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ORIGINAL ARTICLE

Randomized crossover trial comparing two open surgical cricothyrotomy techniques

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Abstract

Objective: Emergency cricothyrotomy is a life-saving procedure that is performed in "can't intubate can't oxygenate" scenario. A recent study comparing an open surgical technique using a bougie and endotracheal tube (ETT) with a Seldinger technique using the Cook Melker catheter showed that the open technique was quicker but suggested that the open technique could be quicker if using the Melker catheter instead of a bougie and ETT. The objective of this study was to compare the surgical technique using bougie and ETT with an open technique using the Melker catheter.

Methods: A randomized crossover trial was conducted involving emergency physicians (EPs) and trainees. Participants performed both techniques in succession on an airway model, with the technique performed first being randomized for each participant. The primary outcome was time to first insufflation of the artificial lung. Participants also indicated their comfort with each technique on a 5-point Likert scale and which technique they preferred.

Results: Seventeen EPs and 19 trainees participated. The Melker catheter technique was performed quicker with a mean time of 29.2 s versus 44.3 s for the bougie/ETT technique (difference 15.1 s, 95% confidence interval 10.8–19.4 s). The Melker catheter was most preferred by participants (61% vs. 39%). There was no significant difference in the comfort ratings between each technique. Time to model lung insufflation was not affected by training level or time since last performed a cricothyrotomy, either real or simulated.

Conclusions: The Melker catheter was quicker to perform and the most preferred by participants.

KEYWORDS
can't intubate can't ventilate, cricothyrotomy, failed intubation, surgical airway, treatment

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INTRODUCTION

Emergency cricothyrotomy is performed in "can't intubate can't oxygenate" (CICO) scenarios.[1–6] When successful, the procedure provides rapid access to a definitive airway. It is ideally done as quickly as possible to prevent complications as well as sequalae from hypoxia.[7,8] Unfortunately, due to the "last resort" nature of the procedure, the incidence is low and is likely performed under considerable stress.[8–10] Therefore, it should only be performed by trained individuals using the technique that offers the quickest time and one they are most comfortable with.[1]

There are many different techniques for emergency cricothyrotomy. Generally, they are categorized into open surgical techniques and Seldinger techniques involving a needle and guidewire. Previous literature reviews have summarized the current evidence and showed that no technique is clearly superior to any other.[4,6] However, a large limitation is the poor quality and quantity of available evidence, with those reviews citing small numbers and study heterogeneity as a substantial problem.[4,6] Despite the conclusions of the reviews, there was suggestion that in general, surgical techniques are much quicker to perform compared to Seldinger.[4,6,8,9,11–13] NAP-4 also states that "… the possibility that it [Seldinger] is intrinsically inferior to a surgical technique should also be considered."[1]

In our recent study comparing a surgical bougie/endotracheal tube (ETT) technique with a Seldinger technique using the Cook Melker catheter, the surgical technique was quicker to perform and preferred by participants.[13] However, it also suggested that the surgical technique would be quicker if using the Melker catheter instead of the bougie/ETT technique. This technique is known but has not been studied in a formal fashion.[14–16]

The objective of this study was to compare time from commencement of the procedure to lung insufflation for the open technique using bougie/ETT with an open technique using the Melker catheter, on a simulated cricothyrotomy task trainer.

METHODS

In 2023 the Department of Emergency Medicine at Nepean Hospital saw approximately 80,100 patients with approximately 20% under 16 years of age and an admission rate of 32%. It is accredited by the Australasian College for Emergency Medicine as a major referral center for 3 years of emergency medicine training and is a regional trauma center as per the NSW Institute of Trauma and Injury Management. Airway management is performed by emergency physicians (EPs) and emergency medicine trainees (trainees). Regular training sessions are held covering airway management, including difficult airway algorithms and cricothyrotomy techniques. Both the bougie/ETT and the Melker techniques are taught in the cricothyrotomy training and were familiar to participants, with surgical airway workshops being held one or two times per year.

The study was conducted from June 2022 until January 2023. Study participants were EPs or trainees trained in cricothyrotomy and who were expected to be able to perform this procedure on a clinical shift. Participants were excluded if they had not been trained in both techniques. A total of 40 EPs and 25 trainees were deemed eligible for the study and were approached for recruitment via mass email inviting them to participate and giving a brief overview of the study. Formal written consent was obtained prior to participation, and participants were provided with two videos demonstrating the techniques involved prior to commencement.[17,18]

The equipment required for both procedures is standard equipment found in the difficult airway trolley in the resuscitation bay in the ED. The equipment provided for the bougie/ETT technique were scalpel, forceps, pediatric airway bougie, bag–valve apparatus, and size 6 cuffed ETT with syringe. Equipment provided for the Melker catheter technique were scalpel, forceps, Cook Melker cuffed emergency cricothyrotomy catheter with syringe, and bag–valve apparatus (Figure 1). Both techniques were performed on a Frova Crico-Trainer airway model (VBM Medizintechnik GmbH; Figure 2), which was familiar to participants as it is used for training and simulation in the ED.

A randomized crossover trial was performed comparing cricothyrotomy techniques using bougie/ETT and Melker catheter. Each participant would perform the two techniques in quick succession in the same session, with the technique performed first being randomized. Randomization was implemented via block randomization with random block sizes. Participants were assigned to the technique performed first sequentially by order of recruitment.

The model and equipment were set up by the researchers, with each technique being set up separately. Participants were allowed a brief period prior to each procedure to familiarize themselves with the equipment, including time to reposition equipment, and palpate relevant structures/landmarks before starting the procedure, to mimic a real-life situation. One researcher would act as an airway assistant to the procedure. In this role the assistant would take a very passive role and only perform tasks that were requested by the participant.

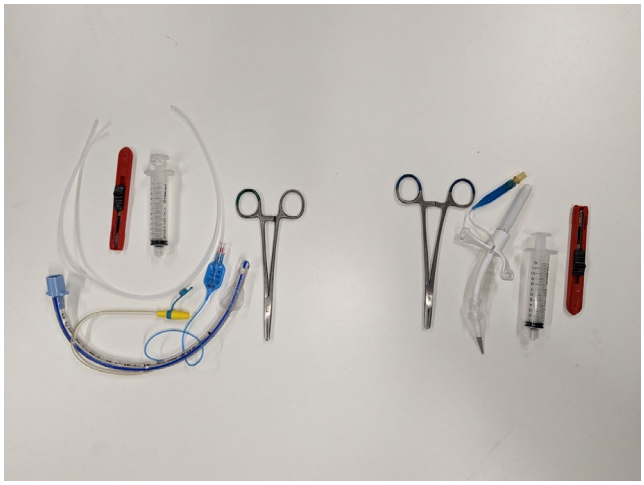

FIGURE 1 Equipment provided to participants. Bougie/ETT technique (left) and Melker catheter technique (right). ETT, endotracheal tube.

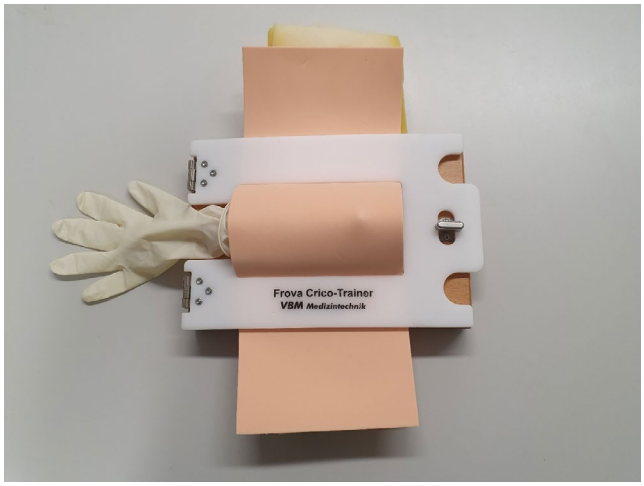

FIGURE 2 Frova Crico-Trainer airway model (VBM Medizintechnik GmbH).

This was explained to the participant during the consent process. Demographic data were collected regarding whether the participant was an EP or trainee and time since they last performed a cricothryrotomy, either real or simulated, dichotomized to either <1 year or ≥1 year.

Time to complete each technique was measured via a stopwatch. Timing would start with the participant being directed to commence the procedure and would finish on successful insufflation of the artificial lung. A postprocedure survey was completed after both techniques were performed, asking participants to rate their comfort with each technique on a 5-point Likert scale from 1 (not at all comfortable) to 5 (very comfortable) and to choose their preferred technique. Technical issues that occurred were noted by the researchers, and participants were able to write comments regarding the techniques in free-text format. Data collected were deidentified, with no personal information collected beyond the demographic data, procedure times, and the postprocedure survey.

Primary outcome was the difference in mean time to insufflation of the artificial lung between the two techniques. Secondary outcomes were the difference in comfort ratings between each technique and which technique was preferred. Time to insufflation data was also analyzed by subgroups (EP vs. trainee and for time since last cricothyrotomy). Data were collated using Microsoft Excel for Microsoft 365 and analyzed using the Real Statistics add-on for excel.[19] Times to lung insufflation with the bougie/ETT technique and the Melker catheter technique were compared using paired t-tests. The comfort ratings were compared using the Wilcoxon signed rank test. Most preferred technique was compared using the z-test for population proportions. Times to lung insufflation between participants who have performed a cricothyrotomy <1 year and ≥1 year, as well as between EPs and trainees, for each specific technique, was compared using independent t-tests.

The null hypothesis was that there is no difference in mean time to perform each technique. Our previous study gave a mean difference of 15 s and a standard deviation (SD) of difference of 17 s.[13] We considered a difference of 10 s clinically significant considering the potential to desaturate quickly in critical scenarios, even within 90 s of induction and especially without the opportunity for preoxygenation.[1] To maximize the sample size required, we used a difference of 10 s between techniques, with an SD of difference of 15 s, alpha 0.05, and beta 0.2, which determined that 20 participants were required. We aimed to recruit 40 participants: first, to ensure the validity of the results, and second, because a study of 40 participants performing 80 procedures would be larger than most previous studies reviewed.[6] Ethics approval was granted by the Nepean Hospital Human Research and Ethics Committee as a low- and negligible-risk study and participants gave written consent prior to participation.

RESULTS

Seventeen EPs and 19 trainees participated. Only two EPs had performed a real-life cricothyrotomy, both using the bougie/ETT technique, with the remainder of participants having simulated experience. The Melker catheter technique was performed quicker with a mean (±SD) time of 29.2 (±9.6) s versus 44.3 (±16.0) s for the bougie/ETT technique (difference 15.1 s, 95% CI 10.8–19.4 s) (Table 1). The Melker catheter was most preferred by participants, but this difference was not statistically significant (61% vs. 39%, $p = 0.059$). There was also no significant difference in the comfort ratings between each technique with a median (IQR) 4 (4-5) bougie/ETT and 5 (4-5) for Melker catheter ($p = 0.48$).

The mean time to insufflation by EPs compared to trainees was not statistically significant for either technique. There was also no statistically significant difference for time since last performed a cricothyrotomy (<1 year vs. ≥1 year; Table 1). There were two technical issues identified, one for each technique, which delayed success of the procedure. These, as well as free comments from participants, are listed in Table 2.

DISCUSSION

The goal of cricothyrotomy is to establish an airway in CICO scenarios. It will likely be done under stressful conditions, which can affect performance.[8–10] Therefore, the ideal technique should be reliable, should take as little time as possible to perform, and should have a high success rate.[1] More recent evidence tends to advocate for an open technique as opposed to needle over wire or Seldinger techniques, citing quicker times and higher success rates.[4,6,8,9,11–13]

This study showed a significantly quicker time to insufflation using the Melker catheter compared to the bougie/ETT technique. One advantage of the Melker catheter technique is that there are fewer steps involved, saving crucial time in the context of a CICO scenario. The Melker catheter is designed to be inserted to the hilt and so there was no need to measure the length of insertion as with the size 6 ETT, further reducing the number of steps and cognitive load required. Although not statistically significant, most participants preferred the Melker catheter technique in the postprocedure

TABLE 1 Time to insufflation of both techniques for all participants by level of training and last performed a cricothyrotomy.

Technique	Variable	Participants	Time (s)	
Bougie/ETT	All participants	36 (100)	44.3 (±16.0)	Difference 15.1 (±12.6) 95% CI 10.8–19.5 $p<0.001$
Melker	All participants	36 (100)	29.2 (±9.6)	
Bougie/ETT	Physician	17 (47)	45.3 (±14.3)	$p=0.711$
	Trainee	19 (53)	43.3 (±17.7)	
Melker	Physician	17 (47)	31.1 (±11.3)	$p=0.243$
	Trainee	19 (53)	27.3 (±7.5)	
Bougie/ETT	<1 year	16 (44)	45.9 (±14.5)	$p=0.573$
	≥1 year	20 (56)	42.8 (±17.3)	
Melker	<1 year	16 (44)	29.3 (±9.4)	$p=0.932$
	≥1 year	20 (56)	29.1 (±9.9)	

Note: Values are *n* (%) or mean (±SD).
Abbreviation: ETT, endotracheal tube, s, seconds.

TABLE 2 Issues noted and comments from participants.

Issues	Melker catheter: not entirely through cricothyroid membrane so poor insufflation.
	Bougie/ETT: tight to insert, hole too small.
Comments	Much more comfortable with bougie/ETT, as it is closest to my intubation style, so less cognitive load during a high stress situation.
	Concern about causing a false passage with sharp tip of Melker catheter.
	Nil issues. Still more comfortable with bougie/ETT.
	Prefer Melker catheter. Less equipment to fiddle with, potentially more teaching is needed as bougie/ETT is familiar.
	Bougie/ETT more comfortable, but Melker catheter felt faster.
	Prefer Melker catheter. Lesser [sic] steps involved, the stylet is stiff enough and feels stable to introduce compared to flexible pediatric bougie.

Abbreviation: ETT, endotracheal tube.

survey. Practitioners performing a cricothyrotomy should choose the technique that they are most comfortable performing.[20]

This study adds to the body of evidence of cricothyrotomy techniques, particularly comparing two different surgical techniques. The results suggest that techniques using equipment specifically designed for cricothyrotomy are likely to be quicker, more comfortable, and more preferred compared to traditional techniques using equipment that was not designed for the procedure.

Comments provided by the participants mention less equipment and fewer steps required to perform the procedure as advantages. One participant commented that the more rigid introducer of the Melker catheter was much easier to insert compared to a bougie. One issue observed with the bougie/ETT is that the incision made was large enough for easy passage of a bougie but not for the subsequent ETT, taking up valuable time.

As shown by this study, the advantages of dedicated equipment for cricothyrotomy appear to be favored compared to standard equipment. However, there is a possibility that specialized equipment is not as readily available depending on the clinical setting. Indeed, some participants rated familiarity as a reason for their preference of bougie/ETT, this equipment being relatively ubiquitous in critical care settings. One participant acknowledged in their comments that, although they prefer the Melker catheter, "potentially more teaching is needed as bougie/ETT is familiar." However, it should be mentioned that teaching the Melker catheter technique is unlikely to be difficult and is already incorporated into our local training.

Like previous results,[13] 20 of the 36 participants had not performed a cricothyrotomy (either real or simulated) within the past year. Time since last performed a cricothyrotomy did not appear to affect times to insufflation significantly, with no difference in times between those that had performed a surgical airway in the previous year compared to those who had not. There was also no difference in times between EPs and trainees. The difficult airway society guidelines suggest regular repeated training, to maintain skills required to perform a cricothyrotomy,[1,3] but the optimal frequency has not been determined.

Interestingly, a post hoc analysis using an independent t-test comparing this study to our previous one[13] showed that the times for the bougie/ETT technique in this study were quicker than the previous study, although nonsignificant (44.3 s vs. 51.6 s, difference 7.4 s, $p=0.070$). The proportion of participants having performed a surgical airway in the past year was similar (20/36 vs. 16/30) and the two studies were conducted more than 2 years apart. The difference in this study is the availability of training videos for the techniques, produced to mitigate against any bias of participants having to perform a newly trained technique (i.e., the new Melker catheter technique). However, viewing a training video may also have contributed to the quicker times for the

bougie/ETT technique in this study and the use of training videos as a refresher for surgical airway training could be investigated in the future.

LIMITATIONS

The study uses low-fidelity training models. Hence, there are aspects that cannot be reproduced such as bleeding or difficulty visualizing the procedural field. The low fidelity may have resulted in a falsely elevated success rate and shorter times to insufflation compared to if they were performed in real scenarios. Identification of surface anatomy landmarks was not an issue with the training models. The use of landmark techniques can be inaccurate[21] and will undoubtedly affect success rate. Other studies using cadavers and animal models showed lower rates of success as well as slower times to establishing an airway.[22–25] Using a different airway model may lead to different times so further studies using different models would serve to validate these results.

Participants would have known the two techniques that were to be studied from the recruitment email and could have refreshed themselves with the techniques prior to participation, which could have affected success rates and performance times, and was not asked about or recorded. The viewing of the two training videos prior to participation could shorten times compared to if there were no videos for revision. There is also a risk that participants could have self-selected as being enthusiasts of surgical airway and might have had a difference in performance compared to a more general cohort. As well, participants' prestudy preferences might have affected times for each technique. It was not possible to blind the participants or researchers to the technique being used. The participants were all EPs or trainees so results may not be generalizable to other specialties.

CONCLUSIONS

This study showed that on a simulated cricothyrotomy task trainer model, an open surgical technique using a Melker catheter was quicker to perform, with a trend to being rated more comfortable and being the preferred technique, compared to using a bougie/endotracheal tube.

AUTHOR CONTRIBUTIONS

Ezra Suria contributed to study concept and design; acquisition of the data; analysis and interpretation of the data; drafting of the manuscript; critical revision of the manuscript for important intellectual content; administrative, technical, or material support; and study supervision. James L. Mallows contributed to the to study concept and design; acquisition of the data; analysis and interpretation of the data; drafting of the manuscript; critical revision of the manuscript for important intellectual content; statistical expertise; administrative, technical, or material support; and study supervision. Mark D. Salter contributed to acquisition of the data; analysis and interpretation of the data; drafting of the manuscript; critical revision of the manuscript for important intellectual content; administrative, technical, or material support; and study supervision.

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CONFLICT OF INTEREST STATEMENT

All authors report no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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