ORIGINAL

Fastrach™ laryngeal mask for out-of-hospital airway management in critical patients

María Luisa CHAYÁN ZAS, José Antonio IGLESIAS VÁZQUEZ, Ángel CHAYÁN ZAS, Vicente FARALDO BALADO, María Victoria BARREIRO DÍAZ, María CEGARRA GARCÍA

Urxencias Sanitarias 061-Galicia. Santiago de Compostela, Spain.

Correspondence:
María Luisa Chayán Zas
Urgencias Sanitarias de Galicia-061
Plaza Martín Herrera, 2. 2ª planta
15706 Santiago de Compostela
A Coruña, Spain.
E-mail:
luisa.chayan.zas@sergas.es

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Objective: To describe the epidemiologic profile of intubations performed with the Fastrach® laryngeal mask and analyze the utility of this mask in critically ill patients attended out of hospital by US-061 ambulance crews.
Material and methods: Retrospective, observational, descriptive study of the period January 2002 through December 2007. Seventy-three patients attended by US-061 crews required airway management with the Fastrach® mask. Data were extracted from computerized medical records. Variables analyzed were age, sex, medical event or trauma, initial cardiac rhythm, survival until arrival at the hospital, and percentage of patients requiring airway management in whom the mask was used.
Results: A total of 4112 patients required airway management. The Fastrach® laryngeal mask was used in 73 (1.8%) (11.1% women). The mean (SD) age of these patients was 50.7 (5) years. Four of the 73 patients (5.5%) could not be intubated with the Fastrach® mask. Intubation was required for medical reasons in 35 (48%) and for trauma in 38 (52%). Twenty-five (71.4%) of the medical patients and 10 (26.3%) of the trauma patients were initially in cardiac arrest. Eighteen medical patients (51.5%) and 24 (63.2%) trauma patients were alive on arrival at the hospital.
Conclusions: Although the outcome of orotracheal intubation is generally good, the airway cannot be managed with this procedure in a small percentage of patients. Therefore, the Fastrach® laryngeal mask provides a second-line option. It is easy to use, facilitating airway management in situations that may be difficult for intrinsic or extrinsic reasons. [Emergencias 2009;21:172-176]

Key words: Laryngeal mask. Intubation. Critical care.

Introduction

The laryngeal mask (LM)[1], created by Dr. Archie Brain, was developed to fill a gap between the facial mask and endotracheal intubation, and has been in clinical use in Europe since 1988. It is an important device for airway management and resuscitation, in both hospital and out-of-hospital emergencies. Dr. Brain later created a variation that incorporates a number of changes to facilitate insertion of an endotracheal tube, and is therefore designed for orotracheal intubation (OTI) without the drawbacks of the former: it is the Fastrach™ intubating laryngeal mask airway (ILMA)[2,3]. The ILMA consists of an anatomically curved, short, wide bore, stainless steel tube sheathed in silicone which is bonded to a laryngeal mask and a guiding handle. It has a single moveable aperture bar to elevate the epiglottis, a guiding ramp and can accommodate an 8 mm tracheal tube (Figure 1). The ILMA can be placed blindly with one hand, and from any position with access to the patient's mouth without moving the head or the neck (Figure 2), which is an important alternative for multiple trauma patients[4,5].

Intubation difficulties occur in approximately 1-2% of patients[6], but may reach 20% in patients with neck damage. Not being able to

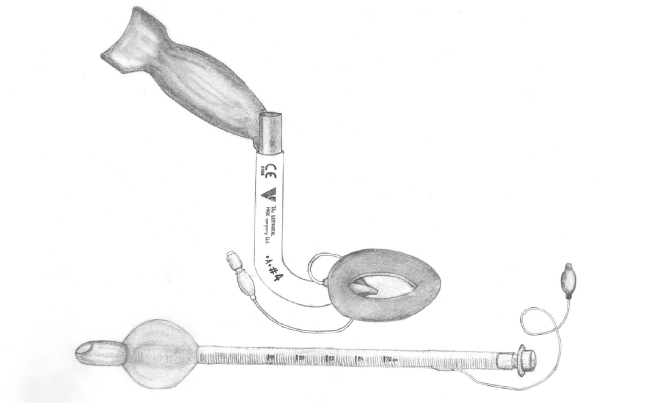

Figure 1. Fastrach™ intubating laryngeal mask airway (ILMA) device and the special tube for intubation.

perform OTI is related with significant morbidity, and ILMA is a fast alternative to conventional intubation which already forms part of the instruments used for airway management in patients where intubation is difficult. Various studies have shown its utility in emergency situations, even with no previous operator experience. The ILMA is placed in the hypopharynx at the junction of the respiratory and digestive tracts, forming a low-pressure circular seal around the glottis, allowing direct access to the airway. Alterations in the oral cavity may hinder its proper placement (Figure 3).

The aim of this paper is to describe the epidemiological profile of patients intubated with ILMA and analyze the utility of this mask in critically ill patients with difficult airway tract, attended by staff of the Service of Emergency Medicine (SEM), Urxencias Sanitarias de Galicia-061 (US-061).

Figure 3. Mechanical ventilation in multiple injury patients intubated with IMLA and prepared for transfer by helicopter.

Method

We performed a descriptive, retrospective, observational study from January 2002 to December 2007 of all out-of-hospital patients requiring ILMA intubation, always as the second alternative. Such emergencies in Galicia are coordinated by the Central Coordination US-061 located in Santiago de Compostela and attended by Primary Care teams, Health Emergency transport network (RTSU) ambulances throughout Galicia, medicalized ambulances located in major cities (2 in A Coruña, 1 in Santiago, 1 in Ferrol, 1 in Lugo 1, 1 in Ourense, 1 in Pontevedra 1, 2 in Vigo and, in summer, 1 in Sanxenxo) and medicalized helicopters based in Santiago de Compostela and Ourense.

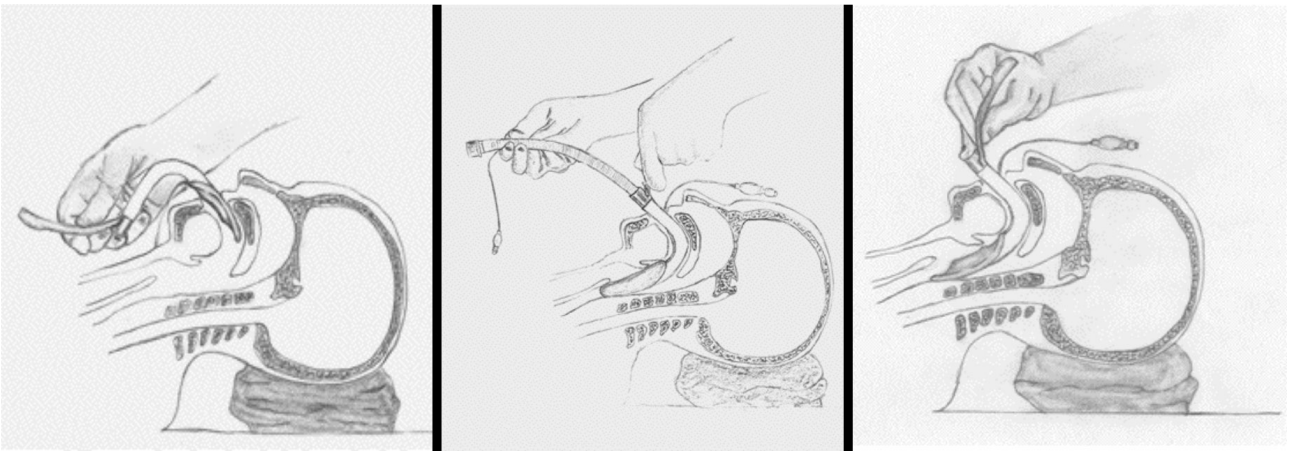

Figure 2. Initial placement for introduction of the ILMA (left), final movement and definitive placement (center) and intubation through the Fastrach ILMA (right).

The term difficult airway was defined as a clinical situation where trained staff experience difficulty in intubation (more than three attempts or more than 10 minutes), face-mask ventilation (inability to maintain $SatO_2$ > 90% despite the administration of 100% O_2) or both[7].

We reviewed the clinical history of all patients attended by 061 medicalized ambulances/helicopters who underwent endotracheal intubation with ILMA. We studied patient variables (age and sex), variables related with the event (reason for the event being medical or trauma, initial cardiac rhythm, location of event), variables related to prognosis (survival until hospital admission) and compared them with those obtained with conventional OTI, and the utilization of this technique in all patients requiring airway management. The medical reason refers to events that occur spontaneously without a triggering accident, while trauma-induced events include traffic, work-place and domestic accidents. Initial cardiac rate was defined as the cardiac rate determined by the health staff on their arrival at the scene of the event. Cardiac arrest corresponded to asystole, electromechanical dissociation (EMD), pulseless ventricular tachycardia (PLVT) and ventricular fibrillation (VF). Patients with a pulse could present any rhythm other than arrest, but we found sinus rhythm (SR), sinus tachycardia and atrial fibrillation (AF).

Qualitative variables are presented as absolute values and percentages, while quantitative variables are presented as means and standard deviations.

For the comparison of the former, we used Fisher's exact test and Odds ratio (OR) with a confidence interval of 95% (CI 95%), whereas for the comparison of quantitative variables, we used Student T test. A value of $p < 0.05$ was considered statistically significant.

All data used were obtained from the US-061 general data base; they are protected according to law and were managed in an anonymous manner.

Results

There were 4112 patients who required airway management, of whom 73 (1.8%) had a difficult airway requiring the use of the ILMA device (11.1% women and 84.9% men). Mean age of these patients was 50.7 ± 20.5 years (range 3 to 85 years). It was not possible to perform intubation by ILMA in 4 patients (5.5%, 3 men and 1 woman), where the cause of the event was medical in 2 cases and trauma in the other two. In these cases, the ILMA was used as a laryngeal mask to ventilate the patient.

Airway management was required for medical reasons [cardiac arrests (PCR), acute respiratory failure] in 35 patients (48%) and trauma (patients with abundant blood in the mouth, facial fracture or edema) in the other 38 (52%). Of those patients with medical causes, 25 (71.4%) had initial cardiac arrest and the remaining 10 showed sinus rhythm or AF (1 case only). Of the patients with trauma, 10 (26.3%) had initial cardiac arrest and the remaining 28 presented sinus rhythm or AF (1 case). These results indicate that the prevalence of cardiac arrest in the medical-cause group was significantly higher than in the trauma-cause group ($P < 0.001$, 7.00, CI 95% 2.95-16.60).

Mortality was 17 (48.5%) in the medical-cause group and 14 (36.8%) ($P = 0.311$) in the trauma-cause group. In the medical-cause group, 16 deaths were recorded in those with initial cardiac arrest and one with sinus rhythm. In the trauma-cause group, 10 deaths were recorded in those with initial cardiac arrest and the remaining 4 had sinus rhythm). These results indicate that the probability of survival in cardiac arrest patients was 36% in the medical-cause group and 0% in the trauma-cause group ($p < 0.01$). The probability of survival among non-cardiac arrest patients was 90% and 85.7%, respectively ($P = 0.731$).

With regard to the scene of the event, in the medical-cause group this was: workplace 2, public areas 8 and home 25. In the trauma-cause group, this was workplace 10, public areas 3, and road traffic accidents 23.

No significant differences in survival rate was observed on comparing the use of ILMA (57.5% survival) and conventional OTI (64.7%) ($P = 0.202$), nor regarding age, sex and reason for airway management being required in the two groups.

The reasons for ILMA use in the medical-cause group were: short neck, reduced cervical mobility, limited mouth opening, morbid obesity, large tongue and mouth fluids. In the trauma-cause group, the reasons were: suspected cervical fracture, facial bone fracture and particularly the mandible, patient's position (trapped inside a car), blood in the mouth and subcutaneous emphysema reaching the neck. And in both groups we found cases of difficult airway after visualizing the vocal cords (Cormack-Lehane classification) which a priori was not suspected.

Discussion

The ILMA device presents advantages over conventional LM and OTI using a laryngoscope. Its special design allows it to be used for manual, mechanical or spontaneous ventilation since placement and withdrawal are not accompanied by important hemodynamic changes and muscle relaxation is not needed for placement.

ILMA is an alternative in the anesthetized patient that cannot be ventilated by a facial mask face, allowing the placement of the orotracheal tube through it and, therefore, useful in situations of difficult tracheal intubation. However, it also has certain drawbacks when the tube is not passed through it, since in this case it is being used as a LM and therefore the airway is not safe because of the possibility of regurgitation.

As mentioned, the ILMA device was used as the second option in 1.8% of all cases, after conventional intubation was unsuccessfully attempted or not possible due to patient characteristics or situation (for example, trapped inside a car). This percentage is very low, but cannot be rated against that of other studies which mostly involve patients in a controlled hospital setting, mainly in the field of anesthesiology and attended by professionals skilled in the use of conventional intubation. Although the reported prevalence of difficult airway and difficult intubation is roughly 1-2%, this can be as high as 20% if there is cervical damage[7].

The success rate in ILMA placement was 100%; however, managing to pass the tube through it, and therefore isolate the airway, was only achieved in 94.5% of the cases. This percentage is high despite the difficulties present in these patients (difficult airway due to short neck, small mouth, large tongue, cervical immobilization in cases of multiple injury, abundant blood in the mouth, being trapped in a car, facial fractures etc.). In the 4 patients where it was not feasible to pass the tube through the ILMA device, 2 were medical-cause and transported alive to hospital (a man and a woman with anatomical features that impeded this maneuver, so the ILMA was used as an LM) and 2 were in the trauma-cause group; one was receiving CPR on arrival of the 061 team and was transported alive[8-10]. Different studies performed in hospital settings have reported very high rates of successful placement and ventilation using this mask.

Thus, Agro et al. reported a success rate of 100% in 104 patients, Baskett et al. 96% in 495 patients, Chan et al. 97% in 100 patients and Kapila et al. 99% in 150 patients[11-13].

We found no significant differences in mortality between the medical and trauma-cause groups. If we look at patient heart rhythm on arrival of the 061 staff, the results indicate that the probability of survival when the patient received PCR was 36% only when the reason for soliciting assistance was medical, because no trauma-cause patient survived. The probability of survival in patients not receiving PCR was 90% (medical) and 85.7% (trauma) respectively. These results show that the probability of success of CPR was much higher in the medical-cause group as compared to patients in the trauma-cause group (no survivors in this group), as shown in other series[14-17].

The conventional OTI method offers good performance in general, since ILMA was only required in 73 patients out of 4112 requiring airway management during the study period.

However, OTI is a simple technique for critical care physicians allowing rapid ventilation and oxygenation of patients whose extrinsic conditions (scene of event, situation and access etc.) and intrinsic conditions (type of neck, mouth fluids etc.) impede the option of conventional endotracheal intubation, obviating the need for invasive surgical access and preserving the patient's life.

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La mascarilla laríngea Fastrach® en el control extrahospitalario de la vía aérea de pacientes críticos

Chayán Zas ML, Iglesias Vázquez JA, Chayán Zas A, Faraldo Balado V, Barreiro Díaz MV, Cegarra García M

Objetivo: Describir el perfil epidemiológico de las intubaciones con mascarilla laríngea (ML) Fastrach® y analizar la utilidad de esta mascarilla en pacientes críticos atendidos extrahospitalariamente por el personal de Urgencias Sanitarias 061 (US-061).
Método: Estudio observacional descriptivo y retrospectivo. De enero 2002 a diciembre 2007. Se incluyeron pacientes atendidos por el personal de US-061 que requirieron para el control de la vía aérea ML Fastrach®. Se revisaron las historias clínicas informatizadas. Las variables analizadas fueron edad y sexo del paciente, causa médica o traumática, ritmo cardiaco inicial del paciente, supervivencia hasta el ingreso en el hospital y el porcentaje de utilización de esta técnica en la totalidad de pacientes que requirieron control de la vía aérea.
Resultados: 4.112 pacientes que requirieron control de la vía aérea, 73 de ellos mediante ML Fastrach® (1,8%). El 11,1% eran mujeres. La edad media fue de 50,7 ± 20,5 años. No fue posible realizar la intubación endotraqueal utilizando la ML Fastrach® en 4 de los 73 casos (5,5%). En 35 pacientes (48%) el motivo de control de la vía aérea fue médico y en el 38 (52%) traumático. De los pacientes de causa médica, 25 (71,4%) presentaban ritmo inicial de parada cardiaca y entre los de causa traumática 10 (26,3%). La supervivencia (llegaron vivos al hospital) fue en los de causa médica 18 (51,5%) y en los de causa traumática 24 (63,2%).
Conclusiones: Aunque la intubación orotraqueal (IOT) convencional presenta en general un buen rendimiento, hay un pequeño porcentaje de pacientes en donde no es posible el control de la vía aérea con esta técnica, por lo que en ellos la ML Fastrach es, como segunda alternativa, una técnica sencilla que permite un rápido control de la vía aérea en pacientes que tanto por sus condiciones extrínsecas como intrínsecas presentan difícil manejo de ésta. [Emergencias 2009;21:172-176]

Palabras clave: Mascarilla laríngea. Intubación. Cuidados críticos.