

Insertion of four different types of supraglottic airway devices by emergency nurses. A mannequin-based simulation study

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Summary. *Background:* During medical emergencies, one of the main steps to improve patient outcomes is to achieve airway management. Orotracheal intubation is highly effective for advanced airway management, but it requires experienced health professionals. The use of a supraglottic airway device (SAD) is an acceptable alternative. *Aim:* To assess which of the four considered SADs takes the shortest time and the lowest number of attempts to be correctly placed. The secondary aim was to evaluate the influence of some characteristics of the study population on time taken and number of attempts required. *Methods:* A crossover trial was conducted at the Advanced Medical Simulation Center of the University of Perugia (Italy) between June and September 2017. Eighty-three nurses were enrolled in the study. Each participant was asked to place four different SADs in a manikin: Laryngeal Tube Suction-D (LTS-D), i-gel™, Ambu® Laryngeal Mask AuraGain™ and LMA® Protector™ Cuff Pilot™. *Results:* The median insertion time for the different devices was: 8.0 seconds (s) for LTS-D, 6.0 s for i-gel, 5.4 s for AuraGain, 5.8 s for LMA Protector ($p < 0.05$); the median number of insertion attempts was: 2 for LTS-D, 1 for i-gel, AuraGain and LMA Protector ($p < 0.05$). There was no significant relationship between insertion time and attempts required and the participants’ working experience, training, or knowledge of the devices. *Conclusion:* With the exception of LTS-D, which had the worst performance, there was a high degree of homogeneity between the studied SADs in terms of time and attempts required to achieve correct placement. (www.actabiomedica.it)

Keywords: Airway management; Supraglottic airway devices; Manikin study; Nurse education; Nurses

Introduction

One of the main steps to improve survival among patients affected by cardiorespiratory arrest (CRA) and other medical emergencies is to achieve airway management (1). According to the most recent guidelines on Advanced Life Support (ALS) provided by the European Resuscitation Council (ERC) and the

American Heart Association (AHA), however, the best technique for airway management has not yet been determined (2- 4).

The relationship between advanced airway management and patients’ prognosis has been assessed by Fouche et al. (5); their meta-analysis reported an increase in short-term and long-term mortality in patients who had been treated with an orotracheal tube

or a supraglottic airway device. These results suggest that patients in need of advanced airway management present the most life-threatening conditions (5).

The kind of airway management chosen depends on the conditions causing CRA, the phase of resuscitation (during CRA or after the return of spontaneous circulation – ROSC) and the health professionals' skills (3).

Orotracheal intubation (OTI), which has always been considered the standard procedure for advanced airway management, requires appropriate skills and regular practice. In fact, a high incidence of complications (e.g. tracheal tube displacements, multiple attempts, and failures) occurs when OTI is performed by inexperienced medical staff (6). Wang reported that more than 30% of patients in out-of-hospital settings are exposed to two or more OTI attempts (7). Moreover, even if the OTI is correctly performed, the patient is at risk of iatrogenic overinflation and interruption of chest compressions (8). Therefore, in the absence of skilled medical staff, the use of a supraglottic airway device (SAD) can be a valid alternative to OTI (3), because SADs allow for the patient's ventilation without having to pass through the glottis with a device. The Laryngeal Mask Airway (LMA, Teleflex, Westmeath, Ireland), was put on the market in 1987 and since then, different SADs have been introduced into clinical practice and play a key role in the management of difficult airways (9, 10, 11).

SADs can be differentiated on the basis of two main characteristics. The first is the presence of an inflatable cuff, which reduces the risk of gas leak during ventilation; this cuff is available on Laryngeal Tube LTS-D, Ambu® Laryngeal Mask AuraGain™ and LMA® Protector™ Cuff Pilot™ SADs, but not on i-gel® (the cuff can, however, potentially damage the airway's mucosa if its inflation pressure is too high). The second is the presence of a dedicated channel that allows the placement of a gastric tube, reducing the risk of pulmonary aspiration of gastric material (12, 13). This channel is present on LTS-D, AuraGain, LMA Protector and i-gel.

Due to the large variety of available SADs, it is important to assess how their use affects the outcome in medical emergencies. A recent meta-analysis, which included 14 clinical trials conducted on manikins,

showed that the time required by unskilled medical staff to place different SADs (newly qualified physicians, medical students, paramedics, and nurses) was very heterogeneous. There were, however, no differences in placement success at the first attempt (14).

On these bases, comparing and assessing ED nurses' ability when using different SADs is essential.

Aim

The main aim of this study was to assess, using a sample of emergency nurses working at an Emergency Department in Umbria (Italy), which of the four studied SADs takes the shortest time and the lowest number of attempts to be correctly placed.

The secondary aim was to determine the presence of a relationship between those results (time and attempts) and some characteristics of the studied population: age, general and specific work experience, type of education, and knowledge of the devices (such as previous utilisation *in vivo* or on a manikin during a course).

Materials and Methods

Study design

We designed a crossover study, which was carried out at the Advanced Medical Simulation Center of the University of Perugia, Italy, between June and September 2017.

Sample and setting

All nurses working at the Emergency Departments of Umbertide Hospital, Città di Castello Hospital, Gubbio-Gualdo Tadino Hospital and at the Emergency Department (ED) of Perugia University Hospital were asked to enter the study. Enrolment was voluntary and there were no exclusion criteria.

The study population comprised 83 nurses:

- 21 working at the Emergency Department of Perugia University Hospital "Santa Maria della Misericordia", Perugia (PG), Italy;

- 23 at the Emergency Department of Gubbio-Gualdo Tadino (PG) Hospital, Italy;
- 26 at the Emergency Department of Città di Castello (PG) Hospital, Italy;
- 13 at the Emergency Department of Umbertide (PG) Hospital, Italy.

Study protocol

Each nurse was asked to place supraglottic devices in a Laerdal SimMan® (Laerdal Medical AS, AUS), which is a manikin specifically designed for airway management simulations and training.

The four studied SADs employed in these ED were the Laryngeal Tube LTS-D (size 3, adults <155 cm, VBM Medical, Sulz, Germany), the i-gel® (size 3, weight 30-60 kg, Intersurgical Ltd., Maidenhead, UK), the Ambu® Laryngeal Mask AuraGain™ (adults, size 3, weight 30-50 kg, Ambu, Ballerup, Denmark) and the LMA® Protector™ Cuff Pilot™ (size 3, weight 30-50 kg, Teleflex International, Dublin, Ireland).

We used the latest version of each device available on the market at the time of the study. Before starting the study, two anaesthesiologists tried to insert each of the four devices into the manikin, in order to verify that the SADs were the correct size for that specific manikin. Before insertion, the cuffs (if present) were deflated and, according to the manufacturers' instructions, both the oral cavity of the manikin and the distal extremity of the devices were lubricated with an appropriate water-based lubricant. After insertion, the cuff was inflated to reach a cuff pressure of 20 mmHg. The placement of the SADs was deemed correct when the manikin's chest was expanded by an Ambu-bag insufflation of about 500 ml of air; evaluation of proper placement was carried out by a single skilled nurse.

The order for placing the SADs was randomised *ex-ante* and was the same for all the nurses: LTS-D, i-gel, AuraGain and LMA Protector.

Age, sex, general and specific work experience, work structure, postgraduate education, emergency education, prior knowledge or placement of SADs,



Figure 1. Supraglottic Airway Device: 1) Laryngeal Tube LTS-D; 2) i-gel®; 3) Ambu® Laryngeal Mask AuraGain™ ; 4) LMA® Protector™ Cuff Pilot™.

and possible experience and skills in advanced airway management were recorded on a personal file for each nurse participating in this study. The researchers also recorded on the personal files the number of attempts and the time required to properly place each of the four SADs.

Data collection and ethical issues

The form for data collection was structured on the basis of similar published studies (15,16,17) and comprised two sections. The first section was a short questionnaire filled in by the participants to collect information regarding prior knowledge of the tested devices, demographic and professional data, and specific education information. The second was filled in by the researchers, who reported the number of attempts and time needed by each participant to properly place the airway devices.

The study protocol was approved by the Management Office of the Perugia University Hospital and by the Management Office of the Local Health Authority in June 2017. Ethical Committee approval was not necessary because the study involved a simulation on a manikin. Before enrolment, each nurse gave informed consent for data collection, analysis and publication. Privacy and anonymity were guaranteed during all phases of the study.

Statistical analysis

Descriptive statistics were performed using frequencies, percentages, median and interquartile range (IQR) for quantitative variables. Friedman's test, followed by post-hoc analysis with the Wilcoxon signed-rank test was performed for dependent sampling. The nonparametric Mann-Whitney U Test was performed to compare continuous variables with non-normal distribution. Categorical variables were evaluated by Pearson's Chi-Squared test. For correlation analysis we used Spearman's rank test.

Data was collected on Microsoft® Excel® (Copyright 2018 Microsoft Corporation, Redmond, Washington) and then analysed using Stata 14 (Copyright 1996–2019 StataCorp LP, 4905 Lakeway Drive, College Station, TX 77845 USA).

A p-value of less than 0.05 was statistically significant.

Results

Characteristics of participants

Demographic, educational and professional information on the study population was reported in Table 1.

Forty-four nurses (53%) claimed to have successfully performed an OTI on a manikin or on a patient at least once, forty-five nurses (54.2%) to have personally used a supraglottic device in a real scenario and fifty-nine nurses (71.1%) to have taken part in the procedure. 96.4% of the nurses stated that they were familiar with LTS-D, 91.6% with AuraGain, 61.5% with LMA Protector, and only 53.0% were familiar with i-gel.

Time and number of attempts and their relationship with variables

The main results on time and attempts required to correctly place the SADs are listed in Table 2.

The LTS-D is the SAD that required more time and more attempts for its correct placement; on the other hand, the AuraGain, the LMA Protector and the i-gel guaranteed the lowest insertion time and number of attempts. The difference in the time required to correctly place the four SADs was statistically significant ($p < 0.001$).

Results of the *post-hoc* analysis (Wilcoxon signed-rank test) are reported in table 3: LTS-D was the SAD that required the longest time and the highest number of attempts.

When LTS-D was compared to i-gel, LMA Protector and AuraGain, the differences were statistically significant ($p < 0.05$), while there were no statistically significant differences between those other devices.

Regarding the LTS-D, neither age nor general or emergency work experience were associated with a lower insertion time (age, $p = 0.33$; general work experience, $p = 0.099$; emergency work experience, $p = 0.099$), but all these factors had a statistically significant weak

Table 1. Demographic, educational and professional variables

Sex [N (%)]	
Male	39 (47.0%)
Female	44 (53.0%)
Age (years) [Median, IRQ]	43 (34, 50)
Work experience (years) [Median, IRQ]	17 (8, 25)
Work experience in Emergency Department (years) [Median, IQR]	8 (3, 16)
Hospital [N (%)]	
Perugia University Hospital	21 (25.3%)
Città di Castello Hospital	26 (31.3%)
Umbertide Hospital	13 (15.7%)
Gubbio-Gualdo Tadino Hospital	23 (27.7%)
Total	83 (100%)
Successful OTI [N (%)]	
Yes	44 (53.0%)
No	39 (47.0%)
Use of SADs [N (%)]	
Yes	45 (54.2%)
No	38 (45.8%)
Involvement in use of SADs [N (%)]	
Yes	59 (71.1%)
No	24 (28.9%)
Postgraduate education [N (%)]	
No course	44 (53.0%)
At least one course	39 (47.0%)
Emergency care education [N (%)]	
Airway management course	47 (56.6%)
Other courses or no course	36 (43.4%)

negative correlation ($r=-0.4$) with the number of attempts (age, $p<0.05$; general work experience, $p<0.05$; emergency work experience: $p<0.001$). Neither knowledge nor participation in airway management courses were associated with a statistically significant lower time or number of attempts: knowledge yes *vs* knowledge no – attempts, $p=0.13$; time, $p=0.22$; course yes *vs* course no – attempts, $p=0.072$; - time, $p=0.14$).

Postgraduate education, on the other hand, lowered the attempts ($p<0.05$) but not the time required for insertion ($p=0.38$).

Regarding the i-gel device, neither insertion time nor number of attempts had a statistically significant correlation with age (attempts, $p=0.39$; time, $p=0.57$), general work experience (attempts, $p=0.29$; time, $p=0.52$) or emergency work experience (attempts,

Table 2. Insertion time and attempts

		Median	IQR	Friedman's test (DF=3)
Insertion time (s)	LTS-D	8.0	5.9-10	p<0.00001
	i-gel	6.0	4.0-8.3	
	AuraGain	5.4	4.0-8.0	
	LMA Protector	5.8	4.2-8.4	
Insertion attempts	LTS-D	2	1-2	p=0.00028
	i-gel	1	1-2	
	AuraGain	1	1-2	
	LMA Protector	1	1-2	

Table 3. Post-hoc analysis (Wilcoxon signed-rank test)

		LTS-D	LTS-D	LTS-D	i-gel	i-gel	AuraGain
		<i>vs</i>	<i>vs</i>	<i>vs</i>	<i>vs</i>	<i>vs</i>	<i>vs</i>
		i-gel	LMA Protector	AuraGain	AuraGain	LMA Protector	LMA Protector
p-value	Time	0.00022	<0.00001	<0.00001	0.9442	0.67448	0.22628
	Attempts	0.00016	<0.00001	<0.00001	0.32708	0.4654	0.79486

p=0.10; time, p=0.97). Knowledge of the device did not lower attempts or insertion time (attempts, p=0.07; time, p=0.14), whereas nurses' postgraduate education lowered attempts (p<0.01), but not insertion time (p=0.11). Nurses who attended an airway management course, on the other hand, needed less time to insert the device (p<0.05) but not fewer attempts (p=0.12).

For the AuraGain, age, general work experience and emergency work experience did not correlate with insertion time (age, p=0.15; general work experience, p=0.14; emergency work experience, p=0.35), but had a statistically significant weak negative correlation (r=-0.3) with the required number of attempts (age, p<0.05; general work experience, p<0.05; emergency work experience, p<0.001). Furthermore, it appeared that neither knowledge of the device nor participation

in airway management courses were associated with a statistically significant lower time or number of attempts (knowledge yes *vs* knowledge no – attempts, p=0.71; - time, p=0.47; course yes *vs* course no – attempts, p=0.42; - time, p=0.10). Trained nurses needed fewer attempts (p<0.05) but not a lower insertion time (p=0.10).

Concerning the LMA Protector, no statistically significant correlation was found between the number of attempts and the nurses' age (p=0.058); insertion time did not correlate with age either (p=0.094) or with general work experience (p=0.064), or emergency work experience (p=0.13). Instead, a weak negative correlation (r=-0.3) was found between the number of attempts and either general work experience (p<0.05) or emergency work experience (p<0.01). Finally,

neither number of attempts nor insertion time had a statistically significant correlation with knowledge of the device, education or participation in an airway management course (knowledge yes *vs* knowledge no – attempts, $p=0.71$; – time, $p=0.47$; education yes *vs* education no – attempts, $p=0.28$; – time, $p=0.48$; course yes *vs* course no – attempts, $p=0.42$; – time, $p=0.10$).

Discussion

In our study all nurses, regardless of their experience, achieved proper placement of each of the four SADs. This finding is consistent with similar studies found in the relevant literature (18, 19).

In a manikin-based simulation study that included 40 unskilled volunteers, Ruetzler et al. reported that during medical emergencies, SADs were the best choice for inexperienced medical staff. As a matter of fact, when using SADs (Laryngeal tube, Combitube, Easytube, LMA and i-gel) all of the enrolled healthcare professionals placed the devices correctly, whereas only one third of the participants achieved airway control using OTI (19).

Moreover, Hanlin et al. tested unskilled healthcare professionals using SADs in a study that included 505 patients who needed general anaesthesia for elective surgery. The insertion success rate was over 97% when these professionals used either SLMA, i-gel or PLMA, whereas a lower insertion rate had been reported when the Supreme LTS-D (93.1%) and SLIPA (90.0%) were used. The lowest times were obtained with the Supreme LMA and the i-gel (20). A recent meta-analysis conducted by Jiwon et al. on manikin-based simulations reported that unskilled healthcare professionals achieved the lowest insertion time with LMA, i-gel, Aura-I and Air-Q (14).

With regard to the main aim of the study, of the four SADs considered, the device with the lowest insertion time and the lowest number of attempts was the Ambu® AuraGain™, although the differences between this device, the i-gel® and the Protector™ Cuff Pilot™ were not statistically significant. It was therefore impossible to determine which of the SADs included in the study guaranteed the lowest insertion time and lowest number of attempts; in fact, i-gel, AuraGain

and LMA Protector were equally efficient. In contrast, when compared to the other SADs, the LTS-D performed worst in terms of both insertion time and number of attempts. This could be due to greater placement difficulties reported by less-experienced and younger participants. In fact, published literature reported that healthcare professionals who had previously attended airways management simulation courses performed better than those who had not (21).

Regarding the secondary aim, the performance of the four SADs did not appear to be affected by nurses' work experience, education, knowledge of the devices or previous experience. Moreover, when insertion time and/or attempts were affected by one of the previous factors, this difference was so minimal that it was not clinically relevant.

Conclusion

In our manikin-based simulation study we considered four different marketed SADs. With the exception of the LTS-D, performance was similar in all other SADs in terms of insertion time and number of attempts. Furthermore, no clinically relevant differences were reported when insertion time and attempts were classified by age, general and emergency work experience, education and knowledge of the devices.

Currently, we cannot identify which of the analysed devices performs best.

When choosing an SAD, however, we suggest that in addition to insertion time and number of attempts, other factors should be taken into consideration, such as airway protection, the possibility of gastric tube insertion and the option of using that device to perform an orotracheal intubation.

Finally, so as to provide validation of all these data, we recommend repeating this study in an "in vivo" (clinical) setting.

Although we included nurses working in different centres, the study population reflected the situation of a single region. Another limitation was the lack of randomisation between the SAD's (randomisation was only carried out once before starting this study; after that the order of devices was maintained for all the participants). Moreover, there was no washout

period between the insertion of the different devices, so a certain carry-over effect produced by skills gained by inserting different devices over time could not be excluded. Finally, we could not carry out an analysis to identify possible differences in the performance of introducing SADs between nurses who had previously attended airways management courses and those who had not.

Contribution Nursing Practice

- Manikin-based simulation studies provide opportunities for testing the skills of emergency nurses.
- Manikin simulation scenarios are valuable tools for engaging with emergency care.
- Clinical simulation promotes the development of technical skills.

Acknowledgements

The authors wish to thank all the Emergency Department nurses who took part to this study.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Received: 7 July 2020

Accepted: 21 October 2020

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