Comparative study of clinical performance of PROSEAL LMA vs I-GEL in elective surgeries.

Dr.Shaik khadar basha[1], Dr.Thondamanati Rajasekhar[2],

Dr. Paritala SubbaRao[3] ,Dr Surisetty Sreenivasarao[4]

Assistant Prefessor[1,2], Associate Professor[3,4], Department of Anaesthesia, ACSR GMC, NELLORE

Corresponding Author- Dr Surisetty Sreenivasarao

ABSTRACT-

BACKGROUND- We want to do a Comparative study the clinical performance of PROSEAL LMA vs I-GEL in elective surgeries

METHODS- A Prospective Randomized single-blinded case-control study, to compare the clinical performance of two Supraglottic airway devises IGel & Pro Seal LMA in 60 adult women, ASA I & II, aged 18 and above undergoing elective surgeries & study was conducted at the Department of Anaesthesiology, ACSR Govt Medical college.

RESULTS-In this study There were no significant differences between the two groups in demographic data. The ease of insertion of I Gel was better than that of Pro Seal LMA which is Statistically Significant at 5% level (P=0.038). The number of attempts required for successful placement for I Gel were fewer than that of Pro Seal LMA but Not Statistically Significant. Time taken for insertion of I Gel was lesser than Pro Seal LMA which is Statistically Significant at 1% level. There is No Significant Haemodynamic changes between I Gel & Pro Seal groups. Blood staining of the devices with I Gel was fewer than Pro Seal LMA which is Statistically Significant at 5% level. So airway trauma was few with I Gel compared to Pro Seal LMA. Incidence of Sore Throat was few with Pro Seal LMA but Sore Throat did not occur in I Gel. The other complications like Bronchospasm, Laryngospasm & Regurgitation did not occur in both groups.

CONCLUSION- IGel is a cheap and effective device which is easier to insert than Pro Seal LMA. It has other potential advantages like rapid placement, less blood staining, less airway trauma than Pro Seal LMA. So I Gel is a useful alternative Supraglottic device to Proseal LMA.

KEYWORDS-LMA-Laryngeal Mask Airway ,Proseal LMA,I-GEL

INTRODUCTION- The laryngeal mask airway has gained recognition as an acceptable device for securing the airway of patients during anaesthesia and emergency airway management within the hospital environment. The LMA revolutionized the anaesthetic practice and has now been used in more than 80 countries throughout the world . 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 the LMA is easier and is less likely to produce gastric insufflations, a common problem with face mask ventilation. The LMA has now been referred to as the gold standard of supraglottic devices.. The LMA offers a relatively "hand-free airway that does not require laryngoscopy for insertion and thereby minimizing laryngeal trauma and unwanted laryngeal reflexes. For these reasons, the LMA is endorsed by the Australian resuscitation council and The American Society Of Anaesthesiologists as 2 rescue airway, and as a first-line airway management device in those with limited airway management experience. It does not provide airway protection in full stomach patients and it increases the chances of aspiration. To overcome the above complications Dr Archie

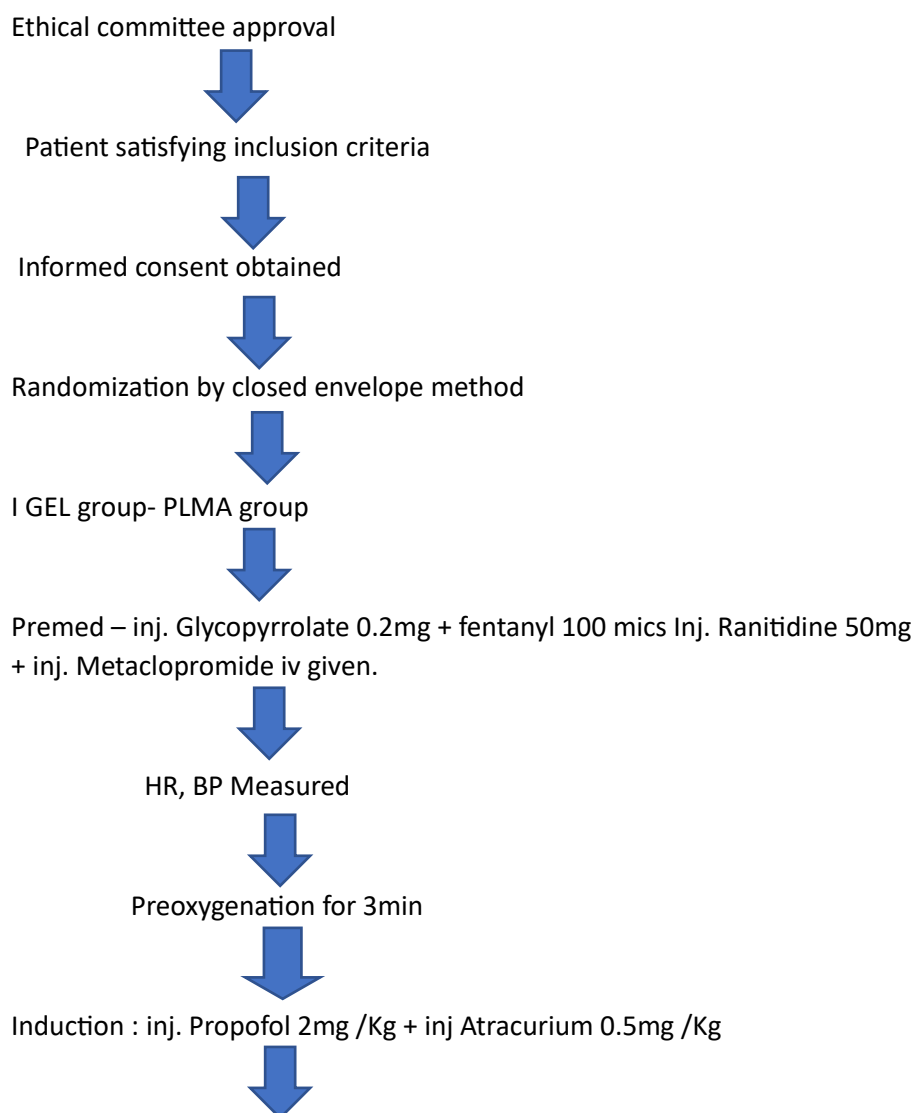*Eur. Chem. Bull.* **2023,**12(Special issue 8), 4754-4761

4754

Brain designed the Pro-seal LMA in 2000, with modifications designed to enable separation of GIT and respiratory tract, to improve airway seal, to enable positive pressure ventilation, and diagnose mask displacement. A drainage tube enables the diagnosis of mask displacement; reduces the risk of gastric insufflations, regurgitation, and aspiration of gastric content. I-gel is a new supraglottic device This will also, reduce the risk of gastric insufflations, regurgitation, and aspiration of gastric contents. With this background this study was conceptualized to compare clinical performance of I-gel and ProSeal LMA in elective surgeries.
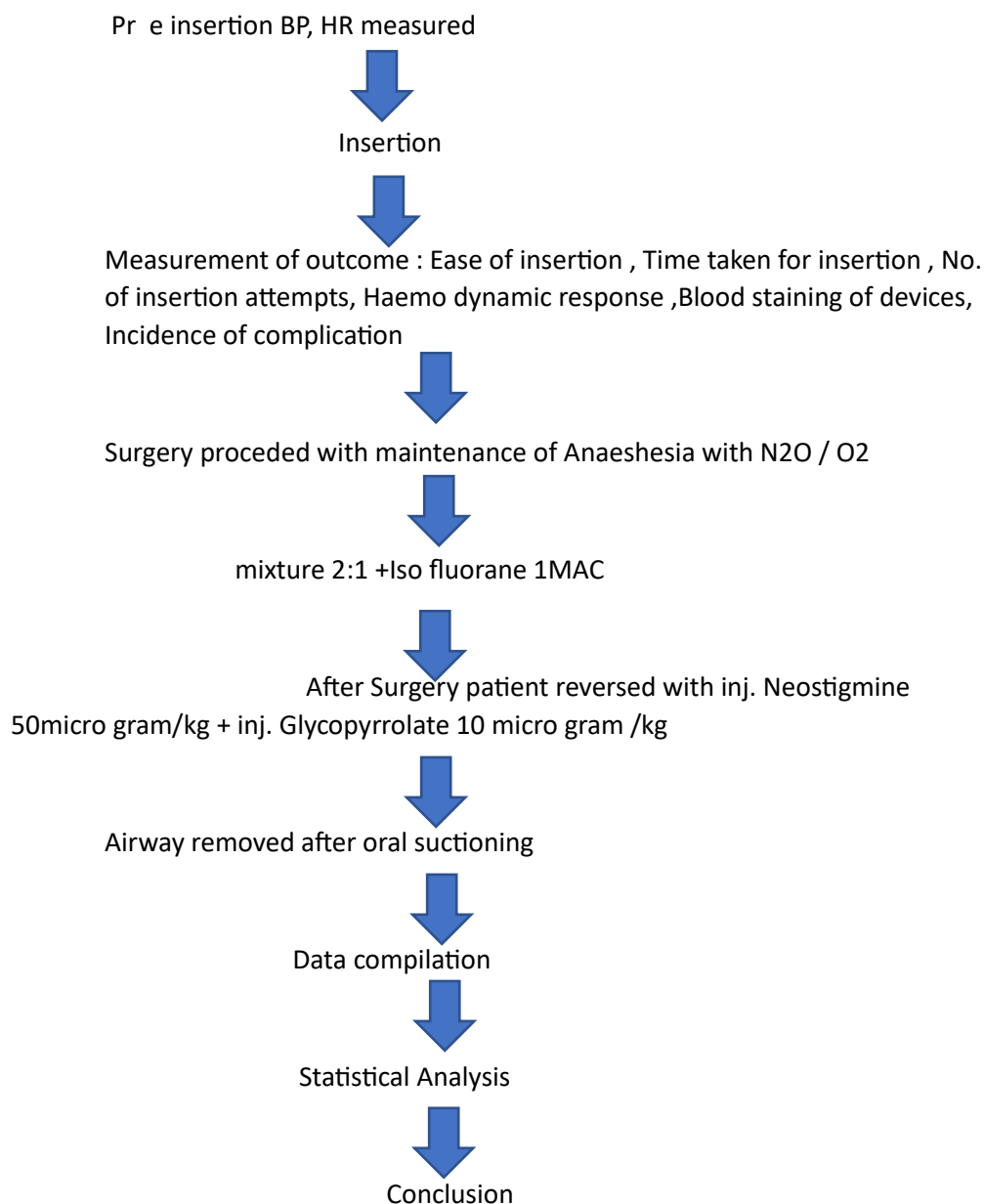
AIMS AND OBJECTIVES- The purpose of this study was to prospectively compare the clinical performance of the two supraglottic airway devices, PROSEAL LMA AND IGEL in elective surgeries in terms of the following parameters. 1. Ease of insertion 2. No. of insertion attempts 3. Time taken for insertion 4. Hemodynamic responses 5. Blood staining of devices 6. Incidence of complication

MATERIALS & METHODOLOGY-

MATERIALS- Proseal lma size 3 , I gel size 3 ,20ml syringe ,Lubricant jelly, Drugs: Glycopyrolate, fentanyl, propofol, , atracurium, isoflourane, neostigmine, ranitidine, metaclopromide,Monitors: ECG, Pulse Oximeter, NIBP, Capnography

METHADOLOGY-

Ethical committee approval

⬇

Patient satisfying inclusion criteria

⬇

Informed consent obtained

⬇

Randomization by closed envelope method

⬇

I GEL group- PLMA group

⬇

Premed – inj. Glycopyrrolate 0.2mg + fentanyl 100 mics Inj. Ranitidine 50mg + inj. Metaclopromide iv given.

⬇

HR, BP Measured

⬇

Preoxygenation for 3min

⬇

Induction : inj. Propofol 2mg /Kg + inj Atracurium 0.5mg /Kg

⬇

Pr e insertion BP, HR measured

⬇

Insertion

⬇

Measurement of outcome : Ease of insertion , Time taken for insertion , No. of insertion attempts, Haemo dynamic response ,Blood staining of devices, Incidence of complication

⬇

Surgery proceded with maintenance of Anaeshesia with N2O / O2

⬇

mixture 2:1 +Iso fluorane 1MAC

⬇

After Surgery patient reversed with inj. Neostigmine 50micro gram/kg + inj. Glycopyrrolate 10 micro gram /kg

⬇

Airway removed after oral suctioning

⬇

Data compilation

⬇

Statistical Analysis

⬇

Conclusion

INCLUSION CRITERIA: 1. Age : 18 Years and above, 2. Weight : BMI < 30 Kg/m2, 3. ASA : I & II, 4. Surgery : Elective, 5. Mouth Opening : > 3cm

EXCLUSION CRITERIA: 1. Emergency Surgeries, 2. Age < 18, 3. Mouth opening < 3cm, 4. BMI > 30 Kg /M2, 5.Pregnant Female, 6. H/O. GERD, 7. Surgery involving upper GIT, 8. Poor lung compliance such as pulmonary fibrosis

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 randamised into two groups using closed envelope technique as proseal LMA group (P) and Igel group(I). After the patient was shifted inside the operation room, intravenous access gained. ECG monitor, pulsoximeter and non invasive blood pressure monitor were connected. Preoperative BP, Heart rate were recorded.After premedication &preoxygenation 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 were recorded.

INSERTION- **'P' Group** Size 3 proseal LMA was inserted in sniffing position by using Index finger insertion technique. Cuff was inflated with 20ml of room air to the manufacturer recommended cuff pressure of 60cm H2O before anaesthetic circuit was connected and patients lung ventilated. Position of PLMA was confirmed by 1. Bilateral chest movement 2. Square EtCO2 waveform 3. Absence of leak With the PLMA, we filled the proximal 3cm of the drain tube with the water soluble lubricant jelly. If a gas bubble rose through the jelly during inspiration indicating a gas leak into the oesophagus. We corrected the position of PLMA and repeated the test until no bubble appeared.

'I' Group Size 3 Igel was inserted in sniffing position. Position of Igel was confirmed by 1. Bilateral chest movement, 2. Square EtCO2 waveform, 3. Absence of leak.

PARAMETERS OBSERVED 1. Ease of insertion 2. No. of insertion attempts 3. Time taken for insertion 4. Hemodynamic responses 5. Blood staining of devices 6. Incidence of complications.

MAINTENANCE OF ANAESTHESIA -Anaesthesia maintained with N20:O2 at 2:1 ratio and 1 MAC of isoflurane. Muscle relaxant was maintained with inj. Atracurium. Postinsertion BP, HR were recorded at 1 min and 5 minutes after insertion of supraglottic airways. Ryles tube was inserted through a drainage tube. Gynaecologist was requested to initiate the surgical procedure.

REVERSAL & EXTUBATION- After completion of surgery and adequate neuromuscular recovery, patient was reversed with inj. Neostigmine 50 microgram/kg, inj. Glycopyrrolate 0.4 mg/kg. Suctioning of gastric content through ryles tube was done. After thorough oral suction, cuff was deflated and supraglottic airways were removed. Blood staining in the airway devices, cough, laryngospasm/stridor, sorethroat and need for airway intervention during emergence from anaesthesia were recorded. Once the recovery was found adequate, the patient was shifted to post operative ward and patients were interviewed for next 24 hours regarding sore throat.

OBSERVATION AND RESULTS -This prospective randomized comparative single blinded case control study of clinical performance of two supraglottic airway devices, IGEL AND PROSEAL LMA in 60 adult women, ASA I AND II, aged 18 years and above undergoing elective surgery . All datawere 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 values 0 to 0.01 was considered as 1 % significant , 0.011 to 0.05 was considered 5% significant , and >0.05 was considered as not significant.

Table :1 Demographic profile : age

Group	N0	Mean	SD	P value
I GEL	30	31.20	9.353	0.460
PROSEAL	30	29.47	8.681	Not significant

The mean age of group IGEL is 31.20 and group PROSEAL is 29.47.The data statistically not significant (p >0.05) and this both groups are comparable in terms of age

Table 2: Demographic profile : BMI

Group	N0	Mean	SD	P value
I GEL	30	21.54	2.0698	0.530

PROSEAL	30	21.25	1.4323	Not significant

The mean BMI of group IGEL is 21.54 and group PROSEAL is 21.25.The data statistically not significant (p >0.05) and this both groups are comparable in terms of BMI.

Table 3 : Ease of insertion

Group	NO;	Easy		Difficult		P value
		NO	%	NO	%	P= 0.038
I GEL	30	28	93.3	2	6.7	Significant
PROSEAL	30	22	73.3	8	26.7	

By using I GEL , 28 cases were inserted easily and 2 cases were inserted with difficulty .By using PROSEAL LMA 22cases were inserted 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:4 No of attempts

Group	No	Success in			P Value
		Ist Attempt	IInd Attempt	IIIrd attempt	
I JEL	30	28	2		P= 0.12
PROSEAL	30	24	6		NON 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 5; Time taken for insertion

Group	N0	Mean	SD	P value
I GEL	30	16.20	5.327	P= 0.000
PROSEAL	30	25.20	5.162	P value < .001

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

Table 6; Blood staining of devices.

Group	Number	Blood Staining		P Value
		Yes	No	

I GEL	30	2	28	P=0.038
PRO SEAL	30	8	22	SIGNIFICANT

Blood staining the airway device noted after removal of the device indicates airway trauma. It occurred in 2/30 cases with I GEL, 8/30 cases with PROSEAL LMA. Chi –square test reveals p value of 0.038 which significant at 5% level. Hence the incidence of airway trauma is low with I GEL.

Table No:7: Incidence of Complications

	Group	Number	Yes	No	P Value
Sore Throat	I GEL	30	-	30	P=0.150 NOT SIGNIFICANT
	PRO SEAL	30	2	28	
	Group	Number	Yes	No	P Value
Bronchospasm Laryngospasm Regurgitation	I GEL	30	-	30	P=1.00 NOT SIGNIFICANT
	PRO SEAL	30	-	30	

Intra & Post Operatively following complications were assessed. 1) Bronchospasm 2) Laryngospasm 3) Sore Throat 4) Regurgitation. Sore Throat assessed for 24hrs Post Operatively. Sore Throat occurred in 2/30 cases with PRO SEAL LMA and no sore throat with I GEL. Statistical analysis reveals P Value of 0.150 which is Not Significant. Laryngospasm, Bronchospasm & Regurgitation does not occur with both the groups. Stastical analysis reveals P Value of 1.000 which is Not Significant. Hence incidence of complications is same with both groups

Table:8: Haemodynamic Response - 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	

Table:9: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	10.620	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, Blood Pressure were measured preoperatively before insertion of airway devices and 1 min & 5 min after insertion. The actual value are documented in the tabular column.

Heart Rate -Mean Preinsertion Heart rate with I Gel Group is 89 and Pro Seal Group is 83.47. Mean Heart rate 1min after insertion with I Gel group is 95.4 and Pro Seal group is 92.6. Mean Heart Rate 5min after insertion with I Gel group is 93.6 and Pro Seal group is 98.7. Statistical analysis reveals P

Eur. Chem. Bull. **2023,**12(Special issue 8), 4754-4761

4759

Values of Pre insertion heart rate, Heart rate 1min after insertion & Heart rate 5min after insertion was 0.073, 0.353 & 0.527 respectively. These P Values are Statistically Not Significant.

Mean Arterial Pressure -P values of pre insertion, mean arterial pressure was 0.906 respectively. P values of mean arterial pressures after 1 minute of insertion was 0.344 respectively. P values of mean arterial pressure after 5 mintues of insertion was 0.419. These p values are statistically insignifigant.

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. I Gel also provides patent airway during positive pressure ventilation. It is also reduces the risk of gastric insufflations, Regurgitation & aspiration of gastric contents. This study was designed to compare clinical performance of this two Supraglottic airway devices I Gel & Pro Seal LMA. This study was conducted in 60 adult Women, ASA I & II, aged 18yrs & above undergoing elective surgeries.

1. **EASE OF INSERTION** –

Ishwer singh and the Monika Gupta[1] compared IGEL and PLMA in 60 patients. They found ease of insertion was more with IGEL (29/30) then with LMA Proseal (23/30) which was statistically significant. In my study the ease of insertion was more with IGEL (29/30) then with proseal LMA (22/30) P value is 0.038 which was statistically significant at 5% level.

Levitan & Kinkle[2] presumed that on insertion of LMA with inflatable mask, the deflated leading edge of the mask can catch the edge of the epiglottis & cause it to downfold or impede proper placement beneath the tongue. Brimacombe and colleagues[3] presumed that the difficulties by larger cuff impeding digital intraoral positioning and propulsion into the pharynx. The lack of back plate making cuff more likely to fold over at the back of the mouth and the need for more precise tip positioning to prevent air leaks up the drainage tube. The finding of my study was in concurrence with the above data. So IGEL is easier to insert as compare to proseal LMA.

2. **NUMBER OF ATTEMPTS**

Ishwar singh and Monika Gupta[1] compared IGEL and proseal LMA in 60 patients they found first attempt success rate with IGEL (30/30) (100%) higher then with proseal LMA (28/30) (93.3) P value is < 0.05 so statistically insignificant. In my study the first attempts success rate with IGEL was (28/30) (93.3%) with proseal LMA was (24/30) (80%) P value is 0.129 (P>0.05) this value or statistically insignificant. The finding of my study was in concurrence with the above data. So number of attempt require for IGEL was fewer than that of proseal LMA.

3. TIME TAKEN FOR INSERTION

J.J. Gatward & T.M. Cook[4] evaluated the size 4 IGEL airway in one hundred non paralyzed patient. In this study they found mean insertion time with IGEL was 15 sec. In my study mean insertion time with IGEL was 16.2 sec, with proseal LMA was 25.2 sec P value is 0.000 which was significant at 1% level. The finding of study was in concurrence with above data. So insertion time with IGEL was shorter than proseal LMA.

4.HAEMODYNAMIC RESPONSE

SHIN WJ, & cheyng. YS[5] compared IGEL proseal LMA and classic LMA in elective surgery. They assessed haemodynamic response. In this study they found there is no difference in heamodynamic deference between IGEL, proseal LMA and classic LMA. In my study also there is no difference in heamodynamic response between IGEL and proseal LMA. The finding of my study was in concurrence with above data.

5. BLOOD STAINING OF DEVICE

In Ishwar singh and Monika Gupta[1] study blood staining of the devices with IGEL was 1/30, with proseal LMA was 6/30 P value is > 0.05 in my study blood staining of the devices with IGEL was 2/30 with proseal LMA was 8/30 P value is 0.038 which is statistically significant at 5% level. In both study blood staining of devices with IGEL was lesser than proseal LMA so airway trauma was less with IGEL than proseal LMA.

6. INCIDENCE OF COMPLICATION

In Ishwar singh and Monika Gupta[1] study there was no incidence of sorethroat, bronchospasm, laryngospasm, Regurgitation in both groups. But in my study there was a incidence of sorethroat in 2 cases with proseal LMA. No incidence of bronchospasm, laryngosmpasm, Regurgitaion with proseal LMA in IGEAL group there was no incidence of sorethroat, bronchospasm, laryngospasm, Regurgitation P value of sorethroat was 0.150 which was statistically not significant. So incidence of complication with IGEL was comparatively less but statistically not significant.

CONCLUSION -IGel is a cheap and effective device which is easier to insert than Pro Seal LMA. It has other potential advantages like rapid placement, less blood staining, less airway trauma than Pro Seal LMA. So I Gel is a useful alternative Supraglottic device to Proseal LMA.

REFERENCES

1)Ishwar singh and Monika Gupta (India Journal of Anaesthesia 2009;53(3);302-305) Comparison of Clinical Performance of I – Gel TM with LMA – Proseal TM in Elective Surgeries.)

2) Levitan RM and Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia 2005;1022-1026.

3) Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology, 2000;93:104-9.

4)J.J GATWARD, T.M.COOK, C.SELLER-found I-GEL was easily and rapidly inserted, providing a reliable airway in over 90% of patients. (Anaesthesia , 2008,63 pages 1124-1130).-

5)Shin WJ, Cheong YS. Yang HS compared I-GEL, Proseal LMA and Classical LMA in Anaesthetised patients. European journal of anaesthesiology 2009 Nov 12