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Comparison of Laryngeal Mask Airway Proseal and Supreme in Patients Posted for Elective Surgeries Under General Anaesthesia: A Randomised Clinical Trial

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Abstract

Background: In spite of tremendous advances in contemporary anesthesia practice, airway management continues to be of paramount importance to anesthesiologist. Hemodynamic changes are the major undesirable consequences of endotracheal intubation and laryngoscopy. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. In view of this, the present study was undertaken to compare the performance of two supraglottic airway devices LMA supreme and LMA proseal. *Methodology*: Sixty ASA I-II patients scheduled for elective surgeries under general anaesthesia were randomised 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. *Results*: 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 anesthesia (Group S; 25.2 1.2, 22.8 1.3, 21.1±.9, Group P; 27.5±1.2,25.6±1.5,23.3±1.1) p (<0.05). ICP increased significantly in proseal LMA at 15 and 30 min during anesthesia (Group P; 68.3±1.3,76.8±2.6, Group S; 63.4±1.1, 68.3±1.32) p (<0.05). There was no significance difference in passing gastric tube and device related complications between both groups. *Conclusion*: Our finding suggested that LMA supreme was better in term of ease of insertion but LMA proseal had better OLP inspite of increase in ICP. Ease of passing gastric tube was similar in both. The complications of usage of LMA are minimal and similar in both the devices.

Keywords: Laryngeal mask airway; Proseal LMA; Supreme LMA.

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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 [1].

Respiratory morbidities are the most common anaesthesia related complications, following dental

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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 [2].

Laryngoscopy and endotracheal intubation produce reflex sympatho-adrenal stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia etc. [3]. 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 [4].

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 Brain's original prototype leading to development of newer supraglottic airway device with better features for airway maintenance [5].

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 [6].

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 [7].

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 [8].

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 airway sealing pressure in anaesthetized and paralyzed adult patients undergoing elective surgeries. Other parameters like intracuff pressure, ease of passing gastric tube and device related post operative complications were also noted.

Materials and method

The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients. Sixty patients aged 18-60 years scheduled for various elective surgical procedures undergoing general anaesthesia belonging to ASA class I and II were included in the study. Those with mouth opening < 2 cm, BMI > 30 kg/m^2 upper respiratory tract infection, increased risk of aspiration (GERD, hiatus hernia, and pregnancy), cervical spine fracture or instability were excluded.

Sample size calculation was done using open epi software. It was a prospective randomised clinical study.

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

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

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

Pre-anaesthetic evaluation was done on the evening before surgery. All patients included in study were kept nil per mouth for six hours prior to surgery.

On arrival to the pre-anaesthetic area patients were secured with IV cannulation, injection metoclopramide 10 mg and injection ranitidine 50 mg was injected IV 30 min before expected time of intubation.

Then the patient shifted to operating room, Ringer lactate infusion was started. The patient's head was placed on a soft pillow of 10 cms height before induction of anaesthesia with the neck flexed

and head extended. The patients were connected to multiparameter monitor which records heart rate, non-invasive blood pressure, et CO_2 and continuous ECG monitoring and oxygen saturation.

Patients were preoxygenated for 3 minutes, injection glycopyrolate 0.005 mg/kg iv, injection midazolam 0.05 mg/kg iv, injection fentanyl 2 µg/kg iv was injected as premedication just before induction. Patienst were induced by injection propofol 2.5 mg/kg iv and injection vecuronium 0.1 mg/kg iv.

After adequate depth of anesthesia was achieved, device was inserted after lubrication with water based jelly by the anaesthesiologist experienced in both device insertion.

In group P, the LMA proseal was inserted according to manufacturer's instruction manual. A size 3, 4 or 5 was used according to weight and cuff was inflated to 20 ml, 30 ml, 40 ml for size 3, 4, 5 respectively as recommended by manufacturer.

Fig. 1: LMA Proseal inserted in patient

For patients of group S, the LMA Supreme size 3, 4, 5 was inserted according to the weight and manufacturer's instructions, cuff was inflated to 30 ml, 45 ml, and 45 ml respectively.

Fig. 2: LMA Supreme inserted in patient

An effective airway was confirmed by bilateral symmetrical chest movement on manual ventilation, square wave capnography, no audible leak of gas and lack of gastric insufflations. If it is not possible to insert the device or ventilate through it, two more attempts of insertion were allowed. If placement fails after three attempts, the case was abandoned and the airway was maintained through other airway device as suitable and this case was considered as failed attempt Both the devices were fixed by taping the tube to the chin and well lubricated gastric tube was introduced in to the stomach.

Patients were maintained with nitrous oxide, oxygen mixture and isoflourane connected to dragger fabius machine and put on Pressure Control Volume mode and intermittent boluses of vecuronium administered intravenously.

Fig. 3: Anaesthesia workstation

At the end of operation, anesthetic agent was discontinued, reversed with injection glycopyrolate 0.01 mg/kg iv, injection neostigmine 0.05 mg/kg iv allowing smooth recovery of consciousness. The device was removed after the patient regains consciousness and breathes spontaneously and responds to verbal commands to open the eye. Blood staining of device, trauma to mouth, tooth or pharynx was noted.

Parameters measured

1. Ease of insertion assessed in terms of number of attempts taken to insert the device and duration (time from picking up the device until attaching it to the breathing system in seconds).

2. Oropharyngeal leak pressure was determined by closing the expiratory valve of the circle at

a fixed gas flow of 3 litre/min, and noting the airway pressure in the anesthetic breathing system(maximum allowed is 40 cm H_2O) at which audible gas leak occurred into the mouth.

3. Intracuff pressure (measured by handheld pressure guage).

4. Ease of passing gastric tube-easy, difficult, failed.

5. Incidence of airway related complications caused by supraglotic device Post-extubation cough, breath holding, laryngospasm, presence of blood on the SLMA or PLMA, lip and dental injury.

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 1: Showing types of surgical procedure

Sl. No	Type of surgical procedures	Group S	Group P
		No. of Patients	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 2: 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

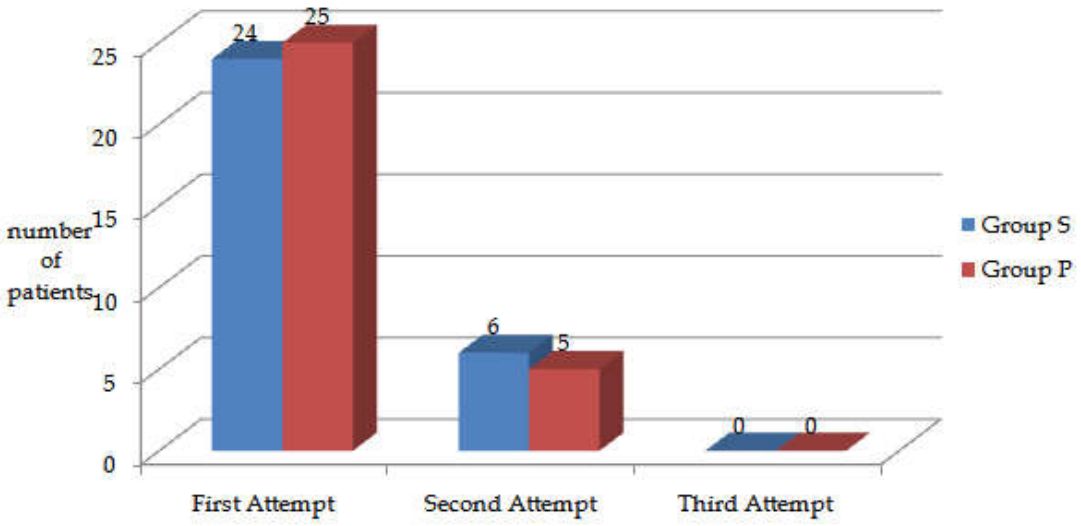
CHI – 0.21, DF = 1, P=0.64

Tables 1 and 2 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 3: 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

Table 3 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).



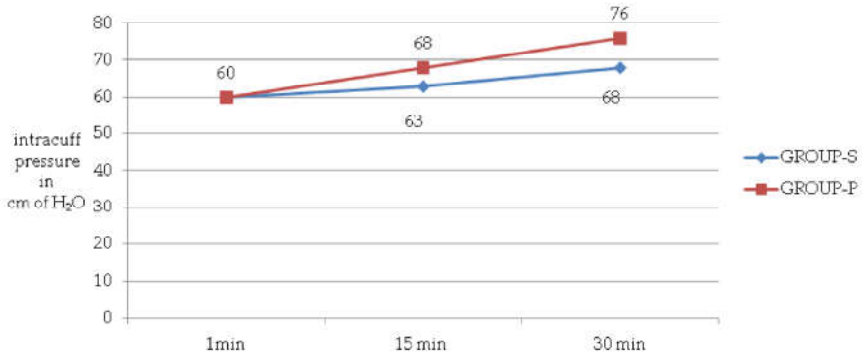
Graph 1: Showing ease of passing ryles tube

Graph 1 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 significant difference between two groups (p>0.05)

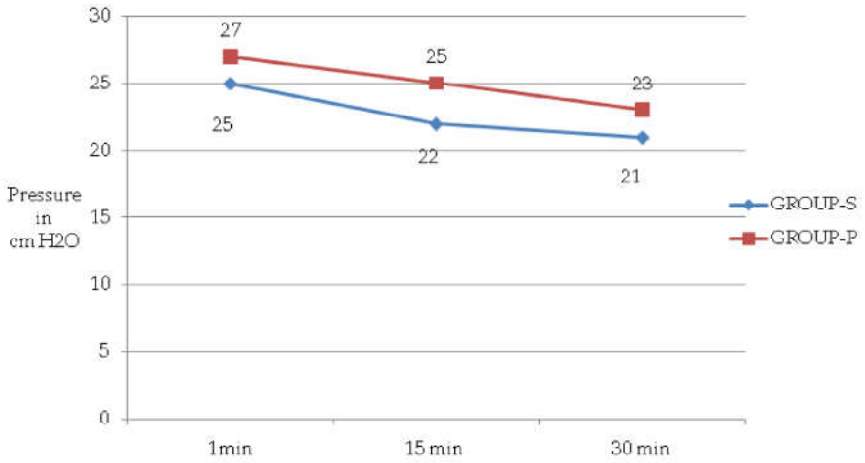
Graph 2 showing intracuff pressure in cm H_2O at time intervals 1 min, 15 min and 30 min. In group LMA-S it was 60, 63 and 68 respectively and in group LMA-P it was 60, 68 and 76 respectively. There was statistical significant difference between two groups at 15 and 30 min (p<0.05).

Graph 3 showing oropharyngeal leak pressure in cm of H_2O in both groups at 1 min, 15 min 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 1 min, 15 min and 30 min (p<0.05).

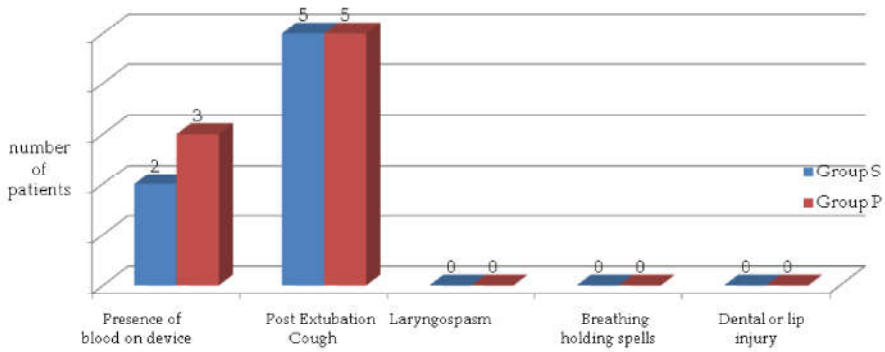
Graph shows 5 patients in both the groups had post extubation cough and 2 patients in LMA-S group and 3 patients LMA-P group had blood tinged LMA after removal.



Graph 2: showing intracuff pressure at respective intervals



Graph 3: Showing Oropharyngeal leak pressure at respective time intervals



Graph 4: Showing complication

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 [9].

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask [10].

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 [7]. The new 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 [8].

There are many literature comparing both these devices with contradictory results.

Thus, 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 21-30 yrs. The difference between two mean ages are not statistically significant.

The male to female ratio in LMA-S group is 12/18 and in LMA-P group is 14/16. There is no statistical difference between the groups.

In our study both the device insertions were easy and there were no failure. In LMA-S group it was inserted in first attempt in 28 patients and in second attempt in rest 2. In LMA-P group it was inserted in first attempt in 27 patients and in second attempt in rest 3. This is similar to the study conducted by Hosten T, et al. [11] who conducted study comparing LMA-S and LMA-P in 60 patients where there was no difference in insertion attempts.

Study conducted by Belena JM, et al. [12] showed success rate of the first attempt insertion was higher in LMA-S group, this difference might be due to not usage of muscle relaxant in this study while inserting LMA.

Time required for insertion in LMA-S group and LMA-P group was 15.90±2.52 sec and 17.80±1.69 sec respectively. Time required for LMA-S was less compared to LMA-P and it showed statistical significance ($p=0.001$). Study done by Hosten T et al. [11] and Belena JM, et al. [12] showed no difference in both groups in time taken for inserting the device. Clinically this difference what we observed has no significance.

Ease of passing ryle's tube was similar in both groups, with success rate of 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 ($p=0.73$). Belena JM, et al. [12] had got similar results but study done by Hosten T et al. [11] showed failure of passing ryles tube in 5 patients in LMA-P group. The drainage tube of S-LMA is directly posterior to the ventilatory side and travels strictly midline and opens at the distal end of the cuff. We believe that an improved drainage tube design may explain the improved success rate of ryle's tube passage in LMA-S. It depends on the amount of jelly used and size in our study we made sure we used adequate jelly for passage and the appropriate size this might be the reason of no failures in our study.

In our study we measured intracuff pressure in cm of H_2O at 1 min, 15 min and 30 min interval in both groups LMA-S and LMA-P it was 60, 63.43±1.10, 68.37±1.32 and 60, 68.37±1.32, 76.87±2.6 respectively, It was observed that as the time elapsed the intracuff pressure increased in group LMA-P ($p<0.05$), similar result was seen in study conducted byHosten T et al. [11] where they measured ICP at 30 and 60 min interval.

The increase in the intracuff pressure in LMA-P group can be explained in the sense that LMA-S is constructed from polyvinyl chloride in contrast to LMA-P, which is constructed from silicon. The cuff of the LMA-P is highly permeable to N_2O and ICP increase during N_2O anesthesia.

In a study conducted by Keller C, et al. [13] they observed the effect of ICP on OLP and fibreoptic position with LMA, they concluded that LMA functions better at sub-maximal cuff volumes.

By observing this it is very necessary to measure and adjust the ICP at time intervals by the help of hand held pressure gauge.

Owing to the moderate pharyngeal seal provided

by the supraglottic airway devices, controlled ventilation may not be always possible and there is a risk of pulmonary aspiration of regurgitant matter. Aspiration requires regurgitant fluid to reach the laryngeal inlet and it depends on the seal the SAD makes with oesophagus (oesophageal seal) combined with seal with pharynx (pharyngeal seal), which will determine the likelihood of spill into the larynx [14].

In our study we measured OLP in cm of H_2O at 1 min, 15 min and 30 min time interval in both groups LMA-S and LMA-P it was 25.27±1.20, 22.83±1.34, 21.17±0.95 and 27.50±1.28 25.67±1.58, 23.23±1.13 respectively it is seen that all time intervals group LMA-P had high OLP compared to the group LMA-S ($p<0.05$).

Similar result was found in study done by Balena JM et al. [12] where they compared LMA Proseal and LMA Supreme among 120 adult patients. They observed mean oropharyngeal leak pressure in the LMA Proseal group was significantly higher than that in the LMA Supreme group (30.7±6.2 versus 26.2±4.1 cm H_2O; $P<0.01$). Lee et al. [15] observed The mean oropharyngeal leak pressure in the LMAS was significantly lower than in the PLMA (27.9±4.7 vs 31.7±6.3 cm H_2O, $P = 0.007$).

Hosten T et al. [11] conducted similar study in 60 adult patients they observed Oropharyngeal leak pressures were similar (LMA Proseal: 26.9±6.6 cm of H_2O; LMA Supreme: 26.1±5.2 cm of H_2O). This study showed no differences in OLP between devices, although it only included female patients with a size 4 LMA.

Verghese C et al. [16] comparing LMA-P and LMA-S in 36 patients showed no difference in the OLP. In only 22 were given muscle relaxant so this might have had an effect on OLP.

The higher OLP for the LMA-P is mainly related to the dorsal cuff and the silicone rubber double cuff design compared to the polyvinyl chloride single cuff of the LMA-S. Lower OLP observed in LMA-S may be due to the movement of the semi-rigid curved airway tube, something which doesnot seem to happen with the elastic tube of the LMA-P.

In our study no patient had serious complication, 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.

Study conducted by Balena JM et al. [12] observed sore throat in both groups 17 and 21 had in group LMA-S and LMA-P respectively and no patients suffered from any serious complication.

Hosten T et al. [11] also showed no difference between two groups in intraoperative and post operative complication rate.

There are limitations to our study. First, insertions were done in patients with normal airway (MPC grade I, II) and normotensive patients. Present results may not apply to patients with difficult airways and hypertensive patients. Second, present results are specific to the anesthetic administered and might not apply for other anesthesia regimes. there was no blinding in the data collection, which is a possible source of bias.

Thus, the results of these various studies comparing the efficacy of the LMA-S and LMA -P shows both devices are similar in terms of insertion attempts, ease of passing ryles tube and complication rate. Insertion time required to insert LMA-S is less compared to LMA-P. Intracuff pressure increased more quickly in LMA-P compared to LMA-S. Oropharngeal leak pressure was better in LMA-P group compared to LMA-S group.

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 Supremeinspite 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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