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IGEL Versus Proseal LMA in Short Elective Procedures: A Comparision of Clinical Performance

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Abstract

Background: The various supraglottic airway devices with their advent have created a revolution in the management of airway. We have made an attempt to compare the clinical performance of the two types of supraglottic devices namely Igel and LMA proseal during general anesthesia in spontaneously breathing patients. *Materials and Methods:* Sixty ASA grade I and II adult patients of either sex were randomly assigned into two groups. Group I (n=30) for I-gel and Group P (n=30) LMA ProSeal. We assessed the ease of insertion, attempts for insertion, ease of gastric tube placement, airway sealing pressure and postoperative sore throat and hoarseness of voice. *Results:* There were no significant differences in demographic data. The airway sealing pressure was higher with Group P (27.87±2.29cm H_2O) than with Group I (23.77 ±2.13cm H_2O) ($p < 0.05$). The ease of insertion was comparable between Group I (29/30) with Group P (26/30) (> 0.05). The success rate of first attempt of insertion was 29/30 in Igel and 28/30 in proseal group ($p> 0.05$). Ryles tube could be inserted easily in all the 30 patients of each of the two groups. The adverse effects like Blood stain on LMA coughing on insertion, sore throat and hoarseness assessed at 6 hours and 24 hours of postoperative period were statistically insignificant among the two groups. *Conclusions:* Proseal provides a better airway sealing pressure than Igel with comparable performance in ease of insertion , number of attempts at insertion and postoperative adverse events.

Keywords: Airway Sealing Pressure; Hoarseness; I-gel; Proseal; Sore Throat.

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Introduction

The field of Anesthesiology has witnessed a series of inventions since decades. In the recent years securing and maintaining the airway with supraglottic airway has eased the job of anesthesiologist during general anesthesia, especially for day care procedures. These devices have undergone various modifications since their advent to ensure better clinical performance and patient safety. LMAproseal has been used with superior performance results even in laparoscopic surgeries [1]. Igel is a newer supraglottic device with anatomically designed non inflatable soft gel like cuff made of thermoplastic elastomer. In our study we have made an attempt to compare the clinical performance and postoperative complications with respect to proseal LMA and I gel.

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Materials and Methods

After approval from the institution's ethics committee, a writtenin formed, valid consent was obtained from all patients afterexplaining the study protocol.Sixtypatients of either sex belonging to ASA 1 and 2 aged 18 to 65 years scheduled for elective surgery in which the duration of anesthesia was expected range between 30 to 90 minutes .The study was conducted over a period of six months. Patients with high risk of aspiration, anticipated difficult airway, Body Mass Index ≥ 30 kg/m2, reactive airway disease, head and neck surgeries and history of recent respiratory tract infection were excluded from the study.The investigators were consultant anaesthesiologists well versed in insertion of both the prototypes of LMA. The type of LMA to be inserted was decided by computer generated random number sequence.

Sample size of 30 was calculated based on the results of previous study [3] to detect a projected difference in airway sealing pressure of 30% between groups with 80% power and 5% alpha error and a reported difference [3] in airway sealing pressure of 15% between two groups.The two groups were compared with each other in terms of age, BMI and sex. Unpaired Student's t-test was used forcomparision of age and BMI. For qualitative data like the sex of the patient, the statistical test employed was chi square test.The ease of insertion, attempts required for insertion, incidence of adverse events were compared using Chi-square test. In all the parameters, $p < 0.05$ was considered to be significant.

Preoperative Evaluation and Premedication

On the day before surgery preoperative evaluation was done. All patients were premedicated with Tab. Alprazolam 0.5 mg orally on the night before and on the morning of surgery. They were kept nil per oral for a period of 6 hours for solids and 3 hours for clear fluids.

Monitoring, Induction and Maintenance

On the day of surgery, after ensuring adequate nil per oral status, patients were shifted to the operating room. They were monitored with pulse oximeter, noninvasive blood pressure, five lead electrocardiogram and capnography Patients were pre-oxygenated for 3 minutes following which they were induced with IV fentanyl (2μg/ kg) and IV propofol (2 mg/ kg). Anesthesia was deepened with 2% isoflurane in Oxygen for 2 minutes. After ensuring adequate depth of anesthesia, LMA prototype according to the study group allocated was lubricated with water soluble jelly and was inserted smoothly as per the recommended standard technique. Number of attempts taken for successful insertion was recorded. Size of the LMA chosen was decided as per body weight of the patient. Ease of insertion and number of insertion attempts were noted. Proseal LMA cuff was inflated with air to achieve a cuff pressure of 40 cm H_2O and appropriate positioning of the LMA was confirmed to ensure no or minimal leak with gentle assisted ventilation and appearance of a normal capnographic trace. The airway sealing pressure was determined by manometer stabilization method. A fixed gas flow of 3 L/min was ensured, after closing the expiratory valve of the circle system the pressure manometer was observed on positive pressure ventilation and the point where equilibrium was achieved was taken as the sealing pressure. Later the intracuffpressure of LMA prosealwas continuously monitored using a cuff pressure manometer and was maintained between 40-60 cm of H_2O throughout the intraoperative period. Anesthesia was maintained with isoflurane in oxygen, and nitrous Oxide with the patients breathing spontaneously.

At end of the procedure, all the patients were ventilatedwith 100% oxygen during emergence from anesthesia.The device was removed when the patient was able toopen the mouth on command. The patient was inspected for any injuries of the airway and the device wasinspected for the presence of any blood stains. All Patients were kept nil per orally for a period of 4 hours for liquids and 6 hours for solids in the postoperative period. Evaluation of sore throat and hoarseness was done at 6 hours and 24 hours postoperatively.

Results

The two groups were comparable with respect to the demographic parameters and type of surgery. There was no statistically significant difference in mallampati class and ASA PS classification among the two groups (Table 1).

We were able to insert I gel in first attempt in 29 out of 30 patients and LMA proseal could be inserted in first attempt in 28 out of 30 patients.Igel was easily inserted in 29 out of 30 patients and LMA proseal was inserted easily in 26 out of 30 patients. The mean airway sealing pressure was higher (27.87±2.29) in proseal group than I gel group (23.77±2.13) and the difference was statistically significant. (p value 0.000).

The insertion of ryles tube was easy in all the cases in both the groups (Table 2).

The adverse effects like Blood stain on LMA, coughing on insertion, sore throat and hoarseness assessed at 6 hours and 24 hours of postoperative period were statistically insignificant among the two groups (Table 3).

Table 1: Demographic data

Parameters	Group I (n=30)	Group P (n=30)	p value
Age (in years) Mean±SD	37.87±13.46	42.53±13.71	0.189
BMI in kg/m2 (mean)	21.37±2.21	22.70±2.41	0.297
Sex			
Male	17 (56.7%)	17 (56.7%)	1.000
Female	13 (43.3%)	13 (43.3%)	
Surgery Type			
Gen surgery	5 (16.7%)	7 (23.7%)	0.316
Orthopedics	7 (23.3%)	2 (6.7%)	
Plastic Surgery	9 (30.0%)	9 (30.0%)	
Urology	9 (30.0%)	12 (40.0%)	
ASA PS			
1	24 (80.0%)	19 (63.3%)	0.152
2	6 (20.0%)	11 (36.7%)	
Mallampati			
1	11 (36.7%)	13 (43.3%)	0.278
2	19 (63.3%)	17 (56.7%)	

p>0.005 not significant

Table 2: Comparison of Attempts of insertion, ease of insertion, Airway sealing pressure and Ryles tube insertion

	Group I (n=30)	Group P (n=30)	p value
Attempts of insertion			
1	29 (96.7%)	28 (93.3%)	0.351
2	1 (3.3%)	2 (6.7%)	
Ease of insertion			
Easy	29 (97.7%)	26 (86.7%)	1.964
Difficult	1 (3.3%)	4 (13.4%)	
Airway sealing pressure(cm H_2O) (Mean±SD)	23.77±2.13	27.87±2.29	0.000*
Ryles tube insertion			
Yes	30 (100.0%)	30 (100.0%)	-
No	0 (0.00%)	0 (0.00%)	

*P value significant < 0.05

Table 3: Profile of adverse events

	Group I	Group P	
Blood Stain			
Yes	1 (3.3%)	0 (0.0%)	1.017
No	29 (96.7%)	30 (100.0%)	
Cough			
Yes	1 (3.3%)	0 (0.0%)	1.017
No	29 (96.7%)	30 (100.0%)	
Sore throat at 6 hours			
Yes	3 (10.0%)	4 (13.3%)	0.162
No	27 (90.0%)	26 (86.7%)	
Sore throat at 24 hours			
Yes	1 (3.3%)	3 (10.0%)	1.071
No	29 (96.7%)	27 (90.0%)	

Sore throat at 24 hours			
Yes	1 (3.3%)	3 (10.0%)	1.071
No	29 (96.7%)	27 (90.0%)	
Hoarseness at 6 hours			
Yes	2 (6.7%)	4 (13.3%)	0.741
No	28 (93.3%)	26 (86.7%)	
Hoarseness at 24 hours			
Yes	1 (3.3%)	2 (6.7%)	0.351
No	29 (96.7%)	28 (93.3%)	

p> 0.005 not significant

Discussion

There was no statistically significant difference among the two groups with respect to the number of attempts at insertion and ease of insertion in our study.

Lu PP et al. [2] have observed lower first attempt insertion success with LMA Proseal when compared to classic LMA.

Singh, et al. [3] found higher success rate of insertion with I-gel (29/30) than with LMA ProSeal (23/30) which was statistically significant (p<0.05).

We were able to insert ryles tube in each of the 30 patients in both the groups without any difficulty. Singh, et al. [2] and Rajaram et al. (4) observed that ease of insertion of gastric tube was more with i-gel (30/30) than with LMA - ProSeal (26/30) but was not statistically significant.

In our study one patient in group I gel had blood stain and none of the patients in group proseal had blood stain on the device.Incidence of blood staining of the device was more with LMA ProSeal (6/30) than with I-gel (1/30)(B). Blood staining of device was observed in three out of 25 patients with LMA ProSeal [3] . One out of 100 patients had blood on the igel after removal as per Gabbottetal [4].

The mean airway sealing pressure was higher (27.87±2.29) in proseal group than I gel group (23.77±2.13) and the difference was statistically significant (p value 0.000).

Gabbott et al. [5] also concluded that I-gel provides a good airway sealing pressure which improved over time and may be due to the thermoplastic properties of gel cuff which forms an effective seal around the larynx after warming to body temperature. They found that the airway sealing pressures for igel was 24 cm H_2O and for ProSeal was 29 cm H_2O .

In a study conducted by Taxak et al. [6] the mean seal pressure in group proseal was 36±6.22 cm H2O and in group I gel was 25.4±3.21 cm H2O. The difference was statistically significant ($p < 0.05$). The mean airway sealing pressure with I-gel was 25.27± 02.94 cm H_2O, and with LMA-Proseal 29.6 cm of H_2O which was statistically significant in the study by Singh et al [3].

At 6 hours of postoperative period, the incidence of sore throat was 10% in I gel group and 13.3% in group ProSeal. On following up to 24 hours it decreased to 3.3% patient in I gel group and 10% inproseal. There was no statistically significant difference among the two groups.

The incidence of hoarseness was 6.7% and13.3% in I gel group at 6 hours and 24 hours of post operative period respectively. The incidence of hoarseness was 3.3% and 6.7% in group proseal at 6 hours and 24 hours of post operative period respectively but was statistically not significant.

As per Brimacombe et al. [7], at 4 hours the incidence of sore throat and hoarseness was 30% and 3% respectively for LMA Proseal. At 18 to 24 hours the incidence of sore throat and hoarseness was 40% and 5% respectively. The incidence of sorethroat with I gel with was 6%,7% and 5% at 1 hour, 24 hours and 48 hours of postoperative period respectively as per Keijzer et al [8]. The incidence of sore throat and hoarseness was lesser in proseal group in our study probably because of the continuous monitoring of intracuff pressure throughout the intraoperative period.

Conclusion

Igel is a novel supraglottic airway device which is simple in structure and cheaper than ProSeal LMA. It provides an effective airway sealing pressure though lesser than proseal. The rest of theclinical performance of igel and LMA ProSeal were comparable with respect to ease of insertion, number of attempts at insertion, ryles tube insertion and postoperative adverse events.

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