## Original article

# A randomized trial comparing laryngeal mask airway to endotracheal tube in children undergoing upper gastrointestinal endoscopy

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**Abstract.** Although the efficacy of laryngeal mask airway (LMA) has been demonstrated for securing patency of the airway in children, it has not yet been compared to endotracheal tube (ET) in this population. This study aimed to compare the safety and efficacy of LMA vs. ET in children undergoing elective diagnostic upper gastrointestinal endoscopies. Sixty ASA I-III patients were randomly allocated to ET (Group I) or LMA (Group II). A set of cardiovascular and respiratory parameters were obtained before, during and after the endoscopic procedure. The recovery time and the time to discharge were also registered. The cardiovascular and respiratory parameters evaluated in the study varied across the different evaluation periods. However, they remained within physiological ranges and were not different between groups. The median (range) recovery time was 4 (2-10) min and the time to discharge was 58 (36-88) min in the ET group and 3 (1-7) min and 50 (35-67) min in the LMA group (P > 0.10), respectively. In a 16 month-old, 80 cm and 10 kg girl, we failed to secure the patency of the airway with LMA. In conclusion, the LMA was as effective and safe as ET for securing the airway of children undergoing diagnostic upper endoscopies. However, the 3% failure rate occurred with LMA. (www.actabiomedica.it)

**Key words:** Digestive system endoscopy, laryngeal mask airway, randomized clinical trial

## Introduction

After the introduction by the American Society of Anesthesiologists of the algorithm for difficult airway intubation (1), the relevance of laryngeal mask airway (LMA) in such conditions has substantially been recognized (2-4). However, its use for endoscopic procedures involving the upper gastrointestinal tract has scarcely been evaluated probably due to the potential anatomic difficulties during the simultaneous positioning of the LMA and endoscope. In contrast, a clinical trial comparing the use of LMA to endotracheal tube (ET) in adult patients undergoing endoscopic retrograde cholangiopancreato-graphy found that the safety and efficacy was similar between the two intubation devices (5). In children, the LMA was successfully used in a one-arm trial of patients undergoing upper endoscopic procedures (6). However, since the two devices had not yet been compared in this population, the question on whether LMA may be a proper alternative to the ET remained unanswered. The present randomized clinical trial in a population of pediatric patients with low risk of difficult airway control, aimed to compare the safety and efficacy of LMA and ET when used to ensure patency of the airway during diagnostic endoscopic procedures of the upper gastrointestinal tract.

## Methods

### Subjects

After institutional ethical approval and parental written informed consent at Hospital Infantil de Mexico "Federico Gomez" (HIM), 60 ASA physical status I-III pediatric patients, aged from six months to 12 years, with a body weight between the 50 and 90 percentile as described in standard growth tables for age, undergoing elective upper gastrointestinal diagnostic endoscopy under inhalatory anesthesia, were considered as eligible for the study. Patients were evaluated for eligibility a day prior to the procedure, and the investigator who did the evaluation did not control or know future patients' group of allocation. Exclusion criteria were: known or predicted difficult airway (e.g. anatomic abnormalities of the upper respiratory tract), cervical spine disease, esophageal or gastrointestinal bleeding, obstructive or restrictive pulmonary disease, tracheotomy, neuro-developmental delay, or relevant drug allergy. The investigators who verified the patients' eligibility for the study (JCR-M & JMA-A) did not control the patients' allocation to the study groups.

The day of the endoscopic procedure, in order to avoid prolonged fasting periods, patients received an oral electrolyte solution 3 hours before the endoscopic procedure (7). Based on a pre-designed table of random numbers, participants were randomly allocated to airway maintenance with a LMA (The Laryngeal Mask Company, Ltd., Bucks, United Kingdom) or an ET (Portex Ltd., Kent, United Kingdom). The investigator who designed the table of random numbers did not participate in the evaluation of the study (AAN-O).

### Procedures

In the operating room, patients were monitored by continuous electrocardiogram, non-invasive blood pressure, and pulse oxymetry. Anesthetic induction was performed with sevoflurane 1.5-2 age-adjusted MAC and oxygen 100% administered by a face mask. Thereafter, a venous catheter was placed and an infusion Ringer lactate 10 ml/kg x h$^{-1}$ was started followed by the administration of atropine i.v. 10 μg/kg

followed by propofol i.v. 3 mg/kg. The safety of propofol in pediatric patients has previously been described in patients undergoing airway protection or LMA placement (2).

In group I, immediately after intravenous induction was performed, patients were placed in the left lateral position and the head was positioned on pillows. The flexible endoscope was carefully introduced through the mouth into the esophagus. In order to avoid the passage of gastric content into the patients' airway, aspiration was gently performed during the introduction of the endoscope. When the tip of the endoscope was located in the upper third of esophagus, the LMA was introduced beside the endoscope.

In group II, immediately after the intravenous induction was performed, and the patients were placed in the supine position, a single pillow was positioned under the occiput and adjusted as required to achieve a "sniffing" position. Participating anesthesiologists then attempted to secure the airway using a proper ET. The patients were placed in the left lateral position and a flexible endoscope was carefully introduced through the mouth, next to the ET.

During intubation, the airway was considered secured once a positive capnographic waveform was observed with hand ventilation in conjunction with positive bilateral pulmonary murmurs and visible chest and reinhalation bag movements. The tubes were attached to a Bain system and sevoflurane 1-2 age-adjusted MAC and oxygen 100% administered was administered for anesthetic maintenance. The patients remained under spontaneous ventilation throughout the endoscopic procedures. The end-tidal carbon dioxide in addition to a set of respiratory and cardiovascular parameters were monitored throughout the entire study. To maximize patient's safety, securing the airway was considered unsuccessful if a capnography waveform was not seen within 60 s from the beginning of the airway maneuver or if more than 2 unsuccessful attempts were made. One investigator carried out all endoscopic procedures on all the participants (GB-R), one performed the intubations (EM-P), and two others performed the anesthetic procedures (VEF-G & MA-A).

At the end of the endoscopy, the endoscope was removed and sevoflurane administration was disconti-

nued. If swallowing and spontaneous breathing movements were present, either the LMA or ET tube was removed. The patients were discharged to the contiguous recovery room when ≥ 8 points of Aldrete scale were reached. Once in the recovery room, patients were clinically monitored and Aldrete scale was evaluated every 15 min until they reached 10 points of the scale and were then discharged.

*Study outcomes*

As primary study outcomes, heart rate (beats x min), systolic and diastolic blood pressures (mmHg), arterial oxygen saturation measured by pulse oxymetry ($SaO_2$ in %), and $EtCO_2$ (mmHg; starting after intubation was performed) were measured every 5 min. However, for study purpose, these parameters were registered at the following times: basal, pre-anesthetic induction, post-anesthetic induction, at the end of anesthesia, post-cannulation, and at the time the patient was discharged. As secondary study outcomes, the extubation time defined as the time (min) elapsed from the end of the endoscopic procedure to the extubation and the recovery time defined as the time (min) elapsed from extubation to the discharge of the patient from the recovery room, were registered.

*Data analysis*

Demographic data (age, weight, and height) were summarized as mean ± SD and were compared between groups using the Student t test for unpaired data. The number of male and female patients was compared between groups using a chi-squared test. Extubation and recovery times were summarized as mean ± SD and were compared between groups using a Mann-Whitney U test. Cardiovascular parameters and $SaO_2$ registered at different period of times were summarized as mean ± SD and were compared between groups using an Analysis of Variance (ANOVA) for repeated measures. A two-tailed P < 0.05 was considered significant in all the statistical tests. Statistical analyses were performed by StatsDirect v. 2.2.5 (StatsDirect Ltd., Cheshire, United Kingdom) by one investigator who was unaware of the patients' allocation group (AAN-O).

# Results

Among the 60 patients included in the randomization, it was not possible to secure the airway with LMA after 2 attempts in a 16 month-old, 80 cm, 10 kg girl with a diagnosis of esophageal stenosis. The patient was placed in the supine position, ventilated with a face mask and once under adequate conditions, an ET was used for securing the trachea. This patient was not included in the analyses.

Data from 59 patients were analyzed. There was no difference between groups regarding the children's demographic data (Table 1). The pre-endoscopic respiratory and cardiovascular parameters of efficacy and safety exhibited significant differences across the evaluation periods but were not different between the two study groups (Table 2). In the two study groups, the endoscopic procedures had a duration ranging from 5 to 10 min, and the study parameters remained whithin normal ranges throughout the endoscopic procedures (data not shown). In relation to the post-endoscopic evaluations, the systolic blood pressure was 92.1 ± 11.5 post-anesthesia, 99.1 ± 11.7 post-extubation and 101.4 ± 12.2 at discharge in the ET group vs. 100.6 ± 14.0, 108.2 ± 16.5, and 106.3 ± 15.2 in the LMA group, respectively (P < 0.001 among the evaluation periods and P < 0.025 between groups; two-way ANOVA test for repeated measures) (Table 3). The other cardiovascular and respiratory parameters varied across the different evaluation periods. However, they remained within physiological ranges and were not different between groups. Finally, the extubation and recovery times were approximately 1 min (P < 0.01) and 8 min (P < 0.005) longer in the endotracheal tube group than in the LMA group (Table 4), respectively.

**Table 1.** Demographic data

|  | Laryngeal mask airway | Endotracheal tube |
|---|---|---|
| Sex (M:F) | 15:15 | 16:14 |
| Age (yr.) | 5.4 ± 4.0 | 5.1 ± 3.3 |
| Weight (kg) | 19.4 ± 10.1 | 17.4 ± 8.5 |
| Height (cm) | 105.6 ± 27.7 | 99.8 ± 27.4 |

Data are numbers cases or mean ± SD

**Table 2.** Pre-endoscopic cardiovascular and ventilatory parameters

| | Laryngeal mask airway (n= 29) | Endotracheal tube (n= 30) |
|---|---|---|
| **$SaO_2$ (%)[a]** | | |
| Basal | 96.6 ± 1.6 | 96.0 ± 1.9 |
| Initial | 98.1 ± 1.7 | 98.2 ± 1.4 |
| Post-induction | 98.7 ± 0.5 | 98.8 ± 0.5 |
| Post-intubation | 98.9 ± 0.4 | 98.7 ± 0.9 |
| | | |
| **$EtCO_2$ (mmHg)[a]** | | |
| Basal | - | - |
| Initial | 37.0 ± 7.7 | 37.5 ± 5.8 |
| Post-induction | 38.4 ± 7.8 | 38.9 ± 7.0 |
| Post-intubation | 39.6 ± 6.7 | 41.0 ± 7.1 |
| | | |
| **Heart rate (beats x min)[a]** | | |
| Basal | 112.5 ± 23.5 | 111.6 ± 22.9 |
| Pre-induction | 114.2 ± 20.9 | 111.8 ± 16.5 |
| Post-induction | 123.4 ± 15.9 | 122.1 ± 14.4 |
| Post-intubation | 126.2 ± 18.5 | 128.3 ± 13.1 |
| | | |
| **Systolic blood pressure (mmHg)[a]** | | |
| Basal | 120.3 ± 26.0 | 110.3 ± 17.6 |
| Initial | 111.1 ± 23.5 | 106.0 ± 19.0 |
| Post-induction | 96.8 ± 15.5 | 97.2 ± 13.3 |
| Post-intubation | 98.2 ± 15.4 | 94.5 ± 14.1 |
| | | |
| Diastolic blood pressure (mmHg)[a] | | |
| Basal | 72.4 ± 19.1 | 67.8 ± 15.0 |
| Initial | 65.5 ± 18.5 | 63.5 ± 13.5 |
| Post-induction | 55.0 ± 10.7 | 57.0 ± 12.2 |
| Post-intubation | 55.0 ± 10.6 | 53.9 ± 8.7 |

Data are mean ± SD. The $EtCO_2$ was not measured at baseline
[a] P < 0.001 for comparison of the different periods and P > 0.10 between groups (two-way ANOVA test for repeated measures)

**Table 3.** Post-endoscopic cardiovascular and ventilatory parameters

| | Laryngeal mask airway (n= 29) | Endotracheal tube (n= 30) |
|---|---|---|
| **$SaO_2$ (%)[a]** | | |
| Post-anesthesia | 98.7 ± 0.8 | 98.7 ± 0.7 |
| Post-extubation | 98.7 ± 0.6 | 98.6 ± 0.9 |
| At discharge | 98.6 ± 0.7 | 98.3 ± 1.4 |
| | | |
| **$EtCO_2$ (mmHg)[a]** | | |
| Post-anesthesia | 41.0 ± 6.6 | 42.2 ± 4.9 |
| Post-extubation | 38.2 ± 6.4 | 40.6 ± 6.1 |
| At discharge | 37.2 ± 5.8 | 38.4 ± 4.3 |
| | | |
| **Heart rate (beats / min)[a]** | | |
| Post-anesthesia | 121.8 ± 16.8 | 125.4 ± 14.6 |
| Post-extubation | 123.3 ± 18.5 | 125.2 ± 14.4 |
| At discharge | 119.8 ± 18.2 | 121.7 ± 15.0 |
| | | |
| **Systolic blood pressure (mmHg)[b]** | | |
| Post-anesthesia | 100.6 ± 14.0 | 92.1 ± 11.5 |
| Post-extubation | 108.2 ± 16.5 | 99.1 ± 11.7 |
| At discharge | 106.3 ± 15.2 | 101.4 ± 12.2 |
| | | |
| **Diastolic blood pressure (mmHg)[a]** | | |
| Post-anesthesia | 54.8 ± 9.1 | 49.2 ± 8.7 |
| Post-extubation | 57.0 ± 10.7 | 55.0 ± 8.8 |
| At discharge | 58.3 ± 10.3 | 57.6 ± 9.9 |

Data are Mean ± SD
[a] P < 0.05 among the different evaluation periods, P > 0.10 between groups (two-way ANOVA test for repeated measures)
[b] P < 0.001 among the different evaluation periods, P < 0.025 between groups (two-way ANOVA test for repeated measures)

**Table 4.** Recovery time and time to discharge

| | Laryngeal mask airway (n= 29) | Endotracheal tube (n= 30) | 95% CI for the difference |
|---|---|---|---|
| Extubation time (min) | 3 (1-7) | 4 (2-10)[a] | -2 to 0 |
| Recovery time (min) | 50 (30-67) | 57.5 (36-88)[b] | -11 to -2 |

Data are mean (ranges)
[a] P<0.01, two-sided Mann-Whitney U test
[b] P<0.005, two-sided Mann-Whitney U test

## Discussion

The present study showed that the use of LMA for securing the airway may be a proper alternative to ET in children undergoing endoscopic procedures of the upper gastrointestinal tract. Since unexpected hypoxic events followed by secondary complications constitute the major risk in patients undergoing upper gastrointestinal endoscopic procedures especially when anesthetic agents are administrated without securing the airway, children at HIM typically receive airway protection with ET. The LMA has successfully been used for tracheal intubation under either scheduled or emergency conditions in adult and pediatric patients (1, 2, 8, 9). In adult patients, its use has also included patients requiring gastrointestinal endosco-

pies. Osborn et al. (5) reported a shorter extubation time in LMA group in comparison with ET group (7.2 vs. 12 min; P = 0.004). In our study, extubation times were shorter with the former than with the latter device. However, the difference between groups was of 1 min, which may be practically irrelevant in the daily clinical setting. The difference in the recovery times between LMA and ET was more evident but still modest.

In children, LMA was previously used in patients undergoing upper gastrointestinal endoscopies (6) and in patients requiring mechanical ventilation (10, 11). The success rate of LMA placement in children has been reported to be as high as 90% (12). However, the present study appears to be the first randomized clinical trial comparing the two intubation devices in children. The respiratory and cardiovascular responses to the different maneuvers were similar between the two study groups. Taking into consideration the different outcomes evaluated in the study, it has to be concluded that LMA and ET were very similar regarding efficacy and safety in children undergoing upper gastrointestinal endoscopic procedures. However, we failed to secure the airway with LMA in a 10-kg child (3% failure rate). Although the rate of failure was low, informing parents about such risk should be considered during the preanesthetic evaluation.

Another factor that may require further considerations is the difference in costs between these devices. Although we did not intentionally evaluate costs, in Mexico, at the time the study was performed, each LMA cost approximately US$175 and was intended to be used for 40 patients whereas ET cost approximately US$3.3 and was intended to be used for 1 patient. However, the global tendency is to use these devices for a single case. Under such circumstances, a formal economic evaluation is required before routinely replacing the latter with the former device.

In conclusion, LMA showed similar efficacy and safety as ET for securing the airways in children undergoing upper gastrointestinal endoscopic procedures. Future studies for clarifying whether the LMA may result in better patient satisfaction due to its lower invasiveness and for testing its safety during uncontrolled clinical conditions, as well as a formal cost evaluation analysis, are needed.

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