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Over-the-scope Technique for Partially Covered Self-expandable Metal Stent Placement to Treat Duodenal Perforation during EUS

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ABSTRACT

Background & Aims: Although endoscopic ultrasound (EUS) is generally safe, duodenal perforation may occur during the procedure. When the iatrogenic break is wide, endoscopic positioning of a covered self-expandable metal stent is indicated to avoid a more invasive surgical approach. We evaluated the efficacy of the 'over-the-scope stenting' (OTSS) technique to treat iatrogenic duodenal perforations occurred during EUS.
Methods: Data of patients with large iatrogenic duodenal perforations treated with OTSS procedure were collected in 5 centers. Technical success was defined as a correct stent placement on the perforation site, and clinical success as complete healing of the duodenal leak at stent removal 3 weeks later.
Results: A total of 15 (7 males; median age: 78 years, range 47-91) patients were included in this series. A correct stent positioning was achieved in all cases (technical success: 100%), and the perforation was healed in all, apart from one patient at stent removal (clinical success: 93%). This patient was successfully treated with a novel stent placement. No immediate post-procedural adverse events occurred, and no need for emergency surgery was recorded. In one (6.7%) patient, stent migration occurred 10 days after positioning, and it was spontaneously expulsed with stool movement without complications two days later.
Conclusions: Our data showed that the OTTS technique for partially covered self-expandable metal stent placement is feasible, safe and effective to tread large iatrogenic duodenal perforation occuring during EUS.

Key words: endoscopic ultrasound – EUS – perforation – stent – duodenum – endoscopy – over-the-scope stenting.

Abbreviations: CT: computed tomography; DP: duodenal perforation; ERCP: endoscopic retrograde cholangio-pancreatography; EUS: endoscopic ultrasound; OTTS: over-the-scope stenting; SEMS: covered self-expandable metal stent; TTS: trough-the-scope.

INTRODUCTION

Endoscopic ultrasound (EUS) is widely used for the diagnosis and treatment of different benign and malignant bilio-pancreatic lesions [1]. Indeed, clinical indications for EUS were considerably expanded in the last years [2]. Although generally safe, some complications may occur during EUS, particularly in complex procedures, frail patients (i.e., comorbidities), some anatomical conditions (previous gastroduodenal surgery), and examination performed during a learning curve or by less expert operators [3]. Among potential complications occurring during EUS - as well as endoscopic retrograde cholangio-pancreatography (ERCP) - iatrogenic perforation of either lateral or medial wall of the duodenum, caused by the scope itself (type I in Stapfer's classification), represents one of the most severe adverse events. In fact, they are usually large and associated with an increased mortality rate up to 20-30% [4]. When a duodenal perforation (DP) is recognized during examination, immediate endoscopic closure of the break is suggested as the treatment of choice [5]. Indeed, surgical intervention is burdened with a higher mortality rate and longer hospital stay than endoscopic treatment [6]. Therefore, surgery should be reserved as a rescue approach when the endoscopic approach fails, when the DP is too large or if it is recognized too late, the patient presenting with peritonitis or ongoing systemic sepsis [7].

Based on the site, type, size of perforation and operator expertise, the endoscopic repair of DP can be performed by using different devices. ESGE guideline suggests that minimal (<10 mm) duodenal defect can be closed with the placement of trough-the-scope (TTS) clips, whilst larger perforations deserve different approaches, including over-the-scope (OTSC) clips, endoscopic stitching, combination of glue and clips, endo-loop and positioning of covered self-expandable metal stent (SEMS) [4].

Data on endoscopic treatment of iatrogenic DPs occurring during EUS procedures are scanty, and the use of either TTS clips or, more recently, of OTSC clips have been mainly described [8, 9]. However, deployment of clipping systems might be technically difficult due to the anatomical site, and the procedure is unsuitable to treat large (>10 mm) duodenal wall breaks. For large DPs, the use of fully or partially covered SEMS is currently increasing as a treatment option to avoid surgery. The most common endoscopic procedure to SEMS placement in the duodenal wall is the trough-the-scope over the wire technique. This procedure requires fluoroscopy guidance, and damage or occlusion of the Vater papilla after stent placement may occur despite radiologic control, since the precise control of the distal stent releasing may be challenging. The over the scope stenting (OTSS) has been proposed as an effective method to place large metal stents under direct endoscopic visualization of intestinal wall without need of fluoroscopic guidance [10].

We report a case series of patients with large DPs occurring during EUS treated with the OTSS procedure.

METHODS

Patients

This was a retrospective analysis of prospectively collected data from September 2018 to April 2021 in five Italian, tertiary referral Endoscopic Units. In detail, the series included patients with a large iatrogenic DP which occurred during diagnostic or therapeutic upper gastrointestinal EUS and was immediately treated with partially covered SEMS positioned according to the OTSS approach. All patients were previously informed about the advantages and risks of EUS procedure as well as on possible complications and signed an informed consent for EUS procedure and therapeutic approach in the case of adverse events. Moreover, as for routine practice, patients were required to consent anonymous use of their data for scientific purpose. Data about endoscopic procedures and clinical and demographic features of patients were recorded in a specific database.

Endoscopic Procedures

All endoscopic procedures were carried out in patients under conscious or deep sedation with anesthesiologist support, by five trained gastrointestinal endoscopists. The standard OTSS technique was followed in each center [10]. Drainage of pneumoperitoneum was emergently performed in all patients to avoid development of the compartment syndrome. A 6 or 8 cm enteral/colonic partially covered SEMS was opened and located externally at the tip of an operator gastroscope (Fig. 1A). A polypectomy snare or a foreign body forceps was deployed through the scope working channel and used to attach the distal end of partially c-SEMS to the tip of the scope (Fig. 1B). The proximal end of partially covered SEMS was maintained from another snare or forceps fixed externally to the scope (Fig. 1C). When the partially covered SEMS fixed over the scope (Fig. 1D), the DP site was reached and then the stentwas released under direct endoscopic view. The distal uncovered end allows the fixing of the stent to the mucosal wall and endoscopic clips were additionally used to anchor the proximal end in order to further prevent migration.

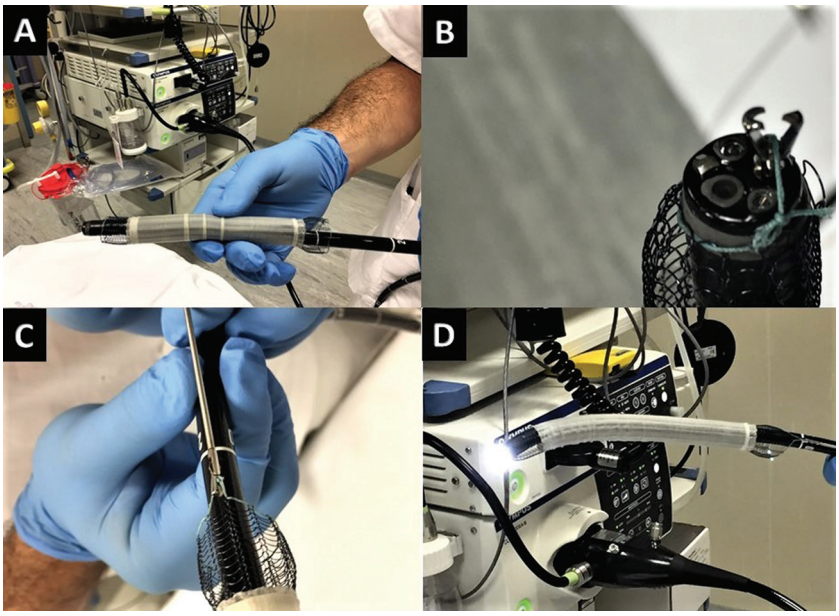

Fig. 1. Partially covered self-expandable metal stent (SEMS) opened and located externally at the tip of an operator gastroscope (A). Distal end of a partially covered SEMS attached with a foreign body forceps at the tip of the scope (B). Proximal end of a partially covered SEMS maintained from another forceps fixed externally to the scope (C). Partially covered SEMS fixed over the scope (D).

A computed tomography (CT) scan with water-soluble contrast medium was performed after endoscopic procedure to assess the correct SEMS deployment according to the wall defect position (Fig. 2). At least 3 weeks following the procedure, perforation healing was checked by a water-soluble contrast examination, and the stent removed. Technical success was defined as correct stent placement on the DP site confirmed by a CT scan with water-soluble contrast medium. The clinical success was defined as the complete healing of the perforation established by water-soluble contrast examination.

Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Since no experimental drugs were administered, no additional costs or procedures for the patients were required, no identification of patients was allowed, and no funds were received, the formal approval by the Investigational Review Board was waived.

Statistical Analysis

Frequency of observations with their 95% confidence intervals (CI) were calculated, as well as the median of main outcomes.

RESULTS

A total of 15 (7 males; Median age: 78 years, range 47-91) patients were included in this series. The EUS procedure were performed for the evaluation of biliary pancreatitis (n=7), pancreatic cyst (n=3), ampulloma (n=4), and cholangiocarcinoma in the remaining case.

The DP site was in the inferior wall of the duodenal knee in all, but one case with the perforation on the superior wall. The echo-endoscope used were the EG-3870 UTK (Pentax, Tokyo, Japan) or the GF-UCT180 (Olympus, Tokyo, Japan) in 10 and 5 patients, respectively, and all perforations were caused by the endoscope itself. The median size of perforation was 20 mm (range: 12-30). All the iatrogenic lesions were recognized during the EUS study, namely intra-procedural, and immediately treated. A 6 cm enteral/colonic partially covered SEMS was used in 11 patients, an 8 cm stent in 3 cases, whilst in the remaining patient a 6 cm esophageal partially covered SEMS as an off-label treatment was placed because of no enteral/colonic SEMS were available in the emergency setting. A correct partially covered SEMS positioning was achieved in all cases as confirmed by CT scan control, so that the technical success was 100%. No immediate post-procedural adverse events were observed, and no need for emergency surgery was recorded after partially covered SEMS placement. In one (6.7%) patient, stent migration occurred 10 days after positioning, and it was spontaneously expulsed with a stool movement without complications two days later. At the time of stent migration, the duodenal defect was completely healed. The CT scan showed a duodenal diverticulum without recognition of gas outside the GI tract as the outcome of the endoscopy treatment. Therefore, no other SEMS was deemed to be necessary. The median hospital stay was 11 days (range: 8-15). According to the clinical conditions, patients were discharged with a recommendation to follow a semi-solid diet and to avoid physical efforts for the successive 3 weeks when re-admitted for stent removal.

Radiologic control was performed at a median of 25 days (range: 21-40). The perforation was healed in all, but one patient in whom the break was not completely sealed, corresponding to a clinical success of 93% (95%CI: 74-100). In this patient, after partially covered SEMS removal, the radiologic guided contrast medium injection performed during upper gastrointestinal endoscopy confirmed a small persistent fistula (2-3 mm in diameter). Therefore, a new 6 cm partially covered enteral/colonic SEMS placement was performed, and a complete duodenal healing was achieved two weeks later. An endoscopic feature of perforated area before and after partially covered SEMS placement are provided in the Fig. 3.

DISCUSSION

Iatrogenic duodenal perforations during endoscopy represent a serious and potentially life-threatening adverse event [11]. Data of a systematic review showed that ERCP-related Stapfer type I perforations are the second most frequent adverse events, with an overall incidence of 0.12%, and with a mortality rate up to 8% [12]. Unfortunately, the surgical approach is burdened by a high (20%) mortality rate, especially when the intervention is delayed (>12-24 h) [6]. Better clinical outcomes were reported in endoscopically treated patients, in terms of

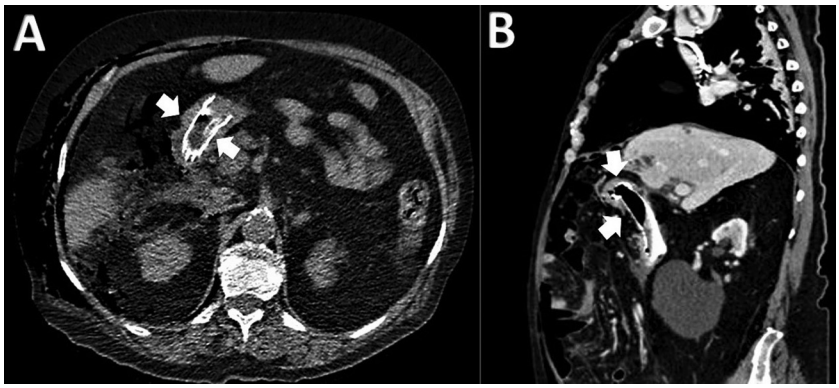

Fig. 2. Computed tomography scan with water-soluble contrast medium assess the correct partially covered self-expendable metal stentdeployment according to wall defect position. The arrows indicate the stent positioned in the duodenum in axial (A) and sagittal (B) scan.

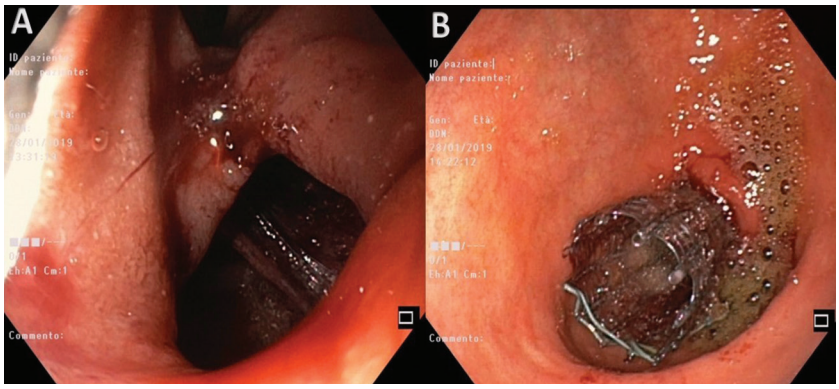

Fig. 3. Large duodenal perforation (A). Partially covered self expendable metal stent deployed on the site (B).

both survival and hospital stay [4]. Recent data suggest that the application of endoscopic stents, either fully or partially covered, might be an effective and minimally invasive therapy for gastrointestinal perforations treatment [13]. Indeed, the stent immediately excludes outflow of the fluid from the intestinal wall break, performs a protection during the mucosal healing, allows an early oral feeding, and prevents strictures formation. Recently, the OTSS technique has been proposed as an effective method to place large metal stents under direct endoscopic visualization of intestinal wall without need of fluoroscopic guidance. In detail, this approach was performed to treat postsurgical leaks, perforations, including the duodenum, and stenosis [10]. The direct vision of papilla at endoscopic examination surely improves stent release in a correct position. In detail, by positioning the endoscope at 5-10 mm from the visualized papilla it is possible to be sure that the distal part of the stent is released aside of papilla. Such a precision is not guaranteed by the radiological approach. In the present series, we applied this technique to treat large DPs. Data found a very high technical (100%) and clinical (93%) success, with an acceptably low (7%) rate of stent migration, and without other adverse events.

In detail, migration occurred in the single patient in whom an 8 cm, partially covered oesophageal SEMS was positioned. Although based on a single observation, it would appear that the choice of stent type (enteral/colonic vs oesophageal) and length (6 vs 8 cm) could be a matter for concern. The positioning of an enteral/colonic stent of 6 cm in length could be preferred due to a better adhesion to the duodenal wall, when considering the vigorous peristalsis in this intestinal tract. The OTSS technique we applied may allow an effective management of post-EUS large and/or sited in difficult position duodenal perforations, without resorting in the X-ray scope, even in the same endoscopic unit where the EUS is performed. When adding the observation that the hospital stay was shorter than 2 weeks following this endoscopic approach, it could be concluded that the overall results seem to be better than that reported with the surgical approach [6]. Our findings are clinically relevant when considering that data of a recent, large meta-analysis found an incidence of 0.21% of EUS-related intestinal perforations, with a fatal event reported in 0.19% cases despite surgical treatment [14]. When considering that diagnostic and therapeutic EUS procedures are increasingly performed, the absolute number of complications, including DPs, is expected to increase in the future. This poses new clinical challenges for the endoscopists to accomplish correct management. On the other hand, the OTSS procedure overcame some limitations of other endoscopic approaches. Indeed, the TTS clips are safe, economic and universally available, but have limitations regarding the size and site of DPs. Similarly, the use of OTSC clips requires a specific skill, and this device is not available in every endoscopic unit.

CONCLUSIONS

Our data showed that the 'over-the-scope technique' for partially covered self-expandable metal stent placement is feasible, safe and effective to treat large iatrogenic duodenal perforation occurring at EUS examination.

Conflicts of interest: None to declare.

Authors' contributions: A.V.S and R.M. conceived and designed the study. All authors contributed to the study with collection. The first draft of the manuscript was written by A.Z.. All authors read and approved the final manuscript.

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