

ANSWERING REVIEWERS



December 20, 2013

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: topic highlight single session minimally invasive management of common bile duct stones.docx).

Title: Single-session minimally invasive management of common bile duct stones

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Name of Journal: *World Journal of Gastroenterology*

ESPS Manuscript NO: 7194

The manuscript has been improved according to the suggestions of reviewers:

1 Format has been updated

2 Revision has been made according to the suggestions of the reviewer

(1) Reviewer 1 comments and response

Major:

English language in the text must be reviewed and corrected.

Revised and corrected

The general structure of the manuscript should be revised in order to better understanding

Made

In the manuscript there should be a special mention for those patients presenting with acute biliary pancreatitis that are not feasible for a single session treatment (for example patients).

Added at the end of conclusion

We have noticed that several references are not properly outlined (see minor changes for more details). We miss some recent articles that specifically covered this topic, whereas there are some old-fashioned papers included in the review.

References were corrected

A list of abbreviations must be included in the manuscript.

Included in the text. Many abbreviations were deleted and others were explained in the text when mentioned in the first time.

One of the main conclusions of the review is that management in a single session is just as effective and safe, with shorter hospital day. I do not agree that there is evidence enough to claim that this option is also cheaper.

We did not claim that one option is better than the other but we rather described the advantages and disadvantages of different management options for management of CBD stones supported with available evidence. However, there is enough recent evidence that single session option may be adventitious to patients when resources and expertise do exist.

Minor:

ABSTRACT:

- Line 1: The incidence of choledocholithiasis in patients with symptomatic cholelithiasis is

5-10% rather than 18%.

The actual incidence varies among different papers. We chose some of them and mentioned what they reported.

- Line 3: It is mentioned that there is no consensus on the management of choledocholithiasis, but in fact there are some guidelines (i.e. ASGE 2010 Guideline: The role of endoscopy in the evaluation of suspected choledocholithiasis GASTROINTESTINAL ENDOSCOPY Volume 71, no. 1: 2010), where it is established that the recommended approach is. ERCP + laparoscopic cholecystectomy, with laparoscopic exploration as an alternative.

I agree but this is a fairly old guideline. More recent metaanalysis and reviews still find the ideal option controversial.

INTRODUCTION:

- First paragraph: Data referred to Collins C et al is inaccurate: those authors detected intraoperative choledocholithiasis in 46 patients, 26% was a false positive, 26% spontaneously expelled it and 48% choledocholithiasis persisted. In that study the incidence of choledocholithiasis was 4.8% (not 10-18%).

For documenting the incidence of CBD stones I didn't use Collins et al as a references but I used references Williams et al and Soltan et al. Collins et al was used as a reference to the natural history of CBD stones. I think data are accurate because among the 46 patients CBD stones were actually detected in 74% of patients and spontaneous passage occurred in one third of them.

- Last paragraph: The same classification used should be kept in similar fashion for the titles used for the review.

Corrected

Two sesión minimally invasive management: CPRE BEFORE LAPAROSCOPIC SURGERY

- First paragraph, point 1:

In your presentation of arguments against performing ERCP + laparoscopic cholecystectomy systematically, the references are not really supportive of this view (reference 11, Erickson RA, concludes that laparoscopic cholecystectomy is better than the open surgery . Also if there is high clinical suspect of choledocholithiasis you should make pre-operative ERCP and if the choledocolithiasis is diagnosed during the colecistectomy, it should make ERCP afterwards. Other study (reference 13, Coppola R et al. , concluded that it would be safe and effective, systematic ERCP before laparoscopic cholecistectomy, (saving the intraoperative cholangiography)

I used references 11 and 13 to support that there is a high risk of false negative results exposing the patients to unnecessary ERCP with its potential complications and the two references report this.

I did not say that open surgery is better than laparoscopic surgery.

I said in my presentation that preoperative ERCP followed by LC is a valid option and still the most widely adopted management strategy but it has drawbacks. The two references did not compare LCBDE to preoperative ERCP to know the best option.

- First paragraph, point 2:

“During LC, 4-24% of patients who had preoperative endoscopic clearance of CBD still had CBD stones[17,18]. “. I don't understand quite well this figures (4-24%). Apparently, study from Pierce RA(reference 17) refers to the incidence of choledocolithiasis during intraoperative cholangiography in patients who underwent ERCP without evidence of choledocolithiasis. False negative rate of ERCP was 8.3 %. Only in 11% of the patients who had

choledocholithiasis in prior ERCP, there were signs of remaining stones during intraoperative cholangiography.

Corrected

- First paragraph, point 3:

The evidence presented does not strongly support that pre-operative ERCP increases the perioperative risks (reference 19 Ishizaki Y et al). The reference 22, (Hasukic et al) concerning lung function in laparoscopic vs open cholecystectomy does not seem pertinent.

Ishizaki et al conducted a study to identify the factors that predict conversion of LC open surgery. The study was done on 1339 elective cholecystectomies between 1993 and 2004. Their conclusion was as follows ' The conversion rate increased over the 12-year interval of the study. A history of preoperative endoscopic sphincterotomy and a thickened gallbladder wall contributed to the likelihood of conversion'. I think this strongly supports our view.

Reference 22 removed

- Point 5: What is the meaning of PES? Please, clarification is needed.

DONE

Single session minimally invasive options:

1- LCBDE:

Paragraph 1:

Line 4: This is a safe and effective alternative, but the rates do not match the figures of the following studies: Reference 32, Rojas-Ortega S, 94% success, morbidity 8.8% and mortality 0%;. Reference 33, Thompson M, success 94-98% (according to the approach path), morbidity 19%, mortality 0%.

In both studies the rate of conversion to open surgery was 6%.

Corrected

Line 8;

Could the author give any evidence for the consideration of malignancy and new lithiasis formation as adverse effects of ERCP, rather than part of the natural history of bile duct stones?

Added

Paragraph 3:

There is a mention to some unpublished data regarding the use of LCBDE (better results of direct choledoscopy vs. fluoroscopy). It would be interesting to provide detailed data regarding different outcomes when compared with ERCP (in a single or two sessions).

In the unpublished data we did not compare LCBDE to LC/ERCP

Paragraph 4:

It would be interesting to know that percentage of patients who require the placement of a T tube. The use of stents could be just as effective as the T tube with less complications, but your references are 2 old-fashion articles (1987, 1990) with no consideration of this possibility.

I did not find recent articles discussing the use of stents for biliary decompression after CBD exploration

2. INTRAOPERATIVE ERCP:

Table 1: I do not understand the meaning of point number 5. Could you explain it more in detail for easy understanding?

Explained

Two session vs. single-session management

paragraph 3: not specified: operative time was higher in the Group 1

specified

(2) Reviewer 2 comments and response

This is an extensive review on the topic. The data are presented thoroughly by the author. In the paragraph above the section of intraoperative ERCP, I presume that instead of "than the T-tube group" it should be "than the primary closure group". In the second paragraph of the intraoperative ERCP section instead of standard sphincterotomy it should be standard sphincterotome. In the Two-session vs. single-session management section, in the phrase starting with "the mean operating time" number 1 in group is missing.

All changes were made and corrected

(3) Reviewer three comments and response

I have no major comments about it, but only some minor remarks, as follows.

1. I would encourage to limit as possible the acronym use, but when necessary always give the extended definition at the first time. page 4 bottom line: PES ? page 8: ...the patients in the T-tube drainage group return to work.....than the T-tube group. I suppose you means "than NO T-tube group" page 8: IOES ? page 9: IOC ? page 11: GS ?
2. page 11: the success rates of LCBDE and ERCP for clearance were similar..... the mean operative..longer in group (which group?)
3. page 12: Two sessions (LC + ERCP/EST) what means EST?
4. page 13 : ElGeidie et al We compared (we is redundant)

All changes were made and corrected

3 References and typesetting were corrected

Thank you again for publishing our manuscript in the *World Journal of Gastroenterology*.

Sincerely yours,

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