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ORIGINAL RESEARCH

Complications of the use of the laryngeal mask in pediatric patients: A Multicenter Study.

José Eduardo Ávalos García *[1], Juan Pablo Pacheco Bacuilima[2], Jaime Rodrigo Morales Sanmartín[1]
https://orcid.org/0000-0003-4523-505X
https://orcid.org/0000-0001-7779-0184

1. Postgraduate Department of Anesthesiology, Faculty of Medical Sciences, Universidad Cuenca, Ecuador.
2. Department of Anesthesia, "Vicente Corral Moscoso" Hospital, Ministry of Public Health, Cuenca-Ecuador.

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Abstract

Introduction: The laryngeal mask is used with the aim of increasing quality, safety, and care; however, despite having universal use and high efficacy for ventilation, this mask is not without complications. The objective of this research was to identify the frequency of complications associated with the use of a laryngeal mask in the Vicente Corral Moscoso and José Carrasco Public Hospitals in the City of Cuenca.

Methods: This study was an observational, descriptive, prospective study involving 220 pediatric patients, classified as American Society of Anesthesiologists (ASA) I, II, or III from all medical specialties who underwent elective and emergency surgeries, required general anesthesia lasting for 30 to 240 minutes, and received different types of masks. The sample was obtained by applying the formula for an unknown population in which n = (Z2 x p x q)/e2), 95% confidence level (1.96), and a margin of error (e) of 5%. The probability of occurrence of the event (p) was 15%, and the probability of non-occurrence (q) was 85%.

Results: Two-hundred twenty cases were enrolled in the study. The rate of laryngeal complications was 5.9%, and included frequent coughing with bloody discharge. Associated factors, such as classic mask, ages ranging from 2 to 5 years, time > 60 min, greater number of attempts, ASA > I, overweight nutritional status, and insert in formation were also evaluated.

Conclusion: The laryngeal mask was validated as a device for pediatric anesthesia due to rapid learning, low failure rate, few complications, and usefulness in difficult airways. The evidence is insufficient to support the use of a cone particular device over another one.

Keywords: Laryngeal Masks; Airway Management; Anesthesia, General; Child; /complications.

*Corresponding author

Email: jose-duardo@hotmail.es (José Eduardo Ávalos García) Servicio de Pediatría, Hospital Vicente Corral Moscoso. Avenida 12 de Abril y Arupos, Cuenca, Ecuador.

Introduction

The laryngeal mask (LM), a device that was developed for the airway, was discovered three decades ago. The first models to the present-day models have undergone modifications to make them easy to handle and quick to insert in order to provide ventilation at higher airway pressures, handle low pressures, lower the risk of gastric aspiration, and decrease stress on tissues. This device is for universal use and the frequency of its use is increasing in clinical situations. These devices have advantages, such as no requirement for a laryngoscope for insertion, which makes it a less invasive technique with less hemodynamic response and less manipulation of the airway; however, this device is not without risks and complications [1].

In a recent census performed in England that included participation of 309 public health system hospitals, it was determined that 56.2% of surgical procedures under general anesthesia were performed with a laryngeal mask, this being a strong change in the paradigm of management of the pathway aerial [2]. In a 2013 meta-analysis, Barreira analyzed 29 prospective and randomized clinical trials and showed that patients undergoing general anesthesia with the use of the laryngeal mask have fewer opportunities to develop complications, such as hoarseness, cough, and laryngospasm [3]. In addition, extubation and recovery times and hemodynamic responses were significantly shorter compared to those of the endotracheal tube [4].

The percentage of complications varies depending on the type of investigation, such as reported in a case series by Frediani et al. In a prospective study of 300 patients, an incidence of 1.7% laryngospasm, 4.3% hypoxia, 1% cough or obstruction, 2.3% cough; 5% trauma, and 0.3% vomiting was found without finding a connection between the size of the LM and complications [5].

Ranieri suggested that the laryngeal mask protects the airways, a fact that could be confirmed by fibroscopy; however, it is not without complications: (1) bronchospasm (4.9%), (2) laryngospasm (0.9%), (3) stridor (1.9%), (4) hoarseness (9.6%), and (5) regurgitation (0.9%) [6].

The problem with pediatric patients using the mask ia application of the same principles and maneuvers of introduction, maintenance, and extraction that are used adults; thus, this device has had different improvements, efforts and technological advances to achieve in order to be considered a safe device with its own characteristics for use in the pediatric population [7].

In airway management, laryngeal discomfort is the most frequent manifestation and its incidence is higher if it is associated with risk factors, so it is extremely important to understand and evaluate then to improve management of the upper airway management [8]. The present observational study describes the frequency and association of complications in a group of patients who received laryngeal masks.

Population and methods

Study Type and Design

This study was an observational, descriptive, prospective study in pediatric patients with ages ranging from 2 to 16 years who underwent elective and emergency surgeries under general anesthesia in 2018.

Investigation area

The study was carried out in the anesthesiology service of the "Vicente Corral Moscoso" and "José Carrasco Artega" third Level of Care Hospitals located in Cuenca-Ecuador, and covered a period of one year (January 1st to December 31, 2018).

Study Setting

This consisted of all male and female patients ranging in ages from 2 to 16 years of age, American Society of Anesthesiologist (ASA) I, II, and III from all medical specialties who underwent elective and emergency surgery under general anesthesia during a time interval of 30 to 240 minutes and whose airway management was performed with a laryngeal mask.

Statistics

Calculation of the appropriate sample size was based on several studies using several criteria: (1) 95% confidence interval (CI) 95%: 1.96, (2) Prevalence: 15%, and (3) Margin of error: 5%. The formula, $n = (Z_2 * p * q)\backslash e^2$ in which n is the sample size, Z_2 is the confidence level

of 1.962, p indicates 15% probability of success (0.15), q is the probability of failure (85% or 0.85), and e^2 represents the margin of error or precision set at 5% (0.05). The sample size was 231 participants, which was randomly obtained from patients admitted for scheduled and emergency surgeries. The pediatric operating room in which laryngeal mask was used was chosen and assigned by the author of the thesis. A probability of loss of 5% was calculated, which was equivalent to 11 patients. The final sample consisted of 220 patients.

Study variables

Registration of laryngeal masks: LMA® classic™ Airway [Laringeal Mask, Teleflex Medical Europe Ltd, Athlone, Ireland], LMA® Fastrach™ Airway mask [Laringeal Mask, Teleflex Medical Europe Ltd, Athlone, Ireland]; LMA® ProSeal™ Airway mask [Laringeal Mask, Teleflex Medical Europe Ltd, Athlone, Ireland]; AIR-Q® [Salter labs, SunMed, Grand Rapids, MI, USA] I-gel® [Laringeal Mask, Teleflex Medical Europe Ltd, Athlone, Ireland], was done.

Characteristics of post-operative laryngeal complications included odynophagia, cough, dysphonia, laryngospasm, bloody pharyngeal discharge, duration of intervention, number of attempts, operator training, and nutritional status and ASA statuses.

Selection of participants

The selection of the participants was carried out in the post-anesthetic care unit by means of a consecutive interview. The simple selection followed a systematic random order.

Inclusion criteria

1. Patients of both sexes, aged between 2 and 16 years.
2. ASA I, II, or III urgency or emergency.
3. Patients undergoing elective and emergency surgery in all surgical medical specialties.
4. Ventilated patients with any type of laryngeal mask
5. Surgery time between 30 and 240 minutes.

Exclusion criteria

1. Patients who present with respiratory symptoms during induction (cough, aphonia, dysphonia, odynophagia).
2. Patients at risk of aspiration (pregnancy, hiatal hernia, gastroesophageal reflux)
3. Previous laparoscopic, cardiothoracic, and/or head and neck surgery.
4. Patients with predictors of difficult airway, history of difficult intubation, psychiatric disorders that make correct evaluation difficult.
5. Patients who require intensive therapy in the post-operative period.
6. Allergies to medications used in this study.
7. Presence of foreign body in the airway, polyps, tumors, retropharyngeal abscess, pharyngeal trauma.
8. Patients or legal representatives who do not want to participate in the study.
9. Patients participating in other research studies

Description of procedures

After approval of the Bioethics Committees from both hospitals and the informed consent of all parents, the study setting consisted of all patients who met the inclusion criteria, who consented to undergoing general anesthesia with the protocol established by the anesthesiology service, and who received prior authorization from the anesthesiology treating physician whose airway management was performed with a laryngeal mask.

The researcher followed up with a structured questionnaire to record the type of laryngeal mask, number of attempts to insert it, anesthesia time, experience of the doctor, change in technique during the procedure, and laryngeal complications, such as cough, odynophagia, bloody discharge, dysphonia, and laryngospasm that were assessed during the trans-operative period as reported by the treating physician and via information provided by the companion of the child patient in the post-anesthetic care room. General and local examinations of the child were carried out with requests for laboratory investigations, especially coagulation studies. The purpose, benefit, procedure, and potential risks of this study was explained in detail to the parents of the children with the assurance that their children will receive the optimal and safe medical care. If they had agreed to participate in the study, each child's guardian signed a written informed consent

Methods and instruments to obtain the information.

The field work was carried out through a structured information questionnaire, which was tested by means

of a pilot trial, and the clinical history was used and recorded on the form.

Data analysis procedure:

After the completion of the research collection and after following the quantitative and qualitative perspective, depending on the information base, data were analyzed in a logical, reflective way and analyzed with the help of EPI-DAT, EXCEL, EPI INFO, SPSS free version (statistical programs).

Procedures to guarantee ethical aspect.

To guarantee that ethical aspects were upheld, approval of the study was required from the Ethics Committee of the Faculty of Medical Sciences of the University of Cuenca. After obtaining permission from the authorities of the Vicente Corral and José Carrasco Hospitals from the post-anesthetic recovery unit, the patients or legal representatives who decided to be part of the investigation gave their informed consent.

Data Analysis and Tabulation Plan

For qualitative variables, descriptive statistics, absolute and relative frequencies were used; on the other hand, for continuous variables (age, surgical time) the mean, median, mode, standard deviation, range, minimum and maximum values were used. Maximum values were used to present the results. In addition, statistical association measures, such as chi square, CI, and P-value were used. A value of $P \leq 0.05$ was considered statistically significant.

Results

Sociodemographic characteristics of the study population.

The mean age of the study group was 6.2 ± 3.7 years. The median was five years, and the mode was two years. The minimum value was two years, and the maximum value was 16 years over an age range of 14 years.

The most frequently encountered age group consisted of 2- to 5-year old children (55.9%). Male sex was more frequently found (62.3%). The predominant ethnic group was Mestizo with (99.1%) as shown in Table 1.

Frequency of Laryngeal Complications

Laryngeal complications occurred in 13/220 cases (5.91%, 95% CI 5.70%–6.12%). Some patients had more than one complication.

Table 1 Sociodemographic data of the study population.

Age (Years)	Frequency n=220	%	Standard deviation
2-5	123	55.9	3.79
6-9	43	19.5	
10-12	37	16.8	
13-16	17	7.7	
Sex			
Male	137	62.3	0.486
Female	83	37.7	
Ethnic group			
Hispanic	218	99.1	0.285
Other	2	0.9	

Table 2 Characteristics of Laryngeal Complications.

Complication	N=220	%	95% CI
Cough	8	3.64	3.47-3.8
Bloody discharge	4	1.82	1.70-1.94
Odynophagia	3	1.36	1.26-1.47
Dysphonia	2	0.91	0.82-0.99
Laryngoespasm	2	0.91	0.82-0.99

Table 3 List of patient-dependent laryngeal complications.

	Complications			
	Yes n=13	No n=207	Total n=220	*P*
Age (Years)				
2-5	8 (6.5%)	115 (93.5%)	123	0.98
6-9	2 (4.7%)	41 (95.3%)	43	
10-12	2 (5.4%)	35 (94.6%)	37	
13-16	1 (5.9%)	16 (94.1%)	17	
Sex				
Male	8 (5.8%)	129 (94.2)	137	0.96
Female	5 (6%)	78 (94%)	83	
ASA				
ASA 1	9 (5.7%)	149 (94.3%)	158	0.80
ASA 2	4 (7%)	53 (93%)	57	
ASA 3	0 (0%)	5 (100%)	5	
Nutritional condition				
Malnutrition	0 (0%)	12 (100%)	12	0.381
Under weight	1 (5%)	19 (95%)	20	
Normal	8 (5.4%)	139 (94.6%)	147	
Overweight	4 (12.9%)	27 (87.1%)	31	
Obesity	0 (0%)	10 (100%)	10	

Characteristics of Laryngeal Complications

The most prevalent complications were cough and bloody discharge (see Table 2).

Relationship of dependent and non-dependent laryngeal complications of the patient

No statistically significant differences based on age of presentation, sex, ASA classification, or nutritional status were found (see Table 3). No statistically significant differences based on hospital center, operator, type of mask, or mask number were found. Complications were found to be statistically significant based on duration of surgery and the number of attempts to place the laryngeal mask (see Table 4). Only on one occasion was the ventilation technique changed to a face mask, which represented 0.5%; 0.9% changed to another type of laryngeal mask, and in no case was an endotracheal tube used. These differences were not statistically significant (P= 0.083).

Table 4 List of laryngeal complications not patient dependent.

	Complications		*P*
	Yes n=13	No n=207	
Institution			
EISS	6 (6.2%)	91 (93.8%)	0.877
MPH	7 (5.7%)	116 (94.3%)	
Duration of anesthesia (minutes)			
15-30	4 (4%)	95 (96%)	
31-60	7 (6.1%)	107 (93.9%)	0.001
61-90	1 (16.7%)	5 (83.3%)	
91-120	1 (100%)	0 (0%)	
Mask Type			
LMA® Classic™	10 (7.4%)	126 (92.6)	
AIR-Q ®	3 (3.7%)	79 (96.3%)	0.501
I-GEL ®	0 (0%)	2 (100%)	
Mask number			
ML 1.5	1 (20%)	4 (80%)	
ML 2	3 (3.4%)	85 (96.6%)	
ML 2.5	6 (8.7%)	63 (91.3%)	
ML 3	2 (4.5%)	42 (95.5%)	0.511
ML 3.5	1 (9.1%)	10 (90.9%)	
ML 4	0 (0%)	3 (100%)	
Operator			
Anesthesiologist	0 (0%)	5 (100%)	0.571
Resident	13 (6%)	202 (94%)	
Number of attemps			
1	5 (2.4%)	203 (97.6%)	
2	5 (55.6%)	4 (44.4%)	0.001
3	3 (100%)	0 (0%)	

EISS: Ecuadorian Institute of Social Security, MPH: Ministry of Public Health

Discussion

Currently, many supraglottic devices are available for use in pediatrics. The laryngeal mask approach (LMA) to the airway has paved the way for important changes in the management of the same approach both in routine procedures and in emergencies because it has multiple advantages. Some of these advantages include lower risk of injury to the teeth, larynx, and trachea, in addition to a decrease in the risk of hypoxia when it is unexpectedly difficult or impossible to intubate the trachea [9].

As with all existing devices, the laryngeal mask also has associated complications; thus, in the present study 5.9% complications were found with the most frequent being cough (3.6%), bloody discharge (1.8%), odynophagia (1.4%), and laryngospasm and dysphonia (0.9%). When compared with a local study, such as one by Torres et al. involving 60 patients undergoing general anesthesia at the Gustavo Domínguez Hospital (Santo Domingo-Ecuador), the laryngeal complication rate was 30%, cough 10%, and bloody pharyngeal discharge 3.3%. These two complications remain prevalent; however, the safety with which the mask can be used was also demonstrated [10].

Similarly, in a prospective randomized clinical study by Rauf et al. in a group of 80 patients, 40 laryngeal mask complications were reported in the recovery room in children aged 1 to 12 years after undergoing strabismus surgeries. reported bloody discharge in 5%, odynophagia 7.5%, in previous studies sex predominant was equally masculine. In a prospective randomized study with 80 patients in loop I in which the incidence of odynophagia ranging from 5.8% to 34%, bloody discharge of 7%, fewer complications in ASA I patients, and similar results as found in this study was reported [11].

In the present investigation, we found that a surgical time greater than 60 minutes, age between 2 and 5 years, and ASA > I was a risk factor for complications. These results are consistent with the investigation of Toledo and Bárbara from 1,285 radiotherapy sessions corresponding to 65 children (94%). After using a laryngeal mask, laryngeal spasms in nine (0.7%) of the sessions were found. None required endotracheal intubation or hospitalization after the event. The mean time to anesthesia was 24.55 minutes, and the age group was between 2 and 3 years [12].

In the study by Haliloglu, which was a prospective observational study, 197 children with physical status ASA I (97%) were evaluated. Pharyngeal complications were (3.6%) with the only complication reported as bloody discharge. The average time of anesthesia was 70 minutes, and the mean age was 4.7 years. In addition, a single mask placement attempt was used (93%), and no need to use an endotracheal tube was found as in our study thus corroborating that in ASA 1 patients on the first attempt and with shorter anesthesia duration, pharyngeal complications decreased [13].

Ranieri et al. conducted a prospective randomized, observational study with 204 pediatric patients who underwent adenoidectomy. Their ages ranged from 2 to 10 years, and they were classified as ASA I. Bronchospasm (4.9%), laryngospasm (0.9%), stridor (1.9%), dysphonia (9.6%), and regurgitation (0.9%) were observed. In agreement with the percentage of laryngospasm in our study and being one of the most feared respiratory complications due to severe hypoxemia that requires immediate treatment, this study presented the lowest incidence of complications, and no need to add another anesthetic technique existed. Thus, the mask has universal use in out-patient procedures and complex upper airway surgeries [6].

The percentage of respiratory complications according to Nascimento et al. was described as 43% in children. This percentage is higher compared to ours because in lactating children the epiglottis folds over the mask thus occluding the larynx, and a risk of movement and displacement of the supraglottic device also exists; thus, the risk increases [6].

Operator training also influences complications, so when the inserter is undergoing training, complications were 6%, according to the Mehryar study in which an index of odynophagia was 4.1% was reported. This rate was proportional to the experience of the professional [14]. Also, with the classic mask a greater number of complications were found compared to second generation devices due to the fact that the classic mask used for children is merely a reduced version of the adult mask, whereas air-q™ and pediatric igel™ masks have specific design characteristics that allow a better seal and greater protection against gastric aspiration and inflation, especially in infants and young children [15].

A study by Mohamed in 90 Egyptian children involving oral surgeries, such as tonsillectomy in which laryngeal masks were used, reported minor complication compared to those receiving an endotracheal tube in which nausea 8.89%, cough 6.67%, laryngospasm 2.22%, odynophagia 4.44% were found. Extubation and recovery times were significantly shorter with the mask thus indicating that the laryngeal mask is safe in airway surgeries [4].

Conclusions

The population that presented the highest risk consisted of a mixed race and mostly male, with the highest percentage being preschoolers (2–5 years). The percentage of complications with devices was 5.9%, which was below that reported as 30% to 36%. Complications appear to be associated with factors, such as surgery time greater than 60 minutes and a greater number of attempts to place the mask.

Abbreviations

ASA: American Society of Anesthesiologist. LM: Laryngeal mask

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Authors' contributions

JEAG: Research idea, data collection, article writing, statistical analysis, editorial corrections.
JPPB: Research idea, study design, critical analysis, research direction.
JRMS: critical analysis, methodological design, statistical analysis.
All authors read and approved the final version of the manuscript.

Authors information

José Eduardo Ávalos García, General Practitioner, Higher Polytechnic School of Chimborazo Specialization in Anesthesiology, Faculty of Medical Sciences, University of Cuenca, Ecuador. Email: jose-duardo@hotmail.es https://orcid.org/0000-0001-6935-1157
Juan Pablo Pacheco Bacuilima, Doctor of Medicine and Surgery from the University of Cuenca, Specialist in Anesthesiology from the University of Cuenca, Master in Health Research from the University of Cuenca.
Jaime Rodrigo Morales Sanmartín, Doctor in Medicine and Surgery from the University of Cuenca, Higher Diploma in University Education in Health Sciences, Master in Management of Educational and Social Projects.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due participant confidentiality but are available from the corresponding author on reasonable request.

Ethical statements

The protocol of this study was approved by the Institutional Teaching Committee and by the Bioethics Committee of the Faculty of Medicine of the Universidad de Cuenca.

Protection of persons

The authors declare that the procedures followed were in accordance with the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki.

Confidentiality of the data

The authors declare that they have followed the protocols of their work center on the publication of patient data.

Consent for publication

The authors have obtained the informed consent from the guardians of the patient referred to in the article. This document is in the possession of the corresponding author. The parents have signed the authorization for publication of this case.

Competing interests

The authors have no competing interests to declare.

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