Author's response to reviews

Title: Sequential algorithm analysis to facilitate selective biliary access for difficult biliary cannulation in ERCP: a prospective clinical study

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Author's response to reviews: see over
Dear Editor,

Thank you for meticulous review of our manuscript and valuable comments. We have made corrections and additional explanations for several comments. The enclosed is the point-by-point reply to the comments.

Editorial requirements:
- Could you please clarify further in your revised manuscript if the treatment protocol you are evaluating is currently standard care at your institute or if this is a new experimental treatment?
- If the treatment protocol is not currently standard care, we will need you to register your trial and include a Trial Registration Number in your revised manuscript.

Answer: Thank you for valuable comments. As you know, described cannulation methods are well-known method in previous numerous reports. Those are not new experimental technique. We just used these known techniques sequentially according to the algorithm to facilitate cannulation. So, at the initiation of this study, we did not register in Clinical Trial Registration. After completion of IRB in our institution, we performed this study. Also, this suggested protocol in our standard method in our institution. Thank you.

Reviewer’s report:

This is a nice prospective study about a sequential algorithm for biliary access in ERC. This study has several limitations, that were all appropriately discussed by the authors. To my opinion, there are only 2 minor remarks:

1. What is the reason to do in all patients CT/MRT instead of endoscopic ultrasound (EUS)?
   Answer: Thank you for valuable comment. As you mentioned, EUS was also performed in patients who refuse MRCP or when the MRCP was not available. Usually we took an abdominal CT with MRCP or EUS. So we added EUS on methods as follows; “All patients underwent abdominal ultrasonography, computed tomography, magnetic resonance cholangiopancreatography or endoscopic ultrasonography prior to ERCP.” Thank you.

2. In figure 1 the success rate of "double wire cannulation" is given. However, the success rate of the other techniques is not stated. This is not consistent.
   Answer: Thank you for valuable comment. As you mentioned, we revised the figure as follows. Thank you.
   Revised figure 1.
Reviewer's report:
The paper reports on a prospective case series of ERCPs using a sequential protocol in situations with difficult biliary cannulation (DBC). The authors describe an algorithm consisting of double guidewire cannulation followed by precut after placement of a pancreatic stent in patients with unintentional pancreatic duct cannulation and early precut fistulotomy in patients with DBC for other reasons. DBC criteria were relatively strict (e.g. cannulation time > 5min) compared to other studies. The procedure performed by a single experienced endoscopist lead to successful cannulation in 136/140 patients and was overall save. Although the study design did not compare different strategies, the case series describes a safe and feasible step by step algorithm for DBC. The patient numbers are sufficient, and the procedures and criteria are clearly described and seem to be well controlled. The study may help other endoscopists in choosing the right strategy in DBC situations and is in my opinion suitable for publication in BMC Gastroenterology.

Minor points:
1. Abbreviations are not always defined at the first appearance in the text (e.g. CBD page 4 or PD page 6)
   Answer: Thank you for valuable comments. As you recommend, we recheck the abbreviations and deleted “PD” and added an abbreviation for CBD in corrected position. Thank you.

2. Although the authors clearly state that complications were classified and graded according the consensus guidelines, it might be helpful for the reader if the criteria for mild, moderate and severe pancreatitis would be shortly described.
   Answer: Thank you for valuable comments. As you recommend, we described more explain about it as follows; “PEP was defined as follows; new or worsened abdominal pain with elevation of serum amylase at least three times above the upper normal limits for 24 hours after a procedure that requires at least 2-3 days (mild), 4-10 days (moderate), and more than 10 days (severe) of hospitalization. Hemorrhage was considered clinically significant only if there was clinical (not just endoscopic) evidence of bleeding, such as melena or hematemesis, with an associated decrease of at least 2 g per deciliter in the hemoglobin concentration, or the need for a blood transfusion. Perforation included retroperitoneal or bowel wall perforation documented by any radiographic images.”
   Thank you.

Finally we revised the manuscript according to the journal style.

Thank you.