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Randomised Controlled Trial of Portex Tracheal Tube and Frova Intubating Introducers used with the GlideScope Videolaryngoscope in Simulated Difficult Intubation

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Abstract

Background: A 'bougie' may be less traumatic than the GlideScope-specific intubating stylet during videolaryngoscopy-guided intubation, but no comparative studies of bougies have been performed.

Study objective: To compare the Portex tracheal tube introducer (PTTI) and Frova intubating introducer (FII) used with the GlideScope videolaryngoscope in simulated difficult intubation.

Design: Randomised controlled study.

Setting: A metropolitan tertiary referral and teaching hospital in Brisbane, Australia. The study was conducted from August 2011 to July 2013.

Patients: Forty patients with American Society of Anaesthesiologists (ASA) grade 1 or 2 physical status who required tracheal intubation for elective surgery were randomly assigned to two equal groups. All completed the study. Those with known or suspected difficult intubation, cervical spine injury, raised intracranial pressure, risk of pulmonary aspiration, and risk of rapid oxygen desaturation were excluded.

Interventions: After standardised intravenous induction, cervical manual in-line stabilisation was performed to increase intubation difficulty. Intubation was performed under GlideScope videolaryngoscopy assisted by either the PTTI or the FII.

Measurements: The primary outcome measures were intubation time (s) and success rate (%). The secondary outcome measures were visual analogue scale (0-100 mm) and ordinal scale (1-4) scores of intubation difficulty.

Main results: The median intubation times (interquartile ranges) in the PTTI and FII groups were 46 (35.3-68) and 55.8 (37.5-112.5) s, respectively (P>0.05). All intubations were successful in the PTTI group, but two intubations (10%) initially failed in the FII group (P>0.05). The median visual analogue scale score was significantly lower in the PTTI group (20 [10-40] vs. 40 [30-60]; P<0.01). The bougies did not cause any injury.

Conclusions: The PTTI seems to be superior to the FII when used with the GlideScope videolaryngoscope in difficult intubation.

Keywords: Videolaryngoscopy; Bougie; Tracheal intubation; Manual in-line stabilization; Visual analogue scale

Introduction

The GlideScope videolaryngoscope (Verathon Inc., Bothell, WA, USA) is a portable device that shows magnified views of the larynx on an anti-reflective screen. It contains a high-resolution camera and an anti-fog mechanism. When compared with direct laryngoscopy, it improves laryngeal views during intubation even by inexperienced operators [1,2], especially in cases of cervical spine immobilisation and difficult intubation [2-7]. The improved views are partly attributable to the 60-degree blade angle, obviating alignment of the oral, pharyngeal, and tracheal axes. This angulation, however, may increase difficulty in endotracheal tube placement and necessitate use of adjunct devices such as an intubating stylet or a 'bougie' for successful intubation [8-12].

Intubating stylets can cause trauma [13-15]. On the other hand, a bougie may be less traumatic because it is softer and more flexible. Bougies have been successfully used with videolaryngoscopes [10,16]. A recent manikin study showed no significant disadvantage of a bougie compared with a standard incubating stylet during Glide Scope

videolaryngoscopy-guided intubation [17]. The enhanced indirect vision by videolaryngoscopy may also reduce risk of endobronchial injury from a bougie by facilitating proper positioning of the introducer tip just distal to the vocal cords.

Two types of bougies are commonly used in our adult anaesthetic practice: the Frova intubating introducer (FII) (Cook Medical Inc., Bloomington, IN, USA) and Portex tracheal tube introducer (PTTI) (Smiths Medical International Ltd, Kent, UK). They facilitate placement of endotracheal tubes with an internal diameter greater than 6 mm. The FII is a single-use 14-French 70-cm-long semi-rigid hollow tube with an angulated ('coude') tip (Figure 1). With the appropriate adapter, it is also used as a temporary ventilatory device during tracheal tube exchange. The PTTI is a 15-French 60-cm-long reusable solid catheter with an external diameter of 5 mm and an angulated tip (Figure 2). To date, no comparative studies of these devices have been performed in videolaryngoscopy-guided intubation. The aim of this study was to compare the PTTI and FII used with the GlideScope videolaryngoscope in simulated difficult intubation.

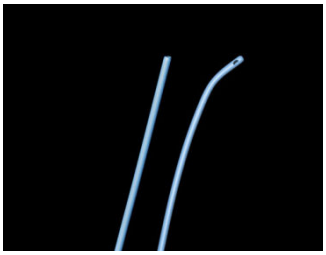

Figure 1: Frova intubating introducer (used with permission from Cook Medical).

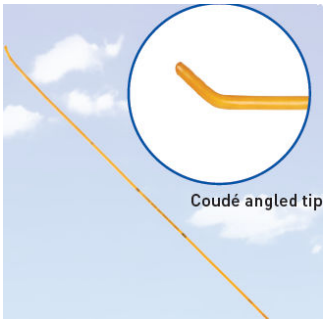

Figure 2: Portex tracheal tube introducer (used with permission from Smiths Medical).

Methods

This randomised controlled trial was conducted at the Princess Alexandra Hospital, a metropolitan tertiary referral and teaching hospital. Ethical approval for the study (HREC 2008/057) was obtained from the Metro South Human Research Ethics Committee, Brisbane (Chairperson: Dr Jennifer Fleming) on 27.5.10. Written informed consent was obtained from all the participants.

The recruited patients required tracheal intubation for elective surgery and had American Society of Anaesthesiologists (ASA) grade 1 or 2 physical status. Patients with known or anticipated difficult intubation, cervical spine injury, and raised intracranial pressure were excluded. Those deemed at risk of pulmonary aspiration (e.g. symptomatic gastro-oesophageal reflux, hiatus hernia, inadequate fasting, acute trauma) or rapid oxygen desaturation (e.g. morbid obesity, concomitant respiratory disease) were also excluded. Finally, 40 patients were randomly allocated to two equal groups according to the type of bougie to be used with the videolaryngoscope: the FII and PTTI groups (Figure 3). Randomisation was achieved by opening the opaque sealed envelope just before the induction of anaesthesia.

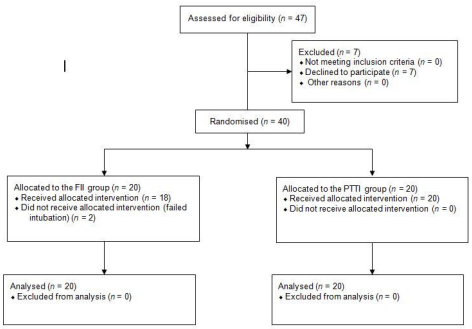

Figure 3: Flow diagram of the experimental protocol. FII, Frova intubating introducer; PTTI, Portex tracheal tube introducer.

The patients were monitored according to the Australian and New Zealand College of Anaesthesia standards, including 5-lead electrocardiography, pulse oximetry, and non-invasive blood pressure, end-tidal oxygen, carbon dioxide, and volatile agent monitoring. They received high-flow oxygen for 3-4 min in a neutral airway position with the head resting on a pillow to achieve an end-tidal oxygen concentration greater than 80%. Thereafter, a standardised intravenous induction regimen was administered: midazolam (1-2 mg), fentanyl (1-2 μg/kg), propofol (2-2.5 mg/kg), and rocuronium (0.6 mg/kg). After induction, the pillow was replaced with a Gel pad (Donut Head Pad) and the patient's head was maintained in the neutral position. Ventilation using the bag-mask technique with sevoflurane and oxygen was continued until neuromuscular paralysis was established.

Manual in-line stabilisation (MILS) of the cervical spine was performed in a standardised manner to increase intubation difficulty [6,7]. In brief, an investigator stood to the right of the patient, facing the intubator, manually gripped the patient's mastoid processes bilaterally (Figure 4), and applied sufficient force to prevent movement of the cervical spine during intubation. Intubation was performed in an operating suite by an experienced anaesthetist familiar with the GlideScope videolaryngoscope and blinded to the bougie until placement. The operator manually received the bougie from an assistant and passed it through the glottic opening under videolaryngoscopic guidance. The appropriate-size endotracheal tube was then 'rail-roaded' over the bougie into the trachea, the bougie was removed, and correct placement confirmed by capnography. Intubation time (s) was calculated from the time required to obtain a laryngeal view to the time when the upstroke of the capnographic trace was obtained.

Figure 4: Cervical manual in-line stabilisation to increase intubation difficulty. The glottic opening and passage of the Frova intubating introducer were viewed on the screen (left of image) by using the GlideScope videolaryngoscope.

MILS were maintained throughout the intubation procedure. However, it was discontinued if the pre-determined time limit of 3 min or oxygen saturation below 94% was reached. The patient was then ventilated by using the bag-mask technique and intubated without MILS. This situation was considered to be failed intubation, but the intubation time was included in the subsequent analysis. Each FII was used only once, and a PTTI was reused up to five times after sterilisation.

Before the intervention, airway was assessed by the Mallampati classification and laryngeal views under video laryngoscopy were graded according to the Cormack-Lehane classification. Difficulty in intubation was assessed by the operator using both a visual analogue scale (VAS) ranging from 0 (easy) to 100 mm (very difficult) and an ordinal scale ranging from 1 (easy) to 4 (very difficult). The primary outcome criteria were intubation time and success rate (%). The secondary outcome measures were VAS and ordinal scores.

The required sample size was calculated by power analysis of the expected intergroup difference in intubation time of 10 s. This duration was considered to represent a clinically meaningful difference that would justify use of one type of bougie over the other. No consensus has been reached on a clinically significant difference in intubation time; other authors chose cut-off points ranging from 5 to 30 s or a 33% reduction in intubation time [17-20]. Non-parametric analysis was used to compare differences in intubation time and difficulty (Mann-Whitney U-test) with standard type I and type II error rates (α=0.05, β=0.20). Fisher's exact test was used to compare intubation success rates between the groups.

Results

The groups were similar with regards to gender, age, weight, body mass index, and physical status (Table 1). No significant intergroup differences were noted in the Mallampati and Cormack-Lehane scores.

The median intubation time was not significantly different between the groups (Table 2 & Figure 5). Two intubations failed in the FII group, but the intubation success rate was not significantly different. The PTTI group had significantly lower VAS scores (P<0.01). Quantile regression analysis showed that use of the PTTI reduced the median VAS score by 10 mm (4.5-14 mm) compared with use of the FII (Figure 6). The ordinal scores of intubation difficulty were not significantly different between the groups.

Characteristic	FII group (n=20)	PTTI group (n=20)
Male gender, n (%)	10 (50)	11 (55)
Age (yr), mean ± SD	50.7 ± 14.3	54.6 ± 18.1
Weight (kg), mean ± SD	81.1 ± 17.4	78.3 ± 14.4
Body mass index (kg/m^2), mean ± SD	28.2 ± 4.2	27.2 ± 4.0
ASA physical status, n (%)		
Grade I	1 (5)	0 (0)
Grade II	19 (95)	20 (100)
Mallampati score		
Class 1	8	12
Class 2	8	6
Class 3	4	2
Class 4	0	0
Cormack-Lehane score		
I	2	6
II	17	14
III	1	0
IV	0	0

Table 1: Demographic data and airway-assessment scores.

Parameter	FII group (n=20)	PTTI group (n=20)	P
Intubation time (s), median (IQR)	55.8 (37.5-112.5)	46 (35.3-68)	P=0.33
Intubation success rate, n (%)			
First attempt	18 (90)	20 (100)	P=0.49
Second attempt	2 (10)	0	
Ordinal score of intubation difficulty, n (%)			

1 (very easy)	1 (5)	5 (25)	
2 (easy)	10 (50)	10 (50)	
3 (difficult)	5 (25)	5 (25)	
4 (very difficult)	3 (15)	0 (0)	P=0.12
VAS score of intubation difficulty (mm), median (IQR)	40 (30-60)	20 (10-40)	P=0.007
P<0.05 is significant. FII: Frova Intubating Introducer; PTTI: Portex Tracheal Tube Introducer; IQR: Interquartile Range; VAS: Visual Analogue Scale.			

Table 2: Intubation outcomes.

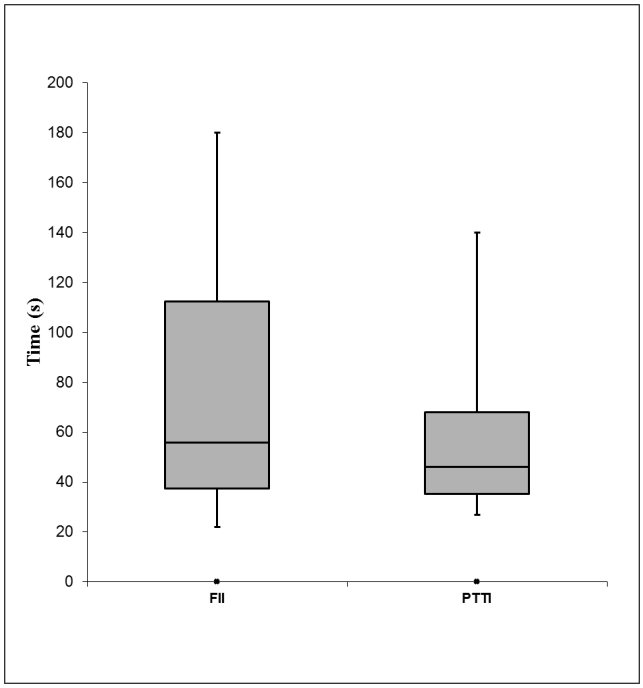

Figure 5: Box and whisker plot of the median intubation time (interquartile range) in the Frova intubating introducer (FII) and the Portex tracheal tube introducer (PTTI) groups.

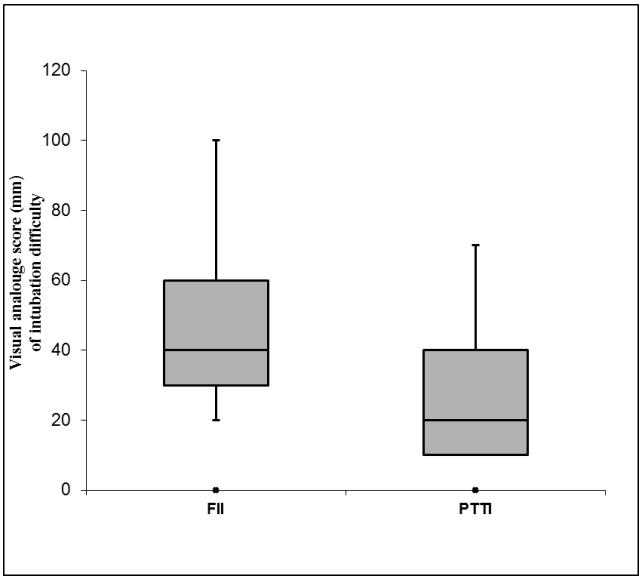

Figure 6: Box and whisker plot of the median visual analogue scale (VAS) score of intubation difficulty (interquartile range) in the Frova intubating introducer (FII) and Portex tracheal tube introducer (PTTI) groups.

Logistic regression analysis revealed easier intubation in male patients (VAS scores) regardless of the bougie used. A learning effect with the technique was not evidenced: the mean intubation time in the first 4 patients (71 s) was similar to that in the last 4 patients (87 s). Dental, oropharyngeal, laryngeal, and lower airway injuries did not occur.

Discussion

This study demonstrated that GlideScope videolaryngoscopy-guided intubation is easier with the PTTI than with the FII. The PTTI has better memory and flexibility than single-use airway catheters [21], as evidenced by its superior performance in difficult intubation under direct laryngoscopy [21,22]. The superior memory allows the bougie to more closely approximate the increased blade angle of the GlideScope videolaryngoscope.

Its increased flexibility reduces impingement on the anterior commissure or proximal trachea and facilitates its passage through the larynx into the trachea despite contact with anatomical structures. On the other hand, the FII is difficult to pass through the vocal cords because of impingement on these structures. The difficulty is exaggerated with introduction of an additional anterior bend in the bougie.

The intubation times were slightly longer in this study than in other studies of the GlideScope videolaryngoscope [4,23,24]. The difference may be attributed to cervical MILS used to increase intubation difficulty in this study. Bathory et al. [3] used the GlideScope videolaryngoscope for intubation in patients with a semi-rigid cervical collar and reported similar intubation times (median intubation time, 50 s) to those in the PTTI group (median intubation time, 46 s). The two failed intubations in the FII group were included in the analysis of intubation times. We considered 3 min as the maximum time allowable for intubation without compromising oxygenation. None of the patients reached the oxygen saturation threshold of 94% during intubation.

The GlideScope videolaryngoscope improved laryngeal views despite cervical MILS. MILS worsens Cormack–Lehane scores during conventional laryngoscopy [6,25]. In a series of 200 patients, Thioboutot et al. [6] showed that the incidence of grade III and IV views during laryngoscopy increased from 4.8% (control) to 58.5% with MILS. In the present study, the incidence of grade III and IV views was only 2.5% with MILS in 40 patients. This result suggests a significant benefit of using the GlideScope videolaryngoscope during MILS and in patients with known or suspected difficult intubation. Other studies have confirmed the superiority of the videolaryngoscope in patients with cervical spine immobilisation [3,25].

Given the different physical characteristics of the bougies in this study, total blinding of the operator was impossible. However, as only one operator performed all the intubations, the comparisons should be valid.

In conclusion, use of the PTTI with the GlideScope videolaryngoscope can reduce intubation difficulty when compared with use of the FII. We recommend the PTTI in clinical settings where the GlideScope videolaryngoscope is used for difficult intubation cases.

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Conflicts of Interest: None declared.

Presentation: None declared.

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