Author’s response to reviews

Title: Single-center evaluation of a next generation fully repositionable and retrievable Transcatheter Aortic Valve Replacement

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Response to editor

1. We feel that your study falls within the International Committee of Medical Journal Editors (ICMJE)’ definition of a clinical trial: any research study that prospectively assigns human subjects to one or more health related interventions to evaluate the effects on health or biological outcomes. As such, Biomed Central requires that a Trial Registration Number is provided in order for the manuscript to be published.

Although a TRN is usually required prior to the start of the peer-review process, the BMC-series journals does accept retrospectively registered trials. If you have not registered the trial, we therefore request that you do so as soon as possible so that your study can be accepted for publication. All trials must be registered with a WHO approved registry, as listed in the WHO guide: http://www.who.int/ictrp/network/primary/en/.
Once you know your trial registration number, please submit a revised version of your manuscript with the number and date of registration included in the abstract. The last section of the abstract should be Trial Registration: listing the trial registry and the unique identifying number, e.g. Trial registration: Current Controlled Trials ISRCTN73824458, as well as the date of registration. Please note that there should be no space between the letters and numbers of the trial registration number. If registration took place after the first participant was enrolled, please state also “Retrospectively registered” at the end of this section.

RESPONSE: The trial has now been registered at ISRCTN, reference number 34395. Since the registration does take some time, we have not at the time of submission received the trial registration number and have thus not put it in the manuscript. We will revise the manuscript accordingly when we receive the registration number. We have added a line to the abstract, page 2: “Trial registration: Current Controlled Trials ISRCTNXXXX, retrospectively registered 06/11/2017.”

2. Please include the full name of the ethics committee (and the institute to which it belongs to) that approved the study.

RESPONSE: Lund University Ethics committee, Lund University. This has been changed accordingly.

3. Please indicate whether consent to participate was obtained and if so how informed consent was given.

RESPONSE: No specific consent was obtained. The rationale was as follows: In the percutaneous valve registry part of the SWEDHEART national quality registry, clinical and procedural variables including follow-up is input into the registry. Since the main indication for using the quality registry (and conducting this trial) is quality assurance of a procedure and/or a new technique, an informed consent is by Swedish standard not necessary (since no change of therapy has occurred). For this trial, data was identical with what was input into the registry, analyzed and put into a manuscript.
4. We would also like to ask for you to provide more justification for the contributions of JH, HB and SN, as currently they do not automatically qualify for authorship.

RESPONSE: We apologize for being too brief in our statement of author contributions. This was indeed a collaborative project from the entire group. We have changed accordingly to clarify. All authors fulfill the ICMJE-guidelines for qualification as an author.

Page 4: “HB, MG and JH designed the study. JH, HB, KB, MG, SK and SN collected the study data. KB, MG and SK performed the main analyses. All authors were involved in drafting and/or critical revision of the manuscript. All authors have given final approval of the manuscript and have agreed to be accountable for all aspects of the work”.

5. In accordance with BioMed Central editorial policies (http://www.biomedcentral.com/submissions/editorial-policies#standards+of+reporting), could you please ensure your manuscript reporting adheres to CONSORT guidelines (http://www.consort-statement.org/) for reporting clinical trials. This is so your methodology can be fully evaluated and utilised. Please include a statement within your manuscript to indicate that your study adheres to CONSORT guidelines and include a completed CONSORT checklist as an additional file when submitting your revised manuscript.

Please complete the checklist in full by inserting the page number/paragraph and section of your manuscript which reports the information that meets the criteria of the checklist. For example “Methods, paragraph 2”. If a criterion is not applicable for your particular manuscript/study, we can accept “N/A”.

Please note that checklists completed incorrectly will be returned for revision as we cannot progress your manuscript to peer review until the checklist has been completed.

RESPONSE: Since this is a non-randomized prospective registry, the CONSORT guidelines are particularly applicable. The CONSORT guidelines main application is randomized clinical trials where information on the randomization and blinding process are important. We have however upon request completed a CONSORT checklist to the best of our abilities. We have also added the following, page 6: “This study conforms to the CONSORT guidelines.”

6. At this stage, we ask that you submit a clean version of your manuscript and do not include track changes or highlighting.