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DOI:
[10.1016/j.tacc.2023.101307](https://doi.org/10.1016/j.tacc.2023.101307)

Publication date:
2023

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Document Version
Publisher's PDF, also known as Version of record

[Link to publication in Discovery Research Portal](#)

Citation for published version (APA):

Vanner, R., & Crawley, S. (2023). Cric-guide – A review of an innovative scalpel designed for adult surgical cricothyroidotomy. *Trends in Anaesthesia and Critical Care*, 53, Article 101307. Advance online publication. <https://doi.org/10.1016/j.tacc.2023.101307>

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Review

Cric-guide – A review of an innovative scalpel designed for adult surgical cricothyroidotomy

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ARTICLE INFO

Handling Editor: Robert Greif

ABSTRACT

This is a review of the design, development and peer evaluation of Cric-Guide – an innovative scalpel device for emergency front of neck access in adults. The Cric-Guide is designed to replace the standard scalpel blade in the scalpel-bougie-tube technique and improve its success by guiding the bougie into the airway. The handle incorporates two depth guards which impact on the skin each side of the incision to limit insertion depth and reduce posterior damage to the airway.

Five research evaluations of Cric-Guide during simulated cricothyroidotomy have been completed. Four compared the performance of Cric-Guide with the standard scalpel in the scalpel-bougie-tube technique, in manikins using porcine larynxes made more difficult with simulated obesity or bleeding or both. Cric-Guide had a lower failure rate on the first attempt particularly with the bleeding simulation and a lower false passage rate in the obese simulations. The other study evaluated Cric-Guide during cricothyroidotomy on intact human cadavers and was successful in all 12 cadavers on the first attempt with no false passages.

The Cric-Guide performs surgical cricothyroidotomy effectively in human cadavers and porcine models and is presented as a possible alternative to the standard scalpel for emergency front of neck access.

1. Introduction

The Cric-Guide is an innovative scalpel that has been developed as an alternative to the standard scalpel blade for surgical cricothyroidotomy. The unique crescent shaped blade is designed to act as a guiding channel for the bougie during its insertion into the trachea; to improve success and to reduce complications of the procedure. Cric-Guide has undergone investigation by research studies on porcine manikins and human cadavers to allow evaluation, development and refinement before assessment by regulatory authorities and clinical use in emergency surgical cricothyroidotomy in adults.

2. Improving the performance of emergency front of neck access

If the upper airway becomes obstructed and ventilation of the lungs is not possible using a facemask, supraglottic airway or tracheal tube (after neuromuscular blockade), hypoxia can cause cardiac arrest and brain injury within minutes. This scenario of multi-model airway management failure is known as “can’t intubate can’t oxygenate” (CICO).

Without delay the medical team must perform “emergency front of neck access” (eFONA); a procedure to pass a tube percutaneously through the front of the neck to deliver oxygen directly into the trachea. This is an urgent, high stress situation with a massive cognitive load added to the need for skilled procedures to be undertaken.

In the past, there were variations of eFONA technique and equipment which allowed for operator choice between cannula (with high pressure source oxygen delivery or insufflation techniques), Seldinger wire through needle procedures or surgical cricothyroidotomy [1]. This changed following the publication of the 4th National Audit Project (NAP4) in 2011. NAP4 was a one-year national audit of airway complications in all NHS hospitals in the UK. It found that 80 patients needed eFONA, of whom 20 died and 8 had permanent non-fatal brain injury. Techniques using a cannula or needle often failed. Although ones using a scalpel and tracheal tube were more successful, they were often slow, taking more than 5 min in 85 % of cases [2].

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2.1. Scalpel-bougie-tube technique

In the 2015 update to the Difficult Airway Society (DAS) guidelines on unanticipated difficult intubation, the authors recommended the introduction of a didactic approach to surgical cricothyroidotomy using a standard size 10 scalpel blade, a bougie and a size 6.0 cuffed tracheal tube; the technique known as “scalpel-bougie-tube” (SBT) [3]. This standardised approach for eFONA was promoted due to its simplicity, use of easily accessible equipment coupled with a lesser need for fine motor control compared to needle techniques. The SBT technique has been widely adopted across UK hospitals and endorsed by the Colleges and Societies of all clinicians who may be involved in managing airway emergencies [4]. It was also acknowledged that although surgical tracheostomy by a surgeon (which can take 5 min to perform) does not usually prevent a poor outcome in CICO, but used later after surgical cricothyroidotomy it can provide a “definitive” airway [4].

Subsequently, SBT was found to be the most popular and the most successful eFONA technique reported internationally in 45 of 99 cases on the “Airway App” [5]. Despite its apparent success, it also reported an 18 % failure rate at the first attempt; a potentially underreported figure within a self-reporting data collection application. Indeed, in two studies of eFONA in anaesthetised live sheep, the SBT technique failed in 37 % in the simulated obese neck and 35 % in the non-obese [6,7]. Failure usually occurred when the bougie did not follow the scalpel blade into the airway creating a false passage in the tissues with the added complication of blood obscuring the view.

2.2. Limitations of the scalpel-bougie-tube technique

The SBT technique [3] describes a transverse stab incision 7.5 mm wide with a size 10 standard scalpel through the skin and cricothyroid membrane into the airway, a 90-degree blade rotation into the sagittal plane with sharp edge facing caudally (to avoid damaging vocal cords and the cricothyroid artery) followed by lateral traction towards the operator to open the incision. The bougie is first aligned in the transverse plane so that its tip stays in contact with the flat blade as it is advanced through the tissues (Fig. 1). Once in the airway the bougie is then rotated into the sagittal plane to pass down the trachea.

A weakness in the SBT technique is when the bougie does not follow the scalpel blade into the airway causing a false passage in the tissues and failure. This manoeuvre requires fine motor skill for bougie control, which may not be possible in an emergency. Bleeding impairs visualisation and adds further hindrance to successful bougie passage into the trachea. A false passage is more likely in an obese patient whose airway

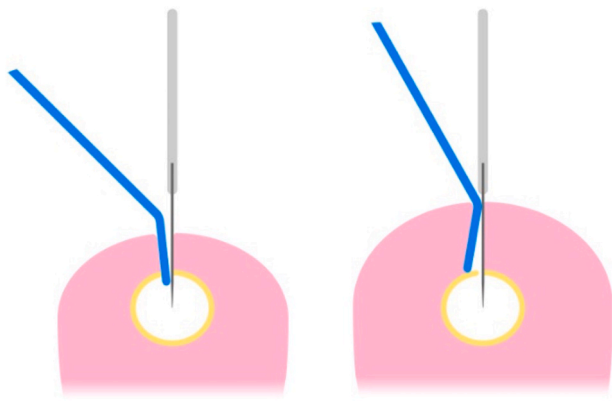


Fig. 1. Scalpel-Bougie-Tube technique for cricothyroidotomy. The two diagrams are of the transverse plane of the neck at the level of the cricothyroid membrane. The correct technique is on the left: the bougie is aligned in the transverse plane during insertion, with its tip staying in contact with the scalpel blade. False passage is more likely with the deeper airway on the right, where it is deeper than the coude tip of the bougie [8].

is deeper than the length of the coude tip of the bougie (Fig. 1). This may vary (8–16 mm) depending on the bougie manufacturer [8].

Although the flat side of the standard size 10 scalpel blade is 16.6 mm long from the handle attachment to the tip [8], its effective length is only 10 mm when excluding the narrow tip of the blade that is less than 6.0 mm wide. Therefore, the narrow tip of the blade should pass into the lumen of the airway so that the bougie can slide on its wider part though the tissues and cricothyroid membrane. Patients weighing more than 95 kg are likely to have a depth from skin to the airway lumen over 10 mm [9], in those patients the blade must be inserted so far that the handle attachment enters the skin incision and may prevent access by the bougie to the flat part of the blade (Fig. 2). This limitation could be addressed by a longer scalpel blade, but none of the standard sizes seem to be ideal for the task at hand. For example, the size 22 scalpel blade (a larger version of the size 10 shape) is longer at 23 mm, but it is 11 mm wide which may be too large for the height of the cricothyroid space when rotated by 90-degrees as part of the technique [8].

If the airway is deeper, the cricothyroid membrane may not be palpable, in which case an 8–10 cm vertical midline scalpel incision (caudad to cephalad in the sagittal plane) is recommended to then identify the anatomy with finger dissection before attempting SBT cricothyroidotomy [3]. Difficulties can arise as correct alignment of the bougie in the transverse plane may be prevented by its impact by the side of the incision [10]. Also, the scalpel blade may not be seen if the incision rapidly fills with blood [10]. In a study of anaesthetised live sheep, simulating obesity with infiltrated saline, 28 out of 35 anaesthetists using this “scalpel-finger-bougie” technique were confident that they had inserted the scalpel into the trachea. However, 10 of those 28 subsequently failed to pass the bougie into the airway [6].

2.3. Human factors

There are both technical and non-technical aspects to improving individual and team performance in eFONA.

Clinicians can show extreme levels of stress when they encounter a

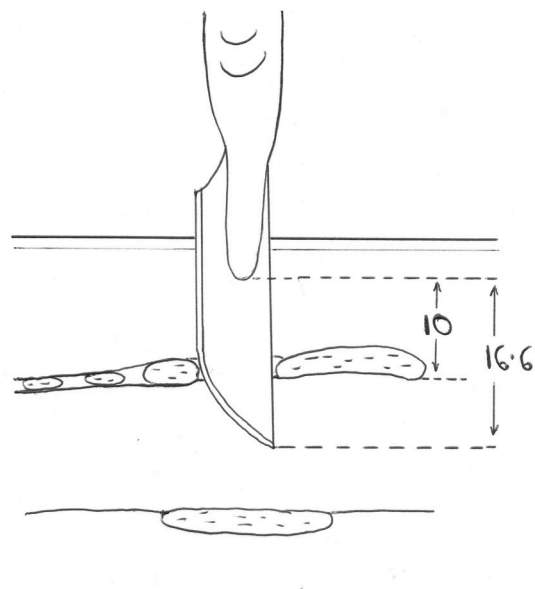


Fig. 2. This drawing is a view of the airway in the sagittal plane and is not to scale. The size 10 scalpel blade is shown rotated into the sagittal plane after being inserted through the cricothyroid membrane in the transverse plane. The narrow part of the tip penetrates the airway lumen to allow the bougie to slide on the wider part of the blade. If the depth of the airway lumen is more than 10 mm the blade must be inserted so far that the handle attachment enters the skin incision and may prevent access by the bougie to the flat part of the blade. Measurements in mm.

CICO emergency. Stress can cause both cognitive overload and fixation error which impair decision making and communication skills. Both may lead to a delay in performing eFONA. Delay in eFONA worsens hypoxia and is a major contributor to morbidity and mortality in CICO situations [11].

These non-technical human factors can be improved by training together frequently as a team with a standardised technique [2,3,11]. However, it is also normal human behaviour to lack confidence and be reluctant to initiate a procedure that has a significant failure rate which may then result in patient mortality.

Technical innovation to provide more specifically designed equipment with a low failure rate, could improve the confidence of the practitioner to perform eFONA at an earlier stage. Also, as fine motor skill and cognition decline markedly under stress, equipment design that minimise the need for complex procedural steps and motor skill may improve the performance of the clinician [12].

3. The Cric-Guide design

The standard scalpel blade in the SBT technique was not specifically designed for eFONA but was recommended as it is “available at almost every location where an anaesthetic is performed” [3]. The Cric-Guide is designed to replace the standard scalpel blade and address its deficiencies in the SBT technique described above. This innovation is an example of an attempt to “design out medical error”. To minimise technical and non-technical impact on eFONA procedural success, the Cric-Guide has an ergonomic design and incorporates these key features.

- A channel in the blade to guide the bougie into the airway to reduce false passages.
- A slot for the bougie to enter the channel of the blade when visualisation is impaired by bleeding.
- Depth guards which allow hold-up of the device to reduce posterior tracheal damage.

Surgical cricothyroidotomy using Cric-Guide is a modification of the SBT technique, with a scalpel blade specifically designed to facilitate bougie passage, addressing both visualisation issues from blood and the creation of false passages with an unchanneled technique. The Cric-Guide is designed to improve success while maintaining the core ethos of the SBT technique; simplicity. The adoption of the new blade is intuitive and straightforward to the clinician, with less procedural steps than with the standard scalpel as there is no need for the rotation of either the blade or the bougie.

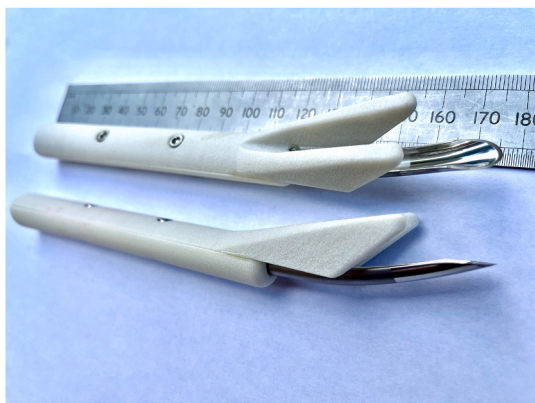


Fig. 3. Cric-Guide, showing in two views the stainless-steel blade (which is both curved and U-shaped in cross section), the two depth guards (one each side of the blade), and the 3D printed nylon handle.

3.1. Design of the blade

The scalpel blade is U-shaped in cross section (Fig. 3), 9 mm at its widest and 4 mm high, and fits easily through the cricothyroid membrane. The blade is curved so it passes in a caudal direction away from the cricothyroid artery and vocal cords. After loss of resistance is felt on entering the airway, the handle is lowered from vertical towards the chin, making the tip of the blade swing anteriorly away from the posterior tracheal wall and down the tracheal lumen. This movement also pinches the tissues (into the angle between the blade and the depth guards) so that once inserted, the Cric-Guide adopts a stable position in the neck.

Once in the airway, the blade forms a 6 mm wide concave channel to guide the passage of a bougie (size 14 or 15 C H) without the need for fine motor skill. The bougie is passed vertically into the channel in the sagittal plane (Fig. 4). The curvature of the blade makes the coude tip of the bougie stay within its channel. Thus, if the trachea has been accessed successfully, the bougie will follow this successful pathway.

3.2. Design of the handle

The handle is made of 3D printed nylon and incorporates two depth guards, one each side of the blade, which impact the skin each side of the incision to control the depth of insertion and reduce potential damage to the posterior trachea. The slot between the depth guards creates an entrance for the bougie to enter the channel of the blade, so it can still be easily inserted even when blood fills the channel (Fig. 5).

3.3. Optimal tube and bougie size

The dimension of the space between the cricoid and thyroid cartilages that can limit tube insertion is the caudad-cephalad distance, known as the height of the cricothyroid membrane. Ultrasound studies show this is less than 8.0 mm in 12 % of females and 5 % of males even when it is maximally opened by extending the head and neck [13]. This dimension of the cricothyroid membrane is generally smaller in the Indian population [14].

Even though the cricothyroid membrane may open further after a transverse incision, a size 6.0 mm internal diameter (ID) tube has an external diameter of 8.3 mm (8.8 mm including a fully deflated cuff) and so difficulty may be encountered during insertion. A size 5.0 mm ID tube with an external diameter of 7.0 mm (7.5 mm with a deflated cuff) is a more appropriate size for adult cricothyroidotomy to ensure ease of insertion through the cricothyroid membrane [15]. However, a 5.0 mm ID tube needs to be used with a size 14 C H bougie with an external diameter of 4.66 mm (with minimal overhang). The size 15 C H bougie is



Fig. 4. Cric-Guide channel entrance for the bougie is a slot between the depth guards. The bougie passes vertically and its coude tip stays within the curved channel of the blade as it advances.

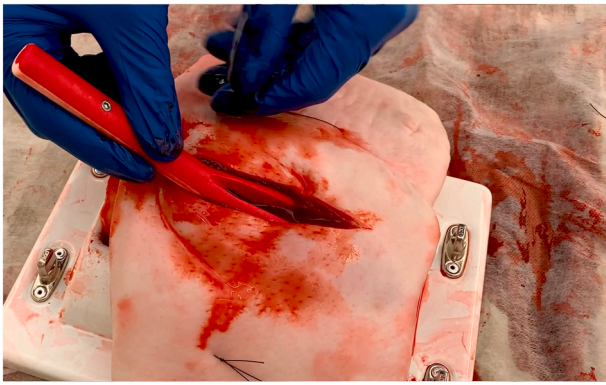


Fig. 5. Cric-Guide channel entrance for the bougie is the slot between the depth guards and is obvious despite blood flooding the view in a deep vertical scalpel incision. This manikin, incorporating porcine skin and larynx, simulates both obesity and bleeding [22]. (Image courtesy of Dr. I. Belford).

too large and is incompatible with the 5.0 mm ID tube [15]. The Cric-Guide pack therefore includes a 5.0 mm ID cuffed tracheal tube and an appropriately sized bougie (14 CH) to allow smooth railroading and to minimise any hold-up on tissues.

3.4. Optimal size of skin incision

The skin incision for eFONA must be large enough to accommodate the tube so it can pass without needing too much force from the clinician and without tearing the skin. Human dermis stretches easily in a linear manner up to an additional 30 % of its normal length (Fig. 6). Its elastic tissue stretches creating a rebound pressure of 5 kPa, enough to tamponade venous bleeding around the tube. Further stretch between 30 and 60 % requires an exponentially increasing force as the collagen fibres in the dermis line up in the direction of stretch and start to carry load. Over 60 % stretch needs much more force as the collagen fibres are

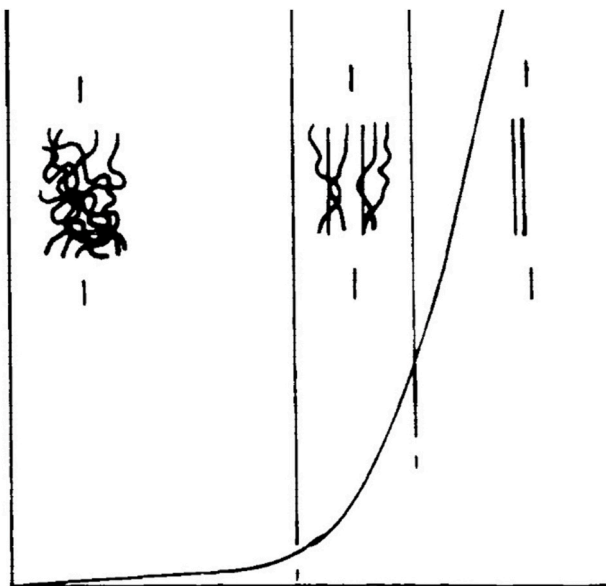


Fig. 6. From C.H. Daly, Biomechanical properties of dermis [16]. Stress (force used to stretch) on the y axis. Strain (length of stretch) on the x axis. Schematic diagram of the collagen fibres lining up with increased stretch.

now all lined up, all carrying load and have limited stretch. Further stretch causes them to rupture and the skin tears at about 70 % [16].

The outside circumference of a 5.0 mm ID tube with its cuff fully deflated is 23.5 mm, and a 6.0 mm ID cuffed tube 27.6 mm. The size 10 scalpel blade makes a stab incision 7.5 mm wide, if opened, the two sides of the incision create an unstretched hole of 15 mm circumference. The skin must stretch 57 % and 84 % to accommodate the circumference of a size 5.0 mm ID and a 6.0 mm ID cuffed tubes respectively. The Cric-Guide is designed to make a 9.0 mm skin incision, which when opened, creates an unstretched hole of 18 mm circumference. The skin must stretch 30 % and 54 % to accommodate the circumference of a size 5.0 mm and 6.0 mm ID cuffed tubes more comfortably.

And so, the design of the Cric-Guide blade makes an incision for the insertion of a 5.0 mm ID cuffed tube without excessive force or impediment to insertion through the skin and cricothyroid membrane.

3.5. Design presentation

An oral presentation of the design of the Cric-Guide was judged by an international peer review committee and won first prize in the innovation competition at the World Airway Management Meeting in Amsterdam 2019 [17].

3.6. Insertion technique

The insertion technique is described in Table 1 and is demonstrated in this YouTube video: https://youtu.be/dQVHp6W_Bag.

Table 1

The Cric-Guide insertion technique for surgical cricothyroidotomy.

A suggested technique is detailed below which could be incorporated into Action Cards for emergency use.	
The technique is also demonstrated in this YouTube video: https://youtu.be/dQVHp6W_Bag	
Contents of Cric-Guide research pack	
•Cric-Guide, Bougie (14 CH), Tube (5.0 mm ID cuffed), Scalpel (size 10), Syringe (10 ml)	
Position	
•Extend the head and neck to open the cricothyroid space.	
•Stand on the left side of the patient if right-handed.	
Identify the cricothyroid membrane	
• If palpable, stretch the skin over the cricothyroid membrane between finger and thumb of non-dominant hand 3 cm apart and stabilise the larynx.	
• If impalpable, make an 8–10 cm vertical midline scalpel incision (caudad to cephalad) then finger dissection to identify anatomy before proceeding.	
Insert Cric-Guide into airway	
• Hold the Cric-Guide handle vertically with the dominant hand to insert.	
• Sideways rocking movement helps skin incision (see video).	
• Loss of resistance is felt going through cricothyroid membrane.	
• After loss of resistance, lower the handle towards the chin so that the curved blade points caudally down the trachea.	
• Depth guards limit the depth of insertion to 20 mm.	
Insert bougie into airway	
• Hold the Cric-Guide in position with the non-dominant hand.	
• Pass the bougie vertically into the channel of Cric-Guide and into the trachea.	
• Pass the bougie 10 cm down the trachea with little resistance.	
Remove Cric-Guide	
• Remove Cric-Guide while holding bougie in place	
Railroad a cuffed tracheal tube over the bougie into the trachea	
• 5.0 mm ID tube with 14 C H bougie.	
Summary of insertion technique	
• If cricothyroid membrane is palpable:	Cric-Guide, Bougie, Tube.
• If cricothyroid membrane is impalpable:	8–10 cm vertical scalpel incision Finger dissection, Cric-Guide, Bougie, Tube

4. Research evaluations of Cric-Guide

To date there are five research evaluations of the Cric-Guide during simulated eFONA, four are published and one accepted for publication, in peer reviewed journals [18–22]. All five evaluated the speed of insertion, success rate, false passages, and posterior damage to the larynx or trachea.

Four studies compared the performance of Cric-Guide to the standard scalpel in the SBT technique on manikins incorporating skin, subcutaneous tissue and larynxes from porcine cadavers. These manikins were made difficult by simulating obesity [18,19], or bleeding [20] or both [22]. Adult porcine larynx and tracheas were used as they are of similar dimensions to that of adult female human [23]. Intact pigs are not, as their larynx is a much deeper structure; even 40 kg pigs have a depth from skin to airway lumen of over 40 mm, more than double that of obese humans [9,24,26]. The other research evaluation was carried out on intact human cadavers (preserved with the Thiel method). This was an assessment of cricothyroidotomy using the Cric-Guide only, without comparison to the standard scalpel in the SBT technique [21].

As the depth of the airway at the cricothyroid membrane varies with the type of manikin being used and patient’s weight [9], the researchers had a choice of three depth guard sizes for evaluation (at 15 mm, 20 mm or 30 mm) [19–22], or an adjustable depth guard in an earlier prototype [18]. Analysing the incidence of posterior tracheal damage with these different sizes can establish the optimum depth of insertion.

Tables 2 and 3 show the detailed results of five studies and Table 4 shows a summary of the findings.

5. Optimum depth of insertion to limit posterior airway damage

To determine the optimum depth of insertion to reduce posterior damage, knowledge of the depth of the posterior wall of the airway from the skin at the level of the cricothyroid membrane is useful. Unfortunately, there are currently no studies with this information. Ultrasound examination only identifies the echo-dense air/tissue interface of the anterior wall with the posterior wall being invisible behind this interference [9].

However, we can estimate the average depth by adding the distance from skin to the anterior airway lumen, to the anterior-posterior diameter of the airway (Fig. 7). In an ultrasound study, the depth from the skin to the anterior airway lumen increased with a patient’s weight but the mean depth was 9 mm (range 4–20 mm) [9]. The mean anterior-posterior diameter of the airway lumen at the cricoid cartilage in 61 adult human cadavers was 16 mm (range 11–23) [25]. Adding these dimensions together, the mean depth of the posterior wall of the airway from the skin could therefore be 25 mm in humans. The force needed to insert a scalpel can reduce this distance by compressing both the subcutaneous tissues and the trachea, albeit less so at the cricoid [26, 27]. So, in theory, 25 mm of penetration could reach and damage the posterior wall of the airway in a large proportion of patients.

The only commercially available cricothyroidotomy device with a

Table 2

Evaluations of Cric-Guide (CG) during cricothyroidotomy, *statistically significant difference $p < 0.05$

Study author and type of evaluation	Obese or not	Manikin type and numbers	Insertion time of tube CG vs SBT Median in seconds	First attempt failure rate CG vs SBT	False Passages CG vs SBT	Preference of anaesthetist CG over SBT
Yeow [18] CG vs SBT	Obese	Porcine cadavers 26 vs 26	85 vs 84	50 % vs 58 %*	31 % vs 65 %*	50 % (13 of 26)
Chauhan [19] CG vs SBT	Not obese	Porcine cadavers 28 vs 28	44 vs 37*	4 % vs 11 %	3 % vs 9 %	71 % (5 of 7)
Dannatt [20] CG vs SBT	Obese	Porcine cadavers 28 vs 28	52 vs 50	29 % vs 71 %*	14 % vs 41 %*	
Belford [22] CG vs SBT	Not obese	Porcine cadavers+ bleeding 25 vs 25	51 vs 62	12 % vs 52 %*	4 % vs 0	40 % (10 of 25)
Maini [21] CG only	Obese	Porcine cadavers+ bleeding+ vertical incision 48 vs 48	58 vs 72* includes vertical incision	35 % vs 46 %	42 % vs 73 %	92 % (11 of 12)
	Not obese	Human cadavers 12	41 range 21–83	0 CG only	0 CG only	75 % (9 of 12)

Table 3

Posterior tracheal wall perforation, *statistically significant difference $p < 0.05$

Study reference and evaluation	Obese or not depth of airway (Skin to lumen)	Depth of guard used with Cric-Guide	Perforation of posterior trachea with Cric-Guide	Perforation of posterior trachea with SBT
Yeow [18] CG vs SBT	Obese >15 mm	30 mm	0	0
Chauhan [19] CG vs SBT	Not Obese	15 or 20 mm	0	7 %
Dannatt [20] CG vs SBT	Obese 30 mm	30 mm	7 %	18 %
	Not obese (Not measured)	30 mm	8 %*	0
Belford [22] CG vs SBT	Obese (but after a 10 cm vertical scalpel incision)	30 mm	8 %*	0
Maini [21] CG only	Not obese (Not measured)	15 or 20 mm	0	not assessed

Table 4

Summary of research findings in 5 cricothyroidotomy studies.

The Cric-Guide was compared to the standard scalpel in SBT technique in four studies of manikins with porcine larynxes [18,19,20,22].

- Standard scalpel in SBT performed well in the easy manikin but when the manikins were made difficult with simulated obesity or bleeding SBT failed in over half of first attempts.
- Cric-Guide failed less frequently at the first attempt in the obese and the bleeding manikin.
- Cric-Guide had less false passages in obese manikins.
- Cric-Guide was faster following a large vertical scalpel incision in the impalpable neck. But with percutaneous insertion there was a similar insertion time for both techniques, usually less than 90 s.
- 39 of 70 experienced anaesthetists (56 %) preferred Cric-Guide, despite prior familiarity with SBT during their previous training.
- Cric-Guide was more likely to injure the posterior wall of the trachea when the depth guard was at 30 mm in a non-obese model and in the obese model following a large vertical scalpel incision (both study groups recommended a shallower depth guard).

The Cric-Guide evaluation in human cadavers [21]:

- 12 human cadavers of estimated weight 60–100 kg.
- Cric-Guide was successful in all 12 cadavers on the first attempt with a range of 21–83 s.
- No false passages on endoscopy.
- One case of posterior tracheal damage but no perforation.
- Through questionnaire all 12 participants (experienced anaesthetists) felt its position was stable after insertion into the neck, reducing the potential for accidental movement during the procedure.
- 10 felt that Cric-Guide was easy to use.
- 10 described a “definite give” and 2 described a “loss of resistance” on entering the airway.
- 9 would use Cric-Guide in future if it was available [17].

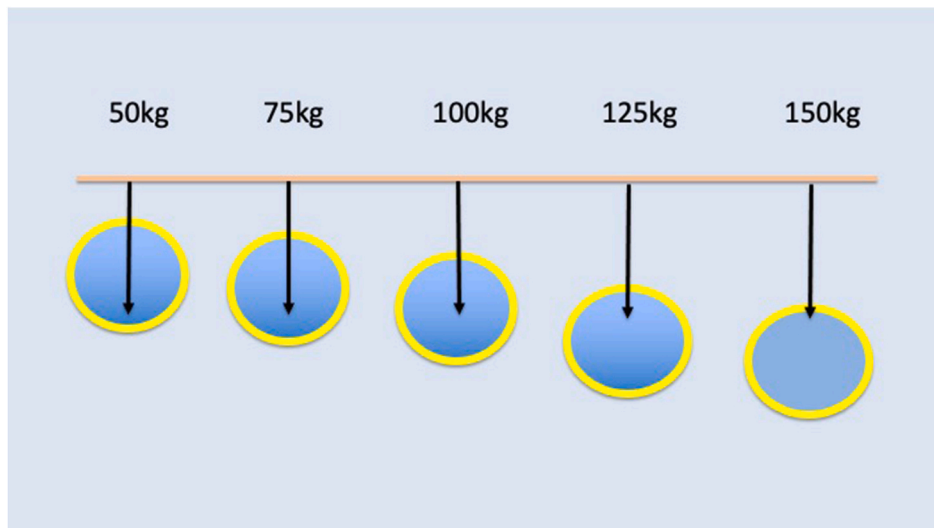


Fig. 7. Schematic diagram of depth of penetration of a 20 mm device in five patients of increasing weight. The depth from skin to the airway lumen increases with weight and there is variation of a few mm between patients of the same weight [9]. There is also variation of a few mm in the internal diameter of the airway [25].

depth guard (Quicktrach VBM), has one adult size at 25 mm. In a study of non-obese porcine larynx manikins, Quicktrach caused posterior damage in 33 % compared to 5 % with a modified Quicktrach which had a depth guard at 20 mm [23]. Also, the previously studied 30 mm depth guard with Cric-Guide had a high incidence of posterior damage in the non-obese porcine cadaver evaluation [20]. However, the depth guard cannot be too short as it may not allow a device to enter the airway at all. Endoscopic observations during eFONA have revealed that the tip of a scalpel blade must reach as far as the mid-tracheal lumen to cut through the mucosa and enter the airway. The tracheal mucosa is elastic, and endoscopic images show it stretch and tent over a scalpel blade by a few mm (Fig. 8) [23,28]. Although the depth guard at 15 mm could allow a device to just reach the airway lumen in many larger patients, it would not be long enough to reach the mid-tracheal lumen to penetrate the mucosa [9].

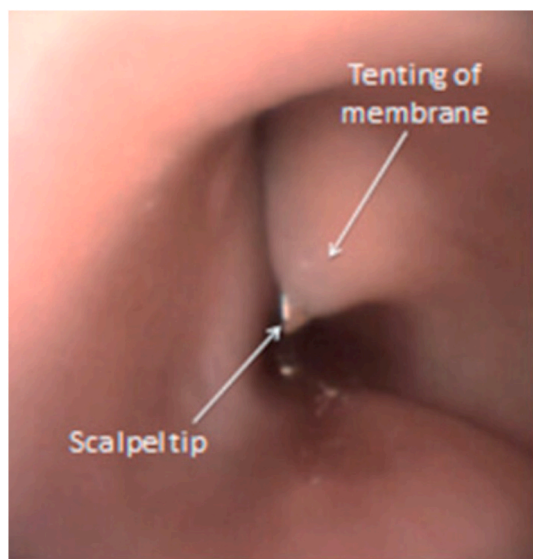


Fig. 8. From C. Yeow, Difficult airway society 2016 conference abstracts. Caught on camera: pitfalls in cricothyroidotomy [28]. Scalpel cricothyroidotomy in a porcine larynx viewed with an endoscope. The tracheal mucosa can be seen tenting over the tip of a size 10 scalpel blade before being cut. This shows the need for a device to enter the middle of the lumen to ensure entering the airway and prevent a false passage.

Choosing between more than one size of depth guard would be an unwanted distraction for the clinician when performing this stressful procedure. Therefore, considering these observations, the optimum size of depth guard for Cric-Guide (or any cricothyrotomy device) would be at 20 mm for all adult patients (Fig. 7). In the smallest patient, care must be taken to avoid posterior tracheal damage. Depth of insertion must be limited to the point where a loss of resistance is felt rather than allowing the depth guard to touch the skin. In the largest patient 20 mm may be too shallow to reach the airway [9], but direct percutaneous insertion may not be their best approach. Their cricothyroid membrane is likely to be impalpable, in which case an 8–10 cm vertical midline scalpel incision with finger dissection is undertaken to identify the anatomy and is recommended before attempting cricothyroidotomy [3]. This incision should splay the tissues off the midline, meaning that the depth to the airway is reduced and a blade with a depth guard at 20 mm can now reach the airway.

6. Cric-guide in the impalpable neck

A recent study from Dundee showed that Cric-Guide was successful following a 10 cm vertical mid-line scalpel incision in simulated obese and bleeding manikins with larynxes from porcine cadavers (Fig. 5) [22]. Cric-Guide was faster to insert, had less attempts before success and had less false passages than SBT technique. While the insertion time was statistically different, the number of attempts before success and false passages were not. However, 11 of the 12 participants (experienced anaesthetists) preferred Cric-Guide to SBT in the setting evaluated. Interestingly, they found that the depth guards entered the wide incision rather than impacting the skin on each side (Fig. 5). The depth guard used allowed 30 mm of blade penetration which caused posterior tracheal perforation in 8 %. Therefore, the study group suggested a depth guard that allows a shallower penetration to minimise posterior trauma when Cric-Guide use follows a vertical incision in the impalpable neck. This video demonstrates the Cric-Guide technique following a vertical midline scalpel incision with an impalpable cricothyroid membrane showing how the fingers of the non-dominant hand can use the depth guards to control the depth of insertion: <https://youtu.be/ZjMDhHoORTQ>.

7. Conclusion

Cric-Guide performs surgical cricothyroidotomy effectively in human cadavers and porcine models. When compared to the standard

scalpel using manikins, Cric-Guide had significantly higher first pass success rate particularly with a bleeding simulation and significantly less false passages in the obese simulation. Insertion was faster with Cric-Guide following a large vertical incision in a bleeding and obese model, and the preferred technique. Cric-Guide is presented as an effective alternative to the standard scalpel for eFONA.

Funding

None.

CRediT authorship contribution statement

Richard Vanner: Writing – review & editing, Writing – original draft, Visualization, Conceptualization. **Simon Crawley:** Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. RV is the inventor of Cric-Guide and has registered its design, as such declares that he was not involved in the conduct or writing of the research studies evaluating the device. RV declares that he has no other competing financial interests or personal relationships that could have influenced the work reported in this paper. SC declares that he has no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

Abbreviations

CICO	Can't intubate can't oxygenate
eFONA	Emergency front of neck access
SBT	Scalpel-Bougie-Tube
NAP4	4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society
NHS	National Health Service in the UK
DAS	Difficult Airway Society
ID	Internal diameter

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