Reviewer’s report

Title: Statistical quality of surgical observational studies in medical and surgical journals: protocol for systematic review

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Reviewer: Forough Farrokhyar

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Major comments:

1- Abstract - The “biases” in the second line should be removed because there is no statistical method to adjust for biases - such as recall bias, detection bias, misclassification bias, etc.

- Rationale and hypothesis for the objective is missing. The authors need to state a hypothesis for the comparative study.

- “methodological principles” should be removed from line 14 in Methods as SAMPL does not discuss methodological aspects of observational studies.

Background – “inherent biases” should be removed from the first line of the second paragraph. For example, regression analysis does not adjust for “misclassification bias” if investigators mistakenly include a case in control group.

- Authors state that “the objective of the proposed systematic review is to assess and compare the quality of statistical methods in surgical observational studies published in the highest-impact general surgical journals, as compared to those in general medical journals in 2013. More specifically, this work will adapt and utilize a tool to evaluate the quality of statistical analysis in observational studies, evaluate the risk of statistical deficiencies, and compare the quality of statistical analysis in studies published on surgical topics in both surgical and medical journals”. Authors do not provide any rationale and hypothesis for these objectives. Are they assuming that the reporting quality of the statistical methods of surgical evidences in medical journals is lower (is higher) than surgical journals and why? One would assume that comparing the reporting quality of the statistical methods between surgical and medical observational studies would be more appropriate as there is good evidence on the low quality of surgical trials to medical trials.

Methods - Study selection – to minimize and avoid bias, all selection processes, including screening titles and abstracts, should be independently done by two reviewers – not by one reviewer as stated in item 3 of study selection.

Outcomes – It not clear what the scoring is based on and how it will be done. I am assuming the authors will be applying the adapted instrument in Appendix 1. However, this instrument is not validated for scoring. SAMPL provides guidelines for reporting statistical analyses and methods and does not provide any scoring
system. It is not clear why the authors are using an adapted version of SAMPL. Authors need to be transparent on their scoring, and describe how the scoring will be done and how reliable and valid it would be. As well, Lang and Altman stated statistical analysis are closely related to the design and methodological principles of the research study. One could not be assessed without the other. I would suggest authors to use the STROBE or the TREND tool to assess the quality of the methodological reporting and relate it to the quality of the statistical analyses reporting.

Data analysis – The quality and details of the data analysis section is very poor. The whole protocol is about the importance of justifying and reporting the methods of statistical analysis a priori. Nowhere in the protocol, there is any mention of hypothesis or specific statistical methods of testing those hypothesis for this review project.

- Authors need to report what statistical methods will be used to analyse each objective and based on what assumptions and hypotheses a priori.
- The rationale for performing sensitivity analyses is unclear except for # 5. In fact, the proposed analyses are subgroup analyses rather than sensitivity analyses. The statistical methods are lacking for this part and all other parts. It would be beneficial that authors collect the demographics of the articles (authors credential, location, etc) for adjustment and some clarification and justification.

Discussion - Authors have not discussed the limitations of the proposed protocol. The limitations need to be listed in details.

Appendices – The abstraction form does not follow the assessment of statistical quality criteria. The assessment of statistical quality criteria does not follow the SAMPL guidelines. Authors have omitted “Reporting hypothesis tests”, “Preliminary analysis” and “Bayesian analysis”. Although, the latter is rarely used in surgical research but the first two are extremely important for any research study and needs to be added.

Minor comments:

Title – The title might be changed to something like “Reporting quality of statistical methods of surgical observations studies in Medical and Surgical Journals” One can assess the reporting quality of the statistical analysis of the surgical observational studies but not the quality of statistical analysis done by authors. Soares et al (2004) evaluated the methodology of radiation oncology randomized controlled trials and concluded that “poor reporting of trials may not indicate poor quality of the trials themselves.”

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

My answer is "No" to all the questions above.