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Application and utility of the endotracheal stylet for direct laryngoscopy. A prospective, randomized, cross-over manikin-based simulation trial

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Abstract

Background. One of the most important priorities in managing life threatening conditions is maintaining the patency of the airway. The aim of the study was to evaluate the efficacy and duration of tracheal intubation with and without intubation stylet in simulated damage to the cervical spine. ***Material and methods.*** The study was prospective, randomized, crossover, manikin trial, with 27 paramedics participants. Paramedics intubated paediatric simulator using Macintosh laryngoscopes with and without endotracheal stylet. Participants performed intubation in two scenarios: Scenario A – normal airway; Scenario B – neck immobilization using cervical collar. The study measured overall success rate, first intubation attempt success rate, and time to intubation. ***Results.*** 27 paramedics participated in this trial. In normal airway scenario first intubation success rate was 100% for endotracheal tube with and without endotracheal stylet. Median time to intubation using distinct methods were 22 [IQR; 19-27.5]s *vs.* 18.5 [IQR; 17-26]s (with and without stylet, respectively). During cervical collar immobilization scenario success of first intubation attempt varied and amounted to 18.5% without stylet, and 48.1% for tube with stylet ($p < 0.001$). The overall intubation success rate was also higher when the stylet was used (88.9%) compared with tube without stylet (51.8%; $p = 0.014$). Median intubation time was 35.5 [IQR; 32-48]s for stylet, and 43.5 [IQR; 38-53]s for intubation without stylet ($p < 0.001$). ***Conclusion.*** For normal airways, the use of an intubation tube with a stylet does not increase the effectiveness of endotracheal intubation; however, with the use of cervical collar immobilization, stylet intubation was associated with a shorter procedure time and higher intubation efficacy. *Anestezjologia i Ratownictwo 2017; 11: 131-137.*

Keywords: endotracheal intubation, paediatric, immobilization, stylet, simulation

Introduction

One of the most important priorities in managing life threatening conditions is maintaining the patency of the airway [1,2]. Despite many methods of airway clearing from simple to advanced, intubation is always the most trusted and effective method. It provides continuous airway patency, but does not relieve us of the obligation to monitor the correct position of the intubation tube. The intubation itself is usually a procedure lasting a dozen or so seconds, but much depends the efficiency of the intubator [3,4]. Unexplained activity can aggravate the appearance of undesirable effects. The main indication for intubation of the patient is the possibility of mechanical ventilation and prevention of aspiration of gastric contents. Post introduction of the intubation tube technique, there has been increasing success in maintenance of the patients airways in certain scenarios.

The most common complications include: soft tissue damage to the airways (larynx, back of the throat, nasal cavity), which is usually manifested by minor transient bleeding; pituitary edema of the larynx with temporary difficulty in breathing or speaking which requires additional treatment (inhalation, medication); permanent damage to vocal cords that manifest as hoarseness; and damage to the gingiva or teeth by the laryngoscope [5,6]. Usually, the cause of complications lies in the unusual construction of the oral cavity and upper respiratory tract, which makes the procedure technically difficult to perform.

In pre-hospital conditions and emergency department, intubation may prove to be a difficult operation because there is little familiarity with the patient at hand, as well as possible injury to the patient, more so in the case of the paediatric population. The fact that the infant's head should not be overextended which poses a challenge to see the glottis (black vertical triangular slit with white cords). The use of cervical collar in stabilization of the cervical vertebra makes it more difficult to complete the procedure. Regardless of whether the stabilization is manual or maintained by the cervical collar, it reduces movement and increases the risk of complications. These actions require staff to be prepared both before and during intubation. Efficient performing of advanced clearing does not only depend on the person who directly performs the intubation, but also on assistants who are involved in the patient's life-threatening condition.

The aim of the study was to evaluate the efficacy and duration of tracheal intubation with and without intubation stylet in simulated damage to the cervical spine.

Material and methods

- **Study Design**

The study is a follow-up study by the authors investigating the most effective method of endotracheal tracheal intubation in a spinal cord injury [7-9]. This was a prospective, randomized, crossover, manikin trial conducted at the Department of Emergency Medicine at the Medical University of Warsaw. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (Approval: 05.02.2017.IRB), and was conducted in March of 2017.

- **Participants**

The participants for this trial were recruited paramedics participating in Airway Management courses organized by Polish Society of Disaster Medicine. All participants agreed for voluntarily participation in the study; written informed consent was obtained from all of the participants. A total of 27 paramedics participated in the study.

- **Study Interventions**

Prior to the study, each participant completed a respiratory tract respiratory training course that consisted of endotracheal intubation with a Macintosh and Miller blade laryngoscope and supraglotic airway devices. The target study was held two months after their initial training. During the study, practicing with the devices prior to the recorded attempts was not permitted in order to minimize the bias, as well as to increase the simulation's reliability and predictability of actual field scenarios.

During the study, participants intubated using the Miller laryngoscope (HEINE Optotechnik, Munich, Germany) with a 5.0 mm internal diameter (ID) tracheal tube. In the study of intubation two general scenarios were examined, with and without an intubation guide.

Participants in the study performed intubation in the following two rescue scenarios:

- Scenario A: Normal airway scenario
- Scenario B: Normal airway with a correctly fitted standard cervical immobilization collar (Stifneck

Select, Laerdal, Stavanger, Norway) applied to the manikin's neck to prevent movement of the cervical spine (figure 1).

All intubation attempts were performed on a standardized pediatric manikin representing 6-year-old boy, with a regular airway (SimJunior, Laerdal, Stavanger, Norway).

Figure I. Cervical spine immobilization scenario using cervical collar

Each paramedic performed a maximum three intubation attempts using both intubation methods in the two scenario. The order of method used (with or without endotracheal stylet) was randomized with a ratio of 1:1 prior the collection of data using Research Randomizer Software (randomizer.org). The procedure for randomization is shown in figure 2.).

- **Outcomes**

Only one investigator collected data on a standardized form. All intubation attempts were recorded with the GoPro HERO5 camcorder, and the timing was precisely confirmed by playback of the recordings. The primary endpoint was endotracheal intubation success rate. Overall success rate of intubation was defined as successful endotracheal intubation with the initial method, during maximum three attempts. Successful intubation attempt was divined as the correct placement of the endotracheal tube into the trachea; confirmed by both the flow of air in inflation using the resuscitator bag and the visualization of the tube by the investigator. An intubation failure was defined by an intubation requiring a time greater than 60s [10]. The endpoints were time to intubation, Cormack & Lehane graduation [11], and ease of intubation. Time to intubation, was defined from the time of picking up the

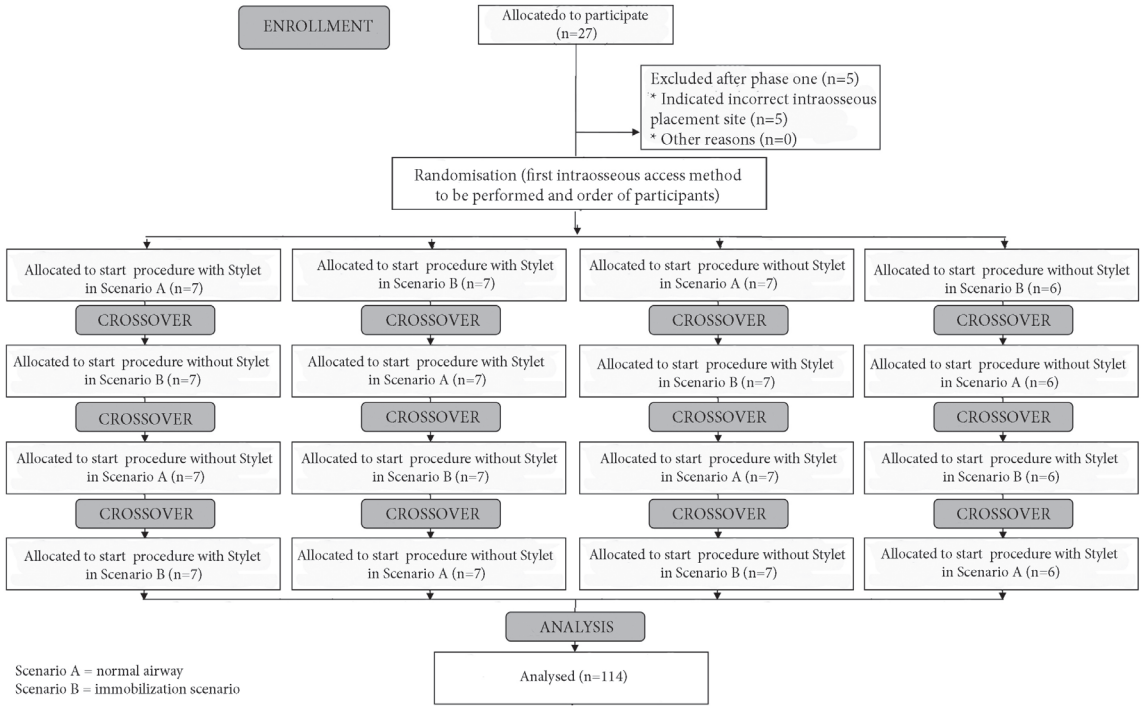

Figure II. Randomization flow chart

airway device to ending with the first effective manual ventilation of the manikin's lungs which was identified by the participant as the manikin's chest rising. The ease of intubation score was rated by the participant using a standard 100 point Likert Scale ranging ("1" being very easy to intubate, "100" being very difficult).

- **Statistical analysis**

The occurrence of normal distribution was confirmed by the Kolmogorov–Smirnov test. All statistical tests were 2-sided. Nonparametric tests were used for the data that did not have a normal distribution. In order to compare the difference and determine the statistical significance in the time needed to achieve a sufficient glottis view and first successful ventilation, the Wilcoxon test for paired observations was used. The McNemar test was used to evaluate the differences in success of intubation. The Cormack&Lehane grade and VAS score were all evaluated using the Stuart–Maxwell test. Percentages were used for qualitative variables and median with interquartile range (IQR) for quantitative variables. A result was considered as significant with p-value less than 0.05. Analysis was performed using statistical software Statistica 13.1 (Statsoft, Tulusa, OK, USA).

Results

Twenty-seven paramedics (12 female, 44.4%) volunteered to participate in this trial. Median age was 26.5 [IQR; 24-33] years, and median work experience in Emergency Medical Services was 4.5 [IQR; 2-7] years.

During scenario A (normal airways) the effectiveness of the first attempt at intubation both with and without stylet was 100%. The median time of intubation in the case of the guide was shorter than in the case of intubation with no conduit without guide (18.5 [IQR; 17-26] *vs.* 22 [IQR; 19-27.5], respectively; Table I). Cervical collar immobilization scenario (B) was associated with a decrease in the effectiveness of intubation both with and without a guide. The efficacy of the first endotracheal tube with stylet was 48.1%, and for endotracheal tube without stylet the efficacy was 18.5% (Table II). The overall efficacy of the tracheal intubation was 88.9%, and was statistically significantly higher than for intubation without guide (51.8%; p = 0.014). Median time using distinct methods varied, amounting to 35.5 [IQR; 32-48]s *vs.* 43.5 [IQR; 38-53] s (with and without stylet, respectively; figure 3). Participants in the study found intubation of the patient with an intubation tube equipped with a guide an easier tracheal intubation method when compared to a tube without a guide. This relationship was related to both intubation in normal airways (p = 0.007) as well as intubation under cervical vertebra (p < 0.001).

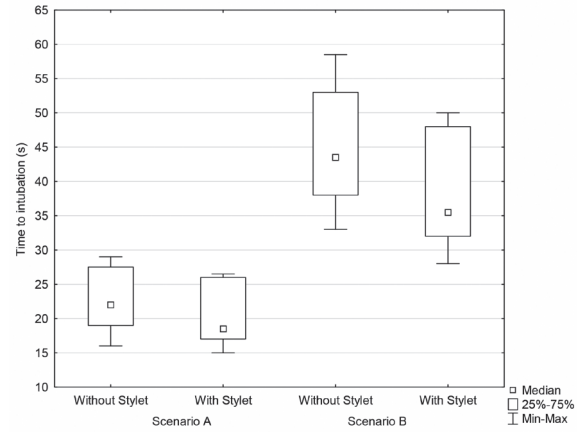

Figure III. Median time to intubation

Discussion

According to the results of this study, the overall success rates as well as the first intubation attempt success rate during the normal airway scenario were similar between the tracheal tube, with and without stylet. However, during intubation in cervical spine scenario (B), intubation with stylet improved the efficiency of intubation and reduce the intubation time when compared to endotracheal tube without stylet method.

There are two major risks involving the intubation of patients with cervical spine injuries [12]. The first risk is prolonged intubation with the risk of vomiting and aspiration, generally occurring in non-fasting patients. The second risk is cervical spine excursion (particularly within the functional region of occiput C3), or defensive cervical spine movement leading to additional cervical spine and neurological damage in sedated patients [13,14]. In addition, more than three tracheal endotracheal intubation efforts may result in soft tissue swelling and bleeding, this will significantly impede subsequent intubation efforts leading to a situation described by the Difficult Airway Society as "cannot intubate, cannot ventilate" [15]. Due to this complication, first attempt success rate is important because fewer intubation attempts ultimately affect

overall intubation success, with repeated intubation attempts associated with the risk of further injury, hypoxemia, and hemodynamic changes [16-18].

Protection of the airway patency in patients with suspected traumatic injury is one of the basic skills that medical staff should attend to [19]. Advanced trauma life support guidelines requires continuous cervical immobilization of the patient by a semi-rigid cervical collar [1]. The cervical collar should not be removed until the cervical injury is excluded by imaging studies in Emergency Department [20]. As indicated by many studies of the use of the neck flange, it reduces the effectiveness of the first intubation test and prolongs the duration of the procedure [7,9,21,22]. This dependency is also reflected in the results of this study in which the introduction of a neck collar resulted in a decrease in the efficacy of a first endotracheal tracheal intubation trial without a guide by 81.5%, and by 51.9% in the case of an intubation tube with a guide.

The study used a laryngoscope with a Macintosh blade. In the study by Passi et al. of infants and children < 2 yrs, optimal laryngeal views may be obtained by either Miller size 1 blade epiglottis or with the Miller or MAC blades lifting the tongue base [23]. Similarly, Verghese and Kurdu [24] demonstrated that, in children aged 1-24, the Miller and the Macintosh blades provide similar laryngoscopic views and intubating conditions. Therefore the study was performed using the Macitnosh laryngoscope.

In a study by Hippard et al. [25] of thirty experienced paediatric anaesthesia practitioners tracheal intubation was performed in an infant model, stating that median intubation time in normal airway using Miller blade was 26 [IQR; 20-32]. In turn Szarpak et al. [26], a study comparing the efficacy of video rigid flexion laryngoscope and Miller laryngoscope, the efficacy of Miller laryngoscope without stylet was 96.9%, and intubation time of 23 [IQR, 19-26] was comparable to the results obtained in our study. The same authors in the difficult airway scenario demonstrated direct laryngoscopy efficacy at 44.7% at intubation 41 (IQR; 34-45] seconds. Rodríguez-Núñez et al. [27] in addition, demonstrated that intubation time using direct laryngoscopy with endotracheal tube without stylet during ongoing chest compression was 28.2 (20.4-34.4) s.

The use of the guide beyond the obvious benefits of increasing the effectiveness of endotracheal intubation may also carry some complications [28-30]. In the study by Komasawa et al. [31] comparing the impact of postoperative pharyngeal pain on postoperative pharyngeal pain or inferiority in patients undergoing elective surgery, indicated that a stylet use can increase the incidence of postoperative pharyngeal pain.

The strengths of our study include the randomization of the collection, as well as the participants, the paramedics group are often forced to perform endotracheal intubation as well as to protect the traumatic patient at the pre-hospital stage. Another strength lied in the use of a medical simulator allowing for the standardization of the difficulties resulting from endotracheal intubation and, secondly, allowing for cross-examination without harm to a potential patient. However, this led to a study limitations of realistic reliability in the use of a dummy rather than clinical cases. Another limitation of the study is the use of only Macintosh laryngoscope; in most ambulances in Poland, the Miller and Macintosh laryngoscopes are most commonly used.

Conclusions

The use of the stylet may be useful during intubation in the scenario of immobilization of the cervical spine, but does not affect the improvement of intubation efficiency under normal airways. Further studies are needed to confirm the results.

Conflict of interest
None

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