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A randomised cross-over study comparing ease of tracheal intubation with straight versus curved tracheal tubes

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1. Introduction

In his paper titled “Technique in Endotracheal Anaesthesia” in 1930, Magill described the use of commercial rubber tubing for intubation [1]. The manufacturing process and storage in coils gave such tubing a natural curve, which by good fortune gave it the ideal shape to follow the course of the upper airway into the trachea. Most present-day tracheal tube (TT) designs have retained such a preformed curve to facilitate passage through the airway. However, competitively priced straight reinforced TTs are also available and in clinical use. Although straight TTs may offer a cost advantage, we hypothesise that they are more difficult to insert. This may manifest in an increased time to intubation and/or frequent use of a Gum-elastic-Bougie, potentially leading to hypoxia, airway soiling or airway trauma. Even though such complications are expected to be rare, they may have serious consequences and should be avoided wherever possible.

In this randomised cross-over study, we aimed to compare the insertion of curved versus straight TTs. The primary outcome was the additional requirement of a Bougie for successful intubation. The secondary outcome was the time taken to intubate. Intubations were performed on a single manikin, which gave a standardised laryngoscopic view for all intubations carried out in the study.

2. Methods

50 anaesthetist participants of various clinical grades were

recruited in person for the study. Each participant was randomised to use either the curved or the straight TT on their first attempt. This was done using the sealed envelope™ application, which performed random permuted blocks to curved or straight TT in a ratio of 1:1. The curved TT was a size 6.5 Covidien Shiley Lo-Contour reinforced cuffed tracheal tube. The straight TT was a size 6.5 Pro-Breath armoured cuffed tracheal tube. The supplied Bougie was Portex. Both TTs and manikin were lubricated with gel before each intubation.

Participants were presented with the same airway manikin (TruCorp AA91100 AirSim Advance model) designed to give a view of the glottis under direct vision, using a standard size 4 Macintosh laryngoscope (grade 1 or 2a Cormack Lehane view). They were instructed to intubate the manikin as they would in usual practice, with a Bougie available if required. They were given as much time as necessary to obtain the best possible laryngoscopic view. Once obtained, a timer was started when the TT was passed into their hand on request. They were instructed to verbally indicate the moment at which the TT cuff had passed through the glottis, at which point the timer was stopped. The grade of anaesthetist (treated as a binary variable with participants classified as either consultant level, or pre-consultant level), reported Cormack-Lehane laryngoscopic view, whether or not a Bougie was used and time to pass the TT were documented. The whole process was repeated for the second TT type.

Our local Research & Development Department was consulted for ethical approval. Despite the use of a randomisation tool and the general clinical applicability of any published results, our Research Governance Manager deemed that no formal ethical approval was required. In keeping with good ethical standards, all participants provided informed consent prior to recruitment, with reassurance that no personal details would be recorded other than training grade.

2.1. Statistical analysis

All statistical analysis was performed using the statistical programming language R (version 3.5.1).

A previous audit of emergency intubations showed an incidence of Bougie use of 12.4% [2]. We estimated that this figure would be slightly higher (15%) in a manikin due to the stiffness of material

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compared with human tissue. We judged a clinically meaningful proportion of Bougie use with the straight TT to be 50% and above. A power calculation indicated 44 pairs of intubations (curved and straight) would be sufficient to detect a difference of at least 0.35 in proportions of intubations that require additional use of a Bougie, when comparing the curved and straight tubes using McNemar's test for paired binary data, with a 5% significance level and 95% power. This assumes that the expected proportions of intubations that require a Bougie are 0.5 and 0.15 for straight and curved tubes, respectively. The total sample size was rounded up to 50 pairs from the required 44.

The primary outcome measure was the need for a Bougie during intubation. Statistical significance for a difference in Bougie use between TT types was examined using McNemar's test. Fisher's exact tests were also performed to see whether there was a difference in rates of successful intubation without a Bougie between consultant and pre-consultant training grades.

The secondary outcome was time to intubation. This was analysed using a mixed effects model (using the R package nlme) with intubation method, randomisation order, and training grade as fixed effects, and participant treated as a random effect. Additional models considered training grade, and a training grade*intubation method interaction as fixed effects. Statistical significance was defined as $p < 0.05$ throughout.

3. Results

50 participants took part in the study, of whom 22 were consultants, and 28 were of a more junior training grade. The anaesthetic grade of participants randomised to each group are summarised in Table 1. All participants completed both arms of the study, performing intubation with both the straight and curved TT. All participants achieved the same laryngoscopic grade for each of the paired intubations. All participants reported a direct view of the glottis (50% grade 1, 50% grade 2a).

When using a curved TT, participants successfully intubated without a Bougie in 90% of cases. When using a straight TT, this figure was reduced to 8% (see Fig. 1). This difference in rates of Bougie use was statistically significant (McNemar's chi-square = 32.2, $p < 0.001$).

Consultants successfully intubated without a Bougie more frequently than pre-consultant trainees when using a straight TT (13.7% compared to 3.6%), but were less successful than pre-consultant trainees when using a curved TT (see Fig. 2). These differences were not statistically significant when compared using Fisher's exact test ($p > 0.3$ for both straight and curved TT).

In keeping with the primary outcome, participants also performed intubation more rapidly when using a curved TT (mean 11.6 s, 95%CI 8.0–15.2 s), as compared to when using a straight TT (mean time 25.3 s, 95%CI 22.1–28.5 s) (see Fig. 3a). This was highly statistically significant ($t = 4.0$, $p < 0.001$), no order effects were apparent ($t = 0.26$, $p = 0.79$), and results were unchanged if a condition by order interaction was also considered.

When training grade was included in the model, there was a statistically significant effect ($t = 2.1$, $p < 0.04$), with consultants intubating more quickly than trainees. When an interaction between TT type and training grade was considered, the main effect of training grade was no longer significant ($t = 0.1$, $p = 0.9$), but the interaction term was significant ($p < 0.01$), indicating that the advantage of a curved TT is particularly apparent for pre-consultant trainees (see Fig. 3b).

4. Discussion

In this manikin study, intubation using a curved TT required use of a Bougie 10% of the time, compared with 92% when a straight TT was used ($p < 0.001$). Intubations with the straight TT also took significantly longer than with the curved TT (mean time 11.6 s vs 25.3 s, $p < 0.001$). When grade of anaesthetist was considered in the analysis, the benefit of the curved TT over the straight TT in terms of shorter intubation time was greater for pre-consultant grades ($p = 0.01$).

The study was limited by the fact that the airway manikin may not truly reflect intubating conditions in clinical practice. There was occasional difficulty in passing the TT through the manikin glottis, despite an adequate view and tube trajectory. This added time to the intubation attempt. However, this problem was infrequent, added minimal time and is likely to have affected both TT types equally. The study was designed to isolate the effect of TT type on ease of intubation by using the same anatomical model (manikin) for all participants. It is therefore not possible to comment on how this effect changes with the varying degrees of laryngoscopic difficulty encountered in clinical practice.

We also acknowledge that the equipment used in this study may not necessarily represent widespread clinical practice. While size 6.5 TTs are commonly used in our tertiary ear, nose and throat centre, larger sized tubes are generally favoured in routine practice. However, we believe that if the TT is sized appropriately to pass through the glottis atraumatically, variations in diameter should not impact the ease of intubation as determined by the degree of tube curvature.

Similarly, videolaryngoscopy (VL) is increasingly favoured in routine practice, with some arguing that the Macintosh blade is becoming obsolete [3]. The current COVID-19 pandemic could accelerate this trend, as many perceive that a safer distance between the patient and operator can be maintained using VL. Most videolaryngoscopes incorporate a TT channel or are used with a stylet routinely, which may abolish the impact of the TT curvature described in this study. However, in our experience and according to relatively recent surveys, universal VL is uncommon in individual centres and standard direct laryngoscopes remain in widespread use [4]. Reasons for this may include issues with efficiency of decontamination and the cost of VL [3].

Although Magill's observations of the advantageous nature of curved rubber tubing for tracheal intubation were based primarily on the nasal route, we believe that this principle is also applicable

Table 1
Anaesthetic grade of participants in both randomised groups.

Anaesthetic Grade	Randomised to use curved tracheal tube on first attempt (number of participants)	Randomised to use straight tracheal tube on first attempt (number of participants)
Physician's assistant (anaesthesia)	1	0
Core trainee (CT1-2)	2	3
Intermediate trainee (ST3-4)	3	3
Higher trainee (ST5-7)	8	8
Consultant	11	11

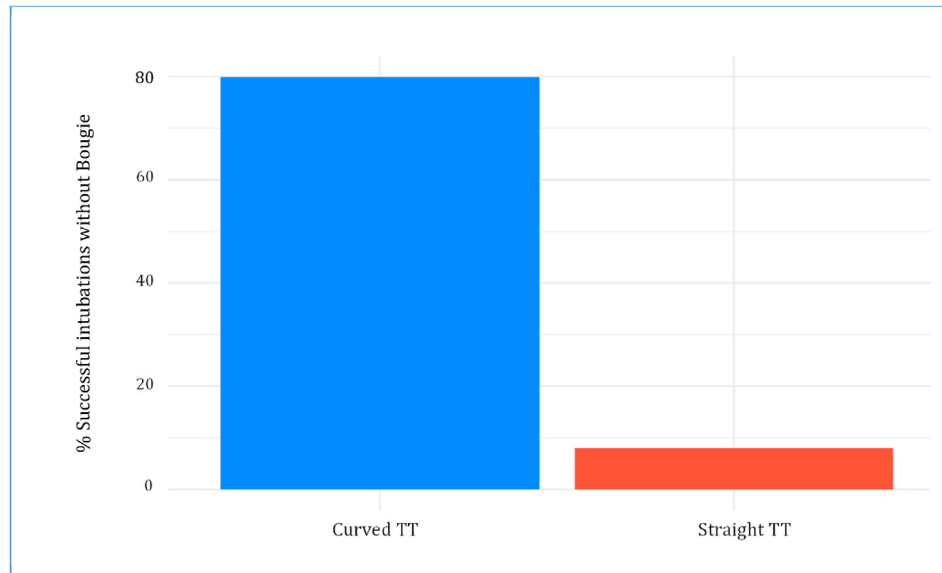


Fig. 1. Successful intubation without Bougie. Participants using a curved tracheal tube (TT) required a Bougie significantly less frequently than those using a straight TT ($p < 0.001$).

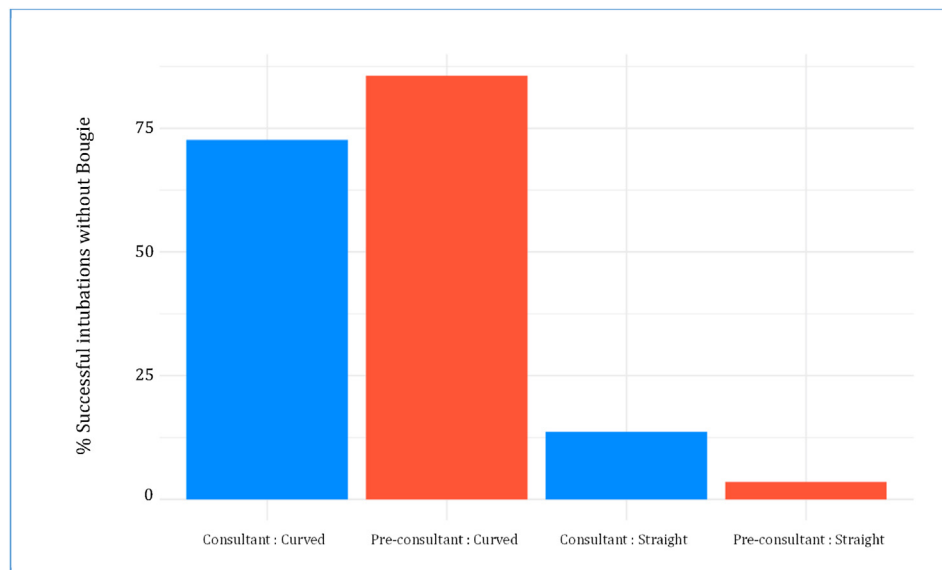


Fig. 2. Successful intubation without Bougie according to training grade and tracheal tube type. Differences between training grades were not statistically significant.

to most oral intubations under direct laryngoscopy. In keeping with our clinical experience, this manikin study suggests that an equivalent straight TT takes significantly longer to insert and frequently requires the additional use of a Bougie. In the majority of cases, a short delay in TT insertion, multiple passes or use of a Bougie will not lead to any noticeable patient harm. However, there are situations in which securing a definitive airway as quickly as possible is critical (e.g. in the case of the soiled airway, or the rapidly desaturating patient). Furthermore, the apparently benign nature of intubation should not be taken for granted. Although rare, several short and long term complications of prolonged or traumatic intubation are recognised. Temporary hoarseness post intubation may be secondary to traumatic vocal cord oedema, lacerations or epiglottic haematomas [5]. If this leads to subsequent granuloma of the vocal cord or is associated with arytenoid dislocation, damage may be permanent and very difficult to treat [6–8].

Although thought to be extremely rare [9], additional use of a Bougie has also been implicated in cases of airway trauma [10]. We suggest that the use of curved TTs may reduce the risk of such complications and that the unnecessary use of straight TTs therefore compromises patient safety. If a straight TT is indicated or no curved alternative is available, we suggest pre-loading with a stylet or careful planned use of a Bougie on the first attempt, regardless of the anticipated view at laryngoscopy.

The subject of this study raises the question of how equipment is introduced into clinical practice that may be clinically inferior to previous standards. This may be explained in part by the way new devices are regulated [11]. All must comply with the European Medical Devices Directive (MDD) to gain the 'CE' mark of approval, which is assessed in the UK by the Medical Devices Agency (MDA). This assessment is based more on manufacturing standards and quality control, than on clinical efficacy. Furthermore, if new

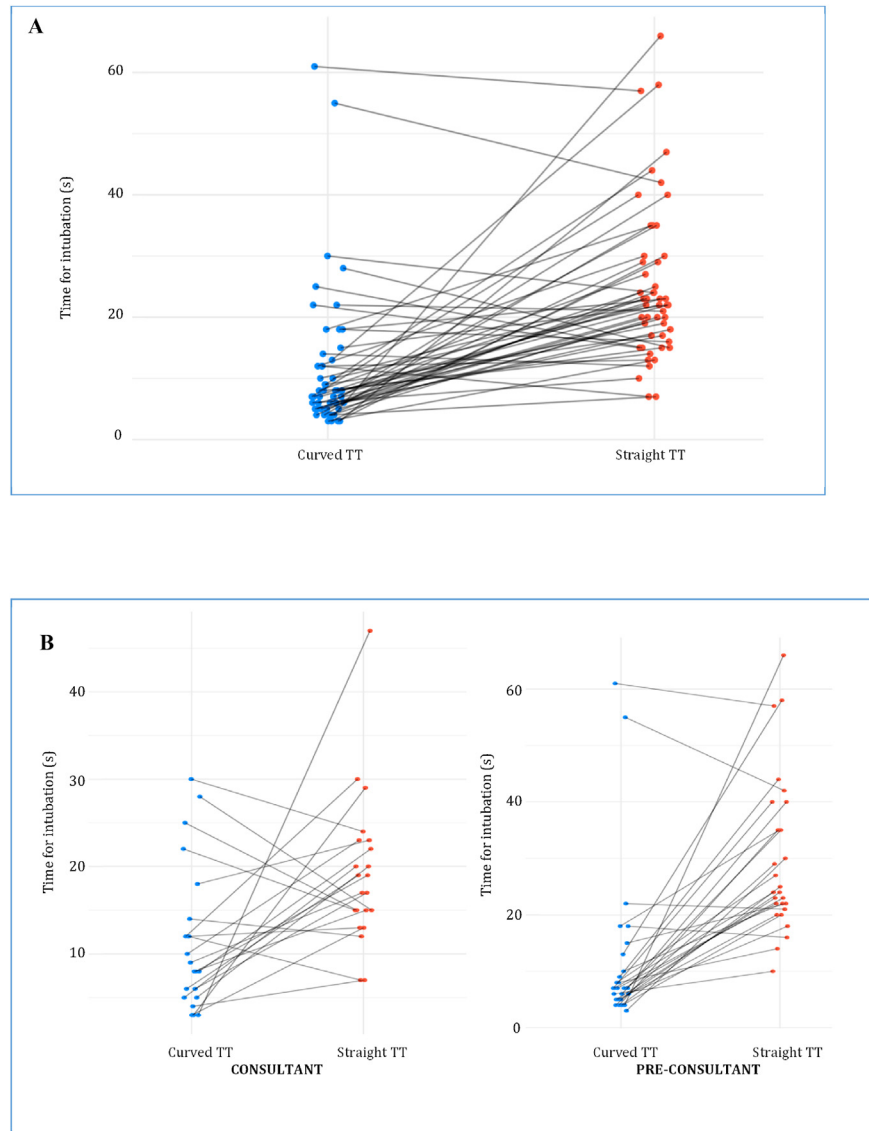


Fig. 3. (a) Intubation was performed faster when using a curved tracheal tube (TT) compared to a straight TT ($p < 0.001$). (b) The benefit of a curved TT in terms of intubation speed was greater for pre-consultant trainees compared to consultants ($p = 0.01$).

equipment is declared equivalent to an existing approved product, no clinical testing is required for gaining a CE mark [11]. Clinical evidence for the efficacy and safety of the new product in clinical practice is therefore often absent. If such products offer a cost saving compared to the previous standard, they may be brought into practice. For example, in relation to this study, the straight TT available in our institution costs £6.22 in comparison to £10.20 for the equivalent curved TT. Although this appears to be a significant reduction in cost, it is likely to be offset by the frequent increased use of disposable Bougies.

In conclusion, this randomised cross-over manikin study supports the hypothesis that intubation with a straight TT is more difficult than with a curved TT, both in terms of the need for a Bougie and the time taken to intubate.

CRedit authorship contribution statement

Charles Prior: Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing, Visualization,

Project administration. **Eleanor Pett:** Methodology, Investigation, Writing - review & editing. **Catriona Ferguson:** Conceptualization, Methodology, Supervision.

Declaration of competing interest

CF has received funding for lectures from MSD and Merck & Co., Inc. The authors declare that they have no other conflict of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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