



Dear reviewers

Thank you for your interest in evaluating our work, we agreed to the comments and made the proposed changes:

### PEER-REVIEW REPORT

**Name of journal:** World Journal of Gastrointestinal Endoscopy

**Manuscript NO:** 37202

**Title:** Comparison between endoscopic sphincterotomy versus endoscopic sphincterotomy associated with balloon dilation for removal of bile duct stones: a systematic review and meta-analysis based on randomized controlled trials.

**Reviewer's code:** 00722601

**Reviewer's country:** Spain

**Science editor:** Li-Jun Cui

**Date sent for review:** 2017-11-21

**Date reviewed:** 2017-11-21

**Review time:** 13 Hours

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> No	<input checked="" type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

### COMMENTS TO AUTHORS

Dear authors, take into account these recommendations: Abstract: -methods: please make it shorter. -results: don't add discussions, only results -Conclusion: write more clear. Introduction: paragraph 3: remove "to the best of our knowledge. Remove "1230



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patients", this is a result. Last paragraph is about discussion, remove from introduction. Outcomes: dont repeat data table/text. Discussion: start this point with the response to your principal objective. A lot of results are repeated. There is a poor discussion about the utility of results in clinical practice, and about recommendations of previous reviews. Put the limitations near the end of the discussion.

Abstract: -methods: we rewrote in order to make it shorter. -results: we withdraw discussions of that part. Conclusion: we rewrote in order to make it more clear.

Introduction: paragraph 3: we removed "to the best of our knowledge. We removed "1230 patients". We removed the last paragraph from introduction.

Outcomes: we withdraw repeated data table/text.

Discussion: we rewrote in order to start this point with the response to our principal objective. We rewrote this part extensively in order to enrich the discussion about the utility of results in clinical practice and to include the findings and recommendations from the previous reviews. Finally, we put the limitations near the end of the discussion.



## PEER-REVIEW REPORT

**Name of journal:** World Journal of Gastrointestinal Endoscopy

**Manuscript NO:** 37202

**Title:** Comparison between endoscopic sphincterotomy versus endoscopic sphincterotomy associated with balloon dilation for removal of bile duct stones: a systematic review and meta-analysis based on randomized controlled trials.

**Reviewer's code:** 03026750

**Reviewer's country:** Egypt

**Science editor:** Li-Jun Cui

**Date sent for review:** 2017-11-21

**Date reviewed:** 2017-11-25

**Review time:** 4 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> No	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		BPG Search:	<input type="checkbox"/> Major revision
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

### COMMENTS TO AUTHORS

Well written manuscript. However, i have some comments: 1. The last 2 paragraphs in the introduction seems inappropriate here. i think better to be in methods. 2. For the discussion, you did not talk about the previous recommendations of this review articles and finally to summarize your recommendations after the meta analysis. 3. Limitations of the study should be at the end of the discussion.

1. We take out the last 2 paragraphs of the introduction.



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2. We have included the findings and recommendations from the previous reviews and summarized our recommendations after the meta-analysis.
3. We reallocate the limitations to the end of the discussion.



**PEER-REVIEW REPORT**

**Name of journal:** World Journal of Gastrointestinal Endoscopy

**Manuscript NO:** 37202

**Title:** Comparison between endoscopic sphincterotomy versus endoscopic sphincterotomy associated with balloon dilation for removal of bile duct stones: a systematic review and meta-analysis based on randomized controlled trials.

**Reviewer's code:** 00504581

**Reviewer's country:** Spain

**Science editor:** Li-Jun Cui

**Date sent for review:** 2017-11-21

**Date reviewed:** 2017-12-01

**Review time:** 10 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> [ Y] Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> [ Y] Grade B: Minor language polishing	<input type="checkbox"/> [ ] The same title	<input type="checkbox"/> [ ] High priority for publication
<input type="checkbox"/> [ Y] Grade C: Good	<input type="checkbox"/> [ ] Grade C: A great deal of language polishing	<input type="checkbox"/> [ ] Duplicate publication	<input type="checkbox"/> [ ] Rejection
<input type="checkbox"/> [ ] Grade D: Fair	<input type="checkbox"/> [ ] Grade D: Rejected	<input type="checkbox"/> [ ] No	<input type="checkbox"/> [ ] Minor revision
<input type="checkbox"/> [ ] Grade E: Poor		BPG Search:	<input type="checkbox"/> [ ] Major revision
		<input type="checkbox"/> [ ] The same title	
		<input type="checkbox"/> [ ] Duplicate publication	
		<input type="checkbox"/> [ ] Plagiarism	
		<input type="checkbox"/> [ ] No	

**COMMENTS TO AUTHORS**

it is a very interesting and well done study, with a very large number of patients included, only except the number of patients with choledocolithiasis greater than 15 mm and the heterogeneity of this group . Despite of the fact of the non great number of patients with choledocolithiasis larger than 15 mm.However , this result allows the reader to get the idea that perhaps the final results were not going to change a lot if the studies would have included a greater N of patients it is surprising the small number of perforations found on the randomized studies included

Thanks for your comment.



## PEER-REVIEW REPORT

**Name of journal:** World Journal of Gastrointestinal Endoscopy

**Manuscript NO:** 37202

**Title:** Comparison between endoscopic sphincterotomy versus endoscopic sphincterotomy associated with balloon dilation for removal of bile duct stones: a systematic review and meta-analysis based on randomized controlled trials.

**Reviewer's code:** 01800530

**Reviewer's country:** India

**Science editor:** Li-Jun Cui

**Date sent for review:** 2017-11-21

**Date reviewed:** 2017-12-04

**Review time:** 13 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
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		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

### COMMENTS TO AUTHORS

In this manuscript entitled as "Comparison between endoscopic sphincterotomy versus endoscopic sphincterotomy associated with balloon dilation for removal of bile duct stones: a systematic review and meta-analysis based on randomized controlled trials", the authors analyzed the outcomes of endoscopic sphincterotomy (ES) vs endoscopic sphincterotomy and balloon dilatation combined (ESBD) in nine randomized studies. The manuscript addresses an important question and is relevant to the readers. I have the following comments to make: Major points 1. What is new in this systematic review and meta-analysis? A recent review compares all the three techniques i.e. ES vs ESBD vs EPBD. (Park CH et al. Comparative efficacy of various endoscopic techniques for the treatment of common bile duct stones: a network meta-analysis. *Gastrointest*



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Endosc. 2017 Jul . pii: S0016-5107(17)32161-2. doi: 10.1016/j.gie.2017.07.038). The only difference is exclusion of two studies in abstract form in this recently published meta-analysis. 2. In the flow chart, the authors mention full text articles assessed for 34 articles. However, full text is not available for few of them (see below). Abstract 1. In the methods, the authors mention that “all relevant articles were accessed in full text”. However, two studies included in the meta-analysis do not appear to have full text and are probably available in abstract form only (Hong GY, Park SW, Seo KS, Moon H. Endoscopic sphincterotomy plus large- balloon dilation versus endoscopic sphincterotomy for removal of large common bile duct stones. *Gastrointest Endosc* 2009; 69: AB148 [DOI: 10.1016/ j.gie.2009.03.233] (Karsenti D, Coron E, Vanbiervliet G, Privat J, Kull E, Bichard P et al. Complete Sphincterotomy PLUS Large Balloon Dilatation of Sphincter of Oddi Versus Endoscopic Sphincterotomy for Large Bile Duct Stones Removal: A Large Prospective Multicenter Randomized Study. *Gastrointestinal Endoscopy*. May 2016 Volume 83, Issue 5, Supplement, Page AB133 DOI) Introduction 2. In the introduction segment, the authors mention “To the best of our knowledge, the present study involves only randomized clinical trials totaling 1230 patients comparing exclusively isolated sphincterotomy (ES) versus combined sphincterotomy and balloon dilation of papilla (ESBD).” Kindly avoid including such statements in the introduction segment, and include ‘what is known’ and what needs to be known’ in this segment. Methods and results 3. Methods and results have been aptly described Discussion 4. The discussion begins with conclusion regarding safety or adverse events. However, there is no mention on stone removal rate. Kindly include the same. 5. The second paragraph discusses regarding limitations of the study. Rather this should be mentioned towards the end of the discussion segment. In addition, if full texts were not available for some of the studies as mentioned above, kindly include that as limitation. 6. Kindly discuss the meta-analysis recently published and compare with the present one. Minor Comments The entire manuscript needs a great deal of language polishing.

Major points:

1. Regarding Park CH *et al* systematic review:

The authors also used only randomized clinical trials, but they did use the indirect analysis feature, we use the direct analysis.

The author identified significant inconsistency between direct and indirect evidence in post-ERCP bleeding and perforation outcomes.



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They selected 25 trials, of which 17 compared sphincterotomy (EST) vs Balloon dilation (EPBD). Only seven articles compared EST to sphincterotomy plus dilation (ESBD), the two methods that our review would like to compare, since it is not part of the current clinical practice in our services the isolated use of balloon dilation, restricting its indication in selected cases with high hemorrhagic risk.

The author excluded the articles published only in Abstract, we did not exclude them, since we were able to extract the necessary data from these trials.

About the included trials:

Park ended up including seven articles comparing EST vs ESBD with search until June 2017, we had included nine:

- Four coincided with ours (Guo, 2015; Teoh, 2013; Kim HG, 2009; Heo, 2007).
- One he did not quote (Chu, 2016).
- One of those he selected (Stefanidis, 2011) compared EST plus ML vs ESBD, that is, had mechanical lithotripsy programmed for all patients in the non-dilating group; this article was deleted in our flowchart.

Other two trials that do not match we had not found in our search:

- Qian, 2013: Small endoscopic sphincterotomy plus large-balloon dilation for removal of large common bile duct stones during ERCP.

- Li, 2014: Dilation-Assisted Stone Extraction: An Alternative Method for Removal of Common Bile Duct Stones.

These 2 trials that Park included did not result in our search, but by reading them we think they should be included in our review. By doing this we obtained that EST group presented more post-ERCP bleeding (3.4% vs 1.9%,  $p = 0.02$ ) with a total of 1,802 patients included in this analysis. Park CH did not observe this difference in bleeding risk between ESBD and EST, but obtained that both ESBD and EST had more bleeding than EPBD.

## 2. We really should have corrected this information

The fact was that initially we had only selected full texts and later, when checking the gray literature (references from other works), we ended up including abstracts, as long as we had conditions to fully extract the relevant data, but the correction in the flowchart and in the methods was lacking.

However, we included three trials published in abstract format; we consider that it brings a limitation for the biases analysis, since they could not be fully evaluated in these works, such as adequate randomization or possible losses. In addition, it is important to emphasize the impossibility of accessing in these trials the adverse events definitions adopted (post-ERCP hemorrhage and pancreatitis). It was not possible to extract sphincterotomy technique data (small or total) from only one trial published in abstract format (Hong).

Regarding the results of these studies, the inclusion of the abstracts was not considered an absolute limitation, since the availability of all required data for the meta-analysis was a pre-requisite for inclusion in our study.

As for the Karsenti's trial cited (Complete Sphincterotomy PLUS Large Balloon Dilatation of Sphincter of Oddi Versus Endoscopic Sphincterotomy for Large Bile Duct Stones Removal: A Large Prospective Multicenter Randomized Study. *Gastrointestinal Endoscopy*, May 2016 Volume 83, Issue 5, Supplement, Page AB133 DOI), it was possible to extract the number of patients involved, the primary endpoint and the secondary endpoints of this review, through the percentages and absolute number of patients, which was confirmed when we compared it with the clinical trial "Complete endoscopic sphincterotomy with. (Kasi) (DOI <https://doi.org/10.1055/s-0043-114411>), which showed exactly the same results, but with the advantage of to dismember each adverse event, which had previously been grouped as 'adverse events', which is why we will replace the previous Karsenti abstract by this published clinical trial in its complete form.

Abstract 1. In the methods we corrected outdated information about the full text assessment.

Introduction 2. In the introduction segment, we withdraw "To the best of our knowledge, the present study involves only randomized clinical trials totaling 1230 patients" and have included 'what is known' and 'what needs to be known' information.

Discussion 4. We have included mention of the stone removal rate founded in our study. 5. We have reallocated limitations of the study at the end of discussion segment. We have included the limitations about including abstracts. 6. We have discussed the meta-analysis recently published and compared with ours.

Minor Comments: The manuscript language was reviewed by an author who is a Native Speaker of English, Jonah M Cohen.



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Dear Dr Li-Jun Cui

We made important changes to the manuscript through the reviewers recommendations, including changes in results after adjusting the work in view of the last review of Park that was cited.

Regarding the forest plots and funnel plots I will attach the complete .rm5 file for appreciation.

I will submit the articles that are not indexed in PUBMED.

Sorry for the delay, but the profound changes added to the holidays and the revision of english did not allow a shorter deadline.

Best regards

Cesar Capel - MD