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A Prospective Randomized Comparative Study of the Clinical Performance of I-Gel and LMA classic Supraglottic Airway Devices in Nonparalysed Anaesthetized Adults Undergoing Elective Surgical Procedures

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ABSTRACT

Background and Aim: Several clinical studies have been performed on supraglottic airway devices to check for the advantages over the latest versions. Comparison of classic LMA (cLMA) and i-gel is yet to be explored further to optimize the use of airway devices.
Methodology: A prospective randomized study was conducted for two years in a tertiary care hospital. Selected 60 patients were divided equally into two groups, C-LMA (group 1) and i-gel (group 2). Both devices were compared with respect to ease of insertion, number of attempts for insertion, airway leak pressure, hemodynamic changes and complications.
Results: There was no observed statistical significance in both the groups regarding age, sex, body weight, ease of insertion, number of attempts, basal heart rate, SBP, DBP, MAP, SpO2 and adverse effects. The mean time duration of insertion was 23.2 ± 7.14 in cLMA and 16.67 ± 4.2 in i-gel which was statistically significant (p=0.001). Airway leak pressure was significantly higher in i-gel group (p=0.001) in the present study.
Conclusion: Both the devices are safe and good in performance with respect to ease of insertion, hemodynamic changes and pharyngolaryngeal morbidity. Mean time duration was less for i-gel which is easier method to perform. A significant gastric insufflation was low in i-gel over c-LMA.

Keywords: Laryngeal mask airway; I-gel; Supraglottic airway device

INTRODUCTION

Endotracheal intubation is the regular procedure followed for delivering anaesthesia for various types of surgeries, foreign body removal from the airways, to visualize the abnormalities in airways, so on and so forth. The process typically is sensitive that it may sometimes lead to complications like distortion of upper airway while reaching the glottis. [1] Further, endotracheal intubations are comparatively complex to perform in facial trauma and high larynx patients. [2] Supraglottic airway device (SADs), a novel invention by Brain A, et al. [1993] has become revolutionary alternative solution to overcome the aforesaid issues by filling the airway gaps and improving the ease of tracheal intubation. [3] These SADs are designed so ergonomically that they provide more safety by reducing the risk of aspiration and offer better pharyngeal sealing. [4] After first invention of SADs in 1983, many modifications have been made to achieve the currently available models i.e. intra and extraglottic airway devices to be suitable for use both in elective and emergency situations. Down the line various companies developed individual designs and registered their own trademarks based on these

models. The initial model of laryngeal mask was introduced in 1987 with the registered trademark classic LMA (laryngeal mask airway) and the subsequent developments were released with names like LMA ProSeal, LMA FasTrach, or the LMA Supreme, LMA Unique, etc. Each SAD has its own unique feature to it. One of the best models following the existing first generation model with major improvements and better performance is i-gel. [5]

One of the major applications of LMAs is to open the airway while administering anesthesia including saving those patients with breathing difficulty. In several cases it is reported that LMA device has been successful in restoration and maintenance of airway over the mask ventilation device both in adult and children. [6-9] Apart from the ventilation, LMAs are also used in handling endotracheal tube associated complications. A major considerable limitation of using LMA is that even if it is correctly positioned, it does not reliably protect the lungs from regurgitated stomach contents. It is estimated that the incidence of aspiration with LMA was 0.02% which is analogous to the tracheal intubation in elective patients. [10] Recent advancements in LMA models contain gastric tubes which may prevent the risk of aspiration. [11]

Another evolution in SAD development in recent times is i-gel which is being widely used across the globe for delivering anesthesia and resuscitation. It is manufactured with medical grade thermoplastic elastomer called styrene ethylene butadiene styrene that conforms to the laryngeal, perilaryngeal, and pharyngeal anatomy.

I-gel also succeeded in minimizing the risk of tissue compression, trauma, and difficulty in insertion, and thus could achieve post insertion stability with inbuilt bite block. [12] This device typically seals laryngo-pharyngeal space with no air being inflated and has an additional esophageal lumen. This additional esophageal lumen offers superior protection in patients with internal risk of aspiration. [13]

There were several comparative clinical studies to understand the differences, advantages, and disadvantages between proseal LMA and i-gel. Comparison of classic LMA (cLMA) and i-gel is yet to be explored further to optimize the use of airway devices. The present prospective randomized study is more focused on the comparative analysis of LMA and i-gel SGDs with respect to various parameters to understand, conclude and recommend the prospective device for securing the airway.

METHODOLOGY

Ethical Committee Approval

The present randomized study was conducted in a tertiary care hospital. The study was conducted for two years after obtaining ethical committee clearance as well as informed consent from all patients.

Study Design

After all the approvals 60 patients of either sex were randomly chosen. The patients of age group 18-80 years who were undergoing different elective surgeries with general anesthesia classified to ASA grade I and II were included in the study. Patients were divided into two groups, 30 in each with the help of a computer-generated table of random numbers (Microsoft Excel) by simple randomization method. Group 1 as classic LMA and Group 2 as i-gel. Patients with emergency surgeries, head and neck surgeries, those with mouth opening <2.5 cm, any pathology of the neck and upper respiratory tract or upper alimentary tract, patients at risk of aspiration i.e. full stomach, hiatus hernia, GORD, and obese patients with BMI >25 kg/m^2 were excluded.

Study Procedure

All the selected patients were evaluated for pre-anesthetic examination and checked for their CBP, standard 12-lead electrocardiogram, screening chest X-ray, blood sugar, serum creatinine, and viral screening. Previous night of surgery, all the

patients were premeditated with Tab. Alprazolam-0.5 mg and Tab. Ranitidine 150 mg orally at bed time. They underwent 12 hr fasting except clear fluids up to 2 hrs before anesthetic induction. Metoclopramide 10 mg iv and ranitidine 50 mg iv was given half hour before the surgery. In the operating room, an 18-gauge intravenous cannula was inserted under local anaesthetic infiltration and an infusion of ringer lactate was started for all the patients. Head was placed on a soft pillow of 10 cms height before induction of anesthesia with the neck flexed and head extended. The patient was connected to multiparameter monitor and the baseline systolic, diastolic blood pressure, mean arterial pressure, heart rate and SPO_2 were recorded.

c-LMA was used in Group I patients and the size of the device was decided by anesthetist based on patient's body weight and manufacturer's recommendation. The size 3 classic-LMA for patients weighing 30- 50 kgs, size 4 for 50-70 kgs and size 5 for patients of >70 kgs were used. The i-gel supraglottic airway was used in Group 2 patients. Size 3 for patients weighing between 30-50 kgs and size 4 between 50-80 kgs. The standard pre use tests for both devices were performed. Both devices were lubricated using lignocaine jelly on the tip and posterior surface as recommended by the manufacturer and the c-LMA fully deflated prior to insertion. After recording the baseline reading, the patient was preoxygenated with 100% oxygen for 3 minutes via a face mask with Bain's circuit.

The patient was premedicated with injection Fentanyl 2 μg/kg body weight and ondansetron 4 mg iv. Intravenous lignocaine (2%) 2 ml was given to prevent pain on injection of propofol. Anesthesia was induced with propofol 2 mg/kg body weight. Before inserting the device as per manufacturer's instruction, mask ventilation with O_2 & sevoflurane 2% with additional doses of propofol, if required, was done until optimal conditions for insertion were obtained (jaw relaxation, no movement). Induction of anesthesia was confirmed by loss of verbal communication with the patient. The patient's head was placed in 'sniffing the morning air' position.

The lubricated i-gel was grasped along the integral bite block and introduced into the mouth in the direction towards the hard palate and glided downwards and backwards along the hard palate until definite resistance was felt. The device was connected to breathing circuit and patient ventilated manually. The lubricated c-LMA was introduced in the classic method introduced by Dr. Archie Brain and the recommended volume of air was introduced into the cuff. (20 ml, 30 ml, 40 ml of air for size 3, 4, 5 size LMA respectively). An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, normal end tidal CO2 and stable SpO2 (>95%). The device was secured with adhesive tape. Bite block was kept in case of c-LMA and secured along with it with adhesive tape. Anesthesia was maintained with O2, N2O and 2% sevoflurane inhalation with spontaneous ventilation and analgesia with morphine 0.05mg/kg iv and paracetamol 1g iv.

At the end of the procedure, the patient remained in the supine position and the device removed after the patient was fully awake. The patient was inspected for any injury of the lips, teeth or tongue, observed for laryngospasm /bronchospasm /cough at extubation and the device inspected for any blood stain. Patient was interviewed for any post operative complications like sore throat. Both the groups were analyzed for ease of insertion (easy, very easy, and difficult), time of insertion, number of insertion attempts, airway leak pressure and hemodynamic parameters (heart rate, systolic & diastolic BP, mean arterial pressure, Saturation SpO_2) and adverse effects.

Statistical Analysis

For the present study Independent-Samples 't' test, Two proportions z-test, and Mann-Whitney U Tests were performed using SPSS software version 16.0. And the p

<0.05 was considered as significant and p <0.01 was considered as highly significant.

RESULTS

Age group

Age in both the study groups was between 18 to 80 years. The maximum age group in c-LMA was 70 yrs and its 79 yrs in i-gel. The mean age in group 1 was 44.7 ± 11.6 and 44.87 ± 17.1 years (Figure 1) in group 2. When calculated for statistical significance, the results showed no significance (p = 0.958) in both the age groups.

Sex Distribution

It was observed that majority of the patients were female (47%) in cLMA group and male (60%) in i-gel group. Statistically there was no significant difference with respect to the gender in both the groups (Figure 2).

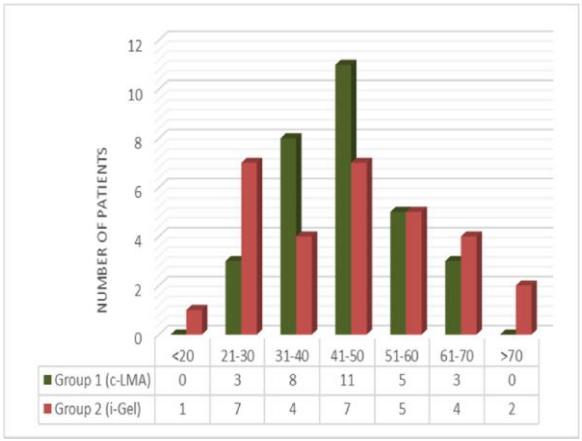

Figure 1: Showing the age distribution.

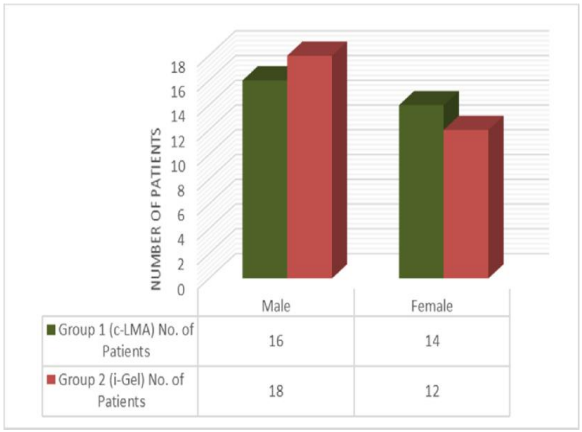

Figure 2: Showing the sex distribution between Group 1 and Group 2.

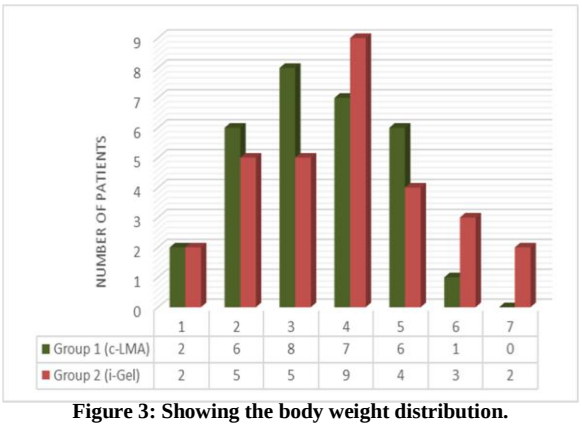

Figure 3: Showing the body weight distribution.

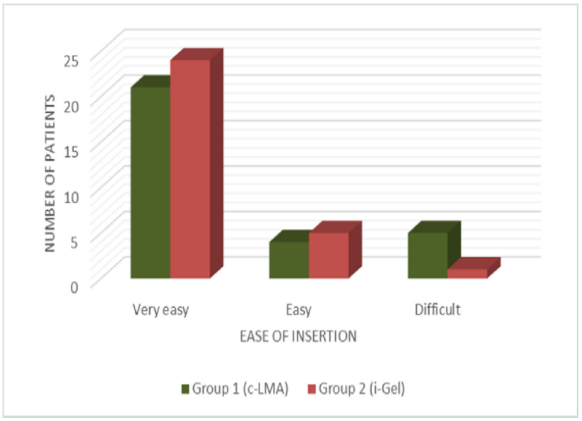

Figure 4: Showing comparison of ease of insertion.

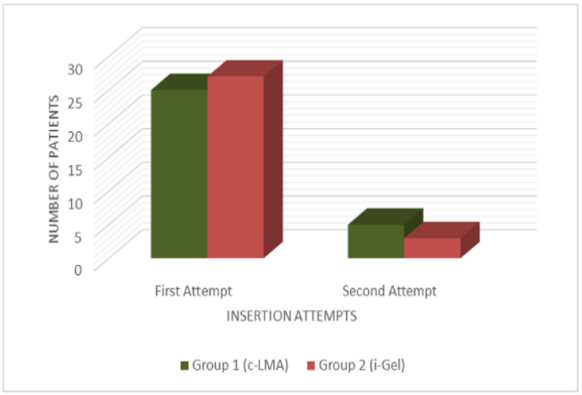

Figure 5: Showing number of attempts of insertion of devices.

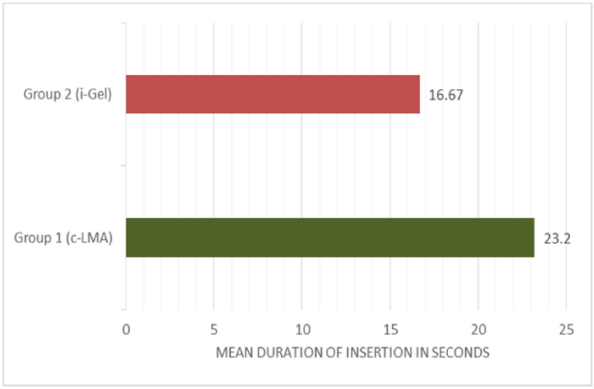

Figure 6: Showing the mean duration of insertion in both groups.

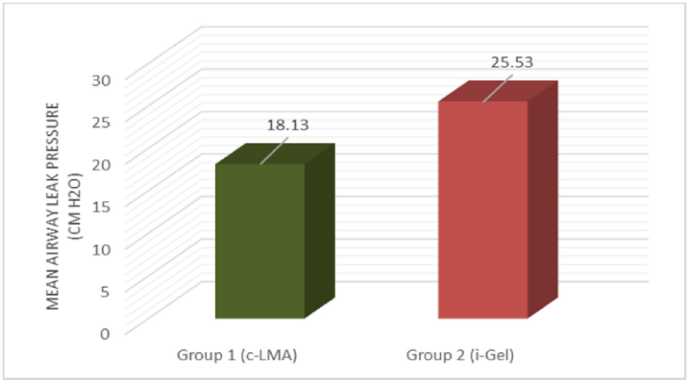

Figure 7: Showing the airway leak pressure.

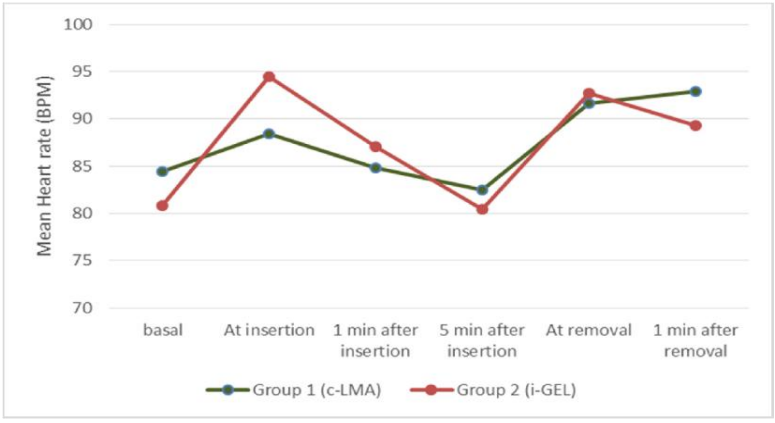

Figure 8: Showing the intergroup comparison of mean heart rate (bpm) changes in response to insertion of i-gel in group 2 and c-LMA in group 1 patients.

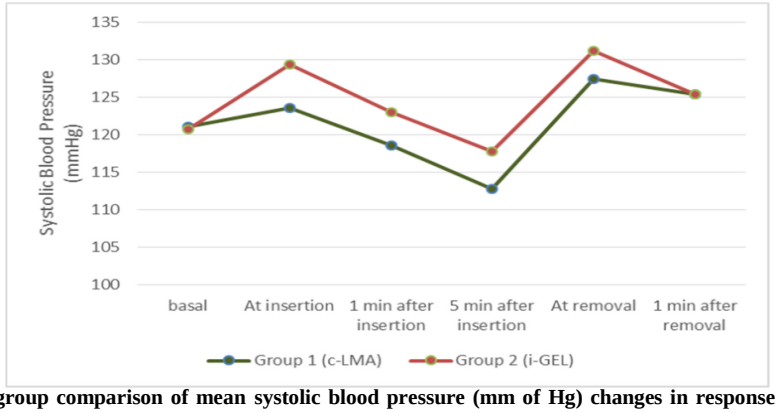

Figure 9: Showing the intergroup comparison of mean systolic blood pressure (mm of Hg) changes in response to insertion of c-LMA in group 1 and i-gel in group 2 patients.

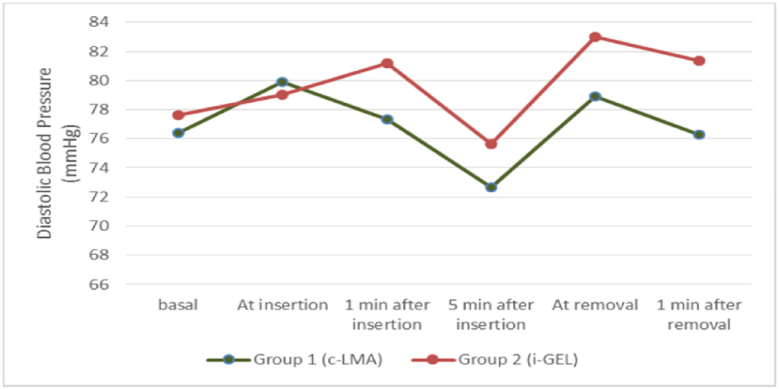

Figure 10: Showing the intergroup comparison of mean diastolic blood pressure DBP (mm of Hg) changes in response to insertion of c-LMA in group 1 and i-gel in group 2 patients.

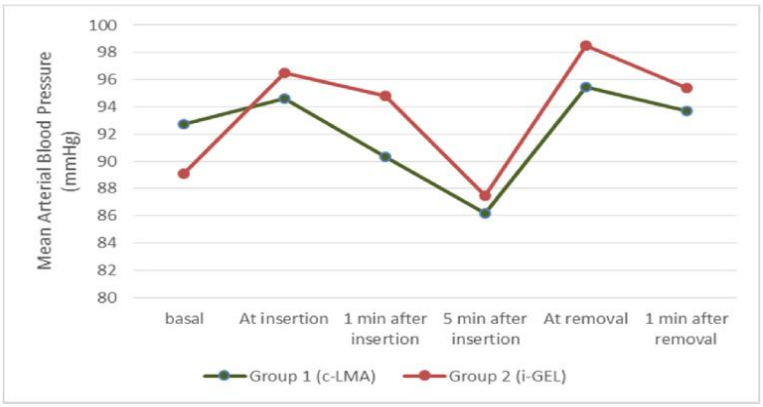

Figure 11: Showing the intergroup comparison of mean arterial blood pressure MAP (mm of Hg) changes in response to insertion of c-LMA in group 1 and i-gel in group 2 patients.

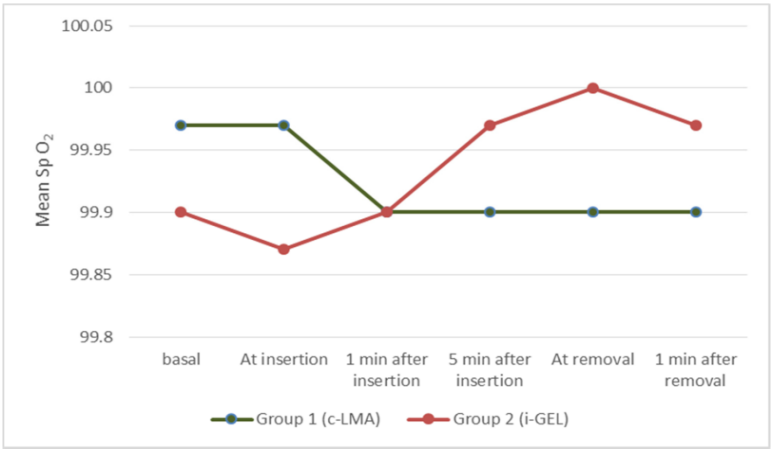

Figure 12: Showing the intergroup comparison of oxygen saturation (%) changes in response to insertion of c-LMA in group 1 and i-gel in group 2 patients.

Table 1: Adverse effects of the cLMA and i-gel device in both the groups.

	Group 1 (c-LMA)		Group 2 (i-GEL)			
Adverse effects	No. of Patients	Percentage	No. of Patients	Percentage	p-vlaue	
Injury to lips/teeth/tongue	1	3%	2	7%	0.552	Not Significant
Bronchospasm/ laryngospasm/ cough at extubation	1	3%	1	3%	1	Not Significant
Blood staining	3	10%	1	3%	0.296	Not Significant
Post operative sore throat	1	3%	1	3%	1	Not Significant

Body weight

Minimum body weight of the patients in both groups was observed to be 40 kgs. Highest body weight was seen in 2 patients (7%) in i-gel with 132 kgs, whereas in case of cLMA maximum body weight was 90 kgs. The mean body weight in Group 1 was 68.6 ± 12.17 kgs and in Group 2 it was 72.5 ± 19.12 kgs. No significant difference in the body weight of patients between the Group 1 and Group 2 (p=0.355) was observed (Figure 3).

Ease of Insertion

Compared parameters in both the groups were very easy, easy and difficult insertion. In cLMA device 70% of the times insertion was very easy, 13% of the times easy, 17% of times difficult, whereas in i-gel 80% of the data fell in very easy category, 17% easy and 3% were difficult (Figure 4). Though there was found difference in ease of insertion in the devices, there was no observed statistical significance (p = 0.416) in both the groups.

Number of Attempts

In cLMA group 83% of the patients required only first attempt and 27% required second attempt. Whereas in i-gel group 90% of the patients succeeded in first attempt and only 10% of them required second attempt (Figure 5). Though it was found that usage of i-gel device was more comfortable over the cLMA device, no statistical significance was noticed ($p = 0.445$).

Time Duration of Insertion

It took 23.2 ± 7.14 seconds of mean time duration for the cLMA device in group 1 and 16.67 ± 4.2 seconds of mean duration in i-gel group 2 patients (Figure 6). It was observed that less time was taken for i-gel insertion which was statistically significant with $p = 0.001$.

Airway Leak Pressure

Mean airway leak pressure in the cLMA was 18.13±3.27 (cm H_2O) and 25.53±3.71 (cm H_2O) in i-gel device (Figure 7). The results were statistically significant with $p = 0.001$.

Basal Heart Rate

The heart rate in both the groups were observed at different intervals i.e. at the time of insertion of the device, 1 min. of insertion, 5 min. of insertion, at removal and 1 min. after removal. Mean heart rate was 84.4, 88.43, 84.83, 82.5, 91.63, and 92.93 BPM at basal, 1 min, 5 min. of insertion, removal and 5 min after removal in group 1 patients respectively. Similarly in group 2 the mean heart rate was 80.83, 94.5, 87.1, 80.47, 92.67 and 89.27 BPM at basal, 1 min, 5 min. of insertion, removal and 5 min after removal respectively. It was observed that the heart rate was slightly increased at the time of insertion in group 2 patients and gradually decreased after 5 mins (Figure 8). Again there was an increase at the time of removal in both the groups and came down to normal rate after 5 minutes.

Systolic Blood Pressure (SBP)

Similar to the heart rate SBP was also recorded at basal, at the time of insertion, 1 and 5 mins after insertion, at the time of device removal and after 5 mins of removal. The data was correlated with the heart rate in increasing SBP at the time of insertion, removal and gradual decrease after that (Figure 9). Statistical evaluation between the groups showed no significant difference in SBP changes between group 1 and group 2 during the insertion of c-LMA or i-gel.

Diastolic Blood Pressure (DBP)

In group 2, it was observed that mean DBP increased after 1min of insertion whereas decreased in group 1 patients (Figures 10). Later it was decreased in both groups to 72.63 and 75.63 mean mm of Hg in group 1 and 2 respectively.

Mean Arterial Blood Pressure (MAP)

Mean arterial blood pressure was gradually decreased from the time of insertion till the time of removal. There was an increase in both the groups at the time of removal and came to normal after 5 mins (Figure 11). In this particular parameter MAP behavior was observed to be same at the set time intervals.

Oxygen Saturation Changes (SpO_2)

In group 1, at basal and insertion time mean SpO_2 percentage was 99.95, then a decrease after 1 min of insertion to 99.9% and the same was maintained up to one minute after removal (Figure 12). A complete contrast result was observed in case of group 2 i-gel patients, where a gradual increase in percentage of SpO_2 after one minute of insertion was seen from 99.9 to 100%. But no statistical significant difference was seen in between the groups.

Adverse Effects

After completion of the surgery all the patients in both the groups were checked for the adverse effects. In group 1, lip injury, bronchospasm, and post operative sore throat was seen in 3% of the patients, blood staining in 10% (Table 1). Whereas in group 2, lip injury in 7%, bronchospasm, blood staining, and postoperative sore throat was seen in 3% of the patients. However, all the incidents were not statistically significant in both the devices.

DISCUSSION

Extensive knowledge on alternative airway devices plays a decisive role in controlling the airway during anesthesia for the patients at a risk of difficult intubation or ventilation. Though the problem is not common in majority of the cases, it is advisable to be prepared for the alternative airway device during anesthesia administration to avoid possible risk of critical intubation. [14,15] A comparison between first generation classic LMA and second generation i-gel SADs in present case with respect to ease of insertion, number of attempts for insertion, airway leak pressure, hemodynamic changes and complications has been carried out in a prospective methodology.

LMAs are used to ventilate patient's lungs during anesthesia but often associated with a less effective seal when compared to the conventional tracheal tubes. I-gel is a novel supraglottic airway device introduced for clinical practice in 2007 by Dr. Muhammed Aslam Nasir. In the present study, it is observed that i-gel performance is superior to the cLMA with respect to the duration of insertion and airway leak pressure.

A comparative study conducted by ElGohary MM, et al. [16] between cLMA, proseal LMA, and i-gel, concluded that i-gel was easier in insertion with better fiberoptic view than the other two devices. The incidence of blood stains on the devices was found to be in 2 patients for i-gel, 6 for P-LMA and 5 for cLMA. The present study reported 3 of cLMA patients with blood stains on the device and only one in the case of i-gel. An ideal result was seen in the study by Richez B, et al. [17] on 72 women, with no blood stain after the removal of i-gel and concluded that i-gel is a reliable device with adequate seal and easy insertion. All the three studies have analogous results with the present study and strengthen the recommendation of i-gel as the best available device to use in nonparalysed anaesthetized patients undergoing elective surgeries.

When the time taken for the insertion is compared, the i-gel took lesser time (16.7 sec.) than cLMA (23.2 sec.) which has made it more time efficient. Analogous results were observed with 29.32 sec in i-gel and 36.72 sec in cLMA in a study by Guptha P, et al. [18] Also the air leak pressure in the present study showed that in the i-gel group it was higher when compared to the cLMA group which is statistically significant with $p<0.001$. This indicates that the sealing capacity of i-gel made of thermoplastic elastomer is better and it fits better in supraglotic anatomy since it is a second generation device with advanced technology. Much of the literature says that both the devices are more or less same in performance yet i-gel has emerged as the preferable device over cLMA in majority of the cases. [19]

Hemodynamic changes like HR, SBP, DBP, MAP, SpO_2 were also calculated at different time points. No statistically significant difference in both cases was observed in all the parameters which are in line with the Helmy A, et al. and Franksen H, et al. Studies. [20,21] In a research by Jindal P et al., [22] it was observed that i-gel produced less hemodynamic changes compared to other SADs. In this particular study the authors concluded that despite the lack of an inflatable cuff, i-gel effectively conformed to the perilaryngeal anatomy. And thus it achieved proper positioning for supraglottic ventilation consistently causing less hemodynamic changes when compared to the existing supraglottic airway devices such as c-LMA.

Post surgical complications such as sore throat, lip injury, and blood stains were compared between cLMA and i-gel. There was no statistical significance observed in any of the postoperative parameters, but one patient among 30 in cLMA group had lip injury, 1 bronchospasm, and 3 cases had blood stains. One patient in both the groups was having sore throat that did not require any treatment. The same results were correlated with the other three studies done by Helmy AM, et al., [20] Fanksen H et al.,

[21] Siddiqui AS, et al. [23] Nevertheless these three studies also reported nausea and vomiting which was significantly higher in LMA due to high incidence of gastric insufflations.

CONCLUSION

Performing comparative studies of the efficiencies of the biomedical devices is a regular process in clinical practice to achieve better results and give effective treatment to the patients. The current comparative prospective study provides deeper insights into the potential contributing parameters like ease of insertion, time of insertion, airway leak pressure, hemodynamic changes and adverse effects of two majorly used SAD devices cLMA and i-gel. By interpreting the current results we could conclude that i-gel's performance is better with respect to airway sealing pressure, and the time for insertion. Both the devices are safe and good in performance with respect to ease of insertion, hemodynamic changes and pharyngolaryngeal morbidity but the better sealing pressure and lesser time for insertion of i-gel in nonparalysed anaesthetized adults undergoing elective surgical procedures make it the recommendable SAD device.

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