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# Randomized controlled trial of the Pentax AWS®, Glidescope®, and Macintosh laryngoscopes in predicted difficult intubation

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**Background.** The purpose of this study was to determine the potential for the Pentax AWS® and the Glidescope® to reduce the difficulty of tracheal intubation in patients at increased risk for difficult tracheal intubation, in a randomized, controlled clinical trial.

**Methods.** Seventy-five consenting patients presenting for surgery requiring tracheal intubation, and who were deemed to possess characteristics indicating an increased risk for difficult tracheal intubation, were randomly assigned to undergo intubation using a Macintosh, AWS®, or Glidescope® laryngoscope ($n$=25 patients per group). All patients were intubated by one of three anaesthetists experienced in the use of each laryngoscope.

**Results.** Both the Glidescope® and the AWS® significantly reduced the intubation difficulty score compared with the Macintosh. The rate of successful tracheal intubation was lower with the Macintosh (84%) compared with the Glidescope® (96%) or the AWS® (100%). There were no differences in the duration of tracheal intubation attempts between the devices. Both the Glidescope® and the AWS® significantly reduced the need for additional manoeuvres and improved the Cormack and Lehane view obtained at laryngoscopy, compared with the Macintosh. Tracheal intubation with the AWS® but not the Glidescope® reduced the degree of haemodynamic stimulation compared with the Macintosh laryngoscope.

**Conclusions.** The AWS® and the Glidescope® laryngoscopes reduced the difficulty of tracheal intubation to a similar extent compared with the Macintosh laryngoscope, in patients at increased risk for difficult tracheal intubation.

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**Keywords**: equipment, Macintosh laryngoscope; equipment, AWS® laryngoscope; equipment, Glidescope® laryngoscope; intubation, tracheal, difficult intubation

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Failure to successfully intubate the trachea and to secure the airway remains a leading cause of morbidity and mortality, in the operative[1–3] and emergency settings.[4 5] Difficulties in securing the airway can lead to serious soft tissue trauma to the upper airway.[6] Of more concern, difficult or failed tracheal intubation is the principal cause of hypoxaemic anaesthetic death and brain damage.[7–9] Problems with tracheal intubation remain the major cause of death and disability due to anaesthesia in analyses of records of the UK medical defence societies[7] and in the American Society of Anesthesiologists closed claims database.[3]

These issues have stimulated the development of novel laryngoscopes, with the aim of reducing the difficulty of laryngeal visualization, particularly in the setting of the anticipated or unanticipated difficult airway. The key novel feature of these 'indirect' laryngoscopes compared with the Macintosh laryngoscope is that they facilitate visualization of the vocal cords without the need to align the oral, pharyngeal, and tracheal axes.

The AWS® (Hoya Corporation, Tokyo, Japan)[10–12] consists of a disposable transparent blade, which fits over a 12 cm fibreoptic cable linked to a charge-coupled device camera, and a 2.4 in. colour liquid crystal display screen (Fig. 1A). The Glidescope® (Saturn Biomedical System Inc., Burnaby, Canada) (Fig. 1B) is a similar indirect laryngoscope, but which does not incorporate a side channel, that also demonstrates considerable promise.[13] Both the Pentax AWS® and the Glidescope® have been

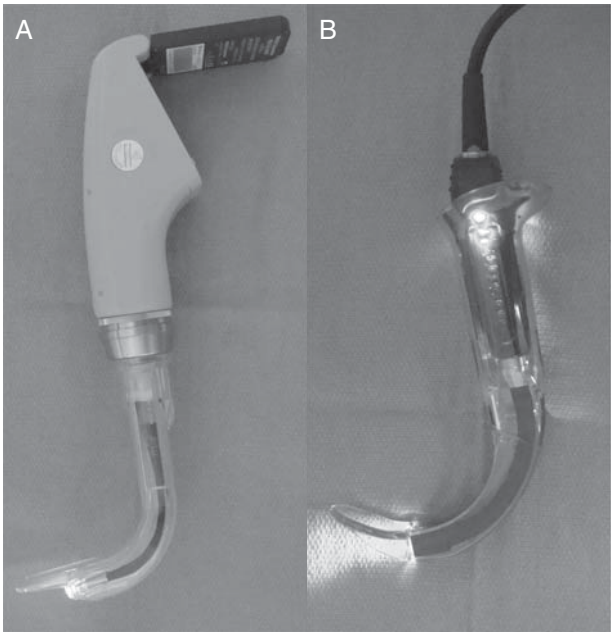


**Fig 1** (A) Photograph of the Pentax AWS® laryngoscope with a single-use blade clipped onto camera system. (B) Photograph of Glidescope® Cobalt with a single-use blade clipped onto fibreoptic system.

demonstrated to perform better than the Macintosh in certain contexts including the normal airway,[12] the simulated difficult airway,[12] and in patients undergoing cervical spine immobilization.[10 11 13 14] In addition, the Airtraq®, an indirect laryngoscope similar to the AWS®, which also incorporates a side channel for the tracheal tube (TT), performed superiorly to the Macintosh in patients at increased risk for difficult tracheal intubation.[15]

Most recently, Asai and colleagues[16] reported high success rates with the AWS® in 270 patients in whom direct laryngoscopy using a Macintosh laryngoscope had been difficult, and also in a second group of 23 patients, at predicted increased risk for difficult intubation and difficult mask ventilation, who were intubated directly with the AWS®. The relative efficacy of the AWS® and Glidescope® devices, and their efficacy in comparison with the Macintosh laryngoscope, has not been determined in patients with a predicted or known difficult airway.

We wished to evaluate the relative efficacy of these laryngoscopes when used by experienced anaesthetists in patients at increased risk for difficult laryngoscopy, and to compare their performance with the Macintosh laryngoscope, in a prospective, randomized clinical trial. We hypothesized that in comparison with the Macintosh, the Pentax AWS® and Glidescope® would reduce intubation difficulty scale (IDS) scores and cause less haemodynamic stimulation after intubation. On the basis of our earlier studies, in manikins,[12] and in patients undergoing cervical immobilization,[12 14] we further hypothesized that the AWS would reduce intubation difficulty compared with the Glidescope® in this setting.

## Methods

After obtaining approval by the Galway University Hospitals Research Ethics Committee (Galway, Ireland) and written informed patient consent, we studied 75 ASA physical status I–III patients, aged 16 yr of age or older, who were deemed on preoperative assessment by their primary anaesthetist to be at increased risk for difficult laryngoscopy, and were undergoing surgical procedures requiring tracheal intubation, in a randomized, single-blind, controlled clinical trial. Patients were excluded if risk factors for gastric aspiration were present, or where there was a history of relevant drug allergy. All data were collected by an independent unblinded observer. The allocation sequence was generated by random number tables, and the allocation concealed in sealed envelopes, which were not opened until patient consent had been obtained. Patients were randomized to tracheal intubation with the Macintosh (size 3 blade in females; size 4 in males), the Pentax AWS®, or the Glidescope® laryngoscope.

After notification by the primary anaesthetist, the eligibility of the patient to participate in the study was determined by one of the investigators. Inclusion criteria consisted of possession of at least two of the following criteria: (i) thyromental distance of $<6$ cm; (ii) Mallampatti classification III or IV; and (iii) inter-incisor distance $<4$ cm. All patients with a previously documented difficult tracheal intubation were also eligible for inclusion. Mallampatti grade was determined with the patient in the sitting position with the tongue maximally extended.[17] Inter-incisor distance was measured with the patient in the sitting position, whereas thyromental distance was measured from inside of the mentum to the thyroid cartilage with the head in full extension.[18]

All patients received a standardized general anaesthetic. Standard monitoring included ECG, non-invasive arterial pressure, $Sp_{O_2}$, and measurement of end-tidal carbon dioxide and volatile anaesthetic levels. Bispectral index (BIS®) (Aspect Medical Systems, Norwood, MA, USA) or Entropy® (GE Healthcare, Helsinki, Finland) monitoring was utilized in all patients. Before induction of anaesthesia, all patients were given fentanyl (1–1.5 $\mu g\ kg^{-1}$) i.v. Propofol (2–4 $mg\ kg^{-1}$) was titrated to induce anaesthesia in a dose sufficient to produce loss of verbal response. After induction of anaesthesia, all patients were manually ventilated with sevoflurane (2.0–2.5%) in oxygen. After confirmation of the adequacy of bag-mask ventilation, atracurium 0.5 $mg\ kg^{-1}$ was administered. Tracheal intubation was not performed until the BIS/Entropy score had decreased below 60, and additional boluses of propofol were administered to increase depth of anaesthesia if required.

Three minutes after the administration of neuromuscular block, laryngoscopy was performed by one of three anaesthetists (M.A.M., R.S., and J.L.) experienced in the use of each laryngoscope. In view of this 3 min interval, the adequacy of neuromuscular block before intubation was not

formally measured. Each anaesthetist had performed more than 500 intubations with the Macintosh laryngoscope and at least 100 intubations with the Pentax AWS® and Glidescope® in manikins, and 50 intubations with the Pentax AWS® and Glidescope® in patients, before this study. The TT was placed in the side channel of the Pentax AWS® laryngoscope in advance of the intubation attempt. The GlideScope® Cobalt, which incorporates a single-use blade (Fig. 1B), was used in these studies. The AWS® and Glidescope® were inserted into the mouth in the midline and advanced slowly over the tongue along the palatal wall, until the epiglottis came into view. The blade was then advanced under the epiglottis and the glottis was seen. In patients intubated with the AWS®, the target symbol was aligned with the glottic opening, the TT was gently advanced through the glottis, detached from the blade, and the AWS® blade was removed. In patients intubated with the Glidescope®, a stylet was passed through the TT, and the tube manipulated into a 'hockey-stick' curve, before the intubation attempt. Once the glottis was seen, the TT was gently advanced through the glottis, and the stylet removed.

The trachea was intubated with a 7.5 mm TT in females and an 8.5 mm TT in males. After successful tracheal intubation, the lungs were mechanically ventilated for the duration of the procedure and anaesthesia was maintained with sevoflurane (1.25–1.75%) in a mixture of nitrous oxide and oxygen in a 2:1 ratio. No other medications were administered, or procedures performed, during the 5 min data collection period after tracheal intubation. Subsequent management was left to the discretion of the anaesthetist providing care for the patient.

The primary endpoint was the IDS score.[19] The IDS score developed by Adnet and colleagues[19] is a quantitative scale incorporating multiple indices of intubation difficulty that more objectively quantifies the complexity of tracheal intubations (Appendix). The secondary endpoints were the duration of the tracheal intubation procedure, and the rate of successful placement of the TT in the trachea. The duration of the intubation attempt was defined as the time taken from insertion of the blade between the teeth until the TT was placed through the vocal cords, as evidenced by visual confirmation by the anaesthetist performing laryngoscopy. However, in patients in whom the TT was not directly seen, passing through the vocal cords, the intubation attempt was not considered complete until the TT was connected to the anaesthetic circuit and evidence obtained of the presence of carbon dioxide in the exhaled breath. A failed intubation attempt was defined as an attempt in which the trachea was not intubated, or which required $>60$ s to perform.

As this study was performed in patients who were potentially difficult to intubate, several specific precautions were taken to minimize the impact of failed tracheal intubation in these patients. First, atracurium was not administered unless adequacy of bag-mask ventilation could be confirmed. Secondly, after a failed tracheal intubation attempt, the facemask was re-applied and the ability to mask ventilate was confirmed. If adequacy of bag-mask ventilation could not be confirmed before or after intubation attempts, the patient exited the protocol, and the standard Difficult Airway Society Failed Intubation algorithm[20] was followed. Thirdly, a maximum of three intubation attempts with the study device were permitted. However, in situations where the investigator deemed that there was a low likelihood of success with a third attempt, this attempt was not performed and laryngoscopy was deemed to have failed. A two-stage backup plan was in place in case of a failed intubation. First, in the event of failure to intubate with the device to which the patient was randomized, intubation attempts with the other devices were then permitted. In the event that no device resulted in successful tracheal intubation, the standard Difficult Airway Society failed Intubation algorithm[20] was followed.

The duration of the first tracheal intubation attempt, and of the successful attempt in the case that the first attempt was not successful, was recorded. Additional endpoints included the number of intubation attempts and the number of optimization manoeuvres required [use of a bougie, external laryngeal manipulation with Backward, Upward, Rightward Pressure (BURP manoeuvre), need for a second assistant] to aid tracheal intubation, and also the Cormack and Lehane grade at laryngoscopy,[21] the lowest recorded arterial oxygen saturation during or immediately after intubation attempts, and the occurrence of minor complications (visible trauma to lip or oral mucosa or blood on the laryngoscope). The type of bougie used was the Frova airway intubating catheter (William Cook Europe Ltd, Bjaeverskov, Denmark).

### *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. On the basis of prior studies in this population,[15] we expected a mean IDS score of at least 4, representing moderately difficult intubating conditions, in patients undergoing tracheal intubation with the Macintosh laryngoscope. We considered that a clinically important reduction in the mean IDS score was a 50% reduction, that is, an IDS score of $\leq 2$ in patients intubated with the AWS® or Glidescope®. Given an expected standard deviation (SD) of 2.25 from prior studies,[15 22] and using an $\alpha=0.05$ and $\beta=0.2$, for an experimental design incorporating three equal-sized groups, we estimated that 24 patients would be required per group. We therefore aimed to enrol 25 patients per group.

All analyses were performed on an intention-to-treat basis. Data for duration of intubation attempts and the instrument difficulty score were analysed using one-way

analysis of variance (ANOVA). Data for the IDS score, the number of intubation attempts, and the numbers of optimization manoeuvres were analysed using ANOVA or Kruskal–Wallis ANOVA on ranks as appropriate. Success of tracheal intubation was analysed using the $\chi^2$ test. The comparisons of haemodynamic data within the groups were analysed using one-way repeated measures ANOVA. For these analyses, the pre-intubation data were taken as baseline data, rather than the pre-induction values. In each case, *post hoc* between-group testing was performed using the Student–Newman–Keuls test. Continuous data are presented as means (SD) or medians [inter-quartile range (IQR)] depending on data distribution, ordinal data are presented as medians (IQR), and categorical data are presented as number and as frequencies. The $\alpha$ level for all analyses was set as $P<0.05$.

## Results

A total of 75 patients were entered into the study. Seventy-eight patients consented to participate, but three patients were not subsequently entered into the study due to changes in planned surgical procedure or delays in their surgical procedure taking place (Fig. 2). Twenty-five patients were randomized to undergo tracheal intubation with each of the three devices. Patient characteristics and airway variables were similar in each group (Table 1).

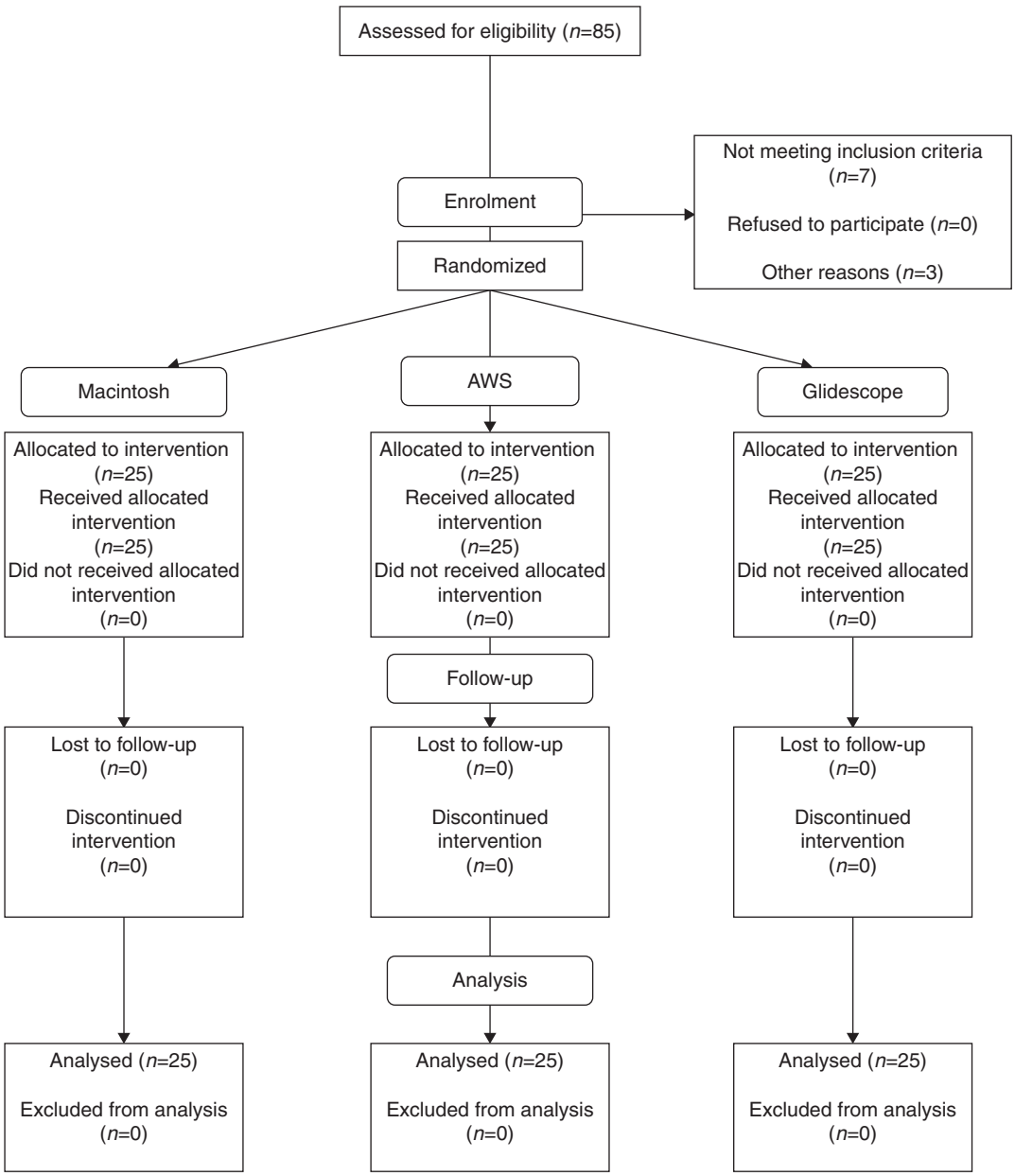


**Fig 2** Consort diagram for study demonstrating the number of patients assessed for inclusion into the study, number enrolled in the study, the numbers followed up, and numbers of patients analysed.

**Table 1** Characteristics of patients enrolled into the study. Data are given as mean (range), mean (SD), median (IQR), or number (%)

| Variable assessed | Macintosh | AWS® | Glidescope® |
|---|---|---|---|
| Male:female ratio | 16:09 | 14:11 | 13:12 |
| Age (yr) | 54 (26–85) | 60 (29–84) | 55 (22–85) |
| Body mass index (kg $m^{-2}$) | 33.6 (9.4) | 33.4 (7.2) | 34.4 (10.7) |
| ASA classification (median, IQR) | II (II, III) | II (II, III) | III (II, III) |
| Airway measurements | | | |
| Thyromental distance (cm) | 6.1 (0.7) | 6.1 (0.5) | 6.0 (0.6) |
| Inter-incisor distance (cm) | 3.0 (0.5) | 3.1 (0.3) | 3.1 (0.5) |
| Mallampatti classification (%) | | | |
| I | 0 (0) | 0 (0) | 0 (0) |
| II | 0 (0) | 1 (4) | 0 (0) |
| III | 19 (76) | 21 (84) | 20 (80) |
| IV | 6 (24) | 3 (12) | 5 (20) |
| Total dose of propofol administered (mg $kg^{-1}$) | 2.3 (0.5) | 2.2 (0.4) | 2.2 (0.6) |
| Number of patients requiring an additional propofol bolus | 7 | 7 | 4 |
| Dose of fentanyl administered (μg $kg^{-1}$) | 1.2 (0.3) | 1.2 (0.3) | 1.2 (0.4) |
| BIS score immediately before tracheal intubation | 36.5 (13.6) | 33.8 (12.2) | 33.2 (13.9) |
| End-tidal sevoflurane immediately post-tracheal intubation | 2.1 (0.4) | 2.2 (0.4) | 2.1 (0.4) |

There were no clinically important between-group differences with regard to anaesthetic management, including the total doses of propofol and fentanyl administered, the number of additional propofol boluses required, or in end-tidal sevoflurane concentrations (Table 1). There were no between-group differences in BIS® or Entropy® scores immediately before or after tracheal intubation (Table 1). No patient was withdrawn from the study protocol due to failure to achieve adequate bag-mask ventilation before or between intubation attempts.

The intubation difficulty scores were significantly higher with the Macintosh compared with both other devices, but were not different between the Glidescope® and the AWS® laryngoscope (Fig. 3A). Twenty-four of the 25 patients in the Macintosh group had an IDS score of $\geq$1, compared with 11 patients intubated with the AWS® and nine with the Glidescope®. In the Macintosh group, 14 patients had an IDS score of $\geq$4, indicating at least a moderate degree of intubation difficulty, compared with no patients intubated with the AWS® and one intubated with the Glidescope® (Fig. 3A). All 25 patients were successfully intubated with the AWS® device, compared with 24 patients with the Glidescope® and 21 with the Macintosh laryngoscope (Table 2). There were no significant differences between the devices with regard to the duration of either the first or the successful tracheal intubation attempts (Table 2).

There were no between-group differences in the number of attempts required with each device (Table 2). A greater number of optimization manoeuvres were required to facilitate tracheal intubation with the Macintosh compared with both other devices. There were no differences in the number of optimization attempts, or need for additional assistance, required for the Glidescope® and the AWS® laryngoscope (Table 2).

The Cormack and Lehane glottic view obtained at laryngoscopy was significantly better with the Glidescope® and the AWS® laryngoscope compared with the Macintosh laryngoscope (Fig. 3B). There were no significant differences between the indirect laryngoscopes with regard to the distribution of Cormack and Lehane scores

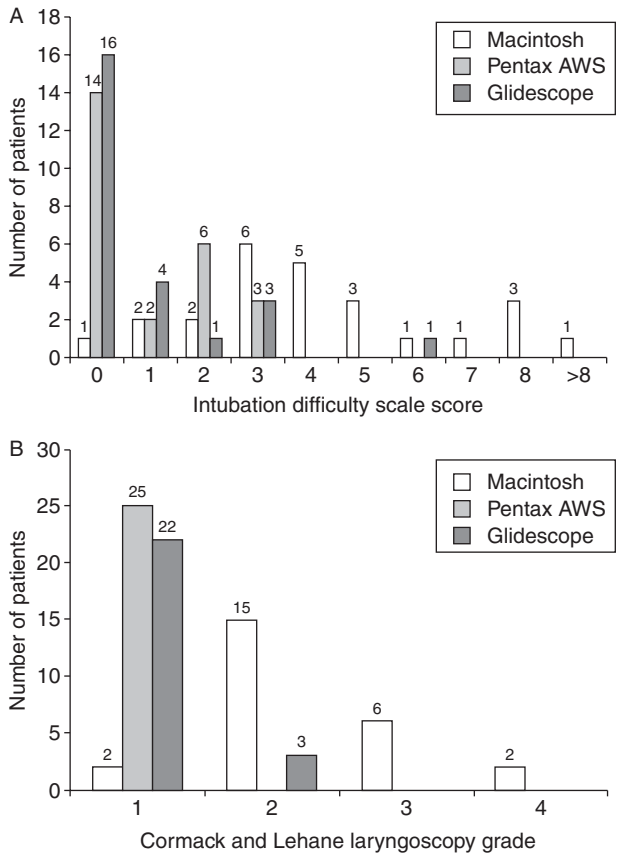


**Fig 3** (A) Comparison of IDS score distributions with each laryngoscope. The number of patients is shown above each bar. The distribution of IDS scores in each group is significantly different ($P<0.001$, Kruskal–Wallis ANOVA on ranks). (B) Cormack and Lehane grade view during the first tracheal intubation attempt with each laryngoscope. The number of patients is shown above each bar. The distribution of Cormack and Lehane grades in each group is significantly different ($P<0.001$, Kruskal–Wallis ANOVA on ranks).

**Table 2** Data for intubation attempts with each device. Data are given as mean (SD), median (IQR), or number (%). *Significantly ($P<0.05$) different compared with the Macintosh laryngoscope

| Variable assessed | Macintosh | AWS® | Glidescope® |
|---|---|---|---|
| Overall success rate (%) | 21 (84) | 25 (100) | 24 (96) |
| Intubation difficulty score (median, IQR) | 4 (3, 5.25) | 0 (0, 2)* | 0 (0, 1)* |
| Duration of first-intubation attempt (s) | 12 (8, 22) | 15 (8, 32) | 20 (14, 33) |
| Duration of successful intubation attempt (s) | 13 (8, 23) | 15 (8, 31) | 17 (12, 31) |
| Mean lowest $Sp_{O_2}$ during intubation attempt | 94.5 (10.6) | 97.7 (1.4) | 97.2 (3.5) |
| Range of lowest $Sp_{O_2}$ | 45–100 | 95–100 | 95–100 |
| Number of intubation attempts (%) | | | |
| 1 | 17 (68) | 18 (72) | 22 (88) |
| 2 | 4 (16) | 7 (28) | 3 (12) |
| 3 | 4 (16) | 0 | 0 |
| No. of optimization manoeuvres (%) | | | |
| 0 | 5 (20) | 17 (68)* | 20 (80)* |
| 1 | 17 (68) | 8 (32) | 5 (20) |
| ≥2 | 3 (12) | 0 | 0 |
| Complications (%) | | | |
| Minor | 8 (32) | 7 (28) | 5 (20) |
| Major | 0 | 0 | 0 |

(Fig. 3B). There were no between-group differences in the lowest oxygen saturations during tracheal intubation attempts (Table 2). One patient did sustain a transient but significant oxygen desaturation to 45% after the third failed attempt to perform tracheal intubation with the Macintosh laryngoscope. The intubation attempt was immediately terminated, effective bag-mask ventilation was re-established, and oxygen saturations rapidly increased to 98%. The patient was subsequently successfully intubated with the Glidescope® laryngoscope. There were no between-group differences in the incidence of complications, including the appearance of blood on the laryngoscope blade, or of minor trauma to the airway (Table 2). There was no incidence of dental or more severe airway laceration with any laryngoscope.

The effects of laryngoscopy and tracheal intubation on the mean arterial pressure and on heart rate were relatively modest. Arterial pressure decreased in each group after induction of anaesthesia. Both heart rate and mean arterial pressure increased significantly in the Glidescope® and Macintosh groups, but did not change in the AWS® group, after tracheal intubation (Fig. 4). After tracheal intubation, the increase in mean arterial pressure and heart rate decreased back to baseline levels in the Glidescope® and Macintosh groups over the 5 min observation period (Fig. 4).

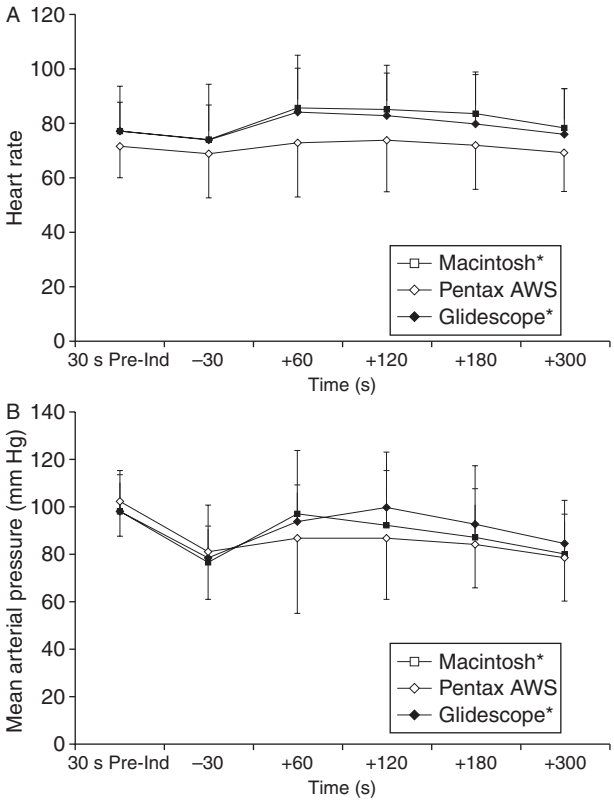


**Fig 4** (A) Graph representing the changes in heart rate after tracheal intubation with each device. The data are given as mean values. The error bars indicate 1 SD. (B) Graph representing the changes in mean arterial pressure after tracheal intubation with each device. The data are given as mean values. The error bars indicate 1 SD. *Significant change over time within each group. 30 s Pre-Ind, 30 s before induction of anaesthesia; −30, 30 s before tracheal intubation, +60, 60 s post-tracheal intubation; +120, 120 s post-tracheal intubation; +180, 180 s post-tracheal intubation; +300, 300 s post-tracheal intubation.

## Discussion

Our study demonstrates that the AWS® and Glidescope® laryngoscopes both performed better than the Macintosh laryngoscope in patients at increased risk for difficult intubation. Both devices reduced the intubation difficulty score, a quantitative measure of the difficulty of tracheal intubation, which constituted the primary outcome measure of this study. The AWS® and Glidescope® laryngoscopes also enhanced the Cormack and Lehane glottic view and reduced the number of optimization manoeuvres required compared with the Macintosh laryngoscope. Although there was no significant difference between the devices in the success rates for tracheal intubation, the

study was not powered sufficiently to rule out differences in this variable. In addition, there was no difference in the incidence of trauma with any of the devices tested.

Our second hypothesis, namely that the AWS® would perform better than the Glidescope® in this patient group, was not proven. These devices performed very similarly overall in this study. The only significant difference between the devices was with regard to the degree of haemodynamic response elicited. In patients who underwent tracheal intubation with the AWS®, there was no significant change in heart rate after intubation, in contrast to patients intubated with either of the other devices. A reduced heart rate response to intubation has also been previously described with the AWS.[10–12 14] These findings are also supported by similar haemodynamic findings with the Airtraq®,[15 22 23] a similar device to the AWS®.

Three important limitations exist regarding this study. First, we acknowledge that the potential for bias exists, as it is impossible to blind the anaesthetist to the device being used. Furthermore, certain measurements used in this study, such as laryngoscopic grading, are by their nature subjective. In fact, the appropriateness of using the Cormack and Lehane classification with indirect laryngoscopes, which may reduce the difficulty of obtaining a good glottic view, but not the difficulty of tracheal intubation, is open to question. The advantage of using the Cormack and Lehane classification is that it is well understood by clinicians and widely used in clinical practice. Reassuringly, there was good agreement between subjective indices of difficulty of intubation and more objective measures, such as the intubation difficulty score.[19] Secondly, this study was carried out in experienced users of each device. The results seen may differ in the hands of less experienced users. Thirdly, this study was not powered to detect differences in tracheal intubation success rates. Finally, the relative efficacies of these devices in comparison with other promising devices such as the Airtraq®,[15 22] McCoy®,[24 25] McGrath®,[26 27] Bonfils®,[28] intubating Laryngeal Mask Airway®,[14 29] or Bullard®[29] laryngoscopes have not been determined. Further comparative studies are needed to determine the relative efficacies of these devices.

In conclusion, both the AWS® and the Glidescope® laryngoscopes possess advantages over the Macintosh laryngoscope, in patients at increased risk for difficult tracheal intubation. Neither the AWS® nor the Glidescope® laryngoscope possessed clear advantages over the other, although the reduced haemodynamic stimulation seen with the AWS® may be an advantage in certain settings.

## Funding

Pentax Ltd provided the Pentax AWS® device and disposable blades free of charge for use in the study. All other support was solely from institutional, departmental, or both sources.

## Appendix: IDS score

The IDS score is the sum of the following seven variables:

N1: number of intubation attempts >1 ——
N2: the number of operators >1 ——
N3: the 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 visualized; 1, adduction) ——

Note: IDS score reproduced from Adnet and colleagues.[19]

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