Original Article

Comparison between LMA ProSeal and I-gel airway in anesthetized patients on spontaneous ventilation during daycare procedures: A prospective randomized study

ABSTRACT

Background: General anesthesia remains the most popular technique for ambulatory surgeries with patients, surgeons, and anesthesia providers. The supraglottic airway (SGA) devices result in fewer incidences of sore throat, laryngospasm, coughing, and hoarseness as compared to inserting a tracheal tube. This study was conducted to compare two second-generation SGA devices, LMA ProSeal and I-gel airway, in anesthetized patients on spontaneous ventilation during daycare procedures to establish the superior SGA device.

Methodology: This prospective randomized study was done on 90 patients of either sex aged 15–60 years, ASA grade I–II, Mallampatti grade I and II, and BMI between 20 and 30 kg/m^2 scheduled for elective surgeries of duration less than 90 min. Patients were randomly allocated into two groups—group A (I-gel) and group B (LMA ProSeal). Insertion parameters, hemodynamic responses, oxygenation, ventilation, peak airway pressure (PAP), and postoperative complications were recorded. Statistical analysis was done using SPSS version 21.0 statistical analysis software.

Results: Mean insertion time of LMA ProSeal was found to be significantly higher as compared to I-gel (33.27 ± 3.88 vs 18.49 ± 3.18 s; $P < 0.001$). No significant difference was found between the groups in the number of attempts and of operators attempted for insertion, as well as in hemodynamic response, oxygenation, and ventilation. Postoperative complications were lesser in group A.

Conclusion: I-gel is an easy-to-insert cuffless SGA device requiring lesser time for insertion, provides adequate ventilation with lesser postoperative complications and thus appears to be better than LMA ProSeal.

Keywords: Ambulatory surgery, general anesthesia, laryngeal mask airway, peak airway pressure, supraglottic airway device

INTRODUCTION

Ambulatory surgeries have been gaining popularity among patients as well as doctors. General anesthesia remains the most popular technique for ambulatory surgeries with patients, surgeons, and anesthesia providers.[1] The maintenance of a patent airway with adequate ventilation and oxygenation has always been a cornerstone of anesthetic practice. For so many years, endotracheal intubation has been the foundation for management of the airway. But with the advent of supraglottic airway devices (SGA), there has been a shift toward the use of these lesser invasive devices having fewer incidences of sore throat, laryngospasm, coughing, and hoarseness and lesser incidence of associated cardiovascular events as compared to inserting a tracheal tube.[2] SGA is an ideal rescue device for ventilating a patient until the definitive

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airway is achieved and many of the oro-maxillofacial surgeries can be undertaken under general anesthesia using SGA as a conduit.

Both LMA ProSeal and I-gel airway are second-generation SGA devices sharing some common features. Both are reusable devices having an airway tube, an integrated bite block, and a gastric drainage tube.[3] The gastric drainage tube allows for gastric access with an orogastric tube and channels any regurgitated gastric contents away from the airway, effectively isolating the respiratory and gastrointestinal tract.[3]

As there are very few studies comparing LMA ProSeal and I-gel in daycare procedures, this study was undertaken to compare the efficacy of LMA ProSeal and I-gel airway devices in anesthetized patients on spontaneous ventilation during daycare procedures. The primary objective was to compare the ease of insertion between the two devices in terms of the number of attempts and the time taken to insert the device. The secondary objectives were to compare their functions in terms of peak airway pressure (PAP), hemodynamic response (heart rate and mean arterial blood pressure), oxygenation (SpO_2), ventilation ($EtCO_2$), and postoperative complications like post-removal cough, laryngospasm, blood on device, and incidence of aspiration.

MATERIAL AND METHODS

This prospective randomized study was conducted in the Department of Anesthesiology at our institute after obtaining approval from Institutional Ethical Committee (ECR/262/Inst/UP/2013/RR-19) and CTRI registration (CTRI/2020/09/028146). Ethical Clearance was obtained from Institutional Ethical Committee with Ref no 530/Ethics/2020 dated 19.06.2020.

Ninety patients of either sex aged 15–60 years, ASA grade I–II, body mass index (BMI) 20–30 kg/m^2, scheduled for elective surgeries duration less than 90 min, MP grade I and II were included. Patients having any abnormality of the neck, anticipated difficult airway, upper respiratory tract infections, history of obstructive sleep apnoea, history of allergy to one or more drugs and/or latex, cervical spine fracture or instability, increased risk of aspiration (gastroesophageal reflux disease, hiatus hernia, pregnant patients) were excluded from the study. A written and informed consent was taken from all the patients on a specially designed consent form. All the enrolled patients were randomly allocated using a chit-based lottery system into two groups—group A: I-gel insertion and group B: LMA ProSeal insertion.

A pre-anesthetic checkup was done a day before surgery. Patients were advised Tab Alprax 0.25 mg and Tab Ranitidine 150 mg, the night prior to surgery. They were kept NPO according to safe fasting intervals (clear liquids not more than 2 h and 6 h for light meals). On the day of surgery, upon arrival of the patients in the operation theatre, standard monitors were attached which included pulse oximeter, electrocardiogram, noninvasive arterial blood pressure monitoring, continual end-tidal CO_2 analysis, and body temperature monitoring.

The SGA, whichever was used, was first examined for any discoloration, cuts, or tears. The standard pre-use test of deflation/inflation for LMA ProSeal was done and then before insertion, the cuff of LMA ProSeal was fully deflated. A water-soluble jelly was then put on the posterior surface of the devices. Pre-medication was done with inj. Ondansetron 0.1 mg/kg, inj. Midazolam 0.01 mg/kg, and inj. Glycopyrrolate 0.005 mg/kg. Patients were pre-oxygenated with 100% oxygen for 3–4 min. Then, inj. Fentanyl 2 mcg/kg was given. Induction was done with inj. Propofol 1.5–2.5 mg/kg. No muscle relaxant was given. After obtaining adequate depth of anesthesia, which was checked by the absence of a motor response to jaw thrust, the chosen supraglottic airway device, either I-gel or LMA ProSeal, was inserted.[4] The size of the device was decided by the patient's weight and according to manufacturer recommendation. The size charts used for LMA ProSeal and I-gel are shown in Tables 1 and 2, respectively.

For both the SGA devices, the number of attempts taken to insert the device, the time taken for insertion of device, and the number of operators attempted for insertion were recorded. It was decided to abandon the procedure after three failed attempts and to intubate or awaken the patient. The time taken for the airway device insertion was calculated from the start of the insertion of device to the correct placement of the device, which was checked by adequate chest rise and effective end-tidal capnography, after connecting to the Bains circuit. Patients were put on ventilator on spontaneous ventilation. Anesthesia was maintained with 50% oxygen and 50% nitrous oxide and adequate MAC of sevoflurane. Patient's heart rate, systolic and diastolic blood pressure, oxygen

Table 1: Size chart for LMA ProSeal

Size	Weight (kg)
2.5	20-30
3	30-50
4	50-70
5	70-90

Table 2: Size chart for I-gel

I-gel size	Patient's size	Weight (kg)
3	Small adult	30-50
4	Medium adult	50-90
5	Large adult	90+

saturation, and end-tidal CO_2 were recorded at pre-induction, post-induction, at the time of insertion, at every 1 min for 5 min, then at every 5 min for 30 min, and then at the time of removal of the device. PAP generated by the device was also recorded at the same time intervals.

At the end of surgery, the device was removed after the full recovery of airway reflexes such as swallowing and cough reflexes. Incidence of complications like gastric distension, regurgitation, and aspiration was recorded. Any incidence of blood on device, post-extubation cough, breath holding, or laryngospasm was also recorded. Patients were followed up for 24 h for sore throat or any throat discomfort.

Statistical analysis

The statistical analysis was done using the SPSS version 21.0 statistical analysis software. (Released 2012. IBM SPSS Statistics for Windows, version 21.0. Armonk, NY: IBM Corp.)

Continuous data were analyzed by Student's *t*-test. For categorical data, Chi-square test and Fisher's exact test were used. For all analysis, $P < 0.005$ was taken to indicate statistical significance.

Sample size

The sample size was calculated based on the proportion of success in one attempt in two groups in the previous study by Jadhav *et al*.[5] and keeping a Type I error of 0.05 and a power of 90%. A total of 38 patients were required in each group, but 45 were included to compensate for possible dropouts.

RESULTS

A total of 90 patients were initially enrolled. After removing dropouts from each group, 81 patients were left who were randomly allocated between the groups—41 patients in group A (I-gel) and 40 patients in group B (LMA ProSeal) [Figure 1].

Patients from both the groups were comparable in terms of baseline demographic profile, i.e. age, sex, MP grade, ASA grade, anthropometric parameter [Table 3], and types of surgeries [Table 4].

There was no statistical difference in the number of insertion attempts and the number of operators attempted for insertion between the two groups. However, mean insertion time was found to be significantly higher in group B as compared to group A (33.27 ± 3.88 vs 18.49 ± 3.18 s; $P < 0.001$) [Table 5]. Peak airway pressure (PAP) generated was higher in group B as compared to group A at all time intervals, but the values were clinically within normal limits [Table 6].

Table 3: Demographic profile

Parameters	Group A	Group B	*P*
Age (yrs)	31.80±9.79	31.18±10.48	0.78
Gender (male/female)	15/26	15/25	0.912
Mallampatti grade (I/II)	20/21	21/19	0.112
ASA grade (I/II)	34/7	33/7	0.95
Anthropometric parameters			
Height (cm)	151.73±5.80	153.27±6.86	0.35
Weight (kg)	56.00±4.68	54.73±3.88	0.25
BMI in kg/m^2	24.31±1.43	23.34±1.63	0.06

Table 4: Types of surgery

Types of surgery	No. (%)		*P*
	Group A	Group B	
Minor eye procedures	2 (4.87)	3 (7.5)	0.995
Tympanoplasty	8 (19.5)	9 (22.5)	
Examination under anesthesia and cervical biopsy	3 (7.3)	4 (10)	
Diagnostic hysteroscopy	6 (14.6)	5 (12.5)	
Sebaceous cyst excision	2 (4.87)	1 (2.5)	
WLE Phyllodes tumor	3 (7.3)	2 (5)	
Suction and evacuation	7 (17)	8 (20)	
Vaginal wall cyst excision	4 (9.7)	3 (7.5)	
Fibroadenoma excision	6 (14.6)	5 (12.5)	

Table 5: Insertion characteristics

Variables	Group A (*n*=41)	Group B (*n*=40)	*P*
Time for insertion (s) Mean±SD	18.49±3.18	33.27±3.88	<0.001
No. of insertion attempts No. (%)			
One	36 (87.8)	34 (85)	0.91
Two	3 (7.3)	4 (10)	
Three	2 (4.8)	2 (5)	
No. of operators No. (%)			
One	38 (92.7)	37 (92.5)	0.15
Two	3 (7.3)	3 (7.5)	

Table 6: Comparison of peak airway pressures (cm of H_2O) between the groups

Time intervals (min)	Mean±SD		*P*
	Group A	Group B	
1	12.88±2.09	19.07±1.79	<0.001
2	13.15±2.1	19.35±2.29	<0.001
3	12.9±2.22	19.525±2.24	<0.001
4	13.15±2.09	19.425±2.39	<0.001
5	13.07±1.99	19.35±2.11	<0.001
10	12.9±2.22	19.8±2.19	<0.001
15	12.9±2.11	19.825±2.17	<0.001
20	12.97±2.14	19.825±2.15	<0.001
25	12.68±1.81	19.9±2.62	<0.001
30	12.85±1.88	19.35±2.17	<0.001

Hemodynamic parameters like mean HR [Figure 2], mean SBP [Figure 3], and mean DBP [Figure 4] were comparable between the groups. There were no

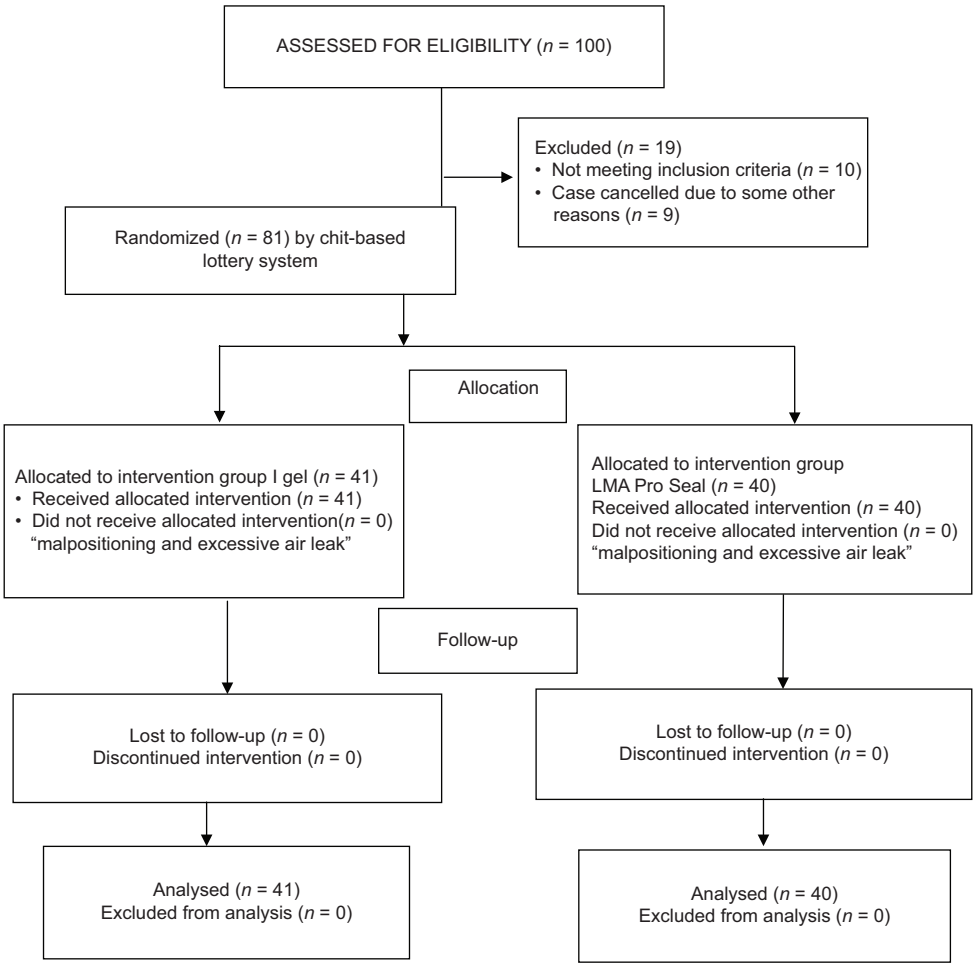

Figure 1: CONSORT flow diagram

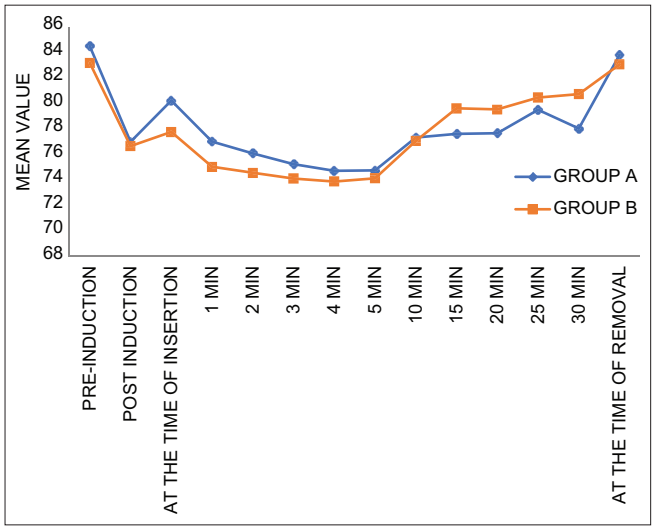

Figure 2: Comparison of mean HR (beats/min) between the groups

significant alterations in oxygenation (SpO_2) between the groups and no episode of desaturation was noted in any of the cases of the two groups [Figure 5]. $EtCO_2$ was within normal limits and no significant difference was found between the groups [Figure 6]. The number of postoperative complications was higher in group B, though the difference was not statistically significant ($P = 0.714$) [Table 7].

DISCUSSION

A surgical day case, as defined by the cofounder of International Association for Ambulatory Surgery (IAAS), is a patient who is admitted for investigation or operation on a planned nonresident basis and who nonetheless requires facilities for recovery. The whole procedure should not require an overnight stay in a hospital bed.[6] General anesthesia remains the most popular technique with both patients and surgeons in ambulatory surgeries.[1] It can be managed by SGA devices resulting in less incidence of sore throat, laryngospasm, coughing, and hoarseness as compared to inserting a tracheal tube.[2]

This study was undertaken to compare the efficacy of two third-generation SGA devices—LMA ProSeal and I gel airway—in anesthetized patients on spontaneous ventilation during daycare procedures.

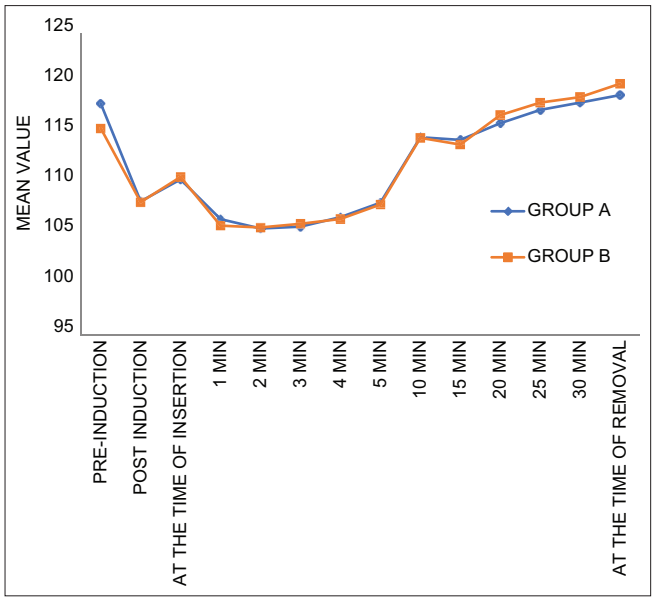

Figure 3: Comparison of mean SBP (mmHg) between the groups

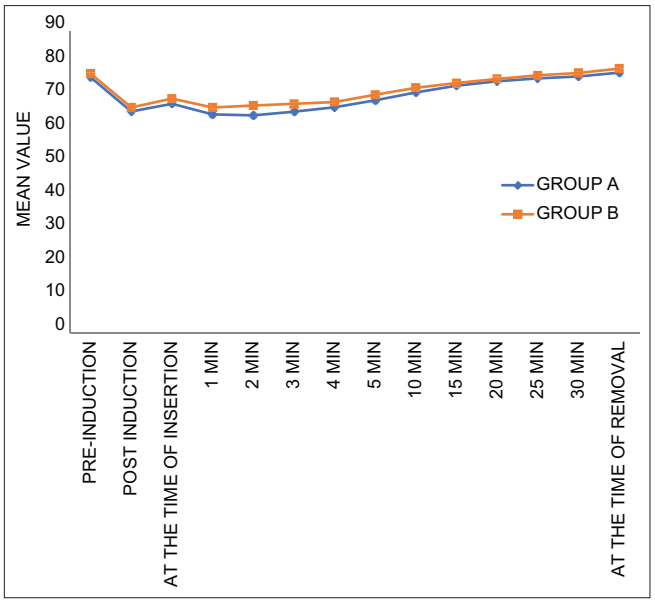

Figure 4: Comparison of mean DBP (mmHg) between the groups

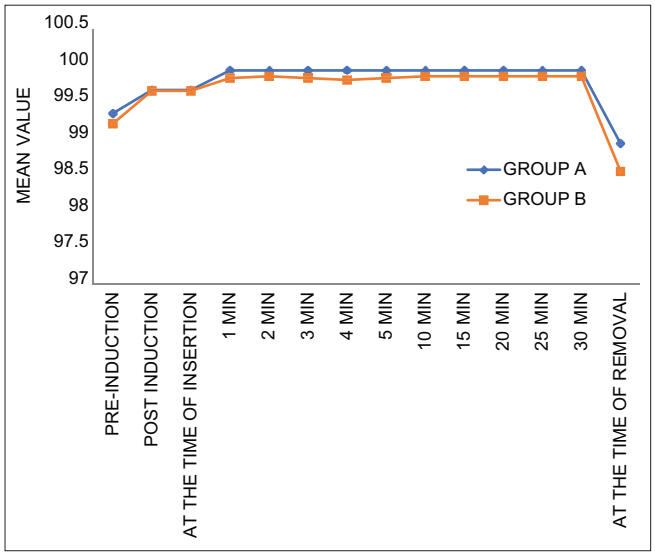

Figure 5: Comparison of oxygen saturation (SpO_2) between the groups

Figure 6: Comparison of $EtCO_2$ (mmHg) between the groups at different time intervals

Table 7: Comparison of postoperative complications between the groups

Complications	Group A ($n=41$) Number (%)	Group B ($n=40$) Number (%)
Sore throat	3 (7.3)	5 (12.5)
Blood on device	0 (0)	2 (5)
Nausea	2 (4.8)	3 (7.5)
Others	0 (0)	0 (0)

In our study, I-gel was found to be easier to insert than LMA ProSeal as it required significantly lesser time for insertion as compared to LMA ProSeal even though the number of attempts and the number of operators required were not significantly different between the groups.

This could be attributed to the larger size of the cuff of LMA ProSeal which made it more difficult to insert in the mouth, hence taking more time. In comparison, I-gel being cuffless and relatively smaller in size with its robust buccal cavity stabilizer was easier to insert requiring no manipulations.

In our study, the overall insertion success rate was 100% in both groups. I-gel was inserted in the first attempt in 88% of patients and LMA ProSeal in 85% of patients. Two operators attempted for insertion in three patients in each of the two groups. There was statistically no significant difference between the groups regarding the attempts of insertion and the number of operators required for an insertion of the airway devices.

Murthy *et al.*[7] compared LMA ProSeal and I-gel in 100 adult patients in elective surgeries and found no statistical

difference between the groups regarding the attempt of insertion. In their study, I-gel was inserted in the first attempt in 98% of patients and LMA ProSeal in 92% of patients. Here also, there was no failure of insertion of both the devices.

Luthra *et al*.,[8] similar to our study, compared I-gel and LMA ProSeal using the non-guided digital technique in forty non-paralyzed patients and found that both the devices were comparable on the first attempt of insertion. Similar results of no significant difference in the ease of insertion of the devices, I-gel and LMA ProSeal, were also found in the study done by Liew *et al*.,[9] Saran *et al*.,[10] and Sanket *et al*.[11]

In our study, mean duration of insertion of LMA ProSeal group was found to be significantly higher as compared to I-gel group. The time taken for insertion of LMA ProSeal was longer as cuff had to be inflated after insertion of the device, which was found clinically irrelevant by many authors in elective surgeries. However, it can be relevant in situations of emergency or resuscitation or difficult airway situation.

Zanfaly *et al*.[12] in their study compared I-gel, LMA ProSeal, and ET tube during minor surgical procedures and reported that I-gel group had a significantly lower insertion time than LMA ProSeal group (9.8 ± 2.5 vs 15.4 ± 3.2 s). Chauhan *et al*.[13] also reported that I-gel takes significantly lesser time to insert than LMA ProSeal (11.12 ± 1.814 s vs 15.13 ± 2.91 s, $P = 0.001$). Our study results were supported by many authors in their study including Jadhav *et al*.,[5] Saran *et al*.,[10] Sanket *et al*.,[11] and Murthy *et al*.[7]

Peak airway pressure, another ventilatory parameter, was also compared in our study and was found to be within normal limits. I-gel group had peak airway pressure range of 10–15 cm of H_2O and LMA ProSeal group had range between 17 and 21 cm of H_2O. As depicted in previous study done by Beylacq *et al*.,[14] a supraglottic airway can be considered as a superior device, that is, having wider margin of safety for ventilation, that can provide ventilation with low peak airway pressure and high leak pressure. In our study, I-gel could provide adequate ventilation with lower mean peak airway pressure as compared to LMA ProSeal group at all time intervals.

Mishra *et al*.[15] studied influence of head and neck position on oropharyngeal leak pressure and cuff position with LMA ProSeal and I-gel and found that effective ventilation can be done with both the devices with head in all positions, neutral, flexion, and extension. However, they reported that LMA ProSeal had better margin of safety for ventilation due to better sealing pressures, but in flexion LMA ProSeal had higher peak airway pressure than I-gel (19 ± 6.09 vs 17 ± 5.25) cm of H_2O.

All our patients in both the groups were hemodynamically stable. HR, SBP, and DBP changes were found to be comparable and statistically insignificant between the groups. Zanfaly *et al*.[12] also in their study found that I-gel and LMA ProSeal groups showed no statistically significant differences in hemodynamic parameters. Similar to our study, Murthy *et al*.[7] also found that heart rate, SBP, DBP, and MAP show an increase after insertion and at the time of removal of the device. However, in their study also, the intraoperative and postoperative changes in hemodynamic parameters were found to be statistically insignificant. Our results were supported by studies done by Maitra *et al*.[16] and Dwivedi *et al*.[17]

There were no significant difference and alterations in SpO_2 within the groups and between the groups at any time throughout the study. Chauhan *et al*.[13] and Jadhav *et al*.[5] also did not find any episode of desaturation or noteworthy variation in oxygenation between the groups—I-gel and LMA ProSeal. In our study, both the I-gel and LMA ProSeal groups showed similar trends of $EtCO_2$ with no statistical difference. Jadhav *et al*.[5] found in their study that LMA ProSeal group had higher values of $EtCO_2$ and owed this to higher sealing pressures of LMA ProSeal, but the difference in values between I-gel and LMA ProSeal were found to be statistically insignificant.

No incidence of gastric distension or regurgitation or aspiration occurred in our study. Sore throat and nausea were seen in some of the patients of both the groups, whereas blood on the device was seen in only two patients in LMA ProSeal group. Though the number of complications was more in LMA ProSeal group, there was no statistically significant difference between the groups. The higher occurrence of complications in LMA ProSeal group can be attributed to larger cuff size and cuff pressure. Murthy *et al*.[7] also found in 100 adult elective patients, a higher occurrence of throat pain and bloodstain on device in LMA ProSeal group than I-gel group. But here also, the difference was found to be statistically insignificant. Also, there was no incidence of bronchospasm, laryngospasm, gastric regurgitation, or aspiration. Studies done by Zanfaly *et al*.[12] and Jadhav *et al*.[5] also reported no significant difference in postoperative complications between the I-gel and LMA ProSeal groups.

Limitations

The study had some limitations. Firstly, investigators had more experience with I-gel than LMA ProSeal as I-gel is used more frequently in our settings. We included low-risk adult patients (ASA grade 1 and 2) who had normal airway; therefore, this study cannot be extrapolated to pediatric patients or patients with difficult airway. As all our patients were adequately fasted, we could not assess the performance

of both the airway devices in patients with high risk of aspiration. We also did not use gastric tube insertion parameter for adequate positioning of the device, but none of the cases presented with failed ventilation issues. Finally, we also did not measure oropharyngeal leak pressures of the devices which can predict adequate margin of safety for ventilation of the SGA. But as our patients were kept on spontaneous ventilation, it was not considered important.

CONCLUSIONS

Based on our findings, we concluded that both LMA ProSeal and I-gel can provide safe airway during daycare procedures. Both the devices were comparable with respect to first attempt success rate, number of operators required for the attempt of insertion, hemodynamic response, oxygenation, and ventilation. However, I-gel required lesser time for insertion and could provide adequate ventilation with lesser postoperative complications besides being cheaper than LMA ProSeal. Hence, I-gel appears to be a better supraglottic airway device in anesthetized patients on spontaneous ventilation during daycare procedures.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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