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Prehospital use in emergency patients of a laryngeal mask airway by ambulance paramedics is a safe and effective alternative for endotracheal intubation

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Received 14 December 2012

Revised 28 March 2013

Accepted 12 May 2013

Published Online First

15 June 2013



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To cite: Bosch J, de Nooij J, de Visser M, et al. *Emerg Med J* 2014;**31**:750–753.

ABSTRACT

Background In Dutch ambulance practice, failure or inability to intubate patients with altered oxygenation and/or ventilation leaves bag-valve mask ventilation as the only alternative, which is undesirable for patient outcome. A novel Laryngeal Mask Airway Supreme (LMA-S) device may be a suitable alternative.

Aim To evaluate the effectiveness and suitability of the LMA-S for emergency medical services in daily out-of-hospital emergency practice.

Methods After a period of theoretical and practical training of ambulance paramedics in the use of the LMA-S, prospective data were collected on the utilisation of LMA-S in an observational study. Procedures for use were standardised and the evaluation included the number of direct intubation attempts before using LMA-S, attempts required, failure rate and the adequacy of ventilation. Data were analysed taking patient characteristics such as age and indication for ventilatory support into account.

Results The LMA-S was used 50 times over a period of 9 months (33 involving cardiorespiratory arrest, 14 primary and three rescue). The LMA-S could be applied successfully in all 50 cases (100%) and was successful in the first attempt in 49 patients (98%). Respiratory parameters showed adequate oxygenation. All paramedics were unanimously positive about the utilisation of LMA-S because of the easiness of the effort of insertion and general use, and emphasised its value as a useful resource for patients in need.

Conclusions Ensuring ventilation support by using LMA-S by paramedics in prehospital emergency practice is safe and effective.

INTRODUCTION

Airway management is of major importance in emergency ambulance care to provide oxygen delivery to patients with altered oxygenation and/or ventilation. The current national protocol in the Netherlands for out-of-hospital emergencies requiring ventilation support endorses first use of bag valve-mask ventilation (BVM) possibly combined with a simple oropharyngeal airway device by ambulance paramedics. As a next step, endotracheal intubation (ETI) can be applied to secure the airway and maintain ventilation support for trauma and resuscitation patients or patients with a low level of consciousness.

The success rates of application of BVM and ETI is however variable leaving restart of BVM ventilation the only alternative for airway management. Failure rates have been reported to be in 3%–31%

of all cases,¹ and in a meta-analysis, Hubble and coworkers described a failure rate of 14% of the intubations by non-physician clinicians.² This is corroborated by the experience in our ambulance region showing that in a 1-year period (2009–2010), failed intubations (defined as unsuccessful attempts at placement of an endotracheal tube or a situation where it was not possible to expose vocal cords during laryngoscopy) occurred in 12% of 350 trauma and resuscitation patients in whom advanced airway management was indicated.

This is undesirable because BVM ventilation is difficult to maintain for longer periods of time, especially under challenging conditions such as inside a moving ambulance. As clinical studies have shown that the laryngeal mask airway (LMA) is an effective alternative in rural trauma patient and emergency departments we examined whether this would also be applicable to our ambulance service.^{2–6} Although the LMA is used worldwide, no relevant study has yet been published offering guidance as to the safest and most effective use in emergency medical services.^{7–13}

We selected the LMA Supreme (LMA-S), a single-use supraglottic airway device (figure 1), for testing. The LMA-S can be used for the same indications as the ‘classic’ LMA but has an extra port (drain tube) to insert a gastric tube. The airway tube is anatomically shaped to facilitate easy insertion, avoiding the need for finger placement in the patient’s mouth, and the cuff is designed to provide higher seal pressure.

METHODS

The aim of the prospective observational study was to assess the operational process and to evaluate the use (safety and efficacy) of LMA-S as an alternative to failed ETI in prehospital emergency care. The protocol was approved by the Committee for Medical Ethics of Leiden University Medical Center, Leiden, The Netherlands.

Prior to initiation of the study, the ambulance service staff had the opportunity to get acquainted and get experience with LMA-S use for a period of 8 months. During this pilot phase, standard operating procedures with an operation schedule (flow-chart) were established to ensure standardised use of the device for appropriate cases and adequate, unambiguous documentation. Documentation was collected by filling out a case report form that was developed during the training period.

Three indications for LMA-S use were selected: cardiopulmonary resuscitation (CPR), primary and





Figure 1 The Laryngeal Mask Airway Supreme device

rescue. Primary was defined as a situation in which application of a non-rebreathing mask to an unconscious patient did not result in adequate saturation. Rescue was defined as a situation in which a semiconscious patient showed a deteriorating clinical condition due to airway problems including stroke and pulmonary complications. If the first ETI procedure failed, a second attempt was recommended. If this second attempt also failed, the LMA-S had to be used. If LMA-S insertion failed, patients had to be ventilated by BVM. Criteria for patient inclusion were: all patients aged 9 years or older in whom ETI failed or the LMA-S was used as the first means of securing the airway. Exclusion criteria were age under 9 years, obstruction of the airway by a foreign body, trismus, and larynx disorders including glottis oedema and epiglottitis. Correct insertion of the LMA-S was defined as efficient ventilation of the patient with normal chest excursions and bilateral breath sounds by auscultation. When possible, adequacy of ventilation was also measured by capnography end-tidal CO₂ and peripheral oxymetry (saturation of peripheral oxygen; SpO₂). The number of intubation and insertion attempts was recorded. Experiences with the procedures of insertion and added value of the LMA-S were described by the paramedics using open questions. Prehospital and clinical complications were registered with a standardised complications registration form.

All electronic monitoring data were sent with the Lifepack 12 monitor (PhysioControl) to a central database for authentication. Case report form data and sent variables were monitored by an independent researcher.

RESULTS

Results were expressed as absolute values (percentages) or median values (range).

Fifty consecutive patients who were eligible were included. The characteristics of the population are summarised in table 1.

Table 1 Patient characteristics

	n=50	%	Mean	Range
Age (years)			60	19–90
Male	37	74	58	19–86
Female	13	26	65	21–90
GCS			3*	3–6

*When applying Laryngeal Mask Airway Supreme.
GCS, Glasgow Coma Scale.

The indication for use of the LMA-S was predominantly for CPR (66%). Primary indications (28% of cases) included LMA-S placement as the first choice following non-rebreathing mask and signs of respiratory insufficiency, low saturation and (reduced) consciousness. Rescue indications accounted for 6% of cases and consisted of patients with multiple trauma, neurological disorders or intoxication with low Glasgow Coma Scale (GCS-3) scores (table 2).

Successful insertion the LMA-S using the standardised procedure was achieved in all 50 cases (100%). Application was successful at the first attempt in 49 patients (98%) and in one patient (2%) three attempts were necessary. The LMA-S was used immediately in 18 (36%) cases for reasons including difficult circumstances on scene and the preference of the nurse paramedic. In all, 11 (22%) patients received an LMA-S after a single ETI attempt, 14 patients (28%) received an LMA-S after a double ETI attempt and in seven patients (14%) LMA-S was used after a triple ETI attempt (table 3).

A total of 48 patients (96%) could be effectively ventilated with LMA-S. Of the remaining two cases, one patient recovered rapidly making LMA-S unnecessary and one patient was intubated by a helicopter emergency medical service-physician (table 4).

Ventilation parameters showed that assessment of efficacy with auscultation was difficult in three cases (6%, all CPR). End-tidal CO₂ could be detected in the vast majority (48/50) of the patients; failure occurred in two CPR patients. SpO₂ measurements were feasible for 28 patients (56%) while in 22 patients (44%) cold acra or other circumstances made SpO₂ measurement impossible or unreliable. The recorded SpO₂ measurements showed normal to high values (between 91% and 100%) of oxygen saturation.

Aspiration, defined as the visual presence of stomach contents in the oropharynx, was encountered only once (2%) in this study. Four patients (8%) showed an increasing GCS during LMA-S ventilation and had a vomiting or coughing reflex without aspiration. Seven patients (14%) had air leakage at the airway sealing, although in six of these this did not affect the respiratory minute volumes. Restarting ventilation with the BVM was necessary in one case. These complications are described in table 5.

Table 2 Indication

	n=50	%
Primary	14	28
Rescue	3	6
CPR	33	66

Primary: Unconscious patient, no adequate saturation with a non-rebreathing mask.
Rescue: Semiconscious patient deteriorating airway problems.
CPR, cardiopulmonary resuscitation.

Table 3 Number of ETI attempts preceding insertion of LMA-S

	n=50	%
None, directly	18	36
One attempt	11	22
Two attempts	14	28
Three attempts	7	14

ETI, endotracheal intubation; LMA-S, Laryngeal Mask Airway Supreme.

The gastric drainage tube to prevent gastric insufflation was easy to insert in 39 patients (78%). In 10 patients (20%), the drainage tube was not applied without recording a reason. One application failed (2%) because the administered drainage tube was of a diameter too large for the LMA-S drainport. Gastric insufflation was not detected in any patient.

The standardised complication registration showed no reports of major complications as a consequence of insertion of the LMA-S.

The paramedics graded insertion and use of LMA-S as easy and described their experiences with LMA-S as favourable. The ambulance staff emphasised in the evaluation their positive experiences, ease of use and the added value of LMA-S as a resource for patients in difficult circumstances.

DISCUSSION

Securing adequate ventilation of a non-fasting patient during prehospital emergency care is probably one of the greatest challenges in airway management. Currently, ventilation (BVM) followed by ETI is the technique that is commonly applied. However, particularly in emergency situations, this solution does not always suffice. We explored the use of the LMA-S that was designed to ensure a secure airway and to allow positive pressure ventilation using a simple procedure. The aim of our study was to assess the operational process and to evaluate the use and efficacy of LMA-S as an alternative to failed ETI in prehospital emergency care. Our results showed that paramedics can effectively apply the LMA-S allowing either bag-valve or machine ventilation. It indicates that the LMA-S offers an effective and alternative method for ventilatory support that is easy to use. Our data suggest that complications are rare. Only one case of aspiration was noted and hypoventilation was not observed despite a number of cases with air leaks during positive-pressure ventilation. In patients where SpO₂ and end tidal CO₂ measurements were available, values were normal. Our results show that the prehospital use of the LMA-S can be considered a safe and efficacious alternative and minimise the effects of failed ETI.

A theoretical limitation of the LMA-S in prehospital care is the risk of aspiration in non-fasting patients because the device

Table 4 Parameters following insertion of LMA-S

	n=50	%	Range	Primary	Rescue	CPR
Ausc. and symm.	47	94				3*
ETCO ₂ (mm Hg)	48	96	8–98			2*
SpO ₂ (mm Hg)	28	56	91–100	1†		21†
Successful ventilation	48	96				2*

*No measurements made or described.

†No values measurable or described.

Ausc., auscultation; CPR, cardiopulmonary resuscitation; ETCO₂, capnography end-tidal CO₂; LMA-S, Laryngeal Mask Airway Supreme; SpO₂, saturation of peripheral oxygen; Symm., symmetry of chest wall movement.

Table 5 Registered complications

	n=50	%	Primary	Rescue	CPR
Aspiration	1	2			1*
Dislocation LMA-S	1	2			1*
Air leakage LMA-S	7	14	1*		6*
Bleeding	0	0			
Ventilation blockage		0	0		
Vomiting reflex/coughing	4	8	2*	1*	1*

*Observed complications in relation to indication.

CPR, cardiopulmonary resuscitation; LMA-S, Laryngeal Mask Airway Supreme.

does not provide a 100% airtight seal around the hypopharynx, the larynx and the trachea. To our knowledge, no studies have described complications with supraglottic devices in prehospital healthcare. Indeed, a systematic review comparing various supraglottic devices with standard ETI did not reveal differences for the risk of aspiration.¹⁴

Although little relevant literature is available on the LMA-S itself, the LMA-S is comparable with the LMA Proseal and intubating Laryngeal Mask Airway ((I) LMA) Fastrach for which a number of studies have been published. Young¹⁵ have noted that the (I) LMA can provide positive pressure ventilation when the oesophagus is included within the edges of the device. Anaesthesia literature indicates that the risk of aspiration with the (I) LMA is approximately 2.6 per 10 000 elective cases and 11 per 10 000 emergencies.¹⁶ Because the method of insertion and the dimensions of the LMA-S are similar to that of the (I) LMA, it is reasonable to assume that these figures may also apply to the LMA-S. Stone *et al* reported a study comparing BVM ventilated patients who subsequently received ETI with BVM ventilated patients who received the LMA. These authors reported 12.4% regurgitation during resuscitation in the BVM group followed by ETI, while patients ventilated with the LMA or mechanically ventilated with the LMA followed by ETI showed a significantly lower incidence of regurgitation (3.5%).¹⁷

A potential limitation of our study is possible reporter bias because of the self-reporting by the nurse paramedics. However, this is almost unavoidable for an implementation project and it may be argued that because this study also included objective measures this is unlikely to have had a major impact on the outcome of our findings.

The findings of our study suggest that the LMA-S may be an easy-to-use, safe and effective alternative to secure adequate ventilation of non-fasting patients at risk of aspiration during preclinical treatment and should be evaluated further in large scale studies.

CONCLUSIONS

This prospective observational study showed that the LMA-S may be an alternative airway management tool in acute ambulance treatment. Application of the device was safe, effective, and easy to use and warrants further investigations.

Acknowledgements The authors wish to thank the following hospital emergency departments for contributing to the study: Erasmus University Medical Center Rotterdam, Groene Hart Ziekenhuis Gouda and the Leiden University Medical Center. The authors also wish to thank Dr G Eindhoven, University Medical Center Groningen, for his assistance as an independent expert-physician.

Contributors JB, JdeN, NT, CH, JB, JdN, Mdv: design of the study. JB, MdeV, NT: collection of data. NT, SC: data analysis. All authors: writing and approving the manuscript.

Funding This study was funded by the Regional Ambulance Service Hollands Midden as Public Service and without external funding.

Competing interests None.

Ethics approval The Committee for Medical Ethics of Leiden University Medical Center. Studynumber: P10.118.

Provenance and peer review Not commissioned; externally peer reviewed.

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