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EUS-guided choledochoduodenostomy for malignant distal biliary obstruction using a lumen-apposing fully covered metal stent after failed ERCP

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Abstract
Background A novel lumen-apposing, self-expanding metal stent to perform EUS-guided drainage procedures has been recently developed. The aim of this study was to analyze the safety, technical and clinical effectiveness of this device for EUS-guided choledochoduodenostomy (EUS-CD) with palliative intent.
Methods Retrospective analysis of all consecutive patients with unresectable malignant distal bile duct obstruction who, between March 2012 and September 2014, underwent EUS-CD using the study devices (AXIOS™ and Hot AXIOS™, Xlumena Inc., Mountain View, CA, USA) after unsuccessful ERCP in seven European centers was carried out.
Results Fifty-seven patients (M/F 31/26; median age 73) underwent EUS-CD using the AXIOS™ stent or the Hot AXIOS™ delivery system. ERCP failure was due to duodenal obstruction in 41 patients (71.9 %) and to inability to cannulate the papilla in the remaining 16 patients (28.1 %). The procedure was technically successful in 56/57 patients (98.2 %), with a mean procedural time of 22.4 min (range 11–65). Clinical success was achieved in 54 of these 56 patients (96.4 %; 94.7 % of the entire cohort). Overall major procedural complication rate was 7 % (two duodenal perforations, one bleeding and one transient cholangitis). During follow-up, 5 out of 54 (9.3 %) patients with clinica success required re-intervention for stent migration in one case and a sump syndrome with transient increase in serum bilirubin concentrations with sludge in the distal duct reservoir in the remaining four patients.
Conclusions Our study shows that EUS-CD using the AXIOS™ and the Hot AXIOS™ devices is a safe procedure, with high technical and clinical success rates.

Keywords EUS-guided biliary drainage · Failed ERCP · choledochoduodenostomy · SEMSs · Interventional EUS

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Endoscopic retrograde cholangiopancreatography (ERCP) is the current standard of care for palliation of patients with unresectable malignant biliary obstruction. However, failure of ERCP due to malignant duodenal obstruction, inability to cannulate the papilla or traverse a common bile duct (CBD) stricture requires alternative methods of decompression [1, 2]. Options include percutaneous drainage, surgical bypass and more recently EUS-guided biliary drainage (EUS-BD) [3–5].

In an attempt to maintain internalized biliary drainage, EUS-guided methods are being used more and more frequently [6–8]. Technical and clinical success rates for EUS-BD have been reported to be high (91 and 88 %,

respectively) [9]. However, the occurrence of complications has also been reported to be high (26 % with mortality of 0.4 %) [9], mostly reflecting the learning curve and the heterogeneity of the techniques used, but also the utilization of accessories not specifically designed for this procedure [10].

In the last few years, efforts to overcome this latter limitation by developing dedicated accessories to facilitate EUS-BD and decrease the risk of complications have been made. In particular, a lumen-apposing, fully covered self-expandable metal stent (LA–FCSEMS) specifically designed with the aim of creating anastomosis has become available and tested for drainage of pancreatic fluid collections and gallbladder, the latter in patients with acute cholecystitis unfit for surgery [11–17]. Moreover, case reports of successful EUS-guided choledochoduodenostomy (EUS-CD) by using this newly available stent have been recently published [18, 19].

The present study aimed to retrospectively analyze the safety and clinical effectiveness of EUS-CD using this newly available LA–FCSEMS in a large cohort of patients prospectively enrolled in seven European centers.

Materials and methods

All consecutive patients who, between March 2012 and September 2014, underwent EUS-BD using the study devices (AXIOS^{TM} and Hot AXIOS^{TM}, Xlumena Inc., Mountain View, CA, USA) in seven tertiary care medical centers were retrospectively retrieved from each single-institution database. All included patients had malignant distal CBD obstruction that was inoperable, or they were unfit for surgery and all underwent attempted palliative ERCP, which failed.

The protocol to carry out retrospective revision of the cases performed was approved by all the local institutional ethics committees. All patients gave their informed consent prior to the use of the AXIOS^{TM} and the Hot AXIOS^{TM} devices.

The AXIOS^{TM} stent and the Hot AXIOS^{TM} system

The AXIOS^{TM} stent is made up of braided nitinol that is fully covered with silicone, with wide flanges on both ends that provide anchoring within the bile duct (Fig. 1; Table 1). The stent is delivered through a 9- or a 10.8-French catheter, which is luer-locked to the inlet port of the echoendoscope's working channel to provide deployment of the stent under full control by the endoscopist. Since the middle of 2013, the AXIOS^{TM} stent was incorporated into a novel device, the Hot AXIOS^{TM}, in which an electrocautery wire was added to the distal tip of the delivery catheter to apply cutting current that allows the passage of the device through the gastrointestinal and the bile duct walls, without the need for prior dilation. The AXIOS^{TM} and Hot AXIOS^{TM} are CE-marked for CBD drainage.

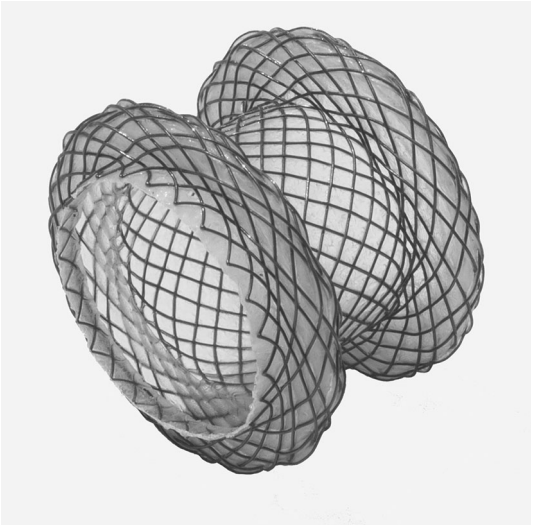

Fig. 1 The AXIOS^{TM} stent made up of braided nitinol that is fully covered with silicone, with wide flanges on both ends to provide anchorage

EUS drainage procedure

All endoscopic procedures were performed under deep sedation or general anesthesia with endotracheal intubation. All, but one operator, were proficient in both ERCP and EUS procedures. Patients who were not undergoing antibiotic therapy prior to the procedure received prophylactic antibiotics, based on each center guidelines. Post-procedural continuation of antibiotics was upon endoscopist's discretion.

A therapeutic linear echoendoscope was used in all cases. The echoendoscope was advanced into the duodenal bulb where by orienting the transducer medially, the dilated CBD or the common hepatic duct was visualized. Biliary access was achieved from the duodenal bulb using a 19-gauge EUS needle, which was followed by contrast injection and placement of a 0.035-in. guidewire. Dilation of the tract was done using a graduated dilation catheter, a 4-mm biliary dilation balloon or a 6-French cystotome (ENDO-FLEX GmbH, Voerde, Germany) based on endoscopist's preference. When the Hot AXIOS^{TM} was used, there was no need for tract dilation and insertion of the device was achieved by direct puncture with the device using pure cut without coagulation.

Table 1 Characteristics of the different commercially available AXIOS stents

Stent type	Length of flange (mm)	Lumen diameter (mm)	Saddle diameter (mm)	Catheter diameter (Fr)
06-08	14	6	8	9
08-08	17	8	8	9
10-10	21	10	10	10.8
15-10	24	15	10	10.8

The choice of the size of the stent to be placed was independently taken by each individual endoscopist, without defined pre-procedural parameters. Once inside the CBD, the proximal flange of the stent was deployed under EUS guidance (Fig. 2), while the distal flange was deployed in the duodenum under EUS guidance or endoscopic view, with or without fluoroscopic assistance (Fig. 3). All procedures were performed using carbon dioxide insufflation.

Procedural time was calculated in all cases from echoendoscope insertion to complete release of the stent.

Outcome parameters

The primary outcome parameters were safety, technical and clinical success. Safety was defined by the frequency of occurrence of major procedure-related complications, such as bile leakage, bleeding or perforation.

Technical success was defined as satisfactory access and drainage of the CBD as determined by the successful placement of the AXIOS stent. Clinical success was defined as decline of serum bilirubin levels in patients with obstructive jaundice to <10 % of the initial levels and of the cholestatic parameters in those with cholestasis without jaundice.

Short- and long-term complications such as stent migration, stent occlusion with recurrent obstructive jaundice and/or cholangitis were assessed during follow-up on the basis of clinical need by biochemical and/or imaging studies.

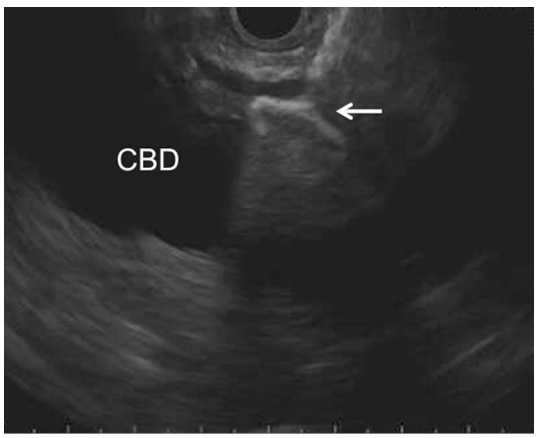

Fig. 2 EUS view of the distal flange of the AXIOS™ stent (*arrow*) opened inside a dilated common bile duct (CBD)

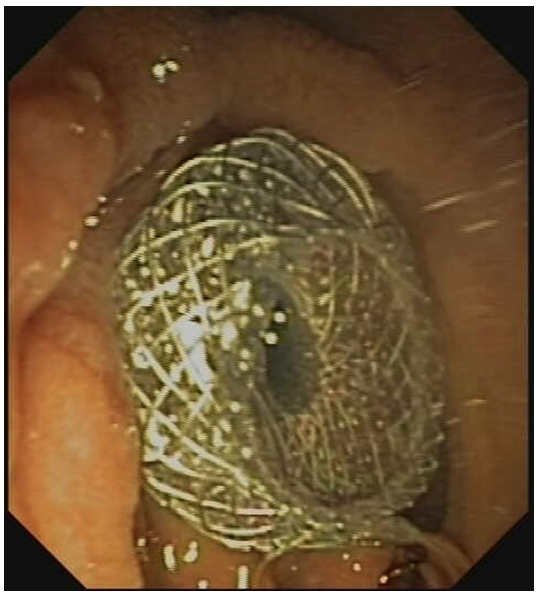

Fig. 3 Endoscopic view of the proximal flange of the AXIOS™ stent placed in the duodenal bulb

Data analysis

Frequencies, percentages, means (±standard deviation) and medians (range) were used, as appropriate, for descriptive analysis.

Results

Study population

During the study period, 57 patients with inoperable malignant distal biliary obstruction who failed ERCP underwent EUS-CD using the study devices. Table 2 shows patient demographics and characteristics of the entire cohort.

The cause for ERCP failure was duodenal obstruction with inaccessible papilla in 41 patients (71.9 %) and inability to cannulate the papilla, despite the utilization of

Table 2 Characteristics of the 57 patients with inoperable malignant distal biliary obstruction who underwent EUS-guided biliary drainage using the AXIOS stent after failed ERCP

Median age: 73 years (range 49–93)
Male/female, *n*, 31/26
Etiology of the neoplasia, *n* (%)
Pancreatic, 38 (66.6 %)
Ampullary, 7 (12.3 %)
Duodenal, 6 (10.5 %)
Breast in 2 (3.5 %)
Stomach, 2 (3.5 %)
Colon, 1 (1.8 %)
Uterine, 1 (1.8 %)
Reason for failed ERPC, *n* (%)
Duodenal obstruction, 41 (71.9 %)
Failed cannulation, 16 (28.1 %)
Indication for drainage
Obstructive jaundice 53 (94.1 %)
Cholestasis 4 (5.9 %)
Cholangitis/sepsis 20 (35.1 %)
Presence of ascites 19 (33.3 %)

different advanced biliary cannulation techniques, in the remaining 16 patients (28.1 %). Fifty-three patients (93 %) had obstructive jaundice, while in 4 patients (7 %) there was cholestasis without increased bilirubin serum concentration. Additionally, 20 patients (35.1 %) were experiencing concomitant cholangitis or sepsis, while in 19 cases (33.3 %) ascites was present mostly detected during the EUS examination.

Drainage procedure and outcomes

Table 3 shows specifics of the drainage procedures. EUS-CD was performed during the same session following ERCP failure in all cases using the AXIOS^{TM} or the Hot AXIOS^{TM} devices in 27 and 30 patients, respectively. The median CBD diameter was 17.9 mm (range 8–35). Stent placement was technically successful in all but one case (98.2 %). In the failed case, duodenal perforation occurred while performing dilation of the tract needed to allow for subsequent insertion of the AXIOS^{TM} stent delivery device. The perforation site was closed by placement of endoscopic clips, and EUS-guided hepaticogastrostomy was successfully performed instead, with uneventful recovery of the patient.

In patients with duodenal stenosis, duodenal stenting using different types of uncovered metal stents was performed, when clinically necessary, before, during the same session or the day after the EUS-CD procedure. When performed after EUS-CD, the duodenal stent overlapped the AXIOS^{TM} stent.

In the 56 patients in whom LA–FCSEMS placement was technically successful, the median procedural time was 22.4 min (range 11–65) with no difference between the AXIOS^{TM} and the Hot AXIOS^{TM}. A 6-mm internal diameter and 8-mm-long stent was used in 36 patients (64.2 %), an 8 mm × 8 mm in 2 patients (3.6 %), a 10 mm × 10 mm stent in 16 patients (28.6 %) and a 15 mm × 10 mm in 2 patients (3.6 %). Clinical success was achieved in 54 of these 56 patients (96.4 %; 94.7 % of the entire cohort). Two patients, who presented with sepsis and multi-organ failure prior to any intervention, died within 4 days of EUS-CD. In both patients, the EUS-CD was technically successful with effective biliary drainage as demonstrated by a substantial decrease in serum bilirubin concentration. This, however, was not enough to reverse their multi-organ failure, and they ultimately died.

Procedure-related complications

In addition to the duodenal perforation described above, another case of duodenal perforation occurred and was caused directly by the tip of the echoendoscope during evaluation of the most appropriate site where to perform the drainage. The perforation site was located at the apex of the duodenal bulb and was immediately closed using an over the scope clip (OTSC®, Ovesco Endoscopy GmbH, Tübingen, Germany). A window opportunity beside the OVESCO clip was found, which allowed the performance of EUS-CD with placement of a clinically effective AXIOS^{TM} stent.

One patient with neoplastic infiltration of the duodenum experienced a severe acute arterial bleeding right after insertion of the Hot AXIOS^{TM}. He required coil embolization of the gastroduodenal artery and temporary placement alongside the LA–FCSEMS of a percutaneous biliary drainage catheter, which was removed 14 days afterward without any further adverse event.

One patient developed transient and self-limiting cholangitis after insertion of the AXIOS^{TM} stent, without any evidence of stent occlusion or malfunction at the endoscopic examination.

Overall, complications occurred more frequently when the AXIOS^{TM} stent was used, but without any significant difference as compared with the Hot AXIOS^{TM}.

Follow-up

The 54 patients with technical and clinical successful biliary drainage were followed up for a mean of 151 ± 145 days. At the end of follow-up, 15 patients were still alive.

One patient experienced spontaneous migration of the stent into the duodenum 7 days after insertion. This was

Table 3 Outcomes and specifics of EUS biliary drainage in 57 patients with unresectable distal common bile duct obstruction who failed ERCP

Outcomes
Technical success, *n* (%) 56 (98.2 %)
Clinical success, *n* (%) 54 (94.7 %; 96.4 % when technically successful)
Median CBD diameter: 17.9 mm (range 8–35)
Median procedure time: 22.4 min
Stent size (diameter and length), *n* (%)[a]
6–8 mm, 36 (64.2 %)
8–8 mm, 2 (3.6 %)
10–10 mm, 16 (28.6 %)
15–10 mm, 2 (3.6 %)
Procedure-related complications, *n* (%)
4 (7 %) (two duodenal perforations one major bleeding, one transient and self-limiting cholangitis)
Re-intervention, *n* (%)
5 (9.3 %) (four sump syndrome, one stent migration)

[a] Excluding one patient who had duodenal perforation before placing the stent

incidentally detected at abdominal CT requested by the oncologist for routine check-up. The patient was completely asymptomatic, with normal liver function tests. Esophagogastroduodenoscopy revealed a mature CD tract with active bile flow. A new AXIOS^{TM} stent of the same diameter and length (6 mm × 8 mm) was placed across the fistula, while the previously placed stent was removed, being wedged by the proximal end of the duodenal stent.

Four patients presented signs of intermittent malfunction of the LA–FCSEMS with transient increase in serum bilirubin concentrations. Control ERCP via CD revealed the presence of sludge in the distal duct reservoir in all patients, without any evidence of food impaction, consistent with a sump syndrome. All these cases were resolved by placement of a double-pigtail plastic stent through the CD, which was removed after 2 weeks without any further recurrence.

Overall at the end of follow-up, the stent was patent without any intervention in 49 patients (90.7 %).

Discussion

We retrospectively evaluated a large cohort of prospectively enrolled patients with malignant distal CBD obstruction who underwent EUS-CD, after failed attempted ERCP, using a newly available LA–FCSEMS specifically designed to create anastomosis. We found that stent placement was technically successful in all but one patient, with a very high clinical success rate of 94.7 % and low rates of procedure-related complications and re-interventions.

EUS-guided biliary drainage has become an attractive treatment alternative to the percutaneous route for effective biliary decompression in patients with unresectable malignant biliary obstruction after unsuccessful ERCP. Recent studies have reported EUS-BD to be as effective as percutaneous drainage [20, 21], with a lower rate of complications and with substantial reduction of costs, mostly due to reduced need for re-interventions [21].

Technically, EUS-BD can be performed with either a transgastric (intrahepatic) or transduodenal (extrahepatic) approach [7, 8, 22]. When a guidewire can be efficiently manipulated across the ampulla into the duodenum, the drainage can be completed by performing either a rendezvous procedure [23] or antegrade transpapillary biliary stent placement directly under EUS guidance [24, 25]. Alternatively, in all the other situations in which the guidewire cannot be passed through the ampulla, direct transluminal stenting can be done [7, 8].

Presently, the choice of the route of access and of the technique utilized to carry out the procedure is not standardized and usually depends on the endoscopist' preference. Both rendezvous and direct transluminal stenting techniques as well as the use of the transhepatic route compared to the transduodenal route appear to be equally safe and effective [26, 27]. Importantly, the overall complications rate remains high (20.6 %), with a reported mortality of 4.4 % [22]. These high rates of complications may be in part related to a learning curve effect, but can also reflect the utilization of accessories not specifically dedicated to this procedure.

The most worrisome complication of EUS-BD using the transluminal stenting approach is bile leakage into the peritoneum or retroperitoneum, which would require surgery in most cases. This may theoretically be prevented by the use of FCSEMS, which can automatically seal the gap between the stent and the walls of the fistula through their expandability [28]. In previous studies, however, the rate of bile leakage with SEMSs ranged between 2.9 and 10 % [8, 22, 29], underlying the need for the development of dedicated SEMSs able to completely prevent the occurrence of this complication.

In our study, we used a novel LA–FCSEMS, the AXIOS™ stent, that has a peculiar design that makes possible to tightly hold together the walls of two hollow structures (in this case the bile duct and the duodenal lumen), thus potentially decreasing the risk of leakage and speeding up the process of a fistulous tract formation [11]. Indeed, no cases of bile leakage were observed in our series and in one patient in whom the stent spontaneously migrated 1 week after placement, the tract was fully developed and perfectly functional.

In the present study, we used both the AXIOS™ device and the Hot AXIOS™ delivery system to create a choledochoduodenostomy. The Hot AXIOS™ represents an evolution of the first device with the stent incorporated into a delivery system with an electrocautery wire mounted on the tip [14]. This allows the procedure to be performed in one step, from penetration in the CBD to delivery of the stent without the need for additional accessories exchange. Moreover, when using the Hot AXIOS™ device, most of the procedure can be done under complete EUS guidance with reduced need for fluoroscopic assistance, as previously shown for drainage of pancreatic fluid collections [16]. This new stent is indeed very visible by ultrasound (see Fig. 2) and represents the first accessory specifically designed for interventional EUS procedures.

In our study, EUS-BD was technically successful in all but one patient in whom a duodenal perforation occurred during balloon dilation of the tract needed to allow for insertion of the AXIOS stent device. Technical success was also obtained in three patients with a CBD diameter less than 1 cm. In these patients, the procedure was technically more challenging, because of the need to push the catheter toward the hilum to find an area of the biliary system with more space where to open the distal flange of the stent. Because of these difficulties, we highly recommend new users to start with patients with a more dilated CBD of at least 15 mm.

Clinical success with resolution of the jaundice and/or of the cholestatic parameters was achieved in 54 of the 56 patients (96.4 %; 94.7 % of the entire cohort) in whom the stent was successfully placed. These high success rates were obtained despite the multicenter nature of the study, involving seven tertiary care centers throughout Europe and the fact that this represented the first experience with this stent for EUS-BD. Most of the participants had previous experience in the use of this stent for drainage of pancreatic fluid collections [13, 16], which can be considered a sort of training opportunity before moving toward other more demanding targets/indications (i.e., the gallbladder and the CBD).

The failure cases were two patients with multi-organ failure prior to EUS-CD who died within 4 days, despite a clinically effective biliary drainage as demonstrated by a substantial decrease in serum bilirubin plasma concentration. Because of this finding, we strongly believe that in these patients death should not be considered as a complication of the EUS-CD procedure.

Procedural complications occurred in four patients (7 %), using both the AXIOS™ and the Hot AXIOS™ without any difference between them. This rate of complications is substantially lower than that reported in recent series and in a review of the published studies [8, 9, 22]. One of the complications was a duodenal perforation caused by the tip of the echoendoscope during evaluation of the most appropriate site where to perform the drainage. This complication should not be attributed to the stent placement procedure, which was indeed successfully achieved after closure of the duodenal defect by an OTSC device.

During follow-up, re-intervention was necessary in 5 of the 54 patients with follow-up (9.3 %). One patient had asymptomatic stent migration, while four patients experienced transient increase in serum bilirubin concentrations with sludge in the distal duct reservoir, consistent with a sump syndrome. All these cases were resolved by temporary placement of a double-pigtail plastic stent through the CD. The sump syndrome, first described in 1976, is a well-known phenomenon occurring after surgical side-to-side choledochoduodenostomy, with a reported prevalence ranging from 2.5 to 15.7 % [30–33], which as shown in our series can be easily treated without major drawbacks.

In conclusion, our study shows that EUS-CD using the AXIOS™ and the Hot AXIOS™ devices is a safe procedure with a high technical and clinical success rates. Future prospective multicenter studies with a standardization of the procedure are needed to fully assess the long-term patency of the stent and the re-intervention rates.

Disclosures Dr. Rastislav Kunda is a consultant/speaker for Boston Scientific Corp. and for Olympus Medical. Dr. Manuel Pérez-Miranda is a consultant/speaker for Boston Scientific Corp., Xlumena and Gore. Dr. Alberto Larghi is a consultant/speaker for Cook Medical, Boston Scientific Corp., Covidien and Xlumena. Dr. Uwe Will, Dr. Sebastian Ullrich, Dr. Markus Dollhopf and Dr. Michelle Meier have no conflicts of interest or financial ties to disclose.

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