Reviewer’s report

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

Version: 1 Date: 22 Dec 2018

Reviewer: Luis Enrique Colunga Lozano

Reviewer's report:

Peer Reviewer description

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

The following document is a revised version submitted to the journal of Pilot and Feasibility studies.

Suggestions to the authors

Comments from each section.

Abstract. The abstract might be improved. The study is label as a Feasibility RCT, however, the authors can use the CONSORT checklist for reporting RCT in journals and conference abstract or the extension for abstract related to the pilot and feasibility trials (available at the equator network website). I would suggest to the authors to use one of the two reporting checklist and include the items that are missing (For example: Funding). (1)

Background. I would suggest to the authors to increase the description related to the Lewis reference (Cochrane Review). This information might be useful for the reader (For example: number of included studies, number of participants, effect estimates related to the study proposal). This suggestion might be overlook if the authors consider that is not necessary (this information is mentioned in the discussion), however, it might be useful also in the background.

Methods:
I would suggest to the authors to use the reporting guideline published by Eldridge et al. for pilot and feasibility trials (CONSORT 2010 statement: extension to randomized pilot and feasibility trials.). (2)

- Trial design: No comments.
- Participants: No comments.
- Intervention: No comments.
- **Outcome:**

  The authors mentioned this information in the discussion, however, it might be useful to report some of this with more detail in the outcome section. "Although outcome assessors were also unblinded to the technique, the primary and secondary outcomes were objective measures, limiting the relevance of blinding at this level" How many researchers were involved in the outcome assessment? Does the authors tested the agreement between the outcomes assessors? What type of objective measures does the authors are referring?

  - I would suggest to the authors to create a subheading for the outcome section. For example. Primary endpoints, Secondary endpoints and feasibility endpoints. This might facilitate the reading process. This suggestion might be overlooked by the authors’ because the information follows the propose structure.

- **Sample size:**

  o In the online registry the authors reported the following description related to calculate the sample size calculation: "We estimate a total of 100 patients will be adequate to test feasibility endpoints but not adequate for the primary endpoint. We estimate from previously published data that the first-pass intubation rates will be approximately 85%. We believe a clinically important absolute difference would be 5%. To find a 5% absolute difference between the performances of laryngoscopy blades we calculated that the sample size of 1480 (alpha= 0.05 and beta= 0.2) or 1940 (alpha=0.05 and beta 0.1) would be needed. Please refer to table in attachments section on page 9 to see calculations."

  o Please provide more information about what statistical measurement was used to calculated the confidence interval approach, Is not clear if the authors replicate the one-side 80% Confidence interval approach. What effect size was used to calculate the sample size? Does the authors used the continuous or binary outcomes recommendations?.

- **Randomization:** Please clarify the following. In the online register the randomization was describe as "Permuted block randomization", in the manuscript is only mentioned as blocked randomization. Also, please describe who performed the randomization process, the randomization was done by a third party?.

- **Blinding:** In the discussion section is mentioned that the outcome assessors were not blinded, this needs to be reported in this section "Although outcome assessors were also unblinded". Also, Does the statistician was unblinded?

**Results:** No comments.

**Discussion.** The discussion section reflects the requirements by the CONSORT statement (limitations, generalisability and interpretation) The following suggestions can be overlook by the authors’, these ideas came to my mind while reading the authors manuscript.
- "Wide range of expertise between the centers for the future trial". Does the authors are considering to use a expertise-based randomized controlled trial design?

- "There is a learning curve for both DL and VL before technical proficiency is achieved". How the authors are going to handle and identified if the recruitment centers had a proper learning curve?. How this situation will be re-evaluated?

- How the authors will handle or minimize the deviation from the protocol?

- Blinding issues: Does the authors are planning to blind the outcome assessor or the statistician for the future trial?

Conclusion. No comments.

Warm regards

Luis C.

Suggested references:


Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable
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Were you mentored through this peer review?

No