Comparison of proseal laryngeal mask and endotracheal tube for airway safety in pediatric strabismus surgery

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ABSTRACT

الأهداف: مقارنة سلامة مجرى الهواء للقناع الحنجري الساد مع الأنبوب الداخل الرغامي والمحافظة على سلامة الاستخدام والاتزان الديناميكي في جراحة الحول لدى الأطفال.

الطريقة: تم إجراء دراسة استرجاعية عشوائية في قسم التخدير،، كلية الطب، جامعة غازي عنتاب، تركيا خلال الفترة من أبريل 2008م حتى يوليو 2009م. تم اختيار 80 طفلاً تتراوح أعمارهم مابين (12–1) عام أوزانهم (30–10) كلغ خضعوا لجراحة الحول. تم إعطائهم جرعة التخدير والتي تحتوي على 8% سولفارين، 50% أكسيد النيروز، خليط الأوكسجين، وحصار عصبي عضلي مع5 ملغ/كلغ أتراكوريوم في كلا المجموعتين. بعد جرعة مناسبة من التخدير تم تقسيم الأطفال عشوائياً إلى مجموعتين: مجموعة القناع الحنجري الساد عدد=40 طفل، ومجموعة داخل الأنبوب الرغامي عدد=40 طفل وتم استعمال أداة للسيطرة على المسالك الهوائية أما الأنبوب داخل الرغامي أو القناع الحنجري الساد. تم قياس عدد محاولات التغيير، المحاولات الناجحة والفاشلة لأنبوب شفط المعدة خلال العملية والمضاعفات الجانبية خلال العملية الجراحية.

النتائج: تم استخدام القناع الحنجري الساد لدى 38 مريض (95%) في مجموعة القناع الحنجري الساد و39 مريض (97.5%) في مجموعة داخل الأنبوب الرغامي وكانت المحاولة الأولى ناجحة $p>0.05$. أظهرت النتائج أنه لايوجد أي اختلاف إحصائي جوهري في مؤشر الدينماكية، وثاني أكسيد الكربون، والأعراض الجانبية.

خاتمة: يعد القناع الحنجري الساد وسيلة بديلة للأنبوب الداخل الرغامي وحيث أن التهوية بالضغط الإيجابي خيار مفضل للأطفال الذين خضعوا لجراحة الحول.

Objectives: To compare proseal laryngeal mask airway (PLMA) with an endotracheal tube (ET) for airway safety, maintained ease of insertion, and hemodynamic stability in pediatric strabismus surgery (PSS).

Methods: This prospective-randomized clinical study was carried out in the Department of Anesthesiology, Faculty of Medicine, Gaziantep University, Turkey between April 2008 and July 2009. Eighty American Society of Anesthesiology (ASA) I-II children, weight 10-30 kg, aged between 1-12 years undergoing PSS were selected. The anesthesia was induced with 8% sevoflurane, 50% nitrous oxide/oxygen mixture, and a neuromuscular blockade with 0.5 mg/kg atracurium in both groups. After a sufficient dosage of anesthesia, the patients were randomized into 2 groups (Group P: PLMA, n= 40, Group T: ET, n=40) and an airway management device; either a PLMA or ET was inserted. The number of placement attempts, placement success or failure, success or failure of a gastric suction tube placement during the procedures and perioperative complications were assessed.

Results: Thirty-eight patients (95%) in the PLMA group, 39 (97.5%) patients in the ET group were successfully placed with a PLMA and ET on the first attempt ($p>0.05$). There were no statistically significant differences in the hemodynamic parameters, end-tidal carbon dioxide, and complications.

Conclusion: This study revealed that PLMA may offer an alternative airway to ET wherein positive pressure ventilation was the preferred choice for children undergoing PSS.

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During strabismus surgery, the immobility of the patients is crucial in order to prevent complications. Therefore, general anesthesia is the preferred method in pediatric ophthalmic surgery. Oro-tracheal intubation is the preferred method in these operations in order to keep the airway open.[1-3] Maintaining airway patency is a very challenging issue for the anesthesiologist; enable the region to be kept sterile when shared with the surgeon. More importantly an increased risk of arrest due to oculo-cardiac reflex and malign hyperthermia emphasizes airway security.[4] Endotracheal intubation (ET) needs expertise, a deeper anesthesia and also has the risk of potentially life threatening complications (bronchospasm and laryngospasm, oropharingeal trauma, and so forth); therefore, an alternative method may be beneficial.[3,5-12] ProSeal Laryngeal Mask Airway (PLMA; Laryngeal Mask Company, Henley-on-Thames, United Kingdom), is gaining popularity in pediatric anesthesia.[6,7,13-15] ProSeal Laryngeal Mask Airway is an alternative airway device with a modified cuff and esophageal drain tube. It helps to prevent gastric aspiration and/or insufflations, facilitates gastric tube insertion, and provides information regarding the position of the device owing to its properties.[14-17] Furthermore, when compared with the conventional technique of tracheal intubation, reduced risk of laryngeal trauma may be theoretical advantage of PLMA.[17] As far as we know, there is no report in the English literature comparing PLMA and ET regarding strabismus surgery in pediatric patients.

The aim of this study is to compare PLMA with ET for airway safety, ease of insertion, maintenance of hemodynamic stability, and the adverse effects in pediatric strabismus surgery.

Methods. Ethical approval for this study (Ethical Committee No. 04-2008/83) was provided by the Ethical Committee of Gaziantep University Hospitals, Gaziantep, Turkey. This study was performed according to the principles of Helsinki Declaration.

Eighty children, weighing between 10-30 kg, with American Society of Anesthesiology (ASA) physical status I-II children, aged between 1-12 years and undergoing strabismus surgery, were enrolled for the present study after obtaining informed parental consent. This randomized, clinical study was designed and performed at the Research Hospital at the Medical School, University of Gaziantep between April 2008 and July 2009.

Preoperatively, the oral cavity was evaluated according to the Mallampati classification system. Patients with a possibility of a difficult airway (Mallampati 3-4, mouth opening <3 cm) risk of aspiration, signs of upper airway infection, and/or a history of asthma, were excluded from the study. Hemodynamic parameters (mean arterial pressure [MAP], heart rate [HR], end-tidal carbon dioxide [ETCO2], and peripheral oxygen saturation [SpO2]) were recorded at 1, 5, and 10 minutes after the PLMA or ET placement. The anesthesia was induced with 8% sevoflurane (Sevorane, Abbott, USA), 50% nitrous oxide/oxygen mixture, and a neuromuscular blockade with 0.5mg/kg atracurium (Tracrium, Glaxosmith-Kline, United Kingdom) in both groups.

After a sufficient dosage of anesthesia (loss of eyelash reflex, loss of movement to chin lift-jaw thrust) the patients were randomized into 2 groups (Group P: PLMA, n=40; Group T: ET, n=40) and an airway management device, either a PLMA or ET was inserted. The randomization was performed by the opening of a sealed envelope by a nurse who was unaware of the study. The size selection of the PLMA was based on patient weight, as recommended by the manufacturer's instructions (size 3 for 20-30 kg, size 2 for 10-20 kg, and 1.5 for 5-10 kg) and an appropriate ET size was selected using formula, (age=year/4) + 4.5mm for uncuffed and (age=year/4) + 4mm for cuffed tubes and absence of leak during manual ventilation was ensured. If a leak was detected around the uncuffed tube, the next higher size was used.[7] The PLMA was inserted according to the manufacturers' instructions using a standard midline digital insertion technique, and tracheal intubation was performed by a laryngoscopy with a Macintosh blade. Before insertion, the cuff of the PLMA was deflated, and a water-soluble lubricant was applied to the dorsal surface of the cuff. The position of the inserted PLMA was adjusted by placing a gastric tube and decompressing the gastric fluid of the patients and auscultating the chests of the patients while they were manually ventilated and successful insertion was confirmed with a capnograpy. A clear airway and optimal airway ventilation was judged by a square-wave capnogram and adequate thoracoabdominal

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movement.[3,7] Gastric insufflation was assessed by listening through a stethoscope over the epigastrium.[13] Gastric tube placement was confirmed by the aspiration of stomach contents. The insertion of the PLMAs and the intubation of the endotracheal tubes were performed by an experienced anesthesiologist, and all data collected was assessed by a second anesthesiologist. The number of insertion attempts (PLMA and ET) was recorded. If the PLMA insertion was unsuccessful after 3 attempts, an alternative airway device (endotracheal tube) was used. An effective airway was defined as 2 consecutive breaths with an expired tidal volume of 6 mL/kg. The anesthesia was maintained with 2-3% sevoflurane and 50% nitrous oxide in oxygen. Patients were ventilated with positive pressure ventilation with a tidal volume set to 10 ml/kg. The respiratory rate was set to maintain end-tidal CO2 between 35 and 45 mm Hg (4.6-5.8 kPa). The PLMA and ET size, intraoperative, and postoperative complications such as desaturation (decrease of SpO2 by 5% below baseline for >30s), dislodgement of the device, airway obstruction, laryngo-bronchospasm (described as sudden increase of airway pressure, wheezing on auscultation, prolonged expiratory phase), bradycardia, gastric insufflation (air intake on epigastric auscultation) were recorded. The PLMA and ET were removed once the children were fully conscious. After removing the devices, the patients were ventilated by face mask ventilation. Both devices were inspected after removal for signs of blood. Any adverse effects, apparent oropharyngeal injury or problems (desaturation, coughing, laryngospasm, bronchospasm, and Blood-staining at removal) from the devices were recorded and the adverse effects (laryngospasm, bronchospasm, coughing, gagging, nausea, hoarseness, sore throat, bradycardia, tachycardia, and/or desaturation) were documented in the post anesthesia care unit. Laryngospasm and bronchospasm can described as an increase effort in respiration, wheezing on auscultation, desaturation, and prolonged expiration time. When bronchospasm and laryngospasm were observed in the patients, 1 mg/kg of steroid prednisolon (Prednol-L, Mustafa Nevzat, Turkey), salbutamol (Ventolin, Glaxosmith Kline, England) and 1 mg/kg of lidocaine (Jetmonal, Adeka, Turkey) was administered. Intravenously, 15 mg/kg of paracetamol (Perfalgan, Bristol MS, England) was given to patients in both of the groups immediately after the operation.[3,4,14] Before discharge from the recovery room, the patients were asked if they had any complaints of a sore throat (>3 years old, if the patient <3 years old, existing agitation feeding facial expression, hoarseness, coughing, and/or combustion of oral cavity).[4] In reference to the locally collected data, we calculated it with alpha-set at 0.20 that 40 patients in each group would give a statistical power of 80% to detect a 25% of difference in insertion time in each group.

Statistical analysis was carried out using repeated Analysis of Variance followed by Bonferonni tests for repeated measurements (HR, MAP, SPO2, and EtCO2). Between groups comparison, categorical data (gender, ASA, mallapati score, number of insertion attempt, gastric tube placement, gastric insuflation, perioperative complications) were analyzed by chi-squared test. Quantitative data (age, height, weight, and insertion time, duration of surgery, tidal volume and airway pressure) were analyzed by student t test using 95% confidence interval. All statistical analyses were performed with a SPSS software version 13.0 (SPSS Inc., Chicago, IL, USA). The $p<0.05$ was considered statistically significant.

Table 1 - Patient's characteristics of ProSeal laryngeal mask airway and endotracheal tube groups.

Patient characteristics	ProSeal laryngeal mask airway (n=40)	Endotracheal tube (n=40)	*P*-value (between groups)
Gender (M/F)	26/14	22/18	0.361
Age (year) (mean±SD)	6.9 ± 3.97	8.27 ± 3.84	0.126
Height (cm) (mean±SD)	117.32 ± 22.6	124.5 ± 20.05	0.138
Weight (Kg) (mean±SD)	22.93 ± 10.33	24.07 ± 9.34	0.607
American Society of Anesthesiology (ASA) I/II	34/6	37/3	0.288
Mallampati classification (I/II)	34/6	36/4	0.499
Duration of surgery (min) (mean±SD)	29.55 ± 11.48	30.3 ± 6.8	0.701
ProSeal laryngeal mask airway or tube size	1.5-3	4-7	-

Results. Patient characteristics for both groups are shown in **Table 1**. There were no differences between the groups regarding patient characteristics; gender, age, height, weight, ASA classification, mallampati classification, and duration of surgery (**Table 1**).

There were no significant difference between groups in terms of the tidal volume, airway pressure, blood oxygen saturation, and end-tidal carbon dioxide (**Table 2**).

There were no significant difference between groups in terms of the hemodynamic parameters including mean arterial pressure (preoperative 1, 5, 10 minutes, p=0.88, p=0.03, p=0.65, p=0.77) and heart rate (p=0.56, p=0.4, p=0.51, p=0.188) (**Figures 1 & 2**). There were no significant difference within groups, compared to preoperative value in PLMA (1, 5, 10. min, p=0.0001, p=0.001, p=0.06) and ET (p=0.0001, p=0.009, p=0.228) (**Figures 1 & 2**).

There was no significant difference between groups in terms of the insertion time. Thirty-eight patients (95%) in both groups were successfully placed at the first attempt; one patient (5%) required a second attempt

Table 2 - Intraoperative ventilation parameters of 80 children.

Parameters	ProSeal laryngeal mask airway (n=40) Mean± SD	Endotracheal tube (n=40) Mean± SD	*P*-value (between groups)
Tidal volume (ml)	190.7 ± 80.9	202.75 ± 78.87	0.502
Airway pressure (cm H_2O)	16.5 ± 2	15.3 ± 2	0.309
$ETCO_2$ (mm Hg)	36.05 ± 0.3	35.35 ± 0.6	0.305
SpO_2 (%)	99.63 ± 0.11	99.62 ± 0.17	0.242

$ETCO_2$ - End-tidal carbon dioxide concentration in the expired air, SpO_2 - oxygen saturation,

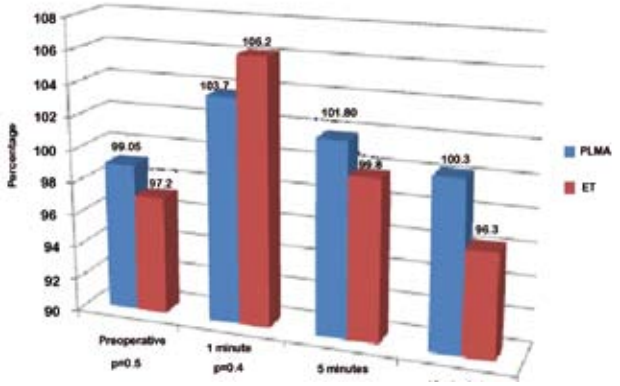

Figure 1 - Peri-intubation mean heart rate (beat/minute).

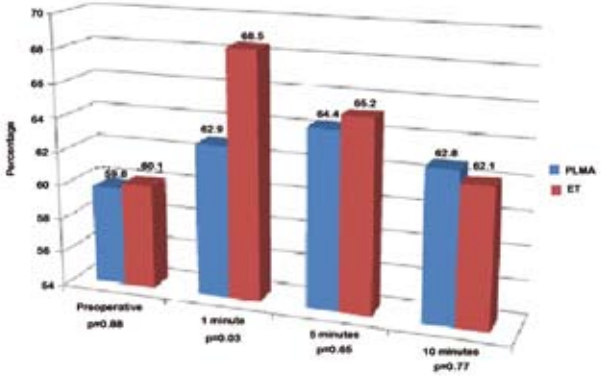

Figure 2 - Peri-intubation mean arterial pressure (mm Hg).

Table 3 - Success rate for ProSeal laryngeal mask airway (PLMA) and endotracheal tube (ET) groups.

Parameters	PLMA (n=40)	ET (n= 40)	*P*-value
Number of insertion attempts (n)			0.556
1	38	39	
≥2	2	1	
PLMA or TT insertion time			0.253
Mean±SD	18.45 ± 7.87	20.42 ±10.05	
Range	(10 - 42)	(10-50)	
Gastric tube placement			0.556
First attempt	38	39	
More than one attempt	2	1	
Gastric insufflation			0.152
No	38	40	
Yes	2	0	

Table 4 - Patients with perioperative complications (N=80).

Complications	PLMA (n=40)	ET (n=40)	*P*-value (between groups)
Blood-staining at removal	2	3	0.456
Sore throat	3	4	0.692
Coughing	2	3	0.644
Bronchospasm	0	1	0.314
Nausea	2	4	0.692
Hoarseness	0	1	0.166

PLMA - ProSeal laryngeal mask airway, ET - endotracheal tube

for the PLMA or ET placement. Thirty-eight patients (95%) were successfully placed at the first attempt; 2 patients (5%) required a second attempt for the gastric tube placement. Gastric insufflation occurred in 2 patients in the PLMA group, but it was not significant between the groups (**Table 3**).

Perioperative complications such as blood-staining at removal, sore throat, hoarseness, nausea, and coughing occurred in both groups. Bronchospasms occurred in the ET group (**Table 4**). Other complications, such as airway obstruction, displacement, desaturation, tachycardia, hypotension, hypertension, and gastric aspiration, did not occur in either group.

Discussion. In recent studies, it has been observed that supra-glottic ventilation devices especially PLMA is as safe in children as it is in the adults. Therefore, PLMA is replacing ET in many pediatric operations.[3,4,13-17] Although White et al[15] report that it can be safely used in routine pediatric operations as an alternative to ET, it is still under investigation, especially in operations that endanger airway safety and which remain in a sterile area. In the present study, we discussed the use of PLMA in pediatric strabismus surgery, ease of the procedure, and hemodynamic effects and complications when compared with ET. The major advantages of supra-glottic ventilation devices are the ease of the procedure and lower complication rate when compared with ET.[3,6,8,16-19] The major disadvantages are difficulties in ventilation due to misplacement of the device in the mouth, gastric insufflations in long procedures, and sore throat and mucosal damage due to the dehiscence of the device. Gastric aspiration is another possible complication.[16,17,20] In a study which compared PLMA and ET in pediatric laparoscopic surgery, Sinha et al[7] reported that airway pressure and hemodynamic parameters were comparable, and concluded that PLMA is a good alternative to orotracheal intubation in children 6 months and older. In our study, the youngest child was 13 months old. Lopez-Gil and Brimacombe[19] reported that size 2 and 3 PLMA successfully isolate glottis and esophagus when properly placed. Goldman[21] reported that absence of the posterior cuff in size 1.5-2 tubes does not cause any problem in ventilation. In our study, 4 patients were below 3 years of age in PLMA group and PLMA sized 1.5-2 were used for these patients. We were able to provide successful ventilation in the range of normal ventilation pressures. In addition, during the use of size 1.5-2 PLMA, the absence of the posterior cuff did not cause any complication during ventilation.

The major advantage of PLMA is the ease of the procedure, which has been demonstrated by comparative studies. It has been reported that the procedure was quickly and easily learnt by first-month anesthesia residents and other allied health-care staff after a brief manikin-only training.[22,23] There is also a consensus about the ease of the procedure both in children and adults.[15,16,20,21] Meanwhile, Brimacombe et al[24] reported that PLMA placement without an introducer was more difficult than with a LMA because of bigger cuff. However, we placed a PLMA using a digital insertion technique (without introducer) with a high success rate (95% in the first attempt and 100% in the second) (**Table 2**). Sinha et al[7] reported the success rate as 88% in the first attempt in a pediatric cohort. Besides the practical placement of the device the most important advantage of PLMA is reducing the incidences of complications due to laryngoscopy and endotracheal intubation (hemodynamic instability, esophageal intubation, laryngeal trauma, bronchospasm, and so forth) Several studies have demonstrated that there are fewer effects of PLMA on hemodynamics when compared to ET.[3,5-8] Cook et al[25] suggested that PLMA use is associated with less hemodynamic disturbance than the use of a tracheal tube, but there was no significant difference between the 2 groups regarding heart rate or blood pressure values. Lalwani et al[3] and Evans et al[20] demonstrated that hemodynamic effects (heart rate, mean arterial pressure) of PLMA were less than those of ET. In accordance with their study, hemodynamic impairment was less in the PLMA group in our study.

Brimacombe et al[26] suggested that PLMA has been successfully used to provide both spontaneous and controlled ventilation in children. Its use has been shown to lower the incidences of coughing and

sore throats, improve oxygen saturation and reduce anesthetic requirements for airway tolerance. Wheeler[16] in their study, performed PLMA in 120 pediatric surgery procedures and announced that no bronchospasm, laringospasm, hypoxemia, dislodgement, or aspiration occurred. A smooth recovery without coughing and decreased pharyngolaryngeal morbidity is a further advantage of the device. Our study was also similar; no ventilation problems, airway obstructions and dislodgements were observed in our patients. Bronchospasm, nausea, sore throats, blood-staining at removal and coughing occurred less frequently in the PLMA group than the tracheal tube group. Blood-staining at removal was 5% in the PLMA group and 7.5% in the ET group; sore throats were 10% in the ET group and 7.5% in the PLMA group. Wheeler[16] reported that there was evidence in only 4 patients (3%) of traumatic placement as judged by blood on the PLMA. Other pediatric studies reported comparably low-blood-staining rates: 3% (4 out of 120), 9% (7 out of 80), and 7% (2 out of 30).[26-29] This situation could be due to children's sensitive mouth mucosa, soft tissue damage due to the insertion of a gastric tube or PLMA, or the over insufflations of PLMA. A bronchospasm was observed following after intubation in one patient in the ET group. A steroid, anti-histaminic, and salbutamol inhaler administration solved this problem immediately. One of the most important features of PLMA is the presence of a drainage tube, which allows gastric drainage and a decreased aspiration risk. Additionally, it helps us to predicate whether the device is placed properly. In our study, the rate of gastric tube placement was similar in both groups which were concordant with the previous data.[18-20]

Study limitations. We determined sore throat in our patients depending on observation, which is due to the difficulty of communication with patients especially under the age of 3 and we observe that this is one of the limitations of our study. Also, another limitation may be that our patients were abundantly between 4-10 years of age, but there were patient below 3 years, especially in the PLMA group. We found that anatomical differences between small size (size 1.5 or 2) and big size PLMAs may have effected the evaluation of results.

In conclusion, the present study revealed that PLMA may offer an alternative airway to tracheal intubation procedures where positive pressure ventilation is a preferred option in children undergoing ophthalmic strabismus surgery. Further research is evident and specific studies regarding PLMA use in surgical procedures in patients less than 3 years of age may give us valuable information.

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