**ARTICLE DETAILS**

**TITLE (PROVISIONAL)**
A comparison of the force applied on oral structures during intubation attempts between the Pentax-AWS airwayscope and the Macintosh laryngoscope: a high-fidelity simulator-based study.

**AUTHORS**
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**VERSION 1 - REVIEW**

**REVIEWER**
Nobuyasu Komasawa
Department of Anesthesiology, Japan

**REVIEW RETURNED**
23-Aug-2014

**GENERAL COMMENTS**
This is a well written paper that describe the AWS utility to oral structure. The method is well described and the result is clear.

I have only two comments to improve the manuscript.

1. Please unify the expression of AWS. There are several phrases. I think that Pentax-AWS Airwayscope is the full expression.

2. To improve the discussion, you may expand the utility of AWS in several situations such as several position or on the ground.

**REVIEWER**
Akihiro Suzuki
Department of Anesthesiology
Asahikawa Medical University

**REVIEW RETURNED**
31-Aug-2014

**GENERAL COMMENTS**
This manuscript compared the applied force on incisor and tongue caused between AWS and DL. Authors found less force was required for laryngoscopy with the AWS.

This draft provide important information for anesthesiologist, ER and ICU physician that the latest video laryngoscope, Pentax-AWS, is less invasive for laryngoscopy. However, there must be some issues to be solved to strengthen the result obtained. At least power analysis is needed to justify their result.

1) Participant includes both novice and experienced laryngoscopist and nearly half of participant were inexperienced. What happen if data was divided into experienced and inexperienced?

2) How authors determined 37 participants needed? Is that the result of power analysis? Then what parameter was chosen for primary outcome and how authors determined significance?

3) Why pressure on incisor was high in normal airway scenario in
contrast to difficult airway scenario with AWS? This unstable result may be the effect of including inexperienced personnel.
4) Authors should compare the result between normal and difficult scenario in each device.
5) Was this simulator commercially available or specially designed for this research?

Minor

Device name “Airway Scope” is only used in Japan, not in other countries. Outside Japan, registered device name is Pentax-AWS. Therefore, there are two stream of authors use airway scope or Pentax-AWS. This difference cause difficulty in searching literature about this device in Pubmed and other engines. I recommend author to use Pentax-AWS airwayscope in the title, or list both Pentax-AWS and airwayscope in the keywords.

P9 L15 p value=0.01 is different from the value listed in the Table 2 (p=0.02).
P10 L25-27 This sentence is different from result. In normal airway scenario, force with AWS is significantly higher.
P10 L27 difficulty should be difficult

VERSION 1 – AUTHOR RESPONSE

Reviewer 1’s (Dr. Nobuyasu Komasawa) comments

This is a well written paper that describe the AWS utility to oral structure. The method is well described and the result is clear.

We thank the reviewer for these positive comments.

1. Please unify the expression of AWS. There are several phrases. I think that Pentax-AWS Airwayscope is the full expression.

As requested, we have changed “AWS” to “Pentax-AWS Airwayscope” and then abbreviated it to “AWS” throughout the manuscript.

2. To improve the discussion, you may expand the utility of AWS in several situations such as several position or on the ground.

We appreciate the helpful suggestion. As suggested, we have added the information regarding the clinical settings, in which the performance and safety of AWS would be superior than those of DL (e.g., cardiopulmonary resuscitation, pregnant patients with lateral tilt-position, and out-of-hospital setting), to the Discussion section (page 11, para 2).

Reviewer 2’s (Dr. Akihiro Suzuki) comments

This draft provide important information for anesthesiologist, ER and ICU physician that the latest video laryngoscope, Pentax-AWS, is less invasive for laryngoscopy.

We thank the reviewer for the positive comment.

1. Participant includes both novice and experienced laryngoscopist and nearly half of participant were inexperienced. What happen if data was divided into experienced and inexperienced?
We appreciate the reviewer’s excellent suggestion. As requested, we performed stratified analysis by categorizing the intubators into two groups based on the previous study: experienced intubators (n = 18) and inexperienced intubators (n = 19)[1]. Experienced intubators were defined as those who had intubated 100 or more cases, while inexperienced intubators were defined as those who had intubated less than 100 cases.

The results of the stratified analyses showed the robustness of our findings. In the experienced intubator group, the forces applied on oral structures were significantly lower with the use of an AWS than that with a DL in the difficult airway scenario (Table 3). Similarly, in the inexperienced intubator group, the forces applied on oral structures were significantly lower with the use of an AWS than that with a DL in the difficult airway scenario (Table 4).

2. How authors determined 37 participants needed? Is that the result of power analysis? Then what parameter was chosen for primary outcome and how authors determined significance?

We appreciate the opportunity to clarify this important point. Because of the availability of the participants in this non-interventional study, the sample size was fixed (n=37). Therefore, we did not calculate the sample size in advance. Nevertheless, as suggested, we performed a post-hoc power calculation. First, we adjusted the sample size based on the Asymptotic Relative Efficiency of the Wilcoxon signed rank test relative to the paired t-test. The Asymptotic Relative Efficiency for the Wilcoxon signed rank test is never less than 0.864 with no matter what the underlying distribution[2,3]. Therefore, we multiplied the sample size (n=37) by 0.864 (n=32) to calculate the power for paired t-test. Then, on the assumption of a standard deviation of mean difference of 12 N force applied on the maxillary incisors between the groups in the difficult scenario (the largest difference in all primary outcomes), the study has 80% power to detect a difference as small as 7 N between the groups, with a 2-sided significance level of P=0.05. Furthermore, the effect size is 0.5 on the assumption that the sample size is 32, the significance level is 0.05, and we require 80% power. We did not present this power calculation in the revised manuscript because of the post-hoc nature and significant results.

3. Why pressure on incisor was high in normal airway scenario in contrast to difficult airway scenario with AWS? This unstable result may be the effect of including inexperienced personnel.

We appreciate the opportunity to clarify this point. The reason for the finding that the maximum force applied on the maxillary incisors in the normal airway scenario was higher with the use of AWS than that with DL was unclear and likely multifactorial. In our study, most intubators were familiar with the use of a DL, while they were less familiar with the use of AWS. Indeed, approximately 80% of the participants had performed less than 10 intubations using an AWS. Therefore, one may surmise that the unfamiliarity with AWS led to this finding. However, the sensitivity analysis demonstrated no significant difference in the applied force on the maxillary incisor between the devices in the experienced intubator group. Alternatively, the size of an AWS – bigger than that of a DL – might have contributed to the finding. As suggested, we have highlighted these potential mechanisms in the Discussion section (page 12, para 2).

4. Authors should compare the result between normal and difficult scenario in each device.

As requested, we have compared the results between the normal and difficult scenarios in each device, and added the results to the Results section (page 9, para 4) and Table 5. With the use of a DL, the forces applied on oral structures were significantly lower in the normal airway scenario (the maximum force applied on the maxillary incisors, 77 N vs. 183 N, P<0.01; the force applied on the tongue, 27 N vs. 40N, P<0.01, Table 5) compared to those in the difficult airway scenario. Likewise, the Cormack-Lehane grade score was significantly lower in the normal airway scenario (median, 1 vs. 2, P<0.01). In contrast, with the use of an AWS, there were no significant differences in any of the outcomes between the two scenarios (Table 5).
5. Was this simulator commercially available or specially designed for this research?

This simulator is commercially available. In the Methods section (page 6, para 3), we have highlighted the information of the simulator.

Minor
Device name “Airway Scope” is only used in Japan, not in other countries. Outside Japan, registered device name is Pentax-AWS. Therefore, there are two stream of authors use airway scope or Pentax-AWS. This difference cause difficulty in searching literature about this device in Pubmed and other engines. I recommend author to use Pentax-AWS airwayscope in the title, or list both Pentax-AWS and airwayscope in the keywords.

We appreciate the reviewer’s excellent suggestion. As suggested, we changed “AWS” to “Pentax-AWS Airwayscope” and then abbreviated it to “AWS”. Additionally, we have listed both Pentax-AWS Airwayscope and airwayscope in the keywords.

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P10 L25-27 This sentence is different from result. In normal airway scenario, force with AWS is significantly higher.
P10 L27  difficulty should be difficult

Revised.

REFERENCES
1. Bishop MJ, Harrington RM, Tencer AF. Force applied during tracheal intubation. Anesth Analg 1992;74:411-4.
2. Myles Hollander, Douglas A. Wolfe. Solutions Manual to Accompany Nonparametric Statistical Methods, Second Edition. John Wiley and Sons, Inc.
3. Erich L. Lehmann. Nonparametrics:Statistical Methods Based on Rankes, Revised. Springer.

VERSION 2 – REVIEW

| REVIEWER             | Akihiro Suzuki |
|----------------------|----------------|
|                      | Dept of Anesthesiology |
|                      | Asahikawa Medical University |
|                      | JAPAN |
| REVIEW RETURNED      | 22-Sep-2014 |
| GENERAL COMMENTS     | Authors responded to the queries raised. I appreciate authors effort to conduct this study. |