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Comparison of Vie Scope® and Macintosh laryngoscopes for intubation during resuscitation by paramedics wearing personal protective equipment

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ABSTRACT

Background: Endotracheal intubation (ETI) is still the gold standard of airway management, but in cases of sudden cardiac arrest in patients with suspected SARS-CoV-2 infection, ETI is associated with risks for both the patient and the medical personnel. We hypothesized that the Vie Scope® is more useful for endotracheal intubation of suspected or confirmed COVID-19 cardiac arrest patients than the conventional laryngoscope with Macintosh blade when operators are wearing personal protective equipment (PPE).

Methods: Study was designed as a prospective, multicenter, randomized clinical trial performed by Emergency Medical Services in Poland. Patients with suspected or confirmed COVID-19 diagnosis who needed cardiopulmonary resuscitation in prehospital setting were included. Patients under 18 years old or with criteria predictive of impossible intubation under direct laryngoscopy, were excluded.

Patients were randomly allocated 1:1 to Vie Scope® versus direct laryngoscopy with a Macintosh blade. Study groups were compared on success of intubation attempts, time to intubation, glottis visualization and number of optimization maneuvers.

Results: We enrolled 90 out-of-hospital cardiac arrest (OHCA) patients, aged 43–92 years. Compared to the VieScope® laryngoscope, use of the Macintosh laryngoscope required longer times for tracheal intubation with an estimated mean difference of −48 s (95%CI confidence interval [CI], −60.23, −35.77; $p < 0.001$). Moreover VieScope® improved first attempt success rate, 93.3% vs. 51.1% respectively (odds ratio [OR] = 13.39; 95%CI: 3.62, 49.58; $p < 0.001$).

Conclusions: The use of the Vie Scope® laryngoscope in OHCA patients improved the first attempt success rate, and reduced intubation time compared to Macintosh laryngoscope in paramedics wearing PPE for against aerosol generating procedures.

Trial registration: ClinicalTrials registration number NCT04365608

1. Introduction

For over a year, medical services have been struggling with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic and the coronavirus disease 2019 (COVID-19) it causes [1]. As of December 28nd, 2021, there have been 281,468,439 confirmed COVID-19 cases, and 5,408,970 deaths. Despite the administration of vaccines, there is still a high risk of infection among healthcare professionals. Emergency medical service staff, being the first line who come into contact with the potential COVID-19 patient, must use personal protective equipment (PPE), which is classified as standard, contact, droplet or airborne precautions [2,3]. A number of procedures are at a high risk of aerosol generation during emergency medicine procedures, including bag–mask

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ventilation, endotracheal intubation or extubation, continuous positive airway pressure, or chest drain management [4,5]. Unfortunately, the use of PPE may affect the psychomotor skills of the person performing the procedure [6].

Regardless of the prevailing pandemic, endotracheal intubation (ETI) is still the gold standard of airway management [7]. However, in cases of sudden cardiac arrest in patients with suspected SARS-CoV-2 infection, ETI is associated with risks for both the patient and the medical personnel. In patients with severe respiratory failure in the course of COVID-19, hypoxia can occur particularly rapidly, and proper oxygenation and airway management are crucial [8]. Rapid oxygenation and airway management are essential in the case of sudden cardiac arrest and delayed or ineffective ventilation may affect neurological prognosis and the probability of survival [9]. In most health care systems, paramedics undertake advanced resuscitation support, including airway management and ETI. However, as shown by numerous studies, ETI is more challenging when performed in PPE suits, which may reduce both the first pass success of intubation and increase the time required for intubation [10].

Because of the challenge of ETI when wearing PPE, alternative intubation methods could be life-saving. An example of such a device is the Vie Scope® laryngoscope, which is a single use bougie introducer that illuminates the entire length of the enclosed translucent barrel from proximal to distal (Fig. 1). This illumination method avoids light blackout from secretions or blood, which can occur with laryngoscopes with a light or camera located at the blade tip [11,12]. The Vie Scope® opens the pharynx and displaces tissue to give the user a straight unobstructed line of sight to the larynx and it allows passage of the bougie between the vocal cords under direct vision. Intubation using the Vie Scope® is performed based on six steps: 1) Inserting the Vie Scope® and identifying the glottic opening between the vocal cords, 2) passing the bougie under direct vision between the vocal cords, and into the trachea, until the green safety band has passed the upper teeth or gums, 3) Removing the Vie Scope® while leaving the bougie in place, 4) Passing the appropriately sized endotracheal tube over the bougie into the trachea, 5) While keeping the endotracheal tube stabilized, removing the bougie, 6) Ventilating and confirming tube placement.

We hypothesized that the Vie Scope® is simpler and more useful for ETI under cardiac arrest than the conventional laryngoscope with Macintosh blade when operators are wearing personal PPE.

2. Methods

A prospective, multicenter, randomized controlled trial was performed by Emergency Medical Services teams in the Polish cities of Warsaw, Poznan, and Katowice. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (approval No. 12.02.2020.IRB) and was registered at ClinicalTrials.gov (NCT04365608). The study was performed according to the Declaration of Helsinki and Good Clinical Practice guidelines. Due to the fact that the strategies used in both study groups are considered components of standard care, and the study concerned patients in cardiac arrest, the requirement for written informed consent was waived by the committee. Where applicable, the Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed, see Fig. 2.

Fig. 1. Vie Scope® laryngoscope.Flow diagram of the study.

Patients were included if they were 18 years or older, in cardiac arrest in the prehospital setting, and cardiopulmonary resuscitation was implemented in full PPE. At paramedic discretion based on the anatomical structure and pathological changes, patients with predicted on the clinical judgement of the intubating paramedic impossible intubation under direct laryngoscopy, were excluded.

As all patients in cardiac arrest were treated as though they may have COVID-19, paramedics wore PPE during each intervention. This consisted of a ProChem I F suit (DuPont Personal Protection, Luxemburg) that provides protection against organic and inorganic chemicals in high concentrations and against particles less than 1 μm in diameter [13], FFP2 masks, face shields, and double nitrile gloves (Fig. 3). During resuscitation and airway management procedures, all patients were placed in a supine position and standard advanced cardiovascular life support was performed according to the European Resuscitation Council guidelines [14].

Before the study, all operators underwent a 30-min theoretical and practical training that included using Vie Scope® and Macintosh laryngoscope as an endotracheal intubation technique. They performed intubation on manikins using Vie Scope® and Macintosh laryngoscope during the training.Two techniques of intubation were randomized for use in the study:

1) Vie Scope® laryngoscope.
2) Laryngoscope with Macintosh (MAC) blade adapted to the patient's size. During the direct laryngoscopy, a standard disposable intubation guide was used.

Intubations were performed by 29 paramedics whose minimum length of service was 2 years (mean 4.7, standard deviation [SD] 2.1 years) and they were not blinded to the intervention.

Randomization was carried out using random number generating software [Urbaniak, G. C., & Plous, S. (2013) Research Randomizer (Version 4.0) [Computer software]. Endotracheal intubation was performed according to AHA/ERC guidelines. The timing of intubation was left to the discretion of the paramedics' team. Reflecting conventional EMS practice, a size 7.0 ETT was used in women and a size 7.5 ETT was used in men. Before intubation, the tracheal tube and the guide were gelled with lubricant. For this purpose, Lidocainum gel (20 mg / g; Jelfa, Jelenia Gora, Poland) was used. At any moment, operator could ask for the use of the “Backwards Upwards Rightwards Pressure” (BURP) maneuver. The correct position of the endotracheal tube was determined by capnography and auscultation of both lungs.

2.1. Outcome measures

The primary outcome was ETI success rate during first laryngoscopy attempt. Failed intubation was defined as time-to-intubation longer than 120 s or wrong placement of endotracheal tube. Secondary outcomes were complications related to ETI, and included ETI failure, esophageal intubation, mainstem intubation, vomiting, pulmonary aspiration, dental trauma, and unplanned extubation. Time to completion of tracheal intubation (TI) procedure was defined as the time from the instant that the laryngoscope blade touches the patient until the moment that the tracheal tube cuff was inflated. This was measured by a second paramedic not

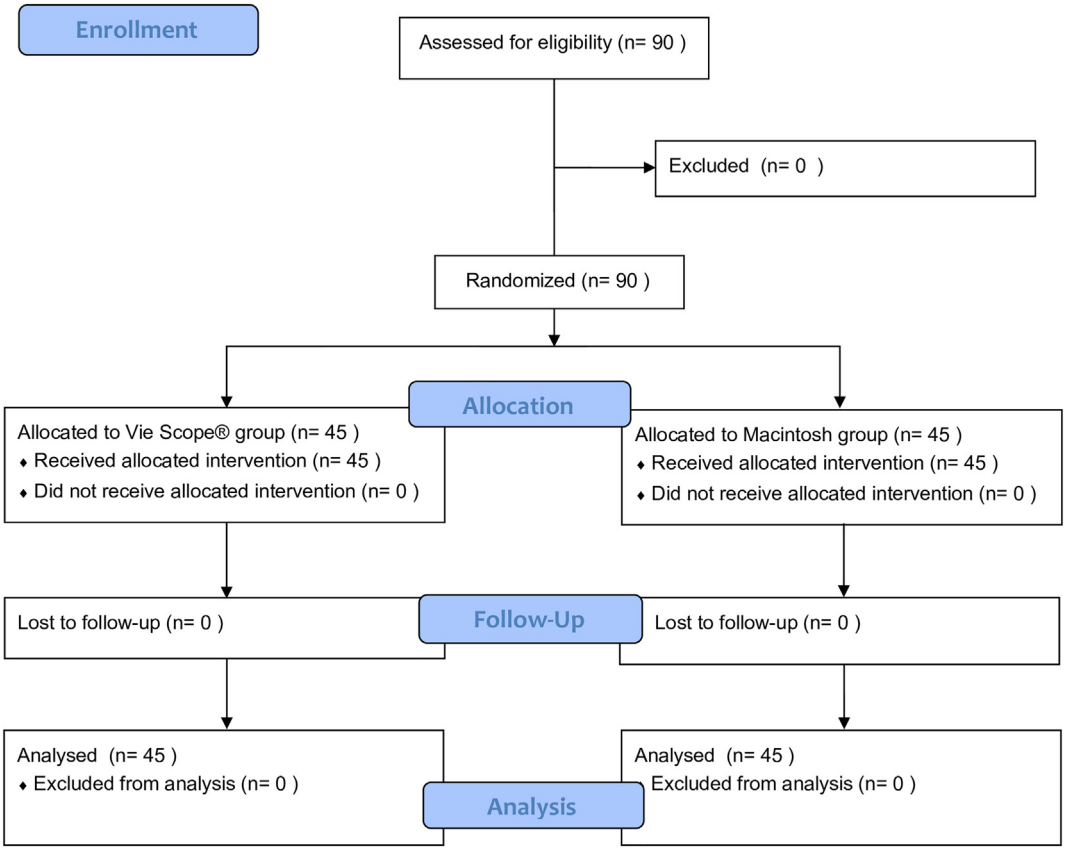

Fig. 2. Flow diagram of the study.

involved in performing the intubation procedure. There was no crossover to the alternative device if the first attempt at intubation failed. Other secondary outcomes included the duration of the interruption of chest compression during ETI procedure, Laryngeal View during intubation using Cormack-Lehane grade system, and self-reported percentage of glottis opening (POGO) score.

Fig. 3. Paramedic wearing personal protective equipment.

2.2. Statistical analysis

The sample size was calculated with the G*Power 3.1 software, and the two-tailed *t*-test was applied (Cohen's d, 0.8; alpha error, 0.05; power, 0.95). We calculated that at least 41 participants would be required (paired, 2-sided). Therefore, we planned to recruit 45 patients in each group to adjust for missing data.

All statistical analyses were performed with statistical package STATISTICA ver. 13.3EN (Tibco Inc., Tulsa, OK, USA) and with Prism 5.0 for Windows (GraphPad Software, Inc., La Jolla, California, USA). The results are presented as medians and 25–75% interquartile ranges (IQRs) or counts and relative frequencies. Data were tested for normal distribution by the Kolmogorov-Smirnov test. Inter-group comparison was performed using student's *t*-test for normally distributed data, and Mann-Whitney *U* test was used for non-normally distributed data. Frequencies were analyzed with the Fisher exact test or Pearson Chi Square, test when appropriate. Additionally, a Bonferroni correction was applied to adjust for the probability of multiple comparisons of the frequencies. Ninety-five percent confidence intervals (CIs) were calculated with the "exact" method, and an alpha of $P < 0.05$ was defined as statistically significant.

3. Results

From May 2020 to February 2021, a total of 90 patients were included in this trial. There was no difference ($P > 0.05$) in the patient characteristics between the groups (Table 1).

A detailed list of the endotracheal intubation results has been shown in Table 2 and Table 3. Overall ETI time (time to success) was lower

Table 1
Patient characteristics data and airway assessment. Values are number of patients (%) or median (IQR).

	Vie Scope® group (n = 45)	Macintosh group (n = 45)
Age	60.7 ± 14.5	61.5 ± 12.9
Male %	57.8%	51.1%
Arrest cause - medical %	82.2%	86.7%
Specific difficult airway characteristics (DACs), n (%)		
None	16 (35.5%)	19 (42.2%)
≥1	29 (64.5%)	26 (57.8%)
Cervical immobility	8 (17.8%)	6 (13.3%)
Obesity	10 (22.2%)	7 (15.6%)
Short neck	3 (6.7%)	5 (11.1%)
Restricted mouth opening	10 (22.2%)	11 (24.4%)
Blood in airway	5 (11.1%)	3 (6.7%)
Vomit in airway	2 (4.4%)	2 (4.4%)
Airway characteristics		
Thyromental distance, cm	7.5 ± 1	7.5 ± 1
Mouth opening (passive), cm	4.6 ± 0.9	4.3 ± 1

Legend: IQR, interquartile range.

using the Vie Scope® laryngoscope compared with the Macintosh laryngoscope (49 ± 8.5 vs. 97 ± 41 s respectively; mean difference (MD) = −48.00; 95% confidence interval (CI): −60.23, −35.77; $p < 0.001$). When ETI was successful at the first attempt, intubation time with Vie Scope® showed a 19.7 s advantage over the Macintosh laryngoscope (42 ± 4.7 vs. 61.3 ± 13.2, seconds respectively; MD = −19.30; 95%CI: −23.39, −15.21; p < 0.001).

The total success rate of ETI was not different between two investigated devices [100% for Vie Scope® vs. 93.3% for Macintosh laryngoscope, odds ratio (OR) = 7.49; 95%CI: 0.38, 149.40; $p = 0.19$). However, the first intubation success rate was almost twice as high with the Vie Scope® than with the Macintosh laryngoscope (93.3 vs 51.1%, respectively) [OR = 13.39; 95%CI: 3.62, 49.58; $p = 0.001$).

The Cormack-Lehane grade was 1 in 80% and 2 in 17.8% among the Vie Scope® group. In Macintosh group, it was 55.6% and 42.2%, respectively. External laryngeal maneuvers for tracheal intubation were necessary in 13.3% of the Vie Scope® group and 55.6% in Macintosh laryngoscope group (OR = 0.12; 95%CI: 0.04, 0.35; $p < 0.001$). Finally, participants found the Vie Scope® laryngoscope significantly easier to use (according to VAS score) than the Macintosh laryngoscope (MD = −3.00; 95%CI: −3.8, −2.19; p < 0.001).

4. Discussion

To our knowledge, this is the first randomized, controlled study comparing the Vie Scope® to the MAC laryngoscope by EMS providers in a real-world clinical setting. We found that use of the Vie Scope® almost doubled the first pass success rate of ETI when compared with the traditional MAC laryngoscope. Moreover, among patients with a successful first-pass intubation, Vie Scope® required almost 20 s less time compared to the standard MAC laryngoscope. Additionally, the Vie Scope® provided a better glottic view, needed fewer laryngeal manipulations and scored a better rating in the overall ease-of-intubation as reported by the study participants.

The first-pass success rate of Vie Scope® is superior to MAC laryngoscopes in this study and is similar to what has been reported for video laryngoscopes [15-18]. This is possibly because the Vie Scope® profile is similar to other anterior commissure laryngoscopes designed for inspection of the larynx and hypopharynx. Added to this profile is a narrow translucent barrel which illuminates the entire length avoiding blackout from secretions or blood, giving the user room for maneuvering and avoiding the prolapse of tissue. Of note, the total success rate of MAC laryngoscope is similar to what has been reported previously, hence reinforcing the validity of the study population, user skill and general design [19].

An important aspect of this study is the improved laryngeal view noted when using the Vie Scope®. Although this is a critical step in direct laryngoscopy, it does not guarantee a successful intubation. However, in this study the superior Cormack-Lehane scores translated to better 1st and 2nd success attempts and no failed intubation with the Vie Scope® compared to the MAC laryngoscope. Moreover, there were fewer external manipulations needed resulting in better ease of intubation scores by users of the Vie Scope®.

A key strength of our study is the fact that it was performed by EMS personnel engaged in contemporary practice in a real-world clinical environment. Although Vie Scope® has been tested in controlled simulations, this study is a stringent test of its superiority in a real-world setting. Additionally, because of COVID-19 pandemic, paramedics worked in a challenging PPE environment, making ETI a truly difficult task. Given all the challenges, our comparator groups were statistically similar as to their mean age, mean body weight and body mass index, as well as the thyromental distance and inter-incisor distance, further increasing the generalizability of our outcomes.

4.1. Limitations

The study has several limitations in the evaluation of the Vie Scope®. First, this study was performed by paramedics providing cardiopulmonary resuscitation. It is possible that the superiority of Vie Scope® noted here may diminish if used by another medical provider or in a less stressful environment (e.g., intubation for elective surgery). Second, the study was conducted in Poland and anatomical data which is correlated to ease of intubation may not be generalizable because of ethnic

Table 2
Intubation characteristics.

	Vie Scope® group (n = 45)	Macintosh group (n = 45)	OR/MD	95%CI	p
Time to success	49 ± 8.5	97 ± 41	−48.00	−60.23, −35.77	<0.001
Duration of intubation when only one attempt was required, s	42 ± 4.7	61.3 ± 13.2	−19.30	−23.39, −15.21	<0.001
Success/total (%)	100%	42 (93.3%)	7.49	0.38, 149.40	0.19
Successful intubation					
1st attempt	42 (93.3%)	23 (51.1%)	13.39	3.62, 49.58	0.001
2nd attempt	3 (6.7%)	13 (28.9%)			
3rd attempt	–	6 (13.3%)			
Cormack-Lehane					
I grade	36 (80.0%)	25 (55.6%)			
II grade	8 (17.8%)	19 (42.2%)	3.20	1.25, 8.17	0.02
III grade	1 (2.2%)	1 (2.2%)			
IV grade	–	–			
POGO score	87 ± 12	63 ± 19	24.00	17.43, 30.57	<0.001
External laryngeal manipulation, %	6 (13.3%)	25 (55.6%)	0.12	0.04, 0.35	<0.001
Ease of intubation (VAS score)	2 ± 1.7	5 ± 2.2	−3.00	−3.8, −2.19	<0.001

Legend: CI, confidence interval; MD, mean difference; OR, odds ratio.

differences. Hence, larger studies, involving multi-specialty providers performing ETI in diverse populations are needed. A further limitation is the varied experience of paramedics in the various methods of endotracheal intubation, including the total level of training in the use of direct laryngoscopy and Vie Scope®. Another limitation is the fact that during the direct Macintosh laryngoscopy, a standard disposable intubation guide was used whereas during Vie Scope® laryngoscopy a special bougie introducer was inserted. Additional limitations are small sample size, lack of outcome data to suggest the clinical relevance of the study and inability to blind participants to study purpose.

5. Conclusions

In this randomized controlled trial, the Vie Scope® was superior to the Macintosh laryngoscope in terms of first attempt success rate, glottic visualization and time to intubation in out-of-hospital cardiac arrest 'by providers in full PPE'. Moreover, Vie Scope® had no failed intubation in this population.

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CRediT authorship contribution statement

Lukasz Szarpak: Conceptualization, Methodology, Data curation, Writing- Original draft preparation Frank W. Peacock: Writing- Reviewing and Editing. Zubaid Rafique: Writing- Reviewing and Editing. Jacek Smereka: Writing- Reviewing and Editing. Klaudiusz Nadolny: Data curation, Writing- Original draft preparation Marek Malysz: Data curation, Writing- Original draft preparation Marek Dabrowski: Data curation, Writing- Original draft preparation Francesco Chirico: Writing- Reviewing and Editing. Jerzy R. Ladny: Writing- Reviewing and Editing.

Declaration of Competing Interest

None.

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