—Original Article—

Efficacy and safety in case of technical success of endoscopic ultrasound-guided transhepatic antegrade biliary drainage: A report of a monocentric study

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ABSTRACT

Background and Objectives: Endoscopic ultrasound (EUS)-guided biliary drainage techniques are alternative procedures in cases of obstructive jaundice with altered anatomy or failed ERCP. Complications related to EUS-guided antegrade drainage (EUS-AD) are still present in up to 10% of cases, and combination of procedures is sometimes suggested to avoid adverse events. The purpose of our study is to evaluate the efficacy and safety of EUS-AD with transhepatic access in case of technical success. **Methods:** We retrospectively reviewed patients who underwent EUS-AD in a single, tertiary care center. **Results:** Twenty patients were included (mean age 68), malignant stenosis in 95%. The reasons for EUS-AD were failed ERCP in 13/20, duodenal stenosis in 4/20, and altered anatomy after surgery in 3/20. A cystostome 6 Fr was always used to create the hepaticogastric tract, without puncture site closure. Self-expandable metallic stent (SEMS) was transpapillary in 95%. Drainage was completed in intraoperative stage by a EUS-hepaticogastrostomy (EUS-HGS) in 1/20 and by percutaneous drainage of the right liver (percutaneous transhepatic biliary drainage) in one out of 20. Overall clinical success was 17/20 (85%). One out of 20 presented a persistent obstructive cholangitis treated by another SEMS through ERCP. Two out of 20 patients died of infectious complications with incomplete drainage, in case of advanced neoplastic disease. One of these two patients was treated by EUS-AD and EUS-HGS at the same time. None of the 20 patients developed bilioma or bile leakage. **Conclusion:** EUS-AD by transhepatic way is clinically effective and safe. Closure of the gastric puncture site is not mandatory and complementary methods for biliary decompression should be combined in case of incomplete drainage and not to prevent potential adverse events.

Key words: Antegrade biliary drainage, benign biliary stenosis, endoscopic ultrasound-guided biliary drainage, malignant biliary stenosis

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INTRODUCTION

Since the advent of biliary drainage guided by endosonography (endoscopic ultrasound [EUS]) in 2001 by Giovannini *et al.*,[1] many groups confirmed the efficacy and safety of this kind of intervention. Recent meta-analysis showed that EUS-guided biliary drainage (EUS-BD) is an emerging therapeutic modality with a pooled technical success rate between 90% and 95% with a cumulative adverse events rate between 14% and 17% for EUS-BD after failed ERCP.[2,3] These results are supported by a new prospective International Multicenter Study with technical and clinical success achieved in 95.7% and 95%, respectively, in intention-to-treat with an adverse events rate of 10.5% for patients with malignant distal biliary obstruction.[4] EUS-BD by rendezvous technique, choledochoduodenostomy (EUS-CDS), hepaticogastrostomy (EUS-HGS) and hepaticoduodenostomy, or antegrade (EUS-AD) stenting technique are the most common interventions encountered. EUS-AD is mainly indicated in case of biliary obstruction with surgically altered anatomy or upper intestinal obstruction, in which the papilla of Vater is not accessible. In actual published data, the overall adverse events rate of EUS-AD differs widely from 0% to 23%.[5-8] The major risk of these procedures is the peritoneal biliary leakage, that is, why some articles describe the advantage to combine a transluminal EUS-BD such as hepaticogastrostomy or hepaticojejunostomy with an EUS-AD.[9,10] Nevertheless, in our daily practice, related bile leakage does not seem to be a major problem in case of technical success of EUS-AD. Moreover, few reports exist regarding one-step EUS-AD. In this context, EUS-AD and potential-related adverse events should still to be analyzed.

MATERIALS AND METHODS

We conducted a retrospective study in a single tertiary referral endoscopy center. We retrieved from the endoscopy and hospital databases, all the computerized and prospectively collected records of all patients that underwent an EUS-AD between 2006 and 2015. The study was conducted and monitored under Institutional Review Board committee approval. One physician affiliated to the unit, external of the 2 expert endoscopists who performed the procedures, conducted data collection in a completely anonymous way. To establish our list of patients, we used a computer-generated database (4D Program®) that allowed to determine all patients that underwent an EUS-AD. Of these patients, we manually collected in an Excel® table; all the different clinical, endoscopic, histopathological, and technical characteristics.

All patients that underwent a one-step EUS-AD with technical success for benign or malignant distal biliary obstruction after failed ERCP were included in the study. No exclusion criteria were retained.

In our daily practice, we used a step-wise decisional algorithm presented in Figure 1 to choose which type of technical biliary drainage was retained depending on the biliary pathology presentation. From the point of view of the technical aspect, a transhepatic approach was favored in our practice. The EUS was positioned in the proximal stomach in a manner to have the best EUS view of the left hepatic lobe and dilated intrahepatic bile ducts (IHBDs). Any interposing vessels were ruled out with color Doppler, and the left IHBDs were punctured either by a 19 G EchoTip® Needle or by a 19 G EchoTip® Access Needle in case of important dilation of the IHBD. A correct positioning in the IHBD was confirmed by bile aspiration and contrast enhancement, allowing at the same time to describe the level and length of the biliary stenosis. A guidewire of 0.035 inch was inserted in an antegrade way to cross the stenosis and to pass into the duodenum under fluoroscopic and EUS control. The hepaticogastric tract was calibrated using a 6Fr cystostoma. A balloon dilation or calibration by cystostoma 6 Fr was done at the level of biliary obstruction in case of tight stricture. The self-expandable metallic stent (SEMS) was deployed at the stenosis, preferably in a transpapillary position. Finally, a protective nasobiliary drainage catheter was introduced in case of reachable papilla, according to the operator's choice. At the end of the intervention, the puncture site was not closed by any clip. In doubt of incomplete biliary drainage, another method of drainage was performed either by a percutaneous or by EUS-HGS.

The aim of this study was to determine the efficacy and safety of EUS-AD with transhepatic access, in case of technical success, for benign or malignant extrahepatic biliary obstruction.

RESULTS

We screened a total of twenty patients treated by EUS-acute gastric dilatation. No patients were

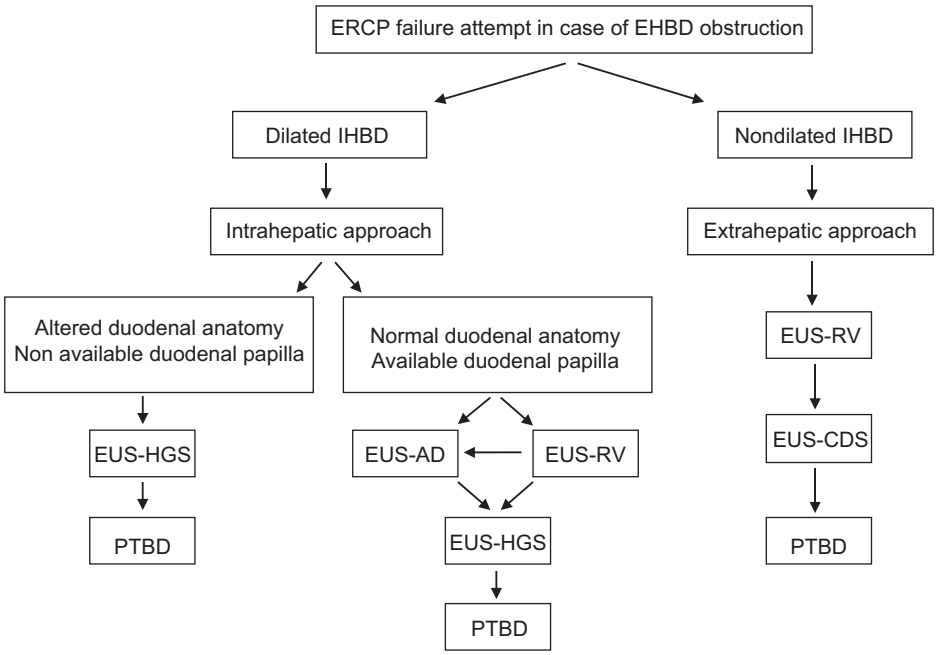

Figure 1. Internal unit decisional algorithm to choose which type of technical biliary drainage is retained depending on the biliary pathology presentation ERCP: Endoscopic retrograde cholangiopancreatography, EHBD: Extrahepatic bile duct, IHBD: intrahepatic bile duct, EUS-HGS: Endoscopic ultrasound-guided hepaticogastrostomy, EUS-AD: Endoscopic ultrasound-guided antegrade drainage, EUS-RV: Endoscopic ultrasound-guided rendezvous drainage, EUS-CDS: Endoscopic ultrasound-guided choledocoduodenostomy, PTBD: percutaneous biliary drainage

excluded from the study. The mean age was 68 years (range 40–90 years) for a majority of men (11 male/9 female), with a median American Society of Anesthesiologists score of 3 [Table 1]. The etiology of biliary obstruction was a malignant disease in 19 out of 20 (95%) and one out of 20 (5%) benign biliodigestive anastomotic stenosis after splenopancreatectomy for a cystadenoma with sarcomatous component. The indications for EUS-AD were a failed ERCP in 13 out of20 (65%), a duodenal stenosis in 4/20 (20%), and an altered anatomy after surgery in 3/20 (15%). The left IHBD puncture was done with a 19 G EchoTip® Needle in 16/20 (80%), with a 19 G EchoTip® Access Needle in 7/20 (35%). IHBD puncture by 19 G EchoTip® Access Needle (10%) failed at the first attempt in two cases and was finally successfully punctured with an 19 G EchoTip® [Table 2]. A cystostoma 6 Fr was always used to create the hepaticogastric tract. The biliary stenosis was dilated with balloon in 15% and calibrated with cystostoma 6 Fr in 45% (1 benign and 8 malignant). One noncovered SEMS was positioned in 17/20 (85%) cases and 2 noncovered SEMS in one-step intervention for 3/20 (15%) cases. The SEMS was in transpapillary position in 95%. The drainage was completed in intraoperative stage by EUS-HGS in 1/20 and by percutaneous drainage of the right IHBD in 1/20 case.

Table 1. Initial characteristics of patients

Characteristics	Values
Number of patients (*n*)	20
Age, median (range), years	68 (40-90)
Sex, *n* (%)	
Male	11 (55)
Female	9 (45)
ASA score, mean (%)	2.55
ASA 1, *n* (%)	1 (5)
ASA 2, *n* (%)	7 (35)
ASA 3, *n* (%)	12 (60)
Reason for EUS-AGD, *n* (%)	
Failed ERCP	13 (65)
Duodenal stenosis	4 (20)
Altered anatomy after surgery	3 (15)
Biliary stenosis, *n* (%)	
Malignant	19 (95)
Benign	1 (5)
Location of the stenosis, *n* (%)	
Biliodigestive anastomosis	2 (10)
Common hepatic duct	5 (25)
Middle bile duct	3 (15)
Distal bile duct	10 (50)
Liver tests before EUS-AD, mean (range)	
Total bilirubin level	239 mg/L (32-478)
GGT level	664 UI/L (85-1818)
Concomitant cholangitis, *n* (%)	9 (45)

EUS-AD: Endoscopic ultrasound-guided antegrade drainage, EUS-AGD: Endoscopic ultrasound-guided acute gastric dilatation, ASA: American Society of Anesthesiologists, ERCP: Endoscopic retrograde cholangiopancreatography, GGT: Gamma-glutamyl transferase

Table 2. Treatment characteristics

Treatment characteristics	Values
EUS-AGD approach, *n* (%)	
Transhepatic route via the left intrahepatic bile duct	20 (100)
IHBD puncture, *n* (%)	
19 G EchoTip® needle	16 (80)
19 G EchoTip® access needle	7 (35)
Success rate of the IHBD puncture, *n* (%)	
19 G EchoTip® needle	16 (100)
19 G EchoTip® access needle	5 (71)
Cystostoma 6 Fr for creation of the hepaticogastric tract, *n* (%)	20 (100)
Modeling of the biliary stenosis, *n* (%)	
6 mm balloon dilation	2 (10)
8 mm balloon dilation	1 (5)
Calibration with a cystostoma 6 Fr	9 (45)
Noncovered SEMS, *n* (%)	20 (100)
One SEMS	17 (85)
Two SEMS embedded inside the other	3 (15)
Transpapillary	19 (95)
Additional preoperative drainage, *n* (%)	
EUS-HGS	1 (5)
Percutaneous drainage of the right IHBD	1 (5)
Protective nasobiliary catheter, *n* (%)	
Additional postoperative drainage, *n* (%)	
Placement of SEMS via ERCP for persistent cholangitis	1 (5)
Duodenal prosthesis	2 (10)
Adverse events, *n* (%)	
Preoperative	0
Postoperative	
Abdominal pain	3 (15)
Death in case of incomplete biliary drainage with advanced cancerous disease	2 (10)
Overall clinical success, *n* (%)	17 (85)

IHBD: Intrahepatic bile duct, ERCP: Endoscopic retrograde cholangiopancreatography, EUS-AGD: Endoscopic ultrasound-guided acute gastric dilatation, EUS-HGS: Endoscopic ultrasound-guided hepaticogastrostomy, SEMS: Self-expandable metallic stent

A protective nasobiliary catheter was positioned in 2/20 (10%) patients and removed after 48 h after ensuring the proper functioning of the biliary SEMS. Overall clinical success was 17/20 (85%). The mean total bilirubin level before drainage was 239 mg/L. The mean delta total bilirubin level at 7 days was 98 mg/L and at 1 month was 171 mg/L [Figure 2]. One out of 20 patients presented a persistent obstructive cholangitis was treated successfully by another SEMS through ERCP. Two out of 20 (10%) patients died of an infectious complication with incomplete biliary drainage due to advanced stage neoplastic disease 2 weeks after EUS-AD. One of these two patients was treated by a combination of EUS-AD and EUS-HGS in the same operative time. None of the twenty patients developed biloma, biliary leakage, or other major complications. Three out of 20 (15%) patients developed mild abdominal pain treated conservatively.

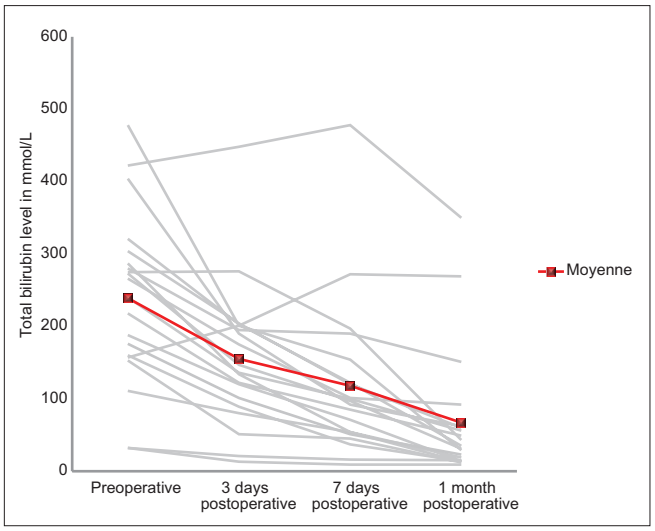

Figure 2. Total bilirubin level evolution in pre- and post-operative phase

DISCUSSION

Our study presented the results of EUS-AD for both malignant and benign distal biliary obstruction in case of technical success. EUS-AD was clinically effective with an overall success rate of 85% associated with an acceptable minor complication rate of 15%, all managed conservatively. The clinical improvement was confirmed by the decrease of the total bilirubin level of more than one-third at 7 days and more than two-third at 1 month postoperatively. These results correlate with the actual published data about EUS-AD[2,11] and confirmed that the EUS-BD was a good alternative in case of failed retrograde biliary drainage. The main limitations of our study were the small number of patients and the retrospective feature. Regarding the indications, we had a majority of malignant versus benign strictures. It was probably due to the fact that our unit was highly specialized and dedicated to the management of digestive cancer disease, which was indeed a bias in the recruitment. Given the few number of patients with benign stenosis, we cannot compare the efficacy of EUS-AD for malignant to benign obstruction.[12]

From the technical aspect, we favored the transhepatic approach and tried to optimize the angle of bile duct access, preferentially in the segment 2 to permit a better passage of the guide through the hilum. We did not use small caliber guidewires to avoid shearing.[7] On the other side, we promoted the use of the 19 G EchoTip® Access Needle to avoid this problem. The 19G EchoTip® Access Needle has the disadvantage with

a risk of submucosal parabiliary route, which is the reason why we preferred the 19 G EchoTip® Needle in case of moderate IHBD dilation. We did not encounter guidewire shearing during our interventions, but we noticed a better rate of IHBD puncture with the 19 G EchoTip® Needle, which allowed in 10% (2/20) to puncture the IHBD after failure by the 19 G EchoTip® Access Needle.

The following key points of our technique may help to explain the low rate of adverse events and especially the lack of bile leakage in our results. It is important to note that we never close the site of puncture in the stomach. We favor the intrahepatic approach for EUS-AD even if there is an adverse event rate higher for the intrahepatic access compared to the extrahepatic access in actual published data, with one multicenter study of Dhir *et al.* which showed with a logistic regression analysis that the transhepatic access is the only independent risk factor for adverse events ($P = 0.031$).[13] However, the intrahepatic access has the same overall success rate as the extrahepatic approach, around 90%–95%,[12,14] and has the benefit to allow in a one-step intervention to complete EUS-AD with an EUS-HGS in case of ineffective drainage.[9] Moreover, even if the number of patients in our study is small, we did not encounter serious adverse events such as pneumoperitoneum, peritonitis, or death related to the intervention. The dilation of the hepaticogastric tract is avoided, and the latter is only created through a cystostoma 6 Fr, with pure cut current, after checking the correct position of the guidewire. Carbon dioxide insufflation is used for all the interventions to reduce the risk of pneumoperitoneum. Finally, we tried to put the biliary SEMS in a transpapillary position (19/20) to reduce the resistance to the bile flow. It is for this reason that we extended the SEMS by a second noncovered SEMS in one-step intervention for 3/20 (15%) patients and ensured the emptiness of the SEMS by the establishment of a protective nasobiliary catheter in 2/20 (10%) patients. We used only noncovered stent mainly due to the presence of malignant obstruction without surgical project. The transpapillary position of SEMS also has the advantage of facilitating a potential secondary intervention through an ERCP in case of a reachable papillary.

EUS-AD was considered insufficient in 2/20 (10%) patients during the intervention, which was why we completed the drainage at the same time by a EUS-HGS for one patient and by a percutaneous drainage of the right IHBD for the other. Both patients did not present adverse events, but the first one died 2 weeks later related to a severe cholangitis with sepsis in the context of an advanced neoplastic disease. The overall mortality rate of our patients was 10%, attributed to the progression of a neoplastic disease and incomplete biliary drainage. No death was related to adverse event of the EUS-BD. For both patients, EUS-BD was considered as a salvage and last therapeutic opportunity given the advanced neoplastic disease.

CONCLUSION

To conclude, EUS-AD with intrahepatic approach is efficient and presents an excellent safety profile in case of technical success. Closure of the gastric puncture is not mandatory if the biliary drainage is efficient. Complementary methods for biliary decompression such as EUS-HGS or hepaticojejunostomy should be combined only in case of incomplete drainage and not to prevent potential adverse events. EUS-AD should be managed by expert centers with an expertise in the field. The different EUS-BD must be adapted and previously discussed for each patient, depending on the anatomy and the level of biliary obstruction. Even if EUS-BD presents a similar technical and clinical success rate, around 95%, compared to ERCP,[15,16] this technique should be actually reserved to cases of failed or impossible ERCP.

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Conflicts of interest
There are no conflicts of interest.

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