Author's response to reviews

Title: Endotracheal intubation with Airtraq versus Storz videolaryngoscope in children younger than two years - a randomized pilot-study

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Author's response to reviews: see over
Dear Dr Hayley Henderson

Thank you for the opportunity to revise the manuscript: 2350810556584594.

Title: "Endotracheal intubation with Airtraq® versus Storz® videolaryngoscope in children younger than two years - a randomized pilot-study".

Please find our response to the referee’s comments below.

Comments from John Fiadjoe:

Comment: What data were they trying to generate that is not available in previous studies. Please state this in the manuscript.
Response: No data from a direct comparison between the Airtraq device and the Storz device in small children has been published before to our knowledge. To make it a fair comparison, one must test the devices in exactly the same environment, with the anesthesia standardized exactly the same way to eliminate as many biases as possible. We also believe that small children have distinct anatomical features in the upper airways special for their age group. Other studies have looked at broader age groups. The following has been added (in italic) to the manuscript:

The main objective of the pilot-study was to make a direct comparison of the Storz® Berci-Kaplan videolaryngoscope (SVL) (Fig. 1) and the Airtraq® Optical videolaryngoscope (AOL) (Fig. 2) using a Macintosh laryngoscope as reference for endotracheal intubation in small children with a normal preoperative airway assessment, thereby generating data that can be used for sample size calculations for larger trials in similar settings.

Section: Introduction; P: 4; L: 15

“In this report we present data from a direct comparison between the Airtraq® and the Storz® Berci-Kaplan videolaryngoscope in small children. In the narrow age group investigated, there are distinct features in the airway dimensions, where they differ from infants and older children. This could pose a challenge in the use of the two devices”.

Section: Discussion; P: 12; L: 3.

“A novel endpoint in the current study was the “ready to intubate” tube positioning. The introduction of this endpoint allowed the use of a paired statistical analysis on a procedural relevant endpoint without increasing the risk for the patients. However, this endpoint is a surrogate endpoint for intubation with limited clinical impact. In a similar but larger trial, we would therefore recommend the use of “time to intubation” or “success rate” in an unpaired design as primary endpoint with our data as the basis for the sample size calculation of a direct comparison between the Airtraq® and the Storz® Berci-Kaplan videolaryngoscope in small children.”

Section: Discussion; P: 12; L: 11.
Comment: The authors methodology is sound and unique.
Response: Thank you for the comment.

Comment: Why couldn’t pilot data be obtained by simply performing intubations with each device separately and documenting the desired outcomes rather than performing a comparative trial with such small numbers.
Response: According to Danish law, data-collection for research purposes must be approved by the Regional Ethics Committee, therefore our study had to have an ambitious protocol. We believe that the testing of the devices, also pilot-testing, must be done by independent investigators and according to a protocol in a transparent setting. Randomizing the intervention is important to eliminate selection bias and making the groups as comparable as possible even for a limited sample size. Paired analyses of several endpoints were possible due to the trial design, and it could limit the potential sample size of a larger trial if based on one of these endpoints in a paired setting. From an ethical point of view limiting the sample size, especially when considering that the patients are small children, would be desirable.

Comment: Please state somewhere in the manuscript that unintentional biases of the intubator could have influenced the results.
Response: We agree that this point must be clearly stated in the manuscript. The following (in italic) has been added to the manuscript:

“It was therefore decided to have only one consultant with extensive training in intubating small children with both devices, although unintentional biases of the intubator could have influenced the results.”

Section: Discussion; P:10 ; L:12.

We hope that the manuscript is now acceptable for publication.

On behalf of the authors
Yours sincerely,

Martin Kryspin Sørensen, MD