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)?

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.

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!!

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,
Gastroenterology,...)

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=...

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)

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

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.

5) Methods: Why did the authors choose 1998? The first CONSORT Statement was published in 1996.

6) Search strategy: the authors should detail the electronic search strategy as an appendix.

7) Was the selection performed by 2 authors independently?

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)”. 

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

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.

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

12) The authors wrote “103 articles… described 107 RCTs” Does it mean that several articles reported at least 2 RCTs? Please explain

13) I would not report Kappa in tables 1 and 4.

14) I would merge Table 2 and Table 3 together.

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.

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

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

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.

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.

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).

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no conflict of interest.