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"A RANDOMIZED TRIAL COMPARING THE LARYNGEAL MASK AIRWAY SUPREME™ WITH THE LARYNGEAL MASK AIRWAY UNIQUE™ IN ANAESTHETISED AND PARALYSED CHILDREN"

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ABSTRACT

Objectives: To compare the laryngeal mask airway Supreme with the laryngeal mask airway Unique in anaesthetised and paralysed children.

Methods: Fourty two children presenting for elective surgery were randomly assigned to receive either the laryngeal mask airway Supreme or laryngeal mask airway Unique.The outcomes measured were airway leak pressure,ease and time for insertion,insertion success rate,quality of airway during anaesthetic maintenance and complications.

Results: The mean airway leak pressure was higher in the LMA Supreme group (18.10 ± 0.83 cm of H2O) compared to that in LMA Unique group (15.48 ± 0.75 cm of H2O),p-value <.001.The mean insertion time was less in the LMA Supreme group (16.67 ± 3.15 secs) compared to that in LMA Unique group (19.10 ± 2.34 secs),p-value =.007.

Conclusion: Laryngeal mask airway Supreme performed better than the laryngeal mask airway Unique and is a better alternative for airway maintenance in children who require positive pressure ventilation during anaesthesia.

KEYWORDS :

Introduction

Laryngeal mask airway(LMA) are supraglottic airway devices (SGA) which have become a standard fixture in airway management, filling the niche between the facemask and tracheal tube in terms of both anatomical position and degree of invasiveness (1). Laryngeal mask airway was initially introduced by Dr Archie Brain in the 1980s and once he was satisfied by the prototype he used the laryngeal mask airway in various surgeries. Since 1987 laryngeal mask airways have become the mainstay of the airway maintenance under anaesthesia. LMA classic was introduced as the first generation LMA and after that laryngeal mask airways have evolved over a period of time and have been classified into various generations (2,3).

The laryngeal mask airway Unique is the original single use first generation laryngeal mask airway with a soft flexible cuff and aperture bars designed to prevent the blockage of airway by epiglottis. The laryngeal mask airway Supreme is a new single use second generation laryngeal mask airway with structural modifications, which include a curved and rigid airway tubing, a channel for passage of a gastric drain tube and a larger cuff made of polyvinyl chloride. The LMA Supreme as well as LMA Unique are now available in all paediatric sizes 1, 1.5, 2 and 2.5. There have been numerous studies evaluating the LMA Supreme in adults but limited clinical studies to date analyzing the performance of the LMA Supreme in children (4,5). Therefore, the aim of this prospective study is to evaluate the clinical performance of the LMA Supreme compared with the LMA Unique in children.

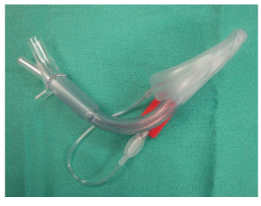
LMA Unique and LMA Supreme have been used in children for various surgical procedures. They form an integral part in the airway management of children. They are easier to use in children and are associated with fewer side effects. Various complications of endotracheal intubation like laryngospasm and laryngeal ischemia are less with laryngeal mask airway. Recovery has been smooth compared to an endotracheal tube intubation (6). Postoperative side effects like sore throat and cough are less in children undergoing procedures with LMA than in children undergoing endotracheal intubation. The aim of this prospective study was to evaluate the clinical performance of the LMA Supreme compared with the LMA Unique in children. Three sizes 1.5, 2 and 2.5 of both LMA Supreme and LMA Unique were compared (7,8,9).

Primary outcome which was measured in our study was the airway leak pressure. Secondary outcomes were ease of insertion, insertion time, insertion success rate, Quality of airway patency and post operative complications.

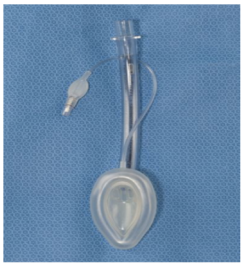
Materials and Methods

The study was conducted at Armed forces medical college (AFMC) Pune which is a tertiary level hospital. The study was conducted between January 2015 to August 2016. Ethical clearance was taken from the institutional ethical committee of Armed Forces Medical College. Written informed consent was taken from the parents of the children and CTRI registration was done. CTRI registration no is REF/2016/04/011223. Children between the age group of 6 months to 8 years, weighing between 10 to 25kg, of ASA status I- III, who were scheduled for various surgeries under general anaesthesia using LMA of three sizes (1.5, 2 and 2.5) were enrolled in the study. Patients with acute respiratory illness (cough, rhinorrhea) on the day of anaesthesia and children with anticipated difficult airway were excluded from the study.

The study population was identified prospectively. Patients were screened and recruited consecutively based on eligibility criteria and availability of the study investigators. Fourty two children (ASA 1–3) were randomly assigned to receive either a LMA Unique or LMA Supreme for airway management A computer generated randomization table was used to allocate one of the two groups to the children and sealed envelopes were used to assign cases. LMA Supreme and LMA Unique that were used were made by The Laryngeal Mask Company Limited Le Rocher, Victoria, Mahé, Seychelles supplied by Teleflex medical Tele ex Medical Europe Ltd, IDA Business and Technology Park, Dublin Road, Athlone, Co Westmeath, Ireland.



(LMA Supreme by Teleflex Medical)



(LMA Unique by Teleflex Medical)

The anaesthetic protocol included intravenous induction with 2mg/kg of propofol followed by administration of 1mcg/kg of fentanyl and 0.2 – 0.3mg/kg of atracurium. Adequate depth of anaesthesia was confirmed by lack of motor response to jaw thrust. A supplementary dose of 1 mcg/kg of fentanyl was administered if depth of anaesthesia seemed inadequate for device insertion. Each device was fully deflated and lubricated with a lubricating agent. Devices were inserted according to the manufacturer's recommendations and instructions. Anticholinergic drugs were not given to any patients at the start of surgery.

With the patient's head in neutral position the time to successful insertion was measured from the moment the face mask was removed until the first capnography upstroke after insertion. The intra cuff pressure was standardized to not more than 60 cm of H2O using an aneroid cuff pressure gauge.

The ease of placement was assessed using a subjective scale of 1-4(1=no resistance, 2=mild resistance, 3=moderate resistance. 4= inability to place the device). The insertion was recorded as a failure when the placement of the device required more than two attempts or when there was a lack of square wave capnography trace, evidence of airway obstruction (SPO2<90%, abnormal thoracoabdominal movements, or obstructive noises), or inadequate ventilation (unable to generate 7ml per kg tidal volume, an audible leak through the drain tube of the LMA Supreme not correctable with gentle advancement of the device).

A gastric tube was placed through the drain tube port of LMA Supreme. Insertion of gastric tube in to the stomach was confirmed by aspiration of gastric contents or insufflation of air heard on auscultation over the epigastrium. The anaesthesia was maintained with oxygen (40%), nitrous oxide (60%), isoflurane (1MAC) and pressure controlled positive pressure ventilation in order to maintain EtCo2 (End Tidal Carbon Dioxide) between 32-35mm of Hg. Hemodynamic parameters like Heart rate, MAP (mean arterial pressure) and SPO2 was recorded every 5 minutes starting from baseline till full recovery in PACU (Post Operative Anaesthesia Care Unit). The quality of airway patency (clear, intermittent partial obstruction, intermittent complete obstruction or complete obstruction) and the number and type of airway manipulations (gentle advancement, withdrawal of device without removal, jaw thrust or head extension) required to maintain airway patency during the cases were recorded. Failure of the device during the maintenance of anaesthesia was defined as inadequate ventilation (fall in SPO2<90 % and fall in tidal volume<6ml/kg) or airway obstruction that could not be corrected by airway manipulation. To determine the airway leak pressure the expiratory valve was closed and a fresh gas flow of 3 l per min was set until equilibrium was reached (airway pressure will not be allowed to exceed 40 cm of H2O) and then was released completely. Airway leakage was defined as the air escape audible with a stethoscope placed on the larynx and leak pressure was defined as the airway pressure at which leak was first detected. All devices were removed after reversing the neuromuscular blockade with neostigmine and glycopyrrolate after return of adequate spontaneous breathing. Complications with each device such as coughing, laryngospasm, bronchospasm, desaturation (SPO2<90%), and mucosal trauma (blood staining on the surface after removal) was also recorded.

All patients were visited in the recovery area by a blinded investigator, and a telephone call was made to the family the following day by an investigator who was not part of the study to document any postoperative complications such as dysphonia, dysphagia, cough, or stridor (4,5).

Statistical Analysis

The sample size was calculated based on the primary outcome of airway leak pressure measured in previous studies as 19.1 (3.6) cm H2O for LMA Supreme. A minimum sample of 21 in each group was required to detect a projected difference of 20% i.e 4 cm H2O between the two devices, with an alpha error of 0.05 and a desired power of 0.9. Data were recorded intra-operatively using a standardised data collection sheet, and analysed using Microsoft Excel Spreadsheet.The data was analyzed using SPSS version 20.0 software. Demographic variables like Age, Gender, Weight and ASA status were compared using chi-square test, Fisher's exact test and 2 Independent sample T-test. Same tests were used to evaluate dependent variables like Airway leak pressure, Ease of insertion and Insertion attempts. Results were expressed as mean ± SD and range. A value of $p<0.05$ was considered significant.

Results

The study was aimed at finding out a primary outcome which is the airway leak pressure and secondary outcomes like ease of insertion, time of insertion, hemodynamic parameters and complications. Fourty two patients were screened for enrolment in this study. There was no violation in protocol or refusal to participate after the consent was signed.

Various statistical tests like Fischer's exact test, Chi-Square test and 2 independent sample t-test were used to evaluate statistical difference in demographic parameters between both the groups. Patient characteristics are compared in Table 1, Comparison of airway leak pressure between both the groups are presented in Table 2 and Insertion time is compared in Table 3. Ease of insertion, Insertion attempts and haemodynamic parameters between both the groups are compared in Table 4. Table 5 shows comparison of quality of airway patency and complications between both the groups.

There was no statistical difference between both the groups in terms of demographic characteristics. In all the cases devices were placed properly in the first or second attempts. First attempt success rate was more with LMA Supreme. There was no instance of device failure, removal of the device or conversion to endotracheal tube insertion during the procedures.

[Table 1. Characteristics of patients anaesthetised using the laryngeal mask airway (LMA) Supreme or laryngeal mask airway (LMA) Unique. Values are presented as Mean ± SD or P- value between both the groups]

Demographic characteristics	LMA Supreme (n=21)	LMA Unique (n=21)	p-value
Age (Mean value ± SD)	2.63 ± 1.56	2.22 ± 1.13	0.338
Gender Male Female	 16 5	 13 8	0.505
ASA Status I II	 18 3	 20 1	0.606
Weight (Mean value ± SD)	12.90 ± 3.86	13.33 ± 3.18	0.697

The main differences between both the groups were in the airway leak pressure and insertion time. The mean airway leak pressure in the LMA Supreme group was 18.10 cm of H2O while that in LMA Unique was 15.48 cm of H2O. 2 independent sample t-test were used to compare the airway leak pressure. P-value was found to be < 0.001. Therefore there is a statistically significant difference between mean air leak pressure in group LMA Supreme and LMA Unique.

[Table 2. Comparison of airway leak pressure between LMA Supreme and LMA Unique. Values are presented as Mean ± SD and p-value]

Group	Number of patients	Air leak pressure		p-value
		Mean	SD	
LMA Supreme	21	18.10	0.83	< 0.001
LMA Unique	21	15.48	0.75	

Time to successful insertion was measured from the moment the face mask was removed until the first capnography upstroke after insertion. It was 16.67 seconds in LMA Supreme group and 19.10 seconds in LMA Unique group. 2 independent sample t-test was used to compare the insertion time between both the groups.

The mean insertion time was less in the LMA Supreme group and the p-value was 0.007 in terms of insertion time between the groups. There was a statistical difference in terms of time to successful insertion between both the groups.

[Table 3. Comparison of insertion time between LMA Supreme and LMA Unique. Values are presented as Mean ± SD and p-value]

Group	Number of patients	Insertion time		p-value
		Mean	SD	
LMA Supreme	21	16.67	3.15	0.007
LMA Unique	21	19.10	2.34	

Various other parameters like ease of insertion, insertion attempts and intraoperative hemodynamic parameters were compared between both the groups. There was no statistical difference between both the groups in the above mentioned parameters.

[Table 4. Comparison of Ease of insertion, Insertion attempts, Mean heart rate, Mean arterial pressure and Mean SPO2. Values are presented as Mean ± SD and p-value]

Parameters	LMA Supreme (n=21)	LMA Unique (n=21)	p-value
Ease of Insertion			
1	15	14	0.454
2	2	3	
3	4	4	
4	0	0	
Insertion attempt			
First attempt	17	12	0.181
Second Attempt	4	9	
Mean Heart Rate (Mean value ± SD)	102 ± 5.94	102.53 ± 6.30	0.806
Mean Arterial Pressure (Mean value ± SD)	96.89 ± 3.45	97.33 ± 4.19	0.745
Mean SPO_2 (Mean ± SD)	98.94 ± 1.11	99.27 ± 0.96	0.378

[Ease of insertion: 1 = No resistance, 2= Minimal resistance, 3= Moderate resistance, 4= Unable to place the device]

Quality of airway patency was measured between both the groups. There was no statistical difference between both the groups in terms of quality of airway patency.

[Table 5. Comparison of Quality of airway patency between both the groups. Value is presented as p-value]

Parameters	LMA Supreme (n=21)	LMA Unique (n=21)	p-value
Quality of Airway Patency			
Clear without obstruction	17	13	0.371
Intermittent partial obstruction	3	7	
Intermittent complete obstruction	1	1	
Withdrawal of the device	0	0	

Intraoperative and post operative complications were also measured between both the groups.

[[Table 6. Comparison of complications between both the groups. Value is presented as p-value]

Parameter	LMA Supreme (n=21)	LMA Unique (n=21)	p-value
Complications			
Airway related	0	0	0.999
Mucosal trauma	1	1	
Cough	1	2	
Dysphonia	0	0	
Aspiration	0	0	
Stridor	0	0	

Bloodstaining of the device was seen in two patients, one in LMA Supreme group after a second attempt insertion which had been moderately difficult to place and one in LMA Unique group. Laryngospasm with oxygen desaturation did not occur in any of the patients. Follow-up phone calls revealed three patients with cough, one in LMA Supreme group and two in LMA Unique group. There were no episodes of dysphonia, gastric regurgitation, aspiration, bronchospasm, or stridor in any of the patients.

Discussion

Our main findings were that in anaesthetised and paralyzed children receiving positive pressure ventilation, the LMA Supreme was associated with higher airway leak pressures and less insertion time when compared with the LMA Unique. There was no difference in age wise distribution, ASA status of patients and weight wise distribution between the groups.

In a study conducted by Varghese et al the Insertion success, glottic seal pressure and gastric access were found to be similar in LMA Supreme and LMA Unique (10). In our study the mean airway leak pressure in LMA Supreme was found to be 18.10± 0.83 and that of LMA Unique was found to be 15.48± 0.75. This showed a higher airway leak pressure with LMA Supreme than with LMA Unique.

A study conducted by Jagannathan et al in which LMA Supreme was compared with LMA Unique in children also showed a higher airway leak pressure with LMA Supreme compared with LMA Unique (4). The higher airway leak pressures of the LMA Supreme in this study were similar to those reported in a randomised trial conducted by Shimbori et al for the size-2 LMA Pro-seal (11). The leak pressures reported in this study for the LMA Unique were within the range reported in the literature for the LMA Unique (12,13).

Our LMA Supreme airway leak pressures were lower than those of the LMA Supreme in adults (14,15). Oropharyngeal leak pressure is indicative of the safety of the device in terms of preventing aspiration and measures the success of positive pressure ventilation. The possible reason for the higher airway leak pressure with the LMA Supreme may be because of its larger proximal cuff which provides a better airway seal (4). The clinical impact of this finding is important as positive pressure ventilation was undertaken in this study and higher airway leak pressure means less chances of aspiration in paralyzed patients.

In our study the mean time of insertion of LMA Supreme was found to be 16.67± 3.15 and that of LMA Unique was found to be 18.10± 2.34. The p-value was 0.007. Thus lesser time was required to establish a successful airway by LMA Supreme when compared to LMA Unique in our study. The previous study by Jagannathan et al showed that less time was required for establishing a successful airway with LMA Unique when compared to LMA Supreme. The less time required for establishing a successful airway by LMA Unique in the previous study was attributed to better familiarity with LMA Unique (4).

Our study shows no difference in ease of insertion between the two groups. The P value for ease of insertion was 0.454 between the groups. The overall insertion success rates in this study are comparable to other studies of the LMA Unique and LMA Classic in children (16,17).

In our study it was found out that there is no difference between LMA Supreme and LMA unique in terms of insertion attempts. The P value for comparison of insertion attempts was found to be 0.181 between the two groups. The absence of difference in insertion attempts between the groups may be due to frequent use of both airways and familiarity with both the devices. It can also be attributed to the design of both the devices which makes them fit into the upper airway (20.21,22).

The difference in mean heart rate, mean arterial pressure and mean SPO2 between the groups was not found to be statistically significant. This shows that the oropharyngeal seal was adequate for maintaining ventilation with both the devices. Previous studies also show similar findings (22,23,24).

Quality of airway patency was divided into clear, Intermittent partial obstruction and obstruction requiring withdrawal of device. In our study there was no significant difference found between the groups in terms of airway patency. Intermittent partial obstruction was more in LMA Unique group (7 devices) and minimal in LMA Supreme group (3 devices). Only one each was withdrawn in both the groups. In the study by N.Jagannathan et al which compared LMA Supreme with LMA Proseal, they also found out that there was no significant difference in airway patency between the two devices(5). Other study by Hjuk Kim et al in which LMA Supreme was compared with i-gel also found out that there is no significant difference in airway patency between both the devices (18).

Ease of gastric tube placement can only be measured in case of LMA Supreme as gastric tube placement is not possible in case of LMA Unique. Gastric tube placement was easy in 18 out of the 21 LMA

Supreme cases. The results are similar to a study conducted by Hosten et al in which LMA Supreme was compared with LMA Proseal in patients undergoing laparoscopic cholecystectomy (24). Gastric tube port is one of the important differences between LMA Supreme and LMA Unique. Drainage of gastric secretions is important in preventing aspiration of gastric contents especially after removal of the device.

Both the devices were comparable in terms of postoperative complications. Various complications like cough, Sore throat, and laryngospasm were assessed. There was no significant difference in the occurrence of complications between the two groups. A study by Seet E et al in which LMA Supreme was compared with Proseal also showed no significant difference in the occurrence of complications between the two devices (25).

Conclusion

We conclude that the LMA Supreme is a useful alternative to LMA Unique for various surgical procedures. Higher airway leak pressures make it safer than LMA Unique by decreasing the risk of aspiration. It also tolerates positive pressure ventilation better than LMA Unique and provides better ventilation by providing a better airway seal. LMA Supreme has a gastric port for the insertion of gastric tube which is absent in LMA Unique. This helps in removing the secretions and there by decreases the risk of aspiration (4,5,20).

Various other parameters like postoperative complications, Intraoperative hemodynamic parameters, and ease of insertion are similar in both the devices. But we need more studies with various other sizes and patients with difficult airway to evaluate the efficacy and safety of both the devices (9,18).

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