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Original Article

Comparison of Size 2 LMA-ProSeal™ and LMA-Supreme™ in Spontaneously Breathing Children: a Randomised Clinical Trial

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ABSTRACT

Objective: The aim of this study was to compare size 2 Laryngeal Mask Airway ProSeal and size 2 Laryngeal Mask Airway Supreme in spontaneously breathing children undergoing lower abdominal elective surgery of <1 hour duration.

Study Design: Randomized clinical trial.

Material and Methods: Sixty children aged 1-7 years, weighing 10-20 kg, ASA I physical status were randomly allocated to the Laryngeal Mask Airway ProSeal and Laryngeal Mask Airway Supreme.

Results: There were no differences in demographic variables, ease of gastric tube placement, ease of insertion and ventilation, number of insertion attempts, hemodynamic changes on insertion, postoperative complications and bloodstaining between the groups. Gastric insufflation was detected and gastric tube was placed in all patients except one in LMA Supreme. Postoperative cuff volumes were comparable with the preoperative values in group itself. Oropharyngeal leak pressures were higher in Laryngeal Mask Airway ProSeal (24.6±5.5 vs 21.3±4.2, respectively; p<0.01).

Conclusion: As a result Laryngeal Mask Airway ProSeal and Laryngeal Mask Airway Supreme can safely be used in spontaneously breathing pediatric population undergoing lower abdominal elective surgery.

Key Words: Laryngeal mask, proseal, supreme, children, oropharyngeal leak pressure

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Introduction

The Laryngeal Mask Airway Supreme (LMA Supreme) (LMA North America, San Diego, CA, USA) is a new single use laryngeal mask airway with a curved rigid airway tube and a channel for gastric drain and an inflatable cuff. LMA Supreme size 2 was studied in spontaneously breathing and neuromuscular blockade receiving children (1-3).

The Laryngeal Mask Airway ProSeal (LMA ProSeal) (LMA North America, San Diego, CA, USA) is a reusable supraglottic airway device with a gastric drain tube and an inflatable cuff that is being routinely used in spontaneously breathing children successfully (4-8).

These airway devices would seem suitable to aid ventilation in children, but we are not aware of any comparative studies in spontaneously breathing children undergoing lower abdominal surgery 1< hour duration. The purpose of this study was to compare the clinical performance of the LMA Supreme compared with the LMA ProSeal regarding oropharyngeal leak pressures, ease of insertion, number of insertion attempts, incidence of gastric insufflation, ease of gastric tube placement, ease of ventilation, hemodynamic changes, preoperative and postoperative cuff filling volumes, postoperative complications, direct viewing of the blood on the device (bloodstaining).

Material and Methods

Following approval by the Kocaeli University Hospital Research Ethics Comittee and written informed patient consent was obtained from the parents of all patients; we studied 60 children aged 1 to 7 years, weighing between 10-20 kg, of ASA physical status I-II, were scheduled for elective surgery. Patients were randomly allocated to either size 2 LMA ProSeal or size 2 LMA Supreme group using a sealed envelope technique. An active respiratory infection (cough, fever, rhinorrhea, wheezing, stridor) or a potentially difficult airway, full stomach were excluded from the study. We documented the patients' age, sex, weight. Patients were premedicated with intravenous midazolam 0.03 mg/kg after intravenous access was administered. Standard monitoring including ECG, non-invasive blood pressure, pulse oximetry, heart rate and end-tidal carbon dioxide monitoring was applied. Anaesthesia was induced with 3 mg/kg propofol (calculated according to the lean body weight) and 1 µg/kg fentanyl. After that, anesthesia was maintained with Sevoflurane 3% in a mixture of 70% N_2O and O_2. Neuromuscular blockade was not administered to any patient. LMA ProSeal was inserted with the index finger technique. LMA Supreme was inserted like the intubating laryngeal mask airway, according to the manufacturer's

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recommendations. Each device was inserted when fully deflated and the dorsal surface lubricated with a lidocaine based agent and inflated with the maximum volume of air according to the manufacturer's recommendations. The investigators experienced in using both devices (over 500 uses) performed all the insertions in the neutral position of the head. Parameters were measured and recorded (ease of insertion, ease of ventilation, oropharyngeal leak pressure, gastric insufflation, ease of gastric tube placement, postoperative complications, preoperative and postoperative cuff volumes, bloodstaining) by an independent unblinded observer. The ease of laryngeal mask insertion was assessed using a subjective scale of 1-3 (1=no resistance 2=resistance 3=impossible). The insertion was recorded as a failure if the placement of the device required more than two attempts, or there was lack of a square-wave capnograph tracing, evidence of airway obstruction (SpO_2<90) or inadequate ventilation (inability to generate 6 ml/kg tidal volume). If the insertion of the devices impossible if then the other device was used. All devices were fixed with a banned routinely. To determine the oropharyngeal leak pressure; the expiratory valve was closed and the fresh gas flow was set to 3 L/min and pressure was slowly increased (airway pressure was not allowed to exceed 40 cmH_2O), and then released completely. Gastric insufflation was performed with the auscultation with a stethoscope over the epigastrium during the oropharyngeal leak pressure testing. 10 FG nasogastric tube was placed on a subjective scale; (1=easy, 2=difficult, 3=impossible). Insertion of the gastric tube into the stomach was confirmed by aspiration of gastric contents or insufflation of air heard on auscultation over the epigastrium. Volume control mode ventilation was used for maintanence of anesthesia. Tidal volume was set to 10 mL/kg and frequency 15-18 per minute. Hemodynamic parameters including heart rate, noninvasive blood pressure, pulse oximetry, peak airway pressure, end-tidal carbondioxide, expiratory tidal volume were also recorded. The number and type of airway manipulations (gentle advancement, withdrawal of the device without removal, jaw thrust and head extension) required to maintain airway patency during the case were also recorded. All devices were removed under deep anesthesia without deflation. Postoperative complications such as; coughing, laryngospasm, diysphagia, stridor, bronchospasm, desaturation (SpO_2<90), aspiration, bloodstaining on the device after the removal were recorded. Tramadolar 1 mg/kg was given to all patients for postoperative analgesia.

Statistical analysis

Based on data published before the mean (SD) oropharyngeal leak pressure for the LMA ProSeal size 2 was found to be 23±1.2 cmH_2O and the median leak pressure for LMA Supreme was found to be 20 (16-21(12-22)) cmH_2O (1, 4). Using this size, an alpha of 0.05 and a desired power of 0.9, we estimated that 29 patients per device would be required to detect a difference of 10% or 3 cmH_2O for the oropharyngeal leak pressure (the minimum difference that is considered clinically significant) between these two devices. This study was designed to enrol 60 patients (30 in each group) for the possible exclusions. Statistical analysis was made with Statistical Package of Social Science 17 (SPSS Inc., Chicago, IL, USA). Statistical comparisons between the devices were made using chi-squared test for categorical data and paired sample t-test, student t-test, Mann-Whitney U test for continuous data. A value of $p<0.05$ was considered statistically significant.

Results

There were no differences in characteristics between the groups (Table 1). All patients were in ASA I physical status. One patient was excluded from the study because nor LMA ProSeal neither LMA Supreme could be inserted to the patient then anesthesia was maintained with LMA Classic successfully. Ventilation, together with insertion were easy with both of the devices. Gastric insufflation was auscultated and gastric tube was placed in all patients except one case in LMA Supreme. The oropharyngeal leak pressures were higher in LMA ProSeal than in the LMA Supreme ($p<0.01$) (Table 2). Postoperative cuff volumes were comparable when compared with preoperative volumes in groups itself. None of the patients demonstrated oxygen desaturation. No statistically significant difference was found regarding the bloodstaining on the devices and hemodynamic parameters. We did not need manipulations like; advancement of the device, withdrawal of the device, jaw thrust or head flexion or extension. No complication related to anesthesia and airway management occured.

Discussion

The main result of this study in anaesthetised children not receiving neuromuscular blockade in lower abdominal surgery 1< hour duration, the LMA ProSeal was associated with higher oropharyngeal leak pressures when compared with LMA Supreme.

Table 1. Characteristics of patients using the LMA ProSeal or LMA Supreme. Values are mean (SD) or as number (proportion)

	LMA ProSeal (n=30)	LMA Supreme (n=30)
Age; years	3.3±1.4	3.2±1.6
Gender (Male/Female) (n)	26/4	26/4
Weight (kg)	14.7±2.6	14.4±3
Type of surgery (n)	9	7
Circumcusion	4	5
Inguinal hernia repair	8	3
Inguinal hernia repair+Circumcusion		
Undecendent testis	-	3
Undecendent testis+Circumcusion	4	7
VUR subureteric injection	1	1
VUR+Circumcusion	2	2
Hidroselektomy+Circumcusion	1	2
Hipospadias+Circumcusion	1	-

*Only the prescriptions issued with physicians' specialty were analyzed
GCPs: Green coloured prescriptions, RCPs: Red coloured prescriptions, CPs: Controlled prescriptions

Table 2. Insertion characteristics for the LMA ProSeal or LMA Supreme. Values are mean (SD) or number (proportion)

	LMA ProSeal (n=30)	LMA Supreme (n=30)	p
Ease of laryngeal mask insertion No resistance/ resistance/impossible (n)	30/0/0	28/2/0	0.2
Nasogastric tube placement Easy/difficult/impossible	26/4/0	29/0/1	0.08
Gastric insufflation Yes/No	30/0	29/1	0.3
Oropharyngeal leak pressures (cmH_2O)	26.4±5.5	21.3±4.2	0.01*
Ppeak (cmH_2O)	13.4±2.8	13.2±2.5	0.7
Expiratory tidal volume (mL)	120.5±28.6	124.4±32.4	0.6
SpO_2 (%)	99.9±4.3	99.9±0.3	0.7
End-tidal carbondioxide (mmHg)	40±5.2	40.5±4.5	0.7

*is a symbol of a p value <0.05

Oropharyngeal leak pressures were reported between 19-25 cmH_2O for the same size LMA Proseal in spontaneously breathing children (4-8). Lardner et al. (9) reported the same leak pressures but Lopez-Gil et al. (10) reported a higher leak pressures in children receiving neuromuscular blockade with same size LMA ProSeal. Leak pressures of LMA Supreme in our study were same with spontaneously breathing but higher than neuromuscular blockade receiving children (1-3).

Jagannathan et al. (3), compare the size 2 LMA ProSeal and LMA Supreme in a new study which is going to be published and used neuromuscular blockade. The surgeries were different from each other such as laparoscopic, opthalmic, urological and orthopedic surgery. So, they found a lower oropharyngeal leak pressures then us.They did not detect any gastric insufflation in both of the devices. Insertion attempts, gastric tube placement were same with our results. They used pressure controlled ventilation because of that expiratory tidal volumes were even higher with both of the devices than our findings. Other previous studies in spontaneously breathing and neuromuscular blockade used with LMA Proseal demonstrated a higher expiratory tidal volumes than our findings (5, 9, 10). The reason is that we used volume controlled mode in spontaneously breathing children.

The incidence of gastric insufflation was 100% and 97% for LMA ProSeal and LMA Supreme respectively in our study. These rates were even higher than neuromuscular blockade receiving and spontaneously breathing children with LMA ProSeal (10-12). The studies comparing the LMA Supreme in spontaneously breathing and neuromuscular receiving children did not detect any gastric insufflation in any patient (1-3).

Brimacombe and colleagues, suggest that gastric insufflation can be possible with LMA ProSeal despite a good seal and the malposition can be excluded by testing drainage tube replacement (13). In adults, the rate of successful gastric tube placement correlates with correct positioning of the LMA ProSeal and LMA Supreme (14). Overall gastric tube placement was 100% in our study with LMA ProSeal same with the previous data published before (5, 12, 13). This rate was 97% for LMA Supreme and it is comparable the previous data too (1-3).

In previous studies, bloodstaining rates of LMA ProSeal resulted higher but LMA Supreme resulted lower than our findings (1-4, 8, 10, 15).

The overall success rate of LMA ProSeal and LMA Supreme has been shown as 100% in same sizes (1-4, 7, 12, 15). These are comparable to our results.

Recently diffusion of the nitrous oxide to the air-filled cuff of the size 2 LMA ProSeal (silicone) and the polyvinilchloride devices were demonstrated and a relationship between cuff pressure and postoperative complications like sore throat when supraglottic airway devices were maximally inflated has been shown. Inflating the cuff with the minimum volume of air recommended (16, 17). We had maximally inflated the cuffs according to the manufacturer's recommendations and we did not see any postoperative complications except bloodstaining, we did not detect any infiltration to the both of the devices either.

Several limitations of our study is; first, only children with normal airways were studied. Second, we did not use neuromuscular blockade. Third, this study compared only size 2 LMA Supreme and LMA ProSeal. Future prospective and comparative trials are needed on all sizes of these devices. Fourth, the results may be different if the surgery exceeds 1 hour. Fifth, all devices were inserted by experienced person. Sixth, there was no blinding in data collection.

Single use devices are encourage to reduce the possibility of transmission of prions and other infectious material from one patient to another (18).

LMA ProSeal and LMA Supreme are both can safely be used in spontaneously breathing children undergoing elective lower abdominal surgery 1< hour duration.

Ethics Committee Approval: *Ethics committee approval was received from Kocaeli University Hospital Research Ethics Comittee for this study.*

Informed Consent: *Written informed consent was obtained from the parents of the patients who participated in this study.*

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Author contributions: *Consept- Design: Z.İ.A., C.B. - Supervision- Resource: Z.İ.A., N.G., Z.İ. - Materials- Data Collection: Z.İ.A., C.B., D.A.O., M.Y., N.G., Z.İ. - Analysis: C.I.Y., Z.İ.A. - Literature Search: Z.İ.A., M.Y. - Writing: Z.İ.A., D.A.O. - Critical Reviews: C.B., N.G., Z.İ.*

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References

1. Jagannathan N, Sohn LE, Sawardekar A, Chang E, Langen KE, Anderson K. A randomised trial comparing the laryngeal mask airway Supreme with the laryngeal mask airway Unique in children. Anaesthesia 2012;67:139-44. [CrossRef]

2. Jagannathan N, Sohn LE, Chang E, Sawardekar A. A cohort evaluation of the laryngeal mask airway-Supreme™ in children. Paediatr Anaesth 2012;22:759-64. [CrossRef]
3. Jagannathan N, Sohn LE, Sawardekar A, Gordon J, Langen KE, Anderson K. A randomised comparison of the LMA Supreme and LMA ProSeal in children. Anaesthesia 2012;67:632-9. [CrossRef]
4. Goyal R, Shukla RN, Kumar G. Comparison of size 2 i-gel suraglottic airway with LMA-ProSeal and LMA-Classic in spontaneously breathing children undergoing elective surgery. Paediatr Anaesth 2012;22:355-9. [CrossRef]
5. Goldmann K, Jakob C. Size 2 ProSeal laryngeal mask airway;a randomised, crossever investigation with the standard laryngeal mask airway in paediatric patients. Br J Anaesth 2005;94:385-9. [CrossRef]
6. Kelly F, Sale S, Bayley G, Cook T, Stoddart P, White M. A cohort evaluation of the pediatric ProSeal laryngeal mask airway in 100 children. Paediatr Anaesth 2008;18:947-51. [CrossRef]
7. Wheeler M. ProSeal laryngeal mask airway in 120 pediatric surgical patients:a prospective evaluation of characteristics and performance. Paediatr Anaesth 2006;16:297-301. [CrossRef]
8. Shimbori H, Ono K, Miwa T, Morimura N, Naguchi M, Hiroki K. Comparison of the LMA - ProSeal and LMA - Classic in children. Br J Anaesth 2004;93:528-31. [CrossRef]
9. Lardner DR, Cox RG, Ewen A, Dickinson D. Comparison of laryngeal mask airway (LMA) - ProSeal and the LMA - Classic in ventilated children receiving neuromuscular blockade. Can J Anaesth 2008;55:29-35. [CrossRef]
10. Lopez - Gil M, Brimacombe J. The ProSeal laryngeal mask airway in children. Paediatr Anaesth 2005;15:229-34. [CrossRef]
11. Lopez-Gil M, Brimacombe J, Garcia G. A randomized non - crossover study comparing the ProSeal and Classic laryngeal mask airway in anaesthetized children. Br J Anaesth 2005;95:827-30. [CrossRef]
12. Karippacheril JG, Varghese E. Crossover comparison of airway sealing pressures of size 1.5 and 2 size LMA - ProSeal and LMA - Classic in children, measured with the manometric stability test. Paediatr Anaesth 2011;21:668-72. [CrossRef]
13. Brimacombe J, Keller C, Berry A. Gastric insufflation with the ProSeal laryngeal mask. Anesth Analg 2001;92:1614-5. [CrossRef]
14. Cook TM, Gatward JJ, Handel J, Hardy R, Thompson C, Srivastava R, et al. Evaluation of the LMA Supreme in 100 non-paralysed patients. Anaesthesia 2009;64:555-62. [CrossRef]
15. Bağuş F, Şahin Yıldız T, Solak M, Toker K. Efficacy of classical LMA and ProSeal LMA in pediatric patients:a comparative study. J Turk Anaesth Int Care 2011;39:311-7. [CrossRef]
16. Maino P, Dullenkopf A, Bernet V, Weiss M. Nitrous oxide diffusion into cuffs of disposable laryngeal mask airways. Anaesthesia 2005;60:278-82. [CrossRef]
17. Maino P, Dullenkopf A, Keller C, Bernet V, Weiss M. Cuff filling volumes and pressures in pediatric laryngeal mask airways. Paediatr Anaesth 2006;16:25-30. [CrossRef]
18. AAGBI. Infection control in Anaesthesia, 2nd ed. London:Association of Anaesthetists of Great Britain and Ireland, 2008.