Reviewer’s report

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

Version: 2 Date: 11 June 2013

Reviewer: Luis F Azevedo

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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 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).

The study question is relevant because, although PTCA is an intervention used in clinical practice for a long time, its safety profile and continuous safety monitoring are still scantily explored in the biomedical literature.

The study question is original, given the non existence of a previous systematic review covering this particular issue.


General comments

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

From the comments that follow, seven of them are “major compulsory revisions” (comments 2, 3, 4, 5, 7, 10 and 14) and six of them are “minor essential revisions” (comments 6, 8, 9, 12, 18 and 19). All other points are just comments or “discretionary revisions”.

In general, the level of the written English is excellent.

It would be helpful for the reviewers if the pages of the manuscript were numbered.

Introduction
1. The authors adequately present the scientific background and justification of the research question.

2. The objective of the study is not adequately described. In this particular case, if a restriction has been imposed on publication date of included studies, this should have been mentioned (please see comment 6 below). Moreover, if the authors aim to explore only post-marketing surveillance studies, this should also be mentioned (please see comment 10 below).

Methods

3. 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 seems to be an important limitation because in many instances this data are regarded by many authors as less important or not deserving full-text publications.

4. Regarding the search strategy used in electronic databases, although the authors adequately describe the main search concepts used, it would be desirable to include a more complete account of the full search queries as supplemental material (available only online).

5. 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.

6. The authors also decided to limit their search to studies published between 2007 and 2012. Although this may not be a major limitation, the authors have to explain more thoroughly the rationale behind this decision. They explain this decision very briefly in the discussion section, but they should also include an explanation in the methods section and change their study objective accordingly. Moreover, the authors should explain if any major changes in the procedures or technologies have occurred that justifies this decision, otherwise this may not be sensible.

7. Unlike systematic reviews about efficacy of interventions, a systematic review aiming to explore the literature regarding adverse events and malfunctions of an intervention should not exclude case reports or case series. In this case there are no solid grounds to exclude this type of studies. It is very well known that in many instances this is a frequently used method to disseminate important information regarding these issues. Although this kind of studies do not give adequate quantitative data regarding events frequency, they are important formats to describe new or more severe adverse events. Moreover, the authors explain in the data analysis section that they aim to present the literature on the subject and not to test any quantitative hypothesis.

Furthermore, although the authors claim to have excluded case series, the
included study by Al-Lamee et al. 2011 is described in table 1 as a retrospective case series and in the results section the authors say that “Three studies were retrospective case series”. Please explain these apparent contradictions.

8. Selection criteria could have included considerations regarding the operational definitions of adverse events or malfunctions used in the included studies.

9. Regarding the methods for selection of studies, the authors should more thoroughly explain how they performed the screening phase (title and abstract assessment?) and ideally also describe reasons for exclusion in this phase.

10. It is not understandable why the authors have decided to exclude studies conducted to demonstrate effectiveness and safety of the devices for market approval, given their stated objective. Please explain the rationale behind this decision in a systematic review that aims to review the literature regarding adverse events and malfunctions of PTCA catheters. Why aren't those studies relevant? If the answer is because the authors aim to explore only post-marketing surveillance studies, then this should be part of the study objective as well.

11. Data extraction should have been performed by two reviewers.

Results

12. Study selection process is briefly described and could be improved (please see comment 9).

13. General and methodological characteristics of studies are briefly but in general adequately described.

14. 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.

15. Results and characteristics of individual studies are briefly but adequately presented in table 1. This is an important table, with relevant information.

Discussion

16. Study conclusions are somehow adequate, but could be changed as a consequence of previous comments.

17. Study limitations are presented, however they should be changed as a consequence of previous comments.

18. In the second paragraph of the discussion the authors write:

“Even for short term studies, the reporting of procedure and device related adverse events was inadequate. For example, several studies did not identify a denominator so that a hazard or risk ratio could be determined. It is unlikely that contacting the principal investigators of the published studies would have yielded in additional insights with regards to the safety of the use of PTCA catheters.”

Regarding the first two sentences, it would be important to clarify if the objective of the study is to systematically review the literature about (the existence of)
adverse events or about the quantitative estimates of the frequency of occurrence of adverse events. Only in the second case would the absence of a denominator be a major limitation.

Regarding the last sentence, it is not understandable why the authors come to this conclusion. Does that mean that the authors did not make an effort to contact authors and obtain additional information about included studies, whenever that was needed? If that is the case, it would be a major limitation.

19. Again in the second paragraph of the discussion the authors write:

“Although the selection criteria did not distinguish between premarket approval and PMS data, we were unable to identify studies that demonstrated the safety of the use of medical devices for market approval despite our comprehensive medical and grey literature search strategy.”

In general, this sentence needs clarification. Specifically, it is not clear why the authors say that “selection criteria did not distinguish between premarket approval and PMS data”, when they indicated in their methods section that “studies conducted (...) for market approval were not included in this systematic review”. Please clarify.

Title

20. The study title is adequate, however, there is no exact agreement between the title and the study objective.

Abstract

21. 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.