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RESEARCH ARTICLE

Study of i-gel and cLMA for their effect on hemodynamic changes in paediatric patients and its statistical significance.

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Abstract

AIM- Study on supraglottic airway devices, i-gel and cLMA for their effect on hemodynamic changes in paediatric patients and its statistical significance.

Methods - We did a prospective, randomised single blind study on Eighty patients of either sex belonging to American Society of Anesthesiologists (ASA) physical status class I or II, between 6 months to 8 years of age, scheduled to undergo elective surgery for less than one and half hour duration under general anaesthesia. With this supraglottic airway devices we studied the hemodynamic changes on pediatric cases.

Results - The heart rate, systolic BP, diastolic BP and mean BP were measured at different intervals for both i-gel and cLMA group and we found no statistically significant differences in heart rate, SBP, DBP and mean BP in both the groups.

The oxygen saturation which is recorded at different intervals in our study on both the groups (i-gel and cLMA) remained 100%.

Conclusion -The i-gel and cLMA are effective and safe devices for use in children. They were comparable for hemodynamic and ventilatory parameters.

Keywords: cLMA, i-gel, systolic blood pressure, diastolic blood pressure, mean blood pressure, paediatric, oxygen saturation, supraglottic airway devices

1 | INTRODUCTION

The Laryngeal Mask Airway (LMA) and related devices have been used extensively in clinical practice since the first such product was introduced. These devices provide an airway intermediate between the face mask and tracheal tube in terms of anatomic position, invasiveness and security in the unconscious patient.[1]

The laryngeal mask has certain advantages- insertion can be performed blindly. It's easy to learn; fast insertion time and airway control, even when used by inexperienced personnel; possible improved outcome in patients with upper respiratory infections; less laryngeal stimulation and fewer cardiovascular responses during insertion/induction and emergence; reduced anaesthetic requirements for airway tolerance; lower incidence of airway morbidity (eg, laryngeal oedema) and postoperative sore throat. Despite these advantages, the LMA has some drawbacks. The airway is not secured, leaving a risk for regurgitation and aspiration. As a result, its use in patients with a full stomach or a history of gastroesophageal reflux is contraindicated. The low sealing pressures of the laryngeal mask airway do not permit ventilation with high positive pressures.[2] Nitrous oxide diffuses into cuff of LMA and this will increase cuff pressure.[5] Inflatable cuff provides an airway seal but can have a negative impact on insertion, positioning and performance of the device.[4] If cuff inflation pressure of cLMA rise above 60 cm of H_2O, injury to recurrent laryngeal nerve can occur.[2]

The cLMA has the widest range of sizes available, from neonates to large adults and it is latex free. The several disadvantages of the LMA, notably compressibility of the breathing tube and a low cuff leak pressure, have led to the development of alternative supraglottic airway devices.[3]

A second generation supraglottic airway device i-gel has a non-inflatable cuff.

It has an anatomically designed mask made up of a thermoplastic elastomer, styrene ethylene butadiene styrene (SEBS) with a soft durometer (hardness) and gel like feel, which does not require inflation with air. The mask of the i-gel is designed anatomically to fit the perilaryngeal and hypopharyngeal structures.[4] The tube section has a widened and symmetrical laterally flattened cross sectional shape which provides good vertical and lateral stability on insertion. The tube section is harder and more rigid than the soft bowl of the device. There is a second lumen that runs on the right side of the airway tube along the entire length of the device to the distal tip that can accommodate a gastric tube.[5] This is intended to separate the airway from gastrointestinal tract resulting in three potential advantages over more traditional supraglottic airway devices; allowing venting of regurgitated gastric content; allowing easy insertion of gastric tube.[6] The proximal end of the tube is a combination of a bite block and a 15mm connector.[5] A small rigid projection from the proximal section of the bowl sits against the base of the tongue and helps in stabilizing the device.[5] Evaluation of the i-gel in adult patients has shown that it is easy to insert and provide an effective airway in majority of patients.[6] The paediatric size i-gel is available in 5 sizes- 1, 1.5, 2, 2.5 and 3. Like adult i-gel, it has a gastric drain except for size 1.

Classic LMA is a well-established device for airway management in children and Paediatric i-gel have been found safe & effective for airway management in children in many studies.

Das et al (2012) did prospective, randomized, single blinded study using size 2 i-gel, PLMA and CLMA. Ninety ASA grade I–II patients aged 1-6years, weight of 10-20kgs undergoing for elective surgeries of less than 1 h duration in the supine position including lower abdominal (e.g., colostomy closure), inguinal (e.g., herniotomy, circumcision) and orthopedic procedures (e.g., upper and lower limb surgeries) were included in their prospective study. The hemodynamic parameters, ease of insertion and postoperative complications were comparable among the i-gel, PLMA and cLMA groups.[7]

Goyal et al did the randomized prospective study on 120 children aged 2-5 years, weighing 10-20 kg, ASA physical status I-II scheduled for routine elective surgeries of <1-h duration using the size 2 i-gel supraglottic airway with LMA-ProSeal™ and LMA-Classic™. They noted the hemodynamic effects on insertion of device, and have not commented any significant hemodynamic changes in their study.[8]

Supplementary information The online version of this article (https://doi.org/10.15520/ijmhs.v11i03.3260) contains supplementary material, which is available to authorized users.

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Mitra et al(2012) planned the randomized and prospective study to compare the size 2.5 i-gel and PLMA in 60 children. They included children of age group 5-10 years of age, weighed between 20-30 kg, with ASA physical status 1 and 2 posted for elective surgeries of duration less than 1hour duration in the supine position, including lower abdominal, inguinal, and orthopedic surgery. They measured the hemodynamic effect. And they concluded that i-gel is comparable to PLMA in relation to hemodynamic parameter.[9]

2 | MATERIAL & METHODS

We did a prospective, randomised single blind study. Eighty patients of either sex belonging to American Society of Anesthesiologists (ASA) physical status class I or II, between 6 months to 8 years of age, scheduled to undergo elective surgery for less than one and half hour duration under general anaesthesia were included in the study.

2.1 | Exclusion Criteria

Patients having difficult airway, restricted mouth opening, risk of aspiration, upper respiratory tract infection, congenital heart disease, surgery in position other than supine, history of upper gastro-intestinal surgery, bleeding or clotting abnormalities, and oesophageal trauma were excluded from the study.

2.2 | Clinical Examination

All the patients were examined during the preoperative visit a day prior to surgery. Informed written consent was obtained from the parents. Patients were subjected to detailed clinical history, complete general physical and systemic examination. Routine investigations like hemoglobin (Hb), bleeding time (BT), clotting time (CT), urine complete examination and other investigation of need were carried out.

2.3 | Preparation of Patient

Preparation of Patient

The patients were kept fasting for six hours for solids, four hours for breast milk and two hours for clear fluid prior to scheduled time of surgery. They were premedicated with syrup midazolam 0.5 mg kg^{-1} one hour before surgery. After arrival in the operation theatre routine monitoring e.g., Heart Rate (HR), Electrocardiography (ECG), Pulse oximetry (SpO_2), Non-invasive blood pressure (NIBP), end-tidal CO_2 ($EtCO_2$), Respiratory rate (RR), inhaled and exhaled anaesthetic gases concentration using Phillips intelliVue MP 50 monitor were set up. Baseline readings of vital parameters were recorded.

Patients were then be randomly allocated to one of the two groups using a computer-generated sequence of random numbers, as follows:

Group-1 – (n=40), LMA Classic was used as an airway conduit.

Group-2 – (n=40), i-gel was used as an airway conduit.

2.3.1 |

2.3.1.1 Anaesthetic technique Induction of anaesthesia was achieved with standardized anaesthesia technique using either intravenous thiopentone 5 mg kg^{-1} or inhaled sevoflurane 6-8% in 100% oxygen along with intravenous glycopyrrolate 0.005 mg kg^{-1} and fentanyl 1 microgm kg^{-1} Inj. atracurium 0.5 mg kg^{-1} was used to facilitate air way device insertion. All patients were ventilated for two minutes via face mask and anaesthesia breathing system using sevoflurane 2% in 100% O_2. The patient′s head were positioned with flexion of the neck and extension of the head using the non-dominant hand. The appropriate size airway device was used as per weight criteria, cLMA cuff was inflated partially before insertion which is slight modification of standard technique described by Brain. Water soluble jelly was applied on posterior aspect of cuff of device to be used. The cLMA and i-gel were held like a pen and inserted while pressing against the hard palate and posterior pharyngeal wall until resistance is felt when the mask tip reached the base of hypo-pharynx.

After insertion, cLMA cuff was inflated to 60cmH_2O pressure. The airway device was connected to the anaesthesia breathing system. Positive pressure ventilation was commenced with a tidal volume of 8 ml kg^{-1}, respiratory rate as per age and I:E ratio of 1:2. Correct placement of the device was confirmed by manual ventilation and obtaining square wave capnograph on the monitor. Presence or absence of oropharyngeal air leaks (detected by listening over the mouth), and gastric leaks (by listening with the stethoscope over the epigastrium) were checked and airway device was fixed with the help of adhesive tape.

The following data was observed-

Hemodynamic and respiratory monitoring

HR, SpO_2, NIBP, RR, inhaled and exhaled anaesthetic gas concentration were monitored at the baseline level, after induction, then after placing airway device at following intervals 2mins, 5mins, 10mins, 15mins. Maintenance of anaesthesia for intraoperative period was achieved as per the requirement of the case and surgery was commenced. After completion of the procedure, neuromuscular blockade was reversed. The airway device was then removed when the patient was awake and able to open the mouth.

3 | OBSERVATIONS & RESULTS

After placement of device. Correct placement of the device was confirmed by manual ventilation and obtaining square wave capnograph on the monitor. Airway device was fixed with the help of adhesive tape.

Different parameters of hemodynamic and respiratory monitoring were studied.

3.1 | Statistical Analysis

We based our sample size calculation on our primary outcome variable. Very little data about the performance of the pediatric-sized i-gel were available for a reliable sample size calculation. The independent two-tailed Student t test and paired t-test were used to compare Heart rate, SBP, DBP and Mean BP at different intervals in i-gel and cLMA groups. All data were analyzed with SPSS version 15 (SPSS) and are presented as mean with standard deviations or number and percentage. A probability of $P = 0.05$ was considered statistically significant.

3.2 | Demographic Profile

The demographic details of the patients show there was no significant difference between the groups in terms of age, sex and weight. The two groups were comparable with respect to duration of surgery and ASA physical status.

3.3 | Hemodynamics

Heart rate, SBP, DBP, MBP was comparable at different intervals for the two devices. On computing the data we found no statistically significant differences in parameters studied at various intervals selected.

3.3.1 | Heart rate (HR)

The heart rate was observed at various intervals in our study for both i-gel and cLMA group. For i-gel group baseline HR was 116.95 ± 18.907/min, after induction HR was 113.07 ± 19.609/min, before placing airway HR was 112.025 ± 21.303/min, after placing airway HR was 130.6 ± 18.377/min, at 2mins interval HR was 124.825 ± 19.356/min, at 5mins interval HR was 119.45 ± 16.976/min, at 10mins interval HR was 117.75 ± 17.457/min and at 15mins interval HR was 114.975 ± 19.002/min. For cLMA group baseline HR was 120.05 ± 13.9/min, after induction HR was 118 ± 16.06/min, before placing airway HR was 117.32 ± 15.78/min, after placing airway HR was 136.27 ± 14.60/min, at 2mins interval HR was 129.57 ± 14.59/min, at 5mins interval HR was 123.90 ± 14.20/min, at 10mins interval HR was 119.82 ± 16.23/min and at 15mins interval HR was 117.3 ± 17.25/min.

Comparing the heart rate at different intervals in cases of i-gel and cLMA, we found no significant statistical difference between the two (Table 1) also shown in graph 1.

On applying paired t-test on heart rate of i-gel group at different intervals with baseline, we found statistically significant increase in heart rate after placing the airway device as compared to baseline (130.6 ± 18.377 vs 116.95 ± 18.907, p-value= 0.000). The increase in heart rate returned to normal baseline value at 5min interval (P value $\geq$ 0.05). Change in heart rate at other time intervals was statistically non-significant when compared with baseline heart rate. Similar results were obtained for cLMA group on applying paired t- test at different intervals with baseline.

3.3.2 | Systolic Blood Pressure (SBP)-

The systolic blood pressure was observed at various intervals in our study for both i-gel and cLMA group. For i-gel group baseline SBP was 104 $\pm$ 8.84 mm Hg, after induction SBP was 103.78 $\pm$ 9.996 mm Hg, before placing airway SBP was 104.23 $\pm$ 8.891 mm Hg, after placing airway SBP was 118.90 $\pm$ 11.50 mm Hg, at 2mins interval SBP was 112.13 $\pm$ 10.598 mm Hg, at 5mins interval SBP was 106.97 $\pm$ 7.74 mm Hg, at 10mins interval SBP was 107.27 $\pm$ 6.83 mm Hg and at 15mins interval SBP was 108.075 $\pm$ 8.30 mm Hg. For cLMA group baseline SBP was 106 $\pm$ 7.72 mm Hg, after induction SBP was 106.62 $\pm$ 9.69 mm Hg, before placing airway SBP was 106.725$\pm$ 9.93 mm Hg, after placing airway SBP was 120.90 $\pm$ 10.157 mm Hg, at 2mins interval SBP was 115.6 $\pm$ 7.50 mm Hg, at 5mins interval SBP was 109.8 $\pm$ 7.82 mm Hg, at 10mins interval SBP was 110.90 $\pm$ 8.199 mm Hg and at 15mins interval SBP was 109.15 $\pm$ 8.100 mm Hg.

Comparing the systolic blood pressure at different intervals in cases of i-gel and cLMA, we found no significant statistical difference between the two (Table 2) (Graph 2).

On applying paired t-test on SBP of i-gel group at different intervals with baseline, we found statistically significant increase in SBP after placing the airway device as compared to baseline (118.90 $\pm$ 11.50 mm Hg vs 104 $\pm$ 8.84 mm Hg, p-value= 0.000). The increase in SBP returned to normal baseline value at 5min interval (P value $\geq$ 0.05). Change in SBP at other time intervals was statistically non-significant when compared with baseline SBP. Similar results were obtained for cLMA group on applying paired t-test at different intervals with baseline.

3.3.3 | Diastolic Blood Pressure (DBP)-

The diastolic blood pressure was observed at various intervals in our study for both i-gel and cLMA group. For i-gel group baseline DBP was 59.95 $\pm$ 8.89 mm Hg, after induction DBP was 60.53 $\pm$ 9.37 mm Hg, before placing airway DBP was 60.58 $\pm$ 8.311 mm Hg, after placing airway DBP was 68.78 $\pm$ 10.129 mm Hg, at 2mins interval DBP was 64.28 $\pm$ 9.151 mm Hg, at 5mins interval DBP was 61.3 $\pm$ 5.87 mm Hg, at 10mins interval DBP was 61.47 $\pm$ 7.24 mm Hg and at 15mins interval DBP was 60.85 $\pm$ 6.76 mm Hg. For cLMA group baseline DBP was 62.8 $\pm$ 6.59 mm Hg, after induction DBP was 62.525 $\pm$ 7.82 mm Hg, before placing airway DBP was 63.33 $\pm$ 7.212 mm Hg, after placing airway DBP was 71.43 $\pm$ 8.006 mm Hg, at 2mins interval DBP was 67.27 $\pm$ 6.14 mm Hg, at 5mins interval DBP was 64.05 $\pm$ 6.10 mm Hg, at 10mins interval DBP was 64.18 $\pm$ 7.186 mm Hg and at 15mins interval DBP was 63.98 $\pm$ 7.902 mm Hg.

Comparing the diastolic blood pressure at different intervals in cases of i-gel and cLMA, we found no significant statistical difference between the two (Table 3) (Graph 3).

On applying paired t-test on DBP of i-gel group at different intervals with baseline, we found statistically significant increase in DBP after placing the airway device as compared to baseline (68.78 $\pm$ 10.129 mm Hg vs 59.95 $\pm$ 8.89 mm Hg, p-value= 0.000). The increase in DBP returned to normal baseline value at 5min interval (P value $\geq$ 0.05). Change in DBP at other time interval was statistically non-significant when compared with baseline DBP. Similar results were obtained for cLMA group on applying paired t- test at different intervals with baseline.

3.3.4 | Mean Blood Pressure (MBP)-

The mean blood pressure was observed at various intervals in our study for both i-gel and cLMA group. For i-gel group baseline MBP was 74.6$\pm$8.5 mm Hg, after induction MBP was 74.9$\pm$9.15 mm Hg, before placing airway MBP was 75.1$\pm$8.0 mm Hg, after placing airway MBP was 85.5$\pm$10.12 mm Hg, at 2mins interval MBP was 80.2$\pm$9.14 mm Hg, at

TABLE 1: Heart rate of the two devices (i-gel and cLMA) at various intervals.

	i-gel(n=40)	cLMA(n=40)	P value
Baseline (beats/min)	116.95 ± 18.907	120.05 ± 13.9	0.406
After induction (beats/min)	113.07±19.609	118 ± 16.06	0.223
Before placing air-way (beats/min)	112.025 ± 21.303	117.32 ± 15.78	0.21
After placing airway (beats/min)	130.6 ± 18.377	136.27 ± 14.60	0.131
2mins (beats/min)	124.825 ± 19.356	129.57 ± 14.59	0.219
5mins (beats/min)	119.45 ± 16.976	123.90 ± 14.20	0.2
10mins (beats/min)	117.75 ± 17.457	119.82 ± 16.23	0.584
15mins (beats/min)	114.975 ± 19.002	117.3 ± 17.25	0.568

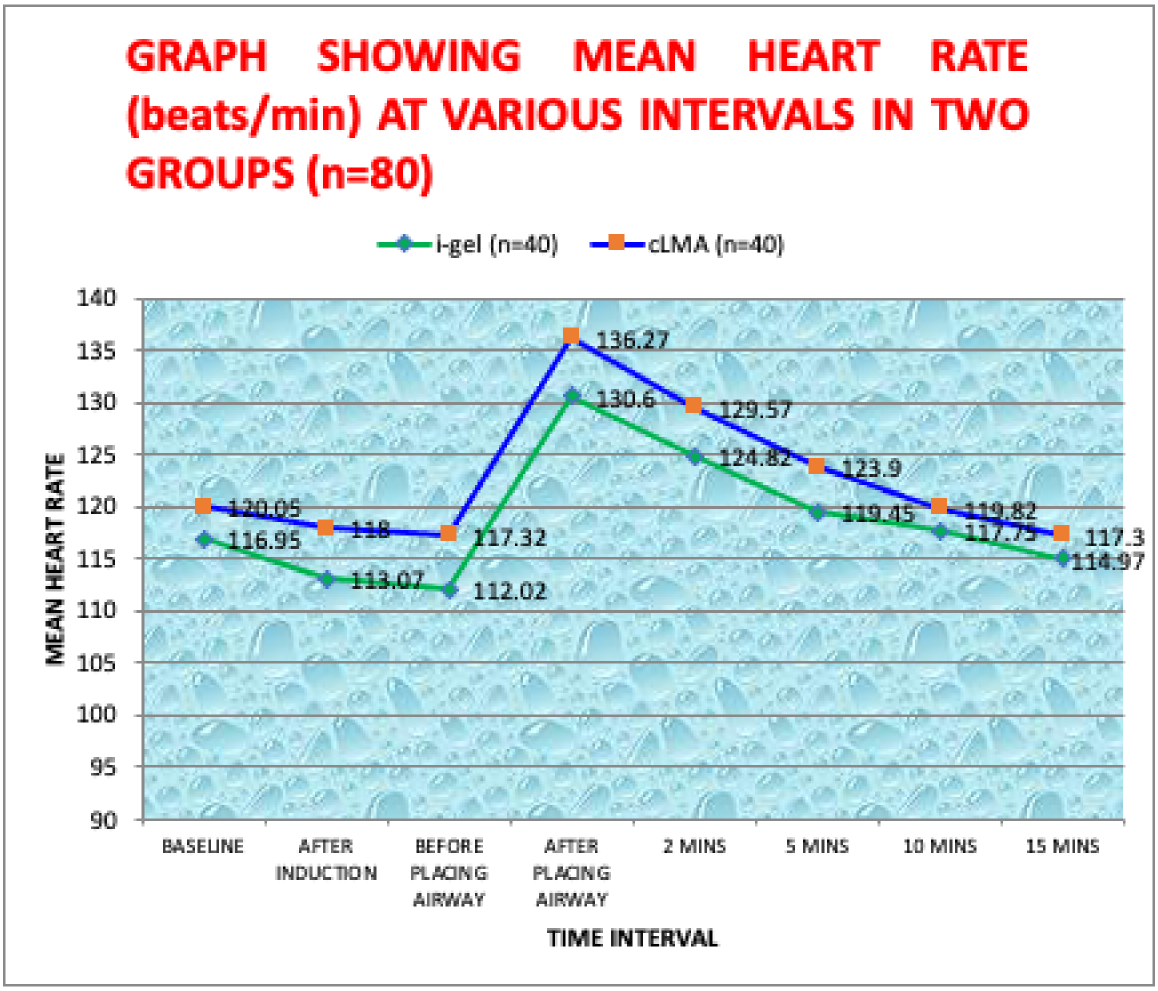

FIGURE 1: GRAPH-1

TABLE 2: Showing systolic BP of the two devices (i-gel and cLMA) at variousintervals.

	i-gel (mean ± SD) (n=40)	cLMA (mean ± SD) (n=40)	P value
Baseline (mm of Hg)	104 ± 8.84	106 ± 7.72	0.235
After induction (mm of Hg)	103.78 ± 9.996	106.62 ± 9.69	0.242
Before placing airway (mm of Hg)	104.23 ± 8.891	106.725± 9.93	0.239
After placing airway (mm of Hg)	118.90 ± 11.50	120.90 ± 10.157	0.412
2mins (mm of Hg)	112.13 ± 10.598	115.6 ± 7.50	0.095
5mins (mm of Hg)	106.97 ± 7.74	109.8 ± 7.82	0.10
10mins (mm of Hg)	107.27 ± 6.83	110.90 ± 8.199	0.527
15mins (mm of Hg)	108.075 ± 8.30	109.15 ± 8.100	0.888

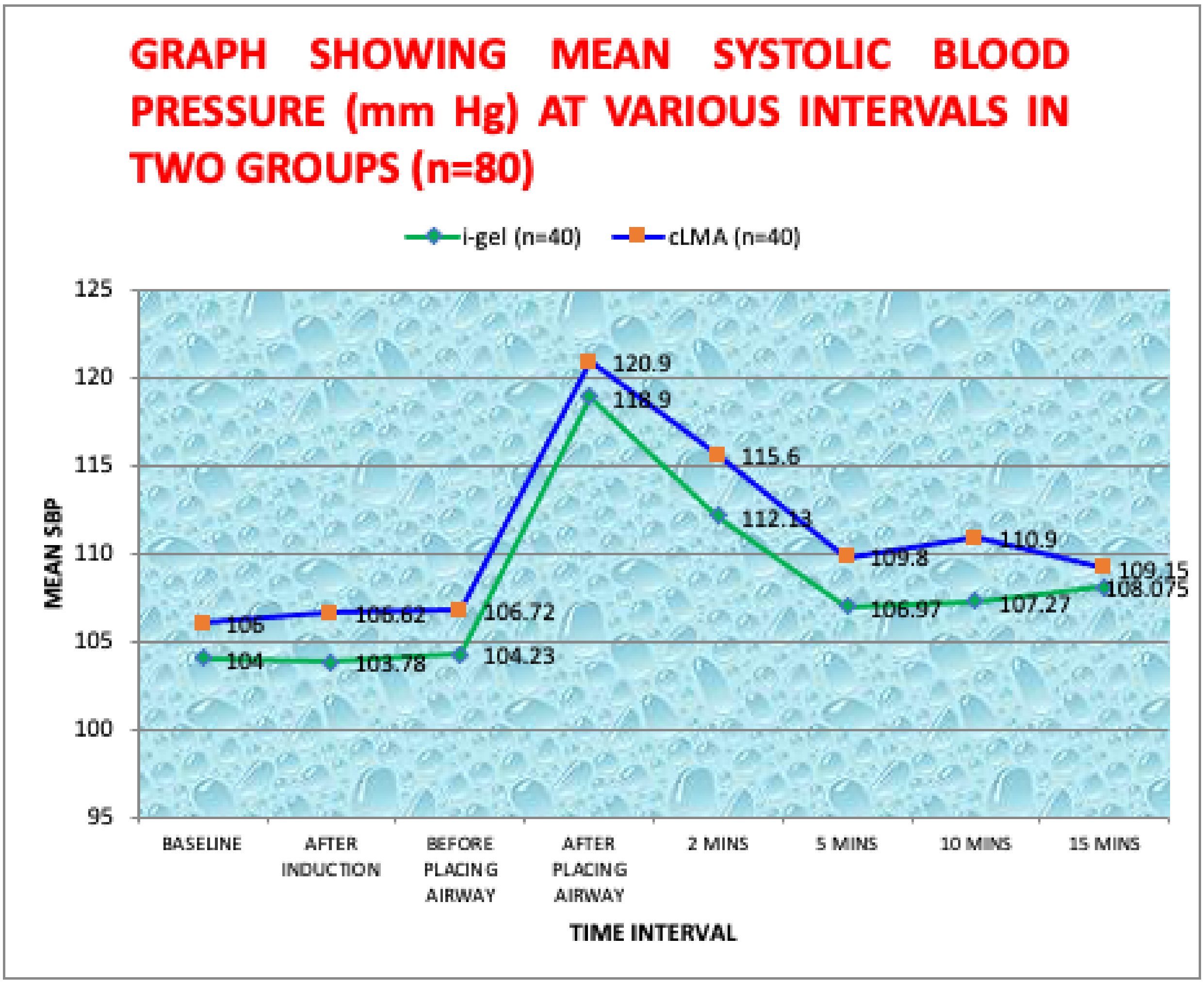

FIGURE 2: Graph 2

TABLE 3: Showing diastolic BP of the two devices (i-gel and cLMA) at variousintervals.

	i-gel (mean ± SD) (n=40)	cLMA (mean ± SD) (n=40)	P value
Baseline (mm of Hg)	59.95 ± 8.89	62.8 ± 6.59	0.108
After induction (mm of Hg)	60.53 ± 9.37	62.525 ± 7.82	0.316
Before placing (mm of Hg) Airway	60.58 ± 8.311	63.33 ± 7.212	0.118
After placing airway (mm of Hg)	68.78 ± 10.129	71.43 ± 8.006	0.198
2mins (mm of Hg)	64.28 ± 9.151	67.27 ± 6.14	0.089
5mins (mm of Hg)	61.3 ± 5.87	64.05 ± 6.10	0.32
10mins (mm of Hg)	61.47 ± 7.24	64.18 ± 7.186	0.655
15mins (mm of Hg)	60.85 ± 6.76	63.98 ± 7.902	0.402

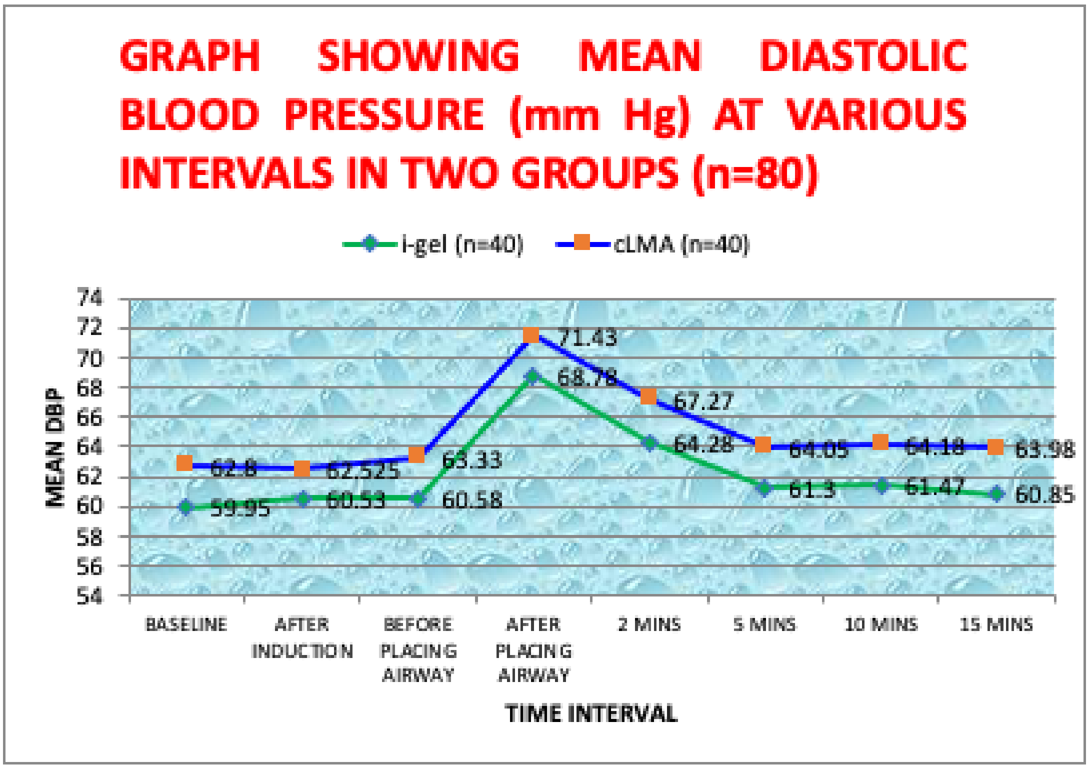

FIGURE 3: Graph-3

5mins interval MBP was 77.9±7.03 mm Hg, at 10mins interval MBP was 78.8±9.27 mm Hg and at 15mins interval MBP was 77.9±8.3 mm Hg. For cLMA group baseline MBP was 77.3± 6.3 mm Hg, after induction MBP was 77.1± 8.0, before placing airway MBP was 77.8 ± 7.7 mm Hg, after placing airway MBP was 87.9 ± 8.2 mm Hg, at 2mins interval MBP was 83.4 ± 5.9 mm Hg, at 5mins interval MBP was 80 ± 5.9 mm Hg, at 10mins interval MBP was 79.0 ± 7.6 mm Hg and at 15mins MBP was 79.03±7.56 mm Hg.

Comparing the mean blood pressure at different intervals in cases of i-gel and cLMA, we found no significant statistical difference between the two (Table 4) (Graph-4).

On applying paired t-test on MBP of i-gel group at different intervals with baseline, we found statistically significant increase in MBP after placing the airway device as compared to baseline (85.5±10.12 mm Hg vs 74.6±8.5 mm Hg, p-value= 0.000). The increase in MBP returned to normal baseline value at 5min interval (P value ≥ 0.05). Change in MBP at other time interval was statistically non-significant when compared with baseline MBP. Similar results were obtained for cLMA group on applying paired t-test at different intervals with baseline.

3.3.5 | Oxygen Saturation (SpO2)

The oxygen saturation recorded at various intervals in our study on i-gel and cLMA. For both the groups it was found to be 100% at all intervals (Table 5).

4 | DISCUSSION

The cLMA is an established supraglottic airway device for airway management in paediatric patients. The i-gel of paediatric size is a relatively newer device, having noninflatable supraglottic airway for use in anesthesia during spontaneous or intermittent positive pressure ventilation.[10]

In the past i-gel and cLMA have been compared individually with other supraglottic airway device and very few studies are available comparing the two devices. So, we undertook this prospective, randomized, single blind study to compare i-gel and cLMA in the Indian paediatric population. This study was designed to compare hemodynamic changes of i-gel and cLMA in children.

The two groups were similar demographically in terms of age, gender, weight, height and BMI. They were also similar with respect to ASA physical status and duration of surgery. Therefore we can say that results obtained after study were purely due to the characteristics attributable to devices rather than any bias associated to the sample selected.

4.1 | Hemodynamic effect

The heart rate, systolic BP, diastolic BP and mean BP were measured at different intervals for both i-gel and cLMA group. The baseline heart rate recorded in our study for i-gel group was 116.95 ± 18.907/min, after induction HR was 113.07±19.609/min, before placing airway HR was 112.025 ± 21.303/min, after placing airway HR was 130.6 ± 18.377/min, at 2mins interval HR was 124.825 ± 19.356/min, at 5mins interval HR was 119.45 ± 16.976/min, at 10mins interval HR was 117.75 ± 17.457/min and at 15mins interval HR was 114.975 ± 19.002/min. For cLMA group baseline HR was 120.05 ± 13.9/min, after induction HR was 118 ± 16.06/min, before placing airway HR was 117.32 ± 15.78/min, after placing airway HR was 136.27 ± 14.60/min, at 2mins interval HR was 129.57 ± 14.59/min, at 5mins interval HR was 123.90 ± 14.20/min, at 10mins interval HR was 119.82 ± 16.23/min and at 15mins interval HR was 117.3 ± 17.25/min.

On applying paired t-test on heart rate of i-gel group at different intervals, we found significant increase in heart rate after placing the airway device as compared to baseline (130.6 ± 18.377 vs 116.95 ± 18.907, p-value= 0.000). The increase in heart rate returned to normal baseline value at 5min interval (P value $\geq$ 0.05). Change in heart rate at other time interval was statistically non-significant when compared with baseline heart rate. Similar results were obtained for cLMA group.

The mean blood pressure recorded at various intervals for i-gel group were baseline MBP was 74.6±8.5, after induction MBP was 74.9±9.15, before placing airway MBP was 75.1±8.0, after placing airway MBP was 85.5±10.12, at 2mins interval MBP was 80.2±9.14, at 5mins interval MBP was 77.9±7.03, at 10mins interval MBP was 78.8±9.27 and at 15mins interval MBP was 77.9±8.3. For cLMA group baseline MBP was 77.3± 6.3, after induction MBP was 77.1± 8.0, before placing airway MBP was 77.8 ± 7.7, after placing airway MBP was 87.9 ± 8.2, at 2mins interval MBP was 83.4 ± 5.9, at 5mins interval MBP was 80 ± 5.9, at 10mins interval MBP was 79.0 ± 7.6 and at 15mins MBP was 79.03±7.56.

On applying paired t-test on SBP, DBP and MBP of i-gel group at different intervals, we found significant increase in SBP, DBP and MBP after placing the airway device as compared to baseline (p-value= 0.000). The increase in SBP, DBP and MBP returned to normal baseline value at 5min interval (P value $\geq$ 0.05). Change in SBP, DBP and MBP at other time interval was statistically non-significant when compared with baseline SBP, DBP and MBP. Similar results were obtained for cLMA group.

TABLE 4: Showing Mean BP of the two devices (i-gel and cLMA) at variousintervals.

	i-gel (mean ± SD) (n=40)	cLMA (mean ± SD) (n=40)	P value
Baseline (mm of Hg)	74.6±8.5	77.3± 6.3	0.121
After induction (mm of Hg)	74.9±9.15	77.1± 8.0	0.263
Before placing airway (mm of Hg)	75.1±8.0	77.8 ± 7.7	0.134
After placing airway (mm of Hg)	85.5±10.12	87.9 ± 8.2	0.24
2mins (mm of Hg)	80.2±9.14	83.4 ± 5.9	0.07
5mins (mm of Hg)	77.9±7.03	80 ± 5.9	0.15
10mins (mm of Hg)	78.8±9.27	79.0 ± 7.6	0.589
15mins (mm of Hg)	77.9±8.3	79.03±7.56	0.516

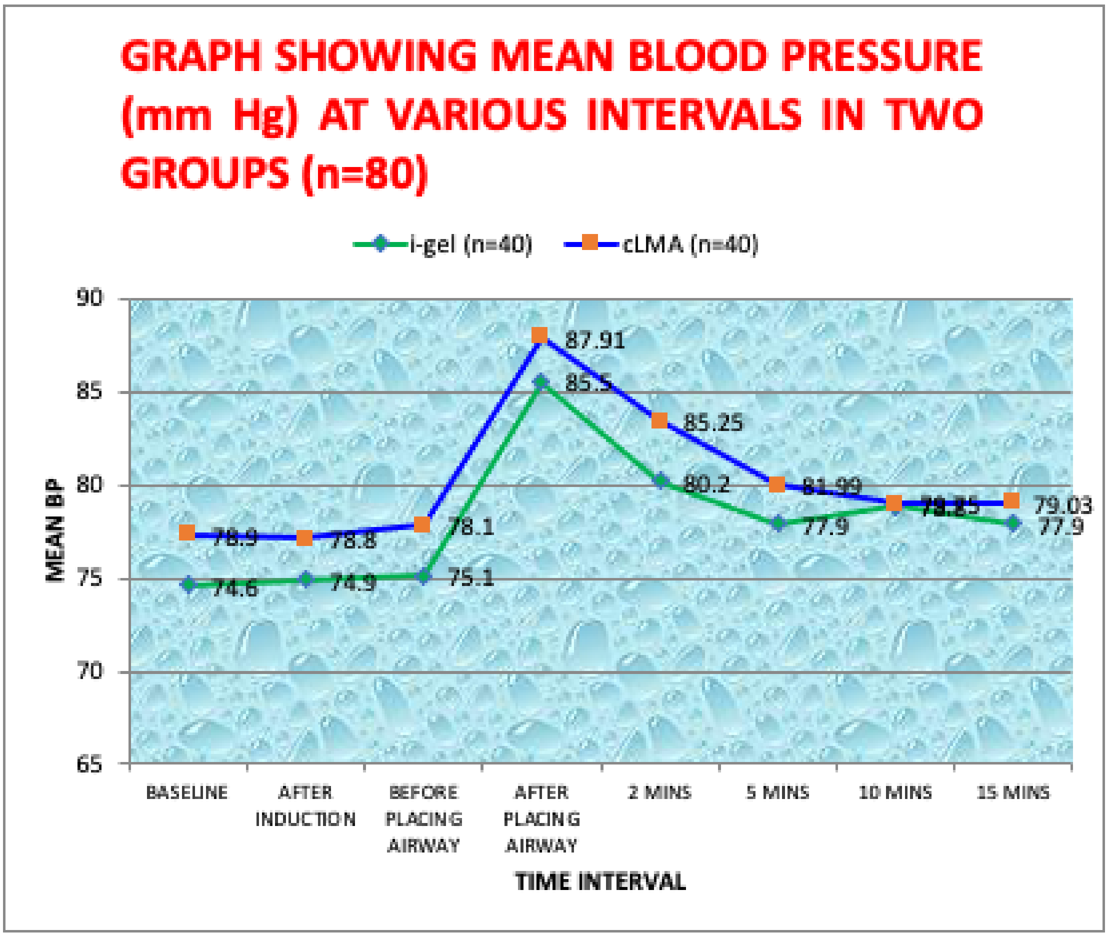

FIGURE 4: Graph-4

From the result comparing the hemodynamic responses between two groups at various time intervals including responses at the time of induction and insertion of these devices, we found no statistically significant differences in pulse rate, SBP, DBP and mean BP in both the groups. Authors like Das et al in their study on cLMA vs PLMA,[11] Goyal et al on cLMA, PLMA and i-gel,[8] Mitra et al on i-gel vs PLMA[9] also have not commented any significant hemodynamic changes in their study. Supraglottic airway devices are less invasive and exert less mechanical pressure on pharyngeal structure during their placement. They usually cause less hemodynamic changes. However, on intragroup analysis by applying paired t-test on HR, SBP, DBP and MBP at different intervals with baseline on i-gel and cLMA group we found highly statistically significant relationship between them. Also hemodynamic response

TABLE 5: Showing Oxygen Saturation of the two devices (i-gel and cLMA) at variousintervals.

	i-gel (n=40)	cLMA (n=40)
Baseline (%)	100	100
After induction (%)	100	100
Before placing airway (%)	100	100
After placing airway (%)	100	100
2mins (%)	100	100
5mins (%)	100	100
10mins (%)	100	100
15mins (%)	100	100

elicitation by both the devices is manifested more at the time of insertion of device than at any time interval.

4.2 | Oxygen Saturation (SpO_2)

The oxygen saturation which is recorded at different intervals in our study on both the groups (i-gel and cLMA) remained 100%. Study by Goyal et al also recorded a 100% SpO_2 in all the three groups' i-gel, cLMA and PLMA when used in paediatric patients.[8] Another study by Das et al on paralyzed children undergoing elective surgery using i-gel, PLMA and cLMA, recorded 100% SpO_2 in all their studied groups.[7] The 100% of oxygen saturation can be explained by proper placement of device and maintenance of sufficient ventilation with adequate seal.

In our study no episodes of hypoxia ($Spo2<90\%$), airway reflex activation (coughing, gagging, retching, laryngospasm, bronchospasm) or aspiration/regurgitation/vomiting were seen by use of any of the two.

5 | CONCLUSION

The heart rate, systolic BP, diastolic BP and mean BP were measured at different intervals for both i-gel and cLMA group and we found no statistically significant differences in heart rate, SBP, DBP and mean BP in both the groups.

The oxygen saturation which is recorded at different intervals in our study on both the groups (i-gel and cLMA) remained 100%.

To conclude, i-gel and cLMA are effective and safe devices for use in children. They were comparable for hemodynamic and ventilatory parameters.

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