ORIGINAL ARTICLE



Influence of clinical experience of the Macintosh laryngoscope on performance with the Pentax-AWS Airway Scope[®], a rigid video-laryngoscope, by paramedics in Japan

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Abstract

Purpose We sought to establish the clinical utility of the Pentax-AWS Airway Scope[®] (AWS) when used by paramedics to intubate the trachea, and to evaluate whether their performance was influenced by previous clinical experience with the Macintosh laryngoscope (ML).

Methods Twenty paramedics attempted tracheal intubation using the AWS in five patients each in the operating room. We recorded the success rate, the number of intubation attempts, and the time for intubation and adverse events, and compared these based on the paramedics' previous clinical experience with the ML. Ten paramedics had no prior clinical experience of the ML (group A) and 10 had used it on more than 30 occasions (group B).

Results The intubation success rate was 99 % (99/100). Notably, 96 % (47/49) of intubations were achieved on the first attempt by the inexperienced paramedics in group A, compared with 64 % (32/50) by the experienced paramedics in group B (p = 0.0001). The time to intubation (mean \pm SD) was significantly shorter in group A than in group B (37 ± 24 vs. 48 ± 21 s, p = 0.002). There were marked variations in the times taken to intubate, but no

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M. Nakao Department of Anesthesiology, Hiroshima General Hospital, Hiroshima, Japan apparent improvement as the intubators gained experience between their first and fifth cases. No complications were encountered in either group.

Conclusion We found that paramedics could achieve a high tracheal intubation success rate using the AWS independent of previous airway management experience. Better intubation performance with the AWS was observed in paramedics without clinical experience with the ML.

Keywords Rigid video-laryngoscope · Endotracheal intubation · Paramedic

Abbreviations

- ML Macintosh laryngoscope
- AWS Pentax-AWS Airway Scope[®]
- OR Operating room
- ID Internal diameter

Introduction

The conventional Macintosh laryngoscope (ML) is the most popular device for tracheal intubation; however, the skills needed to use it correctly require substantial clinical training and the acquisition of expertise. In emergency settings tracheal intubation may be difficult and challenging as a result, for example, of foreign material in the oral cavity, pharynx, or larynx, unexpected abnormality of airway anatomy, or movement caused by chest compressions during cardiopulmonary resuscitation. Intubation may be complicated by injury to the oropharynx and larynx, hypoxemia because of prolonged unsuccessful intubation attempts, or failure to recognize tube misplacement. To address these problems, a variety of devices has been developed [1].

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Among such devices is the Airway Scope[®] (AWS; Pentax-AWS[®], Hoya, Tokyo, Japan), a rigid video-laryngoscope that was designed to facilitate tracheal intubation [2]. The AWS requires fewer operator skills to achieve intubation, which is useful in emergency settings [3, 4] and for difficult airways [5–7] and appears to be particularly suitable for novices [8–11].

Paramedics in Japan are permitted to intubate the trachea using the ML in patients in cardiac arrest. They are required to complete at least 30 successful tracheal intubations in the operating room (OR) before certification by the prefectural medical control committee [12]. We observed that clinical training in the OR, which required written informed consent from each patient and supervision by board-certified anesthesiologists, had become burdensome for paramedic trainees. Furthermore, limited opportunities to perform tracheal intubation in routine practice make it difficult for paramedics to maintain their intubation skills: most paramedics only perform one or two pre-hospital tracheal intubations each year. Therefore, most paramedics have realized the necessity of a re-education program [13]. Despite the several problems just described, no study has examined an alternative method for achieving a higher success rate of tracheal intubation with a shorter training program for paramedics.

We hypothesized that tracheal intubation could be achieved more effectively, and that less clinical training would be required to obtain and maintain airway skills, by paramedics using the AWS in Japan. Nonetheless, it is not clear whether clinical experience with the ML is necessary or required for those learning how to use the AWS. The aims of this study were therefore to determine tracheal intubation success rates, the time taken for intubation, the learning curve needed to achieve a 90 % success rate, and the incidence of adverse events when paramedics used the AWS. We then examined the influence of previous clinical experience with the ML on intubation performance using the AWS.

Methods

This was an observational study. The AWS was not approved for use by paramedics in Japan at the time of the study. Therefore, we obtained approval for the study design and protocol from the Fire and Disaster Management Agency of the Ministry of Internal Affairs and Communications (Soumu-shou Shoubou-chou) and from the Japanese Ministry of Health, Labour and Welfare (Kousei roudou-shou) [14]. Furthermore, the Medical Control Committees of Hiroshima, Nishi-Hiroshima, and Onomichi areas, as well as the Hiroshima Prefectural Medical Control Committee, reviewed and approved the protocol.

Ethics considerations

Any study that challenges an established clinical practice should be undertaken if the hypothesis and objectives of the study are reasonable and the study design is appropriate. We ensured that our study had a sound rationale and ethical basis, justified by (a) the widespread and safe use of the AWS as an aid to intubation in routine clinical practice, (b) the lack of reporting of any severe adverse events with the AWS, and (c) published evidence showing the clinical utility of the AWS in the OR and emergency scenarios–particularly for novice personnel [8–11]. Furthermore, we took the necessary steps to gain the approval of the relevant government agencies and the local Medical Control and Ethics Committees as previously described.

Pre-clinical training program

A 6-h pre-clinical training program was developed, comprising a didactic lecture including video sessions, manikin practice using airway trainers, and case-based scenario practice using a high-fidelity simulator. The program focused particularly on the differences between the AWS and the ML and on improving understanding of the surface anatomy of the pharynx and larynx using video teaching material. The schedule of the lecture and video sessions is shown in Table 1. All paramedics who participated in the study were required to undertake this course and pass a skill test before starting the study in the OR.

For those who were not certified to perform tracheal intubation using the ML at the time of the study, a formal pre-clinical training course for tracheal intubation using the ML advised by the national government [12] was provided in addition to the pre-clinical training program for the AWS.

Table 1 Schedule and content of the training program
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1st and 2nd hours	Basic knowledge of AWS (DVD, lecture)
3rd and 4th hours	Lecture and practice using manikin
5th and 6th hours	Simulation
Contents of lecture and DVD	
Airway anatomy	
Structure and features of AWS	
Comparison with Macintosh laryngoscope	
Basic skills	
Patient position/preparation for intubation	
Intubation technique	
Trouble shooting	
Complications	

Study protocol

Twenty paramedics who had no experience of the AWS before the study were recruited. Ten had no prior clinical training or experience of tracheal intubation using the ML (group A), and the others were certified to use the ML for tracheal intubation (group B). In Japan, paramedics are required to perform 30 successful tracheal intubations using the ML in the OR before they are certified to use the ML for tracheal intubation in the pre-hospital setting.

Written informed consent was obtained from all patients who participated. Only patients with American Society of Anesthesiologists (ASA) physical status level 1 were enrolled.

In the OR, paramedics were asked to use the AWS to intubate the trachea of patients in whom general anesthesia had been established by a supervising board-certified anesthesiologist. The size of tracheal tube used ranged from 7.0- to 8.0-mm internal diameter (ID) for men and from 6.5- to 7.0-mm ID for women. We used a standard disposable cuffed endotracheal tube manufactured from polyvinyl chloride. The AWS blade (Introck[®]; Hoya, Tokyo, Japan) was the normal type designed for adults. We placed patients with their head in a neutral position with or without a thin pillow and avoided the use of the "sniffing position." Standard monitoring of peripheral oxygen saturation (SpO₂), heart rate, and blood pressure had been established. The supervisors provided no advice during intubation attempts. The attempt was aborted if there were any clinically significant changes in the vital signs or if the supervisor considered it inappropriate to continue. This decision was made on the basis of events generally considered as the standard criteria for aborting an intubation attempt when using an ML, such as prolonged time for advancing the tube into the trachea, dental compression, inappropriate manipulation required to elevate the epiglottis, and resistance when advancing the tracheal tube. The supervisors were experienced anesthesiologists certified as Fellows of the Japanese Society of Anesthesiologists.

Patient characteristics including age, sex, Mallampati classification, and Cormack–Lehane classification were recorded. The primary endpoints were success rate of tracheal intubation and the number of attempts required to achieve a successful tracheal intubation. Additional endpoints included the time required for visualization of the glottis (T1), tracheal intubation (T2), and inflation of the lungs (T3). The time to visualization of the glottis was defined as the time from insertion of the blade between the teeth until the glottis was seen. The time to tracheal intubation was defined as the time from insertion of the blade between the teeth until the tracheal tube was deemed to be correctly positioned. The time to inflation of the lungs was defined as the time from insertion of the blade between the

teeth to the time when lung inflation had been confirmed by the investigator. Pressure from the blade on the teeth during the intubation attempt was also noted. The extent of dental compression was recorded as "one" when a single occasion of mechanical pressure between the dorsal aspect of the AWS blade and the maxillary teeth was observed during visualization of the glottis; greater pressure was rated as "two" or "three." We also recorded SpO₂, heart rate, and blood pressure before and immediately after intubation, and any other complications caused by the intubation attempts.

Statistical analysis

We determined the number of patients required for this study based on the limited time available for paramedic OR training. No previous clinical reports have evaluated the number of intubation attempts required during paramedic OR intubation training to achieve a 90 % success rate with the AWS. Because the reported intubation success rates with the AWS are high [9–11], each paramedic was allocated at least five patients for intubation using the AWS. Comparison of nonnormally distributed variables between groups was performed with the Mann–Whitney U test and Kruskal-Wallis test. Comparison of categorical variables between the groups was undertaken with the chi-square test. All statistical analyses were performed using SPSS statistics 20.0 for Windows (SPSS, Chicago, IL, USA). Differences were considered statistically significant when the p value was <0.05.

Results

Twenty paramedics attempted tracheal intubation in 100 patients in the OR. All data were collected except for 1 case in which the time for intubation was not measured correctly. Patient characteristics are summarized in Table 2; no statistically significant differences were observed between the groups. In particular, the proportion of patients with Mallampati scores of I or II in each group were not different. On laryngoscopy, 98 patients were recorded as Cormack–Lehane classification I and 2 patients as class II. No class III or IV laryngoscopic views were observed.

The success rate of all tracheal intubations was 99 % (99/100). One esophageal intubation was detected; the reason for the failure was unexpected distortion of the laryngeal anatomy. This trial was aborted, and the trachea was intubated by the supervisor uneventfully and without clinically significant delay. The mean, minimum, and maximum times required for tracheal intubation (T2) were 42, 10, and 135 s, respectively. Intubations were successfully

Table 2 Patient characteristics

	Paramedics without experi- ence $(n = 50)$	Paramedics with experience $(n = 50)$			
Age (years)	59 (22–77)	64.5 (29–84)			
Male sex	37	24			
Height (cm)	164.4 ± 7.1	159.3 ± 9.8			
Weight (kg)	62.9 ± 10.3	58.3 ± 11.7			
Mallampati classification					
I/II	48	49			
III/IV	2	1			
Cormack-Lehane classification					
Ι	50	48			
II	0	2			
III or IV	0	0			
Vital signs during intubation					
Pre-intubation					
HR (bpm)	66 ± 11	62 ± 13			
sBP (mmHg)	106 ± 23	93 ± 19			
SpO ₂ (%)	99 ± 0.8	100			
Post-intubation	Post-intubation				
HR (bpm)	69 ± 14	78 ± 21			
sBP (mmHg)	101 ± 18	103 ± 28			
SpO ₂ (%)	99 ± 0.8	100			

Values are expressed as mean \pm SD, number or range

achieved at the first attempt in 80 % of cases, at the second attempt in 18 %, and at the third attempt in 2 % of cases. No adverse effects on heart rate, blood pressure, or SpO_2 during intubation attempts were observed. No complications were encountered in this study.

The paramedics in group A intubated successfully on the first attempt on 96 % (47/49) of occasions (Table 3), which was significantly higher than group B (p < 0.0001). Fewer incidences of pressure being applied to the teeth by the blade of the AWS were observed in group A than group B (p < 0.0001). The incidence of esophageal intubation occurred in the fourth case of tracheal intubation performed by a paramedic in group A.

Table 4 shows the mean times required for tracheal intubation. Two cases were excluded from the analysis: the case of esophageal intubation and the other in which the time for intubation was not measured correctly. *T*2 was significantly shorter in group A than group B (p = 0.002).

We evaluated the median time required for tracheal intubation in a sequential order from the first to fifth cases to examine whether intubation was achieved more quickly as the operators became more experienced (Fig. 1). In both groups, there was no case-dependent reduction in the time required for intubation; marked variations in the time required for intubation were observed regardless of number of cases. Table 3 Intubation success rates and variables

	Paramedics without experience $(n = 50)$	Paramedics with experience $(n = 50)$	
No. of successful intubation	49 (98)	50 (100)	
No. of attempts			
1	47*	32	
2	2	16	
3	0	2	
No. of esophageal intubations	1 0		
No. of dental compre	essions		
0	33*	3	
1	14	38	
>2	3	9	

* p < 0.0001 compared with the group of paramedics with experience (chi-square test)

Discussion

We found a high success rate of all tracheal intubation, despite the operators having no previous clinical experience of the AWS. Notably, most (94 %) of successful intubations were achieved on the first attempt in the group of paramedics who had received no clinical training in conventional laryngoscopy and had no clinical experience of the ML. Conversely, there was no apparent learning effect, in that the time needed to intubate did not improve over the first five cases in which the AWS was used.

It has been reported that residents need to have experienced 57 intubations using the ML to achieve a success rate of more than 90 % [1]. Similarly, there is a slow learning curve when paramedics are taught to intubate with an ML [15, 16]. Tracheal intubation using the ML requires a sequence of complex maneuvers, such as wide mouth opening, flexion of the cervical spine, extension of the atlanto-occipital joint, and manipulation of the tongue and epiglottis to create a direct line of vision from the mouth to the vocal cords. These techniques require substantial clinical training to achieve acceptable levels of proficiency. This requirement explains why the 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations advised that emergency tracheal intubation in circumstances such as cardiac arrest should be performed only by skilled personnel [17]. However, the AWS has a unique anatomically shaped blade that does not require alignment of the oral, pharyngeal, and tracheal axes to visualize the glottic opening. In addition, the blade of the AWS has three-dimensional structures that are designed to fit into the pharyngeal space and ensure that there is sufficient space to visualize the glottis, and a target mark on the screen guides

Table 4 Time required for intubation attempt

	<i>T</i> 1	<i>T</i> 2	<i>T</i> 3
Paramedics without experience $(n = 49^{a})$	23.8 ± 17.4	$37.1 \pm 24.4^{\$}$	62.9 ± 28.4
Paramedics with experience $(n = 49^{b})$	27.4 ± 19.3	47.7 ± 20.5	67.3 ± 19.3
Total ($n = 98$)	25.6 ± 18.4	42.4 ± 23.1	65.1 ± 24.3

T1 (s), visualization of the glottis; T2 (s), tracheal intubation; T3 (s), inflation of the lungs

Values are expressed as mean \pm SD

^a Except for one case with esophageal intubation

^b Except for one case in which the time for intubation was not measured correctly

p = 0.002 compared with the group of paramedics with experience (Mann–Whitney *U* test)

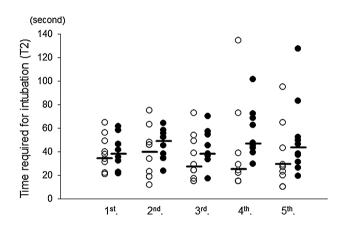


Fig. 1 Time required for intubation using the Airway Scope (AWS) in sequential order of intubation experience. An *open circle* indicates each time required for intubation in the group of paramedics who had no prior clinical training or experience with the Macintosh laryngoscope (group A). A *closed circle* indicates each time required for intubation in the group of paramedics with previous experience (group B). *Bar* indicates the median time required for intubation in each group. *T2*: the time to tracheal intubation was defined as the time from insertion of the blade between the teeth until the tracheal tube was deemed to be correctly positioned

the endotracheal tube through a groove in the blade and then between the vocal cords. These features may enable novice personnel without clinical training to intubate successfully [18, 19].

Interestingly, the group of paramedics with no previous experience of the ML was able to intubate successfully more often and applied less pressure to the teeth than the group with experience, which may reflect the fact that the AWS requires a somewhat different technique. With the anatomically shaped blade of the AWS, less force is required during laryngoscopy. In this study, we observed that the paramedics who had used the ML previously before had a tendency to manipulate the AWS in a similar manner to that required when intubating with an ML. This tendency may in part explain the lower success rates on the first attempt, more dental compressions, and longer time required for intubation compared with those with no clinical experience of the ML. It also emphasizes the importance of stressing the differences between the AWS and ML during training, as the current certification program requires paramedics to complete 30 successful tracheal intubations using the ML in the OR, and to be certified by the local Medical Control Committee, before starting clinical training with the AWS [20].

Our findings could have helped to inform development of the current AWS national certification program [20], but the requirements for a paramedic to complete 30 successful tracheal intubations using the ML in the OR and to have achieved certification by the local Medical Control Committee before embarking on training with the AWS have been mandated. Our findings suggest that previous experience with an ML is not necessary or required for paramedics to be trained to use the AWS effectively.

There are several issues concerning the AWS that should be addressed. First, we noted three cases in which the time taken to advance the endotracheal tube through the glottis was prolonged, apparently because of the discrepancy between the image provided on the monitor and the direction of the tube. The glottis is viewed directly from the front by the camera, but as the tracheal tube is advanced it moves from the right side of the screen to the upper left side. Second, we positioned the patient's head in a neutral position, as the sniffing position may not afford a good view of the glottis when using the AWS; indeed, the sniffing position may cause the tube to abut the anterior tracheal wall. Third, we used slightly smaller tracheal tubes with some intrinsic stiffness; however, even smaller tubes made from softer materials may be easier to manipulate, requiring less time to insert and reducing the number of intubation attempts.

This study has some limitations. First, this was an observational study and consequently differences between group A and B should be interpreted with caution. Second, our primary endpoint was the rate of success of tracheal intubation using the AWS. As this was so high at the first attempt, we could not assess the learning curve needed to acquire experience of the AWS using serial success rates. Third, dental compression was evaluated subjectively by the supervisors, and we did not measure the magnitude of the pressure on the teeth. Fourth, we did not directly compare the AWS with the ML. Although many previous studies have already shown that the AWS is superior in some respects to the ML, differences between the two devices need to be clarified, particularly in difficult situations such as emergency or pre-hospital settings. Further clinical studies are required to address these questions.

In conclusion, we found that the AWS provided a high success rate of tracheal intubation by paramedics, regardless of their previous experience with the ML. The specific features of the AWS that differentiate it from the ML should be emphasized during training.

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