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Prospective Randomized Comparative Evaluation of the Clinical Performance of IGEL LMA and PROSEAL LMA in Patients Undergoing Elective Surgeries.

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ABSTRACT

The laryngeal mask airway has been used as a most common supraglottic. Device I-gel is a new supraglottic device comparatively better than proseal LMA because it reduces the risk of gastric insufflation, aspiration of gastric contents, regurgitation .

Keywords: IGEL LMA, PROSEAL LMA, Surgery, supraglottic.

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INTRODUCTION

The laryngeal mask airway (LMA) has gained recognition as an acceptable device for securing the airway of patients during anaesthesia and emergency airway management. LMA has been widely accepted as a form of airway management in the pre-hospital environment and inexperienced personnel. It has been shown that insertion of LMA is easier and is less likely to produce gastric insufflations, a common problem with face mask ventilation. The LMA now referred to as gold standard of supraglottic devices. The inventor of the LMA Dr Archie Brain, devised the airway to provide an alternative to face mask ventilation. It does not provide full protection in patients with full stomach patients and it increases the risk of aspiration. To overcome the above complications Proseal LMA in 2000,with modification designed to enable separation of GIT and respiratory tract, to improve airway seal,to enable positive pressure ventilation and diagnose mask displacement, reduce the risk of gastric insufflations, regurgitation and aspiration of gastric content [1].

I-gel is a new supraglottic device [2,3] I-gel has been successfully combined the content of non cuffed supraglottic device like SLIPA and the gastric tube of Proseal LMA,yet retaining the shape LMA. This will also,reduce the risk of gastric insufflations,regurgitation and aspiration of gastric contents.

Aims and Objectives

The purpose of this study was to prospectively compare the clinical performance of the two supraglottic airway devices, PROSEAL LMA AND IGEL in elective surgeries in terms of following parameters.

- Ease of insertion
- No of insertion attempts
- Time taken for insertion
- Hemodynamic responses
- Incidence of complications

Study Design

Prospective, randomized, single blinded, case control study.

Study Setting and Population

After getting informed written consent from the patients, the study was carried out. The study was conducted in 60 female patients in the age group of 18yrs and above belonging to ASA I and ASAII posted for elective surgeries.

Inclusion Criteria

- Age - 18 Years and above
- Weight - BMI< 30Kg/m2
- ASA - I & II
- Surgery - Elective
- Mouth opening ->3cm

Exclusion Criteria

- Emergency Surgeries
- Age < 18yrs
- Mouth opening < 3cm
- BMI > 30Kg/m2
- Pregnant female
- H/o GERD
- Surgery involving upper GIT
- Poor lung compliance such as pulmonary fibrosis

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Materials Required

- Proseal LMA size 3
- Igel size 3
- 20ml syringe
- Lubricant jelly
- Drugs : glycopyrolate, fentanyl, propofol, atracurium, isofluraneneostigmine, rantidine, metoclopramide.
- Monitors : ECG, Pulse Oximeter, NIBP,Capnography

METHODOLOGY

Patient satisfying inclusion criteria
↓
Informed consent obtained
↓
Randomization by closed envelope method
↓
IGEL group – PLMA group
↓
Premed – inj.Glycopyrolate 0.2mg + fentanyl 100mcg. Inj. Rantidine 50mg+ inj. Metaclopramide iv given.
↓
HR,BP measured
↓
Preoxygenation for 3 min
↓
Induction : inj. Propofol 2mg/Kg + inj Atracurium 0.5mg/Kg
↓
Pre insertion BP,HR measured
↓
Insertion
↓
Measurement of outcome: ease of insertion,time taken for insertion, no.of insertion attempts, hemodynamic responses, incidence of complications.
↓
Surgery proceded with maintenance of anaesthesia with N20/O2
↓
Mixture 2:1+ Iso flurane 1MAC
↓
After surgery patient reversed with inj. Neostigmine 5o microgram/kg + inj. Glycopyrolate 10 microgram/kg
↓
Airway removed after oral suctioning
↓
Data compilation
↓
Statistical Analysis
↓
Conclusion

Conduct of Study

The patients who had come for surgery, screened for comorbid illness and difficult airway. Age, height, weight and BMI were assessed. If patients satisfied inclusion criteria, informed consent was obtained and the patients were randomized into two groups using envelope technique as proseal LMA group (P) and Igel group (I).

After the patient was shifted inside OT ,i.v. access gained. ECG monitor,pulsoximeter,NIBP were connected.pre operative BP,HEART RATE were recorded.

Patient was premedicated.preoxygenated with 100%O2 for 3 minutes. Patient was induced with inj.propofol 2mg/kg and inj. Atracurium 0.5mg/kg. Patient was mask ventilated for 3 minutes. Pre insertion BP,heart rate recorded.

Insertion

P Group

Size 3 proseal LMA was inserted in sniffing position by using index finger insertion technique. Position was confirmed by

- Bilateral chest movement
- Square ETCO2 waveform
- Absence of leak

I Group

Size 3 I gel was inserted in sniffing positon. Position of I gel was confirmed by

- Bilateral chest movement
- Square ETCO2 waveform
- Absence of leak

Parameters Observed

- Ease of insertion
- No.of insertion attempts
- Time taken for insertion
- Hemodynamic responses
- Incidence of complications.

Maintanence Of Anaesthesia

Anaesthesia maintained with N20:02 at 2:1 ratio and 1 MAC of isoflurane. Muscle relaxant maintained with inj. Atracurium. Post insertion of LMA BP,HR were recorded at 1min and 5 minutes. After completion of surgery and adequate muscle recovery patient was reversed with inj. Neostigmine and inj. Glycopyrolate. Suctioning of gastric contents through Ryles tube done. After thorough oral suction, cuff was deflated and supraglottic airways were removed.

OBSERVATION AND RESULTS

All data were collected,tabulated and expressed as mean +/- standard deviation. Appropriate statistical analysis was conducted. All quantitative data were compared using chi- square test. P values were calculated for all test. A P value 0 to 0.01 was considered as 1 % significant, 0.011 to 0.05 was considered 5% significant, > 0.05% was considered as not significant.

The summated results represented below.

Table 1: Demographic profile: Age

Group	No	Mean	SD	P value
I GEL	30	31.20	9.353	0.460
PRO SEAL	30	29.47	8.681	Not significant

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The mean age group of IGEL is 31.20 and group PROSEAL is 29.47 . The data statistically not significant(p>0.05)

Table 2: Ease of insertion

Group	No	Easy		Difficult		P value
		No	%	No	%	P=0.038 Significant
I GEL	30	28	93.3	2	6.7	
PRO SEAL	30	22	73.3	8	26.7	

By using IGEL, 28 cases were inserted easily and 2 cases were inserted with difficulty. By using PROSEAL LMA 22 cases were inserted with easily and 8 cases were inserted with difficulty. Qualitative data values are compared by chi-square test. Statistical analysis reveals P value is 0.038 which is significant at 5% level.

Table 3: No .of attempts

Group No		Success in			P value
		1st attempt	2nd attempt	3rd attempt	
I GEL	30	28	2	-	P=0.12
PROSEAL	30	24	6	-	Not significant

IGEL insertion was successful in 28/30 in first attempt while 2 patients required second attempt. PROSEAL LMA insertion was successful in 24/30 in first attempt while 6 patients required second attempt. Statistical analysis reveals P value of 0.129. the two groups are statistically insignificant in no. of attempts(P>0.05).

Table 4: Time taken for insertion

Group	No	Mean	SD	P value
I GEL	30	16.20	5.327	P=0.000
PRO SEAL	30	25.20	5.162	P value<.001

Time taken for insertion with IGEL IS 16.20 Seconds and PROSEAL is 25.20 seconds. Student t test reveals P value of 0.000(p<0.001) which is significant at 1% level.

Table 5: Incidence of complications

Complication	Group	NO	Yes	No	P value
Sore throat	I GEL	30	-	30	P=0.150 Not significant
	PRO SEAL	30	2	28	
	Group	NO	Yes	No	P value
Bronchospasm Laryngospasm Regurgitation	I GEL	30	-	30	P=1.00 Not significant
	PRO SEAL	30	-	30	

Intra & post operatively complications were assessed. Sore throat occurred in2/30 cases with PROSEAL and no sore throat with IGEL.P Value of 0.150 not significant. Laryngospasm,bronchospasm,regurgitation does not occur in both groups. P value 1.00 not significant.

Table 6: Hemodynamic responses

Heart rate

	Group	No	Mean	SD	P value
Pre insertion	I GEL	30	89	10.252	P=0.073 Not significant
	PRO SEAL	30	83.47	13.038	
Post insertion after 1 min	I GEL	30	95.43	10.311	P=0.353 Not significant
	PRO SEAL	30	92.60	12.968	
Post insertion after 5 min	I GEL	30	93.67	10.672	P=0.527 Not significant
	PRO SEAL	30	91.73	12.774	

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Systolic blood pressure

	Group	No	Mean	SD	P value
Pre insertion	I GEL	30	122.40	12.036	P=0.790 Not significant
	PRO SEAL	30	121.63	10.128	
Post insertion after 1 min	I GEL	30	122.97	12.019	P=0.382 Not significant
	PRO SEAL	30	119.83	15.324	
Post insertion after 2 min	I GEL	30	118.60	13.903	P=0.799 Not significant
	PRO SEAL	30	119.50	13.292	

Diastolic blood pressure

	Group	NO	Mean	SD	P value
Pre insertion	I GEL	30	80.93	8.416	P=0.817 Not significant
	PRO SEAL	30	80.50	5.782	
Post insertion after 1 min	I GEL	30	82.40	10.388	P=0.191 Not significant
	PRO SEAL	30	77.43	17.751	
Post insertion after 5 min	I GEL	30	77.23	12.356	P=0.313 Not significant
	PRO SEAL	30	80.47	12.272	

Mean arterial pressure

	Group	NO	Mean	SD	P value
Pre insertion	I GEL	30	94.27	8.702	P=0.906 Not significant
	PRO SEAL	30	94.03	6.312	
Post insertion after 1 min	I GEL	30	95.63	10.602	P=0.344 Not significant
	PRO SEAL	30	92.80	12.310	
Post insertion after 5 min	I GEL	30	90.67	12.347	P=0.419 Not significant
	PRO SEAL	30	93.23	12.054	

Heart rate

Mean insertion heart rate with I GEL group is 89 and pro seal group is 83.47. Mean heart rate 1 min after insertion with I GEL group is 95.4 and PRO SEAL group is 92.6. Mean heart rate 5 min after insertion with I GEL group is 93.6 and Pro seal group is 98.7. statistical analysis reveals P values of pre insertion heart rate,heart rate after 1 min & 5 min after insertion was 0.073,0.353&0.527 respectively. These P values are statistically not significant.

Blood pressure

P values of pre insertion systolic,diastolic,mean arterial pressure were 0.790,0.817,0.906 respectively. P values of systolic,diastolic,mean arterial pressures after I min of insertion were 0.382,0.197,0.344 respectively. P values of systolic mean arterial pressure after 5 mins of insertion were 0.799,0.313,0.419 respectively. These p values are statistically insignificant.

DISCUSSION

The PRO SEAL LMA provides an acceptable way to maintain a clear airway and provide positive pressure ventilation. It is also associated with reduced risk of gastric insufflations, regurgitation & aspiration of gastric contents [4].

I GEL provides patent airway during positive pressure ventilation. It also reduces the risk of gastric insufflations, regurgitation & aspiration of gastric contents. This study was designed to compare the clinical performance of two supraglottic devices IGEL & PROSEAL LMA. This study was conducted in 60 adult women, ASA I & II patients ,aged 18 & above undergoing elective surgery. I GEL LMA was easier to insert compared to PROSEAL LMA. Number of attempts taken with IGEL was lesser compared to PROSEAL LMA. Time taken for insertion with IGEL LMA was lesser compared to PROSEAL LMA. Hemodynamic response was the same with both. Incidence of complication was lesser with IGEL compared to PROSEAL LMA [5].

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CONCLUSION

I Gel is a cheap and effective device which is easier to insert than Pro seal LMA. It has other potential advantages like rapid placement,less airway trauma than proseal LMA. So I Gel is a useful alternative Supraglottic device to Pro seal LMA.

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