

Endoscopic ultrasound-guided lumen-apposing metal stent with or without coaxial plastic stent for pancreatic fluid collections: a systematic review and meta-analysis comparing safety and efficacy

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Abstract

Background Endoscopic ultrasound (EUS)-guided lumen-apposing metal stents (LAMS) are preferred for draining symptomatic large pancreatic fluid collections (PFCs). A concurrent coaxial double-pigtail plastic stent (DPPS) is proposed to reduce adverse events associated with LAMS. We aimed to perform a comparative outcome analysis of LAMS with or without DPPS for PFCs.

Methods Electronic databases from January 2005 through July 2023 were searched for studies comparing the use of LAMS with or without DPPS for PFCs. Pooled proportions were calculated using fixed (inverse variance) and random-effects (DerSimonian-Laird) models.

Results After reviewing 1780 studies, we extracted data from 6 studies comprising 348 patients. The weighted odds of overall technical success, using LAMS plus DPPS compared to LAMS alone, were 0.53 (95% confidence interval [CI] 0.15-1.83), and the odds of clinical success were 1.10 (95%CI 0.59-2.05). The weighted odds of total adverse events with LAMS compared to LAMS plus DPPS were 2.21 (95%CI 1.37-3.59). Analysis of individual adverse events showed that the odds of stent occlusion when LAMS alone was used compared to LAMS plus DPPS was 2.36 (95%CI 1.12-4.98). The odds of bleeding were 1.84 (95%CI 0.77-4.38), and the odds of stent migration 0.95 (95%CI 0.40-2.23).

Conclusions EUS-guided LAMS placement is the current standard of care for managing symptomatic large PFCs. Concurrent use of coaxial DPPS can mitigate the overall adverse events observed with LAMS, while maintaining similar technical and clinical success.

Keywords Pancreatic fluid collections, walled-off pancreatic necrosis, lumen-apposing metal stent, double pigtail plastic stents, endoscopic ultrasound

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Introduction

Pancreatic fluid collections (PFCs) are primarily a local complication of acute pancreatitis. PFCs can be identified in up

to 50% of patients following an episode of acute pancreatitis, but most resolve spontaneously or are asymptomatic [1,2]. Pancreatic pseudocysts (PPs) are PFCs persisting beyond 4 weeks after a bout of acute interstitial pancreatitis, and typically result from an evolution of acute peripancreatic fluid collection. PPs have a well-defined, non-epithelialized wall and are free of solid debris [3]. They can also result from acute necrotizing pancreatitis in the setting of disconnected duct syndrome [3,4]. Walled-off pancreatic necrosis (WOPN) is an organized collection of necrotic debris, with a mature encapsulated wall of reactive tissue, that persists beyond 4 weeks after an episode of acute necrotizing pancreatitis [3,4].

The current standard of care for the management of patients with symptomatic PFCs is endoscopic drainage using ultrasound-guided creation of 1 or more fistulous tracts between the PFC and the gastrointestinal lumen (typically the stomach or duodenum) by deploying a transluminal endoprosthesis device [5]. This is achieved by placing multiple double-pigtail plastic stents (DPPS), fully covered self-expanding metal stents (FCSEMS), or, more recently, by covered self-expanding lumen-apposing metal stents (LAMS) [6]. Before

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the advent and refinement of LAMS, the traditional approach to endoscopic management of PFCs was to puncture into the PFC, with or without EUS guidance, and place multiple 7- or 10-Fr DPPS [7]. This method involved multiple procedures, requiring exchanges over guidewires under fluoroscopy and balloon dilations to achieve the desired drainage [8,9]. Overall treatment success with DPPS was reported to be around 80-85%, but this could drop to about 65% in WOPN [9,10]. Since its introduction around 2012, multiple studies have shown the efficacy and superiority of using LAMS in the management of PFCs [9,11-13]. In a study by Siddiqui *et al*, the need for endoscopic reintervention due to persistent infection caused by stent occlusion on follow-up was significantly lower in the LAMS group compared with the DPPS and FCSEMS groups (3.5%, 21.7%, and 21.5%) [9]. The LAMS has now largely replaced the DPPS as the preferred endoprosthesis for endoscopic management of PFCs, provided the expertise and equipment are available.

However, the use of LAMS for the management of PFCs has also been associated with adverse events, some of which can be serious and even fatal [14-16]. One such major adverse event is bleeding, primarily into the necrotic cavity. It is postulated that this results from the high lumen apposing force and impingement of vasculature on the collapsed necrotic cavity caused by the relatively rigid and immobile LAMS, which can subsequently lead to erosion and bleeding [6]. The creation of a large fixed fistulous tract between the gastric cavity and the PFC using a LAMS can also facilitate the accumulation of food and gastric contents in the cavity, resulting in infection or LAMS occlusion. In a large international multicenter study evaluating LAMS for the drainage of PFCs, Khan *et al* reported delayed adverse events of stent migration (7.4%), stent occlusion (7.9%) and major bleeding (2%), which were not insignificant [17]. Placement of a concurrent coaxial DPPS through the LAMS has been proposed as a method to reduce LAMS-related adverse events by improving patency, anchoring the LAMS in the intended position, and reducing its impact on adjacent vasculature [18]. Studies evaluating the safety and efficacy of this approach have shown conflicting or inconclusive results, and there is still no consensus on whether this should be standard practice [19-26]. With the availability of new data, including from a well-designed randomized controlled trial (RCT), we decided to conduct this systematic review and meta-analysis.

Materials and methods

Search methodology

A literature search was conducted using the electronic database engines MEDLINE through PubMed, Ovid, Cochrane Library (Cochrane Central Register of Controlled Trials and Cochrane Database of Meta-Analysis), EMBASE, ACP journal club, Database of Abstracts of Reviews of Effects (DARE), according to the Preferred Reporting Items for

Systematic Reviews and Meta-Analysis (PRISMA) guidelines, from January 2005 through July 2023, to identify studies comparing the outcomes of LAMS, with or without DPPS, when used for the management of pancreatic fluid collections. The keywords used were “Pancreatic fluid collections,” “Walled-off pancreatic necrosis,” “Lumen apposing metal stent,” “LAMS,” “double pigtail plastic stents,” “DPPS,” “Endoscopic ultrasound,” and “EUS.” The retrieved studies were carefully examined to exclude potential duplicates or overlapping data.

Study eligibility

Published studies were eligible if they reported data comparing the outcomes of LAMS with or without concurrent DPPS when used for managing pancreatic fluid collections. Articles were excluded if they were not in the English language. Studies in animal models, editorials, abstracts with incomplete data, and comments were excluded. Two authors (HG, SP) reviewed the full-text articles independently.

Data extraction and quality assessment

The following data were independently abstracted by 2 authors (HG, SP) into a standardized form: (a) study characteristics (primary author, period of study, year of publication, and country of the population studied); (b) study design; (c) baseline characteristics of the study population (number of patients enrolled, participant demographics, etiology for acute pancreatitis leading to PFC, the type, size and location of PFCs); (d) intervention details (type of LAMS used, type of DPPS used, indications, trans-gastric or trans-duodenal approach for stent deployment, experience of the operator); (e) outcomes (technical success, clinical success, procedure duration, if reported); and (f) adverse events.

The quality of included studies was evaluated using the Newcastle-Ottawa scale for non-randomized studies and the Jadad scale for RCTs. Differences were resolved by mutual agreement.

Outcomes evaluated

We compared the overall technical and clinical success when LAMS was used alone or with concomitant DPPS. The definition of clinical success in the included studies was primarily symptom improvement associated with imaging evidence of PFC resolution, or a minimum of 50% reduction in size on follow-up imaging, and we adopted the same definition. We also compared the overall and individual adverse events between these 2 techniques. Individual adverse events analyzed were stent occlusion, stent migration and bleeding. Any other adverse events reported by authors of individual studies were also reviewed.

Statistical analysis

This meta-analysis was performed by calculating weighted pooled effects. Individual study proportions were transformed into a quantity using the Freeman-Tukey variant of the arcsine square-root transformed proportion. The pooled proportion is calculated as the back-transform of the weighted mean of the transformed proportions, using inverse arcsine variance weights for the fixed-effects model (Mantel-Haenszel method) and the random-effects model (DerSimonian-Laird method). The heterogeneity of the studies was evaluated by Cochran's Q test based on inverse variance weights and by calculating the *I*² statistic. *P* values of 0-39% were considered non-significant heterogeneity, 40-75% moderate heterogeneity, and 76-100% considerable heterogeneity. A *P*-value >0.10 rejected the null hypothesis that the studies were homogeneous. Forest plots were drawn to show the point estimates in each study in relation to the summary of the pooled estimate. The width of point estimates in the forest plots indicates the weight assigned to that study. The odds ratio (OR) was used to represent dichotomous outcomes with a 95% confidence interval (CI), where a *P*-value of <0.05 was considered statistically significant.

The Egger bias indicator and Begg-Mazumdar bias indicator were used to test the effects of publication and selection bias on the summary estimates. Funnel plots were also constructed to assess potential publication bias using the standard error and diagnostic PR. The interobserver variability between reviewers was assessed by calculating Cohen's κ. Microsoft Excel 2019 was used to perform the statistical analysis for this study [27].

Results

The initial search identified 1780 studies, from which 120 relevant articles were reviewed after title and abstract evaluation. Data were extracted from 6 studies that met the inclusion criteria, comprising 348 patients [19-24]. A PRISMA diagram with the details of the review process is shown in Fig. 1. The characteristics of the included studies are given in Table 1. The quality of studies was good, as evaluated using the Newcastle-Ottawa scale and Jadad Quality assessment tool for RCTs. Five of the 6 studies were retrospective, while 1 was a prospective RCT. All the pooled estimates given

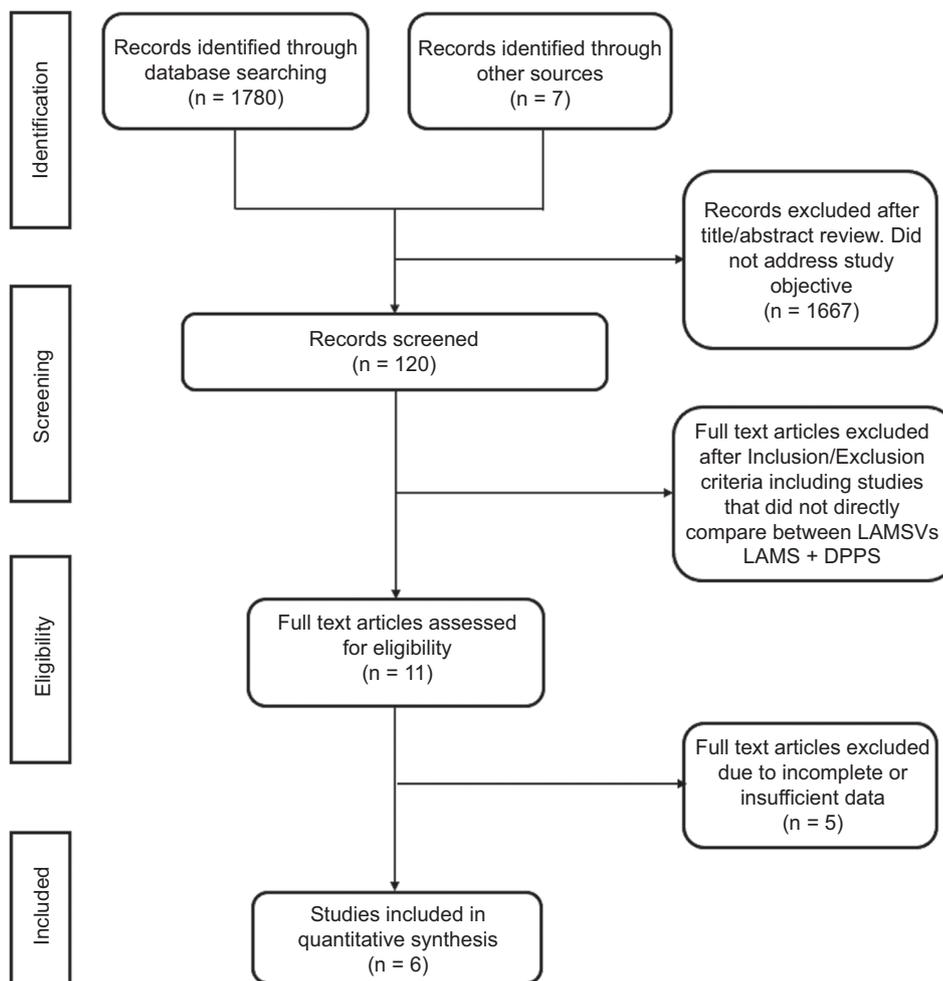


Figure 1 Study flow diagram according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline LAMS +DPPS; LAMS, lumen-apposing metal stent; DPPS, double-pigtail plastic stent

Table 1 Basic characteristics of studies included in this meta-analysis

Author, year [ref.]	Study design, location	Patients, LAMS+DPPS, LAMS only (n)	Males, Females (n)	PFC Classification WOPN, PP, Other (n)		Approach trans-gastric, trans-duodenal		Etiology for acute pancreatitis leading to PFC		
				LAMS+ DPPS	LAMS	LAMS+ DPPS	LAMS	Alcohol	Gallstone	Other
Puga <i>et al</i> 2018 [20]	Single-center retrospective, Spain	20,21	32, 9	12,8,0	11,10,0	19,1	19,1	NR	NR	NR
Aburajab <i>et al</i> 2018 [21]	Single-center retrospective, USA	23,24	36,11	0,23,0	0,24,0	21,2	23,1	23	12	12
Ali <i>et al</i> 2019 [22]	Single-center retrospective, USA	36,21	34,23	29,7,0	14,7,0	21,8	16,5	11	22	24
Shamah <i>et al</i> 2022 [23]	Multi-center retrospective, USA	35,33	44,24	11,18,6	6,26,1	32,3	30,3	24	21	22
Haddad <i>et al</i> 2023 [24]	Single-center retrospective, USA	23,45	36,32	13,7,3	29,14,2	NR	NR	16	24	28
Vanek <i>et al</i> 2023 [25]	Bicentric prospective RCT, Czech Republic	34,33	42,25	34,0,0	33,0,0	32,2	31,2	25	26	16

LAMS, lumen apposing metal stent; DPPS, double pigtail plastic stent; WOPN, walled off pancreatic necrosis; PP, pseudocyst; PFC, pancreatic fluid collection; NR, not reported; RCT, randomized controlled trial

are estimates calculated using the fixed-effects model. The estimates calculated using fixed- and random-effects models were similar. The interobserver variability between reviewers computed using Cohen's κ gave a value of 1.0.

The total sample size was 348 patients, with 35.63% females. A LAMS alone was used in 177 patients, while LAMS with concomitant coaxial DPPS was used in 171 patients to manage PFCs. The mean patient age was 51.54±2.88 years in the LAMS group and 52.51±7.36 years in the LAMS+DPPS group. The overall pooled PFC size was 11.73±2.32 centimeters in the LAMS group and 10.78±1.73 cm in the LAMS + DPPS group. The LAMS used in the studies were almost entirely AXIOS (Boston Scientific Corporation, Natick, MA, USA) 10, 15 or 20 mm, with only 1 study reporting the use of 3 NAVIX Access Device (Xlumena, Mountain View, California, USA) [19].

Technical and clinical success

Analysis showed that the weighted odds of overall technical success using LAMS + DPPS compared to LAMS alone were 0.53 (95%CI 0.15-1.83). There was no significant heterogeneity, with an I^2 score of 17% (95%CI 0-73). The weighted odds of clinical success were 1.10 (95%CI 0.59-2.05) using LAMS + DPPS compared to LAMS alone. Fig. 2 shows the odds of clinical success for the LAMS + DPPS group compared to the LAMS group. The Begg-Mazumdar bias indicator gave a Kendall's tau b value of 0.33 (P-value 0.46), suggesting no publication bias.

Adverse events

The weighted odds of overall adverse events when comparing the LAMS alone group to the LAMS + DPPS group were 2.22 (95%CI 1.37-3.59). The forest plot showing the individual study estimates and the pooled estimate for the odds of total adverse events is shown in Fig. 3. The Begg-Mazumdar bias indicator gave a Kendall's tau b value of 0.06 (P-value=0.99), suggesting no publication bias. Analysis of pooled proportions showed that the pooled rate of overall adverse events was 38.59% (95%CI 31.62-45.79) in the LAMS group and 21.02% (95%CI 15.31-27.38) in the LAMS + DPPS group. Fig. 4 shows the individual rates and weighted pooled rate of overall adverse events in the LAMS alone group, and Fig. 5 shows these results in the LAMS + DPPS group. Analysis of individual adverse events showed that the weighted odds of stent occlusion were 2.36 (95%CI 1.12-4.98) for LAMS alone compared to LAMS + DPPS. There was no significant heterogeneity, with an I^2 score of 0% (95%CI 0-67.9). The weighted odds of bleeding were 1.84 (95%CI 0.77-4.38), and the odds of stent migration were 0.95 (95%CI 0.40-2.23) when LAMS alone was used compared to LAMS + DPPS. Analysis of pooled proportions showed that the rate of stent occlusion was 12.86% (95%CI 8.38-18.13) in the LAMS group and 6.58% (95%CI 3.39-10.73) in the LAMS + DPPS group. The pooled rate of bleeding was 9.16% (95%CI 5.40-13.80) in the LAMS group and 6.20% (95%CI 3.11-10.26) in the LAMS + DPPS group. The pooled rate of stent migration was 7.06% (95%CI

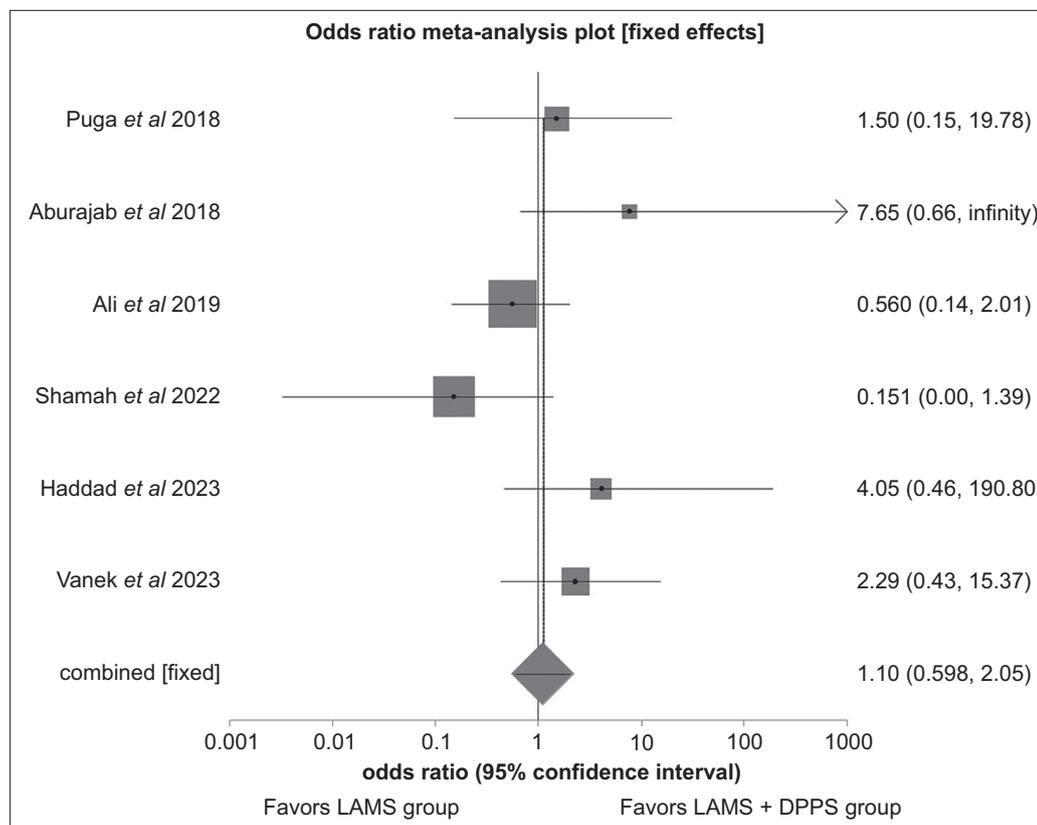


Figure 2 Forest plot showing the individual study estimates and the pooled estimate of the odds for clinical success between the LAMS + DPPS group compared to the LAMS group
LAMS, lumen apposing metal stent; DPPS, double pigtail plastic stent

3.79-11.24) in the LAMS group and 6.11% (95%CI 3.05-10.14) in the LAMS + DPPS group.

Discussion

Endoscopic transluminal drainage by creating a fistulous tract between the PFC and the gastrointestinal lumen is the favored initial approach to managing symptomatic PFCs [4]. Since its introduction, the LAMS has become the preferred endoprosthesis for achieving this, and it is replacing DPPS in many centers, given its better clinical outcomes and ease of use [5]. However, LAMS has also been associated with adverse events, including stent occlusion, stent migration, and bleeding [6]. Concurrent placement of a coaxial DPPS through the LAMS has been proposed to reduce these adverse events. The LAMS was developed to mitigate many of the shortcomings inherent to tubular stents (DPPS and FCSEMS) when used for endoscopic management of PFCs [12]. DPPS were primarily limited by their small diameter, requiring multiple wire-guided cyst access under fluoroscopy guidance and balloon dilations to achieve the intended clinical results [9]. Traditional self-expanding metal stents (SEMS) had high rates of stent migration and could result in tissue injury and bleeding from the ends abutting onto lumen walls

[9]. Studies have indicated that the LAMS is superior to DPPS and SEMS in terms of overall treatment efficacy, with significantly fewer procedures required for clinical success [9]. The findings from this meta-analysis show that the odds of overall technical success using LAMS + DPPS are similar to using LAMS alone, with an OR of 0.53 (95%CI 0.15-1.83). A trend was seen favoring LAMS + DPPS in terms of better clinical success, with an OR of 1.10 (95%CI 0.59-2.05), but this was not statistically significant with the CI including 1. This shows that using a concurrent DPPS does not negate the improved efficacy of LAMS in managing PFCs compared to other endoscopic modalities.

Adverse events, particularly stent occlusion and bleeding, are one of the main concerns with the use of LAMS. In a multicenter study involving 313 patients, Siddiqui *et al* compared LAMS to DPPS and FCSEMS in the management of WOPN and showed that LAMS were more likely to have early adverse events on multivariable analysis [9]. In a recent prospective multicenter study evaluating cauterly-enhanced (“hot”) LAMS for PFCs, Li *et al* reported a stent occlusion rate of 10% and a stent migration rate of about 7% [28]. Our analysis shows that the odds of overall adverse events were 2.2 times lower when DPPS was used concurrently with LAMS, and this was statistically significant. The pooled rate of overall adverse events was 38% in the LAMS group and 19% in the LAMS + DPPS group. From the individual analysis of adverse

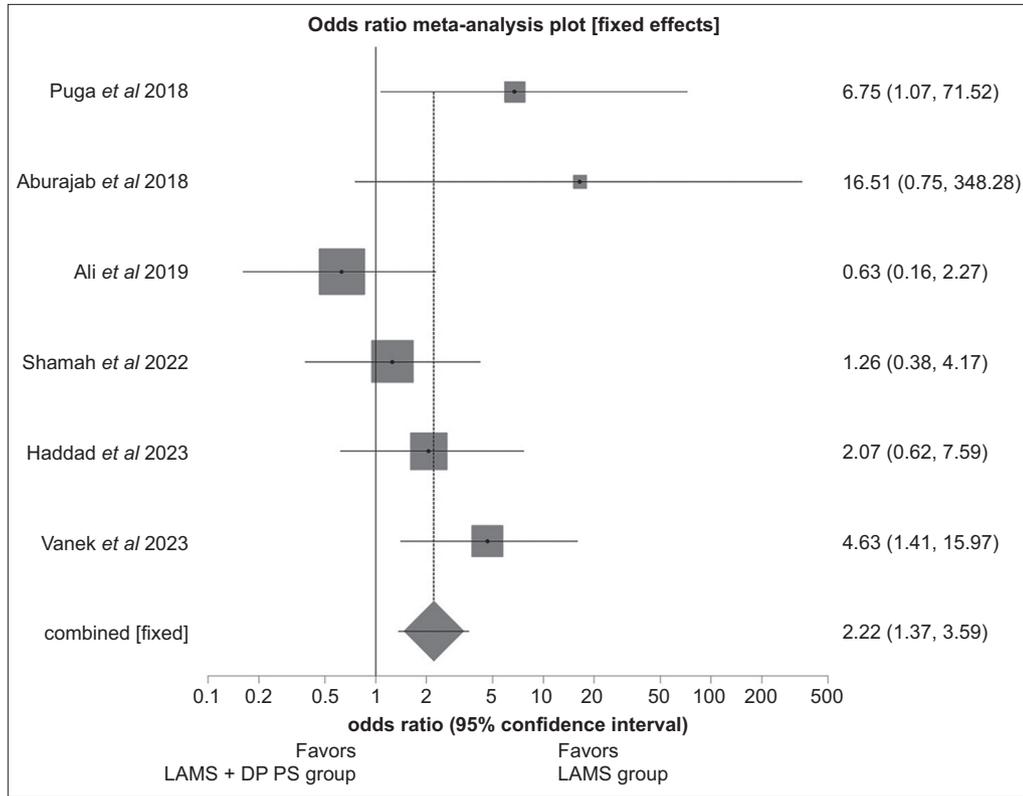


Figure 3 Forest plot showing the individual study estimates and the pooled estimate for the odds of overall adverse events between the LAMS + DP PS group compared to the LAMS group
 LAMS, lumen apposing metal stent; DP PS, double pigtail plastic stent

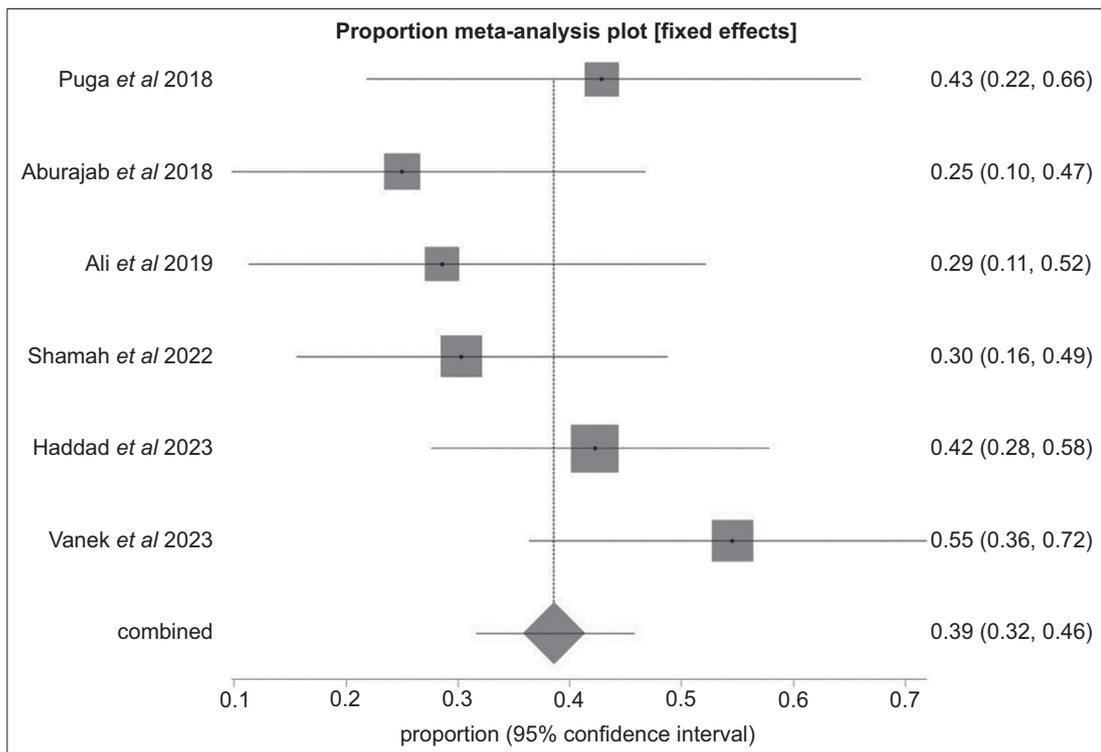


Figure 4 Forest plot showing the individual rates and weighted pooled rate of overall adverse events in the LAMS alone group
 LAMS, lumen apposing metal stent; DP PS, double pigtail plastic stent

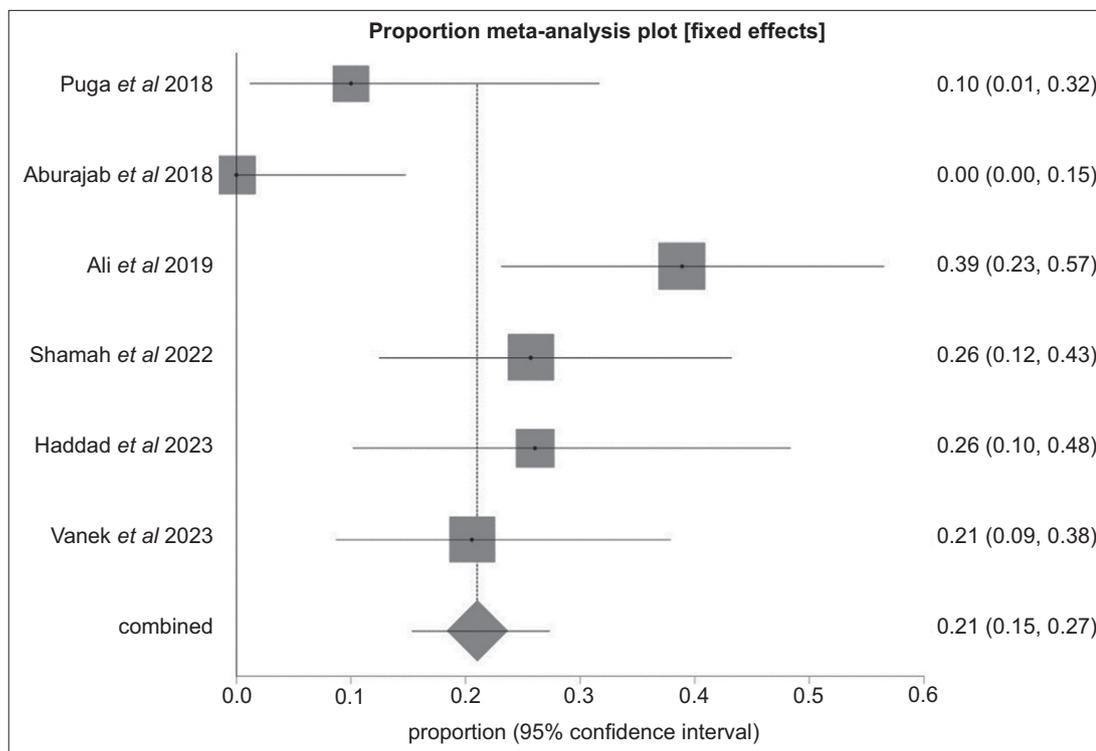


Figure 5 Forest plot showing the individual rates and weighted pooled rate of overall adverse events in the LAMS + DPPS group
LAMS, lumen apposing metal stent; DPPS, double pigtail plastic stent

events, the greatest benefit was seen in reducing stent occlusion (13% vs. 6.5%), with an OR of 2.36 (95%CI 1.12-4.98), which was statistically significant. There were also trends toward reducing bleeding and stent migration with concurrent use of DPPS; however, these were not statistically significant. These findings show that concurrent DPPS can reduce some of the risks associated with LAMS, thus improving its efficacy and safety.

There are currently no defined guidelines regarding the selection of patients for whom adding DPPS to LAMS could improve clinical outcomes. Bang *et al* proposed an algorithm (Orlando protocol) to select the most appropriate endoscopic intervention for PFCs, based on various factors, in which LAMS + DPPS was recommended only for large (>10 cm) WOPN in the setting of disconnected pancreatic duct syndrome [5]. However, studies involving only PPs have shown that adding DPPS to LAMS can reduce the rate of stent occlusion and pseudocyst infection [20]. In one of the first studies that compared the use of DPPS with LAMS to LAMS alone in PFCs, Puga *et al* reported significantly lower rates of adverse events in the DPPS group (42.9% vs. 10%; $P=0.04$) [19]. PFCs in this study included both PP and WOPN, with maximal reduction observed in the rate of bleeding. In a recent bicentric RCT involving only patients with WOPN, Vanek *et al* reported that concurrent DPPS with LAMS significantly reduced global adverse event rates and stent occlusion [24]. Furthermore, earlier studies included in this meta-analysis reported using both cautery-enhanced and non-cautery-enhanced

LAMS [19-21]. Studies have demonstrated a reduction in the risk of LAMS-related bleeding with the introduction of cautery-enhanced systems [28-30]. This suggests that the mechanism by which DPPS can improve outcomes and the affected outcomes could vary, depending on the type of PFCs and the type of LAMS used.

This meta-analysis of all currently available comparative studies suggests that adding concurrent coaxial DPPS to LAMS has the potential to reduce the overall adverse events without compromising the improved technical and clinical success in managing PFCs. A strength of this study is that it includes only data from studies that directly compared LAMS with or without DPPS for the management of PFCs, which reduces the risk of heterogeneity. Furthermore, no adverse events were attributed to the additional use of DPPS in this setting. Previous studies, including meta-analyses by Beran *et al* and Giri *et al*, were inconclusive, but demonstrated a trend favoring this approach [25,26]. Our findings suggest that there is a benefit. Future studies to elucidate the criteria where this approach would be maximally beneficial and to define the number of DPPS required with its minimum indwelling time can help appropriate patient selection.

There are a few limitations to this study. Most of the studies included in this meta-analysis were retrospective, with the inherent risk of selection bias. The decision to use a DPPS with LAMS was at the endoscopist's discretion except in the single RCT, and the reasons behind these decisions are unknown. This might have introduced selection bias.

However, the overall findings in this meta-analysis align with the conclusions of the included RCT. Although there was no significant heterogeneity on statistical analysis, these data include the use of LAMS with DPPS for both PPs and WOPN, which results in clinical heterogeneity. Another limitation is that both cautery-enhanced LAMS and non-cautery-enhanced LAMS were used in the included studies. Reduced rates of adverse events, particularly bleeding, have been reported with the use of cautery. Furthermore, almost all the LAMS used in the available studies were from the same manufacturer. With the increasing use of cautery-enhanced LAMS and novel LAMS from other manufacturers, the rates of adverse events could differ from those noted in the studies included in this meta-analysis. Future studies could be designed to identify those cases where the addition of DPPS could improve clinical outcomes.

In conclusion, endoscopic ultrasound-guided LAMS placement is the current standard of care for managing symptomatic PFCs. Concurrent use of coaxial DPPS has the potential to reduce overall adverse events observed with the use of LAMS in this setting, while showing similar technical and clinical success.

Summary Box

What is already known:

- Symptomatic large PFCs are treated by endoscopic ultrasound-guided creation of one or more fistulous tracts between the PFC and the gastrointestinal lumen
- Lumen-apposing metal stents (LAMS) placement under EUS guidance is the current standard of practice and preferred modality for achieving this
- Concurrent use of coaxial double-pigtail plastic stents (DPPS) with LAMS has been proposed to mitigate overall adverse events by improving patency, anchoring the LAMS in the intended position, and reducing its impact on adjacent vasculature. However, there is still no consensus on whether this should be standard practice

What the new findings:

- Coaxial DPPS placement can potentially reduce the overall adverse events associated with LAMS when treating PFCs
- Adding DPPS did not compromise the improved technical and clinical success observed with LAMS
- No adverse events were attributed to the additional use of DPPS in this setting

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