A Randomized Comparison Between the Pentax AWS Video Laryngoscope and the Macintosh Laryngoscope in Morbidly Obese Patients

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BACKGROUND: The Pentax AWS is a novel video laryngoscope designed to facilitate tracheal intubation by providing indirect visualization of the laryngeal inlet. We sought to compare the intubation success rate and time to intubation for the Pentax AWS and the classic Macintosh laryngoscope. Specifically, we tested the hypothesis that intubation with the Pentax AWS would be easier and faster than with a standard Macintosh #4 blade in obese patients.

METHODS: One hundred five obese patients (body mass index between 30 and 50 kg/m^2) requiring orotracheal intubation for elective surgery were allocated randomly to tracheal intubation with either the Macintosh (using a #4 blade) or the Pentax AWS laryngoscope. Two experienced anesthesiologists served as laryngoscopists. Intubation success rate, time to intubation, ease of intubation, and occurrence of complications were recorded.

RESULTS: Intubations using the Macintosh laryngoscope and #4 blade were significantly faster than with the Pentax AWS device: half of the patients' tracheas were intubated successfully within 26 seconds with the Macintosh #4 blade, whereas the same fraction required 38 seconds with the AWS. The first-attempt success rate with the Pentax AWS was 86%; the rate increased to 90% with a second attempt. In contrast, all patients' tracheas were intubated successfully with the Macintosh #4 blade, with a first-attempt success rate of 92%, which increased to 100% by the second attempt.

CONCLUSION: The time required for tracheal intubation using the Pentax AWS was longer than for the Macintosh laryngoscope and #4 blade. The AWS should not routinely be substituted for a conventional Macintosh #4 blade in morbidly obese patients. (Anesth Analg 2011;113:1082–7)

Difficult and failed tracheal intubations are among the principal causes of anesthetic-related mortality and morbidity.[1–4] Because a good laryngeal view facilitates successful tracheal intubation, new technologies have been introduced to improve visualization. Video laryngoscopes, for example, often use miniature cameras located near the glottic aperture to facilitate visualization of the laryngeal inlet with no need to align the oral, pharyngeal, and tracheal axes.

The Pentax AWS (Ambu A/S, Ballerup, Denmark) is a novel video laryngoscope, available in Japan since 2006, which is designed to facilitate intubation by providing a video image of the glottis. It incorporates a miniature video camera and a battery-powered, built-in LCD monitor. A disposable blade (Interlock; length 131 mm, width 49 mm, depth 96 mm) is attached to the base system. Incorporation of an LCD display (Fig. 1) makes it possible to view the glottis simultaneously with insertion of the endotracheal tube (ETT). In this regard, it differs from some other video laryngoscope designs that use external monitors. The Pentax AWS also differs in having a side channel that positions and guides the ETT. Reports suggest that the Pentax AWS can help intubate,[5–16] but randomized data remain sparse.

The fraction of obese and morbidly obese patients is rapidly increasing worldwide. Tracheal intubation can be difficult in these patients because the limited oropharyngeal space may impede adequate visualization.[17] We therefore tested the hypothesis that intubation with the Pentax AWS would be easier and faster than with a standard Macintosh laryngoscope with a #4 blade (length 162 mm, depth 150 mm, width 34 mm).

METHODS

With IRB approval and written informed patient consent, we enrolled patients with a body mass index between 30 and 50 kg/m^2 who required orotracheal intubation for elective surgery. After oxygen administration and induction of general anesthesia, patients were randomly allocated to intubation using either a conventional Macintosh laryngoscope size 4 blade (Macintosh group) or the Pentax AWS (Pentax group).

Randomization was based on computer-generated, random-block codes maintained in sequentially numbered opaque envelopes. All patients' tracheas were intubated by 1 of 2 attending anesthesiologists, each of whom had previously used the Pentax AWS 5 to 10 times before the study began. Reflecting conventional practice at our institution, a size 7.0 ETT was used in women and a size 7.5 ETT was used in men.

Patients assigned to the Macintosh group were intubated with a size 4 blade. When patients were assigned to

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Figure 1. The Pentax AWS with an endotracheal tube in position.

the Pentax AWS group, the system was prepared by attaching the Interlock blade to the system; the ETT was then lubricated and fitted into the channel of the blade. Our technique of using the AWS was to place the device into the patient's mouth and advance it into the posterior pharynx in the midline until the cross-hair target symbol was centered on the glottic aperture. The ETT tube was then advanced toward the trachea. We inserted the Interlock with its tip toward the glottic side of the epiglottis where possible.

In all cases, the patient's head was positioned in the neutral position on a foam "donut" pillow and the laryngoscopist was free to manipulate the head as needed to obtain the best possible view.

The glottic view for each laryngoscopy was graded using the Cormack-Lehane grading system.[18] The ease of tracheal intubation on a Likert scale (from 0 = extremely easy to 100 = extremely difficult), the presence of any blood staining, and the severity of any postoperative sore throat (0 = none, 1 = mild, 2 = moderate, and 3 = severe) were also recorded during a postoperative visit the following day by observers unaware of the intubation method.

Statistical Analysis

Standard descriptive statistics were used to compare the randomized groups on baseline variables. Balance was assessed using the standardized difference (i.e., the difference in means or proportions divided by the pooled standard deviation). Any covariable with a standardized difference >0.25 in absolute value was adjusted for in the analyses, unless specified.

Our primary outcome of time to intubation was defined as time from start of the first attempt of the insertion of the laryngoscope until a capnogram signal was obtained. If an attempt with the assigned device failed, then another attempt or an alternate technique was used. Intubation using the assigned method within 100 seconds regardless of number of attempts was considered successful. For patients who crossed over to the other method or whose tracheas were intubated after 100 seconds, time to intubation was censored at that technique crossing point or 100 seconds, and labeled as a failure in the analysis. The effect of using the Pentax AWS device (versus Macintosh laryngoscope size 4) on time to intubation was assessed using a multivariable Cox proportional hazards regression. Kaplan-Meier estimates for the 2 groups with equal-precision 95% confidence bands were calculated and plotted. In addition, within the Pentax group, we univariably assessed the relationship between time to intubation and case sequence (as quartiles) using the log-rank test.

Secondary Outcomes

We assessed the effect of Pentax AWS on number of intubation attempts by the Wilcoxon rank sum test (without covariable adjustment). We also evaluated the treatment effect on binary outcomes, including successful intubation on the first attempt, overall successful intubation, bleeding (trace versus none), and glottic view ("good": Cormack-Lehane grade 1 or 2 versus "not good" Cormack-Lehane grade 3 or 4), using the Fisher exact test (without covariable adjustment) or a logistic regression, as appropriate. In addition, the intubation success rates on first attempt and overall were reported with the exact 95% confidence intervals. Finally, we assessed the effect of the Pentax on ease of tracheal intubation score and severity of postoperative sore throat by analysis of covariance and a proportional odds logistic regression, respectively.

SAS software version 9.1 (SAS institute, Cary, NC) and the R statistical software version 2.7.2 (The R Foundation for Statistical Computing, Vienna, Austria) were used for analyses and graphics. The significance level was 0.05 for each hypothesis and all tests were 2-tailed.

Sample Size Considerations

Using available data on time required for intubation with the Macintosh laryngoscope, we planned a maximum of 100 patients to reach 90% power at the 0.05 significance level to detect a hazard ratio of ≥2.

RESULTS

Of 105 randomized patients, 4 did not complete the study because of cancellation of surgery or because the laryngoscopist could not arrive to the operating room on time, and 2 patients in the Pentax group had missing primary outcomes. Thus, data from 99 patients were analyzed. Based on visual inspection of the baseline variable data, the randomized groups are for the most part balanced (Table 1). However, patients in the Pentax group were more likely to have better ASA physical status and better Mallampati scores (absolute standardized difference >0.25). Therefore, we adjusted for these 2 variables when comparing groups on outcomes.

Median [Q1, Q3] time to intubation was 38 [31, 50] seconds with the Pentax AWS and 26 [22, 29] seconds with the Macintosh (Fig. 2). Intubations using the Pentax AWS device were slower than with the Macintosh laryngoscope (hazard ratio: 0.35 (95% CI: 0.23, 0.55), Pentax versus Macintosh; $P < 0.001$, Table 2), after adjusting for ASA status and Mallampati score.

There was no evidence of a learning curve on time to intubation using the Pentax AWS over the course of the study based on our analysis of sequence quartiles ($P = 0.22$); the median intubation time was 43 [32, 54] seconds

Table 1. Demographics and Airway Assessment Data

Variable	Pentax AWS (n = 50)	Macintosh (n = 49)	Standardized difference[a]
Age, y	50 ± 12	49 ± 14	0.14
Gender (male/female), n	11/39	10/39	0.04
Body mass index, kg/m^2	41.2 ± 4.4	42.5 ± 5.9	−0.21
ASA physical status, n (%)			0.41
II	15 (30)	7 (14)	
III	32 (64)	40 (82)	
IV	3 (6)	2 (4)	
Mallampati score,[b] n (%)			0.57
1	21 (42)	14 (29)	
2	18 (36)	21 (44)	
3	7 (14)	13 (27)	
4	4 (8)	0 (0)	

Summary statistics presented as number (%) of patients, or mean ± SD.
[a] The difference (Pentax − Macintosh) in means or proportions divided by the pooled standard deviation.
[b] One patient with missing Mallampati value in the Macintosh group.

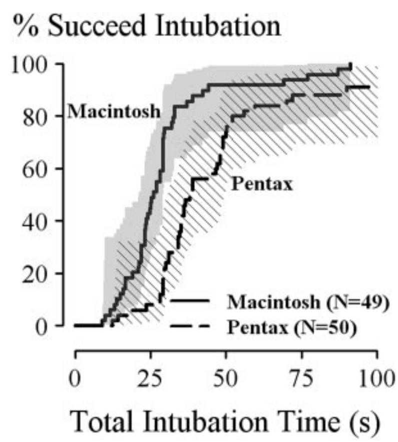

Figure 2. Time to successful intubation for the 2 laryngoscopes. Intubations using the Macintosh laryngoscope and size 4 blade were significantly faster than with the Pentax AWS device ($P < 0.001$), with 50% of the patients' tracheas being intubated at 26 seconds with the Macintosh #4 blade versus 38 seconds with the Pentax AWS.

for the first sequence quartile and 36 [34, 56] seconds for the fourth quartile.

As seen in Table 2, no difference between the Pentax AWS and the Macintosh groups was found in the number of attempts (P = 0.48), successful intubation on the first attempt (P = 0.36), or the overall success rate (P = 0.06). Forty-three patients (86%, 95% exact CI: 73%–94%) in the Pentax AWS group and 45 patients (92%, 80%–98%) in the Macintosh laryngoscope group were successfully intubated on the first attempt, which increased to 90% and 100% with a second attempt, respectively. None of the patients who needed a third attempt was considered to be successfully intubated. Thus, the overall success rate of 100% (95% exact CI: 93%–100%) was achieved in the Macintosh size 4 blade group, whereas the overall success rate was 90% (78%–97%) in the Pentax group (2 patients whose tracheas were intubated in >100 seconds, and 3 patients whose tracheas were not intubated with the Pentax AWS).

The difficulty of tracheal intubation was worse (higher score) in the Pentax group versus Macintosh group (P = 0.02, Table 2). One challenge we sometimes encountered with the Pentax AWS was difficulty in maneuvering the ETT away from the arytenoids and epiglottis and into the trachea. In one of our study cases, initial failure of vocal cord visualization occurred when the head had been hyperextended; repositioning of the head to the sniffing position and reinsertion of the scope changed the view from a grade 4 to a grade 1 view, with successful intubation. Our experience suggests that the sniffing position is sometimes the optimal head position for use of the Pentax AWS.

When Cormack-Lehane scores of 1 and 2 were taken to be "good" and Cormack-Lehane scores of 3 and 4 were taken to be "not good," no difference between the 2 groups was found (P = 0.32, Table 2). The view was good in 86% of patients with the Pentax AWS, but in 2 cases a foggy image on the screen was noted, apparently as a result of not having adequately defogged the unit before use. Furthermore, no between-group difference was found in either bleeding (P = 0.49) or severity of sore throat (P = 0.73). Trace bleeding was noted in 2 patients intubated with the Pentax AWS. One patient whose trachea was intubated with the Macintosh laryngoscope developed a swollen uvula, which was treated with a nonsteroidal antiinflammatory medication. Mild to moderate sore throats occurred in 4 Macintosh and 7 Pentax group patients.

DISCUSSION

We observed a success rate of 86% for intubation with the Pentax AWS during the first attempt, which increased to 90% with a second attempt (Table 2). For the Macintosh blade, the first-attempt success rate was 92%, which increased to 100% by the second attempt. In addition, the time required for tracheal intubation using the Pentax AWS was significantly longer than for the Macintosh size 4 laryngoscope (38 vs 26 seconds on average).

Some prior studies recorded higher success rate and faster intubation than in our study. In a study by Asai et al.,[19] the success rate of intubation using the Pentax AWS was as high as 99.6% in patients with difficult Macintosh laryngoscopy. However, the degree of difficulty was judged subjectively in their study, and the time required for intubation was not reported. A study by Malik et al.[11] showed that the Pentax AWS performed better than the Macintosh, GlideScope, and Truview devices in simulated difficult airway scenarios in manikins. Suzuki et al.[20] compared the laryngeal view using the Pentax AWS and Macintosh laryngoscopes in patients with difficult airways and showed that the Pentax AWS improved the view in cases in which the glottic view was poor using the Macintosh laryngoscope. In this study, external laryngeal manipulation was not allowed, possibly leading to an increased incidence of poor glottic views.

In a 2008 study by Komatsu et al.,[14] patients wearing a rigid cervical collar to simulate a difficult airway were randomized for tracheal intubation with either the Pentax AWS or a Macintosh laryngoscope in conjunction with the "gum elastic bougie." The overall success rate of the Pentax AWS was 100% compared with a 90% rate for the Macintosh group, and intubation required an average of only 34 seconds for the Pentax group compared with 49 seconds on

Table 2. Relationships Between Treatment (Pentax Versus Macintosh) and Outcomes

Outcome	Pentax AWS (n = 50)	Macintosh (n = 49)	Treatment effect (95% CI)	P value*
Primary outcome			Hazard ratio	
Intubation time, s	38 [31, 50]	26 [22, 29]	0.35 (0.23, 0.55)	<0.001†
Secondary outcome			Mean difference	
Ease of intubation (0, easiest to 100)	52 ± 31	40 ± 28	15 (3, 27)	0.02‡
			Odds ratio	
Successful intubation, first attempt,[a] n (%)	43 (86)	45 (92)	0.54 (0.15, 2.0)	0.36§
Overall successful intubation,[a] n (%)	45 (90)	49 (100)	Inestimable[b]	0.06‖
No. of intubation attempts,[a] n (%)			N/A	0.48¶
1	44 (88)	45 (92)		
2	3 (6)	4 (8)		
3	3 (6)	0 (0)		
Cormack-Lehane grade (good), n (%)	43 (86)	38 (78)	1.7 (0.59, 4.9)	0.32§
Bleeding (trace), n (%)	2 (4)	0 (0)	Inestimable[b]	0.49‖
Sore throat,[c] n (%)			0.91 (0.55, 1.5)	0.73#
None	34 (68)	32 (67)		
Mild	9 (18)	12 (25)		
Moderate	5 (10)	3 (6)		
Severe	2 (4)	1 (2)		

Summary statistics presented as median [Q1, Q3], mean ± SD, or number (%) of patients, as appropriate.

[a] In the Pentax group, intubations of 5 patients had failed: 2 required >100 seconds with 1 and 3 attempts, respectively; 1 and 2 patients were not intubated with Pentax with 2 and 3 attempts, respectively.

[b] Odds ratio was inestimable because of zero events (i.e., failed intubation, and bleeding) in the Macintosh group.

[c] One patient in the Macintosh group with a missing throat score was excluded.

*Adjusting for ASA physical status and Mallampati score by: †Cox proportional hazards regression; ‡analysis of covariance; §logistic regression; ‖Fisher exact test (without adjusting for covariable); ¶Wilcoxon rank sum test (without adjusting for covariable); and #proportional odds logistic regression; odds ratio of rating a better score.

average for the Macintosh group. In a later study also using rigid cervical collars, Komatsu et al.[13] compared the Pentax AWS against the StyletScope (a fiberoptic stylet that uses a plastic fiberoptic imaging system incorporated into an ETT stylet). Overall intubation success rates were 98% with the Pentax AWS and 96% with the StyletScope, with the intubation time averaging 19 seconds shorter with the Pentax AWS (Pentax AWS, 32 seconds; StyletScope, 51 seconds). In 2010, in yet another rigid cervical collar study, Komatsu et al.[15] compared the Pentax AWS and the McCoy laryngoscope. Although overall intubation success rates were 100% for both devices, time to tracheal intubation was faster with the Pentax AWS (30 seconds on average) than for the McCoy laryngoscope (40 seconds on average).

As a final example, Enomoto et al.[9] compared the Pentax AWS with the Macintosh laryngoscope in a crossover study in which patients received manual inline neck stabilization. They used a size 3 Macintosh when the patient's height was 175 cm or smaller, and a size 4 when taller than 175 cm. The authors found that the Pentax AWS "provided a better view of the glottis and a higher success rate of tracheal intubation." In this study, only 1 attempt, up to 2 minutes (starting from insertion of the second blade), was allowed for tracheal intubation. Time required for intubation was similar between the Pentax AWS (54 seconds on average) and the Macintosh laryngoscope (51 seconds on average).

As noted above, we found that the time required for tracheal intubation using the Pentax AWS was significantly longer than for the Macintosh laryngoscope (38 vs 26 seconds on average), although we recognize that this difference is clinically unimportant in most cases. However, our average intubation time with the Pentax AWS (38 seconds) was comparable to the 34 seconds on average required in 2008 study by Komatsu et al.,[14] the 32 seconds required in the 2009 study by Komatsu et al.,[13] and the 30 seconds required in their 2010 study.[15] We were also faster than the average of 54 seconds required in the study conducted by Enomoto et al.[9] Also, in our study, intubation with the Macintosh laryngoscope required only 26 seconds on average, as compared with an average of 49 seconds for the gum elastic bougie with Macintosh laryngoscope group method in the 2008 study by Komatsu et al.,[14] and an average of 40 seconds in patients whose tracheas were intubated with a McCoy laryngoscope in the 2010 study by Komatsu et al.[15] Tracheal intubation with the Macintosh laryngoscope was faster in our study than in the studies mentioned above; this may be a reflection of the fact that our patients' heads were not restrained in a collar or subjected to inline stabilization because both these maneuvers are well known to increase the difficulty of intubation by direct laryngoscopy. Thus, although the above studies tended to show that the Pentax AWS performed better than alternate methods, the fact that our study showed the opposite likely reflects that direct laryngoscopy was simply easier in our particular clinical setting.

We also questioned whether these results could be explained in part by the fact that the 2 laryngoscopists in the study had much more experience with the Macintosh laryngoscope than with the Pentax AWS; or, alternatively, that they lacked sufficient experience with the Pentax AWS before embarking on the study. However, this does not seem to be the case, for 2 reasons. First, as noted above, our average Pentax AWS intubation time of 38 seconds was comparable to the average intubation time reported in other studies. Second, there was no evidence of a learning effect during the study, which suggests that more experience with the Pentax AWS would not have significantly altered our results.

Other factors may also be responsible for the differences between our results and the results of other authors. Our patient population was morbidly obese, with an average body mass index of 42 and 43 kg/m^2 in the Pentax AWS and Macintosh groups, respectively, whereas all other studies focused on non-obese subjects. We speculate that a narrow oropharyngeal space in our patient population might have impeded manipulation of the relatively bulky Interlock component of the AWS, and that a Macintosh size 4 blade might have been easier to handle in such a narrow space.

Furthermore, the absence of a rigid cervical collar would be expected to facilitate direct laryngoscopy without significantly improving the view obtained using the Pentax AWS. Similar results would be expected for the use of inline stabilization during intubation. Finally, it should be emphasized that many of the above studies used intubation success criteria that were more liberal than the criteria used in our study, where intubation was considered a failure if it could not be accomplished within 100 seconds (1.67 minutes). Our reason for choosing 100 seconds as the maximal allowable time as compared with, for instance, the 180 seconds allowed by Komatsu et al.[13–15] was in large part a safety consideration because obese patients (our study population) desaturate more quickly than lean patients as a result of their smaller functional residual capacity. However, our 100-second rule likely resulted in a higher (technical) failure rate than a more liberal rule would have produced.

As noted above, one difficulty we sometimes encountered with the Pentax AWS was in maneuvering the ETT away from the arytenoids and epiglottis and into the trachea. Asai et al.[19] overcame this problem by using an Eschmann introducer to guide entry of the tube through the laryngeal inlet; however, this approach can prolong the time needed for tracheal intubation and adds complexity to the procedure. Similar difficulties can also be encountered with other video laryngoscopes, such as GlideScope, in which an excellent view may be obtained, but the ETT might still be difficult to manipulate through the vocal cords.[11] Another limitation of the Pentax AWS that we encountered, lens fogging, can usually be prevented by prewarming the blade.

This study has several limitations. One important limitation of this study was that it focused on obese patients and did not include patients with a history of difficult airway intubation. Second, our protocol did not include use of adjunctive devices such as an Eschmann introducer, which might have improved intubation rates. Third, although the study was randomized, it was impossible to blind the operator to the device being used. Other study limitations include the fact that only the Mallampati score was recorded, such that it is impossible to adequately classify the patients' airways and ensure that the groups were comparable in their potential for difficult intubation, and the fact that patients were only questioned about a sore throat postoperatively. Finally, the comparison between the Pentax AWS and a Macintosh #4 blade may itself be a limitation because of differences in design, the size disparity, and differences in the method of application.

In summary, although the Pentax AWS often provided a superb glottic view, the time required for tracheal intubation using the Pentax AWS was longer than for the Macintosh laryngoscope with a size 4 blade. Furthermore, intubation success was better with the Macintosh blade. Our results thus suggest that the AWS should not routinely be substituted for a conventional Macintosh #4 blade in morbidly obese patients.

DISCLOSURES

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Attestation: Rania Abdallah has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
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Attestation: D. John Doyle has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
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