1130-0108/2015/107/3/183-184
Revista Española de Enfermedades Digestivas

Rev Esp Enferm Dig (Madrid
Vol. 107, N.º 3, pp. 183-184, 2015

Letters to the Editor

Cholecystitis and duodenal fistula as EndoBarrier®-associated complications. Minimally invasive treatment

Key words: EndoBarrier®. Complication. Cholecystitis. Fistula. Treatment.

Dear Editor,

We report the case of a patient with obesity and type-2 diabetes mellitus who, one month after endoscopic duodenojejunal bypass (EndoBarrier® technique) had, as a complication thereof, acute cholecystitis and duodenal fistula secondary to bulbar transmural penetration and gall-bladder impaction by one of the anchors, which could be solved using minimally invasive laparoscopic surgery with endoscopic EndoBarrier® withdrawal.

Case report

A 55-year-old male presented with grade-II obesity (body weight 94.5 kg, 208 lbs, BMI 36 kg/m^2), hypertension, hypercholesterolemia, and type-2 diabetes mellitus on 2 oral antidiabetic drugs (OADs) and 80 UI of insulin. Following a multidisciplinary assessment, endoscopic placement of an EndoBarrier® device was agreed, and the procedure was uneventful. The patient had a follow-up visit at 4 weeks and was in good health, having lost 7.5 kg (16.5 lbs) in weight and reduced OADs and insulin requirements by half.

A week later he presented with fever and abdominal pain. The following was performed:

- Physical examination: Abdominal guarding in the right upper quadrant.
- Lab tests: Leukocytosis (21,000/ul).
- Abdominal CT: Acute alithiasic emphysematous cholecystitis with air bubbles in cystic duct and air level in gall-bladder, and a properly placed EndoBarrier® device.

A laparoscopic cholecystectomy was performed, and acute alithiasic gangrenous cholecystitis secondary to bulbar transmural penetration and gall-bladder impaction by an EndoBarrier® anchor (Fig. 1) was found. Pathology confirmed the presence of acute gangrenous cholecystitis with bile culture positive for *Clostridium perfringens*.

Torpid post-surgical course with abdominal guarding prompted a follow-through evaluation, which showed a small duodenal fistula.

A gastroscopy was performed (Fig. 2), which confirmed a small bulbar fistular orifice, and it was decided to endoscopically withdraw the EndoBarrier® device, the procedure being uneventful.

Subsequently the patient had a satisfactory recovery with conservative medical therapy, and was discharged after 10 days.

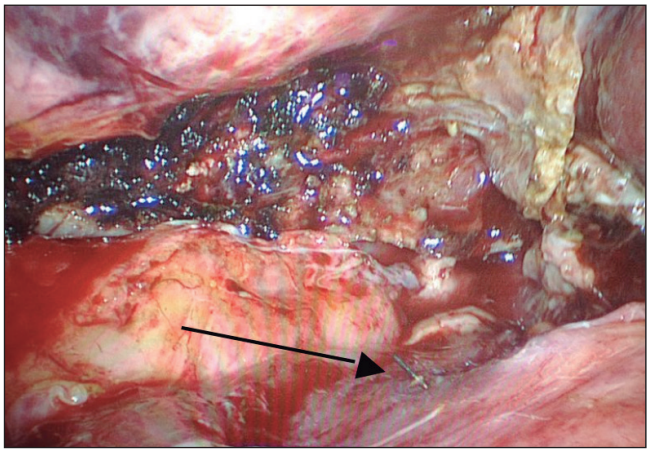

Fig. 1. Surgical image: A device anchor may be seen emerging from the duodenal bulb into the peritoneal cavity.

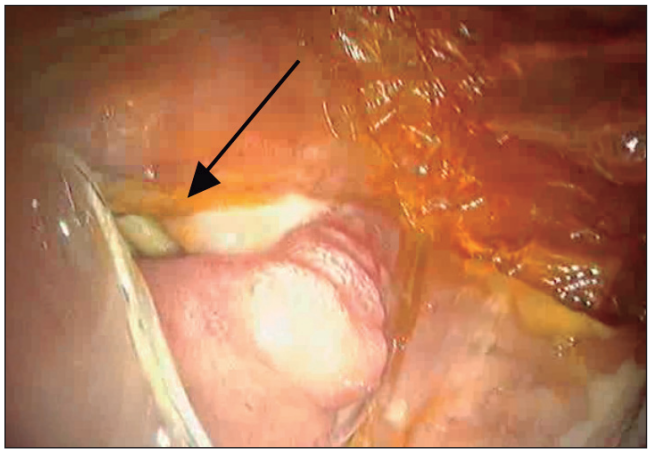

Fig. 2. Endoscopic image: A periulcerative fistular orifice is seen in the bulbar EndoBarrier® anchorage area, which prompts endoscopic removal.

Discussion

The endoscopic duodeno-jejunal bypass provided by the EndoBarrier® device (GI Dynamics, Inc, Watertown, Mass.) entails the placement of a flexible, lined, intraluminal fluoropolymer sleeve (prosthesis) which is endocopically anchored within the duodenal bulb by five crown-shaped rings (each with two 4-mm nitinol anchors), and extends about 60 cm along the duodenum to the proximal jejunum, thus providing an "inner barrier" ("Endo-Barrier") which separates ingested food from intestinal villi, presumably offering a similar effect to surgical gastric bypass (1,2).

Knowledge of a neurohormonal factor operating at the duodenal wall, the device's malabsorptive effect and some mechanical component of delayed gastric voiding position the procedure as an alternative, complementary technique valid for the management of adult patients with obesity and diabetes mellitus in addition to cardiovascular risk factors and related metabolic syndrome (2-9).

The EndoBarrier® technique is exclusively endoscopic. Implantation (5) and removal (7) issues were found with first-generation EndoBarrier® devices (4-7,9). With the technical improvements introduced in second-generation EndoBarrier® devices, primarily involving the anchoring mechanism and location, overall major complications have decreased below 5 %, and the technique is now safe and reliable. In our experience with 24 procedures and follow-up up to 6 months overall tolerability has been excellent, and no other major complications had previously arisen. Acute gangrenous cholecystitis secondary to gall-bladder impaction by an EndoBarrier® anchor is a major complication that had not been reported to this day, likely due to a somewhat rotated placement of the anchoring crown-shaped rings. During laparoscopic cholecystectomy, likely secondary to intraoperative peritoneal washing and handling, anchors budged and gave rise to the small fistula detected by radiology and endoscopy, which could be solved by endoscopic device removal and conservative medical therapy.

To conclude, we consider that, in expert hands, EndoBarrier® represents a safe, effective endoscopic technique, although major complications such as acute gangrenous cholecystitis and duodenal fistula, previously unreported, may arise and require device removal as well as a more invasive therapeutic approach.

For this reason we believe that this therapy should only be offered in reference hospitals with a multidisplinary team, an endoscopic Obesity Treatment Unit specifically trained in this technique, and joint cooperation with a specialist emergency surgery department for the early management of potential major complications.

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