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COMPARATIVE STUDY OF CLINICAL PERFORMANCE OF I-GEL WITH PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS FOR ELECTIVE SURGERIES

Anesthesiology

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ABSTRACT

AIM: To compare the I-GEL and Proseal LMA(PLMA) in elective surgeries with regard to Ease and success rate of insertion,, time of insertion Airway sealing pressure, Ease of gastric tube placement and associated complication.

Materials: In a prospective randomized study, 60 adult patients of ASA I-II of either gender between 18 and 60 years presenting for a short surgical procedure under general anesthesia using either i-gel or PLMA. An experienced anesthesiologist inserted appropriate sized i-gel or PLMA in patients using standard insertion technique and assessed the intraoperative findings of the study regarding time taken for respective device insertion, effective seal, ease of gastric tube insertion and complications were done.

RESULTS: There were no significant differences in demographic and hemodynamic data. Ease of insertion and success rate were comparable no significant difference in both devices ($P > 0.05$) (Chi-square test). The mean time for insertion was more with PLMA (25.23 + 5.463 sec) than with IGEL (16.80 + 3.336 sec) ($P < 0.05$). Although the airway sealing pressure was significantly higher with PLMA (28.93 + 2.212 cm of H^2O), the airway sealing pressure of IGEL (26.07 + 3.073 cm of H^2O) was very well within normal limit (Student's *t* test). Ease of gastric tube placement were much easier in IGEL than PLMA with (p=0.031). Incidence of complications were comparable.

CONCLUSION: I-Gel is a supraglottic device with acceptable airway sealing pressure, easier to insert gastric tube and less sore throat incidence. Hence I-Gel can be a good alternative to PLMA.

KEYWORDS:

Airway sealing pressure, I-gel, P LMA, time of insertion

INTRODUCTION

Supraglottic airway devices (SADs) have been widely used as an alternative to tracheal intubation during general anesthesia[1-7] The current guidelines on cardiopulmonary resuscitation also recommend SADs as an alternative to tracheal intubation[8,9] The ProsealTM laryngeal mask airway (PLMA) (intavent Orthofix, Maidenhead, UK) and the i-gel airway

(Intersurgical Ltd, Wokingham, Berkshire, UK) are the two SADs which provide higher airway leak pressure than the classic LMA (cLMA) and can be used for spontaneous as well as positive pressure ventilation (PPV).[10,11] Both these devices have separate channel for gastric tube insertion and are recommended for spontaneous as well as controlled ventilation.

I-gel is a novel supraglottic airway device with anatomically designed, non-inflatable mask, which is soft gel like and transparent made of medical grade thermoplastic elastomer called styrene ethylene butadiene styrene. The soft noninflatable cuff fits snugly onto the perilaryngeal framework and its tip lies in the proximal opening of the esophagus, thus isolating oropharyngeal opening from the laryngeal opening. The device has a buccal cavity stabilizer which has a propensity to adapt its shape to the oropharyngeal curvature of the patient. This buccal cavity stabilizer houses airway tubing and a separate gastric channel.[12,13,14]

METHOD

After obtaining the approval of the Institutional Ethics committee and written informed consent from the patients, 60 patients were included. All the patients was received injection midazolam 1mg, glycopyrrolate 0.2mg, ranitidine 50 mg and metoclopramide 10 mg intravenously 30 minutes before surgery. Anaesthesia induction with propofol 2 mg/kg and fentany 1µg/kg and neuromuscular blockade with scoline 2mg/kg. Both I-gel and Proseal LMA was lubricated with water soluble jelly. Once adequate depth is achieved each device was inserted by an experienced anaesthesiologist. Both the devices will be fixed by taping the tube over the chin and lubricated gastric tube placed into the stomach through the gastric channel. Maintenance was achieved by oxygen, nitrous oxide, isoflurane and intermittent doses of

intravenous vecuronium. Hemodynamic parameter's like heart rate, non-invasive blood pressure and oxygen saturation were recorded before induction, at insertion, at 1, 5, and 15 minutes after insertion of device, then at end of surgery and 1 minute after removal of device.

The number of insertion attempts and the ease of insertion of device were recorded. Ease defined as no resistance to insertion in the pharynx in a single maneuver. In a difficult insertion there will be resistance to insertion or more than one maneuver or attempt required for the correct placement of the device. An effective airway was judged by a square wave capnograph trace, normal thoraco - abdominal movement and absence of leak. If an effective airway could not be achieved with the device then rescue airway with endotracheal tube was achieved after three unsuccessful attempts and failure of insertion recorded.

The ease of placement of gastric tube was also recorded and its correct placement was confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Failure of gastric tube placement was also recorded and it was defined as failure to advance the gastric tube into the stomach within two attempts.

The airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/minute and recording the airway pressure (Cuff inflator/pressure gauge) at which equilibrium was achieved. At this time gas leakage was determined at the mouth by the audible leak or by detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage. At the end of surgical procedure anaesthesia was discontinued, patient was reversed

with standard dose of neostigmine and glycopyrrolate and the device was removed. adverse effects like blood staining of the device and tongue, lip and dental trauma recorded. Regurgitation of gastric contents also assessed. Pharynaolaryngeal morbidity was assessed as sore throat.

The sample size was based on a crossover pilot study of 10 patients and was selected to detect a projected difference of 30% between the groups for airway sealing pressure for type I error of 0.05 and a power of 0.8. Statistical analysis for airway sealing pressure was done by Fisher's t–test. For the two variables, ease of insertion of gastric tube & bronchospasm/laryngospasm dichotomous nominal scale data correlation was applied. For the remaining characteristics Chi square test with Yate's correction was applied. Significance was taken as $p < 0.05$.

RESULTS

There was no difference between the two groups with respect to demographic and surgical details.

Table 1 demographic data.

Particulars	IGEL	PROSEAL
Age	37.87+10.28	34.20+11.24
Sex		
Male	5	6
Female	25	24
Weight	57.13+13.74	51.17+13.35
Type of surgery		
Appendicitis	1	5
CA breast	13	10
Fibroadenoma	6	10
Hernia	1	3
Hydrocele	2	1
Lipoma	4	1
Tubectomy	3	0

Table 2 Comparison of airway sealing pressure, ease of insertion, insertion attempts and mean insertion time

Data	IGEL	PROSEAL	P value
Airway sealing pressure	26.07+3.073	28.93+2.212	0.001
No. of attempts			0.301
First	29	27	
Second	1	3	
Ease of insertion			0.192
Easy	29	27	
Difficult	1	3	
Time of insertion	16.80+3.336	25.23+5.463	0.001

Table 3 ease of gastric tube insertion and complications

Data	IGEL	PROSEAL	P value
Gastric tube insertion			0.031
Easy	28	20	
Difficult	2	8	
Failed	0	2	
Sore throat	0/30	3/30	0.076

DISCUSSION

The time for insertion was considered according to the study conducted by Gaurav Chavan,[15] from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography, normal range end tidal CO2 and stable arterial SpO2 (>95%). In our study, the time for insertion of i-gel (16.80s) was shorter compared to P-LMA (25.23s) which was highly significant statistically (p=0.001). The i-gel SAD is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to c-LMA which has a cuff to be inflated after its insertion. Consistent with our study Gaurav Chavan et al35, Gurudas Kini et al[16] and Apeksha patwa[17] also shows significant difference in the insertion times.

The mean airway sealing pressure with I – gel was 26.07 + 3.073 cm of H2O , and with Proseal LMA 28.93 + 2.212 cm of H2O which was statistically significant (p = 0.001) but it was not clinically significant. The airway sealing pressure provided by the I – gel was enough to prevent aspiration. Ishwar Singh et al [18] also noted that the airway sealing pressure provide by Proseal LMA (29.6 cm of H2O) was higher than that with the I – gel (25.27 cm of H2O). Shin WJ et al[19] and Gaurav chavan et al[15] also noted the higher values of airway sealing pressure as shown in above table, data was statistically significant but it was not clinically significant.

In our study ease of gastric tube insertion was easy in 28/30, difficult in 2/30 and failed 0/30 in IGEL group whereas easy in 20/30, difficult in 8/30 and failed in 2/30.so P value was 0.031 which is statistically significant. Our results concordance with study of Gaurav Chavan et al[15], ease of gastric tube insertion was significantly higher in IGEL group (P=0.001). also in Ishwar Singh et al[18] and Gurudas kini et al[16] found ease of gastric tube with P value >0.05 and 0.230 respectively which was not statistically significant.

CONCLUSION

To conclude the I-gel is a cheap and effective device which is easier to insert. It has other potential advantages like effective airway sealing pressure which was within the normal limit and easier gastric tube placement. Lack of inflatable cuff also resulted in lower incidence of sore throat. Thus an I-gel can be a useful tool for maintaining airway and intermittent positive pressure ventilation.

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