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ORIGINAL PAPER

The effectiveness of paediatric blind intubation using an Ambu® AuraGain™ Disposable Laryngeal Mask – a randomised, cross-over, simulation trial

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ABSTRACT

Introduction: The main causes of cardiac arrest in paediatric patients are airway obstruction and progressive hypoxia. Rapid endotracheal intubation and the implementation of mechanical ventilation during cardiopulmonary resuscitation (CPR) can affect the minimisation of chest compressions and adequate oxygenation of the blood, and thus increase the chances of spontaneous circulation return.

Aim of the study: The aim of the study was to compare intubation using a standard Macintosh blade (MAC) laryngoscope and blind intubation using an Ambu® AuraGain™ Disposable Laryngeal Mask (AMBU) as a guide for the tracheal tube under simulated CPR conditions of a paediatric patient with and without chest compressions.

Material and methods: Fifty-six students from the final year of medicine studies participated in this trial. The study was designed as a randomised, cross-over, simulation study. Participants of the study performed endotracheal intubation during simulated CPR of a paediatric patient, with and without chest compressions during an intubation procedure. Participants had a maximum of three attempts to intubate each of the techniques in individual research scenarios.

Results: The median time of intubation in CPR without chest compressions using MAC and AMBU was 32 s (interquartile range – IQR; 27–41.5) and 30 s (IQR; 22–43), respectively. The efficacy of the first intubation trial was 28.6% for MAC and 48.2% for AMBU, and the total intubation efficiency for both techniques was 100%. In the case of intubation during uninterrupted chest compressions, blind intubation using AMBU as the guide for the endotracheal tube was associated with better parameters than in the case of intubation using MAC, with respect to both intubation time (32 s [IQR; 22–45] and 47 s [IQR; 33–57], respectively; $p = 0.017$), effectiveness of the first intubation trial (33.9% and 5.4%, $p = 0.002$), as well as the total effectiveness of intubation (73.2% and 46.2%, $p < 0.001$).

Conclusions: In our study, blind endotracheal intubation using AMBU was associated with more effective endotracheal intubation than standard intubation using direct laryngoscopy, both when the chest compressions were interrupted for the time of intubation and in the case of intubation during uninterrupted chest compressions.

KEY WORDS:
tracheal intubation, blind intubation, child, cardiopulmonary resuscitation, medical simulation.

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INTRODUCTION

The ability to protect airway patency and assist breathing is one of the basic skills that should be demonstrated by medical personnel [1]. This is particularly important in the case of paediatric patients in whom airway obstruction and progressive hypoxia are the main causes of cardiac arrest [2, 3]. Moreover, oxygen metabolism is increased; therefore, rapid implementation of oxygen therapy is crucial in this group of patients. As indicated by Lee, a number of endotracheal intubation attempts were associated with desaturations [4]. In addition, as indicated by Ehrlich *et al.*, airway complications and multiple endotracheal intubations were associated with transport delay, lower Glasgow Coma Scale (GCS), longer hospital stay, and lower discharge GCS [5]. During cardiopulmonary resuscitation (CPR), skilful endotracheal intubation allows for asynchronous resuscitation [2]. There is no need to take breaks in chest compressions to perform rescue breaths, thus minimising breaks in chest compressions and improving the quality of perfusion pressure, according to Evy *et al.* [6].

The efficacy of endotracheal intubation in paediatric patients under conditions of emergency medicine is insufficient. As shown by Long *et al.* in a paediatric emergency department, the overall first-pass success rate was 78%, although first-pass success without desaturation or hypotension was only 49% [7]. In turn, studies by Eisenberg *et al.* indicate the effectiveness of the first intubation attempt at the level of 71% [8], while the study by Pallin *et al.* showed 83% [9]; however, in the above studies the intubation was performed by emergency physicians or anaesthesiologists. In out-of-hospital conditions or in a situation where intubation is performed by less experienced personnel, the effectiveness of intubation can range from 63.4% to 78.6% [10–12]. The lower effectiveness of intubation in relation to paediatric patients may be dictated by less experience with intubation in this group of patients, as well as anatomical differences in a relatively large tongue than in adults, larger and more flaccid epiglottis, or much higher placement of the glottis [13].

FIGURE 1. Ambu® AuraGain™ Disposable Laryngeal Mask with tracheal tube

The aim of the study was to compare intubation using a standard Macintosh blade (MAC) laryngoscope and blind intubation using an Ambu® AuraGain™ Disposable Laryngeal Mask (AMBU) as a guide for the tracheal tube under simulated CPR conditions of a paediatric patient with and without chest compressions.

MATERIAL AND METHODS

The study was conducted as a prospective, interventional, randomised, cross-over simulation and is a continuation of the authors' research on the most effective method of protecting the respiratory tract of paediatric patients during CPR [13]. The study protocol was accepted by the Institutional Review Board of the Polish Society of Disaster Medicine (approval no. 11/03/2018.IRB). Participation in the study was voluntary, and informed, written consent was obtained from each participant.

Fifty-six students from the last year of medicine studies who participated in the Airway Management Course organised by the Polish Society of Disaster Medicine were preliminarily qualified for the study. The study was conducted in the period of April 2018 to June 2018.

Prior to the study, all participants took part in training in the field of instrumental methods of airway patency in children and adults. The training included the basics of respiratory anatomy and physiology as well as the discussion of various methods of airway management. At the end of the training, an experienced instructor demonstrated the correctness of the implementation of standard intraoperative intubation using direct laryngoscopy (Macintosh laryngoscope) and blind intubation using the supraglottic airway device as a guide for the endotracheal tube. Two endotracheal intubation techniques were used in the study:

1) standard intubation of tracheal tubes based on direct laryngoscopy using a laryngoscope with a MAC size 2 (HEINE USA LTD., Dover, USA),
2) blind intubation using an AMBU (Ambu A/S, Ballerup, Denmark) as a guide for the tracheal tube (Fig. 1).

After completing the theoretical part, the participants of the study participated in a 20-minute practical training during which they had the opportunity to perform intubation with the tested devices using a phantom to study the intubation of an adult patient – AT Kelly Torso (Laerdal, Stavanger, Norway). During the training phase, an adult person's phantom was deliberately used to avoid learning how to perform activities in relation to the paediatric patient simulator.

In the target study carried out one week after the training, the participants had to perform endotracheal intubation of a paediatric patient with and without chest compression. In order to simulate a paediatric patient requiring immediate protection of the airways, the Sim-Junior® simulator was used (Laerdal, Stavanger, Norway) – an interactive paediatric simulator, designed to repre-

sent a six-year-old boy. Endotracheal intubation was performed in two scenarios:

1. Scenario A: normal airway without chest compressions.
2. Scenario B: normal airway with continuous chest compressions. In order to standardise the difficulties resulting from chest compressions, a LUCAS3 chest compression device was used (Physio-Control, Inc., Redmond, WA, USA). The device during scenario B was included in the continuous chest compressions mode.

All intubations were performed using a standard 5.0 internal diameter intubation tube. Both the intubation tube itself and the supraglottic ventilation channel were sprayed with a lubricant. Participants of the study had a maximum of three endotracheal intubation attempts for each device in each scenario.

Both the order of the participants and the research methods were random. For this purpose, the Research Randomiser program (randomizer.org) was used. A detailed randomisation procedure is shown in Figure 2.

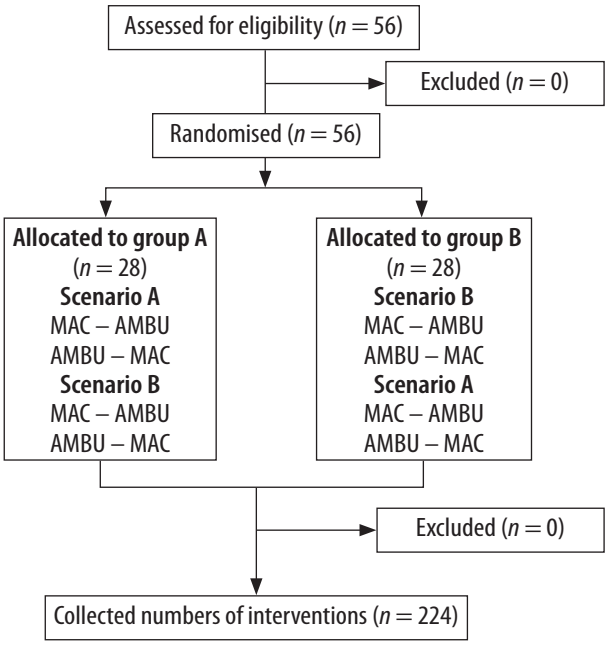
The main parameter measured in the study was time to intubation, defined as the time from taking the laryngoscope or the AMBU supraglottic device, until the confirmation of ventilation with the use of the endotracheal tube. Ventilation tests were performed using a self-expanding bag. During the study, the effectiveness of the first intubation test and the total effectiveness of intubation were also measured. After the intubation procedure, the participants were asked to specify the ease of intubation using a 100-degree scale (1 – extremely easy, 100 – extremely difficult).

Sample size calculation was performed using G*Power 3.1 with a two-tailed t-test (Cohen's *d*: 0.8, α error: 0.05, power: 0.95). According to the calculation, a minimum of 52 participants were necessary.

Categorical data are reported as frequency (*n*) and percentage (%), and numerical data as median and interquartile range (IQR). All analyses were performed using the statistical package STATISTICA 13.1EN (StatSoft, Tulusa, OK, USA). Normal distribution was assessed using the Kolmogorov-Smirnov test. Fisher's exact test was used to compare categorical data. Numerical data were analysed using the Mann-Whitney U-test and/or the Kruskal-Wallis test. Statistical significance was set as a two-tailed *p*-value of less than 0.05.

RESULTS

Fifty-six final-year medical students participated in the study (28 female, 41.4%). The median age of participants was 24.5 years (IQR; 24–25.5). All participants finished with a positive result in the training module in the field of anaesthesiology and intensive therapy and declared their ability to perform endotracheal intubation based on direct laryngoscopy. None of the participants before the trial had had clinical or experimental experience with supraglottic airway devices and blind intubation.



MAC – Macintosh laryngoscope, AMBU – blind intubation via AMBU, Scenario A – normal airway without chest compression, Scenario B – normal airway with ongoing chest compression

FIGURE 2. Randomisation flow chart

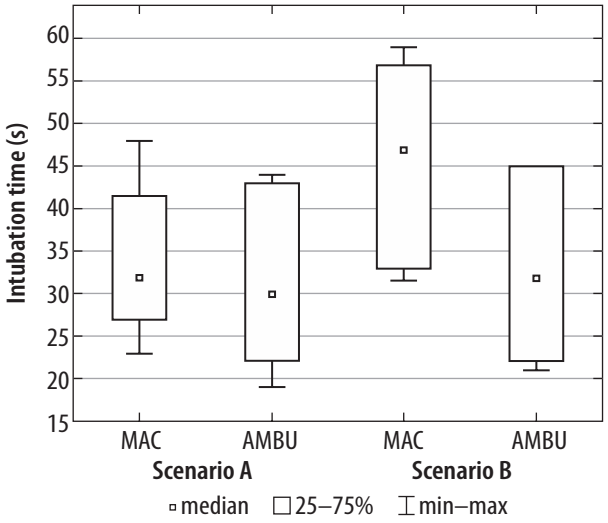


FIGURE 3. Median intubation time using standard intubation and blind intubation

SCENARIO A: INTUBATION WITHOUT CHEST COMPRESSION

In scenario A, during which intubation took place without chest compressions, the median intubation time for MAC and AMBU was 32 s (IQR; 27–41.5) vs. 30 s (IQR; 22–43), respectively. Analysis of the intubation time between MAC and AMBU did not show statistically significant differences ($p = 0.061$) (Fig. 3). The effectiveness of the first intubation trial using the tested devices was varied and amounted to 28.6% and 48.2% for MAC

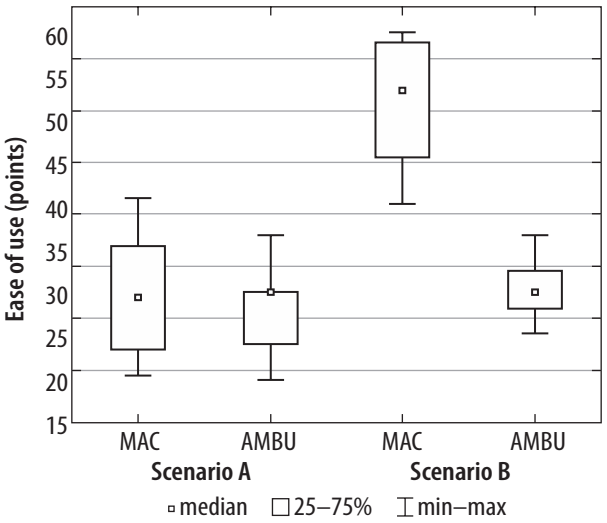


FIGURE 4. Ease of use of distinct intubation methods

and AMBU, respectively. The total efficiency using the tested devices was 100%. There were no statistically significant differences in ease of intubation between MAC and AMBU (34 points [IQR; 23–44] vs. 35 points [IQR; 25–41], respectively; $p = 0.379$) (Fig. 4).

SCENARIO B: INTUBATION WITH UNINTERRUPTED CHEST COMPRESSIONS

Median intubation time during scenario B (uninterrupted chest compressions) was 47 s (IQR; 33–57) for MAC and it was a statistically significantly time longer than in the case of blind intubation using AMBU – 32 s (IQR; 22–45) ($p = 0.017$) (Fig. 3). The efficacy of the first intubation trial was 5.4% for MAC and 33.9% for AMBU ($p = 0.002$). The total intubation efficiency for MAC and AMBU was 46.2% and 73.2% ($p < 0.001$), respectively. The participants of the study using the AMBU test determined the level of ease at 35 points (IQR; 32–39), and it was substantially statistically easier to carry out than intubation using MAC, with 74 points (IQR; 61–83) ($p < 0.001$; Fig. 4).

DISCUSSION

In the conducted simulation test, final-year medical students were able to perform blind intubation with the use of an AMBU as a guide for the endotracheal tube after just a short training. To our knowledge, this is the first study evaluating the effectiveness of this intubation method with the use of the AMBU.

Intubation of the tracheal tube allows complete isolation of the airways, thus preventing aspiration of the alimentary tract to the respiratory tract and subsequent toxic pneumonitis [14]. It should be remembered that in out-of-hospital settings, each patient should be treated as a patient with potentially difficult airways; the patient can have a full stomach, as well as the potential to encounter anatomical anomalies in the airways. Endotracheal intubation, except for the possibility of using end-air pressure in the airways, or constant monitoring of ventilation using capnometry, also allows for asynchronous resuscitation, thus minimising breaks in chest compressions and thus indirectly increasing chances of survival.

In the study, the median intubation time for normal airways without chest compression was not significant between standard intubation based on direct laryngoscopy (32 s) and blind intubation using a laryngeal mask as a guide for the tracheal tube (30 s). However, in the case of chest compressions, the differences in intubation times were statistically significant and were 47 s for MAC and 32 s for AMBU. Current guidelines for resuscitation [2, 15] recommend that endotracheal intubation be performed by the most experienced person on the team and that it be carried out without the need to stop compressing the chest or only with a short interval allowing the insertion of the endotracheal tube between the vocal folds. Numerous studies indicate a decrease in the effectiveness of direct laryngoscopy in the case of intubation in conditions of resuscitation with continuous chest compressions [16–18]. This is related to difficulties in visualising the glottis when the patient is moving due to chest compressions [16, 17]. This problem is neglected in the case of blind intubation, as confirmed by our research. Bielski *et al.* [19] indicate that blind intubation is also possible in the case of traumatic patients and using other vigilant devices. In the study by Bielski *et al.* [19], paramedics performed intubation of a patient stuck in a vehicle with a Macintosh laryngoscope and blind intubation using an iGEL laryngeal mask, achieving a significant reduction in the duration of the procedure in the case of blind intubation than direct laryngoscopy (15 [IQR, 12–19] vs. 43 [IQR, 38–59], $p < 0.001$). In turn, Ladny *et al.* [20] indicated that chest compressions do not affect the time necessary for blind intubation via various SADs performed by nurses.

As Benumoff's research suggests, more than three attempts of intubation can lead to a vicious circle, where every subsequent attempt to intubate can cause soft tissue bleeding and swelling [21], thereby leading to the situation described by the Difficult Airway Society as "cannot intubate, cannot ventilate" [22, 23]. In the conducted study, the efficacy of the first intubation attempt using MAC and AMBU in CPR without chest compression was 28.6% and 48.2%, respectively, and the total intubation efficiency was 100%. However, chest compressions have significantly reduced the effectiveness of intubation in the case of MAC, where the efficacy of the first intubation attempt and the overall efficacy of intubation were 5.4% and 46.2%, respectively. In the case of blind intubation via AMBU, the effectiveness of the first intubation trial was 33.9% and the total effectiveness was 73.2%. The low effectiveness of intubation based on direct laryngoscopy may be dictated by the relative lack of experience of

final-year medical students in the context of intubation of paediatric patients. In addition, the pressure to perform intubation as soon as possible in CPR may also affect the efficiency of intubation. As indicated by studies of the effectiveness of intubation performed by paramedics carried out by Szarpak *et al.* [24] under simulated resuscitation conditions, the total effectiveness of intubation using the Macintosh laryngoscope was 81.7%. The greater effectiveness of intubation in the Szarpak *et al.* [24] study may be due to the fact that paramedics are taught about airway protection throughout their education period. The reduction in the effectiveness of direct laryngoscopy in continuous chest compression situations is also indicated by other authors [24, 25].

Blind intubation in the study proved to be an easier procedure to perform than standard intubation – especially in the case of continuous chest compressions. This may be due to the fact that the establishment of a supraglottic ventilation device is a relatively simple procedure, and, as indicated by many authors, after a short training, medical personnel are able to effectively protect the patient's respiratory tract by means of supraglottic ventilation devices [26]. Due to the anatomical arrangement of the epiglottis in the vicinity of the larynx entrance, the inserted tracheal tube into the SAD ventilation duct is likely to be inserted into the trachea, thanks to which the patient will be intubated. In the case of this procedure, it is not necessary to directly visualise the glottis, which also translates into the duration of the procedure as well as its effectiveness in refractive conditions [27, 28].

The research carried out has both limitations and strengths. The limitations include the fact that the study was conducted on the basis of medical simulation rather than real CPR; however, such a selection of the test procedure was intentional because it allowed full standardisation of the performed procedures without any potential harm to the patient [16, 19]. The second limitation is that the research group was limited only to final-year medical students; however, this professional group will soon start independent clinical work and may encounter situations related to the necessity of instrumental respiratory protection and CPR. Among the strengths of the study is the randomised, cross-over nature of the study, as well as the use of a mechanical chest compression system to standardise the discomforts resulting from chest compressions.

CONCLUSIONS

In the study, blind intubation with the use of the AMBU was associated with more effective endotracheal intubation than standard intubation using direct laryngoscopy, both when chest compressions were interrupted for the time of intubation as well during uninterrupted chest compressions. Further tests are necessary to confirm the results obtained.

DISCLOSURE

The authors declare no conflict of interest.

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