Author's response to reviews

Title: Reporting of harm in randomized controlled trials evaluating stents for percutaneous coronary intervention

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We should be grateful if you would consider our manuscript for publication in Trials.

Concerns have been voiced recently regarding the long-term outcomes and safety of drug-eluting stents, leading to wide debate on the real efficacy and safety of this new technology. This debates raises the issue of the assessment and reporting of harm in randomized controlled trials evaluating stents. Previous studies have shown that data pertaining to harm are underreported in articles on randomised controlled trials. Further, compared to reports pertaining to drugs, reports of trials assessing nonpharmological treatments more often lack descriptions of harm. Our study systematically appraises the reporting of harm in randomized controlled trials evaluating stents for percutaneous coronary intervention and shows that several harm-related data were adequately accounted. Some data such as data on Data Safety Monitoring Board should be improved.

I confirm that I had full access to all of the data in the study and had final responsibility for the decision to submit for publication. All authors have read and approved submission of the manuscript. The manuscript is an original work is not being considered for publication elsewhere and none of the contents have been previously published. All authors have participated sufficiently in the work to take responsibility for its content.

We hope that the enclosed article is of interest to the readers of Trials.

We look forward to hearing from you.

Yours sincerely

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