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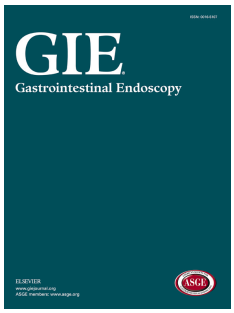

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PII: S0016-5107(17)32462-8

DOI: 10.1016/j.gie.2017.11.002

Reference: YMGE 10824

To appear in: *Gastrointestinal Endoscopy*

Received Date: 10 July 2017

Accepted Date: 4 November 2017

Please cite this article as: Tutticci NJ, Hewett DG, Cold endoscopic mucosal resection of large sessile serrated polyps at colonoscopy (with video), *Gastrointestinal Endoscopy* (2017), doi: 10.1016/j.gie.2017.11.002.

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Running head: Cold endoscopic mucosal resection

Abstract

Background and Aims: The optimal technique for the resection of sessile serrated polyps (SSPs) is unknown, with established limitations and risks with conventional polypectomy. Although cold snare polypectomy is safe, the efficacy of piecemeal resection for large lesions is untested. In this study, we evaluate the safety and efficacy of cold endoscopic mucosal resection (EMR) for large SSPs.

Methods: Patients presenting for elective colonoscopy at an academic endoscopy center with 1 or more SSPs ≥10mm in size were enrolled, excluding those on anticoagulants or antiplatelets other than aspirin. Lesions were resected with a cold EMR technique comprising submucosal injection of succinylated gelatin and dilute methylene blue before piecemeal cold snare resection of all visible polyp with a margin of normal tissue. Outcomes were the presence of residual serrated neoplasia in biopsies from the defect margin, and findings on surveillance colonoscopy.

Results: Cold EMR was performed on 163 SSPs during 105 procedures in 99 patients (97% female; median age 57 years). The mean size was 17.5 mm: 61 SSPs were ≥20 mm, 13 SSPs ≥30 mm, and 97.5% were in the proximal colon. Cytological dysplasia was present in 2 (1.2%). Margin biopsies were positive in 2 (1.2%) lesions. Surveillance colonoscopy for 82% of lesions (median 5 months) showed residual serrated tissue in 1, treated with cold snare, but no evidence of recurrence in the remainder. Minor adverse events were seen in 3 patients; no delayed bleeding was observed.

Conclusions: Cold EMR is a safe and effective method for the removal of large SSPs.

Despite the importance of sessile serrated polyps (SSPs) as colorectal cancer precursors, the optimal method for their removal remains unknown, particularly for large SSPs (≥10 mm in size).[1, 2] The cornerstone of colorectal cancer prevention remains the removal of polyps at colonoscopy[3], which may be performed with ("hot") or without ("cold") the use of electrocautery.

The conventional paradigm of hot snare polypectomy (HSP) has been challenged by the cost and safety advantages of cold snare polypectomy (CSP).[4-6] Currently, CSP is recommended for polyps <10 mm in size and hot polypectomy for polyps ≥10 mm, yet the use of electrocautery remains associated with appreciable rates of post polypectomy bleeding, pain, and the threat of perforation.[7] In addition to these risks, the efficacy of HSP for large serrated polyps is not assured with incomplete resection rates of up to 47% [8]. The injection of fluid into the submucosa before hot snare polypectomy forms the basis of conventional endoscopic mucosal resection (EMR) [9]. The efficacy of EMR for large SSPs appears superior to conventional HSP, however postpolypectomy bleeding remains a challenge.[10] Clip closure of the EMR defect appears to mitigate this risk[11, 12]; however, its cost-effectiveness has been questioned.[13]

A safer, more effective and less costly technique for the removal of large SSPs is therefore needed. Is a technique based on cold snare the answer?[14] Practically, there is an upper limit of tissue amenable to mechanical transection by cold snare. Large polyps, by necessity, require piecemeal resection to be completely removed with a margin of normal tissue. Emerging interest in this approach to large polyps suggests an impressive safety profile for piecemeal CSP with and without submucosal injection in serrated and adenomatous lesions 10 to 45 mm in size.[15-17] There are no data on the efficacy of CSP for large polyps without adjunctive thermal therapy or cold forceps avulsion.

Submucosal injection before hot snare resection for larger lesions is a key element of endoscopic mucosal resection (EMR), providing a thermal cushion and aiding to define the margin of the lesion. The use of submucosal injection before CSP appears safe.[16, 18] Although injection is not required for thermal safety with CSP, enhanced endoscopic delineation of the polyp margin may be helpful particularly for subtle flat serrated polyps. The aim of this study was to assess the efficacy and safety of EMR without electrocautery for large SSPs.

Methods

Design & setting

We conducted a prospective observational cohort study of piecemeal cold EMR in patients undergoing colonoscopy at an academic endoscopy unit. The study was conducted as a quality evaluation of current polypectomy practice, and permission to report the study was granted by the Metro South Health Human Research Ethics Committee. We followed the *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) guidelines in reporting our findings.[19]

Procedures

All colonoscopies were performed by 2 experienced colonoscopists (N.J.T. and D.G.H.) whose current clinical practice for removal of flat serrated lesions ≥10 mm in size is piecemeal cold EMR. We used high-definition colonoscopes (CF-HQ190L and PCF-H190L, Olympus Corp, Tokyo, Japan) with a transparent distal attachment (D-201-14304 and D-201-12704; Olympus Corp) and carbon dioxide insufflation. All patients received split dose bowel preparation with polyethylene glycol electrolyte lavage solution and were sedated with propofol. Other than aspirin, patients on antiplatelet agents or anticoagulants at the time of colonoscopy were excluded.

We performed mucosal inspection on instrument withdrawal. Use of a transparent cap facilitated mucosal exposure and access to polyps between or under colonic folds. All sessile serrated lesions 10 mm or greater were eligible for inclusion.[20, 21] We used a fully open snare to assess lesion size. Each lesion was interrogated with white light and narrow-band imaging with magnification. Lesions were excluded from this study if there had been a previous attempt at resection or if the lesion contained an area of suspicious for cytologic dysplasia, characterized by the presence of a type 2 surface and vessel pattern under narrow-band imaging [20, 22]. Lesions were also excluded if synchronous colorectal cancer was diagnosed during the colonoscopy.

All lesions were removed using a cold EMR technique in which submucosal injection was performed before cold piecemeal snare resection. We used a conventional EMR injectate comprising succinylated gelatin 4% (Gelofusine, B. Braun Australia Pty Ltd), methylene blue, and dilute epinephrine (0.01 mg/mL).[23] Epinephrine was omitted from the injectate in the second half of the study period, to ensure it did not mask clinically significant bleeding. We used a 23-gauge injector needle (NM-610U-0323, Olympus Australia), and 1 of 3 snares at the discretion of the colonoscopist (Exacto, U.S. Endoscopy, Belrose, Australia, Captivator II 10 mm Boston Scientific, Mascot, Australia, Accusnare 15 mm minihexagonal, Cook Medical, Eight Mile Plains, Australia).

After endoscopic injection, the polyp and a margin (3-4 mm) of normal tissue were removed by cold snare in a piecemeal fashion. All lesions were retrieved and evaluated by gastrointestinal pathologists.

Resection technique

We used a consistent cold EMR technique, standardized between the endoscopists (Figure 1A-F, supplementary video 1):

- With the submucosal injection, we aimed to elevate the entire lesion with a margin of surrounding normal mucosa.
- Resection then commenced from one side of the lesion margin, including a margin (3-4 mm) of normal tissue.
- After injection, the first capture of tissue by the snare wire was sometimes difficult, particularly with a very flat lesion and adjacent normal mucosa which is often tense with submucosal injectate. Downward angulation of the instrument tip with forward movement to anchor the snare catheter assisted tissue capture,[14, 24] but we often tolerated a small initial resection. Once achieved, this initial resection permitted easy access to the submucosal space for subsequent snare placement and tissue capture along the advancing resection margin.
- The transparent distal cap allowed for gentle suction of the target tissue to enhance tissue capture.
- For each snare resection, we aimed to snare about 8 to 10 mm of tissue avoiding excessive submucosal tissue capture which may preclude efficient tissue transection. Where transection stalled, we used a standardized technique to facilitate cutting without resnaring the tissue.[14] First, we maintained full snare closure to allow slow transection, followed by techniques to maximize force transmission from the snare handle or release entrapped submucosa.
- During resection, we generously washed the defect via the auxiliary water channel to facilitate suction of specimen fragments and further expand the submucosal space to aid resection.

- We continued resection until all visible polyp tissue was removed, with a generous 3 to 4 mm margin of normal tissue. Narrow-band imaging was used to inspect for residual serrated crypts along the resection margin. In the case of uncertainty about residual polyp tissue, further snare resection of the area was always performed.
- We retrieved all tissue fragments through the suction channel, typically progressively during the resection and without removal of the snare catheter.
- All specimen fragments were submitted for histopathologic evaluation.
- After resection and defect washing was complete, we sampled the margins of the defect using cold biopsy forceps (Radial Jaw 4, Boston Scientific, Mascot, Australia)[8] Biopsy sampling was evenly spaced around the marginal circumference of the defect to assess for residual microscopic polyp tissue. We obtained a minimum of 4 biopsy specimens for each defect, with at least 6 biopsies for lesions 20 mm or greater in size. These biopsy specimens were submitted separately to the polyp specimens.
- Defects were observed for a minimum of 60 seconds to exclude persistent intraprocedural bleeding. Persistent bleeding was treated with endoscopic clips. No thermal therapy of any form was applied during or after resection.

Outcomes and statistics

The primary study outcomes were the per lesion rate of positive margin biopsies, per lesion rate of residual serrated neoplasia detection on surveillance, and the adverse event rate after cold EMR. Descriptive data were generated for all variables. All categorical data were expressed as proportions; all continuous data were expressed as means unless indicated. The study was descriptive of our experience

in clinical practice, and therefore our sample size was arbitrary and based on the time period of the study.

All patients followed standard postcolonoscopy recovery and clinical follow-up. All patients were contacted at 30 days by telephone and all adverse events were recorded after a structured interview. After cold EMR, patients were scheduled for early interval surveillance colonoscopy within 12 months as recommended in Australian guidelines[25] and suggested by the U.S. Multi-Society Task Force on Colorectal Cancer surveillance guidelines for piecemeal resection.[26] Biopsy results were used to guide patient surveillance intervals. Patients with positive-margin biopsies were scheduled for surveillance colonoscopy at 3 to 6 months, and patients with negative biopsies had surveillance scheduled within 12 months at the discretion of the endoscopist and based on the overall polyp burden, polyposis phenotype, and presence of dysplasia. At surveillance, the EMR site was identified and endoscopically evaluated in white light and narrow-band imaging. An example of residual serrated tissue within a cold EMR scar is seen in figure 2.

Results

We performed cold EMR on 163 lesions (mean 17.5 mm, median 15 mm, range 10-40 mm) during 105 procedures in 99 patients (30.3% male; median age 57 years) over 18 months between November 2015 and May 2016 (Table 1). All lesions were successfully removed in a single session using cold EMR, with no conversion to conventional EMR with electrocautery, full-thickness, or surgical resection. Lesions were predominantly (97.5%) located in the proximal colon. There were 61 lesions >20 mm in size and 13 lesions ≥30 mm in size. Histology showed sessile serrated polyps in all lesions. Unanticipated cytological

dysplasia was identified in 2 (1.2%) lesions only. No residual serrated tissue was identified in these 2 cases on margin biopsies or surveillance colonoscopy.

Efficacy

In 2 of the 163 lesions (1.2%), a single margin biopsy (one of 4) contained residual serrated tissue. These lesions were a 10 mm cecal SSP and a 15 mm descending colon SSP. In both patients, we performed early interval surveillance at 6 months. In the first case a 1 mm focus of serrated tissue was identified at the site. This was removed using CSP without injection and a wide margin of normal tissue was obtained without adverse event. There was no residual tissue at second surveillance (12 months) colonoscopy. In the second case, there was no residual tissue identified at the site at either first (4 months) or second (9 months) surveillance colonoscopy.

Surveillance colonoscopy data are available for 134 lesions (82.2%) at a median interval of 154 days. Residual serrated tissue was identified for a single lesion only (0.6%), in which a positive margin biopsy was returned at the time of the original EMR.

Safety

Intraprocedural bleeding lasting greater than 60 seconds occurred at a single resection site. This was after resection of a 12-mm ascending colon SSP in which bleeding was observed in the center of the defect after snare resection before margin biopsy. The patient was not on aspirin, and no epinephrine was used in the injectate. Bleeding was controlled with 2 hemostatic clips (Instinct, Cook Australia) with immediate hemostasis and no further adverse events.

Minor post procedural bleeding which settled within 48 hours without need for physician review or hospital admission was seen in 2 cases. Pain requiring readmission to hospital within 24 hours was observed in a single patient. This patient had undergone colonoscopy to investigate recurrent unexplained abdominal pain. There were no findings on clinical examination, blood tests, or CT scan, and the patient was discharged well without pain within 24 hours.

Discussion

In this prospective study of 163 SSPs ≥10 mm, we have shown the safety and efficacy of cold piecemeal EMR. Adverse events were minor, rare and comparable with rates seen with CSP for small and diminutive polyps.[5] The efficacy of cold EMR was substantial, in comparison with previous reports of conventional hot snare polypectomy in which incomplete resection rates of up to 47% have been observed.[8] Residual serrated tissue was only seen in margin biopsies in 2 out of 163 (1.2%) lesions, and in only one of these cases at follow-up (0.6%) that was easily treated with CSP. To our knowledge, this is the largest study of cold polypectomy for large (≥10 mm) polyps and the only study where EMR margin biopsies have been performed to assess for efficacy.

Other studies in adenomatous and serrated polyps have assessed the safety of piecemeal CSP,[15 16] and efficacy,[17, 18] although none have specifically evaluated serrated lesions. An Argentinian study assessed safety of piecemeal CSP without submucosal injection in 171 small and large polyps (43 were 10-20mm) in which the sole adverse event was postcolonoscopy pain that quickly settled.[15] Efficacy was not assessed. A small retrospective U.S. study also assessed safety of piecemeal CSP after submucosal

injection in fifteen patients with a colonic lesion 12 to 45 mm in size.[16] Cold biopsy forceps were also used to remove residual endoscopically visible polyp. Efficacy was not assessed. Adverse events occurred in 4 patients, including readmission for abdominal pain in 1 patient and low-volume hematochezia that did not require intervention in 3 patients.

Two retrospective studies have assessed the safety and efficacy of cold piecemeal polypectomy after submucosal injection.[17, 18] Piraka et al[17] reported on 94 polyps ≥10 mm in size in 73 patients removed with cold piecemeal polypectomy after injection and included cases with the adjunctive use of cold biopsy forceps.[17] Intraprocedural bleeding requiring a clip was seen in 1 case. No additional adverse events were recorded. Seventy-two lesions were assessed at surveillance colonoscopy with residual polyp identified in 9.7%. Residual polyp was universally adenomatous. Muniraj et al reported on 30 polyps (10-30 mm) where adjuvant thermal therapy with argon plasma coagulation of polypectomy margins and bleeding sites was applied in 30%.[18] Surveillance identified residual neoplasia in 20%, which was treated predominantly with cold biopsy forceps. The concept of applying adjuvant thermal therapy, in our view, blurs the cold versus hot paradigm, and eliminates the risk reduction of cold resection.

We found residual serrated neoplasia at surveillance in only a single lesion (0.6%), which contrasts markedly with these cold resection studies[17, 18] and conventional techniques. [10,12] The reasons for this require further study, but possibly reflect lesion biology and technique. Our study only included endoscopically non-dysplastic serrated lesions, which we consider to be ideal lesions for cold EMR. Cold resection of adenomas may be less efficacious due to biology or morphology. Further, we used a standardized and fastidious cold EMR technique that required a generous margin of normal tissue,

resection of further tissue where any question of residual remained, and repeated washing of the defect. Further study of this technique with adenomatous lesions is required.

Our cold EMR technique has clear advantages over conventional hot snare polypectomy for SSPs. It eliminates the risks of electrocautery, and is a simple modification of current conventional EMR technique. Some may argue that submucosal injection is not required, however from our experience it appears to offer several benefits. First, submucosal injection clearly delineates the margins of the lesion (Figure 1), which can be extremely difficult to distinguish and may contribute to the failure of conventional techniques.[8] By expanding the submucosal space, injection also appears to make tissue transection easier with the snare less likely to stall and fail to cut; rather, the snare wire squeezes the submucosal fluid during closure and effectively separates the mucosa from the submucosa. Finally, bleeding is typically minimal and careful inspection of the defect margins using magnified NBI is possible without loss of view from a bloody field.

There are limitations to our study. Although biopsies from the margin of the polypectomy defect have been widely used to assess for residual neoplasia,[8, 27, 28] its validity is not assured and focal residual polyp may have been missed. We took 4 margin biopsy specimens for lesions up to 20 mm in size and 6 for larger lesions; however, a substantial portion of the margin remained unsampled. This technique also assumes that residual polyp tissue is not harbored in the base of the polypectomy defect. Given these shortcomings, we therefore validated our margin biopsy findings with data from surveillance of the polypectomy site in 82% of lesions, and identified no residual serrated tissue when margin biopsies were negative. However, we did not tattoo the original resection site or take biopsies from the polypectomy site on surveillance, and surveillance was not complete. Finally, our study was not a randomized clinical

trial, and also findings may not be generalizable as procedures were performed by 2 experienced endoscopists at a single center with an interest in colonoscopic polypectomy.

Further study of cold resection techniques for both serrated and adenomatous lesions >10 mm in size is required.[14] Although a stiff thin wire snare appears more efficacious for CSP of <10 mm polyps,[29] the ideal snare characteristics for cold EMR after injection where the distended mucosa can be challenging to initially capture, are unstudied. The constituents of the ideal injectate for cold EMR are unknown as is the need for preinjection at all. We used a well described conventional EMR injectate solution with demonstrated superiority to saline.[23] During the study, we omitted epinephrine without clinically significant bleeding, additional adverse events or reduction in efficacy. Anecdotally, we did observe more minor venous bleeding after discontinuing epinephrine, although its role in preventing or delaying clinically significant bleeding is unclear. We did not assess the time taken for cold EMR, but it may be quicker than conventional EMR and so the advantages of a more viscous injectate may be less relevant.

Cold EMR shows excellent promise for the resection of large colonic SSPs, which to date have been poorly served by conventional polypectomy techniques designed for the treatment of adenomas. It uses equipment and techniques already available and familiar to established colonoscopists. Further definition of the technology requirements for this technique are required, before randomized trials and multicenter study outside of an expert center before its widespread adoption can be considered.

Table 1. Characteristics of the patients, lesions and findings on surveillance.

Patients, n	99
Male, n (%)	30 (30.3)
Median age, years	57
Colonoscopies, n	105
Lesion, n	163
Size: mean / median, mm	17.5 / 15
≥ 20 mm, n (%)	61 (37.7)
≥ 30 mm, n (%)	13 (21.0)
Location	
Proximal colon, n (%)	159 (97.5)
Cecum, n (%	21 (12.9)
Ascending colon, n (%)	59 (36.2)
Transverse colon, n (%)	79 (48.5)
Descending colon, n (%)	4 (2.5)
Snare type used, n (%)	
Exacto	77 (47.2)
Captivator II 10mm	70 (42.9)
Accusnare 15mm minihexagonal	16 (9.8)
Histology	
Sessile serrated adenoma/polyp, n (%)	163 (100)
With cytologic dysplasia, n (%)	2 (1.2)
Positive margin biopsy, n (%)	2 (1.2)
Surveillance (per lesion)	
Surveillance completed	134 (82.2%)
Surveillance interval: median, days	154
Positive surveillance, 1 (%)	1 (0.92)

Figures

Figure 1. Cold EMR of 20 mm transverse colon SSP. The mucus cap (A) is washed to permit detailed examination of the polyp surface (B). The entire lesion is elevated with submucosal injection (C). Cold piecemeal snare resection begins at the lesion margin with careful and deliberate inclusion of margin of normal tissue; the white lesion margin is clearly visible against the blue injectate (D). Cold snare resection is repeated to remove the entire lesion with a margin of normal tissue (E). The cold EMR defect margin is interrogated with magnified narrow-band imaging to assess for residual serrated tissue (F).

Figure 2. An example of residual serrated tissue (*yellow arrows*, A-B) in a cold EMR scar at 6-month surveillance colonoscopy. A subtle linear area of residual serrated tissue at the right margin of an otherwise bland scar viewed under white light A). Endoscopic features of serrated tissue, thin lacy vessels and dark spots, appreciable with magnified narrow-band imaging (B). The focus of residual serrated tissue and adjacent normal mucosa and bland scar all removed with cold snare polypectomy without submucosal injection (C).

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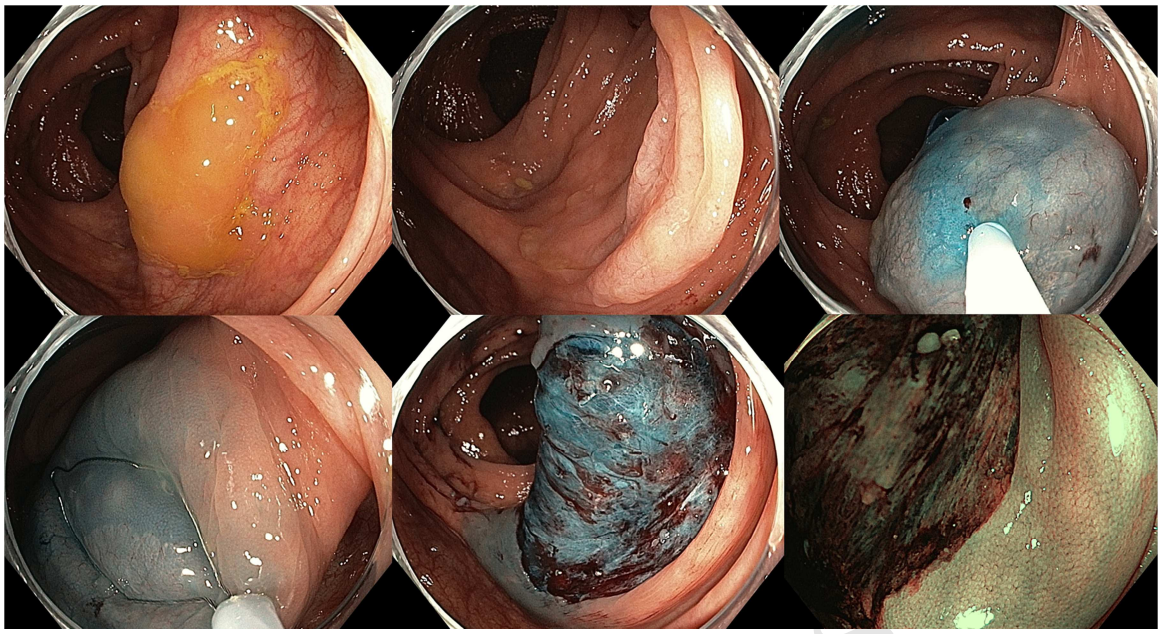

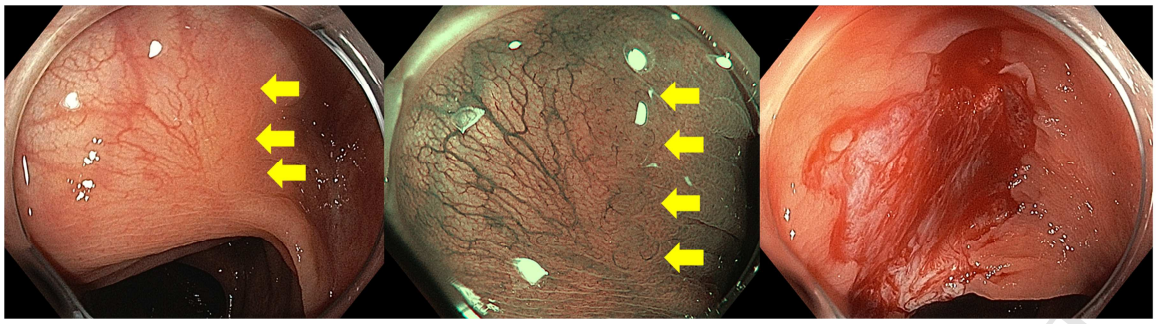

Abbreviations: CSP, cold snare polypectomy; EMR, endoscopic mucosal resection; HSP, hot snare polypectomy; SSP, sessile serrated polyp.