



A Comparison of Three Different Supraglottic Airway Devices in Neonatal Airway Training during Resuscitation Simulation

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Abstract

Objective: The aim of this study was to compare the success rates for insertion using the laryngeal mask, laryngeal tube, and I-gel supraglottic airway devices in a neonatal airway manikin during a resuscitation simulation course.

Methods: Three groups of health care professionals were given a brief supervised training in using the devices. For each participant the positioning of each device was recorded. Success rate of insertion and time until adequate ventilation was measured. Furthermore, use and handling of a SAD was scored for ease of insertion, clinical and fiber-optic position, and ventilation.

Results: A total of 66 health care providers (22 nurse anesthetists, 22 paramedics, and 22 anesthesia residents) participated in the study. The median time to establish ventilation of both the laryngeal mask and the laryngeal tube was significantly longer than for the I-gel for all professional groups ($p < 0.001$). Success rate was 100% for the used supraglottic airway devices on first attempt. The fiber-optic evaluation score of the laryngeal tube was (not significantly) lower than the scores of the I-gel and laryngeal mask.

Conclusion: This manikin study demonstrated equal success rates, but shorter time to establish adequate ventilation with the I-gel supraglottic airway device than the laryngeal mask or laryngeal tube devices in a neonatal airway management simulation by differently trained health care professionals. While simulations are appropriate for practicing the use and the training of a supraglottic airway device, the results of the present study must not be applied to corresponding situations in real humans without further investigation.

Keywords

Neonatal Airway Management, Supraglottic Airway Device, Laryngeal Mask, Laryngeal Tube, I-Gel

resuscitation, the American Heart Association and the European Resuscitation Council Guidelines also endorse the use of supraglottic airway devices (SAD) for neonates, infants, and children [1,2]. In addition to the classical laryngeal mask (LMA), several other devices like the laryngeal tube (LTS) or I-gel have been investigated for use with children and infants. The LTS airway consists of a dual tube with a distal and a proximal cuff. While the LTS has shown to be effective in adult airway management, clinical and manikin studies in children demonstrate different results [3,4]. The I-gel mask is a further development of the LMA with a gel-filled anatomical mask and a non-inflatable cuff. The I-gel mask has been successfully used in manikin studies and in clinical studies in children [5,6].

Although various types of SADs have been compared in studies of pediatric patients, no investigations have compared the use of the LMA, LTS and I-gel devices during neonatal resuscitation or during training in neonatal airway management.

Neonatal airway management requires mandatory airway management training for neonatologists, anesthesiologists and other health care professionals. While practice under constant supervision of experienced anesthesiologists is a cornerstone in the education of anesthesia residents in neonatal airway management in the operating theatre, the training of different health care professionals with the neonatal airway is predominantly simulator-based. Although recent studies question the efficacy of training that uses airway simulation [7,8], for ethical reasons, training with and evaluation of new airway equipment should undergo a three-stage process before introduction to the market. While the first stage is a manikin-based evaluation, stage two and three will be conducted on patients [9].

Therefore, the aim of the present study was to compare the success rates for insertion using the LMA, LTS and I-gel airway devices in a neonatal airway manikin during a resuscitation simulation course for differently educated health care professionals. Furthermore, considering the recent results regarding simulation training, the results of the present study should be compared with clinical studies in children.

Introduction

Although for experienced personnel endotracheal intubation is the first choice for establishing airway control during neonatal

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Methods

The goal of this study was to determine the success rates of differently trained health care workers in neonatal airway management when placing three different supraglottic airway devices.

Airway devices

- The LMA-unique™ (LMA, Bonn, Germany) is the original single-use laryngeal mask airway. It consists of an inflatable mask and a single tube.
- The Laryngeal Tube™ (LTS) (VBM Medizintechnik, Sulz a. N., Germany) is a double-lumen tube that consists of a smaller distal and a larger proximal high-volume, low-pressure cuff. The ventilation tube terminates between the proximal and the distal cuffs. The tip of the device with the drain port orifice is inserted into the esophagus, and the cuffs are simultaneously inflated.
- The I-gel™ (Intersurgical, Sankt Augustin, Germany) is a newly developed device consisting of a non-inflatable cuff made of a soft, gel-like, medical-grade, thermoplastic elastomer. In contrast with pediatric or adult sizes, the gastric channel is absent in a size 1 I-gel. The airway seal provided by the gel-like cuff improves as the device warms to body temperature.

All devices were inserted according to the instructions provided by the manufacturer.

Participants

Approval was obtained from the local ethics committee of the University of Regensburg due to a study with health care participants. The participants were anesthesia residents, paramedics from the local emergency service, and nurse anesthetists. The study conducted separate training sessions for each professional group.

Protocol

Before the start of the study, a group of five expert anesthesiologists from the department of anesthesiology of the University Hospital of Regensburg, all experienced in neonatal airway management, evaluated all three airway devices to determine the most appropriate size of each to be used on our Ambu M-Mega Code Baby (Ambu, Bad Nauheim, Germany). This manikin model is a neonate dummy. In a previous test, this manikin was the only model of all of the models available in Germany into which the used supraglottic airway devices could be inserted. Each specialist ranked the size according to his or her best and easiest performance. In a final discussion, the following sizes for the different supraglottic airway devices were chosen by the anesthesiologists:

LMA-unique™, single use, size 1

LTS II™, re-usable, size 0

I-gel™, single use, size 1

All participants of the study received standardized instructions from the same individual on how to use the LMA-unique™, LTS II™, and I-gel™ devices, including advice on insertion techniques for the manikin. Both the LMA direct technique and the rotational technique with a partially inflated cuff were demonstrated [10,11]. All participants were informed of the purpose of the study and the goals of the airway management simulations. They were informed that insertion times and the number of attempts to establish efficient ventilation for each device would be measured.

Standardized training in small groups of three participants each was performed for 10 min with each of the three supraglottic airway devices under guidance and supervision of the observer. Silicone lubricant and a standard bag-valve mask were used as additional equipment.

After the training the participants inserted each device according to the protocol in random order blindly and without a laryngoscope. The participants had 90 seconds until cut off with each SAD to

establish and secure the airway sufficiently. During this time frame the participants was allowed to retry his attempts if there was no visible chest rise. All attempts for each device were counted and protocolled.

Measurements

The number of insertion attempts was not limited unless the participant took longer than the 90-second cut-off time to establish sufficient chest inflation. A failure to insert was defined as an insertion that was not completed after 90 seconds or a completed insertion that did not cause sufficient chest inflation. A single unblinded observer recorded the number of attempts needed to successfully insert the LMA-unique™, LTS II™ or I-gel™ into the manikin. The observer also recorded the time (= lung inflation time) from picking up and positioning a SAD in the supraglottic airway until adequate ventilation was confirmed. Adequate ventilation was defined as a bilateral rise in the chest of at least 1.5 cm, corresponding to the manikin's tidal volume of 20 to 50 ml. The ventilation was scored by a flexible measuring tape (2 = good ventilation: bilateral rise > 1.5 cm (20 – 50 ml tidal volume), 1 = poor ventilation: bilateral rise 0-1.5 cm (1 – 19 ml tidal volume), 0 = ventilation not possible, no chest rise).

Once the devices were inserted, the positions of the devices were fiber-optically controlled after the final “successful” insertion attempt and ventilation, by the same unblinded observer using the following rating system: visualization of the vocal cords (score 2), visualization of the laryngeal structures only (score 1) or no visualization of the laryngeal structures (score 0). All participants were also required to assess the ease of device insertion (2 = easy, 1 = difficult, 0 = not possible) and clinical position (2 = SAD remaining in midposition, 1 = mask rising out). The participants were also asked whether the simulations were lifelike (2 = lifelike, 1 = not lifelike).

Finally, the fiber-optic score for placement, the participant's scores and the ventilation score were added, yielding a maximum score of 10. A score of less than 7 was considered a poor score (adopted Cook scoring system for SADs [12]).

Data analysis

The time required for a completed insertion was analyzed using the Kruskal-Wallis rank sum test. A post hoc comparison was made using the Dunn procedure. Categorical data are presented as numbers. The analysis of categorical data (success rate, rating system) was performed using the χ^2 -test. Values were considered significant for a type I error (p) of less than 0.05. Statistical analyses were performed separately for each professional group.

Results

A total of 66 health care providers (22 anesthesia nurse specialists, 22 paramedics, and 22 anesthesia residents) participated in the study. Each participant performed insertion attempts with each supraglottic airway device on the neonatal manikin in random order according to the protocol.

The median lung inflation time for the I-gel was significantly shorter than for both the LMA and the LTS in all of the professional groups (p < 0.001) (Table 1).

Table 1: Median lung inflation time (in seconds) of the three devices.

	LMA	I-gel	LTS
Nurse specialists	11.16 (5.57-14.93)	6.29 (3.52-11.81)	12.51 (8.46-21.49)
Paramedics	12.26 (8.22-22.06)	7.11 (4.60-11.84)	12.71 (10.09-23.47)
Anesthesia residents	10.08 (4.69-20.20)	6.30 (4.08-10.19)	13.50 (7.09-21.31)

Median (Range); p < 0.001 I-gel vs. LMA; p < 0.001 I-gel vs. LTS

Table 2: Success rate in %.

	LMA	I-gel	LTS
Nurse specialists	100 % (22/22)	100 % (22/22)	100 % (22/22)
Paramedics	100 % (22/22)	100 % (22/22)	100 % (22/22)
Anesthesia residents	100 % (22/22)	100 % (22/22)	100 % (22/22)

(All participants succeeded insertion on first attempt within the 90 seconds for each device)

Table 3: Fiber-optic evaluation and number of participants in each visual scoring group

	LMA			I-gel			LTS		
	2 Vocal cords	1 Laryngeal structures	0 No laryngeal structures	2 Vocal cords	1 Laryngeal structures	0 No laryngeal structures	2 Vocal cords	1 Laryngeal structures	0 No laryngeal structures
Nurse specialists	21	1	0	22	0	0	5	14	3
Paramedics	22	0	0	22	0	0	4	17	1
Anesthesia residents	22	0	0	22	0	0	8	13	1

Visualization of the vocal cords was rated with score 2, visualization of the laryngeal structures only with score 1, and no visualization of the laryngeal structures with score 0.

Table 4: Scoring system with a maximum of 10 points (adopted Cook scoring system for SADs [12]).

Score	LMA		I-gel		LTS	
	≤ 6	7-10	≤ 6	7-10	≤ 6	7-10
Nurse specialists	0	22	0	22	3	19
Paramedics	0	22	0	22	5	17
Anesthesia residents	0	22	0	22	3	19

Median (Range): $p < 0.05$ LMA vs. LTS; $p < 0.05$ I-gel vs. LTS

All participants of the study inserted the LMA, I-gel and LTS successfully on the first attempt (Table 2).

The fiber-optic evaluation of the inserted I-gel allowed for visualization of the vocal cords in all professional groups. The vocal cords could also be visualized, when the LMA was used by paramedics and anesthesia residents and 21 of 22 nurse specialists. One nurse could not insert the LMA optimally: only the laryngeal structures could be visualized.

For anesthesia residents, paramedics and nurse specialists, it was not possible to identify the laryngeal structures following insertion of the LTS in 1/1/3 of the 22 cases, respectively. In addition, the laryngeal structures but not the vocal cords were visible in 13/17/14 of the 22 insertion attempts, respectively. Thus, the fiber-optic evaluation score of the LTS is lower but not significantly lower than the scores of the I-gel and LMA (Table 3).

In all instances, the nurse specialists, paramedics and anesthesia residents' SAD performance scores for LMA and I-gel ranged between 8-10 points, which was considered a good ventilation score (Table 4).

For the LTS, however, 3 of the 22 nurse specialists and anesthesia residents, respectively, scored 6 or less points on insertion and ventilation success, which was considered a poor ventilation score. For the paramedics, 5 trials out of 22 with the LTS received a score of 6 or less points. In contrast, 7 or more points were scored for all attempts using LMA and I-gel, which was a significant result ($p < 0.05$).

Discussion

While investigations regarding adult emergencies have demonstrated a high success rate for the LTS, as well as for the I-gel [3,13], data for neonatal emergencies are not yet available, and the optimal device for this purpose remains unclear. Thus, the use and comparison of different SADs in manikins is necessary before the devices can be used in patients.

Therefore, the aim of this study was to compare the rate of successful insertion and the time to establish adequate ventilation of a manikin for the laryngeal tube, I-gel and laryngeal mask by health care professionals with different backgrounds in neonatal airway management.

In summary, in this neonatal manikin study, each of the three SADs used could be inserted on the first attempt, and sufficient ventilation could be provided. The health care provider's level of education did not affect the success rate of insertion with either the LMA or I-gel. There might be a potential for bias in any comparison between the three groups of participants, because the observer was not blinded to the professional group being observed. Nevertheless,

there was no significant difference between the groups. The I-gel could be inserted faster than both the LMA and LTS, and should be considered as an alternative for airway management in neonates.

To date, only a few studies that use SADs in a neonatal manikin and compare the success rates of insertion, time to insertion or time to successful ventilation have been published. These trials also report high success rates. The first investigation compared the time from insertion to the first inflation of an artificial lung for the LMA ProSeal™ and the LMA Classic™. The success rates of the first attempt were significantly higher with the LMA ProSeal™ compared to the LMA Classic™ (97% versus 92%) [14]. A second study compared the LMA Classic™, LMA ProSeal™, and LMA Supreme™ in a manikin model to assess the amount of time that it took to establish adequate ventilation. The success rate of inserting a laryngeal mask on the first attempt was comparable between the three SADs [15].

Even though data of clinical investigations in neonatal patients are not available, the results of the present manikin study are contrary to results of clinical investigations in pediatric patients. In a randomized controlled trial in pediatric patients under 10 years old, the placement of LTS on the first attempt by a senior consultant anesthesiologist was possible in 2 of 15 patients [4]. The insertion of I-gel by residents under constant supervision by two experienced pediatric anesthesiologists was successful in 94% of children aged 2-5 years [16]. In a randomized study in children aged 2-5 years, experienced anesthesiologists could establish a clear airway in 90% of the children with the LMA ProSeal™ or the LMA Classic™ [17].

Simulation is not a substitute to real life scenarios. The extent to which the results of manikin studies are influenced by simulation conditions remains an important issue. The manikin used in the present study was the only model of all of the simulator models in Germany into which the SADs could be inserted. Therefore, the results of the present study could be specific to the simulator model used. A recent investigation evaluated the anatomic features of a pediatric high-fidelity simulator [7]. The results imply inadequate realism of this pediatric manikin for airway training. Unrealistic simulation anatomy may cause the adoption of inappropriate airway management techniques [18]. To our knowledge, there are no data for how close neonatal simulation is to a real neonate.

Nevertheless, data obtained in any manikin study should be confirmed in anatomical studies and in patients. An insertion success rate of 100% for all three SADs on the first attempt in three groups of differently trained health care providers in the present manikin study may not be realistic. However, when performed by experienced anesthesiologists, SADs such as the laryngeal mask, could potentially be used successfully in newborn infants [19].

In conclusion, this manikin study demonstrated equal success rates, but shorter time to establish adequate ventilation with the I-gel supraglottic airway device than the LMA or LTS devices in a neonatal airway management simulation by health care professionals with different levels of training.

While simulations are absolutely appropriate for practicing the handling and use of a SAD, the results of the present study must not be applied to corresponding situations in real humans without further investigation. Nevertheless, clinical trials are needed to determine

the outcome differences of this manikin study of supraglottic airway devices for airway management and resuscitation practices in newborn infants.

End points

Section 1: What is already known on this subject

- According to the guidelines of the European Resuscitation Council supraglottic airway devices (SAD) could be used in pediatric and neonatal resuscitation.
- Neonatal SADs are already evaluated in numerous observational manikin studies but there is no study comparing three different SADs including the I-gel during neonatal airway management training.

Section 2: What this study adds

- Our study suggests that the laryngeal mask, I-gel and laryngeal tube can be used for the airway management in neonatal manikin resuscitation by different experienced healthcare providers.
- It is significantly faster to establish adequate ventilation with the I-gel than with both the laryngeal mask and the laryngeal tube in this manikin study.

Competing Interests

The authors have no financial disclosure to report. No money or funds were received for this study.

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