Author's response to reviews

**Title:** Post-Marketing Surveillance for Percutaneous Transluminal Coronary Angioplasty Catheters: A Systematic Review

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**Version:** 5  **Date:** 16 September 2013

**Author's response to reviews:** see over
September 16, 2013

Dr. Lesley Stewart
The Systematic Reviews Editorial Team
Systematic Reviews

Subject: Manuscript Submission

Dear Dr. Stewart:

Thank you for the opportunity to revise our manuscript, “Post-Marketing Surveillance in the Published Medical and Grey Literature for Percutaneous Transluminal Coronary Angioplasty Catheters between 2007 and 2012: A Systematic Review”, based on the reviewer comments for consideration by the editorial staff of Systematic Reviews to be published as an article. Enclosed please find our responses to all comments.

The manuscript was completed through the contribution of the authors named in the manuscript. As per the original manuscript submission, none of the authors declared any conflict of interests, and each has approved the version submitted. The content of this manuscript has not been published nor is being considered for publication elsewhere.

Sincerely,

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1st Reviewer's report

Title: Post-Marketing Surveillance for Percutaneous Transluminal Coronary Angioplasty Catheters: A Systematic Review

Version: 4 Date: 23 August 2013

Reviewer: Mariska M. G. Leeflang

Reviewer's report:
The manuscript has much improved. It is much clearer and more consistent. Also, the authors have responded to almost all of my comments in a satisfactory way. Only a few revisions remain.

Major Compulsory / Discretionary:
SIGN50 is not a checklist to assess quality, SIGN50 is a guide about how to do guidelines. It refers to several other checklists for quality. It would have been better if the authors would have referred to the checklists they used directly, rather than to an overall guidance. Anyway, I think the statement that SIGN50 is a checklist, is incorrect.

Author's response: The authors made the following changes in the Quality assessment of included studies section:

Two reviewers (JP and KC) critically appraised independently the internal validity of the included studies using checklist tools for RCTs and cohort and case-control studies available on the Scottish Intercollegiate Guidelines Network website. Separate methodology checklists by study design were used to assess the internal validity and overall assessment of the study, including the generalizability. Each tool addresses how well each study meets the different components of the study design that may impact the study findings and conclusions.[19]

Minor Essential:
A typo under 'Selection criteria', 6th line: "For the our systematic review...".
Remove either the or our.

Author’s response: Thank for bringing the typo to our attention. We corrected the sentence accordingly.

Discretionary:
The search strategy looks fine, I don't think they missed a lot. Still, although the authors claim that restricting their search to English and French papers only will not result in bias, their aim was not to test a hypothesis or to come with a certain (pooled) percentage. The question is whether the authors would have found sufficient other studies in other languages to change their conclusion about the
gap there is between the number of reports found and the number of reports from the FDA (probably not, as this gap is huge, even finding 10 additional studies may not close this gap).

**Author’s response:** Thank you for the insightful comment. We added the following statement to the Discussion section:

Studies were also restricted to English and French publications due to limited resources and time restrictions. Although Morrison et al. found no systematic bias when English-language restrictions were imposed in systematic reviews, the authors of the current review acknowledge that some bias may still exist by imposing language restrictions in the literature search strategy as further research is required in this area.[37] It is unlikely that we would have found a sufficient number of studies in other languages to change our conclusion about the gap there is between the number of reports in the published medical and grey literature and the number of reports from the FDA as the gap is significant.

Level of interest: An article of importance in its field

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 competing interests
Title: Post-Marketing Surveillance for Percutaneous Transluminal Coronary Angioplasty Catheters: A Systematic Review

Version: 3 Date: 1 August 2013

Reviewer: Luis F Azevedo
Reviewer's report:
Manuscript Review for “Systematic Reviews”
Manuscript Number: 2427546749546026

Title: “Post-Marketing Surveillance for Percutaneous Transluminal Coronary Angioplasty Catheters: A Systematic Review”

Polisena et al. present the resubmission after revisions of an interesting systematic review aiming to explore the medical literature regarding adverse events and malfunctions associated with the use of percutaneous transluminal coronary angioplasty (PTCA) catheters in clinical practice among patients with coronary artery disease (CAD).


General comments
The work presented in this manuscript is of clinical relevance, however, even after revisions there are still several issues that should be improved or corrected if the manuscript is to be published.

From the comments that follow, six of them are still “major compulsory revisions” (comments 1, 2, 3, 4, 9 and 10). All other points are just comments or “discretionary revisions”.

Introduction
1. The objective of the study is still not adequately described. In this particular case, if a restriction has been imposed on publication date of included studies, this should have been mentioned.

Author’s response: The study objective has been revised to as follows:

The primary research objective is to systematically review the published medical and grey literature between 2007 and 2012 for post-marketing surveillance studies on the frequency of incidents and malfunctions associated with the use of PTCA catheters in clinical practice among patients with CAD.
Methods

2. The literature search methods did not include search for abstracts in proceedings of relevant scientific conferences or scientific meetings. Given that the authors aim to review the medical literature for adverse events and malfunctions associated with PTCA catheters, this is a very important limitation. The authors claim that they have excluded abstracts because they provide insufficient information. It is hard to believe that was the case for every abstract, particularly if the authors have had really tried to contact the authors of the abstracts to obtain additional information. Even if all abstracts fail to be informative, it would be preferable to include them and explain that no further analysis could be performed because of insufficient information.

Author’s response: The authors acknowledged that abstracts were excluded from the literature search strategy and included the following statement in the Discussion section.

As our primary study objective was to review the PMS studies in the medical and grey literature published between 2007 and 2012, we did not contact the authors of the included studies to obtain additional details. The limited information available in some of these studies is indicative of the inadequate reporting of PMS associated with the use of PTCA catheters in patients with CAD in the medical and grey literature.

3. Regarding the search strategy used in electronic databases, although the authors claim that they have included a supplemental table with the complete literature search strategy, I have not found such a table in the supplementary material.

Author’s response: We apologize for this omission. The complete literature strategy has been added.

4. The authors decided to limit their search to French or English language papers. This is a major limitation. Although the authors cite in their discussion section a study claiming that this is not a major issue, the fact is that there is a large body of evidence showing that exclusions based on the language of publication are a major limitation in systematic reviews. In this particular case, and given the study aims, there are no solid grounds to justify exclusions based on language of publication.

Regarding the conclusions of the paper by Morrison et al. cited by the authors, I call your attention to the following two statements (A and B) in the discussion and conclusion of this paper:

A – “One limitation of this review is that no studies examined single fields of medicine, preventing analysis of LOE (languages other than English) trials in particular specialties. Egger et al. demonstrated that LOE trials are important in psychiatry, rheumatology, and orthopedics (4). Pan et al. concluded that Chinese studies are crucial in molecular medicine (18). These studies indicate that the
influence of LOE trials in different specialties may vary. Although the primary computation of RORs in several included articles did not identify significant changes in overall pooled measures of effectiveness, stratified analyses showed the impact of LOE trials is heterogeneous across medical specialties and there are more LOE trials in some areas of medicine (11;12;19).”

B – “These findings do not rule out the potential for language bias when language restrictions are used. Searches should include LOE studies when resources and time are available to minimize the risk of a biased summary effect. More research, in different medical specialties, will provide better evidence on the effect of language restriction on systematic reviews.”

Additionally, what Morrison et al. describe is that eventually in some areas the pooled estimates of effects in systematic reviews with language restrictions may be unbiased. That is not the same thing as saying that the inclusion of studies in other languages is not important. By the contrary, in systematic reviews about adverse events all reports are crucial, because you are more interested in finding all adverse events than in presenting an unbiased estimate of an effect (in this case you have confirmed that you are not trying to estimate an effect).

As to the rest of the existing evidence that indicates that language exclusions in systematic reviews are major limitations, please see, for example, the following studies:


Although the scarcity of resources may be attenuating, the language restriction remains a major limitation of the present manuscript.

Author’s response: We added the following statement in the Discussion section:

Studies were also restricted to English and French publications due to limited resources and time restrictions. Although Morrison et al. found no systematic bias when English-language restrictions were imposed in systematic reviews, we acknowledge that some bias may still exist by imposing language restrictions in the literature search strategy as further research is required in this area.[37] It is, however, unlikely that we would have found a sufficient number of studies in other languages to change our conclusion about the gap there is between the number of reports in the published medical and grey literature and the number of reports from the FDA as the gap is significant.
5. The authors have adequately explained why they decided to limit their search to studies published between 2007 and 2012.

Author’s response: Thank you for your comment.

6. The authors have adequately explained that they have indeed included Case series and case reports.

Author’s response: Thank you for your comment.

7. The authors adequately included considerations regarding the operational definitions of adverse events or malfunctions used in the included studies. They have included this as part of the selection criteria.

Author’s response: Thank you for your comment.

8. Regarding the methods for selection of studies, the authors have adequately improved the description of the screening phase.

Author’s response: Thank you for your comment.

Results
9. The justification for not having performed the assessment of study quality for almost half of the included studies is insufficient. A more serious effort to contact authors of included studies to obtain more details should have been undertaken and described. The justification presented by the authors is not sufficient. There are indeed reporting guidelines and checklists for quality assessment of case series or case reports that could have been used. The fact that these studies do not test hypothesis is not a justification for not assessing their quality.

Author’s response: The authors were unable to identify a validated quality assessment tool for case series. We did come across the following oral presentation, “Validation of a quality assessment checklist for case series studies” scheduled for September 23rd at the Cochrane 2013 Colloquium by Bing Guo (http://colloquium.cochrane.org/fr/abstracts/validation-quality-assessment-checklist-case-series-studies). Suggestions for validated quality assessment tools for case series studies would be most welcomed.

Discussion
10. The authors confirm that they did not make an effort to contact authors and obtain additional information about included studies. That is a major limitation given the limited information in some of the included studies.

Author’s response: The authors included the following statement in the Discussion section.
As our primary study objective was to review the PMS studies in the medical and grey literature published between 2007 and 2012, we did not contact the authors of the included studies to obtain additional details. The limited information available in some of these studies is indicative of the inadequate reporting of PMS associated with the use of PTCA catheters in patients with CAD in the medical and grey literature.

Title
11. The study objective has been changed and now adequately matches the study title.

Author’s response: Thank you for your comment.

Abstract
12. The study abstract seems globally adequate, however it may have to be changed as a consequence of the previous comments.

Author’s response: Thank you for your comment.

Level of interest: An article of importance in its field

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 competing interests.