

## Peer Review File

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### Review Comments

#### Reviewer A

Can the authors suggest the mechanism for which the patient suffered a stenosis. Can the authors explain "PO inflammatory stenosis".

Figure 1. Has no D reference. references are not clear.

For a surgeon experiences with SADI, the Figure 1 is strange as you do not move portion D2 of the duodenum and it seems that you dissected all the duodenum, starting even in D3, D2. (??)

#### Reply:

Dear Reviewer A,

First, I really appreciated your suggestions and in name of the team, I deeply thank you for your comments to enhance the redaction of this paper.

We detailed more as requested, the hypothesis that leads us to conclude to an iatrogenic stenosis of the distal part of the common bile duct (a). Considering the location, the repair of the intraoperative duodenal perforation and the time of apparition of clinical jaundice, we believe that an inflammatory reaction of the suture caused an indirect stenosis of the distal bile duct at the papilla.

We also improved the description of the legends and title of all the images presented (b).

Finally, we are an experienced team since we performed almost 300 SADI procedures in our institution since 2016. Adherences between pancreas and duodenum at that precise location can be more or less severe to dissect from a patient to another. As for the surgeon in charge of this case, it is unpredictable, there was really no reason in this particular patient that those adherences would be so intense to go through. By doing always the same technique (that we described much more in detailed after revision of the manuscript), we aim to avoid doing harm to the important anatomical structures in this area by respecting thoroughly the anatomical landmarks (c). I believe that you see on the figure 1 a dissection of the D2-D3, but it is not; the tension put with the left hand might have caused the serotomy below, really close from the D2 (d). A redundant posterior duodenal wall with such adhesions made the passage difficult and the loss of good anatomical landmarks. With all the humility that one must have in surgery, even in overtrained teams, technical difficulties causing surgical injuries can arise, and it seems important to us to describe the occurrence of these complications, which are difficult to manage because they are rare, to describe them, to prevent them, and to expose the effective treatments that can be made available.

#### Changes in the text:

\* **(a) pages 5-6, 1.140 -147** "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. "

#### \* **(b) page 11, and figures attached**

\* **(c) pages 5, 1.110-121** " The first step of this procedure was to locate the ileal loop, 300cm 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 (that is adherent to the posterior duodenal wall), the gastroduodenal artery (that is met right after the pylorus on the dissection path), and the hepatic pedicle (that is 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 2cm distal to the pylorus,

but before the second duodenum, avoiding a damage on the anatomical structures previously cited and preserving the 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).''

**\* (d) pages 6-7, 1.170-194** '' 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 2cm 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, but 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=55kg/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 1000 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 3cm 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. bipartitional transit as an alternative. ''

## Reviewer B

''I disagree with the title and the way the entire manuscript has been written. What the authors have actually had is an iatrogenic injury while doing a SADI. The way the title has been written and the manuscript has been written implies that obstructive jaundice is a complication from SADI as a procedure.

They suggest complex retroduodenal dissection due to pancreas adherent to duodenum caused the injury. What was the pathology that caused this adhesion!!

What was the training and experience of the surgeon performing this surgery and how many cases of SADI-S ad the surgeon done prior to this case.

The cause after imaging is suggested to be injury to the papilla of Vater and presumed " inflammatory". The papilla of vater is at the lower end of the longitudinal fold, on the posteromedial wall of the junction of the middle and lower thirds of the descending part of the duodenum. What was the surgeon doing there!! The dissection for Sadi is limited by the Gastroduodenal artery which is a few cms away from pylorus at Junction of D1 and D2. What was the surgeon doing near the ampula of Vater?

I feel that the injury has happened because of non-recognition of the anatomy of the pancreato-duodenal area and this highlights the need of properly trained surgeons with experience of operating in that anatomical area doing the surgery.

Although I feel the interventional radiologists did well in managing these complications, the tone and writing of this paper needs a major overhaul!

The authors seem to be blaming the complication as an acceptable complication SADI-S whereas it is not!!

The emphasis needs to be on why the complication happened, how could it have been prevented and the technique of how it was managed radiologically.

This paper needs to be rewritten extensively.

## Reply:

We are sorry that our manuscript has caused you so much inconvenience and questions. We revised the manuscript extensively, so to correct it for a better readability and we thank you for the opportunity it gives us to improve the manuscript. You will see below (in the section ''changes in the text'') that it has been revised extensively.

We have reworked the title and all appellations in the text because you are right this is an iatrogenic event on technical difficulties and not a complication of the procedure itself (a).

Our hypothesis of diagnostic was an inflammatory reaction (secondary to the suture performed for the perforation) that caused an obstruction of the distal part of the common bile duct, then a jaundice. The delay of apparition of jaundice, the absence of other cause (like lithiasis), and the location of the intraoperative incident led us to this hypothesis. The fact that, later, it was successfully treated with an antiangiogenic agent gave right to this hypothesis, retrospectively (b).

Furthermore, we are an experienced team since we performed almost 300 SADI-S procedures in our institution since 2016 (primary and revisional – publication under submission). The surgeon in charge did about a hundred procedure before this undesirable event happened. And I totally understand your surprise to hear about this, because it has not been previously described in the literature. It seems to us that exposing on a public platform a surgery-induced injury should be reported by high volume center and experienced team. And we addressed that in the discussion part (c).

For better comprehension, we explained more details on our technique for the dissection part, in the case description (d), and we also dedicated the whole first paragraph of the discussion to analyse retrospectively what happened wrong during the surgery, as we did at the morbi-mortality board of the department (e). The prevention of such an incident resides in the respect of good anatomical landmarks to avoid doing harm to the important anatomical structures in this area. As an experienced team, we noticed that adherences between pancreas and duodenum at that precise location can be more or less severe to dissect from a patient to another. Here, there was really no reason in this particular patient that those adherences would be so intense to go through. The tension put with the left hand might have caused the serotomy below, really close from the D2, that needed repair, but the transection has been performed closer from the pylorus thereafter. We aim to leave space between the anastomosis and the pylorus, but we might have been deported too much on the D2, by trying to make the passage. Adding to that, the BMI of this patient and eventually a variation of the location of the common distal part of the main bile duct and so the papilla of Vater... and we mentioned all that in the discussion too.

As requested, we highlighted the rationale of the radiological choices (f), and rewrite the manuscript extensively so as to emphasize that this situation is not desirable, and that the loss of good anatomical landmarks is the responsibility of the surgeon and not of the risk taken to benefit from this procedure.

With all the humility that one must have in surgery, even in overtrained teams, technical difficulties causing surgical injuries can arise, and it seems important to us to describe the occurrence of these complications, which are difficult to manage because they are rare, to describe them, to prevent them, and to expose the effective treatments that can be made available. We also aimed to write this manuscript not to blame the surgical gesture, but to highlight the decision that can be made intra-operatively and / or postoperatively, and consequently enhance what can be done when access to bile ducts is not so easy (g).

I really hope this revised version of this case report suits you better since it has been improved in detail and all the comments of the editorial board and other reviewers have been addressed.

### **Changes in the text:**

- (a) **Page 1, 1.1-2:** *“Outcomes after Paclitaxel-Coated Balloon after iatrogenic biliary injury following Single-Anastomosis Duodeno-Ileal bypass: a case report”*
- (b) **Pages 5-6, 1.140-147:** *“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. ''*

- (c) **Page 6, l.170-173:** *'' 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. ''*
- (d) **Page 5, l.111-128:** *'' The first step of this procedure was to locate the ileal loop, 300cm 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 (that is adherent to the posterior duodenal wall), the gastroduodenal artery (that is met right after the pylorus on the dissection path), and the hepatic pedicle (that is 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 2cm distal to the pylorus, but before the second duodenum, avoiding a damage on the anatomical structures previously cited and preserving the 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 Eso-Gastro-Duodenoscopy (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 60mm stapler. After the transection, it was easier to repair the duodenal perforation using a running absorbable suture (3.0V-Loc™) secured by a clip on the duodenal stump. ''*
- (e) **Page 6-7, l.169-194:** *'' Here, 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 2cm 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, but 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=55kg/m2, 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 1000 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 3cm 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. bipartitional transit as an alternative.’’*

- (f) **Page 6, l.153-157:** *‘‘ Unfortunately, due to persistent residual stenosis of the pancreatic papilla, the drain could not be weaned off. So, at 7 months PO, a technique using a 6mm paclitaxel coated-balloon (dose density 3,5µg/mm2) was used to dilate the residual stenosis, followed by placing of 16Fr internal-external drain (in order to add delay to improve an optimal response of the stenosis, and to prevent the need for bile duct access in case of failure).’’* **And page 7-8, l.202-232:** *‘‘ We adopted the PTHBD approach which present a high success rates (17) and is less invasive. It doesn't require an operating room, it 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 one 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. Theses procedures seems 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)(21). 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.’’*

(g) **Page 8, 1.234-241:** *''Retro-duodenal dissection during SADIs, 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.''*