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Title:

Intubation performance using different laryngoscopes while wearing chemical protection equipment – a manikin study

Authors:

H. Schröder^{1,2}, N. Zoremba^{1,3}, R. Rossaint¹, K. Deusser⁴, C. Stoppe¹, M. Coburn¹, A. Rieg¹, G. Schälte¹

- (1) Department of Anesthesiology (Chair: Prof. Rolf Rossaint), Uniklinik RWTH Aachen University, Germany
- (2) Department of Operative Intensive Care and Intermediate Care (Chair: Prof. Gernot Marx) Uniklinik RWTH Aachen University, Germany
- (3) Department of Anesthesiology and Intensive Care, St. Elisabeth Hospital Gütersloh, Germany
- (4) Department of Internal Medicine, Medizinisches Zentrum Städteregion Aachen, Germany

Correspondence to:

Gereon Schälte

Department of Anesthesiology
University Hospital Aachen, RWTH Aachen University
Pauwelsstraße 30
D-52074 Aachen
Germany

Phone: 49 (0) 241 – 80 88179

Fax: + 49 (0) 241 – 80 82406

E-mail: gschaelte@ukaachen.de / hschroeder@ukaachen.de

ABSTRACT

Background:

Chemical, biological, radiation or nuclear (CBRN) hazards can lead to the release of contagious or toxic agents, which can result in respiratory failure that requires on-site securing of the airway.

Objective:

This study aimed to compare the performance of visualizing vocal cords and intubating with four different laryngoscopes while wearing full chemical protection equipment.

Setting: Anesthesiology department, RWTH Aachen University Hospital, Germany.

Method:

42 anesthetists participated in a manikin intubation scenario using four laryngoscopic intubation devices while wearing chemical protection gear, including body suit, rubber gloves, fire helmets and breathing apparatus. Participants intubated with the Macintosh (MAC), Airtraq (ATQ), Glidescope (GLS) and AP Advance (APA) laryngoscopes.

Outcome Measures:

The points of measurement were the time to complete intubation, visualization recorded with Cormack Lehane Score (CLS), as well as impairments caused by the protection equipment and assessed by questionnaire.

Results:

The time to tracheal intubation using the MAC was 31.4 ± 16.3 s, for ATQ it was 37.1 ± 28.2 s, for GLS it was 35.4 ± 21.6 s, and for APA it was 23.6 ± 14.5 s. Intubation with the APA was significantly faster than all the other devices in the overall study group ($P < 0.05$). Evaluating the visualization of the vocal cords revealed a significant improvement for the APA and GLS.

Conclusion

Despite restrictions from the equipment, the anesthetists intubated the manikin successfully within adequate time. The APA outperformed the other devices in time of intubation, and it has been evaluated as an easily manageable device for various degrees of experienced (low to high) anesthetists, with good visualization in scenarios that require chemical protection equipment.

Strengths and Limitations of this study:

- To the best of our knowledge until now, video laryngoscopes have not been sufficiently assessed or compared under the use of chemical protection equipment (CPE). This study aimed to compare three types of optical and video laryngoscopes with the standard Macintosh, examining their influence on the ease and speed of insertion of an endotracheal tube while wearing CPE.
- The AP Advance Laryngoscope (video-extended standard laryngoscopy) has proved to be an easily manageable device for anesthetists with various experience levels (low to high) and demonstrated beneficial visualization in scenarios requiring chemical protection equipment.
- A limitation of our study is the artificiality of difficult airway simulation with a manikin that could have determined the scenario and could have caused a training effect for the participants.
- The cohort of participants consisted of anesthetists of different levels of experience. We did not include paramedics in this study. This needs to be considered depending on the emergency medical services at place.
- Further investigation into efficacy and outcomes of securing the airway in real preclinical emergencies are required.

INTRODUCTION

Chemical, biological, radiation or nuclear (CBRN) hazards, due to industrial activities, transport accidents, warfare incidents, communicable diseases or even terrorist attacks, can endanger the public.[1] The uncontrolled release of toxic or contagious agents can lead to harmful inhalation and can cause respiratory failure, which can require on-site treatment and the retaining of a secure airway.[2-3] Immediate preclinical treatment, including early airway management, must be performed before decontamination or evacuation to avoid delayed intubation and the negative consequences for the patients' outcomes.[2,4] Hazards as the Ebola outbreak in West Africa in 2014 confronts hospital personnel with the need for intubating patients with respiratory failure while wearing full personal protection equipment (PPE) and use of video laryngoscopes.[5]

Impairment of manual dexterity, as well as limited view during intubation, is caused by wearing CBRN-PPE protection gear, including the rubber gloves, fire helmet, visor and hood.[6] This impairment adversely affects the successful performance of endotracheal intubation,[7] as well as oropharyngeal airway devices.[8] Furthermore, the positions of the patients, who are most likely to be lying on the floor, can cause prolonged intubation times and increase the numbers of failed intubation attempts.[9]

In past years, video-laryngoscopy has become increasingly popular in clinical and preclinical settings. Video-laryngoscopes reduce the time for endotracheal intubation and have significantly improved the success rates in manikins and humans, as well as for expectedly and unexpectedly difficult airways.[10,11] While indirect laryngoscopy with an optical laryngoscope as the Airtraq has been assessed and mainly failed against conventional intubation devices,[9] until now, video laryngoscopes have not been sufficiently assessed or compared under the use of CBRN-PPE. There are indications for benefits in visualization and time to tracheal intubation with video laryngoscopes while wearing CBRN-PPE as shown by Shin et.al. solely for the Pentax-AWS video laryngoscope.[12] Because video laryngoscopes have steep learning curves, despite brief instructional periods, they are attractive for investigating in hazard situations because of their improvements on the glottic view and their ease of use and learning intubation techniques.[13]

This study aimed to compare three types of laryngoscopes with the standard Macintosh laryngoscope, examining their influence on the ease and speed of insertion of an endotracheal tube while the operators were wearing CBRN-PPE. We further assessed the operators' subjective impressions of the devices, with a focus on their ability to adequately visualize the glottis.

METHODS

Participants

After approval from our local ethical board (Rhine-Westphalia University of Technology Aachen, Medical Faculty, Ethical Review Committee, Chairman: Prof. G. Schmalzing, Number of Approval: EK 115/12), 42 anesthetists from Aachen University Hospital, Germany, were invited to participate in the scenario of this comparative pilot study. The ethical committee waived the need to obtain written informed consent. All of the participants agreed to their performances being evaluated and anonymously used for scientific and educational purposes. The prerequisites for inclusion were the educational level of at least a first year residency in anesthesiology, implying a license to practice medicine.

Equipment

The Laerdal Resusci® Anne including the Anne Airway Trainer Update Kit (Laerdal Medical GmbH, Puchstein, Germany) was chosen as the manikin type for the study, and 7 mm endotracheal cuffed tubes were used for intubation (best fit). The manikin's airway was lubricated with silicon spray before and was cleaned after each insertion.

All of the tasks were completed while the participants were wearing ISOTEMP®-4000 chemical protection gear (type), including a complete body suit, rubber gloves, German DIN 14940 fire helmets and a 15k g self-contained breathing apparatus underneath (Dräger AG, Lübeck, Germany). Because use of the breathing apparatus requires special training and qualification, the participants did not connect it.

For comparison, the following 4 laryngoscopic intubation devices were selected: Macintosh (MAC) (conventional standard laryngoscope worldwide), Airtraq® A-011 (ATQ) (established single-use indirect laryngoscope offering optics and guiding channel) (Prodol Ltd., Vizcaya, Spain), the Glidescope® (GLS) (video laryngoscope with high quality of visualization on an external monitor, no guiding channel) (Verathon Medical B.V., Rennerod, Deutschland), and the A.P. Advance® (APA) (video extended standard laryngoscope with a directly attached display and certain blade options, including a difficult airway blade with a guiding channel) (Venner Medical GmbH, Dänischenhagen, Germany).

The device sizes and blades proved congruent and were fit to the manikin's specifics prior to testing. All of the devices were used with blades that were equivalent to the MAC blade size 3 and, for the A.P. Advance® specifically, the DAB (difficult airway blade). Intubation stylet standard CH (Charrière) 14 was applied for use of the conventional Macintosh. For the Glidescope®, according to the manufacturer's recommendations, the GlideRite® stylet was used for intubation. Because the Airtraq and AP Advance devices offer a guiding channel, no stylets were used.

Study protocol

All of the participants were familiar with all of the devices tested, based on previous "managing the difficult airway" education and subsequent manikin training. Before testing, all of the participants were once again instructed in the correct use of the laryngoscopes. The participants were not allowed to practice any tasks in their chemical protection gear. Two participants declared that they had former training experience with chemical protection gear.

In the scenario, the manikin was placed on the floor with all four devices preassembled and easily accessible, close to the manikins' head. (Fig. 1) All of the participants performed the complete process of intubation with each device, from grasping the device until the first ventilation with a bag-valve-mask. The process included inflation of the cuff.

Successful intubation was identified as regular chest extension of the manikin and was further verified by the authors after completion.

Data assessment

Anesthetists were assessed by the study team, and time for complete intubation was recorded from the entrance of each laryngoscope through the mouth until the moment of chest extension by the first ventilation. After completing all four intubations, the participants were asked to complete a questionnaire on the difficulties experienced during the performance. The questionnaire included restrictions in handling the devices caused by the gear, as well general comments about their handling, rated on a numeric scale from 1 (no restriction) to 7 (maximum restriction). To qualify the visualization of the vocal cords we used standard Cormack-Lehane (CL) classification I-IV for classic direct laryngoscopy. To obtain comparability between direct, indirect and video laryngoscopy and in absence of an alternative practical score we chose to keep CL to assess visualization from all devices, knowing that CLS is evaluated only for direct laryngoscopy. The data were collected over 11 days with an average daily assessment of 4 participants.

Statistical analysis

The results are presented as the means $\pm$ standard deviation ($M \pm SDs$) for continuous variables. Parameters were compared using the Friedman test as an alternative to ANOVA for non-parametric groups. Bonferroni-Dunn correction was used to determine the significance of the analysis. Comparisons were considered statistically significant when $P < 0.05$. Statistical analysis was conducted with Prism 5 software (version 5.0 for Mac OS X, Copyright© 1994-2009, the Graph Pad).

RESULTS

Data from 42 anesthetists (15 female and 27 male) were recorded. The participants were grouped according to their professional education in anesthesiology with residency experience of <2 years and <5 years or as specialist in anesthesiology with >5 years of experience (Table 1).

Table 1: Participant characteristics			
	Participants	male	female
Total	42	27	15
Residents 0-2 years	10	4	6
Residents 2-5 years	12	7	5
Specialists	20	16	4

Data are presented as numbers.

Wearing CBRN-PPE, all of the participants successfully intubated the manikin’s trachea with the MAC, GLS and APA. One inaccurate intubation was recorded for the ATQ. The time to tracheal intubation using the MAC was 31.7± 16.3 s (mean ± standard deviation) (range: 13.8 – 96.4), using the ATQ, it was 37.1 ± 28.2 s (12.1 – 156.0), using the GLS, it was 35.4 ± 21.6 s (13.5 – 93.3), and using the APA, it was 23.6 ± 14.5 s (11.4 – 99.4). Intubation using the APA was significantly faster than all the other devices in the overall study group (Table 2), (Fig. 2).

Table 2: Differences in time for intubation between the devices and levels of professional experience

Total Participants	MAC	ATQ	GLS	APA
Successful Intubation	42	41	42	42
Minimum	13,8	12,1	13,5	11,4
Maximum	96,4	156	93,3	99,4
Mean	31,4	37,1	35,4	23,6#
Std. Deviation	16,3	28,2	21,6	14,5
Residents < 2 years				
Successful Intubation	10	10	10	10
Minimum	16,3	17,3	20	14,2
Maximum	63,3	59,2	92,2	38,75
Mean	34,9	34,3	46,6	23,7*
Std. Deviation	13,8	13,7	25,7	8,6
Residents 2-5 years				
Successful Intubation	12	12	12	12
Minimum	16,8	22,3	17,9	17,9
Maximum	96,4	156	66,6	49,5
Mean	33,2	47,8	31,0	26,4
Std. Deviation	20,8	39,1	14,7	10,9
Specialists > 5 years				
Successful Intubation	20	19	20	20
Minimum	13,8	12,1	13,45	11,4
Maximum	78,1	99,3	93,3	99,4
Mean	28,5	31,9	32,4	21,9**
Std. Deviation	14,7	25,1	21,8	18,5
Data are presented as the numbers, time(s), and means $\pm$ SDs. #Tracheal intubation was significantly faster using the APA, compared to all of the other devices ($P < 0.05$). *Residents with experience of <2 years intubated significantly faster with APA than with GLS ($P < 0.05$). **Specialists with experience of >5 years intubated significantly faster with APA than with GLS or MAC ($P < 0.05$).				

Regarding the level of experience, residents with <2 years performed significantly faster ($P < 0.05$) intubation with the APA 23.7 ± 8.6 s, compared with the GLS 46.6 ± 25.7 s. For specialists with >5 years experience were significantly faster with the APA 21.9 ± 18.5 s compared with the GLS 32.4 ± 21.8 s and MAC 28.5 ± 14.7 s. (Table 2).

By answering the questionnaire, the participants subjectively assessed the visualization and restriction caused by the protection gear (Fig. 3) on a numeric scale from 1 (no restriction) to 7 (maximum restriction). Evaluation of the visualization revealed a Cormack-Lehane I for the MAC in 45%, an CL I for the ATQ in 62%, for the GLS in 88% and for the APA in 95%. A significant difference in the rank sum was detected for the APA (42.9) and GLS (37.5) ($P<0.05$) (Fig. 4).

Restriction of visualization was evaluated with the highest scores for the MAC (4.3), followed by the ATQ (4.2) and the GLS (2.7). Lowest restriction of view caused by the CBRN-PPE was recorded for the APA (2.4). Wearing PPE restricted the handling of the laryngoscopes for the MAC 3.8, ATQ 4.1, GLS 3.0 and APA 2.6. Compared to their former experience without wearing CBRN-PPE, participants assessed the restriction caused by PPE as 4.9 for the MAC, 4.5 for the ATQ, 3.3 for the GLS and 2.8 for the APA. (Fig. 3)

Within the free comment section major problems with the ATQ in adjusting the angle of view (41%) were expressed. For the MAC, obtaining a sufficient glottic view was mentioned by 45% as a major difficulty. Impairment of manual dexterity and fine motor skills was confirmed by 36 participants (86%), specifically for advancing the tube into the trachea (36%). To the question which laryngoscope they would prefer while wearing CBRN-PPE, 4 chose the MAC, 1 chose the ATQ, 16 chose the GLS, and 18 chose the APA. Three participants did not answer this question.

DISCUSSION

In this trial, we could demonstrate that video laryngoscopes were feasible, safe and easy to handle – even when wearing CBRN-PPE – on the manikin. Compared to conventional MAC laryngoscopy, video-laryngoscopes provided better intubation conditions for visualization despite participants looking through a glass shield integrated into the protective gear. Moreover, the APA outperformed the other laryngoscopes in terms of visualization and the time to tracheal intubation.

Tracheal intubation in preclinical situations should always be performed by the most experienced medical staff. Because chemical intoxication and environmental circumstances can complicate intubation, it must be assessed whether supraglottic airway devices (SADs) can secure the airway sufficiently until an experienced physician and equipment are available.

SADs (e.g. laryngeal mask) have been evaluated for use with CBRN-CPE, and their benefits are in the ease and speed of insertion. Additionally, less stringent training requirements have been confirmed.[14-16] Despite such advantages SADs, do not offer the same quality of separation of the respiratory and digestive tracts.[17] There is a lack of airway protection, particularly as positive pressure ventilation becomes relevant after inhalative chemical intoxication.[3] Thus, endotracheal intubation remains the gold standard in the early airway management of contaminated patients to avoid higher mortality rates from the hypoxia that is caused by delayed intubation.[2]

Video-laryngoscopy provides a better view of the vocal cords, a higher success rate, a shorter time to tracheal intubation and less need for optimizing maneuvers.[18] These devices are considered easy to use regardless of previous experience, and they have been recommended for difficult airway situations.[18-19] For preclinical settings the option to perform direct and video laryngoscopy with the same device has been emphasized.[20]

A steep learning curve enables personnel to perform successful tracheal intubations after short instructions.[11] A former investigation on the use of the Pentax-AWS video-laryngoscopes in CBRN-PPE scenario has shown that suited intubations with the Pentax-AWS required shorter time than unsuited intubation with MAC.[12]

Intubation performance with the different laryngoscopes

Inserting the tube through the glottis into the trachea is essential for performance analysis of the ease and speed of endotracheal intubation. This maneuver is mainly influenced by the view of the vocal cords, it certainly depends on the type of laryngoscope used for the intubation. Both, a guiding channel at the laryngoscope and the required intubation

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technique with visual and manual coordination can influence the outcome. Although most video-laryngoscopes establish high-quality visualization of the anatomy, it does not automatically ensure successful tracheal intubation.

Regarding speed and ease of intubation the APA performed best in his trial. The monitor is directly aligned to the familiar shape of a laryngoscope and enables anesthetists to apply well-known techniques of intubation, similar to standard MAC use. Additionally, the APA offers high-quality visualization, and the guiding channel of the blade directs the path for the tube into the trachea. These advantages of the APA can be transferred from a standard airway scenario,[21] on our scenario while wearing complete CBRN-PPE.

The mean intubation time with the GLS was comparable to ATQ, and both required more time than the standard MAC. Anesthetists with less than 2 years of experience performed slower with the GLS than with the MAC or ATQ. Despite the excellent quality of view on the external monitor, the unfamiliar technique of visual and manual coordination posed a challenge for less experienced participants. Although the survey revealed less restriction of view with the GLS (compared to the MAC and ATQ), it further indicated more limitations in advancing the tube into the trachea. Similar findings for the GLS have shown this effect under non-CPE-wearing conditions.[21]

In particular, the GLS required even greater dexterity under PPE-wearing conditions, and performance would have benefitted from training in the unfamiliar coordination needed for successful and fast performance.

The ATQ, with indirect laryngoscopic optics and clear guiding channel for the tube, showed the slowest performance for intubation. Nevertheless, it has been investigated as a feasible and fast device for routine tracheal intubation.[22] However, in our scenario with CBRN-PPE the ATQ could not demonstrate such efficiency. The fixed angle of the ATQ might have limited the adjustment for achieving adequate visualization of the vocal cords while the operator was protected by the visor of the helmet and suit, which would have additionally restricted the eye piece of the optical unit of the ATQ. These limitations were mentioned in the survey by more than 40% of the participants. Castle et. al. found the slowest intubation performance for the ATQ while wearing CBRN-PPE. In contrast to our findings, the study did not show interference from a helmet or visor.[14,15] Recently Claret et al. confirmed MAC to be superior to ATQ in speed, efficiency and overall ease of use.[23]

The MAC laryngoscope is a well-known reference device with confirmed usability under difficult circumstances. Although the intubation times showed adequate performance and were only exceeded by the APA, the anesthetists' assessments of the visualization and range of the restriction from CBRN-PPE was remarkable, as were the findings for the CL classification. The great range of experience with the MAC compensated for the lack of visualization, compared to the other devices.

Survey: Restrictions from CBRN-PPE

Participants confirmed that the protection gear, including rubber gloves, fire helmet, visor and hood, relevantly impaired the procedure of endotracheal intubation [6,7]. Fine motor skills were needed for advancing the tube into the trachea or inflation of the cuff and were claimed to be restricted mainly due to the rigidity and inflexibility of the rubber gloves.

Evaluating the glottic view, participants indicated less restriction from the gear and PPE for the APA vide-laryngoscope (Fig. 3). The high quality of the resulting image may explain this finding, as well the fact that APAs display is directly attached to the familiar form of the laryngoscope. Visualizing the vocal cords did not require averting one's eyes to a separate monitor, as with the GLS. To acquire an adequate view with the MAC, the participants had to align the angles among the glottis, laryngoscope and themselves, which were specifically restricted by the visor and hood of the protection gear and the position on the floor, as mentioned by 19 of 42 participants. Castel et al. showed that the ATQs' performance was *not* limited by the distance between the eyepiece and laryngoscope, which was created by the visor of the gear.[14,15] In contrast, 17 of 42 participants in our study specifically reported this problem as the reason for an impaired view while intubating with the ATQ.

Our findings were further reflected in the recorded Cormack-Lehane scores when used for indirect laryngoscopy and video-laryngoscopy. It has been shown that visualization benefits from using the APA prior to the GLS, ATQ, or MAC. We also noted that quality of visualization was not in agreement with time of intubation because the MAC outperformed the GLS and ATQ despite the poorer view.

Limitations

We recognize that the artificial scenario for difficult airway assessment was limited by the lack of proper simulation of collapsible soft tissues, secretion of blood, vomit or sputum and the use of rigid plastic, which determined the scenario and could have caused a training effect for the participants.[24] Additionally, chemical incidents in or out of hospital situations could be further determined by fog, fire, noise, dirt or any other external conditions. Considering the setting and conditions of our study while the participants wore chemical protection equipment and the manikin was lying on the floor, we defined this as a difficult airway scenario, without considering the standard anatomic glottic situation of the manikin. The American Society of Anesthesiologists (ASA) Task Force on Management of the Difficult Airway defined the difficult airway as a complex interaction among patient factors, the clinical setting, and the skills of the practitioner.[25]

Particularly for use of the APA, which consists of a plastic guiding channel on its downside, the friction of rigid plastic on the manikin's plastic larynx might have worsened the

outcomes. Furthermore, the difficult airway blade used for the APA might have facilitated the use of the device, while the MAC and GLS options were restricted to the use of a stylet. Additionally, the ATQ had a supporting guiding channel. We did not consider aspects such as battery life span or economic feasibility in our study.

Conclusion

The APA has proved to be an easily manageable device for anesthetists with various experience levels (low to high) and demonstrated beneficial visualization in scenarios requiring chemical protection equipment. Emergency scenarios require devices that are not only easy to use but are also well known by the staff. Therefore, the MAC remains a reliable option for anesthetists in the field, even under complicated conditions. The use of video-laryngoscopes, such as the APA, under CBRN-PPE circumstances requires further investigation into the efficacy and outcomes of securing the airway.

Abbreviations:

AP Advance	- APA
Airtraq	- ATQ
Chemical, biological, radiation or nuclear	- CBRN
Personal Protection Equipment	- PPE
Chemical protection equipment	- CPE
Cormack Lehane Score	- CLS
Glidescope	- GLS
Macintosh	- MAC
Standard deviation	- SD
Supraglottic airway device	- SAD

Legend for tables and figures:

- Table 1: Participant characteristics
- Table 2: Intubation times for devices and levels of professional experience
- Fig.1: Picture of participant wearing CBRN-PPE using the Airtraq optical laryngoscope for intubation.
- Fig.2: Intubation Time of all devices
- Fig.3: Questionnaire Data: Restriction from chemical protection equipment
- Fig.4: Visualization by Intubation Score

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Competing Interests

GS received fees for general lectures in "difficult airway management" from the German Airtraq® distributor Medisize Deutschland GmbH, Neunkirchen-Seelscheid, Germany. The authors declare that they have no competing interests

Authors Contributions:

HS and NZ equally developed the conception and design, performed the interpretation of the data and drafted and finalized the manuscript. GS and KD participated in the data collection and interpretation. CS, MC, and RR critically revised the manuscript and supervised the statistical analysis. RR and GS critically revised the manuscript, and GS coordinated the trial. All of the authors read and approved the final manuscript.

Data Sharing Statement:

No additional Data available.

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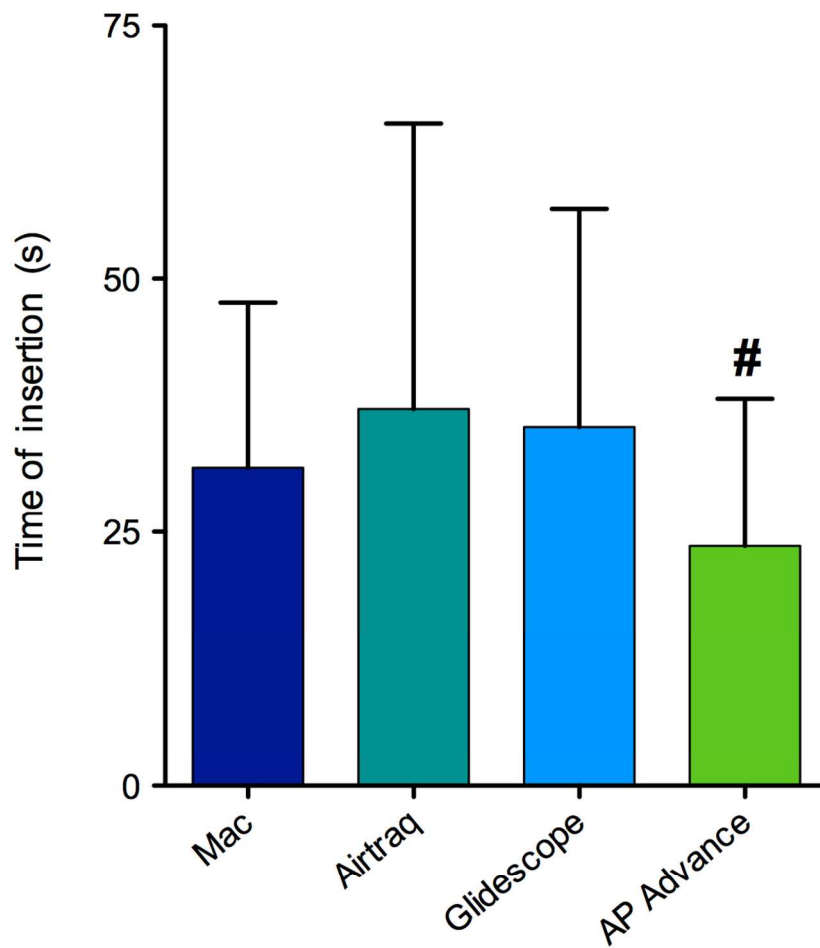
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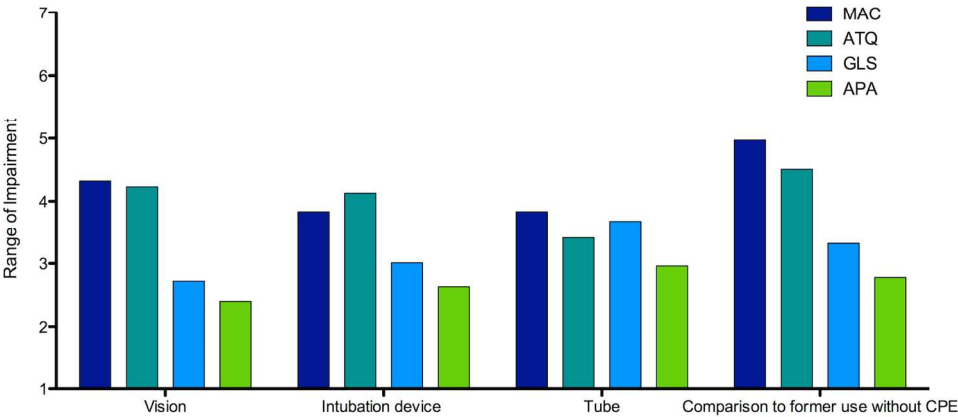
Picture of participant wearing CBRN-PPE using the Airtraq optical laryngoscope for intubation.
70x93mm (300 x 300 DPI)

Fig. 2: Intubation time of all devices.
Data are presented as means $\pm$ SD.
marks significant difference ($p < 0.05$)



Intubation Time of all devices
100x135mm (300 x 300 DPI)

Fig.3: Questionnaire Data: Restrictions from chemical protection equipment
Values recorded on a Likert-Scale from 1 (none) to 7 (maximum restriction) are presented as mean.
CPE = Chemical Protection Equipment



Presented questions:
- Vision: Did wearing CPE restrict your view of the vocal cords?
- Intubation device: Did wearing CPE restrict the handling of the intubation device?
- Tube: Did wearing CPE restrict your ability to advance the tube into the trachea?
- Rating the restriction of CPE on the devices compared to former use of the devices without CPE

Questionnaire Data: Restriction from chemical protection equipment
160x102mm (300 x 300 DPI)

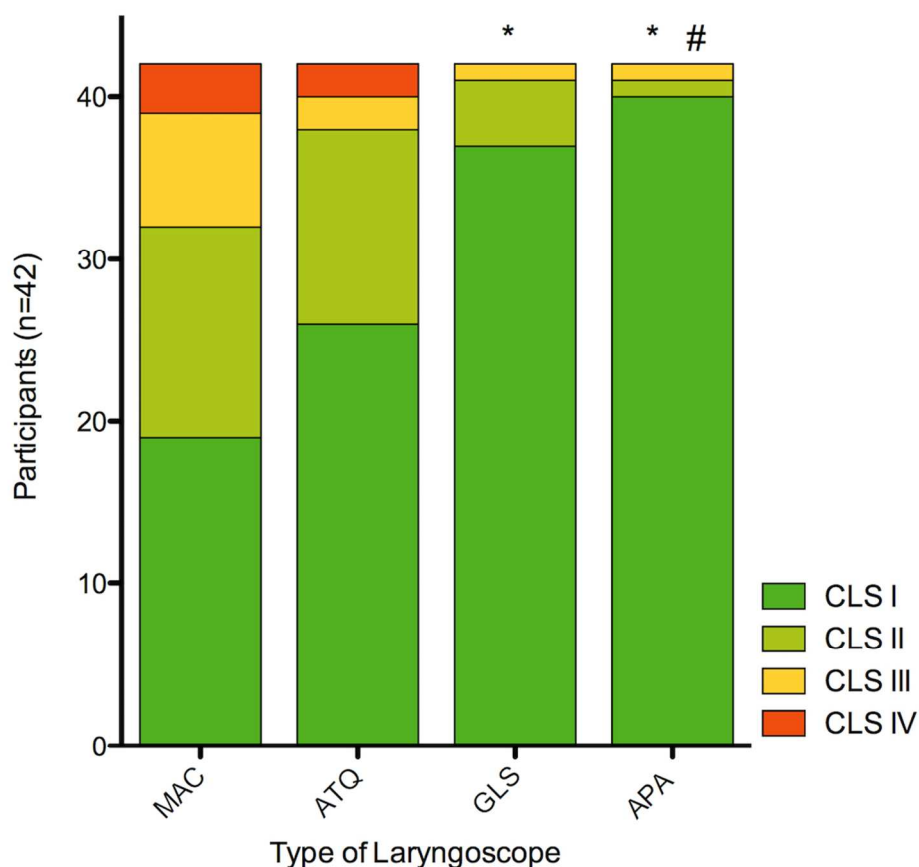


Fig. 4 Visualization by Cormack Lehane Score:

* GLS and APA show significant difference in rank sum compared to MAC ($p < 0.05$).

APA shows significant difference in rank sum compared to ATQ ($p < 0.05$).

MAC = Macintosh, ATQ = Airtraq, GLS = Glidescope, APA = AP Advance

Visualization by Intubation Score
99x108mm (300 x 300 DPI)

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Intubation performance using different laryngoscopes while wearing chemical protective equipment – a manikin study

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Title:

Intubation performance using different laryngoscopes while wearing chemical protective equipment – a manikin study

Authors:

H. Schröder^{1,2}, N. Zoremba^{1,3}, R. Rossaint¹, K. Deusser⁴, C. Stoppe¹, M. Coburn¹, A. Rieg¹, G. Schälte¹

- (1) Department of Anesthesiology (Chair: Prof. Rolf Rossaint), Uniklinik RWTH Aachen University, Germany
- (2) Department of Operative Intensive Care and Intermediate Care (Chair: Prof. Gernot Marx) Uniklinik RWTH Aachen University, Germany
- (3) Department of Anesthesiology and Intensive Care, St. Elisabeth Hospital Gütersloh, Germany
- (4) Department of Internal Medicine, Medizinisches Zentrum Städteregion Aachen, Germany

Correspondence to:

Gereon Schälte

Department of Anesthesiology
University Hospital Aachen, RWTH Aachen University
Pauwelsstraße 30
D-52074 Aachen
Germany

Phone: 49 (0) 241 – 80 88179
Fax: + 49 (0) 241 – 80 82406
E-mail: gschaelte@ukaachen.de

ABSTRACT

Objectives:

This study aimed to compare visualization of the vocal cords and performance of intubation by anesthetists using four different laryngoscopes while wearing full chemical protective equipment.

Setting:

Medical Simulation Center of a University Hospital, Department of Anesthesiology

Participants:

42 anesthetists (15 females and 27 males) completed the trial. The participants were grouped according to their professional education as anesthesiology residents with experience of <2 years or <5 years or as anesthesiology specialists with experience of >5 years

Interventions:

In a manikin scenario participants performed endotracheal intubations with four different direct and indirect laryngoscopes (Macintosh (MAC), Airtraq (ATQ), Glidescope (GLS) and AP Advance (APA)), while wearing chemical protective gear, including a body suit, rubber gloves, a fire helmet and a breathing apparatus.

Primary and secondary outcome measures:

With respect to the manikin setting time to complete "endotracheal intubation" was defined as primary endpoint. Glottis visualization (according to the Cormack-Lehane Score (CLS), and impairments caused by the protective equipment, were defined as secondary outcome measures.

Results:

The times to tracheal intubation were using the MAC (31.4 s; 95% CI; 26.6-36.8), ATQ (37.1 s; 95% CI; 28.3-45.9), GLS (35.4 s; 95% CI 28.7-42.1), and APA (23.6 s; 95% CI 19.1-28.1), respectively. Intubation with the APA was significantly faster compared with all of the other devices examined among the total study population ($P<0.05$). A significant improvement in visualization of the vocal cords was reported for the APA compared with the GLS

Conclusions

Despite the restrictions caused by the equipment, the anesthetists intubated the manikin successfully within adequate time. The APA outperformed the other devices in the time to intubation, and it has been evaluated as an easily manageable device for anesthetists with varying degrees of experience (low to high), providing good visualization in scenarios that require the use of chemical protective equipment.

Strengths and limitations of this study:

- To the best of our knowledge, video laryngoscopes have not been sufficiently assessed or compared under the use of chemical protective equipment (CPE). This study aimed to compare three types of optical and video laryngoscopes with the standard Macintosh, examining their influences on the ease and speed of insertion of an endotracheal tube while wearing CPE.
- The AP Advance laryngoscope (video-extended standard laryngoscope) has been proven to be an easily manageable device for anesthetists with varying experience levels (low to high) and has been demonstrated to allow for adequate visualization in scenarios requiring the use of CPE.
- A limitation of our study is the artificiality of difficult airway simulation using a manikin, which could have affected the scenario and had a training effect on the participants.
- The cohort of participants consisted of anesthetists with different levels of experience. We did not include paramedics in this study. This aspect needs to be considered depending on the emergency medical service available.
- Further investigation into the efficacy and outcomes of securing the airway in real prehospital emergencies are required.

INTRODUCTION

Chemical, biological, radiation or nuclear (CBRN) hazards due to industrial activities, transport accidents, warfare incidents, communicable diseases or even terrorist attacks can endanger the public.[1] The uncontrolled release of toxic or contagious agents can lead to harmful inhalation and cause respiratory failure, which can require on-site treatment and the retaining of a secure airway.[2-3] Immediate prehospital treatment, including early airway management, must be performed before decontamination or evacuation to avoid delayed intubation and the negative consequences on patients' outcomes.[2,4] Hazards such as the Ebola outbreak in West Africa in 2014 confront hospital personnel with the need to intubate patients with respiratory failure using a video laryngoscope while wearing full personal protective equipment (PPE).[5]

The wearing of CBRN-PPE gear, including rubber gloves and a fire helmet, visor and hood, results in impaired manual dexterity and limited vision during intubation.[6] This impairment adversely affects the successful performance of endotracheal intubation,[7] as well as the use of oropharyngeal airway devices.[8] Furthermore, the positions of patients, who are most likely to be lying on the floor, can result in prolonged intubation times and increase the number of failed intubation attempts.[9]

In the past years, video laryngoscopy has become increasingly popular in clinical and prehospital settings. The use of a video laryngoscope reduces the duration of endotracheal intubation and significantly improves the intubation success rates in manikins and humans, as well as in patients with expectedly and unexpectedly difficult airways.[10,11] While indirect laryngoscopy with an optical laryngoscope such as the Airtraq has been assessed and has been mainly demonstrated to be inferior to the use of conventional intubation devices,[9] until now, the use of a video laryngoscope while wearing CBRN-PPE has not been sufficiently evaluated. Benefits of using a video laryngoscope while wearing CBRN-PPE on intubation have been reported by Shin et al. in relation to visualization and time to tracheal intubation, solely for a Pentax-AWS video laryngoscope.[12] Only a brief instructional period is required to learn to operate video laryngoscopes; thus, they are attractive for use in hazardous situations because they not only allow for adequate visualization of the glottis but are also relatively easy to use.[13]

This study aimed to compare three types of laryngoscopes with the standard Macintosh (MAC) laryngoscope, examining their influences on the ease and speed of insertion of an endotracheal tube by operators wearing CBRN-PPE. We further assessed the operators'

subjective impressions of the devices, with a focus on the ability to adequately visualize the glottis.

METHODS

Participants

After obtaining approval from our local ethical board (Rhine-Westphalia University of Technology Aachen, Medical Faculty, Ethical Review Committee, Chairman: Prof. G. Schmalzing, Number of Approval: EK 115/12), 42 anesthetists from Aachen University Hospital, Germany, were invited to participate in this comparative pilot study. The ethical committee waived the need to obtain written informed consent. All of the participants agreed to have their performances evaluated and anonymously used for scientific and educational purposes. The prerequisite for inclusion was an educational level of at least a first year residency in anesthesiology, implying the possession of a license to practice medicine.

Equipment

A Laerdal Resusci® Anne, including an Anne Airway Trainer Update Kit (Laerdal Medical GmbH, Puchstein, Germany), was chosen as the manikin type for this study, and 7 mm endotracheal cuffed tubes were used for intubation (best fit). The manikin's airway was lubricated with silicon spray before and cleaned after each insertion.

All of the tasks were completed while the participants were wearing ISOTEMP®-4000 chemical protection gear (type), including a complete body suit, rubber gloves, and German DIN 14940 fire helmets with a 15 kg self-contained breathing apparatus underneath (Dräger AG, Lübeck, Germany). Because the use of the breathing apparatus requires special training and qualification, the participants did not connect it.

For comparison, the following 4 laryngoscopic intubation devices were selected: an MAC (a conventional standard laryngoscope used worldwide), an Airtraq® A-011 (ATQ) (an established single-use indirect laryngoscope offering optics and a guiding channel) (Prodol Ltd., Vizcaya, Spain), a Glidescope® (GLS) (a video laryngoscope that allows for high-quality visualization on an external monitor, with no guiding channel) (Verathon Medical B.V., Rennerod, Deutschland), and an AP Advance® (APA) (video extended standard laryngoscope with a directly attached display and certain blade options, including a difficult airway blade (DAB), with a guiding channel) (Venner Medical GmbH, Dänischenhagen, Germany).

The device sizes and blades were found to be congruent and were fit to the manikin's specifics prior to testing. All of the devices were used with blades that were equivalent to a size 3 MAC blade and, for the APA specifically, a DAB. A standard intubation stylet (14

Charrière (CH)) was applied for use of the conventional MAC. For the GLS, a GlideRite® stylet was used for intubation according to the manufacturer's recommendations. No stylets were used for the ATQ and APA devices because they offer a guiding channel.

Study protocol

All of the participants were familiar with all of the devices tested, based on the receipt of previous "managing the difficult airway" education and subsequent manikin training. Before testing, all of the participants were once again instructed on the correct techniques for using the laryngoscopes. The participants were not allowed to practice any tasks in their chemical protection gear. Two participants declared that they had former training experience with chemical protective gear.

In the scenario, the manikin was placed on the floor with all four devices preassembled and easily accessible, close to the manikin's head (Fig. 1). All of the participants performed the complete process of intubation with each device, from the grasping of the device until the first ventilation with a bag-valve mask. The process included inflation of the cuff.

Successful intubation was identified as regular chest extension of the manikin and was further verified by the authors after completion. The order of devices 1 to 4 (MAC, ATQ, GLS, and APA, respectively) was rotated for every second participant, from the sequence 1,2,3,4 to 2,3,4,1 to 3,4,1,2 and finally to 4,1,2,3 to compensate for potential learning bias.

Data assessment

The anesthetists were assessed by the study team, and the time to complete intubation was recorded from the entrance of each laryngoscope through the mouth until the moment of chest extension by the first ventilation. After completion of all four intubations, the participants were administered a questionnaire on the difficulties experienced during the performance. The questionnaire included restrictions in handling the devices caused by the gear, as well general comments about their handling, rated on a numeric scale from 1 (no restriction) to 7 (maximum restriction). To qualify the visualization of the vocal cords, we used the standard Cormack-Lehane (CL) classifications of I-IV for classic direct laryngoscopy. To achieve comparability between direct, indirect and video laryngoscopy in the absence of an alternative practical score, we chose to use the CL classification to assess visualization with all devices, although it is typically used only for direct laryngoscopy. The data were collected over 11 days, with an average daily assessment of 4 participants.

Statistical analysis

The results are presented as the mean $\pm$ standard deviation (M $\pm$ SD) for the continuous variables. The parameters were compared using the Friedman test as an alternative to

ANOVA for non-parametric groups. Bonferroni-Dunn correction was used to determine the significance of data. Comparisons were considered statistically significant at a $P<0.05$. Statistical analysis was conducted with Prism 5 software (version 5.0 for Mac OS X, copyright© 1994-2009, GraphPad).

RESULTS

Data were recorded for 42 anesthetists (15 females and 27 males). The participants were grouped according to their professional education as anesthesiology residents with experience of <2 years or <5 years or as anesthesiology specialists with experience of >5 years (Table 1).

Table 1: Participant characteristics			
	Participants	Male	Female
Total	42	27	15
Residents 0-2 years	10	4	6
Residents 2-5 years	12	7	5
Specialists	20	16	4
Data are presented as numbers.			

Wearing CBRN-PPE, all of the participants successfully intubated the manikin’s trachea with the MAC, GLS and APA. One inaccurate intubation was recorded for the ATQ. The time to tracheal intubation using the MAC was 31.7 ± 16.3 s (mean $\pm$ standard deviation) (range: 13.8 – 96.4), and it was 37.1 ± 28.2 s (12.1 – 156.0) using the ATQ, 35.4 ± 21.6 s (13.5 – 93.3) using the GLS, and 23.6 ± 14.5 s (11.4 – 99.4) using the APA. Intubation using the APA was significantly faster compared with all of the other devices among the total study population (Table 2) (Fig. 2).

Table 2: Differences in the time for intubation according to the device used and level of professional experience

Total Participants	MAC	ATQ	GLS	APA
Successful Intubation	42	41	42	42
Minimum	13.8	12.1	13.5	11.4
Maximum	96.4	156	93.3	99.4
Mean	31.4	37.1	35.4	23.6#
Std. Deviation	16.3	28.2	21.6	14.5
Residents <2 years				
Successful Intubation	10	10	10	10
Minimum	16.3	17.3	20	14.2
Maximum	63.3	59.2	92.2	38.75
Mean	34.9	34.3	46.6	23.7*
Std. Deviation	13.8	13.7	25.7	8.6
Residents 2-5 years				
Successful Intubation	12	12	12	12
Minimum	16.8	22.3	17.9	17.9
Maximum	96.4	156	66.6	49.5
Mean	33.2	47.8	31.0	26.4
Std. Deviation	20.8	39.1	14.7	10.9
Specialists >5 years				
Successful Intubation	20	19	20	20
Minimum	13.8	12.1	13.45	11.4
Maximum	78.1	99.3	93.3	99.4
Mean	28.5	31.9	32.4	21.9**
Std. Deviation	14.7	25.1	21.8	18.5
Data are presented as numbers, time(s), and means $\pm$ SDs. #Tracheal intubation was significantly faster using the APA compared to all of the other devices ($P<0.05$). *Residents with experience of <2 years performed intubation significantly faster with the APA than with the GLS ($P<0.05$). **Specialists with experience of >5 years performed intubation significantly faster with the APA than with the GLS or MAC ($P<0.05$).				

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Regarding the level of experience, the residents with <2 years experience performed intubation significantly faster ($P<0.05$) with the APA compared with the GLS (23.7 ± 8.6 s versus 46.6 ± 25.7 s, respectively). The specialists with >5 years experience were significantly faster with the APA compared with the GLS and MAC (21.9 ± 18.5 s versus 32.4 ± 21.8 s and 28.5 ± 14.7 s, respectively) (Table 2).

The participants completed the questionnaire by subjectively assessing the restrictions of visualization and laryngoscope handling caused by the protective gear (Fig. 3) using a numeric scale ranging from 1 (no restriction) to 7 (maximum restriction). The questionnaire results showed that 45% of the participants achieved CL-I visualization with the MAC, in addition to 62% with the ATQ, 88% with the GLS and 95% with the APA. A significant difference in the rank sum was detected between the APA (42.9) and GLS (37.5) ($P<0.05$) (Fig. 4).

Evaluation of restriction of visualization caused by the CBRN-PPE resulted in the highest score (indicating the greatest restriction) for the MAC (4.3), followed by the ATQ (4.2) and the GLS (2.7), and the lowest score was observed for the APA (2.4). Wearing PPE restricted the handling of the MAC, ATQ, GLS, and APA laryngoscopes with associated scores of 3.8, 4.1, 3.0 and 2.6, respectively. In addition, the participants compared their former experiences with using these laryngoscopes without wearing CBRN-PPE with their current experiences and scored the restriction caused by the PPE as 4.9 for the MAC, 4.5 for the ATQ, 3.3 for the GLS and 2.8 for the APA (Fig. 3).

Within the free comment section of the questionnaire, the participants indicated that they had experienced major problems in adjusting the angle of view (41%) for the ATQ. In addition, 45% of the participants reported major difficulty with obtaining a sufficient glottic view using the MAC. Impairments of manual dexterity and fine motor skills were confirmed by 36 participants (86%), specifically for advancing the tube into the trachea (36%). In response to the question regarding which laryngoscope they would prefer to use while wearing CBRN-PPE, 4 chose the MAC, 1 chose the ATQ, 16 selected the GLS, and 18 opted for the APA. Three participants did not answer this question.

DISCUSSION

In this trial, we have demonstrated that video laryngoscopes are feasible, safe and easy to handle – even when wearing CBRN-PPE – for use on a manikin. Compared to conventional MAC laryngoscopy, the video laryngoscopes allowed for better visualization during intubation, despite the fact that the participants were looking through a glass shield integrated into the protective gear. Moreover, the APA outperformed the other laryngoscopes in terms of visualization and the time to tracheal intubation.

Tracheal intubation in prehospital situations should always be performed by the most experienced medical staff. Because chemical intoxication and environmental circumstances can complicate intubation, it must be assessed whether a supraglottic airway device (SAD) can secure the airway sufficiently until an experienced physician and equipment are available.

SADs (e.g. a laryngeal mask) have been evaluated for use with CBRN-chemical protective equipment (CPE), and their benefits include ease of use and speed of insertion. Additionally, less stringent training requirements for their use have been confirmed.[14-16] Despite their advantages, SADs do not offer the same quality of separation of the respiratory and digestive tracts.[17] Further, they do not provide adequate airway protection, particularly during positive pressure ventilation after respiratory intoxication.[3] Thus, endotracheal intubation remains the gold standard in the early airway management of contaminated patients to avoid the higher mortality rate resulting from the hypoxia caused by delayed intubation.[2]

Video laryngoscopy provides a better view of the vocal cords, a higher success rate, a shorter time to tracheal intubation and less need for optimizing maneuvers.[18] These devices are considered easy to use regardless of previous experience, and they have been recommended for difficult airway situations.[18-19] In prehospital settings, the option to perform both direct and video laryngoscopy with the same device has been emphasized.[20]

A short learning curve enables personnel to perform successful tracheal intubations with limited instruction.[11] A previous study of the use of a Pentax-AWS video laryngoscope in a CBRN-PPE scenario has shown that suited intubation with a Pentax-AWS can be performed in a shorter period of time than unsuited intubation with an MAC.[12]

Intubation performances with the different laryngoscopes

Insertion of a tube through the glottis into the trachea is essential for performance analysis of the ease and speed of endotracheal intubation. This success of this maneuver is mainly

influenced by the view of the vocal cords, and it certainly depends on the type of laryngoscope used for intubation. Both, the presence or absence of a guiding channel on a laryngoscope and the relevant intubation technique, requiring visual and manual coordination, can influence the outcome. Although most video laryngoscopes provide high-quality visualization of the anatomy, successful tracheal intubation is not guaranteed.

The APA performed the best in this trial with regard to the speed and ease of intubation. The monitor of the APA is directly aligned to the laryngoscope with its familiar shape, enabling anesthetists to apply well-known intubation techniques, similar to the standard MAC. Additionally, the APA offers high-quality visualization, and the guiding channel of the blade directs the path for the tube into the trachea. These advantages of the APA can be transferred from a standard airway scenario[21] to our scenario involving the wearing of complete CBRN-PPE.

The mean intubation time with the GLS was comparable to that with the ATQ, and both of these laryngoscopes required more time than the standard MAC. Anesthetists with less than 2 years of experience performed intubation slower with the GLS than with the MAC or ATQ. Despite the excellent quality of the view on the external monitor, the visual and manual coordination required by the unfamiliar technique posed a challenge to the less experienced participants. Although the survey revealed that vision was less restricted with the GLS (compared to the MAC and ATQ), it further indicated limitations of the GLS in advancing the tube into the trachea. Similar findings for the GLS have been demonstrated under non-CPE-wearing conditions.[21]

In particular, the GLS requires even greater dexterity under PPE-wearing conditions, and the participants' performances would have benefitted from a training period to familiarize them with the coordination necessary for successful and fast intubation with this laryngoscope. The use of the ATQ, with indirect laryngoscopy optics and a clear guiding channel for the tube, has been investigated as a feasible device for performing routine tracheal intubation rapidly.[22] However, in our scenario involving the wearing of CBRN-PPE, this laryngoscope did not demonstrate such efficiency. In fact, its use resulted in the slowest intubation times. The fixed angle of the ATQ might have limited the possible adjustments made by the operators for achieving adequate visualization of the vocal cords while they were protected by the visor of the helmet and suit, which would have additionally restricted the use of the eye piece of the optical unit. These limitations were mentioned in the survey by more than 40% of the participants. Castle et al. observed the longest intubation time for participants using the ATQ while wearing CBRN-PPE. However, in contrast with our findings, their study did not describe interference from a helmet or visor.[14,15] Recently, Claret et al. have confirmed that the MAC is superior to the ATQ in terms of speed, efficiency and overall ease of use.[23]

The MAC laryngoscope is a well-known reference device with confirmed utility under difficult circumstances. Although the intubation times for the MAC were adequate and were only exceeded by those for the APA in this study, the anesthetists' experienced restrictions of visualization and laryngoscope handling while wearing CBRN-PPE, as demonstrated by the CL classification and questionnaire results. Notably, the anesthetists' greater experience with using the MAC compensated for the lack of visualization compared to the other devices.

Survey: Restrictions from CBRN-PPE

The participants confirmed that the protective gear, including rubber gloves and a fire helmet, visor and hood, impaired the performance of endotracheal intubation [6,7]. Fine motor skills were needed for advancing the tube into the trachea and for inflation of the cuff, and the participants claimed to be restricted mainly due to the rigidity and inflexibility of the rubber gloves.

With regard to visualization of the glottis, the participants indicated that they were less restricted by the PPE gear when using the APA video laryngoscope (Fig. 3). The high quality of the resulting image may explain this finding, as well as the fact that the display of the APA is directly attached to the familiar body of the laryngoscope. Visualization of the vocal cords does not require averting one's eyes to a separate monitor, similar to the GLS. To acquire an adequate view with the MAC, the participants had to align the glottis, laryngoscope and themselves, but they were specifically restricted by the visor and hood of the protective gear and the position of the manikin on the floor, as mentioned by 19 of 42 participants. Castel et al. have shown that performing intubation with the ATQ is *not* limited by the distance between the eyepiece and laryngoscope, which is increased by the visor of the gear.[14,15] In contrast, 17 of 42 participants in our study specifically reported this distance as the reason for an impaired view while intubating with the ATQ.

Our findings were further supported by the recording of CLSs for the use of indirect laryngoscopy and video laryngoscopy. It has been shown that the best visualization is achieved using the APA, followed by the GLS, ATQ, and MAC. We also found that the quality of visualization was not correlated with the time of intubation because the MAC outperformed the GLS and ATQ despite the poorer visualization.

Limitations

We recognize that the artificial scenario for difficult airway assessment was limited by the lack of proper simulation of collapsible soft tissues and secretion of blood, vomit or sputum, as well as the use of rigid plastic, which established the scenario and could have had a training effect on the participants.[24] Additionally, chemical incidents occurring in or out of hospital can be further assessed according to the presence of fog, fire, noise, dirt or other

external conditions. Considering the setting and conditions of our study, with the participants wearing CPE and the manikin lying on the floor, we defined this as a difficult airway scenario without considering the standard anatomic glottic location of the manikin. The American Society of Anesthesiologists (ASA) Task Force on Management of the Difficult Airway has defined the difficult airway as a complex interaction among patient factors, the clinical setting, and the skills of the practitioner.[25]

Particularly with the use of the APA, which consists of a plastic guiding channel on its downside, the friction of rigid plastic on the manikin’s plastic larynx might have worsened the outcome. Furthermore, the DAB of the APA might have facilitated the use of the device, while the MAC and GLS options were restricted to the use of a stylet. In addition, the ATQ has a guiding channel for support. Moreover, we did not consider the blinding of the observers to the tested devices, as it was not possible to acquire a “neutral” image quality that would prevent the experienced observer from determining the device used. We also did not consider aspects such as battery life span or economic feasibility in our study. Due to the lack of a reliable quantitative parameter for the primary goal of success of, we chose “time to successful intubation” as our best descriptive term.

Conclusions

The APA has been demonstrated to be an easily manageable device for anesthetists with various experience levels (low to high) that can be used to achieve adequate visualization in scenarios requiring CPE. Emergency scenarios require devices that are not only easy to use but are also well known by staff. Therefore, the MAC remains a reliable option for anesthetists in the field, even under complicated conditions. The findings of this study serve as a foundation for further clinical studies on outcomes of securing the airway using video laryngoscopes, such as the APA.

Abbreviations:

AP Advance	- APA
Airtraq	- ATQ
Chemical, biological, radiation or nuclear	- CBRN
Personal Protective Equipment	- PPE
Chemical protective equipment	- CPE
Cormack-Lehane Score	- CLS
Glidescope	- GLS
Macintosh	- MAC
Standard deviation	- SD
Supraglottic airway device	- SAD

Legend for tables and figures:

Table 1: Participant characteristics

Table 2: Intubation times for devices and levels of professional experience

Fig. 1: Picture of participant wearing CBRN-PPE and using an Airtraq optical laryngoscope for intubation

Fig. 2: Intubation times for all devices

Fig. 3: Questionnaire data: restriction caused by chemical protective equipment

Fig. 4: Visualization according to intubation scores

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Competing Interests

GS received fees for general lectures in "difficult airway management" from the German Airtraq® distributor Medisize Deutschland GmbH, Neunkirchen-Seelscheid, Germany. The authors declare that they have no competing interests.

Authors' Contributions:

HS and NZ equally developed the conception and design of the study, performed the data interpretation and drafted and finalized the manuscript. GS and KD participated in the data collection and interpretation. CS, MC, and RR critically revised the manuscript and supervised statistical analysis. RR and GS critically revised the manuscript, and GS initiated, coordinated and supervised the trial. All of the authors read and approved the final manuscript.

Data Sharing Statement:

No additional data are available.

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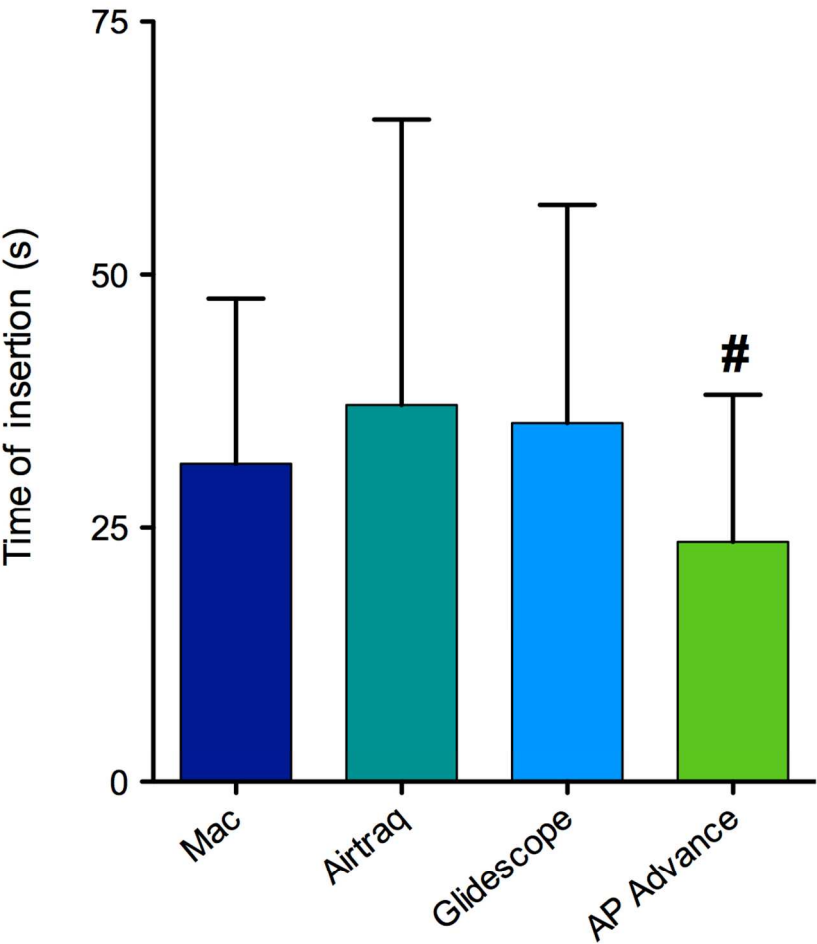
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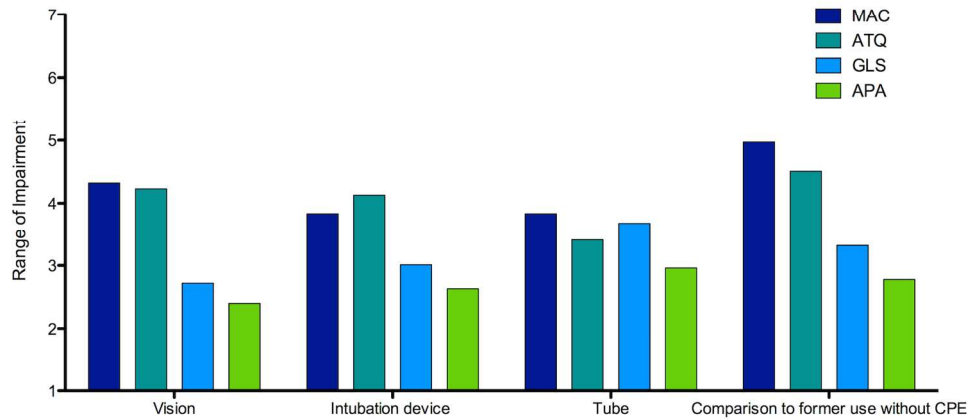
Picture of participant wearing CBRN-PPE using the Airtraq optical laryngoscope for intubation.
70x93mm (300 x 300 DPI)

Fig. 2: Intubation time of all devices.
Data are presented as means $\pm$ SD.
marks significant difference ($p < 0.05$)



Intubation Time of all devices
100x135mm (300 x 300 DPI)

Fig.3: Questionnaire Data: Restrictions from chemical protection equipment
Values recorded on a Likert-Scale from 1 (none) to 7 (maximum restriction) are presented as mean.
CPE = Chemical Protection Equipment



Presented questions:
- Vision: Did wearing CPE restrict your view of the vocal cords?
- Intubation device: Did wearing CPE restrict the handling of the intubation device?
- Tube: Did wearing CPE restrict your ability to advance the tube into the trachea?
- Rating the restriction of CPE on the devices compared to former use of the devices without CPE

Questionnaire Data: Restriction from chemical protection equipment
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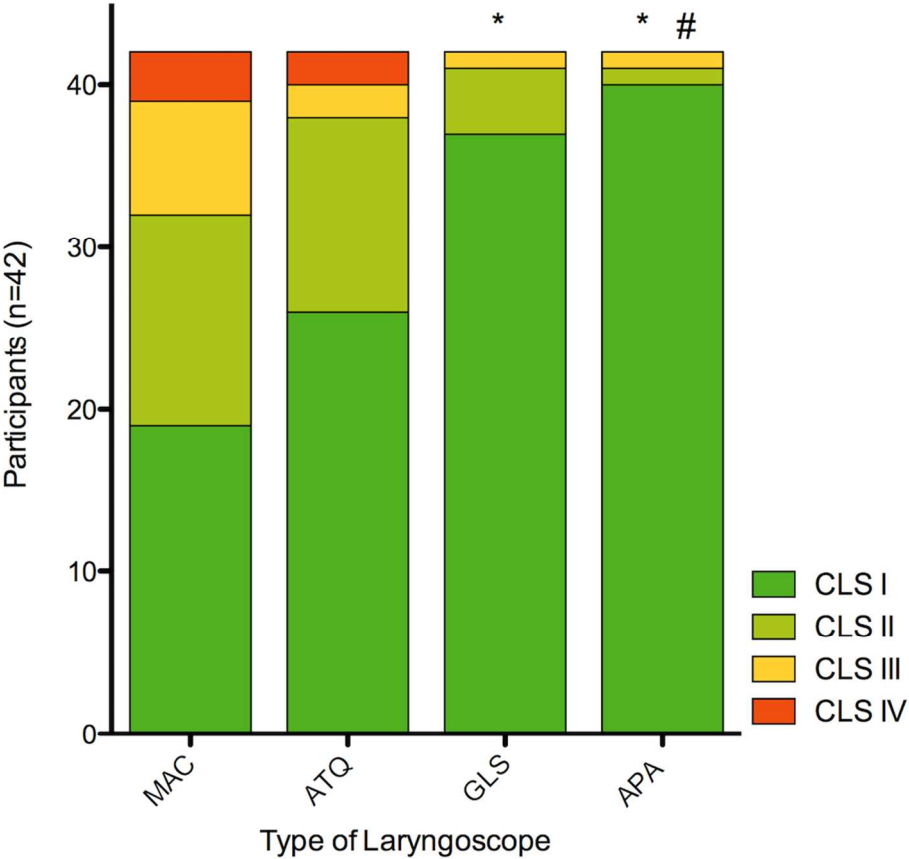


Fig. 4 Visualization by Cormack Lehane Score:
* GLS and APA show significant difference in rank sum compared to MAC ($p < 0.05$).
APA shows significant difference in rank sum compared to ATQ ($p < 0.05$).
MAC = Macintosh, ATQ = Airtraq, GLS = Glidescope, APA = AP Advance

Visualization by Intubation Score
99x108mm (300 x 300 DPI)

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Intubation performance using different laryngoscopes while wearing chemical protective equipment – a manikin study

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Title:

Intubation performance using different laryngoscopes while wearing chemical protective equipment – a manikin study

Authors:

H. Schröder^{1,2}, N. Zoremba^{1,3}, R. Rossaint¹, K. Deusser⁴, C. Stoppe¹, M. Coburn¹, A. Rieg¹, G. Schälte¹

- (1) Department of Anesthesiology (Chair: Prof. Rolf Rossaint), University Hospital RWTH Aachen, Aachen, Germany
- (2) Department of Operative Intensive Care and Intermediate Care (Chair: Prof. Gernot Marx) University Hospital RWTH Aachen, Aachen, Germany
- (3) Department of Anesthesiology and Intensive Care, St. Elisabeth Hospital, Gütersloh, Germany
- (4) Department of Internal Medicine, Aachen District Medical Center, Würselen, Germany

Correspondence to:

Gereon Schälte

Department of Anesthesiology
University Hospital Aachen, RWTH Aachen University
Pauwelsstraße 30
D-52074 Aachen
Germany

Phone: 49 (0) 241 – 80 88179
Fax: + 49 (0) 241 – 80 82406
E-mail: gschaelte@ukaachen.de

ABSTRACT

Objectives:

This study aimed to compare visualization of the vocal cords and performance of intubation by anesthetists using four different laryngoscopes while wearing full chemical protective equipment.

Setting:

Medical Simulation Center of a University Hospital, Department of Anesthesiology

Participants:

42 anesthetists (15 females and 27 males) completed the trial. The participants were grouped according to their professional education as anesthesiology residents with experience of <2 years or <5 years or as anesthesiology specialists with experience of >5 years

Interventions:

In a manikin scenario participants performed endotracheal intubations with four different direct and indirect laryngoscopes (Macintosh (MAC), Airtraq (ATQ), Glidescope (GLS) and AP Advance (APA)), while wearing chemical protective gear, including a body suit, rubber gloves, a fire helmet and a breathing apparatus.

Primary and secondary outcome measures:

With respect to the manikin setting time to complete "endotracheal intubation" was defined as primary endpoint. Glottis visualization (according to the Cormack-Lehane Score (CLS), and impairments caused by the protective equipment, were defined as secondary outcome measures.

Results:

The times to tracheal intubation were using the MAC (31.4 s; 95% CI; 26.6-36.8), ATQ (37.1 s; 95% CI; 28.3-45.9), GLS (35.4 s; 95% CI 28.7-42.1), and APA (23.6 s; 95% CI 19.1-28.1), respectively. Intubation with the APA was significantly faster compared with all of the other devices examined among the total study population ($P<0.05$). A significant improvement in visualization of the vocal cords was reported for the APA compared with the GLS

Conclusions:

Despite the restrictions caused by the equipment, the anesthetists intubated the manikin successfully within adequate time. The APA outperformed the other devices in the time to intubation, and it has been evaluated as an easily manageable device for anesthetists with varying degrees of experience (low to high), providing good visualization in scenarios that require the use of chemical protective equipment.

Strengths and limitations of this study:

- To the best of our knowledge, video laryngoscopes have not been sufficiently assessed or compared under the use of chemical protective equipment (CPE). This study aimed to compare three types of optical and video laryngoscopes with the standard Macintosh, examining their influences on the ease and speed of insertion of an endotracheal tube while wearing CPE.
- The AP Advance laryngoscope (video-extended standard laryngoscope) has been proven to be an easily manageable device for anesthetists with varying experience levels (low to high) and has been demonstrated to allow for adequate visualization in scenarios requiring the use of CPE.
- A limitation of our study is the artificiality of difficult airway simulation using a manikin, which could have affected the scenario and had a training effect on the participants.
- The cohort of participants consisted of anesthetists with different levels of experience. We did not include paramedics in this study. This aspect needs to be considered depending on the emergency medical service available.
- Further investigation into the efficacy and outcomes of securing the airway in real prehospital emergencies are required.

INTRODUCTION

Chemical, biological, radiation or nuclear (CBRN) hazards due to industrial activities, transport accidents, warfare incidents, communicable diseases or even terrorist attacks can endanger the public.[1] The uncontrolled release of toxic or contagious agents can lead to harmful inhalation and cause respiratory failure, which can require on-site treatment and the retaining of a secure airway.[2-3] Immediate prehospital treatment, including early airway management, must be performed before decontamination or evacuation to avoid delayed intubation and the negative consequences on patients' outcomes.[2,4] Hazards such as the Ebola outbreak in West Africa in 2014 confront hospital personnel with the need to intubate patients with respiratory failure using a video laryngoscope while wearing full personal protective equipment (PPE).[5]

The wearing of CBRN-PPE gear, including rubber gloves and a fire helmet, visor and hood, results in impaired manual dexterity and limited vision during intubation.[6] This impairment adversely affects the successful performance of endotracheal intubation,[7] as well as the use of oropharyngeal airway devices.[8] Furthermore, the positions of patients, who are most likely to be lying on the floor, can result in prolonged intubation times and increase the number of failed intubation attempts.[9]

Videolaryngoscopy may be beneficial for performance of successful endotracheal intubation under difficult conditions due to their improved ability to provide adequate glottic visualization. [10,11] However, there is little current evidence for or against the use of videolaryngoscopy when wearing chemical protective equipment. [12,13] The aim of the current small, unblinded, pilot study is to describe the performance characteristics of various laryngoscopic techniques

This study compares three types of laryngoscopes with the standard Macintosh (MAC) laryngoscope, examining their influences on the ease and speed of insertion of an endotracheal tube by operators wearing CBRN-PPE. We further assessed the operators' subjective impressions of the devices, with a focus on the ability to adequately visualize the glottis.

METHODS

Participants

After obtaining approval from our local ethical board (Rhine-Westphalia University of Technology Aachen, Medical Faculty, Ethical Review Committee, Chairman: Prof. G. Schmalzing, Number of Approval: EK 115/12), 42 anesthetists from Aachen University Hospital, Germany, were invited to participate in this comparative pilot study. The ethical committee waived the need to obtain written informed consent. All of the participants agreed to have their performances evaluated and anonymously used for scientific and educational purposes. The prerequisite for inclusion was an educational level of at least a first year residency in anesthesiology, implying the possession of a license to practice medicine.

Equipment

A Laerdal Resusci® Anne, including an Anne Airway Trainer Update Kit (Laerdal Medical GmbH, Puchstein, Germany), was chosen as the manikin type for this study, and 7 mm endotracheal cuffed tubes were used for intubation (best fit). The manikin's airway was lubricated with silicon spray before and cleaned after each insertion.

All of the tasks were completed while the participants were wearing ISOTEMP®-4000 chemical protection gear (type), including a complete body suit, rubber gloves, and German DIN 14940 fire helmets with a 15 kg self-contained breathing apparatus underneath (Dräger AG, Lübeck, Germany). Because the use of the breathing apparatus requires special training and qualification, the participants did not connect it.

For comparison, the following 4 laryngoscopic intubation devices were selected: an MAC (a conventional standard laryngoscope used worldwide), an Airtraq® A-011 (ATQ) (an established single-use indirect laryngoscope offering optics and a guiding channel) (Prodol Ltd., Vizcaya, Spain), a Glidescope® (GLS) (a video laryngoscope that allows for high-quality visualization on an external monitor, with no guiding channel) (Verathon Medical B.V., Rennerod, Deutschland), and an AP Advance® (APA) (video extended standard laryngoscope with a directly attached display and certain blade options, including a difficult airway blade (DAB), with a guiding channel) (Venner Medical GmbH, Dänischenhagen, Germany). (Fig. 1)

The device sizes and blades were found to be congruent and were fit to the manikin's specifics prior to testing. All of the devices were used with blades that were equivalent to a size 3 MAC blade and, for the APA specifically, a DAB. A standard intubation stylet (14 Charrière (CH)) was applied for use of the conventional MAC. For the GLS, a GlideRite® stylet was used for intubation according to the manufacturer's recommendations. No stylets were used for the ATQ and APA devices because they offer a guiding channel.

Study protocol

All of the participants were familiar with all of the devices tested, based on the receipt of previous "managing the difficult airway" education and subsequent manikin training. Before testing, all of the participants were once again instructed on the correct techniques for using the laryngoscopes. The participants were not allowed to practice any tasks in their chemical protection gear. Two participants declared that they had former training experience with chemical protective gear.

In the scenario, the manikin was placed on the floor with all four devices preassembled and easily accessible, close to the manikin's head (Fig. 1). All of the participants performed the complete process of intubation with each device, from the grasping of the device until the first ventilation with a bag-valve mask. The process included inflation of the cuff.

Successful intubation was identified as regular chest extension of the manikin and was further verified by the authors after completion. The order of devices 1 to 4 (MAC, ATQ, GLS, and APA, respectively) was rotated for every second participant, from the sequence 1,2,3,4 to 2,3,4,1 to 3,4,1,2 and finally to 4,1,2,3 to compensate for potential learning bias.

Data assessment

The anesthetists were assessed by the study team, and the time to complete intubation was recorded from the entrance of each laryngoscope through the mouth until the moment of chest extension by the first ventilation. After completion of all four intubations, the participants were administered a questionnaire on the difficulties experienced during the performance. The questionnaire included restrictions in handling the devices caused by the gear, as well general comments about their handling, rated on a numeric scale from 1 (no restriction) to 7 (maximum restriction). To qualify the visualization of the vocal cords, we used the standard Cormack-Lehane (CL) classifications of I-IV for classic direct laryngoscopy. To achieve comparability between direct, indirect and video laryngoscopy in the absence of an alternative practical score, we chose to use the CL classification to assess visualization with all devices, although it is typically used only for direct laryngoscopy. The data were collected over 11 days, with an average daily assessment of 4 participants.

Statistical analysis

The results are presented as the mean $\pm$ standard deviation ($M \pm SD$) for the continuous variables. The parameters were compared using the Friedman test as an alternative to ANOVA for non-parametric groups. Bonferroni-Dunn correction was used to determine the significance of data. Comparisons were considered statistically significant at a $P < 0.05$.

Statistical analysis was conducted with Prism 5 software (version 5.0 for Mac OS X, copyright© 1994-2009, GraphPad).

RESULTS

Data were recorded for 42 anesthetists (15 females and 27 males). The participants were grouped according to their professional education as anesthesiology residents with experience of <2 years or <5 years or as anesthesiology specialists with experience of >5 years (Table 1).

Table 1: Participant characteristics			
	Participants	Male	Female
Total	42	27	15
Residents 0-2 years	10	4	6
Residents 2-5 years	12	7	5
Specialists	20	16	4
Data are presented as numbers.			

Wearing CBRN-PPE, all of the participants successfully intubated the manikin’s trachea with the MAC, GLS and APA. One inaccurate intubation was recorded for the ATQ. The time to tracheal intubation using the MAC was 31.7± 16.3 s (mean ± standard deviation) (range: 13.8 – 96.4), and it was 37.1 ± 28.2 s (12.1 – 156.0) using the ATQ, 35.4 ± 21.6 s (13.5 – 93.3) using the GLS, and 23.6 ± 14.5 s (11.4 – 99.4) using the APA. Intubation using the APA was significantly faster compared with all of the other devices among the total study population (Table 2) (Fig. 2).

Table 2: Differences in the time for intubation according to the device used and level of professional experience

Total Participants	MAC	ATQ	GLS	APA
Successful Intubation	42	41	42	42
Minimum	13.8	12.1	13.5	11.4
Maximum	96.4	156	93.3	99.4
Mean	31.4	37.1	35.4	23.6#
Std. Deviation	16.3	28.2	21.6	14.5
Residents <2 years				
Successful Intubation	10	10	10	10
Minimum	16.3	17.3	20	14.2
Maximum	63.3	59.2	92.2	38.75
Mean	34.9	34.3	46.6	23.7*
Std. Deviation	13.8	13.7	25.7	8.6
Residents 2-5 years				
Successful Intubation	12	12	12	12
Minimum	16.8	22.3	17.9	17.9
Maximum	96.4	156	66.6	49.5
Mean	33.2	47.8	31.0	26.4
Std. Deviation	20.8	39.1	14.7	10.9
Specialists >5 years				
Successful Intubation	20	19	20	20
Minimum	13.8	12.1	13.45	11.4
Maximum	78.1	99.3	93.3	99.4
Mean	28.5	31.9	32.4	21.9**
Std. Deviation	14.7	25.1	21.8	18.5
Data are presented as numbers, time(s), and means $\pm$ SDs. #Tracheal intubation was significantly faster using the APA compared to all of the other devices ($P<0.05$). *Residents with experience of <2 years performed intubation significantly faster with the APA than with the GLS ($P<0.05$). **Specialists with experience of >5 years performed intubation significantly faster with the APA than with the GLS or MAC ($P<0.05$).				

Regarding the level of experience, the residents with <2 years experience performed intubation significantly faster ($P<0.05$) with the APA compared with the GLS (23.7 ± 8.6 s versus 46.6 ± 25.7 s, respectively). The specialists with >5 years experience were

significantly faster with the APA compared with the GLS and MAC (21.9 ± 18.5 s versus 32.4 ± 21.8 s and 28.5 ± 14.7 s, respectively) (Table 2).

The participants completed the questionnaire by subjectively assessing the restrictions of visualization and laryngoscope handling caused by the protective gear (Fig. 3) using a numeric scale ranging from 1 (no restriction) to 7 (maximum restriction). The questionnaire results showed that 45% of the participants achieved CL-I visualization with the MAC, in addition to 62% with the ATQ, 88% with the GLS and 95% with the APA. A significant difference in the rank sum was detected between the APA (42.9) and GLS (37.5) ($P < 0.05$) (Fig. 4).

Evaluation of restriction of visualization caused by the CBRN-PPE resulted in the highest score (indicating the greatest restriction) for the MAC (4.3), followed by the ATQ (4.2) and the GLS (2.7), and the lowest score was observed for the APA (2.4). Wearing PPE restricted the handling of the MAC, ATQ, GLS, and APA laryngoscopes with associated scores of 3.8, 4.1, 3.0 and 2.6, respectively. In addition, the participants compared their former experiences with using these laryngoscopes without wearing CBRN-PPE with their current experiences and scored the restriction caused by the PPE as 4.9 for the MAC, 4.5 for the ATQ, 3.3 for the GLS and 2.8 for the APA (Fig. 3).

Within the free comment section of the questionnaire, the participants indicated that they had experienced major problems in adjusting the angle of view (41%) for the ATQ. In addition, 45% of the participants reported major difficulty with obtaining a sufficient glottic view using the MAC. Impairments of manual dexterity and fine motor skills were confirmed by 36 participants (86%), specifically for advancing the tube into the trachea (36%). In response to the question regarding which laryngoscope they would prefer to use while wearing CBRN-PPE, 4 chose the MAC, 1 chose the ATQ, 16 selected the GLS, and 18 opted for the APA. Three participants did not answer this question.

DISCUSSION

In this trial, we have demonstrated that video laryngoscopes are feasible, safe and easy to handle – even when wearing CBRN-PPE – for use on a manikin. Compared to conventional MAC laryngoscopy, the video laryngoscopes allowed for better visualization during intubation, despite the fact that the participants were looking through a glass shield integrated into the protective gear. Moreover, the APA outperformed the other laryngoscopes in terms of visualization and the time to tracheal intubation.

Tracheal intubation in prehospital situations should always be performed by the most experienced medical staff. Because chemical intoxication and environmental circumstances can complicate intubation, it must be assessed whether a supraglottic airway device (SAD) can secure the airway sufficiently until an experienced physician and equipment are available.

SADs (e.g. a laryngeal mask) have been evaluated for use with CBRN-chemical protective equipment (CPE), and their benefits include ease of use and speed of insertion. Additionally, less stringent training requirements for their use have been confirmed.[14-16] Despite their advantages, SADs do not offer the same quality of separation of the respiratory and digestive tracts.[17] Further, they do not provide adequate airway protection, particularly during positive pressure ventilation after respiratory intoxication.[3] Thus, endotracheal intubation remains the gold standard in the early airway management of contaminated patients to avoid the higher mortality rate resulting from the hypoxia caused by delayed intubation.[2]

Video laryngoscopy provides a better view of the vocal cords, a higher success rate, a shorter time to tracheal intubation and less need for optimizing maneuvers.[18] These devices are considered easy to use regardless of previous experience, and they have been recommended for difficult airway situations.[18-19] In prehospital settings, the option to perform both direct and video laryngoscopy with the same device has been emphasized.[20]

A short learning curve enables personnel to perform successful tracheal intubations with limited instruction.[11] A previous study of the use of a Pentax-AWS video laryngoscope in a CBRN-PPE scenario has shown that suited intubation with a Pentax-AWS can be performed in a shorter period of time than unsuited intubation with an MAC.[12]

Intubation performances with the different laryngoscopes

Insertion of a tube through the glottis into the trachea is essential for performance analysis of the ease and speed of endotracheal intubation. This success of this maneuver is mainly influenced by the view of the vocal cords, and it certainly depends on the type of

laryngoscope used for intubation. Both, the presence or absence of a guiding channel on a laryngoscope and the relevant intubation technique, requiring visual and manual coordination, can influence the outcome. Although most video laryngoscopes provide high-quality visualization of the anatomy, successful tracheal intubation is not guaranteed.

The APA performed the best in this trial with regard to the speed and ease of intubation. The monitor of the APA is directly aligned to the laryngoscope with its familiar shape, enabling anesthetists to apply well-known intubation techniques, similar to the standard MAC. Additionally, the APA offers high-quality visualization, and the guiding channel of the blade directs the path for the tube into the trachea. These advantages of the APA can be transferred from a standard airway scenario[21] to our scenario involving the wearing of complete CBRN-PPE.

The mean intubation time with the GLS was comparable to that with the ATQ, and both of these laryngoscopes required more time than the standard MAC. Anesthetists with less than 2 years of experience performed intubation slower with the GLS than with the MAC or ATQ. Despite the excellent quality of the view on the external monitor, the visual and manual coordination required by the unfamiliar technique posed a challenge to the less experienced participants. Although the survey revealed that vision was less restricted with the GLS (compared to the MAC and ATQ), it further indicated limitations of the GLS in advancing the tube into the trachea. Similar findings for the GLS have been demonstrated under non-CPE-wearing conditions.[21]

In particular, the GLS requires even greater dexterity under PPE-wearing conditions, and the participants' performances would have benefitted from a training period to familiarize them with the coordination necessary for successful and fast intubation with this laryngoscope. The use of the ATQ, with indirect laryngoscopy optics and a clear guiding channel for the tube, has been investigated as a feasible device for performing routine tracheal intubation rapidly.[22] However, in our scenario involving the wearing of CBRN-PPE, this laryngoscope did not demonstrate such efficiency. In fact, its use resulted in the slowest intubation times. The fixed angle of the ATQ might have limited the possible adjustments made by the operators for achieving adequate visualization of the vocal cords while they were protected by the visor of the helmet and suit, which would have additionally restricted the use of the eye piece of the optical unit. These limitations were mentioned in the survey by more than 40% of the participants. Castle et al. observed the longest intubation time for participants using the ATQ while wearing CBRN-PPE. However, in contrast with our findings, their study did not describe interference from a helmet or visor.[14,15] Recently, Claret et al. have confirmed that the MAC is superior to the ATQ in terms of speed, efficiency and overall ease of use.[23]

The MAC laryngoscope is a well-known reference device with confirmed utility under difficult

circumstances. Although the intubation times for the MAC were adequate and were only exceeded by those for the APA in this study, the anesthetists' experienced restrictions of visualization and laryngoscope handling while wearing CBRN-PPE, as demonstrated by the CL classification and questionnaire results. Notably, the anesthetists' greater experience with using the MAC compensated for the lack of visualization compared to the other devices.

Survey: Restrictions from CBRN-PPE

The participants confirmed that the protective gear, including rubber gloves and a fire helmet, visor and hood, impaired the performance of endotracheal intubation [6,7]. Fine motor skills were needed for advancing the tube into the trachea and for inflation of the cuff, and the participants claimed to be restricted mainly due to the rigidity and inflexibility of the rubber gloves.

With regard to visualization of the glottis, the participants indicated that they were less restricted by the PPE gear when using the APA video laryngoscope (Fig. 3). The high quality of the resulting image may explain this finding, as well as the fact that the display of the APA is directly attached to the familiar body of the laryngoscope. Visualization of the vocal cords does not require averting one's eyes to a separate monitor, similar to the GLS. To acquire an adequate view with the MAC, the participants had to align the glottis, laryngoscope and themselves, but they were specifically restricted by the visor and hood of the protective gear and the position of the manikin on the floor, as mentioned by 19 of 42 participants. Castel et al. have shown that performing intubation with the ATQ is *not* limited by the distance between the eyepiece and laryngoscope, which is increased by the visor of the gear.[14,15] In contrast, 17 of 42 participants in our study specifically reported this distance as the reason for an impaired view while intubating with the ATQ.

Our findings were further supported by the recording of CLSs for the use of indirect laryngoscopy and video laryngoscopy. It has been shown that the best visualization is achieved using the APA, followed by the GLS, ATQ, and MAC. We also found that the quality of visualization was not correlated with the time of intubation because the MAC outperformed the GLS and ATQ despite the poorer visualization.

Limitations

We recognize that the artificial scenario for difficult airway assessment was limited by the lack of proper simulation of collapsible soft tissues and secretion of blood, vomit or sputum, as well as the use of rigid plastic, which established the scenario and could have had a training effect on the participants.[24] Additionally, chemical incidents occurring in or out of hospital can be further assessed according to the presence of fog, fire, noise, dirt or other external conditions. Considering the setting and conditions of our study, with the participants

wearing CPE and the manikin lying on the floor, we defined this as a difficult airway scenario without considering the standard anatomic glottic location of the manikin. The American Society of Anesthesiologists (ASA) Task Force on Management of the Difficult Airway has defined the difficult airway as a complex interaction among patient factors, the clinical setting, and the skills of the practitioner.[25]

Particularly with the use of the APA, which consists of a plastic guiding channel on its downside, the friction of rigid plastic on the manikin’s plastic larynx might have worsened the outcome. Furthermore, the DAB of the APA might have facilitated the use of the device, while the MAC and GLS options were restricted to the use of a stylet. In addition, the ATQ has a guiding channel for support. Moreover, we did not consider the blinding of the observers to the tested devices, as it was not possible to acquire a “neutral” image quality that would prevent the experienced observer from determining the device used. We also did not consider aspects such as battery life span or economic feasibility in our study. Due to the lack of a reliable quantitative parameter for the primary goal of success of, we chose “time to successful intubation” as our best descriptive term.

Conclusions

The APA has been demonstrated to be an easily manageable device for anesthetists with various experience levels (low to high) that can be used to achieve adequate visualization in scenarios requiring CPE. Emergency scenarios require devices that are not only easy to use but are also well known by staff. Therefore, the MAC remains a reliable option for anesthetists in the field, even under complicated conditions. The findings of this study serve as a foundation for further clinical studies on outcomes of securing the airway using video laryngoscopes, such as the APA.

Abbreviations:

AP Advance	- APA
Airtraq	- ATQ
Chemical, biological, radiation or nuclear	- CBRN
Personal Protective Equipment	- PPE
Chemical protective equipment	- CPE
Cormack-Lehane Score	- CLS
Glidescope	- GLS
Macintosh	- MAC
Standard deviation	- SD
Supraglottic airway device	- SAD

Legend for tables and figures:

Table 1: Participant characteristics

Table 2: Intubation times for devices and levels of professional experience

Fig. 1: Fig. 1. Devices and Equipment: Upper Left: Airtraq® (ATQ); Upper Right:

Glidescope® (GLS); Lower Left: ISOTEMP® Chemical Protection Equipment (CPE); Lower

Right: AP Advance® (APA)

Fig. 2: Intubation times for all devices

Fig. 3: Questionnaire data: restriction caused by chemical protective equipment

Fig. 4: Visualization according to intubation scores

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Competing Interests

GS received fees for general lectures in "difficult airway management" from the German Airtraq® distributor Medisize Deutschland GmbH, Neunkirchen-Seelscheid, Germany. The authors declare that they have no competing interests.

Authors' Contributions:

HS and NZ equally developed the conception and design of the study, performed the data interpretation and drafted and finalized the manuscript. GS and KD participated in the data collection and interpretation. CS, MC, and RR critically revised the manuscript and supervised statistical analysis. RR and GS critically revised the manuscript, and GS initiated, coordinated and supervised the trial. All of the authors read and approved the final manuscript.

Data Sharing Statement:

No additional data are available.

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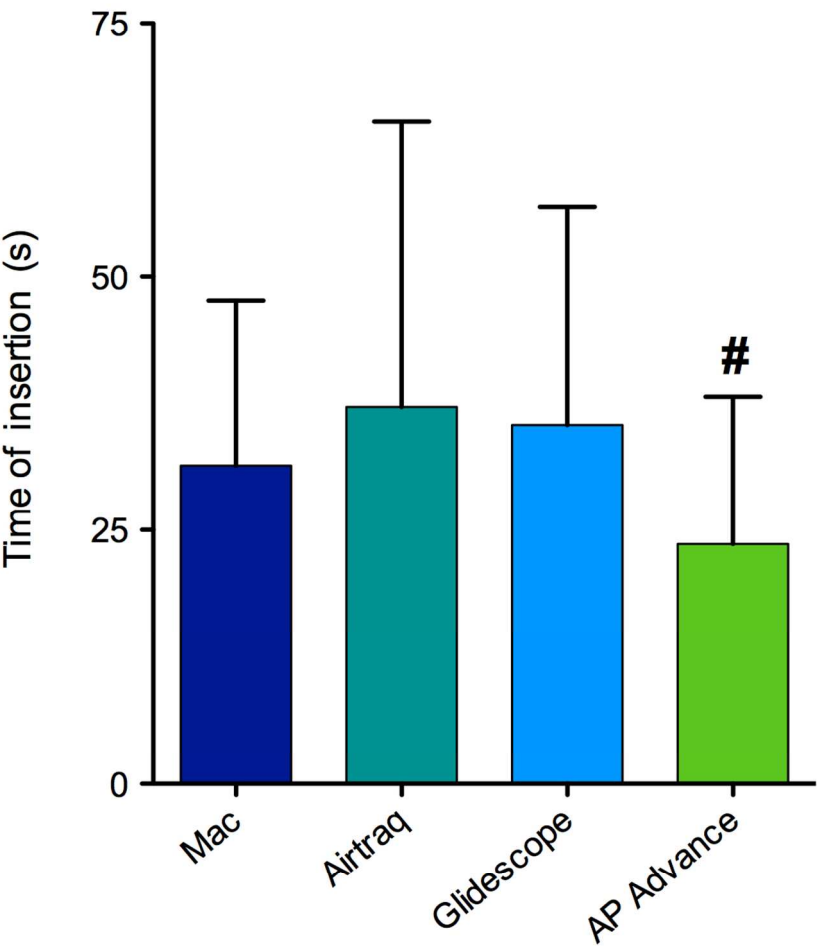
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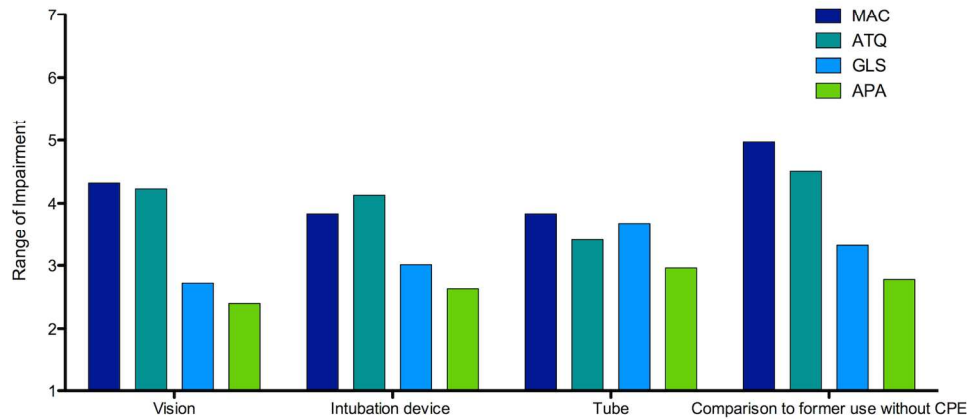
Fig. 1. Devices and Equipment: Upper Left: Airtraq® (ATQ); Upper Right: Glidescope® (GLS); Lower Left: ISOTEMP® Chemical Protection Equipment (CPE); Lower Right: AP Advance® (APA)
291x246mm (200 x 200 DPI)

Fig. 2: Intubation time of all devices.
Data are presented as means $\pm$ SD.
marks significant difference ($p < 0.05$)



Intubation Time of all devices
100x135mm (300 x 300 DPI)

Fig.3: Questionnaire Data: Restrictions from chemical protection equipment
Values recorded on a Likert-Scale from 1 (none) to 7 (maximum restriction) are presented as mean.
CPE = Chemical Protection Equipment



Presented questions:
- Vision: Did wearing CPE restrict your view of the vocal cords?
- Intubation device: Did wearing CPE restrict the handling of the intubation device?
- Tube: Did wearing CPE restrict your ability to advance the tube into the trachea?
- Rating the restriction of CPE on the devices compared to former use of the devices without CPE

Questionnaire Data: Restriction from chemical protection equipment
160x102mm (300 x 300 DPI)

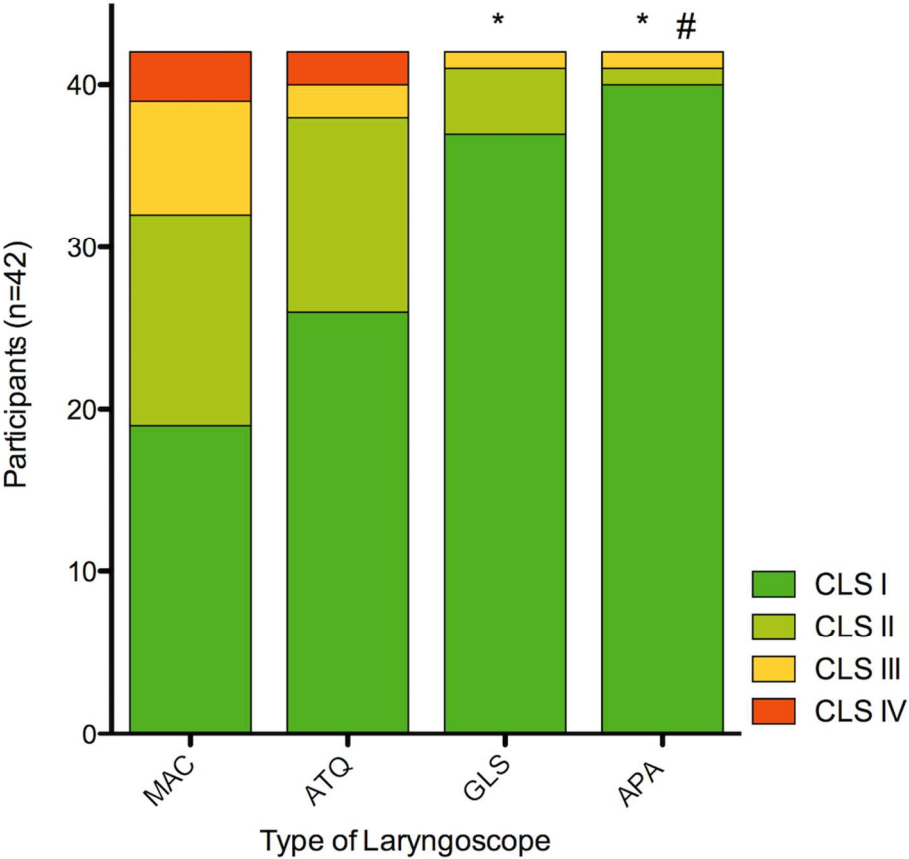


Fig. 4 Visualization by Cormack Lehane Score:
* GLS and APA show significant difference in rank sum compared to MAC ($p<0.05$).
APA shows significant difference in rank sum compared to ATQ ($p<0.05$).
MAC = Macintosh, ATQ = Airtraq, GLS = Glidescope, APA = AP Advance

Visualization by Intubation Score
99x108mm (300 x 300 DPI)

Correction

Schröder H, Zoremba N, Rossaint R, *et al.* Intubation performance using different laryngoscopes while wearing chemical protective equipment: a manikin study. *BMJ Open* 2016;**6**:e010250. doi:10.1136/bmjopen-2015-010250

There is a mistake in the Contributors section. It should say:

“**Contributors** HS and NZ developed the conception and design of the study and performed data interpretation. HS performed statistical analysis, wrote and finalized the manuscript. NZ revised the manuscript. GS and KD participated in the data collection and interpretation. CS, MC, RR critically revised the manuscript and supervised statistical analysis. RR and GS critically revised the manuscript, and GS initiated coordinated and supervised the trial. All of the authors read and approved the final manuscript”.

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BMJ Open 2017;**7**:e010250corr1. doi:10.1136/bmjopen-2015-010250corr1



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