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Establishing a definitive airway in the trauma patient by novice intubators: A randomised crossover simulation study

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ABSTRACT

Background: Establishing a definitive airway, defined as a tube placed in the trachea with cuff inflated below the vocal cords, is standard of care in pre-hospital airway management of the trauma patient. However, in this setting, and using manual in-line stabilisation of the neck, success rate of intubation by inexperience providers is suboptimal. The use of supraglottic airway devices that allow blind tracheal intubation has been suggested as an alternative method by the Advanced Trauma Life Support (ATLS) programme of the American College of Surgeons. We aimed to compare intubation with the standard intubation technique (direct laryngoscopy [DL]) with blind intubation through an intubating-laryngeal mask airway (I-LMA) during manual in-line stabilisation of the neck.

Materials and methods: A randomised, crossover manikin study was performed with 29 emergency medical technicians undergoing training for paramedic status. Outcome measures were success rate in one intubation attempt, duration of intubation, and assessment of ease-of-use.

Results: Study subjects had a higher success rate of tracheal intubation with I-LMA than with DL (27/29 vs. 18/29, $p < 0.025$), and I-LMA was assessed as easier to use (4 vs. 3, $p < 0.0001$). Longer duration of intubation was found with I-LMA compared to DL (54.2 vs. 42.8 s, $p < 0.002$). Success rate of correct placement of I-LMA within the airway was 28/29 (96.5%). Time to achieve correct placement of I-LMA within the airway was shorter than duration of tracheal intubation with DL (26.9 vs. 42.8 s, $p < 0.0001$).

Conclusions: Novice intubators had a higher success rate of intubation with I-LMA than with DL, but duration of intubation was longer with I-LMA. Time to achieve correct placement of I-LMA within the airway was shorter than duration of tracheal intubation with DL. Findings of this simulation study suggest that in the presence of manual in-line stabilisation of the neck, I-LMA-guided intubation is the preferred technique for novice intubators.

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Introduction

Establishing a definitive airway defined as a tube placed in the trachea with cuff inflated below the vocal cords is standard of care in pre-hospital airway management of the trauma patient [1]. However, previous studies revealed that the success rate of intubation of injured patients using standard intubation technique (direct laryngoscopy [DL]) in the pre-hospital setting is suboptimal [1–4]. Furthermore, the success rate of pre-hospital intubation with DL by providers inexperienced in tracheal intubation is even lower [5].

The use of supraglottic airway devices that allow blind tracheal intubation has been suggested as an alternative method in the last edition of the Advanced Trauma Life Support (ATLS) textbook, of the American College of Surgeons [1,2]. Three types of such devices are currently used in the practice of anaesthesia: the I-gel®, the Air-Q®, and the Fastrach® laryngeal mask airway (intubating-LMA, I-LMA) [6,7]. Previous studies revealed that, as a conduit for

Abbreviations: I-LMALMAFastrach®, intubating laryngeal mask airway; DL, direct laryngoscopy; ETT, endotracheal tube.

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tracheal intubation, I-LMA is superior to the I-gel® and to the Air-Q®, and that I-LMA caused less neck extension at C1-2 and C2-3 than intubation with DL [6–9]. This makes the I-LMA a potentially ideal device for trauma patients in whom cervical spine movement is undesirable [1].

The objective of this simulation study was to compare intubation with DL with blind intubation through I-LMA during manual in-line stabilisation of the neck. We examined the hypothesis that novice intubators would have higher success rates of tracheal intubation with the I-LMA than with DL.

Material and methods

Study design

A randomised, crossover manikin study was performed. We compared participants' performance of intubation using DL with their performance of intubation with I-LMA. The study was conducted at a simulation laboratory of a level-1 trauma care centre. The Institutional ethics committee waived the need for ethical approval for this study.

Study participants

Study participants were military emergency medical technicians undergoing initial training for paramedic status. Three months prior to the study, participants had completed courses in Advanced Cardiac Life Support (ACLS) and in Pre-Hospital Trauma Life Support (PHTLS) as part of the standard paramedic curriculum. None of the study subjects had prior clinical experience with the I-LMA. However, all had completed a 3-hour workshop with DL during the PHTLS course before the study.

Randomisation

The sequence of device insertion was randomised to either DL-first or I-LMA-first. Using a computerised random-number generator, an allocation sequence was created and course participants were divided into the two groups of the study: DL-first and I-LMA-first.

Study instruments

1) Laerdal® Airway Management Trainer (Laerdal Medical AS, Stavanger, Norway).
2) Laryngoscope with a size 3 Macintosh blade, standard cuffed endotracheal tube (ETT) size 7.0, 10 ml syringe, water soluble lubricant.
3) LMA Fastrach® reusable size 3 (Fig. 1), a polyvinyl chloride (PVC) disposable ETT (LMA® ETT single use), 50 ml syringe, water soluble lubricant.
4) Ambu® oval silicon reusable resuscitator and mask.

Testing technique – blind intubation through I-LMA

First, the cuff was totally deflated and the posterior surface of the mask tip was lubricated with 3–4 ml of gel, to facilitate insertion. Then, the mask tip was carefully positioned so that it was flat against the hard palate. Sliding it backward, the tube curvature closely followed the anatomical curve of the palate and posterior pharyngeal wall [10]. As soon as the I-LMA reached the larynx, the cuff was inflated to a volume of 30 ml. An optimal position was verified by using the two-step Chandy manoeuvre [10]. This is followed by slight rotation of the device in the sagittal plane, using the handle, until the least resistance to bag ventilation is achieved (Fig. 2A). This helps to align the internal aperture of the device with the glottis opening. Just before blind intubation, the I-LMA was slightly lifted away from the posterior pharyngeal wall using the handle. This prevents the tracheal tube from colliding with the arytenoids and facilitates the smooth passage of the tracheal tube into the trachea.

Fig. 1. The intubating Laryngeal Mask Airway (I-LMA, LMA Fastrach®).

Then, a 7.0 mm well-lubricated LMA® ETT was inserted through the I-LMA until it reached the 15 cm depth marker, so that its tip did not enter the mask aperture (Fig. 2B). The tube was then advanced gently to about 1.5 cm past the 15 cm transverse line and, if no resistance was felt, indicating correct tube position, it was passed freely into the trachea to its desired depth, and the cuff was inflated.

Study procedure

Participants received a 30-min lecture on the two techniques used in this study (intubation with DL and intubation using I-LMA), followed by two standardised educational videos on the two techniques and a 10-min demonstration of each technique (LG). Immediately after, each participant in turn practiced the two techniques on a manikin model (Laerdal® Airway Management Trainer without neck immobilisation). Practicing the two techniques was ended when each participant was satisfied with his understanding of the two methods of intubation. Participants were then randomly divided into the two groups (DL-first, I-LMA-first). Immediately after, each participant in turn entered the study room in which the study instruments were placed on a table and two study investigators were present (NB, BL). Each participant was asked by a study investigator to independently perform *one intubation attempt* using the first technique (DL or I-LMA) on the manikin model, while manual in-line stabilisation of the neck was performed by a study investigator (BL) (Fig. 1).

Immediately after performing the first procedure, the participant was asked to perform the second procedure using the second technique (DL or I-LMA). The study investigators (NB, BL) did not intervene with the procedure or provide any consultation or recommendation, and participants were not allowed to watch others perform the procedure. For each intubation attempt with DL, a newly cuffed ETT was used and, for each intubation attempt with the I-LMA, a new LMA® ETT was used.

If a failed intubation occurred, the participant was asked to explain the problem to a study investigator (BL) who recorded this information on a designated data collection sheet. Each procedure was videotaped by one of the study investigators (NB) using a digital video HD camera iPhone 6 (Apple Inc., Cupertino, CA, USA) located at a fixed position 50 cm from the manikin. Recording began 20 s before the procedure (before the participant

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Fig. 2. Blind tracheal intubation through I-LMA during manual in-line stabilisation of the neck.

had the I-LMA or the laryngoscope in his hands), continued throughout the procedure, and ended 20 s after the procedure.

Study outcomes and measurements

Study outcome measures were evaluated from the videotapes.

Primary outcome measure – intubation success rate

The primary outcome measure was success rate of tracheal intubation in one attempt using DL or I-LMA. Success was defined as ETT placed in the trachea as verified by inflating the manikin's lungs through the ETT using a self-inflating bag. Failed intubation was defined as unsuccessful intubation of the trachea in one attempt [11].

Secondary outcome measure – duration of intubation

The duration of intubation with DL was defined as the time taken from insertion of the ETT between the lips until the ETT was correctly positioned in the trachea by the participant. The time taken to connect the ETT to the self-inflating bag and to inflate the manikin's lungs was included in the duration of the attempt [11].

The duration of intubation with I-LMA was defined as the time taken from insertion of the I-LMA between the lips until the ETT was correctly positioned in the trachea by the participant. The time taken to connect the ETT to the self-inflating bag and to inflate the manikin's lungs was included in the duration of the attempt [11].

Tertiary outcome measure – ease-of-use

Following the study procedure, participants were asked to complete a questionnaire independently and anonymously. They were asked to record the 'ease-of-use' of the DL technique and the I-LMA technique, using a five-point Likert Scale ("the tracheal tube was easily inserted into the trachea"; 1 – strongly disagree, 2 – disagree, 3 – neither agree nor disagree, 4 – agree, 5 – strongly agree) [12]. Data were collected anonymously by a study investigator.

Correct placement of I-LMA within the airway

Success of correct placement of I-LMA within the airway was verified by inflating the manikin's lungs through the I-LMA using a self-inflating bag [13]. Failure to inflate the manikin's lungs in 60 s or less was defined as unsuccessful attempt. The time to achieve correct placement of I-LMA within the airway was defined as the time taken from insertion of the I-LMA between the lips until I-LMA was correctly positioned by the participant. The time taken to connect the I-LMA to the self-inflating bag and to inflate the manikin's lungs was included in the duration of the attempt [13].

Data analysis

The primary end-point for the sample size calculation was the expected difference in the one-attempt success rates between the DL-first group and the I-LMA-first group. Based on the results of a previous study using the same manikin, we estimated that a total of 25 participants would be sufficient to detect a group difference with type-I error of 0.05 and type-II error of 0.1 (90% power) [5]. As this was a crossover trial, pairing was taken into account in the statistical analysis. McNamer's *Chi* square test was used for comparing the success rate of tracheal intubation with DL and I-LMA. The paired Student's *t* test was used for comparing duration of tracheal intubation with DL and with I-LMA, and for comparing duration of tracheal intubation with DL with duration of I-LMA placement within the airway. A two-sided Wilcoxon signed-rank test was used for comparing the scoring of the 'ease-of-use' with DL and I-LMA. All statistics were calculated using the StatsDirect statistical software (v2.6.6, StatsDirect Limited, Cheshire, UK).

Results

All 29 paramedic students approached by the principle investigator (IS) participated in the study.

Demographic data

The I-LMA-first group had 15 participants with a median age of 20 (IQR, 19–20) years and a 5:10 female:male ratio. The DL-first group consisted of 14 participants with a median age of 19.5 (interquartile range [IQR], 19–20) years and a 4:10 female:male ratio.

Tracheal intubation success rate (Table 1)

Participants had a significantly higher one-attempt success rate with I-LMA than with DL (27/29 vs. 18/29; $p < 0.025$). In 10/11 unsuccessful attempts with DL, participants explained that they had failed to visualise the vocal cords. In one attempt, the participant failed to insert the ETT via the cords. The two unsuccessful attempts with the I-LMA were related to difficulties with the practice of the Chandy manoeuvre.

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Table 1
Tracheal intubation success rates with direct laryngoscopy (DL) versus blind intubation through an intubating-laryngeal mask airway (I-LMA).

	DL	I-LMA	*p* Value	95% CI
Tracheal intubation success rate on first attempt				
Total (%)	18/29 (62.0)	27/29 (93.1)	0.025	1.0–3.4
DL-first (%)	9/14 (64.3)	14/14 (100.0)	0.087	0.9–5.2
I-LMA-first (%)	9/15 (60.0)	13/15 (86.7)	0.2	0.8–4.0
Duration of tracheal intubation				
Total, s, mean (SD)	42.8 (9.7)	54.2 (9.8)	0.002	−15.6 to −3.8
DL-first, s, mean (SD)	41.2 (8.9)	51.8 (9.0)	0.04	−18.6 to−1.4
I-LMA-first, s, mean (SD)	44.7 (10.7)	56.9 (10.2)	0.008	−19.4 to −2.6
Assessment of 'ease-of-use'				
Total, median (IQR)	3 (2–4)	4 (4–5)	0.0001	0.5–2.0
DL-first, median (IQR)	3 (2–4)	4 (4–5)	0.002	0.5–1.5
I-LMA-first, median (IQR)	4 (2–4)	4 (4–5)	0.002	0.5–1.5
Success rate of correct placement of I-LMA within the airway (%)	–	*28/29* (*96.5*)		
Time to achieve correct placement of I-LMA within the airway, s, mean (SD)	–	26.9 (4.8)		

Notes: DL, direct laryngoscopy; I-LMA, intubating laryngeal mask airway; ETI, endotracheal intubation; SD, standard deviation; IQR, interquartile range; CI, confidence interval between means or medians. Significant values are indicated in italics ($p < 0.05$).

Duration of tracheal intubation (Table 1)

Participants had a significantly longer duration of intubation with I-LMA than with DL (54.2 vs. 42.8 s; mean time difference 9.7 s; 95% confidence interval [CI] 3.8–15.6 s; $p < 0.002$).

Assessment of ease-of-use (Table 1)

Participants assessed the I-LMA as easier to use than DL (4 vs. 3; median difference 1, 95% CI 0.5–2.0; $p < 0.0001$).

Correct placement of I-LMA within the airway (Table 1)

Success rate of correct placement of I-LMA within the airway was 28/29 (96.5%). Correct placement was achieved in less than 60 s in all attempts. Time to achieve correct placement of I-LMA within the airway was shorter than duration of tracheal intubation with DL (26.9 vs. 42.8 s; mean time difference 16.3 s; 95% CI 12.5–20.2 s; $p < 0.0001$).

Discussion

Securing the airway is of major importance in the early management of the trauma patient, and establishing a definitive airway is standard of care in pre-hospital airway management of the injured patient [1,2]. In this simulation study, we found that in the presence of manual in-line stabilisation of the neck, novice intubators had a higher success rate in establishing a definitive airway with the I-LMA than with DL (93.1% vs. 62%). These findings are consistent with two previous studies that examined performance of I-LMA by novice intubators without neck stabilisation. These studies reported higher first attempt success rates of tracheal intubation with the I-LMA compared to DL in anesthetised patients (92.2% vs. 40%) and in a manikin model (90% vs. 50.4%) [14,15]. Another study reported the use of I-LMA in the operating room in patients with unstable cervical spines that were immobilised in rigid Philadelphia collars [9]. The 92.6% tracheal intubation rate on the first attempt recorded in this study is in line with the results found in our study [9].

An important finding of our study is that the time taken to establish a definitive airway was approximately 10 s longer with the I-LMA than with DL (the time from insertion of the laryngoscope or the I-LMA between the lips until the ETT was correctly positioned in the trachea). However, success rate of correct placement of I-LMA within the airway was high (27/28, 96.2%), and the time from insertion of the I-LMA between the lips until it was correctly placed within the airway was 26.9 s, approximately 16 s shorter than the duration of intubation with DL. A similar period of time for deploying I-LMA within the airway in patients with an immobilised cervical spine was reported in a previous study (30 s) [9]. The clinical implication of these findings is that, although I-LMA required longer duration to establish a definitive airway, shorter time was needed for deploying it within the airway, which means earlier oxygenation and ventilation of the injured patient. A previous simulation study that used a high fidelity critical care scenario found that paramedics were able to deploy the I-LMA in a success rate of 97.5% and to successfully oxygenate and ventilate the manikin [13].

Our study demonstrated high success rates of tracheal intubation at first attempt with the I-LMA. In our study, all participants underwent tracheal intubation training with DL 3 months prior to the study and were familiar with its use; however, none of them had any experience with the I-LMA. These findings suggest that inexperienced providers can be easily trained to successfully place an I-LMA within the airway, and to successfully perform tracheal intubation through it. Study subjects assessed the I-LMA as easier to use compared to DL. This finding may reflect the fact that participants felt comfortable with the I-LMA and further supports its use by novice intubators.

Our study has certain limitations. Firstly, since a manikin model was used, the applicability of our data to human subjects needs to be verified in clinical studies. Secondly, we did not compare DL and I-LMA with other supraglottic airway devices that allow blind tracheal intubation (I-gel® and Air-Q®) and with other techniques such as the gum elastic bougie [1].

Conclusions

Novice intubators had a higher success rate of intubation with I-LMA than with DL, but duration of intubation was longer with I-LMA. Time to achieve correct placement of I-LMA within the airway was shorter than duration of tracheal intubation with DL. Study findings suggest that in the presence of manual in-line stabilisation of the neck, I-LMA-guided intubation is the preferred technique for novice intubators. Future studies on human models are needed to determine if I-LMA-guided intubation is the preferred technique.

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Authors' contribution

- Dr. Itai Shavit conceived the idea for the study, designed the study, directed study implementation, analysed the data, performed statistical analysis, and drafted the manuscript.
- Dr. Barak Levit assisted in study design, performed manual in-line stabilisation of the neck, collected the data, reviewed the manuscript, and approved the final manuscript as submitted.
- Mrs. Nofar Ben Basat videotaped the patients, collected the data, reviewed the manuscript, and approved the final manuscript as submitted.
- Dr. Dekel Lait assisted in study design, directed study implementation, reviewed the manuscript, and approved the final manuscript as submitted.
- Dr. Mostafa Somri critically revised the manuscript and approved the final manuscript as submitted.
- Prof. Luis Gaitini designed the study, directed study implementation, critically revised the manuscript, and approved the final manuscript as submitted.

All authors have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

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Conflict of interest

None.

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