Peer Review File

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Reviewer A

This paper asks does a fenestrated tracheostomy aid decanulation in patients requiring tracheotomy for head and neck cancer surgery. The authors measured respiratory function in patients with fenestrated and unfenestrated inner cannula who where otherwise already tolerating capping. They found when a size 6 Shelley tube was capped fenestration did not improve airflow or patient comfort for males. Within the female cohort the fenestration may have improved perceived patient comfort in some. Thus, the authors conclude that a fenestrated 6 Shelley ETT does not improve decanulation in males but may be beneficial in some females. This is generally a well designed and written paper.

Comment 1: Line 227 - reference incorrect

Reply 1: I have amended the formatting of the reference within the text in keeping with the Vancouver guidelines for referencing a direct quote (please refer screenshot from the source paper included).

Changes in the text: Changed on line 234 from "fenestrated tubes often fit poorly and thus do not work as intended" (4 p960) to "fenestrated tubes often fit poorly and thus do not work as intended" (*4 p. 960*). Please let me know if I have misinterpreted the reviewer's comment.

taneously breathing patients.

Fenestrated Tracheostomy Tubes

The fenestrated tracheostomy tube (Fig. 5) is similar in construction to standard tracheostomy tubes with the addition of an opening in the posterior portion of the tube above the cuff. With the inner cannula removed, the cuff

breathe through the fenestrations and around the tube.

Fenestrated tracheostomy tubes often fit poorly and thus do not work as intended. The standard commercially available tubes can significantly increase flow resistance through the upper airway if the fenestrations are not properly positioned. The risk of this complication may be decreased if a tube is used with several fenestrations rather than a single fenestration. Moreover, custom-fenestrated tubes can be ordered from several manufacturers. Even with these

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Comment 2:

Discussion:

Could height or BMI be as important as gender? Eg were the females who did not tolerate the unfenestrated tube shorter or have lower BMI? This would likely also correlate with ethnic variations.

Reply 2: Agreed, BMI could be important

Changes in text: New paragraph and reference included at line 265, and reference 20.

"Other potential confounders include the patients' body mass index (BMI) and impact on respiratory effort (20) with the relationship of the tracheal diameter and BMI an area for further investigation."

Comment 3:

The authors note that the fenestration is malpositioned more commonly in the male population. This is an expected complication given that a 6 tube is not designed for the dimensions of the male trachea. Thus, the fenestration is likely to sit against the posterior wall. In the longer-term tracheostomy setting a 6 would rarely be recommended due to its increase risk of accidental decanulation due to its relatively short length for an average male. A fenestrated 6.5 or 7 may be preferred if fenestration is being used as a tool towards a difficult decanulation or to aid voicing.

Similarly, if a 5.5 was used in the female population similar malposiiton may also be seen. It may also suggest that the females who better tolerated the fenestrated tube may have better tolerated an unfenestrated 5.5.

Reply 3: Agreed

Changes in text: Additional text included at lines 248 and 253 respectively.

"This is not entirely unexpected, given that a size 6 tube is not designed for the dimensions of the male trachea, despite its frequent clinical use in downsizing towards decannulation."

"Alternatively, another option to fenestrated tracheostomy tubes could be the consideration of downsizing to an even smaller diameter uncuffed non-fenestrated tracheostomy tube (e.g. a size 4) to increase the space available around the occluded tube."

Comment 4:

The conclusion I would draw from this study is that fenestrated 6 Shelley in the male population in those already tolerating capping does not aid the decanulation process. For patients struggling with decanulation fenestration may have a role but other causes for failure should always be sort eg suprastomal granulation. For a female population a fenestrated tube might be more comfortable but equally downsizing may give the same result. It is a reminder that females should always be considered for smaller size ETT and tracheostomies than their male counterparts.

Some patients may benefit from fenestration to facilitate voicing or decanulation. But checking the position of the fenestration with scope should be always be recommended. Downsizing may be as valuable as a fenestration.

Fenestrations when used for extended periods may carry risks associated with granulation at the fenestration site.

Reply 4: Agree with reviewer conclusions

Changes in text: Additional text in previous response reinforces the consideration of downsizing versus fenestration (line 253). We have also included the following text in the discussion (line 313)

"It is a reminder that females should always be considered for smaller size endotracheal and tracheostomy tubes than their male counterparts."

Reviewer B
Comment 5:

This study sets out to evaluate a very clinically relevant objective, namely the differences in airflow between fenestrated and non fenestrated tracheostomy tubes in a head and neck surgical population.

The paper itself is well written and the statistics are sound, however, a significant limitation in the study design means that the study objective itself is not able to be assessed and the conclusion essentially flawed.

The main limitation of this paper is that 71% of patients had a partially or completely obstructed fenestrated tracheostomy tube. Thus, when comparing a population of mostly obstructed fenestrated tubes vs a non fenestrated tubes there was no significant difference in airflow which is not unexpected. The subgroup of patent fenestrations vs non fenestrated tubes is too small to make any meaningful statistical findings. To properly address the study aim one would need to assess patent fenestrations vs non fenestrated tubes.

Reply 5: Agreed, this is a significant limitation to the study – and is now more prominently highlighted in the discussion as a key limitation. In the design of the study, the research team did not expect such high incidence of malposition. Indeed, it has not been previously reported in the literature to this extent.

Changes in the text: Existing text within Limitations re-ordered and emphasised (line 298).

"*However, we acknowledge the limitations of our research, **a key one being** that we did not exclude patients for whom the position of the fenestration was observed to be malpositioned."*

Additional text has also been added to line 304.

*"We did not expect such high incidence of malposition, **and this frequency of occurrence has not previously been reported."***

Comment 6:

What this paper does demonstrate, is that when placing a size 6 Shiley tracheostomy tube in all head and neck surgical patients the fenestration is occluded partially or completely 71% of the time and thus there is no real advantage of its use when improperly positioned or the position not checked.

Reply 6: Agreed

Changes in the text: This succinct summary by the reviewer has been highlighted in the conclusions (line 321) and the conclusion now reads:

"In a Head and Neck surgical population, size 6 fenestrated uncuffed tracheostomy tubes were partially or completely obstructed 71% of the time. Nearly all males (90%) experienced malposition. Fenestrated tracheostomy tubes showed no significant effect in improving three airflow outcomes when corked (FEV1, PEF, MPT). We conclude fenestrated tubes provide no advantage prior to decannulation, in males. In females with small tracheal size, fenestrated tracheostomy tubes may still offer clinical benefit."

Editorial Comments

As a randomized crossover trial, this study evaluated the suitability and feasibility of fenestrated tracheostomy tubes, providing high-level evidence for the selection of tracheostomy tubes. Overall, the research design is reasonable, and the conclusions are logically derived. We offer the following suggestions in the hope of further improving the manuscript.

Editorial Comment 1:

1. As this study is designed as a randomized crossover trial, it would be more appropriate for the authors to follow the CONSORT 2010 statement: extension to randomized crossover trials. A reformatted version created for our journal is provided in the attachment. For each item in the checklist, please state the relevant **page/line and section/paragraph number** in the manuscript. If an item is not applicable, please mark it as "NA". Please submit the completed checklist as supplementary material.

Below are suggestions on reporting quality and transparency based on the CONSORT 2010 statement: extension to randomized crossover trials:

Reply E1: Completed as suggested

Changes in the text: The sub-section *Reporting Guideline* has been amended to include: extension to randomised crossover trials on line 125.

Comment E2: Extension of CONSORT item 1a

Please identify the study as a randomized crossover trial in the title. In addition, it would be better if the authors include the "head and neck patients" in the title.

Reply E2: Agree

Changes in the text: Title is now "*A randomised crossover trial examining the perceived clinical benefits of fenestrated tracheostomy tubes in head and neck patients."*

3. Extension of CONSORT for abstracts item 7

Comment E3: Please explain how participants were allocated to sequences (ABAB/BABA), specifically, how the randomization was achieved.

Reply E3: Agree

Changes in the text: Line 75, "*Patients were randomised by computer generated random sequence to the order of inner cannula insertion (ABAB or BABA)"*

4. Extension of CONSORT for abstracts item 12

Comment E4: Abstract, Results: "there was no difference in … (P>0.05)", please avoid reporting only vague bounds, such as P<0.05, or simply stating "not significant". Instead, provide the exact P-value.

Reply E5: Agree

Changes to the text: *Of 28 participants (14 in each arm), there was no difference in PEF, FEV1 or MPT between fenestrated and non-fenestrated cannulas (p=0.66, p=0.93, p=0.66 respectively).*

5. Extension of CONSORT item 2a

Comment E5: Could the authors introduce the application of tracheostomy in head and neck surgery? Under what circumstances does head and neck surgery require a tracheostomy intubation rather than an oral intubation? This would provide a rationale for selecting patients who have undergone head and neck surgery as the study population.

Reply E5: Agreed, relevant to the audience.

Changes to the text: Line 94 "*A tracheostomy also provides or maintains a patent airway, which is particularly relevant in head and neck surgery due to obstruction imposed by post-surgical oedema or as a result of the surgical restoration or repair*."

6. Extension of CONSORT item 3a

Comment E6: How long is the duration of each intervention? In other words, how often should the inner cannula be changed?

Reply E6: Agree

Changes to the text: Line 170 now reads – "*In the participating hospital, the preferred decannulation protocol is to remove the tube 24 hours following successful corking of a fenestrated tracheostomy, **with fenestrated inner cannula in situ**."*

7. Extension of CONSORT item 5

Comment E7:

Methods and materials: "All patients had a Size 6 Shiley CFN … (Covidien, Australia)", please also report the name, size, and manufacturer of the non-fenestrated inner cannula.

Reply E7: The Size 6 Shiley CFN package includes both fenestrated and non-fenestrated inner cannulas and agree this is not clearly articulated in the text.

Changes to the text: Line 155: "*The Shiley CFN comes with both fenestrated and non-fenestrated inner cannulas*."

8. Extension of CONSORT item 10

Comment E8:

The authors need to provide descriptions of the allocation concealment, which is a critical mechanism that prevents foreknowledge of the treatment sequence and thus shields participants and those who enroll participants from being influenced by this knowledge.

Reply E8: Agreed

Changes to the text: Additional text included at line 158.

*"Following enrolment (by investigator LP), patients were randomised by computer generated random sequence, **in sequentially numbered sealed envelopes**, to the order of inner cannula insertion"*

Comment E9. Extension of CONSORT item 12

It's stated that three females had missing data for the 3rd and 4th readings. The authors should include the steps for addressing missing data in the methods section.

Reply E9: The lmer function, which performs linear mixed modeling in R, automatically excludes rows with any missing data in the outcome variable of interest, and as such, these rows are not used in building the models. However due to the hierarchical nature of mixed models, it would still allow us to utilize the data from other rows from these same patients when available (e.g. from their 1st and 2nd readings) in building the models.

Changes to the text:

Line 196 *"Due to the hierarchical nature of mixed models, in cases of missing data, data from other rows from the same patients were utilised in building these models."*

Comment E10. Extension of CONSORT item 13a

Please include in Figure 2 (Participant Flow Diagram) that three female participants dropped out halfway through the trial, and indicate their respective sequences.

Reply E10: Agree

Changes to the text: I have changed Figure 2 to reflect this and have included reference to the allocation order at line 259: "*The three participants were all allocated to the fenestrated cannula first, followed by change to the non-fenestrated inner cannula (insertion order AB).*"

Comment E11. Extension of CONSORT item 15

Please reorganize Table 1 (the baseline characteristics table) by separating the groups according to their different treatment sequences, namely ABAB and BABA. Also, the reasons for the surgery could also be added in Table 1.

Reply E11: Agree

Changes to the text: Please refer to amended Table 1 (line 451)

Comment E12. Extension of CONSORT item 17a

(1) Lines 202-203, it's stated that "Male gender was significantly associated with a predicted increase of PEF and MPT of approximately 67.7 L/min ($p = 0.02$) and 6.1 seconds ($p = 0.05$), respectively (Table 2)", but it seems that we cannot derive the values 67.7 and 6.1 from Table 2.

Reply (1) It was incorrect of me to reference Table 2 following this statement, as they are separate calculations.

These values are the estimated marginal means that have been calculated through running the multivariate mixed model that controls for other several factors in the model (random ordering, fenestration) and controlling variability within each patient through assigning the participant as a random effect. As such, these values could not be derived via a simple subtraction of the values found in Table 2.

Changes to the text: I have removed the reference to Table 2 on line 209.

(2) Please place the measured variables (PEF, FEV1, MPT) in the first column, with gender groups and obstruction levels in the first row. And list the *P*-values instead of using symbols to represent them.

Reply: The original Table 2 has been reorganised. In doing so, it seemed clearer to split the original table into two – one displaying the incidence of fenestration malposition according to gender (Table 2), and one displaying the airflow measures (Table 3).

Changes to the text: Refer revised Table 2 (line 453), and new Table 3 (line 455).

(3) Please indicate key data in the results section of the main text, rather than merely providing qualitative descriptions. For example:

(i) Results, para 2: "After controlling for gender … there was no significant effect of the tracheostomy tube fenestration on PEF, FEV1 or MPT". Please specify the exact *P*-values.

Reply: Apologies for the lack of clarity, the p values had been included within Figure 3 but are now included within the text also.

Changes to the text: Line 206 - *After controlling for gender and the (randomised) order of inner cannula insertion, there was no significant effect of the tracheostomy tube fenestration on PEF (p=0.66), FEV1 (p=0.93) or MPT (p=0.66) (Figure 3).*

(ii) Results, para 4: "There was no significant difference in PEF, FEV1 or MPT between the three groups in univariable models and in multivariable models (controlling for gender) ($p > 0.05$)". Please present these data in a table or specify the exact *P*-values in results section.

Reply: Due to the large amount of data we are presenting them in a Supplementary table as an Appendix and have removed the all-encompassing bracketed p value > 0.05 from the text.

Changes to the text: Line 217 - There was no significant difference in PEF, FEV1 or MPT between the three groups in univariable models and in multivariable models (controlling for gender) *(Supplementary table, Appendix).*