ORIGINAL RESEARCH PAPER VOLUME-6 | ISSUE-8 | AUGUST - 2017 | ISSN No 2277 - 8179 | IF : 4.176 | IC Value : 78.46

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARISON OF I-GEL SUPRAGLOTTIC DEVICE WITH PROSEAL LARYNGEAL MASK AIRWAY IN ANAESTHETIZED PARALYZED PATIENTS UNDERGOING ELECTIVE SURGERY

Anesthesiology

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ABSTRACT

Introduction- This study was conducted for comparison of I-GEL supraglottic device with Proseal laryngeal mask airway in anesthetized paralysed patients undergoing elective surgery.

Method- This study is a hospital based randomized prospective comparative study conducted in our hospital. Sixty patients of ASA Grade 1 & 2 were randomly divided in two groups. Group "I" for I-GEL and group "P" for proseal. After induction with propofol and succinylcholine device was inserted, both group were premedicated with inj Glycopyrolate and inj Fentanyl and compared with respect to time of insertion, and number of attempts made.

Result- In group P average time of insertion was 16.60±3.37sec while in group I average time of insertion was 10.37±1.30sec and this was statistically significant (P value was <.001 sec). Device was inserted in 29 of 30 (96.7%) in group I while 25 of 30 (83.3%) in group P in first attempt and the difference was statistically not significant (P=0.085). Ng tube was inserted in 27 (90%) in group I while 24 of 30 (80%) in the group P in first attempt. The difference was not statistically significant (p=0.27). Mean systolic, diastolic BP and mean HR rises significantly just after insertion and during removal of device in both groups but does not require any intervention i.e. changes from baseline is less than 20%. Only one patient in group I had developed post operative sore throat compared to five patients in group P. The incidence was not statistically significant (p=.085) when compared between the groups. The sore throat in all the cases was mild requiring no treatment. None of the patients in both the groups developed post operative hoarseness or dysphagia. In group I two patients was found with blood staining of device or lip trauma while in group P six patients. However the incidence was not statistically significant (P=0.13) when compared between two groups

Conclusion- Both device can be used for airway management in anesthetized patient with success rate more than 80% but I-GEL is provides more easy, quick and efficient method to secure airway when compared to proseal with less trauma during insertion and less postoperative sore throat.

KEYWORDS:

Laryngeal Masks, I-GEL, Proseal, Propofol, Succinyl choline, Airway management

INTRODUCTION

Maintenance of airway is integral part of general anaesthesia. LMAs are also used to ventilating patient during anaesthesia; Archie Brain first introduced LMA and later modified and developed ProSeal LMA. I-gel was introduced by Intersurgical Ltd., Wokingham, England. It is made up of medical grade thermoelastomer SEBS, soft gel like material without inflatable cuff. It is a single used device which overcome the disadvantage of ProSeal like high cost, demand for careful handling to prevent cuff damage. I-gel has a gastric channel for nasogatric tube insertion. During inflation of cuff of ProSeal device can move buccal cavity stabilizer of I-gel avoid this because of non inflatable cuff. The firm tube section allow device to be inserted by grasping the proximal end of I-gel and its natural oropharyngeal curvature helps to glide the leading edge against the hard palate into the pharynx. I-gel can be inserted without putting finger in patient's mouth.

We compare these two supraglottic airway devices in terms of ease of insertion, number of insertion attempts, ease of gastric tube placement, hemodynamic changes, trauma, post operative hoarseness in anaesthetized, paralyzed adult patients posted for elective surgeries under general anaesthesia.

METHOD

This study was conducted in the Department of Anaesthesiology, Jawaharlal Nehru Medical College, Ajmer with due permission from institutional ethical committee and review board and written informed patient consent. Sixty ASA grade I and II adult patients of either sex scheduled for elective surgery were selected. Head and neck surgeries, Predicted difficult airway, History suggestive of increased risk of aspiration, Patients with abnormal or distorted anatomy of the pharynx, Patients with obstruction of the airway beyond the larynx, Patients with history of lung diseases, Obese patients with BMI >28 kg/m2 were excluded from the study.

After recording the baseline readings of SBP, DBP, PR, ETCO2, the patient was premedicated with injection midazolam 0.02 mg/kg, glycopyrolate 4mcg/kg, fentanyl 2mcg/kg body weight. Then the patient was preoxygenated with 100% oxygen for 3 minutes via a face mask. Anaesthesia was induced with propofol 2 mg/ kg body weight. After achieving adequate depth, patient was paralyzed by giving intravenous succinylcholine (1.5 mg/kg body weight). The patient was mask ventilated with 100% oxygen for 1 minute and device was inserted. Anaesthesia was maintained using 66% nitrous oxide and 33% of oxygen with isoflurane 1%w/v. After the patient recovered from succinylcholine further neuromuscular blockade was maintained with veccuronium loading 0.1mg/kg followed by 0.05 mg/ kg body weight as required. Intraoperative vitals were recorded at the time of insertion and 1,3,min after insertion and at the time and one minute after removal.

Ease of insertion was also recorded and graded as very easy (when assistant help is not required), easy (when jaw thrust is needed by assistant) and difficult (when jaw thrust and deep rotation or second attempt is used for proper device insertion).

Time of insertion was recorded time taken from holding the lubricated device to the first square shaped tracing in $ETCO_2$ including no of attempts if more than two attempt are taken called as failed. Number of attempt and time required for the insertion of gastric tube insertion was also recorded.

Patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery. Any post operative complications like sore throat, dysphagia and hoarseness.

RESULT

There was no difference between the two groups with respect to

demographic and surgical details. In all patients the supraglottic device, I-gel or LMA – ProSeal, was inserted within two attempts.

Table 1- Demographic Profile

	Group I	Group P	P value
Mean age±SD(years)	39.13±13.72	38.27±10.73	0.78
Mean weight±SD(Kg)	61.40±8.59	64.73±8.38	0.13
Male	53.3%	46.7%	0.61
Female	46.7%	53.3%	

Table 2- Assessment

Parameter		Group I	Group P	P value
Ease of insertion	Very easy Easy Difficult	25(83.3%) 4(13.3%) 1(3.3%)	16(53.3%) 9(30%) 5(16.7%)	0.086
Attempts of insertion	One Two	27(90%) 3(10%)	25(83.3%) 5(16.7%)	0.085
NG tube Insertion attempts	One Two	29(96.7%) 1(3.3%)	24(80%) 6(20%)	0.27
Mean duration of insertion±SD		10.37±1.30	16.60±3.37	<.001
Mean NG tube insertion time (sec) ±SD		6.87±0.73	8.23±0.94	<.001

Table 3 Comparison of systolic blood pressure (SBP) at various time intervals

Time	Group I	p value-compared with pre op	Group P	p value-compared with pre op
	Mean SBP±SD(in mm Hg)		Mean SBP±SD(in mm Hg)	
Pre OP	133.47±8.07		129.20±9.82	
Just after insertion	139.37±10.66	<0.001	134.47±11.43	0.002
1 min	135.73±9.14	0.037	129.87±11.24	0.734
3 min	131.27±9.86	0.108	123.20±13.50	0.160
At time of removal	137.47±7.56	<0.001	134.07±9.62	0.003
1 min after removal	132.60±8.60	0.412	129.20±7.48	0.990

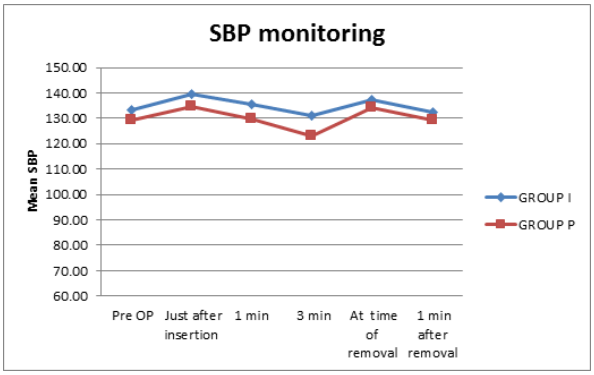


Table- 4 Comparison of diastolic blood pressure (DBP) at various time intervals

Time	Group I	p value-compared with pre op	Group P	p value-compared with pre op
	Mean DBP±SD(in mm Hg)		Mean DBP±SD(in mm Hg)	
Pre OP	83.17±5.65		81.90±6.24	
Just after insertion	85.37±7.28	0.004	84.07±6.23	0.005
1 min	82.00±6.41	0.116	81.17±6.06	0.470
3 min	79.27±5.64	<0.001	77.73±6.72	0.004
At time of removal	84.33±4.58	0.132	84.07±5.60	0.062
1 min after removal	81.27±3.77	0.044	80.53±4.03	0.314

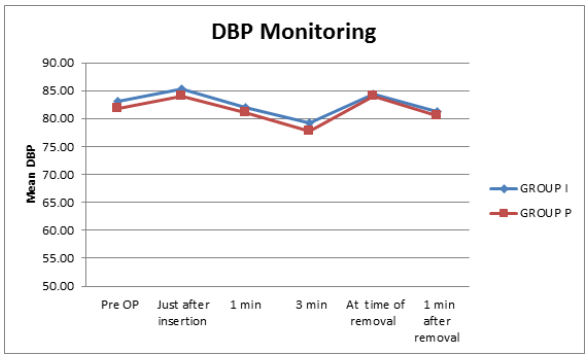


Table- 5 Comparison of Pulse Rate (PR) at various time intervals

Time	Group I	p value-compared with pre op	Group P	p value-compared with pre op
	Mean PR±SD(beats per minute)		Mean PR ±SD(beats per minute)	
Pre OP	82.87±7.98		80.93±8.09	
Just after insertion	86.07±9.74	<0.001	84.20±7.74	0.021
1 min	84.47±8.60	0.030	82.13±8.80	0.390
3 min	82.70±8.52	0.840	80.20±8.01	0.560
At time of removal	84.53±7.01	0.079	82.80±7.60	0.021
1 min after removal	83.13±7.44	0.710	80.87±7.86	0.940

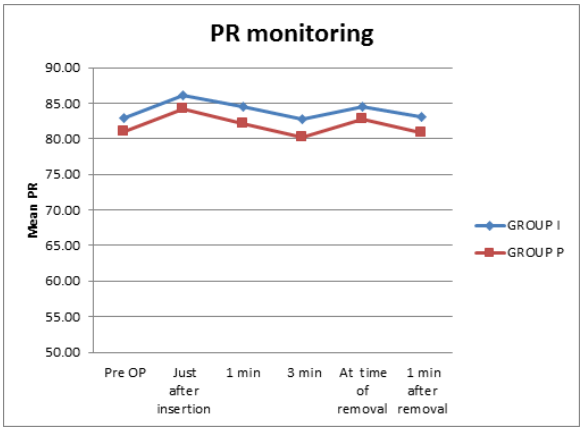


Table- 6 trauma and postoperative complications

Parameter	Group I	Group P	P value
Blood staining of device	2(6.7%)	6(20%)	0.13
Postoperative sore throat	1(3.3%)	5(16.7%	.085

The insertion of I-gel in group I patients was graded very easy in 25 patients, easy in four and was difficult in one patient. The insertion of ProSeal in group P patients was graded very easy in 16 patients, easy in nine patients and difficult in five patients. Device was inserted in 29 of 30 (96.7%) in group I while 25 of 30 (83.3%) in group P in first attempt (P=0.085). Ng tube was inserted in 27 (90%) in group I while 24 of 30 (80%) in the group P in first attempt(p=0.27). The mean duration of insertion of I-gel in group I patients and ProSeal in group P patients were 10.37±1.30 and 16.60±3.37 seconds respectively and was significantly less in group I (P value<.001). The mean duration of insertion of nasogastric tube in group I patients and ProSeal in group P patients were 6.87±.73 and 8.23±.94 seconds respectively and was significantly less with group I. (p<0.001).

Mean systolic, diastolic BP and mean PR rises significantly just after insertion and during removal of device in both groups but does not require any intervention i.e. changes from baseline is less than 20%. Although Mean systolic, diastolic BP and mean HR comes to normal after 1 min and remain below pre OP level. There was no significant difference when compared in both group.

Only one patient in group I had developed post operative sore throat compared to five patients in group P (p=.085). The sore throat in all the

cases was mild requiring no treatment. None of the patients in both the groups developed post operative hoarseness or dysphagia. In group I two patients was found with blood staining of device or lip trauma while in group P six patients (P=0.13).

DISCUSSION

One of the primary objectives of our study was to compare the ease of insertion between the two devices. The grading of insertion of device was recorded as; very easy (when assistant help was not required), easy (when jaw thrust was needed by assistant) and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).

In our study, the ease of insertion of I-gel was very easy (score 1) in 26 patients (86.7%) and easy (score 2) in the remaining (13.3%). On the other hand insertion of ProSeal in our study was graded very easy in 20 patients (66.7%), easy in nine patients (30.0%) and difficult in one patient (3.3%). Consequently, the insertion of I-gel was found easier and required less skill as compared to ProSeal (p>.05). Similarly Ishwar singh et al found that there was no significant difference between ease of insertion between I-gel and ProSeal.

In our study insertion of I-gel was successful in first attempt in 96.7% patients while insertion of ProSeal was successful in first attempt in only 83.3% patients (p.>05). The parallel results were found in study conducted by Osman Ekinci et al, compared the I-gel and ProSeal and achieved successful insertion in 100% of cases on the first attempt in the I-gel group, while the rates in the ProSeal group were 82.5% and 17.5% for the first and the second attempts respectively.

The time for insertion was well thought-out from picking up the device to confirmation of effective ventilation by bilateral chest movement & auscultation, square wave pattern capnography and normal range ends tidal CO2. In our study, the time of insertion of I-gel(10.37±1.30S) was shorter compared to ProSeal (16.6±3.37S) which was statistically significant(p<.001)

I-gel is fabricated of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to ProSeal which has a cuff to be inflated after its insertion. I-gel has a buccal cavity stabilizer, which provides good stability and facilitates insertion without even using finger to guide the device into mouth of patient. The smooth contiguous surface, allows the device to slide potentially along the hard palate, pharynx and into hypopharynx easily. Brimacombe and colleagues presumed that the difficulties in inserting LMA – ProSeal were caused by larger cuff impeding digital intraoral positioning and propulsion into the pharynx, the lack of a backplate making cuff more likely to fold over at the back of mouth and the need for more precise tip positioning to prevent air leaks up the drainage tube.

Our results are unswerving with the studies done by Gaurav Chauhan et al who also found significant difference in the insertion times.

Studies regarding the ease of insertion of the gastric drainage tube involved an equal number of studies reporting two devices to be similar and insertion with the I-gel was found to be easier than with ProSeal. Among the researchers comparing the gastric tube insertion and drainage, Osman Ekinci et al reported that both procedures are performed more easily with the I-gel than with the ProSeal. In the present study, the rates of insertion on the first attempt were 90% and 80% for I-gel and ProSeal respectively.

The systolic BP diastolic BP, PR, SPO2 were monitored in the following time interval- Basal before premedication, at the time of insertion,1 minute after insertion,2 minutes after insertion, at the time of removal and 1 minute after removal.

In our study, there were significant changes in mean systolic, mean diastolic and mean heart rate when compared with baseline values during insertion and removal of devices. The results of our study were similar to the studies done by Braudeet al. and Wilson et al. they observed that there was significant increase in hemodynamic variables after LMA insertion. The significant increase in hemodynamic may be due to lack of proper analgesia or may be induced by the passage of the LMA through the oral and pharyngeal spaces, pressure on the larynx and the pharynx by an inflated cuff and the dome of the LMA. The utmost cardiovascular response occurs during the stimulation of epipharynx. Introduction of the device and inflation of the cuff stimulates and exerts pressure on the anterior pharyngeal wall. This may be the mechanism by which the increases in blood pressure and pulse rate occur; the transient nature of the response suggests that this is not related to the continuous pressure exerted by the sealing cuff. The reduced response may reflect the lesser stimulus compared to laryngoscopy, the lack of direct laryngeal and tracheal stimulation or the shorter duration of stimulus that results from quicker insertion. During removal of LMA, the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of cuff.

The inflatable supra glottis airway devices, during insertion, the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue and can cause pharyngeal injury. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.

In our study, the patients were inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery similar to study done by Bikramjit das et al,. Blood stain on the device on removal was noted in two patients in group I (I-gel) and in six patients in group P (ProSeal) out of 30 patients in each group. However the incidence was not statistically significant (p=0.13). Lower incidence of trauma or blood staining of I-gel may be due to non inflatable cuff.

18-24 hours after surgery, patients were interviewed for any post operative complications like sore throat, dysphagia and hoarseness. Only one patient in group I had developed sore throat post operatively as compared to five patients in group P. The incidence was statistically not significant. (p=0.08) when compared between two groups. The sore throat in all the five cases was mild requiring no treatment. None of the patients in both the groups developed post operative hoarseness or dysphagia.

Our results were concordant with the studies done by Gaurav Chauhan et al where the difference between LMA and I-gel regarding post operative complications was not statistically significant Because of the absence of an inflatable cuff, the authors hypothesized that use of the I-gel produced fewer postoperative throat and neck complaints compared with a standard LMA. Devices with an inflatable mask have the potential to cause tissue distortion, venous compression, and nerve injury, which explains the increased incidence of associated postoperative morbidity. However Osman Ekinci Found the difference was statistically significant with I-gel having lesser postoperative sore throat.

This observation of our study is supported by the study of Wong et al., where they stated that sore throat could be minimal even with supraglottic devices with inflatable cuff, if the intracuff pressure remains less than 60 cm H_2O.

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