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Original Article

An assessment of the tolerability of the Cook staged extubation wire in patients with known or suspected difficult airways extubated in intensive care

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Summary

The Cook staged extubation set (Cook Medical) has been developed to facilitate management of the difficult airway. A guidewire inserted before tracheal extubation provides access to the subglottic airway should re-intubation be required. This prospective cohort study examines patients' tolerance of the guidewire and its impact on clinical status around tracheal extubation in the intensive care unit. Vital signs, incidence of symptoms and patient tolerance of the wire were recorded. Twenty-three patients were enrolled and 17 (73%) tolerated the wire for 4 h. Nasendoscopy was performed in 11 of these patients and revealed one wire was in the oesophagus. The most common symptom was a mild intermittent cough in 13 patients. There was no impact of the guidewire on nursing care in 16 patients, tolerable impact in five and severe impact necessitating removal of the wire in one patient.

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Introduction

The findings of the Fourth National Audit Project (NAP4) in Anaesthesia, Intensive Care and Emergency Medicine [1], and a recent review of tracheal extubation in adult ICUs highlighted the risks and the need to approach the process with the same degree of planning and preparation as for intubation [2]. The airway exchange catheter (AEC; Cook Medical, Bloomington, IN, USA) has been used as part of staged extubation strategies. However, the use of these catheters has led to several problems including barotrauma [3–5], and their use as a conduit for re-intubation following staged extubation is unlicensed and not recommended. The Cook staged extubation set (CSES; Cook Medical) (Fig. 1) is an alternative method which provides a guidewire which is left in situ to maintain airway access after tracheal extubation and a re-intubation catheter which can be passed over the guide wire to provide a conduit for railroading a tracheal tube or to allow delivery of oxygen through a central channel. Currently, there is limited research concerning this two-step system for extubation [6–8] and no prospective studies assessing the tolerability of a tracheal guidewire left in situ after extubation in patients in ICU.

Methods

We conducted a prospective cohort study using the Cook staged extubation set in 23 patients undergoing tracheal extubation in the ICUs of Cairns and Townsville hospitals. The Townsville Hospital and Health Service Human Research Ethics Committee approved the study for both sites. As difficult airway situations often become apparent only after a patient has been sedated, it was not possible to obtain informed consent in advance from the patient and approval for deferred consent was granted, which we aimed to obtain within three days of the intervention.

We used a convenience sampling method for patients as this study required the availability of a trained operator and a suitable patient to perform the staged extubation. Inclusion criteria were all patients in the ICU with a known or suspected difficult airway. There are no therapeutic goods administration-listed contra-indications for the device. Exclusion criteria comprised severely agitated or unco-operative patients, and any patient with known severe coagulopathy, use of antiplatelet agents other than aspirin and patients with a history of brittle asthma.

Staged extubation was performed as follows: a patient with a known or suspected difficult airway was identified by the treating intensivist as co-operative and suitable for extubation; pre-oxygenation and airway suction was performed as routine; the 0.9-mm guidewire was passed into the trachea to at least the 25-cm mark at the incisors, taking care to not stimulate the carina by aligning the length markings on the guidewire with those on the tracheal tube. The wire is soft tipped, tapered, kink and bite resistant, and polymer coated to reduce airway irritation. It is softer and thinner than the tracheal suction catheters routinely used in the ICU. The tracheal tube was removed over the wire, taking care to ensure that the wire remained in the trachea with the 25-cm mark visible at the incisors. The external length of the guidewire was secured by coiling it into the provided sheath and taping it to the side of the face. The patient was then observed for 4 h.

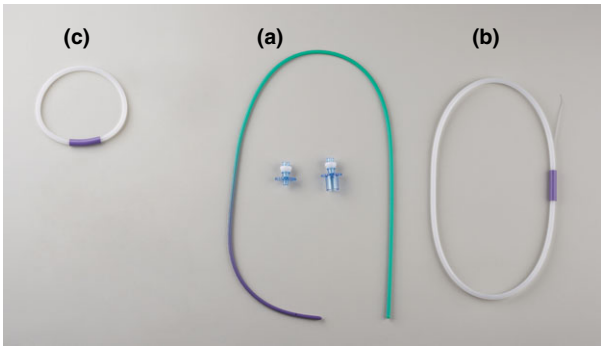

Figure 1 The Cook staged extubation set consists of a soft tipped, bite-resistant 0.9-mm diameter guidewire which is 145 cm long (b), a 14 French 83-cm tapered intubating bougie (a) which can be railroaded on the guidewire. There is a circular securing sheath (c) for coiling and securing the external guidewire (additional components not shown include adhesive dressing and tape).

If re-intubation was required, a specifically-designed bougie of graduated stiffness (soft end first) with a central lumen for the wire could be advanced over the wire into the trachea. The tracheal tube can then be advanced on the bougie into the trachea or the bougie can be connected via an adaptor to an oxygen source or circuit. Local anaesthesia was not used. Five patients had ongoing analgesic infusions post-extubation: low-dose fentanyl was used in three, with clonidine and dexmedetomidine in one patient each. The wire was removed earlier than 4 h if deemed necessary by the patient, bed-side nurse or treating doctor, and the reason documented. With patient consent, nasendoscopy was performed on those who tolerated the wire for 4 h, to confirm non-dislodgement from the trachea before its removal. Due to limited availability of endoscopes, this was only performed on patients in Townsville. The data collected included: age; sex; ICU admission diagnosis; past medical history; comorbidities; and smoking history. In addition, the following parameters were recorded: airway assessment; Cormack and Lehane laryngoscopy grade [9] (if recorded before intubation); type of airway abnormality/difficulty; ease of insertion and securing guidewire; any dislodgement of guidewire; duration of guidewire tolerance; symptoms of intolerance (including vomiting, cough, gag, salivation, haemoptysis, wheeze, clinical parameters (including heart rate, respiratory rate, blood pressure and oxygen saturation); nursing staff assessment of the impact on patient care of the wire; and its location on nasendoscopy before its removal.

For physiological variables (heart rate, blood pressures and respiratory rate), regression analysis considered the cross-sectional time series nature of the data. Results are described as the slope of the regression line (β) and the associated p value. If significant, 95%CI for the slope is also quoted. The level of significance was set at $p < 0.05$ throughout. All analyses were performed using STATA™ 14.1 (Stata corp, College Station, TX, USA).

Results

We enrolled 23 patients, 18 (78%) of whom were men; mean (SD) age was 48.7 (17.1) years. Of the 23 patients in the study, 18 had tracheal intubation by the oral route and five nasally, with one nasal fibreoptic intubation. In one patient, the guidewire dislodged during the process of extubation, leaving 22 patients who were available for assessment of tolerability (Fig. 2). The baseline characteristics are listed in Table 1 and the tolerability assessment by the bed-side ICU nurse is listed in Table 2.

Inserting the guidewire was assessed as easy in all 23 patients; however, securing the guidewire was easy in only 6 (26%), moderately difficult in 15 (65%) and difficult in 1 with one other instance not recorded. A mild tolerable cough was the most common symptom noted by the bed-side nurse, occurring in 13 out of 22 patients (59%). Cough, gag and salivation were severe in one patient necessitating removal of the guidewire. Nasendoscopy was performed to confirm intra-tracheal location of the guidewire in 11 out of the 17 (65%) patients who tolerated it for 4 h. The guidewire was found to be in the oesophagus in one patient. We noted that eight patients had no cough and, in six of these patients, the intra-tracheal location of the guidewire was confirmed before its removal on nasendoscopy.

There was no impact of the guidewire on nursing care provision in 16 (76%) patients and tolerable impact in five with the main concern being a reluctance to move the patient for pressure area care and avoidance of chest physiotherapy for fear of dislodging the guidewire. No patients required tracheal re-intubation and there were no serious adverse events.

As vital signs may become deranged by the extubation process or comorbidities in ICU, we collected hourly data on arterial blood pressure (Fig. 3), heart rate (Fig. 4), respiratory rate (Fig. 5) and oxygen saturation around insertion, and removal of the guidewire. There was a statistically significant rise in heart rate ($p < 0.001$), although it was not of clinical significance to warrant intervention. As all patients routinely received supplemental oxygen after extubation, they all maintained oxygen saturation above 93% with no significant change over time.

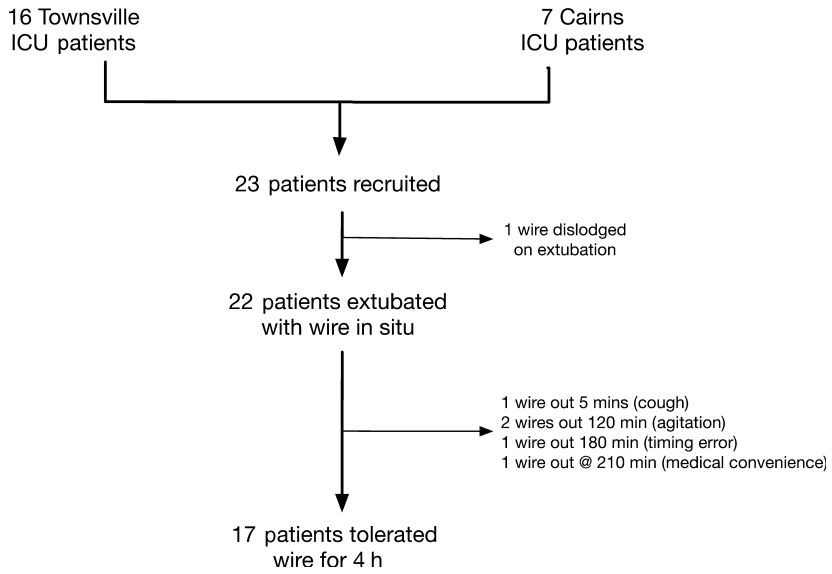

Figure 2 Study flow diagram.

Table 1 Characteristics of laryngoscopic view, setting in which airway difficulty encountered, comorbidities and smoking status of 23 patients.

		Number
Cormack and Lehane grade	4	6
	3	9
	2	3
	1	4
	Elective awake fibreoptic	1
Setting of airway concern	Trauma of face/neck	5
	Infection of face/neck	9
	Difficult airway in other elective surgery	7
	Difficult airway in other emergency surgery	2
Comorbidity (not exclusive)	Hypertension	12
	Chronic Renal Impairment	2
	Type 2 Diabetes	2
	Asthma	1
	COPD	1
	Obstructive Sleep Apnoea	1
	Arrhythmia	1
Smoking status	Current smoker	7
	Never smoked	6
	Ex-smoker	10

Table 2 Guidewire tolerability assessment by the ICU nurse caring for the patient.

	Incidence of symptom/issues			
Symptom/issue	None	Tolerable	Intolerable	Total
Cough	8	13	1	22
Gag	20	1	1	22
Salivation	16	5	1	22
Wheeze	20	2	0	22
Vomiting	22	0	0	22
Haemoptysis	19	3	0	22
Impact of wire on nursing care provision	16	5	1	22

Discussion

Our study has shown that the Cook staged extubation set guidewire can be tolerated by patients whose tracheas have been extubated in ICU for up to 4 h without the need for local anaesthesia and without clinically significant changes in vital signs, when sited to avoid carinal stimulation. Users need to be aware that there is a risk of dislodgement of the wire from the trachea during or after extubation and the need to have contingency plans prepared. Bed-side nursing staff noted a tolerable cough as the most frequent symptom and a few had concerns that nursing and physiotherapy care might dislodge the wire.

The UK's NAP4 in Anaesthesia, Intensive Care and Emergency Medicine [1] and the US closed-claims data [10] both showed that patients in ICUs have a higher rate of morbidity and mortality following airway

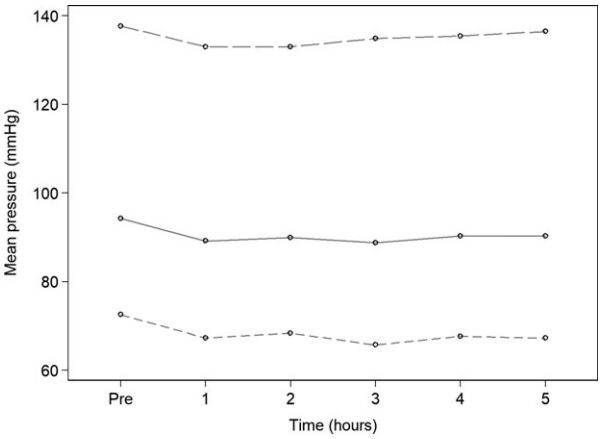

Figure 3 Systolic blood pressure (---), mean arterial pressure (—) and diastolic blood pressure (-----) vs. time. No significant changes noted over time. Regression slopes and p-values were +0.27, p = 0.68, −0.34, p = 0.46 and −0.65, p = 0.16 respectively. For the sake of clarity, the individual 95% confidence intervals were omitted from the figure.

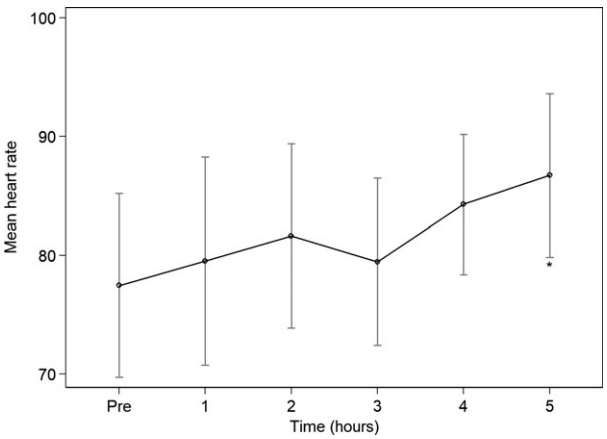

Figure 4 Heart rate vs. time. An increase in heart rate was noted over time (regression slope = +1.39 (95%CI 0.67 − 2.11), p < 0.001). The figure illustrates interconnected mean values with associated 95% confidence intervals.

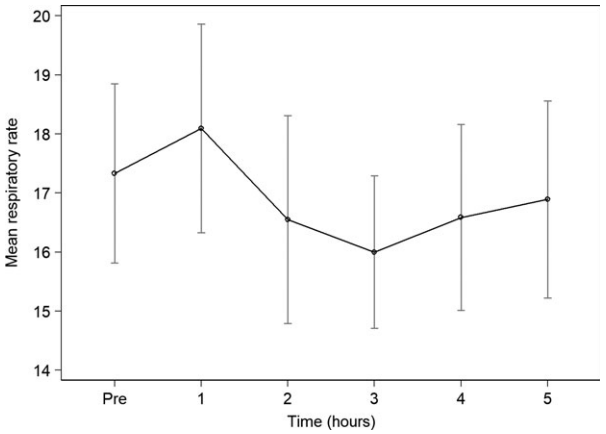

Figure 5 Respiratory rate vs. time. No significant change noted over time. Regression slope was −0.22 (p = 0.19). The figure illustrates interconnected mean values with associated 95% confidence intervals.

management due to reduced physiological reserve. The NAP4 report [1] identified that at least one in four major airway events in hospital are likely to occur in the ICU or the Emergency Department and these are associated with increased morbidity and mortality. Their recommendations included that every ICU should have algorithms for the management of tracheal extubation and re-intubation and the need for evidence-based airway management algorithms in ICU. The Difficult Airway Society in the UK [11], and the American Society of Anesthesiology [12] argue that an extubation strategy is an essential part of a comprehensive difficult airway management plan. Demling et al. [13] showed a 4–12% re-intubation rate for patients in surgical ICU and up to 40% in-hospital mortality rate for those who were re-intubated, which varied by the underlying disease process.

The best-established tool to facilitate staged extubation is the Cook airway exchange catheter, which also offers the ability to oxygenate a patient through its central channel. Although smaller studies of the airway exchange catheter [14, 15] have shown good success rates with few complications, a large retrospective examination of 354 uses of the airway exchange catheter with 51 tracheal re-intubations using the device noted success on the first pass in 42 cases and on the second pass in six cases. Four failures occurred – three from the airway exchange catheter slipping out of the glottis and one from laryngeal oedema [16]. Another more recent study of 527 attempted tracheal tube exchanges over the airway exchange catheter observed 73 failures (13.8%), 41 airway injuries (7.8%) and 8 pneumothoraces (1.5%). All complications occurred in patients whose airways were considered to be difficult [17]. Considering these complications, the differences between the airway exchange catheter and the Cook staged extubation set wire are worth highlighting. Although the staged extubation set requires an additional step (insertion of the specifically-designed bougie), the wire is far less likely to directly damage the respiratory tree given its soft tip. Another potential advantage of the staged extubation set is its small diameter (0.9 mm) guidewire which, being a fraction of the size of any airway exchange catheter, allows minimal resistance to flow of oxygen, especially in airways that may be narrowed by swelling or masses.

During staged extubation, we avoided local anaesthesia so as to not diminish airway reflexes and, therefore, enable assessment of the true tolerability of the guidewire which is marketed as non-irritant. The guidewire was noted to be easy to insert via the tracheal tube but moderately difficult to secure in a coiled form into its sheath. This required one person to hold the guidewire near the mouth while an assistant coiled it into the provided sheath to minimise risk of dislodgement. Most patients tolerated the wire with a mild intermittent cough. Although the majority of the nursing staff noted no impact of the wire on nursing care, it was deemed tolerable but mildly problematic in 5 out of 22 patients over concerns that moving the patient for pressure area care or chest physiotherapy may dislodge the wire. Such concerns are understandable and likely to be most pronounced early in the introduction of the technique.

A time interval of 4 h was chosen for the wire to be left in situ to allow sufficient time for any deterioration and to make this study comparable with a study by Loudermilk et al. [15] on the use of the paediatric airway exchange catheter (Cook Medical) for staged extubation. In our study, 5 out of 22 patients (18%) were intolerant of the wire and this generally occurred within the first 2 h after insertion, suggesting that, once the wire had 'settled in', leaving it in for a trial of extubation for 4 h appeared to be a reasonable strategy. We also noted that, in eight of the patients who had no

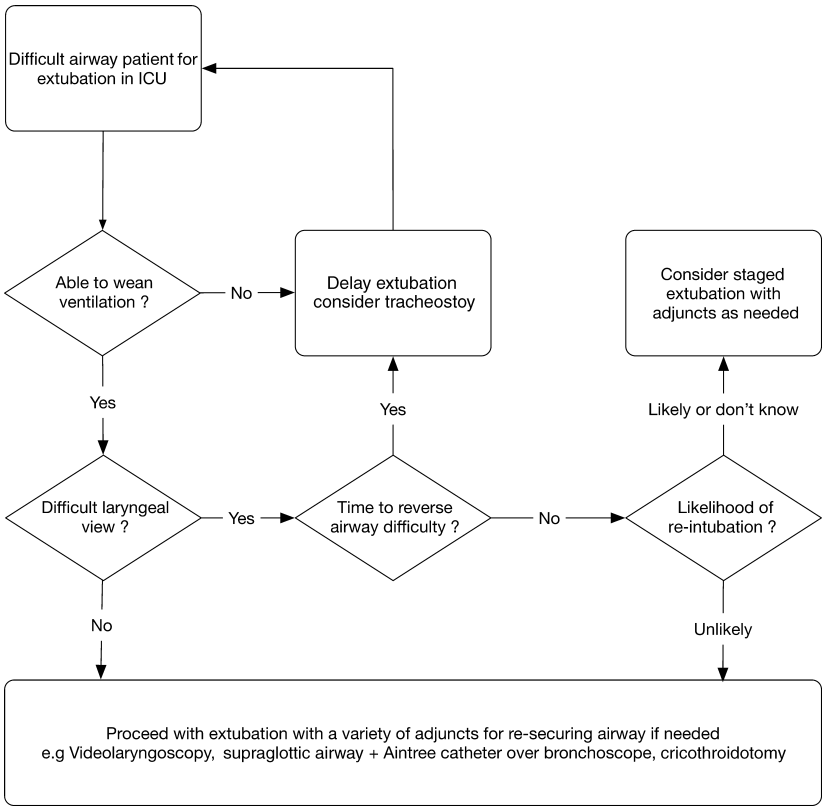

Figure 6 A suggested role for staged extubation in the ICU decision process.

cough, the guidewire was confirmed by nasendoscopy to be in the trachea in six, suggesting that the absence of cough is not necessarily indicative of a dislodged guidewire. The rate of dislodgement after 4 h was 1 out of 11 (10%). On an intention to treat basis, 6 out of the 23 patients (26%) failed to tolerate the wire for 4 h or suffered dislodgement of the wire after extubation. However, given this is a small study, it should be noted that two patients had their wires removed prematurely due to a timing error and a requirement for the clinician to be elsewhere, rather than due to symptoms of intolerance.

The usefulness of staged extubation for patients in ICU needs further study but this will be challenging due to the rarity of difficult airways. Although a case can be made for treating every airway in ICU as difficult, the case for wider use of the staged extubation set will also require evaluation of the ease of re-intubation using the set. A recent study assessed the reliability of intubation and ease of use of the Cook staged extubation set in 23 elective surgical patients with simulated difficult airways and found that re-intubation failed in two attempts and significant difficulty in re-intubation was encountered in a further four [6]. A potential role for staged extubation in the decision framework in ICU is suggested in Fig. 6, using a patient with an anatomically difficult airway requiring a trial of extubation.

Tracheal intubation was not initially considered to be difficult in some of our patients, but the intensivists raised concerns about delayed difficult airway either due to postoperative swelling or the application of devices that would impede neck movement such as a halo brace for cervical spine injury. We recruited patients by convenience sampling at each site and, although this selection bias should be accepted as a limitation of the study, assessment of tolerability was always by the bed-side nurse on duty who was not associated with the research trial. Nasendoscopy to confirm tracheal location of the wire before its removal was only done at one centre due to limited availability of the required equipment. There were no

tracheal re-intubations, so we were unable to report on the use of the full Cook staged extubation set in this respect.

Our results suggest that the Cook staged extubation set guidewire is generally well tolerated by patients in ICU without any specific need for local anaesthesia. Its potential to be a useful adjunct in the management of potentially difficult extubation with a well-considered 'plan B', should be further assessed in a larger multi-centre study.

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