

Peer Review File

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Reviewer A

OVERVIEW

The purpose of the present study was to evaluate the incidence of unplanned tracheostomy change and identify the reasons for it. The manuscript describes a retrospective observational cohort study at a single center of patients with COVID-19 with tracheostomies. Overall, I found the paper of great interest since the institution uses the Shiley Flexible Adult Taperguard Tracheostomy, and there have been anecdotal reports of suboptimal seal and positioning. However, several revisions are recommended to improve the clarity and structure of the manuscript.

STRENGTHS

1. Interesting topic

SPECIFIC COMMENTS

Introduction

1. Line 36. The references could be combined to “16-19”.

Reply: Thank you, this has been changed

2. Line 37. Quotations can be added to “late” to replicate “early”.

Reply: Thank you, this has been added

3. Lines 51-61. The added information here could be shortened and written more succinctly.

Reply: Thank you. This section is an expansion of the original manuscript in order to reflect the suggestions of the first-round review. We have instead made this part of the text its own paragraph in the hopes that this will both address the other Reviewer’s initial suggestion for more detail, and your own suggestion of increasing clarity. We feel it reads better as a standalone paragraph. (Lines 52-63)

4. Lines 77 and 80. Recommend removing the commas in these lines.

Reply: Thank you, these have been removed

5. Line 82. Please, change to “...placement, irritation, or patient...” for correct grammar.

Reply: Thank you, this has been changed as suggested

Methods

6. Line 110. “Decruitment” is misspelled.

Reply: This has been changed to “derecruitment”

7. Line 111. This phrase is confusing and can be removed.

Reply: Thank you, this line has been removed

8. Line 113. Recommend capitalizing Insertion Method for consistency.

Reply: Thank you, this has been done

9. Line 124. Please, clarify what you mean by “both surgical tracheostomies.”

Reply: Thank you, this had been clarified:

Changes in the text: The two patients who required surgical tracheostomies had these performed in the operating theatres.

10. Lines 124-125. This is a run-on sentence. Please, correct.

Reply: Thank you, this has been changed as above

11. Line 136. WHO and CDC words can be removed since these abbreviations are not used anywhere else in the manuscript.

Reply: These have been removed

12. Line 141. Recommend including how often cuff pressures were checked. It may also be useful information to add cuff pressure readings for patient who required an unplanned tracheostomy change, if known, in the results section. This may be an indicator of cuff leak requiring overinflation.

Reply: Thank you. Cuff pressures were monitored and recorded 4 hourly and kept in the green zone of the manometer 20-30mmHg. Where leaks were apparent, cuffs were inflated to higher pressures to maintain tidal volumes. We have added this information directly into the manuscript on Lines 141 -143.

We agree that this information would likely have have added to the study, and perhaps a prospective evaluation of the exact volumes required to maintain a seal would have been informative. For this study, that data was not recorded.

Lastly, to provide clarity, local practice in the setting of a leak was as follows: overinflating the cuff was the first step in a strategy to temporize the situation, with a complete change of the tracheostomy being the last step though the exact volume of air required to maintain this new seal pressure was not recorded.

***Changes to the text:* Cuff pressures were monitored and recorded four hourly and kept in the green zone of the manometer 20-30mmHg. Where leaks were apparent, cuffs were inflated to higher pressures to maintain tidal volumes. (Lines 141 -143)**

13. Line 152. The abbreviation PP has already been delineated previously. Recommend using the abbreviation throughout for consistency.

Reply: Thank you, this has been changed

14. Line 153. Recommend rephrasing “overall outcome of alive v dead” to “mortality rate.”

Reply: This has been changed as suggested

15. Line 160. Please, clarify why both means and medians were used.

Results

Reply: Table 1 consists of quantitative and qualitative variables. We used descriptive statistics to describe and analyze this data. In tables 3 and 4, we used the mean and median as an input for the inferential statistics. We have offered two separate versions of table 3 and 4 combined – one that keeps both and one that uses the mean for Fio2 and PP, and median for PEEP. Either would be acceptable.

16. First paragraph could be shortened and rewritten to improve clarity, including that 43 patients were included in the study analysis. Please, clarify the indication for the 2 surgical tracheostomies.

Reply: Thank you, we have made some alterations to the first paragraph for clarity. We have also clarified the indication for surgical tracheostomy. Changes in the text: Two tracheostomies were inserted surgically by ENT due to unfavorable anatomy and anticipated difficulty with the percutaneous approach.

17. In the 2nd paragraph: Please, clarify why the 4 patients who were transferred for tracheostomy insertion were excluded from analysis of ICU LOS and time to decannulation.

Reply: Thank you, this has been addressed with the following addition to the text.

Changes in the text: This was because, following successful tracheostomy insertion, these patients were repatriated back to their referring hospital for ongoing care.

18. Tables. Recommend consistent use of decimal points to the tenths place throughout. Per the methods section, determine if both mean and median values are needed.

Reply: Thank you, this has been done. Also, we have offered 2 versions of the same table as mentioned in reply to comment 15 above.

19. Table 1. Recommend changing the Outcome Alive/Dead to 6-month mortality rate. This table can also be renamed to Patient Characteristics and ICU Outcomes. There is an extra parenthesis after Time from admission to intubation (days)). In the last line, Secretions does not need to be capitalized. Recommend similar thorough editing throughout the tables for consistency.

Reply: Thank you, this has been addressed and changed as suggested. All decimals have been rounded to the nearest tenth.

20. Table 3 and 4 should be combined.

Reply: This has been done.

21. Table 5 is not necessary since the first row of data is already included in Table 1.

Reply: Table 5 has been removed as suggested

22. Line 232. Recommend spelling out 33 as it is starting a sentence.

Reply: This has been changed as suggested

23. Line 233. Recommend adding “and” before 10.

Reply: This has been changed as suggested

24. Line 239. If true, would add a sentence mentioning that none of the patients with an initial extended length tracheostomy underwent an unplanned change.

Reply: Thank you. As described in the same paragraph, 1 patient had a standard tracheostomy changed to an XLT and then further changed to a larger standard size. However, no patient with an extended length tracheostomy as their initial tracheostomy required an unplanned change. This has been clarified in the text with the additional line:

Change to the text: None of the patients who had an extended length tracheostomy inserted as their initial tracheostomy required an unplanned change.

25. Line 242. Recommend changing “patients” to “patient.” There are additional grammatical errors that need correction in the manuscript.

Reply: Thank you, we have sought to address these

26. Line 243. Please, clarify if changing the tracheostomy over a guidewire is standard local practice.

Reply: The text has been changed to confirm this.

Changes to the text: This is standard practice in our institution.

27. Line 268. Add that the overall mortality was 23.3% at 6 months.

Reply: This has been changed as suggested.

Discussion

28. Recommend moving paragraphs 5-11 to the beginning. The primary outcome is the rate of unplanned tracheostomy change so the discussion should start with this.

Reply: Thank you for this very helpful suggestion. We have done this, and re-arranged the references as required.

29. Line 327-328. Although tracheostomy selection is an individualized, patient-specific approach, it is also important to understand the properties of the tracheostomies available. Recommend including the known information regarding the Shiley Taperguard as mentioned in your response to reviewer E.

Reply: Thank you for this suggestion. Our reply to Reviewer E was using information known about taperguard type cuffs. In response, we have added the following line in the text:

Changes to the text: Regarding Taperguard type cuffs, Data provided from Covidien on their endotracheal tubes demonstrates high pressure contact area of the taper-guard cuff was 2.7 times lower the barrel cuff. This may be similar with tracheostomies and contribute to potential leaks at high pressures

Conclusion

30. Recommend starting with the 33% incidence of unplanned tracheostomy as this is the primary outcome. The first sentence currently is not the main purpose of the study.

Reply: Thank you, we have done this.

Reviewer B

This is a very long text with a negative relation to the information given. Please bring it to a shorter, concrete and solid presentation with a certain take home message. It is still confusing.

Please check the number of references. There are 88 references.

Reply: Thank you for the feedback. We have altered the flow by re-arranging paragraphs in the discussion as suggested by other reviewers. The take home message is the unexpectedly high incidence of clinically required tracheostomy changes, highlighting the need to carefully consider tracheostomy choice with regard to each patient.

If it is felt that the manuscript should be shortened, we could remove lines 43-51, however we feel it provides useful information regarding risks of aerosolization and transmission risks. However, in the context of the paper's central message, this could be removed if the Reviewers and/or editorial team felt it was beneficial to do so.

Reviewer C

Mine and the other reviewers' concerns regarding content have been appropriately addressed. There are a few changes that I would recommend to help with flow of information.

1. Lines 51-62, the additional information provided should probably be a separate paragraph of its own.

Reply: Thank you. We have done this as suggested.

2. I would place lines 241-245 in the materials and methods section, as it describes the generalized process of care rather than results. The end of line 245, "No adverse incidents were reported," could then be appended to the end of the previous paragraph at line 239.

Reply: Thank you for this suggestion. We have made these changes

Changes to the text: Lines 241-245 have been moved to materials and methods.

The end of line 245 has been appended to the previous paragraph.

Reviewer D

Thank you for the detailed responses to reviewer comments and revisions to manuscript text. The manuscript is much improved, with more comprehensive referencing and greater clarity regarding the methods. The only suggested edits that I recommend relate to syntax and style. In several cases, there is suboptimal sentence construction. For example, sometimes a comma is used where a period is needed (resulting in a run-on sentence). Below, I've suggested minor edits to improve clarity for readers.

1. Please fix the following typo: request change "This many increase" to "This may increase"

60 known risk factor for severe respiratory failure in Covid-19 (51). This many increase the technical

61 complexity of percutaneous tracheostomy, occasionally necessitating a surgical approach.

Reply: Thank you, this typo has been corrected

2. The last clause of the following excerpt is unclear. Perhaps consider replacing, "arising the change in a cohort" with "arising from the change in tracheostomy tube occurring in a cohort" or some similar revised wording.

Change in the text: Page 5, Lines 108 -111.

“This was done to determine if changing a tracheostomy led to any clinically relevant decruitment, characterized by increasing PEEP requirements and peak airway pressures, arising the change in a cohort of patients with high ventilatory requirements.”

Reply: Thank you. This sentence contains a typo was supposed to read “... arising from the change in a cohort of patients...” This was also highlighted by Reviewer A, who also found it unclear and confusing. In Response to Reviewer A, we have removed “arising the change in a cohort of patients with high ventilatory requirements” from the text.

3. Please replace the comma after "theatres" with a period. As written, the sentence to avoid a run-on sentence. Also I suggest changing "muscles, division" to "muscles and division"

124 Both surgical tracheostomies were performed in the operating theatres, a horizontal incision was

125 followed by dissection of the strap muscles, division of the thyroid isthmus to expose tracheal rings

126 2-4.

Reply: Yes, thank you. On review, there should be a period after theatres, and this has now been addressed. The word ‘and’ has now replaced the comma as kindly suggested.

4. Please correct the run-on sentence by replacing the comma after proximity with a period (or replace the comma with the word "and").

Changes in the text: Page 12, Lines 244– 245

“The ICU airway trolley was always in close proximity, no adverse incidents were recorded.”

Reply: Thank you, this has been corrected

5. Please correct the minor erroneous capitalization (the should be a lowercase i beginning the clause "in our institution")

Changes in the text: Page 13, Lines 270-272

“Regarding staff transmission, In our institution, each member of staff infected with Covid-19 underwent rigorous contact tracing. No cases of transmission were attributed to tracheostomy placement.”

Reply: Apologies for not spotting that typo before resubmission. It has now been corrected.

6. Please delete extra period at end of the text below (

Line 310 -314: “Leak was characterized by the audible air escape through the mouth synchronous with the highest inspiratory pressures seen during each respiratory cycle. Clinically important leak was associated with a significant loss of expired tidal

volume and failure to maintain airway pressures which was likely to lead to de-recruitment for the patient and environmental contamination for the staff..”

Reply: This has been corrected

7. I suggest changing "v" to either "vs." or "versus". Also please consider replacing the comma after the word decannulation with the word "and"

153 insertion. The follow-up time to determine time to decannulation, overall outcome of alive v dead

154 was 6 months post tracheostomy insertion.[oc9]

Reply: Thank you. In response to Reviewer A’s suggestion, we have removed ‘alive v dead’ and changed it to ‘mortality rate.’