



A Comparitive Study of Laryngeal Mask Airway Proseal and Laryngeal Mask Airway Supreme in Patients Posted for Elective Surgeries Under General Anaesthesia

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INTRODUCTION

In spite of tremendous advances in contemporary anesthesia practice, airway management continues to be of paramount importance to anesthesiologist. Till date, the cuffed endotracheal tube was considered as gold standard for providing a safe glottic seal. Respiratory morbidities are the most common anaesthesia related complications, following dental damage during endotracheal intubation. The three main causes of respiratory related morbidities are inadequate ventilation, oesophageal intubation and difficult tracheal intubation. Difficult tracheal intubation accounts for 17% of the respiratory related injuries and results in significant morbidity and mortality. In fact up to 28% of all anaesthesia related deaths are secondary to inability to mask ventilate or intubate. Laryngoscopy and endotracheal intubation produce reflex sympatho-adrenal stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia etc. Airway devices can be classified as intraglottic and extraglottic airway devices, which are employed to protect the airway both in elective as well as emergency situations. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Dr Archie Brain a British anaesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet be simple and atraumatic to insert. Careful observations and clinical experience have led to several refinements of Brian's original prototype leading to development of newer supraglottic airway device with better features for airway maintenance. The primary limitation of the laryngeal mask airway (LMA) is that it does not reliably protect the lungs from regurgitated stomach contents, although it may act as a barrier at the level of the upper oesophageal sphincter if it is correctly positioned. The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation in elective patients. Proseal laryngeal mask airway has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture and permits high airway pressure without leak. The drain tube parallel to the ventilation tube permits drainage of passively regurgitated gastric fluid away from the airway and serves as a passage for gastric tube. A new laryngeal mask airway, LMA Supreme allowing gastric drainage has become available for clinical use. The LMA supreme is a latex free laryngeal mask airway, made of medical grade PVC (Poly vinyl chloride). The firm, elliptical and anatomically shaped airway tube facilitates easy insertion, without placing fingers in patient's mouth or requiring an introducer tool for insertion. It enables passive drainage or active drainage of gastric contents independent of ventilation with significantly lower postoperative pharyngolaryngeal morbidity. There are numerous literature on comparison between these two supraglottic airway devices with contradictory results. The main aim of this study is to compare the clinical efficacy of LMA Proseal and LMA Supreme for ease of insertion and oropharyngeal leak pressure in anaesthetized and paralyzed adult patients undergoing elective surgeries.

OBJECTIVES

The study was to compare LMA Proseal and LMA Supreme for ease of insertion and oropharyngeal leak pressure (OLP) in anesthetized and paralyzed adult patients undergoing elective surgeries. Secondary objectives were intracuff pressure (ICP), ease of passing gastric tube and device related complications.

MATERIALS AND METHODS

Sixty patients, scheduled for various elective surgical procedures undergoing general anaesthesia belonging to ASA class I and II were included in the study.

INCLUSION CRITERIA

- 1) Patients aged 18-60 yrs.
- 2) American society of anesthesiologist's (ASA) grade I and II
- 3) Scheduled for elective surgery under general anesthesia

EXCLUSION CRITERIA

- 1) Mouth opening < 2 cm
- 2) BMI > 30 kg/m²
- 3) Upper respiratory tract infection
- 4) Increased risk of aspiration (GERD, hiatus hernia, and pregnancy)
- 5) Cervical spine fracture or instability
- 6) History of allergy to one or more drugs

Study design: Prospective, randomized clinical study

Sample size calculation was done using open epi software

At 95% of confidence level, 5% of a error, $Z_{\alpha}=1.96$

At 80% of power $Z_{\beta}=0.84$

According to study done by Belena J M et al³¹

Oropharyngeal leak pressure (cm of H₂O) in PLMA (mean ± SD) = 30.7 ± 6.

Oropharyngeal leak pressure (cm of H₂O) in SLMA (mean ± SD) = 26.8 ± 4.1

The sample size was calculated using the formula

$$N = \frac{2(Z_{\alpha} + Z_{\beta})^2 a^2}{\Delta^2}$$



The sample size calculated is 30 in each group

Sampling technique: In this study 60 patients were divided randomly into two groups.

Allocation into two groups was done by computer generated randomization table.

Sixty(60) patients scheduled for different elective surgeries under general anaesthesia were

randomly allocated to one of the two groups of 30 patients each group.

Group S- Patients were inserted with LMA Supreme (n=30)

Group P - Patients were inserted with LMA Proseal (n=30)

PROCEDURE

Pre-anaesthetic evaluation was done on the evening before surgery. A routine pre-anaesthetic examination was conducted assessing;

- General condition of the patient
- Airway assessment by Mallampatti grading and rule of 1- 2- 3
- Nutritional status and body weight of the patient
- A detailed examination of the cardiovascular system
- A detailed examination of the Respiratory system

STATISTICAL ANALYSIS

Statistical analysis was done using SPSS software 11.0. Data obtained is tabulated in the Excel sheet analysed.

All values are expressed as mean ± standard deviation.

Chi - square test for proportions in qualitative data.

Student’s unpaired t – test for Quantitative data.

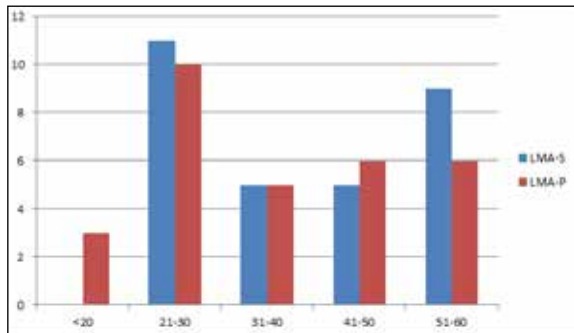
P< 0.05 was considered statistically significant.

RESULTS

TABLE 6: showing age distribution between group S (LMA supreme) and group P (LMA proseal)

Age (years)	Group S (LMA-S)		Group P (LMA-P)	
	No.of patients	%	No.of patients	%
<20	0	0	03	10
21-30	11	38	10	34
31-40	05	16	05	16
41-50	05	16	06	20
51-60	09	30	06	20
Total	30		30	
Mean age (SD)	39.1+14.24		36.83+14.37	
Minimum age	21		19	
Minimum age	60		60	
T=0.61	P=0.54			

T = 0.61 P=0.54



Graph 1 : showing age distribution

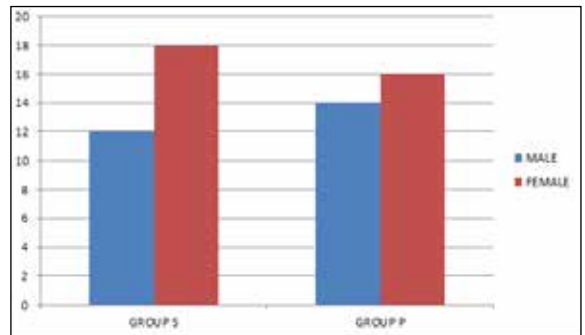
Table and graph shows age distribution of the patients in both the groups. The

minimum age in group LMA-S and group LMA-P was 21 years and 19 years respectively. The maximum age group LMA-S and group LMA-P was 60 years and 60 years respectively. The mean age in group LMA-S and group LMA-P was 39.1 and 36.8 years respectively.

TABLE 7: showing sex distribution

SEX	Group S		Group P	
	No.of Patients	%	No.of Patients	%
Male	12	40	14	47
Female	18	60	16	53
Total	30	100	30	100

CHI – 1.27, DF = 1, P=0.60



Graph 2: showing sex distribution

From the above table and graph it is seen that group LMA-S had 12 males and 18 females, group LMA-P had 14 males and 16 females there was no statistical difference between two groups (p>0.05)

TABLE 8: Showing types of surgical procedure

Sl.No	Type of surgical procedures	Group S No. Of PATIENTS	Group P No. Of PATIENTS
1	Lap appendicectomy	6	9
2	Lap cholecystectomy	9	5
3	Modified mastectomy	1	3
4	Fibro adenoma of Breast	5	3
5	Hernia	5	3
6	Burns debridement	0	4
7	Hemangioma cheek	1	1
8	Pleomorphic adnoma	1	0
9	Tubectomy	1	0
10	Axillary mass	1	0
11	Phyllodes tumour	0	1
12	Debridement upper limb	0	1
	TOTAL	30	30

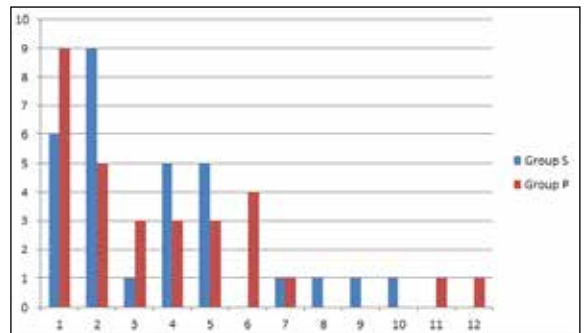
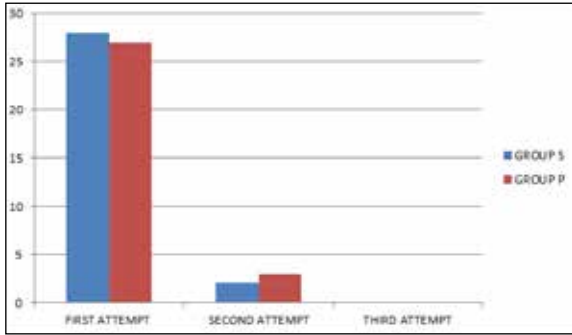


TABLE 9: showing number of attempts taken to insert device in each group

Insertion attempts	Group S		Group P	
	No.of Patients	%	No.of Patients	%
First Attempt	28	93	27	90
Second Attempt	02	07	03	10
Third Attempt	00	00	00	00
Total	30	100	30	100

$X^2 = 0.21$ $P=0.64$

CHI - 0.21, DF = 1, P=0.64



Graph 4: showing number of attempts taken for device insertion

Table and graph shows 28 of 30 insertions in group LMA-S were in the first attempt and only 2 patient required 2nd attempt. 27 of 30 in the group LMA-P required only one attempt and 3 patients required 2nd attempt. The attempt of insertion was not statistically significant between the two groups ($p>0.05$).

TABLE 10: Showing insertion time

GROUP	GROUP S	GROUP P	P value	T value
Time in sec (mean duration)	15.90±2.52	17.80±1.69	0.001	3.4

Graph 5: Showing insertion time

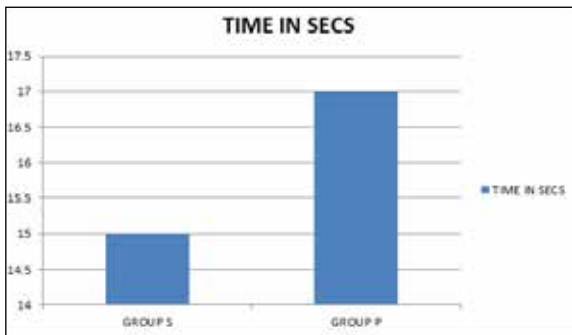


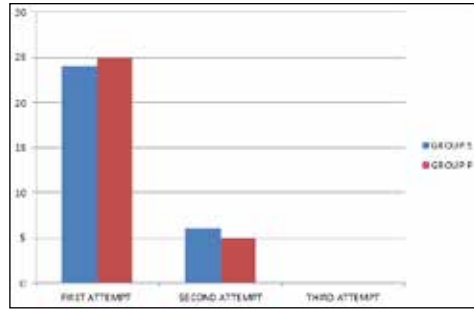
Table and graph shows the mean duration of insertion of LMA-S and LMA-P in patients were 15.90±2.52 and 17.80 ±1.69 seconds respectively and was statistically significant ($p<0.05$).

TABLE 11: Showing ease of passing ryles tube

EASE OF PASSING RYLES TUBE	Group S		Group P	
	No.of Patients	%	No.of Patients	%
First Attempt	24	80	25	83
Second Attempt	06	20	05	17
Third Attempt	00	00	00	00
Total	30	100	30	100

$X^2 = 0.11$ $P=0.73$

CHI - 0.11, DF = 1, P=0.73



GRAPH 6: Showing ease of passing ryles tube

Table and graph shows ease of passing ryles tube in group LMA-S in 24 patients it was passed in first attempt and 6 patients in second attempt. In group LMA-P in 25 patients it was passed in first attempt and 5 patients in second attempt, there was no statistical difference between two groups ($p>0.05$).

TABLE 12: Showing intracuff pressure at respective time intervals

Time	GROUP S	GROUP P	P value	T value
1 min	60	60	-	-
15 min	63.43±1.10	68.37±1.32	0.001	15.6
30min	68.37±1.32	76.87±2.6	0.001	15.9

GRAPH 7: showing intracuff pressure at respective intervals

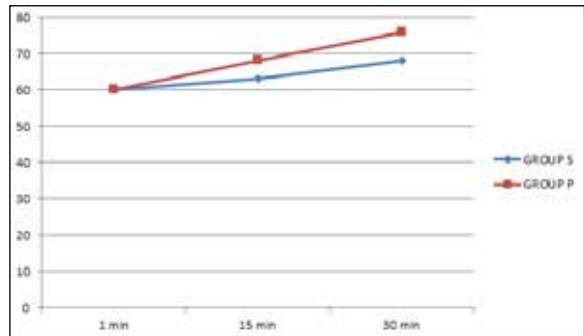


Table and graph showing intracuff pressure in cm H2O at time intervals 1 min, 15min and 30 min. In group LMA-S it was 60,63 and 68 respectively and in group LMA-P it was 60,68 and 76 respectively. There was statistical significance between two groups at 15 and 30 min ($p<0.05$).

TABLE 12: Showing Oropharyngeal leak pressure at respective time intervals

Time	GROUP S	GROUP P	P value	T value
1 min	25.27±1.20	27.50±1.28	0.002	6.9
15 min	22.83±1.34	25.67±1.58	0.001	7.4
30min	21.17±0.95	23.23±1.13	0.001	7.6

GRAPH 8: Showing Oropharyngeal leak pressure at respective time intervals

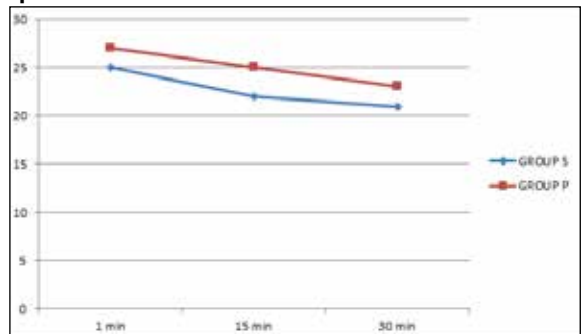


Table and graph showing oropharyngeal leak pressure in cm of H₂O in both groups at 1min, 15min and 30 min. In group LMA-S it was 25.27±1.20, 22.83±1.34, 21.17±0.95 respectively and in group LMA-P it was 27.50±1.28, 25.67±1.58, 23.23±1.13. There was statistical significance at 1mi ,15 min and 30 min (p<0.05)

TABLE 14: Showing complications

POST OPERATIVE DEVICE RELATED COMPLICATIONS	Group S		Group P	
	No.of Patients	%	No.of Patients	%
Presence of blood on device	2	06	3	10
Post Extubation Cough	5	17	5	17
Laryngospasm	0	0	0	0
Breathing holding spells	0	0	0	0
Dental or lip injury	0	0	0	0

GRAPH 9 : Showing complication

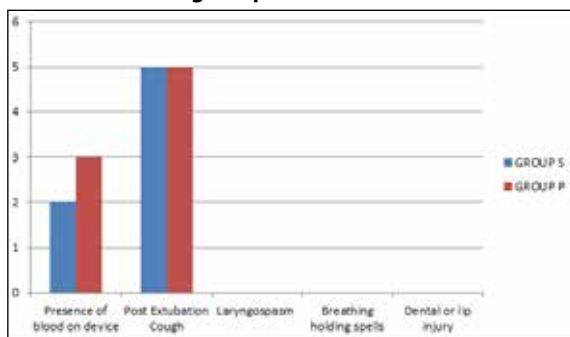


Table and graph shows 5 patients in both the group had post extubation cough and 2 patients in LMA-S group and 3 patients LMA-P group had blood tinged LMA after removal.

DISCUSSION

The major responsibility of the anesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing respiration is maintenance of patent airway. The tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Proseal laryngeal mask airway has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture. LMA supreme is a latex free laryngeal mask airway, made of medical grade PVC. The firm, elliptical and anatomically shaped airway tube facilitates easy insertion. This study was designed to compare the clinical efficacy of LMA-P airway and LMA-S to evaluate insertion attempts, oropharyngeal leak pressure, duration of insertion, ease of passing ryles tube, intracuff pressure and any complications in patients undergoing elective surgeries under general anaesthesia. A total of 60 ASA grade I-II patients aged 18-60 who were scheduled for surgery under general anaesthesia were randomized into two groups 30 in each and enrolled in our study. Age incidences between two groups were comparable. Most of the patient's age in both the groups ranged from 21 -30yrs. The difference between two mean ages are not statistically significant.

CONCLUSION

Both LMA Supreme and LMA Proseal can be used safely and effectively in selected patients undergoing general anaesthesia. LMA supreme is easy to insert compared to LMA Proseal but LMA Proseal had better oropharyngeal seal compared to LMA Supreme in spite of increased intracuff pressure. Ease of passing ryles tube was similar in both groups, complication of usage of LMA are minimal and similar in both the devices.

SUMMARY

Sixty ASA I-II patients scheduled for elective surgeries under general anaesthesia were randomized into two groups of 30 each. In Group

S (n=30) LMA supreme and Group P (n=30) LMA proseal were used respectively. Both the devices were compared in relation to ease of insertion assessed in terms of attempts taken and duration, Oropharyngeal leak pressure(OLP), Intracuff pressure(ICP), Ease of passing gastric tube and device related postoperative complications. The insertion attempts were similar between two groups. Time taken to provide an effective airway was less in LMA supreme (group S; 15.9 2.5 group P; 17.8 1.6) p (0.001). OLP was significantly less in LMA supreme at 1, 15 and 30 min during anaesthesia (group S; 25.2 1.2, 22.8 1.3, 21.1 , group P; 27.5) p (<0.05). ICP increased significantly in proseal LMA at 15 and 30 min during anaesthesia (group P; 68.3 S; 63.4 p (<0.05). There was no significance difference in passing gastric tube and device related complications between both groups. Both LMA Supreme and LMA Proseal can be used safely and effectively in selected patients undergoing general anaesthesia. LMA supreme is easy to insert compared to LMA Proseal but LMA Proseal had better oropharyngeal seal compared to LMA Supreme in spite of increased intracuff pressure. Ease of passing ryles tube was similar in both groups, complication of usage of LMA are minimal and similar in both the devices.

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