Use of partially covered and uncovered metallic prosthesis for endoscopic ultrasound-guided hepaticogastrostomy: Results of a retrospective monocentric study

Chiara De Cassan[1,2], Erwan Bories[1], Christian Pesenti[1], Fabrice Caillol[1], Sébastien Godat[1], Jean Philippe Ratone[1], Jean Robert Delpero[1], Jacques Ewald[1], Marc Giovannini[1]

[1]Endoscopic Unit, Institut Paoli-Calmettes, Marseille, France; [2]Department of Surgery, Oncology and Gastroenterology, Division of Gastroenterology, University of Padua, Padua, Italy

ABSTRACT

Background and Objectives: Endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) represents an option to treat obstructive jaundice when endoscopic retrograde cholangiopancreatography (ERCP) fails. The success rate of this procedure has been shown to be very high. Up to now, plastic and self-expandable metallic stents (SEMSs) have been employed, each of them presenting some limitations. The aims of this study were to evaluate the technical and functional success rates of EUS-HGS using a dedicated biliary SEMS with a half-covered part (Giobor® stent). **Methods:** We retrospectively reviewed data of patients, who underwent EUS-HGS at our center, with at least 6 months of follow-up. Demographic, clinical, and laboratory data were extracted from the patient's charts and electronic records. Technical success rate was defined as the successful passage of the Giobor stent across the stomach, along with the flow of contrast medium and/or bile through the stent. Functional success rate was considered achieved when the decrease of bilirubin value of at least 25% within the 1st week was obtained. The rate of early and late complications was assessed. **Results:** A total of 41 patients were included (21F/20M, [mean age 66, range 45–85]). Technical success rate was obtained in 37 (90.2%) of patients. Functional success rate, analyzable in 29 patients, occurred in 65%. Between the 37 patients in whom HGS was technically feasible, 13 patients (31.7%) presented an early complication, mostly infective. At 6-month follow-up, 10/37 patients (27.0%) required a new biliary drainage (BD) and 11/37 (29.7%) died because of their disease. **Conclusions:** EUS-HGS using Giobor® stent is technically feasible, clinical effective, safe, and may be an alternative to percutaneous transhepatic BD in case of ERCP failure for biliary decompression.

Key words: Endoscopic retrograde cholangiopancreatography, hepaticogastrostomy, percutaneous transhepatic biliary drainage

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is the first-line treatment for biliary tree

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Address for correspondende

Dr. Erwan Bories, Endoscopic Unit, Institut Paoli-Calmettes, Marseille, France.
E-mail: erwan.bories@outlook.fr

drainage, even in case of malignant obstructive jaundice.[1,2] Unluckily, this technique fails in up to 3%–12% of cases: Cannulation failure, postsurgical status, or tumor infiltration.[3] Biliary drainage (BD) has been traditionally obtained by percutaneous transhepatic BD (PTBD) or by surgery in case of ERCP failure.[4] PTBD presents a high rate of complications, up to 25%–30% of cases, mostly represented by biliary leakage or hemorrhagic peritonitis, and is associated with a patient discomfort due to external drainage.[5-7] Surgery can be associated with decrease in patients' quality of life, due to high recovery time required, and to the possible delay in chemotherapy.[8]

Endoscopic ultrasound-guided BD (EUS-BD) has been introduced as a possible alternative to PTBD and to surgery.[9,10] Multiple techniques and routes have been experimented, depending on the possibility of transpapillary approach: anterograde transpapillary biliary stent placement or rendezvous technique versus transgastric (intrahepatic [IH]) or transenteric (extra-hepatic [EH]) approaches.[11-13]

The anterograde transpapillary biliary stent consists of EUS-guided puncture of left-IH or EH biliary duct, followed by the passage of a guidewire, and then a metallic stent is inserted transpapillary across the strictures in an anterograde fashion.[14] Rendezvous technique consists of the EUS-guided insertion of a wire into the biliary tree, and then, through the papilla, into the duodenum. This allows a cannulation of the papilla 'over-the-wire' and consequently a conventional retrograde BD through ERCP.[15]

Transgastric and transenteric approaches should be reserved in case of papillary inaccessibility and consist of creating a fistula between the digestive tract and the IH left biliary duct or the common bile duct for EUS-guided hepaticogastrostomy (EUS-HGS) and choledocoduodenostomy (CDS), respectively.

Since the first cases described in 2003 by Giovannini *et al*.[9] and Burmester *et al*.,[16] EUS-HGS technique has evolved. Several stents have been experimented, particularly plastic and uncovered (UC) or fully covered (FC) self-expandable metallic stents (SEMSs).[17]

In this study, we evaluated the feasibility and usefulness of EUS-HGS using a new half-covered and half-UC stent, the Giobor® prosthesis (Taewoong Medical®).

METHODS

Subjects
We performed a retrospective study on patients who underwent EUS-HGS using Giobor® stent in our center between July 2009 and July 2014. During this period, a total of 2875 patients underwent BD, of whom 349 underwent PTBD (12%), 2483 ERCP (86%), and 43 combined ERCP and PTBD (2%). We included patients in whom biliary cannulation or bile duct decompression by ERCP or percutaneous approaches had failed. Indications of EUS-HGS were postsurgical anatomy, duodenal tumoral invasion, and selective left biliary duct drainage. Exclusion criteria included EUS-HGS performed with plastic or metallic stents different from Giobor® prosthesis and patients included in a randomized controlled trial comparing EUS-HGS and PTBD.

Study protocol
All the procedures were carried out with the patient in a supine position, under general anesthesia and after oral intubation. A therapeutic linear echoendoscope (EG3830UT; Pentax, Hamburg, Germany) was used, and the procedure was done under endoscopic, ultrasound, and fluoroscopic guidance, using CO_2 insufflator. Procedures were performed by two experienced endoscopists (MG and EB). Informed consent had been obtained from each patient. Left biliary duct puncture was achieved with standard (Echo 19, Cook Endoscopy, Limerick, Ireland) or modified (access needle, Cook Endoscopy, Limerick, Ireland) 19-gauge needle. After successful EUS-guided puncture and ductal visualization by contrast injection [Figure 1a], a 0.035 inch or 0.025 inch hydrophilic guidewire was inserted into the biliary duct [Figure 1b]. Afterward, the diameter of the tract was increased by means of a 6 Fr cystotome (Endo-Flex Company, Voerde, Germany).[10] An SEMS made of nitinol wire with the proximal half-covered of silicon (Giobor® stent; Taewoong Medical®, Korea) was then placed to keep open the fistula between the left biliary duct and gastric lumen [Figure 1c]. The covered part is positioned to cover the space between left hepatic lobe and the stomach while the UC part is located inside the left biliary duct. Two different lengths of stents were available, 8 cm and 10 cm, both 10 mm diameter, with a covered part length of 4 cm or 5 cm, respectively. The fluoroscopic markers are at both ends of the stent and the junction between covered and
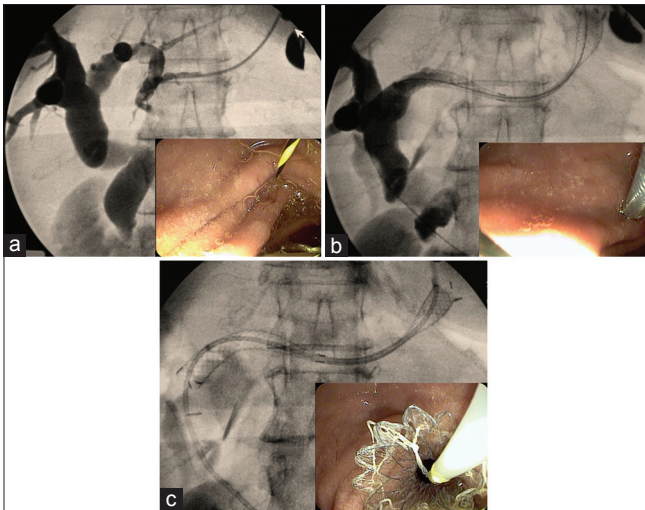
Figure 1. (a-c) Endoscopic ultrasound-guided hepaticogastrostomy procedure using Giobor® stent

UC parts. The choice of the stent's length was done according to the personal judgment of endoscopist, based on the anatomical patients' characteristics, so that the intragastric portion must be at least 2 cm. The delivery system was 180 cm in length and 8.5 Fr in diameter. A 6- or 7-Fr nasobiliary drain (NBD) was positioned through the EUS-HGS in aspiration for 48 h at the end of EUS-HGS in case of high risk of stent migration (e.g., ascites) or according to endoscopist's preference. All patients received antibiotic prophylaxis during the procedure (Cefazolin; Merck, Darmstadt, Germany). If a patient had presented with cholangitis before the drainage procedure, antibiotics were administered intravenously over the 10 days following the procedure. Median total procedure time, including preparation, general anesthesia by propofol after tracheal intubation, intervention, and awake of the patient, was 75 min (34–199). Food was given when the pain disappeared. Patients were discharged after at least 1 day following the endoscopic procedure.

Demographic and clinical characteristics of all the patients who agreed to undergo EUS-HGS were retrospectively evaluated. These characteristics included gender, age, type of disease, stenosis localization, presence of previous BD, indication of EUS-HGS, position of NBD at the end of EUS-HGS and, when available, laboratory data such as total and, direct bilirubin levels before and the week after EUS-HGS.

Technical success rate was defined as the passage of the Giobor® prosthesis across the stomach, along with the flow of contrast medium and/or bile through the stent.

Functional success rate was defined as the decrease of bilirubin value of at least 25% of the pretreatment value within the 1st week ($\Delta25$). Complications were defined as any stent-related complication, including stent migration, stent obstruction, bile leakage with or without bile peritonitis, pneumoperitoneum, and bleeding. Complications were defined "early" when occurred within the 1st month after EUS-HGS and "late" when occurred between the first and the 6th month after EUS-HGS.[18] Biliary reintervention was defined as any type of BD required in the 6 months after the procedure to treat persistence/recurrence of jaundice and/or cholestasis and/or dilated biliary ducts found on ultrasonography, computed tomography, or magnetic resonance imaging.

Statistical analysis

Descriptive statistics were used to analyze the baseline characteristics. Percentages were calculated for the discrete data. Means with ranges were calculated for the continuous data. Chi-square test/Fisher's exact test and *t*-test were used for discrete and continuous data, respectively. $P < 0.05$ was considered statistically significant.

RESULTS

Clinical and demographic data of the enrolled population

Details on the clinical and demographic features of the enrolled patients are shown in Table 1. Overall, 41 patients (mean age 66 years, range 45–85, 20 men) satisfied the inclusion criteria and were included in the analysis.

Thirty-nine patients (95.1%) presented a malignant disease while two patients (4.9%) underwent EUS-HGS because of benign stenosis in the hepaticojejunal anastomosis. Most of malignant diseases were represented by pancreatic adenocarcinoma (41.5%), followed by cholangiocarcinoma (14.6%), ampulloma (4.9%), hepaticocarcinoma (2.4%), and metastasis (31.7%). Secondary lesions were represented by perihilar lymph nodes or hepatic metastasis due to colonic cancer (7.3%), breast cancer (7.3%), gastric cancer (4.9%), urogenital cancer (9.7%), and anal cancer (2.4%).

Reasons of HGS included failed biliary cannulation in 18 patients (43.9%) (because of altered postsurgical anatomy in seven patients and duodenal obstruction

or periampullary tumor ingrowth in 11 patients) and complementary of left hepatic duct (hilar stricture) in 23 patients (56.1%).

Twenty-four patients (58.1%) had already received a BD, corresponding to 17 patients (41.5%) in ERCP BD, four patients (9.7%) in PTBD, and three patients (7.3%) in both ERCP and PTBD.

Median total and direct bilirubin serum levels were 101 mmol/L and 65 mmol/L, respectively, corresponding to a median increase of nine times the normal levels.

Technical and functional success rates

Technical success rate was obtained in 37/41 patients (90.2%). In only two cases, EUS-HGS failed. A 6- or 7-Fr NBD was left in 22 patients (59.4% of successful procedures).

Bilirubin levels both before and 1 week after EUS-HGS were available in only 29 patients over the 37 patients in whom EUS-HGS was positioned (78.4%). Functional success rate ($\Delta25$) was obtained in 19/29 patients (65.5%). Mean decrease of bilirubin levels was 30%. When any decrease of bilirubin level

after EUS-HGS was considered (Δneg), the rate of EUS-HGS functional success increased to 79%. Total bilirubin trend is shown in Figure 2. The difference of total bilirubin before and after EUS-HGS was statistically significant ($P = 0.04$).

Early complications

Thirteen patients (31.7%) presented some complication during the thirty postprocedure days. Most of complications were represented by infections (nine patients, 21.9%), followed by Giobor® prosthesis migration (two patients, 4.9%) and hemorrhage (two patients, 4.9%).

Infection was represented by bacteremia with fever in all patients. No episodes of sepsis were registered. *Escherichia coli* or *Enterobacteriaceae* was identified in five cases.

Infections were treated by large spectrum antibiotics, and if possible, treatment was adapted to antibiogram. The rate of infectious complications was exactly the same for patients who received an NBD (NBD⁺) or not (NBD⁻), with 5/22 cases (22.7%) and 4/15 cases (26.6%), respectively [$P = 1$, Figure 3a]. We did not find any statistically significant difference in the rate of infectious complications between the group of patients who received a previous BD and the group in whom EUS-HGS represented the first drainage [$P = 0.2$, Figure 3b].

Table 1. Demographic and clinical characteristics at study entry

Parameters	Value
Sex (%)	
Male	20 (48.8%)
Age, mean (range) in years	66 (45-85)
Disease (%)	
Malignant	39 (95.1%)
Malignant disease (%)	
Pancreatic adenocarcinoma	17 (41.5%)
MTS	13 (31.7%)
Cholangiocarcinoma	6 (14.6%)
Ampulloma	2 (4.9%)
Hepaticocarcinoma	1 (2.4%)
HGS representing the first biliary drainage	17 (41.5%)
Indication of HGS	
Failed biliary cannulation	18 (43.9%)
Duodenal obstruction or periampullary tumor ingrowth	11 (61.1%)
Postsurgical altered anatomy	7 (38.9%)
Failed bile duct decompression	23 (56.1%)
Incomplete left biliary drainage	10 (43.5%)
High-grade hilar stricture	13 (56.5%)
Median total bilirubin serum levels (mmol/L), range; NV <17 mmol/L	101 (6,7-761)
Median direct bilirubin serum levels (mmol/L), rang; NV <3,4 mmol/L	65 (1,9-319)

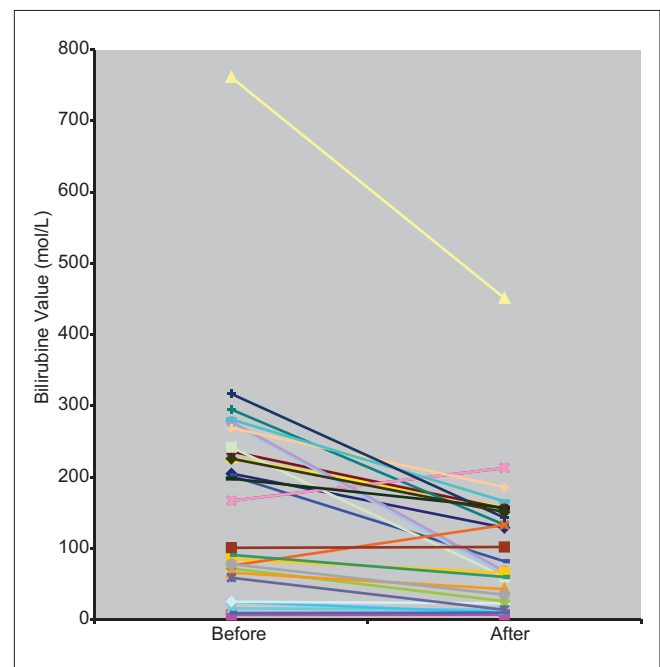HGS: Hepaticogastrostomy, MTS: Metastasis, NV: Normal value

Figure 2. Total bilirubin trends in the week after endoscopic ultrasound-guided hepaticogastrostomy positioning
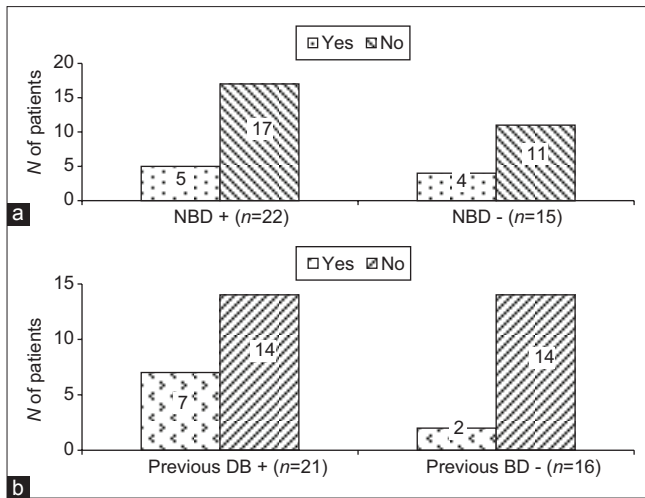
Figure 3. Rates of infectious complications according to positioning of NBD (P = 1) (a) and previous BD (P = 0.2) (b). NBD: Nasobiliary drainage; BD: Biliary drainage

Both stent migrations were treated endoscopically. The two cases of bleeding resolved spontaneously and did not require any endoscopic intervention. No case of bile leakage and bile peritoneum was observed. No procedure-related death occurred.

Six-month follow-up
Of 37 patients, 10 (27%) who underwent EUS-HGS required a BD in the 6-month follow-up after EUS-HGS. Indications for reintervention were HGS migration in one patient (2.7%) and cholangitis in nine patients (24.0%); cholangitis was due to obstruction of the EUS-HGS in four patients, obstruction of a biliary stent other than EUS-HGS in four patients and obstruction of both EUS-HGS and biliary prosthesis different from EUS-HGS in one patient . Reintervention was performed using HGS or, when HGS was not possible, by PTBD. In some cases, HGS needed to be repermeabilized, using the same procedure as described for ERCP. The limited number of stent migration in our study makes difficult the identification of patients with high risk of stent migration. Migration of transgastric stent is probably due to the motility of the stomach. To avoid it, we choose to place Giobor® stent to have a long part in the stomach, at least 2 cm. Migration occurring in this study should be explained by a too short part of the stent in the stomach. The ascitis (increasing space between the gastric wall and the left hepatic lobe) is also a potential cause of migration in our experience.

Of 37 patients, 11 (29.7%) who underwent EUS-HGS died, during the postprocedure months, from cancer disease.

DISCUSSION

This is the first study that evaluates the Giobor® prosthesis, a semi-covered stent, dedicated for EUS-HGS.

EUS-HGS is quite a new EUS-BD technique, in alternative to PTBD or surgical BD, considering that up to now a large size, prospective, randomized, controlled trial comparing EUS-BD to PTBD has not been published. Indications to EUS-BD remain limited to inaccessible papilla because of tumor invasion or surgically altered anatomy, failed biliary cannulation by an experienced endoscopist, or difficult PTBD (limited IH bile duct dilatation or dilatation limited to the left IH bile duct).[13] However, a recently published small size, prospective, and randomized study has shown that EUS-guided CDS has a comparable technique and clinical success compared to PTBD, with no differences in the complication rate or in costs.[19] These results are encouraging for a more extensive use of EUS-BD.

Between the various techniques of EUS-guided BD, HGS is the technique with most potential indications, mainly the impossibility to reach the papilla or hilar block, while CDS is limited to cannulation failure and to the distal block.

In one retrospective study published by Dhir *et al.*, involving 104 patients, the complication rate in case of distal block seemed significantly higher when transhepatic access route was chosen compared to transduodenal route.[20] These data are in contrast with what emerged from the retrospective study by Gupta *et al.*, where no significant difference in the complication rate was observed between 240 patients undergoing intra- or EH EUS-BD.[21]

Up to now, plastic and SEMS have been used for EUS-HGS; between SEMS, both FC-SEMS and UC (UC-SEMS) have been experimented.[17,22] UC stent was associated with high risk of bile leakage and was not recommended. Plastics stents (PSs) have the advantage of being cheap, but the disadvantage of a short duration and stent dysfunction, requiring frequent reintervention. However, need for any further reintervention should be minimal considering that EUS-BD is frequently used in palliative setting for patients with malignant obstructive jaundice. Furthermore, PSs can undergo migration, dislocation

or can cause biliary leakage when there is a difference between the fistula size and the PS diameter.[9,10,16,22-26]

For these reasons, SEMSs have been introduced.[10,18,20,23,24,27-33] The advantages of SEMS are mainly the long-term patency and easier management in case of dysfunction by tumor ingrowth or clogging but are more expensive compared to the PS. Both FC- and UC-SEMS have been experimented. FC-SEMS has limitations: the higher risk of stent migration or dislocation and of obstruction of side-branch bile duct. UC-SEMS has a higher risk of tumor ingrowth, a more difficult removability and increased risk of biliary leakage. Considering their several limitations, UC-SEMS and PS are not more used for EUS-HGS. To decrease both the risk of migration and biliary leakage, the stent in stent technique was used with an FC-SEMS inserted into the UC-SEMS; this approach should allow avoiding the disadvantages and taking the advantages of each SEMS but increase cost and necessitate more manipulation. In this context, the Giobor® stent has been ideated. A preliminary prospective study by Park et al. evaluated a partially covered stent with anti-migration flaps at both ends of the covered portion, showing a high technical and functional success rates and a low rate of migration and biliary leakage.[33]

Technical success rate using Giobor® prosthesis remains high (91% of cases), comparable to other published data. However, functional success rate was lower than previously reported. Data should be interpreted considering that most of the patients in our cohort present complex hilar stricture or metastatic disease and already had at least one BD.

Complication rate reached 31.7%, mainly due to infection. We believe that the multiple BD previously performed played an important role in the rate of infections; the fact that we did not show a statistically significant difference according to previous BD is due to the limited number of patients enrolled. However, only three cases of stent migrations were observed and no bile leakage was observed, suggesting that Giobor® stent could effectively reduce the risk of migration compared to FC-SEMS and eliminate the risk of bile leak compared to UC-SEMS. NBD positioning immediately after the procedure did not influence the infection rate in the month after the EUS-HGS and it is not recommended for all procedures but could be useful in procedure with high risk of stent migration.

Our study presents some limitations, such as the retrospective nature and the limited sample size. Giobor® stent is efficient and safe for transgastric biliary anastomosis and because its manipulation is easy, is considered, in our center, as a standard device for this procedure.

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Conflicts of interest
There are no conflicts of interest.

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