A clinical trial evaluating the laryngeal mask airway-Supreme in obese children during general anesthesia

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Abstract

Introduction: The laryngeal mask airway (LMA)-Supreme is a disposable double-lumen laryngeal mask airway that is widely used in clinical practice. However, its use in obese children has not been evaluated. The aim of this study was to determine whether the LMA-Supreme could perform equally as well as endotracheal intubation in obese children having a minor surgical procedure.

Material and methods: After ethical board approval, 100 obese male children receiving non-emergent appendectomy for chronic appendicitis or surgery to correct concealed penis were randomly divided into an endotracheal intubation group and an LMA-Supreme group. Endotracheal intubation was performed under direct vision laryngoscopy. In the LMA group, a size-3 LMA-Supreme was placed and a stomach tube inserted via the drainage tube of the mask. Cardiovascular and respiratory parameters, time taken for placement, placement attempts, time to removal of the endotracheal tube/LMA, length of stay in the post-anesthesia care unit (PACU), and complications were recorded.

Results: Insertion time was significantly longer ($p < 0.001$) in the LMA-Supreme group than in the endotracheal intubation group. Peak airway pressure was significantly higher, and pulmonary compliance and PACU stay time lower in the LMA-Supreme group. No significant differences between endotracheal intubation and the LMA-Supreme were seen in other parameters, except for a higher incidence of coughing in the endotracheal intubation group.

Conclusions: The LMA-Supreme can be easily inserted and effectively used for airway management in obese children undergoing minor surgery.

Key words: laryngeal mask airway, ventilation, obese children, peripheral oxygen saturation, airway sealing pressure.

Introduction

The laryngeal mask airway (LMA)-Supreme is a new disposable double-lumen laryngeal mask airway developed according to the principles used in designing the ProSeal LMA, a device that has an esophageal drainage tube and is widely used in clinical practice [1]. The size-2 and size-3 LMA-Supreme can be used for children [2, 3], and the mask design has a number of advantages compared to the LMA-Unique including a tube that can be used for insertion of a stomach tube to prevent intraoperative aspiration due to the gastroesophageal reflux that can occur in patients with high abdominal pressure. A single-lumen LMA does

not have this advantage. The double-lumen LMA can be used for normal weight or obese adults, and also for normal weight children [3–5]. However, whether use of the LMA-Supreme can ensure good ventilation for obese children has not been clarified.

The thick abdominal wall and high abdominal pressure in obese patients make them prone to intraoperative reflux of gastric contents, either food or, in the case of fasted patients, gastric fluid. The LMA-Supreme can be used in laparoscopic gynecological surgery and laparoscopic cholecystectomy that requires an increase in abdominal pressure in order to create a pneumoperitoneum [4, 6–10], and therefore it can be used in surgery for patients with high abdominal pressure due to other causes, such as obesity.

The incidence of childhood obesity is increasing [11, 12], and anesthetizing the obese child is associated with an increased risk of difficult mask ventilation and adverse perioperative respiratory events [13–15]. However, few reports about airway management of obese children using the LMA-Supreme have been published. Because the LMA-Supreme can be used in surgery for obese adult patients [4, 16], we hypothesized that the LMA-Supreme would perform equally well in ventilation efficiency compared to tracheal intubation in obese children undergoing minor surgery, such as laparotomy for appendectomy or surgery to correct concealed penis. Obese children with appendicitis often have to undergo surgery because conservative treatment may easily result in perforation [17]. Furthermore, a concealed penis, a penis buried or concealed by the pubic fat pad due to various reasons, is often observed in obese children [18].

In the current study, we used the size-3 LMA-Supreme in general anesthesia of obese children undergoing surgery for non-emergent appendectomy or concealed penis, and compared its ventilation efficiency with that of endotracheal intubation.

Material and methods

The present study was approved in advance by the Ethics Committee of Shengjing Hospital of China Medical University, and written informed consent was obtained from the parents of the children. Obese male children who underwent elective surgical correction of concealed penis or non-emergent appendectomy at our hospital between November 2011 and January 2013 were eligible for inclusion in the study. Obesity was defined by the body mass index (BMI) classification recommended by the Working Group of Obesity, China (WGOC). According to the recommendation, a child between 7 and 18 years of age is defined as obese if their BMI is above the 95th percentile of the BMI of children of the same age and sex, based on reference curves for the Chinese population [19–23]. Other inclusion criteria were: American Society of Anesthesiologists (ASA) grade I or II; 7–12 years old; 30–60 minutes operative time. Exclusion criteria were: respiratory infection (cough, fever, and rhinorrhea), abnormal airway anatomy or preoperative evaluation suggesting a difficult airway, asthma, gastroesophageal reflux disease (dysfunction of the lower esophageal sphincter) or hiatal hernia leading to the separation of the lower esophageal sphincter from the diaphragm angle, laparoscopic surgery, surgery requiring a head-down position, and severe obstructive sleep apnea syndrome (dyspnea and obstruction more than 66% of the time during sleep).

Patients were randomized in a 1 : 1 manner to receive either endotracheal intubation or the LMA-Supreme. The allocation order was hidden from the researchers responsible for recruiting patients. The grouping details were written on cards of the same size, placed in sealed opaque envelopes that were sequentially numbered, and provided by the secretary of the hospital research center. The envelope was given to a single specialized anesthesiologist, who had previously inserted the LMA-Unique more than 100 times, when patients entered the operating room, and then the corresponding intervention (tracheal intubation or laryngeal mask placement) was performed based on the allocation sequence in the envelope. Patient assessment and data were collected independently by another researcher, who did not participate in data analysis and results evaluation. Finally, the statistician who performed the data analysis and results evaluation did not know the details of grouping.

Fasting was required 6–8 h before surgery for every child, including those undergoing appendectomy (the appendectomy subjects had chronic appendicitis and emergent surgery was not required). No preoperative medication was given. Blood pressure, electrocardiogram, and peripheral oxygen saturation (SpO_2) were monitored routinely. Subjects were oxygenated for 5 min through a face mask before anesthesia was initiated. Fentanyl (2 µg/kg), propofol (2 mg/kg), and succinylcholine (1.5 mg/kg) were given for induction, and vecuronium (0.8 mg/kg) for maintenance in both groups. Ideal body weight, rather than actual weight, was used to determine the doses; thus, the total dosage for the two groups was similar. After induction of anesthesia, all children received 15 mg/kg intravenous paracetamol (Perfalgan; UPSA Laboratories, Agen, France) for the control of postoperative pain, and 0.1 mg/kg intravenous dexamethasone for the control of postoperative nausea and vomiting.

In the endotracheal intubation group, the tube size was selected according to the patient's age (3.5 + age/4), and intubation was performed under direct vision laryngoscopy. A size-3 LMA-Supreme (Laryngeal Mask Company, Singapore) was inserted in the LMA group. For insertion, the air inside the cuff of the mask was removed completely, water-soluble lubricant was applied on the dorsal surface, and the child was placed in a head-down position. The LMA-Supreme was inserted until it met resistance from the bottom of the pharynx. The cuff was then inflated to 40 mm Hg, and a size-12 stomach tube was inserted through the drainage tube of the mask. No stomach tube was used in the endotracheal group. Capnography, the presence of bilateral chest movements, and the gel displacement test were used to determine successful placement of the LMA tube. The gel displacement test was performed by placing a blob of water-soluble jelly over the drainage tube and looking for its ejection during gentle manual ventilation. Displacement of the gel indicated a gas leak into the drainage tube, and required the LMA to be repositioned.

Successful endotracheal intubation or LMA insertion was defined as visual observation of rise and fall of the chest with ventilation, normal end-tidal carbon dioxide ($PetCO_2$) waveform, even bilateral breath sounds, and no air leakage detected at the outer end of the drainage tube [3]. Unsuccessful insertion was defined as an endotracheal tube or LMA-Supreme insertion attempt that lasted 45 s or misplacement of the device. A "failed attempt" was defined as removal and re-insertion of the device. In the LMA group, if the insertion of the LMA-Supreme did not succeed after three trials or if severe air leakage occurred during surgery, the mask was removed and endotracheal intubation was performed.

Positive pressure mechanical ventilation was carried out in both groups using the Primus anesthesia machine (Draeger AG, Lübeck, Germany). Tidal volume was set at 10 ml/kg, ventilation frequency was 12–18 times/min, and the inspiratory to expiratory ratio was 1 : 2. Sevoflurane (2–3%) was given by inhalation, and the fresh gas flow was 2 L (O_2 : N_2O = 1 : 1). Ventilation was considered optimal if the partial pressure of end-tidal carbon dioxide ($PetCO_2$) was 4.6–5.8 35–45 mm Hg, and failed if it was > 52 mm Hg. Oxygenation was maintained at a SpO_2 > 95% and considered failed at a SpO_2 < 90%.

Ten minutes after successful insertion and ventilation, respiratory parameters for five consecutive breaths were measured (expiratory tidal volume, peak airway pressure, $PetCO_2$, lung compliance) and the means were calculated. Oxygen saturation, mean arterial pressure and heart rate values were recorded before induction of anesthesia (T_0), before placing the endotracheal tube/LMA (T_1), immediately after placing the tracheal tube/LMA (T_2), 3 min after placing the endotracheal tube/LMA (T_3), immediately after removing the endotracheal tube/LMA (T_4), and 3 min after removing the endotracheal tube/LMA (T_5). We also recorded (1) the time taken to insert the tracheal tube/LMA (from the time of removing the face mask to the time of successful placement) and the number of insertion attempts, (2) respiratory mechanic parameters 10 min after mechanical ventilation was stabilized, (3) time to removal of endotracheal tube/LMA (the time from discontinuation of sevoflurane until removal of the endotracheal tube or LMA), (4) the success rate of intraoperative ventilation.

After surgery, all children were sent to the post-anesthesia care unit (PACU). Length of stay in the PACU and complications in the peri-extubation period (before transfer to the PACU) were recorded by independent researchers. Complications recorded in the recovery period after extubation (after transfer to the PACU) were emergence agitation [24, 25], sore throat, and gastric distention.

Expiratory tidal volume was defined as the primary endpoint, and the secondary endpoints were $PetCO_2$, peak airway pressure, pulmonary compliance, the frequency of placement, and the success rate of intraoperative ventilation.

Sample size calculation

Assuming the LMA-Supreme could perform equally well as endotracheal intubation in expiratory tidal volume with a tolerance limit of 0.5 ml/kg, the expected background standard deviation was set as 0.8 ml/kg. Based on the above assumptions, 88 patients (44 for each group) were required to be 80% certain that the limits of a two-sided 90% confidence interval (CI) would exclude a difference in means of more than 0.5 ml/kg.

Statistical analysis

Continuous data were presented as mean and standard deviation, and categorical data as number and percentage. Differences between the two independent groups were tested with the independent two sample *t*-test and Fisher's exact test for continuous and categorical data, respectively. The change trends between various time points within a group were analyzed by the repeated measurement ANOVA with Bonferroni correction. A two-tailed *p*-value < 0.05 was considered statistically significant. Statistical analyses were assessed by using SPSS 15.0 statistics software (SPSS Inc, Chicago, Illinois, USA).

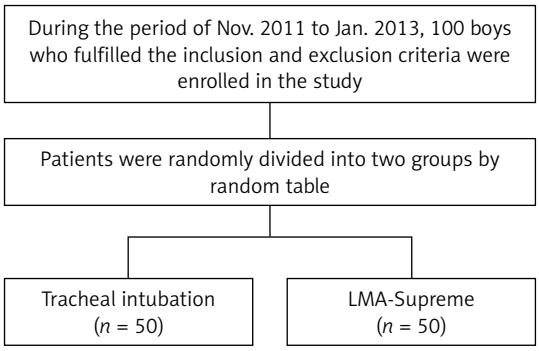

Figure 1. CONSORT diagram of study

Results

During the period from November 2011 to January 2013, 100 boys who fulfilled the inclusion and exclusion criteria were enrolled in the study and randomly divided into two groups: the endotracheal intubation group (n = 50) and the LMA-Supreme group (n = 50) (Figure 1). In the endotracheal intubation group, 24 patients received penile surgery and 26 appendectomy, and in the LMA group 26 received penile surgery and 24 appendectomy. The groups were similar with respect to surgery time and baseline characteristics of age, height, weight, BMI, or obesity type (all, $p > 0.05$) (Table I).

The insertion time for the LMA-Supreme was significantly longer than the time taken for endotracheal intubation (mean 22.2 vs. 15.3 s, $p = 0.001$). Almost all patients in the endotracheal intubation group (96.0%) had only one intubation attempt, but two boys required two attempts. Eighty-two percent of the patients (n = 41) in the LMA-Supreme group had only one placement, but 6 required 2 attempts and 3 required 3 attempts. The difference in the frequency of placement attempts between the two groups did not reach statistical significance ($p = 0.082$).

Successful ventilation was achieved in all patients. No significant difference was observed between the two groups in expiratory tidal volume or $PetCO_2$. Peak airway pressure was significantly higher ($p = 0.032$), and pulmonary compliance and PACU stay time were significantly lower in the LMA-Supreme group than in the endotracheal intubation group ($p = 0.008$, $p = 0.035$, respectively). There was no significant difference between groups in complications after surgery, except for cough, which was significantly more frequent in the endotracheal intubation group (70.0% vs. 4.0%, $p < 0.001$) (Table II).

The mean arterial pressure (MAP) of the LMA-Supreme group remained stable at 60 mm Hg during and after placement. The MAP of the endotracheal intubation group was also stable except at 3 min after placement (T_3), when it was significantly higher than at the other five time points (80.0 mm Hg at T_3 vs. 63.8, 61.7, 61.4, 63.4, 64.8 mm Hg at T_0, T_1, T_2, T_4, T_5, respectively, all $p < 0.001$), and significantly higher than the LMA-Supreme group at the same time point (80.0 mm Hg vs. 59.4 mm Hg, $p < 0.001$) (Figure 2).

The heart rate of the LMA-Supreme group remained stable at about 95 beats/min at all time points, but the heart rate of the endotracheal intubation group increased significantly immediately after placement (T_2), immediately after removal (T_4), and 3 min after removal (T_5) compared to the other three time points (115.4, 117.6, 113.6 beats/min vs. 97.2, 96.4, 95.8 beats/min, respectively, $p \leq 0.003$), and compared to the LMA-Supreme

Table I. Patient characteristics

Parameter	Tracheal intubation (N = 50)	LMA-Supreme (N = 50)	P-value
Age [years]†	9.2 (1.4)	9.0 (1.4)	0.575
Height [cm]†	138.3 (5.6)	139.1 (4.6)	0.460
Weight [kg]†	44.4 (5.4)	45.4 (4.0)	0.318
BMI [kg/m²]†	23.1 (1.3)	23.4 (0.8)	0.165
Obesity type:			
Mild	18 (36.0%)	14 (28.0%)	0.521
Moderate	32 (64.0%)	36 (72.0%)	
Surgery:			
Reconstructive penile surgery	24 (48.0%)	26 (52.0%)	0.842
Appendectomy	26 (52.0%)	24 (48.0%)	
Surgery time [min]†	45.0 (8.1)	46.7 (6.4)	0.233

†*Data are presented as mean and standard deviation; other categorical data are presented as number and percentage. Mild obesity: weight 20% to 29% greater than average weight for an individual of the same age. Moderate obesity: weight 30% to 39% greater than average weight for an individual of the same age.*

Table II. Comparison of surgical characteristics and complications between the two groups

Parameter	Tracheal intubation (*N* = 50)	LMA-Supreme (*N* = 50)	*P*-value
Placement time [s]†	15.3 (5.8)	22.2 (12.7)	0.001*
Placement attempts:			
1	48 (96.0%)	41 (82.0%)	0.082
2	2 (4.0%)	6 (12.0%)	
3	0 (0.0%)	3 (6.0%)	
Expiratory tidal volume [ml/kg]	7.6 (1.0)	7.3 (0.8)	0.098
$PetCO_2$ [mm Hg]†	40.7 (3.8)	41.3 (2.1)	0.330
Peak airway pressure [cm H_2O]†	18.1 (2.4)	19.0 (1.9)	0.032*
Pulmonary compliance [ml/cm H_2O]†	21.1 (2.7)	19.6 (2.9)	0.008*
Time of extubation/LMA removal [min]†	10.2 (2.1)	9.8 (2.0)	0.289
PACU stay time [min]†	20.0 (4.2)	18.4 (3.4)	0.035*
Complications:			
Laryngospasm	2 (4.0%)	0 (0.0%)	0.495
Cough	35 (70.0%)	2 (4.0%)	< 0.001*
Mucosal injury	4 (8.0%)	6 (12.0%)	0.741
Sore throat	8 (16.0%)	6 (12.0%)	0.774
Gastric distension	0 (0.0%)	2 (4.0%)	0.495
Emergence agitation	10 (20.0%)	4 (8.0%)	0.148

*PACU – post-anesthesia care unit. *P-value < 0.05 indicates a significant difference between groups. †Data are presented as mean and standard deviation; other categorical data are presented as number and percentage. Laryngospasm: increased effort in respiration, wheezing on auscultation, desaturation, and prolonged expiration time. Mucosal injury: blood staining on removal. Sore throat: constant pain, independent of swallowing. Gastric distention: hyperinflation on inspection or hyper-resonance on percussion of the epigastrium. Emergence agitation: a dissociated state of consciousness in which the child is irritable, uncompromising, incoherent, and inconsolably crying, moaning, kicking or thrashing.*

group at the same time points (T_2: 115.4 beats/min vs. 96.8 beats/min, $p < 0.001$), before removal (T_4: 117.6 beats/min vs. 95.30 beats/min, $p < 0.001$), and 3 min after removal (T_5: 113.6 beats/min vs. 96.8 beats/min, $p < 0.001$) (Figure 3).

The SpO_2 of the two groups remained stable at 99–100% at all times measured, and no significant difference between the groups was observed (all, $p > 0.05$) (Figure 4).

Discussion

In the current study, the use of the LMA-Supreme during anesthesia of obese children undergoing minor surgery gave similar respiratory and airway management values compared to endotracheal intubation, except that the incidence of coughing during LMA removal was significantly less than that seen during extubation. Jagannathan *et al.* [3] observed no coughing upon removal in a cohort evaluation of the LMA-Supreme in children. Successful ventilation (adequate abdominal movement, square wave capnography, $PetCO_2$ 35–45 mm Hg) was achieved in all children.

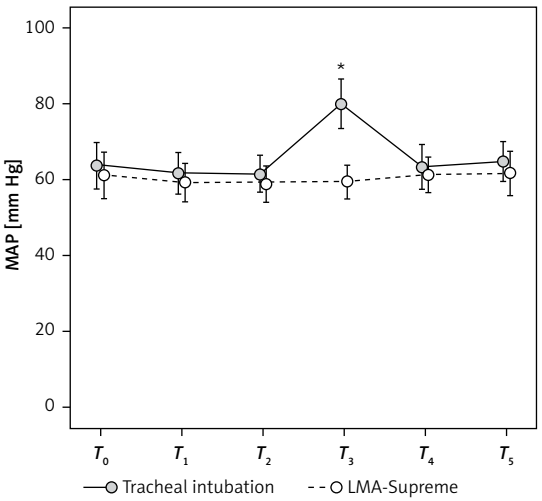

Figure 2. Comparison of mean arterial pressure (MAP) between the two groups

*T_0 – before anesthesia, T_1 – before placement, T_2 – immediately after placement, T_3 – 3 min after placement, T_4 – before removal, T_5 – 3 min after removal. *Indicates that a significant difference was observed between two groups at the time point.*

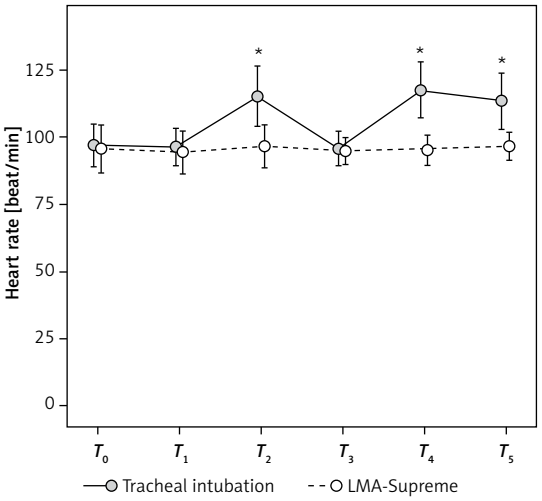

Figure 3. Comparison of heart rate between the two groups

*T_0 – before anesthesia, T_1 – before placement, T_2 – immediately after placement, T_3 – 3 min after placement, T_4 – before removal, T_5 – 3 min after removal. *Indicates that a significant difference was observed between two groups at the time point.*

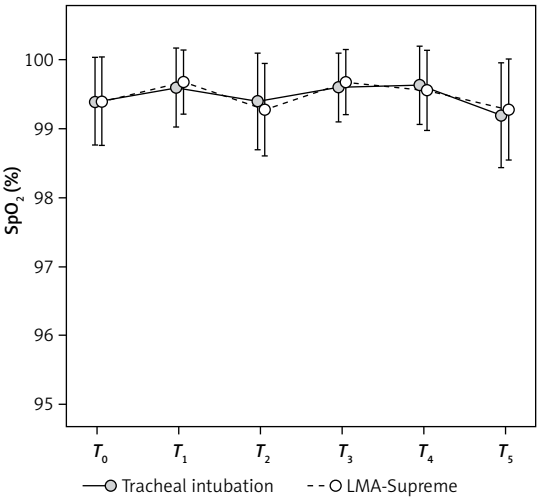

Figure 4. Comparison of SpO_2 between the two groups

T_0 – before anesthesia, T_1 – before placement, T_2 – immediately after placement, T_3 – 3 min after placement, T_4 – before removal, T_5 – 3 min after removal.

The LMA-Supreme is a new disposable double-lumen LMA composed of a curved rigid ventilation tube, a drainage tube for inserting a stomach tube, and a relatively large ventilation cuff [1]. It is widely used in clinical practice, including in adult laparotomy and laparoscopic surgery [6, 10], minor pediatric surgery [2, 3], airway management of obese adult patients [13, 16], and patients with known difficult airways [26]. During laparoscopic surgery, the airway sealing pressure using the LMA-Supreme was reported to be as high as 26.8 ±4.1 cm H_2O, and the maximum inspiratory tidal volume as high as 475 ±55 ml [10]. These findings suggest that this laryngeal mask device can meet clinical requirements even when a high airway resistance is present.

Obese children are commonly seen in clinical practice. These patients have a small mouth opening and a reduced degree of head-tilt-back, which contributes to increased difficulty of intubation. Our results showed that the LMA-Supreme could be successfully inserted in obese children within three attempts. Though our previous experience with the use of the LMA-Supreme in obese children was limited, the success rate for first-time insertion reached 82%, and no air leakage from the laryngeal mask occurred. In addition, peak airway pressure was controlled within an acceptable range (< 35 cm H_2O), and there was no significant difference from the endotracheal intubation group in respiratory mechanical parameters. These results show that the LMA-Supreme is well tolerated, and can achieve an accurate alignment in obese children.

This success may be related to the following specific features. First, the LMA-Supreme design is similar to that of the intubating laryngeal mask, and it can be inserted directly without a guiding device or moving the head and neck of the patient. Hence, its manipulation is very easy. Second, the mask was designed with a low volume cuff. Therefore, its width and thickness are much smaller than those of the Proseal or Unique LMA of the same size after removing the air within the mask. Third, the hard tube fixes the mask during the operation, and no displacement occurs between it and the oropharyngeal tissue [1, 6].

In the current study, the manipulation time for the LMA-Supreme group was longer than that for the tracheal intubation group ($p < 0.05$). A possible reason is that we did not have enough experience in the insertion of the LMA-Supreme in children. In addition, at times appropriate adjustment was needed when inserting the LMA-Supreme in obese children, and this extended the manipulation time. Excessive lengthening of the manipulation time may result in hypoxemia because the LMA-Supreme cannot be connected to the anesthesia machine. However, the longer manipulation time seen was not of clinical significance, because no hypoxemia occurred during the LMA insertion.

Repeated manipulation may also damage the oropharyngeal mucosa, and result in postoperative sore throat or hoarseness. However, because no brute force is needed for LMA insertion, and because the smooth surface of the LMA-Supreme does not cause serious damage to the laryngopharyngeal mucosa, the incidence of postoperative complications is relatively low. In the current study, no laryngospasm or hoarseness occurred in the LMA-Supreme group. Although hiccups oc-

curred in 1 patient after recovery from anesthesia, because of the preset stomach tube no regurgitation-induced aspiration occurred during the hiccups. The incidence of sore throat and mucosal injury in the LMA-Supreme group was similar to that seen in the tracheal intubation group. Appropriate LMA size selection is very important for obese children to ensure adequate intraoperative ventilation. Kim *et al.* [27] found that though development of oropharyngeal cavity is mainly related to age, a higher oropharyngeal leak pressure can be obtained if body weight is used when selecting the double-lumen LMA for obese children, thus making ventilation safer and more effective. In the current study, the body weight of the children ranged from 33 to 50 kg; therefore we used the size-3 LMA-Supreme.

There are limitations of the current study. Appendectomy and surgical correction of concealed penis are relatively minor procedures, and the operative time is less than 60 min for both types of surgery. Studies should be carried out for overweight children undergoing longer surgery in order to further verify the efficacy of the LMA-Supreme. The sample size was relatively small, and all patients were male. The current study only used the size-3 LMA-Supreme, and not the size-2 Supreme. Therefore, we cannot deduce that "the size-2 LMA-Supreme also can be used for preschool obese children", and this hypothesis should be studied in the future. Because the current study was carried out for children with mild to moderate obesity (BMI was less than the 99th percentile in all cases), our conclusions may not apply to morbidly obese children. We used data from two types of surgery, while data from only one type of surgery would have minimized selection bias. However, previous preliminary research by our team showed that both the operative time and postoperative pain in children in these procedures were similar, and the effect of either type of surgery on airway pressure was minimal.

In conclusion, the results show that the LMA-Supreme can be effectively used for airway management of obese children undergoing minor surgery. The ventilatory outcome is similar to that of endotracheal intubation, and coughing is significantly reduced.

Conflict of interest

The authors declare no conflict of interest.

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