

# Outcomes after paclitaxel-coated balloon after iatrogenic biliary injury following single-anastomosis duodeno-ileal bypass: a case report

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**Background:** Single anastomosis duodeno-ileal bypass (SADI) is becoming more famous in the therapeutic arsenal of bariatric/metabolic issues. The most dreaded postoperative (PO) complications are bleeding, leaks and long-term malabsorption. During the retro-duodenal dissection, a crucial part of this procedure, an iatrogenic injury can occur, due to the presence of important adjacent anatomical structures. The management of a surgery-induced biliary injury, in this specific procedure, is not much described in current literature.

**Case Description:** The patient was 39 years old and had a history of hypertension, obstructive sleep apnea syndrome, with no previous abdominal surgery. She was eligible for bariatric management within our institution, a high-volume center of metabolic and bariatric surgery. First, she underwent a sleeve gastrectomy (SG) [initial body mass index (BMI): 65 kg/m<sup>2</sup>] with uneventful PO course. One year PO, the BMI stagnates at 55 kg/m<sup>2</sup> with remission of the comorbidities, then an SADI was performed. But, due to a complex intraoperative retroduodenal dissection, an iatrogenic perforation of the distal part of the proximal duodenum was deployed and sutured. At 20 days PO, she developed clinical jaundice. A biological cholestasis with conjugated bilirubin without inflammatory syndrome is identified. An abdomino-pelvic tomodensitometry shown dilated intra- and extrahepatic bile ducts upstream of the pancreaticoduodenal junction. Then, we suspected a PO inflammatory stenosis of the common biliary duct secondary to the suture of the previous duodenal perforation. An internal-external transhepatic drain was positioned under radiological control to bypass the obstruction and lift the jaundice. In the following months, the stenosis was dilated by successively increasing drainages, but a residual stenosis persisted. Finally, at 7 months PO, a paclitaxel-coated balloon (anti-angiogenic agents) was placed, allowing the removal of the drain at 9 months PO. At 1 year PO, bilirubinemia is normalized, her excess weight loss (EWL) is 45% and she did not develop any long-term complications.

**Conclusions:** Accessing bile ducts after biliopancreatic diversion, such as SADI, remains challenging. In our case, the paclitaxel-coated balloon was effective against the inflammatory reaction that caused the stenosis of the distal part of the common bile duct. It may be a rescuer to inhibit neointimal hyperplasia.

**Keywords:** Case report; paclitaxel-coated balloon; single anastomosis duodeno-ileal bypass (SADI); biliopancreatic diversion; bile duct iatrogenic injury

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## Introduction

Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) is a simplified version of the biliopancreatic diversion with duodenal-switch (BPD-DS) (1). It was first proposed by Sánchez-Pernaute *et al.* in 2010 (2) and is gaining momentum in North America (3). It is a sleeve gastrectomy (SG), associated with a single anastomosis of the ileum, proposed at 250 or even 300 cm from the ileo-caecal valve, on the duodenum, 2 cm distal from the pylorus, at least. Its advantage over BPD-DS is simplicity of execution due to his single anastomosis. The physiopathological principles are the same as those of the BPD-DS, associating a food restriction caused by the SG, and hypo-absorption caused by the biliopancreatic diversion, while preserving the pylorus (theoretically protecting from bile reflux and dumping syndrome). The results suggest that BPD-DS would be slightly better than SADI in terms of weight loss at the cost of slightly worse long-term morbidity (4,5). Surgery is performed as a primary (SADI-S) or revisional procedure (SADI) in the arsenal of bariatric surgical therapies (6,7). SADI is now recognized as a bariatric/metabolic procedure, with acceptable mid-term outcomes, but long-term results analysis still being needed (7,8). Currently, primary SADI-S is an alternative to BPD-DS for patients suffering from severe obesity with a body mass index (BMI)  $>50 \text{ kg/m}^2$ , in order to achieve optimal outcomes (7,8). For patients who are poor responders to an initial SG, it can also be considered as a second stage. Actually, no consensus is made on the definition of weight recurrence or insufficient weight

loss. Judging the effectiveness of SG on the basis of excess weight loss (EWL) only might be insufficient. Since the American Society for Metabolic & Bariatric Surgery and the International Federation for the Surgery of Obesity and Metabolic Disorders published their updated positions, it is recommended to consider revisional surgery in case of persistence or recurrence of severe obesity (BMI  $\geq 35 \text{ kg/m}^2$ ) or in case of persistence or recurrence of obesity-related comorbidities after primary treatment (7-11). Major early postoperative (PO) complications described are mostly leaks (0.9–1.8%) and bleeding (1.1%) (6,12,13). Intraoperative injuries on adjacent anatomical structures to the duodenum, such as bile ducts, can occur during SADI and are not much described in the existing literature.

We expose an iatrogenic injury that occurred on common bile duct during an SADI procedure and that caused an early jaundice. We explain the diagnostic strategy, the possible therapeutic management and how to prevent such incidents. We present this article in accordance with the CARE reporting checklist (available at <https://amj.amegroups.com/article/view/10.21037/amj-23-90/rc>).

## Case presentation

This case reports a female patient of 39 years old with a history of hypertension, obstructive sleep apnea syndrome, without previous abdominal surgery. She is eligible for bariatric management within our institution, a high-volume center of metabolic and bariatric surgery. First, she underwent an SG (initial BMI:  $65 \text{ kg/m}^2$ ) with uneventful PO course. At 1 year PO, the BMI stagnates at  $55 \text{ kg/m}^2$  with remission of the comorbidities. To achieve better weight loss, a laparoscopic SADI is proposed.

The first step of this procedure was to locate the ileal loop, 300 cm from the ileo-caecal valve, to ensure that there is no tension on the future anastomosis. The next step was the retroduodenal dissection of the first part of the duodenum, after the pylorus. This is a complex part of the procedure, where the surgeon has to respect multiple adjacent structures such as, the pancreatic head (adherent to the posterior duodenal wall), the gastroduodenal artery (met right after the pylorus on the dissection path), and the hepatic pedicle (encountered at the end of the retroduodenal passage and has to be left on the right side of the dissection path). Then, the ideal duodenal section would be done at least at 2 cm distal to the pylorus, but before the second duodenum, avoiding a damage on the anatomical structures previously cited and preserving the

### Highlight box

#### Key findings

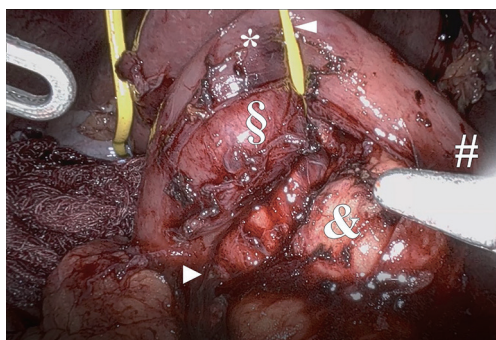
- Paclitaxel-coated balloon dilatation could be a therapeutic alternative in refractory bile duct stenosis.

#### What is known and what is new?

- Retroduodenal dissection during single anastomosis duodeno-ileal bypass (SADI) is challenged by the proximity of adjacent anatomical structures. Accessing bile ducts after SADI is complex.
- Surgical duodenal injury during SADI may predispose to bile duct injury. Iatrogenic biliary stenosis can resist to simple balloon dilatation using transhepatic radiological approach.

#### What is the implication, and what should change now?

- Paclitaxel-coated balloon can be considered to treat iatrogenic biliary stenosis after SADI if a mini-invasive management like transhepatic radiological approach can be used.



**Figure 1** Intraoperative view of the duodeno-pancreatic site of dissection. \*, duodenum; &, pancreas; #, pylorus; <, vascular loop repairing the retroduodenal passage; \$, tear; >, iatrogenic perforation with emission of digestive fluids.

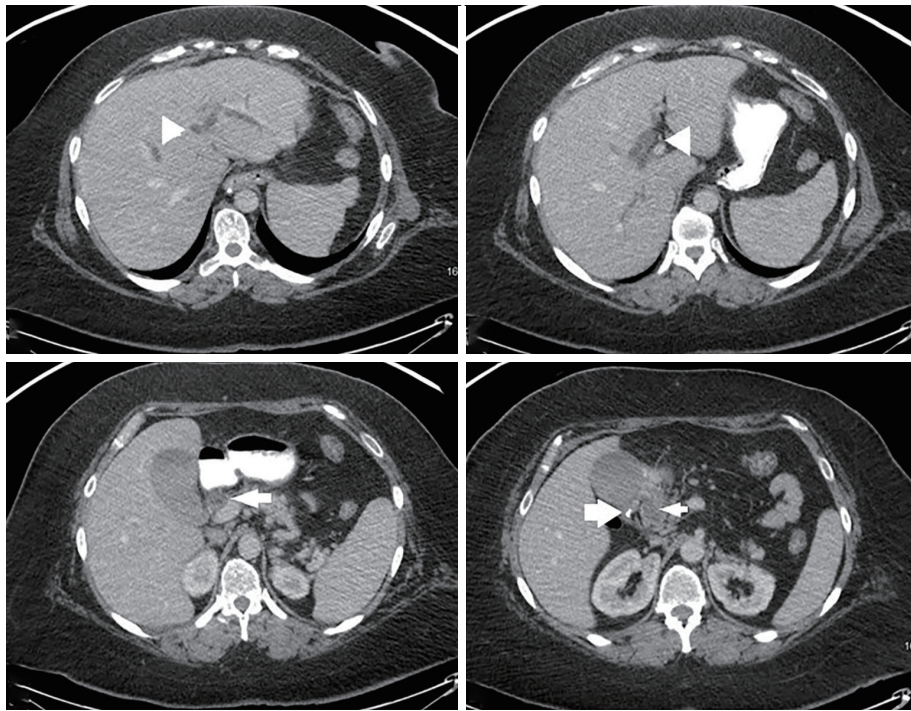
pancreatic papilla. Unfortunately, in this case, the pancreatic head was intimately adherent to the duodenal posterior wall with absence of the usual anatomic plane, making this step more difficult than usual and an iatrogenic perforation occurred on the distal part of the first duodenum (*Figure 1*). At this time, a second surgeon is called for help, the question being aborting the procedure, or continue the dissection. Due to logistic considerations, it was not possible to perform an intraoperative esophagogastroduodenoscopy (EGD) to locate precisely the perforation, and according to anatomical landmarks, it appears to be on the distal part of the first duodenum. The patient being stable, having no bleeding issues at this point, and the duodenum passage being almost completed, we finally achieved the retroduodenal passage and, transected it using a 60 mm stapler. After the transection, it was easier to repair the duodenal perforation using a running absorbable suture (3.0 V-LoC™, Minneapolis, USA) secured by a clip on the duodenal stump. Thereafter, a tension-free duodeno-ileal side-to-side anastomosis was created manually with negative intraoperative leak test, using 120 cc of methylene blue and a nasogastric tube. Due to this intraoperative incident, an intrabdominal drainage was left in contact with the anastomosis and patient was kept overnight (length of stay =24 h) for further surveillance.

The drain was removed at 7-day PO in outpatient department. Patient presented 20-day PO with jaundice associated with dark urine but no fever, nor pruritus. Physical examination was unremarkable. Further investigations confirmed the cholestasis (bilirubinemia: 114  $\mu\text{mol/L}$ ), associated with cytotoxicity [alanine aminotransferase (ALT): 236 U/L], without evidence of inflammation or pancreatic reaction. Further workup with abdominal and

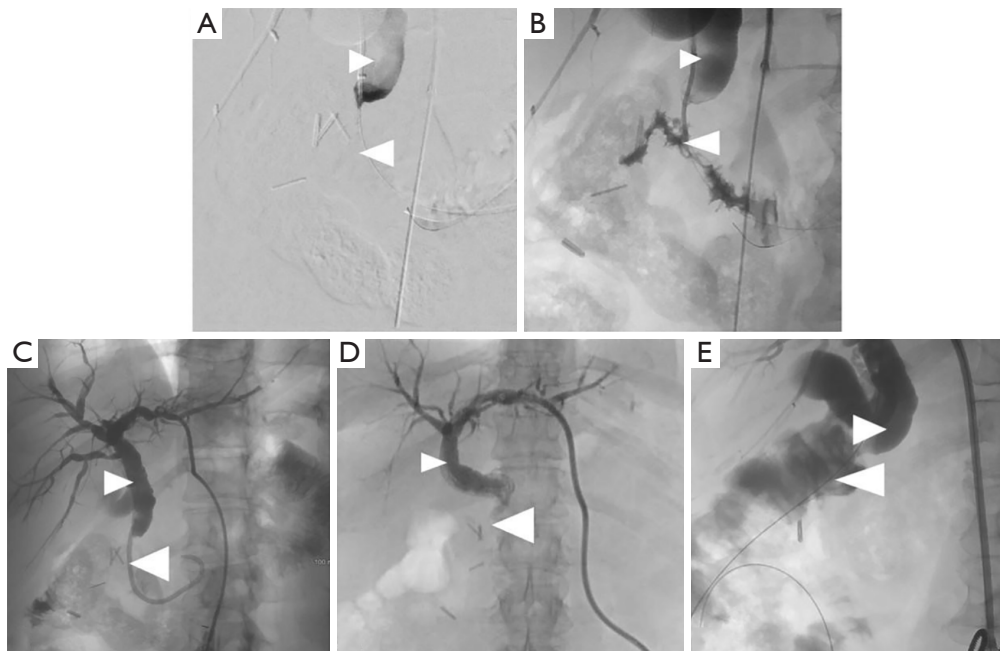
pelvic computed tomography (CT) scan revealed firstly an acalculous gallbladder but especially a dilatation of intra- and extra-hepatic biliary system, upstream of the pancreaticoduodenal junction with an area of artifact due to surgical clips which deprive proceeding with magnetic resonance imaging (*Figure 2*). The duodeno-ileostomy was otherwise unremarkable. After reviewing the CT scan with an expert radiologist and in view of overall findings and the challenges encountered during the surgery, we suspected that the jaundice was caused by an inflammatory stenosis secondary to an iatrogenic duodenal repair close to the distal part of the common bile duct up to the major duodenal papilla. Indeed, the absence of any other etiology, the apparition of the jaundice 20 days later, the intraoperative considerations, leading to an iatrogenic posterior perforation repaired, led us to conclude to an inflammatory reaction near the distal part of the common bile duct, causing an indirect stenosis of the one.

The patient was admitted and managed initially with an image guided insertion of percutaneous transhepatic internal-external drainage catheter (10 Fr), named percutaneous trans-hepatic biliary drainage (PTHBD) (*Figure 3*). In the following days, patient improved clinically and biochemically and was discharged with clamped catheter (length of stay: 8 days). The stenosis was gradually dilated over 4 months duration by successively upsizing drainage catheter reaching 14 Fr internal-external drain. Unfortunately, due to persistent residual stenosis of the pancreatic papilla on the cholangiography (*Figure 3*), the drain could not be removed. So, at 7 months PO, a technique using a 6 mm paclitaxel-coated balloon (dose density 3.5  $\mu\text{g}/\text{mm}^2$ ) was used to dilate the residual stenosis, followed by placing of 16 Fr internal-external drain (to add delay to improve an optimal response of the stenosis, and to prevent the need for bile duct access in case of failure).

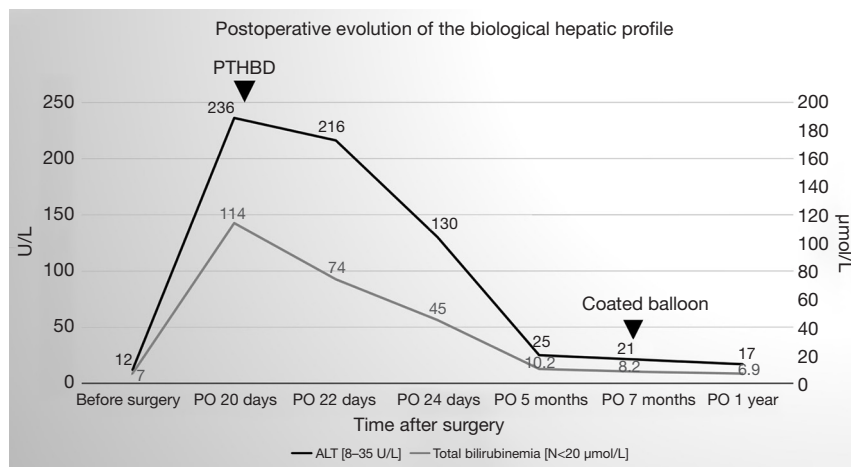
Fortunately, 2 months later, cholangiography depicts complete resolution of the stenosis, and the drain is finally removed (*Figure 3*). At 1 year PO, the BMI is 47  $\text{kg}/\text{m}^2$  (EWL =45%) and she did not develop neither long-term complications, nor recurrence or sequelae of this iatrogenic event [bilirubinemia =6.9  $\mu\text{mol/L}$  and ALT =17 U/L (*Figure 4*)]. Having opted for a minimally invasive strategy for the treatment of her iatrogenic stenosis, allowed the patient to maintain an appropriate socio-professional and family life, and helped her to have patience and compliance throughout of his treatment (no pain, no jaundice, a small drain kept under clothes). No further exploration is scheduled, apart from monitoring blood tests every 6 months for his bariatric



**Figure 2** Abdomino-pelvic CT at hepatic level in axial view (20-day PO). ▷, intra-hepatic bile duct dilatation; ◁, dilatation of the junction between right and left hepatic duct; ⇨, dilatation of the common biliary duct; ⇩, stenosis on the common biliary duct—artefact of surgical clip. CT, computed tomography; PO, postoperative.



**Figure 3** Cholangiography in frontal view. (A) Initial cholangiography 20-day PO showing the stenosis; (B) catheterism of duodenum stump 20-day PO; (C) internal-external drainage (10 Fr type cook) 20-day PO; (D) persistence of a residual stenosis at 5 months PO; (E) post-therapeutic cholangiography 9 months PO. ▷, common bile duct; ◁, duodenum. PO, postoperative.



**Figure 4** Postoperative evolution of the biological hepatic profile. PTHBD, percutaneous trans-hepatic biliary drainage (it was used to access the biliary system at PO 20 days); PO, postoperative; ALT, alanine aminotransferase.

surgery (including a hepatic profile). Since the removal of the final drainage, the follow-up is 9 months and the patient has no recurrence of jaundice nor cholestasis until this day.

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

## Discussion

We present a rare early iatrogenic injury of the common bile duct due to challenging intraoperative considerations after a second-stage SADI. Since 2016, almost 300 SADI procedures have been performed in our institution. According to this large experience, this was the first time we revised retrospectively a surgical-induced injury of the common bile duct at the morbi-mortality board of the bariatric and metabolic department. Here, it appears that the surgeon was trying to preserve the anatomical landmarks previously described above. This is the hinge point to avoid injuring the bile duct. As described above, the goal of this dissection is to free the retroduodenal passage at least 2 cm distal to the pylorus, but before the second duodenum (to give room for future revisional surgery if needed and limiting malabsorption of some micronutrients) (14). Obtaining this space requires navigating in an anatomical area provided

with elements not to be harmed (gastroduodenal artery, duodenum, pancreatic head, hepatic pedicle...). But this task was made difficult by the absence of a dissection space between the head of the pancreas and the posterior duodenal wall, and the severity of adhesions between these two elements (unpredictable situation, particularly intense in this case). This may have caused excessive tension on the grasper instrument, held in the left hand, lifting the duodenum for exposure (*Figure 1*), that led to shift dangerously to the beginning of the second duodenum. It is also necessary to consider the technical difficulty of performing laparoscopy on a patient with a BMI =55 kg/m<sup>2</sup>, and the parietal constraints applied to the instruments, even for trained team. It also appears that the position of the pancreatic papilla can variate (15,16). After an analysis of 1,000 cholangiograms, the pancreatic papilla is located in the second duodenum in 82% of cases, just downstream of the bulb and genu superius. In the remaining 18%, it is located further downstream. Clearly, the papilla can be closer than we think (15). On the same subject, another publication described a few cases (2%) of papilla located less than 3 cm from the pylorus, but these are autopsy series (16). Even if it had been possible to perform intraoperative EGD, this could have demonstrated the position of the pancreatic papilla, but the inflammation due to the repair could still have occurred later. Once the damage is done close to the papilla, the only way to keep a natural access to bile ducts is to abort the surgery and eventually come back later, or to switch to a bariatric approach without duodenal section, e.g., transit bipartition as an alternative.

As the duodenal transection no longer allows classic endoscopic access to the bile ducts, other approaches to access the biliary system are proposed (17): laparoscopy-assisted endoscopic retrograde cholangiopancreatography (LAERCP), balloon-assisted enteroscopy (BAE), Endoscopic ultrasound Directed transGastric ERCP (EDGE), laparoscopic common bile duct exploration (LCBDE), EUS-guided intra-hepatic puncture with antegrade clearance (EGHAC), PTHBD and rendez-vous guidewire-associated (RGA). Surgery like sphincterotomy or bilio-digestive diversion can also be considered (18).

We adopted the PTHBD approach which present high success rates (17) and is less invasive. It doesn't require an operating room, can be performed in a classic interventional radiology room, with local anaesthetic, as opposed to a general anaesthesia for other techniques. In addition, the risks of bleeding and infection are much lower than with endoscopic or surgical techniques, such as the risks of secondary pancreatitis (17,19). Moreover, during the therapeutic course, the patient was able to return actively to her professional and social life, with minimal pain, clamped drain under clothes and did not experience any incidents.

Unfortunately, after the classic dilatation, we faced the persistence of bile duct stenosis on the cholangiography. After reviewing the situation with the radiological team, it was acted that removing the drain would expose to a recurrence of the jaundice and it was suggested to try the use of the paclitaxel-coated balloon. Its use is described in vascular endoscopy to treat hemodialysis arteriovenous access where it seems to has benefits over plain balloon angioplasty in terms of target lesion patency and circuit patency up to 1 year to stenosis (20). It is also used in urology on male urethral stricture regardless of etiology where it appears to lower recurrence rate compared to no coated balloon use. These procedures seem to be effective to inhibit neointimal hyperplasia (21). Regarding biliary application, the coated balloon has also been successfully tested on biliary anastomosis stricture after liver transplantation which represent 8% to 20% of all liver transplantation complication (22). In a cohort of 13 strictures of common bile duct after liver transplantation, the success of the paclitaxel-coated balloon was achieved in 12 of 13 patients (92.3%) [after one dilation in nine patients (69%), after two dilations in one patient, and after three dilations in two patients] (22). So, this treatment seems to have already a low failure rate on patients with a low immunity status. Endoscopic treatment of an anastomotic stricture after liver transplantation usually requires many

procedures before healing. Paclitaxel-coated balloon helps to reduce the number of procedures needed to achieve treatment. In our case, we used the classic dilatation balloon as first-line treatment. It was only when this first strategy failed that paclitaxel-coated balloon was used. This prolonged the delay of management, but finally leads to complete resolution of the inflammatory stenosis of the distal part of common bile duct, in a less invasive manner and preserving the patient's autonomy. The fact that an antiangiogenic agent solved the stenosis comforted us in the initial hypothesis that the lesion was caused by an inflammatory reaction to the suture. Our interpretation is limited by the scarcity of this situation and we presented a way of dealing with this iatrogenic surgical-induced injury, without pretending to be the only solution. But also, it is limited by the short follow-up we have on the situation and the risk of recurrence that remains unknown.

## Conclusions

Retro-duodenal dissection during SADI-S, remains the most delicate stage of the procedure because of the proximity of its environmental vascular structures, but especially because of the intimate relationship with the pancreas and the common biliary duct that runs through it. As described, the suture of the duodenal perforation can lead to iatrogenic jaundice consecutive to a stenosis of the terminal portion of the common bile duct. As the access to bile ducts is challenging after SADI, we exposed an efficient mini-invasive management. Paclitaxel-coated balloon appeared to be an effective solution to injure intimal hyperplasia of the common biliary duct in this situation, in case of failure of classic balloon dilatations.

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## Footnote

*Reporting Checklist:* The authors have completed the CARE reporting checklist. Available at <https://amj.amegroups.com/article/view/10.21037/amj-23-90/rc>

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*Conflicts of Interest:* All authors have completed the ICMJE

uniform disclosure form (available at <https://amj.amegroups.com/article/view/10.21037/amj-23-90/coif>). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

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