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Comparison of Three Airway Devices Used by Prehospital Teams During Simulated Difficult Airway: A Mannequin Based Study

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Abstract

Background: Supraglottic Airway(SGA)s are recommended for airway management in emergency situations as alternatives for tracheal intubation, especially for inexperienced personnel. The aim of this study was to compare the two newer SGAs; the I-Gel and the ProSeal Laryngeal Mask Airway (LMA), with the Combitube used by prehospital team members in simulated difficult airway management situations.

Methods: Fifty two paramedics and Emergency Medical Technicians working in the Antalya 112 Emergency Medical Service (EMS) were involved this study. Participants were given a brief lecture and supervised a mannequin training in using the three devices. Afterwards they were asked to place the airway device under a simulated difficult airway scenario in a mannequin. For each participant the success rate (successful positioning at the first attempt), insertion time and number of attempts for successful positioning of each device was recorded. The participants reported their ease of placement with each device using a 100-cm Visual Analog Scale (VAS).

Results: All airway devices were inserted without problems. The success rate was significantly higher with the I-Gel and PLMA than with the CT ($p<0.05$). The mean insertion time was shorter with the I-Gel than with the CT ($p<0.05$) or the PLMA ($p>0.05$). None of the participants failed to insert each device after three attempts. The median number of attempts for successful positioning of the devices were 2, 1.5 and 1 for the CT, PLMA and I-Gel respectively (p for CT vs I-Gel <0,05). The VAS score expressing ease of insertion was higher for the I-Gel and ProSeal LMA than for the CT (p for CT vs I-Gel <0,05).

Conclusion: The following twoI-Gel and Proseal LMA were found to be more effective than the Combitube, because of greater success rates and ease of insertion for novice EMS personnel in difficult airway management.

Keywords: Airway; Prehospital; Simulation; Supraglottic Airway Devices

Introduction

Successful airway management is the first priority in a variety of prehospital settings and emergency care. Endotracheal İntubation (ETI) is considered the gold standard for securing the airway [1]. Nonetheless it is a difficult skill to acquire and must be practised continually to ensure safety and if performed incorrectly, could result in serious adverse events [2,3]. Supraglottic Airway(SGA) s, can be used by untrained personnel, by those with less experience, and for when ETI is not possible. The European Resuscitation Council hashighlighted the SGAs as being suitable devices for use during resuscitation [4,5]. Clinicaland mannequin studies have demonstrated that various SGAs adequately and effectively secure the airway [6-9]. The Combitube(CT) - also known as the esophageal tracheal airway - is a blind insertion airway device (Figure 1). It consists of a cuffed, double-lumen tube that is inserted through

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the patients mouth to secure an airway and enable ventilation. Inflation of the cuff in the oesophagus allows a level of protection against aspiration of gastric contents similar to that found in the laryngeal mask [10]. The Proseal Laryngeal Mask Airway (PLMA) has a dorsal cuff, in addition to the peripheral cuff of LMA, that pushes the mask anteriorly to provide a better seal around the

Figure 1: Combitube.

glottic aperture permitting high airway pressures without leakage (Figure 2). The drain tube parallel to the ventilation tube permits drainage of passively regurgitated gastric fluid away from the airway and serves as a passage for the gastric tube [11]. The I-gel is an innovative, secondgeneration supraglottic airway with a soft, gel-like, non-inflatable cuffdesigned to fit perfectly over the pharyngeal, laryngeal and perilaryngealstructures (Figure 3). It incorporates a gastric channel to provide an early warning of regurgitation, facilitate venting of gas from the stomach and allow the passing of a suction tube to empty the stomach contents [12].

Figure 2: The ProSeal laryngeal mask airway.

Figure 3: I-Gel.

Three of these devices have been used successfully in resuscitation and emergency scenarios [12-15]. However, no randomised trials comparing their insertion by Emergency Medical Service personnel with limited airway management skills in difficult airway management situations have been conducted. This single-centre, randomised comparison study was designed to do just that. The primary endpoint of the study was the successful firsttime insertion of each airway device. Secondary endpoints were insertion time, number of attempts for successful positioning of each device and ease of placement score in a difficult airway situation.

Materials and Methods

Paramedics and Emergency Medical Technician (EMT) working as a crew member of the Antalya 112 Ambulance Service were involved this study for which written informed consent was previously obtained. None of participants had clinical experience with the SGAsorCT. The SimMan (Laerdal, Stavanger, Norway)was used as the mannequin according to the manufacturer's instructions. Participants were asked to insert each of the three airway devices, attach a ventilating bag, and attempt to ventilate the lungs of the mannequin as soon as possibleunder simulated difficult airway conditions. The following airway devices were evaluated: the CT (Esophageal-Tracheal Combitube, The Kendall Company, Mansfield, MA,USA); the LMA-Proseal™ (PLMA, Intavent Orthofix, Maidenhead, UK) and the I-Gel (Intersurgical, Workingham, Berkshire, UK). Before the study, participants were provided with a standardised audio-visual lecture lasting 30 minutesfollowed by practice insertion of the three devices, with the instructor available to give advice.

Study parameters were; the success rate (successful positioning at the first attempt), insertion time; from the starting point (when the participants took the device in their hands) to the end point (when they performed ventilation with a respiratory bag following insertion). Correct positioning of the device was confirmed by bilateral visible chest rise judged by the same observer. If incorrect positioning of the device was recognised by the paramedics or EMTs, repositioning was allowed. For insertion attempts lasting longer than 30 seconds, paramedics were instructed to stop airway management and start interposed bag-mask ventilation. After a maximum of three unsuccessful attempts airwaymanagement was defined as a failure. Number of attempts to successfully position each devicewas recorded. The participants reported their ease of placement with each device using a 100-cm visual analog scale (VAS; 0 cm= extremely easy, 100 cm= extremely difficult).

The sample size was calculated to detect a 10% difference in success rate in insertion between devices with a type-1 error of 0.05 and a power of 90%, requiring 25 patients. We analyzed all data with SPSS version 15 (SPSS, Inc., Chicago, IL). Repeated measures analysis of variance was used for intragroup comparisons of insertion time and VAS scores for each device, followed by Tukey's multiple comparisons. The Yate chi-square test was used to compare the rate of successful insertions. The level of statistical significance was set a $P < 0{,}05$.

Results

Fifty two participants took part in the study. The characteristics of the participants were summarised in (Table 1). The success rate was significantly higher with the I-Gel and PLMA than with the

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CT (p=0.041). The difference between groups on the second and third attempswere comparable. None of the participants failed to insert each device after three attempts (Graph1).

The mean insertion time was shorter with the I-Gel than with the CT (p=0.032) or the PLMA (p=0.068; Table 2).The median number of attempts for successful positioning of the devices were 2 (range 1-3), 1.5 (range 1-3), 1 (range 1-3) and for the CT, PLMA and I-Gel respectively (Graph 1).

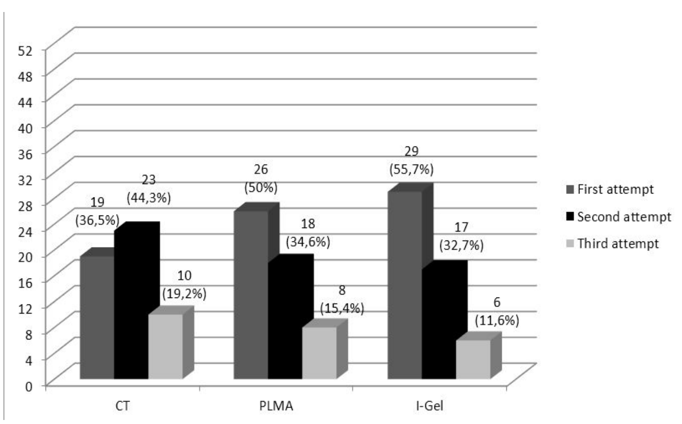
The VAS score expressing ease of insertion was higher for the I-Gel and PLMA than for the CT. The difference between the I-Gel and the CT was significant (p=0,031; Table 2).

Item	Values
Age (years)	22.25 ± 2.67
Gender (M/F)	30 / 22
Healthcare professional (PM/ EMT)	29 / 23
Duration of the serving in 112 (Months)	23.69 ± 7.65
ALS training sessions past 3 years (n)	21
Values are mean ± standard deviation or number. (Paramedic: PM, Emergency Medical Technician: EMT, Adult Life Support: ALS)	

Table 1: Characteristics of study participants.

	Combitube	Proseal LMA	I-Gel	p
Insertion time (seconds)	42.75 ± 37.1	34.07 ± 14.56	29.67 ± 12.28	0, 026
VAS (cm)	5.28 ± 1.68	6.23 ± 1.57	7.05 ± 1.48	0, 041
Data was expressed as mean ± standard deviation (p values belong to three group comparisons)				

Table 2: Insertion time and VAS values of study devices.



Graph 1: Number of attempts needed for successful positioning of each device.

Data was given as numbers and percentages (CT:Combitube, PLMA: Proseal LMA).

Discussion

This study was planned to compare the two newer SGAs: the I-Gel and the PLMA, with an old but still available one; the CT, used by prehospital team members in simulated difficult airway management scenarios.

Several studies have compared various airway management devices in different settings with varying degrees of success. Some of them were performed in clinical settings; others were animal experiments or mannequin studies. Nevertheless studies comparing the use of these devices by novice prehospital emergency staff in difficult airway situations are few. In human studies it is possible to create a difficult airway; for example a rigid neck collar was used to simulate restricted neck mobility in anesthetized patients in two of the studies [16,17].We preferred to use mannequin based scenariosin our study because it is easier to create difficult airway conditions with mannequins and all our participants are novice EMS personneltherefore we wanted to preclude thepossibility to harm to real patients. The reason for evaluating the CT, PLMA and I-Gel in our study was the fact that these devices have the advantage of an improved airway seal, a reduced risk of aspiration and the possibility of inserting a gastric tube into the patient esophagus.These features may prove useful during difficult airway management especially if the patient has a known history or a suspicion of a full stomach.

It is mandatory to secure the airway as quickly and as safely as possible, in critical patients, especially in a prehospital emergency situation.In this senseETI remains the gold standard. However, it is a difficult skill to acquire, besides persistent and prolonged attempts at intubation may cause catastrophic events [3]. Failure rates by inexperienced EMS personnel in prehospital settingshave been reported at around 25%-30% [18,19]. Therefore, alternative airway devices have been developed. The CT, PLMA and I-Gel, are three of them, and their use is endorsed by the 2005 and 2010 Resuscitation Council guidelines [4,5]. In the American Society of Anesthesiologists Difficult Airway Algorithm 2003 [20], the LMA was listed as an important alternative device for ventilation during the management of difficult airways. Since then, numerous SGAs have been introduced and included as must-have items in the 2013 ASA algorithm [21].

The advantage of the CT and SGAs are the ease of use for novice operators especially in prehospital emergency situations [20]. The dual-lumen design of the CT allows for ventilation to proceed regardless of esophageal or tracheal placement. Nonetheless, the drawbacks of CTs are evidenced by reports of some serious complications associated with their use [22]. Also with demonstration of efficacy of some alternatives as SGAs, it's use is decreased. In their study Duckett et al concluded that, introduction of the I-Gel has enhanced the choice of advanced airway management options for their paramedics with no reported compromise in patient safety [23]. The reason of using CT in this study is that

CT is still available and been using in lower and middle income countries for difficult airway management.

It is important to know which airway device will perform with a high success rate during prehospital emergency interventions. "Success rate" is defined as successful insertion of the airway device after a maximum of three attempts or succeedingby a set time interval in different studies [13,24]. In a retrospective study over a period of 3 years by Calkins et al, CT insertion was attempted on 162 patients by EMS personnel of which, 113 (70%) were successful [25]. Compared with those studies our rates are lower but the reason is probably that the above mentioned studies were performed under physiological airway conditions which were different from ours. Ragazzi, et al. had a first-time insertion success rate with the I-Gel of 54% in their study, which is very close to our results [26]. In other studies, higher success rates were also reported using the CT, PLMA and I-Gel in mannequin studies by inexperienced personnel [14,27]. In a study by Theiler et al the success rate for the I-Gel was 93% in a simulated difficult airway scenario [17]. This is a higher percentage than found in our study. But the reason is most probably that the participants in their study were staff anesthesiologists with extensive experience compared with that of our inexperienced personnel. In another study performed under simulated pathological airway conditions, 50 medical students succeeded inserting the CT and I-Gel successfully in the simulated situation of tongue edema [24].

In our study, we used clear starting and ending points in measure of the duration of insertion. Castle et al assessed six different SGAs including the CT and I-Gel for speed and ease of insertion in a mannequin study performed by 58 paramedic students. The I-Gel was the fastest device to insert with a mean (SD) insertion time of 12(4)seconds, with the CT the slowest with a mean 35 (12) seconds [28]. Insertion times found in the literature for the I-Gel differs between 8,8-18,4 seconds [14,15]. In all these studies various SGAs compared favorable with the I-Gel. However the common result of these studies was that the I-Gel was consistently the fastest airway device. In a mannequin study for assessing the performance of airway management by paramedics using seven different airway devices the insertion time was significantly shorter with the I-Gel(14.95 ± 5.29 seconds) than was that of the PLMA (43.85 ± 11.85 seconds) and The CT (36.21 ± 9.15 seconds) [14]. In our study the similarity with the above studies is that the I-Gel was the fastest and the CT was the slowest device to insert. In a study by Robak et al the insertion time was significantly longer with I-Gel than with the CTunder simulated conditions such as trismus, limited mobility of the cervical spine, and combined pathological conditions [24]. In another study performed in a simulated difficult airway scenario in anesthetized patients the I-Gel was inserted in 42 ± 23 seconds [17]. In our study the I-Gel had a significantly shorter insertion time than did either PLMA or CT. The difference was significant with the CT. Besides blocking two cuffs with the CT is more time-consuming than blocking the single cuff of the PLMA or the lack of need to inflate any cuff on the I-Gel, as published by [29].

In our study, participants were allowed three attempts to insert the airway devices and no attempt was longer than 30 seconds. All our participants succeeded insertingboth the CT and the SGAs under these conditions. Our result was in accordance with Ruetzler and Robak's studies [13,24] in which all the paramedics succeeded inserting the I-Gel, PLMA and CT within three attempts. Our participants determined that the CTwas more difficult to insert than was the I-Gel and PLMA. In the studies comparingthe difficulty scores for inserting different SGA's the I-Gel was evaluated as easier to insert compared with the other SGAs in studies similar to our, due mainly to the non necessity of cuff inflation [30-32].

A limitation of our study was the use of a mannequin rather than patients, so the study results cannot be directly extrapolated to humans. On the other hand, the advanced patient simulator (SimMan) permitted a realistic demonstration of the difficult airway and provided good standardisation of the study conditions. Further, because of its design, the study was not blinded. When considering which of the numerous SGAs to use in difficult airway management, a number of clinical and non-clinical factors need to be considered. Proper training and expert medical supervision probably have more influence on the successful use and impact of these devices than do factors related to the devices themselves. We concluded that the I-Gel and Proseal LMA offer better success rates and ease of insertion than does the Combitube for novice EMS personnel in difficult airway management, although other devices may confer improved airway management options. Additional controlled, directcomparison studies of these alternative devices should be conducted in properly supervised emergency medical services systems.

Conflict of Interest: None (The preliminary results of this study was presented as a poster at SESAM 2015 Congress in Belfast).

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