Author’s response to reviews

Title: A single-centre, randomised controlled feasibility pilot trial comparing performance of direct laryngoscopy versus videolaryngoscopy for endotracheal intubation in surgical patients

Authors:

Alice Loughnan (a.loughnan@nhs.net)
Carolyn Deng (caro.deng@gmail.com)
Felicity Dominick (fliss_dom@hotmail.com)
Lora Pencheva (lioliu_nz@yahoo.com)
Douglas Campbell (d.campbell@adhb.govt.nz)

Version: 1 Date: 23 Nov 2018

Author’s response to reviews:

Reviewer #1:

This research is a randomised controlled trial comparing the first-pass intubation success of videolaryngoscopy and direct laryngoscope. Although this research results are very interesting, the author need to review the research method again. Moreover, the author should study how to write manuscripts.

Major points

1. Although, the author argues that "studies with 50 to 200 participants have small sample sizes”, the participants of this study are as low as 100 people at maximum. Although the author is criticizing the low number of samples of past research, it is difficult to understand that this research is also using a similar number of samples.

Response: The sample size is justified on page 7 para 3, using standard methods for estimating sample size in pilot and feasibility trials. Previous studies were standalone RCTs that were underpowered to estimate the treatment effect in the comparison of the two interventions. The aim of our study was to test feasibility prior to conducting a large, adequately powered RCT that will accurately estimate the size of the treatment effect. Our aim is not to hide a small, underpowered study and label it as a pilot or feasibility study. As a research group we have a
track record of conducting pilot trials and following up with large multicentre RCTs 1,2. We are currently in the planning stage for a multicentre RCT with a sample size of 980 based on the results of this pilot trial. Members of this group are currently involved in recruiting for three multicentre RCTs that were based on pilot trial data.

2. The purpose of the study is unclear.

Response: We have reworded the final paragraph of the Background to make this clearer. It now reads “The aim of the study was to assess the feasibility of a larger, multicentre randomised controlled trial. Feasibility outcomes were recruitment rate, acceptability of the trial protocol, eligibility criteria, and data completeness. In addition, we estimated first-pass intubation success rate for assistance in future large trial sample size calculation.”

3. Despite claiming that "Evidence relating to different videolaryngoscopic techniques, such as direct versus indirect VL, also require further examination, as devices with different designs are unlikely to perform equally", different videolaryngoscopy (Glidescope and McGrath) are combined to give statistical results. This is a clear bias. The greatest advantage of randomised controlled trial is that it can get rid of such bias.

The authors should statistically processed by comparison between the three groups of Glidescope, McGrath and direct laryngoscope.

Response: This type of subgroup analysis is appropriate for an adequately powered large trial. We plan to perform such a subgroup analysis in our subsequent large trial. The pilot trial provided useful information regarding our description of VL devices and whether it is appropriate to group them for analysis. We have amended the protocol for the large trial to include indirect VL devices only. The planned large trial is comparing techniques but we have planned an a priori subgroup analysis based on device. This is not an appropriate comparison in a pilot trial where subgroup size is insufficient to make meaningful comparisons and is not the aim of the trial eg demonstrating feasibility for a large trial.
4. The author should study how to write a paper.

For example, the contents described in Background in abstract section and Background in body of paper are different.

Response: Thank you for noticing this. We have amended the Background in the abstract to align with the Background in the main paper. It now reads “Most trials comparing effectiveness of laryngoscopy technique use surrogate endpoints. Intubation success is a more appropriate endpoint for comparing effectiveness of techniques or devices. A large pragmatic clinical trial powered for intubation success has not yet been performed.”

Reviewer #2: An interesting proposal yet being investigated several times and with many works available, including few RCT.

My major concern is the power of the study and the overall aim of the study since it is not clear what a study with 100 subjects will add to determine one or other inferiority or not inferiority. It is known that unless recruiting more a large cohort no significant findings cannot be found.

Response: We believe we have responded fully to this comment in our reply to Reviewer comment 1 above