Author's response to reviews

Title: Assessment of data quality in an international multi-centre randomised trial of coronary artery surgery

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Author's response to reviews: see over
Reviewer 1.

Dear Professor Nixon,

We appreciate your thoughtful review of the manuscript. Please find below responses to the points raised.

Q1: Table 2. We have clarified that the timelines compared were to time “data received”, sorry for any confusion.

Q2: Table 3 gives the reader a general insight in subjects’ characteristics. However as you correctly point out this data is not directly relevant to the analysis of the data quality we have removed the table.

Q3: Thank you for suggestion to include more data regarding recruitment of subjects. We have added this information to the second paragraph in the Results. The total recruitment period was 42 months. Only 6 centres recruited patients for 3 years or more. The median number of months for recruitment was 28 (range: 3 – 42) (32 for ‘Developed’ and 22.5 for ‘Developing’; p<0.001).

Q4: Our stated intention was not to identify centres or countries from which data were gathered. Those two outliers represent the same centre which recruited only a few patients. That site had no previous experience in participation in a multicentre trial. Possibly that’s why so many queries were generated shortly after the CRFs had been received. They were corrected by the centre soon after edit queries had been generated by CTEU. As presented in figures, those ‘dirty’ data had a significant impact on the statistics from that centre. Globally, due to limited number of subjects those data had no important impact on our conclusions, even for ‘Developing’ countries. Those data had also no impact on recruitment rates on general. However we need to be cautious in the further analysis of data.

Q5: The ethnicity of the patient was recorded by each site. The majority of Caucasians in the ‘Developing’ group were from Poland (596), 87 patients from India were South Asian and the remaining subjects come from Brazil. As we intended not to reveal data regarding centres or countries so as to remove any confusion about ethnicity we decided to remove Table 3. For your information, we include a short figure below showing the median number of patients recruited by country (with interquartile range).
Q6: We divided countries on the basis of their economic level according to the World Bank data. We are aware of the fact that the type of generalisation we used may be imperfect but it parallels the experience of countries participation in multicentre trials. In the “Developing” countries, 77.8% of subjects were from Poland, 10.7% were from Brazil and 11.5% were from India. We believe that these numbers are sufficient to make reasonable conclusions.
Reviewer 2.
Dear Dr Matata,
We appreciate your thoughtful review of the manuscript. Below we append our responses to your points raised.

Q1: Thank you for your comment regarding inclusion of the findings from other large trials. The point is that the novelty of our study is to assess data quality in the multicentre international trial. To our knowledge, this paper is the first that has made an attempt to estimate and publish the magnitude of failure in data management in such a trial. According to your query, issue by issue, we reviewed papers published in two top journals in clinical trials (Trials + Current Controlled Trials in Cardiovascular Medicine, and Clinical Trials) in the recent 6 years. To make it more effective, we broadened our search in MEDLINE using ‘data’ + ‘quality’ as the key words. Unfortunately we found no more than 3 original papers that met the inclusion criteria. None of them reflects the results from a cardiac (surgery) trial, however we have added these trials to the ‘Discussion’ (references 12, 13 and 14)

Q2: All information regarding study design and management have been already published in ‘Trials’ and therefore we did not discuss in detail in this current manuscript. However, as requested we have added some further detail regarding the study design and management to the ‘Methods’ section.