A COMPARATIVE STUDY OF THREE SUPRAGLOTTIC AIRWAY DEVICES- CLASSIC LMA, PROSEAL LMA AND I-GEL, IN ADULT PATIENTS UNDERGOING ELECTIVE SURGERIES

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ABSTRACT

BACKGROUND

Supraglottic airway devices are gaining popularity because of their ease of insertion, simplicity as well as effective ventilation. This study is aimed at comparing the clinical performance of LMA-Classic, LMA-ProSeal and i-gel in adult patients undergoing short elective procedures under general anaesthesia with spontaneous respiration.

MATERIALS AND METHODS

The American society of Anaesthesiologists physical status I-II patients (n=120) posted for elective surgeries were included in this study. General anaesthesia was achieved with intravenous infusion of propofol, fentanyl and midazolam. The patients were randomly assigned to Classic LMA (Group A), ProSeal LMA (Group B) and i-gel (Group C). Properly sized classic LMA (size 3,4 & 5), ProSeal LMA (size 3, 4 & 5) and i-gel (size 3 & 4) was inserted. We assessed the ease of insertion, adequacy of ventilation, hemodynamic stability, intraoperative and postoperative complications

RESULTS

There were no differences in the demographic data and the hemodynamic data immediately after insertion in all the three groups. The first attempt success rate was better with classic LMA but was not statistically significant. There was a significant reduction in the time to insert i-gel compared to the other two groups (P = 0.005). There was lesser incidence of sore throat and blood staining on the device with i-gel. While gastric insufflation was nil in patients with ProSeal LMA.

CONCLUSION

From the study we conclude that i-GEL is a better alternative to classic LMA with regard to gastric insufflation and is also a better substitute to ProSeal LMA as it takes much lesser time for insertion and reduced incidence of post-operative complications.

KEYWORDS

Supraglottic Airway Devices, Short Surgical Procedures, Ease of Insertion, First Attempt Success Rate, Hemodynamic Response.

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BACKGROUND

Airway management is the most fundamental and crucial part of anaesthesia. It is a life-saving entity that is practised both as part of delivering general anaesthesia as well as in emergency situations such as out of hospital cardiac arrests.

Endotracheal intubation is the gold standard⁽¹⁾ of airway management. However, endotracheal intubation is a skill that needs capable training, practice and has a difficult learning curve.

The SAD's (Supraglottic Airway Devices) offered various advantages such as avoiding the hemodynamic response associated with endotracheal intubation as well as lesser laryngotracheal morbidity. It allows for the administration of general anaesthesia without the use of neuromuscular

blockers. They gained massive popularity because of their ease of insertion, simplicity as well as effective ventilation.⁽²⁾

Various studies have shown that the first-time insertion success rate was higher with supraglottic airway devices when compared to endotracheal intubation. Also, the time taken to secure the airway was lesser, and so was the ease of insertion.⁽³⁾

Studies have been done comparing the efficacy and ease of use of the second-generation devices with Classic LMA. Though there is considerable literature comparing ProSeal LMA with Classic LMA, fewer studies exist comparing i-gel with Classic LMA and ProSeal LMA, especially in the South Indian population. We hence planned this prospective, randomized trial to compare the clinical performance of two second generation SAD's- ProSeal LMA and i-gel with Classic LMA and with each other, in adult patients undergoing general anaesthesia with spontaneous respiration.

MATERIALS AND METHODS

This was a prospective, randomized control study done in the department of Anaesthesiology, Government Mohan Kumaramangalam Medical College, Salem conducted between December 2015 and June 2017 after obtaining institutional ethics committee approval. For the sake of convenience, it was decided to include 120 subjects in the study, with 40 subjects randomized to each of the three study groups.

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Those patients with airway abnormalities, non-fasted state, emergency surgeries, obese (BMI>30 kg/m²) and those with upper respiratory tract infections were excluded from the study.

Informed written consent was obtained in the native vernacular language.

The 120 Patients were randomly divided into Three Groups as-

- **Group A:** Patients receiving anaesthesia with LMA-Classic
- **Group B:** Patients receiving anaesthesia with LMA-ProSeal
- **Group C:** Patients receiving anaesthesia with i-gel

Randomization was performed using a random number table using Random allocation software Version 1.0.0

All patients underwent routine pre-anaesthetic assessment, where their complete medical and surgical history was recorded. Height, weight and BMI of patients were noted. Thorough assessment of airway was done. Vital signs were recorded. After systemic examination and appropriate lab investigations, patients were assessed for fitness for surgery under suitable ASA physical status groups.

Administration of General Anaesthesia

All patients received Tab. Ranitidine 150 mg PO and Tab. Diazepam 10 mg PO the night prior to the surgery. They were fasted for 8 hours overnight. On the morning of surgery, patients received Tab. Ranitidine 150 mg and Tab. Metoclopramide 10 mg PO two hours prior to the surgery with sips of water.

After shifting patients into the OR, standard monitors were connected (NIBP, SpO₂, ECG) and after obtaining IV access, patients were given Inj. Glycopyrrolate 10 mic/kg, Inj. Midazolam 0.02 mg/kg and Inj. Fentanyl 2 mic/kg IV. Standard monitors such as NIBP, SpO₂, HR, ECG and ETCO₂ were applied and recorded for all patients. After preoxygenation with 100% O₂ for 3 minutes, patients were induced with 2 mg/kg of Inj. Propofol IV. After achieving adequate depth of anaesthesia (loss of verbal response plus jaw relaxation), the devices were inserted.

In patients belonging to Group A, the LMA-Classic, of size 3, 4 or 5, depending on the weight of the patient was inserted according to the insertion method in the manual.⁽⁴⁾ The cuff was inflated with 20 ml (Size 3), 30 ml (Size 4) or 40 ml (Size 5) air according to the size of the LMA.

In Group B patients, LMA-ProSeal of size 3 (30-50 kg), 4 (50-70 kg) or 5 (70-100 kg), depending on the weight of the patients, was used. The cuff was inflated with air as specified in the instruction manual.⁽⁵⁾

Group C patients received i-gel, which was inserted according to the instructions in the user's manual by Intersurgical.⁽⁶⁾

Adequacy of ventilation was assessed by adequate chest rise, SpO₂ >95% and a square wave capnography with normal range ETCO₂

A maximum of three attempts was taken for insertion. If there was difficulty in insertion initially, airway manoeuvres such as jaw thrust, and chin lift were attempted to ease the insertion. If the device was not placed properly even after three attempts, or if there was inadequacy of ventilation even

after three attempts, it was considered a failed attempt and an alternate means of airway management- endotracheal intubation was done.

Anaesthesia was maintained with N₂O:O₂ mixture of 66%:33% and 0.6-0.8% Halothane. Ventilation was assisted until the patients had smooth spontaneous respiration, after which general anaesthesia was maintained under spontaneous ventilation without paralysis. At the end of the surgery, the volatile agent was cut off and time was given for complete return of consciousness. After return of consciousness, adequate response to verbal commands and ensuring stability of vital signs, after suctioning, the device was removed and patient observed.

Parameters like ease of insertion, in terms of number of attempts to insert and duration of insertion (From picking up the device to connecting the circuit), occurrence of gastric insufflations, hemodynamic parameters (heart rate, mean arterial pressure, ETCO₂ and SpO₂) at baseline and at 1 minute, 3 minutes, 5 minutes, 10 minutes after insertion and every 10 minutes thereafter, any intraoperative complications, occurrence of cough, blood staining of device or laryngospasm during removal of the device and postoperative complications like sore throat, nausea, vomiting, dysphagia, dysphonia, ear pain, odynophagia and numbness of tongue were observed.

MATERIALS AND METHODS

Statistical methods: Ease of insertion was assessed by number of attempts taken for insertion of the SAD and time taken for insertion, which were considered as primary outcome variables. Occurrence of intraoperative and postoperative complications such as blood on device, occurrence of cough, sore-throat etc., were considered as safety related outcome parameters. Haemodynamic parameters like Heart rate (HR), Mean Arterial Pressure (MAP), Saturation (SpO₂) and End-Tidal Carbon Dioxide (ETCO₂) were considered as other outcome variables. The type of device was considered as the explanatory variable.

Descriptive Analysis

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

Quantitative Outcome

Quantitative variables were compared at baseline between three groups using One-way ANOVA. The change in the quantitative variables from baseline and different follow up periods within each group was assessed by One-way repeated measures ANOVA. The significance of changes in hemodynamic parameters with time across the groups was compared using Two-way repeated measures ANOVA.

Categorical Outcome

The association between type of device and categorical outcomes was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.⁽⁷⁾

RESULTS

Device	Age Mean $\pm$ Std. Dev	Mean Difference	95% Confidence Interval for Mean		P value
			Lower Bound	Upper Bound	
cLMA	35.2 $\pm$ 10.44				
pLMA	38.78 $\pm$ 8.91	-3.58	-7.89	0.74	0.104
i-gel	38.4 $\pm$ 9.84	-3.20	-7.52	1.12	0.145

Table 1. Comparison of mean AGE across study groups (N=120)

The mean differences in age across the three groups was statistically not significant (P value=0.145).

Device	Mean $\pm$ Std. Dev	Mean Difference	95% Confidence Interval for Mean		P value
			Lower Bound	Upper Bound	
LMA Classic	56.78 $\pm$ 10.01				
ProSeal LMA	55.43 $\pm$ 6.2	1.35	-2.19	4.89	0.452
i-gel	57.2 $\pm$ 7.3	-0.43	-3.97	3.12	0.813

Table 2. Comparison of mean WEIGHT across study groups (N=120)

The mean differences in weight across the groups was also statistically not significant (P value=0.813).

Device	Mean $\pm$ Std. Dev (in minutes)	Mean Difference	95% Confidence Interval for Mean		P value
			Lower Bound	Upper Bound	
Classic-LMA	28.75 $\pm$ 9.04				
ProSeal LMA	27.63 $\pm$ 7.42	1.13	-2.28	4.53	0.514
i-gel	25.75 $\pm$ 6.36	3.00	-0.40	6.40	0.084

Table 3. Comparison of mean duration of surgery (in minutes) across study groups (N=120)

The mean duration of surgery in LMA-Classic group was 28.75 minutes, it was 27.63 minutes in ProSeal-LMA group and 25.75 minutes in the i-gel group. The mean difference in duration of surgery across the groups was also statistically not significant. (p value=0.084).

(I) Device	Mean $\pm$ Std. Dev	Mean Difference	95% Confidence Interval for Mean		P value
			Lower Bound	Upper Bound	
LMA Classic	21.18 $\pm$ 4.43				
ProSeal-LMA	38.4 $\pm$ 6.96	-17.225	-19.43	-15.02	<0.001
i-gel	17.98 $\pm$ 2.52	3.200	1.00	5.40	0.005

Table 4. Comparison of mean DURATION OF INSERTION (In seconds) across study groups (N=120)

The Mean duration of insertion in LMA classic group was 21.18 seconds, it was 38.4 seconds in ProSeal-LMA and 17.98 seconds in i-gel. The mean difference of duration of insertion across the groups was statistically significant. (p value=0.005)

Figure 1. Comparison of Heart Rate trend between the three Groups (N=40)

There was an initial fall in Heart Rate after induction in all the three groups, followed by a gradual rise towards the baseline. The differences in Heart Rate from baseline at all the follow up intervals were statistically not significant.

Figure 2. Comparison of change in MAP with time between the three groups (N=40)

Patients in all three groups uniformly showed an initial drop in Mean Arterial Pressure (MAP) from the baseline immediately after induction, followed by a rising trend towards baseline at later intervals. The differences in MAP from baseline at all the follow up intervals were statistically not significant.

Post OP Sore throat	Device			Chi square	P-value
	LMA Classic	ProSeal LMA	i-gel		
Yes	9 (22.5%)	5 (12.5%)	2 (5%)	5.337	0.069
No	31 (77.5%)	35 (87.5%)	38 (95%)		

Table 5. Association of DEVICE with POST OP SORE THROAT (N=120)

Among the LMA-Classic group, 9 patients (22.5%) had postoperative sore throat. Among the ProSeal-LMA, 5 patients (12.5%) developed sore throat. Among the i-gel group, 2 patients (5%) had post op Sore throat. The difference was statistically not significant (p value 0.069).

DISCUSSION

Endotracheal intubation has been the gold standard method of securing the airway during general anaesthesia. With the invention of the supraglottic airway devices, an alternative method of securing the airway was born and these devices have flourished over the past three decades.

We chose to compare the clinical efficacy of these three devices in a tertiary health care centre such as ours, especially for short surgeries, avoiding the use of muscle relaxants. We included 120 patients, 40 with each group of SAD.

The patients in all three groups were comparable preoperatively in terms of age ($p=0.145$) and gender distribution ($p=0.421$). All three groups had a higher proportion of females (70% in C-LMA, 82.5% in P-LMA and 75% in i-gel). This was because the most common surgeries that we included were excision of fibroadenoma- breast, puerperal sterilisation and fractional curettage of the endometrium or cervix biopsy. The mean duration of surgeries included was around 25 -28 minutes and this was also comparable between the three groups ($p=0.084$).

The mean weight across all three groups was comparable ($p=0.813$) and so was the preoperative airway assessment ($p=0.122$). We included only those patients with no predictors of a difficult airway, such as restricted mouth opening or a Mallampatti score of III or higher.

We measured two parameters to assess the ease of insertion, the number of attempts for correct insertion and the time taken to insert the device, which was measured from picking up the device to connecting the breathing circuit.

The first attempt success rate was highest with LMA-Classic (97.5%) whereas it was 82.5% for LMA-ProSeal and 87.5% for the i-gel group. 6 patients in the ProSeal group (15%), 5 in the i-gel group (12.5%) and one patient in the Classic-LMA group (2.5%) required two attempts for correct insertion. Only one patient in the ProSeal group required three attempts at insertion. Though the first-attempt success rate was higher with Classic-LMA, this was not statistically significant. A study by Shin et al also reported a similar lower first attempt success rate with i-gel.⁽⁸⁾ Many studies have reported a statistically significant high first-attempt success rate with i-gel compared to ProSeal-LMA and Classic-LMA, both in airways that were adequate⁽⁹⁾ as well as difficult airways.⁽¹⁰⁾ Revi et al also reported that the ease of insertion with i-gel was more (96%) compared to that with cLMA (88%) and ProSeal LMA (80%), though it wasn't statistically significant ($p=0.194$).⁽¹¹⁾ This increased first-attempt success rate with Classic-LMA in our study could possibly be because of the increased familiarity with the usage of LMA-Classic by the anaesthesiologists involved in the study, compared to their relatively new acquaintance with the other two devices.

There was a significant reduction ($p=0.005$) in the time taken to insert the i-gel (17.98 seconds) compared to Classic-LMA (21.18 seconds) and LMA-ProSeal (38.4 seconds). Several studies have quoted similar reduced time for insertion in i-gel compared to Classic-LMA and ProSeal-LMA.⁽¹²⁻¹⁴⁾ However, a study by Theiler et al comparing LMA-Supreme (disposable version of LMA-ProSeal) and i-gel in simulated difficult airway scenarios showed longer insertion times with i-gel.⁽¹⁵⁾ I-gel is a cuffless device, whereas LMA-Classic and ProSeal are cuffed SAD's, hence the increased time taken to introduce these two devices may be explained

by the time taken to inflate the cuffs. Out of the cuffed SAD's, the insertion of ProSeal-LMA took a significantly longer time ($p < 0.001$), again possibly due to the lesser familiarity with the use of ProSeal-LMA, and the bulkier nature of this device compared to Classic LMA, contributing to increased difficulty in manoeuvring the device intraorally during insertion. Brimacombe et al published a study comparing ProSeal LMA with the Classic-LMA and also concluded that the insertion of ProSeal LMA was more difficult compared to Classic-LMA as the larger cuff is more difficult to introduce with the finger method and there are more chances of the cuff folding over.⁽¹⁶⁾ Saran et al reported an increased difficulty with i-gel use, attributing it to the overlap of size of device prescribed by the manufacturer, leading to a difficulty in selection of appropriate size of device for the patients.⁽¹⁷⁾

Gastric insufflation of air during ventilation was compared between the three devices. There was found to be no insufflations with ProSeal, whereas gastric insufflation was encountered in 3 patients (7.5%) in the Classic-LMA group and 1 patient in the i-gel group (2.5%). This could be explained by the lack of a gastric access channel in the LMA-Classic, it being a first-generation SAD. A study by Helmy et al comparing LMA-Classic with i-gel also observed that gastric insufflation was significantly higher with LMA-Classic.⁽¹²⁾

Intraoperatively, hemodynamic parameters such as heart rate, blood pressure, saturation and end-tidal CO₂ were measured. We observed an initial fall in heart rate and blood pressure, followed by a steady rise towards baseline. This was seen uniformly in all three groups. There was no statistically significant change in these parameters between the groups. This was similar to the results of studies conducted by Helmy et al⁽¹²⁾ and Shin et al.⁽⁸⁾ There are also some contrasting reports regarding hemodynamic variations, a few studies have reported higher increase in heart rate and blood pressure from baseline in Classic-LMA,⁽⁹⁾ probably because of the inflated cuff of the Classic-LMA causing a sympathetic response.⁽¹⁸⁾

End tidal CO₂ was monitored with all three devices throughout the surgery. A gradual increase in ETCO₂ was seen with all three devices. There was a statistically significant increase in ETCO₂ at intervals 10, 20 and 30 minutes. However, this increase in ETCO₂- 42.33 mmHg (in ProSeal LMA) vs 39 mmHg (in Classic LMA) and 40.67 mmHg (in i-gel) is clinically not very significant.

We encountered blood staining of the device in 3 patients in the LMA-Classic group (7.5%), 4 patients in the ProSeal group (10%) and one patient in the i-gel group (2.5%). The association of the device with the blood staining was not statistically significant. ($p=0.392$). Higher blood staining of device in LMA-Classic and LMA-ProSeal was also reported in a study by Shin et al, which was explained as probably the presence of inflatable cuffs in these devices.⁽⁸⁾

Cough during extubation was encountered only in 2 patients (5%) in the LMA Classic and none of the patients in the other two groups. This association was also not significant statistically ($p=0.131$).

Post-operative sore throat was seen in 9 patients (22.5%) in the LMA-Classic group, 5 patients (12.5%) in the ProSeal-LMA group and 2 patients (5%) in the i-gel group. Jadhav et al reported a higher incidence of sore throat with ProSeal-LMA.⁽¹⁹⁾ Although this association of device type and sore throat was not statistically significant ($p=0.069$), Shin et al in

their study reported a significantly higher incidence of sore throat in Classic-LMA.⁽⁸⁾

None of the other anticipated postoperative complications such as nausea and vomiting, dysphonia, dysphagia or trauma to teeth and lips were encountered in any of the patients. In a study by Helmy et al, they observed that nausea and vomiting was higher in the Classic-LMA group compared to i-gel group.⁽¹²⁾ A study in non-paralysed anaesthetised patients comparing ProSeal- LMA with Classic-LMA found no differences in intraoperative complications in total, but there was increased occurrence of minor trauma to lip/tongue in the ProSeal group, postulated to be due to the larger cuff. They also found an increased occurrence of hiccups in the Classic-LMA group, possibly because of the rigid tube in c-LMA stretching the hypopharynx more vigorously than the p-LMA.⁽²⁰⁾

CONCLUSION

From our study, we conclude that the i-gel is a better alternative to the first generation supraglottic airway device- LMA-Classic, as the time taken to insert the device is lesser and there is a gastric access channel and lesser occurrence of gastric insufflation, hence there is more refined separation of the airway.

i-gel is also a better substitute to the more commonly used second generation supraglottic airway device- ProSeal LMA as it does not have an inflatable cuff, thus taking much lesser time for insertion, furthermore avoiding complications such as blood staining of device, cough and sore throat associated with a bulky cuff.

I-gel does not provide any advantages over the other two devices in terms of intraoperative haemodynamic variations or complications.

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