Over-The-Scope Clip for the Immediate Management of Stapfer Type-1 Duodenal Perforation during Endoscopic Retrograde Cholangiopancreatography

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Keywords
Over-the-scope clip \cdot Stapfer classification \cdot Duodenum \cdot Perforation \cdot Endoscopic retrograde cholangiopancreatography

Abstract
Iatrogenic Stapfer type-1 duodenal perforations during endoscopic retrograde cholangiopancreatography (ERCP) typically necessitate surgical management and carry significant morbidity and mortality risk. Here, we present a case of a large duodenal perforation during ERCP managed endoscopically with an over-the-scope clip (OTSC) and describe the subsequent post-procedural management. An 80-year-old woman presented to the emergency department with acute cholangitis. Abdominal ultrasound scan revealed a dilated biliary tree with echogenic material in the common hepatic and intrahepatic ducts. The patient proceeded to ERCP, where filling defects consistent with stones were found in the proximal main bile duct on cholangiogram. Stone retrieval was complicated by a large iatrogenic perforation of the infero-lateral duodenal wall, distal to the major ampulla (Stapfer type-1). Following unsuccessful attempts to close the defect using through-the-scope clips, a decision was made to attempt closure endoscopically using an OTSC. The duodenoscope was exchanged for a forward-viewing gastroscope mounted with the OTSC. The perforation defect was fully suctioned into the cap and the clip was successfully deployed. Subsequent on-table fluoroscopy with contrast injection...
did not demonstrate any extra-luminal contrast leak. The patient developed a post-procedure infra-duodenal collection, however, made a complete recovery with bowel rest, negative pressure regulation at the site of the OTSC using a dual-lumen nasogastric/nasojejunal feeding tube and intravenous piperacillin-tazobactam. Thus, OTSCs potentially offer a safe and effective endoscopic treatment modality for the immediate management of ERCP-related Stapfer type-1 duodenal perforations.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) related perforations are rare, with the reported incidence ranging between 0.3 and 1.3% [1]. Stapfer et al. [2] classified them into four subtypes according to their location. Of these, Stapfer type-1 perforations occur distal to the ampulla on the lateral or medial duodenal wall, as a result of duodenoscope-related trauma. While the majority of ERCP perforations can be managed conservatively [3], Stapfer type-1 perforations can be large, carry significant risks of morbidity and mortality, and often necessitate surgical management [1, 2, 4, 5]. Over-the-scope clips (OTSCs) potentially offer a less invasive treatment modality, but their routine use in this context is not yet well supported by the current literature.

Case Presentation

An 80-year-old woman presented to the emergency department with upper abdominal pain, fever, and new onset of jaundice for 3 days. The patient had a relevant past history of ERCP and sphincterotomy for choledocholithiasis, and subsequent laparoscopic cholecystectomy 2 years prior. She was otherwise well and lived in her home independently.

Physical Examination

Initial observations revealed fever with a temperature of 37.8°C, and a heart rate of 90 b/min, with normal blood pressure and oxygen saturations. Physical examination was significant for the presence of scleral icterus. Abdominal examination elicited right upper quadrant and epigastric tenderness, without signs of peritonism.

Investigations

Initial blood tests showed a normal full blood examination with a leukocyte count of 4.6 × 10^9/L, obstructive liver chemistry tests (bilirubin 176 U/L [<20 U/L], alanine aminotransferase 22 U/L [<30 U/L], aspartate aminotransferase 91 U/L [<30 U/L], alkaline phosphatase 371 U/L [30–110 U/L], gamma-glutamyl transferase 602 U/L [<35 U/L]), and a c-reactive protein of 143 mg/L (<10 mg/L). Serum lipase was normal at 27 U/L. An upper abdominal ultrasound scan revealed dilated intrahepatic bile ducts with intraductal echogenic material present in the intrahepatic ducts and the proximal main bile duct (Fig. 1). The common bile duct (CBD) was mildly dilated at 8 mm but incompletely visualized. Given her past history of cholelithiasis and choledocholithiasis, the clinical picture, along with abdominal ultrasound images and obstructive liver chemistry tests, was consistent with a working diagnosis of ascending cholangitis with biliary obstruction secondary to recurrent choledocholithiasis and/or sludge.
Therapeutic Intervention

Empiric intravenous antibiotic therapy with piperacillin-tazobactam was commenced. The patient did not have further pre-procedural imaging but rather proceeded to ERCP, which demonstrated filling defects suggestive of two stones sized up to 12 mm in the proximal main bile duct. Although the proximal CBD appeared significantly more dilated, the distal CBD tapered and was less dilated at 12 mm in width (Fig. 2). Following wire-guided biliary cannulation and biliary dilatation balloon sphincteroplasty up to 11 mm, balloon sweeps using a 12 mm extraction balloon catheter removed one stone (Fig. 3); removal of the second stone was more difficult, however, was achieved with backward traction on the extraction balloon catheter, and clockwise torque on the duodenoscope. Further extraction balloon sweeps were clear.

Complications

At this point, a large iatrogenic perforation of the infero-lateral duodenal wall was recognized, distal to the major papilla, likely as a result of the torquing scope maneuver (Fig. 4). Attempts to close the perforation defect using through-the-scope clips were unsuccessful, as the size of the defect was too large to achieve adequate opposition of the edges. Therefore, a decision was made to attempt closure using an OTSC. The duodenoscope was exchanged for
a forward-viewing gastroscope mounted with an 11 mm diameter OTSC. The perforation defect was entirely suctioned into the cap of the delivery device, and the clip was successfully deployed (Fig. 5). Subsequent on-table fluoroscopy did not demonstrate any extra-luminal contrast leak (Fig. 6). A dual-lumen nasogastric/nasojejunal feeding tube (NGJT), with a pressure regulation lumen (Freka Trelumina®, Germany) was then placed, with the proximal chamber positioned close to the perforation site in the second portion of the duodenum, and
the distal end beyond the perforation site, in the proximal jejunum. An abdominal computed tomography (CT) scan performed immediately after ERCP demonstrated small-volume free fluid and retroperitoneal gas adjacent to the perforation site. However, there was no leak of orally administered contrast. The patient developed a temperature of 38.6°C on day-2 post-ERCP, in association with a rising c-reactive protein that peaked at 230 mg/L. A repeat abdominal CT scan demonstrated a 44 mm × 28 mm × 30 mm gas and fluid containing collection adjacent to the perforation site (Fig. 7).

**Clinician and Patient Assessed Outcomes**

The proximal chamber of the NGJT was placed on continuous low suction. Nasojejunal feeds were commenced on day 3. With ongoing intravenous antibiotics, the patient improved clinically with no further fevers or abdominal pain and falling c-reactive protein levels. The patient's...
liver chemistry tests gradually normalized. She was gradually escalated to an oral diet and discharged home 15 days post-ERCP, on a 5-day course of oral amoxicillin-clavulanate.

**Follow-Up**

The patient underwent 6-weekly outpatient clinic follow-up. She remained clinically well, with no further symptoms. At 4 months, a repeat abdominal CT scan demonstrated that the collection had completely resolved, with the OTSC still in situ (Fig. 8).

**Discussion**

Procedural risk factors for ERCP-related perforation include surgically altered anatomy, challenging cannulation requirements, prolonged procedure times, need for sphincterotomy or endoscopic papillary large balloon dilatation (EPLBD), biliary stricture dilation, and needle-knife precut [6–8]. However, intra-procedurally, endoscopists typically rely on their experience and tactile feedback from the endoscope and working channel instruments to gauge the safety margin for endoscopic maneuvers. Factors that may have contributed to perforation in this case warrant discussion.

EPLBD has been shown to be a safe and effective adjunct technique after biliary sphincterotomy for the extraction of larger stones ≥10 mm. The degree of dilatation performed during EPLBD should not exceed the estimated width of the distal CBD, defined as 1 cm proximal to the papillary opening [8, 9]. In this case, the distal CBD was estimated to be 12 mm in width (Fig. 2). We did not dilate further than 11 mm before attempting stone extraction, as first, the distal CBD was angulated and tapered significantly; therefore, a graded approach to dilatation was undertaken. Second, the patient had safely tolerated biliary dilatation up to 11 mm during her previous ERCP. Third, the 12 mm extraction balloon came through the sphincteroplasty during the previous balloon sweep removing one of the stones. Although stone removal was successful in this instance, given resistance was encountered, rather than exert further torque on the duodenoscope, alternative approaches should have been considered. These include further cautious graded dilatation, use of mechanical or electrohydraulic lithotripsy, or reattempting stone extraction after initial biliary decompression via placement of a biliary stent.
The management of ERCP-related Stapfer type-1 duodenal perforations remains contentious, with few studies reporting its frequency and management due to its rarity [5, 10]. Historically, surgical management has been favored. In a recent systematic review of the management and outcome of ERCP-related duodenal perforations, 54 out of 305 perforations in 42,374 ERCPs were Stapfer type-1. The rate of nonoperative management for Stapfer type-1 perforations was only 13% [10]. Furthermore, failure of nonoperative management occurred for 42.8% of cases and postoperative mortality for these cases was very high at 75% [10]. In a retrospective study of 9,880 ERCP, 6 of 7 Stapfer type-1 perforations underwent operative management, with a mortality rate of 33.3% (2 of 6) [1]. In another retrospective study of 4,358 ERCP, 9 patients with Stapfer type-1 perforations underwent primary surgical repair, with no mortality reported [4].

More recently, there is emerging data regarding the efficacy of nonsurgical management. In a large retrospective multicenter study including >20,000 ERCPs, 59 cases of perforation were recorded, of which 17 were Stapfer type-1 perforations. Early diagnosis (<6 h post-ERCP) and the absence of peritoneal irritation and systemic inflammation were associated with better prognosis [5]. Seven patients underwent endoscopic clipping and these patients had a lower duration of hospital stay with no other complications or mortality reported [5]. The European Society for Gastrointestinal Endoscopy (ESGE) has recently recommended OTSCs as the first-line therapeutic modality for iatrogenic gastrointestinal perforations sized 10–20 mm [11]. In a systematic review that included 30 studies and 351 cases of perforations where OTSCs were used, the clinical success rate was 85% [12]. In a recent retrospective study that compared OTSC with surgery for Stapfer type-1 perforations, 8 out of 20 patients were treated with OTSC, while the remainder underwent surgery [13]. For those treated with OTSC, there were no inpatient complications and no mortality at 3 months. Time to oral intake (2 vs. 7 days; \( p = 0.013 \)) and median hospital stay (2 vs. 22 days \( p = 0.003 \)) were significantly shorter [13].

Medical management of gastrointestinal perforations consists of therapeutic fasting, diversion of luminal contents and secretions away from the perforation site, ensuring adequate nutrition by enteral or parenteral means, and intravenous antibiotics [5]. Endoscopic negative pressure therapy is a novel adjunct treatment strategy that has yielded promising outcomes in the management of gastrointestinal perforations [14]. In our case, the post-procedural course was complicated by the development of a retroperitoneal collection secondary to intra-procedural contamination. We used a dual-lumen feeding tube and positioned the gastric chamber with the pressure regulation channel at the location of the OTSC in the second portion of the duodenum, with continuous negative pressure exerted at the site of the perforation. This facilitated internal drainage of duodenal and gastric secretions and made distal enteral feeding possible.

**Conclusions**

There are other reports of ERCP-related duodenal perforation closure with OTSC systems [15]. However, this case highlights multiple ERCP practice points. Stapfer type-1 perforations during ERCP typically occur via a predictable mechanism and this case serves to discuss intra-procedural factors that may have contributed to it and strategies that could be considered to minimize its risk. Importantly, it also describes the post-procedural course and subsequent management of an intra-abdominal collection that developed as a result of the perforation. This included the use of continuous negative pressure via a pressure regulated dual-lumen NGJT at the perforation site and early facilitation of distal enteral feeding. Stapfer type-1 perforations in the second portion of the duodenum are typically easily accessible with a front-on approach using a forward-viewing gastroscope. OTSCs offer a safe and effective endoscopic treatment modality for their immediate management, and their use in this setting should be considered by all ERCP practitioners.
Statement of Ethics

This study was reviewed and approved by the Ethics Committee of Western Health, Project No. CS2021.04. Written informed consent was obtained from the participant of this study, for publication of the details of their medical case and any accompanying images.

Conflict of Interest Statement

Kathryn Gazelakis, Grace Lovett, Robert Chen, Yahya Al-Hebbal, and Kumanan Nalankilli have no conflicts of interest to declare.

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Author Contributions

Kathryn Gazelakis, Grace Lovett, Robert Chen, Yahya Al-Hebbal, and Kumanan Nalankilli each contributed to the conceptualization and writing of this manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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