Reviewer’s report

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

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Reviewer: Luis F Azevedo

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Manuscript Review for “Systematic Reviews”

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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.

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.

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.

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.

5. The authors have adequately explained why they decided to limit their search to studies published between 2007 and 2012.

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

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.

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

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.

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.

Title
11. The study objective has been changed and now adequately matches the study title.
Abstract
12. The study abstract seems globally adequate, however it may have to be changed as a consequence of the previous comments.

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.