ORIGINAL ARTICLE

A COMPARITIVE STUDY ON CARDIOVASCULAR RESPONSE AND EASE OF INSERTION IN CLASSICAL LARYNGEAL MASK AIRWAY, PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL DURING SURGERY UNDER GENERAL ANAESTHESIA

Revi N[1], Harikishore[2], Binu Puthur[3], Ershad[4]

HOW TO CITE THIS ARTICLE:
Revi N, Harikishore, Binu Puthur, Ershad. "A Comparitive Study on Cardiovascular Response and Ease of Insertion in Classical Laryngeal Mask Airway, Proseal Laryngeal Mask Airway and I-Gel During Surgery Under General Anaesthesia". Journal of Evidence based Medicine and Healthcare; Volume 2, Issue 20, May 18, 2015; Page: 3039-3046.

ABSTRACT: OBJECTIVE: The I-gel is a new single-use supraglottic airway device without an inflatable cuff. This study was designed to investigate the usefulness of the I-gel compared with the classic laryngeal mask airway (cLMA) and ProSeal laryngeal mask airway (pLMA) in anaesthetized patients. **METHODS:** The American Society of Anesthesiologists physical status I-II patients (n=75) scheduled for surgery were included in this prospective study. General anaesthesia was achieved with intravenous infusion of propofol, fentanil. The patients were randomly assigned to I-gel, pLMA and cLMA groups of 25 each. Properly sized I-gel (No. 3-4) or LMA (No. 4-5) was inserted. We assessed haemodynamic data, ease of insertion, duration of insertion attempts and postoperative complications. **RESULTS:** There were no differences in the demographic data and haemodynamic data one minute after insertion of devices among the three groups. The ease of insertion was 96% with I-gel group 88% for cLMA and 80% for pLMA group which was not statistically significant (p=0. 194). Mean time taken for successful insertion is significantly less in I-gel group (p=0. 03) and success in first attempt of insertion were high in I gel compared to other groups. There were no differences in the incidence of adverse events except for the 2 cases of blood stain on removal in pLMA group. **CONCLUSION:** Hemodynamic parameters were comparable among I-gel, pLMA and cLMA. I-gel is easy to insert and duration of insertion attempts are significantly less, and is not associated with adverse events. I-gel might be an effective alternative as a supraglottic airway device.
KEYWORDS: I-gel, Classic LMA, Pro Seal LMA.

INTRODUCTION: Laryngoscopy and endotracheal intubation are the traditional methods of securing a definite airway for administering general anaesthesia. Tracheal intubation is the gold standard method for maintaining a patent airway during anesthesia.(1) However laryngoscopy and endotracheal tube intubation produce profound changes in cardiovascular physiology of the body through reflex sympathetic responses. These responses may be of short duration and insignificant in healthy patients. But in patients with coronary artery diseases, reactive airway, intracranial pathology, serious consequences like left ventricular failure, myocardial ischemia, cerebral hemorrhage, arrhythmias, rupture of cerebral aneurysms can occur through cardiovascular response.(2)

In 1983, Archie I. J. Brain developed the laryngeal mask airway (LMA), which provides a useful alternative for airway management during spontaneous or controlled ventilation.(3) LMA

was found to be relatively a traumatic to pharynx and larynx during insertion. The insertion technique is easily learned, less invasive, and require less anaesthetic dose but airway protection from secretion and blood is of lesser degree than tracheal tube intubation.[3,4] Laryngeal masks are used broadly for elective and emergency airway management and are an essential part of the American and European difficult airway management algorithm.[1,5]

The Laryngeal Mask Airway ProSeal TM (LMA-ProSeal TM; Laryngeal Mask Company Limited) is a reusable supraglottic airway device developed to enhance supraglottic airway protection and extend the benefits of the classic LMA (Laryngeal Mask Airway) to a greater number of patients. Added features include an additional drain tube to channel fluid away from the airway and a tighter seal against the glottic opening with no increase in mucosal pressure. Clinicians have extended the use of the LMA-ProSeal inside and outside the operating theatre including use for difficult airway management and airway rescue.

I-gel is the single use supraglottic airway from inter surgical, UK (Inter surgical Ltd, Wokingham, Berkshire, UK) added to airway armamentarium in 2007 with an anatomically designed mask made of a gel like thermoplastic elastomer. The shape, softness and contours accurately mirror the perilaryngeal framework itself and create the perfect fit. As it has no inflatable cuff, it has several potential advantages including easier insertion, minimal risk of tissue compression, and stability after insertion. An integrated gastric channel is provided for gastric suction and for passage of nasogastric tube to empty the stomach.[6]

In this study we compare cardiovascular response, ease of insertion and insertion time in classic Laryngeal Mask Airway (LMA), Proseal laryngeal mask airway and I-gel during surgery under standard general anaesthesia.

METHODS: A prospective cohort study was designed among 75 patients belonging to ASA I or II of age groups between 18 and 60 years, posted for elective surgeries under general anaesthesia in Amala Institute of Medical Sciences. The study was approved by our institutional ethics committee, and patients provided written, informed consent before inclusion.

Patients undergoing emergency surgeries, known pulmonary and cardiovascular problems, facial abnormalities with anticipated difficult intubation, ASA grade III and IV and known allergies to medications and Latex were excluded from the study.

The study spanned for a period of 3 months and a total of 75 patients were involved. Patients were randomly assigned into three groups of 25 each. In Group A Classic LMA of appropriate size was inserted and cuff inflated with the appropriate volume of air as recommended by the manufacturer. In Group B Proseal LMA of appropriate size was inserted and cuff inflated with the appropriate volume of air. In group C, I-gel of appropriate size was inserted. Primary objectives was to study and compare the cardiovascular response of classic laryngeal mask airway insertion cLMA, pLMA and I-gel in general anaesthesia and to compare ease of insertion and duration of insertion of classic laryngeal mask airway, proseal laryngeal mask airway and I-gel.

The sample size was calculated using the formula, $n= (Z\alpha + Z\beta) \times (SD)^2 \times 2/ d^2$.

SD=average of standard deviations: d=difference in mean of both groups:

From a study, Shin WJ, Cheong YS, Yang HS, Nishiyama T. "The supraglottic airway I-gel in comparison with ProSeal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients" the sample size obtained was 25 patients in each group.

PROCEDURE: All patients were premedicated with midazolam 0.05mg/kg IV and glycopyrollate 0.01mg/kg IV. Anaesthesia was induced with propofol 2mg/kg IV, fentanyl 2micrograms/kg IV and sevoflurane. Once adequate depth was achieved, each device was inserted by an experienced anaesthesiologist. The classic LMA, was inserted by standard insertion method according to the recommended instructions by Laryngeal Mask Company™ and inflated accordingly.[7] Pro Seal LMA was inserted using an introducer as recommended by the manufacturer. I- gel size 3 and 4 were selected according to manufacturer's instruction. No muscle relaxants were used for induction or maintenance of anaesthesia.

Duration of insertion was defined as the time from the start of insertion until attaching to the breathing system.

Ease of insertion was defined as no resistance to insertion until the device reaches hypopharynx in single attempt. In difficult insertion there was resistance to insertion or more than one maneuver was required for correct placement. Airway maneuvers include jaw lift, chin thrust, head extension or flexion on the neck.

Correct position of airway was confirmed with bilateral chest lift and auscultation of breath sounds, and normal capnography curves. Number of attempts and time taken for insertion were noted. More than three attempts of insertion with failed placement of airway were excluded from the study. Presence of blood, lip injury or dental injury were noted while removing the supraglottic airway device

All patients were connected to a closed breathing system with Datex Aestiva 700 series anaesthesia machine and allowed to breath spontaneously. Anesthesia was maintained with nitrous oxide, oxygen and sevoflurane with a fresh gas flow of 3 l/min. Systolic arterial pressure (SAP), diastolic arterial pressure (DAP), Mean arterial blood pressure [MAP] and heart rate (HR) were recorded immediately before during and 1, 3, 5, 10, and 15 min after airway insertion using Nihon Koden monitor. End tidal Carbon dioxide and oxygen saturation by pulse oximetry were recorded intraoperatively.

STATISTICAL ANALYSIS: Results were reported as the arithmetic mean +/- the standard deviation and scores as median with interquartile range. Pearson correlation coefficients were used to determine the presence of linear relationships and analysis of variance (ANOVA) used for statistical comparisons. Multiple comparisons were done using Dunnett T-test. Mann Whitney test was used to compare between different groups. A p value of ≤ 0.05 were considered significant. Analysis was done using SPSS software.

RESULTS: No significant differences were detected among the three groups with respect to age, weight gender and duration of surgery. 57.3% of the study population was males. Mean age and weight of the study group was 37.44±10.563 and 65.81±13.088 respectively. Mean duration of surgery was one hour and 29 minutes. (TABLE 1).

There was no statistically significant change in heart rate in three groups studied. Mean heart rate of Group A, B and C before insertion of the supraglottic device was 78.96±6.89, 80.04±7.83 and 79.04±7.35 respectively. At insertion of the supraglottic device there was a minimal increase in heart rate in all groups (Group A 83.2±5.01 GROUP B 85.24±5.22 Group C 84.04±5.37) which was not statistically significant among the groups. There was non-significant decrease in heart rate at 1, 3 and 5 minutes post insertion of the supraglottic airway. (Table 2)

Systolic blood pressure measured pre insertion, during insertion and post insertion at 1 minute, 3minute and 5 minutes showed no significant difference in values among the groups. (Table 3)

Diastolic blood pressure was comparable in all groups before insertion and all groups had a minimal increase in diastolic blood pressure at time of insertion of airway device. Group A and group B took longer time to reach baseline values compared to Group C. This was statistically significant. (Table 4)

Ease of insertion was more (96%) in I gel group. Out of 25 patients studied only one patient needed a second attempt to insert airway. In Proseal LMA group, 5 out of 25 required more than one attempt to pass the airway while in classic LMA group 3 out of 25 required more than one attempt in securing the airway device. (Table 5) But none of the groups required more than 2 attempts to pass the supraglottic airway device.

Mean duration of insertion of Igel was 11.24±2.29 seconds while that of Pro Seal LMA and Classic LMA were 20.36±5.65 and 18.16±4.66 seconds respectively. Insertion time was significantly shorter in I gel group compared to other groups and the results were statistically significant.

Blood staining of the device on removal were not seen in Igel or Classic LMA group. Two cases in Pro Seal LMA group had blood staining on removal of the device.

DISCUSSION: In our study there were no differences in demographic data among three groups. Hemodynamic variables like heart rate and systolic blood pressure had stastistically insignificant changes. The results were consistent with previous studies reported by Shin WJ et al.[8] In their study general anaesthesia was achieved with intravenous infusion of propofol, remifentanil and rocuronium. All our patients were induced with fentanyl 2µ/kg, propofol and sevoflurane titrated according to required depth. Similar results were also published by Bikramjit das et al,[9] and Amer MJ et al,[10] in their studies on I-gel compared with LMA. No muscle relaxants were used prior to insertion of airway device. All groups showed a minimal increase in heart rate during insertion of the airway. In group B Pro seal LMA was inserted using an introducer provided by the manufacturer.

Ease of insertion was more with I gel 96% (24/25) compared to pLMA 80% (20/25) and cLMA 88% (22/25). (Figure 2) But the results were not statistically significant (p=0.194). Mean duration of insertion attempts were significantly less in I-gel group (11.24±2.29 seconds) compared to pLMA and cLMA group. (p=0.03) (Figure 1).

Amr et al,[10] Richez et al,[11] and Ascott C J,[12] have reported similar results in their study comparing I gel with other supraglottic devices. According to Brimacombe and colleagues,[13,14] the difficulty in inserting p LMA is due to larger cuff impeding digital intra oral positioning and

propulsion into the pharynx and the lack of a back plate making cuff more likely to fold over at the back of mouth.

There was no blood stain on removal of I gel, while 2 cases in pLMA group had blood stain on the device. Levitan & Kinkle,[15] presumed that inflatable masks have the potential to cause tissue distortion, venous compression & nerve injury. This proves the fact that Igel is less traumatic to airway compared to pLMA. This was consistent with results from studies done by Gaurav Chauhan et al,[16] and Amr m et al.[10]

CONCLUSION: We conclude that the supraglottic airway devices cLMA, pLMA and I gel do not cause any significant alteration in hemodynamic status of the patient. Though not statistically significant, insertion of I gel is easier and less traumatic. I gel insertion time is more rapid compared to cLMA and pLMA and is statistically significant.

Sex	Frequency	Percent
Male	43	57.3
Female	32	42.7
Total	**75**	**100.0**

Statistics	Age	wt	Duration
Number	75	75	75
Mean	37.44	65.81	1.49
Std. Deviation	10.563	13.088	.305

	Igel	Plma	Clma
Age	36.76±10.525	37±8.568	38.56±12.563
Weight	67.88±12.471	66.44±14.492	63.12±12.255
Duration Of surgery	1.44±.25	1.49±.291	1.55±.366

Table 1

Heart rate	Classic IMA	Proseal IMA	I Gel	p value
Pre insertion	78.96±6.89	80.04±7.83	79.04±7.35	0.702
Insertion	83.2±5.01	85.24±5.22	84.04±5.37	0.691
1	76.24±4.25	77.28±4.43	76.76±4.81	0.367
3	73.2±3.95	73.08±4.19	72.18±4.36	0.544
5	72.16±3.77	71.32±4.47	70.60±3.73	0.372

Table 2

SBP	Classic IMA	Proseal IMA	I Gel	p value
Pre insertion	126.80±8.98	125.28±6.13	125.36±7.25	0.726
Insertion	122.16±8.36	122.32±5.34	122.96±7.66	0.918

1	118.64±8.69	118.40±4.35	119.12±6.58	0.930
3	116.80±8.36	116.80±4.04	155.76±6.59	0.812
5	115.00±7.55	115.68±3.94	113.36±6.07	0.382

Table 3

DBP	Classic IMA	Proseal IMA	I Gel	p value
Pre insertion	78.48±2.10	78.56±2.04	78.00±2.44	0.626
Insertion	76.04±4.10	76.76±2.22	75.60±2.30	0.393
1	74.84±4.48	75.48±2.22	73.04±3.32	0.042
3	73.60±4.25	74.56±2.34	72.24±2.66	0.042
5	73.04±3.92	74.00±2.44	71.44±2.41	0.013

Table 4

Ease	Group			Total
	Classic IMA	Proseal IMA	I Gel	
Easy	22	20	24	66
Difficult	3	5	1	9
Total	**25**	**25**	**25**	**75**

Table 5

p-value = 0.194

Time of insertion				
	Mean	N	Std. Deviation	
Pro seal	20.3600	25	5.65597	
LMA classic	18.1600	25	4.66976	
I GEL	11.2400	25	2.29637	P<0.05

Table 6

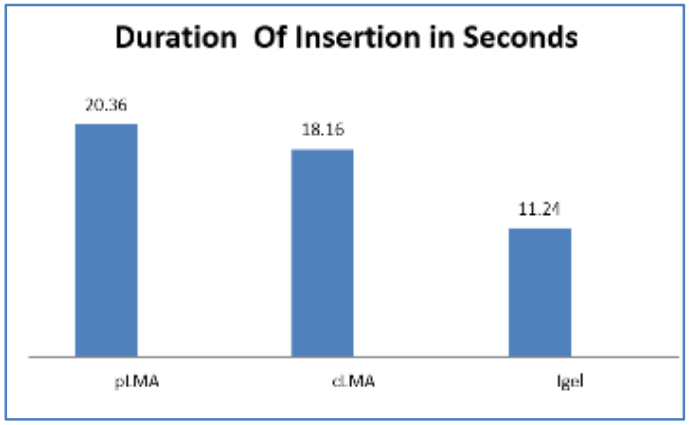

Fig. 1

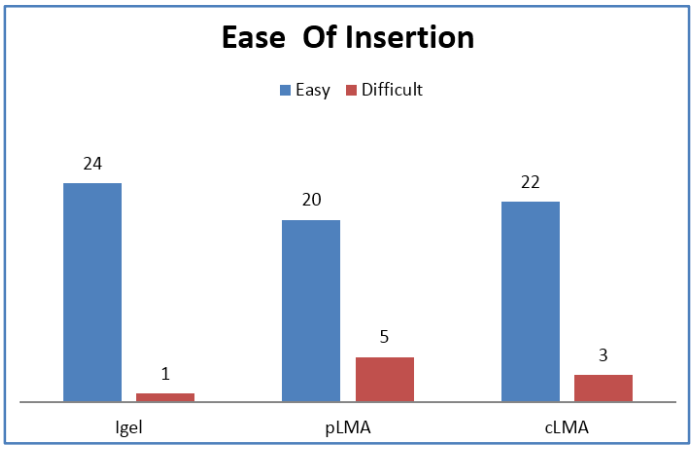

Fig. 2

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AUTHORS:

1. Revi N.
2. Harikishore
3. Binu Puthur
4. Ershad

PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Anaesthesiology, Amala Institute of Medical Sciences, Thrissur, Kerala.
2. Professor & HOD, Department of Anaesthesiology, Amala Institute of Medical Sciences, Thrissur, Kerala.
3. Assistant Professor, Department of Anaesthesiology, Amala Institute of Medical Sciences, Thrissur, Kerala.
4. Junior Registrar, Department of Anaesthesiology, Amala Institute of Medical Sciences, Thrissur, Kerala.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Revi V.
Associate Professor,
Department of Anaesthesiology,
Amala Institute of Medical Sciences,
Thrissur, Kerala.
E-mail: revimonu@gmail.com

Date of Submission: 08/05/2015.
Date of Peer Review: 09/05/2015.
Date of Acceptance: 12/05/2015.
Date of Publishing: 18/05/2015.