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Safety of cold resection of non-ampullary duodenal polyps: Systematic review and meta-analysis

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Keywords
Endoscopy Upper GI Tract, Endoscopic resection (ESD, EMRc, ...), Endoscopy Small Bowel, Neoplasia

received 25.4.2023
accepted after revision 22.3.2024
accepted manuscript online 15.4.2024

Bibliography
Endosc Int Open 2024; 12: E732–E739
DOI 10.1055/a-2306-6535
ISSN 2364-3722

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Supplementary Material is available at https://doi.org/10.1055/a-2306-6535

ABSTRACT

Background and study aims Endoscopic resection has traditionally involved electrosurgical cautery (hot snare) to resect premalignant polyps. Recent data have suggested superior safety of cold resection. We aimed to assess the safety of cold compared with traditional (hot) resection for non-ampullary duodenal polyps.

Methods We performed a systematic review ending in September 2022. The primary outcome of interest was the adverse event (AE) rate for cold compared with hot polyp resection. We reported odds ratios with 95% confidence intervals (CIs). Secondary outcomes included rates of polyp recurrence and post-polypectomy syndrome. We assessed publication bias with the classic fail-safe test and used forest plots to report pooled effect estimates. We assessed heterogeneity using I_2 index.

Results Our systematic review identified 1,215 unique citations. Eight of these met inclusion criteria, seven of which were published manuscripts and one of which was a recent meeting abstract. On random effect modeling, cold resection was associated with significantly lower odds of delayed bleeding compared with hot resection. The difference in the odds of perforation (odds ratio [OR] 0.31 [95% confidence interval [CI] 0.05–2.87], $P=0.2$, $I_2=0$) and polyp recurrence (OR 0.75 [95% CI 0.15–3.73], $P=0.72$, $I_2=0$) between hot and cold resection was not statistically significant. There were no cases of post-polypectomy syndrome reported with either hot or cold techniques.

Conclusions Cold resection is associated with lower odds of delayed bleeding compared with hot resection for duodenal tumors. There was a trend toward higher odds of perforation and recurrence following hot resection, but this trend was not statistically significant.

Introduction

Tumors of the duodenum are rare compared with those of other parts of the gastrointestinal tract [1].Duodenal carcinomas represent a mere 0.5% of all malignant gastrointestinal tumors. Among patients undergoing esophagogastroduodenoscopy (EGD), the prevalence of duodenal polyps is 0.4% [2,3]. When polyps are detected, though, the duodenum presents a

particularly challenging location for resection [1, 4, 5].Both surgical and endoscopic resection of duodenal polyps can be complex and invasive due to anatomical restrictions such as the anatomical proximity to the head of the pancreas and the biliary system [2, 6].Endoscopic submucosal dissection within the duodenum has been shown to be especially difficult and prone to adverse events (AEs) such as bleeding and perforation due to the very thin muscular layer of the duodenum [7, 8, 9, 10].

Resection of duodenal polyps can be done by cold or hot resection. Cold resection includes cold-snare polypectomy (CSP, without submucosal injection), or by cold endoscopic mucosal resection (c-EMR). Hot or traditional resection includes hot-snare polypectomy (HSP) or hot EMR. EMR is a well-established technique that has been shown to be a safe and effective method for rection of duodenal polyps [11]. Traditional EMR carries a small risk of bleeding and perforation [12]. Cold resection methods have recently been gaining momentum as safer alternatives to hot resection for treatment of colonic polyps, and limited data have supported its use in the duodenum as well [7, 13, 14, 15].The absence of thermal injury to the muscularis propria is thought to reduce rates of delayed bleeding and perforation. However, robust data on use of cold resection in the duodenum remain sparse.

We, therefore, aimed to conduct a systematic review and meta-analysis comparing cold resection versus hot resection of non-ampullary duodenal polyps and to compare rates of early and delayed AEs between the two techniques.

Patients and methods

Study selection

This study was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines using a protocol developed a priori by the study team [16]. Our protocol was not registered. We included all studies of non-ampullary duodenal polyps that included CSP or C-EMR or compared these techniques to HSP or H-EMR. Inclusion criteria were as follows: 1) randomized controlled clinical trials, prospective studies, retrospective studies, or meeting abstracts from 2017 to 2022; 2) studies that were published in peer-reviewed journals; and 3) endoscopically diagnosed non-ampullary duodenal polyps (biopsy before treatment was not necessary). Studies were excluded if they were: 1) studies of ampullary polyps or lesions; 2) case reports or case series (10 or less patients); and 3) English language full text were not available.

Search strategy and data extraction

The literature search was conducted with the help of an expert health science librarian (RR). We searched MEDLINE (Ovid), Web of Science, Embase, Cochrane Library and CENTRAL, and World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) from inception. Details of our search strategy are listed in Appendix 1. The last update of the search was in September 2022. The PRISMA 2020 checklist can be found in Appendix 2. Citations were saved as an EndNote library (Thompson Reuters, Carlsbad, California, United States) then imported into Covidence (Covidence.org). Duplicates were removed in both EndNote and Covidence. We reviewed the studies via titles and abstracts. Studies were excluded if they were not original articles (i. e., reviews, case reports, case series, editorials, or conference papers), or were irrelevant to the study topic. Based on our review of the full text, eight papers were included in the final meta-analysis.

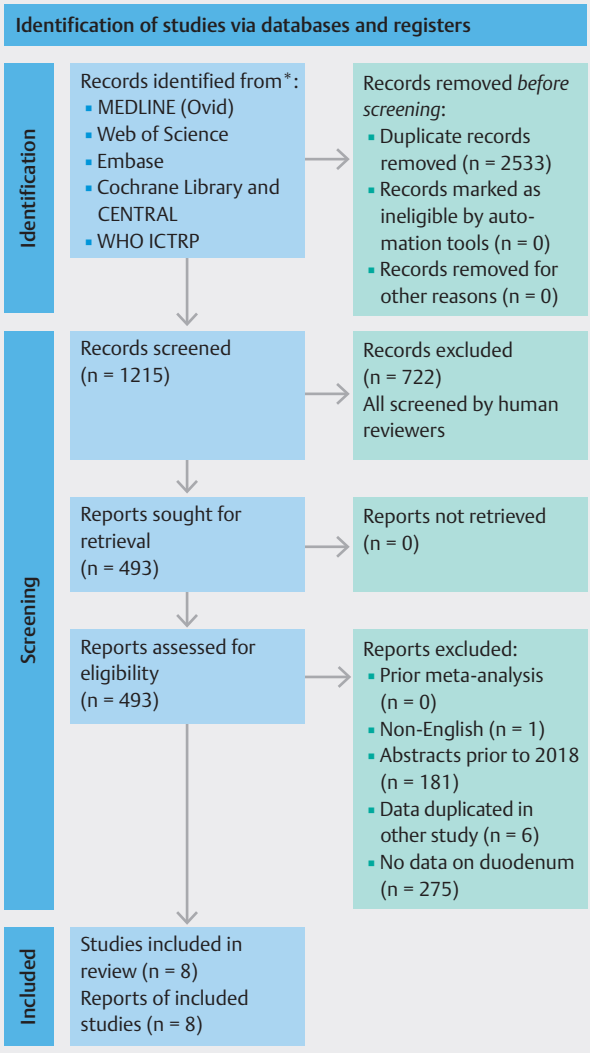
For each study the following data were extracted: primary author, publication journal and year, country/countries where the study was carried out, study design, number of patients, distribution of patient age, patient gender, race (if reported), endoscopic equipment, endoscopic techniques, number of endoscopists in the study, prevalence of duodenal polyps in the study population (if reported), mean and range of polyp sizes, morphology and histology of polyps, en-bloc resection rate, rates of complete resection with each technique, and post-procedure AEs (early bleeding, delayed bleeding, transfusion need, early perforation, delayed perforation, readmission, polypectomy syndrome, and polyp recurrence rate following complete resection).

Outcome of interest and quality assessment

The study was designed based on the PICO (population, intervention, control, and outcomes) format. The population of interest were patients with duodenal polyps who had polypectomy. The intervention was cold resection; the comparator was hot resection. Outcomes of interest included: AEs, residual polyp rate, recurrent polyp rate, and cost-effectiveness.

AEs included: early bleeding (defined as bleeding that occurred during the procedure or within 24 hours), delayed bleeding (defined as bleeding that occurred more than 24 hours after the procedure), early perforation (documented by cross-sectional imaging or endoscopy), delayed perforation (perforation more than 24 hours after the procedure), blood transfusion need, readmission (defined as patient being readmitted for a polypectomy complication), post-polypectomy syndrome, residual polyp rate (defined as histology-confirmed residual polyp on biopsies done during procedure), and recurrent polyp rate (defined as finding polyp tissue at the site of previous polypectomy on follow-up endoscopy). EMR was defined as submucosal injection with a lifting solution followed by resection using a snare. Many patients with bleeding required endoscopic intervention (cautery, injection with epinephrine, or clipping). In a sensitivity analysis, we identified the rate of delayed bleeding in H-EMR. We used the historic data to perform an indirect analysis comparing the rates of bleeding in CSP (as identified by our study) compared with HSP (as identified from previous meta-analysis).

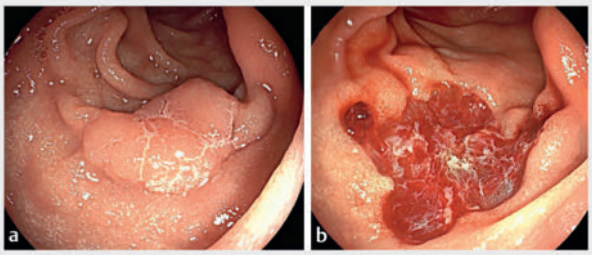
We used the Quality Assessment for Meta-Analysis Scoring system (Qumseya scale) for quality assessment of individual studies [17]. Quality assessment was conducted only for the manuscripts that were included, because abstracts lack sufficient information to properly assess their quality. The results were reported quantitatively. Studies deemed to be outliers or of low quality were removed from the analysis. Studies were deemed to be outliers based on an effect estimate that was six to eight times higher or lower than the pooled effect estimate, as previously reported [18, 19].



▶ **Fig. 1** PRISMA plot of the included studies.

Statistical analysis

The primary effect estimate was the odds ratio (OR) of AEs in cold compared with hot techniques (for comparative studies). All analyses were done per patient (not per polyp). We decided a priori to use random effects modeling, DerSimonian and Laird, in all analyses. We reported outcomes using forest plots. We used I^2 (the ratio of true heterogeneity to total observed variation) to measure heterogeneity. We used the classic fail-safe test to check for publication bias. For studies with no patients having the outcome of interest, a correction number of 0.1 was used instead of zero. We used CMA V3 (BioSTAT, Inc., Englewood, New Jersey, United States) for all statistical analyses.



▶ **Fig. 2** **a** 15-mm duodenal adenoma and **b** same location after cold snare resection.

Results

Our searches resulted in 3,748 citations. Of these, 2,533 were removed as duplicates; 1,215 were screened by title and abstract; 722 were excluded as irrelevant by title and abstract, leaving for 493 for detailed review. Of these, eight met inclusion criteria [7, 20, 21, 22, 23, 24, 25, 26] and were included in the analysis. Seven [7, 21, 22, 23, 24, 25, 26] were published manuscripts, and one [20] was a recent meeting abstract (▶ **Fig. 1**). These eight studies included 470 patients. Mean polyp size ranged from 3 to 25.5 mm. An example of cold-snare resection from the authors' institution is shown in (▶ **Fig. 2**).

We identified three comparative studies [20, 21, 22], (1 prospective and 2 retrospective). Two of these studies [20, 22] compared hot and cold EMR. The third study [21] included a mix of EMR and CSP (▶ **Table 1**). A total of 206 patients underwent polypectomy with hot resection, of whom 39 suffered delayed bleeding. There were no cases of delayed bleeding reported in the 95 patients who underwent cold resection. On random effect modeling, the odds of delayed bleeding were significantly lower in cold resection compared with hot resection (OR 0.067; 95% CI 0.013–0.35; $P = 0.001$). No heterogenicity was detected with $I^2 = 0\%$, (▶ **Fig. 3a**).

From the five non-comparative studies [7, 23, 24, 25, 26] there was one confirmed case of delayed bleeding [25] out of 169 patients who had polypectomy with cold resection. On meta-analysis, using random effects modeling, the pooled odds of delayed bleeding for resection were 2% (95% CI 1.3–3.2%; $P < 0.001$) (▶ **Fig. 3b**). No heterogenicity was detected, with $I^2 = 0\%$. Removing the data from the only abstract did not change the results (OR 1.6%; 95% CI 0.3–8.6%; $P < 0.001$; $I^2 = 0$).

The comparative studies reported no cases of perforation with cold resection (0 of 95), whereas there were 12 cases of perforation (early or delayed) out of 206 treated with hot techniques. This difference did not reach statistical significance on meta-analysis (OR 0.31; 95% CI 0.05–2.87; $P = 0.2$; $I^2 = 0$). Similarly, there were no early or delayed perforations reported in the non-comparative studies.

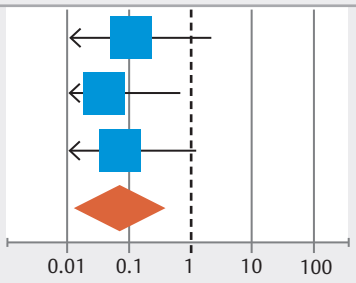
Polyp recurrence was noted in nine of 95 patients who had cold resection, compared with 30 of 206 patients treated with hot techniques. On meta-analysis, there was a trend toward a lower recurrence rate in the cold resection group compared with the hot resection, but this trend was not statistically signif-

▶ **Table 1** Patient and study characteristics of each of the included studies.

Study	Study type	Pub type	Procedure	Sample size (# lesions)	Sample size (# patients)	% Male	Mean age (yrs)	Poly size included (mm)	Mean polyp size (mm)	Delayed bleed	Perforation	# of endoscopists	Qumseya score
Beany 2022	Retrospective, comparative	Abstract	EMR	57	57	51.4	65.25	>10	25.5	0 cold 6 hot	0 cold 1 hot	NR	NR
Trivedi 2022	Retrospective, comparative	paper	HSP (66.2% EMR) CSP (37% EMR)	120	41 cold 69 hot	68 cold 49 hot	72 cold 68 hot	≥5	12 cold 15 hot	0 cold 6 hot	0 cold 1 hot	7	8
Repici 2022	Retrospective, comparative	paper	EMR	NR	33 cold 101 hot	55 cold 42 hot	63 cold 68 hot	NR	NR	0 cold 1 hot	0 cold 10 hot	4 European Centers	6
Takizawa 2021	Prospective, non-comparative	paper	CSP	21	21	76.2	71	≤10	8	0	0	4	7
Daisuke 2017	Prospective, non-comparative	paper	CSP + CFP	39	30	66.7	64.1	<6	3.9	0	0	1	6
Okimoto 2021	Retrospective, non-comparative	paper	CSP	46	35	68.6	66.6	<10	4.2	0	0	NR	6
Dang 2022	Retrospective, non-comparative	paper	CSP	39	39	30.8	66.8	>10	26.6	1	0	5	6
Okimoto 2021	Retrospective, non-comparative	paper	CSP + CFP	57	44	68.1	66	<10	3	0	0	NR	6

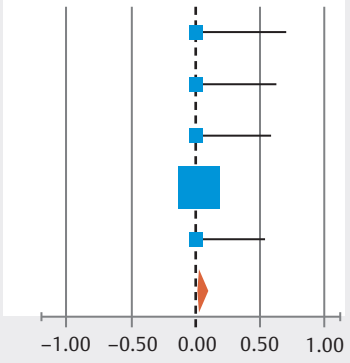
C-EMR = cold endoscopic mucosal resection. H-EMR = hot endoscopic mucosal resection. CSP = cold snare polypectomy. HSP = hot snare polypectomy. NR = not reported

Study name	Statistics for each study				Events/Total		Odds ratio and 95% CI	Relative weight
	Odds ratio	Lower limit	Upper limit	*P*-Value	cold	hot		
Beany 2022 (EMR)	0.109	0.006	2.041	0.138	0/21	6/36		31.99
Trivedi 2022	0.039	0.002	0.670	0.025	0/41	16/69		33.97
Repici 2022 (EMR)	0.072	0.004	1.233	0.069	0/33	17/101		34.04
	0.067	0.013	0.350	0.001				



a

Study name	Statistics for each study					Odds ratio and 95% CI	Relative weight
	Event rate	Lower limit	Upper limit	*P*-Value	Total		
Takizawa 2021	0.005	0.000	0.705	0.092	0/21		7.25
Daisuke 2017	0.003	0.000	0.624	0.072	0/30		7.26
Okimoto 2021	0.003	0.000	0.587	0.064	0/35		7.26
Dang 2022	0.026	0.004	0.530	0.055	0/39		70.96
Okimoto 2021c	0.002	0.000	0.530	0.055	0/44		7.27
	0.014	0.003	0.071	0.000			



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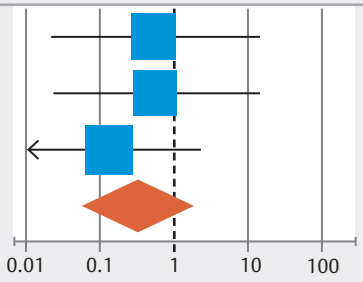
Study name	Statistics for each study				Events/Total		Odds ratio and 95% CI	Relative weight
	Odds ratio	Lower limit	Upper limit	*P*-Value	cold	hot		
Beany 2022 (EMR)	0.55	0.02	14.13	0.718	0/21	6/36		30.33
Trivedi 2022	0.55	0.02	13.82	0.716	0/41	16/69		30.74
Repici 2022 (EMR)	0.13	0.01	2.28	0.163	0/33	10/101		38.93
	0.31	0.05	1.87	0.204				



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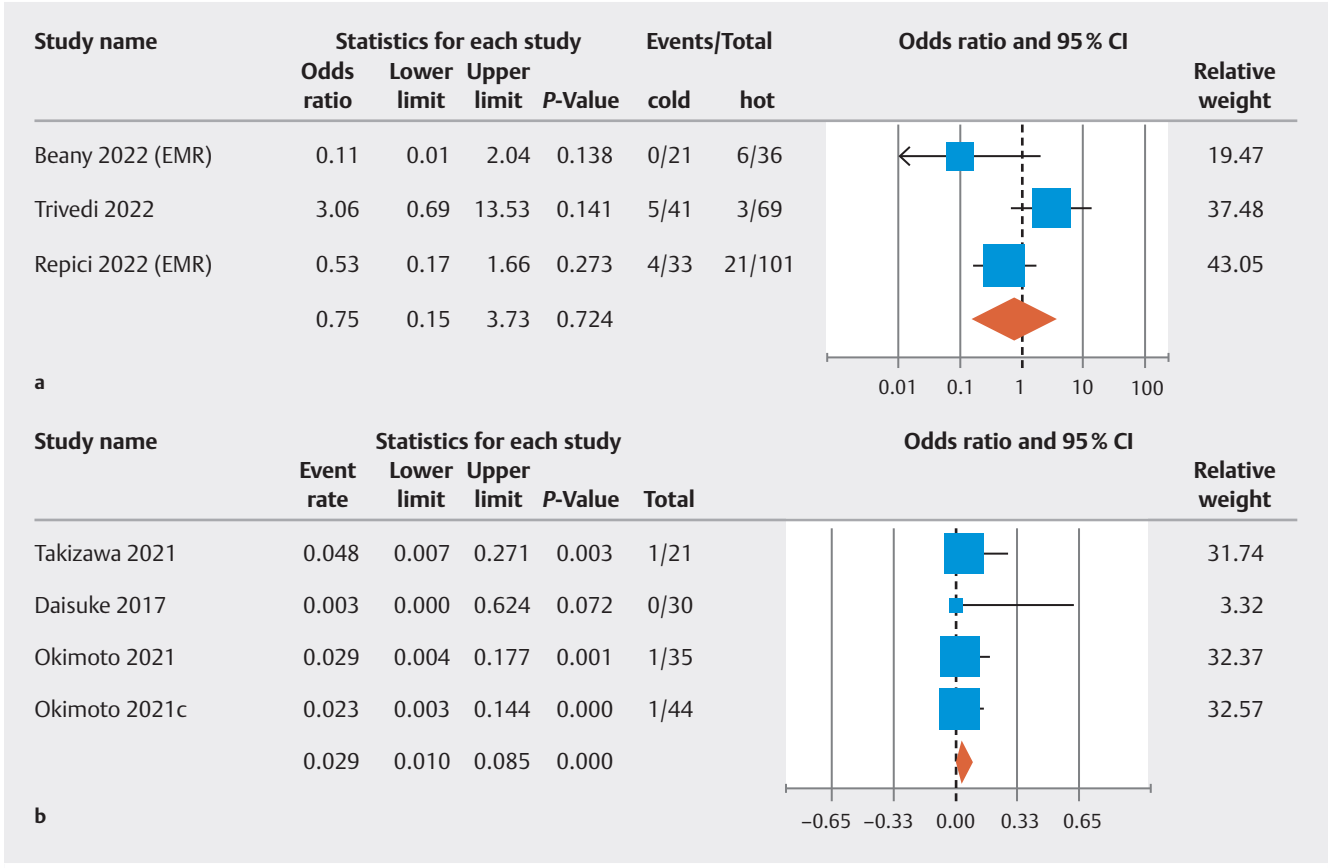
▶ **Fig. 3** Forest plots of: **a** odds of delayed bleeding in cold compared to hot resection of duodenal lesions; **b** rates of delayed bleeding in cold resection of duodenal polyps; and **c** odds of perforation in cold compared to hot EMR of duodenal lesions. EMR, endoscopic mucosal resection.

icant (OR 0.75; 95% CI; 0.15–3.73; $P=0.72$, $I^2=0$) (▶ **Fig. 4a**). The non-comparative studies that reported polyp recurrence had follow-up times ranging from 6 months to 3 years. All studies defined recurrence as histologically confirmed dysplastic or metaplastic tissue at follow-up surveillance colonoscopy. One study [24] was removed from the pooled analysis due to being an outlier. The pooled rate of polyp recurrence was 2.9% (95% CI 1%–8.5%; $P<0.001$, $I^2=0\%$) (▶ **Fig. 4b**).

Quality assessment and publication bias

All included studies had adequate scores on the Qumseya scale [16]. Funnel plots were not assessed due to the low number of studies (10 studies are generally required to generate an adequate funnel plot). However, using the fail-safe test, we found that the risk of publication bias was low; 26 negative studies would be needed to reach $P>0.05$.



▶ **Fig. 4** Forest plots of: **a** odds of polyp recurrence in cold compared with hot resection of duodenal polyps; and **b** rates of polyp recurrence after cold resection of duodenal lesions.

Discussion

In this systematic review and meta-analysis, we report that cold resection (CSP and C-EMR) of non-ampullary duodenal polyps is associated with lower AE rates than hot resection (HSP and H-EMR). Cold resection was associated with lower rates of early bleeding, delayed bleeding, and perforation. Rates of polyp recurrence were similar in both groups. To our knowledge, this is the first systematic review with meta-analysis to evaluate cold resection compared with hot resection for duodenal polyps.

Clinical implications

Despite the low rate of adenomas and carcinomas in the duodenum compared with the colon, duodenal polyps requiring endoscopic resection are often encountered, especially in tertiary centers and advanced endoscopy programs [27]. The elevated rate of AEs in the duodenum is multifactorial; the thinner duodenal wall, increased vascular supply around the head of pancreas, and impaired endoscopic maneuverability within the duodenum likely all play contributing roles [13]. Rates of delayed bleeding in our pooled analysis of hot resection (39 of 206) are consistent with bleeding rates of 18% to 22% quoted in prior studies [5, 6, 28, 29]. In comparison, delayed bleeding following cold resection occurred in only one of the 169 patients in the observational studies and none of the patients in the comparative ones.

Perforation is the most serious and second most common potential complication of polypectomy [30]. A recent literature review from Switzerland showed that two of 78 patients diagnosed with non-ampullary duodenal adenomas suffered from early perforation during traditional HSP (2.6%) [31]. Fortunately, both of these perforations were treated with an over-the-scope clip device [32]. On the other hand, our systematic review found that cold techniques carry a lower rate of perforation. Given the rarity of perforation, the statistical significance of this finding suggests a substantial difference in perforation risk between the two modalities. We suggest that by sparing patients electrocautery, cold resection protects the thin muscularis layer, thereby minimizing perforation risk. Although the anatomy and technical details of polypectomy in the colon are vastly different, it is notable that emerging data from the lower gastrointestinal tract have supported a similar conclusion [32].

A common justification for electrocautery is its higher chances of achieving en-bloc resection. We did not report this outcome because it is self-evident that cold resection is much less likely to achieve en-bloc resection of large polyps (>10 mm). However, this is the same reason that cold resection has a superior safety profile; it cannot cut through deeper submucosal blood vessels or injure the muscularis propria. In addition, we

argue that en-bloc resection is unnecessary for most duodenal polyps. In our experience, most polyps encountered in general endoscopy and even in advanced endoscopy practices can safely be removed piecemeal. This point is further supported by the similar rates of recurrence across hot and cold resections as well as the low overall recurrence rate of 2.9% in cold resection studies. As noted in the results, we excluded one study [25] from this analysis because the study reported 18 recurrences among 39 patients, a rate much higher than expected and that may represent a poor technique or early learning experience.

Our systematic review did not identify a study analyzing cost-effectiveness of cold resection. One of the manuscripts [25] did speculate about how procedure time, complication rates, and timing of surveillance endoscopy may impact cost. One prospective non-comparative study [33], which was excluded from the meta-analysis, mentioned an increase in health care costs following "not negligible number of bleeding episodes following HSP."

Therefore, we believe that the benefits of en-bloc resection with hot techniques are outweighed by the increased rate of AEs. The authors postulate that an evidence-based shift to cold resection would result in a significant drop in AE rates.

Strengths and limitations

There are several strengths to our systematic review and meta-analysis. To our knowledge, this is the first meta-analysis to compare cold versus hot techniques for resection of duodenal polyps with AEs as the primary outcome of interest. Second, our study focused on comparative studies but used observational studies as supportive evidence. The heterogeneity was low in all comparisons.

Our analysis does have several limitations. First, the number of studies included was low, with most of them being non-comparative and none of them being randomized controlled trials. Therefore, the overall quality of the included data is likely low to moderate. Second, many of the cohort studies were small, retrospective, and single center. In addition, we cannot rule out some patient overlap in some of the studies. For example, three of the included studies [23, 24, 26] were from the same center but were conducted during different time periods. Furthermore, there was widespread variation in definitions of AEs. For example, the amount of blood loss required to count as "early bleeding" ranged from any visible oozing at the site to brisk bleeding requiring blood transfusion. In addition, the rates of AEs are low overall, thus lowering the power of the study to detect some differences. Finally, the follow-up times for assessment of recurrence ranged from 6 months to 3 years.

Conclusions

This systematic review and meta-analysis showed that cold resection for non-ampullary duodenal polyps caused fewer AEs than the traditional hot techniques without any significant difference in adenoma recurrence rates. This meta-analysis supports the routine use of cold polypectomy techniques as first line over hot polypectomy techniques for such duodenal polyps. These findings are consistent with recent data from other parts of the gastrointestinal tract indicating that cold resection is safer than hot resection. Our results add to the mounting evidence that cold resection techniques should be more widely adopted to minimize risks of delayed bleeding and perforation in duodenal polyps.

Conflict of Interest

Dr. Qumseya is a consultant for Medtronic, Assertio Management, and Endogastric Solutions, and is a speaker for Castle Biosciences. All of the other authors confirm that they have no conflicts of interest.

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