



Airway exchange devices: Evaluation of airway trauma potential

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ABSTRACT

Background: Several airway management guidelines recommend the use of airway exchange devices (AED) in airway management strategy.

Aim: We aimed to evaluate airway trauma potential of four AEDs - Cook, Aintree Exchange Catheter (Aintree), Frova Intubating Introducer (Frova) and Rüschi EndoGuide (Rusch) during airway exchange or oxygen administration.

Methods: Airways were simulated using a manikin (incidence of insertion beyond 26 cm) and a porcine lung model (barotrauma potential). Seventy-two anaesthetists were observed using three commonly used AEDs: Cook, Frova and Aintree in a manikin model. We tested two AED designs, Rüschi and Cook to evaluate whether differing AED design influences barotrauma potential.

Results: The Frova, Cook and Aintree airway exchange devices were inserted beyond 26 cm on 63 (88%), 63 (88%) and 18 (25%) occasions respectively ($p < 0.001$). In the porcine model the mean (SD) time to barotrauma for oxygen flows of 2 and 4 l/min for the Cook was 22s (1.9) and 11s (1.8) and for the Rüschi was 12s (1.3) and 5s (1.1) respectively ($p < 0.001$).

Conclusion: We concluded that AEDs should be used with caution during airway exchange, not as a means of oxygen insufflation. A new design may be required to improve their safety profile.

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1. Introduction

National UK extubation guidelines [1] and a number of international airway management guidelines [2,3] are recommending the use of an airway exchange devices (AED) as part of the airway management strategy. The AEDs are designed with two functions in mind: firstly as an adjunct for exchanging one airway device for the other (tracheal tubes or supraglottic airway devices) and secondly to facilitate protected extubation and potential airway rescue after extubation of patients with difficult airways [1,4–7]. Both circumstances may require administration of oxygen through the AED [7–9]. However, a series of case reports have identified a number of potentially serious complications associated with their use. These include direct airway trauma following insertion of an AED [10,11], and barotrauma when used to insufflate oxygen [9,12–15]. McLean et al. reported the airway injury rate of 7.8% with 1.5% rate of pneumothorax in a cohort of 1177 patients [16]. The risk of airway perforation is considered to increase when the AED is inserted

beyond the depth of 26 cm or when resistance is encountered [5]. Several publications [1,5,17] and one manufacturer (Cook Medical) [18] have suggested limiting the depth of insertion to 25 or 26 cm in order to avoid both direct airway injury and injury associated with oxygen administration when AED is inserted into the airway beyond 26 cm. Bougies, devices used for managing difficult intubations are commonly used as airway exchange devices [19,20]. When used for intubation, bougies are inserted to the median depth of 30.5 (23–40) cm from the incisors [21] with potentially serious consequences [22]. Furthermore, bougies are also used as an airway exchange device and extubation in difficult airways [23].

Previous authors have stated that oxygen insufflation via AED is safe when there is an adequate space around the AED for gas to escape [1,2,5]. A recently published in-vitro case series found that oxygen insufflation above the carina is unlikely to cause barotraumas whatever the oxygen flow rates [24]. Oxygen insufflation via airway exchange catheter when inserted to the depth of the first point of resistance, however, has the potential to cause barotrauma within few seconds [24].

We could find no evidence related to the incidence of AED insertion beyond 26 cm when used by anaesthetists. In addition, there appears to be no evidence related to the effect of the type of

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the AED on the incidence of insertion beyond 26 cm or the potential for direct airway trauma when this occurs. Although, recent publication found no difference in barotraumas potential between standard and soft-tipped airway exchange catheters there is no evidence evaluating airway trauma potential of other commercially available AED designs [24].

The devices evaluated in this study included the Frova Introducer (Cook UK, Hitchin Herts UK) (Frova), the Cook Airway Exchange Catheter (Cook UK, Hitchin, Herts UK), the Rusch EndoGuide T (Teleflex Medical UK, High Wycombe, Bucks, UK) and the Aintree Intubation Catheter (Cook UK Hitchin Herts UK). The Frova introducer (Frova) is designed to facilitate tracheal intubation and is associated with a high incidence of successful intubation when used during potentially difficult airways [25]. It has a length of 70 cm, an outer diameter of 4.7 mm. A number of reports describe the use of a bougie as an airway exchange device [23]. The Cook Airway Exchange Catheter (Cook) is a device intended for tracheal tube exchange with a separate adaption allowing the device to be connected to an oxygen source. Evidence from a series of case reports also suggests it can be used in the management of difficult extubations [26,27]. Cook catheters are available for use with tracheal tube sizes of 3, 4, 5 and ≥ 7 . The device evaluated in this study was for adult use with a length of 83 cm, and an outer diameter of 6.3 mm (19 French Gauge) The Aintree Intubation Catheter (Aintree) is designed to be used for fibreoptic-guided placement of tracheal tubes via a laryngeal mask airway and also for the exchange of laryngeal mask airways for tracheal tubes using a fibreoptic bronchoscope [28]. Aintree is 56 cm long with an outer diameter of 6.3 mm. All aforementioned AEDs are provided with oxygen connectors, either standard 15 mm and luer-lock for jet ventilation. The Rusch EndoGuide T (Rusch) is designed for tracheal tube exchange. It has a connector set which allows the device to be attached to an oxygen source. The device used was intended for use in tracheal tube sizes between 6.5 and 11. This is the only size available for adult use. It has a length of 83 cm and an outer diameter of 5.0 mm (15 French Gauge). In addition of having smaller outer diameter when compared to Cook, this AED has single hole at the tip for delivery of oxygen, compared to tip and side holes in the Cook's AED.

We therefore decided to conduct a study using manikin and porcine models. We used a manikin model set to evaluate the incidence of insertion of AED beyond 26 cm and forces exerted at the tip of the device when the AEDs are accidentally inserted beyond carina. We tested Frova, Cook and Aintree for depth of insertion during airway exchange. We hypothesized that the varied length of the three tested devices (70 cm, 83 cm and 56 cm respectively) may have effect on the incidence of insertion beyond 26 cm and forces exerted at the tip of AED during airway exchange. We used a porcine lung model to determine the speed of onset of barotraumas using oxygen flows of 2 and 4 l/min (oxygen flow rates considered to be safe by expert opinion [10]) when the AED is lodged into the airway [10]. We hypothesized that different design related to the oxygen delivery function of the two AEDs (different size and location of the oxygen delivery holes at the tip of the AED and different outer diameters) may have an effect on the speed of barotrauma. We tested Cook and Rusch AEDs as they differed in outer diameter (6.3 mm and 5 mm respectively) and in the distribution and number of oxygen delivery holes at the AED tip (two side and one opening at the tip for the Cook and one single opening at the tip for the Rusch).

2. Methods

This study was approved by the Cardiff and Vale University Health Board Research and Development committee who advised

us that NHS ethics committee approval was not required. Advice was sought from the Cardiff University ethics committee regarding the porcine lung model study and it was deemed that formal approval was not required.

2.1. Manikin model

Written informed consent was obtained from 72 anaesthetists with two or more years of anaesthetic experience working in the South Wales region (University Hospital of Wales and the Royal Gwent Hospital). We modified two Laerdal Airway Management Trainers (Laerdal manikin) by using transparent plastic tube extensions attached to the main bronchi (Fig. 1) simulating airway length of 26 cm. This allowed visual detection of the airway exchange device when it was inserted beyond 26 cm. This manikin's airway extension was aligned to a force gauge transducer (Mecmesin PFI200N; Mecmesin, Slinford, West Sussex, UK). (Fig. 1). We used two manikin models. One manikin was intubated with a size 7 tracheal tube (Portex, Smiths Medical, Watford, UK), which was exchanged using the Cook exchange catheter and the Frova bougie for an identical tracheal tube. The other manikin had an i-gel size 4 laryngeal mask in situ (Intersurgical, Wokingham, UK). Participating anaesthetists were asked to exchange i-gel for a size 7 tracheal tube (Portex, Smiths Medical, Watford, UK) using an Aintree catheter loaded onto a re-usable fibreoptic scope (Pentax Medical, Pentax House, Slough, UK). Participating anaesthetists were blinded to whether they advanced the AED too far in the airway during airway exchange (theatre drapes were used to screen the participants from the lower part of the manikin's airway). The manikins were positioned on patient trolleys so that participating anaesthetists can adjust the height of the trolley according to their preference. Each participant was asked to complete the three standardized tasks, tracheal tube exchange using Frova bougie and Cook exchange catheter on one manikin and i-gel for tracheal tube exchange using Aintree catheter and fibreoptic scope on the second manikin, in a computer generated randomized order using modified excel program. We recorded whether the device was advanced beyond 26 cm (visualization of the device at the end of the manikin's airway), the peak force exerted at the tip of the devices introduced too far and the time to exchange the airway device (from the time the AED is handed over for airway exchange to the time the device is handed back after the airway exchange). Each anaesthetist was also asked to state their preferred device for airway exchange. The peak force was not measured for the Aintree.

2.2. Porcine lung model

A porcine lung case series was used to test the speed of barotraumas at oxygen flow rates of 2 L/min and 4 L/min when the device is advanced and lodged into the airway. We used porcine lungs attached to the upper airway sourced from a local abattoir that were tested within 24 hrs of slaughter. The specimens were stored in a refrigerator until collection ($<4^{\circ}\text{C}$). All samples were tested on the day of collection. Specimens were inspected before testing and specimens that showed signs of visible damage were excluded. Ten samples each of the Cook and Rusch airway exchange devices were evaluated for barotrauma potential.

The speed of onset of barotrauma was measured after inserting the AED into the lumen of the porcine airway. The AED was gently inserted until minimal resistance was encountered. Once the point of hold-up has been reached the AED position was maintained by the researcher and the AED was connected to the oxygen delivery tubing. Oxygen was administered via the AED at 2 l/min and 4 l/min. Timing began once the oxygen tubing had been connected to the AED and stopped once there was visible evidence of

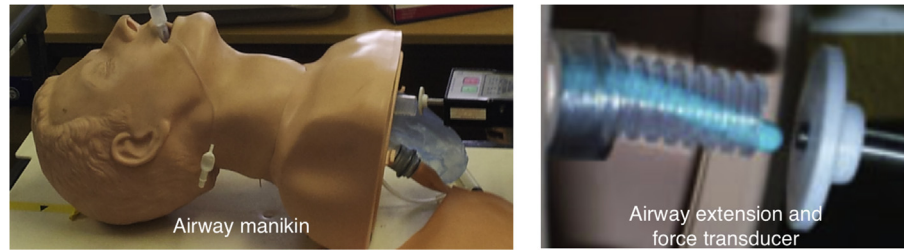


Fig. 1. Modified airway manikin with airway extension and force transducer.

barotrauma, defined as visible evidence of air under the overlying pleura (Fig. 2). Each AED was tested three times at each flow rate.

2.3. Statistical analysis

We used SPSS version 20 (SPSS Inc, Chicago, IL, USA) to evaluate the data. Cochran's Q test was used to analyse nominal data and Friedman and Wilcoxon tests used to analyse continuous data. For data collected from the porcine lung model *t*-test was used. A *p* value < 0.05 was considered to be significant.

Sample size, manikin model. As we could not find a study that looked at the incidence of insertion beyond 26 cm during airway exchange to guide our sample size calculation we decided to conduct a pilot study inviting 72 anaesthetists to take part to allow for the range of experience and location of work to be included.

Sample size, porcine lung model. We based sample size calculation upon a similar study by Marson et al. that evaluated bougie related airway trauma using a porcine lung series [23]. We used sufficient number of fresh porcine lung models to test ten Cook and

ten Rusch AEDs, repeating the test three times for each device to compensate for the variation in the recording process.

3. Results

3.1. Manikin model

The Frova and Cook had a significantly higher incidence of being inserted beyond 26 cm compared with the Aintree (Table 1). The mean (SD) force exerted at the tip of the devices inserted too far was 6.7 (3.2) N and 4.4 (4.1) N for the Cook and Frova respectively ($p < 0.001$). The Frova was preferred by 41 (57%) and Cook by 29 (40%) anaesthetists for tracheal tube exchange.

3.2. Porcine lung model

The mean onset time for barotrauma was significantly faster with the Rüschi compared with the Cook (Table 2).

4. Discussion

The results of this study demonstrate that the Frova and Cook were advanced beyond the safe distance of 26 cm by a significant proportion of anaesthetists during tracheal tube exchange. Forces exerted at the tip of the Frova and Cook during airway exchange were high but significantly higher for Cook AED. Barotrauma occurred within a few seconds with both devices at both flows but the onset of barotrauma was significantly faster with the Rüschi compared with the Cook irrespective of flow.

Several case reports documenting AED related trauma also highlight that in the majority of these cases the AED was inserted beyond the recommended distance of 26 cm and thus airway trauma is more likely to occur when these devices are advanced too far [5,9,10,15,21,29]. Our findings suggest that collectively 48% of all attempts by participants were inserted beyond 26 cm. Eighty-eight per cent of anaesthetists inserted the Frova and the Cook beyond the recommended distance of 26 cm. In comparison the Aintree was only inserted beyond 26 cm by 32% of participants. The Aintree was less likely to be inserted too far, possibly due to it being a much shorter device (56 cm vs 83 cm and 70 cm for the Cook and Frova respectively). Furthermore the force exerted at the tip when the AED is inserted too far is enough to cause perforation as documented by Marson et al. [22]. This data proposes the idea whether a different design of AED with clear markings related to length or a shorter overall length would be of benefit in decreasing the incidence of over insertion. A design of a 'traffic-light bougie', a bougie with a colour modification to indicate depth has already been shown to be effective in reducing the depth of bougie insertion [21]. The Frova was the preferred device for airway exchange in comparison with the Cook and this may be related to familiarity with this equipment among the participants in our study. The shorter length of the Frova (70 cm vs 83 cm for the Cook) also did not



Fig. 2. Porcine lung testing using O₂ flows of 2 and 4 L/min.

Table 1

Incidence of insertion beyond 26 cm and time to complete tracheal tube exchange. Values are number (%) and median (range [IQR]) as appropriate. n = 72.

	Frova	Cook	Aintree	p value
Inserted >26 cm	63 (88%)	63 (88%)	18 (25%)	<0.001*
Time (s)	28 (18–59 [24–34])	29 (19–69 [25–37])	43 (28–125 [42–69])	<0.001†
Force (N)	4.4 [1.5–6.9]	6.3 [3.5–9.9]	NA	

*p value refers to overall effect of device on the incidence of insertion beyond 26 cm.

†p value refers to overall effect of device time to complete tracheal tube exchange.

Table 2

Time for barotrauma to develop (s). Values are mean (SD).

O ₂ flow	Rüsch	Cook	Diff [95% CI]	p value
2 l/min	12 (1.3)	22 (1.9)	10 [9–12]	<0.001
4 l/min	5 (1.1)	11 (1.8)	6 [5–7]	<0.001

appear to hinder tracheal tube exchange which was 28 s and 29 s for the Frova and Cook respectively. This suggests a modification of a piece of equipment already widely used and preferred by anaesthetists for tracheal tube exchange may be a more attainable option in reducing the risk of over insertion and thus improving the safety profile of AEDs than designing a new device altogether [29,30].

Barotrauma potential was assessed in both the Cook and Rüsch devices at 2 and 4 L/min. Overall both devices caused visible airway trauma within just a few seconds. Not surprisingly the onset of barotrauma occurred in less time with 4 L/min of oxygen insufflation than 2 L/min. Of note when the Rüsch was used to insufflate oxygen at a rate of 4 L/min was that barotrauma occurred in just 5 s; even at a flow of 2 L/min, barotrauma occurred in less than 30 s irrespective of the type of AED used. Nevertheless, the speed of barotrauma at both flows was significantly faster with the Rüsch compared with the Cook. The differing findings of the two devices can be attributed to design. The Cook has a larger diameter than the Rüsch so is more likely to be only inserted into larger airways and consequently insufflated oxygen into a larger lung unit. More importantly, the Cook has two holes on the outer aspect of the tip of the device thus allowing insufflating oxygen to escape laterally and this postpones the build-up of pressure and the subsequent risk of barotrauma within the lung unit (Fig. 2). The design of the device may be an important factor as demonstrated by Cooper [31] The device used by Cooper to produce tracheal oxygen insufflation was designed with several side holes along the lateral and medial aspect of the distal end. The use of this device was associated with no reports of barotraumas when used as a conduit for low flow oxygen insufflation at 3–6 L/min [31]. We can therefore potentially hypothesise that the inclusion of side holes may help delay the onset of barotrauma during oxygen insufflation. There has been much debate regarding the safety of using an airway exchange device (AED) for oxygen insufflation [5,32,33]. Some opinion identifies a risk of using an AED as a conduit for oxygen delivery because if it is used distal to the carina it can create a situation where the flow of insufflating oxygen exceeds the amount of passive air exit thus causing hyperinflation and barotrauma [5]. There is little published evidence and opinion on what flow of oxygen is considered safe for insufflation via an AED. Others have suggested that compared with jet ventilation, oxygen insufflation at low pressures may be safer [14,15,32]. However, it has been suggested that this role of an AED as a method of oxygenation should be confined to emergency situations rather than routine use [32,33]. This is corroborated by the recent NAP4 report which states that due to the potential serious complications, the indications for oxygenation via an AED are rare [17] The manufacturers'

instructions for use for each device do not document a recommended safe flow for the delivery of oxygen. An expert opinion from a fatal accident inquiry suggested that if oxygen was insufflated at a rate of 2 L/min compared to high flows of 15 L/min, it would significantly reduce or even avoid the potential for barotrauma to occur [9]. Our results are pertinent in clinical practice if as suggested by some authors the use of an AED as a conduit for oxygen should be confined to emergency scenarios when higher flows are more likely to be used [32,33]. Our results further highlight that there is a significant risk of these AEDs of causing serious barotrauma even when low flows of 2 L/min are used.

These findings are corroborated with recently published data highlighting a significant potential to cause barotraumas when insufflating oxygen via a Cook Airway Exchange Catheter and a Cook Airway Exchange Catheter extra firm with soft tip in a porcine lung model [24]. Axe et al. demonstrated that when the AED was positioned above the carina there was no evidence of visible barotrauma. However, when the AED was intentionally placed below the carina barotrauma occurred irrespective of the rate of delivery of oxygen, including via means of jet ventilation. The aforementioned study involved 32 series of data values in total whereas the study conducted by the authors of this paper involved 90 recordings of data for each device tested and thus 180 data sets in total. This allowed us to perform statistical analysis on the data collected and gain exact values for the time for barotrauma to occur. Therefore we were able to demonstrate a statistically significant difference between each device and show that the smaller of the two devices, the Rüsch, caused barotrauma more quickly than the larger Cook highlighting the fact that design of the device may influence how the AED is inserted into the airway. The smaller device (the Rüsch) could be lodged in smaller lung units therefore requiring less time of oxygen insufflation to cause barotraumas and could reflect the safety of their use. Additionally we evaluated the incidence of insertion on AEDs beyond 26 cm, beyond the carina in most patients and showed that there is a high incidence of anaesthetists inserting these devices too far.

5. Limitations

This study was conducted in a non-clinical environment requiring us to consider a number of limitations. Firstly, there is a degree of uncertainty how much our set up resembles clinical practice. However, ethical considerations would not allow this research on human subjects. In addition, the findings of a number of similar laboratory based studies [22] have been supported with case reports [11–16] making this type of research reliable enough. Secondly, we failed to make a record of the forces recorded at the tip of the Aintree during airway exchange. Our manikin set up was such that due to the short length of this device, we could not reliably record forces exerted at the tip of this device during airway exchange. This however appears to indicate further that the length of the AED may be an important design feature to consider in order to reduce AEDs airway trauma potential. Thirdly, we did not include Frova in our porcine lung model testing for the barotrauma potential. It is clear now that Frova would be an obvious choice and it

should be the subject of investigation in future similar studies. Lastly, although a porcine lung model was chosen due to its anatomical similarities to human lungs [34,35], our model involved trachea and lung tissues representing only part of the full airway. This may have influenced the time for barotrauma to become visible. In addition, presence of muscle tone and chest cavity 'in vivo' may have effect on time to barotrauma too. However, barotrauma appears to happen within seconds emphasizing the danger of oxygen insufflation via AEDs. The difference between 'in vivo' and 'in vitro' time to barotrauma is likely to be negligible compared to overall danger of oxygen insufflation via these devices.

6. Conclusion

The purpose of this study was to evaluate the potential of AEDs to cause airway trauma by recording the incidence of AEDs being inserted too far into the airway during airway exchange and evaluating the speed of barotrauma when these devices are used for oxygen insufflation. We found that the longer AEDs, Frova (70 cm) and Cook (83 cm) were inserted too far during airway exchange by a large majority (88%) of the participants, which is significantly lower than shorter Aintree (56 cm), with only 25% participants advancing it too far into the airway. We established that barotrauma occurred with Cook and Rusch AEDs when lodged into the airway at low insufflation flows within a matter of seconds, which is likely to happen when AED is advanced too far into the airway during airway exchange.

We conclude that different devices may differ in their potential to be inserted too far influenced by their length, with longer devices associated with a higher incidence of over-insertion. A larger outer diameter of an AEDs seems to offer some protection when inserted too far into the airway as it appears to delay the onset of barotrauma during oxygen insufflation. However, the potential for barotrauma is high at any flow rate when an AED is lodged into the airway. We recommend that the current airway exchange devices be used with caution, keeping in mind anaesthetists' tendency to over-insert with potential to cause serious airway trauma during airway exchange. The AEDs should not be used for oxygen insufflation in any circumstances until these devices are re-designed with clear length markings, a shorter overall length and tested again for airway trauma potential.

Conflicts of interest

No external funding and no competing interests declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.tacc.2018.12.002>.

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