ISSN 1948-9366 (online)

World Journal of *Gastrointestinal Surgery*

World J Gastrointest Surg 2024 July 27; 16(7): 1956-2364

Published by Baishideng Publishing Group Inc

World Journal of Gastrointestinal Surgery

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The *WJGS* is now abstracted and indexed in Science Citation Index Expanded (SCIE, also known as SciSearch®), Current Contents/Clinical Medicine, Journal Citation Reports/Science Edition, PubMed, PubMed Central, Reference Citation Analysis, China Science and Technology Journal Database, and Superstar Journals Database. The 2024 Edition of Journal Citation Reports® cites the 2023 journal impact factor (JIF) for *WJGS* as 1.8; JIF without journal self cites: 1.7; 5-year JIF: 1.9; JIF Rank: 123/290 in surgery; JIF Quartile: Q2; and 5-year JIF Quartile: Q3.

RESPONSIBLE EDITORS FOR THIS ISSUE

NAME OF JOURNAL
World Journal of Gastrointestinal Surgery

ISSN
ISSN 1948-9366 (online)

LAUNCH DATE
November 30, 2009

FREQUENCY
Monthly

EDITORS-IN-CHIEF
Peter Schemmer

EDITORIAL BOARD MEMBERS
https://www.wjgnet.com/1948-9366/editorialboard.htm

PUBLICATION DATE
July 27, 2024

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World J Gastrointest Surg 2024 July 27; 16(7): 1981-1985

DOI: 10.4240/wjgs.v16.i7.1981

ISSN 1948-9366 (online)

EDITORIAL

Role of endoscopic-ultrasound-guided biliary drainage with electrocautery-enhanced lumen-apposing metal stent for palliation of malignant biliary obstruction

Smit S Deliwala, Emad Qayed

Specialty type: Gastroenterology and hepatology

Provenance and peer review: Invited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's classification
Scientific Quality: Grade D
Novelty: Grade C
Creativity or Innovation: Grade C
Scientific Significance: Grade C

P-Reviewer: Zhao H, China

Received: April 1, 2024
Revised: May 9, 2024
Accepted: May 24, 2024
Published online: July 27, 2024
Processing time: 111 Days and 15.2 Hours

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Abstract

In this editorial, we discuss the article by Peng *et al* in the recent issue of the *World Journal of Gastrointestinal Surgery*, focusing on the evolving role of endoscopic-ultrasound-guided biliary drainage (EUS-BD) with electrocautery lumen apposing metal stent (LAMS) for distal malignant biliary obstruction. Therapeutic endoscopy has rapidly advanced in decompression techniques, with growing evidence of its safety and efficacy surpassing percutaneous and surgical approaches. While endoscopic retrograde cholangiopancreatography (ERCP) has been the gold standard for biliary decompression, its failure rate approaches 10.0%, prompting the exploration of alternatives like EUS-BD. This random-effects meta-analysis demonstrated high technical and clinical success of over 90.0% and an adverse event rate of 17.5%, mainly in the form of stent dysfunction. Outcomes based on stent size were not reported but the majority used 6 mm and 8 mm stents. As the body of literature continues to demonstrate the effectiveness of this technique, the challenges of stent dysfunction need to be addressed in future studies. One strategy that has shown promise is placement of double-pigtail stents, only 18% received the prophylactic intervention in this study. We expect this to improve with time as the technique continues to be refined and standardized. The results above establish EUS-BD with LAMS as a reliable alternative after failed ERCP and considering EUS to ERCP upfront in the same session is an effective strategy. Given the promising results, studies must explore the role of EUS-BD as first-line therapy for biliary decompression.

Key Words: Endoscopic-ultrasound; Malignant biliary obstruction; Lumen apposing metal stent; Choledochoduodenostomy; Hepaticogastrostomy

Core Tip: Endoscopic-ultrasound (EUS)-guided biliary drainage with lumen apposing metal stent proves to be a viable and secure alternative following failed endoscopic retrograde cholangiopancreatography (ERCP) for distal malignant biliary obstruction. Given these promising results, adding EUS to ERCP upfront for distal obstruction is a reasonable strategy. Despite its efficacy, stent dysfunction remains a notable constraint. When performing this procedure, careful consideration must be given to the stent size, patient anatomy, availability of accessories, and therapeutic objectives. Patients should have regular follow-ups to ensure the patency of these stents.

Citation: Deliwala SS, Qayed E. Role of endoscopic-ultrasound-guided biliary drainage with electrocautery-enhanced lumen-apposing metal stent for palliation of malignant biliary obstruction. *World J Gastrointest Surg* 2024; 16(7): 1981-1985
URL: https://www.wjgnet.com/1948-9366/full/v16/i7/1981.htm
DOI: https://dx.doi.org/10.4240/wjgs.v16.i7.1981

INTRODUCTION

Malignant biliary obstruction, encompassing distal, hilar, or intrahepatic cases, often manifests insidiously, leading to late-stage presentations. Approximately 70% of cases stem from pancreatic cancer or cholangiocarcinoma (CCA), with the remainder attributed to metastasis or ampullary cancer[1]. Surgical resection is feasible for less than 20% of patients, necessitating reliance on endoscopic or interventional radiology for palliative relief[2]. Optimal patient outcomes hinge on a multidisciplinary approach involving oncologists, radiologists, gastroenterologists, and surgeons.

METHODS OF BILIARY DRAINAGE

Palliative biliary drainage options include internal and external methods. External drainage can be performed by percutaneous transhepatic biliary drainage (PTBD), endoscopic nasobiliary drainage, or postoperative T-tube drainage. Internal drainage is achieved through biliary stenting *via* endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic ultrasound-guided bile duct drainage (EUS-BD). Compared to surgery and PTBD, endoscopic drainage offers fewer complications, reduced mortality, shorter hospital stays, lower readmission rates, and improved quality of life[3], effectively supplanting surgery in many cases. Preoperative ERCP or PTBD for patients who are candidates for surgical resection remains controversial due to potential seeding and infection risks. Therefore, these procedures are recommended in cases of severe symptomatic biliary obstruction[3,4]. However, a recent study found that compared to patients undergoing preoperative ERCP, EUS-BD with lumen-apposing metal stents (LAMS) was easier and more effective for distal obstruction with fewer surgical complications after the pancreaticoduodenectomy without compromising the oncological outcome[5].

ERCP BILIARY DRAINAGE AND FAILURE

ERCP-based solutions include self-expanding metal stents (SEMS) and plastic stents with comparable outcomes, although metal stents have the added benefit of fewer re-intervention rates, symptom-free duration, and reduced sepsis incidence [6]. Similarly, no differences were seen between covered and uncovered SEMS, but covered SEMS was associated with a lower risk of tumor ingrowth but a higher risk of stent migration and sludge occurrence. ERCP failure, encountered in approximately 10% of cases, due to either failed cannulation (including needle knife), altered anatomy, tumor infiltration, periampullary diverticulum, in-situ stents, or stenosis can delay care and diminish quality of life[3]. In this setting, a few solutions exist: Interval ERCP within two to four days, PTBD, single or double staged percutaneous transhepatic endoscopic rendezvous (PTE-RV), or EUS-BD. Traditionally, PTBD was used as salvage therapy, and PTE-RV was an improved modification to the technique with fewer adverse events; despite this, both procedures have high morbidity.

EUS-GUIDED BILIARY DRAINAGE

EUS-BD has emerged as a viable alternative *via* three methods. First, the rendezvous technique guides a wire into the intrahepatic or extrahepatic bile duct and is retrieved by a side-viewing endoscope; second, bypassing the ampulla *via* choledochoduodenostomy (EUS-CD) or hepaticogastrostomy (EUS-HG), and third, EUS-guided antegrade transpapillary stent placement. EUS-RV is generally used in benign biliary and stone disease. EUS-CD and EUS-HG have demonstrated success rates of over 90% in clinical trials, and a large part of this has been due to improvements in the stents used to create the anastomosis[1]. Initial experiences of EUS-BD using SEMS were compared to PTBD, EUS-BD demonstrated higher success, lower adverse events, costs, and need for re-interventions in cases after failed ERCP[7]. Similarly, compared to ERCP-BD, no differences in success rates and stent patency were seen, but EUS-BD had fewer episodes of

stent dysfunction[8].

EUS-BD WITH LAMS

As EUS became more mainstream, with it came the availability of dedicated accessories, and soon, there was a drive to improve the mechanics and adverse events that came with SEMS[9]. This led to the introduction of LAMS with the ability to support the anchorage between nonadherent and luminal structures, making them pliable yet resistant to tumor ingrowth and track leakage[10]. LAMS are available as noncautery-enhanced (cold technique-internal diameter 10 mm or 15 mm) or as electrocautery-enhanced (hot technique-internal diameter 6 mm, 8 mm, 15 mm, or 20 mm). The hot technique eliminates the need for guidewire exchange and tract dilation prior to stent deployment, and this "free-hand" technique can be done without fluoroscopy. LAMS placement for EUS has a high technical and clinical success of over 90.0% and can also be placed through the mesh of duodenal stents[11]. LAMS has an adverse event rate of 5.6%.

A network meta-analysis of five randomized controlled trials comparing various biliary drainage modalities post-failed ERCP demonstrated similar clinical success rate between PTBD, surgery and EUS; however, PTBD was associated with higher adverse events. Moreover, surgery did not exhibit superiority over EUS[12], however the capabilities of EUS were limited in these studies, as they were published before LAMS adoption. The benefits of EUS are evident, leading the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society for Gastrointestinal Endoscopy (ESGE) to recommend its addition to ERCP for distal biliary strictures[13] at specialized centers. Upfront EUS with ERCP can also be considered in the same session in distal obstruction. With the widespread adoption of LAMS, improved procedural techniques, and refined patient selection, periodic summarization and reassessment of the impact of LAMS is warranted.

META-ANALYSIS

We have read with great interest the article by Peng *et al*[14]. The authors performed a comprehensive random-effects meta-analysis, obtaining pooled proportions and describing the efficacy and safety of EUS-BD with electrocautery-enhanced LAMS. This study builds upon their previous work from 2021, focusing on the use of LAMS for biliary obstruction following unsuccessful ERCPs. Incorporating data from eight additional studies between 2020 to 2022, the analysis encompasses a total of 14 studies conducted across tertiary centers worldwide: Europe (n = 10), Asia (n = 2), Oceania (n = 1), and North America (n = 1). Among these, seven studies were multicenter and two were prospective in design. This meta-analysis included 620 patients, 51.5% were male with a mean age of 73.7 years ± 13.8 years. Mean follow-up duration was 203.6 days ± 179.4 days. Pancreatic cancer and CCA were the most common causes of obstruction, while duodenal stenosis was the most common cause of ERCP failure.

The primary outcome of EUS-BD with LAMS demonstrated a high technical success of 96.7% unaffected by subgroup variables such as region, study size, year, or study scale. However, publication bias and a moderate level of heterogeneity were observed, likely due to differences in study design. Similarly, clinical success was 91%, with slightly higher rates in studies outside Europe of high methodological quality, smaller cohorts, and published post-2021. The heterogeneity is likely due to the variability in the definition; a recent study used the degree of bilirubin drop as a clinical measure[15], which can be considered in future studies. Adverse events occurred in 17.5%, with the most common reasons being intraprocedural (bleeding), post-procedural (cholangitis), and late (stent dysfunction), with one case of duodenal perforation and a reintervention rate of 7.3% from 553 patients and 13 studies. The authors reported a P value in all their outcomes; however, a comparator arm was not used in this study design, where a pair-wise analysis or effect measures such as odds-ratio or risk-ratio can be performed to generate a P value. Therefore, the P value reported in this study cannot be used with the same confidence. All except one study used Boston Scientific (Marlborough, MA) LAMS between 6-15 mm; the majority used 6 and 8 mm, with only one case using a 15 mm stent. The study did not provide outcomes based on stent size, a major limitation as the current literature has mixed results. A recent study demonstrated the safety of LAMS and suggested that stent size was an independent risk factor for adverse events, while common bile duct size had no influence on the efficacy or safety of LAMS placement. When selecting LAMS size, the superior success rates of 6mm must be balanced against the increased radial force of 8 mm stents to mitigate migration, as no differences in technical or clinical success exists between them, albeit a lower adverse event rate with 8 mm stents[16]. Many of the late adverse events (after 14 days) were related to stent dysfunction. Results from the SCORPION-p study reported high rates of stent dysfunction in LAMS of 55% at six months, higher than previously reported in retrospective studies. This may have been due to the use of smaller diameter stents and the low rates of prophylactic double-pigtail stents[17].

Prophylactic coaxial double-pigtail plastic stenting during the index procedure is still controversial but has been described as a method to mitigate LAMS dysfunction; in this study, 109 cases (18%) had pigtail plastic stents placed; however, it is unclear which sized stents were used, and their outcomes were not reported. Future studies can explore the impact of prophylactic pigtail stents on repeat interventions.

The study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, excluding conference abstracts and addressing study overlap. Study quality was evaluated using the Methodological Index for Non-randomized Studies criteria, with nine studies deemed high quality and five low quality. In conclusion, we believe these findings enhance comprehension of the efficacy and safety amid its rising utilization. With the established role of EUS-BD post-failed ERCP, further investigations into its potential as a first-line intervention and bridge to surgery for biliary obstruction and its role in proximal strictures are warranted, given the promising results thus far[15]. As the

body of evidence grows, this would appear to be a natural next step in the application of EUS-BD for biliary obstruction.

CLINICAL IMPLICATIONS

Electrocautery-enhanced LAMS is an effective and safe modality for decompressing the bile duct in cases of distal biliary obstruction. It has established itself in the treatment algorithm after failed ERCPs. Consider adding EUS to ERCP upfront for distal biliary obstructions, which could be an effective method for managing these conditions. This would be particularly helpful in cases where the ampulla is inaccessible. This study did not provide guidance on the optimal stent size or its role as a bridge to surgery.

CONCLUSION

This random effect meta-analysis reaffirms recent studies and the growing body of literature that the worldwide success and safety rates are at acceptable levels as EUS-BD is rapidly adopted. However, the challenges of stent dysfunction and migration still need to be addressed as well as the optimal stent size.

FOOTNOTES

Author contributions: Deliwala SS and Qayed E designed the overall concept and outline of the manuscript; both authors contributed to writing and editing the manuscript.

Conflict-of-interest statement: The authors report no conflict of interest.

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S-Editor: Chen YL
L-Editor: A
P-Editor: Cai YX

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