A Clinical Comparative Study Of Evaluation Of Proseal LMA V/S I-GEL For Ease Of Insertion And Hemodynamic Stability; A Study Of 60 Cases

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Citation

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Abstract

BACKGROUND:- In the present study we studied 60 adult patients of ASA grade-I and II posted for routine surgeries under general anaesthesia, divided equally into two groups group-I and group-II. METHODS:- Premedication was given to all patients as inj.promethazine 25mg, inj.pentazocine 30mg and inj.glycopyrrolate 0.2mg intramuscularly 30 min prior to induction. Induction of anaesthesia was done with inj xylocard 2%1.5mg/ kg followed by 2 min after, inj.propofol 2-2.5mg/kg, inj.succynylcholine 1.5-2mg/kg i.v. In group-1, the airway was secured with a PROSEAL LMA (PLMA) while in group-II it was secured with I-GEL. Maintenance was done with N2O+O2+IPPV+inj. Vecuronium and traces of isoflurane. Reversal was given with inj.neostigmine 0.05mg/kg+inj.glycopyrrolate 0.008mg/kg after completion of the surgery and when criteria for extubation were satisfied. Number of attempatients of insertion and mean duration of insertion in each case of both groups was noted. Patient monitoring done for pulse rate, NIBP, SPO2, ECG intraoperatively. Alderets recovery score was measured in each case in post operative period in both groups.RESULTS;-In group-I the mean duration of insertion was 11.73 (±3.084) sec while in group-II it was 9.63 (±2.23) sec. Changes in mean pulse rate in both groups were comparable, statistically not significant. Changes in mean arterial pressure (MAP) was significant intraoperatively, higher in group-I than group-II with p-value <0.05. Alderetes recovery score was similar in all cases of both groups. No significant complications were noted in any patients of both groups. CONCLUSION: - It was concluded that I -gel airway is a better alternative user friendly device than PLMA in patients with high risk and having predicting difficult airway because of ease of insertion and maintenance of haemodynamic stability.

INTRODUCTION

The major responsibility of anaesthesiologist is to provide adequate ventilation to patient. The most vital element in providing functional respiration is the airway. It has been established that inability to successfully manage very difficult airway was been responsible for as many as 30% of death totally attributable to anaesthesia.

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between facemask and tracheal tube internal of both anatomical position and degree of invasiveness. These devices sit outside trachea but provide a hands free means of achieving a gas tight airway. The first successful supraglottic airway device the laryngeal mask airway (LMA) classic became available in 1989, first described by Archie Brain. As the time went on additional devices were added to LMA family to satisfy specific needs[1,2].

The I-gel is the most recent development in supraglottic airway devices. It was developed by Dr. Mohammad Aslam Nasir in January 2007. The I-gel is truly anatomical device[1]. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work, mirroring the shape of the epiglottis, aeryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation.

The proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in clinical practice in 2000 with its improved feature modified cuff to improve the seal around the glottis and a drain tube to provide a bypass channel for regurgitated gastric contents, its seal is more effective than that of classic LMA[2,3,4,5]. The drain tube prevents gastric insufflations, allows easy placement of gastric tube and also helps in placement of mask with the help of bougie.

It has been shown in recent studies that I-gel airway is better alternative device compared to PLMA for ease of insertion

and maintenance of anaesthesia[1,2].

In the present study we compared clinically I-gel v/s PLMA for ease of insertion i.e. no. of attempatients of insertion and mean duration of insertion and hemodynamic stability and any possible complications.

METHODS

A total of 60 patients aged between 18-55 yrs were selected from the routine list of surgical procedures under general anaesthesia lasting ≤ 2hrs after approval of ethical committee clearance according to hospital rules and regulations. They were divided equally into two groups as group-I (n=30, PLMA) and group-II (n=30, I-GEL). For each group 30 patients were studied. All patients had undergone elective surgery under ASA grade- I and II. All 60 patients were examined to assess their preoperative condition on the previous day of operation. Patient demographic data like age, weight, sex, complaints, past history, general examination and findings of cardiovascular and respiratory and other systems were recorded. Routine investigations like Hb, urine sugar, CxR, blood urea, serum creatinine were done in all patients. Vital data were taken in all patients. Patients were fasted for 8 hours before time of operation. Written informed consent was taken.

All patients of groups I and II were premediated with Inj glycopyrrolate 0.2mg, Inj.Promethagine 25mg and Inj.pentazocine 30mg intramuscularly 30 minutes prior to surgery. Before and after premedication all vital data like temp, pulse rate, NIBP, SPO_2, Respiratory rate were taken. All 60 patients were preoxygenated for 3 min by facemask with Bain circuit before induction. Induction of anaesthesia was done with inj. xylocard 2%1.5mg/ kg followed by 2 min after inj.propofol 2-2.5mg/kg, inj.succynylcholine 1.5-2mg/kg i.v stat.

In group-I, the airway was secured with PLMA while in group-II it was secured with an I-gel airway (photo-1). All insertions were done by consultants anaesthesiologist. Maintenance of anaesthesia was done with N2O +O2+IPPV+ inj. Vecuronium and traces of isoflurane. All vital data like temp, pulse rate, NIBP, RR, SPO_2, were recorded before induction, after induction and at regular intervals throughout the surgery. ECG monitoring was done using cardioscope ECG monitor. Reversal was given in the form of inj.neostigmine 0.05mg/kg and inj.glycopyrrolate 0.008mg/kg after completion of the surgery and when criteria for extubation were satisfied.

Number of attempatients of insertion and mean duration of insertion in seconds i.e. time from insertion of intubating device into mouth to time of confirmation by mechanical ventilation in each case of both groups was noted. Aldretes recovery score was measured in each case in post operative period. Other complications if any were also noted.

Both the groups were compared by using unpaired student 't'test with regard to number of attempatients of insertion, mean duration of insertion, mean pulse rate, mean arterial pressure(MAP), Aldretes recovery score. Difference between the two groups was considered significant if 'p' value<0.05.

Figure 1

Fig1 - I-GEL AIRWAY NO.-3

RESULTS

Table-1 shows the demographic data of both the groups. There were no statistically significant differences between the two groups with respect to age, sex, weight, ASA physical status and the duration of surgery.

Figure 2

TABLE-1 DEMOGRAPHIC DATA

	GROUP-1	GROUP-2	P-Value	S
MEAN AGE (YRS)±SD	31.16±11.16	28.13±10.01	>0.05	NS
MEAN WEIGHT (KG)±SD	51.4±6.70	47.9±7.67	>0.05	NS
SEX (MALE : FEMALE)	5:25	3:27	>0.05	NS
ASA GRADE-1:2	11:19	8:22	>0.05	NS
MEAN DURATION OF SURGERY (MIN)±SD	50±30.59	49.5±30.80	>0.05	NS

Table-2 and Bar chart-1 shows mean pulse rates/min of both groups compared statistically using student-t test. Difference between the two groups was considered significant if P-Value <0.05. Mean pulse rates were compared at before premedication, after premedication, induction,intraoperatively for 30min(0,5,10,15,30)andpostoperatively for 1hr(0,5,10,15,30,60).At all these points mean pulse rates are comparable and there is no statistically significant difference between the two groups with p value >0.05.

Figure 3

TABLE-2 MEAN PULSE RATE/MIN OF BOTH GROUPS

	GROUP-1 (n=30)	GROUP-2 (n=30)	P-Value	S
Before premed	83.06±4.09	84.2±4.4	0.29	NS
After premed	84.533±3.59	84.6±3.90	0.94	NS
Induction	84.73±3.463	84.46±4.09	0.78	NS
Intra op 0 min	84.6±3.75	84.53±3.89	0.94	NS
5min	84.66±3.53	84.2±3.33	0.60	NS
10min	84±3.48	84.26±3.59	0.77	NS
15min	84.26±3.74	83.8±3.87	0.636	NS
30min	83.8±3.72	83.93±4.05	0.829	NS
Post op 0min	84.93±3.13	85.66±3.64	0.407	NS
5min	84.4±3.03	85.26±3.128	0.280	NS
10min	83.6±2.74	84.13±3.67	0.527	NS
15min	83.33±3.07	83.6±3.57	0.758	NS
30min	83.2±3.17	83.2±3.22	1	NS
60min	83.06±3.18	83.33±3.87	0.771	NS

Figure 4

Fig2 - SHOWING MEAN PULSE RATE/MIN OF BOTH GROUPS

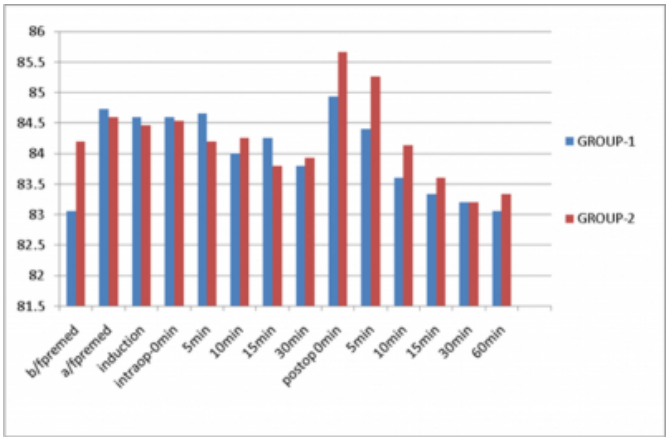


Table-3 and Bar chart-2 shows mean arterial pressures(MAP) of both groups. MAP was also compared before premedication, after premedication, induction, intraoperatively for 30 min(0,5,10,15 , 30)and postoperatively for 1hr(0,5,10,15,30,60). Changes in MAP was significant intraoperatively at 5min,10 min and 15min with MAP being higher in group-I (PLMA group) than group-II (I-gel group) with p-value <0.05 as shown in the table-3 and also in chart 2. Changes in MAP were again significant at post operative period of 10min, 15min and 30min with MAP being higher in group-I(PLMA group) than group-II(I-gel group) as shown in the table-3.

Figure 5

TABLE-3 MEAN ARTERIAL PRESSURE(mmhg) OF BOTH GROUPS

	GROUP-1(n=30)	**GROUP-2(n=30)**	**p-value**	**S**
Before premed	91.82±2.30	91.46±2.151	0.398	NS
After premed	93.42±2.55	92.51±2.149	0.068	NS
Induction	93.644±2.44	92.64±2.248	0.104	NS
Intra op 0min	94.04±3.036	93.17±2.46	0.308	NS
5min	94.95±2.84	92.92±2.51	0.005	S
10min	94.77±2.53	93.15±2.41	0.0139	S
15min	95.26±2.70	93.15±2.21	0.0016	S
30min	94.4±2.97	93.2±2.57	0.1003	NS
Post op 0min	95.22±2.65	94.51±2.62	0.301	NS
5min	94.35±2.52	93.46±2.48	0.174	NS
10min	94.66±2.67	93.06±2.16	0.013	S
15min	94.86±2.57	92.95±2.57	0.0056	S
30min	94.26±2.84	92.8±2.68	0.044	S
60min	93.8±2.72	92.77±2.173	0.113	NS

Figure 6

Fig3 - SHOWING MEAN ARTERIAL PRESSURE (mmhg) OF BOTH GROUPS

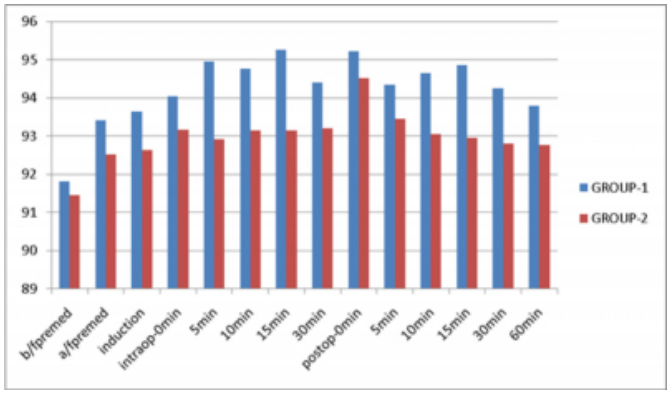


Table-4 shows mean duration of insertion of devices in both the groups. In group-I mean duration was 11.73 (±3.084) sec while in group-II it was 9.63 (±2.23) sec. When compared by student-t test p-value was 0.00389 which is <0.05. So difference between the two groups with regard to mean duration of insertion was much significant indicating shorter time required for insertion of I-gel airway than PLMA.

All insertions were done by consultants. In group-I there were two attempatients in 3 cases for securing airway while there were two attempatients in cases for securing airway in group-II. In the rest of all the patients of both the groups a single attempt was successful. So the number of attempatients in securing airway in both the groups was comparable and there was no significant difference. In group-I there were two incidents of failure to secure the airway and in both the cases the airway was finally secured by endotrachel tubes. In group-II, there were two incidents of failure to secure the airway, later also secured by endotracheal tubes. The failure rate in both the groups was similar. In our study failure of the device insertion was considered when it was not able to secure airway with effective ventilation, even after two attempatients by a consultant anaesthesiologist. All the four failures of both the groups may be attributed to improper size of device and fitting.

Figure 7

TABLE-4 MEAN DURATION FOR INSERTION (SECONDS) OF DEVICE IN BOTH GROUPS

	GROUP-1 (PLMA)	GROUP-2 (I-GEL)	P-Value	S
DURATION (SEC)	11.73 ± 3.084	9.63 ± 2.23	0.00389	S

Table-5 and Bar chart-3 shows the Aldretes recovery score in the post operative period. There was no significant difference between the two groups with regard to recovery score.

No significant complications were noted in any patients. Only two patients in each group complained sore throat. Later sore throat resolved within 2 hours without necessity of active treatment. No patient developed cyanosis, hypotension, bradycardia, tachycardia or edema, bruising, erythema on throat examination in any group.

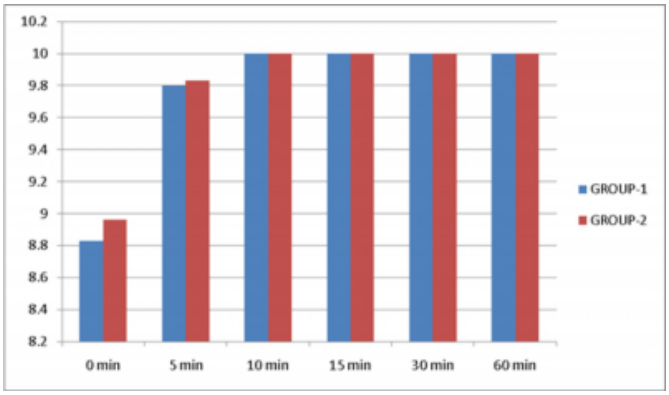
Figure 8

TABLE-5: SHOWING ALDERETES RECOVERY SCORE IN POSTOPERATIVE PERIOD IN BOTH GROUPS

	GROUP-1	GROUP-2	P-value	S
0 min	8.83±0.379	8.96±0.319	>0.05	NS
5min	9.8±0.343	9.83±0.379	>0.05	NS
10min	10	10		NS
15min	10	10		NS
30min	10	10		NS
60min	10	10		NS

Figure 9

Fig4 - SHOWING POSTOPERATIVE ALDRETES RECOVERY SCORE



DISCUSSION

The LMA is an established safe airway device for gynaecological laparoscopic procedure, where procedure usually last less than 2hours[6]. LMA is also safe device for controlled ventilation, where airway pressure is maintained at 15 to 20 cm of H2O[7].

I-gel airway is found to be easier to insert when compared to PLMA[8]. I-gel is also found to produce less hemodynamic changes than PLMA[8].

P.M. Bodrick et al studied 100 ASA grade I and II spontaneously breathing patient aged 16-65yrs, weighing 35-75kg using LMA in a variety of general surgery, gestourinary surgery, gynecological surgery and orthopedic surgery9. A total of 18 different anaesthetists, none having experience in use of LMA, were involved in the study. All patients were premedicated with T-tenazepam orally 2hours preoperatively. Anaesthesia was induced with inj. Thiopentone 6mg/kg in over 45 sec. followed by airway securation with an LMA. When adequate Jaw relaxation was confirmed anaesthesia was maintained with volatile anaesthetics in 70% N_2O and 30% O_2. Patients were allowed to breath spontaneously from a Magill system with a fresh gas flow of 7 liters per minute with proper modifications. Clinically satisfactory airway was obtained in 98 patients without need to support jaw, extend the head or to handle the patient in anyway. The LMA passed easily without introducer in 92 patients. Insertion was successful in first attempt in 80%, in second attempt in 70% of remaining 20 patients, in third attempt in 4 of the remainder and LMA was replaced with a Guedel oropharyngeal airway in the other two patients and in the other 10 patients, severe airway obstruction, coughing and laryngospasm occurred. In 8 patients the leak was large enough to make ventilation insufficient, two patient had temporary stridor on removal which quickly settled of all, 12 patients had a temporary sore throat in postoperative period excellent airway patency was obtained in 98% patients.

In our study, a PLMA was used in a total of 30 patients and all insertions were made by a consultant anaesthetists out of which three patients required double attempatients for securing airway and other two patients required endotracheal tube due to failure of securing airway with PLMA even after two attempatients because of smaller size of device.

Tae-Hyung Han et al studied 1067 ASA I and II patients aged 19-40 years weighing 34-84kg undergoing elective caesarean section using LMA[10]. The patients were fasted for six hours and given ranitidine, sodium citrate, immediately before surgery. A rapid sequence induction with Inj. Thiopentone 3-4mg/kg i.v. Inj. Suxamethonium 1.5mg/kg i.v. and single handed cricoid pressure by an assistant was done. Anaesthesia was maintained with N_2O + 50% O_2 and volatile agent enflurane 1-1.5% or isoflurane 0.5-1.5% LMA No. 3 for patient <45kg No. 4 for patient >45kg was introduced and cuff inflated according to manufacturer advise. An effective airway was obtained in 99% patients, 98% at the first attempt and 1% at the second or third attempt. Air leakage or partial airway obstruction occur in 21% patients and 0.7% patients required intubation. Incidence of hypoxia (SPO_2 <90%) aspiration regurgitation, laryngospasm, bronchospasm or gastric insufflations was not noted in any patients. surgical condition were satisfactory and APGAR scores were >7 after 5 min. The LMA was effective and probably safe for elective caesarean section in healthy selected patients when managed by experienced LMA users. In our study also there were no incidence of aspiration regurgitation, laryngospasm, bronchospasm in all insertions of PLMA

N. M. Wharton et al evaluated performance of I-gel supraglottic airway device in manikins and anaesthetized patients when used by novices medical students, non anaesthetist physicians and allowed health professional all unfamiliar with the I-gel[11]. 50 I-gel were placed in manikins. 80% (44/50) were placed on first attempt with median insertion time of 14 sec (range 7-45). I-gel were placed in 40 healthy anaesthetized patients success on first attempt was 82.5% (33/40) and on the second attempt 15%(6/40) after three attempatients there were no failures median insertion time was 17.4sec (range 7-197) median airway seal was 20cmH_2O (13-40) one case of regurgitation and partial aspiration occurred.

In our study all insertions were made by a consultant anaesthetist and mean duration of insertion for I-gel was 9.63sec.

Parul Jindal et al have done a study to evaluate and compare the hemodynamic changes during insertion of supraglottic devices LMA, SLIPA or I-gel8. This prospective study was conducted on 75 patients of either sex, 20-70 years, ASA I and II scheduled to undergo elective surgical procedures under general anaesthesia. All three supraglottic devices were introduced using standard techniques by a single anaesthesiologist who had considerable experience in all three techniques. No. of intubation attempatients was similar among all groups but intubation time was significantly longer in LMA group (7.68 + 6.9) while compared to I-gel (3.48 + 1.41) and SLIPA (5.16 + 0.68).It was observed that I-gel produced less hemodynamic changes than SLIPA. In our study also I-gel has taken lesser mean insertion time (9.63sec) than PLMA (11.73) sec and produced less changes in MAP than PLMA.

Ishwarsingh etal studied comparison of clinical performance

of I-gel with LMA proseal in elective surgeries[12]. 60ASA gr-I and II adult patients were randomly assigned into two groups. Group –I (n=30) for I-gel and group P (n=30) for LMA proseal. The success rate of first attempt of insertion and ease of gastric tube placement was more with group I (P >0.05). Blood staining of device and tongue, lip and dental trauma was more with group P (P > 0.05) there was no evidence of bronchospasm, laryngospasm, regurgitation, aspiration or hoarseness in either group. This study resembles our study and the results of the study are also comparable.

A preliminary study was conducted for I-gel airway device by Ashish Kannaujia et al [13]. This study was conducted on 50 consecutive patients of ASA physical status I-II to determine the ease of insertion time to achieve effective airway, oropharyngyeal pressure and airway stability on head and neck movement. The success rate at first attempt was 90% with a median insertion time of 11 sec (range 8-45). Five patients needed second attempt while none needed 3rd attempt. In our study, out of 30 patients using I-gel only two patients required second attempt and other two patients required endotracheal tube due to failure to secure airway with I-gel even after second attempt.

Bimla Sharma et al conducted a randomized prospective comparative study of proseal LMA versus tracheal tube in Laparosocpic cholecystatomy[14]. In this study success rate of first attempt at insertion was higher for tracheal tube but not significant P(<0.05). The PLMA group was associated with better hemodynamic profile (P <0.05) than tracheal tube group.

CONCLUSION

From present study we conclude that I-gel airway is a better alternative supraglottic device than PLMA with controlled ventilation and for securing airway in difficult airway management especially in high risk cardiac patients since it produces lesser hemodynamic changes and easy to insert than PLMA.

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