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APPARATUS

Evaluation of the Airtraq® and Macintosh laryngoscopes in patients at increased risk for difficult tracheal intubation*

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Summary

The Airtraq®, a novel single use indirect laryngoscope, has demonstrated promise in the normal and simulated difficult airway. We compared the ease of intubation using the Airtraq with the Macintosh laryngoscope, in patients at increased risk for difficult tracheal intubation, in a randomised, controlled clinical trial. Forty consenting patients presenting for surgery requiring tracheal intubation, who were deemed to possess at least three characteristics indicating an increased risk for difficulty in tracheal intubation, were randomly assigned to undergo tracheal intubation using a Macintosh (n = 20) or Airtraq (n = 20) laryngoscope. All patients were intubated by one of three anaesthetists experienced in the use of both laryngoscopes. Four patients were not successfully intubated with the Macintosh laryngoscope, but were intubated successfully with the Airtraq. The Airtraq reduced the duration of intubation attempts (mean (SD); 13.4 (6.3) vs 47.7 (8.5) s), the need for additional manoeuvres, and the intubation difficulty score (0.4 (0.8) vs 7.7 (3.0)). Tracheal intubation with the Airtraq also reduced the degree of haemodynamic stimulation and minor trauma compared to the Macintosh laryngoscope.

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The Airtraq® (Prodol Meditec S.A., Vizcaya, Spain) is a new single use laryngoscope designed to facilitate tracheal intubation in patients with both normal and difficult upper airway anatomy. As a result of the exaggerated curvature of the blade and an internal arrangement of optical components, a view of the glottis is provided without alignment of the oral, pharyngeal and tracheal axes. Our group has recently demonstrated that the performance of the Airtraq is superior to that of the Macintosh laryngoscope in patients at low risk for difficult intubation [1], and in patients undergoing simulated cervical immobilisation by means of manual in-line axial stabilisation [2]. The Airtraq also produced less haemodynamic stimulation in these patients, a potentially important advantage in certain clinical situations [1, 2]. In manikin studies, the Airtraq performs better than the Macintosh laryngoscope in the simulated difficult airway when used by experienced [3], inexperienced [4] and even novice [5] laryngoscopists. Recent reports have highlighted the utility of the Airtraq in a number of difficult airway settings, including post traumatic asphyxia [6], in morbid obesity [7], and following failed conventional approaches to tracheal intubation [8].

The purpose of this study was to evaluate the usefulness of this new device for use by experienced anaesthetists in a randomised controlled trial of patients at increased risk for difficult intubation. We hypothesised that, in comparison with the Macintosh laryngoscope, the use of the Airtraq would be result in reduced laryngoscopy times, lower intubation difficulty scale (IDS) scores, and reduced haemodynamic stimulation following intubation. Data relating to four of the patients included in this study that were not successfully intubated with the Macintosh laryngoscope have previously been published as part of a series of cases of failed tracheal intubations rescued with the Airtraq laryngoscope [8].

Methods

After obtaining approval from the Galway University Hospitals Research Ethics Committee (Galway, Ireland), and written informed patient consent, we studied 40 ASA physical status 1–3 patients, aged 18 years of age or older, who were deemed on pre-operative assessment by their primary anaesthetist to be at increased risk for difficult tracheal intubation, and scheduled for surgical procedures requiring tracheal intubation, in a randomised, single blind, controlled clinical trial.

Following notification by the primary anaesthetist, the eligibility of the patient to participate in the study was determined by one of the investigators on the evening prior to surgery. Inclusion criteria consisted of possession of at least three of the following criteria:

1 thyromental distance < 6 cm;
2 Mallampatti classification 3 or 4;
3 interincisor distance < 4 cm;
4 previously documented difficult intubation.

Mallampatti grade was determined with the patient in the sitting position with the tongue maximally protruded [9]. Interincisor distance was measured with the patient in the sitting position, and thyromental distance was measured from inside of the mentum to the thyroid cartilage with the head in full extension [10]. Patients were not studied if risk factors for gastric aspiration were present, or where there was a history of relevant drug allergy.

Patients were randomly assigned to two groups using sealed envelopes and were unaware of their group assignment. All patients received a standardised general anaesthetic. Standard monitoring, including ECG, non-invasive blood pressure (NIBP), S_pO_2, end-tidal carbon dioxide and volatile anaesthetic levels, were utilised throughout. Prior to induction of anaesthesia all patients were given fentanyl (1–1.5 $\mu g.kg^{-1}$) intravenously. A sleep dose of propofol (2–3 $mg.kg^{-1}$) was titrated to induce anaesthesia. Following induction of anaesthesia, all patients were manually ventilated with sevoflurane (2.0–2.5%) in oxygen, and atracurium 0.35 $mg.kg^{-1}$ was administered. Three minutes after administration of atracurium, the patient was placed in the 'sniffing the morning air' position, and laryngoscopy was performed by one of three anaesthetists (CM, BH, JL) experienced in the use of both laryngoscopes. Each anaesthetist had performed > 500 intubations using the Macintosh laryngoscope, and at least 50 intubations with the Airtraq in manikins, and 50 intubations with the Airtraq in patients, prior to this study.

Thereafter, in all patients, the lungs were mechanically ventilated for the duration of the procedure and anaesthesia was maintained with sevoflurane (2.0–2.5%) in a mixture of nitrous and oxygen in a 60 : 40 ratio. No other medications were administered, or procedures performed, during the 5-min data collection period following tracheal intubation. Further management was left to the discretion of the anaesthetist providing care for the patient.

All data were collected by an independent unblinded observer. The primary endpoints were the duration of the tracheal intubation procedure and the IDS score [11]. The duration of the intubation attempt was defined as the time taken from insertion of the blade between the teeth until the tracheal tube was placed through the vocal cords, as evidenced by visual confirmation by the anaesthetist. If the tracheal tube was not visualised passing through the vocal cords, the intubation attempt was not considered complete until the tracheal tube was connected to the anaesthetic circuit and evidence obtained of the presence of carbon dioxide in the exhaled breath. The IDS score, developed by Adnet et al. [11] is a quantitative scale of intubation difficulty that can objectively compare the complexity of tracheal intubations (Appendix 1).

A secondary endpoint was the rate of successful placement of the tracheal tube in the trachea. An unsuccessful intubation attempt was defined as an attempt in which the trachea was not intubated, or where tracheal intubation attempts were terminated after 120 s had elapsed. The number of optimisation manoeuvres to aid tracheal intubation, which included the BURP (Backward Upward Rightward Pressure) manoeuvre, lip retraction and use of a stylet, and in the case of the Macintosh laryngoscope, the use of a bougie, was also recorded. Additional endpoints included the number of intubation attempts, the Cormack and Lehane grading of the glottic view obtained, the lowest recorded arterial oxygen saturation during or immediately following intubation attempts, the severity of dental trauma, and the occurrence of minor complications (visible trauma to lip or oral mucosa or blood on laryngoscope).

As this was a study in patients that were potentially difficult to intubate, a two-stage back-up plan was in place in case of a failed intubation. Firstly, in the event of failure to intubate with the device to which the patient was randomly allocated, intubation attempts with the other device were then permitted. In the event that neither device resulted in successful tracheal intubation, the standard Difficult Airway Society failed Intubation algorithm [12] was followed.

Statistical analysis

We based our sample size estimation on the IDS score. An IDS score of zero represents ideal intubating conditions, and increasing scores represent progressively more difficult intubating conditions. Based on initial pilot studies, we projected an IDS score of ≥ 4, representing moderately difficult intubating conditions, in 80% patients undergoing tracheal intubation using the Macintosh laryngoscope. We considered that a clinically important reduction in the number of patients with an IDS score greater than zero in these low risk patients would be a 30% reduction, i.e. an IDS score of ≥ 1 in 50% of patients. Based on these figures, using an $\alpha = 0.05$ and $\beta = 0.2$, for an experimental design incorporating two equal sized groups, we estimated that 17 patients would be required per group. We therefore aimed to enrol 20 patients per group.

All analyses were performed using SIGMASTAT 3.5 (Systat Software, San Jose, CA). Data for duration of intubation attempts were analysed using the *t*-test. Data for the success of tracheal intubation attempts, incidence of minor trauma and of arterial desaturation < 93% (determined a priori) were analysed using Fisher's exact test. Data for the IDS score, the number of intubation attempts, and the number of optimisation manoeuvres required were analysed using the Mann–Whitney Rank sum test. The comparisons of haemodynamic data within groups were analysed using one-way repeated measures analysis of variance (ANOVA), with post hoc testing using the Student–Newman–Keuls test. For these analyses, the pre-intubation data were taken as baseline data, rather than the pre-induction values. Between-group comparisons were made using an unpaired *t*-test with the Bonferroni correction as appropriate. Continuous data are presented as means (SD), ordinal data are presented as medians (quartiles (IQR)), and categorical data are presented as number and as frequencies. The α level for all analyses was set as $p < 0.05$.

Table 1 Demographic characteristics of patients enrolled in the study.

Parameter assessed	Macintosh	Airtraq
Male : Female ratio	10 : 10	8 : 12
Age; years	50.2 (18.2)	51.7 (14.6)
Body mass index; kg.m^{-2}	29.9 (6.8)	29.4 (4.7)
ASA classification; median (IQR)	2 (1,3)	2 (1,3)
Mallampatti classification		
1	0 (0)	1 (5)
2	1 (5)	2 (10)
3	15 (75)	13 (65)
4	4 (20)	4 (20)
Thyromental distance; cm		
≥ 6	2 (10)	1 (5)
4.1–6	12 (60)	16 (80)
≤ 4	6 (30)	3 (15)
Interincisor distance; cm		
> 4	1 (5)	1 (5)
3.1–4	8 (40)	9 (45)
≤ 3	11 (55)	10 (50)
Documented previous difficult intubation	10 (50)	9 (45)

Data are given as mean (SD), median (IQR), or *n* (%).

Table 2 Anaesthetic regimen.

	Macintosh	Airtraq
Induction of anaesthesia		
Fentanyl (μg.kg^{-1})	1.3 (0.3)	1.2 (0.3)
Propofol (mg.kg^{-1})	2.4 (0.6)	2.3 (0.6)
Atracurium (mg.kg^{-1})	0.5 (0.2)	0.5 (0.2)
Maintenance of anaesthesia		
Oxygen : nitrous oxide ratio	40 : 60	40 : 60
Sevoflurane, End-tidal (%)*	2.3 (0.6)	2.3 (0.60)*

Data are given as mean (SD) or as ratios.
*Measured immediately following tracheal intubation.

Results

A total of 40 patients were entered into the study. No patient who fulfilled the inclusion criteria refused consent to participate in the study. Twenty patients were randomly assigned to undergo tracheal intubation using the Macintosh laryngoscope, and 20 to undergo tracheal intubation using the Airtraq laryngoscope. There were no significant differences in demographic or baseline airway parameters between the groups (Table 1). All patients recruited possessed at least three of the criteria for difficult intubation, and 50% of patients in the Macintosh group and 45% in the Airtraq group had a documented history of prior difficult intubation. There were no between-group differences with regard to anaesthetic management, with similar mean doses of propofol and fentanyl, and end-tidal sevoflurane post tracheal intubation in both groups (Table 2).

All patients randomly assigned to the Airtraq laryngoscope group were intubated with the Airtraq laryngoscope on the first attempt (Table 3). In contrast, tracheal intubation was unsuccessful in four patients in the Macintosh group. All four of these patients were successfully intubated on the first attempt with the Airtraq. Data on these four patients have previously been reported [8]. Nineteen of the 20 patients were successfully intubated on the first attempt with the Airtraq laryngoscope. Three of the 16 patients that were successfully intubated with the Macintosh laryngoscope required two or more intubation attempts (Table 3). The Airtraq significantly reduced mean intubation difficulty score (Fig. 1), and improved the Cormack and Lehane glottic view obtained at laryngoscopy (Fig. 2), compared to the Macintosh group. All 20 patients in the Macintosh group had an IDS score of ≥ 1, compared to five in the Airtraq group. In the Macintosh group, 19 patients had an IDS score of 4 or greater, indicating at least a moderate degree of intubation difficulty, compared to none in the Airtraq group (Fig. 1).

Table 3 Data for intubation attempts with each device.

Parameter assessed	Macintosh	Airtraq
Overall success rate; *n* (%)	16 (80)	20 (100)
Intubation difficulty score	7.7 (0.7)	0.4 (0.2)†
Duration of first intubation attempt; s	41.6 (18.8)	13.7 (6.5)†
Duration of successful intubation attempt; s	47.7 (8.5)	13.4 (6.3)†
Lowest S_pO_2 during intubation attempt; (%)	95.4 (5.2)	99.1 (0.9)†
No. of intubation attempts; *n* (%)		
1	13 (65)	19 (95)
2	3 (15)	1 (5)
3	4 (20)	0
No. of optimisation manoeuvres (%)		
0	12 (60)	20 (100)
1	5 (25)	0
2	3 (15)	0
Complications (minor)	9 (45)	0 (0)†

Data are reported as mean (SD) or as *n* (%).
†Significantly ($p < 0.001$) different compared with the Macintosh laryngoscope.

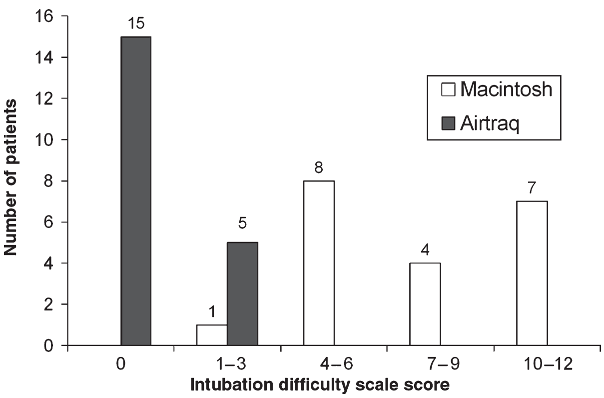

Figure 1 Comparison of intubation difficulty scale (IDS) score distributions with the Airtraq vs Macintosh laryngoscopes. Number of patients is shown above each bar. $p < 0.001$ between groups, Mann–Whitney *U*-test.

The duration of intubation attempts was significantly shorter with the Airtraq (Table 3). Fewer manoeuvres were required in the Airtraq group to improve the glottic exposure compared to the Macintosh group (Table 3). A bougie was required in five patients who were intubated using the Macintosh laryngoscope. The Airtraq significantly reduced the incidence of minor complications. There were nine such complications in the Macintosh group, including four lip lacerations, one visible laceration to the oral mucosa and four cases of blood on the tip of the laryngoscope blade. Patients intubated with the Macintosh had a significantly greater degree of arterial desaturation during intubation attempts (Table 3). Five patients in the Macintosh group sustained a transient

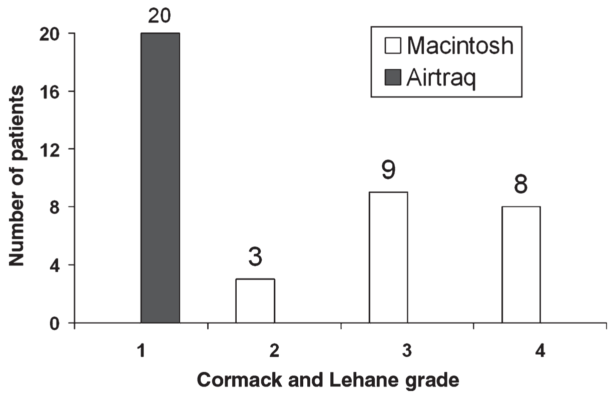

Figure 2 Cormack and Lehane grade view during the first intubation attempt with the Airtraq vs Macintosh laryngoscopes. Number of patients is shown above each bar. $p < 0.001$ between groups, Mann–Whitney *U*-test.

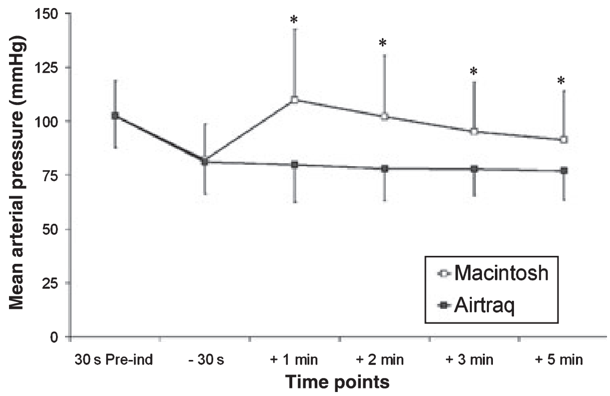

Figure 3 Graph representing the changes in heart rate following tracheal intubation with each device. The data are given as mean (SD). *Indicates significant difference compared to the Airtraq Laryngoscope. 30 s Pre-Ind, 30 s prior to induction of anaesthesia; − 30 s, 30 s prior to tracheal intubation, + 1 min, 1 min post tracheal intubation; + 2 min, 2 min post tracheal intubation; + 3 min, 3 min post tracheal intubation; + 5 min, 5 min post tracheal intubation.

arterial desaturation to 93% or lower, compared to none in the Airtraq group ($p = 0.047$, Fisher's exact test). There was no case of significant dental trauma in either group. Tracheal intubation with the Macintosh resulted in a significant increase in heart rate and mean arterial blood pressure compared to pre-intubation values, in contrast to the Airtraq. There was a significant between-group difference in heart rate and mean blood pressure at all time points post intubation (Figs 3 and 4).

Discussion

Our findings demonstrate, for the first time in the clinical setting, the superiority of the Airtraq compared to the

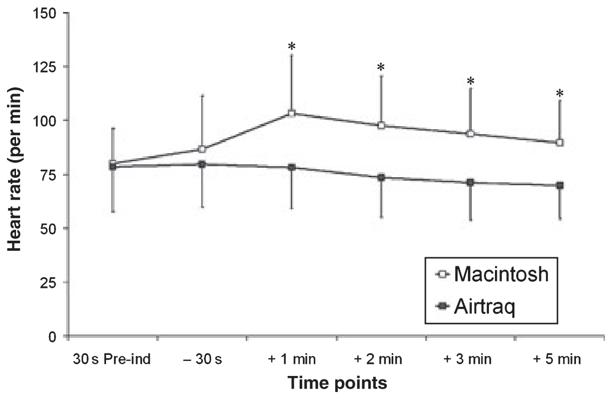

Figure 4 Graph representing the changes in mean arterial blood pressure following tracheal intubation with each device. The data are given as mean (SD). *Indicates significantly different compared with the Airtraq laryngoscope. See legend to Fig. 3 for explanation of abbreviation.

Macintosh laryngoscope in patients who were predicted to be at increased risk for difficult tracheal intubation. In comparison with the Macintosh laryngoscope, the Airtraq reduced the duration of tracheal intubation attempts, increased the success rate, and resulted in fewer minor complications and reduced haemodynamic stimulation.

Management of the potential difficult airway remains a major clinical challenge. Unfortunately, despite predictive tests such as the Mallampatti classification, mouth opening, and thyromental distance, no single factor reliably predicts these difficulties [13]. Consequently, many difficult intubations will not be recognised until after induction of anaesthesia. The rapid securing of the difficult airway, by means of tracheal intubation with an immediately available, easy-to-use alternative to the direct laryngoscope is a priority if complications are to be avoided. Our group has previously demonstrated that the Airtraq possesses advantages over the Macintosh laryngoscopes when used by anaesthetists [3], inexperienced medical personnel [4], and novices [5] in simulated difficult laryngoscopy scenarios. Further support for the utility of the Airtraq in clinical settings likely to be associated with difficult airways, comes from reports of its effectiveness in facilitating tracheal intubation in a patient following traumatic asphyxia [6]. The Airtraq has also been demonstrated to be effective in morbidly obese patients presenting for surgery [7]. However, to date, the utility of Airtraq vs the Macintosh laryngoscope has not been determined in a randomised clinical trial in patients at increased risk for difficult intubation.

The patients in this study were at substantially increased risk for difficult tracheal intubation. All patients recruited possessed three of the following criteria: 1 – thyromental distance < 6 cm; 2 – Mallampatti classification 3 or 4; 3 – interincisor distance < 4 cm; and 4 – previously documented difficult intubation. Nineteen of these patients had a documented previous difficult intubation, which had been performed by experienced anaesthetists in our institution. The decision to use this combination of variables was made because no one test is sufficiently sensitive and specific, and there is no clearly defined combination of variables that accurately yet specifically predicts difficult intubation [14]. The success of our approach to the identification of patients at increased risk is borne out by our intubation difficulty scores for the patients in the Macintosh group, where all patients had scores consistent with a moderate to very difficult tracheal intubation.

The Airtraq provided superior intubating conditions in patients at increased risk for difficult tracheal intubation. The Airtraq resulted in reduced duration of intubation attempts, and reduced intubation difficulty scale scores. The Cormack and Lehane grading system, although originally designed to compare glottic views at direct laryngoscopy [15], provided a useful comparison of the direct and indirect laryngoscopic views achieved in this study. All 20 patients intubated with the Airtraq had a grade 1 Cormack and Lehane glottic view, compared to no patient in the Macintosh group. Fewer patients required additional manoeuvres to improve glottic exposure with the Airtraq device. However, the limitations of this latter measurement are acknowledged. All patients who sustained a significant arterial oxygen desaturation were in the Macintosh group. The lowest S_aO_2 values were seen in the situation where more than one attempt at tracheal intubation was required and where bag-mask ventilation had become suboptimal.

The Airtraq resulted in less stimulation of heart rate and blood pressure post tracheal intubation in comparison with the Macintosh laryngoscope. In fact, the Airtraq produced minimal haemodynamic stimulation in these patients. The relative contribution of laryngoscopy per se and insertion of the tracheal tube into the trachea to the degree of haemodynamic stimulation produced by the procedure of tracheal intubation is unclear. However, laryngoscopy alone has been demonstrated to produce similar increases in plasma adrenaline and noradrenaline to that seen with laryngoscopy followed by tracheal intubation [16]. Therefore, our finding probably reflects the fact that the Airtraq provides a view of the glottis without a need to align the oral, pharyngeal and tracheal axes, and therefore requires less force to be applied during laryngoscopy. The haemodynamic findings for direct laryngoscopy in our study were similar to those described previously [1, 17–19]. In a recent study comparing the GlideScope® (Verathon Inc., Bothell, WA) to the intubating laryngeal mask airway, in which a near identical anaesthetic technique to that used in this study was utilised, no change was seen in heart rate, whereas blood pressure decreased slightly following tracheal intubation with both devices [20]. Taken together, these findings underline the potential for indirect laryngoscopes to produce less haemodynamic stimulation.

A number of important limitations exist regarding this study. In particular, we acknowledge that the potential for bias exists, as it is impossible to blind the anaesthetist to the device being used. Furthermore, certain measurements employed in this study, such as laryngoscopic grading, are by their nature subjective. However, there was good agreement between subjective indices of difficulty of intubation and more objective measures, such as the intubation difficulty score [11]. In addition, the possibility remains that factors other than the difficulty of laryngoscopy may have contributed to our haemodynamic findings. However, these findings are not explained by between-group differences in the anaesthetic regimen, as there were no differences in the anaesthetic agents used in each group. Furthermore, our haemodynamic data for intubation with the Macintosh laryngoscope are consistent with previously reported data [1, 17–19], although the time required for tracheal intubation with the Macintosh laryngoscope was shorter than previously described. This study was carried out in experienced users of each device. The results seen may differ in the hands of less experienced users. The depth of anaesthesia or adequacy of muscle relaxation was not monitored. Some comparisons made on categorical data in the study, such as success of tracheal intubation, are likely to have had insufficient power to detect clinical important differences. Nevertheless, the data consistently demonstrate advantages for the Airtraq compared with the Macintosh laryngoscope. Finally, the Airtraq was compared with the Macintosh laryngoscope in this study, as this remains the gold standard. Similar results to those seen with the Airtraq have been demonstrated with other indirect laryngoscopes, such as the GlideScope [21] and video optical stylet [22]. Further comparative studies are needed to determine the relative efficacies of these devices.

In conclusion, the Airtraq laryngoscope offers a new approach to tracheal intubation of patients at increased risk for tracheal intubation. The Airtraq reduced the difficulty of tracheal intubation and the degree of haemodynamic stimulation compared with the Macintosh laryngoscope in these patients. These findings demonstrate the efficacy of the Airtraq in this clinically important group of patients, and add to the evolving body of knowledge regarding this potentially useful device.

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Conflict of interest

The authors have no conflict of interest in regard to the Airtraq device.

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Appendix 1: Intubation difficulty scale score

The IDS score is the sum of the following seven variables:
N1: Number of intubation attempts > 1;
N2: Number of operators > 1;
N3: Number of alternative intubation techniques used;
N4: Glottic exposure (Cormack and Lehane grade minus 1);
N5: Lifting force required during laryngoscopy; (0 = normal; 1 = increased);
N6: Necessity for external laryngeal pressure (0 = not applied; 1 = applied);
N7: Position of the vocal cords at intubation (0 = abduction/not visualised; 1 = adduction).

Note: Intubation difficulty scale score reproduced from Adnet et al. [11].