Author’s response to reviews

Title: First clinical experience with the Kora pacemaker system in congenital complete heart block in newborn infants

Authors:

Stefan Kurath-Koller (stefan.kurath@medunigraz.at)
Sabrina Schweintzger (sabrina.schweintzger@medunigraz.at)
Gernot Grangl (gernot.grangl@medunigraz.at)
Ante Burmas (ante.burmas@medunigraz.at)
Andreas Gamillscheg (andreas.gamillscheg@medunigraz.at)
Martin Koestenberger (martin.koestenberger@medunigraz.at)

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Author’s response to reviews:

Dear reviewer,

Thank you very much for your carefully conducted review of our manuscript “First clinical experience with the Kora pacemaker system in congenital complete heart block in newborn infants”. We appreciate your comments and suggestions as they add important value to our paper and improve its quality significantly.

We addressed all points raised by you and provide a concise item based reply. Below please find detailed information on our response and all corrections made in the manuscript.

Reviewer #1:

1. General. The manuscript should be checked for typing and grammar errors.

The manuscript has again been checked for typing errors and language.
2. Complications. One of the patients required a pocket revision due to "skin traction and suture dehiscence," resulting in 33% complication rate. This is important to note and should be addressed in the discussion section.

As suggested, the complication rate of 33% has been inserted in the discussions section. It is of importance to outline this, relatively high complication rate despite using a small pacemaker system.

3. Development. The authors mention that Denver Developmental Screening Test was used and showed appropriate results. It might be interesting to provide these test sheets, i.e. as supplemental figures.

We now included Denver Developmental Screening Test sheets as supplementary figures 4-6.

4. Also, given that the authors praise the minute ventilation sensor, providing the patient histograms would be helpful.

We agree that patient histograms would be helpful to illustrate MV sensor function, unfortunately we cannot provide these. We apologize for the inconvenience.

5. Patient growth curves. Patients were stated to have appropriate growth, this would be interesting to see as a supplemental table.

We now included patient growth curves sheets as supplementary figures 1-3.

Reviewer #2:

1. Page 2, conclusion; The use of a pacemaker system with a maximum upper rate interval of 95 beats per minute in infants suffering from congenital complete heart block and showing high aortic VTI values seem to be sufficient for adequate growth and development.

The question is: what is adequate??? All neonates grew along their percentile curve: although it is difficult so extract exact numbers from the percentile curves, all infant grew along the 10th percentile (either in height or in weight): per definition: this is underweight.
We agree that our statement might be misleading. What we meant was that all children grew along their specific growth curves without dropping to lower centiles. We now included a statement to clarify this (page 5, line 4).

2. Page 3, VTI development; Authors hypothesize that the Kora pacemaker system allows for adequate growth and development in newborns and infants suffering from CCHB, as cardiac output adaption took place prenatally. The neonatal high aortic velocity time integral (VTI) might be an adaption mechanism parameter, however it would be highly interesting to see, how VTI develops during follow up.

VTI values remained constant during follow up and did not show an increase as with VTI values of regular infants. We inserted a corresponding statement. (discussion, line 7).

3. There is no evidence that the minute ventilation sensor function also works with epicardial leads.

We agree that this should be outlined. We included a statement on this fact (page 6, line 3).

4. There is no matched control group with infants paced with higher frequencies.

We agree that this is a limitation to our case study. We hope to be able to put together a study design including a control group in the future as this topic should be further investigated.

5. With a change of perspective this paper should be accepted for publication to force industry to provide better devices for these small patients - they do have the right for that!

Thank you for your clear words. We fully agree that children do have the right to be taken serious by the industry and that they deserve better devices more tailored to pediatric needs. We included a statement in the conclusion section.