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RESEARCH ARTICLE

Comparing vie scope® and Macintosh laryngoscopes in suspected/confirmed Covid-19 cardiac arrest patients being intubated by paramedics: a prospective randomized crossover simulation trial

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ABSTRACT

Aim: This study was designed with the aim of evaluating Vie Scope®'s role in placing an endotracheal tube (ETT) by paramedics wearing full personal protective equipment who are experienced in direct laryngoscopy but inexperienced in using the Vie Scope® for intubation.

Material and Methods: Twenty-seven paramedics participated in this prospective, randomized, single-blinded crossover simulation trial using manikins. Participants performed endotracheal intubation on simulated adult cardiac arrest patients with suspected/confirmed COVID-19. During all procedure's, paramedics wore Level C personal protective equipment (PPE). Primary endpoint was time to intubation (TTI).

Results: Time to intubation using the Vie Scope was 43.5±12 seconds, statistically significantly faster than the Macintosh laryngoscope at 57.5±15.6 seconds (MD = -14.00; 95% CI [-21.42, -6.58]; $p < 0.001$). First pass success rate using the Vie Scope® and Macintosh laryngoscope was 88.9% and 63.0%, respectively (OR = 4.71; 95% CI [1.12, 19.70]; $p = 0.03$). The overall intubation success rate was 100% for each group.

Conclusions: With paramedics wearing full PPE, the Vie Scope laryngoscope provided faster endotracheal intubation and a better first pass success rate than the Macintosh laryngoscope. Further studies involving clinical trials are necessary to confirm these results.

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Introduction

The world has been struggling with the SARS-CoV-2 (COVID -19) coronavirus pandemic over the past year. The pandemic has been a challenge for medical personnel (Dzieciatkowski et al., 2020), especially as we are currently observing numerous mutations of the virus that are more virulent than the original. Currently, a third wave of the disease caused by SARS-CoV-2 is being observed. According to data provided by John Hopkins University,123,349,088 confirmed cases have been found for COVID-19 as of March 22, 2021, with a mortality rate of 2.2%. The situation is particularly dangerous for medical personnel, especially for pre-hospital emergency medical teams (Brown & Chan, 2020; Pruc et al., 2021; Smereka & Szarpak, 2020a). Due to the increasing prevalence of COVID-19 within communities, each patient should be treated as potentially infectious in the pre-hospital setting (Smereka & Szarpak, 2020b). This fact is even more important because, despite vaccinations, some cases of disease have been observed among people who have received both doses of the vaccine.

Tran et al. indicated tracheal intubation to be a significant risk factor for transmitting SARS to healthcare workers in their meta-analysis (Tran et al., 2012). Tra-

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cheal intubation (ventilation) in a patient with SARS-CoV-2 is therefore equally dangerous. The emergency medical service (EMS) teams that manage patients should be performing medical procedures using full personal protective equipment (PPE), especially during aerosol generating procedures (AGP). The use of PPE-AGP however, may result in extending the duration of individual procedures, reducing their effectiveness, and also resulting in excessive fatigue for the rescuers themselves (Benítez et al., 2020; Drozd et al., 2021; Kang et al., 2017; Martín-Rodríguez, 2019; Smereka et al., 2020).

One of the most demanding clinical situations in the pre-hospital setting is cardiopulmonary resuscitation, a key element of which is effective airway management and using rescue breathing. Tracheal intubation based on the Macintosh laryngoscope is still the gold standard of endotracheal intubation. In a meta-analysis by Ludwin et al. (2020) the effectiveness of direct laryngoscopy while using PPE-AGP was 93.6%, but the studies on intubation did not take place in the prehospital environment. Many other uncontrolled factors occur in the prehospital setting, including time pressure and poor lighting/weather conditions, as well as patients' difficult airways. These were shown to reduce the effectiveness of the Macintosh laryngoscope intubation to 89.94% in Mallick et al.'s study (Mallick et al., 2020) and to 58% in Suzuki et al.'s study (2029). Therefore, searching for the most effective methods for performing procedures involving endotracheal intubation while medical staff wear PPE is important. One example of an alternative to the Macintosh laryngoscope may be the Vie Scope, a patented bougie introducer that illuminates the entire length of the barrel proximally and distally (Figure 1). With its angled flared tip, the design is based on ear, nose, and throat (ENT) surgeons' laryngoscopes that have been used for over a century. The Vie Scope opens the pharynx to give the user a straight line of sight to the larynx to allow passage of the bougie between the vocal cords under direct vision. Placement of the ETT is achieved using the Seldinger technique.

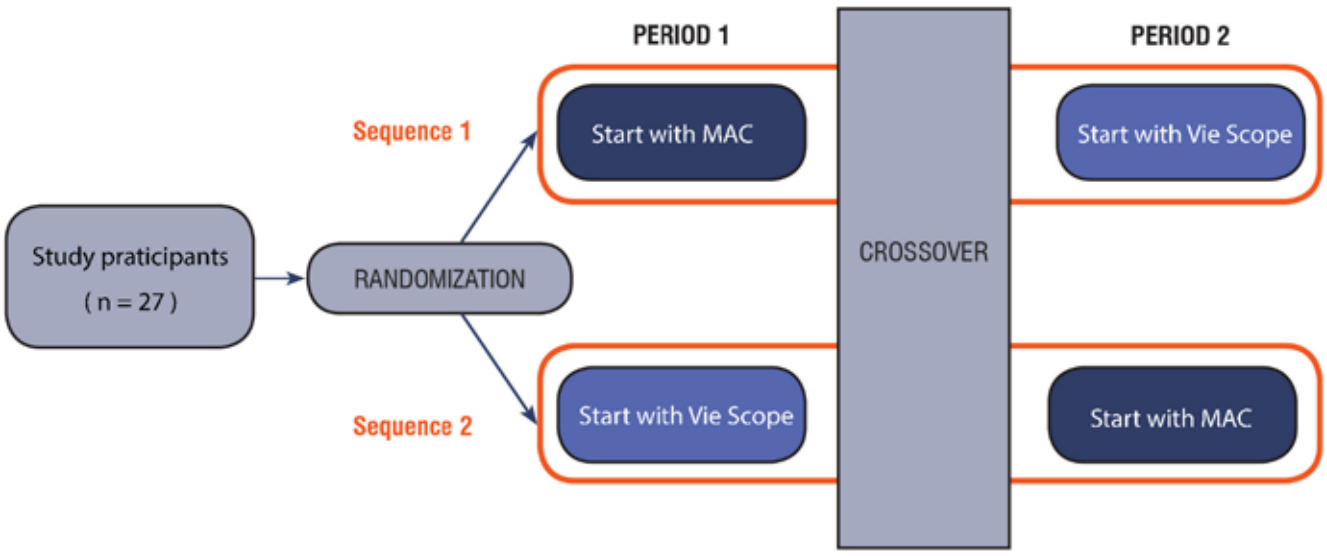

Figure 1. The Vie Scope® laryngoscope comparison with the Macintosh laryngoscope.

This study was designed with the aim of evaluating Vie Scope®'s role in ETT placement by paramedics wearing full PPE who are experienced in direct laryngoscopy but not in the use of the Vie Scope® for intubation.

Methods

This trial was designed as a prospective, randomized, single-blinded crossover simulation trial. The study's protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (Approval. No. 03.02.2020. IRB) and was performed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Turner et al., 2012). The study is a continuation of the authors' research undertaken with the aim of showing the most effective method for securing the airway in conditions requiring the use of PPE (Ludwin et al., 2020; Maslanka et al., 2020; Szarpak et al., 2016)

Participants

All participants have at least two years' experience in prehospital emergency medicine as well as experience with the Macintosh laryngoscope for intubation in cardiac arrest patients (> 10 intubations using Macintosh). Participant exclu-

sion criteria included refusal to participate in the study, shortness of breath, or infection symptoms. Following written informed consent, 27 paramedics were recruited for the study.

Study Design

Prior to the study, all paramedics participated in standard training involving both the theoretical aspects of endotracheal intubation using the Vie Scope® laryngoscope and the Macintosh laryngoscope, as well as a 30-minute practice session during which they performed endotracheal intubation with the tested devices under normal airway conditions using a Laerdal Airway Management Trainer (Laerdal®, Stavanger, Norway) manikin.

Both the order of participants and the research methods were randomized using a Research Randomizer program (Urbaniak & Plous, 2013). The participants were divided into two groups, the first of which performed endotracheal intubation using the Vie Scope® laryngoscope, and the second group using the Macintosh laryngoscope. After a maximum of three intubation attempts, participants had a 30-minute break and then performed endotracheal intubation using the other method. The detailed randomization procedure is presented in Figure 2.

Figure 2. CONSORT flowchart for participant recruitment.

During the actual study, a SimMan 3G simulator (Laerdal®, Stavanger, Norway) manikin was used, which was placed on a flat floor in a room with 1000 lux lighting intensity, simulating a cloudy day.

During each procedure, paramedics wore full Level C PPE, which consists of the full suit with full-face air purifying respirators, inner and outer chemical-resistant gloves, and disposable chemical-resistant outer boots.

Measurements

The primary endpoint was time to intubation (TTI), defined as the time from advancing the laryngoscope through the dental arches to confirmation of endotracheal tube placement through first ventilation using a resuscitator bag. Additionally, time to glottis visualization (TTG) was measured and defined as the time starting from the advancement of the laryngoscope through the dental arches to the visualization of the glottis. A total of three attempts with each laryngo-

scope was allowed for each operator. Attempts requiring more than 120 seconds or more than two attempts (withdrawal of the device from the mouth followed by repositioning) or esophageal intubations were recorded as failure to intubate. We also recorded the rate of first-pass success intubation as well as the number of intubation attempts needed for correct intubation. To assess the glottic view, the Cormack and Lehane (CL) grade was used. Ease of use was assessed with a visual analogue scale score ranging from 1 to 10, with 1 meaning "easiest" and 10 the "most difficult."

Statistical Analysis

Results were blinded prior to the statistical analysis stage. All statistical analyses were performed using the STATA Version 16.1EN for MacOS software (StataCorp LLC, College Station, TX, USA). All reported *p* values were two-sided, with *p* values less than 0.05 being considered statistically significant. Data for the rate of successful intubation were analyzed using Cochran`s Q test followed by Dunn-Bonferroni post-hoc tests. Data for the TTI, TTG, number of intubation attempts, number of optimization maneuvers, number of audible dental clicks, Cormack-Lehane score, and view and difficulty of tracheal intubation were analyzed using paired non-parametric tests. All continuous outcome variables were expressed as means and standard deviations (*SD*) and analyzed using the Mann-Whitney U test. The inverse variance estimator was used to calculate the 95% confidence interval (CI) for the median difference.

Results

Twenty-seven paramedics participated in this trial. All participants prior to this study had clinical experience with direct laryngoscopy, but no one had previous experience with the Vie Scope® in either clinical or medical simulation conditions.

A detailed summary of the results is presented in Table 1. Time to intubation for the Vie Scope was 43.5 ± 12 seconds and was statistically significantly faster than the Macintosh laryngoscope's 57.5 ± 15.6 seconds (*MD* = -14.00; 95% CI [-21.42, -6.58]; $p < 0.001$). The time to glottis visualization using the Vie Scope was 12.4 ± 6.5 compared to the Macintosh laryngoscopes at 16.5 ± 9 seconds (*MD* = -4.10; 95% CI [-8.29, 0.09]; $p = 0.05$).

Table 1

Summary of the Outcomes

Parameter	Events/Participants		Events		*p* value for differences across groups
	Vie Scope group	Macintosh group	OR / MD	95% CI	
1st attempt	24/27 (88.9%)	17/27 (63.0%)	4.71	1.12, 19.70	**0.03**
Overall success rate	27/27 (100%)	27/27 (100%)	NE	NE	1.00
TTG	43.5(12)	57.5(15.6)	-14.00	-21.42, -6.58	**<0.001**
TTI	12.4(6.5)	16.5(9)	-4 .10	-8.29, 0.09	0.05
CL grade					
1	25 (92.6%)	19 (77.8%)	5.26	1.00, 27.69	
2	2 (7.4%)	4 (14.8%)	0.46	0.46, 2.75	**<0.001**
3	0 (0.0%)	2 (7.4%)	0.19	0.01, 4.05	
4	0 (0.0%)	0 (0.0%)	NE	NE	
Ease of use	3(0.6)	5.3(0.9)	-2.30	-2.71, -1.89	**<0.001**

Legend: CI = confidence interval; CL = Cormack and Lehane grade; MD = mean difference; NE = not estimable, OR = odds ratio; TTI = time to intubation; TTG = time to glottis view.

The first pass success rates using the Vie Scope® and Macintosh laryngoscope were 88.9% and 63.0%, respectively (OR=4.71; 95%CI [1.12, 19.70]; $p = 0.03$). The overall intubation success rate was 100% for each group.

Based on the Cormack and Lehane scale, intubation with the Vie Scope laryngoscope compared to the Macintosh laryngoscope was associated with improved visualization of the glottis ($p < 0.001$).

Subjective ease of intubation using the VAS revealed that participants found intubation to be an easier procedure when using the Vie Scope (3 ± 0.6 s) compared to the Macintosh laryngoscope (5.3 ± 0.9 s; *MD* = -2.30; 95% CI [-2.71, -1.89]; $p < 0.001$).

Discussion

Despite the introduction of supraglottic airway devices, endotracheal intubation is still the gold standard for airway management. Due to its price and widespread availability, the Macintosh laryngoscope is the device used most for performing endotracheal intubation both in pre-hospital and inpatient settings (Raimann et al., 2019; Szarpak, 2018). Our study is one of the first to demonstrate the Vie Scope laryngoscope (Maslanka et al., 2020; Maslanka, Smereka et al., 2020; Maslanka, Szarpak et al., 2020) to be able to be more suitable for endotracheal intubation in suspected or confirmed COVID-19 patients with cardiac arrest when the operator is wearing PPE-AGP compared to the Macintosh laryngoscope.

In this study, intubation times using the Macintosh laryngoscope were 57.5 ± 15.6 seconds. Similar results assessing the Macintosh laryngoscope have been obtained among studies, including Burns et al. at 53.4 ± 46.4 s (Burns et al., 2010) and Castle et al. at 50.8 ± 15.6 s (2011). Greenland et al. demonstrated shorter intubation times using the Macintosh laryngoscope at 22.2 ± 6.6 s (2007); however, the participants in this study included four consultant anesthetists and 14 anesthetic trainees, which is not representative of prehospital paramedics.

Intubation using the Vie Scope laryngoscope had statistically significantly shorter intubation times (i.e., 43.5 ± 12 s) despite using the Seldinger technique. Ludwin et al.'s meta-analysis indicated the advantage different types of video-laryngoscopes have over the Macintosh laryngoscope (2020). These results are important from the clinical standpoint because endotracheal intubation should be performed as quickly as possible as CPR requires many concurrent activities using advanced algorithms, including chest compressions, heart rhythm monitoring, and pharmaco-therapeutical implementation. All these activities may be performed in two- or three-person EMS teams (Szarpak & Madziala, 2020). Therefore, the operator should secure the airway as expediently as possible in order to be able to focus on the other aspects of CPR.

Apart from the time to intubation itself, another key parameter is the effectiveness of the first intubation attempt (i.e., first pass success). Currently, the effectiveness of endotracheal intubation in the emergency medicine prehospital environment has been unsatisfactory. This study has shown the first pass success using the Vie Scope to be as high as 88.9%, with a maximum of two attempts for achieving 100% success. This point alone confirms a shorter learning curve for laryngoscopy using the Vie Scope, as the entire training process was based on a 30-minute training session. First-pass success intubation is important, as repeated intubation attempts may increase soft tissue damage and bleeding, which can make the procedure more difficult or cause a scenario described by the Difficult Airway Society as "can't intubate, can't ventilate" (Braun et al., 2010; Higgs et al., 2018) if the tissues around the entrance to the glottis become swollen.

Strengths and Weaknesses of the Study

Our study has several limitations. First, the study was conducted in a medical simulation environment using manikins as opposed to real clinical rescue operations undertaken by EMS teams. The choice was deliberate and dictated by the following factors: a) the current SARS-CoV-2 pandemic has limited the possibility of conducting clinical trials, especially in pre-hospital conditions, and b) the current difficulties related to the performance of procedures in PPE-AGP increase the risk of reducing the effectiveness of the performed procedure. Medical simulation allows for full standardization of the performed procedures without harm to the potential patient.

The second limitation is that only paramedics were tested. The choice of paramedics was dictated by the fact that this professional group provides immediate assistance to patients at the pre-hospital stage and this group often has to conduct cardiopulmonary resuscitation, including securing the patient's airway. The third limitation is the participant group contained 27 people; however, in the pandemic era and analyzing other studies, the authors concluded such a group size to be sufficient for conducting a pilot study.

One of this study's strengths is firstly its randomized crossover nature with the results being blinded prior to the statistical analysis stage. Another strength of this study is that we evaluated the newest laryngoscope available (i.e., the Vie Scope), which has limited scientific reports that have been published about it.

Conclusions

With paramedics wearing full PPE, the Vie Scope laryngoscope provided faster endotracheal intubation and a higher first-pass success rate for intubation compared to the Macintosh laryngoscope after only 30 min of training. Further studies, including clinical trials, are necessary to confirm these results.

Abbreviation's list

AGP = aerosol generating procedures

CI = confidence interval

CL = Cormack and Lehane grade

CONSORT = Consolidated Standards of Reporting Trials

EMS = Emergency medical service

MD = mean difference

OR = odds ratio

PPE = personal protective equipment

SD = Standard deviation

TTG = Time to glottis visualization

TTI = Time to intubation

VAS = Visual analog scale

Authors' contribution

PW as the study designer carried out the clinical studies, analyzed the data, and drafted the manuscript. MMas, performed the study and data analysis; MMal performed the study; WW performed the study; MZ performed the study; MG searched bibliographies; LK drafted the manuscript; LS as the study designer performed the clinical studies, analyzed the data, and drafted the manuscript. All authors read and approved the final manuscript.

Peer-review

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Disclosure statement

The authors report no conflict of interest.

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