Author's response to reviews

Title: SUrgical versus PERcutaneous Bypass: SUPERB-trial; Heparin-bonded endoluminal versus surgical femoro-popliteal bypass; a multicentre randomized controlled trial: design and rationale

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Author's response to reviews: see over
Dear Editors,

Thank you for the interest shown in our article. Please find enclosed the revised version of this manuscript, which incorporates all the changes that you advised.

Answers to the reviewers comments

Overall, this is a straightforward randomized trial comparing surgical to endovascular fem-pop bypass. I have only relatively minor comments, which are nevertheless compulsory to address.

1. The wording for the power calculation was unclear: “The power analysis was based on a non-inferiority principle, with an effect size of 90% and 10% margins (alpha 5%, power 80%).” Effect size usually refers to the difference between the control and treatment group. Does 90% refer to the estimated patency rate at one year in the control (surgical) arm? Please clarify the protocol.

Reply: The reviewer is correct. The 90% refers to the estimated patency rate at one year in the surgical arm. This information has been added to the text.

2. This study has two primary aims. One is a non-inferiority aim. The other is a superiority aim. The statistical analysis should show power calculations for both primary study aims.

Reply: The requested information has been added.

3. The subgroup analysis is a bit unclear. Usually, subgroup analyses are conducted to explore the possibility of heterogeneity of treatment effect (i.e. differences in the treatment effect across subgroups). In this case, the subgroup analysis refers to analyzing a different outcome only within a subset of patients. A non-inferiority trial analyzed only on a subsample of patients is very likely to show non-inferiority in that subset, if only due to lack of power. The authors
should estimate the power for this subset analysis, or (probably more appropriate) clearly label these analyses as exploratory (hypothesis generating, not hypothesis testing).

Reply: We agree with the reviewer that these analyses are exploratory and thus hypothesis generating. We have added this information to the manuscript.

In addition to the above comments, the authors should carefully review the writing, as there are grammatical issues that degrade the clarity of the writing in several sections. Also, please make sure that all the abbreviations are fully spelled out at first use (e.g. TLR (in abstract), PSV, etc.).

Reply: The spelling and abbreviations have been checked.

We agree that our manuscript has become more concise and thereby improved following your clues.

Again, I would like to thank you for your interest in our manuscript.

Yours sincerely,

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