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"Comparisonof Classic- Laryngeal Mask Airway with I-Gel Airway,during Anaesthesia with Controlled Ventilation in Routine Surgical Procedures"

Dr. Prateek Singh Bais[1],Dr. Amit Tyagi[1],,Dr. Deepesh Saxena[2,] [*]Dr. Manoj Tripathi[3],Dr. Neha Rusia[4], Dr. Amir Laique Khan[1]

[1]*Senior Resident, Department of Anesthesia and ctitical care, Dr.Ram Manohar Lohia Institute Of Medical Sciences, Lucknow, Uttar Pradesh India*
[2]*Senior Resident, Department of Anesthesia and Critical care, Swami Dayanand Hospital, New Delhi*
[3]*Assistant Professor, Department of Anesthesia and ctitical care, Dr.Ram Manohar Lohia Institute Of Medical Sciences, Lucknow, Uttar Pradesh India*
[4]*Senior Resident, Department of Anesthesia and Critical care, Hindu Rao Hospital and North MCD Medical College, New Delhi*
Corresponding Author- Dr Manoj Tripathi

Abstract:
Background: *Classic LMA was the first LMA to be introduced and has been considered the gold standard of all supraglottic airway device(SGAD). The I-gel is another recently developed non-inflatable supraglottic airway device made of thermoplastic elastomer that provides seal, which improves as device warms to body temperature.*
Aims:*The present study was conducted to evaluate and compare efficacy of LMA-classic & I-gel in terms of (i) number of attempts (ii) time taken to insert airway device.*
Setting and Design:*This is a prospective randomized comparative controlled study done in our operation theatre over a period of 1 year, after ethical committee clearance.*
Material and Methods: *The patients were randomly assigned in 2 groups comprising 25 patients each. Allocation was done using sealed envelope*
Group L*: Classic LMA. (Size was selected as per kg body weight of the patient) = 25 patients.*
Group I*: I-Gel (Size was selected as per kg body weight of the patient) = 25 patients.*
Statistical Analysis:*The statistical analysis with Chi-Square test / Fisher exact test,student t-test/Paired t-test, Wilcoxon–Mann Whitney test were applied for categorical variables, statistical significance of different continuous variables ,respectively.*
Results& Conclusion: *The mean time taken to insert LMA was more than I-gel (15.44± 2.48 sec vs 11.24± 1.94 sec, P<.05) and the success rate of insertion in first attempt was 96%in LMA group and 100% in I-gel group.*
Keywords:*Classic LMA, I-Gel, Supraglottic airway devices, Laryngeal mask airway.*

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I. Introduction

Maintenance of airway is an integral part of general anaesthesia. Now a day's airway management of patients has progressed from endotracheal tube to lesser invasive supraglottic airway devices. The supraglottic airway devices (SGAD) have been increasingly used since the introduction of Laryngeal Mask airway by Dr.Archie Brain in 1988.[1,2] The Classic LMA was the first LMA to be introduced and has been considered the gold standard of all SGAD. The Classic LMA is a single use, latex free, supraglottic airway device made of medical grade polyvinyl chloride with an inflatable cuffto wedge into the hypopharynxto provide a perilaryngeal seal, and hence it produces less pressor response and less hemodynamic changes.The I-gel is recently developed non-inflatable supraglottic airway device made of thermoplastic elastomer with an in-built gastric port and its perilaryngeal seal improves as the device warms to body temperature.

Aims and Objectives: The aims and objectives of this study were to: (i) assess and compare the ease of insertion, (ii) number of attempts taken and time taken to insert LMA- Classic & I-gel airway (iii) assess and compare the adequacy of ventilation and compare hemodynamic response and to know the incidence of regurgitation and other perioperative complications.

II. Materials & Methods

This is a prospective randomized comparative controlled study with title **"Comparison of Classic-Laryngeal Mask Airway with I-gel Airway during Anaesthesia with Controlled Ventilation in Routine Surgical Procedures"**, after approval from ethical committee and institutional review board was conducted in our institute during period of one year.The patients were randomly assigned to one of the 2 groups comprising 25 patients each. Allocation was done using sealed envelope.

Group L: Classic LMA. (Size was selected as per kg body weight of the patient)

Group I: I-Gel (Size was selected as per kg body weight of the patient)

Inclusion Criteria: (1) ASA physical status I & II patients. (2) Age between 18 years to 60 years. (3) Patients undergoing elective surgical procedures. (4) Weight between 40 to 100 kg. (5) Provision of written consent.

Exclusion Criteria: (1)Patients refusal to give consent. (2) Inability to comply with the study procedures. (3) Uncooperative patient. (4) Any pathology of neck, upper respiratory tract or upper alimentary tract. (5) Predicted difficult airway, mouth opening < 2.0 cm, the view of the mouth will be scored by the method of Mallampati as modified by Samsoon & Young. (6) A body mass index > 35kg/m2. (7) Patients with history of obstructive sleep apnea. (8) Potentially full stomach patients. (9) Oesophageal reflux (hiatus hernia).

A thorough pre-anaesthetic evaluation was done for all patients. Baseline hematological, biochemical & radiological investigations appropriate for the surgery were done. Also assessment was done to identify cases with difficult intubation.A full free voluntary, written and informed consent to participate in the study was taken from all patients included in study. All patients were given Tab.Alprazolam 0.25 mg orally night prior to surgery and at morning of surgery with sip of water. All patient were kept nil per orally for at least 8 hours pre-operatively.The patient monitoring included pulse oximetry, non-invasive blood pressure monitoring, capnography and electrocardiography. After intravenous cannula, a drip of Lactated Ringer was started. Baseline measurements of pulse rate, non-invasive blood pressure, oxygen saturation and end tidal carbon dioxide were taken just before induction and administration of muscle relaxant, just before insertion of either device. Check test for airway devices was performed before use as recommended and it was lubricated with a water based gel. All patients were given intravenous Inj.Ondansetron 4mg and Inj. Glycoprrolate 4 µg/kg body weight, 5 minutes before insertion of SGAD. After pre-oxygenation with 100% oxygen for 3minutes anesthesia was induced with Inj.Thiopentone 5mg/kg body weight and maintained with Halothane at MAC 0.8% with N_2O and Oxygen. Muscle relaxation was achieved by inj Vecuronium 0.1 mg/kg. The number of attempts, time taken, ease of insertion and hemodynamic changes were assessed and noted while procedure was done by anesthesiologist. All time duration were measured on a stopwatch.

Lma-Classic Insertion Technique: The LMA is depicted with a semi-inflated cuff, held by the shaft with the left hand and introduced straight into the mouth. The LMA is held with the dominant hand. The hand holds the LMA like a pen, with the index finger placed at the junction of the cuff and the shaft, with the LMA opening oriented over the tongue. The LMA is passed behind the upper incisors, with the shaft parallel to the patient's chest and the index finger pointing toward the intubator. As the LMA is advanced, the mask portion is pressed against the hard palate by using index finger. The tube is then advanced in one smooth movement until a characteristic resistance is felt, as the upper esophageal sphincter is engaged.Without holding the tube cuff is inflated with the air, this causes a characteristic outward movement of the tube of approximately 1.5cm. The longitudinal black line on shaft of tube should lie in midline against the upper lip. Any deviation may indicate misplacement of cuff and partial airway obstruction.

I-Gel Insertion Technique: The standard technique of insertion involves the device to be held like a pen, guided into pharynx with index finger of the operator. Under direct vision, device is grasped and is introduced continuously into mouth towards hard palate until resistance is felt. Adequate placement of the device will be assessed by gently squeezing reservoir bag and observing end-tidal CO2 waveform and movements of chest wall, absence of audible leak & gastric insufflation.

After insertion of airway device anaesthesia was maintained with Halothane MAC 0.8% and N_2O in Oxygen. Vecuronium Bromide 0.01 mg/kg was used as muscle relaxant.Monitoring of Heart Rate (HR),Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP)and saturated partial pressure of O_2(SPO_2) was done immediately after insertion of device (IAI), then 1 minute, 3 minute, 5 minute, 10 minute and 15 minute after insertion of airway device. At the end of surgery neostigmine 0.04 mg / kg i.v. + glycopyrrolate 0.02 mg / kg was administered for reversal of residual muscle relaxation and airway device was removed.

III. Statistical Analysis

The statistical Chi-Square test / Fisher exact test were applied for categorical variables. For comparing the statistical significance of different continuous variables between two groups (LMA & I-Gel) "student t-test" was used and in case where variable were not following normal distribution non-parametric Wilcoxon–Mann Whitney test was applied. For determining statistical significance between baseline and over a different period of time of the same variable under each group, Paired t-test was applied. The level of statistical significance was taken as $p \leq 0.05$ and the data was analyzed by using SPSS statistical software 12.0.

IV. Observation And Result:

As seen in Table no.1 there is no statistical difference between the two groups in terms of number of attempts, as the p value is 0.871(>0.05). Only in 1 patient two attempts were taken to insert C-LMA (L) while in I-gel was inserted in all the 25 patients in one attempt. Now as per the study, the mean time taken for insertion of LMA was 15.44 ± 2.48 seconds when compared to I-gel, in which mean time taken for insertion were 11.24 ±1.94 seconds shown in Table no.2. There was statistically significant difference between the two groups as p-value was 0.034(< 0.05).As evident from Table no.3, the groups responded to the airway instrumentation with a rise in MAP from the baseline values, reaching its peak after 15-30 seconds after airway insertion. The rise in MAP was statistically significant in both groups till 1min from baseline values but was almost similar in both groups. The p-value was significant in both groups up to 1min as compared with the baseline values (0.000 in group L and 0.004 in group I at 1 min, which is <0.05).

Table 1: Comparison of number of attempts between both groups

Group	No. of Attempts		Total	P-value.
	I	II		
LMA(L)	24	1	25	0.871
	96.0%	4.0%	100.0%	
IGEL(I)	25	0	25	
	100.0%	0%	2.0%	
Total	25	25	50	
	100.0%	100.0%	100.0%	

Table2- comparison of time taken for insertion (seconds).

Group	Time Taken (sec.)		P-value.
	Mean	SD	
LMA(L)	15.44	2.48	0.034
IGEL(I)	11.24	1.94	

Table 3: variation of mean arterial pressure (mmhg) values among the patients in both the group

	LMA(L)			**IGEL(I)**		
	Mean	SD	p-value	Mean	SD	p-value
MAP –BL	93.40	10.69	N/A	94.00	7.39	N/A
MAP - IAI	98.48	10.62	0.000	97.88	6.60	0.000
MAP - 1 Min.	96.76	10.89	0.000	97.44	7.34	0.004
MAP - 3 Min.	90.44	10.06	0.067	94.12	6.05	0.900
MAP - 5 Min.	87.72	9.71	0.087	92.68	6.44	0.197
MAP - 10 Min.	85.80	8.68	0.342	92.60	5.96	0.100
MAP - 15 Min.	84.35	7.94	0.007	92.40	5.40	0.105

V. Discussion

Supraglottic airway devices (SGAD) have been modified in various ways following the overwhelming success of the laryngeal mask airway (LMA). They are being increasingly used each day and now considered the choice devices for airway management in majority of the cases.The advantages of classic LMA(C-LMA) are hemodynamic stability at induction and emergence, reduced anaesthetic requirements for airway tolerance, lower frequency of coughing during emergence and a lower incidence of sore throat. The disadvantages are increased risk of gastric insufflation, gastroesophageal reflux, aspiration of regurgitated gastric contents and displacement of the cuff. This led to the development of I-Gel, which is a non-inflatable device made of a thermoplastic elastomer with a gastric channel in it.

The analysis of our observational data reveals that a statistically significant rise in pulse rate to 85.96 ±8.49 b/min (4.27 % ±4.93) from baseline value of 82.44 ±8.93 b/min Group-L and 88.20 ±8.54 b/m(4.06 % ±2.84) from the baseline value of 84.76±8.79 b/m in Group-I, was observed after insertion of the airway (p-value <0.05 in both Group-L and Group-I), but it lasted for 15-30 seconds in both groups. As evident from the Table 3, the groups responded to the airway instrumentation with a rise in mean arterial pressure (MAP) from baseline values, reaching its peak after 15-30 seconds after airway insertion. The rise in MAP was statistically significant in both groups up to 1 min from baseline (BL) values but was almost similar in both groups. The rise was 98.48± 10.62 mmHg (BL 93.40 ±10.69) in Group-L while it was 97.88 ±6.60 mmHg (BL 94.00± 7.39) in Group-I (p-value=0.000). On comparing MAP between pre-airway manipulation and post-airway manipulation period, the percentage rise was 5.44± 9.65% in Group-L and 4.13 ±10.69 % in Group-I, almost similar in both groups.

The regular occurrence of pressor responses associated with laryngoscopy and tracheal intubation, to achieve airway control has been bothering anesthesiologists .The hemodynamic responses manifesting as increase in heart rate and blood pressure are due to reflex sympatho-adrenal discharge provoked by epilaryngeal and laryngotracheal stimulation as studied by Devault et al (1960).Devault et al[3] said that mechanical stimulation by pressure of laryngoscopy on the soft tissue was probably the major factor in producing stress response to laryngoscopy and tracheal intubation, and it was later supported by other workers like Davidson[4](1968); Shribman[5] (1987), Prys Roberts et al[6](1971). Although in majority of patients undergoing anaesthesia these responses are transient and of little consequence but they may be harmful to patients with myocardial and cerebrovascular diseases.In our study we found both LMA Classic and I-gel airway are better than endotracheal tube as they are associated with less hemodynamic changes which are manifested by the rise in pulse rate, blood pressure and mean arterial pressure.

Also both the devices are easy to insert and first attempt success rate is very high in both the groups irrespective of the anesthesiologists experience when comparing with endotracheal intubation. In our study success rate in first attempt was comparable between two groups. The success rate of insertion in first attempt in Group-L (LMA) was 96 % as compared to 100 % in Group-I (I-Gel). One patient required two attempts for insertion of LMA as the seal was not proper as suggested by air leak. This is in accordance with the prospective observational study conducted by Richetz et al[7](2008) in 71 ASA physical status I-II female patients scheduled for gynecologic surgery, I-gel was evaluated as a supraglottic airway device.Also in our study, mean time taken for insertion of LMA was 15.44 ± 2.48 sec as compared to I-gel in which mean time taken was 11.24 ±1.94 sec and there was statistical significant difference in two groups as p-value =0.034 . Even time taken to insert I-gel was less than LMA.Our results also corroborates with Helmy et al[8]who corned out a prospective randomized clinical trial to compare I-Gel and C-LMA among 80 patients undergoing different surgical procedures under general anaesthesia with spontaneous ventilation. It was concluded that both I-gel and C-LMA did not cause any significant alterations in the hemodynamic status of the patients, end tidal CO_2 and SPO_2. The mean duration of insertion attempts was 15.62± 4.9 sec in I-gel group, while it was 26.2±17.7 sec in LMA group(p=0.0023). The postoperative complications were not significantly different except nausea and vomiting which was statistically higher in C-LMA group (p=0.032). Insertion of I-gel was significantly easier and more rapid than insertion of C-LMA. The leak pressure was significantly higher with I-gel than C-LMA and incidence of gastric insufflation was lower with I-gel.

A comparison of I-Gel and classic LMA insertion in manikins by experienced and novice physicians was done by Stroumpoulis K etal[9] to assess the use of laryngeal mask airway (LMA), classic LMA (C-LMA) and the I-Gel. Insertions were performed using a size-4 C-LMA and I-Gel respectively. The primary endpoints were success rate for each device and duration of the insertion attempt. Secondary endpoint was the perception of ease of use with each device from experienced and novice anesthesiologists. First attempt success rate was 90.5% for I-Gel and 63.8% for C-LMA (P<0.001). I-Gel use reduced insertion times (13.32±4.99 s vs. 17.99±6.87 s, P<0.001) and was related with significantly higher first attempt success rates than C-LMA (90 vs. 48.3%, P<0.001). In addition, I-Gel use provided almost equal success rates for experienced and novice (91 vs. 90%, P=not significant), whereas C-LMA use resulted in significantly lower success rates for novices (48.3 vs. 80.4%, P<0.001). So they conclude that both the devices are easy to insert but I-Gel is slightly better than C-LMA in ease of insertion.

VI. Conclusion

Hence we conclude that both LMA and I-gel airway are easy to insert, maintains ventilation well intraoperatively, better alternate to endotracheal intubation as they cause minimal hemodynamic changes, and also associated with low incidence of any postoperative complications.But I-gel airway is better than Classic-LMA as it takes less time for insertion and is associated with less incidence of pharyngolaryngeal complications.

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