

Surgicric 2: A comparative bench study with two established emergency cricothyroidotomy techniques in a porcine model

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Abstract

Background: 'Can't Intubate, Can't Oxygenate' is a rare but life threatening event. Anaesthetists must be trained and have appropriate equipment available for this. The ideal equipment is a topic of ongoing debate. To date cricothyroidotomy training for anaesthetists has concentrated on cannula techniques. However cases reported to the NAP4 audit illustrated that they were associated with a high failure rate. A recent editorial by Kristensen and colleagues suggested all anaesthetists must master a surgical technique. The surgical technique for cricothyroidotomy has been endorsed as the primary technique by the recent Difficult Airway Society 2015 guidelines.

Methods: We conducted a bench study comparing the updated Surgicric 2 device with a scalpel-bougie-tube surgical technique, and the Melker seldinger technique, using a porcine model. Twenty six senior anaesthetists (ST5+) participated. The primary outcome was insertion time. Secondary outcomes included success rate, ease of use, device preference and tracheal trauma.

Results: There was a significant difference ($P < 0.001$) in the overall comparisons of the insertion times. The surgical technique had the fastest median time of 62 s. The surgical and Surgicric techniques were significantly faster to perform than the Melker (both $P < 0.001$). The surgical technique had a success rate of 85% at first attempt, and 100% within two attempts, whereas the others had failed attempts. The surgical technique was ranked first by 50% participants and had the lowest grade of posterior tracheal wall trauma, significantly less than the Surgicric 2 ($P = 0.002$).

Conclusions: This study supports training in and the use of surgical cricothyroidotomy by anaesthetists.

Key words: airway management; intubation, intratracheal; trachea, tracheostomy

'Can't Intubate, Can't Oxygenate' (CICO) is a rare (1:50000¹) but life threatening event. All anaesthetists must therefore be trained and have appropriate equipment available for such an eventuality.

We know that in two studies comparing the Melker technique with other cricothyroidotomy devices and surgical techniques,^{2,3}

the Melker technique was rated highest by anaesthetists² and had a higher success rate than a surgical technique.³ However, in cases reported to NAP4, cannula techniques were associated with a worryingly high failure rate.⁴ In contrast, a more recent study⁵ and a meta-analysis⁶ have found surgical techniques to

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Editor's key points

- Insertion time was compared between the Melker Seldinger technique emergency cricothyroidotomy set, the VBM Surgicric 2 set and a scalpel-bougie-tube surgical technique, using a porcine model.
- Insertion time was significantly faster with surgical and Surgicric techniques than the Seldinger technique, and the incidence of posterior tracheal wall trauma was significantly less with surgical than with Surgicric 2.
- In case of a "Can't Intubate, Can't Oxygenate" scenario, surgical cricothyroidotomy may be better than the other methods.

have a high success rate. This was also demonstrated when surgical techniques were used as a rescue technique in morbidly obese manikins.⁷ As highlighted by these opposing findings, it remains unclear as to which cricothyroidotomy technique is superior. This is further supported by a systematic review by Langvad and colleagues⁸ which showed no clear advantage of any device and no significant difference in success rates. The recent Difficult Airway Society guidelines⁹ have advocated a surgical technique as the default technique for cricothyroidotomy.

The aim of this study was to compare the insertion time and success rate of the new updated Surgicric 2 (VBM Medical, Germany)¹⁰ system, to other well established techniques for achieving successful emergency tracheal access. The Surgicric 2 device comprises a pre-assembled surgical cricothyroidotomy kit, which aims to bridge the divide between cannula cricothyroidotomy techniques and a surgical technique. It has not been formally evaluated in any previous trial.

Methods

The protocol was reviewed and approved by the local Research and Development Department. Written informed consent was obtained from all participants.

We performed a randomized crossover bench study, comparing three cricothyroidotomy techniques on a porcine model.

The recruitment of participants took place in a single location during a one day study period. We recruited 26 senior anaesthetists; trainees (ST5+), Non-Consultant Career Grades and Consultant Anaesthetists. All anaesthetists volunteering to take part, first completed a questionnaire to determine their grade, experience of cricothyroidotomy procedures, and how recently they had received training in these techniques.

Participants were asked to watch three short, standardized videos, demonstrating the three different cricothyroidotomy techniques. After this, participants had the opportunity to practice one insertion with each technique on a part-task neck manikin (Crico trainer Frova, VBM, Germany), consisting of a plastic trachea covered by artificial skin.

The techniques compared were the Melker seldinger technique emergency cricothyroidotomy set, the VBM Surgicric 2 set and a scalpel-bougie-tube surgical technique. We used the seldinger side of the Melker emergency cricothyroidotomy catheter set universal tray (COOK Medical), with a 5.0 mm cuffed tube. The Surgicric 2 set contains a pre-assembled dilator and 6.0 mm cuffed tracheal tube, size 11 scalpel, tracheal hook, blunt scissors, a dilating speculum, 10 ml syringe, neck tape and extension tubing. The video supplied by VBM demonstrated the following technique: a vertical skin incision was made using the scalpel, the

dilating speculum was used to separate subcutaneous tissues, a horizontal incision through the cricothyroid membrane with the scalpel, then insertion of the preassembled Surgicric 2 device into the trachea with the aid of the dilating speculum. For the surgical technique we supplied a size 11 scalpel, a bougie and a 6.0 mm cuffed tracheal tube, and the technique depicted involved an initial vertical skin incision, digital palpation followed by a horizontal incision through the cricothyroid membrane, insertion of the bougie and railroaded of the tracheal tube (Fig. 1).

The porcine model consisted of a pig larynx with a long length of trachea held by pins within a purpose built crico trainer (VBM Germany). This was covered with a tightly stretched artificial skin, which was unable to move and allowed palpation of the underlying laryngeal anatomy. A tight fitting balloon was stretched over the caudal end of the trachea of each pig larynx, to demonstrate effective ventilation.

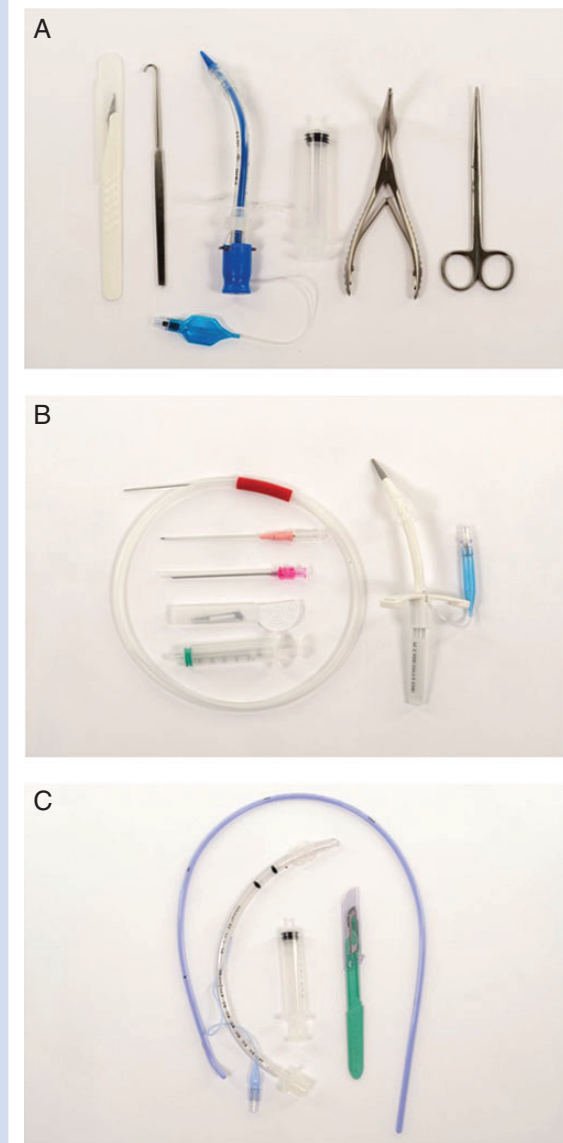


Fig 1 VBM Surgicric 2 set (A), Melker seldinger cricothyroidotomy set (B), surgical cricothyroidotomy equipment supplied (C).

Participants were randomized as to in which order they carried out the cricothyroidotomy techniques. The six possible sequences of the three techniques were concealed in plain envelopes and shuffled. The shuffled envelopes were opened in sequential order for each participant. Concealment of the sequence in which the participant would carry out the techniques was maintained until the envelopes were opened just before starting the first technique on the porcine model.

Participants were asked to perform an emergency cricothyroidotomy with each of the three techniques in turn, as if they were in a real life emergency situation. Each participant was given a new unopened cricothyroidotomy set and a fresh pig larynx for each cricothyroidotomy technique.

The primary outcome was the time taken for successful placement of a tube in the trachea. This included set up time and insertion time, as participants were timed from the moment of opening of the cricothyroidotomy set to the first effective ventilation, as depicted by the successful inflation of the balloon on the porcine trachea. The timer was stopped and the attempt with that technique was deemed a failure when the time reached 300 s.

Secondary outcomes included the number of attempts required with each technique, and the success rate. Investigators recorded the reasons for any unsuccessful attempts at insertion, even if subsequent attempts were successful within the 300 s time limit. Failed attempts had the time recorded as 300 s and the reasons for failure were documented.

The specimen was inspected, the device removed, and then the pig larynx was placed in a ziplocked numbered bag. The larynges were subsequently dissected by an Ear, Nose and Throat surgeon, who was blinded as to which technique had been used, to ascertain the grade of damage to the posterior tracheal wall. Participants were not made aware of this secondary outcome before the study. The extent of posterior tracheal wall trauma was graded as 1 none, 2 mild (partial thickness laceration <5 mm), 3 moderate (>5 mm puncture/laceration), 4 full thickness perforation.

Once participants had completed all three techniques, they were asked to complete a post study questionnaire. Participants were asked to rate the ease of use of the techniques (numeric rating scale: 0 minimum to 10 maximum ease of use), to rank the three techniques in order of preference, and to give any feedback regarding the techniques used.

In addition, participants were asked their subjective rating of their ability to and their confidence in performing these cricothyroidotomy techniques, both before and after completion of the study (numeric rating scale: 0 minimum to 10 maximum confidence/ability).

Statistical analysis methods

The primary endpoint of the study was to compare the insertion time of the three techniques. Using 2-sided, 5% significance level and 80% power, we expected the operating times for a pair of the devices to differ by more than a threshold value of 45 s and standard deviation of difference of around 80. The required number of volunteers was assessed to be 25; this was based on Murphy and colleagues² and a previous study by our group.¹¹

Descriptive analysis method was used to describe the primary and secondary outcomes data followed by appropriate statistical testing. Mean/median and standard deviation/range or interquartile range (IQR) and frequency with percentages were used as appropriate for the data description.

The observed data for insertion times (total of setup and duration times) for the three techniques, did not fulfil the normality assumption when investigated by graphical visual inspection.

Therefore Friedman's non-parametric method was used to compare insertion times. A post hoc test was then performed to identify the pair wise differences by means of the Bonferroni method.

Wilcoxon Sign Rank Test method was used to compare the techniques in a pair wise manner in all other outcome data. For the pair wise comparison a significance level (α 0.05/3=0.017) was used to assess significant differences between the techniques.

Results

Participant characteristics

Twenty six anaesthetists participated in the study. All participants had received some form of cricothyroidotomy training within the last 5 yr. Information on participant characteristics and experience is detailed in Table 1.

Primary outcome: duration of insertion

There was a significant difference ($P<0.001$) in the overall comparisons of the insertion time of the three techniques. Statistically the significant differences were between the VBM Surgicric 2 and Melker (86 vs 138s respectively) and between Melker and surgical (138 vs 62s respectively) with the same post hoc adjusted P-values of $P<0.001$. There was no significant difference between

Table 1 Description of the participants and their experience of cricothyroidotomy

Anaesthetist and experience	Sample number=26 (n (%))
Grade of Anaesthetist:	
Specialty trainee (ST 5/6/7)	8 (31)
Non-consultant Career Grade	2 (8)
Consultant	16 (61)
Trained to perform cricothyroidotomy (any)	
Never	0
Within 0–6 months	6 (23)
6–12 months	7 (27)
1–5 yr	13 (50)
>5 yr	0
Trained to perform percutaneous tracheostomy:	
Never	3 (12)
Within 0–6 months	4 (15)
6–12 months	2 (8)
1–5 yr	14 (54)
>5 yr	3 (12)
Trained to use Melker:	
Never	3 (12)
Within 0–6 months	6 (23)
6–12 months	6 (23)
1–5 yr	10 (38)
>5 yr	1 (4)
Trained to perform surgical cricothyroidotomy	
Never	2 (8)
Within 0–6 months	3 (12)
6–12 months	4 (15)
1–5 yr	16 (61)
>5 yr	1 (4)
Trained to use VBM Surgicric:	
Never	14 (54)
Within 0–6 months	1 (4)
6–12 months	2 (8)
1–5 yr	9 (35)
>5 yr	0

the VBM Surgicric 2 and surgical (86 vs 62s respectively), adjusted $P=0.563$ (Fig. 2).

Success rate and number of attempts required

The surgical technique was successful on the first attempt in 22 (85%) of cases, with a 100% success rate within two attempts. The initial unsuccessful attempts by four of the participants with the surgical technique were as a result of incorrect positioning of the bougie or tracheal tube. The bougie was inserted paratracheal in two cases and just under the skin in one case. In the last case the participant was unable to ventilate the balloon through the tracheal tube, so it was removed and the procedure restarted.

The other two techniques both had a failed insertion, and had lower initial success rates. The problems encountered with the

VBM Surgicric 2 technique, were mainly paratracheal insertion of the dilating speculum or the device itself. With the Melker technique the problems encountered were the cannula kinking, inability to thread the wire or paratracheal insertion of the wire. Where participants were struggling with this technique, they often switched between the cannula and the needle, or reversed the wire to use the stiff end to gain entry to the trachea.

There was no significant difference (at 0.017 significant level) in the number of insertion attempts between the pair wise comparisons of the devices. Secondary outcome data is detailed in Table 2.

Tracheal trauma grading

Trauma resulting from the cricothyroidotomy techniques was graded in relation to posterior tracheal wall injury and was present in some specimens from all techniques.

The surgical technique appears to be the least traumatic compared with the other techniques, with eighteen (69%) larynges showing no trauma associated with this cricothyroidotomy technique.

The VBM Surgicric 2 technique resulted in the highest level of tracheal trauma, with 50% of larynges showing moderate or severe trauma to the posterior tracheal wall (Fig. 3).

There was a significant difference in the grade of trauma/damage between Surgicric and surgical $P=0.002$, but no significant differences between the other pairs: Surgicric vs Melker $P=0.036$ and Melker vs surgical $P=0.063$.

Preference, confidence and self assessment of ability

The surgical technique was ranked as first preference by 50% of anaesthetists and was rated the easiest to use, significantly easier than Melker ($P=0.003$).

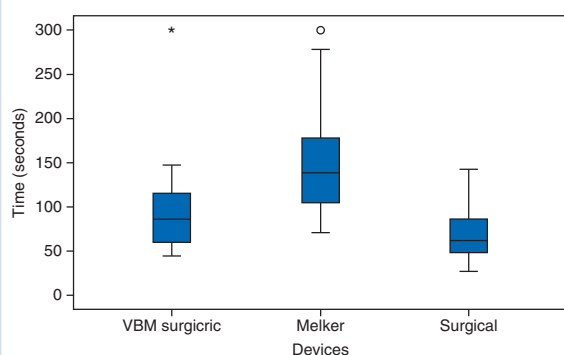


Fig 2 Box plot displaying insertion time for the techniques.

Table 2 Secondary outcomes and pair wise comparisons

Procedure	VBM Surgicric (n=26)	Melker (n=26)	Surgical (n=26)	Wilcoxon Sign Rank Test
Insertion attempts				
Median (Min, Max)	1 (1-6)	1 (1-6)	1 (1-2)	VBM vs Mel $P=0.336$
Median (IQR)	1 (1-1.75)	1 (1-2)	1 (1-1)	
Freq: n	n	n	n	
1 (%)	19 (73)	16 (62)	22 (85)	VBM vs Sur $P=0.285$
2	6	7	4	
3	0	2	0	
6 (both >300s, failed)	1	1	0	Mel vs Sur $P=0.019$
Trauma grade				
Median (Min, Max)	2.5 (1-4)	1 (1-4)	1 (1-3)	VBM vs Mel $P=0.036$
Median (IQR)	2.5 (1-3)	1 (1-2.75)	1 (1-2)	
Freq: n (%)	n (%)	n (%)	n (%)	
1	8 (31)	16 (62)	18 (69)	VBM vs Sur $P=0.002$
2	5 (19)	3 (11)	7 (27)	
3	8 (31)	6 (23)	1 (4)	
4	5 (19)	1 (4)	0	Mel vs Sur $P=0.063$
Ease of use (score)				
Median (Min, Max)	7 (2; 9)	6 (0; 9)	8 (3; 10)	VBM vs Mel $P=0.138$
Median (IQR)	7 (6; 8)	6 (4; 7)	8 (7; 9)	
Technique ranking	n (%)	n (%)	n (%)	VBM vs Sur $P=0.076$ Mel vs Sur $P=0.003$
1 st	8 (31)	5 (19)	13 (50)	
2 nd	10 (38)	10 (38)	7 (27)	
3 rd	8 (31)	11 (42)	6 (23)	

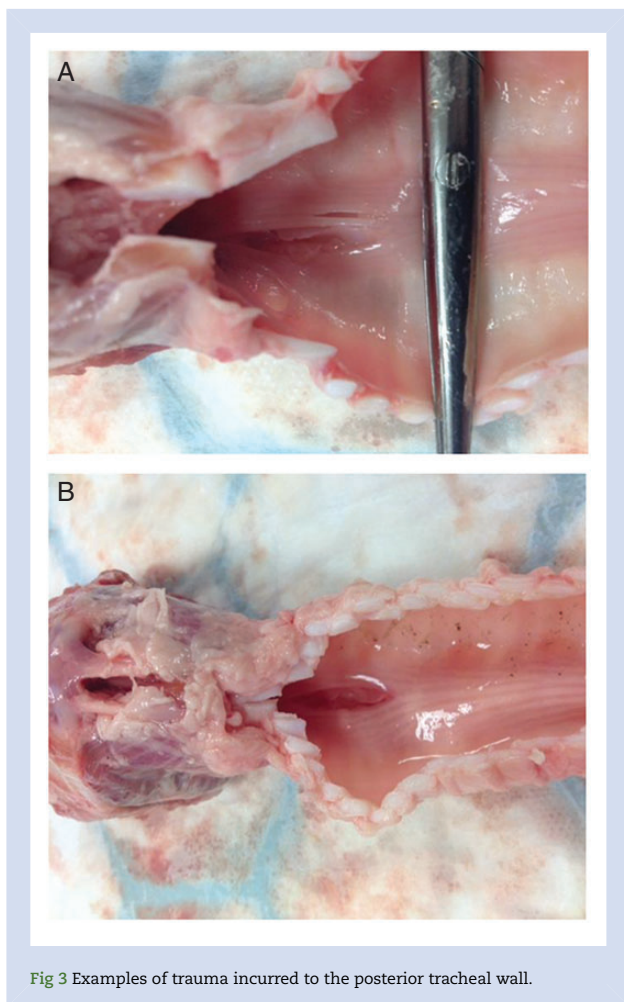


Fig 3 Examples of trauma incurred to the posterior tracheal wall.

There was a significant improvement ($P < 0.001$) in the confidence and self assessment of ability of the participants from pre to post procedure assessments, with the scores for both improving from a median score of 5.5 before the procedure to a median score of 8 post procedure.

Discussion

In this study, we found the surgical technique had the fastest median insertion time of 62 s, which was significantly faster than the Melker technique ($P < 0.001$). There was no statistically significant difference in insertion times between the surgical technique and the VBM Surgicric 2 (62 vs 86 s, $P = 0.563$).

We found the surgical technique had a 100% success rate within one or two attempts. It was successful on the first attempt in 85% of cases, a higher proportion than for the other techniques. Of note, in this study participants were all anaesthetists, rather than emergency physicians, as has been the case in many previous studies of surgical techniques.^{6 12–14}

The ideal cricothyroidotomy technique should have a high success rate, a low complication rate, be easy to master, involve only a few steps and allow adequate ventilation, ideally with protection against aspiration.¹⁵

NAP4 reported a high failure rate with cannula cricothyroidotomy (60%),⁴ but the surgical technique was reported to be consistently successful. However this technique was often performed by surgeons and emergency physicians, and perhaps in

less emergent situations than the cannula cricothyroidotomies. The NAP4 cases therefore do not provide any useful data on the success rate of anaesthetists with a surgical technique. Kristensen, Teoh and Baker¹² reviewed some of the literature from the realm of emergency and prehospital medicine, and concluded that a 'surgical technique must be mastered by all anaesthetists'.¹²

Percutaneous identification of the cricothyroid membrane can be poor¹⁶ but ultrasound guided identification by anaesthetists will result in a significantly higher success rate than palpation alone.¹⁷ Training in its use has been advocated,^{9 18 19} but it is unclear of the benefits in an emergency airway situation. The 'laryngeal handshake' (using the whole hand to palpate the hyoid-thyroid-cricoid protective laryngeal cage) may be used to rapidly identify the cricothyroid membrane in an emergency.^{20–22}

The new Difficult Airway Society guidelines 2015⁹ endorse a surgical cricothyroidotomy as the default technique, and suggest that a cannula cricothyroidotomy should be reserved for those anaesthetists skilled in this technique. The Canadian Airway Focus Group also advocate that options should be limited to a surgical technique or wide bore cannula technique, unless a clinician is very experienced with jet ventilation.²³ Several variations of surgical cricothyroidotomy technique have been described in the literature with varying complexity [e.g. the 'rapid 4 step technique',¹⁴ bougie assisted cricothyroidotomy technique,¹⁵ and simpler variants, such as that described by Heard and colleagues,²⁴ (with high success rates)]. The DAS guidelines 2015 advocate a simple scalpel 'stab, twist, bougie, tube' technique, similar to that used in this study, with either a 'laryngeal handshake' or vertical incision and blunt dissection to locate the cricothyroid membrane depending on whether it is palpable or not.⁹

Regular training with familiar available equipment recognizes the impact of human factors in an emergency situation.^{9 25 26} In advocating a single standardized technique, the DAS guidelines aim to simplify training and unify the response of anaesthetists to a CICO situation.⁹

The question arises as to should we therefore be abandoning regular training for anaesthetists in cannula techniques? In our study, 19% of anaesthetists still ranked the Melker selinger technique as their first choice, and it had a wide range of insertion times (71–300s), perhaps suggesting differing abilities with this technique. It could be argued that a less invasive technique is preferable in patients with difficult anatomy where the midline is not obvious, or to prevent complications from profuse bleeding. Despite making our porcine model as realistic as possible, the fact that it did not bleed could have led to participants favouring a more invasive technique. Also the interface between an artificial skin and the porcine larynx could have contributed to difficulty with the delicate actions (e.g. guidewire advancement) involved in the Melker technique. However a technique involving fine motor control may be less suited to a stressful situation.⁹

VBM Medical's Surgicric 1¹¹ showed a high level of tracheal trauma (68% of cases associated with moderate or severe posterior tracheal wall trauma), and inability to ventilate successfully through the device, because of poor positioning in the trachea.¹¹ The revised versions of Surgicric, including Surgicric 2, are made from a softer and more compliant PVC composition (DEHP free), have a locking introducer, a more tapered transition of the tube onto the introducer (so less shouldering), and a twenty degree more acutely angled tip.^{10 11} In line with the DAS ADEPT guidance,²⁷ we tested the modified Surgicric 2 device in this study and found that it was still associated with the highest level of trauma. Device curvature and insertion force may be important determinants of trauma associated with cricothyroidotomy.^{28 29}

Within the surgical technique, we used the Pro-Breathe single use bougie (ProAct Medical Ltd, Northampton), but it has been demonstrated that greater peak force and trauma results from a disposable introducer than a multiple use bougie^{30,31} suggesting less posterior tracheal wall trauma with the latter.

Limitations

We used a post mortem porcine larynx as a realistic anatomical representation of the human airway,^{32,33} because a human study was not feasible. Our porcine model was the best model available to us and was similar to that used by Murphy and colleagues,² as previously published by this journal. The lack of additional factors such as complex anatomy, obesity, oedema, and bleeding within a bench top study, may bias participants towards a more invasive technique. It is difficult to recreate the stress of a real life emergent CICV situation in a study, and therefore we cannot comment on the additional contribution of human factors which would affect the participants' performance.

In this study it was not possible to blind the investigators or participants to the cricothyroidotomy technique, however the ENT surgeon was blinded to the technique used when he dissected the larynges to assess the trauma caused.

This study was not specifically designed to look at the degree of trauma associated with cricothyroidotomy, although we did find some examples of trauma in specimens from all techniques. In this study we graded the posterior tracheal wall trauma in terms of depth. An interesting further study could investigate trauma incurred in more detail, by examining length and direction of traumatic injuries, and thus analyse the probable cause of trauma with each technique.

In conclusion, this study showed the surgical technique to be fastest to perform, to have a high success rate, and to be the preferred option, at the hands of anaesthetists. It also had the lowest level of posterior tracheal wall trauma compared with the other techniques. The Surgicric 2 technique was the second fastest to perform but was associated with the greatest degree of trauma.

This study supports the DAS guidelines in advocating training in and the use of surgical cricothyroidotomy by anaesthetists.

Authors' contributions

Study design: L.C., W.K., K.B.M., B.P.

Study conduct: L.C., W.K., S.J.C., B.P.

Data analysis: L.C., K.B.M.

Writing paper: L.C., K.B.M.

Revising paper: all authors

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Declaration of interest

None declared.

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