Author’s response to reviews

Title: Reporting of critical care trial abstracts: a comparison before and after the announcement of CONSORT guideline for abstracts

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Version: 1 Date: 26 Dec 2016

Author’s response to reviews:

Doug Altman, DSc and Jeremy Grimshaw, MBChB, PhD

Editors-in-Chief

Trials

Dear Professor Altman and Professor Grimshaw

Thank you for the opportunity to revise our manuscript entitled, "Reporting of critical care trial abstracts: a comparison before and after the announcement of CONSORT guideline for abstracts" for consideration for publication in Trials. We have carefully read your editor’s and reviewers’ comments and believe that this revised manuscript is sufficiently improved. Especially, both reviewers helped us to change our descriptions clearer and easier to comprehend for readers. We have tried to address all the concerns and comments from your editor and reviewers, and have indicated on the attached pages how we revised. We hope this will be sufficient.

Our study examined the adherence to the CONSORT guideline for abstracts in critical care journals. The Reviewer #2 pointed out that the current study is not the ‘latest’, but given the scarcity of such studies and low awareness of and adherence to the CONSORT guideline, we believe that our study should still serve as a fundamental study on this topic for any area. We know the necessity to update the survey on critical care journals that were published recent years, but we would appreciate if you would allow us to submit the current manuscript as it is.

Naomi Takahashi, RN, MPH substantially contributed to this study, and we thus list her as the first author that equally contributed. There is no conflict of interest for this study.
We would like to thank you for considering our manuscript. Please feel free to contact me if you have any questions or require further information.

Sincerely,

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Editor:

I would also find data on studies in JAMA and NEJM very interesting.

Response: Thank you for your comment. In the original manuscript, we already compared our finding with a study by Mbuagbaw et al. conducted on leading general medicine journals such as NEJM or JAMA over the same period. Also, a study updated on the same topic with five leading general medicine journals, including NEJM, Lancet, BMJ, and JAMA, from 2011 to 2014 was published. Per the reviewer #2’s comment, by quoting some details from these studies, we have detailed the comparison as follows; “Mbuagbaw et al. examined 100 to omly selected trials published in each of 2007 and 2012 in six leading general medicine journals (New England Journal of Medicine, Lancet, British Medical Journal, Journal of the American Medical Association. Annals of Internal Medicine, Canadian Medical Association Journal). Abstracts in these journals tended to report on the title (66%), trial design (59%), and methods section except randomization and blinding (about 60% or more), while they tended to underreport on numbers randomized (53%) and analyzed (26%), recruitment (25%), and harms (53%) in the Results, conclusions (22%), and funding (0%) in 2007. In 2012, in contrast, most items were more frequently reported compared with 2007, but randomization (13%) and blinding (59%) in the Methods, numbers randomized (61%), recruitment (49%), harms (60%) in the Results, and conclusion (26%) remained lower compared with the other items. Significant improvements were seen on the title, trial design, participants, objectives, randomization, and blinding in the Methods, and recruitment and numbers analyzed in the Results, and funding (p<0.05). Overall, all items except interventions and objectives in the Methods and Conclusions were much less frequently reported in critical care journals compared with those in leading general medicine journals. In contrast to general medicine journals, significant improvement was observed in different items except the title and funding in critical care trial abstracts. Hays et al. examined randomized controlled trial abstracts published in five leading general medical journals (New England Journal of Medicine, Lancet, British Medical Journal, Journal of the American Medical Association. Annals of Internal Medicine), from 211 to 2014, and suggested that that there was still low adherence to the guideline (overall adherence, 67%).”
Reviewer #1:

Abstract

1) In the results the authors mention "Less than 50% of abstracts adequately reported", what does the author refer to by the word 'adequately', it implies a subjective assessment. Were they studies that did not report these or was judged to inadequate by the authors?

Response: Thank you for your comment. We deemed an abstract adequately reported a required item, only when it was reported AND when it adhered to the example in the explanation and elaboration of the CONSORT guideline for abstracts. We deemed an abstract was inadequately reporting, when it did not have any description on a required item and/or did not report as suggested by the explanation and elaboration of the CONSORT guideline for abstracts. We added a sentence saying, “For each item in the CONSORT guideline for abstracts, we considered that an abstract was well-reporting when it reported a relevant item and adhered to the guideline.”

We think that this comment of yours was related to the one below about the data extraction. We thus decided to detail the method about the data extraction and assessment.

2) Was there variations between the journals?

Response: Thank you for your comment. As we wrote in the subsection “Evaluation by journals” in the Results, there was a variety of changes by journal during the periods. We summarized this subsection and reported in the abstract as follows, “Improvements were seen in reporting of participants in the methods section in CCM, and outcomes in results and trial registration in AJRCCM and CCM between the two periods. A significant decline was noted in reporting of interventions in methods section in AJRCCM and ICM, and the numbers randomized in results section in CC over time.”

Methods

1) How were the four journals selected? What criteria were used to determine that they were 'major' critical care journals

Response: Thank you for your comment. We set out to examine critical care journals that published articles on general critical care topics. We did not intend to include those that focus on specific topics or subspecialty such as shock or neurocritical care. As of 2006 and 2007, American Journal of Respiratory and Critical Care Medicine, Intensive Care Medicine, Critical Care Medicine, and Critical Care were ‘general’ critical care journals, and had the four highest impact factors, provided by Thomson Reuters.

We reflected this saying, “We included critical care journals that focused on ‘general’ critical care topics, and excluded those on subspecialty or specific areas. As of 2006 and 2007, American Journal of Respiratory and Critical Care Medicine, Intensive Care Medicine, Critical
Care Medicine, and Critical Care were the ‘general’ critical care journals that had the four highest impact factors, provided by Thomson Reuters. We thus selected these four journals.”

2) Data extraction section not very clear

Response: Thank you for your comment. First, this section refers to the assessment of abstracts rather than data extraction. So, we changed the title of this paragraph to “Assessment of abstracts”. Second, the sentence regarding the discrepancies in descriptions about “Registration” and “Funding” can be difficult to grasp. We revised this part as follows; “Occasionally, two items such as “Registration” and “Funding” were described on the journal websites, whilst they were not on PubMed. We therefore preferentially assessed the descriptions on journal websites to overcome this discrepancy.” Lastly, we revised the sentence regarding how we evaluated whether an abstract is adequately reporting, as responded to your next suggestion.

3) Again the 1 point i raised in the abstract section needs to clarified here

Response: Thank you for your comment. We revised this section as follows; “For each item, we deemed that an abstract was adequately reporting, only when it reported the relevant item and fully adhered to the explanation and elaboration of CONSORT guideline for abstracts. We considered that an abstract was under-reporting or inadequately reporting, when a relevant item was either not reported or was not described as suggested by the explanation and elaboration of the guideline.”

Discussion

1) What are the authors recommendations to improve the current situation?

Response: Thank you for your comment. We have already noted this in the original manuscript as follows: “Endorsing the CONSORT checklist as a journal policy is also known to be associated with improved reporting of trial. Thus, first of all, it is desirable for editors of critical care journals to consider adopting the CONSORT guideline for abstracts as a prerequisite at submission as a journal editorial policy. This would facilitate adoption of the CONSORT guideline for abstracts by authors of trial manuscripts, making abstracts sound and readable. Likewise for reviewers, completeness and efficiency of assessing abstracts could be improved if the CONSORT guideline for abstracts was better disseminated.”

Reviewer #2:

Thank you for this manuscript. The subject is highly interesting when we consider the large number of RCT published every week in international journals. Indeed, abstract's structure must be perfect to allow the clinician/scientist to appreciate manuscript's results at first sight.

Response: Thank you for your comment. We hope that our manuscript will help improve the reporting quality of trial abstracts in critical care journals.
Abstract: Can you mention clearly the primary outcome of your study?

Response: Thank you for your comment. Our primary outcomes were to describe the proportion of abstracts that adhered to the guideline for each item in each period, and the changes between the two periods. We thus reflected this in the abstract.

The sentence Page 7: "while a significant decline was seen between periods (p<0.01), intervention …….. " may be reformulated to improve clarity.

Response: Thank you for your helpful comment. We revised the sentence as follows; “Interventions were adequately described in both periods, but a significant decrement in reporting of this item was noted in the post-CONSORT (pre-CONSORT, 92.4% vs post-CONSORT, 81.9%; p<0.01).”

Could you add other reflexion/hypothesis in the discussion section on the "WHY" consort guideline are not fully respected by authors and editors/reviewers?

Response: Thank you for this thoughtful comment. Cobo et al. conducted a masked randomized trial to investigate the effect of additional review based on reporting guidelines on the quality of manuscript, compared with the conventional review (Cobo, BMJ 2011). In their discussion, they proposed some following hypothesis; firstly, authors were not aware of the CONSORT guideline for abstracts and authors might prefer to concentrate their efforts on more conventional suggestions. This might be true with the abstract reporting.

Critical care trials quite often look at undesirable outcomes such as mortality as a primary outcome. In this case, harms could be omitted from the abstracts (Bbuagbaw 2014). Also, when the intervention was not found to be effective, the harms were not discussed.

We therefore reflected these in the revised manuscript as follows; “There are several hypotheses regarding the suboptimal adherence of critical care journals to the guideline. The authors were unaware of the CONSORT guideline for abstracts in the first place. They might prefer to concentrate their efforts of the manuscripts, or the adherence to the guideline for abstracts could be felt as an extra “work” for the authors. Specifically regarding the harms, critical care trials often examine undesirable outcomes such as mortality, and harms could be omitted from the abstracts. Also, when the intervention of interest was found be effective, it imaginable that the harms were not discussed as well.”

Can you argue not to have compared the evolution of these abstract's quality markers of publication to very high impact factor journals' such as JAMA and NEMJ or journal endorsing CONSORT guideline over the same period? David Moher (JAMA) did not focused specifically on abstract's quality.

Response: Thank you for your comment. In the original manuscript, we already compared our finding with a study by Mbuagbaw et al., which was conducted on leading general medicine journals such as NEJM or JAMA over the same period. Per yours and the editor’s comment, we decided to detail the changes of adherence to the CONSORT guideline for abstracts. We also
cited a recent update on leading five medicine journals (NEJM, Lancet, BMJ, JAMA, and Annals of Internal Medicine) by Hays et al. We revised as follows; “Mbuagbaw et al. examined 100 randomly selected trials published in each of 2007 and 2012 in six leading general medicine journals (New England Journal of Medicine, Lancet, British Medical Journal, Journal of the American Medical Association. Annals of Internal Medicine, Canadian Medical Association Journal). Abstracts in these journals tended to report on the title (66%), trial design (59%), and methods section except randomization and blinding (about 60% or more), while they tended to underreport on numbers randomized (53%) and analyzed (26%), recruitment (25%), and harms (53%) in the Results, conclusions (22%), and funding (0%) in 2007. In 2012, in contrast, most items were more frequently reported compared with 2007, but randomization (13%) and blinding (59%) in the Methods, numbers randomized (61%), recruitment (49%), harms (60%) in the Results, and conclusion (26%) remained lower compared with the other items. Significant improvements were seen on the title, trial design, participants, objectives, randomization, and blinding in the Methods, and recruitment and numbers analyzed in the Results, and funding (p<0.05). Overall, all items except interventions and objectives in the Methods and Conclusions were much less frequently reported in critical care journals compared with those in leading general medicine journals. In contrast to general medicine journals, significant improvement was observed in different items except the title and funding in critical care trial abstracts. Hays et al. examined randomized controlled trial abstracts published in five leading general medical journals (New England Journal of Medicine, Lancet, British Medical Journal, Journal of the American Medical Association. Annals of Internal Medicine), from 211 to 2014, and suggested that that there was still low adherence to the guideline (overall adherence, 67%).”

It is difficult to draw conclusion on these results in 2016 (nearly 2017) considering the after period in 2011-2012. Have you any data on secular trends?

Response: Thank you for your comment. No similar studies on the critical care journals have been published. We did this study as the first one in critical care medicine, and examined two periods (2006-2007 and 2011-2012) according to the previous similar ones. We know the necessity to update the survey on abstracts that were published recent years, but we would appreciate if you would allow us to submit the current manuscript as a fundamental study for the next update for the same area or others. We also added the following sentence in the limitation, “Second, a few years have passed since the second study period in our investigation. The trial abstracts published in five leading general medical journals from 2011 to 2014 still showed low adherence to the guideline (overall adherence 67%), and thus an update for each area is warranted. The current study is the first one to examine the adherence to the CONSORT guideline for abstracts in critical care journals. This study thus should serve as the foundational investigation for the update on the same topic in critical care medicine and other areas.”