ORIGINAL RESEARCH

Comparative Evaluation of Single Use Laryngeal Mask Airways: The Laryngeal Mask Airway-Unique Ambu Laryngeal Mask with Reusable Laryngeal Mask Airway Classic in Pediatric Patients

[1]Dr. Jyoti Sharma, [2]Dr. Sanjeev Kumar, [3]Dr. Subhash Chander, [4]Dr. Geetika Duggal

[1,2,4]Department of Anesthesia, Maharaja Agrasen Medical College, Agroha, Haryana, India
[3]Department of Anesthesia, Civil Hospital, Fatehabad, Haryana, India

Corresponding author
Dr. Sanjeev Kumar
Department of Anesthesia, Maharaja Agrasen Medical College, Agroha, Haryana, India
Email: docsnajeevparmar77@gmail.com

Received: 15 January, 2023 Accepted: 20 February, 2023

ABSTRACT

Background and Aims: Laryngeal Mask Airway has become a basic airway gadget needed for all age group patients. Search for the most successful laryngeal mask airway in terms of ease of insertion and oropharyngeal seal pressure continues. We evaluated the success rate of three types of LMA.

Material and Methods: One hundred and twenty patients of either sex belonging to American Society of Anesthesiologists (ASA) physical status class I or II, between 1 to 6 years of age, scheduled to undergo elective surgery under general anaesthesia were included in the study. Patients were then randomly allocated to one of the three groups using coded envelopes as: group-I – (n=40), LMA Classic, group-II – (n=40), LMA Unique and group-III – (n=40), Ambu laryngeal mask. *After induction with standard anaesthetic technique* in group I and II, the LMA (Classic or Unique) was inserted using the standard method described by Brain with slight modification of partial inflation of cuff. In group III, the Ambu laryngeal mask was inserted using the pencil insertion technique as described in the instruction manual. Number of attempts for successful placement, ease of insertion, insertion time, fiber optic grade, oro-pharyngeal leak pressure and any evidence of post-op airway morbidity were noted.

Results*:* The mean insertion time was 15.40±2.31 seconds for group I, 15.87±2.12 seconds for group II (LMA Unique) and 12.42±3.16 seconds in group III. There was no patient with oropharyngeal seal pressure (OSP) in the range of <15 cm H_2O in group I (LMA Classic), while there were 2 (5%) ingroup II (LMA Unique) and 1 (2.56%) in group III (Ambu laryngeal mask). Maximum no. of patients in the three groups were in 15-20 cm H_2O range of seal pressure. Fiber optic view Grade I was seen in 25 (62.5%) in group I & II and 24 (61.5%) patients in group III. The FOB grades were comparable in all the groups (p value=0.666). Overall all the groups had maximum number of grades I (62.18%) followed by grade II (26.05%).

Conclusion: Ambu laryngeal mask and LMA Unique are comparable to LMA Classic in terms of the ease of insertion.

Keywords: Oro-pharyngeal seal pressure, fiber optic, laryngeal mask airway.

INTRODUCTION

Maintenance of patent airway during general anaesthesia is one of the prime responsibilities of the anaesthesiologist. Tracheal intubation is the conventional way of securing the airway and has been considered the gold standard.[1] The Laryngeal mask airway (LMA) was designed primarily as a means of offering some advantages of endotracheal tube while avoiding its fundamental disadvantages, since the vocal cords need neither be visualized nor forced apart.[2,3]

The laryngeal mask airway sizes for use in children are scaled down version of the adult form. The anatomic fit has been shown as adequate in infants as

in the older children, where physical features already have the adult configuration. Possibly the softness of the cuff allows for easy adaptation to the different physical characteristics found in various age groups.[4] Over the years several alternative laryngeal mask airways have been introduced into clinical practice, most of which are intended for single use.

The first single use laryngeal mask airway, LMA-Unique was released in 1997(LMA co. Henley on Thames, U.K.) at approximately one-third of the cost of a LMA Classic. A recent introduction in the disposable generation is the Ambu laryngeal mask can be placed without introducing the index finger in to oral cavity[5]. The disposable laryngeal mask airways are available in pediatric sizes also. However, there is paucity of published literature establishing superiority of one airway device over the other. Therefore, this study was designed to know the relative ease of insertion of different supra-glottic airway devices in pediatric cases

MATERIAL & METHODS

One hundred and twenty patients of either sex belonging to American Society of Anesthesiologists (ASA) physical status class I or II, between 1 to 6 years of age, scheduled to undergo elective surgery under general anaesthesia were included in the study.

Patients having difficult airway, restricted mouth opening, risk of aspiration, upper respiratory tract infection, congenital heart disease, surgery in position other than supine, difficult history of upper gastro-intestinal surgery, bleeding or clotting abnormalities and oesophageal trauma, head and neck surgery, were excluded from the study.

They were premedicated with syrup midazolam 0.5 mg kg^{-1} one hour preoperatively. After arrival in the operation theatre routine monitoring was set up. Baseline readings of vital parameters were recorded.

- Patients were then randomly allocated to one of the three groups usingcoded envelopes as follows:
- Group-I – (n=40), LMA Classic was inserted. Group-II – (n=40), LMA Unique was inserted.
- Group-III – (n=40), Ambu laryngeal mask was inserted.

Anaesthesia was induced with standardized anaesthetic technique using either intravenous thiopentone 5 mg kg^{-1} or inhaled sevoflurane 6-7 % in 100% oxygen along with I/V glycopyrrolate 0.005 mg kg^{-1} and fentanyl 2mcg kg^{-1}. Injection atracurium 0.5 mg kg^{-1} was used to facilitate air way device insertion. Patients were ventilated for 3 minutes via face mask using sevoflurane 2-3% in 100% O2. The supraglottic airway device of appropriate size was used as per standardweight criteria.

In group I and II, the LMA (Classic or Unique) was inserted using the standard method described by Brain with slight modification of partial inflation of cuff.

In group III, the Ambu laryngeal mask was inserted using the pencil insertion technique as described in the instruction manual.

Correct placement of the device was confirmed by manual ventilation and auscultation of breath sounds, chest movements, ability to ventilate the patient without substantial leak at an airway pressure of $\leq$15 cm of water andsquare wave capnography.

The outcome was measured in terms of number of attempts, ease of insertion, insertion time, pharyngeal positioning and airway seal pressure. The pharyngeal positioning was graded using fiberoptic bronchoscope.

NUMBER OF ATTEMPTS

A maximum of three insertion attempts made before the placement of the device was considered a failure. In case of failure alternative airway device was used to secure the airway.

INSERTION TIME

The time interval between picking up the laryngeal mask airway and obtaining effective ventilation was recorded.

PHARYNGEAL PLACEMENT

An easy insertion was defined as insertion within the pharynx without resistance in a single maneuver while difficult insertion faced resistance and more than one attempt.

AIRWAY SEAL PRESSURE

Airway seal pressure was determined by switching off the ventilator at a fixed gas flow of 3 litres min^{-1} and recording the airway pressure (maximum allowed 30 cm of water) at which equilibrium is reached.

FIBREOPTIC (FOB) GRADING OF PLACEMENT

A flexible Fibreoptic scope was introduced into the airway tube till its junction with the LMA bowl to score the laryngeal view. Fibreoptic position was graded as follows:

Grade 1- Trachea in line with distal lumen of LMA and clear view of glottis.

Grade 2- Glottis and posterior (glottic surface) epiglottis visualised.

Grade 3- Glottis and anterior (vallecular surface) epiglottis with lessthan 50% glottis obscured.

Grade 4- Glottis and anterior (vallecular surface) epiglottis with morethan 50% glottis obscured.

Grade 5 - Glottis not seen.

Maintenance of anaesthesia for intraoperative period was achieved as per the requirement of the case and surgery was commenced.

All data were compiled and analyzed using excel sheet (Microsoft Co. USA). Comparison between the groups was done using ANOVA, student t-test and chi square test. The level of significance was set at 0.05.

RESULTS

The demographic parameters were compared with no significant difference between three group (table 1).

The ease of insertion was mostly easy in all the three groups (table 2). The mean insertion time was 15.40±2.31 seconds for group I (LMA Classic) with minimum time of 10 and maximum time of 20 seconds. It was 15.87±2.12 seconds for group II (LMA Unique) with minimum of 12 andmaximum of 22 seconds. In group III (Ambu laryngeal mask) it was 12.42±3.16 seconds with minimum and maximum of 8 and 18 seconds respectively.

There was no patient with oropharyngeal seal pressure (OSP) in the range of <15 cm H2O in group I (LMA Classic), while there were 2 (5%) in group II (LMA Unique) and 1 (2.56%) in group III (Ambu laryngeal mask). Maximum no. of patients in the three groups were in 15-20 cm H2O range of seal pressure. In this range there were 25 (62.50%), 26 (65%) and 17 (43.58%) patients in the respective groups. There were significantly a smaller number of patients i.e. 12 (30%) in group II as compared to group I i.e. 15 (37.50%) and group III i.e.16 (41.02%) in the higher seal pressure (20-25 cm H2O) range. However only in group III (Ambu laryngeal mask) highest seal pressure of 20-25 cm H2O was observed in 5 patients. There were no patients with seal pressure of 25-30 cm H2O in group I and II (table 3).

FOB grade I was observed in 25 (62.5%) cases each in group I & II and 24 (61.5%) cases in group III. While grade II was observed in 10 (25%), 13 (32.50%) and 8 (20.5%) cases in group I (LMA Classic), group II (LMA Unique) and group III (Ambu laryngeal mask) respectively. Grade III was seen in 5 (12.5%), 1 (2.5%) and 6 (15.3%) cases in group I, II and III respectively. Grade IV was seen in 1 (2.5%) in group II and 1 (2.5%) in group III. The p value between group 1 & 2 (0.772), between 2 & 3 (0.888), between 3 & 1 (0.888) was not significant. The FOB grades were comparable (table 4) in all the groups (p value=0.666). On the whole all the groups had maximum number of grades I (62.18%) followed by grade II (26.05%).

The overall incidence of blood stain on airway device was 8 (6.72%) outof 119 and all the three groups were comparable (p value=0.597). There were no cases of post operative dysphagia in any of the groups. Blood was present in 3, 4 and 1 cases in group I, II and III respectively indicating some airway mucosal injury. The outcome was successful insertion achieved in all cases in group I (LMA Classic) and II (LMA Unique) and in 97.5% cases in group III. When analyzed using chi square test morbidity was similar in all the groups (p>0.05).

Table 1: The demographic profile of patients

	Group I	**Group II**	**Group III**	**Total**
Age (Mean±SD)In years	3.8±1.78	3.9±1.69	4.27±1.68	3.99±1.71
Wt. (Mean±SD) In kg.	14.86±5.18	15.75±4.78	14.95±3.99	15.18±4.66
Sex (M/F)	40/0	37/3	37/3	114/6
ASA (I/II)	40/0	40/0	40/0	120/0

Table 2: Distribution of patients as per ease of insertion

	Number of patients			
Ease of insertion	**Group I(n=40)**	**Group II(n=40)**	**Group III(n=40)**	**Total (n=120)**
Easy (E)	36 (90%)	33 (82.5%)	36 (90%)	105 (87.5%)
Difficult (D)	4 (10%)	7 (17.5%)	3 (7.5%)	14 (11.66%)
Failure (F)	0 (0%)	0 (0%)	1 (2.5%)	1 (0.83%)

Chi square test (p=0.403) Student's t-test (p=0.6601, 2, 0.486,2,3 0.262 3,1)

Table 3: Distribution of patients as per seal pressure(cmH_2O)

Seal pressure (cm H2O) range	**Number of patients**			**Total (n=120)**
	Group I (n=40)	**Group II (n=40)**	**Group III (n=40)**	
<15	0	2 (5%)	1 (2.56%)	3 (2.52%)
15-20	25 (62.50%)	26 (65%)	17 (43.58%)	68 (57.14%)
20-25	15 (37.50%)	12 (30%)	16 (41.02%)	43 (36.13%)
25-30	0	0	5 (12.82%)	5 (4.20%)

chi square test (p = 0.025)

Table 4: Distribution of patients as per FOB grade

Group	**FOB grade**				**p value***
	1	**2**	**3**	**4**	

Group I (n=40)	25 (62.5%)	10 (25%)	5 (12.5%)	0 (0%)	0.772[1,2]
Group II (n=40)	25 (62.5%)	13 (32.5%)	1 (2.5%)	1 (2.5%)	0.888[2,3]
Group III (n=39)	24 (61.5%)	8 (20.5%)	6 (15.3%)	1 (2.5%)	0.888[3,1]
Total (n=119)	74 (62.18%)	31 (26.05%)	12 (10.08%)	2 (1.68%)	0.6661,2,3

*Unpaired student's t-test, Univariate analysis of variance (ANOVA) (p= 0.666[1,2 3])

DISCUSSION

The overall success was comparable and difference was statistically insignificant among the three groups. The first attempt success rate was equal for group III (Ambu laryngeal mask) and group I (LMA Classic) but higher as compared to group II (90% vs 82.5%); (p=0.413), however this was not statistically significant. Two attempts were required in 3(7.5%), 6(15%), and 2(5%) patients in all groups. Three attempts were required in 1 (2.5%) patient each in group I, II & III respectively. There was a single failure and that was in group III. The difficult insertions in group I, II & IIIwere 4 (10%), 7 (17.5%), 3 (7.69%) respectively and were comparable.

Our study is in accordance with Mason et al who conducted a study in 200 children in a variety of surgical procedures. The LMA Classic was correctly inserted on first attempt in 89.5% cases. They observed that a clear airway was achieved in 191 children by LMA Classic.[4]

Genzwuerker et al conducted a study in 100 children of age group 2-8 years to compare two laryngeal masks; LMA Classic and the single-use Ambu laryngeal mask and observed that first attempt insertion for LMA Classic and Ambu laryngeal mask were 45 (90%) and 47 (94%), respectively[6]. The results are in accordance with our study.

The time taken for insertion was for group III(Ambu laryngeal mask) and was statistically significant less (p value=0) as compared to the rest of the groups The shorter time of insertion could be attributed to the 90° angle incorporated into the airway tube of Ambu laryngeal mask which matches with oro-pharyngeal anatomy and facilitates the insertion by creating a 90^0 angle with a rigid stylet close to the laryngeal portion of the laryngeal mask airway (LMA)improves the rate of successful insertion. Based on these results Vaida et al. suggested that a 90^0angle close to the junction of the airway tube and mask either by design, as in the Ambu Laryngeal Mask, or by inserting a rigid stylet, simplifies the insertiontechnique and improves the rate of successful insertion[7].

Our results are in accordance with that of Lauritsen et al who conducted a study in 66 non paralysed children with a weight of less than 30 kg to compare efficacy of Ambu laryngeal mask and LMA-Unique and observed insertion time of (15.1±1.1 SD sec) in Ambu laryngeal mask group which was less as compared to that in LMA-Unique group (18.8±4.5 SD sec).[8] Our study is in accordance with Francksen et al who observed that the time of insertion was significantly shorter in Ambu laryngeal mask group (median 14 sec) than LMA-Unique (median 19sec.). The results are in accordance with our study.[9]

On comparing oropharyngeal seal pressure in between the three groups, the highest seal pressure was achieved in group III (Ambu laryngeal mask) and lowest in group II (LMA Unique). When compared statistically significantly better seal pressure was achieved with Ambu laryngeal mask and LMA Classic than LMA Unique. Tan et al compared LMA Classic, LMA Unique and Soft Seal on 135 adult patients and observed that the seal pressure (Mean±SD) for LMA Classic was (17±7 cm H2O) and LMA Unique was (16±6 cm H2O) which is similar with our results 20.17±2.67 cm H2O in group I (LMA Classic), 19.27±2.83 cm H2O in group II (LMA Unique). [10] Szmuk et al. observed the seal pressure (Mean±SD) with LMA Unique group of 18±5 cm H2O (size 1, 1.5)and 16±5 cm H2O (size 2, 2.5) which is similar with our results 19.27±2.83 cm H2O (size 1.5, 2 & 2.5). [11] Monclus et al. and Theiler et al. found oropharyngeal seal pressure for Ambu laryngeal mask comparable to our results[12,13].

A flexible fiberscope was introduced into the airway tube to grade the laryngeal view, maximum number of patients in all the three groups had gradeI or grade II view. Rowbottom et al reported 79% of patients had grade I and II which is like our results 88.23%[14].

Patients were monitored for any adverse events including hypoxic episodes (SpO2 below 95%), airway obstruction, coughing, gagging, laryngospasm and trauma (defined as presence of blood on removal of airwaydevice). Blood-stained secretion was present on airway device at removal asevidence of injury in 3, 4 and 1 cases in group I, II and III respectively. There was no significant difference (p>0.05) between all the three groups about morbidity. No episode of desaturation or laryngospasm was noted in any case in our study.

Ambu laryngeal mask and LMA Unique are comparable to LMA Classic in terms of the ease of insertion. Ambu laryngeal mask has shorter insertion time and provided better seal pressure during positive pressure ventilation and lesser incidence of post operative sore throat. The use of Ambu laryngealmask and LMA Unique to manage the airway in paediatric patients appears to be safe, swift, and easy.

FINANCIAL INTEREST
None

CONFLICTS
None

REFERENCES

1. Shahin NJ, Mehtab A, Hammad U, Khan MM. A study of the use ofLaryngeal Mask Airway (LMA) in children and its comparison with endotracheal intubation. Ind J Anaesth 2009;53:174-8.
2. Verghese C, Brimacombe J. Survey of laryngeal mask usage in 11,910 patients-safety and efficacy for conventional and nonconventional usage. Anesth Analg 1996;82:129-33.
3. Verghese C, Smith TGC, Young E. Prospective Survey of the laryngeal mask usage in 2359 patients. Anaesthesia 1993;48:58-60.
4. Mason DG, Bingham RM. The laryngeal mask airway in children.Anaesthesia 1990;45:760-3.
5. Pennant JH, White PF. The laryngeal mask airway- its uses inanesthesiology. Anesthesiology 1993;79:144-63.
6. Genzwuerker HV, Sinkowitsch J, Hinkelbein J, Jandewerth O, Hohl EC. Recommended inflation volumes result in lower cuff pressures in paediatric patients with Ambu Aura Once when compared to LMA- Classic. Eur J Anaesth 2007;24:130.
7. Vaida SJ, Yodfat UA. Angulation of the airway tube in the Ambu Laryngeal mask could be responsible for improved insertion success. Anesth Analg 2005;101:264.
8. Lauritsen T, Horber RK, Marciniak B, Thomas M, Larsen WS, Hanneberg S. Similar efficacy of Ambu laryngeal mask and LMA unique in childrenless than 30 kg. Eur J Anaesth 2006;23:165.
9. Francksen H, Bein B, Cavus E, Renner J, Schoiz J, Steinfath M et al. Comparison of LMA-Unique, Ambu laryngeal mask and Soft Seal during routine surgical procedures. Eur J Anaesth 2007;24:134-40.
10. Tan MGE, Chin ERC, Kong CS, Chan YH, Yam PC. Comparison of the re- usable LMAClassic™ and two single-use laryngeal masks (LMA Unique™ and Soft Seal™) in airway management by novice personnel. Anaesth Intensive Care 2005; 33: 739-41.
11. Szmuk P, Ghelber O, Matuszczak M, Rabb MF, Ezri T, Sessier DL. A prospective, randomized comparison of Cobra Perilaryngeal airway and laryngeal mask airway Unique in paediatric patients. Anaesth Analg 2008;107:1523-30.
12. Monclus E, Garce A, Maria BJ, Arte D, Mabrock M. Study of the adjustment of the Ambu laryngeal mask under magnetic resonance imaging. Pediatr Anaesth 2007;17:1182-6.
13. Theiler LG, Brueggeney MK, Luepold B, Stucki F, Seiler S, Urwyler N. etal Performance of the pediatric-sized i-gel compared with the Ambu AuraOnce laryngeal mask in anesthetized and ventilated children. Anesthesiology 2011;115:102-10.
14. Rowbottom SJ, Simpsom DL, Grubb D. The laryngeal mask airway inchildren. Anaesthesia 1991;46:489–91.