

Meta-Analysis

Cannulation rates and technical performance evaluation of commercially available single-use duodenoscopes for endoscopic retrograde cholangiopancreatography: A systematic review and meta-analysis

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ABSTRACT

Background: Single use duodenoscopes were developed to reduce the risk of infection transmission from contaminated reusable duodenoscopes. To this end, we examined various biliary interventions using single use duodenoscopes in patients undergoing endoscopic retrograde cholangiopancreatography (ERCP).

Methods: Medline, Embase, Scopus, and Cochrane databases were searched from inception through Aug 2022 to identify studies reporting on the performance of single use duodenoscopes for ERCP.

Results: Seven articles were included in the final analysis that included 642 patients (318 males). The Exalt Model D duodenoscope was used in most cases (88.8%) followed by the aScope Duodeno (11.2%) for ERCP. Most ERCPs had a complexity grade of 2 ($n = 303$) and 3 ($n = 198$). The pooled cumulative rate of successful cannulation was 95% (95% Confidence Interval (CI): 93–96%, $I^2=0\%$, $P = 0.46$). Sphincterotomy was successfully performed in all cases. The pooled cumulative rate of PEP was 2% (95% CI: 0.4–3.4%, $I^2=0\%$, $P = 0.80$). The pooled cumulative rate of total adverse events was 7% (95% CI: 4–10%, $I^2=47\%$, $P = 0.08$).

Conclusions: The results of this systematic review and meta-analysis show that single use duodenoscopes are associated with high cannulation rates, technical performance, and safety profile.

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1. Introduction

Duodenoscopes play a critical role in the diagnosis and treatment of diseases of the pancreas and bile ducts and are used in

more than 700,000 endoscopic retrograde cholangiopancreatography (ERCP) procedures annually in the United States [1]. Due to complex designs that include components that are difficult to access and fully disinfect, such as the elevator mechanism and the working channel, duodenoscopes containing retained microorganisms can result in patient-to-patient disease transmission. Current estimates suggest that the range of duodenoscope-related infection was 0.4%–1% and a 15.25% contamination rate of reprocessed patient-ready duodenoscopes [2,3].

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Over the past decade, outbreaks of multi-drug resistant infections (MDRI) have been linked to the use of traditional, reusable duodenoscopes [4]. Accordingly, in 2019 the FDA issued a safety communication, recommending transitioning to duodenoscopes with innovative designs that are either fully disposable or reusable with disposable components that would make reprocessing easier, more effective, or even unnecessary [5].

To date, the FDA has approved two single use duodenoscopes: the Boston Scientific Corporation (Marlborough, Massachusetts, USA), EXALT Model D single use duodenoscope (fully disposable duodenoscope cleared under K193202), and the Ambu Inc (Columbia, Md, USA), Ambu aScope Duodeno (fully disposable duodenoscope cleared under K201098) [6,7].

Disposable duodenoscopes have been commercially available for over 1 year but have yet to be widely adopted in the USA. Guidelines on the adoption of disposable duodenoscopes suggest that for most medium- and large-volume ERCP centers, a hybrid approach of using reusable duodenoscopes for most patients and single-use duodenoscopes for select patients is likely to be the selected strategy to allow for optimal performance and mitigate risks in high-risk groups [8]. However, guidelines also emphasize that there is limited long-term, high-volume data regarding the performance, risks, and costs associated with disposable duodenoscopes [8].

If the functionality of newly designed duodenoscopes is sub-optimal, then it will likely lead to trade-offs where one adverse event (i.e. infection) is reduced while possibly reducing the rates of technical and clinical success of ERCP procedures. As a result, it is important to determine whether disposable duodenoscopes are technically comparable to older, reusable duodenoscopes to inform clinical practice and future clinical guidelines. To this end, we examined the technical performance of various biliary interventions with the use of single use duodenoscopes in patients undergoing ERCP via a systematic review and meta-analysis.

2. Methods

2.1. Search strategy

Search strategies were created and performed by a librarian using inputs from the study authors using a combination of keywords and controlled vocabulary in the databases: Medline, Embase, Scopus, and Cochrane from inception through November 2022. Key words used in the literature search included a combination of “disposable duodenoscope,” “duodenoscope,” “single-use” “endoscopic retrograde cholangiopancreatography,” “disposable equipment.” See supplementary Table 1 for complete search strategy.

No filters or limits were applied to this search. We followed the Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) and Meta-Analysis of Observational Studies in Epidemiology (MOOSE) guidelines to identify studies assessing the performance of disposable duodenoscopes for ERCP.

The search was restricted to studies performed on human subjects and published in the English language in peer-reviewed journals and conference abstracts. Two authors (DR, ES) independently reviewed the title and abstract of studies identified in the primary search and excluded studies that did not address the research question, based on pre-specified exclusion and inclusion criteria. The full text of the remaining articles was reviewed to determine whether it contained relevant information. Any discrepancy in article selection was resolved by consensus, and in discussion with a third co-author. The bibliographic section of the selected articles, as well as systematic and narrative articles on the topic, were manually searched for additional relevant articles.

2.2. Study selection

We included studies that evaluated technical performance associated with disposable duodenoscopes for ERCP procedures. Studies irrespective of the sample-size, inpatient/outpatient setting, and geography were included if they provided data needed for the analysis. Inclusion criteria were as follows: (1) Patients undergoing ERCP with a disposable duodenoscope. Exclusion criteria included: (1) pediatric (age <18 years) studies, (2) studies not published in the English language, (3) case reports. In the event of multiple publications from the same cohort and/or overlapping cohorts, data from the most recent and/or most appropriate comprehensive report were retained.

2.3. Data abstraction and quality assessment

Study references and citations were collected in Rayyan (<https://www.rayyan.ai/>). Duplicated citations were removed. The full text of each selected article was reviewed to verify that it contained relevant information. Data on study-related outcomes in the individual studies were abstracted by two authors (DR, ES), and two authors (DR, ES) did the quality scoring independently. Non-randomized studies were assessed via the Risk of Bias in Non-randomized Studies—of Interventions [ROBINS-I] tool [9,10]. No further assessment tools were necessary as there were no randomized controlled studies based on our literature search. Using the ROBINS-I tool, each form of bias was awarded either a low, moderate, serious, or critical risk of bias.

2.4. Study outcomes

Outcomes of interest included successful biliary cannulation, successful maneuvers including biliary sphincterotomy, clearance of bile duct stones, stent placement and/or removal, and dilation of the biliary duct. Adverse events and their severity were extracted according to the American Society for Gastrointestinal Endoscopy lexicon when possible; otherwise, adverse events were extracted as reported in the original studies. These included but were not limited to post-ERCP pancreatitis, procedure-related infections, and mortality.

2.5. Statistical analysis

We used meta-analysis techniques to calculate the pooled estimates in each case following the methods suggested by DerSimonian and Laird using the random-effects model [11–13]. According to the Cochrane handbook, the choice between fixed and random-effects model should be based on an expectation of whether the intervention effects are truly identical, preferring the fixed-effect model if this is likely and a random-effects model if this is unlikely. Since it is generally considered to be implausible that intervention effects across studies are identical, this leads to the prevalent use (like in this case) of the random-effects model.

We assessed heterogeneity between study-specific estimates by using Cochran Q statistical test for heterogeneity and the I² statistics [14–16,9]. In this, values of <30%, 30–60%, 61–75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively [9,10].

Publication bias was ascertained, qualitatively, by visual inspection of funnel plot and quantitatively, by the Egger test [17,18]. P-value <0.05 was considered statistically significant for comparison of groups. All statistical analyses were conducted using RevMan 5.3 software (the Cochrane Collaboration, Oxford, UK).

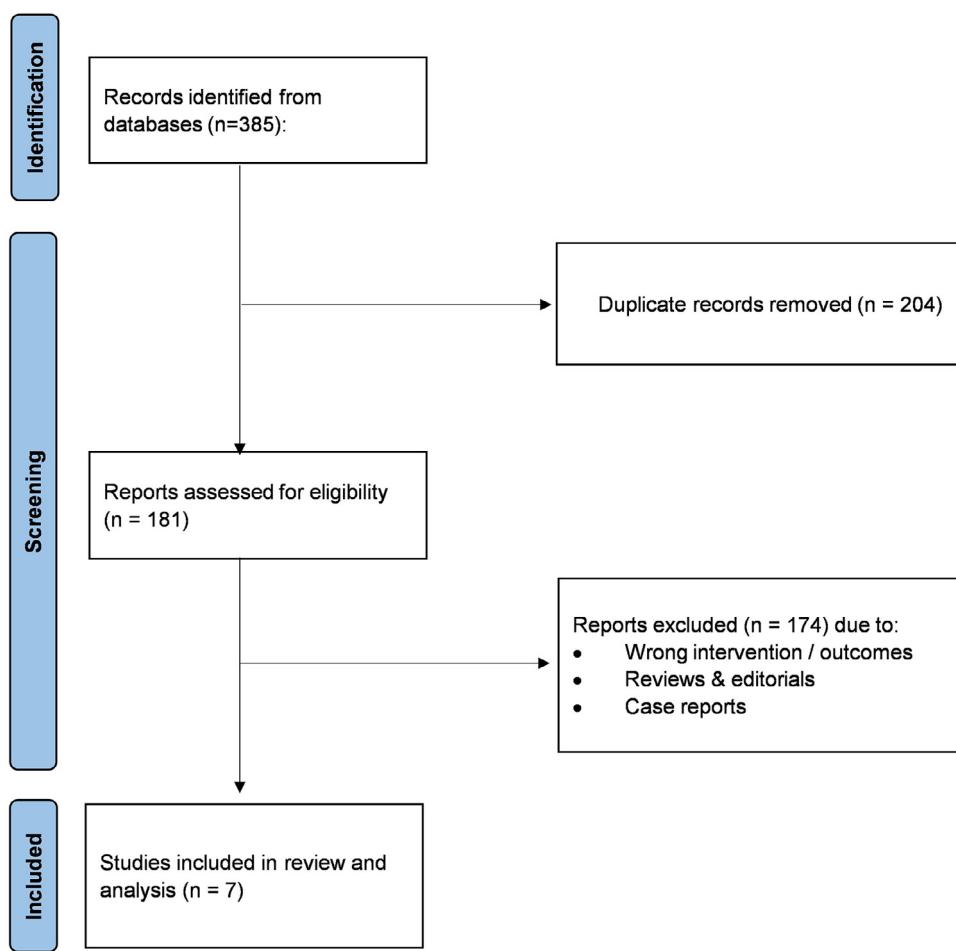


Fig. 1. PRISMA study flowchart.

3. Results

3.1. Search results and characteristics

From an initial total of 385 identified articles, 181 titles were screened after removal of duplicates. The final analysis included 7 studies [19–25]. The schematic diagram of study selection is illustrated in Fig. 1. Of included studies, 1 study was a randomized trial [19], 4 studies were prospective [20–23], 1 study was a case series [24], 1 was a multi-center retrospective study [25].

A total of 642 patients were included in our final analysis; average age was 62.7 years. 318 patients were male, 316 patients were female, and 8 patients were unspecified. From five studies, 45% (206/456) of patients had undergone a prior sphincterotomy. From four studies, 59% (244/412) of patients, underwent a prior ERCP. From three studies, 53% (143/269) of patients had a native papilla. From our study cohort, the study by Bang et al. enrolled only patients with a native papilla ($n = 48$) which showed a high technical success rate of 95.8% [19].

The Exalt Model D duodenoscope was used in 88.8% with the remaining 11.2% of cases utilizing the aScope Duodeno. Most ERCPs had a complexity grade of 2 ($n = 303$) or 3 ($n = 198$). Only one study compared two disposable duodenoscopes (EXALT D vs. aScope Duodeno) which showed similar technical success rates (92% in both groups; $n = 119$ Exalt group, $n = 66$ aScope Duodeno group) [25]. Additional study characteristics are described in Table 1.

3.2. Study quality

Overall, most studies were considered to have low to moderate bias; one study had significant bias [21]. Supplementary Table 2 provides a detailed assessment of study quality.

3.3. Meta-analysis outcomes

The pooled cumulative rate of successful biliary cannulation was 95% (95% Confidence Interval (CI): 93–96%, $I^2=0\%$, $P = 0.46$) (Fig. 2). Biliary sphincterotomy, reported by four studies, was successfully performed in all cases ($n = 68/68$, 100%). The pooled cumulative rate of successful clearance of bile duct stones was 100% (95% CI: 95–100%, $I^2=2\%$, $P = 0.38$) (Fig. 3). The pooled cumulative rate of successful stent placement and removal was 97% (95% CI: 89–100% $I^2=0\%$, $P = 0.1$) and 100% (95% CI: 96–100%, $I^2=0\%$, $P = 0.88$), respectively (Figs. 4 and 5). The pooled cumulative rate of successful dilation of biliary strictures was 97% (95% CI: 81–100%, $I^2=0\%$, $P = 0.74$) (Supplementary figure 1) (Table 2).

Overall, adverse events included post-ERCP pancreatitis (PEP) ($n = 8$), post-sphincterotomy bleeding ($n = 3$), other bleed ($n = 4$), infection ($n = 4$), pain ($n = 3$), and choledocholithiasis ($n = 1$). The pooled cumulative rate of total adverse events was 7% (95% CI: 4–10%, $I^2=47\%$, $P = 0.08$) (Fig. 6). Adverse events were not particularly related to single use duodenoscopes. Four studies stated that adverse events were not from single use duodenoscopes while one study stated no serious adverse event was related to single use duodenoscopes. The remaining two studies did not clarify if adverse events were related to single use duodenoscopes. The pooled

Table 1
Study characteristics.

Study	Design	Duodenoscope	Age	Total pts	Male	Female	Previous pancreatic-biliary procedure	Previous Sphincterotomy	ERCP Complexity 1	ERCP Complexity 2	ERCP Complexity 3	ERCP Complexity 4
Muthusamy et al. [24]	Case Series, multi-center	EXALT Model D	63.6	60	46	27	72.6%	58.9%	7	26	26	4
Bang et al. [3]	Randomized clinical trial, single-center	EXALT Model D	67.2	48	26	22	NA	NA	9	31	4	4
Slivka et al. [23]	Prospective, multi-center	EXALT Model D	62.6	200	97	103	64.5%	53.0%	20	94	59	25
Napoleon et al. [22]	Prospective, multi-center	EXALT Model D	65.5	60	26	34	46.7%	33.0%	1	35	21	6
Persyn et al. [20]	Prospective, single-center	EXALT Model D	65	52	27	25	43.0%	45.6%	0	25	17	13
Rivallin et al. [21]	Prospective, single center	EXALT Model D	49.5	21	NA	NA	NA	NA	3	9	6	3
Shahid-1 et al. [25]	Retrospective, multi-center	EXALT Model D	63.4	129	66	63	NA	NA	24	54	35	16
Shahid-2 et al. [25]	Retrospective, multi-center	aScope Duodeno	64.75	72	30	42	NA	NA	11	29	30	2

Table 2
Summary of meta-analysis outcomes.

	Pooled Rate	95% Conf. Interval	Heterogeneity (I ²)
Successful cannulation	95%	93–96%	0%
Sphincterotomy	100%	–	–
Bile duct stone clearance	100%	95–100%	2%
Stent placement	97%	89–100%	0%
Stent removal	100%	96–100%	0%
Balloon dilation	97%	81–100%	0%
Post-ERCP Pancreatitis	2%	0.4–3.4%	0%
Adverse events	7%	4–10%	47%

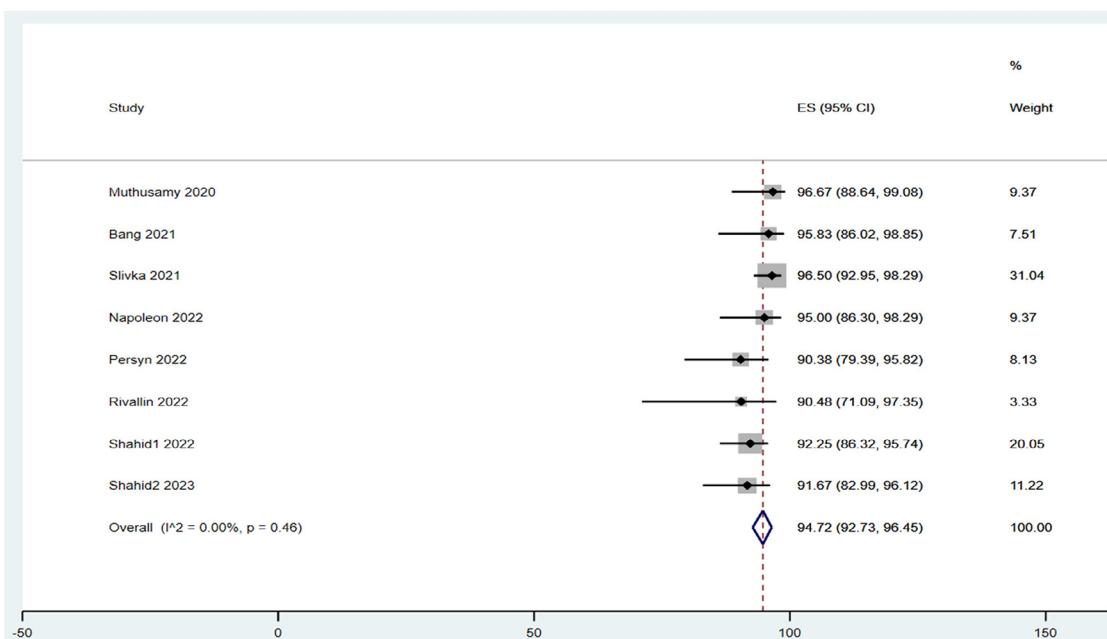


Fig. 2. Forest plot of pooled rate of successful cannulation.

cumulative rate of PEP was 2% (95% CI: 0.4–3.4%, I²=0%, P = 0.80) (Supplementary figure 2). Cases of PEP were all rated as mild to moderate.

3.4. Validation of meta-analysis results

Heterogeneity: We assessed dispersion of the calculated rates using I² percentage values. I² tells us what proportion of the dis-

persions is true versus chance. Heterogeneity was noted in all meta-analysis outcomes (listed above) except sphincterotomy. Further subgroup analysis and/or meta-regression analysis to explore the source of heterogeneity was not feasible because of limited study data points.

Publication bias: A publication bias assessment was deferred because fewer than 10 total studies were included in the final analysis.

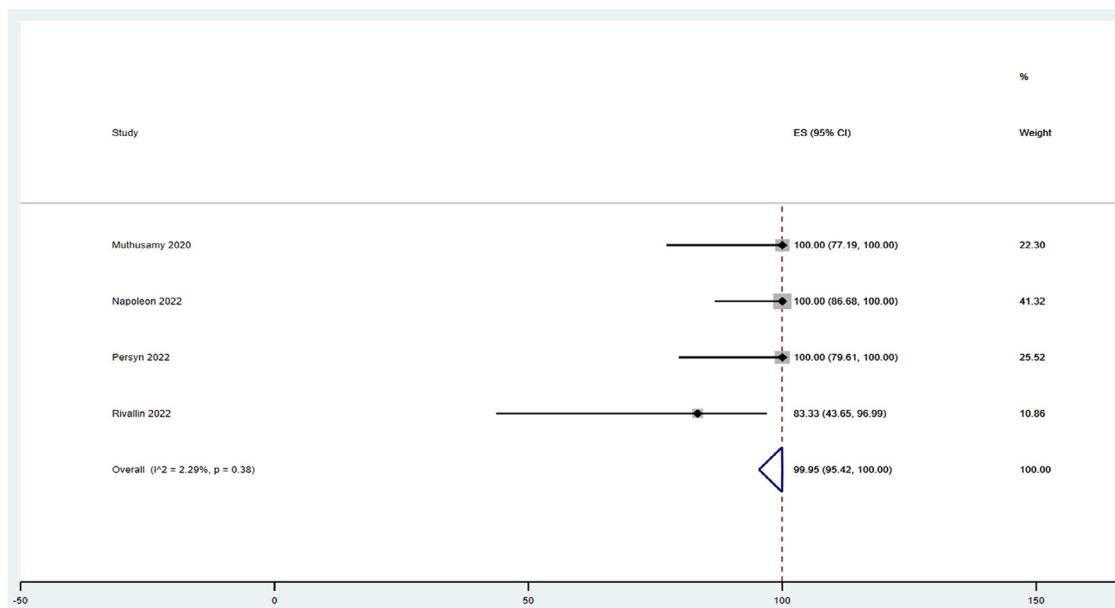


Fig. 3. Forest plot of pooled rate of cleared biliary stones.

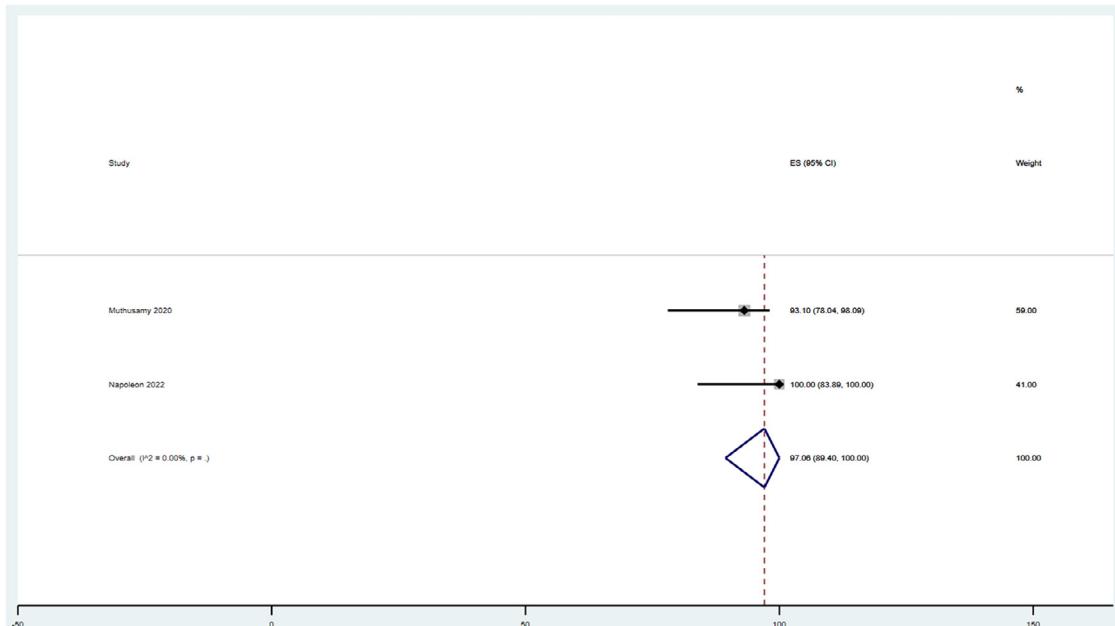


Fig. 4. Forest plot of pooled rate of stent placement.

4. Discussion

Our meta-analysis provides evidence that the use of single use duodenoscopes are comparable to reusable duodenoscopes. Overall, disposal duodenoscopes were associated with high cannulation rates and acceptable technical performance and low rate of associated adverse events.

The cumulative cannulation rate in our study was 95%, which is similar to a review of 18,182 ERCP procedures performed in the United States and 3172 in the UK which showed cannulation rates of 97% and 93%, respectively [26]. The same authors reported similar rates of bile stone clearance ranging from 96% to 99%. While it is difficult to compare the complexity of procedures between datasets, the difficulty of ERCP was rated on a scale from 1 to 4 in our meta-analysis, while the difficulty rating used for the

reusable duodenoscopes was 1 to 3. However, 35% of the American ERCP's in the study by Oppang et al. were rated as "most difficult" while 42% of the ERCP's using disposable duodenoscopes were rated 3 or 4 in difficulty.

The post-ERCP pancreatitis rate in our study was 2%, with previous estimates of post-ERCP pancreatitis being 2–10% [27,28]. The incidence of adverse events in our study (7%) was similar to that seen in a study of 295 ERCPs performed at the Cleveland Clinic of 6–10% [29]. These data confirm that disposal duodenoscopes are safe for ERCP.

Besides objective data on outcomes, five of the included studies included endoscopist surveys with regards to their experience using single use duodenoscopes. Two studies reported difficulty with inadequate insufflation [22,25] and two studies documented concern for stent placement or removal with the EXALT D [20,24]. One

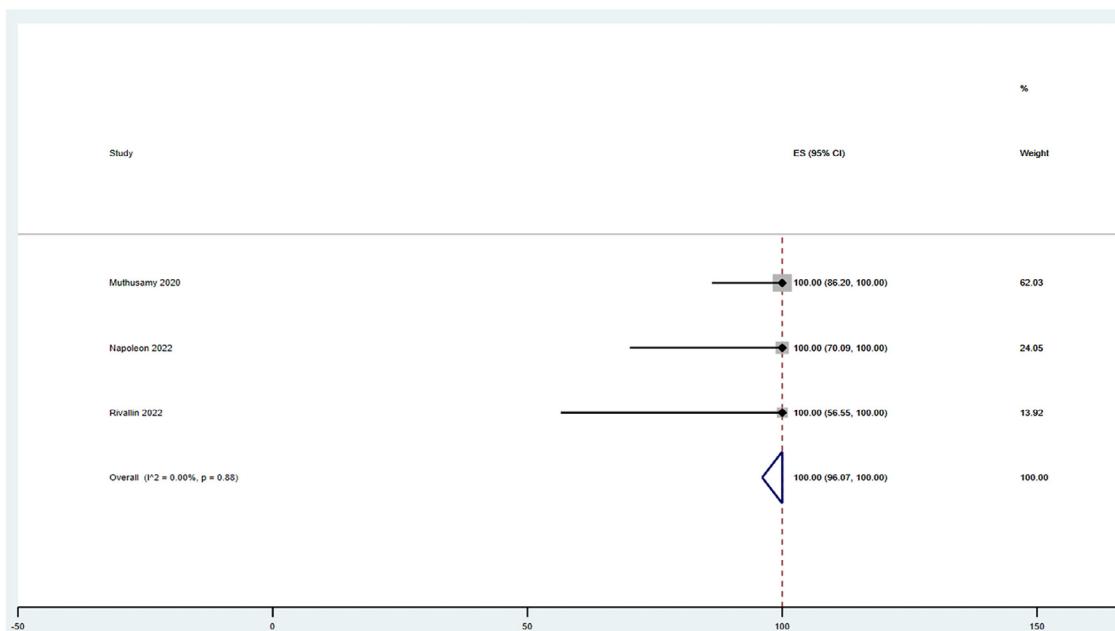


Fig. 5. Forest plot of pooled rate of stent removal.

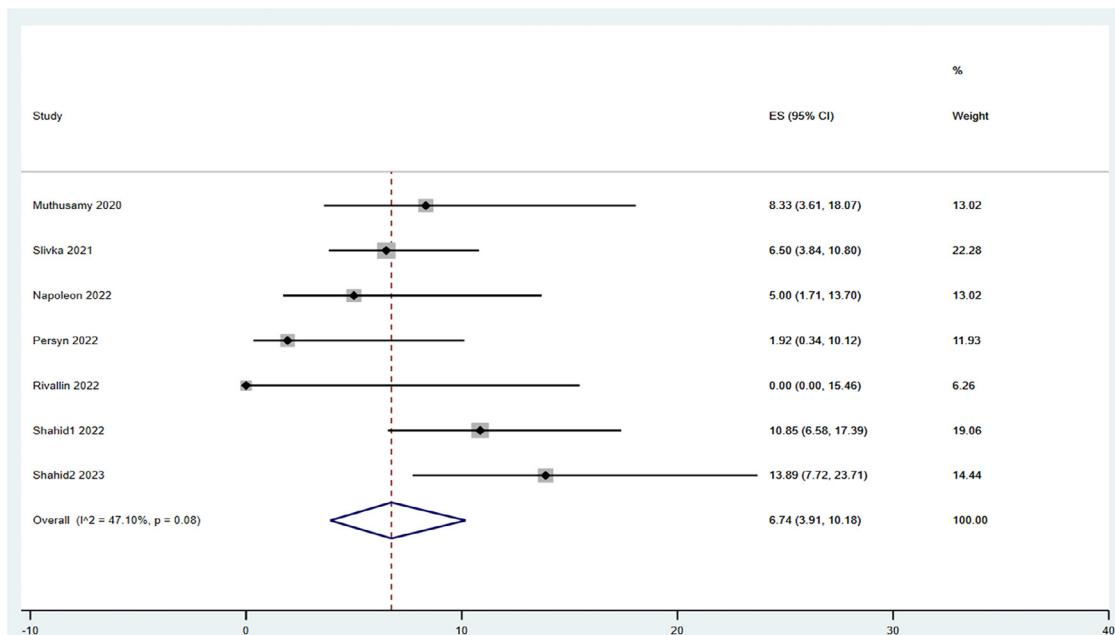


Fig. 6. Forest plot of pooled rate of adverse events.

study cited the stiffness of the duodenoscope as inhibiting movement within the duodenum [21]. However, one study opined that the increased stiffness of the single use duodenoscope improves engagement of the papilla, anchoring the device for better stone extraction [19].

Interestingly, while sphincterotomy was associated with a very high technical success, two endoscopists from the Persyn et al. study rated sphincterotomy with the EXALT disposable duodenoscope as 'not preferred' and cited that the elevator's insufficient upward bending capacity [20]. Despite this, complaints about the duodenoscopes themselves were not common and may be related to endoscopists' adjustment to a novel device. The safety and effectiveness data collected seems to indicate that these factors do not lead to clinically relevant limitations in ERCP.

Cannulation of a native papilla can be challenging and may require advance endoscopic techniques [30,31]. While some studies did report the number of patients with a native papilla, cannulation rate was not clearly specified. However, from limited data, it appears that cannulation of a native papilla does not hinder the success of performing ERCP using a disposable duodenoscope [19]. On a similar note, the study by Shahid showed that there was no significant difference in the type of disposable duodenoscope and ERCP success [25]. Larger studies comparing cannulation rates between these two disposable duodenoscopes, particularly in patients with native papilla is warranted.

Our study is not without limitations. Our data does not address concerns of cost-effectiveness and environmental impact of single use duodenoscopes that have been documented elsewhere

[32,33]. Only one of the included studies was randomized and confounding factors may exist with other studies. In our meta-analysis most procedures were performed by endoscopists with a cumulative personal experience of over 2000 ERCPs performed, and this data may not represent the average endoscopist. These studies represent academic centers and may not reflect endoscopy in the community setting. Although our data included patients with high complexity ERCPs, it is possible that endoscopists preferentially chose traditional duodenoscopes for their more challenging cases. That said, it is also likely that endoscopists would prefer single use duodenoscopes while working with immunocompromised patients and those with complicated medical histories to mitigate the risk of serious infections.

In conclusion, our study shows that disposable duodenoscopes are associated with high cannulation rates, technical performance, and safety profile. To this end, disposable duodenoscopes are similar to the outcomes reported in the literature with reusable duodenoscopes and offer endoscopists good technical operability while performing ERCPs.

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None.

Conflict of interest

Dr. Douglas Adler is a consultant for Boston Scientific and Micro Tech. All other authors declare no conflicts of interest.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.dld.2023.02.022](https://doi.org/10.1016/j.dld.2023.02.022).

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