SYSTEMATIC REVIEW AND META-ANALYSIS

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CLINICAL ENDOSCOPY

Coaxial plastic stent placement within lumen-apposing metal stents for the management of pancreatic fluid collections: a systemic review and meta-analysis

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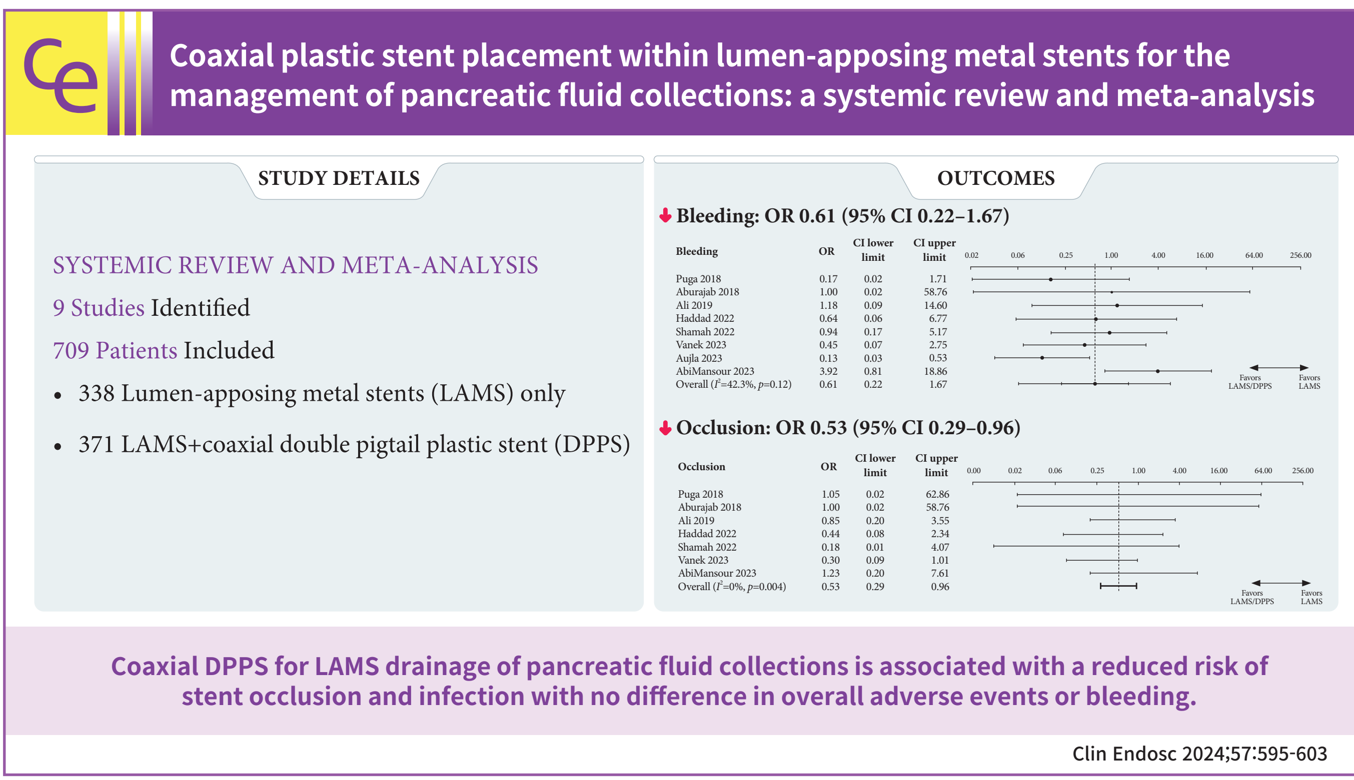

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Background/Aims: Coaxial placement of double pigtail plastic stents (DPPS) through lumen-apposing metal stents (LAMSs) is commonly performed to reduce the risk of LAMS obstruction, bleeding, and stent migration when used for the drainage of pancreatic fluid collections (PFCs). A systematic review and meta-analysis were performed to compare the outcomes of LAMS alone and LAMS with coaxial DPPS placement in the management of PFCs.

Methods: A systematic review was conducted to identify studies comparing LAMS and LAMS/DPPS for PFC drainage. Primary outcomes included the rate of clinical success, overall adverse events (AEs), bleeding, infection, occlusion, and stent migration. The pooled effect size was summarized using a random-effects model and compared between LAMS and LAMS/DPPS by calculating odds ratios (ORs).

Results: Nine studies involving 709 patients were identified (338 on LAMS and 371 on LAMS/DPPS). LAMS/DPPS was associated with a reduced risk of stent obstruction (OR, 0.59; $p=0.004$) and infection (OR, 0.55; $p=0.001$). No significant differences were observed in clinical success (OR, 0.96; $p=0.440$), overall AEs (OR, 0.57; $p=0.060$), bleeding (OR, 0.61; $p=0.120$), or stent migration (OR, 1.03; $p=0.480$).

Conclusions: Coaxial DPPS for LAMS drainage of PFCs is associated with a reduced risk of stent occlusion and infection; however, no difference was observed in the overall AE rates or bleeding.

Keywords: Acute necrotizing pancreatitis; Chronic; Endosonography; Fat necrosis, Pancreatic pseudocyst; Pancreatitis; Peripancreatic

INTRODUCTION

Inflammatory pancreatic fluid collections (PFCs) result from disruption of the pancreatic duct and can occur as a sequela of acute or chronic pancreatitis. The majority of PFCs resolve spontaneously; however, intervention may be required in case they become symptomatic, infected, or develop local complications.[1] Minimally-invasive approaches, including endoscopic and percutaneous drainage, have replaced surgery as the preferred first-line interventions.[2-5] An endoscopic step-up paradigm has been associated with high rates of clinical success, lower rates of re-intervention, and shorter duration of hospital stay, establishing it as the primary drainage modality in facilities with access to endoscopic expertise.[6-9]

Advancement in endoscopic ultrasound (EUS) technology has enabled real-time assessment and ultrasound-guided formation of a cystogastrostomy or enterostomy.[10] Lumen-apposing metal stents (LAMSs) with or without an integrated electrocautery-enhanced delivery system represent the most recent development designed for PFC drainage with interventional EUS.[11] The stents available in the United States (AXIOS Stent and Electrocautery Enhanced Delivery System; Boston Scientific Corporation) are United States Food and Drug Administration-cleared for drainage of pseudocysts and walled-off necrosis adherent to the bowel wall.[12]

In the initial encounters with LAMS, effective drainage of PFCs was observed[13,14]; however, the placement was associated with an increased risk of bleeding within the cavity and pseudoaneurysm formation.[15] Recent data suggests that bleeding risk is independent of stent type; however, it remains a major clinical concern, alongside adverse events (AEs) related to stent migration, stent obstruction, and infection of the collection. This underscores the importance of close patient monitoring.[16] Placement of a coaxial double pigtail plastic stent (DPPS) through the LAMS is believed to minimize these risks by limiting damage to the contralateral cavity wall after the collection has decompressed. Furthermore, coaxial DPPS may decrease the risk of LAMS migration and PFC infection by providing an anchor and deeper drainage into the collection, while maintaining patency through the LAMS. However, this practice has not been studied in large patient cohorts that are sufficiently powerful for detecting noticeable differences in event rates. Therefore, this study aimed to perform a systematic review and meta-analysis to compare the clinical efficacy and safety of LAMS with or without coaxial DPPS for the treatment of PFCs.

METHODS

Data sources and search strategies

A comprehensive search of several databases from inception to September 2023 for relevant English-language publications was conducted. These databases included the Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Embase, Ovid, Medline, and Scopus. Manual searches of relevant journals and abstracts on conference proceedings were also conducted. The search strategy was designed and conducted by an experienced librarian (L.P.) with input from the principal investigator (V.C.). Supplementary Material 1 outlines the search strategy.

Eligible studies for meta-analysis

Eligible studies meeting all the following criteria were included in this meta-analysis: (1) only studies comparing LAMS and DPPS in EUS-guided drainage for PFC, including the pancreatic pseudocyst and walled-off necrosis; and (2) studies including data and details for at least technical success and clinical success. The exclusion criteria were as follows: (1) articles published in languages other than English; (2) case reports, reviews, guidelines, or letters; (3) studies without adequate outcomes; and (4) non-human studies. Two authors (JA and SV) independently reviewed and evaluated the eligibility of the retrieved articles. Differences in the study eligibility were resolved by discussion with a third individual (VJ) until a consensus was reached. The quality of the included studies and risk of bias were evaluated using an assessment tool established by the National Institute of Health for observational studies[17] and the Revised Cochrane risk-of-bias tool for randomized studies (RoB2).[18]

Statistical analysis

Success rates and AEs were calculated as proportions in each study. The pooled effect size and 95% confidence intervals (CIs) were estimated using a random-effects model with the DerSimonian and Laird approach. The between-study heterogeneity of effect size estimates across studies was quantified using the Q statistic and I^2. The heterogeneity of the effect size estimates across these studies was quantified using the Q statistic, its p-value, and I^2 ($p<0.10$ was considered significant). A value of I^2 of 0% to 50% indicated insignificant heterogeneity and 51% to 75% indicated significant heterogeneity. The use of funnel plots was deemed inappropriate given that the power of the test was too low to distinguish chance from actual funnel plot asymmetry. All analyses were performed using Open Meta Analyst software (CEBM; Brown University). Statistical significance was set at $p<0.05$.

RESULTS

In total, 1221 potentially relevant articles were identified from the outlined search strategy, with 300 duplicate records removed prior to screening and 886 excluded after abstract and title review (Supplementary Fig. 1). The nine identified studies reported the outcomes of 709 patients in total, including 338 patients who underwent LAMS only and 371 who underwent LAMS/DPPS (Table 1).[19-27] Details of the stent types used are outlined in Supplementary Table 1.[19-27] The studies were evaluated for the risk of bias, with concerns in observational studies largely driven by small sample sizes and a lack of blinding (Supplementary Table 2).[19-27] The single randomized controlled trial displayed some concerns about bias related to a lack of blinding; however, the overall risk of bias was low (Supplementary Fig. 2).

Clinical success (Fig. 1A) and technical success (Fig. 1B) were not significantly different between the two cohorts with a pooled odds ratio (OR) of 0.96 (95% CI, 0.48–1.89; I^2=17.7%; p=0.440) and 1.08 (95% CI, 0.59–1.96; I^2=0%; p=0.390), respectively (Table 2). No statistically significant difference was observed in the overall AE rate (OR, 0.57; 95% CI, 0.25–1.29; I^2=56.6%; p=0.060) (Fig. 1C). The overall incidence of stent

Table 1. Details of studies identified on systematic review and included in the meta-analysis

Study	Year	Counrty	Total patient (n)		Walled-off necrosis (n)		Clinical success (n)		Overall AE (n)	
			LAMS	LAMS/DPPS	LAMS	LAMS/DPPS	LAMS	LAMS/DPPS	LAMS	LAMS/DPPS
Puga et al.[20]	2018	Spain	21	20	11	12	18	18	9	2
Aburajab et al.[21]	2018	USA	23	23	0	0	21	23	0	6
Ali et al.[22]	2019	USA	21	36	14	29	15	21	6	14
Haddad et al.[23]	2023	USA	45	23	29	13	38	22	13	4
Shamah et al.[24]	2022	USA	33	35	6	11	32	29	10	9
Vanek et al.[25]	2023	USA	33	34	33	34	10	14	17	7
Aujla et al.[26]	2023	USA	21	80	NR	NR	NR	NR	10	14
Perez Estrada et al.[27]	2022	Spain	58	18	NR	NR	56	18	14	2
AbiMansour et al.[19]	2024	USA	83	102	62	80	63	71	13	16

AE, adverse event; LAMS, lumen-apposing metal stent; DPPS, double pigtail plastic stent; NR, not reported.

A

Clinical success	OR	CI lower limit	CI upper limit
Puga 2018	1.50	0.21	10.71
Aburajab 2018	5.47	0.23	131.37
Ali 2019	0.56	0.17	1.83
Haddad 2022	4.05	0.45	36.59
Shamah 2022	0.15	0.02	1.39
Vanek 2023	1.61	0.58	4.50
Perez Estrada 2023	1.64	0.07	37.55
AbiMansour 2023	0.73	0.38	1.41
Overall (I^2=17.7%, p=0.44)	0.96	0.48	1.89

B

Technical success	OR	CI lower limit	CI upper limit
Puga 2018	3.00	0.10	86.62
Aburajab 2018	1.00	0.02	58.76
Ali 2019	1.70	0.03	96.95
Haddad 2022	0.52	0.01	28.92
Shamah 2022	1.06	0.02	59.14
Vanek 2023	1.03	0.02	57.57
Perez Estrada 2023	0.32	0.01	17.62
AbiMansour 2023	1.23	0.02	64.18
Overall (I^2=0%, p=0.39)	1.08	0.59	1.96

C

Overall AE	OR	CI lower limit	CI upper limit
Puga 2018	0.15	0.03	0.85
Aburajab 2018	17.46	0.85	359.67
Ali 2019	1.59	0.49	5.21
Haddad 2022	0.52	0.14	1.86
Shamah 2022	0.80	0.27	2.35
Vanek 2023	0.24	0.08	0.73
Aujla 2023	0.23	0.08	0.66
Perez Estrada 2023	0.39	0.08	1.97
AbiMansour 2023	1.00	0.45	2.23
Overall (I^2=56.6%, p=0.06)	0.57	0.25	1.29

D

Occlusion	OR	CI lower limit	CI upper limit
Puga 2018	1.05	0.02	62.86
Aburajab 2018	1.00	0.02	58.76
Ali 2019	0.85	0.20	3.55
Haddad 2022	0.44	0.08	2.34
Shamah 2022	0.18	0.01	4.07
Vanek 2023	0.30	0.09	1.01
AbiMansour 2023	1.23	0.20	7.61
Overall (I^2=0%, p=0.004)	0.53	0.29	0.96

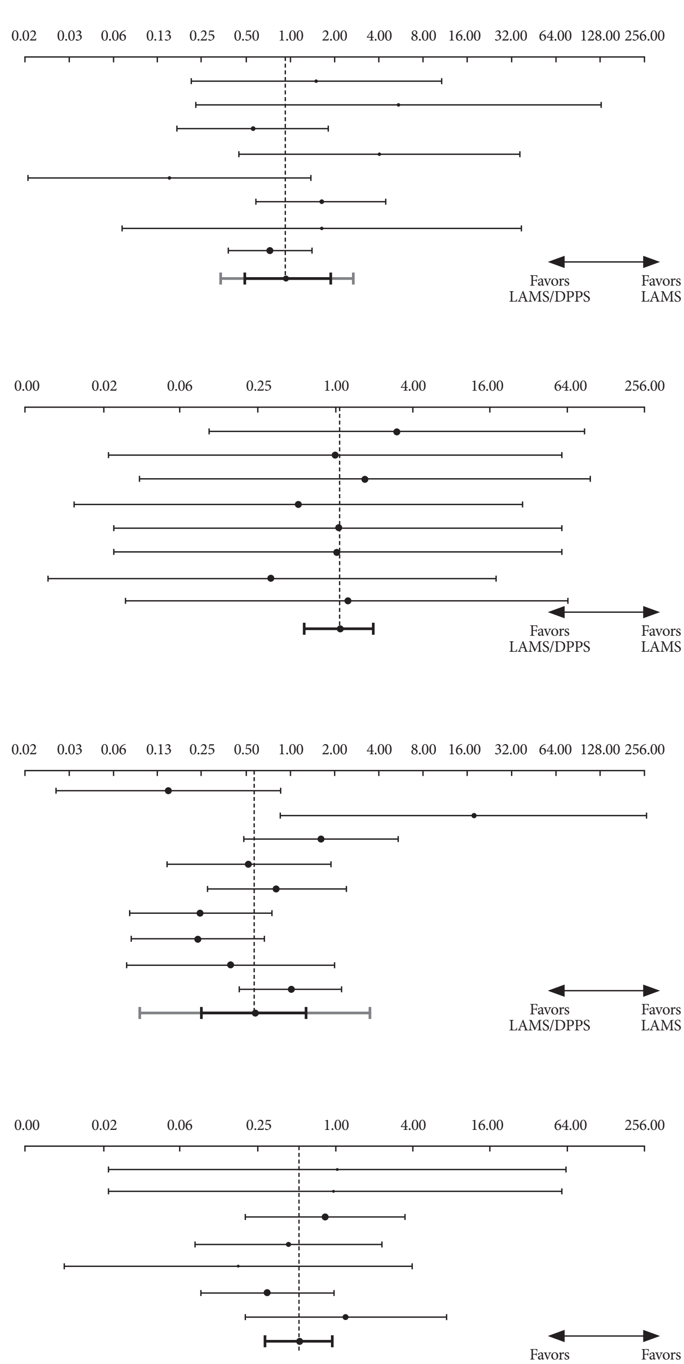
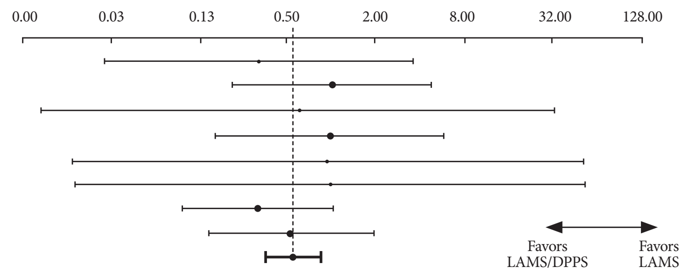


Fig. 1. Pooled odds ratio (OR) for (A) clinical success, (B) technical success, (C) overall adverse events, (D) occlusion, (E) infection, (F) bleeding, and (G) migration. CI, confidence interval; LAMS, lumen-apposing metal stent; DPPS, double pigtail plastic stent; AE, adverse event.

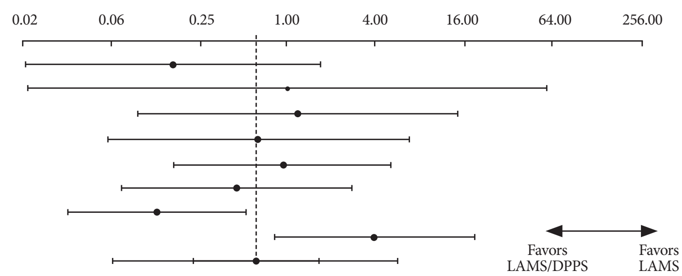
E

Infection	OR	CI lower limit	CI upper limit
Puga 2018	0.32	0.03	3.58
Aburajab 2018	1.00	0.21	4.80
Ali 2019	0.59	0.01	33.64
Haddad 2022	0.98	0.16	5.97
Shamah 2022	0.94	0.02	52.67
Vanek 2023	0.97	0.02	54.28
Aujla 2023	0.32	0.10	1.04
AbiMansour 2023	0.52	0.14	1.94
Overall (I^2=0%, p=0.001)	0.55	0.35	0.84



F

Bleeding	OR	CI lower limit	CI upper limit
Puga 2018	0.17	0.02	1.71
Aburajab 2018	1.00	0.02	58.76
Ali 2019	1.18	0.09	14.60
Haddad 2022	0.64	0.06	6.77
Shamah 2022	0.94	0.17	5.17
Vanek 2023	0.45	0.07	2.75
Aujla 2023	0.13	0.03	0.53
AbiMansour 2023	3.92	0.81	18.86
Overall (I^2=42.3%, p=0.12)	0.61	0.22	1.67



G

Migration	OR	CI lower limit	CI upper limit
Puga 2018	1.05	0.02	62.86
Aburajab 2018	3.13	0.11	88.80
Ali 2019	4.00	0.43	37.60
Haddad 2022	0.47	0.05	4.62
Shamah 2022	1.67	0.35	7.83
Vanek 2023	0.18	0.01	4.19
AbiMansour 2023	0.26	0.03	2.63
Overall (I^2=42.3%, p=0.12)	1.03	0.36	2.90

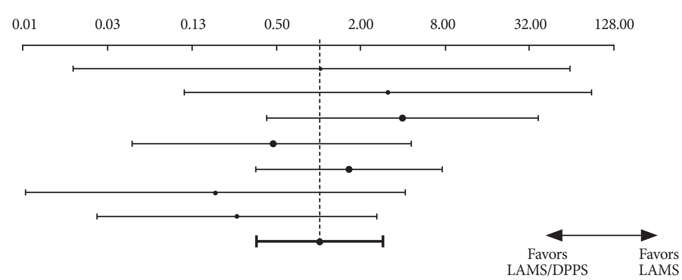


Fig. 1. Continued.

Table 2. Meta-analysis results with pooled OR for lumen-apposing metal stent with coaxial stent placement compared to lumen-apposing metal stent placement alone

Meta analysis results	Pooled OR (95% CI)	I^2(%)
Clinical success	0.96 (0.48–1.89)	17.7
Overall AE	0.57 (0.25–1.29)	56.6
Bleeding	0.61 (0.22–1.67)	42.3
Migration	1.03 (0.36–2.90)	0
Infection	0.55 (0.35–0.84)	0
Occlusion	0.53 (0.29–0.96)	0

OR, odds ratio; CI, confidence interval; AE, adverse event.

occlusion (Fig. 1D) and infection of the collection (Fig. 1E) was lower in patients who underwent coaxial DPPS placement with ORs of 0.53 (95% CI, 0.29–0.96; I^2=0%; p=0.004) for stent occlusion and 0.55 (95% CI, 0.35–0.84; I^2=0%; p=0.001) for infection compared to the patients who underwent LAMS only. There was no significant difference in rates of bleeding (OR, 0.61; 95% CI, 0.22–1.67; I^2=42.3%; p=0.120) (Fig. 1F) or stent migration (OR, 1.03; 95% CI, 0.36–2.90; I^2=0%; p=0.480) (Fig. 1G) between the two groups. No significant heterogeneity was noted in the outcomes of interest (I^2<50%) except for overall AEs which showed significant heterogeneity among the included studies (I^2=56.6%).

DISCUSSION

Several technical modifications to PFC drainage have been described to improve outcomes and limit AEs, including multimodal therapy[28] and multi-gated drainage.[29] However, the rationale for coaxial DPPS placement to mitigate AEs remains predominantly theoretical owing to the limited rigorous data available, and the technique has not been described in initial prospective studies.[30,31] Placement of a coaxial DPPS likely evolved from initial experiences with self-expanding metal stents for the drainage of PFCs.[32] LAMS, on the other hand, have large bilateral flanges to aid with tissue apposition and prevent migration, which can obviate the requirement for coaxial stent placement.[5] However, the potential benefit of a coaxial DPPS extends beyond mere anchoring, as the soft and rounded ends provide a level of protection after the collection collapses. Furthermore, coaxial DPPS can preserve patency, as the inner channel of the LAMS becomes occluded by solid necrosis or food debris, and maintain a potential space within a cavity, especially in case of rapid decompression of the collection. The latter is particularly helpful in situations where a patient is suspected of having a disconnected pancreatic duct, for which management entails long-term transmural DPPS drainage.[33-35]

Data on the use of coaxial plastic stenting are largely limited to single-center retrospective studies, as highlighted in the systemic database review. A previously performed meta-analysis included 460 patients and suggested no difference in clinical outcomes of interest.[36] However, our study improves on prior reports with an updated and more robust cohort of 709 patients and demonstrates lower rates of occlusion and infection with the use of coaxially-placed DPPS for the management of PFC. This finding is clinically plausible considering that impaired drainage resulting from stent obstruction is a mechanism for the onset of collection infection. It aligns with the findings of the only randomized trial on the subject, which observed lower rates of LAMS occlusion in patients who underwent coaxial DPPS placement, albeit no difference in infection was seen.[25] Despite a lower incidence of obstruction and infection, no difference was noted in the cumulative rate of overall AEs. This may be due to the varying definitions of AE used in the included studies, and the overall AE rate was the only outcome of interest that exhibited significant heterogeneity, which limited the interpretability.

Notably, no difference was observed in the incidence of bleeding between groups. Initial single-center studies investigating the use of LAMS suggested an increased risk of bleeding-related AEs and the need for unplanned intervention, with an incidence of 2.5% to 25%.[15,16,37] A theorized benefit of coaxial DPPS placement is that the soft and rounded edges of the plastic stent limit erosion into the nearby vasculature compared to the metal flanges of LAMS. The risk of bleeding may have been overestimated in earlier cohorts in which LAMS was routinely maintained until clinical resolution. Because experience with LAMS and related AE, such as bleeding, increased over time, prompt LAMS removal after PFC resolution was prioritized. Therefore, modern practices focusing on timely LAMS removal may blunt any protective benefit from bleeding with coaxial DPPS placement.

Downsides of DPPS placement include the risk of migration of the DPPS itself, as well as added cost, time, and the necessity to remove/replace the stent to access the fluid cavity. Smaller caliber plastic stents may be more prone to migration than larger ones (e.g., 5 Fr versus 10 Fr). No difference in stent migration was observed in this study, although the definitions for stent migration varied from incidental migration of plastic stents to symptomatic LAMS migration, limiting the external validity of this finding. While the risk of plastic stent migration must be considered, plastic stent migration did not seem to negatively impact patient outcomes in one study that tracked incidental migration.[19]

The main limitation of this meta-analysis is the quality of the included studies. Most studies have not protocolized follow-ups, with practice variations between individual centers and endoscopists. This included the timing of repeat clinical evaluation, imaging, and necrosectomy. The definitions of each outcome of interest varied among studies that introduced heterogeneity, particularly for reporting overall AEs. However, comparing the included cohorts is still beneficial, because heterogeneity is likely to exist in both arms of each study. Notably, the incidence of AEs may be related to other fluid collection variables, including size, presence of infection, and paracolic extension, which were not accounted for in this analysis, particularly in the absence of patient-level data.[38] Lastly, publication bias was not formally evaluated, considering that a funnel plot would be inadequately powered to provide useful conclusions. Several of the included studies did not report any differences in the outcomes, which is notable because publication bias generally introduces bias against the null hypothesis.

CONCLUSIONS

In summary, this meta-analysis demonstrated that coaxial DPPS placement with LAMS for PFC drainage is associated with a reduced risk of LAMS occlusion and PFC infection. However, no differences in the overall AEs, or more specifically, bleeding, were observed. This study provides key information for endoscopists in the absence of robust randomized data or technical guidelines. Endoscopists should consider the placement of a coaxial DPPS to reduce the risk of LAMS occlusion and infection while also considering patient anatomy, imaging, and other risk factors.

Supplementary Material

Supplementary Material 1. Search strategy.

Supplementary Fig. 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources.

Supplementary Fig. 2. Bias assessment of randomized trial.

Supplementary Table 1. Details on stent type in included studies.

Supplementary Table 2. Bias assessment of observational cohorts.

Supplementary materials related to this article can be found online at https://doi.org/10.5946/ce.2023.297.

Ethical Statements

Not applicable.

Conflicts of Interest

Andrew C. Storm is a consultant for Apollo Endosurgery and received research support from Apollo Endosurgery and Boston Scientific. Ryan Law is a consultant for ConMed and Medtronic, and receives royalties from UpToDate. Bret T. Petersen is a consultant for Olympus America and an investigator for Boston Scientific and Ambu. Barham K. Abu Dayyeh is a consultant for Endogenex, Endo-TAGSS, Metamodix, and BFKW; a consultant and received grant/research support from USGI, Apollo Endosurgery, Medtronic, Spatz Medical, EndoGastric Solutions, Aspire Bariatrics, and Boston Scientific; speaker roles with Olympus and Johnson and Johnson; and received research support from Cairn Diagnostics. Vinay Chandrasekhara is a consultant for Covidien LP and Boston Scientific and is a shareholder in Nevakar Corporation. The other authors have no potential conflicts of interest.

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Author Contributions

Conceptualization: VC; Data curation: JA, SV; Formal analysis: VJ; Investigation: VJ, SV, RL, ACS, MT, MJL, RA, EJV, ABG, JAM, BTP, BKAD; Methodology: VJ; Supervision: VC; Writing-original draft: JA; Writing-review & editing: JA, RL, ACS, MT, MJL, RA, EJV, ABG, JAM, BTP, BKAD, VC.

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