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Parker Flex-Tip or standard tracheal tube for percutaneous emergency airway access?

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Background: Percutaneous emergency airway access (PEAA) can be established utilising a scalpel, bougie and cuffed tracheal tube. The study compared the Parker Flex-Tip tracheal tube with a standard tracheal tube for PEAA in cadavers. We hypothesised that a standard tracheal tube would be more likely to advance over a bougie into the trachea during a PEAA procedure than a Parker Flex-Tip tracheal tube.
Methods: Three anaesthetists performed a PEAA with a scalpel, bougie and cuffed tracheal tube, 12 times each. Recorded times included: loading the tracheal tube onto the bougie and advancing the tube over the bougie to the skin, advancing the tube through the skin into the trachea and completion of the whole procedure. Subjective opinion regarding the ease of tube insertion was recorded by visual analogue scoring.
Results: Subjective opinion, overall time and time to complete each component of the procedure were not significantly affected by the type of tube used. The mean time for three novice anaesthetists to complete PEAA on a cadaver was 37.5 (8.8) s, after 1 h of training. In two of the 12 cadavers, the cricothyroid membrane could not be palpated or located with the scalpel.
Conclusion: The Parker Flex-Tip tube and a standard tracheal tube perform equally well during PEAA procedures on adult cadavers.

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Percutaneous emergency airway access (PEAA) is indicated whenever ventilation by face mask, supraglottic airway device or tracheal intubation cannot maintain acceptable levels of oxygenation. Several techniques have been described to manage the 'cannot intubate, cannot oxygenate' scenario including the rapid four-step surgical cricothyroidotomy. The original description of this technique by Brofeldt included a size 20 scalpel, a tracheal hook with a large radius and a cuffed tracheostomy tube.[1] A variation of this technique has since been described by Morris et al. without the tracheal hook, utilising a scalpel, a bougie and a standard tracheal tube.[2] In an adult, the cricothyroid membrane is first identified, and then a transverse stab incision is performed through overlying tissue and the cricothyroid membrane using a size 20 scalpel. The scalpel is rotated 90 degrees to form a triangular-shaped pocket through which a bougie is then introduced and advanced down the trachea. Finally, a size 6.0-mm internal diameter (ID) cuffed tracheal tube is railroaded over the bougie using a rotating action, and a secure airway is established after removal of the bougie. This method has been called the scalpel bougie technique by Heard et al. and includes the option of re-oxygenation through the Frova intubating introducer (Cook® Medical, Bloomington, IN, USA) prior to tube insertion.[3]

Tracheal tube diameter and design affects tracheal intubation success rates for oral and nasal intubation. Although the diameter of the tracheal tube has been considered for adult rapid four-step surgical cricothyroidotomy,[4] a comparison of tube tip design has not yet been investigated. We have previously observed that during training for emergency tracheotomy in anaesthetised pigs, the Parker Flex-Tip tube occasionally everts at the edge of the tracheal wall prior to tube insertion. Our observation inspired this randomised controlled trial.

The Parker Flex-Tip tracheal tube has a soft hemispherical curved bevel tip and was designed to reduce trauma during oral and nasal intubation. The

Table 1

Characteristics of cadavers including age, gender and neck circumference.

Cadaver	Age	Gender	Neck circumference (centimetres)
1	71	F	44
2	88	M	35
3	99	F	27
4	60	F	42
5	78	M	37
6	84	F	36.5
7	72	M	37.5
8	73	F	35.5
9	91	F	34.5
10	83	F	36
11	81	F	33
12	96	F	30

S, standard; PFT, Parker Flex-Tip.

tip of the Parker Flex-Tip tube reduces the gap between the inside of the tube and the bougie, thereby reducing the chance of impingement on the larynx. Therefore, there is a theoretical advantage of advancing the Parker Flex-Tip tube over a bougie during PEAA. This advantage could theoretically be undermined by impingement due to the eversion of the soft tube tip on the tissue margins of the narrow cricothyroidotomy or tracheotomy incision.

We hypothesised that a standard tracheal tube would be more likely than a Parker Flex-Tip tracheal tube to advance over a bougie into the trachea during a PEAA procedure. The aim of this study was to compare the efficacy of a Parker Flex-Tip tube with a standard tracheal tube for PEAA in adult cadavers. The primary end point was the time taken to pass the tube through pre-tracheal tissue.

Methods

Approval was obtained from the Northern X Regional Ethics Committee (NTX/11/EXP/241), registration was completed with the Australian and New Zealand Clinical Trials Registry (ANZCTR: ACTRN12611001121954), and written informed consent was gained from each of the participating anaesthetists. Nine female and three male adult preserved human cadavers were used in this study, and their age, gender, weight and neck circumference appear in Table 1.

One female and two male consultant anaesthetists, aged 41, 37 and 36 years, responded to a departmental advertisement for study participants. Inclusion criteria required consultant anaesthetists less than 45 years of age and 10 years after residency,[5] with no prior experience performing PEAA or attendance at PEAA training during the last 2 years. Participants attended a preliminary 1-h didactic and manikin-based training session to familiarise them with PEAA techniques including the scalpel bougie technique. A video of the scalpel bougie technique was also shown.*[6]

Fig. 1. The Parker Flex-Tip tube (right) has a soft hemispherical curved bevel which creates a smaller gap between the tube and the Frova bougie than the standard tracheal tube (left).

The two tracheal tubes used were the Parker Flex-Tip™, 6.0-mm ID, 8.2-mm outside diameter (OD), high-volume low-pressure cuff tube (Parker Medical, Englewood, CO, USA) and the Mallinckrodt™ Hi-Lo™, 6.0-mm ID, 8.2-mm OD, high-volume low-pressure cuff tube (Covidien, Mansfield, MA, USA). A Frova intubating introducer was used for all intubations (14 French catheter, 65 cm long, 3.0-mm ID, recommended for placement of tracheal tubes with internal diameters ≥ 6.0 mm) (Fig. 1).

Anaesthetist, cadaver and type of tracheal tube were all randomised by a statistician (J. T.). The first procedure on each cadaver was a cricothyroidotomy, then two percutaneous tracheotomy procedures were performed below the cricothyroid incision, using the same PEAA technique. Anaesthetists were asked to conduct the technique as if it were an emergency and were video-recorded performing the pro-

**http://www.youtube.com/watch?v=TveIsbjmakU [Accessed 10 December 2012].*

Table 2

Timed events and subjective visual analogue scale (VAS) for the percutaneous emergency airway access (PEAA) technique.

Timed events	Total times Mean (SD) seconds	Parker Flex-Tip™ Mean (SD) seconds	Standard tube Mean (SD) seconds	T (*P*-value)
Time between bougie and TT access for ventilation	12.8 (2.7) $n = 28$			
TT load (TT starting to load until TT contacts skin)		3.6 (1.4) $n = 14$	3.5 (0.9) $n = 14$	–0.3 (0.76)
Time to advance TT from skin incision into trachea		4.8 (1.3) $n = 14$	5.4 (2.0) $n = 14$	0.8 (0.4)
Stopwatch time for total procedure	37.5 (8.8) $n = 34$	36.8 (8.8) $n = 17$	38.2 (9.0) $n = 17$	0.4 (0.7)
Subjective VAS score for ease of intubation (mm)		24.5 (16.7) $n = 17$	18.5 (13.5) $n = 17$	–1.2 (0.3)

TT, tracheal tube; SD, standard deviation.

cedure. The cadavers were positioned with their necks extended as much as possible. All necessary equipment required for the procedure was immediately available, and an assistant handed equipment to the participant as required. A new tracheal tube was used for each procedure. It was not possible to blind the anaesthetist to the tube tip design because the tube had to be loaded onto the bougie by the anaesthetist; the anaesthetists were not told, however, that the tubes were being studied.

Each procedure was timed by stopwatch from the beginning of neck palpation until the first inflation of a self-inflating bag. Video recordings were analysed, and segments of the procedure were timed using an on-screen digital timer on the recordings. Times were measured for loading of the tracheal tube onto the bougie and advancing it to the skin, and also advancing the tracheal tube from the skin down the trachea. Times were measured and compared for bougie and tracheal tube availability for oxygenation. Tracheal intubation was confirmed by direct anatomical inspection.

Following each procedure, the participants completed a questionnaire using a 100-mm visual analogue scale (VAS) to measure their responses to the following question: Please rate the ease of tracheal tube insertion off the bougie during this procedure.

The left and right ends of the VASs were labelled 'Very easy' and 'Very difficult', respectively.

Statistical analysis was carried out using *t*-tests to determine differences in time between the Parker Flex-Tip tubes and standard tracheal tubes. Statistical significance was defined as $P < 0.05$. Our sample was a sample of convenience. The trial was only possible because of the availability of cadavers usually used for teaching purposes. Our design using 12 cadavers three times each gave a sample of 18 attempts with each tube. With 80% power at the 5% level of significance, this allowed us to detect a difference of 0.962 s.d. for differences in times between the two groups.

Results

A tracheal tube was successfully guided over the bougie and through the surgical incision in 34 of 36 attempts. In two cadavers, the cricothyroid membrane could not be palpated or located with the scalpel, and the procedure was abandoned after 3 min 45 s and 2 min 22 s, respectively. These two cadavers (1 and 4) had been randomly allocated a Parker Flex-Tip and a standard tracheal tube. They had short thick necks with circumferences of 44 cm and 42 cm (Table 1). Two successful tracheotomy procedures were subsequently performed on these two cadavers.

Five video recordings of tracheotomies failed and a sixth recording was incomplete, leaving 28 complete recordings. The mean times and subjective VAS score for the procedure appear in Table 2. We did not find any difference in any of the times that involved comparison of Parker Flex-Tip tube or standard tracheal tube. After 1 h of training, three novice anaesthetists were able to complete PEAA in a cadaver using a scalpel, bougie and tracheal tube in a mean time of 37.5 (8.8) s.

Discussion

The time and ease of placement of a Parker Flex-Tip and a standard tracheal tube over a bougie during a PEAA procedure were compared. The overall time to complete these procedures was not affected by the type of tracheal tube used. When examining the time to load the tube onto the bougie and advance it to the skin, and the time to advance the tube over the bougie from the skin down the trachea, there was no significant difference between each tube. The differences seen were well below those able to be detected

by our sample size and not considered to be of any clinical significance. There were no examples of severe tube impingement at the tissue margin for either tube. There was no subjective difference between the ease of inserting a standard tracheal tube or a Parker Flex-Tip tube off a bougie during a surgical tracheotomy.

Several studies have examined the impact of tracheal tube design on intubation success during oral and nasal intubation.[7–10] The factors that can influence intubation success include tube diameter, the relative distance between a bougie or a flexible bronchoscope and the inside of the tube, material used by the manufacturer, tube flexibility and tip design. Decreasing tracheal tube diameter can improve intubation success. A size 6 cuffed Shiley tracheostomy tube was originally proposed for the rapid four-step surgical cricothyroidotomy.[1] This 6.0-mm internal ID tube has an 11-mm OD and a distal length of 49 mm, and therefore has a shorter length, larger OD and surface flanges that restrict the length of intubation compared with a size 6.0-mm ID tracheal tube (8.2-mm OD).[2,11,12] In a cadaver study of standard surgical cricothyroidotomy with cephalad tracheal hook retraction, compared with the rapid four-step technique using caudal tracheal hook retraction, it was found that there was no significant difference in tubes passing with internal diameters of 6.0, 7.0, 7.5 and 8.0 mm.[4] From an anatomical point of view, dimensions of the adult cricothyroid membrane limit the maximum outside diameter of a tracheal tube to 8.0 mm.[13] The OD of the bougie and the ID of the tracheal tube are also important variables for intubation success. A size 6.0-mm ID tracheal tube is the minimum diameter suitable for the Frova 14 F intubating introducer. This combination has the advantage of providing the minimum gap between the inside of the tracheal tube and the outer surface of the bougie. This gap can be further reduced by the tip design of the Parker Flex-Tip tube. The Parker Flex-Tip tube has been shown to cause less bleeding during nasal intubation and improve intubation success over oral tube exchangers and flexible fibreoptic bronchoscopes because of its soft hemispherical curved bevel tip, which minimises the gap between bougie and tube.[9,14,15]

The rapid four-step surgical cricothyroidotomy was designed for its speed and simplicity. This method is easy to learn, has been successfully used clinically and uses airway equipment that is readily available.[2] The procedure can be completed in 30 s, which is one-third of the time required for the standard surgical cricothyroidotomy technique.[16] The three novice anaesthetists in our study were able to perform the procedure in mean time of 37.5 (8.8) s (Table 2), after 1 h of training. If anatomical landmarks cannot be rapidly palpated, such as in obese patients, the neck should be incised with a longitudinal midline incision in order to internally palpate and clearly identify laryngeal cartilages before making a horizontal incision through the cricothyroid membrane.[1,16] Percutaneous palpation of the cricothyroid membrane is time consuming and is associated with a low success rate.[17] Pre-operative identification and marking of the cricothyroid membrane could shorten this time and improve the success rate.

The type of bougie selected should be suitably rigid, such as the Frova, to allow manipulation through the tissue and provide support for the tracheal tube. The 14 F Frova bougie has a 3.0-mm ID lumen that can be attached to an oxygen source with Rapifit® adapters (Cook Medical Inc, Bloomington, IN, USA) for either jet ventilation or low-pressure ventilation. This connector can also be used to confirm correct tube placement by capnography[18] or oesophageal bulb.[19] We found that ventilation of oxygen through the Frova could have occurred 12.8 (2.7) s earlier than ventilation through the tracheal tube (Table 2); however, this time did not include the time to locate, attach and set up a suitable ventilation device. The benefits of slightly earlier oxygenation using this technique need to be balanced by the potential risks. The incorrect use of a high-pressure oxygen source for re-oxygenation through an airway exchange catheter can cause barotrauma, leading to fatal consequences.†[20] It is essential not to advance the bougie or the tracheal tube beyond the carina, and these devices should be held or secured in order to prevent migration beyond or out of the trachea.[21] Caution is also required during jet ventilation to maintain a patent airway for the egress of gas and to prevent over-vigorous insufflation of oxygen. The risks associated with using airway exchange catheters are discussed in the Difficult Airway Society Guidelines for the management of tracheal extubation.[22]

In this study, we included both cricothyroidotomy and tracheotomy because the aim of the study was to measure the time to advance a tracheal tube through pre-tracheal tissue. The characteristics of the overlying tissue at the cricoid or upper tracheal level are very similar in terms of advancing

†*http://www.scotcourts.gov.uk/opinions/2010FAI15.html [Accessed 10 December 2012].*

a tracheal tube, and, in a study of adult cadavers by Holmes et al. of standard surgical cricothyroidotomy and rapid four-step cricothyroidotomy, inadvertent tracheotomies were relatively common, all between the cricoid cartilage and the first tracheal ring.[16] In some clinical circumstances, such as paediatrics,[23] a tracheotomy is preferable to a cricothyroidotomy. Needle cricothyroidotomy in a child under the age of 5 is technically challenging because of the difficulty identifying surface landmarks. In neonates, the larynx is prone to injury during cricothyroidotomy.[13,24] PEAA is the common clinical goal for surgical cricothyroidotomy and tracheotomy.

There are limitations to this study. The cadavers were not examined for signs of airway trauma after each procedure because this was not the aim of the study. Several studies have found a higher incidence of major complications associated with the rapid four-step technique compared with the standard cricothyroidotomy technique.[4,16,25] Complications included complete transection of the cricoid cartilage, fracture of the cricoid cartilage and puncture of the posterior trachea and anterior oesophagus.[16] Using preserved cadavers as our experimental model, the procedures were not affected by bleeding, which would occur in a clinical situation.[13,26] In a clinical series of 24 successful 'scalpel-finger-tube' techniques, significant bleeding occurred in four cases, all of which were managed conservatively and successfully.[27] We did not visualise tracheal intubation by endoscopy during the procedure. Direct anatomical confirmation of tracheal intubation was performed from the pre-dissected thorax when difficulty was encountered passing the tracheal tube over the bougie. The tracheal tube was found to be in the trachea in every instance.

The principal finding of this study is that the Parker Flex-Tip tube can be advanced over a bougie during a PEAA as effectively as a standard tracheal tube. Based on these results, we therefore conclude that the Parker Flex-Tip tube is a satisfactory alternative to a standard tracheal tube during PEAA procedures.

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Conflicts of interest: The study was funded by institutional and departmental sources. P. A. Baker has received free airway equipment for research and teaching from a variety of manufacturers. He is also the owner of Airway Simulation Ltd. A.E. Hamaekers is a member of the medical advisory board of Ambu A/S. She has no financial interest in any company. No competing interests are declared by the other authors.

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