Author’s response to reviews

Title: Quality of Reporting Internal and External Validity Data from Randomized Controlled Trials Evaluating Stents for Percutaneous Coronary Intervention

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Author’s response to reviews: see over
Editor comments
We would be grateful if you could address the comments in a revised manuscript and provide a cover letter giving a point-by-point response to the concerns. As you will see, the reviewers have raised a number of substantial concerns on the manuscript. While we are ready to allow revisions on the paper, please note that further consideration of the manuscript is dependent on a thorough revision that adequately and exhaustively addresses all of the criticisms raised by the reviewers. We therefore expect the revised manuscript to incorporate the statistical analyses indicated and an updated analysis that includes trials published after 2005 as requested by the reviewers. The other points raised by the referees should also be thoroughly addressed in the revised paper. You should address all of the comments in a revised manuscript and provide a cover letter giving a point-by-point response to the concerns.

Answer: We are very grateful for giving us the opportunity to resubmit this manuscript. We answered all reviewers’ comments and modified the article accordingly. Particularly, as requested, we updated the analysis to include all trials published after 2005 (i.e., 374 new articles were screened, and 52 new reports were included in the analysis). We also took into account clustering by journal in the statistical analysis as requested. Despite these modifications, the results were similar. Other points raised by reviewers are addressed in the revised paper.

ANSWERS TO REVIEWERS

Reviewer 1

Title: Quality of reporting of randomized controlled trials evaluating stents for percutaneous coronary intervention

Version: 1 Date: 29 October 2008

Reviewer: Lehana Thabane
Reviewer's report:
• Major Compulsory Revisions

1. Abstract, Methods: Provide some brief description of the statistical methods sued to analyse the data.

Answer: As requested, we added a brief description of the statistical methods in the methods section of the abstract.

2. Background/Introduction: Provide a subtitle “Background” or “Introduction” on page 4.
Answer: A subtitle “Background” was added on page 4.

3. Statistical Analysis:
a. Replace “Interquartile range [IQR]” with “Q1 to Q3”. Note that IQR = Q3 – Q1, which is the difference between the two quartiles.
b. Consider providing the estimates of Kappa statistics to measure agreement between data abstractors. This will be helpful to readers to assess the reliability of the data abstraction process.
c. Consider using appropriate techniques to account for potential clustering among papers published in the same journal. T-tests and Mann-Whitney tests may not be appropriate if clustering is present.

Answer:
As requested, we replaced “interquartile range” with “Q1 to Q3”.
We estimated the interrater reliability. The data are reported in the following table. We did not use the kappa coefficient because of the kappa paradox [High agreement but low kappa: I. The problems of two paradoxes, Feinstein AR, Cicchetti DV. J Clin Epidemiol. 1990;43(6):543-9].

<table>
<thead>
<tr>
<th>% agreement [CI]</th>
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<tbody>
<tr>
<td>Funding</td>
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<tr>
<td>Details of intervention intended</td>
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<tr>
<td>Adequate generation of allocation of sequence</td>
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<tr>
<td>Concealment of treatment allocation</td>
</tr>
<tr>
<td>Details of intervention used in each group available</td>
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</table>
Participants adequately blinded & 88% [68.8 - 97.5] \\
Care providers adequately blinded & 96% [79.7 - 99.9] \\
Outcome assessors adequately blinded to assess the primary outcomes & 60% [38.7 - 78.9] \\
Main outcomes analyzed according to the intention-to-treat principle & 64% [42.5 - 82.0] \\
CI=confidence interval

We completely agree that the effect of clustering by journal should be taken into account in the statistical analysis. We now report the results adjusted on the effect of clustering by journal.

Answer: As requested, we replaced “Jama” with “JAMA”.

Reviewer 2

Version: 1 Date: 7 November 2008

Reviewer: Adrian V.Hernandez

Reviewer's report:
• Major Compulsory Revisions

1. The selection process was performed by one author, a strategy which is not standard and may lead to a biased group of trials.
Answer: We clarified the selection process in the text. Articles were selected by one reviewer (ME). The reviewer read the title and abstract and, in case of doubt, retrieved and read the full text. When doubt persisted after the full text was read, another reviewer (IB) read the full text and the selection of the article was decided by consensus. This method is common in methodological systematic reviews in which the objective is to assess the quality of reporting but not to perform a meta-analysis. There is no evidence to suggest that such methods could lead to a biased group of reports.
2. The data extraction was performed mainly by one author and partially by a second author. It is unclear if they agreed or not, and how much. It is also necessary to provide the data extraction form.
Answer: We estimated the interrater reliability. The data are reported in the table. We did not use the kappa coefficient because of the kappa paradox [High agreement but low kappa: I. The problems of two paradoxes, Feinstein AR, Cicchetti DV. J Clin Epidemiol. 1990;43(6):543-9].
The data abstraction form is available in the appendix as requested.

3. This analysis is based on trials published until dec 2005, a long time ago.
Answer: As requested, we updated the systematic review by retrieving articles published after 2005, particularly those published between January 1, 2006 and September 30, 2008: 374 new reports were identified in the Medline and Cochrane databases. On the basis of the title and abstract, 282 articles were excluded, for 92 articles selected. After obtaining the full text, 40 articles were excluded, for a final 52 reports assessed. Despite this update and adjusting on the clustering effect as requested by reviewer 1, the results were similar.

4. There are two general pieces of information that should be shown and commented: quality of reporting of specific procedures, and overall quality of reporting trials as per CONSORT. This should be clarified in title and abstract.
Answer: Thank you for pointing this point out. We completely agree that we focused on the quality of reporting of data related to internal validity and that related to external validity (intervention, centers, etc.). The title was clarified as requested.

6. Quality of reporting procedures cannot be satisfactory probably because these details were previously published in separated manuscripts. did authors check this?
Answer: We completely agree that details may have been previously published, so we excluded articles for which materials and methods were previously published. Information on these excluded articles appears in the study screening process of our study (n = 16).

- Discretionary Revisions
1. Please include reporting and quality as keywords
2. Some information given in the results section is also shown in Tables. Please restrict to one of them.
3. a very recent paper (Lim et al. Ann Intern Med 2008; 149: 612-7) can be referenced in support of the statement on the discussion section (page 10, last paragraph), regarding problems with composite outcomes.
Answer: We added “reporting” and “quality” as keywords.
We simplified the text and left the tables, which seem more comprehensive.
We agree that Lim’s paper is interesting regarding problems with composite outcomes in cardiovascular diseases, so we included it on our bibliography.