Reviewer's report

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

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Reviewer: Mariska M. G. Leeflang

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Major compulsory revisions

1. Under Objectives, the authors state: “The primary research objective is to systematically review the medical literature for adverse events and malfunctions associated with the use of PTCA catheters in clinical practice among patients with CAD.” From the last few sentences of the Background, I read that their actual aim is to “determine whether the published medical literature is a useful source of information to estimate the safety of the use of PTCA catheters.”. If this is correct, shouldn’t the latter then be the objective as well?

2. Because the success of this study or the accomplishment of the aim (to determine whether published literature is a useful tool) is very much depending on the completeness of the data retrieved, it would be very helpful if the authors could show the complete and detailed search strategies (including the exact search terms), at least for one of the electronic databases.

3. There is some inconsistency in terminology. The authors start by stating that they are interested in the value of published literature, but they also include grey literature (which is defined by some others as being unpublished literature), and in their discussion they state that “a systematic review of the medical literature” is not useful for this purpose, without stating whether these systematic reviews should only include published articles or also unpublished articles. I think that it will make a difference when assessing the ability of systematic reviews to provide useful information about harmful events, if one includes only published articles or also unpublished data.

4. It would also be very helpful if the authors could explain a little bit more elaborate what kind of studies they were looking for. They include RCTs, case-controls studies and cohort designs, but no case series. That implies that they are looking for comparisons, presumably comparisons between a device and its alternative. But from the background, it could be implied that they are not necessarily looking for comparisons. Could the authors describe in the methods section what the outcomes are that they expected to find and what the comparisons were that they expect to find?

5. Please provide a bit more information about the SIGN50 quality assessment tool. Is it specific for adverse events studies? If it is mainly developed to assess the quality of effectiveness studies, then it may not be the most appropriate tool
to assess quality of adverse event studies.

6. Results: “Three studies were retrospective cases series”, while under Methods they claimed that they would not include case series…

7. I am not sure if the Data analysis and Synthesis section is very helpful. It only reports percentages (so no relative or comparative measures) for a number of outcomes. I cannot indicate whether these percentages are high or low, or what their impact on practice would be.

8. Discussion section. “Our study highlights that a systematic review of the medical literature as a method to identify potential safety issues with the use of medical devices or device ruptures is inadequate.”. I am not sure if this is indeed the case. If one would extrapolate the percentages found in these studies to the total numbers of patients using these devices, wouldn’t you come close to the numbers of adverse events as reported by the manufacturers? And if you just want to know what kind of adverse events would occur, wouldn’t that be helpful?

9. Do the authors think this conclusion holds for all adverse events questions? They say a bit about one other example, but there may be many more existing systematic reviews of adverse events. Are they all as useless?

10. “In addition, the inclusion criteria were defined by the published and grey literature. It is, therefore, a challenge to accurately estimate the extent of adverse events and device malfunctions in clinical practice based solely on the medical literature.” I don’t understand these sentences. Please rephrase.

Discretionary revisions

11. Abstract, Background: “In addition, PMS studies may be mandatory or voluntary.” I don’t see the rationale behind this sentence, can it be removed?

12. Abstract: “In 2011, 1,942 adverse event reports related to the use of PTCA catheters were submitted to the FDA by the manufacturers, an increase from 883 reported in 2008.” I don’t see the rationale behind this sentence, can it be removed? Or just state that the number of adverse events reports has increased?

13. “Instead, most applications undergo a 510(k), where manufacturers claim that their device is as safe and effective as the comparator device available on the market.” What is a 510(k)?

14. “The patient outcomes for 1,662 adverse events reported in 2011 remain unknown.” Does that mean of the other 1,942 minus 1,662 = 280 the patient outcomes are known? And what are these outcomes? Do they correspond with the outcomes found in the included studies in the review?

**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