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CRITICAL CARE

Comparison of three cuffed emergency percutaneous cricothyroidotomy devices to conventional surgical cricothyroidotomy in a porcine model

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Key points

- Anaesthetists may be reluctant to perform emergency cricothyroidotomy in a 'cannot intubate cannot ventilate' scenario.
- Percutaneous cricothyroidotomy uses skills familiar to anaesthetists and this study compared three cuffed cricothyroidotomy devices.
- The cuffed Melker® had the highest success rate and was ranked highest by anaesthetists.
- The Quicktrach 2® device had the fastest insertion times and caused least posterior laryngeal wall trauma.
- The PCK® device had the lowest success rate and caused most posterior wall trauma.

Background. Emergency cricothyroidotomy is a potentially life-saving procedure in the 'cannot intubate cannot ventilate (CICV)' scenario. Although surgical cricothyroidotomy remains the technique recommended in many 'CICV' algorithms, the insertion of a tracheostomy as a cannula over a trocar, or using the Seldinger method, may have advantages as they are more familiar to the anaesthetist. We compared the utility of three cuffed cricothyroidotomy devices: cuffed Melker®, Quicktrach 2®, and PCK® devices, with surgical cricothyroidotomy.

Methods. After ethical committee approval and written informed consent, 20 anaesthetists performed cricothyroidotomy with all four devices in random order, in a pig larynx and trachea model covered in cured pelt. The primary endpoints were the rate of successful placement of the cricothyroidotomy device into the trachea and the duration of the insertion attempt.

Results. The Melker® and Quicktrach 2® devices possessed advantages over the surgical approach, in contrast to the PCK® device, which performed less well. All 20 participants inserted the Melker®, with 19 being successful using the surgical approach and the Quicktrach 2®, whereas only 12 successfully inserted the PCK® device (PCK® *vs* surgical, $P=0.02$). The Quicktrach 2® had the fastest insertion times and caused least trauma to the posterior tracheal wall. The Melker® was rated highest by the participants and was the only device rated higher than the surgical technique.

Conclusions. The Melker® and Quicktrach 2® devices appear to hold particular promise as alternatives to surgical cricothyroidotomy. Further studies, in more clinically relevant models, are required to confirm these initial positive findings.

Keywords: complications, intubation tracheal; equipment, airway; tubes, tracheostomy; surgery, tracheostomy; ventilation, transtracheal

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Emergency cricothyroidotomy remains the final, potentially life-saving procedure, for the management of the 'cannot intubate cannot ventilate' scenario.[1 2] Currently, cricothyroidotomy via surgical access is the technique recommended in most airway algorithms.[3] However, anaesthetists infrequently perform surgical procedures and may lack the confidence to perform this procedure in what is likely to be an already tension-filled situation.[4] The acquisition and retention of competency in performing surgical cricothyroidotomy is further complicated by the lack of an ideal training model and difficulties in reproducing life-or-death scenarios.[5–10] These issues may lead to delays in making the decision to perform a cricothyroidotomy, which may be associated with devastating clinical outcomes.[11]

For this reason, several kits have been developed to 'simplify' the percutaneous cricothyroidotomy procedure. These devices may be easier to insert as they require minimal or no incision or dissection.[12–16] The tracheostomy tube is inserted as a cannula over a trocar, or by a Seldinger method, which most anaesthetists are already familiar with. Unfortunately, earlier versions of these devices have performed relatively poorly due to a small diameter and lack of a cuff.[3 13 17 18]

Recently, three new cuffed cricothyroidotomy devices have entered the marketplace. These are the cuffed Melker® (Cook

Medical, USA), the Quicktrach 2® (VBM, Germany), and PCK® (Smiths Portex, UK) (Fig. 1A–C). The Melker® and Quicktrach® devices are revised versions of earlier devices that now have low profile cuffs (Table 1). It is possible that one or all of these devices have advantages over surgical cricothyroidotomy. Although the cuffed Melker® and PCK® devices have previously been studied,[19–21] no study has compared all three devices with surgical cricothyroidotomy.

Methods

After ethical committee approval and written informed consent, 20 anaesthetists with at least 4 yr clinical experience consented to participate. Each anaesthetist had received formal training in the performance of surgical cricothyroidotomy. However, no recruited anaesthetist had prior experience of using any of the three new cricothyroidotomy devices.

Table 1 Physical characteristics of tracheostomy devices

	Technique	Diameter (mm)	Cuff volume (ml)	Length (mm)
PCK®	Cannula over Verres needle	6	12	113
Melker®	Seldinger	5	10	116
Quicktrach 2®	Cannula over needle	4	10	83
Shiley®	Surgical access	6.4	10	90

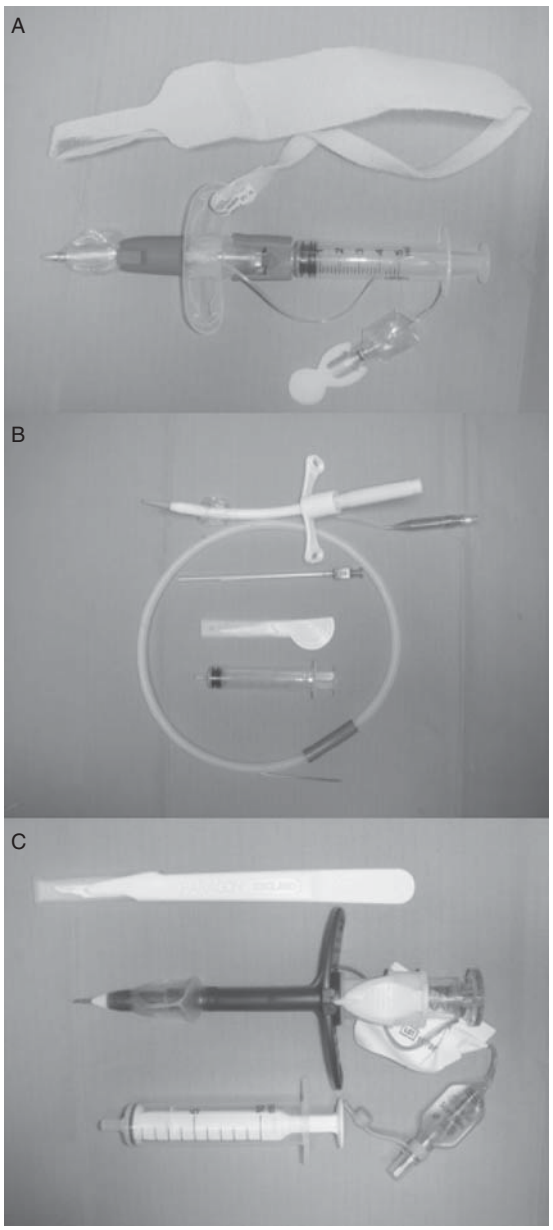

Fig 1 Three cuffed cricothyroidotomy devices used in the study: (A) Quicktrach 2®, (B) cuffed Melker®, and (C) PCK®.

The larynx model comprised a pig larynx and trachea covered in the cured pelt (pig skin), which was placed on a dissection table in a laboratory setting as described previously[15 22 23] (Fig. 2). The size of specimens was standardized, in that the laryngeal orifice dimensions approximated tracheal tubes from size 7.0 to 9.5. A cuffed tracheal tube (size 7.0) was inserted retrogradely into the distal trachea and the cuff inflated. This tube served as a sealed conduit between the trachea and a lung simulator (Fig. 2) (Pneuview 2601*i*, Michigan Instruments, Grands Rapids, MI, USA) set at a compliance of 20 ml cm^{-1}.[13 21]

The design of the study was a four-group randomized crossover design. As there were four cricothyroidotomy approaches, 24 possible sequences existed. A list of all device sequences was generated and each possible sequence placed in an opaque envelope that was sealed, and these envelopes were then numbered sequentially. After recruitment of an anaesthetist to the study, the next envelope in the sequence was opened, and the participant then used the devices in this order. As a result, 20 of the 24 possible sequences were utilized.

Individual anaesthetists were given a standardized 5 min demonstration, according to the manufacturer's instructions, of each technique by one of the investigators. Surgical cricothyroidotomy was carried out using a size 11 blade and a size 6.0 tracheostomy tube (Shiley®, Covidien, USA). Each participant was allowed one practice insertion with each device.[10] The anaesthetist then used this device under study conditions with a fresh specimen. The use of the next device was then explained to the participant and this device was then studied, until all techniques were assessed.

The primary endpoints were the rate of successful placement of the cricothyroidotomy device into the trachea and the duration of the insertion attempt. A failed cricothyroidotomy attempt is defined as an attempt in which the trachea was not cannulated, or which required >300 s to perform.[20] All devices were sealed in original packaging before use. The duration of the successful intubation was

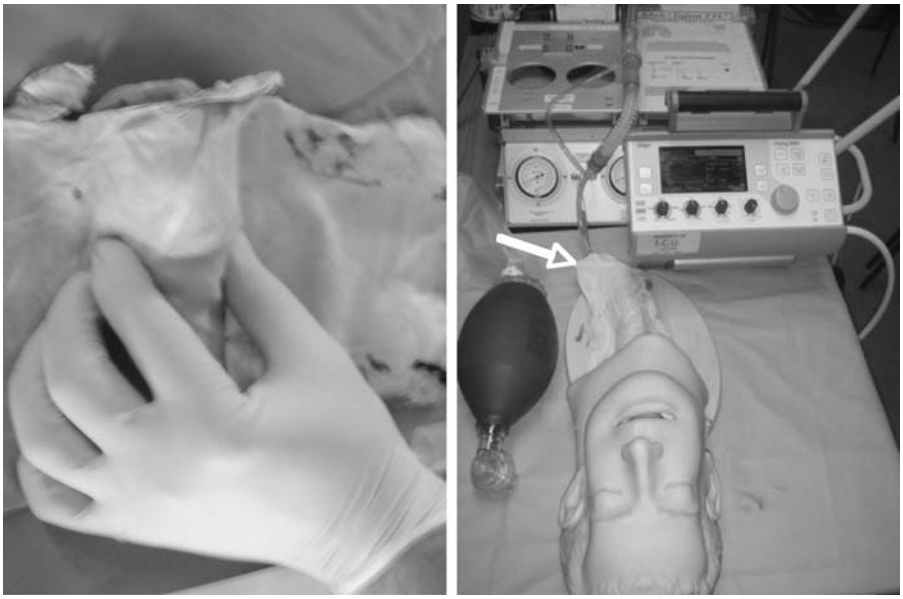

Fig 2 Cricothyroidotomy model: pig trachea covered in cured pelt and model connected to a lung simulator by a tracheal tube (arrow).

defined as the time taken from opening the cricothyroidotomy kit packaging until the cricothyroidotomy device was placed into the trachea, as evidenced by the presence of inflation of the simulated lung after connection of the device to a manual inflation device (Ambu® bag). Where the cricothyroidotomy attempt was not successful, the duration of the attempt, to the pre-specified maximum duration of 300 s, was recorded. In any case, the final cricothyroidotomy device position was verified in all cases by an investigator. Additional endpoints included the number of attempts required to insert the cricothyroidotomy device.

Once the cricothyroidotomy device was successfully inserted into the trachea, it was attached to an Oxylog 3000 ventilator (Dräger®, Lëubeck, Germany) and ventilation attempted with the following settings: tidal volume (VT)=500 ml, *I:E* ratio=1:2, PEEP=0 cm H_2O, and ventilatory rate=10. The tidal volume inflated into the test lung, the expired tidal volume, the pressure required to inflate the test lung, and the distal airway pressure were all measured.

An investigator, blinded to the device used, graded the incidence and severity of posterior laryngeal and tracheal wall trauma using a grading system: 0, none; 1, mild (partial thickness puncture or laceration <5 mm); 2, moderate/severe (partial thickness puncture or laceration >5 mm); and 3, full thickness perforation (Fig. 3A–D). Of note, participants were not informed in advance that posterior laryngeal wall trauma would be assessed.

Patient characteristic data collected included grade, experience (years) of the anaesthetist, and previous training in cricothyroidotomy or percutaneous tracheostomy. Participants completed a questionnaire before and after participation in the study in which they rated their ability and confidence in carrying out a cricothyroidotomy by any method (numeric rating scale: 0, minimum confidence or ability; and 10, maximum confidence or ability). Ease of use (numeric rating scale: 0, very easy to use; and 10, very difficult to use) and device preference (devices were ranked from 1 to 4 where 1 was the most preferred and 4 was the least preferred device) were expressed on a numeric rating scale. Expired tidal volume (VT_{EXP}) and peak airway pressure (P_{Peak}) were measured on both the lung simulator and the ventilator, whereas mean and plateau airway pressure (P_{Plat}) were measured on the ventilator only.

We performed a sample size calculation based on the duration of the insertion attempts. We proposed, based on the pilot studies, that the insertion time (not including the setup time) for the surgical approach would be 90 s, with a standard deviation (SD) of 25 s. We considered that a clinically importance difference in the insertion time would be 30 s. Using these figures, we calculated that we would require 16 participants to detect this difference with a power of 0.8 and an α of 0.05. To minimize the effects of data loss, we decided to recruit 20 participants to the study.

The distribution of data was assessed using the Kolmogorov–Smirnov test. Data for the success of cricothyroidotomy attempts was analysed using a χ^2 test, followed by a Fisher's exact test. Data for the duration of cricothyroidotomy attempts and the overall device difficulty scores were analysed using repeated-measures one-way ANOVA (one-way RM ANOVA) or ANOVA on ranks (Friedman's repeated-measures test) as appropriate. The number of cricothyroidotomy attempts and the severity of laryngeal wall trauma were analysed using the Friedman's repeated-measures ANOVA on ranks test. The data regarding pre- and post-confidence and ability

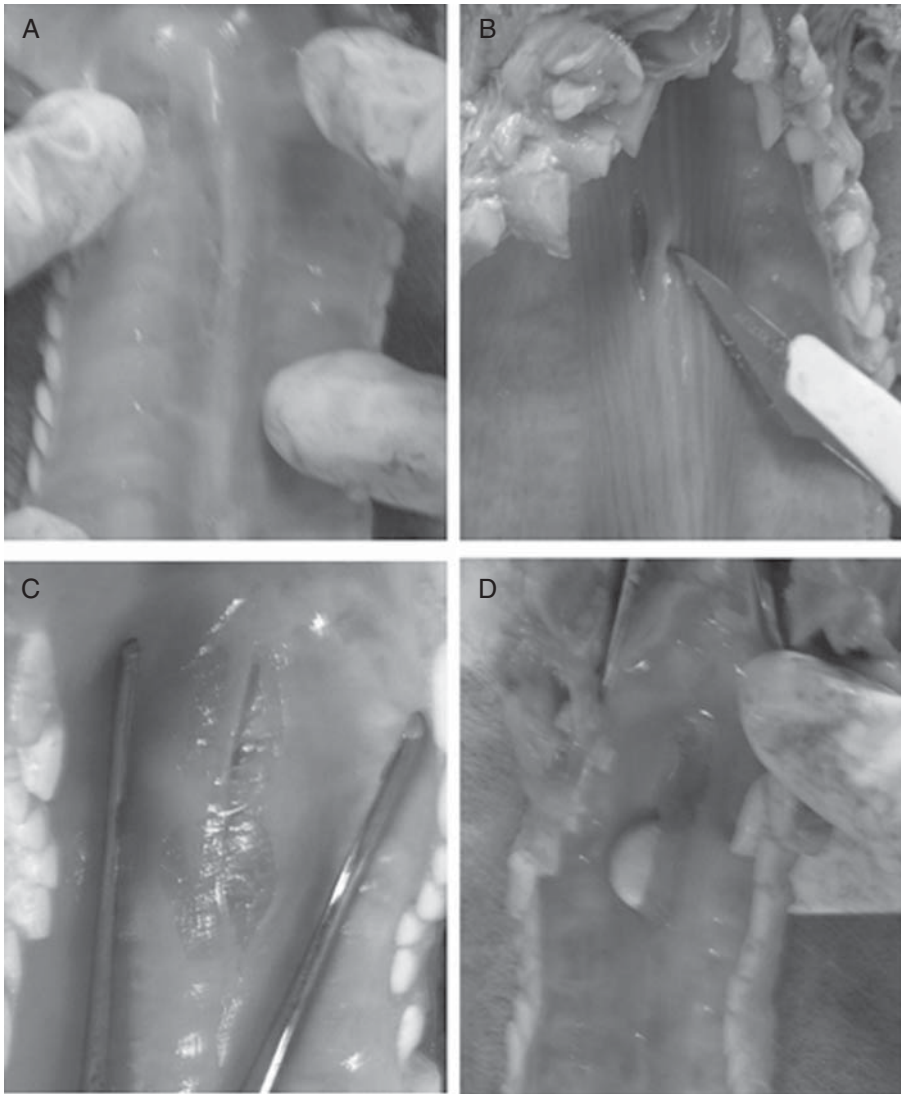

Fig 3 Posterior tracheal wall injury after cricothyroidotomy. (A and B) Minor (<5 mm) linear partial thickness laceration, (C) major (>5 mm) linear laceration, and (D) full thickness perforation. A scalpel handle has been inserted through the defect for illustrative purposes.

rating scores were analysed using paired *t* testing with corrections for multiple comparisons. For the multiple group comparisons, where the one-way RM ANOVA demonstrated a significant effect of group, *post hoc* testing was carried out using the Student–Newman–Keuls (SNK) tests.

Parametric data are presented as means with SD, whereas non-parametric continuous data are presented as median (inter-quartile range). Ordinal data and categorical data are presented as raw number and as frequencies. The α level for all analyses was set as $P<0.05$.

Results

Twenty anaesthetists of varying seniority consented to participate in the study. Nineteen had received formal training in surgical cricothyroidotomy, whereas 16 had received training in percutaneous tracheostomy. No participants had received training with any of the cricothyroidotomy sets.

Success and duration of cricothyroidotomy attempts

One anaesthetist failed with surgical cricothyroidotomy (Table 2). Eight of the 20 participants failed to successfully insert the PCK® cricothyroidotomy tube (Table 2). Seven failures were due to perforation or false passage formation in the posterior wall and one was due to exceeded time limit. The procedure time was significantly longer *vs* the surgical approach ($P<0.05$, SNK test). One participant failed to successfully ventilate with the Quicktrach 2® device (cuff tear but correct placement). All anaesthetists successfully inserted the cuffed Melker® into the trachea. However, the insertion time was significantly longer

Table 2 Data for insertion of cricothyroidotomy. Data are reported as mean (SD) or as number (percentage). CTO, cricothyroidotomy; IQR, inter-quartile range. *Significantly ($P<0.05$) different compared with surgical cricothyroidotomy. †Significantly ($P<0.01$) different compared with surgical cricothyroidotomy. ‡Significantly ($P<0.05$) different compared with Quicktrach

Variable assessed	PCK®	Melker®	Quicktrach®	Surgical
Overall success rate (%)	12 (60)†	20 (100)	19 (95)	19 (95)
Time required to setup (s) [mean (SD)]	32.9 (13.6)	32.9 (8.4)	27.5 (9.4)*	38.8 (14.2)
Duration of CTO attempt (s) [median (IQR)]	181.5 (71–300)*	94 (77–132)*	52 (38–77)*	59 (41–127)
Number of CTO attempts (%)				
1	9 (45)*	15 (75)	15 (75)	14 (70)
2	5 (25)	4 (20)	5 (20)	4 (20)
≥3	6 (30)	1 (5)	0 (0)	2 (10)
Posterior wall trauma score [median (IQR)]	2 (0–3)‡	0 (0–3)	0 (0–1)	0 (0–2)
VAS difficulty score for each technique [mean (SD)]	5.7 (2.5)*	2.8 (2.5)	4.8 (0.7)*	3.1 (2.4)
Rank—ease of use [median (IQR)]	4 (2.75–4)	1 (1–2.25)	3 (2–3)	2 (1–3)

Table 3 Data for ventilation through cricothyroidotomy. Data are reported as mean (SD) or as number (percentage). CTO, cricothyroidotomy; IQR, inter-quartile range. †Significantly ($P<0.01$) different compared with surgical cricothyroidotomy

Variable assessed	PCK®	Melker®	Quicktrach®	Surgical
Proximal (pre-CTO) P_{AW} (mm Hg) [median (IQR)]	25 (25–27.25)†	26 (25–27)†	28 (24.5–33.5)†	23 (21–23.5)
Distal (post-CTO) P_{AW} (mm Hg) [median (IQR)]	23 (20–24)	22 (20.5–23)	20 (17.25–22)	20 (20–22)
Mean airway pressure (mm Hg) [median (IQR)]	6 (5.75–7.25)†	6 (5–6)†	6 (5.25–8.75)†	5 (4.5–5)
VTE-V (ml) [median (IQR)]	367 (0–394)	391 (372–400)	384 (307–387)	386 (357–402)
VTE-lung (ml) [median (IQR)]	365 (0–400)	390 (30–400)	300 (200–380)	365 (294–390)

($P<0.05$, SNK test) *vs* both the Quicktrach 2® and surgical approach (Table 2).

Ventilation using cricothyroidotomy devices

There was a significant effect of the device used on the pressure required to ventilate via the cricothyroidotomy devices ($P=0.002$, one-way RM ANOVA). The pressures required to ventilate were significantly higher with the PCK®, cuffed Melker®, and Quicktrach 2® ($P<0.05$, SNK test) compared with the surgical airway (Table 3). The pressures required to ventilate via the cricothyroidotomy devices were highest with the Quicktrach 2® (Table 3).

However, there were no differences in distal airway pressure between the approaches ($P=0.07$, one-way RM ANOVA), indicating that the higher ventilation pressures seen with the percutaneous cricothyroidotomy devices were due to their increased resistance, likely as a result of their smaller diameters and increased lengths (Table 3).

There was a significant effect of the device used on the tidal volumes delivered ($P=0.007$, one-way RM ANOVA) and on the expired tidal volumes ($P=0.007$, one-way RM ANOVA). The Melker® device performed best in this regard, with the PCK® performing worst and the Melker® delivering significantly higher volumes than the PCK® device ($P<0.05$, SNK test) (Table 3).

Safety of cricothyroidotomy devices

There was a significant effect of the approach used on the severity of trauma to the trachea ($P=0.002$, Friedman's RM ANOVA). The trauma scores were highest with the PCK® device and were lowest with the Quicktrach 2® device. The trauma scores were significantly higher with the PCK® device compared with the Quicktrach 2® approach. There was no difference in trauma scores between the surgical technique and the Melker® device (Table 2).

User-rated variables

There was a significant difference in the user-rated ranking of the devices ($P<0.001$, Friedman's RM ANOVA). The participants ranked the cuffed Melker® kit as the easiest to use, followed by the surgical approach, the Quicktrach®, and the PCK® device (Table 2). The Melker® device was rated as significantly easier to use than all other devices ($P<0.05$, SNK test). In contrast, the PCK® was ranked significantly more difficult to use than all other devices ($P<0.05$, SNK test). The PCK® and Quicktrach® devices were considered significantly more difficult to use than the surgical approach (Table 2). The participants also ranked the devices in the same order of preference, with the cuffed Melker® device being the most preferred and the PCK® device the least preferred (Table 2).

There was a significant increase in participants' confidence in performing cricothyroidotomy, from a score of 5.85 (SD 2.3) before participating in the study to 7.8 (1.6)

after the study. There was a similar increase in participants' self-rated ability to perform cricothyroidotomy, from a score of 5.75 (2.3) before participating in the study to 7.5 (1.6) after the study.

Discussion

New cuffed cricothyroidotomy devices may offer some advantages over surgical cricothyroidotomy. However, no human prospective clinical trials exist, or are likely to be completed, comparing cricothyroidotomy kits with surgical cricothyroidotomy, due to the obvious logistic and ethical difficulties in conducting such studies.[24] Our findings demonstrate that the Melker® and Quicktrach® devices possessed advantages over the surgical approach. In contrast, the PCK® device performed less well.

Cricothyroidotomy success rates

All 20 participants successfully performed emergency cricothyroidotomy with the Melker® device, compared with 19 (95%) participants in the Quicktrach 2® and surgical cricothyroidotomy groups. In contrast, only 60% of the participants successfully performed emergency cricothyroidotomy with the PCK® device. These rates compare well with those reported in the literature, where there is variability depending on the airway model used and level of training of the participants involved. Chan and colleagues[12] reported successful placement of 93% with the uncuffed Melker® and 87% with a surgical technique after a similar training session to that used in this study. In a cadaver model, the surgical and Seldinger techniques performed relatively poorly (70% *vs* 60%, respectively).[14] In contrast, success rates of 100% in both of these techniques are reported in other studies, although several attempts may have been required.[16 21] Although no study to our knowledge has looked at the performance of the Quicktrach 2®, success rates of 95% and 100% have been described using the uncuffed Quicktrach®.[15 16] In our study, there was a 40% failure rate in the PCK® group. However, other studies of this device[19 20] have reported success rates of 93% and 80%, respectively. Unlike our study, anaesthetists in these studies had multiple attempts with the PCK® device and performance was shown to improve with repeated attempts. Our study may more closely reflect the clinical scenario in this respect.

Duration of insertion attempts

The Quicktrach 2® performed best with a median insertion time of 52 s. This compares well with previous studies of the uncuffed Quicktrach®.[15 16] The PCK® performed worst with a median insertion time of 181.5 s. This result contrasts the mean times of 32.6 and 54 s described previously.[19 20] Of note, there was only one timed PCK® insertion per participant in our study compared with 5–10 timed insertions per participant in these prior studies.[19 20] Also, in unsuccessful attempts, the pre-specified timing of 300 s was recorded. Studies comparing wire-guided *vs* emergency surgical airway placement also show variation in the duration of insertion. We recorded median times of 59 s using a surgical technique and 94 s with the Melker® Seldinger technique. These times compare well with times of 44.3 s for surgical cricothyroidotomy and 87.2 s for the cuffed Melker® previously reported in a study of anaesthetists.[21] In a study group of emergency medicine physicians, similar insertion times for both techniques were observed (72.8 s for surgical placement and 74.7 using an uncuffed Melker®).[12] Overall, factors that may account for a difference in times recorded in our study include device packaging, airway model used, perceived competency of practitioners, and timed single-trial insertion.

Efficacy of ventilation via devices

All four devices in this study were cuffed and provided an effective seal in the trachea, as evidenced by the lack of a difference between inspired and expired tidal volumes. The internal diameters of the PCK®, cuffed Melker®, and Quicktrach 2® are 6, 5, and 4 mm, respectively, compared with 6.4 mm for the Shiley® size 6 tracheotomy tube. Proximal airway pressures were higher in the percutaneous cricothyroidotomy devices compared with the surgical airway. However, there were no inter-group differences in recorded distal airway pressure. This pressure gradient generated across the three devices was greatest in the Quicktrach 2® group, as might be expected given the fact that it had the smallest diameter.

Trauma to the trachea

A substantial degree of posterior laryngeal wall injury was demonstrated with all devices tested. The incidence of posterior laryngeal wall trauma was highest with the PCK® device at 70%, intermediate with the cuffed Melker® (40%), and with surgical cricothyroidotomy (45%) and was lowest with the Quicktrach 2® (15%). Similarly, the severity of the damage to the posterior tracheal wall was greatest with the PCK® device, intermediate with the Melker®, and with surgical cricothyroidotomy and lowest with the Quicktrach 2®. Seven of 20 insertion attempts with the PCK® device resulted in significant posterior tracheal wall injury. These findings are supported by previous reports in the literature. Benkhadra and colleagues[20] dissected airways to assess injury incurred during PCK® and cuffed Melker® insertion. Eight of 20 cadavers in the PCK® group had major injuries, including four cases of posterior wall perforation. In the cuffed Melker® group, only four minor punctiform lesions were found. Assmann and colleagues[19] recorded two retro-tracheal and two pre-tracheal placements with the PCK® device, *vs* none with the cuffed Melker® kit. Complications resulting from device insertion have been attributed to insertion force and device diameter and curvature.[17] However, it would seem that the combination of the PCK® features (posterior tracheal wall contact with the Verres needle and use of a rigid linear dilator over which the airway is advanced) increases the risk of posterior wall trauma. The use of a small pilot needle to guide cannula placement in the Seldinger technique has been shown to help minimize

complications.[17] Schaumann and colleagues[25] had no observed injuries with the Seldinger technique, but there were six thyroid vessel punctures resulting from surgical cricothyroidotomy in a human cadaver model. We observed no significant difference in incidence and severity of posterior wall injury in the wire-guided and surgical cricothyroidotomy groups. Eisenburger and colleagues[14] also recorded no significant difference in complication rates using a human cadaver model, although observed incidence was 10% and 15%, respectively. Equal incidences of damage to the posterior wall by the uncuffed Melker® and Quicktrach® have been reported.[16] We found the Quicktrach 2® group to have the lowest incidence of injury in our airway model. This device is significantly shorter than the cuffed Melker® or PCK® device. The presence of a cuff on all the devices, combined with the force of insertion into a model that lacks the same anatomical support structures seen in the clinical setting, may result in increased compressibility of the larynx and trachea and increased posterior wall contact, potentially explaining the relatively high incidence of injury observed in our study.

Limitations regarding the model

We used the pig larynx covered in the cured skin to model the human neck in these studies. This model is frequently used for training and research[15] due to its widespread availability and relative anatomical similarity to the human larynx.[26] In addition, the ability to couple the larynx to a simulated lung allowed for standardized assessment of flow characteristics. However, the model generally lacks significant subcutaneous tissue and may therefore not reflect the complexity of the human neck anatomy. Alternative models exist, but they also possess disadvantages. Although mechanical lung models are particularly useful for the measurement of flow through, and pressure gradients across, airway devices while standardizing lung compliance, they poorly reproduce laryngeal anatomy or real-life situations.[13 27 28] Manikins and simulators, widely used,[16 19 29] are less realistic than animal models. Live ovine or porcine resuscitation models reliably reproduce life or death situations and test the efficacy of airway devices in reversing hypoxia.[30 31] As the circulation is intact, bleeding can occur making the scenario more realistic. However, large numbers of animals would have been required to conduct this device comparison study in this model, posing considerable logistic and other difficulties. Fresh human cadaver models are useful models as they accurately reflect relevant anatomy,[12 14 20] but are difficult to source in adequate numbers for a study of this design, and standardized assessment of flow through airway devices is impossible due to variations in pulmonary compliance.

Conclusions

In this study, the Melker® and Quicktrach 2® devices possessed advantages over the surgical approach, in contrast to the PCK® device which performed less well. The Melker® device, which uses the Seldinger insertion technique familiar to anaesthetists, was successfully inserted by all participants, was rated highest by participants, and, in fact, was the only device rated higher than the surgical technique, in these studies. In contrast, the Quicktrach® device had the fastest insertion times and caused least trauma to the posterior laryngeal wall. These devices appear to hold particular promise. Further studies, in more clinically relevant models, are required to confirm these initial positive findings.

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Conflict of interest

None declared.

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