Author's response to reviews

Title: The quality of reporting of RCTs used within a postoperative pain management meta-analysis, using the CONSORT statement

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Author's response to reviews: see over
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Dear BMC Anesthesiology Editor  

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The quality of reporting of RCTs used within a postoperative pain management meta-analysis, using the CONSORT statement  
Victoria Borg Debono, Shiyuan Zhang, Chenglin Ye, James Paul, Aman Arya, Lindsay Hurlburt, Yamini Murthy and Lehana Thabane

Thank you for the opportunity to resubmit a revised version of our manuscript. We thank the reviewers for their thorough review of the paper and their insightful comments. We have revised the manuscript in accordance with the reviewers’ suggestions where possible. In this cover letter we have provided a point-by-point response to the concerns and have addressed all the comments. We hope this version is now in an acceptable form for publication. We look forward to hearing from you.

Sincerely,

Lehana Thabane, PhD  
Professor, Clinical Epidemiology and Biostatistics, McMaster University
We thank the reviewers for their helpful comments. Below are our point-by-point responses to their comments.

**Referee 1**

**Comment 1**

Comment 1 made by reviewer: “As the authors mentioned their limitations section, the major weakness of this study is small sample size. It would be good to be able to generalize the findings the authors have, at least for the anesthesia field, so that community and other journals can derive more substantial benefit. The small sample size also appears to have prevented them from achieving some statistically significant results with regard to the factors associated with high quality of reporting. Nevertheless, given the nature and objective of the study, we can say that it properly achieves its purposes.”

Our Response to comment 1: We thank the reviewer for their comment and I agree that the small sample size is a major limitation for the study. We have already addressed this in our discussion as one of the major limitations that may reduce the generalizability of our study. *(See page 16 of the manuscript).*

**Comment 2**

Comment 2 made by reviewer: “High journal impact factor has been associated with improvement in the quality of reporting of RCTs by many articles. The below are two examples: BMJ 2011 Sep 26;343:d5886; J Clin Oncol 2011 Mar 20;29(9):1204-9. I suggest that this topic be discussed more widely in the discussion section.”

Our Response to comment 2: Thank you for the examples. We have discussed impact factor and its association with the improvement in the quality of reporting more widely in our discussion as suggested. Within our discussion of this association we have also cited the articles mentioned in comment 2 above in addition to ones we found that were relevant to impact factor’s association with improvement in the quality of reporting of RCTs. *(See page 20 of Manuscript)*

We have also added the citations of these articles to further support the point that higher journal impact factors has been associated with improved quality of reporting of RCTs in another important part of the manuscript. *(See page 10 of the Manuscript)*
Comment 3

Comment 3 made by reviewer: “The 2010 version of CONSORT statement includes the “Trial Registry” as one of the items suggested to improve quality. I do not know if there was any reason for not investigating the trial registry as a quality measure in this study. The authors can easily add the survey of trial registry name and number by taking a look at the RCTs as no inter-rater disagreement is anticipated for this specific item.”

Our Response to comment 3:
The reviewer raises a very important issue. We decided not to include “trial registry” in the quality score for two reasons:

Reason 1) The choice of the items in the overall quality of reporting checklist and the three methodological items were chosen on the basis of consistency with previous studies (Rios, Odueyungbo, Moitri, Rahman, & Thabane, 2008; Rios, Ye, & Thabane, 2010). As mentioned in our study, quality scores based on checklists may not be a reliable representation of the reporting quality. (Page 19 of Manuscript)
Moreover, the score will definitely vary depending on the scoring system used for the particular study (Herbison, Hay-Smith, & Gillespie, 2006; Juni, Witschi, Bloch, & Egger, 1999). Therefore, we used a previously used checklist in order to maintain consistency which can also lead to better comparison between studies since a similar measuring instrument (the quality score checklist) is used. As more articles in the area of assessing the reporting quality of journals are done, it is important to have consistency between the instruments used in order to make more scientifically sound comparisons between studies. Trial Registration is an item we are sure to include in the future. We mentioned our desire and the importance to include trial registration as an item as part of the Overall Quality of Reporting Score (OQRS) in our future studies in our discussion.

Reason 2) Many of the included trials assess in this study were published prior to the RCT trial registration requirement made by many publications. The trial registry is new to the CONSORT 2010 statement and now even more journals may now be requesting this information by authors submitting papers. (See Page 19 of the Manuscript)

Comment 4

Comment 4 made by reviewer: “The typing error of “Randomized Control Trial” should be corrected as “Randomized Clinical Trial” or “Randomized Controlled Trial”.”

Our Response to comment 4: The typing error has been corrected throughout the manuscript to “Randomized Controlled Trial” as suggested (Fixed within the entire Manuscript)
Comment 5

Comment 5 made by reviewer: “The number of RCTs reporting “blinding” as a key item is 5 in Table 3 and 6 in Figure 2.”

Our Response to comment 5: The correct number of RCTs reporting “blinding as a key item is 5 as indicated in Table 3. Figure 2 has been removed from the manuscript completely. (See page 32 of the Manuscript)

Referee 2

Major Compulsory Revisions

Comment 1

Comment 1 made by reviewer: “Table 1 & 2 and Figures 1 & 2 give similar information but the tables also give confidence intervals, so only the tables should be presented”

Our Response to Comment 1: We removed Figure 1 and Figure 2 entirely from the manuscript as suggested by this comment.

Comment 2

Comment 2 made by reviewer: “Page 8, 1st paragraph, 1st sentence: The authors state that “Two additional items that are considered important to be present in RCT publications were also assessed (Table 1)”; were these 'additional items' included in the calculation of OQRS?”

Our Response to Comment 2: Thank you for mentioning this. No, these additional items were not included in the calculation of the OQRS. In order to clarify this we added to that same sentence a statement to make this clearer by stating “Two additional items that are considered important to be present in RCT publications were also assessed (Table 1), however they were not included in the calculation of the OQRS.” (See Page 8, 1st paragraph, 1st sentence.)

Comment 3

Comment 3 made by reviewer: “Page 10, 1st paragraph, 1st and Table 4: the response variable KMIS takes on values 0, 1, 2, 3. Could the authors justify the use of Poisson regression instead of polytomous logistic regression or logistic regression with the count (1, 2, 3) combined.”

Our Response to comment 3: Poisson regression is a common choice of model for analyzing count data. We wanted to analyze the outcome as number of counts as opposed to considering them as 4
separate categories, therefore we used the Poisson regression instead of polynomial logistic regression. We also wanted to report our results with incidence rate ratios to compare with previous findings. Because the previous studies used incidence rate ratios we wanted to be consistent so people could compare the findings easily.

**Comment 4 and 6**

**Comment 4 and 6 made by reviewer:**
“4. Page 10, 2nd and 3rd paragraphs, and Tables 4 & 5: Could the authors comment on collinearity between the predictor variables in their fitted models.”
“6. Separate cross-tabulations of the response variables (OQRS and KMIS) by the predictor variables would provide useful information on the 23 trials included in the study.”

**Our Response to comment 4 and 6:** We calculated variance inflation factor (VIF) for each predictor we included and there was no presence of multi-collinearity among the 4 predictor variables we had. We made note of the collinearity between predictors in the manuscript.
(See the 1st paragraph of page 12 of the Manuscript)

In addition, the response variables, OQRS and KMIS, were measured as the number of counts (producing an ordinal score) so they were not analyzed as nominal variables. Thus we did not produce cross-tabulations of the response variables by the predictors.

**Comment 5**

**Comment 5 made by reviewer:** “Page 12, 1st paragraph, 6th sentence: The abbreviations KMIS must be defined earlier even though it is defined at the end of the paper”

**Our Response to Comment 5:** As suggested this was fixed by defining KMIS earlier in the 1st paragraph of page 10, where it is first introduced in the study.
(See 1st Paragraph of Page 10, of Manuscript)

**Comment 7**

**Comment 7 made by reviewer:** “Could the tables be included in the text but not given as separate files.”

**Our response to Comment 7:** We included the tables in the text and removed them as separate files. This was also allowed by BMC Anesthesiology as indicated in their manuscript instructions to the authors. All 5 tables were added and can be seen from page 31 to 33 of the manuscript (See Page 31 to 33 of Manuscript). The following is the link to the author's information in regards to preparing tables that we used - http://www.biomedcentral.com/bmcanesthesiol/authors/instructions/researcharticle#preparing-tables
Minor Essential Revisions

Comment 1

Comment 1 under the heading “minor essential revisions” made by reviewer: “Could the authors comment on the importance of year of publication of the result of the RCTs given that the OQRS is based on the CONSORT statement of 2010.”

Our Response to comment 1: Yes, a comment on the importance of the year for publication has been made in the discussion of the manuscript. (See page 16 and 20 of the manuscript)

Discretionary Revisions

Comment 1

Comment 1 made by reviewer: “The sample size of 23 trials it too small for the results to be generalizable.”

Our Response to comment 1: Please see our response to comment 1 under Referee 1 as it addresses the same concern. (See page 16 of the manuscript).

Papers Referred to in our Responses:


