

3D Laparoscopic common bile duct exploration with primary repair by absorbable barbed suture is safe and feasible

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Review timeline:

Received: 14 March, 2021

Editorial decision: 17 April, 2021

Revision received: 17 May, 2021

Editorial decision: 19 May, 2021

Published online: 16 July, 2021

1st Editorial decision

17-Apr-2021

Ref.: Ms. No. JCTRes-D-21-00050

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Journal of Clinical and Translational Research

Dear author(s),

Reviewers have submitted their critical appraisal of your paper. The reviewers' comments are appended below. Based on their comments and evaluation by the editorial board, your work was **FOUND SUITABLE FOR PUBLICATION AFTER MINOR REVISION**.

If you decide to revise the work, please itemize the reviewers' comments and provide a point-by-point response to every comment. An exemplary rebuttal letter can be found on at <http://www.jctres.com/en/author-guidelines/> under "Manuscript preparation." Also, please use the track changes function in the original document so that the reviewers can easily verify your responses.

Your revision is due by May 17, 2021.

To submit a revision, go to <https://www.editorialmanager.com/jctres/> and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #1:

Introduction, 10 to 15 % of patients with gallstones have CBD stones. Is this really true, or is it 10 to 15% of patients with gallstone disease.

The introduction is quite long, but does summarise the clinical landscape. please try to shorten the introduction and perhaps move some parts to the discussion. Especially the expert opinion parts.

Methods, the procedure is adequately described. enough details.

Results, Age does not need a decimal. truncate age to whole numbers.

Round percentages to whole numbers, 0.1 percent of 27 patients is not relevant.

discussion, the section on general 2d versus 3d comparison is too long. I think the message of the manuscript is more to CBD stone management and less 3D laparoscopy. can the authors shorten the 3D laparoscopy section and further discuss their results against 2D results in literature

What is known on 3D laparoscopy for CBD stones_ How do these results compare_

What experience to the surgeons at the authors centers have, what is the case volume, what is the setting, what type of hospital, how many biliary procedures.

How would the authors suggest to other centers to initiate this technique_

what place should 3d laparoscopic exploration have in clinical practice, is ERCP always step 1, or do the authors suggest otherwise

Authors' response

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Dear Mr Michal Heger,

Thank you for giving us an opportunity to resubmit a revised version of our manuscript entitled “3D Laparoscopic common bile duct exploration with primary repair with barbed suture is safe and feasible.”

We have addressed the comments of reviewers, and edits are included in red font. We are grateful for the time and the useful comments of the reviewers, which has helped us to improve the manuscript.

On behalf of the all the authors,

Regards,

Tan Yen Pin

Comment 1: Introduction: 10 to 15 % of patients with gallstones have CBD stones. Is this really true, or is it 10 to 15% of patients with gallstone disease.

Response1: This is an important issue. We agree with reviewer that a distinction made between patients with asymptomatic gallstones and symptomatic gallstone disease. Overall, there is substantial literature to cite that 10-15% of patients with gallstones have common bile duct (CBD) stones. Transter et al demonstrated a 14.2% incidence of choledocholithiasis in 1000 consecutive laparoscopic cholecystectomies with routine intraoperative cholangiogram (ref 1 in manuscript). Patients presenting with cholecystitis, biliary colic, pancreatitis, and jaundice were found to have common duct stones 7%, 16%, 20%, and 45% of the time, respectively. In

essence though there is minimal distinction in available reports if the patients are asymptomatic or symptomatic; by and large published reports relate symptomatic gallstones. On the other hand, asymptomatic patients are also at risk of having biliary events (and symptoms) over time. We have previously reported that 15% patients with gallstones develop CBD stones (doi: 10.9738/INTSURG-D-13-00168.1. PMID: PMC4337440). To eliminate confusion and to align to reviewer views, which we largely agree with, we have changed the statement as - **Up to 10-15% of patients with gallstone disease have common bile duct stones (CBDS).**

Comment 2: The introduction is quite long, but does summarise the clinical landscape. please try to shorten the introduction and perhaps move some parts to the discussion. Especially the expert opinion parts.

Response 2: We are grateful for the comment. We have shortened the introduction as well as taken out parts which include the expert opinion.

For the first paragraph of introduction section, this sentence was removed :

Tantau M et al. have reported 98% cannulation success and 2.3% stone extraction failure in 2986 ERCPs over a decade (8).

The 1st paragraph of introduction has been modified and shortened, now reads :

LCBDE is not widely adopted due to the technical difficulty of intracorporeal suturing, training, and the need for special equipment (e.g., flexible choledochoscope). Koc B et al. reported a randomized control trial of 120 patients comparing single-stage LCBDE and two-stage ERCP-LC and reported comparable outcomes (8).

For the 2nd paragraph of introduction, this sentence was removed :

Li ZQ et al. has recently reported a meta-analysis of 11 randomized studies including 1338 patients comparing single-stage LCBDE with two-stage ERCP-LC and reported no significant difference regarding total operating time, CBDS clearance, retained stones, conversion to other procedures, length of hospital stays, postoperative morbidity, and mortality (11). We caution to generalize these results due to the heterogeneity of patient demography, clinical profile, local resources, and technical expertise.

The paragraph was shortened and modified, now reads :

The majority of published reports of LCBDE are with routine two-dimensional (2D) laparoscopy. Two-dimensional (2D) laparoscopy's significant limitations include the lack of depth perception and spatial orientation loss with potential increasing surgical strain, risk of errors, and operative time (10). 3D laparoscopy enhances depth perception, facilitates

intracorporeal suturing, and is increasingly reported to reduce laparoscopic surgery's learning curve (11). The adoption of LCBDE may be easier with the availability of 3D camera systems.

Comment 3: Methods, the procedure is adequately described. enough details.

Response 3: Thanks for the kind comments.

Comment 4: Results, Age does not need a decibal. Truncate age to whole numbers. Round percentages to whole numbers, 0.1 percent of 27 patients is not relevant.

Response 4: We have corrected both points as per suggestion. In addition, we have made minor edits in Table 1 and Table 2 also to align reporting format.

Comment 5: Discussion, the section on general 2d versus 3d comparison is too long. I think the message of the manuscript is more to CBD stone management and less 3D laparoscopy. Can the authors shorten the 3D laparoscopy section and further discuss their results against 2D results in literature?

Response 5: Thanks for the suggestion. We have shortened the part on general 2d versus 3d comparison accordingly.

The following sections were removed:

Prior reports on 3D imaging technology were restricted to animal experiments or the feasibility of 3D laparoscopic surgery. McDougall EM et al. evaluated 22 urologic and gynecologic surgeons during a live porcine laboratory workshop to compare 2D with a 3D laparoscopic camera system in 1996 (27). He reported that 3D video did not improve surgeons' ability to dissect the kidney, securing the renal vessels, laparoscopic suturing, or knot tying. Innovations in imaging technology have improved, enabling improved depth perception, which is perceived as necessary for precision and safety. In a study including 21 clinical trials comparing 2D with 3D laparoscopy and reporting on various surgical procedures, Cheng J et al. concluded that 3D laparoscopy reduced surgical time, blood loss, perioperative complications, and hospital stay (28)

These results are similar to other published reports on the benefits of 3D laparoscopy in reducing operating time and shortening the learning curve. In a Bariatric surgery program, Padin EM et al. compared 104 patients managed with 3D laparoscopy, and 208 patients managed with 2D laparoscopy (30). 3D laparoscopy reduced operating time and hospital stay. This effect was independent of the type of procedure or experience of the surgeon. Further, they

have shown that complications were reduced in the 3D cohort, where novice surgeons performed surgeries. In a small randomized study including 15 first-year surgical postgraduate residents, Dawidek MT et al. showed that incorporating 3D visualization before training under standard 2D conditions significantly reduced the total training time to proficiency by 32.4% for peg-transfer task (31).

The robotic surgical community also propagates the benefits of 3D visualization, and hence it could be argued that 3D laparoscopy would be more value for money due to the high cost of robotics. In our hospital, the patient pays an extra of 3.5 USD for using the 3D laparoscopy compared to the additional 3500-5000 USD (estimated) expense for a robotic procedure. 3D technology cannot replace robotic surgery as a robot provides additional advantages of tremor elimination and multi-dimensional maneuverability. Recently, 4K ultra high definition technology has emerged, and it was reported in clinical surgery (33). We do not have experience using a 4K system in an operating theatre. In our experience, for the LCBDE procedure, 3D laparoscopy bridges the gap between 2D imaging and robotic surgery.

Comment 6: What is known on 3D laparoscopy for CBD stones. How do these results compare?

Response 6: There is not enough data on utility of 3D laparoscopy for CBD exploration surgery. There is only one study published regarding 3D Laparoscopy for CBD stones (reference 24). We have compared our results with that study and the following is included in discussion section:

The benefit of an LCBDE with a 3D system is further proven by a recently published study by B Xiaobo comparing 2D vs. 3D LCBDE. In this study, 3D LCBDE was found to have significantly shorter operative time, less blood loss, and less open conversion than the 2D group after propensity score matching. Despite our small series on 3D LCBDE, we noted a similar outcome in terms of hospital length of stay, operative duration, intraoperative blood loss, and postoperative complications compared to the study by B Xiaobo on 3D LCBDE. Of note, we have no open conversion as compared to an 8.5% conversion rate (18/213) in this study (24). This could be due to the small sample size of our study.

Comment 7: What experience to the surgeons at the authors centers have, what is the case volume, what is the setting, what type of hospital, how many biliary procedures.

Response 7: Thanks for the suggestion. We have added the following in the first paragraph of method section.

In our tertiary centre, we performed an average of about 50 cases of major biliary procedures and 20-30 cases of LCBDE per year. 3D laparoscopy was introduced in 2017, and the patient

pays an extra 3.5 USD equivalent for using the 3D laparoscopy.

Comment 8: How would the authors suggest to other centers to initiate this technique

Response 8: Thanks for the suggestion. This is very important. We have included an added paragraph on this as below in the discussion section.

To initiate and adopt one stage LCBDE with primary CBD repair, we recommend selecting patients with CBD \geq 1cm and smaller, non-impacted stones. We recommend utilising 3D laparoscopy to provide better depth perception for facilitating intracorporeal suturing and reducing the learning curve. Barbed sutures are user-friendly and safe in our experience. We also recommend the careful use of a flexible choledochoscope to avoid equipment wear and tear.

Comment 9: What place should 3d laparoscopic exploration have in clinical practice, is ERCP always step 1, or do the authors suggest otherwise

Response 9: This is very important comment. We believe that management of individual patient should be determined by local resources, available technical expertise, and patient choices. ERCP is mandatory in septic patients where biliary decompression is critical to ensure clinical stability prior to definitive stone clearance. Thus, ERCP has its own role in management of CBD stones. In patients who are not hemodynamically unstable, who respond well to resuscitation, and where technical expertise for single stage LCBDE is available, in those select situations, a patient should be offered an option of LCBDE as equivalent to two-stage modality of ERCP followed by laparoscopic cholecystectomy. We have also included this view in discussion as – “Further, it is essential to promote one-stage LCBDE as an equivalent treatment option to the two-stage ERCP-LC process which is the current universal 'default', as one stage LCBDE is proven to be safe with comparable.”

2nd Editorial decision
19-May-2021

Ref.: Ms. No. JCTRes-D-21-00050R1
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Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: