

A Comparison of Laryngeal Mask Airway-Supreme and Endotracheal Tube Use with respect to Airway Protection in Patients Undergoing Septoplasty: A Randomized, Single-blind, Controlled Clinical Trial

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Abstract

Background There are doubts among anesthesiologists on the use of the Laryngeal Mask Airway in nasal surgeries because of concerns about the occurrence of blood leakages to the airway. The primary purpose of this study on septoplasty cases was to compare Laryngeal Mask Airway-Supreme (LMA-S) and endotracheal tube (ETT) use in protecting the airway against blood leakage, as evident through the fiberoptic bronchoscopy method. The secondary purpose of the study was to evaluate oropharyngeal leakage pressure (OLP), heart rate (HR), mean arterial pressure (MAP), and postoperative adverse events.

Methods The present study was conducted in a prospective, randomized, single-blind, controlled manner on 80 patients, who underwent septoplasty procedures under general anesthesia, after dividing them randomly into two groups according to the device used (LMA-S or ETT). The presence of blood in the airway (glottis/trachea, distal trachea) was analyzed with the fiberoptic bronchoscope and a four-point scale. Both groups were evaluated for OLP; HR; MAP; postoperative sore throat, nausea, and vomiting; dysphagia; and dysphonia.

Results In the fiberoptic evaluation of the postoperative airway, less blood leakage was detected in both anatomic areas in the LMA-S group than in the ETT group (glottis/trachea, $p = 0.004$; distal trachea, $p = 0.034$). Sore throat was detected less frequently in the LMA-S group at a significant level in the 2nd, 6th, and 12th hours of postoperative period; however, other adverse events were similar in both groups. Hemodynamic parameters were not significantly different between the two groups.

Conclusion The present findings demonstrate that the LMA-S provided more effective airway protection than the ETT in preventing blood leakage in the septoplasty procedures. We believe that the LMA-S can be used safely and as an alternative to the ETT in septoplasty cases.

Background

For many years, the endotracheal tube (ETT) has been accepted as the standard method for airway safety[1]. High pressure and long-term use of mucosal hypoperfusion and submucosal stenosis are among the major disadvantages of cuffed tubes[2]. The Laryngeal Mask Airway (LMA), which was first produced in the 1980s, has been used as a minimally invasive airway device in many general anesthesia practices and has become an alternative to the ETT in many surgeries [3,4,5].

The LMA has many advantages over the ETT, such as having no direct contact with the tracheal mucosa, no need for direct laryngoscopy during inserting, and less adverse events [6]. In recent years, supraglottic airway devices (SGHAs), which are similar to the LMA-Supreme™ (LMA-S) in that their features are superior to LMA-Classic, have been developed [7].

The LMA-S is one of the second-generation semi-rigid and elliptical LMAs; it can be easily and quickly inserted without placing fingers in the patient's mouth, and it does not include latex. These second-generation models were designed to provide higher sealing pressures than the LMA-Classic. In addition, they have a gastric duct for a gastric tube, which is among their important advantages [8]. There are hesitations among anesthesiologists about using the LMA because of concerns regarding vocal cord contamination and tracheal blood leakage in nasal surgical procedures [9]. There are studies on nasal surgeries with LMA-Classic in the literature, but studies on second-generation LMAs, which protect the airway better than classical LMAs, are limited [6].

Blood leaking from the posterior to the hypopharynx in nasal surgeries contaminates the vocal folds and the tracheobronchial tree. We predict that the LMA-S, which is a minimally invasive airway device with a high sealing pressure, will reduce the blood leakage to the glottis/trachea and distal trachea. The primary purpose of this study, which was conducted on septoplasty cases, was to compare the effectiveness of the LMA-S and the ETT in protecting the airway against blood leakage using fiberoptic bronchoscopy. The secondary purpose of this study was to evaluate oropharyngeal leakage pressure (OLP); hemodynamic response, including HR and MAP; and postoperative adverse events.

Methods

Protocol

This study was approved by the Local Ethics Committee (Protocol no: 2018/165) and registered at www.ClinicalTrials.gov (# NCT03903679). We conducted a prospective, randomized, single-blind, and controlled clinical study with 80 adult patients undergoing septoplasty surgery at a university hospital. This manuscript adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement[10].

Study Design

For the purposes of randomization, it was ensured that the patients were randomly assigned to the study groups, and selection bias was avoided. For this purpose, the MedCalc for Windows, Version–16 statistical software (medcalc.com.tr) was used. A total of 80 patients were randomized into two groups: LMA-S (n = 40) and ETT (n = 40).

Study Participants

The patients agreed to participate in the study voluntarily. After they were informed about the potential risks and predicted results of the study, they completed the written informed consent forms. The study was conducted with patients, aged 18–65, who were scheduled for elective nasal septum surgery (American Society of Anesthesiologists (ASA) I-II).

In the preoperative anesthesia evaluation, patients with scores higher than ASA II and patients who had severe respiratory, hepatic, or renal dysfunction; neurology and/or psychiatry disorders; an allergy to anesthesia drugs, a body mass index (BMI) over 30; a difficult airway history (cervical spine pathology, modified Mallampati class 4, or thyromental distance < 65 mm); or a history of gastroesophageal reflux or hiatal hernia were excluded from the study.

Preoperative Procedures

The general anesthesia was standardized for all patients. Noninvasive blood pressure (NIBP), pulse oximetry (SpO₂), electrocardiogram (ECG), and standard monitoring were applied to the patients who were admitted to the surgery room. Following this stage, preoperative oxygenation was performed with 100% oxygen for three minutes (min).

General Anesthesia

Anesthesia induction was carried out with propofol 2.5 mg.kg⁻¹ intravenously (IV) + remifentanyl 3 µg.kg⁻¹ IV in both groups, and no myorelaxants were used. After the patients lost consciousness and following adequate mandibular relaxation, the LMA-S was inserted using a single-hand rotation technique with the cuff lubricated. The back side of the cuff was lubricated with a water-soluble gel (K-Y[®], Johnson & Johnson[™], Les Moulinaux, France), and the cuff of the mask was fully deflated before insertion. Intubation and the previous steps were carried out by the same anesthesiologist, who had at least five years of experience with an over 90% success rate in orotracheal intubation and laryngeal mask placement. Cases in which the endotracheal tube or the LMA-S was not inserted correctly were excluded from the study.

The LMA-S size was chosen according to body weight in accordance with the manufacturer guidelines (< 50 kg, size 3; 50–70 kg, size 4; 70–100 kg, size 5) and previous studies [11,12]. The ETT size was 8 in male patients and 7 in female patients (cuffed endotracheal tube). The LMA-S intracuff pressure of 60 cm H₂O was adjusted to the ETT cuff pressure of 20 cm H₂O/1 manometer (Portex Cufator Endotracheal Tube Inflator and Manometer, Portex[®] Limited, Hythe, Kent, United Kingdom) [13]. The accuracy of the airway devices used in both groups was confirmed by the lack of sound from leaking air from the mouth, the expansion of the chest during ventilation, five consecutive capnography curves on the monitor, and osculation. With the LMA-S, a nasogastric tube was inserted into the LMA drainage tube. Air leakage to the stomach was controlled by checking for bubbles (foam) at the proximal end of the nasogastric tube [14].

Anesthesia was maintained in all patients with sevoflurane 50% oxygen and air, and the sevoflurane was titrated to maintain bispectrality index (BIS) values between 40 and 60 during surgery. The depth of anesthesia was monitored using the BIS (VISTA

Monitoring System, Massachusetts, United States of America). BIS sensors were placed in the right and left frontal areas under the hairline and covered with tape to prevent exposure to light. In addition, 0.1–0.3 µg/kg/min IV remifentanyl infusion was used.

Mechanical ventilation was used in both groups in the volume-controlled ventilator mode (Dräger Primus ventilator, Dräger AG, Lübeck, Germany). The tidal volume was adjusted as 8 mL/kg and the respiratory rate was EtCO₂ of 35–45 mm Hg intraoperatively.

Outcome Measures

The primary purpose of the present study was to evaluate tracheal blood leakage in patients, who underwent septoplasty and whose airway patency was maintained by the LMA-S or the ETT, using a fiberoptic bronchoscope. At the end of the surgeries, a 3.5 mm fiberscope (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) was used to examine blood leakage through both airway devices (glottis/trachea, distal trachea). In the patients for whom an ETT was used, the posterior oropharynx was aspirated carefully at the end of the surgeries; after extubation, the presence of blood around the distal area of the ETT cuff was examined. To evaluate the presence of blood (glottis/trachea, distal trachea), a four-point scale was used (1 = absent, 2 = mild, 3 = moderate, 4 = severe) [9].

The secondary purpose of the study was to evaluate OLP; hemodynamic response, including HR and MAP; adverse events, including sore throat, nausea, and vomiting; dysphagia; and dysphonia. OLPs were measured for the LMA-S and the ETT when the head was in a neutral position. The O₂ flow was set to 3 L/min in the flowmeter, and the expiratory valve was closed. To prevent bias, one researcher covered the airway device so that the airway device type was not visible; then, another researcher checked the peak pressure value as soon as the first researcher heard an oropharyngeal leak sound, confirming that the pressure remained constant (manometer stability test) [15]. This value was recorded as the OLP. To avoid exposing the lungs to barotrauma, when the peak inspiratory pressure reached 40 cm H₂O, the expiratory valve was opened, and the test was ended. MAP and HR were measured immediately before anesthesia induction and at the 5th, 15th, 30th min of perioperatively and 5th min after the extubation and airway placement were confirmed.

In the 24-hour postoperative period, sore throat, nausea, vomiting, dysphagia, and dysphonia were recorded at the 2nd, 6th, 12th, and 24th hours. Sore throat was defined as continuous pain felt independently from swallowing, evaluated using a numeric rating scale (NRS) between 0–10. According to the NRS, the sore throat score was evaluated as “0–1 none; 2–4 mild; 5–7 moderate; and 8–10 severe” [16]. A 4-point scale was used to determine the severity of the nausea and vomiting (0 = no nausea, 1 = mild-moderate nausea, 2 = less than two vomits an hour, 3 = more than two vomits an hour). Dysphonia was defined as difficulty in speaking because of difficult speech or pain. Dysphagia was defined as difficulty in swallowing or painful swallowing¹⁷.

Postoperative Management

The patients who opened their eyes with stimuli and had regular spontaneous breathing, a respiratory rate of 12–20/minute, and an oxygen saturation larger than 95% were extubated and taken to the recovery room. The patients were transferred to the Otorhinolaryngology ward when they achieved a modified Aldrete’s score of nine or greater (on a 0–12 scale), indicating recovery sufficient for the patient to be transferred from Postoperative Care Unit (PACU) to the ward¹⁸. All patients received a standard postoperative analgesic regime of paracetamol (1g) and tramadol (1–2 mg/kg) IV.

Sample Size

A type I error (alpha) 0.05, strength of the test (1-beta) 0.9, effect size 0.71 for the amount of blood in the primary output variable airway (glottis/trachea), and the alternative hypothesis (H1) were employed as the variables used to calculate the minimum sample size. Subsequently, the minimum sample size was determined to be 40 for each group and 80 patients in total in order to find a significant difference [9].

Statistical Analysis

The data was expressed as mean with standard deviation and median (min-max) values or frequency (percentage) for overall variables. Normality distribution was assessed using the Shapiro Wilk test. Quantitative data was analyzed using the independent samples t-test and the Mann Whitney U-test, where appropriate. Qualitative data was analyzed with the Pearson chi-square or the Fisher's exact test, where appropriate. A value of $P < 0.05$ was considered as significant. IBM SPSS Statistics version 25.0 for Windows was used for the statistical analysis.

Results

A total of 80 patients were included in this study. A flow diagram is presented in Figure 1. The age, weight, height, gender, Mallampati score, BMI, and ASA values were similar in both groups. Using the LMA-S, surgery duration was 54.03 ± 13.75 min and anesthesia duration was 70.95 ± 13.55 min. Using the ETT, surgery duration was 51.48 ± 11.92 min and anesthesia duration was 69.53 ± 11.42 min. There were no statistically significant differences between the groups. The rates of success for the first insertion attempt were not significantly different between the two groups (36 (90%) in the LMA-S group and 34 (85%) in the ETT group). For all patients with an unsuccessful first insertion attempt, success was achieved in the second attempt. The demographic characteristics of the patients are given in Table I.

OLP was 21.60 ± 3.74 cmH₂O in the LMA-S group and 22.88 ± 5.52 cmH₂O in the ETT group; there was no statistically significant difference between the groups ($p = 0.577$). The blood leakage in the glottis/trachea was significantly lower in the LMA-S group in the ETT group (LMA-S: 1 (1–3) and ETT: 2 (2–4), $p = 0.004$). The blood leakage in the distal trachea was significantly lower in the LMA-S group than in the ETT group (LMA-S: 1 (1–2) and ETT: 1 (1–4), $p = 0.034$). Clinical outcome variables by airway type are presented in Table II.

HR was significantly lower in the LMA-S group at 15 min after intubation than in the ETT group ($p = 0.003$). There was no significant difference between the groups at other time points. The HR of the patients in the two groups at various time points are presented in Table III. MAP was significantly lower in the LMA-S group at 15 min after intubation than in the ETT group ($p = 0.029$). There was no significant difference between the groups at other time points. The MAP of the patients in the two groups at various time points are presented in Table IV. Sore throat was observed at the 2nd, 6th, and 12th postoperative hours to be at less significant levels ($p = 0.003$, $p = 0.017$ and $p < 0.001$, respectively). There were no differences between the groups in terms of having a sore throat at the 24th postoperative hour ($p = 0.057$). Nausea, vomiting, dysphagia, and dysphonia were similar in both groups. The postoperative adverse events are presented in Table V.

Discussion

In this study, in which LMA-S and ETT use was compared in terms of tracheal blood leakage and adverse events in septoplasty cases, the blood leakage in the LMA-S group was statistically less than in the ETT group; this was determined by examining the airway for the presence of blood with a fiberoptic bronchoscope. Sore throat had high significance levels in the ETT group at the 2nd, 6th, and 12th postoperative hours.

Many anesthetists and otolaryngologists are suspicious about using the LMA due to concerns that blood leakage from the posterior to the hypopharynx during nasal and endoscopic sinus surgery could contaminate the vocal folds and the tracheobronchial tree, causing laryngospasm and bronchospasm. Therefore, for such operations, the ETT has been the first choice for airway safety. In the literature, there are studies comparing LMA and ETT use in nasal surgeries [9,19]. However, a standardization of the cases could not be made in most studies. We achieved surgical standardization by conducting our study on septoplasty cases only. In addition, the presence of blood in the airway devices was evaluated visually, and indirect data was obtained about tracheal leakage. In our study, the presence of blood in the airway (glottis/trachea, distal trachea) was evaluated more objectively using a fiberoptic bronchoscope.

In septoplasty cases, the LMA-S avoids blood leakage to the glottis and the trachea, with its high sealing effect in the oropharynx, by surrounding the supraglottic and glottic area [9]. With the ETT, however, as the cuff is below the glottis level, blood produced during surgery can easily reach the glottis and lower parts of the airway using the outer surface of the ETT [20].

Although the ETT is considered to protect the airway better in terms of blood leakage through its traditional approach, in our study, we predicted that the LMA-S, which is a minimally invasive airway device with a high sealing pressure, would reduce blood leakage to the glottis-distal trachea line.

Kaplan et al. conducted a study in which 74 patients, who underwent septoplasty or endoscopic sinus surgery, were compared in terms of ETT and LMA-Classic use; they reported that the presence of blood in the glottis/trachea level was at a less significant level in the LMA-Classic group than in the ETT group [9]. However, they also reported that there was blood in fewer cases in the ETT group (3.2%) than the CLMA group (19.6%), although it was not statistically significant in the distal trachea. Kaplan et al. also reported that the ETT protected the distal trachea better. Williams et al. conducted a study with children and adult tonsillectomy cases using the LMA-Classic and the ETT; at the end of surgery, they observed less blood in the larynx and trachea in the LMA-Classic group when an evaluation was made using a fiberoptic bronchoscope [21]. This is in agreement with the results of our study. Ahmet et al. compared ETT and reinforced LMA use in 200 septal, sinus, and septal and sinus (combined) surgery patients and reported that the blood contamination was less in the LMA cuff in visual evaluation [20]. In the present study, blood leakage in the glottis/trachea and distal trachea was at a less significant level with the LMA-S (glottis/trachea: LMA-S: 10 cases (25%), ETT: 22 cases (45%), $p = 0.004$); distal trachea: LMA-S: 4 cases (10%), ETT: 11 cases (27.5%), $p = 0.034$). Unlike Kaplan et al., we found significantly less blood in both the glottis/trachea and the distal trachea in the LMA-S group. The reasons for the differences between the two results may be, first that our study examined only septoplasty cases, while Kaplan et al. included septoplasty, endoscopic sinus surgery, and combined septoplasty/endoscopic sinus surgery cases in their study. Second, in our study, the intracuff pressure was applied as 60 mm H₂O in the LMA-S and 20 H₂O in the ETT, but Kaplan et al. did not report any information on which intracuff pressures they used in the airway devices. Therefore, differences in cuff pressures may have affected the results. In many studies in which the LMA and the ETT were compared without using fiberoptic bronchoscopes in patients who underwent nasal and sinus surgeries, it was concluded that the LMA provided better airway protection [22]. However, visually evaluating the presence of blood in the airway is a more subjective approach than evaluating with a fiberoptic bronchoscope. In summary, we showed that the LMA-S provided better protection than the ETT in both anatomical regions of the airway.

OLP is a gas leak occurring around the airway device. In general, the verification of the position of the airway device shows the success of positive-pressure ventilation and the degree of airway protection. It is also used to evaluate the effectiveness of different airway devices [23]. Seet et al. reported that OLP was 21 cmH₂O in 99 cases in which the LMA-S was used with an intracuff pressure of 60 cmH₂O [24]. In another study, which was conducted with the LMA-S at three different intracuff pressures (80, 60, 40 H₂O) in 123 cases, OLP was measured as 26, 20, and 18 H₂O, respectively [25]. In our study, the OLP value was measured as 21.60 cmH₂O in LMA-S and 22.8 in ETT, and there were no statistically significant differences between the groups. In summary, the OLP values in these other studies are consistent with our OLP values.

HR and MAP were found to have less significant levels in the LMA-S group at the 15th minute after intubation. While a few HR and MAP differences between the two groups reached statistical significance, all results were within normal ranges and none of the differences suggested any significant clinical differences.

Postoperative sore throat is among the pharyngolaryngeal adverse events that commonly occur after general anesthesia, decreasing patient satisfaction and causing prolonged hospital stays. In addition to the direct trauma of the rigid materials that are inserted in the upper airway, the physical tension caused by the laryngoscopy, tube size, gender, surgery type, and cuff pressures may cause postoperative throat complaints after tracheal intubation [26,27]. In their study, Hermite et al. compared three different supraglottic airway devices (LMA-S, Laryngeal Mask Airway Unique (LMA-U), and the I-Gel) with an intracuff pressure of 60 cmH₂O; they reported no significant differences between the LMA-S and other airway devices in terms of postoperative sore throat [28]. For this reason, in our study, we used an intracuff pressure of 60 cmH₂O as a reference. Barreriera et al. compared LMA-S and ETT use in their study and found that the incidence of sore throat was significantly higher with the ETT when they adjusted the ETT cuff pressure to 25–30 mm cmH₂O [29]. Similarly, Radu et al. compared ETT and LMA use in breast surgery patients and found incidences of sore throat at the 6th postoperative hour to be significantly higher with the ETT [30]. In contrast, in our study, sore throat complaints were significantly lower in the LMA-S group at the 2nd, 6th, and 12th

postoperative hours ($p = 0.003$, $p = 0.017$ and $p < 0.001$, respectively). Therefore, we believe that the LMA-S causes fewer sore throats at appropriate intracuff pressures in septoplasty cases than the ETT.

CONCLUSION

As evident in our findings, we have determined that the LMA-S is superior to the ETT in protecting the airway against blood contamination and reducing postoperative sore throat associated with general anesthesia in septoplasty surgeries. We also believe that the LMA-S may be a more reliable and better alternative to the ETT for airway management in septoplasty surgeries.

Abbreviations

LMA-S: Laryngeal Mask Airway-Supreme

ETT: Endotracheal tube

OLP: Oropharyngeal leakage pressure

HR: Heart rate

MAP: Mean arterial pressure

ASA: American Society of Anaesthesiologists

BMI: Body mass index

VAS: Visual analogue scale

NRS: Numeric rating scale

Declarations

Ethics Approval And Consent To Participate

The study was approved by the Local Ethic Committee of Inonu University (Protocol no: 2018/165) and this trial is registered at the US National Institutes of Health ([ClinicalTrials.gov](https://clinicaltrials.gov)) # NCT03903679 on April 5, 2019. The patients agreed to participate in the study voluntarily. After they were informed about the potential risks and predicted results of the study, they completed the written informed consent forms.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request

Competing interests

The authors declare that they have no competing interests

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Author information

Contributions

EK, SA, ASO, ZB and CÇ collected and analyzed the data. EK and SA wrote the manuscript draft. ZB and ASO helped with the study design and interpretation of the data. EK and CÇ helped to collect and analyze the data. EK conceived the idea, designed the study, interpreted the data, and rewrote the manuscript. All authors read and approved the final manuscript

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Tables

Table I. Characteristics of the groups

Variable	LMA-S (n=40)		ETT (n=40)		p value
	Range	Mean ± SD or n(%)	Range	Mean ± SD or n(%)	
Age, years	18 - 65	34.18 ± 14.16	18 - 64	35.78 ± 13.59	0.608 ^a
Gender, male/female	-	21/19	-	19/21	0.655 ^b
Height, cm	150 - 183	168.55 ± 8.22	152 - 185	167.63 ± 9.43	0.642 ^a
Weight, kg	48 - 90	67.28 ± 9.01	47 - 105	69.63 ± 14.60	0.855 ^a
BMI, (kg/m ²)	19 - 29	23.58 ± 2.41	18 - 31	24.13 ± 3.27	0.323 ^a
ASA, n					
1	-	23 (57.5%)	-	21 (52.5%)	0.653 ^b
2	-	17 (42.5%)	-	19 (47.5%)	
Mallampati Score					
1	-	25 (62.5%)	-	26 (65.0%)	0.816 ^b
2	-	15 (37.5%)	-	14 (35%)	
LMA, Size no					
3	-	2 (5.0%)	-	4 (10.0%)	
4	-	20 (50.0%)	-	24 (60.0%)	0.348 ^b
5	-	18 (45.0%)	-	12 (30.0%)	
First attempt success rate, n (%)		36 (90%)		34 (85%)	0.735 ^b
Smoking, n (%)		12 (30%)		10 (25%)	0.802 ^b
Duration of Anesthesia, min	52 - 115	70.95 ± 13.55	50 - 98	69.53 ± 11.42	0.613 ^a
Duration of Surgery, min	35 - 100	54.03 ± 13.75	37 - 88	51.48 ± 11.92	1.48 ± 11.92
				51.48	11.923

ASA: American Society of Anesthesiology; BMI: Body Mass Index; cm: centimeter; kg: kilogram; min: minutes; n: number, SD: Standard Deviation; a: independent samples t test; b: Chi-square test.

Table II. Clinical outcomes variables by Airway type

Variable	LMA-S (n=40)		ETT (n=40)		p value
	Range	Mean ± SD or Median	Range	Mean ± SD or Median	
Oropharyngeal leak pressure (cm H ₂ O)	16 - 32	21.60 ± 3.74	18 - 37	22.88 ± 5.52	0.577 ^a
Airway blood (glottis/tracheal)					
1	(1-3)	1	1-4	2	0.004 ^b
2					
3					
4					
Distal Tracheal Blood					
1	1-2	1	1-4	1	0.034 ^b
2					
3					
4					

Airway blood (glottis/tracheal and distal tracheal) scores: 1= none, 2=mild, 3= moderate, 4= severe; a: independent samples t test; b: Chi-square test. LMA-S: Laryngeal Mask Airway Spreme, ETT: endotracheal tube.

Table III. Heart rate of patients at various timepoints in two groups

Variable	LMA-S (n=40)		ETT (n=40)		p value
	Range	Mean ± std	Range	Mean ± std	
Baseline	60– 115	84.50± 14.65	58– 121	82.78 ± 14.07	0,647 ^a
After intubation					
5 th min	52-98	75.20 ± 12.07	54 – 119	80,30 ± 15.20	0.127 ^a
15 th min	51– 90	70.58 ± 11.16	53–116	81.15 ± 16.13	0.003 ^a
30 th min	57– 96	74.43 ± 9.54	60 – 110	77.93 ± 12.13	0.264 ^a
After extubation					
					0.878 ^a
5 th min	56 –104	77.25 ± 10.60	63 – 103	77.73 ± 9.98	

a: independent samples t test;

Table IV. Mean arterial pressure of patients at various timepoints in two groups

Variable	LMA-S (n=40)		ETT (n=40)		p value
	Range	Mean ± std	Range	Mean ± std	
Baseline	60 – 115	89.88 ± 13.59	57– 114	84.23 ± 16.18	0.083 ^a
After intubation					
5 th min	43-94	70.63 ± 11.16	46 – 118	74.30± 16.06	0.438 ^a
15 th min	57– 121	71.7± 14.78	57 – 121	79.03 ± 15.04	0.029 ^a
30 th min	49 – 98	71.28 ± 11.39	47 – 112	75.25 ± 13.38	0.260 ^a
After extubation					
					0.988 ^a
5 th min	56 – 95	74.53 ± 9.80	56 – 105	75.00 ± 72.50	

a: independent samples t test;

Table V: Postoperative adverse events

Variable	LMA-S (n=40)				ETT (n=40)				p values			
	n				n							
	(%)				(%)							
	2 nd hour	6 th hour	12 th hour	24 th hour	2 nd hour	6 th hour	12 th hour	24 th hour	P _{2nd} ^a	P _{6th} ^a	P _{12th} ^a	P _{24h} ^a
Postoperative period												
Sore throat	28/8/4/0	28/11/1/0	37/3/0/0	39/1/0/0	15/8/14/3	16/17/6/1	22/14/4/0	39/1/0/0	0.003	0.017	<0.001	0.057
(None/mild/moderate/severity)	(70/20/10/0)	(70/28/2/0)	(92.5/7.5/0/0)	(97.5/2.5/0/0)	(37.5/20/35/7.5)	(40/42.5/15/2.5)	(55/35/10/0)	(97.5/2.5/0/0)				
Nausea-vomiting	28/7/5/0	35/3/1/1	38/1/1/0	39/1/0/0	29/4/6/1	36/0/4/0	39/1/0/0		0.76	0.12	0.61	1
(0/1/2/3)*	(70/17.5/12.5/0)	887.5/7.5/2.5/2.5	(95/2.5/2.5/0)	(97.5/2.5/0/0)	(72.5/10/15/2.5)	(90/0/10/0)	(97.5/2.5/0/0)	40/0/0/0				
							(100/0/0/0)					
Dysphagia	35/5	39/1	40/0	40/0	33/7	34/6	37/3	37/3	0.75	0.10	0.24	0.24
(Absent/present)	(87.5/12.5)	(97.5/2.5)	(100/0)	(100/0)	(82.5/17.5)	(85/15)	(92.5/7.5)	(92.5/7.5)				
Dysphonia	38/2	37/3	38/2	39/1	37/3	37/3	38/2	39/1		1	1	1
(Absent/present)	(95/5)	(92.5/7.5)	(95/5)	(97.5/2.5)	(92.5/7.5)	(92.5/7.5)	(95/5)	(97.5/2.5)	1			

*Nausea and vomiting score: 0=none, 1=mild-moderate nausea, 2 = vomiting less than 2 times per hour, 3 = vomiting more than 2 times per hour; a: Pearson chi-square test.

Figures

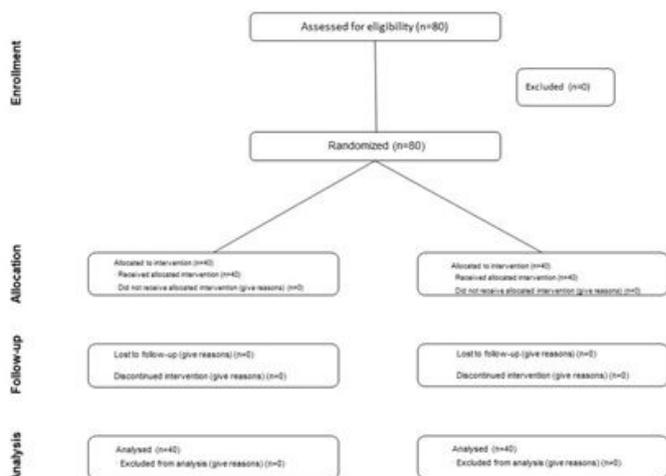


Figure 1

Flow Diagram CONSORT flow chart for patients' recruitment