Author's response to reviews

Title: Reporting quality of randomized controlled trials in major hepato-gastroenterology journals in 2008 and 1998: a comparative study

Authors:

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Version: 3 Date: 6 February 2011

Author's response to reviews: see over
Reviewer's report

Title: Quality of reporting of randomized controlled trial in major gastroenterology and hepatology journals in 2008 and 1998: a comparative study
Version: 1 Date: 7 January 2011
Reviewer: Agnes Dechartres

Reviewer's report:

Major compulsory revisions:
1) A huge quantity of literature assessing quality or quality of reporting in RCTs was published in the past years (Dechartres et al., Journal of Clinical Epidemiology, 2011, epub 2010). An important issue of such studies is the use of many different tools for assessing the quality or the quality of reporting without providing the definitions which makes the reproducibility and interpretation of results difficult. Another issue is the frequent confusion made between the quality and the quality of reporting. The CONSORT Statement was not initially developed to assess the quality but to help improving the reporting in RCTs which is the pre-requisite for assessing quality. This study presents the 2 shortcomings.

The objective stated by the authors is to assess the quality of reporting and to so they used some of the items of the CONSORT checklist. However, in the results they wrote “reporting of adequate sequence generation, concealment,…” which means that they assessed the adequacy of these items. They did not provide clearly the definitions that were used only referenced to the Cochrane Handbook for sequence generation, allocation concealment and blinding. What was an adequate sample size calculation for the authors? I would like to see all definitions that were used as an appendix. The authors should make the distinction between the quality and the quality of reporting. What was the reporting of sequence generation or allocation concealment,…? Among the RCTs reporting these items, what was the proportion of adequacy and non-adequacy (or low risk and high risk of bias according to the Cochrane Handbook)?

We revised our objective and methods of our studies.

2) The method is not well-adapted to the objective: if the objective is to assess the impact of the CONSORT Statement on the quality of reporting, it would have been more interesting to compare quality of reporting before and after endorsement of the CONSORT by the journals. The methods employed only allow for answering the question: was there an improvement between 1998 and 2008. The role of the CONSORT should only be discussed and reference to the CONSORT should be omitted from the objective and used more carefully in the conclusion. The authors should mention whether the journals assessed endorsed the CONSORT Statement and if yes, when.

We revised our objective and methods of our studies.

3) The manuscript should be more focused around the objective: authors performed secondary analyses according to several characteristics (funding source, single-center or multicenter RCTs, area of the world) that are not specified in the methods section. Moreover, discussion of these results takes a large place in the discussion. The authors should start the discussion section with
the discussion of the main results compared with other published studies on the same topic and
discussion of the possible role of the CONSORT Statement with mention to the studies assessing
the impact of the CONSORT (Plint, 2006, Med J Aust,…). I absolutely don’t understand why
there is an important discussion concerning problems with industry-sponsored RCTs. This is not
the objective of the study!!

We revised our objective and methods of our studies.

4) The literature should be more assessed. The authors stated that there was no study concerning
the quality of reporting in the field of gastroenterology and hepatology but in the study cited above,
our team retrieved several studies assessing quality or quality of reporting in the field of
gastroenterology and hepatology (Gluud C, 1998, J Hepatology; Kjaergard LL, 1999, hepatology,

We have revised in our studies.

Minor essential revisions:
1) Abstract: presentation of the results may be improved: for each item, n/N (%) should be
presented for both years with p-value. Ex: reporting of sequence generation increased from 35% to
76%, p=…

We have revised in our studies.

2) Introduction: The authors should be more precise in the first paragraph: “Unclear or
inadequate allocation concealment was associated with an overestimation of treatment effect
estimate ” instead of “flaws in the randomization can overestimate the efficacy”. The
association between lack of blinding and treatment effect was inconsistent between
meta-epidemiological studies and depend on whether the outcome is subjective or not (Wood,
BMJ, 2008)

We have revised in our studies.

3) Introduction: The 2010 revised version of the CONSORT Statement has been published: please
update the manuscript and add the reference.

We have revised in our studies.

4) Methods: What is the rational for choosing these journals? The authors should be more precise:
these journals are the 5 highest impact-factor journals in hepatogastroenterology.

We have revised in our studies.

5) Methods: Why did the authors choose 1998? The first CONSORT Statement
was published in 1996.
We told the reasons in the text.
The CONSORT Statement was first published in 1996, revised in 2001, updated in 2010, and we wanted to know whether the reporting quality of key methodological items were improved or not in the past 10 years (this study was began in 2009), so we selected these two years: 1998 and 2008.

6) Search strategy: the authors should detail the electronic search strategy as an appendix.
Yes, we have revised in our studies.

7) Was the selection performed by 2 authors independently?
Yes, we have revised in our studies.

8) Extraction of data was performed independently by 2 authors for 24% of RCTs (50). I would rather say “for 50 RCTs (24% of the sample)”.
We have revised in our studies.

9) The method of analysis to compare quality of reporting between 1998 and 2008 should be clearly stated (tests used, # risk).
We have revised in our studies.

10) The authors should have estimated agreement between the 2 reviewers for the 50 RCTs assessed in duplicate using Kappa. Was it the case? The sentence “The sample results and the overall results were compared using the Kappa score” is confusing.
We have revised in our studies.

11) Results: reasons for exclusion should be more detailed in the Flow chart. The Flow chart should present double entry for 1998 and 2008.
We have revised in our studies.

12) The authors wrote “103 articles… described 107 RCTs” Does it mean that several articles reported at least 2 RCTs? Please explain.
We have revised in our studies.

13) I would not report Kappa in tables 1 and 4.
We have revised in our studies.

14) I would merge Table 2 and Table 3 together.
We have revised in our studies.

15) The “comparison of reporting of descriptive characteristics in 2008 or 1998” is too much detailed, the authors should refer to the Table. The title is not adapted (the authors confound the 2 questions: whether the characteristic was reported and what was the characteristic): title corresponds to the first question, text corresponds to the second one.

We have revised in our studies.

16) The analysis reported as “reporting of methodology in 2008 according to the different strata” is not prespecified in the methods.

We have revised in our studies.

17) Discussion: for blinding, the authors should take into account the fact that blinding is not always possible (for certain non-pharmacological interventions).

We have revised in our studies.

18) The conclusion in the abstract is different from the conclusion in the manuscript: “has improved significantly” in the abstract and “trend in improvement” in the manuscript.

We have revised in our studies.

19) In Table 5: only a significant p-value is presented for the country. The overall p for each item (sequence, concealment,…) should be presented.

We have revised in our studies.

20) Please update: trials in the title, Australia page 7, 1st line, was instead of is page 8 second line of the second paragraph, Jüni page 12 (ref 7). The police is not always the same (in the references).

We have revised in our studies.

Reviewer’s report

Title: Quality of reporting of randomized controlled trial in major gastroenterology and hepatology journals in 2008 and 1998: a comparative study

Version: 1 Date: 29 December 2010

Reviewer: Jinhui Tian
Dear Sir,

Thank you very much for your hard work. Your comments were very pertinent, and I will answer them one by one below. If my article can be published in your magazine, I would be very honored.

Reviewer's report:

1# In the “method” section, the authors did not explain why they chose only five journals and two years. If they could give clear descriptions of the reasons, that must be more scientific in the study design.

We have revised in our studies.

2# In the “method” section, the authors did not state “the process for selecting studies and its relevant details (including who, why, how)”. This process can tell readers and users how this study was conducted and whether biases were produced in the process. So if this process was stated clearly, it will be much better.

We have revised in our studies.

3# In the section “Assessment of quality of reports”, the authors said “based our analysis on some of the important checklist items recommended in the revised CONSORT Statement (2001) to evaluate the quality of RCT reporting”. But the authors did not list those important checklist items, and stated the reasons why they chose. In the last paragraph, the authors listed some items, where the authors did not distinguish the Cochrane Handbook for Systematic Reviews of interventions from CONSORT statement. But CONSORT statement also mentioned these items. So these must be corrected by the author.

We have revised in our studies.

4# In the “method” section, the authors did not state the method of statistical analysis, but the authors mentioned results of statistical analysis in the “result” section. So the method of statistical analysis needed to be added by the authors.

We have revised in our studies.

5# In the “result” section, the authors just described the process of selecting studies in 2008 and provided a flow chart. But why did not give a figure to describe the process of selecting studies in
1998? It is necessary to present such a figure.

We have revised in our studies.

6# In the “Reporting of methodology in 2008 according the different strata” section, the author compared the reporting quality of different factors. This is an innovation of such a study. And it would be better to conduct such an analysis for the studies in 1998 and compare the differences between 1998 and 2008 focusing on each factor?

We have revised in our studies.

7# There were also some languages mistakes in their article, so it is better to ask a native English speaker to help revise this paper.

yes, we did.

Sincerely,

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