Hepaticogastrostomy versus choledochoduodenostomy: An international multicenter study on their long-term patency

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ABSTRACT

Background and Objectives: EUS-guided biliary drainage (EUS-BD) offers minimally invasive decompression when conventional endoscopic retrograde cholangiopancreatography fails. Stents can be placed from the intrahepatic ducts into the stomach (hepaticogastrostomy [HG]) or from the extrahepatic bile duct into the small intestine (choledochoduodenostomy [CCD]). Long-term patency of these stents is unknown. In this study, we aim to compare long-term patency of CCD versus HG.

Methods: Consecutive patients from 12 centers were included in a registry over 14 years. Demographics, procedure info, adverse events, and follow-up data were collected. Student’s t-test, Chi-square, and logistic regression analyses were conducted. Only patients with at least 6-month follow-up or who died within 6-month postprocedure were included. Results: One-hundred and eighty-two patients were included (93% male; mean age: 70; HG n = 95, CCD n = 87). No significant difference in indication, diagnosis, dissection instrument, or stent type was seen between the two groups. Technical success was 92% in both groups. Clinical success was achieved in 75/87 (86%) in the HG group and 80/80 (100%) in the CCD group. A trend toward higher adverse events was seen in the CCD group. A total of 25 patients out of 87 needed stent revision in the HG group (success rate 71%), while eight out of 80 were revised in the CCD group (success rate 90%). Chi square shows CCD success higher than HG (90% vs. 71%, P = 0.010). After adjusting for diagnosis, jaundice or cholangitis presentation, instrument used for dissection, and gender, CCD was 4.5 times more likely than HG to achieve longer stent patency or manage obstruction (odds ratio 4.5; 95% 1.1548–17.6500, P = 0.0302).

Conclusion: CCD is associated with superior long-term patency than HG but with a trend toward higher adverse events. This is particularly important in patients with increased survival. Additional studies are required before recommending a change in practice.

Key words: therapeutic EUS; EUS-guided biliary drainage; hepaticogastrostomy; choledochoduodenostomy; percutaneous transhepatic biliary drainage
INTRODUCTION

ERCP is the gold standard procedure for biliary decompression. However, the inability to cannulate the biliary duct in ERCP is seen in 5%–10% of cases.[1,2] Variable comorbidities, compounding medical problems, and anatomical structural alterations such as upper intestinal obstructions, periampullary diverticula, and periampullary tumor infiltration can lead to ERCP failure. Until recently, percutaneous transhepatic biliary drainage was the only option in such cases of failure, however, the past two decades have seen the rise of EUS-guided biliary drainage (EUS-BD) as a safe and efficacious alternative.[3,4]

Biliary decompression in EUS-BD is achieved through four techniques. The different techniques involve (1) the access point within the biliary tree: Intrahepatic or extrahepatic and (2) the location of stent placement: transgastric/transenteric or transpapillary/transanastomotic.[5] Intrahepatic biliary access requires the endoscope to be positioned in the gastric cardia or lesser curvature of the stomach with creation of a fistula between the stomach and the left intrahepatic duct. This step is followed by the placement of a stent either from the dilated left intrahepatic duct to the stomach (EUS-guided hepaticogastrostomy, [HG]) or across the ampulla/anastomosis in an antegrade fashion (EUS-antegrade stent placement). In the extrahepatic approach, the common bile duct (CBD) or common hepatic duct (CHD) is visualized and accessed through the duodenal bulb, a fistula is created between the duodenum and the duct, and a stent is deployed from the CBD or CHD into the small bowel lumen (EUS-guided choledochoduodenostomy [CCD]) or a rendezvous is performed with transpapillary stent placement through conventional ERCP after retrieving the guidewire from the duodenum.[6,7]

An HG can be prioritized in cases where the papilla is not endoscopically accessible due to gastric outlet obstruction, an obstructing proximal duodenal tumor, or altered anatomy (Whipple, roux-en-Y etc.).[7] Alternatively, CCD may be preferable in cases of ampullary neoplasm, malignant infiltration from pancreatic cancer, or when access to the papilla is restricted due to the presence of stenosis.[7] The decision of which approach to use is typically made by the endoscopist and is dependent on the patient's anatomy, clinical diagnosis, and operator expertise.[8]

Comparative studies have showed no significant difference in efficacy and safety between the two approaches.[9]

There continues to exist a lack of data surrounding long-term consequences of CCD and HG. In this study, we aim to compare long-term patency of CCD versus HG in patients with prior failed ERCP.

METHODS

Consecutive patients from 12 centers were included in an IRB-approved dedicated registry over 14 years (NCT 01522573). This included patients with biliary obstruction who failed conventional ERCP and received HG or CCD. All patients were consented for ERCP and EUS-guided biliary drainage procedures [Tables 1 and 2]. All echoendoscopists performing those procedures had previous experience with therapeutic EUS with at least fifty successful EUS-guided biliary drainage. Demographics, procedure info, adverse events, and follow-up data were collected. Only patients with at least 6-month follow-up or who died within 6-month postprocedure were included.

Contraindications included hemodynamically, unstable patients, uncontrolled coagulopathy, severe ascites, patients with diffuse metastatic diseases, or evaluated for hospice care.

Technical success was defined as successful biliary drainage with stent placement. Clinical success was defined as relief of cholangitis, jaundice, and/or pruritus with at least a 30% decrease in the pretreatment bilirubin level within a week after placement or normalization of bilirubin within 30 days (i.e.: long-term patency).[8,9]

Table 1. Centers and cases included (n=182)

| Centers | Cases included (n) |
|---------|--------------------|
| Jean Mermoz private hospital, Lyon, France | 62 |
| Instituto Ecuatoriano de Enfermedades | 10 |
| Digestivas, Guayaquil, Ecuador | 9 |
| Ochsner Medical Center, New Orleans, Louisiana | 10 |
| Mount Sinai Hospital, New York, New York | 20 |
| Hospital Vithas Xanit Internacional, Malaga, Spain | 10 |
| Hospital Universitario Ramón y Cajal, Madrid, Spain | 3 |
| Asian Institute of Gastroenterology, Hyderabad, India | 13 |
| Weill Cornell Medical, New York, New York | 26 |
| Hospital das Clínicas da FMMPUSP, Sao Paulo, Brazil (2 centers) | 17 |
| Methodist Dallas Medical Center, Dallas, TX, USA | 4 |
| Institut Paoli-Calmettes, Marseille, France | 18 |
Stent patency was defined as the absence of any malfunction, obstruction, or migration that would adversely affect biliary drainage.

Stent patency failure was defined as any stent malfunction (including occlusion and migration).

Stent obstruction was defined as any occlusion of the stent placed.

Long-term stent patency was defined as a need for repeat stenting after 30 days postprocedure.

Procedural technique
All procedures were performed under general anesthesia with carbon dioxide insufflation by three interventional endoscopists trained in both EUS and ERCP using therapeutic linear echoendoscopes (GF-UCT-180, Olympus, Center Valley, PA).

Hepaticogastrostomy
The echoendoscope is inserted into the stomach and placed facing the left side of the liver. The left hepatic system is accessed with a 19G needle after using color flow Doppler to assess local vasculature. A cholangiogram is obtained through contrast injection. A wire is advanced through the needle into the biliary tree.

The wire is coiled in the distal biliary tree above the confluence. A needle-knife or cystotome is used to dissect the fistulous tract. A dilating balloon is advanced over the wire, and the fistulous tract is sequentially dilated. A stent is advanced over the wire and deployed with the proximal end in the biliary tree and the distal end in the stomach.

Choledochoduodenostomy
An echoendoscope is inserted into the duodenum and the CBD is identified by ultrasonography. After checking local vasculature with color flow Doppler, the bile duct is punctured with a 19G needle and a cholangiogram is performed using contrast injection. A wire is advanced through the needle into the biliary tree.

A needle-knife or cystotome or cautery-enhanced LAMS is used to dissect the fistulous tract. A stent is then deployed with the proximal end in the bile duct and the distal end in the small bowel.

When the patency of the stent was compromised short term or long term; the stent was accessed with a wire guided catheter and new stent deployed within the first occluded stent (if uncovered or partially covered). In the case, the stent was fully covered; it was simply replaced over a wire.

Statistics
Student’s t-test analyses were conducted for comparing continuous variables, while Chi-square and Fisher’s exact tests were used for categorical variables. Multivariate analyses (logistic regression analyses) were conducted to determine odds ratios and predictors associated with stent patency. Two-sided P < 0.05 was considered statistically significant. All descriptive and statistical analyses were conducted using MedCalc V14.8.1 (MedCalc Software, Ostend, Belgium).

RESULTS
One-hundred and eighty-two patients were included (93% M, mean age; 70). Ninety-five subjects underwent HG and 87 underwent CCD. Most cases (94% HG and 87% CCD) were due to malignant obstruction. Most cases had undergone failed conventional ERCP (n = 172, 95%). The HG group had 57/95 cases with abnormal anatomy (60%), while the CCD group had 28/87 cases with abnormal anatomy (32%). The HG group had a larger number of patients initially diagnosed with cholangitis when compared to CCD group (P = 0.018) [Table 2]. Technical success was 92% in both groups. Technical failure (8%) occurred either due to inability to progress guidewire or stent over the guidewire. Clinical success was achieved in 75/87 (86%) in the HG group and 80/80 (100%) in the CCD group. A total of 25 patients out of 87 needed re-stenting in HG group (29%), while 8 out of 80 (10%) were re-stented in the CCD group.

In the HG group, six cases received percutaneous reintervention (6%), while eight cases received percutaneous reintervention in the CD group (9%).

At the 6-month follow-up, 77/182 subjects were alive (42%), with similar percent survival in both groups.

No significant difference in indication, diagnosis, dissection instrument, or stent type was seen between
Table 2. Hepaticogastrostomy versus choledochoduodenostomy demographics and clinical outcomes (n=182)

| Characteristics          | HG (n=95) | CCD (n=87) | P  |
|--------------------------|-----------|------------|----|
| Age (years), mean (SD)   | 69.9 (12.7)| 69.7 (12.8)| 0.320102 |
| Gender-male, n (%)       | 52 (55)   | 41 (50)    |    |
| Diagnosis, n (%)         |           |            |    |
| Benign                   | 6 (6)     | 11 (13)    | 0.142818 |
| Choledocholithiasis (1)  |           |            |    |
| Malignant                | 89 (94)   | 76 (87)    |    |
| Ampullary adenocarcinoma (1) |    |            |    |
| Gallbladder cancer (5)   |           |            |    |
| Cholangiocarcinoma (19)  |           |            |    |
| Pancreatic cancer (42)   |           |            |    |
| Colorectal cancer (6)    |           |            |    |
| Others (16)              |           |            |    |
| Indication, n (%)        |           |            |    |
| Obstructive jaundice     | 75 (79)   | 77 (89)    | 0.018186 |
| Cholangitis              | 25 (21)   | 10 (11)    |    |
| Instrument for dissection|          |            |    |
| Balloon dilator          | 25        | 26         |    |
| Needle knife             | 20        | 20         |    |
| Cystotome                | 55        | 21         |    |
| Cautery tipped           | -         | 9          |    |
| Stent type               |           |            |    |
| Plastic (7 or 10 French diameter) | 8        | 15         | 0.086553 |
| Metal (8- or 10-mm diameter) | 82       | 70         |    |
| LAMS                     | 0         | 25         |    |
| FCSEMS                   | 61        | 45         |    |
| Partially covered or uncovered | 21    | 0          |    |
| Technical success, n (%) | 87/95 (92)| 80/87 (92)| 0.010|
| Clinical success, n (%)  | 25/87 (71)| 8/80 (90)  |    |
| Adverse events, n (%)    | 20 (21)   | 26 (30)    | 0.170817 |
| Biloma                   | 1         |            |    |
| Cholangitis              | 2         | 1          |    |
| Bleeding                 | 6         | 3          |    |
| Peritonitis              | 1         |            |    |
| Perforation              | 2         | 2          |    |
| Migration                | 1         | 1          |    |
| Infection                | 2         | 3          |    |
| Other                    | 5         | 10         |    |
| Successful management of obstruction, n (%) | 75/87 (86) | 80/80 (100) |    |
| Total follow up duration (months) | 6       | 5.6        | 0.422554 |
| Total endoscopic sessions (range) | 1.9 (1-13) | 1.22 (1-3) | 0.0043 |

LAMS: Lumen-apposing metal stent; FCSEMS: Fully-covered self-expanding metal stent; SD: Standard deviation; CCD: Choledochoduodenostomy; HG: Hepaticogastrostomy

the two groups. A trend toward higher adverse events was seen in the CCD group but was not statistically significant (30% vs. 21%, P = 0.1708).

Mean follow-up time was not statistically different between the two groups (6 months and 5.6 months). After adjusting for diagnosis, jaundice or cholangitis presentation, instrument used for dissection, and gender, CCD was 4.5 times more likely than HG to achieve longer stent patency or manage obstruction (odds ratio [OR] 4.5; 95% 1.1548–17.6500, P = 0.0302).

After adjusting for diagnosis, jaundice or cholangitis presentation, and gender, the usage of cystotome and cautery tipped catheter was 3.5 times more likely to achieve long-term patency (OR 3.55; 95% 1.5–8.7, P = 0.0006) than balloon dilator and needle knife.

**DISCUSSION**

ERCP has been the standard of care for biliary drainage for at least 40 years. However, ERCP can fail in the setting of upper intestinal obstruction,
periampullary diverticulum, periampullary tumor infiltration, or structural alterations. EUS-BD was introduced two decades ago as a novel technique for biliary drainage.\[^{11}\] Since then, it has risen as a minimally invasive technique for biliary decompression and has shown high rates of technical success with minimal adverse events.\[^{11}\]

The two transluminal approaches of EUS-BD are EUS-guided CCD and EUS-guided HG. We compared the two techniques in terms of safety and efficacy. It is intuitive to place a stent in the transpapillary/transanastomotic fashion as it follows the anatomy of the patient; even with the added anatomical advantage; however, there exists no clear consensus on which technique is optimal.\[^{12-15}\] One algorithm has been proposed to select an approach based on the presence of intrahepatic dilation.\[^{8}\] The technical success of EUS-BD with the use of the algorithm was 96%, a rate comparable and even higher than other published reports.\[^{4}\] Interestingly, a lower rate of adverse events involving both techniques was seen when using this algorithm.

Many studies have established no difference in safety and efficacy between HG and CCD.\[^{8,16,17}\] In a meta-analysis, Uemura et al. showed that CCD and HG have equal efficacy and safety and are both associated with a very high technical and clinical success rate.\[^{4}\] In a separate study involving jaundiced patients with distal malignant biliary obstruction at multiple international centers, Khashab et al. showed that both CCD and HG are similarly effective and safe techniques; however, adverse events occurred more commonly in the HG group. The 1-year stent patency probability was greater in the CCD group, but overall patency was not significantly different.\[^{18}\] A summary of the characteristics of included studies is shown in Table 3.

Our study can add a crucial element to the algorithmic approach described by Tyberg et al.: The concept of long-term patency. This study demonstrated that CCD was 4.5 times more likely to achieve longer stent patency than HG. When comparing both procedures, we found a statistically significant difference in the number of endoscopic procedures between CCD and HG, indicating that those in the CCD group had a lower number of total endoscopic sessions than those in the HG group. In addition, we noted a higher trend toward requiring stent revision in the HG group than

| Reference                | Number of procedure | Number of technical success | Average age | Number of clinical success | Adverse events                                                                 | Stent patency (days) |
|--------------------------|---------------------|-----------------------------|-------------|----------------------------|--------------------------------------------------------------------------------|----------------------|
| Artifon et al.           | 24                  | NR                          | NR          | NR                         | Bile leakage (1), perforation (1), bleeding (1)                                | NR                  |
| Khashab et al.           | 25                  | NR                          | 62.3        | NR                         | Bacteremia (2), biloma (2), bleeding (1), cholangitis (1), pancreatitis (1)    | NR                  |
| Ogura et al.             | 60                  | 56                          | 71          | 56                         | Peritonitis (1), bile leakage (1), bleeding (1), pancreatitis (1)             | NR                  |
| Guo et al.               | 61                  | 56                          | 38          | 56                         | Peritonitis (1), bile leakage (1), bleeding (1), pancreatitis (1)             | NR                  |
| Cho et al.               | 13                  | 13                          | 71          | 13                         | Cholangitis (6)                                                                | NR                  |
| Kawakubo et al.          | 33                  | 33                          | 62.3        | 33                         | Pneumoperitoneum (1), bleeding (1), cholangitis (3)                            | NR                  |

NR: Not reported; CCD: Choledochoduodenostomy; HG: Hepaticogastrostomy
in the CCD group (28.7% vs. 10%, respectively). These results indicate that CCD is associated with superior long-term patency than HG but with a higher trend toward adverse events. On the contrary, other studies have reported a higher trend toward adverse events in the HG group, demonstrating that there is a need for more studies comparing the two procedures.[18,19]

While previous studies have showed both procedures deemed equivalent in terms of safety, our higher number of adverse events noted in the CCD technique could be attributed to the higher rate of malignancy in many patients, known to make the procedures more challenging.[4,20]

Importantly, most reoccurrence of obstruction can be managed endoscopically as previously described by Nakai et al.[21]

CONCLUSION

In patients who have failed ERCP, CCD is associated with superior long-term patency than HG, independent of diagnosis, indication, instruments used, or gender but with a trend toward higher adverse events. However, further studies are required to assess long-term patency and the need for re-intervention.

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Conflicts of interest

Carlos Robles-Medranda and Sundeep Lakhtakia are Editorial Board Members of the journal, Michel Kahaleh is an Associate Editor, and Marc Giovannini is a Founding Editor. The article was subject to the journal's standard procedures, with peer review handled independently of these Editors and their research groups.

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