensnarable due to previous EMR attempts (three patients), previous biopsy (one patient), previous combination of therapies (one patient), and submucosal fibrosis (one patient). The two patients from the HA cohort with residual polyp were non ensnarable due to difficult location at the appendiceal orifice (one patient) and submucosal fibrosis (one patient). Three patients in the APC arm and one patient in the HA arm were lost to follow up at 18 months, with none of these patients having adenoma detected at the 6-month follow-up colonoscopy. At 18 months, the residual rates were similar, two in the HA and one in the APC arm (7% *vs* 4%, $P = 0.25$). The rate of eradication and residual adenoma in both treatment arms is summarized in Figure 1.

The patient from the APC arm with residual adenoma at 18 months also had residual adenoma present at the initial 6-month

Table 1 Baseline characteristics

Baseline characteristics	HA	APC
Number of patients	31	28
Age in years, Mdn (IQR)	69 (60–74)	69 (59–75)
Female, *n* (%)	13 (42)	14 (50)
Previous EMR attempt, no. patients (total no. of attempts)	20 (27)	19 (27)
Residual size polyp, mm, Mdn (IQR)	10 (8–15)	10 (5–12)

Table 2 Polyp location

Polyp Location ($P = 0.58$)	HA	APC
Rectum	7	5
Sigmoid	0	2
Descending colon	2	2
Splenic flexure	0	1
Transverse colon	2	5
Hepatic flexure	3	1
Ascending colon	9	6
Caecum	8	6

Table 3 Reason for non-ensnarable polyp

Reason for non-ensnarable polyp	Number of patients
Non lifting polyp	
Previous EMR	30
Multiple previous biopsies	6
Combination of techniques (EMR, biopsy, spot tattoo, TEMS)	8
Submucosal fibrosis	3
Spot tattoo at base	2
Previous TEMS	1
Difficult location of polyp	9
	3 Ileocecal valve
	2 Cecum
	2 Ascending colon
	2 Appendix orifice

EMR, Endoscopic mucosal resection; TEMS, Transanal endoscopic microsurgery.

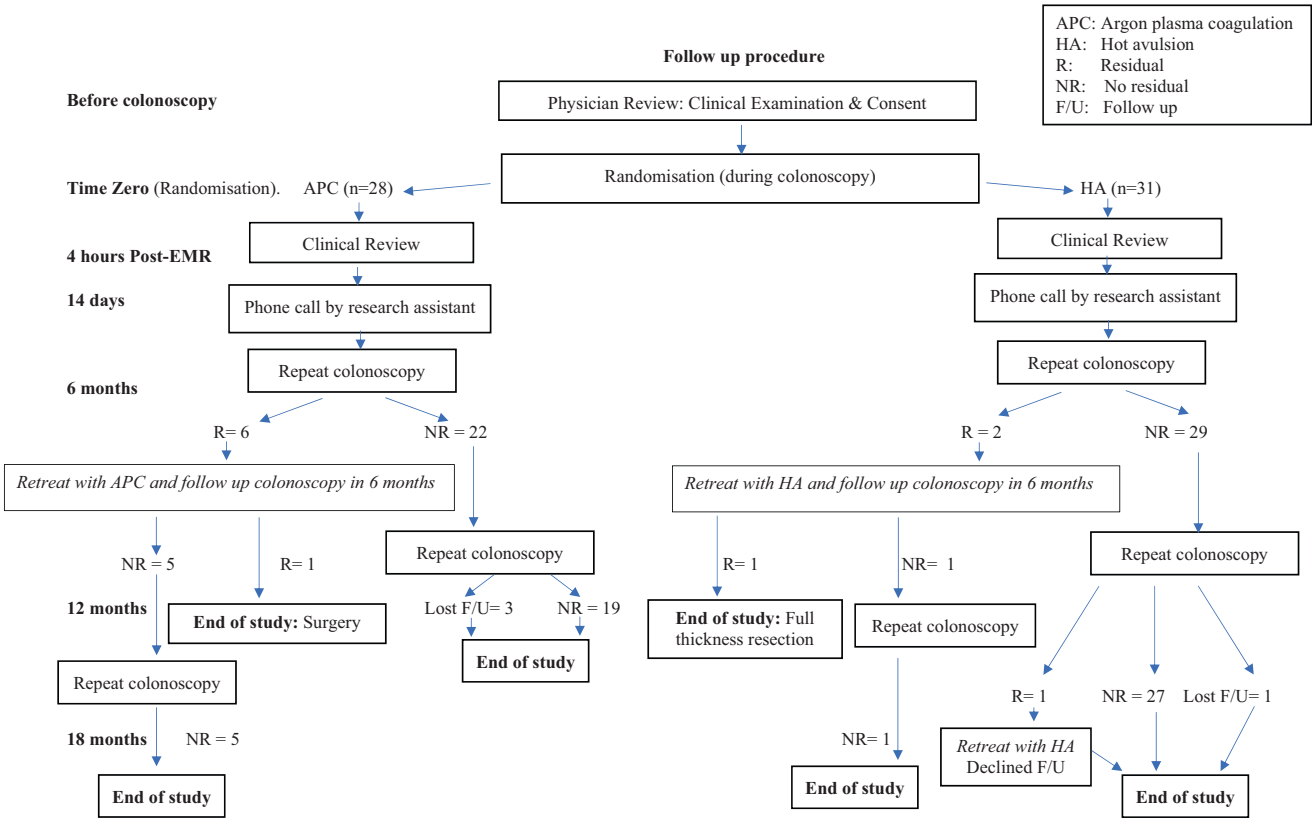

Figure 1 Participant flow diagram.

colonoscopy. This patient proceeded to surgical management. In the HA arm, two patients had detectable adenoma at the polypectomy site at 18 months. The first had residual adenoma present at both the 6-month and 18-month colonoscopy, and subsequently underwent endoscopic full-thickness resection. The second patient had no adenoma at the 6-month colonoscopy and 12 mm of residual adenoma on the 18-month colonoscopy. The residual polyp was treated as per study protocol with repeat HA; however, the patient declined subsequent follow-up colonoscopy.

The immediate and delayed complication rates including hospital presentations of both therapies remained low and were not significantly different (Table 4). This included a one-night hospitalization for a patient in the APC arm for a post-polypectomy bleed, which was managed conservatively. There were no perforations.

The median time to complete HA was 5 min 52 s (3 min–15 min 24 s), APC was 2 min 20 s (1 min 6 s–4 min 30 s).

One patient in the APC arm was diagnosed with metastatic cancer of likely colorectal origin in June 2018 despite benign histology in the original polypectomy specimen (October 2016). The residual polyp histopathology is summarized in Table 5.

Discussion

Non-ensnarable colon polyps are commonly caused by submucosal fibrosis (traction, previous attempts to resect, previous spot injection), resulting in poor lift and less frequently malignant infiltration.[3,5] The latter should be apparent due to the presence of ulceration, induration, friable mucosa, nongranular surface morphology, or Kudos pit pattern V.[1,5,16] Nonlifting colonic polyps are encountered in 13% of polypectomies where previous intervention has been performed.[5] Nonlifting benign colonic polyps are difficult to resect completely using snare alone.[3–5] Difficulty with snare resection alone can also be encountered depending on polyp location including at the ileocecal valve, appendix orifice, flexures, and dentate line where repeated slippage by snare is more common.[17]

We report the first randomized control trial comparing HA and APC in this group of patients.

Residual adenoma rates were no different to APC at 6 and 18 months. However, a trend was seen toward lower recurrence rates in the HA group at 6 months (6.4% *vs* 21.4%, p 0.09). This trend supports retrospective studies, which showed HA to be a safe and effective technique for nonlifting polyps.[13,14] The sample size achieved had 80% power to detect a higher (35%) proportional difference. Unfortunately, due to a low recruitment rate, we did not achieve the required sample size by study termination date to confirm this trend statistically, causing a potential type II error. Recruitment was low due to several factors. This included a lower number of patients requiring non-snare techniques due to improved education of referring doctors not to biopsy or attempt resection of polyps that were unlikely to be completely removed by snare resection alone. Larger studies are needed to determine which one of these techniques is superior.

Table 4 Polypectomy outcomes

Outcomes	HA (31)	APC (28)	*P*
Duration removal, min, s Mdn (IQR)	5 min 52 s (3 min–15 min 24 s)	2 min 20 s (1 min 6 s–4 min 30 s)	<0.01
Immediate complications	0	0	-
Day 14 complications	0	1 (3.6%)	0.29
Hospital admission nights	0	1 (3.6%)	0.29
Residual adenoma at 6 months, *n* (%) 95% CI	2 (6.5%) 95% CI (0%, 15.2%)	6 (21.4%) 95% CI (6.2%, 36.6%)	0.09
Residual adenoma at 12 months/final colonoscopy, *n* (%) 95% CI	2 (6.5%) 95% CI (0%, 15.2%)	1 (3.6%) 95% CI (0%, 10.5%)	0.25

Table 5 Residual polyp histopathology

Histopathology	Number of patients
Benign lesion (hyperplastic, normal colonic mucosa)	3 (5.1%)
Sessile serrated lesion	5 (8.5%)
Traditional serrated adenoma	3 (5.1%)
Tubular lesion	26 (44.1%)
Tubulovillous lesion	20 (33.9%)
Villous lesion	2 (3.4%)

Of note, the adenoma eradication rate using APC in our study was much higher than previously reported. Our study had an adenoma recurrence rate of 21.4% at 6 months in contrast to studies by Moss (44.4% at 4 months) and Holmes et al. (59.3% at 4–12 months).[8,14] We feel the likely reason for this is a strong protocol emphasis on as extensive snare resection as possible prior to use of either APC or HA. Hence, the size and depth of area treated with ablation were minimized as much as possible.

Traditional HB has fallen out of favor as it has been reported as having an increased risk of perforation.[10,12,18,19] As HA uses the same forceps, there has been concern regarding the safety of this technique.[3] However, important differences exist between HA and HB. HB uses a forced current, which increases the risk of transmural injury, serositis, and delayed perforation.[10,12,18,19] Additionally, there is less emphasis on traction with HB, with the end point of prolonged coagulation being a wide based thermal injury around the neoplastic tissue (Mount Fuji effect).[11] In contrast, HA applies gentle lifting mechanical traction with short bursts of cutting current via the EndoCut I mode, which delivers only a superficial burn while avulsing tissue.[9,13] The safety of this technique has been demonstrated in several retrospective studies.[9,13] In the present study, of the 31 patients who were assigned into the HA arm, there were no complications recorded. This also contrasts the cold avulsion technique, where immediate perforation has been described in both previously attempted non lifting polyps (5.3%) and naïve nonlifting polyps (1.6%).[3]

Endoscopic submucosal dissection (ESD) for residual or locally recurrent colonic lesions after previous EMR has an intraoperative perforation rate of 7.5%. ESD is better suited to lesions/residual tissue over 20 mm, while HA has a better safety profile for diminutive tissue.[20,21] The use of other techniques such as underwater EMR in contrast to traditional EMR have been shown to be another useful technique for small recurrent lesions (<15 mm). With studies finding that the use of underwater EMR results in a lower rate of salvage therapies such as APC.[22]

One significant clinical advantage of HA over APC is of tissue acquisition from the nonlifting area. All cases treated with HA had interpretable histology by each institutional pathologist, with no cases in the cohort without evaluable histology. The literature reports histopathology confirmed invasive cancer to be present in 10% of nonlifting polyps.[5] Indeed, in our study, one patient in the APC arm was diagnosed with metastatic cancer of likely colorectal origin despite benign histology in the original polypectomy specimen. It is known that biopsies of polyps alone may not be accurate.[23,24] Possible explanations for this include only a small part of the residual polyp being biopsied, and therefore the malignant component not sampled or difficulties in accurate histology in the setting of scarred neoplastic tissue when only a biopsy is taken. This highlights the importance of tissue acquisition over ablative techniques alone.

We would not advocate overtly malignant appearing nonlifting polyps (based on morphology and pit pattern) being managed by APC or HA.

The HA technique took more time than APC (5 min 52 s *vs* 2 min 20 s, $P < 0.01$). This is due to the additional time to acquire and process the histopathological sample.

The equipment and accessories required for HA should be readily available in all endoscopy units. HB forceps cost approximately $20 AUD in Australia and can be used with a standard diathermy generator. We did not conduct a cost analysis, but setup costs for the HA arm are substantially cheaper ($280/patient) compared with APC, even when not considering the Erbe generator and costs of training.

As discussed, the major limitation of the study is the small case numbers. Further limitations of the study include a lack of data on the index polypectomy, for example, the number of resected pieces at the first snare polypectomy was not recorded. These data were not collected as patients were randomized into the study after all attempts were made for snare resection. Equally, many of the cases had been referred from other centers where one or more prior attempts had been made and the level of reporting from those first procedures was not sufficient to gather this information. An additional limitation of the study is the heterogeneity of underlying etiology of fibrosis in patients with nonlifting polyps.

We have demonstrated that the management of non-ensnarable colonic polyps HA is safe with a trend for lower rates of residual adenoma at 6-month follow-up colonoscopy compared with APC. Larger studies are needed to determine whether one of these techniques is superior.

Acknowledgment

The authors would like to acknowledge the University of Western Australia for supporting the publication costs of this article. Open access publishing facilitated by The University of Western Australia, as part of the Wiley - The University of Western Australia agreement via the Council of Australian University Librarians.

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