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VIESCOPE® LARYNGOSCOPE VERSUS MACINTOSH LARYNGOSCOPE DURING DIFFICULT INTUBATION PERFORMED BY PARAMEDICS: A RANDOMIZED CROSS-OVER MANIKIN TRIAL

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ABSTRACT

INTRODUCTION: The aim of this study was to evaluate intubation performance by paramedics using Macintosh laryngoscope and VieScope® laryngoscope under simulated difficult airway conditions.

METHODS: In a randomized, single-blinded, cross-over simulation trial, 42 paramedics performed endotracheal intubation using VieScope® and Macintosh (MAC) laryngoscopes in two difficult airway scenarios: (A) tongue edema, (B) manual cervical inline stabilization. The order of participants and intubation methods was random. Time to ventilation constituted the primary outcome, and the secondary outcomes were the success rate of first intubation attempt, overall intubation success rate, Cormack and Lehane grade, and ease of use.

RESULTS: In scenario A, the median overall intubation time was 55s (46–109) in the MAC group and 30.5s (26–35) in the VieScope® group ($p < 0.001$). The efficacy of the first intubation attempt with MAC and VieScope® varied and amounted to 64.3% vs. 95.2% ($p < 0.001$). During scenario B, VieScope® offered better intubation conditions than MAC ($p < 0.001$), including shorter intubation time, higher first attempt and overall intubation success rates, as well as better glottic view.

CONCLUSIONS: In this simulation trial, we found that VieScope® could be successfully used for intubation in difficult airways by paramedics with little simulation experience with this device. VieScope® was associated with shorter time and higher success rates of intubation attempt compared with MAC. Nevertheless, we recommend that the performance of VieScope® and MAC should be further evaluated in the clinical setting to confirm our results.

KEY WORDS: endotracheal intubation, difficult airway, VieScope® laryngoscope, channeled laryngoscope, medical simulation, paramedic

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INTRODUCTION

Endotracheal intubation is still considered the gold standard of airway protection in many clinical situations. It occupies a special place in emergency medicine in-hospital as well as pre-hospital conditions. In pre-hospital conditions, endotracheal intubation is associated with the risk of hypoxia, tracheal tube misplacement, esophageal intubation, hypotension, vomiting and aspiration, cardiac arrhythmia, dental injury, or bleeding [1]. Rapid, uncomplicated, and accurate placement of the tracheal tube is one quality indicator of good advanced airway management [2]. In accordance with many society guidelines, endotracheal intubation must be performed by the most experienced operator in the team [3].

Emergency intubation based on direct laryngoscopy arouses a high risk of failure. As many authors indicate, the effectiveness of the first intubation attempt with a Macintosh laryngoscope is 57.6% [4], 84.4% [5], 89.94% [6]. The issue concerns not only adults but also pediatric patients [7]. In pre-hospital situations, the effectiveness of intubation may be even lower owing to the conditions under which intubation is performed and the experience of medical staff. As Crewdson et al. [8] indicate in their meta-analysis, only 14,913 intubations out of the total of 19,178 (77.8%) were successful at the first attempt. Rognås et al. [9] report that following rapid sequence intubation, the incidence of first-pass success was 85.8% and the overall incidence of complications equaled 22.0%, with the incidence of hypotension of 7.3% and that of hypoxia of 5.3%. Therefore, it is reasonable to search for alternative methods of endotracheal intubation to direct laryngoscopy, which will allow for more efficient performance of the medical procedure by paramedics and other medical personnel.

The aim of this study was to evaluate intubation performance by paramedics using Macintosh laryngoscope and VieScope® laryngoscope under simulated difficult airway conditions. We hypothesized that the intubation time in the case of paramedics using VieScope® would be superior to that for Macintosh laryngoscope.

MATERIAL AND METHODS

Study design

We conducted a randomized, single-blinded, crossover simulation trial to evaluate intubation conditions when using VieScope® and Macintosh laryngoscopes in difficult airway scenarios. The study was performed between November 2019 and February 2020. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (approval No.: 15.11.2019.IRB). The Consolidated Standards of Reporting Trials (CONSORT) statement was applied (see Supplementary Tab. 1) [10].

Participants

The study involved 42 paramedics who had no experience in endotracheal intubation with VieScope® but had experience in intubation with Macintosh laryngoscope. Voluntary written informed consent was obtained from each participant. All participants were active paramedics and worked in an Emergency Medical Services team in Poland.

Equipment and materials

Two types of laryngoscope were used in the study: a standard Macintosh laryngoscope with blade #3 (HEINE Optotechnik GmbH & Co. KG, Gilching, Germany) and a new VieScope® laryngoscope (Adroit Surgical, Oklahoma City, USA; see Fig. 1). VieScope® laryngoscope is a self-contained, battery-powered, disposable scope that takes advantage of a closed circular tube with a beveled end to visualize the vocal cords. The light is transmitted through the sidewall of the tube from end to end as well as within the lumen of the tube to give the user the best illumination of the target tissue with minimal chance of light obstruction by secretions or blood. Endotracheal intubation with VieScope® involved a two-step process. Firstly, the device was inserted orally to obtain visualization of glottis through the clear cylindrical lumen of the intubation channel. The second step involved a bougie

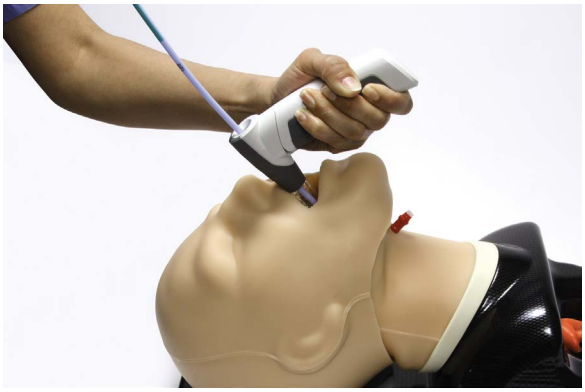

FIGURE 1. VieScope® laryngoscope

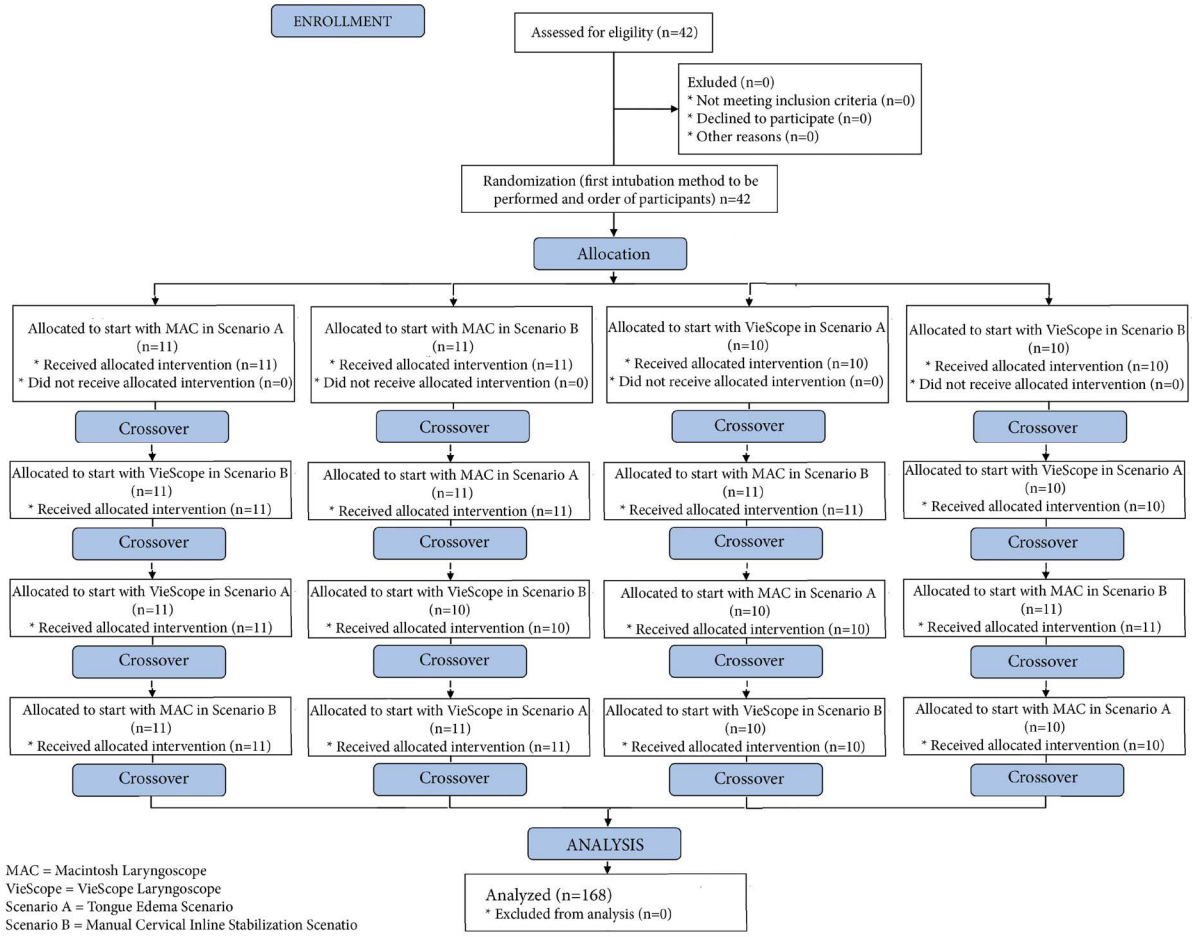

FIGURE 2. Randomization flow chart

guide insertion and removal of VieScope® followed by railroading the endotracheal tube over the bougie. The Voir Bougie guide size 15 Fr is dedicated to VieScope®. For intubation with Macintosh laryngoscope, a standard intubation stylet was used. In each case, the stylet, guide, and tube were covered with a lubricant dedicated for simulators.

Interventions

All participants listened to a 30-min lecture covering anatomical and physiological basics, as well as principles of endotracheal intubation with the particular devices. At the end of the theoretical part, the instructor demonstrated correct endotracheal intubation with VieScope® and Macintosh laryngoscopes. Afterwards, the paramedics had an opportunity to participate in a workshop session, during which they performed endotracheal intubation using the two types of investigated laryngoscopes under normal airway conditions. To this purpose, an AirSim Combo Bronchi X airway simulator (TrueCorp®, Ireland) was used.

One month later, the 42 paramedics participated in the proper evaluation. With the use of the Research Randomizer program (randomizer.org), they were randomized into individual groups. The order of both participants and intubation methods was random. The detailed randomization procedure is presented in Figure 2. An advanced SimMan 3G adult patient simulator (Laerdal, Stavanger, Norway) was used to simulate a patient requiring intubation. The simulator was placed on a flat floor in the neutral position. The paramedics were asked to perform endotracheal intubation using the VieScope® and Macintosh laryngoscopes in two separate difficult airway scenarios:

a) scenario A: tongue edema (simulated by inflating the tongue using the simulator software);
b) scenario B: manual cervical inline stabilization.

All participants performed a maximum of three intubation attempts with each device in the differ-

Table 1. Data from intubation in Scenario A: Tongue edema. Data are presented as median (IQR), or as number (percentage)

Parameter	Macintosh laryngoscope	VieScope®	p-value
Duration of intubation when one attempt needed, s	48.5 (44–58)	30 (23–39)	< 0.001
Overall intubation time, s	55 (46–109)	30.5 (26–35)	< 0.001
Overall success rate (%)	39 (92.9)	42 (100)	0.081
Number of intubation attempts (%) 1 2 3 Median (IQR)	 27 (64.3) 5 (11.9) 7 (16.7)	 40 (95.2) 2 (4.8) –	< 0.001
Cormack & Lehane grade 1 2 3 4	 – 10 (23.8) 30 (71.4) 2 (4.8)	 31 (73.8) 11 (26.2) – –	< 0.001
Ease of use (0–10; VAS score)	5 (3–7)	0 (0–3)	< 0.001

IQR — Interquartile Range

ent airway scenarios, with a 10-min break between the scenarios.

Outcomes

The primary outcome was time to first ventilation required by one intubation attempt, defined as the time from picking up the laryngoscope to the first visible ventilation of the lungs in the absence of gastric infiltration. Besides, overall intubation time was calculated, defined as the sum of times of individual intubation attempts where more than one intubation attempt was needed. The secondary outcomes were the success rate of first intubation attempt, overall intubation success rate, Cormack and Lehane grade, and ease of use [11]. Each airway scenario was limited to a maximum of 60 s, up to 3 intubation attempts. Between the airway scenarios, the paramedics had a break lasting 10 min. Following the completion of a scenario, the subjects were asked to grade each device for the ease of its technical use (0 — easy, 10 — difficult).

Statistical analysis

The results obtained for 10 paramedics in the preliminary study showed that the time required for successful intubation with VieScope® was approximately 27 ± 5 s. We estimated that 41 participants would be adequate for 2 independent groups with $\alpha = 0.05$ and $\beta = 0.2$.

All statistical analyses were performed with the use of the Statistica 13.3EN for Windows software (Tibco Inc.; Tulsa, USA). Qualitative variables are presented as absolute values and relative frequencies. Numerical variables are presented as means and standard deviations or medians and interquartile ranges. The relationship between categorical variables was analyzed with the Fisher exact test and the McNemar test. For numerical variables, the parametric and non-parametric tests applied were Student's *t*-test, the Wilcoxon test, and the Mann-Whitney test. A two-tailed p-value of 0.05 was considered significant.

RESULTS

Overall, 42 paramedics (15 women, 35 men; age: 32 (27–36) years; work experience: 6 (3–10) years participated in the trial. All participants had clinical experience in endotracheal intubation with Macintosh laryngoscope.

Tongue edema

The intubation time when only one intubation attempt was required equaled 48.5 s (44–58) for Macintosh laryngoscope vs. 30 s (23–39) for VieScope® ($p < 0.001$; Tab. 1). The total intubation time for Macintosh and Vie Scope® laryngoscopes varied and amounted to 55 s (46–109) vs. 30.5 s (26–35), respectively. The efficacy of the first intubation attempt with VieScope® was significantly higher than that for Macintosh laryngoscope (95.2% vs. 64.3%; $p < 0.001$). The total efficacy was comparable between the intubation methods and equaled 100% for Vie Scope® and 92.9% for Macintosh

Table 2. Data from intubation in Scenario B: Manual cervical inline stabilization. Data are presented as median (IQR), or as number (percentage)

Parameter	Macintosh laryngoscope	VieScope®	p-value
Duration of intubation when one attempt needed, s	49 (39–52)	30 (24–34)	< 0.001
Overall intubation time, s	88 (51–114)	30.5 (24–35)	< 0.001
Overall success rate (%)	41 (97.6)	42 (100)	0.328
Number of intubation attempts (%) 1 2 3	 16 (38.1) 7 (16.7) 18 (42.9)	 37 (88.1) 5 (11.9) –	< 0.001
Cormack & Lehane grade 1 2 3 4	 – 13 (30.9) 22 (52.4) 7 (16.7)	 29 (69.0) 11 (26.2) 2 (4.8) –	< 0.001
Ease of use (0–10; VAS score)	5 (4–7)	1 (0–3)	< 0.001

IQR — Interquartile Range; NS — not statistically significant

($p = 0.081$). Intubation with VieScope® compared with Macintosh laryngoscope involved better glottis visibility according to the Cormack and Lehane scale ($p < 0.001$); it also turned out easier ($p < 0.001$).

Manual cervical inline stabilization

In the manual cervical inline stabilization scenario, the duration of intubation when one attempt was needed equaled 30 s (24–34) when using VieScope® and 49 s (39–52) with Macintosh laryngoscope; the difference was statistically significant ($p < 0.001$; Tab. 2). The overall intubation time needed for successful intubation with VieScope® and Macintosh laryngoscope varied and amounted to 30.5 s (24–35) vs. 88 s (51–114) ($p < 0.001$). The success rate of first intubation attempt was 88.1% with VieScope® and 38.1% with Macintosh ($p < 0.001$). In turn, the total efficacy of intubation was close to 100% vs. 97.6% ($p = 0.328$). Intubation with VieScope® was characterized by statistically significantly better intubation parameters compared with Macintosh laryngoscope ($p < 0.001$) in terms of both glottis visibility and ease of the procedure.

DISCUSSION

The aim of the study was to evaluate difficult intubation performance among paramedics using standard Macintosh laryngoscope and VieScope® laryngoscope. To our knowledge, this is the first comparison of VieScope® laryngoscope with a direct laryngoscope in adult difficult airway conditions.

As the scientific literature lacks reports on the VieScope® laryngoscope, which would enable discussion of the results, the authors decided to relate the obtained data to articles on channeled laryngoscopes, which include VieScope®.

In the conducted simulation study, intubation with the new VieScope® laryngoscope was associated with higher efficiency of the first intubation attempt and shorter procedure duration for both tongue edema and manual cervical inline stabilization. Rognås et al. [9] showed that multiple endotracheal intubation attempts were associated with an increased overall incidence of complications, such as bleeding or pharyngeal edema, and might lead to a situation referred to as "cannot intubate, cannot ventilate" [12, 13].

As indicated by Driver et al. [14], the effectiveness of emergency intubation among difficult airway patients is insufficient and equals only 82% when an endotracheal stylet is used. Moreover, hypoxemia was observed in 14% of patients during intubation. In a tongue edema simulation study, Szarpak et al. [15] reported a 63.6% effectiveness of first intubation attempt with Macintosh laryngoscope.

Research indicates that alternative types of laryngoscopes, including channeled laryngoscopes, can be used instead of direct laryngoscopes, as they guarantee better glottis visibility in difficult airways. The above thesis has also been confirmed by the results obtained in the present study, where the efficacy of the first VieScope® endotracheal intubation attempt for tongue edema was 95.2% and turned out statistically significantly higher than that for Macintosh

laryngoscope (64.3%; $p < 0.001$). Szalast et al. [16] also emphasize the advantage of channeled laryngoscopes over direct laryngoscopes in difficult airways intubation: the efficacy of the first attempt intubation equaled 70.4% for Airtraq and 14.8% for Macintosh laryngoscope. The lower efficacy of intubation with both devices compared with our outcomes may result from the fact that in the Szalast et al. study, intubation was performed by a nurse and our study involved paramedics, who learn how to protect the airways with, among others, Macintosh or Miller laryngoscopes. In turn, Al-Ghamdi [17] indicate that Airtraq requires longer intubation times but less frequently causes sore throat compared with Macintosh when used by anesthesiologists with limited experience in patients with normal airways.

Endotracheal intubation under trauma conditions or suspicion of cervical spine injury in pre-hospital settings requires cervical spine stabilization with at least manual cervical inline stabilization. Numerous studies have shown that direct laryngoscopic intubation under such conditions is ineffective and prolonged in time compared with normal airway intubation [17–19]. In patients undergoing endotracheal intubation with cervical immobilization, Hosalli et al. [20] showed that channeled laryngoscopes were superior to Macintosh laryngoscopes, with greater ease of intubation and lower impact on hemodynamic variables. In turn, as reported by Çolak et al. [21], a minimal cervical motion was obtained during tracheal intubation with the use of Airtraq types of laryngoscope compared with the Macintosh laryngoscope. The advantage of channeled laryngoscopes over Macintosh devices in terms of less movement of the cervical spine was also indicated by Hirabayashi et al. [22]. A meta-analysis conducted by Suppan et al. [23] relating to cervical spine immobilization intubation revealed that the Airtraq device reduced the risk of intubation failure when compared with Macintosh laryngoscope.

Another important aspect, besides the efficacy of intubation itself, is the duration of the procedure, directly related to the risk of hypoxia and thus of hypoxia-induced changes in the central nervous system. In the tongue edema and manual cervical inline stabilization scenarios, Vie Scope® intubation was significantly shorter than the procedure with Macintosh laryngoscope (30.5 s vs. 55 s and 30.5 s vs. 88 s, respectively). In pre-hospital conditions, the long duration of intubation also poses additional problems, i.e. limited strength during rescue procedures; the intubating paramedic is excluded for more than 1 min from performing other procedures. In this case, it is necessary to make specific therapeutic choices. In a Szalast et al. study [16], intubation with Airtraq was significantly shorter than that with Macintosh (26 vs. 53 s, respectively). Rendeki et al. [24] indicated that Airtraq was superior to the Macintosh laryngoscope in difficult airway intubation performed by novice users. This finding is in line with studies by other researchers [25, 26].

Limitations and strengths

Owing to its specificity, the study has its strengths and weaknesses. The limitations may include, first of all, the conditions of medical simulation; however, this procedure was deliberate and dictated by the randomized, cross-over study design. Medical simulation is now a rapidly growing branch of medical science and allows for full standardization of the conditions of procedures without potential damage to a patient's health [27, 28]. Another limitation is the inclusion of paramedics; nevertheless, this professional group, acting under pre-hospital conditions, relatively often has to protect the patient's airways and can only count on their knowledge and skills [29]. Therefore, it is justified to search for intubation methods which will increase the effectiveness of this procedure when performed by paramedics under pre-hospital conditions. Currently, studies are planned to extend the research group to other medical professions.

The strengths of the study include its randomized, cross-over character, which was intended to minimize the learning curve effect. Also, we used the most modern simulators of an adult patient, as well as performed the first evaluation of a new type of laryngoscope. Another strong point of the study is the blinding of results at the stage of statistical analysis.

CONCLUSIONS

In this simulation trial, we found that VieScope® could be successfully used for intubation in difficult airways by paramedics with little simulation experience with this device. VieScope® was associated with shorter time and higher success rates of intubation attempt compared with Macintosh. The presented study is the first to report that VieScope® shows promise for further clinical evaluation.

Conflict of interest

The authors declare no conflict of interest.

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