Randomized, controlled trial of the double setup tracheal tube during fibreoptic orotracheal intubation under general anaesthesia

A. H. Jackson 1*, P. Wong 2 and B. Orr 1 3

1 Department of Anaesthetics, Royal Prince Alfred Hospital, Missenden Road, Camperdown 2050, New South Wales, Australia. 2 Guy’s, King’s and St Thomas’ Hospital Trust, St Thomas Street, London SE1 9RT, UK. 3 University of Sydney, New South Wales 2060, Australia

*Corresponding author. E-mail: andrewhjackson@hotmail.com

Background. Impingement of the tracheal tube (ETT) on upper airway structures during railroading over the fibreoptic bronchoscope (FOB) occurs commonly. Potential complications of impingement include prolonged intubation time, leading to arterial desaturation, failed intubation and laryngeal trauma. The objective of this randomized, controlled trial was to assess the effect of the double setup ETT (a paediatric ETT is placed inside an adult ETT) on the incidence of impingement during orotracheal fibreoptic intubation.

Method. Two hundred patients were randomized to have a single ETT or double setup ETT. After induction of anaesthesia, fibreoptic orotracheal intubation was performed. The degree of impingement of the ETT during advancement over the FOB was assessed using a standardized scoring system based on the manoeuvres required to overcome the impingement.

Results. The incidence of impingement was lower using the double setup ETT compared with the single ETT (18% vs 93%, P<0.001). The double setup ETT also reduced the incidence of impingement requiring more than a simple 90° counterclockwise rotation to achieve intubation (3% vs 14%, P=0.01) and reduced the median intubation time (31 s vs 35 s, P=0.046).

Conclusions. The double setup ETT is effective in reducing ETT impingement and in reducing intubation time. We did not find an association between ETT impingement and arterial desaturation.

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The flexible fibreoptic bronchoscope (FOB) has, over the last 35 yr, become an essential aid in managing the difficult airway. Impingement of the tracheal tube (ETT) on upper airway structures during railroading over the FOB is a common problem. The potential complications of ETT impingement include increased intubation time, leading to arterial desaturation, failure of intubation, and trauma to upper airway structures. While previous studies have shown that various techniques can reduce the incidence of impingement, few have specifically addressed the issue of complications related to impingement.

Marsh 1 suggested that impingement of the ETT was related to the difference in size between the external diameter (ED) of the FOB and the internal diameter (ID) of the ETT. This difference allows the tip of the ETT to get caught on various upper airway structures. He described the double setup ETT, in which an uncuffed paediatric ETT is placed between the FOB and the adult ETT, and reported smooth passage of the ETT in 27 patients in whom there had been impingement when the adult ETT was used alone.

Rosenblatt 10 compared the double setup ETT with a mock double setup ETT in a randomized, controlled,
blinded trial, and demonstrated a significant reduction in ETT impingement. In this larger study, we compared the double setup ETT with a standard single ETT (the true control), and investigated whether it would reduce the incidence of impingement, failed intubation, episodes of arterial desaturation, and intubation time.

Materials and methods
After obtaining local Ethics Review Committee approval and written informed consent from all patients, we studied 200 patients at Royal Prince Alfred Hospital, aged 17–82 yr, in whom orotracheal intubation was indicated for elective surgery. Patients were excluded if clinical evaluation revealed an increased risk of aspiration necessitating rapid sequence induction, or if there was an anticipated difficult intubation.

Patients were randomly allocated to one of two groups by a computerized random number generator. The single-setup ETT group (Group S) had a standard cuffed Portex ETT (Portex, Hythe, Kent, UK) (ID 8.0 mm for males, 7.5 mm for females) mounted on an Olympus LF-GP bronchoscope (Olympus Optical, Tokyo, Japan) (ED 4.2 mm) (Fig. 1A). The double setup ETT group (Group D) had an uncuffed Mallinckrodt ETT (Juarez, Mexico) (ID 5.5 mm for males, 5.0 mm for females) placed inside the cuffed Portex ETT. The Portex tubes were cut at 24 cm for males and 22 cm for females so that the inner tube extended beyond the tip of the outer tube in Group D (Fig. 1B). Lubricant was applied to the FOB and the inner and outer tubes, and the cuffs were deflated.

With the patient’s head resting on one standard pillow, general anaesthesia was induced as deemed appropriate to the surgery, and rocuronium 0.6 mg kg⁻¹ was administered. A Berman airway (Vital Signs, Totowa, NJ, USA) of appropriate size (as estimated by the operator) was inserted into the patient’s oropharynx, and face mask ventilation with sevoflurane in oxygen was performed for 3 min. An anaesthetic assistant applied jaw thrust and the FOB was passed via the Berman airway until the carina was visualized. Before intubation, the FOB was removed out of the side of the Berman airway. The ETT was then railroaded over the FOB and into the trachea. The time from ceasing face mask ventilation until carinal visualization was recorded (hereafter referred to as FOB placement time), as was the time from carinal visualization until recommencement of ventilation, as confirmed by capnography (hereafter referred to as intubation time). These time frames were chosen to indicate the true period of apnoea during the intubation process. The operator recorded any problems encountered during the procedure, including any decrease in $\text{SpO}_2$. If carinal visualization took longer than five min or if there was arterial desaturation (defined here as a decrease in $\text{SpO}_2$ to <90%) during passage of the FOB, the study was abandoned and appropriate treatment instituted. Only one attempt at fibreoptic tracheal intubation was allowed. All intubations were performed by the authors. A scoring system, similar to the one described by Koga and colleagues,² was used to assess impingement of the ETT on upper airway structures (Table 1).

If impingement occurred, the ETT was pulled back a few centimetres, rotated 90° counterclockwise, and re-advanced. If impingement recurred, further manoeuvres were employed, including the use of more than one rotation, alteration of the head and neck position, application of tongue traction, and the additional use of a rigid laryngoscope.

Table 1 Grade of ETT impingement (from Koga and colleagues)²

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>No impingement</td>
</tr>
<tr>
<td>Grade II</td>
<td>Impingement relieved by 90° counterclockwise rotation</td>
</tr>
<tr>
<td>Grade III</td>
<td>Impingement requiring more than one rotation, alteration of head and neck position, tongue traction, or the additional use of a rigid laryngoscope</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Failure (ETT not able to be positioned in the trachea despite visualization of the carina with the FOB)</td>
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Statistical analysis
For the purpose of sample size calculation, we estimated a 40% incidence of ETT impingement based on reported rates of 11–90% in previous studies.² ⁸ We then calculated that 200 patients were required to give us an 80% power to
detect a reduction in this incidence from 40% to 20%. $P<0.05$ was considered statistically significant. In previous studies, the incidence of failed intubation due to ETT impingement was highly variable, with values including 3%,\(^3\) 10%,\(^2\) 20%\(^10\) and 35%.\(^4\) Given the sample size calculated above, this study had 80% power to detect a reduction in the incidence of failure from 15% when using the standard ETT to 3% when using the double setup ETT.

The Mann–Whitney $U$-test was used to compare times. Fisher’s exact test was used to compare Grades of impingement and the incidence of desaturation. While the overall significance level was kept at 0.05, the Bonferroni method was used to adjust for individual alpha levels. Calculations were performed with SPSS v11.5 (SPSS Science, Chicago, IL, USA).

**Results**

Two hundred patients were enrolled in the study between January and December 2002. One hundred and one patients were randomly allocated to Group S and 99 patients to Group D. One of the patients in Group S was withdrawn from the study as there was failure to place the FOB in the trachea (five of 24 patients, 21%). The incidence of arterial desaturation was significantly higher in the patients with FOB placement problems than in those without FOB placement problems (21 vs 0%, $P<0.001$).

Of the 24 cases (12%) in which we encountered problems passing the FOB into the trachea, 19 were associated with the Berman airway. In nine patients, the Berman airway was too long and guided the FOB into the vallecula or the oesophagus. In seven patients, the assistant had difficulty maintaining the distal portion of the Berman airway in the midline, causing the FOB to veer off to the side and make visualization of the cords difficult. In two cases, the Berman airway was too short and its curvature directed the FOB towards the base of the tongue, leading to difficulty directing the FOB towards the vocal cords. Other recorded problems included excessive secretions and a poor light source on the FOB.

**Discussion**

The main findings of this study were that the use of the double setup ETT resulted in a significant reduction in overall rate of impingement (Grades I–IV combined, 18 vs 93%); a significant reduction in Grade III impingement (2 vs 13%); no significant effect on Grade IV impingement; and a small, but statistically significant, reduction in intubation time. Our study supports the work of Rosenblatt\(^10\) and Marsh\(^1\) in finding a reduction in overall impingement with the double setup ETT.

Most cases of impingement were overcome by one simple 90° counterclockwise rotation of the ETT (Grade II). This adds only a few seconds to the intubation time and, if it were the only manoeuvre required, the double setup ETT would have limited clinical significance. However, cases of Grade III impingement required at least two (and often more)

### Table 2 Physical characteristics of patients. Group S=single ETT group, Group D=double setup ETT Group. Values are mean (range) for age and mean (SD) for weight

<table>
<thead>
<tr>
<th></th>
<th>Group S</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male/female)</td>
<td>46/54</td>
<td>47/52</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>52 (17–80)</td>
<td>50 (18–82)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>73 (17.6)</td>
<td>74 (17.5)</td>
</tr>
</tbody>
</table>

### Table 3 Grade of impingement, FOB placement time, intubation time and number of episodes of desaturation. Group S vs Group D for Grades I–IV combined, $P<0.001$. Times are median (range). *After Bonferroni adjustment where appropriate

<table>
<thead>
<tr>
<th>Grade of impingement</th>
<th>Group S</th>
<th>Group D</th>
<th>$p$*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=100)</td>
<td>(n=99)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>7 (7%)</td>
<td>81 (82%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>II</td>
<td>79 (79%)</td>
<td>15 (15%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>III</td>
<td>13 (13%)</td>
<td>2 (2%)</td>
<td>0.010</td>
</tr>
<tr>
<td>IV</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
<td>0.749</td>
</tr>
<tr>
<td>FOB placement time (s)</td>
<td>23 (11–160)</td>
<td>21 (12–180)</td>
<td>0.068</td>
</tr>
<tr>
<td>Intubation time (s)</td>
<td>35 (15–75)</td>
<td>31 (15–60)</td>
<td>0.046</td>
</tr>
<tr>
<td>Episodes of desaturation</td>
<td>2 (1%)</td>
<td>3 (1.5%)</td>
<td>0.991</td>
</tr>
</tbody>
</table>
The importance of minimizing attempts to pass the ETT over the FOB was highlighted in a recent small case series reported by Maktabi and colleagues. They reported traumatic complications in three patients in whom there were between one and 10 attempts to pass an ETT despite uneventful placement of a FOB. These complications included supraglottic swelling and vocal cord bruising (resulting in a high-pitched voice), serious laryngeal trauma (resulting in an immobile vocal fold) and extensive haematoma of the pharyngeal mucosa. Our study did not examine whether the double setup ETT could reduce laryngeal trauma. However, it is likely that most laryngeal trauma is related to difficulty in railroading the ETT (as the FOB itself is narrower and is passed under direct vision), and that techniques which reduce impingement may also reduce laryngeal trauma.

Methods to reduce ETT impingement which have previously been studied include a 90° counterclockwise rotation of the ETT, alternatively shaped ETT tips, a larger diameter FOB, use of a tapered sleeve on the FOB, and the double setup ETT. In 1972, Stiles and colleagues reported a series of 100 fibreoptic tracheal intubations in which they described ‘occasional difficulty encountered in slipping the tube past the larynx’. They described how ‘spiral motion’ of the ETT might overcome this. Several investigators have since confirmed that impingement can usually be overcome by a 90° counterclockwise rotation of the ETT.

Use of a smaller diameter ETT reduces the size of the gap between the outer surface of the FOB and the inner surface of the ETT. However, the increased resistance to ventilation caused by decreasing the internal diameter of the ETT may make this inappropriate. The Moore tube has a tapered tip which is also designed to reduce the gap between the FOB and ETT, but this is not commercially available. Hakala and Randell showed that a FOB with a larger diameter, which also reduces the gap between the FOB and the ETT, reduces the incidence of impingement. Fibreoptic bronchoscopes of different diameters are, however, expensive and unlikely to be readily available.

The use of an obtuse-tipped ETT has had varied results. Brull and colleagues found that the flexible, spiral-wound, wire-reinforced Spiral-Flex ETT reduced impingement when compared with a standard ETT. In contrast, Hakala and colleagues found that impingement occurred frequently with the Spiral-Flex ETT. The Parker Flex-Tip tube and the silicone-tipped tube designed for use with the LMA-Fastrach have also been shown to reduce the incidence of impingement, but both require high cuff inflation pressures and may not be readily available. Ayoub and colleagues described a tapered PVC sleeve which, when fitted over the distal part of the FOB, successfully reduced the incidence of ETT impingement. However, this is not available commercially, requires a suture to keep it in place, and is non-disposable.

An incidental finding of this study was that episodes of arterial desaturation were associated with problems placing the FOB in the trachea but not with ETT impingement. This suggests that, although impingement does prolong intubation, the relatively small increases in intubation time do not usually lead to arterial desaturation.

One limitation of this study was the potential bias introduced by the lack of blinding of the operators. Rosenblatt used a mock double setup ETT, in which the inner tube was cut short in the control group so that it would not protrude from the end of the adult tube. The inner ETT was disengaged from the adult tube until the latter had been advanced into the mouth, thus blinding the operator. However, while testing this method we found that the short inner ETT reduced lateral movement of the adult ETT over the FOB when compared with a single ETT (the true control). As lateral movement of the ETT over the FOB may be an important factor in impingement, we did not use a mock double setup ETT to blind the study as we felt it did not represent a true control.

Another limitation of this study was that only anaesthetized, paralysed patients who did not have anticipated difficult airways were recruited. Whether the double setup ETT would reduce the incidence of impingement during awake fibreoptic orotracheal intubations in patients with difficult airways is not known. A study which shows this would be difficult to perform, given the low incidence of difficult airways.

In conclusion, our study supports previous work in finding that the double setup ETT significantly reduces impingement during orotracheal fibreoptic intubation when compared with the standard ETT.

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