RESPIRATION AND THE AIRWAY

Randomized comparison of the Pentax AirWay Scope and Macintosh laryngoscope for tracheal intubation in patients with obstructive sleep apnoea

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Editor’s key points

- Tracheal intubation may be difficult in patients with obstructive sleep apnoea.
- This study compared the ease of tracheal intubation using either the Pentax AirWay Scope (AWS) or a Macintosh laryngoscope.
- The investigators found better views at laryngoscopy overall using the Pentax AWS.
- The study has some limitations and further data are needed to confirm these findings.

Background. Patients with obstructive sleep apnoea (OSA) can often present difficulties in intubation. This study aimed to compare the efficacy of the Pentax AirWay Scope (AWS) with that of the Macintosh laryngoscope for tracheal intubation in patients with OSA.

Methods. Forty-six patients undergoing uvulopalatopharyngoplasty were randomly allocated to tracheal intubation with either the Macintosh laryngoscope or the Pentax AWS. In all patients, intubation was performed by one of two anaesthetists experienced with both devices. The primary and secondary endpoints of this study were the intubation difficulty scale (IDS) score and success/failure and duration of the first successful intubation attempt.

Results. With the Pentax AWS, tracheal intubation was successful on the first attempt in all patients whereas four patients required repeated attempts at intubation with the Macintosh laryngoscope. The IDS score was significantly lower using the Pentax AWS and glottic exposure was better (the Cormack and Lehane grade 1 in all patients vs grade 2 or higher in all patients, \(P = 0.0001\)). Average duration of successful intubation was shorter (12.9 vs 29.9 s, \(P < 0.0002\)) and fewer manoeuvres were needed to improve the glottic exposure (0 in all patients vs 1 or more in 16 patients, \(P < 0.0001\)) with the Pentax AWS, compared with the Macintosh laryngoscope.

Conclusions. In this study of patients with OSA, tracheal intubation by experienced anaesthetists was facilitated using the Pentax AWS compared with the Macintosh laryngoscope.

Keywords: intubation, intratracheal; laryngoscopes; sleep apnoea, obstructive

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The diagnosis of obstructive sleep apnoea (OSA) is often presumed to be a risk factor for difficult airway.¹⁻⁴ In fact, the incidence of difficult intubation is reportedly higher in patients with OSA than in patients without OSA.⁵ Conversely, patients who presented with difficult intubation were more likely to have OSA.² Therefore, patients with diagnosed OSA should be deemed to have difficult airway during anaesthesia, which is associated not only with narrowing of the upper airway, but also with morphologic abnormalities, such as small mandible, short and thick neck, and large tongue.¹

Direct laryngoscopy using a curved Macintosh blade remains the gold standard technique. However, various videolaryngoscopes, equipped with a camera eye near the blade tip and an external display, have been developed. With videolaryngoscopes, anaesthetists can theoretically get a better glottic exposure and thus make a more straightforward intubation compared with conventional laryngoscopes.⁶ The Pentax AirWay Scope (AWS; AWS-S100®, Pentax Corporation, Tokyo, Japan) is a videolaryngoscope with a disposable transparent blade (ITL-5®) that incorporates a channel to pass a tracheal tube down to the glottic opening. For tracheal intubation, the AWS is reportedly more valuable than the Macintosh laryngoscope in various conditions, such as normal airway,⁷ predicted difficult airway,⁸ ⁹ and in patients with restricted neck motion.⁶ However, the efficacy of the AWS has not been evaluated in a single group of patients with OSA.
This clinical trial aimed to compare the efficacy of the AWS and the Macintosh laryngoscope when an experienced anaesthetist performed tracheal intubation in patients with OSA. The hypothesis was that the AWS would provide an easier intubation condition in terms of the intubation difficulty scale (IDS) score, success rate, and duration for successful intubation attempt compared with the Macintosh laryngoscope.

**Methods**

After approval from the local Institutional Review Board on human studies and registration in clinicaltrials.gov (Unique Identifier: NCT01428570), written informed consent was obtained from all the patients enrolled. Patients, who were aged 20 yr or more, and undergoing uvulopalatopharyngoplasty (UPPP) under general anaesthesia, were included. These patients were diagnosed as having OSA, which was confirmed by polysomnography, but otherwise healthy (ASA physical status I–II). A total of 46 patients were recruited. Patients who had loosened teeth or a mouth opening of < 18 mm, which is a minimum clearance for the ITL-S®, were excluded from the study. Patients with any pathology in the neck, pharynx or larynx, a risk factor for aspiration of gastric contents, or a history of hypersensitivity to an anaesthetic drug, were also excluded.

Patients were randomly allocated into either the Macintosh group or AWS group using the sealed envelope method. Baseline airway parameters, including Mallampati classification without phonation, thyromental distance, and interincisor distance, were measured before operation at the pre-anaesthesia evaluation clinic by blinded senior residents in rotation. Standard monitoring devices, including electrocardiography, non-invasive arterial pressure, pulse oximetry, and end-tidal concentrations of carbon dioxide and volatile anaesthetic agent, were applied when a patient arrived in the operating theatre. Patients were preoxygenated for 3 min using a face mask and 100% oxygen. Anaesthesia was induced with i.v. administration of fentanyl (1–1.5 μg kg⁻¹) and propofol (1.5–2 mg kg⁻¹). Rocuronium (0.6 mg kg⁻¹) was given to facilitate tracheal intubation. Sevoflurane (2–3 vol%) in 100% oxygen was given via a face mask. After loss of all four twitches on the train-of-four obtained by ulnar nerve stimulation, the patient was placed in the sniffing position, and then laryngoscopy and tracheal intubation were performed by one of the two anaesthetists (M.K.K. and S.W.P.). Before this study, both anaesthetists experienced > 3 yr of clinical anaesthesia, and had performed > 500 and at least 100 tracheal intubations with the Macintosh laryngoscope and the AWS in patients, respectively. The cuffed tracheal tubes with an internal diameter (ID) of 7.0 and 7.5–8.0 mm were used in females and males, respectively. The size selection was at the discretion of the anaesthetist who performed the laryngoscopy, based on the patient’s build. When the Macintosh laryngoscope was used, a gum elastic bougie was allowed for use. With the AWS, a well-lubricated tracheal tube was attached into a channel on the right side of the ITL-S® before insertion. After the confirmation of successful intubation, the lungs were mechanically ventilated throughout the surgery, and anaesthesia was maintained with sevoflurane in a mixture of oxygen and air at a 1:1 ratio. Further anaesthetic management was at the discretion of the anaesthetist assigned to each patient.

An independent, but unblinded observer collected all data in every case of this trial. The primary endpoint was the IDS score, which was developed by Adnet and colleagues as a quantitative scale incorporating multiple parameters of intubation difficulty and thus has been adopted to enable objective comparison of the complexity of tracheal intubation. The secondary endpoints were success/failure and the duration of the first or first successful intubation attempt. Failure of tracheal intubation was determined as an attempt in which the trachea was not intubated or an attempt that took > 60 s to complete. Up to three attempts at intubation were permitted. The duration of the first attempt and that of the successful attempt were recorded. Other endpoints were: number of intubation attempts, number of optimization manoeuvres required for a better glottic exposure (use of a gum elastic bougie, external manipulation of larynx, and a requirement of second assistant), the Cormack and Lehane grade of glottic exposure, the lowest oxygen saturation recorded during or immediately after intubation attempts, and complications such as visible trauma to lip or oral mucosa, bleeding, or dental trauma.

To prevent an intubation failure in patients with potential risk for difficult airway, back-up plans were put in place as follows: first, if intubation attempts with one device failed twice consecutively, the third intubation attempt with another device would be permitted. Secondly, if intubation attempts had failed with both devices, the failed intubation algorithm of the Difficult Airway Society Guidelines was followed.

**Statistical analysis**

The sample size was calculated based on the IDS score, beginning with zero, an ideal condition for intubation, and then increasing with progressively more difficult conditions for intubation. Based on previous studies, we considered a reduction of > 2.0 in the mean IDS score, which is approximately half of the expected mean IDS score with the Macintosh laryngoscope, as clinically important. Power analyses suggested that the inclusion of 21 patients per group would be required with an expected standard deviation of 2.25 (α = 0.05, β = 0.2). The size of study was finally determined to be 23 patients per group to account for drop-outs.

All analyses were performed with SAS 9.2 (SAS Institute, Inc., Cary, NC, USA). Data are presented as mean (SD), median (interquartile range), and numbers (proportion) for continuous, ordinal and categorical variables, respectively. The duration of intubation attempt was analysed by a t-test. Fisher’s exact test and Wilcoxon’s rank-sum test were used to analyse categorical and continuous data, respectively. Where appropriate, 95% confidence interval of difference between the groups is presented. A P-value of < 0.05 was considered to be significant for all analyses.

**Results**

In a total of 46 patients enrolled, one patient in the AWS group was excluded because of a change in surgical plan. No
significant differences in patient characteristic or baseline airway parameters were found between the two groups (Table 1). Mean doses of anaesthetic drugs, including propofol, fentanyl, and rocuronium, and end-tidal concentrations of sevoflurane measured just before the tracheal intubation were comparable between the two groups. In all patients in the AWS group, tracheal intubation was successfully performed on the first attempt (Table 2). In the Macintosh group, however, the first attempt was unsuccessful in four patients. Tracheal intubation was then successfully done on the second attempt in these four patients. When the AWS was used, the median IDS score was significantly reduced and the Cormack and Lehane grade of the glottic exposure was improved, compared with the Macintosh laryngoscope (Table 2). All 23 patients in the Macintosh group had an IDS score of $\geq 1$ while only three patients in the AWS group did. Furthermore, 14 patients in the Macintosh group had an IDS score of $\geq 4$, indicating more than moderate degree of intubation difficulty, but no patient in the AWS group did (Fig. 1). The duration of intubation attempt was significantly shorter in the AWS group (Table 2). In the AWS group, significantly fewer manoeuvres were required to improve the glottic exposure compared with the Macintosh group (Table 2). No significant differences in the lowest oxygen saturation during intubation attempts and in the incidence of complications, including the appearance of blood on the laryngoscope blade or minor trauma to the airway, were found between the two groups (Table 2). No dental

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient characteristic data and baseline airway parameters in patients with OSA. Values are mean (SD), median (interquartile range), or numbers (proportion), as appropriate, except for age as mean (range). CI, confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Macintosh ($n = 23$)</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>19/4</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>43.7 (19–64)</td>
</tr>
<tr>
<td>Body mass index (kg m$^{-2}$)</td>
<td>25.8 (3.2)</td>
</tr>
<tr>
<td>ASA status (I/II)</td>
<td>9/14</td>
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<tr>
<td>Apnoea-hypopnea index</td>
<td>25.8 (5.9–34.4)</td>
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<tr>
<td>Airway measurements</td>
<td></td>
</tr>
<tr>
<td>Thyromental distance (cm)</td>
<td>5.3 (0.7)</td>
</tr>
<tr>
<td>Interincisor distance (cm)</td>
<td>4.6 (0.6)</td>
</tr>
<tr>
<td>Mallampati classification</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4 (17.4%)</td>
</tr>
<tr>
<td>2</td>
<td>9 (39.1%)</td>
</tr>
<tr>
<td>3</td>
<td>6 (26.1%)</td>
</tr>
<tr>
<td>4</td>
<td>4 (17.4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Data on tracheal intubation with the Macintosh laryngoscope and the Pentax AWS in patients with OSA. Values are mean (SD), median (interquartile range), or numbers (proportion), as appropriate. *P&lt;0.01, Wilcoxon’s rank-sum test; †P&lt;0.01, Fisher’s exact test; ‡P&lt;0.01; t-test, between groups</th>
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<tbody>
<tr>
<td></td>
<td>Macintosh ($n = 23$)</td>
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<tr>
<td>Overall success</td>
<td>23 (100%)</td>
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<td>IDS score</td>
<td>4 (3–4)</td>
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<td>Cormack and Lehane grades 1/2/3/4 (number of patients)</td>
<td>0/8/14/1</td>
</tr>
<tr>
<td>Duration of first intubation attempt (s)</td>
<td>24.3 (16.6)</td>
</tr>
<tr>
<td>Duration of successful intubation attempt (s)</td>
<td>29.9 (28.5)</td>
</tr>
<tr>
<td>Number of intubation attempts</td>
<td></td>
</tr>
<tr>
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<td>19 (82.6%)</td>
</tr>
<tr>
<td>2</td>
<td>4 (17.4%)</td>
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<tr>
<td>Number of optimization manoeuvres$^+$</td>
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<tr>
<td>0</td>
<td>7 (30.4%)</td>
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<tr>
<td>1</td>
<td>14 (60.9%)</td>
</tr>
<tr>
<td>2</td>
<td>2 (8.7%)</td>
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<tr>
<td>Lowest $S_pO_2$ (%)</td>
<td>99.5 (0.7)</td>
</tr>
<tr>
<td>Incident of complications</td>
<td>1 (4.4%)</td>
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</tbody>
</table>
trauma or major trauma to the airway occurred with either laryngoscope.

**Discussion**

We found that tracheal intubation was facilitated with significantly lower IDS scores in patients with OSA when the AWS was used by experienced anaesthetists, compared with the Macintosh laryngoscope. In addition, glottic exposure was better, average duration of successful intubation attempt was shorter, and fewer manoeuvres to improve the glottic exposure were used with the AWS, compared with the Macintosh laryngoscope.

A number of videolaryngoscopes have been developed to compensate for the shortcomings of the Macintosh laryngoscope. Compared with other laryngoscopes, the AWS has certain structural and functional features that improve the glottic view in patients with OSA. First, patients with OSA have a larger tongue with a relatively smaller pharyngeal space surrounded by the skeletal structures of jaws. Furthermore, the mid to lower face is elongated to compensate for the decreased space for larger tongue. These features limit mouth opening and require more anterior displacement of the tongue during direct laryngoscopy, because such a compensation would increase the posterior displacement of the tongue, especially with mouth opening. By virtue of anatomical design which conforms to the pharyngeal structures, the ITL-S® can be passed down just over the tongue, and thereby enables the operator to see the tongue base continuously. Moreover, the ITL-S® is wide and rigid enough to push away the structures around the airway. As a result, the operator can easily place the ITL-S® in the adequate position and have a sufficient room to visualize the glottis without excessive displacement of the tongue and other soft tissues in the pharynx. Kariya and colleagues demonstrated that the AWS had an advantage over the Macintosh laryngoscope in a simulated model of pharyngeal obstruction with tongue oedema. In our patients, the best glottic exposure (Cormack and Lehane grade 1) was provided with the AWS in all patients (100%) in spite of the higher Mallampati classification in the AWS group compared with the Macintosh group. In fact, no patients had a Cormack and Lehane grade 1 exposure with the Macintosh laryngoscope (Table 2). Secondly, the limited head extension observed in patients with OSA resembles the intubation conditions in patients with restricted neck movement. Enomoto and colleagues reported that a better glottic exposure was produced by the AWS in patients with restricted neck movement, resulting in faster intubation with an increased success rate compared with the conventional Macintosh laryngoscope. The AWS was also shown to be superior to other devices including Airtraq® and the LMA® Trach® in a simulated model and patients with cervical immobilization. In addition, the AWS was shown to cause less cervical movements during tracheal intubation than the Macintosh or McCoy® laryngoscopes. Better glottic exposure with the AWS in this study could be attributed to the fact that the AWS causes less cervical movement, and requires no additional effort to align the oral, pharyngeal, and laryngeal axes.

Even when an anaesthetist has a clear glottic exposure with a videolaryngoscope, it would be difficult to direct the tracheal tube into the trachea because the pharyngeal space is occupied by the relatively larger blade of the videolaryngoscope with the integrated camera eye. In contrast, such a weakness can be overcome with the AWS. The tip of the tracheal tube, which is inserted into the channel in the ITL-S®, is already seen on the LCD screen before insertion, and the target symbol on the LCD screen enables the operator to optimally direct the loaded tracheal tube into the glottic opening. Furthermore, the design of the ITL-S® allows guiding the loaded tracheal tube toward the glottis when the tube is advanced down the channel of the ITL-S®. In spite of a clear glottic exposure, the AWS reportedly has a certain difficulty in advancing the tracheal tube into the glottic opening, because the tip of the tracheal tube impinged on the arytenoids. In our patients, however, impingement of the tracheal tube on the arytenoid cartilages occurred in only 1 of 22 patients in the AWS group and was easily overcome with adjusting the direction of the ITL-S®.

This study has several limitations. First, randomization of this study was not fully achieved. Even though the best efforts of randomization were made, more patients with higher Mallampati classification were included in the AWS group. This could be attributed to the limited number of patients recruited. However, the AWS was shown to overcome such a disadvantage. Furthermore, it was impossible to blind both the operator and the observer to the device being used. Secondly, this study was carried out in a limited number of patients by anaesthetists experienced with both devices. The results might be different if the users were less experienced. Therefore, the interpretation or extrapolation of the results of this study must be cautious. Finally, the IDS score has a limitation in evaluating the efficacy of videolaryngoscope because the IDS score adopts the Cormack and Lehane grade, which was originally developed for the direct laryngoscope and is inevitably subjective. However, the IDS score can be a more
objective quantitative measure by incorporating multiple parameters. Many investigators adopted the IDS score as a primary endpoint to compare the AWS with other videolaryngoscopes or Macintosh laryngoscope,7 11 12 and verified index of intubation difficulty is not available other than the IDS score. Furthermore, the success rate of tracheal intubation was not reported to be significantly different between the AWS and Macintosh laryngoscope in various clinical settings.25 – 27 For these reasons, we adopted the IDS as a primary endpoint instead of success rate or elapsed time for tracheal intubation.

In conclusion, this study involving a small number of patients with experienced anaesthetists, the Pentax AWS was shown to be more useful for tracheal intubation in patients with OSA, compared with the conventional Macintosh laryngoscope. The unique structural and functional features of the AWS would contribute to overcoming the anatomical characteristics in patients with OSA, which are well known to be associated with difficult intubation.

Authors’ contributions
M.K.K.: study design, performance of laryngoscopy, writing up of the first draft of the paper. S.W.P.: performance of laryngoscopy, correction of the manuscript of the paper. J.W.L.: data collection and analysis, making up of the manuscript of the paper.

Declaration of interest
None declared.

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References

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