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Comparison of perioperative pulse rate, systolic blood pressure, diastolic blood pressure of intubating LMA and I-gel

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Abstract
Background: The most common and important being the deleterious haemodynamic consequences in response to laryngoscopy and intubation due to reflex sympathoadrenal stimulation.
Objectives: to compare perioperative hemodynamic stability (pulse rate, systolic blood pressure, diastolic blood pressure) of these two devices.
Study design: Randomised controlled prospective study.
Participants: 80.
Sampling: Systematic Random Sampling.
Study period: from October 2016 to October 2018.
Results: When hemodynamic variables are compared between two groups, statistically significant rise in heart rate from baseline value in group G upto 5 minutes and at removal than I-lma. Blood pressure variations in both groups were compared and they shown, statistically significant rise in systolic blood pressure from baseline value in group G upto 5 minutes and at removal than I-lma. Statistically significant rise in diastolic blood pressure in group G upto 3 minutes and at removal than I-lma group. Statistically significant rise in mean arterial blood pressure in group G upto 3 minutes and at removal than I-lma group.
Conclusion: It was concluded that I-LMA causes significantly less hemodynamic perturbations than I-gel at various time intervals.

Keywords: I-LMA, I-gel, Endotracheal intubation, Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial blood pressure

Introduction
Most effective means of direct airway Ventilation and protection against aspiration is tracheal intubation, but it is not free from complexities and complications. Difficult tracheal intubation and inability to maintain a patent airway also remains an important cause of anaesthetic morbidity and mortality [1, 2]. The unanticipated difficult airway occurs with a low but consistent incidence in anaesthesia practice [3, 4]. Therefore, although Endotracheal Intubation is regarded as the Gold Standard for maintenance of airway.
Devices such as the I-gel are effective in establishing a patent airway, may reduce morbidity and are occasionally lifesaving. I-gel is a new addition to the ever expanding field of supraglottic airway devices. I-gel is a new single use, non-inflatable supraglottic airway device for use in anaesthesia dining spontaneous or intermittent positive pressure ventilation [5].
Supraglottic airway devices such as classic LMA or proseal LMA are not ideal intubating aids as the airway conduit is too narrow to accommodate an adult diameter endotracheal tube. Intubating LMA is specially designed for passage of endotracheal tube through it whereas I-gel is supraglottic airway device not requiring inflation of cuff for lung ventilation, its design allows for unobstructed passage of a endotracheal tube. Hence this study was carried out with the following objectives to compare perioperative hemodynamic stability of intubating LMA and I-gel.

Materials & Methods: The present randomized controlled prospective study was conducted in S.C.B Medical College Cuttack under the Department of Anaesthesiology in different Operation Theatres during the period from October 2016 to October 2018, after obtaining necessary permission from hospital ethical committee. A written informed consent was taken from all patients included in the study. Patients posted for elective operations with

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age 20-60 yrs, ASA I & II, BMI between 18.50-24.99kg/m2 and body weight between 30-60 kg.

Sample Size Calculation: The sample size was calculated to detect a 10% difference in first-attempt success rate in ETT insertion between devices with a type-1 error of 0.05 and a power of 90%, requiring 25 patients per group. We included 40 patients in each group to allow for potential drop-outs.

A total of 80 patients were randomly assigned using a chit method into two groups of 40 each. One group will be allocated I-LMA (group L) and other I-GEL (group G). Randomization will be done using concealed envelop technique.

Inclusion Criteria:
- Age group-18-60 years
- Body weight- 30-60kg
- ASA Grade I/I!
- Adequate mouth opening
- Sex-male and female
- BMI-18.5-24.99 kg/m2

Exclusion Criteria:
- ASA Grade III/IV
- Underweight, overweight, obese patient
- Mouth opening < 2cm
- Presence of respiratory tract infections
- History of pulmonary disease
- Oral pathology
- Presence of hypertension, diabetes mellitus, chronic renal failure etc.

Study tools and techniques: Study will be conducted in the operation theatres of S.C.B MEDICAL COLLEGE.CUTTACK using the various tools required during the procedures like PAC form, consent form, anaesthesia machine, I-GEL(size 3&4), I-LMA (size 3&4), Endotracheal tube(6.0mm,6.5mm,7.0& 7.5 mm) drugs etc. The findings obtained through the procedure performed on the randomly selected patients will be recorded on pre-structured table.

A thorough preoperative assessment was done before selecting the patient for the study. Demographic data, physical examination findings and laboratory investigations were recorded systematically in the proforma. Fasting was ensured as per ASA guidelines. Written informed consent was taken.

After shifting the patient to operation theatre, intravenous line was established using 18G IV cannula and standard monitors like automated noninvasive blood pressure (NIBP), continuous 5 lead ECG and Pulse Oximetry were attached.

Base line vital parameters were recorded.

Pre-anaesthetic medication

All patients will be administerd injection glycopyrolate (0.004mg/kg), injection ranitidine (50mg i.v), injection ondansetron (0.1 mg/kg i.v), injection Nalbuphine (0.2mg/kg I.V) before induction.

Induction: Preoxygenation with 100% oxygen for 3 minutes.Induction will be done with injection Propofol (2.5 mg/kg i.v). I-gel no.3 will be used for female and no. 4 will

be used for male. Endotracheal tube size 6.5 mm/7mm for female and size 7mm/7.5mm will be used for male. Endotracheal tube will be introduced through I-gel/I-LMA.

Maintenance: Maintainence will be done with 66% nitrous oxide & 33% oxygen and sevoflurane. I-gel will be inserted in sniffing morning position while Intubating-lma will be inserted in neutral neck position with continuation of anesthesia with sevoflurane inhalational agent.

Parameters Recorded: The study evaluated the control of the patients' airway using the two devices on the basis of the following parameters:

Airway trauma by postoperative blood staining of the device, and tongue-lip-dental trauma: The device was removed and was inspected for any blood stain. The patient was also inspected for any injury to lips, teeth, or tongue

Haemodynam Sc responses, changes in spo2 and etco2: Basal values of Heart rate, Systolic, Diastolic and mean blood pressure, SpO2 and EtCO2 were recorded just prior to induction. Further values were recorded after insertion of airway device at interval of 1 minute, 3 minutes, 5 minutes, 10 minutes after placement of the device, then after removal and 5 minutes after removal.

Statistical analysis: Statistical analysis would be done using Statistical Package for Social Sciences (SPSS/ Version 21) software. Arithmatic mean, standard deviation, number & percent would be calculated for each parameter. For categorised parameters chi-square test, fischer exact test would be used for data less than 5 in each cell. While for numerical data t-test would be used to compare the groups. The level of significance would be p-value<0.05.

Results: The effects were observed by monitoring heart rate, blood pressure and spo2 preoperatively (as baseline), after placement of endotracheal tube via I-gel or I-lma at 1 min, 3 mins, 5mins,10mins then at removal of the device and 5 mins after removal. For both the groups baseline etco2 was taken from connection of etco2 cable following placement of airway devices.

The 80 patients selected for the study were randomized into two groups of 40 each. One of the group was administered the I-gel (Group G) and the other group was given I-LMA (Group L).

The observation was compiled and results were analyzed statistically. The observation are tabulated as: Demographic variables (Age distribution, Weight, Sex, ASA status, MPS)

Haemodynamic variables (Heart rate, Systolic Blood Pressure SBP, Diastolic Blood Pressure (DBF) Mean Arterial Pressure (MAP)

Both groups shown statistically significant difference in weight and height but both the groups were comparable in terms of mean age, sex distribution, and BMI. Two groups were statistically similar in terms of distribution of ASA physical status grading ($p<0.05$). Two groups were statistically similar in terms of mallampati score distribution. Distribution of duration of surgery was not statistically significant in both the groups ($p>0.05$).

HR increase after instrumentation in Group G was statistically highly significant ($p<0.01$) after intubation,

at1min, 3min and 5 min. Thereafter HR touched the baseline and HR change remain insignificant throughout the procedure till removal of ET tube when HR increase was significant even after 5 mins after removal but it was clinically acceptable. In Group L the change was clinically significant ($p<0.01$) after device placement and at 1min. thereafter HR touched baseline and HR remained significant throughout the procedure, at removal as wel, as at 5 mins after removal. Table 1

Table 1: Heart Rate variation – Percentage change from baseline Group G

	Data	Baseline	After placement	I min	3 min	5 min	LO Min	At removal	5 mins after removal
HR (bpm) SPO 2 (%)	Mean	81.48	107.78	95.35	91.75	84.75	83.40	98.45	84.72
	Diff. of mean from Baseline % diff. of mean		26.3	13.87	10.27	3.27	1.92	16.97	3.24
			32.27%	17.02%	12.60%	4.01%	2.36%	20.82%	3.97%
	Significance		P<O.01	P<O.01	P<O.01	P>0.05	P>0.05	P<0.01	P<0.01

Group L

	Data	Baseline	After placement	I min	3 min	5 min	LO min	At Removal	5 mins after removal
HR (bpm) SPO 2 (%)	Mean	83.78	94.5	90.35	84.05	83.30	82.72	84.45	83.78
	Diff. of mean from baseline		10.72	6.57	0.27	-0.48	-1.06	0.67	0
	% diff. of mean		12.79%	7.84%	0.03%	0.57%	1.26%	0.80%	0
	Significance		P<O.01	P<O.01	P>O.05	P>0.05	P>0.05	P>0.05	P>0.05

HR variation was highly significant after device placement, at 1min, 3min and 5 min. Thereafter HR variation was insignificant until the device removal when again HR variation was highly significant between the two groups which became insignificant 5mins after device removal. the rise in mean HR was more with I-gel as compared to I-LMA. Table 2

Table 2: Heart Rate variation – both the groups (Bpm)

	Group	Baseline	After placement	1 min	3 min	5 min	10 min	At removal	5 mins after removal
G	Mean	81.48	107.78	95.35	91.75	84.75	83.4	98.45	84.72
	SD	5.458	8.248	7.095	5.913	9.644	5.656	8.336	5.248
L	Mean	83.78	94.5	90.35	84.05	83.30	82.72	84.45	83.78
	SD	5.933	9.905	7.853	5.277	5.268	5.510	5.905	5.989
	t	-1.804	6.514	2.988	6.145	0.834	0.541	8.668	0.755
	P value	P>0.05	P<O.05	P<O.05	P<O.05	P>O.05	P>0.05	P<O.05	P>0.05

In Group G the increase in mean SBP was highly significant after endotracheal tube placement, at 1min, 3min and 5min after which SBP change was insignificant till extubation when again the change was highly significant at removal and it returned to the baseline at 5 mins after removal. In Group L, the mean SBP increase was highly significant during device placement, at 1min,3min after which the SBP change was insignificant throughout the procedure,at device removal as well as at 5 min after device removal. Table 3

Table 3: SBP variation – percentage change from baseline Group G

	Data	Baseline	after placement	1 min	3 min	5 min	10 min	at removal	5 mins after removal
SBP (mm of Hg) (BPM) SPO 2 (%)	Mean	123.8	145.02	144.98	141.00	128.32	123.98	140.5	123.55
	Diff. of mean from baseline % diff. of mean		21.22	21.18	17.2	4.52	0.18	16.7	-0.25
			17.14%	17.11%	13.89%	3.65%	0.14%	13.49%	0.20%
	Significance		P<O.01	P<O.01	P<O.01	P<0.01	P>0.05	P<0.01	P>0.05

Group L

	Data	Baseline	after placement	1 min	3 min	5 min	10 min	at removal	5 mins after removal
SBP (mm of Hg) (BPM) SPO 2 (%)	Mean	122.88	136.62	135.1	130.8	123.32	122.58	122.38	123.2
	Diff. of mean from baseline % diff. of mean		13.74	12.22	7.92	0.44	-0.30	-0.50	0.32
			11.18%	9.94%	6.44%	0.35%	0.24%	0.40%	0.26%
	Significance		P<O.01	P<O.01	P<O.01	P>0.0	P>0.05	P>0.05	P>0.05

On comparing the two groups it was found that SBP variation was highly significant ($p<0.01$) during device placement, at 1min,3min and 5min after which the variation was insignificant throughout the procedure. At removal again SBP vaiation was highly significant ($p<0.01$). The increase in mean SBP during placement and removal was more with I-gel than I-LMA. Table 4.

Table 4: SBP variation- both groups (mm 0f Hg)

	Group	Baseline	After placement	1 min	3 min	5 min	10 min	At removal	5 mins after removal
G	Mean	123.8	145.02	144.98	141.00	128.22	123.98	140.50	123.55
	SD	9.067	9.681	7.979	7.466	6.852	8.435	7.981	9.470
L	Mean	122.88	136.62	135.10	130.80	123.32	122.58	122.38	123.12
	SD	7.579	12.021	11.368	12.976	9.908	6.633	8.536	6.618
	t	0.495	3.422	4.497	4.309	2.537	0.825	9.810	0.233
	P value		0.000	0.000	0.000	0.031	0.393	0.000	0.531
	P value	P>0.05	P<O.01	P<O.01	P<O.01	P<O.01	P>0.05	P<O.01	P>0.05

It was found that there was highly significant DBP varation between the two groups during device placement, at 1min and 3min after which variation was insignificant.DBP variation was again highly significant at device removal and became insignificant 5min afterwards. rise in DBP was significantly more with I-gel than the I-LMA. Table 5

Table 5: DBP variation – both the groups (mm of Hg)

	Group	Baseline	After placement	1 min	3 min	5 min	10 min	At removal	5 mins after removal
G	Mean	82.28	98.45	97.25	94.65	82.95	82.42	92.92	82.78
	SD	4.297	6.691	6.033	5.686	4.145	5.252	4.649	3.826
L	Mean	82.28	92.82	86.72	82.72	82.28	82.70	83.10	82.48
	SD	4.580	8.212	5.575	3.803	4.443	4.065	8.122	6.664
	T	0	3.359	8.104	11.025	0.703	0.262	6.037	0.247
	P value		0.000	0.000	0.000	0.031	0.393	0.000	0.531
	P value	P>0.05	P<O.01	P<O.01	P<O.01	P>O.05	P>0.05	P<O.01	P>0.05

It was found that among the two groups MAP variation was highly significant after device placement, at 1min and 3 mins after which the MAP variation was insignificant. MAP variation became insignificant 5mins after device removal. The increase in MAP during device placement and removal was significantly more with I-gel than with I-LMA. Table 6.

Table 6: MAP variation – both the group (mm of Hg)

	Group	Baseline	After placement	1 min	3 min	5 min	10 min	At removal	5 mins after removal
G	Mean	95.45	114.38	112.32	109.18	95.10	95.60	109.30	95.88
	SD	4.350	6.808	6.553	5.053	3.448	4.241	6.580	4.304
L	Mean	95.70	107.65	102.50	97.00	95.90	95.72	95.50	95.42
	SD	4.681	8.610	6.377	5.857	5.537	3.623	8.178	6.852
	t	0.247	3.875	6.796	9.954	0.776	0.142	8.316	0.352
	P value		0.000	0.000	0.000	0.031	0.393	0.000	0.531
	P value	P>0.05	P<O.01	P<O.01	P<O.01	P>O.05	P>0.05	P<O.01	P>0.05

Discussion: Both groups shown statistically significant difference in weight and height but both the groups were comparable in terms of mean age, sex distribution, and BMI.

Hemodynamic variables

Heart Rate (HR): There was an increase in HR immediately after instrumentation and at I min in both the groups. In Group L, HR came down towards the baseline by 3mins where as in Group G, although there was a fall in HR but it remained at higher levels as compared to Group L (PO.01) upto 5mins. Comparison between the two groups showed that rise in HR in Group G was significantly higher than Group L. There was a significant increase in HR during extubation in Group G which touched baseline 5mins after extubation. With removal of I-lma, the HR change was not significant from baseline.

Thus it can be interpreted that the HR increased after both I-gel and I-lma placement, but the magnitude and duration of this increase was less in Group L as compared to Group G. At removal of ET tube in Group G, there was a significant rise in HR but, HR change was insignificant during I-lma removal.

Systolic Blood Pressure (SBP): It was observed that rise in mean SBP was much more in Group G as compared to Group L during device placement, at Imin and 3min (P<0.01, highly significant).The variation between the two groups became significant at 5min (P<0.05) after which the variation was insignificant and again the SBP variation was highly significant at removal and it became insignificant 5 mins after device removal.

Diastolic Blood Pressure (DBP): It was observed that the difference between the two groups wasstatistically significant after instrumentation, at Imin and 3min after which variation was insignificant till device removal when DBP variation was again highly significant and became insignificant 5min afterwards. The rise in DBP from baseline on instrumentation was significantly more with I-gel group as compared to I-lma). Also extubation was associated with asignificant rise in DBP (92.5mmHg) in Group G whereas removal of I-lma was not associated with any significant rise in DBP (83.06mmHg) in group L.

Mean Arterial Pressure (MAP): When intergroup comparison was done, it was observed that rise in MAP was significantly higher (PO.01) in Group G as compared to Group L during instrumentation. MAP variation remained significant between the two groups at 1min and 3mins with higher MAP values in Group G. MAP variation was insignificant from 5min onwards till device removal when again MAP variation was highly significant between the two groups with Group G showing increased MAP.

Shribman AJ *et al.* in 1987 observed significant increase in heart rate, arterial pressure and circulating catecholamine level immediately after laryngoscopy and 1,3,5 minutes after endotracheal intubation [2].

Hosam M Atef *et al.* in 2013 performed a study on ET Tube vs I-gel vs LMA. Insertion of airway devices produced significant increases in HR, SBP and DBF in (LMA and ET) groups. HR criterions were 0%, 30% and 60% in I-gel, LMA and ET, respectively, after insertion of the airway devices. SBP criterion was 0%, 30% and 40% in the studied group respectively. In addition, DBF criterion was 0%, 10% and 40% [6].

Present study: I-gel vs I-lma as a conduit for ET tube insertion. Statistically significant rise in heart rate in group G upto 5 minutes and at removal than group L. Statistically significant rise in SBP in group G upto 5 minutes and at removal than group L. Statistically significant rise in DBF in group G upto 3 minutes and at renoval than group L. Statistically significant rise in MABP in group G upto 3 minutes and at removal than group L.

At last we can say that ET tube insertion via I-LMA offers better haemodynamic stability than ET tube insertion via I-gel.

Conclusion: It was concluded that I-LMA causes significantly less haemodyanamic perturbations than I-gel at various time intervals. I-gel can be used as a conduit for endotracheal intubation. Though it is an effective SAD, it is slightly inferior to LMA Fastrach as the intubating device.

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