

Correspondence

Evaluation of a new bougie design for the difficult airway: a manikin crossover trial

Endotracheal tube introducers (ETI) are commonly used to facilitate difficult and emergent tracheal intubation^{1,2}. Despite videolaryngoscopes now being widely used to facilitate intubation, this has not always been translated to successful intubation and has created the scenario of 'I can see but can't intubate'³. A flexible tip ETI may provide a solution to this problem. We compared the Flexible Tip Bougie (Construct Medical, Melbourne, Victoria) (Figure 1) to the Frova Intubating Introducer (Cook Medical, Bloomington, IN, USA) in this manikin crossover trial study (ethics approval no: 2017000348). The latter was chosen as a comparator because it is specifically mentioned in the Australian and New Zealand College of Anaesthetists guidelines⁴, and the null hypothesis was that two devices were equivalent in their efficacy to establish intubation. The primary and secondary outcomes were time to intubation and participant's ease of use, respectively.

Twenty Fellows of the Australian and New Zealand College of Anaesthetists, the Australasian College for Emergency Medicine or the College of Intensive Care Medicine of Australia and New Zealand were recruited. Participants were tasked to intubate a Laerdal® ALS (Laerdal Pty Ltd, Oakleigh, Victoria) manikin with the tongue inflated and a Laerdal Stifneck® Select™ cervical collar (Laerdal Pty Ltd, Oakleigh, Victoria) applied. Participants were given five minutes to

familiarise themselves with each ETI before attempts at intubation. Participants could not remove the collar or reposition the manikin. A percentage of glottic opening score of 0% was confirmed by the research team by direct laryngoscopy using a Macintosh laryngoscope with a number-three blade, prior to each intubation attempt.

Each participant had two intubation attempts, one with each ETI, and the order of use of each ETI was randomised, using a C-MAC® videolaryngoscope (Karl Storz Endoscopy Australia Pty Ltd, Lane Cove, New South Wales) fitted with a D-blade. A research team anaesthetist acted as assistant. Intubation time was defined as the time the laryngoscope tip passed the lips until the beginning of the first chest rise after successful endotracheal tube placement. There was no time limit, with participants allowed to progress at their own speed. Ease of use was measured using a visual analogue scale. Participants indicated the ease of use by marking on a 100 mm line with 0 being very easy and 100 was considered very difficult. Free text comments were also allowed.

On reviewing the videos, all participants obtained a percentage of glottic opening score of 40% or more. In 37 of 40 attempts this occurred in less than ten seconds. The longest time taken to obtain a laryngeal view (percentage of glottic opening score of 40%) was 20 seconds. The time taken to successfully intubate ranged between 28 and 211 seconds for all attempts, despite a good view being obtained by most participants quickly. Intubation times with the Flexible Tip Bougie were significantly shorter (mean [standard deviation,

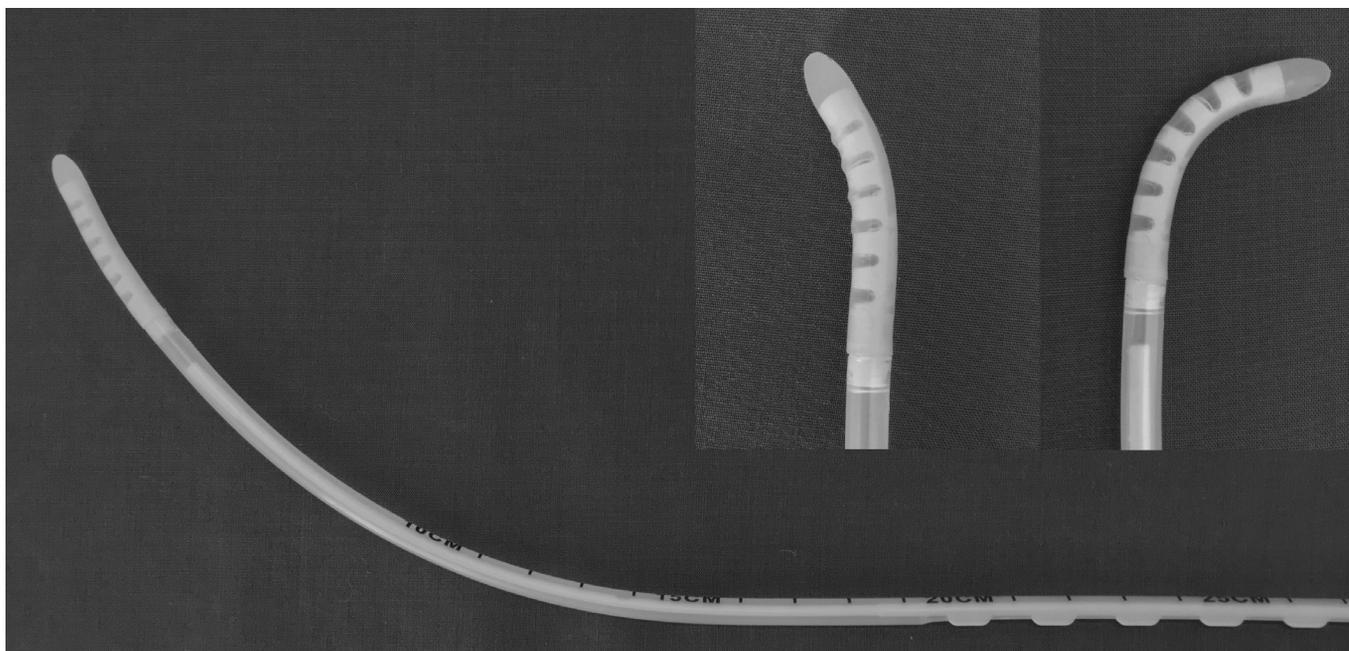


Figure 1: Flexible Tip Bougie (Construct Medical, Melbourne, Victoria). The yellow tip can be flexed anteriorly and posteriorly (inset) by using the slider on the posterior side of the endotracheal tube introducer.

SD] 77.2 [40.5] seconds, median 66.5 seconds) than for the Frova Intubating Introducer (mean [SD] 142.2 [81.2] seconds, median 126.0 seconds) (Wilcoxon $Z = -2.82$, $P < 0.01$). Four intubation attempts were abandoned by the participants, all with the Frova device (times for abandoned attempts were replaced with mean plus three SDs of the same type of ETI for this calculation, 270.6 seconds). Excluding those participants with failures the mean (SD) and median intubation times were 71 (39.2) seconds and 63.0 seconds for the Flexible Tip and 110.1 (53.5) seconds and 95.5 seconds for the Frova (Wilcoxon $Z = -1.97$, $P = 0.05$).

The mean 'ease of use' score for the Frova (76.7 [SD 19.4]) was significantly higher than the Flexible Tip (46.5 [SD 21.6]) ($t = 4.93$, $P < 0.001$). Eighty percent of the participants indicated the Flexible Tip was easier to use than the Frova, and this preference was not affected by the order of the attempts ($P = 0.99$).

The written feedback suggested that the Flexible Tip had an advantage, but the tip was too flexible (it folded back onto itself during their attempt). The bidirectional flexing, or 'unflexing', of the tip was considered useful to facilitate directing the endotracheal tube down the centre of the trachea. In contrast, the Frova sometimes caught on the anterior wall of the trachea. Participants also noted the Frova needed to be deformed significantly to reach the cords. Three participants noted that the Flexible Tip would be useful for an anterior larynx.

The body of the Flexible Tip itself has an anterior curve of approximately 45°; the tip can be flexed anteriorly to guide the ETI into the trachea, and the tip can be retroflexed within the trachea to guide the ETI down the trachea, without impinging on the anterior rings. All these could be anticipated to favour the Flexible Tip over the straight Frova with limited tip bend. Notably, there were no abandoned attempts with the Flexible Tip Bougie. In contrast, the absolute failure rate was 20% with the Frova. However, we only studied one type of difficult airway. According to Greenland's model, this study's manikin reproduced a fixed posterior complex associated with an increased submandibular space and poorly compliant submandibular tissues⁵. This mimics many, but not all, difficult airways. Additionally, in our study's airway scenario, using newer D-blade versions with an ETI channel may have made intubation easier.

Based on the positive results of this study, we believe the Flexible Tip Bougie warrants further testing in vivo.

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