ORIGINAL ARTICLE

Impact of VieScope® on first-attempt success during simulated COVID-19 patients intubation: A randomized cross-over simulation trial

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ABSTRACT

BACKGROUND: The purpose of our study was to determine the efficacy of intubation with VieScope® and Macintosh laryngoscope in different scenarios of simulated COVID-19 patients by paramedics wearing personal protective equipment (PPE) for aerosol generating procedures (AGPs).

METHODS: Study was designed as a prospective, observational, randomized, crossover simulation trial. 37 paramedics took part in the study. They performed endotracheal intubation (ETI) of a person suspected of COVID-19. Intubation was performed using VieScope® and Macintosh laryngoscopes in two research scenarios: Scenario A - normal airway and Scenario B - difficult airway. Both the order of participants and the methods of intubation were random.

RESULTS: In Scenario A, time to intubation using VieScope® and Macintosh laryngoscope amounted to 35.3 (IQR; 32–40) seconds and 35.8 (IQR: 30–40)s, respectively. Nearly all participants performed ETI successfully both with VieScope® and Macintosh laryngoscope (100% vs. 94.6%). In scenario B, intubation with the VieScope®, compared to the Macintosh laryngoscope, was associated with a shorter intubation time (p<0.001), a higher success rate of the first intubation attempt (p<0.001), a better visualization degree glottis (p=0.012) and ease of intubation (p<0.001).

CONCLUSION: Our analysis suggests that the use of a VieScope® compared to Macintosh laryngoscope in difficult airway intubation performed by paramedics wearing PPE-AGP is associated with shorter intubation times, greater intubation efficiency as well as better visualization of the glottis. Additional clinical trials are necessary to confirm the obtained results.

Keywords: COVID-19; endotracheal intubation; laryngoscope; Macintosh; personal protective equipment; SARS-CoV-2, VieScope®.

INTRODUCTION

Proper airway management and implementation of ventilation are one of the basic skills that medical personnel should have. [1] This is of particular importance in the case of paramedics who, while working in outgoing medical rescue teams, rela-

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tively often meet patients who, as a result of cardiac arrest, injuries or acute respiratory failure, require an airway management.[2,3] Despite the development of medical technology, endotracheal intubation (ETI) is still the "gold standard" of airway protection.[4]

Numerous studies show that direct laryngoscopy is not a 100% effective method, especially in the pre-hospital setting or in the Emergency Medicine Department.[5–8] Since December 2020, the world is also struggling with a new problem, which is the new coronavirus SARS-CoV-2 and the COVID-19 disease it causes.[9] Due to the fact that the coronavirus spreads, among others by respiratory aerosol, oral procedures, including respiratory protection and mechanical ventilation, are considered particularly dangerous due to the high risk of infection. According to the guidelines of numerous scientific societies, in the case of procedures generating respiratory aerosol such as COVID- 19, medical personnel should wear personal protective equipment (PPE) for aerosol generating procedures (AGPs).[10–13] However, numerous studies indicate that the performance of procedures in PPE-AGP may reduce the effectiveness of these procedures as well as extend their duration.[14–17] This also applies to the effectiveness of intubation with the use of direct laryngoscopy.[18] Therefore, it is reasonable to look for methods of ETI alternative to direct laryngoscopy. An example of such a device is the VieScope® device (Androit Surgical LCCC, Oklahoma City, USA) which represents a new type of laryngoscopes. The laryngoscope consists of a handle to which a round, straight tube is attached, which is illuminated with LED diodes. Thanks to that, when introducing the device into the patient's mouth - inside this tube, we can see the highlighted anatomical structures, the next step is to insert the bougie guide, remove the laryngoscope and then insert the endotracheal tube over the guide and stabilize the endotracheal tube (Fig. 1).

The purpose of our study was to determine the efficacy of intubation with VieScope® and Macintosh laryngoscope in different scenarios of simulated COVID-19 patients by paramedics wearing PPE-AGP.

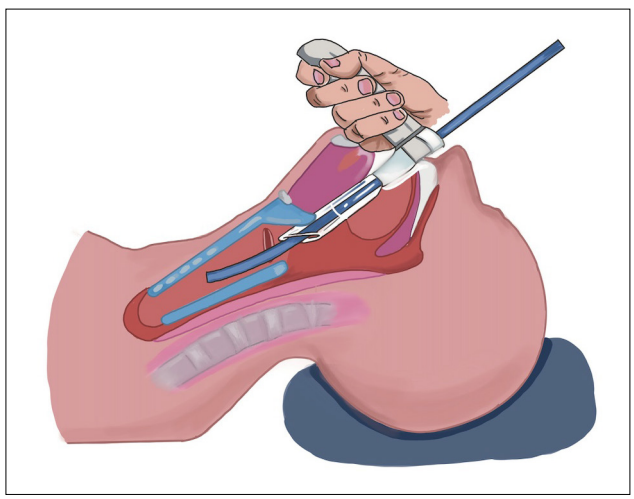

Figure 1. Method of intubation with the use of VieScope® laryngoscope.

MATERIALS AND METHODS

The study was designed as a prospective, observational, randomized, cross-over trial. The study was conducted under medical simulation conditions. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (Approval no. September 03, 2021.IRB). The study is a continuation of the research undertaken by the authors, devoted to the assessment of the effectiveness of various techniques of ETI in patients suspected of having an infectious disease.[19,20]

The study included 37 active paramedics who participated in training courses in the field of advanced resuscitation procedures conducted by the Polish Society of Disaster Medicine (Warsaw, Poland) or EasyRescue training school (Katowice, Poland). Study participants were recruited from December 2021 to March 2022. Voluntary informed consent was obtained from each participant.

The study included two methods of ETI:

a. VieScope® laryngoscope with dedicated bougie stylet.
b. Macintosh laryngoscope with blade no. 3 (MAC; HEINE Optotechnik, Gilching, Germany) recognized as the "gold standard" of ETI in both pre-hospital and inpatient settings (Fig. 2).[1]

Before starting the study, all study participants took part in a 30-min training course, during which the correct techniques of intubation with the use of VieScope® and MAC were presented. Then, the participants of the study had the opportunity to participate in a 30-minute practical training with the use of the tested devices in normal airway conditions using the Airway Management Trainer (Laerdal, Stavanger, Norway).

The advanced adult simulator SimMan 3G (Laerdal, Stavanger, Norway) was used to simulate a patient with COVID-19 confirmation. The mannequin was placed on an anesthesia bed. Intubation was conducted by study participants wearing full PPE-AGP[15] and was conducted in two research scenarios:

a. Scenario A - normal airway;
b. Scenario B - difficult airway. Difficult airways were obtained by inflating the tongue with air until the glottis was visualized at level 3 of the Cormack-Lehane scale,[21] which was assessed each time by direct laryngoscopy by one of the investigators.

Both the order of participants and the research methods were random. For this purpose, the program ResearchRandomizer (randomizer.org) was used. The detailed procedure of randomization of the study is presented in Figure 3. The participants of the study performed a maximum of one intu-

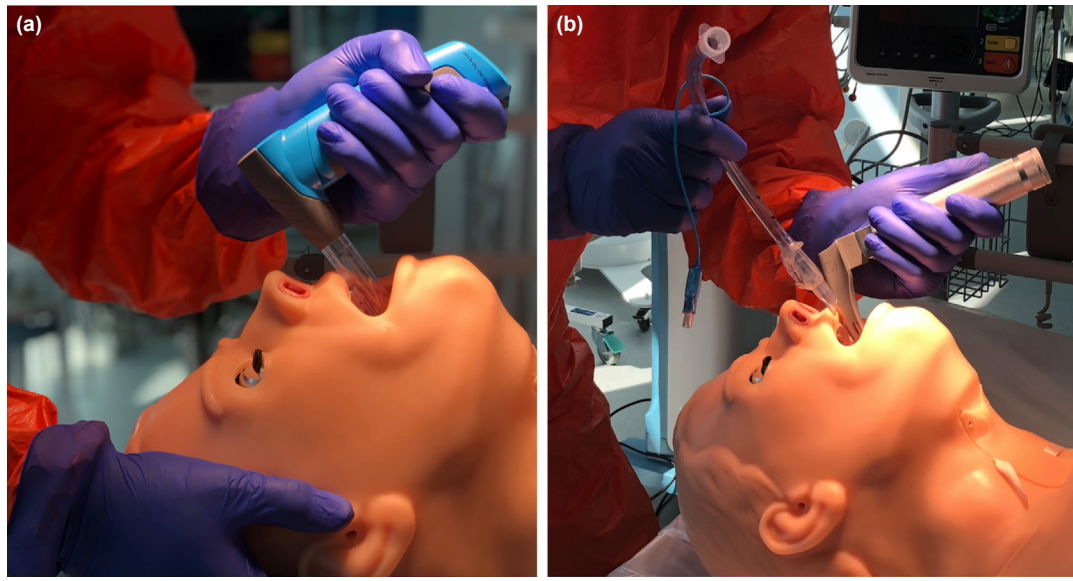

Figure 2. Endotracheal intubation with: **(a)** VieScope® laryngoscope; **(b)** Macintosh laryngoscope.

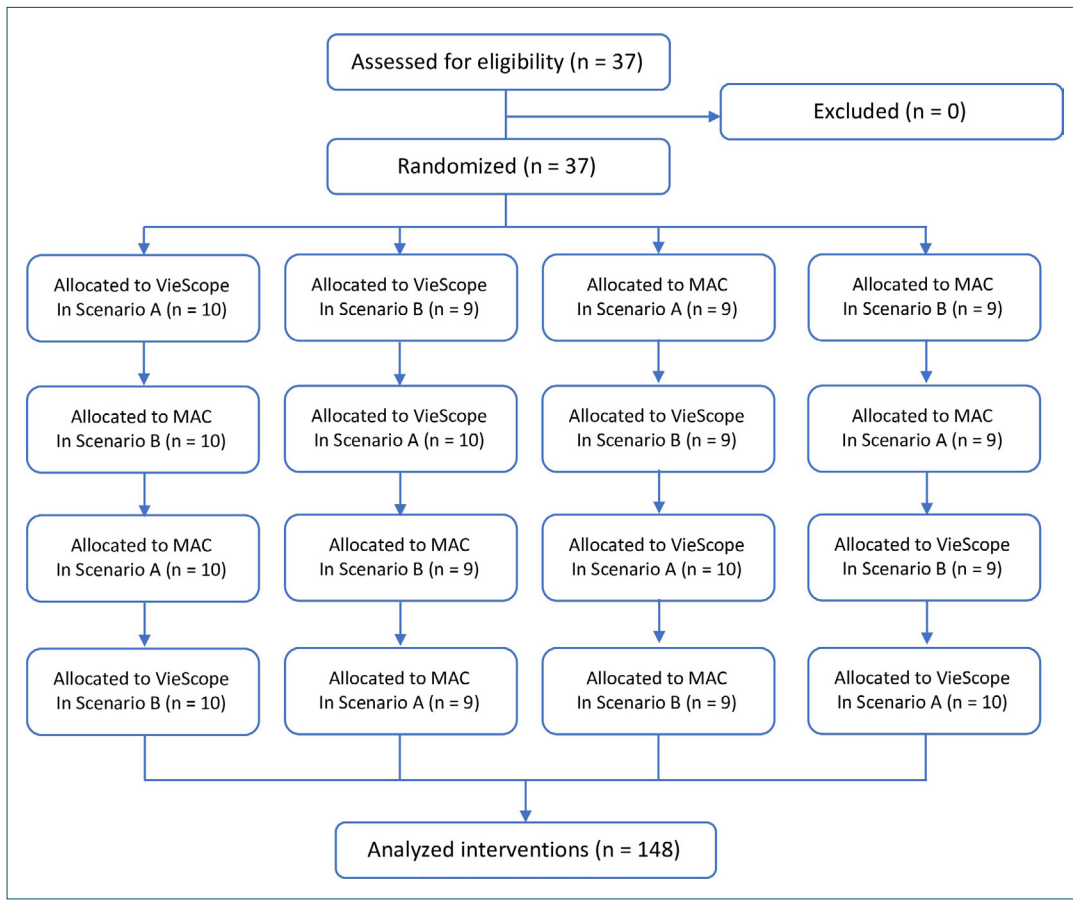

Figure 3. Randomization flow chart.

bation attempt with each of the laryngoscopes in individual research scenarios.

Parameters such as intubation time, the effectiveness of the first intubation attempt, the degree of glottis visualization and the ease of intubation were analyzed. The time of intubation was defined as the time from taking the laryngoscope in the hand until the first attempts at ventilation with an endotracheal tube using a self-inflating bag. The first attempt at intubation was effective when, after inserting an endotracheal tube and inflating the sealing cuff during bag ventilation, the simulator sensors detected lung ventilation. In addition, the

correctness of intubation was assessed each time by direct inspection by one of the researchers. The degree of visualization of the glottis was assessed each time by a person performing ETI using the Cormack-Lehane scale.[21] Ease of intubation was assessed by individuals performing ETI with the use of 10-points audio visual scale (where "1" - easy procedure and "10" - difficult procedure).

Sample size calculation revealed that 32 participants were required to detect a minimal difference of 20% difference with 80% power at a significance level of 5%. We decided to include 37 participants to account for possible dropouts.

Statistical Package for the Social Sciences (SPSS) 16.0 SPSS® (SPSS Inc. Chicago, Illinois, USA) package program was used for statistical analysis. A P-value below 0.05 was considered to be statistically significant. The Kolmogorov-Smirnov test was applied to check for normal distribution. For the comparison of the primary endpoint "Intubation time" with VieScope® and Macintosh laryngoscope in the different airway scenarios ("normal" and "difficult"), Fisher's Exact Test was performed. Secondary endpoints "first pass rate," "glottis visualization," and "ease of use," were analyzed after normality test (Shapiro–Wilk) and equal variance test (Brown-Forsythe), using a one-way analysis of variance for repeated measurements to determine the overall statistical significance between the groups. This was then followed by *post hoc* Student Newman Keuls method for pairwise multiple comparisons between two groups.

RESULTS

The study was carried out between December 2021 and March 2022. In total, 37 paramedics (13 women and 24 men aged 28.3±5.2 years) participated in the study. Before study, all participants have clinical intubation experience with Macintosh laryngoscope, but have not experience with VieScope®.

Detailed parameters of ETI are presented in Tables 1 and 2 for the intubation scenario under normal and difficult airway conditions, respectively.

During scenario A (normal airway) time to intubation using VieScope® was 35.3 sec (IQR; 32–40) and 35.8s (IQR; 30–40; Fig. 4a). The effectiveness of the first intubation attempt with the VieScope® was 100%, and with the Macintosh laryngoscope it was slightly lower (94.6%; p=0.156). The degree of visualization of the glottis according to the Cormack Lehane scale for both laryngoscopes was statistically significantly better for the VieScope® (p=0.032; Fig. 4b). In the opinion of the

Table 1. Intubation with VieScope® and Macintosh laryngoscope in normal airway scenario

Parameter	VieScope®	Macintosh laryngoscope	p-alue
Time to intubate (s), median (IQR)	35.3 (32–40)	35.8 (30–40)	0.783
Success of first intubation attempt, n (%)	37 (100)	35 (94.6)	0.156
Cormack-Lehane grade, n (%)			
1	35 (94.6)	26 (70.3)	0.032
2	2 (5.4)	11 (29.7)	
3	–	–	
4	–	–	
Ease of intubation (1–10), median (IQR)	3 (2–4)	3 (3–5)	0.002

Table 2. Intubation with VieScope and Macintosh laryngoscope in difficult airway scenario

Parameter	VieScope®	Macintosh laryngoscope	p-alue
Time to intubate (s), median (IQR)	36 (33–40)	41 (38–45.5)	<0.001
Success of first intubation attempt, n (%)	37 (100)	27 (73.0)	<0.001
Cormack-Lehane grade, n (%)			
1	11 (29.7)	6 (16.2)	0.012
2	23 (62.2)	21 (56.8)	
3	3 (8.1)	10 (27.0)	
4	–	–	
Ease of intubation (1–10), median (IQR)	4 (3–5)	5 (5–7)	<0.001

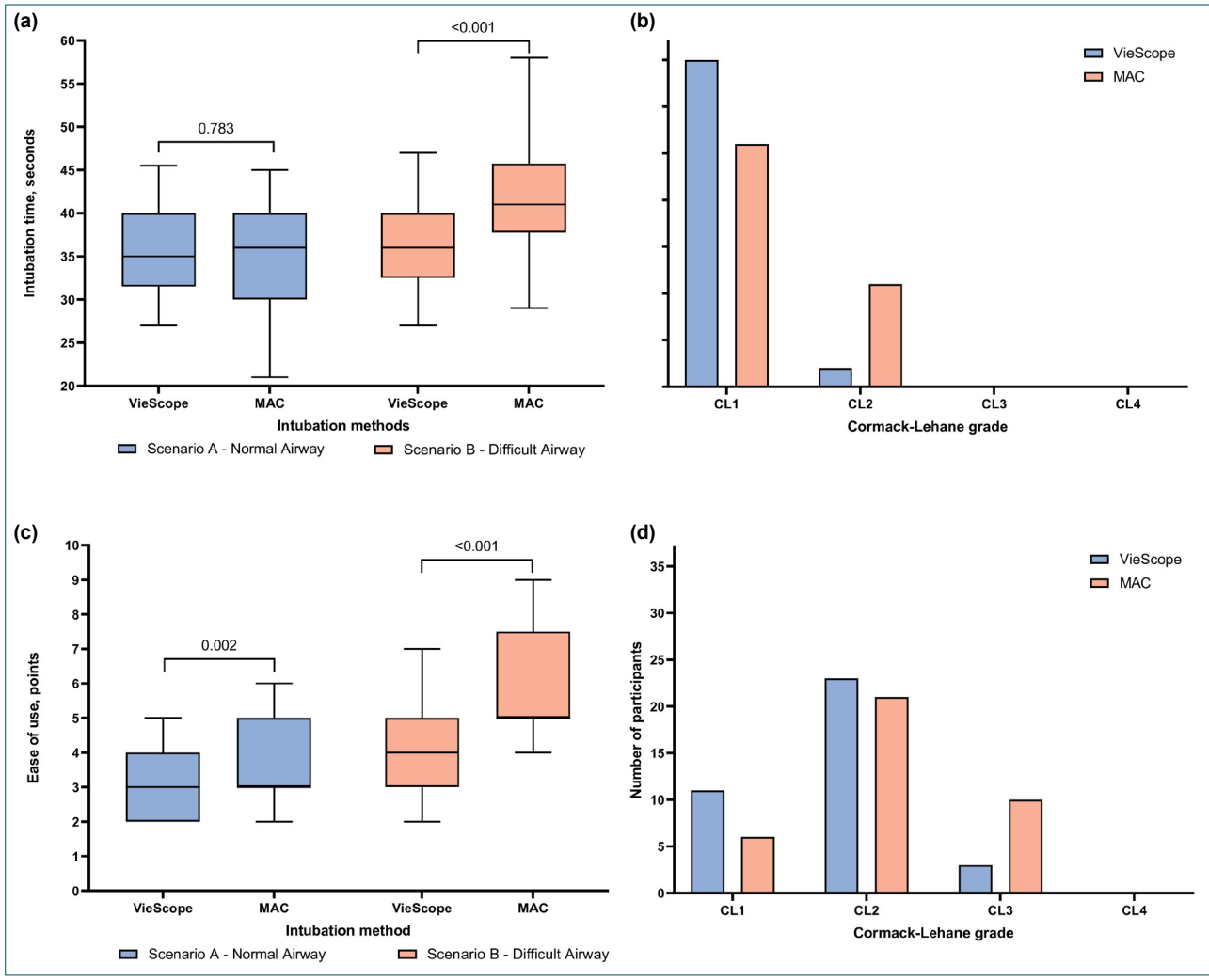

Figure 4. (a) Intubation time graph using VieScope® and Macintosh laryngoscope in normal and difficult airway scenarios. **(b)** Cormack-Lehane grade among distinct laryngoscopes in normal airway scenario. **(c)** Ease of intubation graph using VieScope® and Macintosh laryngoscope in normal and difficult airway scenarios. **(d)** Cormack-Lehane grade among distinct laryngoscopes in difficult airway scenario.

participants of the study, intubation was statistically significantly easier to perform with the VieScope® than with the Macintosh laryngoscope (p=0.002; Fig. 4c).

Intubation in difficult airway conditions with the VieScope®, compared to the Macintosh laryngoscope, was associated with a shorter intubation time (p<0.001; Fig. 4), a higher success rate of the first intubation attempt (100% vs. 73.0%; p<0.001), a better visualization degree of glottis (Fig. 4d) and ease of intubation (p<0.001).

DISCUSSION

The aim of the study was to compare ETI using two methods: VieScope® and Macintosh laryngoscope. Protection of the airway patency in COVID-19 patients with concomitant respiratory failure or during cardiac arrest should be performed as soon as possible to prevent further decompensation of the organism.[22] Then, oral procedures - as AGPs - should be performed in the PPE-AGP.[23,24]

During intubation under normal airway conditions, the intubation time with the VieScope® and the Macintosh laryngoscope was compared, however, the study showed a better visualization of the glottis in the case of the VieScope®. Also carried out by Liu et al.[25] the study indicates that in the case of non-difficult airway intubation using a video laryngoscope yielded significantly higher intubation success rates and significantly fewer postoperative complications than direct laryngoscopy. Furthermore, a study by Sanguanwit et al.[26] showed that video-laryngoscopes can increase the first-attempt intubation success and provide a better glottis view in emergency intubation. Petzoldt et al.[27] in prospective randomized non-inferiority trial showed no difference in first attempt success rates between VieScope® and Macintosh laryngoscope. Moreover, visualization of the larynx was superior using the VieScope®, while intubation time was prolonged and tube placement through bougie was more challenging.

In the case of difficult airways, the effectiveness of intubation

with the use of direct laryngoscopy decreases.[28–31] It is associated with a reduction in the degree of glottis visualization, and thus a reduction in the effectiveness of intubation and an extension of its duration in the case of direct laryngoscopy. In addition, the use of PPE-AGP suits by medical personnel may reduce the effectiveness of intubation.[32–34] In a study by Gadek et al.[19] tracheal intubation using the Macintosh direct laryngoscope in PPE-AGP conditions compared with a scenario without PPE-AGP was associated with a decrease in both the first-pass intubation success rate (ISR) (30% vs. 87%; p<0.001), overall ISR (83% vs. 100%; p=0.001), as well as increasing the intubation time (34 vs. 22.5 s; p<0.001). Other authors have also come to similar observations.[35] In our study, intubation with the use of the VieScope® laryngoscope compared to the Macintosh laryngoscope was associated with a reduction in intubation time, an increase in the effectiveness of the first-pass ISR, as well as a better visualization of the glottis in the subjects based on the Cormack-Lehane scale. These results are also reflected in the study conducted by Szarpak et al.[20] Intubation techniques that are alternative to direct laryngoscopy may bring benefits in terms of the effectiveness of intubation. However, these relationships are usually observed in the case of people who are not anesthesiologists, and therefore do not have extensive experience in ETI.[36] Then, as shown by this study and numerous scientific publications, a short training of medical personnel in the use of new types of laryngoscopes (including video laryngoscopes) is enough for these people to perform ETI at a level comparable or higher than in the case of direct laryngoscopy.[37] In the case of the study by Ecker et al.[38] the time of ETI under difficult airway conditions was 36.3±10.1 s for the VieScope® compared to 20.8±8.1 s for Macintosh laryngoscope intubation. However, it is worth emphasizing that only anesthesiologists who have extensive experience in the field of direct laryngoscopy participated in this study. In turn, in the study by Ecker et al.[39] in which the VieScope® was compared with the GlideScope®, the advantage of the video laryngoscope over the VieScope® laryngoscope was shown in terms of both intubation time and the effectiveness of the first intubation attempt. However, staff anesthesiologists or critical care specialists with experience in intubation with GlideScope also participated in this study but had no training in intubation with VieScope®. In turn, Petzoldt et al.[27] indicated that VieScope® could be an alternative to MAC in patients with difficult laryngoscopy.

The conducted study is not without limitations. Among them, the main limitation is the fact that the study was conducted under medical simulation conditions - not during clinical practice. However, simulation tests allow for full standardization of the conditions for performing individual medical procedures, without causing any danger to both the participants and the potential patient.[40] In addition, when testing procedures in relation to patients with suspected infectious disease - medical simulation is the optimal method. The second potential limitation of the study is the evaluation of only two types of laryngoscopes; however, such an action was deliberate. The VieScope® laryngoscope was chosen because it is one of the newest types of laryngoscopes. On the other hand, the Macintosh laryngoscope was included in the study, because due to its common use, it is a good reference point for other types of laryngoscopes. The study also has strengths, including the randomized crossover nature of the study.

Conclusion

Our analysis suggests that the use of a VieScope® compared to Macintosh laryngoscope in difficult airway intubation performed by paramedics warning PPE-AGP is associated with shorter intubation times, greater intubation efficiency as well as better visualization of the glottis. Additional clinical trials are necessary to confirm the obtained results.

Ethics Committee Approval: This study was approved by the Polish Society of Disaster Medicine Ethics Committee (Date: 01.09.2021, Decision No: 43/2021).

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: T.E., L.G.; Design: T.E., L.G.; Supervision: L.G.; Resource: L.G., M.P., W.W., M.C.; Materials: L.G.; Data: L.G., M.P., W.W., M.C., G.D.Ö.; Analysis: J.S., L.Ö.S., A.N., L.G.; Literature search: A.N., L.G., T.E., L.Ö.S.; Writing: T.E., L.G., M.P., L.Ö.S., G.D.Ö.; Critical revision: T.E., L.Ö.S., L.G., M.P., A.N., W.W., M.C., J.S., G.D.Ö.

Conflict of Interest: None declared.

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ORİJİNAL ÇALIŞMA - *ÖZ*

Simule edilmiş COVID-19 hastalarının entübasyonunda ilk girişim başarısına VieScope®'un etkisi: Randomize çapraz simulasyon çalışması

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AMAÇ: Çalışmamızın amacı, aerosol oluşturma prosedürleri (AGP'ler) için kişisel koruyucu ekipman (PPE) giyen sağlık görevlileri tarafından simüle edilmiş COVID-19 hastalarının farklı senaryolarında VieScope® ve Macintosh laringoskop ile entübasyonun etkinliğini belirlemekti.

GEREÇ VE YÖNTEM: Çalışma ileriye yönelik, gözlemsel, randomize ve çapraz tasarlanmış simülasyon çalışması olarak tasarlanmıştır. Çalışmaya 37 sağlık görevlisi katıldı. COVID-19 olduğundan şüphelenilen hastaların endotrakeal entübasyonunu (ETI) gerçekleştirdiler. Entübasyon, iki araştırma senaryosunda VieScope® ve Macintosh laringoskoplar kullanılarak gerçekleştirildi: Senaryo A - normal hava yolu ve Senaryo B - zor hava yolu olarak tasarlandı. Hem katılımcıların sırası hem de entübasyon yöntemleri rastgele idi.

BULGULAR: Senaryo A'da VieScope® ve Macintosh laringoskop kullanılarak entübasyona kadar geçen süre (TTI) sırasıyla 35.3 (IQR; 32–40) saniye ve 35.8 (IQR: 30–40) saniye idi. Neredeyse tüm katılımcılar hem VieScope® hem de Macintosh laringoskop ile ETI'yi başarıyla gerçekleştirdi (%100'e vs. %94.6). B senaryosunda, Macintosh laringoskop ile karşılaştırıldığında VieScope® ile entübasyon, daha kısa entübasyon süresi ($p<0.001$), ilk entübasyon girişiminde daha yüksek başarı oranı ($p<0.001$), daha iyi görüntü alma ($p=0.012$) ve entübasyonun daha kolay olduğu saptanmıştır ($p<0.001$).

TARTIŞMA: Analizimiz, PPE-AGP'yi kullanan sağlık görevlileri tarafından gerçekleştirilen zor hava yolu entübasyonunda Macintosh laringoskopa kıyasla VieScope® kullanımının daha kısa entübasyon süreleri, daha yüksek entübasyon verimliliği ve ayrıca glottisin daha iyi görüntülenmesi ile ilişkili olduğunu göstermektedir. Elde edilen sonuçları doğrulamak için ek klinik deneyler gereklidir.

Anahtar sözcükler: COVID-19; endotrakeal entübasyon; kişisel koruyucu ekipman; laringoskop; Macintosh; SARS-CoV-2; VieScope®.

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