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ET-View compared to direct laryngoscopy in patients with immobilized cervical spine by inexperienced physicians: a randomized crossover manikin trial

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Abstract

Background: Immobilization of the cervical spine is indicated in all patients with the potential risk of any cervical spine injury. Airway management in these patients is challenging and direct laryngoscopy is the standard of care. Videolaryngoscopes like the ET-View were introduced into clinical practice to provide better airway visualization and ease intubation. Although the ET-View is essentially a conventional endotracheal tube, it is equipped with a miniature camera in its tip. The ET-View has not been investigated in patients with immobilized cervical spine so far. The aim was to evaluate the performance of the VivaSight SL compared with Macintosh when performed in patients with immobilized cervical spine by inexperienced physicians.

Methods: This was a prospective, randomized, cross-over manikin trial. Fifty novice physicians were randomly assigned to intubate a manikin in three airway scenarios including a normal airway and two cervical immobilization techniques. The overall and first intubation attempt success rate, time to intubation, dental compression and airway visualization according to the Cormack and Lehane classification were assessed.

Results: All physicians were able to intubate the manikin in all scenarios using the ET-View, whereas direct laryngoscopy failed in 16% with immobilized cervical spine using the patriot cervical extraction collar. The first intubation attempt success rate was higher and airway visualization was better in all three scenarios using the ET-View compared to direct laryngoscopy.

Conclusion: The ET-View offered much better 62 airway visualization and provided higher overall and first intubation attempt success rates. Therefore, the ET-View is a valuable alternative in patients with difficult intubation due to immobilized cervical spine. Further clinical trials are indicated to confirm these findings.

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Key words: endotracheal intubation; trauma; immobilization; physician; simulation

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About 5% of adult trauma patients experience a cervical spine injury, of which about 14% are classified as unstable [1]. As a consequence, immobilization of the cervical spine is mandatory in all trauma patients with a potential risk of cervical spine injury in order to avoid any secondary neurological injuries, ranging from neurological deficit to even death [2, 3]. Emergency management of airways in traumatic patients with immobilized cervical spine is challenging, and sometimes even impossible [4–6].

Although endotracheal intubation using direct laryngoscopy is considered the standard of care in airway management, difficulties during laryngoscopies are frequently observed [7–11]. Videolaryngoscopy has been introduced into clinical practice to ultimately ease endotracheal intubation by better visualization of the airway [12]. Several videolaryngoscopes are currently available which differ in the design and angle of the blade. Although there is increasing evidence that videolaryngoscopes obtain better airway visualization and potentially ease endotracheal intubation, the best device has not been determined yet.

The ET-View has been recently introduced into clinical practice and is essentially a conventional single lumen tube, but is equipped with a miniature camera at the end of the tube tip [13] (Fig. 1).

The resulting images are transferred via cable to a portable monitor and help the provider to navigate the tube during the intubation procedure. As all providers are usually familiar with the technique of direct laryngoscopy, the ET-View combines the advantage of using familiar laryngoscope and offering real-time visualization on the monitor. Therefore, the ET-View may be an ideal airway technique in patients with expected difficult intubation due to cervical spine immobilization.

We therefore aimed to compare the overall success rate of endotracheal intubation of the ET-View and direct laryngoscopy using a Macintosh blade during normal and various cervical spine immobilization scenarios. The number of intubation attempts, times until first ventilation, glottis visualization and passage of the tube beyond vocal cords, dental compression pressure, neck movement, grading of best airway visualization, and ease of intubation served as secondary outcomes.

METHODS

TRIAL DESIGN AND PARTICIPANTS

This study was a randomized, cross-over, single-centre study, was conducted at the Department of Emergency Medicine, Medical University of Warsaw, and was approved *a priori* by the Institutional Review Board of the Polish Society of Disaster Medicine (Approval no.: 23.01.2017.IRB), and registered at the ClinicalTrials register (http://www.clinicaltrials.gov, identifier NCT02733536). Novice physicians were asked to participate on a voluntary basis in this study. All physicians were inexperienced in the use of any videolaryngoscope and had limited experience (< 5 intubations) with "real-life" intubation using direct laryngoscopy. The study is a continuation of the authors' research concerning increasing the effectiveness of emergency intubation [14–17].

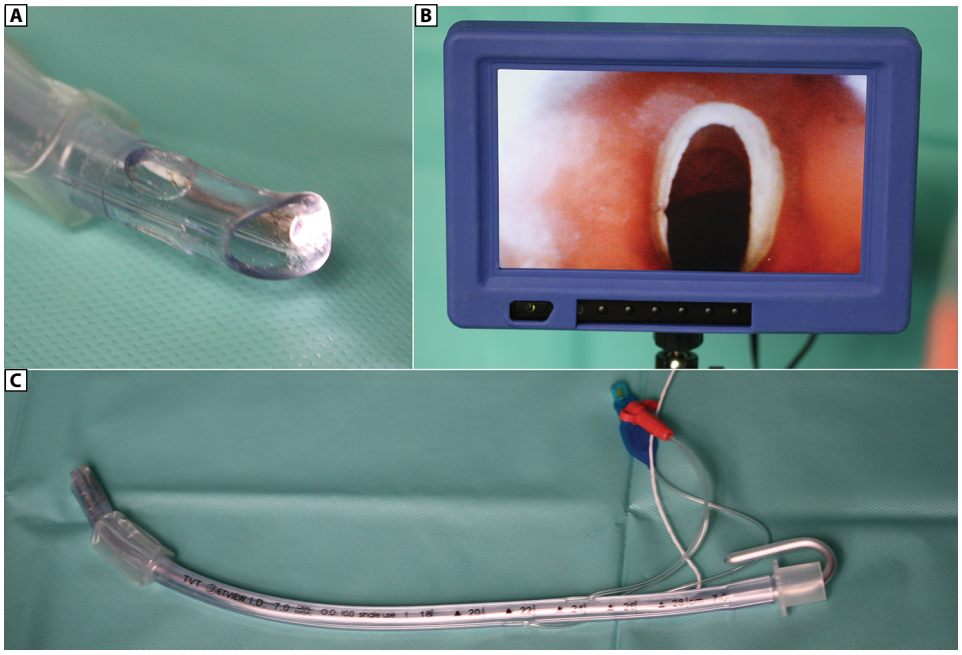

Figure 1. ET-View video-tube

PROTOCOL

After following a standardized lecture covering basic principles of airway management and details about the ET-View and the Macintosh laryngoscope, all physicians were allowed to practice with both devices and perform up to 5 intubations on a standard airway management trainer (Laerdal, Stavanger, Norway) with both devices. No further assistance was given during the training session.

The devices used during this study were:

1. Direct laryngoscopy using a Macintosh laryngoscope with a size 3 blade (Mercury Medical, Clearwater, FL, USA) with a conventional 7.0 mm internal diameter (ID) tracheal tube (Covidien, Mansfield, MA, USA).
2. The ET-View VivaSight-SL (ETView; ETView Ltd, Misgav, Israel), tube 7.0mm ID introduced with a Macintosh laryngoscope with a size 3 blade.

Both tubes were equipped with a hockey-stick shaped stylet and wetted thoroughly with lubricant in advance. If necessary, physicians were allowed to adjust the stylet.

After the training session, all physicians were randomly assigned into one out of two groups (direct laryngoscopy or ET-View) using the Research Randomizer program (randomizer.org). A manikin (Airway Assessment Training Model BT-CSIE BT Inc., A-313, Samsung Techno-Valley, Tongil-ro Goyangi-si Gyeonggido, Republic of Korea) was used in order to simulate the human airway. All physicians were asked to perform endotracheal intubation with both devices in each of these three different airway scenarios:

A. Scenario A — manikin with normal standard airway;
B. Scenario B — Cervical immobilization using a standard Patriot cervical extraction collar (Össur Americas, Foothill Ranch, CA, USA), applied to the manikin's neck by an instructor;
C. Scenario C — Cervical immobilization using a vacuum mattress (Ferno-Washington, Inc. Wilmington, OH, USA), applied to the manikin's neck by an instructor (Fig. 2).

In all scenarios, the manikin was placed on a floor in a bright room. Furthermore, elevation of manikin's head was not allowed during airway management. Each participant performed intubation attempts using each device in all airway scenarios. The order of use of one or the order of devices was randomized with a ratio of 1:1 prior to the collection of data (Supplementary File — Fig. 1). For randomization we used the Research Randomizer program (randomizer.org). Each scenario was limited to a maximum of three intubation attempts, while each intubation attempt was limited to a maximum of 120 seconds. After a break of ten minutes, the physicians were asked to perform intubations with the second device. All intubation attempts were recorded using 156 a HERO5 Black sport camera (GoPro GmbH, Munich, Germany).

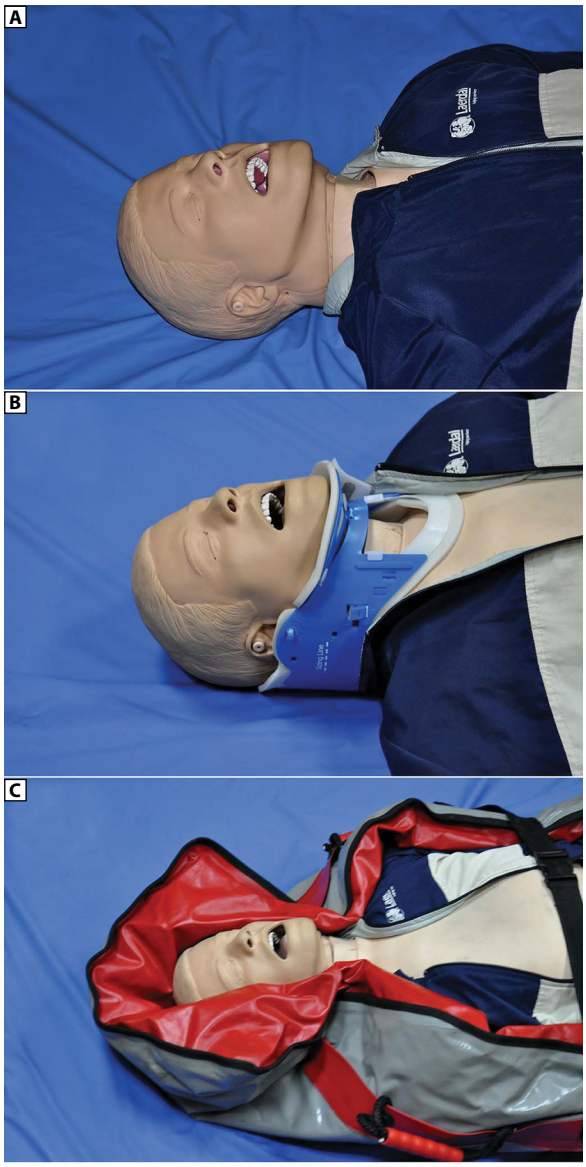

Figure 2. Study simulation scenarios: (**A**) Manikin with normal standard airway; (**B**) Cervical immobilization using a standard Patriot cervical extraction collar; (**C**) Cervical immobilization using a vacuum mattress

MEASUREMENTS

The primary endpoint was overall endotracheal intubation success, defined as successful intubation within a maximum of three intubation attempts and confirmed by the inflation of both lungs and chest rise during ventilation. Secondary endpoints were as follows: the success rate after first intubation attempt; the time from introducing the laryngoscope into oral cavity until visualization of the glottis (Time T1); the time until the tube passing the vocal cords (Time T2); the time until the first ventilation (Time T3); the maximum force applied to the incisors, measured in newtons (N); and glottis visualization according to the Cormack-Lehane classification [18]. All

Table 1. Results for simulated normal airway scenario A

	Direct laryngoscopy	ET-View	*P*-value
Overall success rate (%)	50 (100%)	50 (100%)	NS
No. of intubation attempts (%)			0.039
1	38 (76%)	50 (100%)	
2	12 (34%)	–	
3	–		
Time T1 — Time to glottis visualization (s)	6 [IQR; 6–7]	4 [IQR; 3–4]	< 0.001
Time T2 — passage of tube below the vocal cords (s)	13 [IQR; 12–14]	6 [IQR; 5–7]	< 0.001
Time T3 — Time until first ventilation	21 [IQR; 19–21]	12 [IQR; 12–13]	< 0.001
Dental compression (N)	30 [IQR; 28–37]	23 [IQR; 18–26]	< 0.001
Cormack-Lehane grade			< 0.0001
1	12 (24%)	50 (100%)	
2	38 (76%)	–	
3	–	–	
4	–	–	
Ease of intubation VAS (0-100)	21 [IQR; 16–23]	23 [IQR; 15–23]	NS
Preferences of use in real life (%)	39 (78%)	11 (22%)	< 0.001

VAS — visual analogue scale; NS — not significant

Table 2. The cervical collar immobilization scenario

	Direct laryngoscopy	ET-View	*P*-value
Overall success rate (%)	42 (84%)	50 (100%)	0.003
No. of intubation attempts (%)			< 0.001
1	18 (36%)	46 (92%)	
2	20 (40%)	4 (8%)	
3	4 (8%)	–	
Time T1 — Time to glottis visualization (s)	9 [IQR; 8–11]	6 [IQR; 5–6]	< 0.001
Time T2 — passage of tube tip just beyond glottis (s)	17 [IQR; 15–20]	8 [IQR; 8–10]	< 0.001
Time T3 — Time to first ventilation attempt (s)	24 [IQR; 22–28]	15 [IQR; 14–15]	< 0.001
Dental compression (N)	31 [IQR; 27–34]	19 [IQR; 17–24]	< 0.001
Cormack-Lehane grade			< 0.001
1	–	46	
2	38	4	
3	12	–	
4	–	–	
Ease of intubation VAS (0-100)	73 [IQR; 55–82]	38 [IQR; 28–41]	< 0.001
Preferences of use in real life (%)	2 (4%)	48 (96%)	< 0.001

VAS — visual analogue scale; NS — not significant

times were precisely calculated afterwards by examining the records. Finally, each physician was asked about their subjective evaluation of ease of intubation scoring on a 100-mm visual analogue scale (VAS) ranging from 0 (very easy) to 100 (impossible).

SAMPLE SIZE CALCULATION

Based on the data of a pilot study, we expected to have a margin of error of 5%, a statistical power of 80% and a total estimated size of 45 physicians to be included in this study. We eventually included 50 physicians in this study.

Table 3. The vacuum mattress immobilization scenario

	Direct laryngoscopy	ET-View	*P*-value
Overall success rate (%)	50 (100%)	50 (100%)	NS
No. of intubation attempts (%)			0.009
1	30 (60%)	45 (90%)	
2	15 (30%)	5 (10%)	
3	5 (10%)	–	
Time T1 — Time to glottis visualization (s)	9 [IQR; 8–10]	5 [IQR; 4–6]	< 0.001
Time T2 — passage of tube tip just beyond glottis (s)	17 [IQR; 15–19]	8 [IQR; 7–8]	< 0.001
Time T3 — Time to first ventilation attempt (s)	25 [IQR; 23–26]	12 [IQR; 12–13]	< 0.001
Dental compression (N)	31 [IQR; 28–33]	17 [IQR; 15–18]	< 0.001
Cormack-Lehane grade			< 0.001
1	–	50 (100%)	
2	40 (80%)	–	
3	10 (20%)	–	
4	–	–	
Ease of intubation VAS (0–100)	37 [IQR; 31–42]	32 [IQR; 21–35]	< 0.001
Preferences of use in real life (%)	19 (38%)	31 (62%)	0.025

VAS — visual analogue scale; NS — not significant

STATISTICAL ANALYSIS

The data was compiled using a standard spreadsheet application (Excel, Microsoft, Redmond, USA) and was analysed using the Statistica software ver. 13.1EN (StatSoft, Tulsa, OK, USA). We described variables using percentages for qualitative variables and using a median with interquartile variables. The occurrence of a normal distribution was confirmed by the Kolmogorov-Smirnov test. Nonparametric tests were used for the data that did not have a normal distribution. Fisher's exact test and the Kruskal-Wallis test were used to compare qualitative variables. We compared quantitative variables with Student's t-test. The degree of dental compression, Cormack-Lehane grade, and VAS score were all evaluated using the Stuart-Maxwell test. All *P* values were two-sided and *P* values of < 0.05 were considered statistically significant.

RESULTS

A total 50 physicians (23 female; 46% and 27 males; 54%) were enrolled into the study. The median age of participants was 29 years [IQR; 26–33], while the median period of work experience was 2 years [IQR; 0–2.5]. The results of the study are summarized in Tables 1–3.

SUCCESS RATE AND NUMBER OF INTUBATION ATTEMPTS

All physicians were able to intubate the manikin with normal airway and immobilization with the vacuum mattress with both devices, namely the ET-View and direct laryngoscopy (overall success rate 100%). Intubation of the manikin with immobilized spinal cord using the Patriot cervical extraction collar was possible for 44 out of 50 physicians using direct laryngoscopy (overall success rate 84%), whereas all physicians were successful using the ET-View (overall success rate 100%, $P < 0.001$). With respect to intubation attempts, ET-View users were able to intubate in the first attempt for > 90% of the times in all three scenarios while Macintosh users varied widely regarding the number of attempts required as shown in Tables 1–3.

TIME TO VISUALIZE GLOTTIS (T1)

Compared to direct laryngoscopy, ET-View users required less median time to visualize the glottis in all three scenarios as shown in Figure 3. The results were statistically significant ($P < 0.001$) in all three scenarios.

TIME TO PASS TUBE JUST BEYOND GLOTTIS (T2)

Results for the time to pass the tube beyond the glottis are presented in Figure 4. In all three scenarios, the ET-View outperformed direct laryngoscopy with statistically significant ($P < 0.001$) results.

TIME TO FIRST VENTILATION ATTEMPT (T3)

The results are presented in Figure 5. The median time to achieve ventilation was also significantly less with the ET-View compared to direct laryngoscopy in all three scenarios. All three scenarios achieved statistically significant ($P < 0.001$) results.

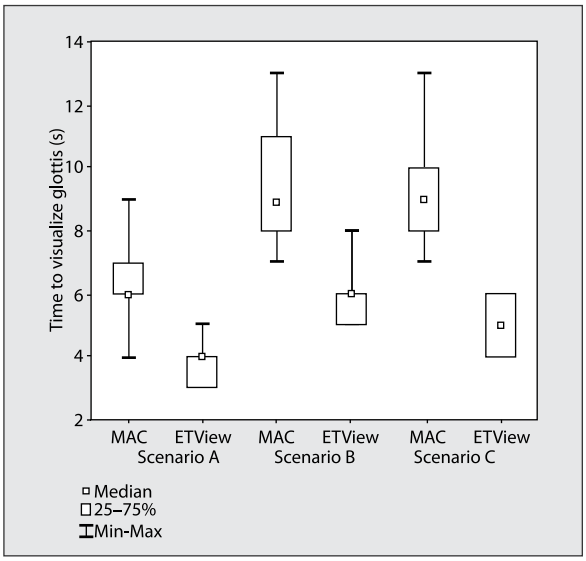

Figure 3. Time to visualize glottis

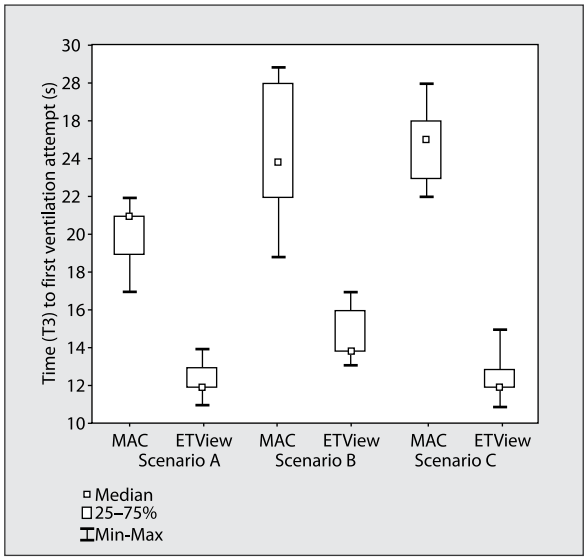

Figure 5. Time to first ventilation attempt

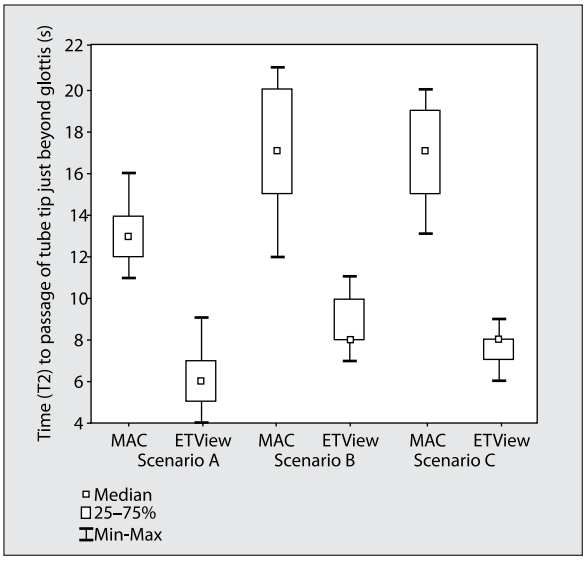

Figure 4. Time to pass tube just beyond glottis

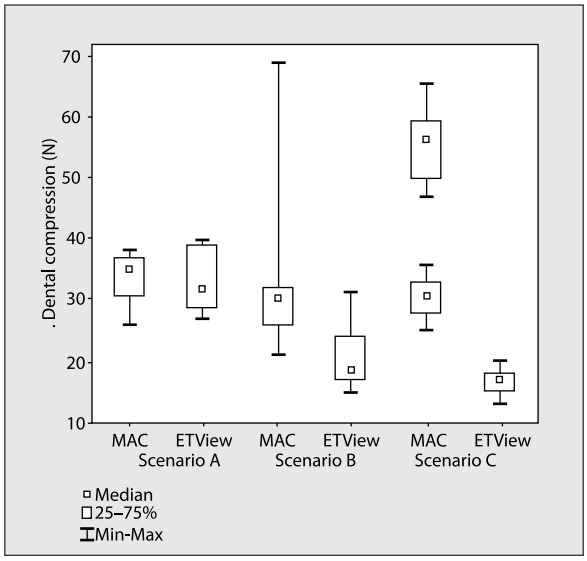

Figure 6. Dental compression

DENTAL COMPRESSION

The median force applied to the incisors was measured in newtons and was found to be less in scenario B ($P < 0.001$) and C ($P < 0.001$) if using Et-View and comparable in scenario A ($P < 0.001$) as shown in Figure 6.

CORMACK AND LEHANE GRADE

Glottis visualization was improved in all three scenarios if using ET-View compared to direct laryngoscopy in all three scenarios (Tables 1–3, $P < 0.001$).

EASE OF INTUBATION

Results are presented in Figure 7. Physicians rated the ease of intubation using the ET-View as similar compared to direct laryngoscopy in the normal airway scenario. In both scenarios with immobilized cervical spine, intubation using direct laryngoscopy was rated much more difficult when compared to the ET-View.

DISCUSSION

The most important findings of this study are namely: that endotracheal intubation using the ET-View tube was associated with a better overall success rate and glottis visualization; fewer intubation attempts; less force applied to the teeth; and, finally, was rated easier to intubate with, compared with direct laryngoscopy using the Macintosh laryngoscope. Our study therefore confirms previous studies, reporting videolaryngoscopes to be superior compared

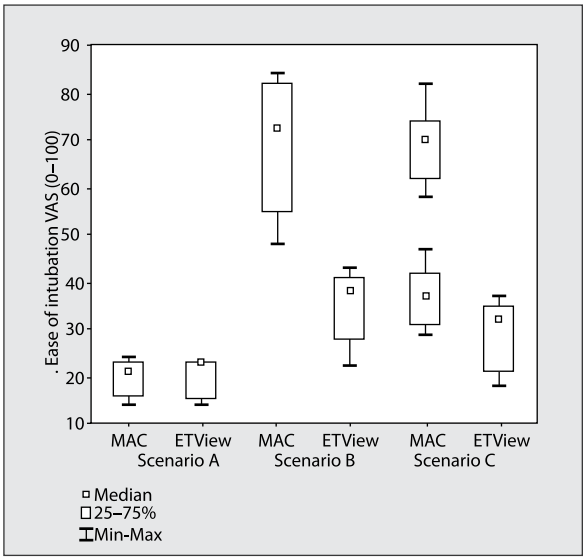

Figure 7. Ease of intubation

to direct laryngoscopy in patients with immobilized cervical spine [5, 19–21].

Physicians were able to intubate in all three airway scenarios using the ET-View, resulting in an overall success rate of 100% in each scenario. When using direct laryngoscopy, although physicians were successful in all intubations in scenario A, the overall success rate was 84% in scenario B and 50% in scenario C. Furthermore, the Macintosh laryngoscope was consequently associated with a lower first intubation attempt success rate in all three airway scenarios. In airway scenario B, physicians were able to successfully intubate on the first attempt in 90%, compared to 36% in the direct laryngoscopy group. This trend was also observed in scenario C with initial intubation attempt success rates of 60% versus 90%, respectively. As a consequence, intubation using the ET-View was associated with higher overall and first intubation attempt success rates. These findings are clinically important, as each intubation attempt is associated with increased risk of airway trauma, injury, desaturation and even a higher risk of failed intubation [22]. The results of our study confirm previous findings of the ET-View obtained in a human cadaver study and during an adult resuscitation scenario [14, 23].

We also assessed airway visualization and found, that the ET-View provides better visualization, as indicated by the Cormack and Lehane classification. This finding is in line with several previous publications, reporting better airway visualization by using videolaryngoscopes [12, 24–26]. Although there is increasing evidence that better airway visualization may lead to a higher intubation success rate, this effect may be limited to relatively low-experienced healthcare providers. In contrast, highly skilled providers, such as anaesthesiologists may not benefit to this extent, as these healthcare providers are very familiar with direct laryngoscopy and achieve high success rate with both techniques [12, 27]. However, initial intubation attempt and overall success rate by our inexperienced physicians were much higher when compared with direct laryngoscopy using the Macintosh blade.

Although, our physicians were relatively inexperienced with direct laryngoscopy and complete novices in using videolaryngoscopes, all physicians were able to achieve adequate visualization with the videolaryngoscope, even successful endotracheal intubation. We therefore conclude, that videolaryngoscopy is easy to learn and provides better visualization and success rates in patients with potential difficult airway might, especially in inexperienced hands.

It is impossible to predict the clinical advantage of videolaryngoscopy in inexperienced hands and translate this into clinical outcomes. However, we can easily speculate that a lower number of intubation attempts, a higher intubation success rate, along with a decreased time to intubate may lead to better outcomes and prevent complications such as hypoxemia, aspiration, airway trauma and bradycardia [28].

Dental injuries are assumed to be caused by strong forces applied during intubation [29]. The maximum force applied on the incisors was also found to be less (by 7 newtons) with the ET-View which may result in fewer complications, such as teeth and upper airway injuries.

Despite these advantages, healthcare providers preferred the direct laryngoscopy technique using the Macintosh blade during the normal airway. On the other hand, in difficult airway scenarios with immobilized cervical spine, our physicians preferred the ET-View. We therefore conclude that providers prefer the more familiar technique in normal and easy situations, whereas the less familiar videolaryngoscopy technique might be advantageous in more difficult airway scenarios.

The cost of the ET-View is undoubtedly higher than direct laryngoscopy-guided endotracheal intubation using a conventional endotracheal tube. As a consequence, the possible advantages with possible benefits in certain scenarios must be adequately weighed against the higher costs and need for further equipment, including a monitor.

Our study has several limitations. First, this study was performed on manikins. Although manikins do not reflect human anatomy in every single detail, they are accepted training tools for fundamental skills. Endotracheal intubation in a patient with immobilized cervical spine is a critical event and, therefore, needs highly skilled and experienced providers. Based on ethical issues, this study is impossible to perform, especially with inexperienced providers.

CONCLUSIONS

Airway management in patients with immobilized cervical spine is challenging. Although direct laryngoscopy is considered state-of-the-art, it requires high level of experience and skill. In conclusion, intubation using the C-MAC was associated with higher first intubation attempt and overall success rates, less time to intubate and better airway visualization compared to direct laryngoscopy using a Macintosh laryngoscope. Further clinical trials are indicated to confirm the results obtained in this manikin study.

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2. Conflicts of interest: none.
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