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Comparison of Hemodynamic Changes Associated with Insertion of three Different Supraglottic Airway Devices (Classic LMA Vs PLMA Vs I-Gel) in Anaesthetized Paralyzed Patients

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Abstract
Background: *Supraglottic airway devices(SAD) have created a niche in the field of airway management. Furthermore, they create less hemodynamic alterations as compared to endotracheal intubation using direct laryngoscopy. The present study was designed to assess these changes while insertion of three different SAD – classic LMA, Proseal LMA & I-gel.*
Methods: *This prospective randomized study was conducted in 150 adult patients of either sex belonging to ASA status I & II undergoing surgery under general anaesthesia. The patients were randomized into three groups of 50 patients each depending upon the device used - group C(classic LMA), group P(PLMA) and group I(I-gel). Standard anaesthesia protocol comprising of propofol, vecuronium, isoflurane, nitrous oxide and fentanyl was followed. Changes in heart rate and blood pressure while insertion and removal of device were continuously monitored and recorded at various time intervals. Success rate, time taken for insertion and perioperative complications were also noted.*
Results: *Slight increase in heart and blood pressure was noted in all three groups (group P>group C>groupI) but they were not different statistically. Within 5-10mins of insertion these alterations were settled. There was only one failure in group C and first attempt success rate was higher in I-gel group. Postoperative complications were slightly more in group P.*
Conclusions: *Our study suggest that all three SAD(cLMA, PLMA, I-gel) cause similar hemodynamic disturbances but I-gel has higher success rate, take less time for insertion, associated with less perioperative complications and lead to comparatively less pressor response.*
Keywords: *general anaesthesia, hemodynamics, supraglottic devices,*

Introduction

The cardiovascular alterations associated with laryngoscopy and intubation have been recognized since long. They occur due to reflex sympathetic discharge in response to laryngotracheal stimulation. These effects are deleterious in susceptible individuals like hypertensive and cardiac patients since they may lead to myocardial ischaemia, heart failure and stroke.[1-3]

Supraglottic airway devices have proved a revolutionary development in the field of airway management.[4] Their insertion do not require laryngoscopy, therefore pressor response is attenuated.[5,6] There are several types of such devices but the most commonly used are classic laryngeal mask airway (cLMA), Proseal laryngeal mask airway(PLMA), and I-gel. All three of them have certain unique features and the effects of their insertion on hemodynamics are not well addressed in the literature. Hence the present study was planned with null hypothesis that all the three devices will cause similar cardiovascular alterations. The primary objective was to assess changes in hemodynamics while their insertion at the beginning of surgery and removal at the time of recovery. The secondary objectives were to assess success rate and complications if any occurred.

Materials and methods

After obtaining approval from institutional research committee and informed consent from patients, 150 adult patients(age-18-65yrs), of either sex having American society of anesthesiologists(ASA) physical status I or II scheduled to undergo elective surgery under general anaesthesia were enrolled for the study. Exclusion criteria were patients with anticipated difficult airway, mouth opening less than 2.5cm, BMI>30 and patients at the risk of aspiration. During preanaesthetic checkup a day prior to surgery, a detailed clinical history was obtained and thorough physical examination was carried out. Routine investigations were carried out and patients were kept fasting 6hrs prior to surgery and tablet alprazolam 0.25mg at night and tablet ranitidine 150mg at night and 2hrs preoperatively were given.

On arrival in the operating room, the patients were made to lie supine with a pillow 7cm below the head. Routine monitors such as heart rate, ECG, noninvasive blood pressure and pulse oximetry were attached and intravenous access obtained and ringer lactate solution started. Preoxygenation for 3mins was done and induction of anaesthesia was carried out with injection propofol 2-3mg/kg and after confirming face mask ventilation inj vecuronium 0.1mg/kg was administered. Mask ventilation continued for 3mins with oxygen in 1% isoflurane, followed by insertion of supraglottic airway device as per the group allotted according to computer generated randomization number.
Group C – cLMA inserted using digital technique
Group P – PLMA inserted using introducer tool technique
Group I – I-gel inserted using digital technique

The sizes selected were 3 or 4 according to patient's weight. All the insertions were done by one investigator who had experience of more than 25 insertions of each supraglottic airway device. Insertions were done in sniffing position of the patients and water soluble jelly was applied on pharyngeal surface of device. The correct placement was judged by seeing chest inflation, auscultating breath sounds and $EtCO_2$ curve when patient's lungs were ventilated with bag-mask. A maximum of three attempts were allowed and in case of failure, conventional direct laryngoscopy was done to secure airway. The case was taken as failure and excluded from further study. The time taken for insertion was defined as time from holding the device in hand till appearance of square capnograph trace on the monitor.

Hemodynamic monitoring was done continuously and recorded at various intervals (baseline, after induction, before insertion, after insertion and 1, 3, 5 and 10mins after insertion). Maintenance of anaesthesia was done with oxygen (35%) and nitrous oxide(65%) in isoflurane(0.8%). For intraoperative analgesia fentanyl (2mcg/kg) and for neuromuscular relaxation inj vecuronium(0.02mg/kg) were administered. Intravenous fluid was given as per standard protocol. After completion of surgery, neuromuscular relaxation was reversed with inj glycopyrrolate(0.01mg/kg) and inj neostigmine(0.05mg/kg). The airway device was removed once the patient became fully conscious and the vitals were recorded after removal, 1, 3 & 5 mins after removal. Any complication such as blood stained device, oropharyngeal injury, cough, sore throat if occurred were noted.

Statistics - The entire data was entered in MS-excel file. The parametric data was expressed in mean±standard deviation and range. The categorical data was expressed in number and percentage. Kolmogorov Smirnov test was used to test whether the data was normally distributed. All the data was normally distributed. One-way ANOVA test was used to compare parametric data between the groups and Kruskalis-wallis test for categorical data. Repeated measures ANOVA was used to test hemodynamic changes in a group over various time interval. The entire data was analyzed using SPSS software package 17 (Chicago, IL) and p value less than 0.05 was considered as significant.

Results

The demographic profile of the patients is depicted in table I and the data was comparable in all groups($p>0.05$). Majority of patients in all groups were ASA-I. There were 4,3 & 5 hypertensive patients in group C, P & I respectively but none of them was on betablockers. Table 2 shows the surgery patients underwent in various groups (most common was open cholecystectomy in all groups). This data was also comparable. The intraoperative details are shown in table 3. There was one failure in classic LMA group while other two groups had 100% success rate though first attempt success rate was higher in group I. There was slight difference in time taken for insertion of device; shortest in I-gel group but it was statistically non- significant. The changes in heart rate, systolic blood pressure & diastolic blood pressure over various time intervals is shown in figure 1,2 & 3 respectively. After induction of anaesthesia there was slight decrease in hemodynamic parameters in all groups followed by increase at the time of insertion which came down to normal values within 5 to 10 mins of insertion. The increase was however comparable between three groups. Similar changes were noted at the time of removal of device after completion of surgery. The postoperative complications as shown in table 4 were slightly higher in group P.

Table 1. Demographic profile of patients. Age, height & weight expressed in mean±SD. ASA, gender & mallampati grade expressed in number and percentage.

	Group C(n=50)	Group P(n=50)	Group I(n=50)
Age(in yrs)	38.6±10.1	39.78±11.1	36.0±10.66
Gender M/F	29(58%)/21(42%)	24(48%)/26(52%)	22(44%)/28(56%)
Height(in cm)	160.8±4.5	162±4.8	161±5.5
Weight(in kg)	57.0±9.0	59.2±10.1	56.8±9.8
ASA I/II	38(76%)/12(24%)	40(80%)/10(20%)	35(70%)/15(30%)
Mallampati grade I/II	31(62%)/19(36%)	32(64%)/18(36%)	30(60%)/20(40%)

Table 2 Distribution of patients shown as per the surgery performed. Data expressed in number and percentage.

	Group C(n=50)	Group P(n=50)	Group I(n=50)
Open cholecystectomy	20(40%)	24(48%)	21(42%)
Pyelolithotomy	4(8%)	2(4%)	3(6%)
Hysterectomy	10(20%)	12(24%)	14(28%)
Upper limb surgery	8(16%)	7(14%)	8(16%)
Others(squint, hernia etc)	8(16%)	5(10%)	4(8%)

Table 3 Intraoperative details of the patients. Data expressed in number & percentage or mean±SD

	Group C(n=50)	Group P(n=50)	Group I(n=50)
Success Ist/IInd/IIIrd attempts	40(80%)/7(14%)/2(4%)	43(86%)/5(10%)/2(4%)	48(96%)/2(4%)
Failure	1(2%)	nil	nil
Time taken for insertion(in secs)	18.7±1.8	16.11±2.3	15.04±1.1
Duration of surgery (in mins)	68.4±10.1	65.7±11.1	69.8±10.5

Table 4 Postoperative complications

	Group C	Group P	Group I
Trauma to oral cavity	2(4%)	2(4%)	1(2%)
Bld stained device	-	2(4%)	-
Sore throat	1(2%)	-	-
Cough	2(4%)	3(6%)	1(2%)
Nausea & vomiting	1(2%)	-	-

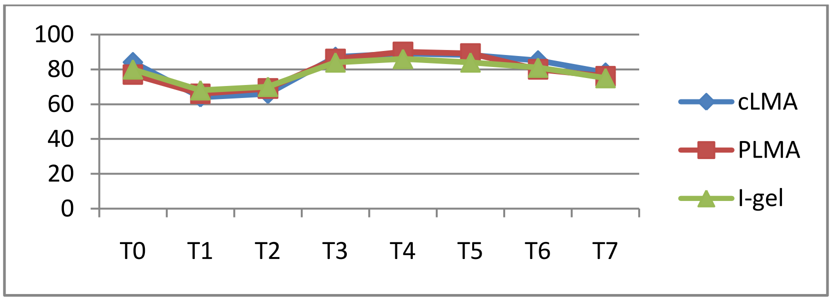

Fig. 1: Variation in heart rate(bpm) in three groups at various time intervals*

Time intervals* are T0 (base line), T1 (After induction), T2 (Before insertion), T3 (After insertion) , T4 (1 min after insertion), T5 (3 min after insertion), T6 (5 min after insertion), T7 (10 min after insertion)

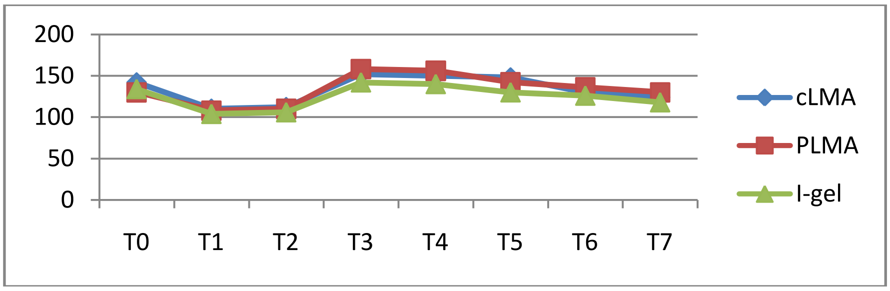

Fig. 2: Variation in Systolic blood pressure(mmHg) in three groups at various time intervals*

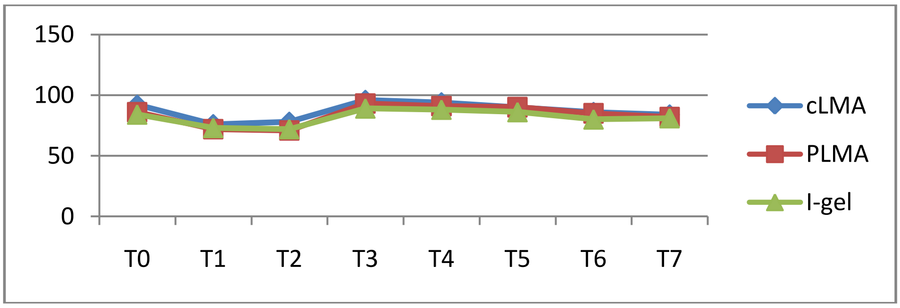

Fig. 3: Variation in Diastolic blood pressure(mmHg) in three groups at various time intervals*

Discussion

Ever since introduction of LMA by AIJ Brain in 1989, supraglottic airway devices have come a long way and become indispensable part of airway management.[7,8] In order to overcome limitations of cLMA, PLMA came into existence in2000. It has modified double cuff to improve seal around the glottis and a drain tube to provide a channel for aspirating gastric contents. But it too had few disadvantages like difficulty in insertion and high cost.[9] Dr MA Nasir in2007 developed I-gel which is soft, noninflatable made up of gel like thermoplastic elastomer. It fits snugly onto the perilaryngeal framework. It too has conduit for gastric channel.[10] All the devices may look similar but they possess certain structural differences, hence compared frequently in terms of their clinical performance and efficacy.

We found that pressor response occurred in all three groups while insertion and removal of the device. During passage through the oral and pharyngeal space, the pressure is exerted on the mucosal surface which is transmitted to the brain through trigeminal, glossopharyngeal and vagus nerves. These nerves carry the afferent impulses to the vasomotor centre which in turn activates the sympathoadrenal system to release catecholamines resulting in increased cardiac output. The responses are maximal during stimulation of epipharynx, whereas the response arising from the stimulation of tracheobronchial tree is least marked.[11] Least perturbations in vitals were noted in I-gel group probably due to its soft structure which caused less stimulation of oral cavity. PLMA caused maximum increase in heart rate and blood pressure. We used introducer tool technique as described by manufacturer.[12] Introducer tool is rigid and makes the device bulky which may result in more pressure on oropharyngeal cavity. This seems similar to a finding by Keller in which pressure exerted on oral mucosa by intubating laryngeal mask airway was measured and found to be high. It was attributed to its bulky and rigid structure.[13] Statistically and clinically these hemodynamic changes were nonsignificant. At the time of removal slight transient increase in heart and blood pressure was seen in all groups which was probably triggered by pharyngeal stimulation during reverse rotation of the cuff.[6]

LMA causes less response in comparison to conventional direct laryngoscopy and intubation because force exerted by laryngoscopic blade is absent.[6,13] Hemodynamic changes associated with LMA insertion are similar to those of guedel's airway and less than those with SLIPA.[14,15] Insertion of PLMA is known to cause non-significant pressor response.[16] Both the techniques of its insertion – digital as well as introducer tool technique are similar in terms of hemodynamic changes.[17] We however used introducer tool technique which is most commonly used and prescribed by manufacturers. In a recent study by Jindal et al, I-gel insertion was found to be more hemodynamically stable as compared to LMA and SLIPA. But the authors carried out insertions in anaesthetized nonparalyzed patients unlike our study where we used neuromuscular blockade prior to insertions.[18] All the insertions in our study were done by experienced anaesthesiologist, thus use by novice cannot be commented. They might take a longer time for insertion and hence lead to more cardiovascular alterations.

Success rate was similar in all three groups. Though first attempt success rate was more in I-gel group because it is easier to insert due to its gel like soft structure and there is less chances of downfolding of tongue.[18] The time taken for insertion was maximum in LMA group probably it took longer time manipulating it in deflated form followed by its inflation.

Supraglottic airways may cause injury and trauma to oropharyngeal cavity while their passage through it. Contributing factors are device type, size, insertion technique and cuff pressure.[4] We found that postoperative complications were more in PLMA group. Most likely it was due to use of rigid introducer. Device materials with extreme low coefficients of friction such as I-gel are associated with fewer injuries.

There were few limitations of the study. First, we used non-invasive methods of blood pressure measurement. Invasive arterial BP monitoring is considered better but it was inappropriate to put arterial line in ASA I & II patients undergoing routine surgeries. Second, the person could not be blinded to the device used. Though, the vital monitoring was done by other anaesthetist who was blinded to the procedure and device used. Third, catecholamine levels should have been measured but they were not available at our institute. Fourth, we enrolled only ASA I & II patients, patients with uncontrolled hypertension may exhibit different responses. Use of beta blockers may attenuate increase in heart rate; but in our study none of the patient was on beta blocker.

sThe present study lead us to conclude that all three supraglottic airway devices (cLMA, PLMA, I-gel) cause slight hemodynamic changes while their insertion and removal in anaesthetized paralyzed patients; least being in the I-gel group. Moreover, latter has more success rate, quick to insert and associated with less postoperative complications.

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