Original Article

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Comparison of the Efficacy of Classic LMA (CLMA) and Proseal LMA (PLMA) in Paralysed, Anesthetized Patients

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Abstract

Context: Laryngeal mask airway (LMA) has revolutionized airway management in the administration of general anesthesia. Proseal LMA offers advantages like better sealing pressure, drain tube and lesser risk of aspiration. The present study is designed to compare the efficacy of Classic LMA (CLMA) and Proseal LMA (PLMA) in anesthetized patients coming for Gynaecological surgery. *Methods and Material:* 60 female patients of age group 18 years and older of American society of anaesthesiologists (ASA) physical status 1 and 2 who underwent elective gynaecological surgeries under general anaesthesia were divided into 2 groups, Group P (n = 30) comprised of patients who were managed with Proseal LMA and Group C (n = 30) comprised of patients who were managed with classic LMA. Outcomes measured were Fibreoptic grading of LMA placement, Oropharyngeal sealing pressure (OSP), Ease of insertion, Time taken for insertion, Number of attempts and incidence of Complications. *Results:* The oropharyngeal sealing pressure was found to be significantly higher with proseal LMA(31.27±5.0 cm H_2O) than classic LMA (17±3.4 cm H_2O). The best fiberoptic score (grade 4) were found in 22 patients of Proseal LMA group and 7 patients of Classic LMA group which was statistically significant. *Conclusions:* Proseal LMA is superior to Classic LMA in anatomical placement defined in terms of clinical end points, oropharyngeal sealing pressure and fiberoptic view in anesthetised patients coming for Gynaecological surgery.

Keywords: Laryngeal Mask Airway; PLMA; CLMA; Airway; Muscle Paralysis.

Introduction

The laryngeal mask airway was designed by Archie Brain [1] and it has revolutionised airway management. Currently its use has become the standard practice in general anaesthesia. LMA has its advantages over endotracheal tube in terms of ease of insertion, smooth awakening, lesser hemodynamic changes during its placement and also minimal complications to patient's upper airway [2].

Classic LMA (CLMA) and Proseal LMA (PLMA) are two such LMA's which are used widely in the practice of Anesthesia. The purpose of this study was to compare the efficacy of Classic LMA and Proseal LMA in paralysed, anesthetized patients coming for Gynaecological surgery.

Aim of the Study

To compare Classic LMA and Proseal LMA in anesthetised patients coming for Gynaecological surgery in terms of Fibreoptic view (FOB), Oropharyngeal sealing pressure (OSP), Ease of insertion, Time taken for insertion, Number of attempts and Complications.

Materials and Methods

After obtaining institutional ethical committee clearance and written informed consent, 60 patients of age group ≥ 18 years and ASA status I and II who underwent gynaecological surgeries under general anaesthesia were enrolled for the study and

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randomly allocated into two groups viz Group P (proseal) and Group C (classic) by computer generated random allocation. Patients with difficult airway, pregnancy, history of gastrooesophageal reflux disease, acute or chronic respiratory disease, severe cardiovascular disease, musculoskeletal abnormality affecting cervical vertebrae, history of allergic reaction to the anaesthetic drugs were excluded from the study.

The patients were subjected to pre anaesthetic assessment the day before surgery with complete medical history, physical examination and investigations. They were kept fasting overnight and were given oral ranitidine 150 mg and metoclopramide 10 mg as acid aspiration prophylaxis the night before surgery. In the operation theatre, five lead electrocardiogram, oxygen saturation (SpO2), non invasive blood pressure were connected. The patients were premedicated with inj.glycopyrrolate 0.2 mg, inj.Ranitidine 50 mg and inj Metoclopramide 10 mg intravenously half an hour before induction of general anaesthesia. Inj.Fentanyl 2 μg/kg was given intravenously to all patients 5 minutes prior to induction. The patients were preoxygenated with 100% oxygen for 3 minutes. Preinduction baseline cardio-respiratory parameters like heart rate, blood pressure and oxygen saturation were recorded. Anaesthetic induction was done with intravenous Propofol 2mg/kg followed by neuromuscular blockade with Atracurium 0.5 mg/kg. Patient was ventilated with bag and mask with 2% sevoflurane and oxygen for 3 minutes and an appropriate sized LMA based on body weight was inserted in sniffing position by an anaesthesiologist with atleast 2 years of experience and who had previously done > 100 insertions of both classic and proseal LMA. Both Classic and proseal LMA were inserted by digital technique to maintain parity between the insertion techniques of both the LMAs. Cuff was fully deflated and lubricated with water soluble gel in both the LMA groups after insertion, the cuff was inflated with the recommended volume of air for that particular size. A gastric tube was inserted through the drain tube of Proseal LMA. The proper insertion of LMA was confirmed by the ability to achieve effective ventilation with expiratory tidal volume of 7 ml/kg and end tidal capnography waveform. The LMA was fixed and the cuff pressure was checked with the help of Portex cuff pressure monitor and ensured to be 60 cm of H_2O. Anaesthesia was maintained with oxygen and nitrous oxide (1:3) with sevoflurane 1-2%. Outcomes measured were Fiberoptic view (FOB), Oropharyngeal sealing pressure (OSP), Ease of insertion, Time taken for insertion, Number of attempts, hemodynamic parameters and Complications.

Ease of insertion was graded as: 1-easy, 2-difficult, 3-impossible. In case of failure to insert the LMA properly as judged by an audible leak or inability to achieve adequate chest expansion, the device was removed and reinserted. Maximum three attempts were allowed and if effective ventilation could not be achieved endotracheal intubation was planned. Time taken for insertion was defined as time elapsed between picking up of an airway device in hand and achieving effective ventilation. The oropharyngeal leak pressure was determined by closing the adjustable pressure limiting (APL) valve of the circle system at a fixed gas flow of 3 litres/min and recording the airway pressure at which equilibrium was reached (maximum allowed was 40 cm H_2O). Equilibrium was taken as the point at which an audible leak could be heard from the mouth [2,3]. Hemodynamic parameters measured were heart rate, systolic and diastolic blood pressure and it was measured during the preinduction period and 1, 5 minutes after insertion of LMA.

After recording the above observations, a 4.9 mm fibreoptic bronchoscope was passed through the LMA till its tip lies 1 cm proximal to the end and the view was assessed by a standard score devised by Brimacombe and Berry [4]. Grade 1: vocal cords not seen, Grade 2: vocal cords and anterior epiglottis seen, Grade 3: vocal cords and posterior epiglottis seen and Grade 4: only vocal cords seen. Grade 3 and 4 were taken as desired views, grade 2 as satisfactory while grade 1 as non satisfactory view. The surgery was then allowed to commence and both intraoperative and postoperative complications like bronchospasm, aspiration, nausea, vomiting, sore throat and blood staining of the device after removal were noted and treated accordingly. At the end of surgery, the neuromuscular blockade was reversed with glycopyrrolate and neostigmine at the appropriate dose and the LMA was removed when the patient had adequate neuromuscular recovery. Patient was shifted to recovery room and observed for 6 hours and the sore throat was assessed immediately and 6 hours after surgery. Power analysis was done using G* Power (version 3.1.9.2, United states) and the sample size was calculated to get an expected 30% difference between the two groups with respect to oropharyngeal leak pressure with alpha error of 0.05 and power of 0.8.

Analysis was done using SPSS version 15.0 and students t- test and chi square test was applied for interpretation of results and a P value of <0.05 was considered statistically significant. All the outcome

measures are expressed as mean and standard deviation. The qualitative parameters such as ease of insertion, number of attempts, fibre-optic score and the complications were analysed using the Pearson Chi-square test. The quantitative parameters such as demographic data, the time taken for insertion, the oropharyngeal sealing pressure (OSP) and the hemodynamics were analysed using the unpaired T test.

Results

The two groups PLMA and CLMA were comparable with respect to the demographic characteristics (Table 1). The oropharyngeal sealing pressure (Figure 1) was found to be significantly higher with proseal LMA (p - 0.001). The best fiberoptic score (grade 4) were found in 22 patients of PLMA group and 7 patients of CLMA group which was statistically significant. Fiberoptic scores of both the groups are shown in Figure 2. Outcome measures are shown in Table 2.

Other outcome measures (ease of insertion, number of attempts required for insertion, Time taken for insertion and hemodynamic parameters) were comparable between both the groups. Hemodynamic parameters are shown in Table 3. Incidence of complications was also found to be comparable between both the groups (Table 4 and Figure 3). Aspiration and vomiting were seen in 1 patient of classic LMA group which was treated by conservative management without the need of mechanical ventilation. Sore throat was seen in 8 patients of PLMA group and 3 patients of CLMA group.

Table 1: Demographic Characteristics

	Group P (n = 30)	Group C (n = 30)
Age (years)	38.63 ± 11.3	42.17 ±10.8
BMI	23.89	24.17
Duration of surgery (minutes)	120 ±10.5	118 ±12.8

Table 2: Outcome measures

	Group P (n = 30)	Group C (n = 30)	Significance
Ease of insertion			
Easy	27 (90%)	26 (86.7%)	NS
Difficult	3 (10%)	4 (13.3%)	
No. of attempts			
First	29	28	NS
Second	1	2	
Mean Time for insertion(Seconds)	20.63 ± 3.9	19.53 ± 6.0	NS
OSP (cm of water)	31.27 ± 5.0	17.00 ± 3.4	S
Fiberoptic score			
Grade 2	2	14	S
Grade 3	6	9	NS
Grade 4	22	7	S

*NS– Not significant, S– Significant, OSP– Oropharyngeal sealing pressure

Table 3: Hemodynamic parameters

	Group P (n = 30)	Group C (n = 30)	Significance
Heart rate(beats/min)			
Preinsertion	86.53 ± 10.7	85.47 ± 9.8	NS
1 min postinsertion	93.73 ± 11.2	92.33 ± 10.5	NS
5 min postinsertion	89.33 ± 13.2	89.17 ± 12.6	NS
Systolic BP(mm Hg)			
Preinsertion	121.6 ± 13.5	123.8 ± 10.7	NS
1 min postinsertion	134.1 ± 14.2	134 ± 11.6	NS
5 min postinsertion	128.27 ± 15.4	126.2 ± 14.3	NS
Diastolic BP(mm Hg)			
Preinsertion	78.5 ± 8.4	79.93 ± 8.5	NS
1 min postinsertion	86.53 ± 9.6	87.9 ± 10.2	NS
5 min postinsertion	80.37 ± 11.2	82 ± 7.3	NS

*NS – Not significant

Table 4: Complications

	Group P (n = 30)	Group C (n = 30)	Significance
No Complication	19	24	NS
Sore Throat	8	3	NS
Blood Tinge	3	1	NS
Aspiration	0	1	NS
Vomiting	0	1	NS
Total	30	30	NS

*NS – Not significant

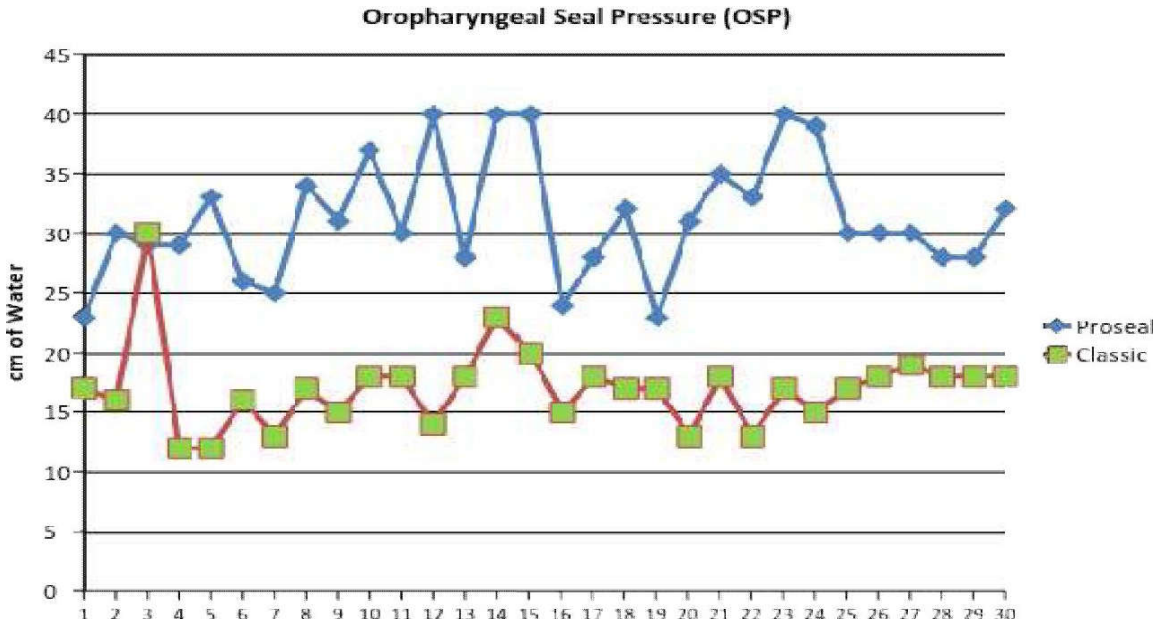

Fig. 1: Oropharyngeal sealing pressure

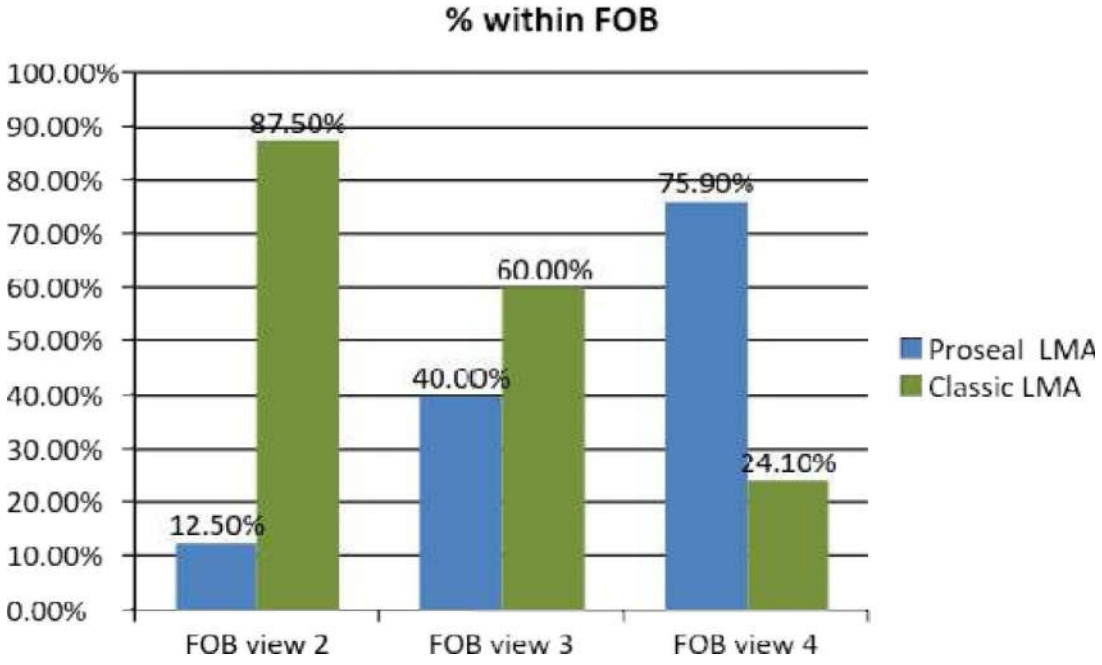

Fig. 2: Fiberoptic views of both the groups (given in percentage)

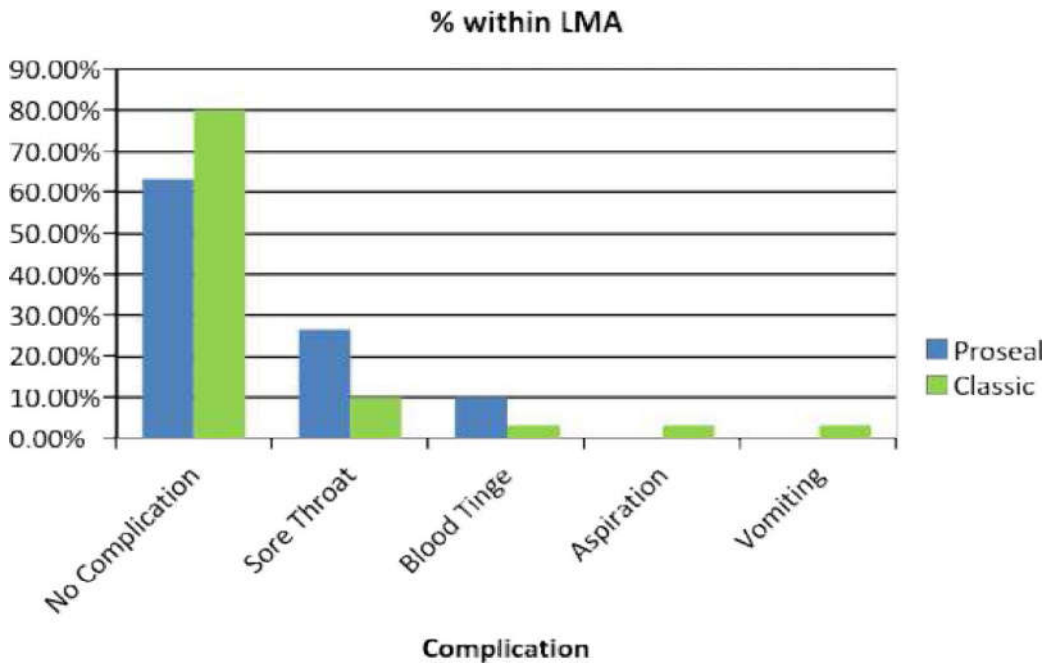

Fig. 3: Incidence of complications (given in percentage)

Discussion

Proseal LMA is a type of supraglottic airway device which provides better seal which in turn reduces the incidence of aspiration. Since it has an additional drain tube, it can be used as a preferred airway device in case of the need for controlled ventilation and access to the gastrointestinal tract [2]. Our results suggest that proseal LMA has better airway seal and placement than classic LMA in terms of oropharyngeal sealing pressure and better fiberoptic scoring. Oropharyngeal sealing pressure in our study was higher with proseal LMA than classic LMA (31.27 ± 5.0 cm H2O vs 17.00 ± 3.4 cm H2O). These findings were similar to the study done by park et al [5] who recorded oropharyngeal sealing pressure of 32 ± 5.9cm H_2O with proseal LMA. The number of patients with fibreoptic score in proseal group (grade 1,2,3,4 - 0,2,6,22) was better(p – 0.001) than Classic LMA (grade 1,2,3,4 - 0,14,9,7). This finding correlated with the study done by Lardner and colleagues [6] and Brain et al [7] who also found that the Proseal LMA gave better view of the cords. The possible reasons for Proseal LMA giving a better view of the larynx could be that its dorsal cuff pushes the ventral cuff more firmly into the periglottic tissues and thus not only forms a better seal around the larynx but also prevents rotation of the LMA thus providing stability to the device [8]. However, poor anatomical placement of LMA can still have clinically acceptable placement. But the point of debate is whether the anatomic placement has a valid correlation with the clinically acceptable placement. Arguably still, a malpositioned LMA could be the reason for complications like gastric distention, aspiration and airway trauma. Hence, a good anatomical placement has some clinical implications in terms of lesser incidence of complications [9,10,11].

We found that the ease of insertion, number of attempts and time taken for insertion was comparable in both the groups in our study. The LMA's of both the groups could be successfully inserted in more than 95% of patients in the first attempt and none of the patient required an alternative device or intubation which was similar to the study by Brimacombe and colleagues [12]. Although introducer is recommended by the manufacturer for insertion of Proseal LMA, we inserted it by digital technique to maintain parity between both the LMA's. The pilot study done by Brain and colleagues in adult female patients for insertion of Proseal LMA had similar findings to our study. A similar study done by Brimacombe et al [12] in adult patients concluded that the Proseal LMA was more difficult to insert and took longer time for insertion (23 ± 18 seconds vs 15 ± 13 seconds) than the Classic LMA. The mean duration of insertion (20.63 ± 3.9 seconds vs 19.53 ± 6.0 seconds) in our study was comparable. This discrepancy could be due to the insertion technique used by brimacombe and colleagues since they compared the time for

insertion with and without the introducer tool and found that the use of introducer made the insertion of Proseal easier.

Hemodynamic parameters in both the groups were comparable. Braun and colleagues [13] did a randomized comparative study in 280 patients and they also reported that the hemodynamic response to classic and proseal LMA was similar. The incidence of complications was comparable between the two groups. One patient had aspiration and one patient had regurgitation in classic LMA group and was managed conservatively without invasive ventilation. However, none of the patient in proseal LMA group had regurgitation or aspiration. Though there is a small risk of regurgitation with proseal LMA, very few cases of aspiration has been reported till now with proseal LMA. These results are concurrent with the results of our study. One important fact to always consider is that even proseal LMA is not absolutely safe in patients with risk of aspiration. High ventilation pressure can cause oropharyngeal leak which gets vented through the drain tube unlike classic LMA [14-18]. Incidence of aspiration found in literature for classic LMA is one in four to 11,000 and clinically detected regurgitation as 18 in 10,024. For proseal LMA, there were 3 confirmed cases in an estimated 1,000,000 uses [19]. Airway trauma (blood tinge found in LMA) was seen in 3 cases of PLMA group and 1 case of CLMA group in our study which was different from the literature. Studies have reported higher incidence of airway trauma with proseal than classic LMA [13,20]. However one study have shown similar results to our study [12]. There were 8 cases(26%) of sore throat in PLMA group compared to 3 cases(10%) in CLMA group which was not statistically significant. Similar incidences of sore throat was reported in other studies too [2].

Limitations of this study are that this study couldn't be blinded since it is not possible to double blind a LMA study. Since this study was done in paralysed patients, the results of our study may not apply to anesthetized patients who are spontaneously breathing.

Conclusion

We conclude that Proseal LMA is superior to Classic LMA in anatomical placement defined in terms of clinical end points, oropharyngeal sealing pressure and fiberoptic view in anesthetised patients coming for Gynaecological surgery. However there was no difference between the two LMA's in terms of ease of insertion, number of attempts, time taken for insertion, hemodynamic parameters and incidence of complications.

Key Messages

Proseal LMA is superior to Classic LMA in placement.

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