Peer Review File

Article Information: https://dx.doi.org/10.21037/acr-23-171

Reviewer A

The authors present a case of acute pancreatitis caused by gastric balloon. A few of these cases were already published this year, for example:

1. doi: 10.7759/cureus.38094

2. doi: 10.7759/cureus.45230

Still, it is considered as a rare complication. It is hard to establish a pathogenesis of AP in this cases, however, the direct compression of the balloon on the pancreas and distension of the pancreatic duct caused by compression on the duodenal papilla are taken under consideration.

This case report is potentially interesting, but a few points are missing to consider it as suitable for publication. I would like the authors to answer the following questions:

Since the Spatz3 balloon can remain in the stomach for twelve months it has to be checked in specific periods of time in an outpatient clinic. According to the producer the first volume adjustment needs to take place after about 4 months. When did the patient had the volume adjustment? Is it possible that the adjustment led to onset of symptoms?

Reply 1: The balloon was inserted in Turkey. Body weight and clinical symptoms of the patient were self-monitored and reported regularly. On a 4-month follow-up, the balloon was well tolerated and the patient didn't experienced any weight loss plateau, so that there was no need for an endoscopic balloon adjustment. No control endoscopy was performed.

Changes in text: See Line 46-48.

Did the patient take any specific medications? Especially those for overweight and/or obesity? Did the patient take any PPI? Some of these drugs may lead to drug induced pancreatitis.

Reply 2: The patient took no medication, especially no anti-obesity drugs or PPI, no vitamins, supplements of micronutrients or homeopathic agents.

Changes in text: See Line 49.

How did you screen for autoimmunity? Did you check the IgG4 or made some genetic testing?

Reply 3: We measured only IgG4 level, no genetic testing was performed.

Changes in text: See Line: 54

When did you perform the ultrasound? You state that there were no stones, but what about the biliary sand, biliary sediment or thick bile? Did the CT examination (when was it performed) also supported the results of the ultrasound? What was the view of the pancreas in the CT examination? The weight loss itself can cause the formation of biliary sedimentation that may lead to AP. Did the patient during the 12 month follow-up had any other radiological examination?

Reply 4: The first ultrasound scan was performed on admission in the Emergency Department. Abdominal ultrasound is very sensitive in visualizing gall bladder stones and sludge. The gall bladder could be visualized very well, we haven't seen any stones or sediment in the lumen. CBD and intrahepatic bile duct were not dilated. Cholestatic laboratory parameters and transaminase levels were in normal range on admission and as well as at on follow-up laboratory testing. We think, that these result support a non-biliary aetiology of the pancreatitis.

In regard to the severe abdominal pain and tenderness, we performed an urgent abdominal CT to exclude gastric perforation or bowel obstruction. No CBD or intrahepatic bile duct dilation could be detected, supporting the ultrasound findings. The balloon could be seen slightly compressing the body of the pancreas without any pancreatic duct dilation, there were no inhomogeneity of the pancreatic parenchyma or pancreatic fluid collection visible. We repeated the abdominal ultrasound on the third day, which showed no abnormality of the pancreas or the peripancreatic region. We performed routine laboratory tests and ultrasound 6 weeks after discharge, they were also without any pathologic findings.

Changes in text: See Line 55-63 and Line 68-72

In few places there are spelling mistakes (like line 33 it should be "safe AND effective" instead of "safe an effective") – these types of errors can be found in couple of places throughout the manuscript. There are also grammatical errors, like line 71 "in recent years were significantly…", which has to be rephrased.

Reply: we corrected spelling and grammatical errors using a spelling software.

Reviewer B

I read with interest the case report that suggests intragastric balloon as a possible aetiology for acute pancreatitis based on circumstantial features as mentioned - absence of gallstone, no alcohol consumption, normal lipids and calcium, absence of ERCP or trauma and normal autoimmune screen. However, i have some comments and critics.

Was she on any medications that is known to cause pancreatitis

Reply 1: The patient took no medication, especially no anti-obesity drugs or PPI, no vitamins, supplements of micronutrients or homeopathic agents.

Changes in Text: See Line 49.

Mention and clarify which autoimmune markers were tested and were normal.

Reply 2: We measured only IgG4 level, no genetic testing was performed.

Changes in Text: See Line: 54

If there are 20 reports, you may want to consider making a table of 20 reports - summary. I mention "may consider" as this will lead to an increase in citation count and if our journal does not have limits, than this should be done. If the journal has limits on citation count than probably can be omitted but other relevant cases should be discussed in discussion section.

Reply 3: We made a table of 21 reports and added to the references as you suggested.

Changes in Text: Table 1 added.

You have to explicitly mention that this is mere association and not causation.

Reply 4: We mention in the discussion part, that we only suppose an association of the balloon insertion and the acute pancreatitis, as you suggested.

Changes in Text: See line 97-98

You have to mention that due to not doing MRCP for pancreas divisum, EUS for microlithiasis, genetic testing for pancreatitis - this report has limitations to determine the strength of association.

Reply 5: We completed our text with the suggested aspects regarding to limitations to determine the strength of association between gastric balloon insertion and pancreatitis. EUS was not performed to exclude microlithiasis of the CBD, however, at absence of gallbladder stones/sludge, normal CBD diameter and normal cholestatic parameters, a biliary cause is rather unlikely.

Changes in Text: See line 102-106

You should consider using the modified Naranjo score that is reported to be used in drug-induced pancreatitis (PMID: 32848081) and covid pancreatitis (PMID: 37155526) to demonstrate the strength of association and relate it to your report.

Reply 6: Naranjo score is classically applied to assess the association between drug intake and adverse events. We could unfortunately not find any literature about adapting it for a medical device. We think, in lack of a specific modification of the score system it is not an adequate method to assess the strength of association in our case.

You have to mention your patient had mild or moderately severe or severe.

Reply 7: The pantient had a mild panceatitis, we extended our text.

Changes in the text: See line 76-77.

What analgesia was given?

Reply 8: For analgesia were 2x20 mg morphine hydrochloride and 3x1 g metamizole administered intravenously in the first 24 hours. On the following days were paracetamol and metamizole given intravenously and oral.

Changes in the text: See line 70-72

is the BMI before balloon placement or after? if after than what was pre balloon BMI.

Reply 9: Before the balloon insertion, her BMI was 35,5 kg/m2 , she reached a total body weight reduction of 20 kg. Her BMI was 28,3 kg/m^2 on admission.

Changes in text: See line 51-52

How to prevent this issue?

Reply 10: Analysis of more reported cases is needed to identify potential risk factors (balloon type, size, shape, volume) to possibly prevent this complication. We suggest to measure lipase/amylase levels besides routine laboratory tests and perform adequate imaging in patients with intragastric balloon and relevant abdominal pain as not to misinterpret the symptoms as gastric distension or oesophagitis.

Changes in text: See line 108-112