Author’s response to reviews

Title: A Modified Technique of Single-Incision Laparoscopic Hepaticojejunostomy for Children with Choledochal Cysts

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Author's response to reviews:

Dear Editors,

We are resubmitting our work entitled “A Modified Technique of Single-Incision Laparoscopic Hepaticojejunostomy for Children with Choledochal Cysts” to your journal, with careful revisions having taken into account your valuable feedback and our professional judgement.

We very much appreciate the comments that you had obviously put in great effort to provide, and it definitely contributed to the improvements we diligently sought to achieve.

Please find below our point-by-point reply to the comments. All authors have approved the revision. We have gone through a thorough process of debating and addressing these comments, and hope that you’d find it satisfactory.

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Responses to Editor Comments:

- Thank you for considering BMC Surgery for your research. In accordance with the IDEAL Framework, we have identified your research as being 'Stage 2a: development'. We would encourage you to follow the guidelines of the IDEAL Framework to ensure that this is clear and that your reporting is accurate and transparent.
R: Thank you for the suggestion. It may appear that our modification is developmental and we acknowledge that we had previously failed to deliver a clear presentation of our technique, which in effect offers the surgeon a tool to achieve an enlarged and stabilized surgical field, and actually does not change the essence of laparoendoscopic single site surgery, which is widely used by general surgeons, hence not explorational either.

Rather, this technique allows the operator to gain more control of the surgical view without having to rely on a surgical assistant to hold still the trocars that render various functions. A surgical assistant on trocar duty, experienced or not, may render less than optimal surgical field due to fatigue (e.g., long surgical hours) or other human errors. The lifting sutures in our modified method, in a triangle fashion, can offer a stabilized operative space, with enlarged view, which is particularly relevant in paediatric surgery due to the small size of the patients and limited selection of surgical equipment for children.

Our technique won the Fujian Provincial Hospital Innovation Award in surgery in 2015, since when it has been adopted in all paediatric patients with CCs seen in our department.

- Development of a novel surgical approach involves the planned use of a procedure in and an initial small group of patients to support experience with its first use and often to refine or modify the precise technique. As such, we do recommend that protocols for prospective development studies are registered before patient recruitment begins, describing patient selection principles, operative methods, and outcomes to be measured. If this was not achieved, please can you confirm this in your manuscript for transparency purposes. You may wish to discuss this in the Declarations section under the 'Ethical approval' heading.

R: We apologize for not having been able to make clear that our technical modification is actually not a new surgical approach. Rather, it works like a tool for paediatric surgeons in an established surgical modality (laparoscopic total excision of CC) enabling the operators to have more control of his/her surgical field and achieve the same outcome more easily.

We strive to describe and present this technique to share with the surgical community, which was awarded the Hospital Innovation Award in our hospital, where double-digit cases of paediatric CCs are seen annually. The protocols of our technical studies were registered with our hospital and patients are followed up for long-term health outcomes.
- Technical modifications may be common during stage 2a: their nature and timing should be meticulously recorded to allow understanding of their possible effect on outcomes. Learning curves are also an important issue in this phase, and need to be discussed in the Methods and Results section, with further assessment in the Discussion section. Clear sequential outcome reporting of all cases should also be done, without omissions. Ethical considerations require that all reasonable precautions are taken to avoid harm to patients during the learning curve, including, when possible, mentoring. Agreement should exist about who is responsible for ensuring risk minimization between the surgeon, the institution, and their ethics committee. Please can you ensure that these points are discussed in your manuscript.

R: We understand your point very well. Again, our presented work is not developmental, nor is it explorative. Also, it does not involve alteration of an established surgical modality in the management of CC cases. It made no changes in the management of our patients, but works as an aid in the operation, allowing the operator to have a better and clearer surgical view, hence optimizing the surgical experience.

The learning curve related to this experience indeed pertains to the single-port laparoscopic component of the surgery, which needs to be researched and reported in another work. We have now addressed these points in Discussions.

- Reporting during this stage needs to include: clear selection criteria and proportion of eligible patients selected; a clear description of the procedure and each modification, with timing; and relevant outcomes, with recognized standard definitions of important categories, such as specific complications. Can you please also revise your Methods section to remove the numbering of the different steps/stages.

R: We do not selectively perform this operation. Since 2015, the single-incision laparoscopic total cyst excision method has been the standard of care for our pediatric CC patients (6 months of age and older) with no comorbidity. Infants less than 6 months of age are advised to schedule for a later operative time. Our technique does not change the nature of the standard single-site laparoscopic surgery, which is now an established surgical approach. Rather, our modified technique renders improvement of the surgical experience, with geometric positioning of sutures and arrangement of the operative field.

We have now revised the description of the procedures to make it clearer and easier to follow.
- In addition to rewriting your manuscript so that it is evident you have followed the IDEAL Framework recommendations, we also ask that you adhere to the STROBE reporting guidelines (visit the EQUATOR Network website for further details) to ensure your reporting is complete and transparent - please can a completed copy of the STROBE checklist be included as an additional file when submitting your revisions.

R: We think the recommendations are very helpful and the suggestion reasonable. We have made every effort in the revision to adhere to these guidelines as closely as possible, though our work is not developmental or explorational. And our goal is to describe our technique modification which improves the surgical experience and share with the general surgeons community, particularly relevant for pediatric surgeons. The cohort of our CC patients are followed up with a long-term study plan, which needs to be dealt with in another report, upon which the STROBE guidelines will be definitely useful.

- Also, can you please discuss whether the follow-up time of 6 months was sufficient to investigate the recurrence rate of any problems, or whether this is a limitation of the study. The limitations of the study, including why no control group was included, need to be better discussed in your manuscript.

R: Because our modified technique improves the surgical experience and offers a better surgical view, changes in operational time, stitching in the anastomosis and healing of tissues and scars are the main considerations, rather than recurrence of complications, which should be comparable to standard approach as we do not essentially change the surgical method. Hence 6-month of followup time is sufficient to observe any abnormality in healing as scars tend to stabilize in 3-6 months. And this can be reflected with length of hospital stay, time needed to resume normal activity, postoperative pain, etc. However, our report is not aimed to reflect longer term complication rate, and that has to be attended to in another work.

As we deem it superior to a simple laparoscopic single-incision surgery for children and have started using this method as standard approach for all pediatric patients in 2015, no controlled comparison is possible within our patient population. We have revised the discussions to include such limitations.

- In your manuscript (Discussions and/or Conclusions section) can you please state what the next stages of assessment are. Will you progress to Stage 2b and Stage 3 of the IDEAL framework? Test on a larger cohort, in other institutions, include control groups etc.
R: The current work preludes a 10-year cohort project of our paediatric patient population with CCs. The long-term goal of the cohort would be to follow up on the general health indicators of the pediatric patients particularly in regard of conditions of hepatic and biliary tract and relations with future malignant development. As CCs are commonly seen in our population, such follow-up can offer insight as to its etiology and epidemiology and point of comparison with other populations.

- In the Abstract, can you please provide a sentence that puts your research study into context. You have listed the objectives in the 'Background' section of the Abstract, but why is this important/relevant to the field and to the reader?

R: Good point. We acknowledge that we were not able to effectively communicate the relevance of this technique in the first submission. This technical modification does not change the single site laparoendoscopic surgical methods per say, rather, it offers a tool for the surgeon to stabilize the surgical view and space, which is very important in pediatric patients due to their small size and limited choice of surgical equipment specifically designed for children.

- Since you have modified an existing technique, ethical approval should have been sought. You have confirmed in your manuscript that ethical approval was not required. Therefore, can you please clarify why your study was exempt listing institutional/country level legislation. Also, consent forms should have been collected from each other since a new technique was being tested. Please can you confirm whether written informed consent was obtained from each patient?

R: That was a miscommunication. Ethical approval was obtained for the cohort study which our study is housed under, when our surgical technique was awarded the Hospital Innovation Award in 2015. This report to describe the technical modification was exempt from needing separate approval. This is now corrected in the manuscript. Informed consent was obtained from all patients receiving this procedure.

- Please can you include a Figure Legends section. This should appear in the main manuscript document and should not be attached to the image source files.

R: Done. Please see the Figure Legends in the main manuscript.
- Please can you upload the images separately as figure files. Please do not include any written text, including the figure number, title or legend to these uploaded images. We just require the original source file for formatting purposes.

R: Done. We also removed two images to make the procedures easier to follow.

We thank you again for your kind consideration and look forward to your timely decision.

Best regards,

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