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Original Research Article

A Comparative Study of Haemodynamic Changes during General Anaesthesia with I-GEL or Intubating Laryngeal Mask Airway

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ABSTRACT

Aims and Objective: The technique of securing upper airway that avoids or minimizes pharyngo - laryngeal stimulation may produce lesser hemodynamic response. We compared hemodynamic response with ILMA and I-gel insertion during general anaesthesia.
Materials and Methods: The study was carried out as a prospective, randomized, blinded clinical study among 70 patients, divided in two equal groups 35 each, who underwent different surgical procedures under general anesthesia. After induction of anaesthesia, Supraglottic airway device was inserted in both groups, tracheal intubation was attempted through the ILMA. HR, SBP, DBP, ST-T segment changes and SPO_2 values were recorded before insertion of airway device, at one minute and at five minute after insertion in each case.
Results: There was no change in HR at 1 min in I-gel group, while in ILMA group, it increased. Rise in SBP at 1 min after insertion of supra-glottic airway device was observed in both groups, but at 5 min rise was insignificant in I-GEL group and significant in ILMA group. When both groups were compared significant difference ($P<0.05$) was observed. Rise in DBP in I-GEL group was insignificant but in ILMA group, rise was significant. When both groups were compared significant difference ($P<0.05$) was observed in HR and BP. Saturation did not change in both groups and also no change in ST-T segment was observed.
Conclusion: We conclude that insertion of I-gel is accompanied by minimal cardiovascular responses than those associated with intubation through intubating laryngeal mask airway (ILMA), so it is recommended for patient where a minimal pressure response to airway manipulation is desired.

Key Words – Tracheal intubation, supraglottic device, cardiovascular responses

INTRODUCTION

Laryngoscopy and tracheal intubation are required to control and maintain a safe airway during anesthesia. The procedure violates the patient's airway reflexes and predictably leads to hypertension and tachycardia which may have detrimental effects on the other organ systems. Haemodynamic stability is an integral and essential goal of any anaesthetic management plan.

Hypertensive patients have increased activity of the sympathetic nervous system and may exhibit an exaggerated hemodynamic response to the induction of anesthesia compared with normotensive patients. Marked increase in catecholamine concentration and in the sensitivity of

peripheral vessels to catecholamines in these patients have been reported.

Supraglottic airway devices are now widely used for surgery requiring general anaesthesia. They provide a perilaryngeal seal with a cuff and an alternative to tracheal intubation. There are some contraindications, like non-fasting patients, morbidly obese patients and obstructive or abnormal lesion of oropharynx.

I-gel is a supra-glottic airway device. It has a soft and non-inflatable cuff, made up of thermoplastic elastomer or SEBS (Styrene Ethylene Butadiene Styrene), which is soft gel like and transparent. This is a disposable airway device. Soft cuff of I-gel is designed so that it matches the peri-laryngeal anatomy and currently available in three sizes-3, 4 & 5 for adults. I-gel also favors the passage of nasogastric tube size 12-14 French via its gastric channel. [1]

Intubating laryngeal mask airway (ILMA) - a modified supraglottic airway device, has been introduced that facilitates tracheal intubation without resorting to laryngoscopy. I-LMA comes in three sizes: 3, 4, & 5 which can accommodate 7.0, 7.5, & 8 mm tracheal tube respectively. Tracheal tubes are specially designed for I-LMA but standard tracheal tube can also be used. [2,3]

MATERIALS AND METHODS

This prospective, comparative, clinical study was conducted at S.R.N. Hospital (Associated to M.L.N. Medical College, Allahabad) over a period of one year, after approval from The Ethical Committee. A total of 70 patients of either sex of age 20 to 45 years belonging to ASA physical status I or II undergoing elective surgery were selected. After blinding and randomization patients were allocated one of the two groups as follows -

Study Groups -

Group-1: I-gel insertion was done

Group-2: Tracheal intubation through intubating laryngeal mask airway was done

Patients having following diseases were excluded from study –

1. Cardiovascular, Respiratory, endocrine or hepatic diseases.
2. Abnormality of upper airway
3. Obesity
4. Emergency operation
5. Pregnancy

A written and informed consent was obtained from the participants. All patients received inj. Glycopyrrolate 0.2mg plus midazolam 1mg IV, as premedication agent 5 minutes before procedure.

All the patients were preoxygenated with 100% oxygen for 3 minutes. Insertion of device was done under anaesthetic technique comprising of Inj. Propofol 2 mg per kg body weight and Inj. Succinylcholine 1.5 mg per kg body weight intravenously. After an adequate depth of anesthesia had been achieved, the supra glottic devices was introduced according to the study group. Continuation of anesthesia was maintained with nitrous oxide and oxygen (67:33) along with inj Vecuronium 0.1 mg per kg body weight. Following parameters were recorded by another observer at 1 minute and at 5 minute after insertion of devices.

A: Heart Rate
B: Systolic Blood Pressure
C: Diastolic Blood Pressure
D: Pulse Oxymetry
E: St-Segment Changes in ECG

Isoflurane was used in maintenance of anesthesia only 5 minutes after induction. At the end of the surgical procedure, reversal of the neuromuscular blockade with inj. Neostigmine and inj. Glycopyrolate was done.

OBSERVATIONS AND RESULTS

All the results were expressed as mean±S.D. For statistical analysis t-test was done for comparing the haemodynamic changes of both supraglottic devices. Repeated measure ANOVA was done for tests of within and between subject effects. Multiple comparisons, were done by using post hoc test to obtain the significance Bonferroni correction, was applied. A two-

tailed (α=2) p value less than 0.05 (p<0.05) was considered statistically significant. Analyses were performed on SPSS software (PSAW, Windows version 17.0)

Both the groups i.e. I-gel group (group I), Intubating Laryngeal Mask group (group II) were comparable with respect to demographic profile i.e. sex, age, weight, height & vital parameters i.e. HR, SBP, DBP SPO_2 and ST-T Segment changes at baseline, preinsertion, post-insertion at 1 min and at 5 min.

Analysis of HR, SBP, DBP and SPO_2 at Different Time Intervals:

Table- 1: Within Subject Variation

	Dependent Variable
1	Pre-insertion
2	Post at 1 minutes
3	Post at 5 minutes

Table-2: Comparison of Age, Height, and Weight in Between Two Groups –

Variable Name	Group	Number	Mean ±SD	P Value
AGE	GROUP-1	35	35.97±12.93	0.865
	GROUP-2	35	36.46±10.71	
HEIGHT	GROUP-1	35	160.31±7.94	0.138
	GROUP-2	35	163.03±7.16	
WEIGHT	GROUP-1	35	59.23±8.53	0.283
	GROUP-2	35	61.49±8.49	

ANALYSIS:

Age (P=0.865), Height (P=0.138) and weight (P=0.283) in two groups were comparable i.e. there was no statistically significant difference (P>0.05)

Table-3: Comparison of Heart Rate at Different Time Interval in Between Two Groups

Variable Name	Group	Mean ±SD	P Value
HEART RATE AT BASELINE (T00)	GROUP-1	83.49±7.10	0.83
	GROUP-2	83.77±3.96	
HEART RATE BEFORE INSERTION (T0)	GROUP-1	84.09±7.46	0.85
	GROUP-2	83.83±3.64	
HEART RATE AT AFTER 1 MINUTE OF INSERTION(T1)	GROUP-1	84.60±8.07	0.01
	GROUP-2	89.29±8.02	
HEART RATE AT 5 MINUTE OF INSERTION(T5)	GROUP-1	84.71±7.41	0.20
	GROUP-2	86.83±4.46	

ANALYSIS:

This study did not find any difference of Heart rate at Baseline (p=0.83), at Pre-insertion (p=0.85) and at 5 min after insertion (p=0.20) in between two groups (p>0.05), but at 1 minutes after insertion, difference of Heart rate was statistically significant (p<0.05).

Table- 4: Comparison of SBP at Different Time Interval in Between Two Groups

Variable Name	Group	Mean ±SD	P Value
SYSTOLIC BLOOD PRESSURE AT BASELINE (T00)	GROUP-1	125.09±10.16	0.256
	GROUP-2	127.89±10.30	
SYSTOLIC BLOOD PRESSURE BEFORE INSERTION (T0)	GROUP-1	126.11±8.33	0.375
	GROUP-2	127.94±8.77	
SYSTOLIC BLOOD PRESSURE AT AFTER 1 MINUTE OF INSERTION(T1)	GROUP-1	127.77±8.09	0.000
	GROUP-2	137.20±7.14	
SYSTOLIC BLOOD PRESSURE AT AFTER 5 MINUTE OF INSERTION(T5)	GROUP-1	126.97±7.08	0.009
	GROUP-2	131.20±6.12	

ANALYSIS:

This study did not find difference of the systolic blood pressures at Baseline (p=0.256) and before insertion (p=0.375) of I-gel and intubating laryngeal mask airway groups but at 1 minutes (p=0.00) and at 5 minutes after insertion (p=0.009) of airway devices, difference of systolic blood pressure were statistically significant (p<0.05).

Table-5: Comparison of DBP at Different Time Interval in Between Two Groups

Variable Name	Group	Mean ±SD	P Value
DIASTOLIC BLOOD PRESSURE AT BASELINE (T00)	GROUP-1	76.97±6.93	0.97
	GROUP-2	77.03±6.35	
DIASTOLIC BLOOD PRESSURE BEFORE INSERTION (T0)	GROUP-1	77.43±5.16	0.83
	GROUP-2	77.71±6.10	
DIASTOLIC BLOOD PRESSURE AT 1 MINUTE AFER INSERTION (T1)	GROUP-1	77.77±5.21	0.002
	GROUP-2	81.94±5.34	
DIASTOLIC BLOOD PRESSURE AT 5 MINUTE AFTER INSERTION (T5)	GROUP-1	77.03±4.86	0.03
	GROUP-2	79.43±4.66	

ANALYSIS:

This study found difference in Diastolic blood pressure at baseline

(p=0.97) and before insertion (p=0.83) of I-gel and intubating laryngeal mask airway was statistically insignificant (p>0.05), but at 1 minute (p=0.002) and at 5 minute (p= 0.03) after insertion of airway devices had statistically significant difference of Diastolic blood pressure (p<0.05).

Table-6: Comparison of SPO_2 at Different Time Interval in Between Two Groups

Variable Name	Group	Mean±SD	P Value
SATURATION AT BASELINE (T00)	GROUP-1	100±0.00	——
	GROUP-2	100±0.00	
SATURATION BEFORE INSERTION (T0)	GROUP-1	100±0.00	——
	GROUP-2	100±0.00	
SATURATION AT 1 MINUTE AFTER INSERTION(T1)	GROUP-1	99.89±0.32	0.40
	GROUP-2	99.94±0.23	
SATURATION AT 5 MINUTE AFTER INSERTION (T5)	GROUP-1	100±0.00	0.054
	GROUP-2	99.89±0.32	

ANALYSIS:

This study found the difference of Arterial Saturation during insertion of I-GEL and Fastrach-LMA at Baseline, Pre-insertion, at 1 minutes and at 5 min (p=1.00) after insertion of devices was statistically insignificance (p>0.05)

There were no changes in ST-T segment in ECG after insertion of I-gel and ILMA.

DISCUSSION

Rise in pulse and blood pressure during laryngoscopy and intubation has little effect on healthy patients, but may have detrimental effect on those having hypertension or Ishemic heart disease. Several drugs have been successfully used for attenuation of cardiovascular response to tracheal intubation.

The study was undertaken with an idea that use of I-gel (supraglottic airway device) will evoke lesser cardiovascular response to insertion than compared to tracheal intubation since I-gel use is expected to have lesser laryngeal stimulation.

Lee JH et al [4] (2014) compared the usefulness of I-gel versus a classic laryngeal mask airway (cLMA) in small children Sixty-three children (age range: 4-72 months) were randomly assigned to an I-gel or cLMA group and evaluated hemodynamic data, airway sealing ability, the success rate of insertion, and adverse events including an inadvertent sliding out during ventilation. Demographic data and hemodynamic data obtained immediately after the insertion of these devices did not differ between the two groups. The success rates for insertion on the first attempt were 77 and 84% for I-gel and cLMA, respectively (P = 0.54), and the overall success rates were 87 and 100% respectively (P = 0.14). There were no significant differences in terms of airway leak pressure. The inserted I-gel inadvertently slide out in 8 of 31 patients but only one sliding out case occurred in the cLMA group (P = 0.02). There were no differences between the groups in terms side effects (e.g., coughing, bleeding) associated with the use of I-gel and cLMA (P = 0.75 and 0.49, respectively). Oropharyngeal leak pressure and insertion success rate of I-gel was similar to those of cLMA. However, I-gel is prone to inadvertent sliding out of the mouth in small children.

In our study demographic data (age, sex, weight and height) and haemodynamic data did not differ before insertion of airway devices; i.e. it was statistically insignificant (p>0.05). Insertion of I-gel produces fewer changes in HR, SBP, and DBP than insertion of ILMA.

Singh D. et al [5] (2014) compared hemodynamic responses in 60 anaesthetized, paralyzed ASA-I and ASA-II patients among two airway maintenance devices: Pro-seal LMA (PLMA) and I-GEL airway. Mean duration of insertion was significantly shorter in I-GEL airway than PLMA. Changes in mean pulse rate were comparable in both groups. In mean arterial pressure, changes were significantly higher in group-I than group-II. They concluded I-GEL as a better alternative airway maintenance device than PLMA because of ease of insertion and maintenance of hemodynamic stability.

In our study, we found that insertion of I-gel produces statistically insignificant (>0.05) changes in HR, DBP, SBP and SATURAION at 1 min and at 5 min after insertion but increase in SBP at 1 min after insertion of I-gel was significant (p<0.05). No ST-T Segment changes was seen with I-gel insertion.

Jindal P et al [6] (2010) determined the safety and efficacy of placing different airway devices by first-time users. Fifty volunteer doctors regularly involved in cardiopulmonary resuscitation and emergency medicine were divided into two groups on the basis of their experience and were timed to insert the two supraglottic devices, I-gel and laryngeal mask airway (LMA), in ASA grade I, II and III anaesthetized patients under expert guidance. In both the groups, I-gel was inserted in less time than LMA. The time taken for insertion of I-gel by both the groups was not significant. The success rate of inserting I-gel by both groups was not significant (p >0.05). Ninety-six percent of participants in both the groups found that I-gel was easier to insert and required minimal adjustment. Their results suggest that I-gel is rapidly inserted by novices, and produced less haemodynamic changes compared to those resulting from insertion of classic LMA. They suggested that the device was safe and can be used by first-time users and experts in cardiopulmonary resuscitation and in emergencies.

Our study is in consistent with this study, but insertion of I-gel showed increase in systolic blood pressure at 1 minute that was statistically significant. Insertion of ILMA and intubation through it showed significantly increase in HR, SBP, and DBP (P<0.05).

Choyce A et al [7] (2002) evaluate the cardiovascular response with insertion of intubating laryngeal mask airway. Sixty-one patients received a standardized anaesthetic and were randomly assigned to three groups: tracheal intubation via direct laryngoscopy, tracheal intubation via an intubating laryngeal mask airway with immediate removal of the device, and tracheal intubation via an intubating laryngeal mask airway with delayed removal. The cardiovascular response to intubation was of a similar magnitude in all groups, although delayed removal of the intubating laryngeal mask airway was associated with a second pressure response. Nor-epinephrine changed significantly over time following direct laryngoscopy and following immediate removal of the intubating laryngeal mask airway, but not after delayed removal.

In our study, there was increased in heart rate, systolic blood pressure and Diastolic blood pressure at 1 min and at 5 min after insertion of ILMA and intubation through ILMA: i.e. statistically significant (p<0.05). But I-gel insertion showed less significant changes in HR, SBP, DBP and SpO2 because I-gel insertion causes less sympathetic stimulation and less catecholamine release than ILMA insertion.

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