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A Prospective, Randomized, Comparative Study of Ease of Insertion of Laryngeal Mask Airwayclassic and I-Gel Supra Glottic Airway Devices in Anaesthetized, Adult Patients

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Abstract
Background And Objectives- *Maintenance of airway is an integral part of general anaesthesia. Various airwaydevices are used for this purpose. Hemodynamic changes are major hazards of general anesthesia and are probably generated by direct laryngoscopy &endotracheal intubation. Supraglottic airway devices have been widely used as analternative to tracheal intubation during general anaesthesia.Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. Thei-gel is a novel supraglottic airway device made of thermoplastic elastomer which is soft, gel-like and transparent. Unlike the conventional LMA, it does not have an inflatable cuff.In view of this, the present study was undertaken to compare the performance oftwo supraglottic airway devices classic laryngeal mask airway and i-gel in anaesthetized, paralyzed adult patients posted for elective surgeries under general anaesthesia.*
Methodology-*One hundred patients, scheduled for various elective surgical procedures undergeneral anaesthesia belonging to ASA class I and II were included in the study and wererandomly divided into two groups with 50 patients in each group. In Group 1 (n=50),i-gel supraglottic airway device was used and in Group 2 (n=50) classic laryngeal maskairway was used. Both the devices were compared in relation to the ease of insertion,number of insertion attempts, and time of insertion, airway leak pressure, haemodynamicchanges, intra and post-operative complications.*
Results-*There was no statistically significant difference between the devices with respectto ease of insertion and number of attempts of insertion. The mean airway leakpressure with i-gel was significantly higher as compared with c-LMA (26.38±2.76 and19.7±2.10 cm H2O, respectively, p=0.000). The mean time of insertion for i-gel was17.12±3.42 seconds which was significantly shorter compared to c-LMA with a meaninsertion time of 25.62±5.28 seconds (p=0.000). There were no statistically significant differences in haemodynamic changes and the postoperative complications between the devices.*
Interpretation And Conclusion-*Both i-gel and c-LMA are easy to insert and provide an effective airway duringpositive pressure ventilation, with i-gel providing a better airway sealing pressure ascompared to c-LMA.*
Keywords: *Laryngeal mask airway; i-gel; supraglottic airway device*

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I. Introduction

The supraglottic airway device is a novel device that fills the gap in airwaymanagement between tracheal intubation and use of face mask. Dr Archie Brain, aBritish anaesthesiologist, for the first time introduced the laryngeal mask airway in1983, designed to be positioned around the laryngeal inlet that could overcome thecomplications associated with endotracheal intubation, and yet, be simple andatraumatic to insert.[1]Careful observations and clinical experience have led toseveral refinements of Brain's original prototype leading to development of newersupraglottic airway devices with better features for airway maintenance.[1]The wide variety of airway devices available today may broadly beclassified as intraglottic and extraglottic airway devices, which are employed toprotect the airway in both elective as well as emergency situations.[2] There are a large number ofsupraglottic airway devices, some of which appear similar to the LMA family andothers that work under a different concept.[3]Laryngoscopy and endotracheal intubation produce reflex sympatheticstimulation and are associated with raised levels of plasma catecholamines,hypertension,

tachycardia, myocardial ischemia, depression of myocardialcontractility, ventricular arrhythmias and intracranial hypertension.[2]Transitoryhypertension and tachycardia are probably of no consequence in healthyindividuals but either or both may be hazardous to those with hypertension,myocardial insufficiency or cerebrovascular diseases.[4]This laryngoscopic reactionin such individuals may predispose to development of pulmonary edema,myocardial insufficiency and cerebrovascular accident.[5,6]Supraglottic airwaydevices are now widely used for surgery requiring general anaesthesia, so as toavoid the complications associated with tracheal intubation.[7]LMA-classic is thegold standard for supraglottic airway devices and is in use since 1981.[8] Thepopularity of the device for routine use stems from its perceived benefits to thepatient and anaesthetist over traditional forms of airway management.[9]Laryngeal mask airway is a supraglottic airway device with an inflatablecuff forming a low pressure seal around the laryngeal inlet and permitting ventilation.[1]The i-gel is a new supraglottic airway device with a non inflatablecuff, composed of soft gel like, transparent thermoplastic elastomer. It is designedto achieve a mirror impression of pharyngeal and laryngeal structures and toprovide a perilaryngeal seal without cuff inflation. A drain tube is placed lateral tothe airway tube, which allows insertion of gastric tube.[7] The incidence of aspiration with the LMA has been estimated at0.02%, which is similar to tracheal intubation in elective patients.[10]The newer supraglottic airway device, i-gel was introduced byDr.MuhammedAslamNasir in 2007. It has the potential advantages includingeasier insertion, minimal risk of tissue compression, stability after insertion and aninbuilt bite block. [8]It seals the laryngo-pharyngeal space without any air beinginsufflated and additionally has an oesophageal lumen. It can be assumed that airway devices that offer an especially good seal and that are equipped with anadditional oesophageal lumen are superior for use in patients with an increasedrisk of aspiration.[11] This study was undertakeninSVRRGGH&SVMedicalCollege,Tirupati during the period January 2017 to May 2018 to compare these two supraglottic airway devices in relation to the ease ofinsertion, number of insertion attempts, time of insertion, airway leak pressure,haemodynamic changes, intra and post operative complications in anaesthetized, adult patients posted for elective surgeries under general anaesthesia.

II. Objectives

To study and compare two supraglottic airway devices i-gel and classiclaryngeal mask airway, in anaesthetized adult patients posted forelective surgeries under general anaesthesia with respect to,

Primary objectives

1. Ease of insertion
2. Number of insertion attempts
3. Time for insertion
4. Airway leak pressure
5. Haemodynamic changes and O2 saturation

Secondary objectives

Adverse effects like,

- Tongue, lip or dental trauma
- Postoperative sore throat, dysphagia or hoarseness

III. Methodology

A study entitled "A PROSPECTIVE, RANDOMIZED, COMPARATIVESTUDY OF EASE OF INSERTION OF LARYNGEAL MASK AIRWAY –CLASSIC AND I-GEL SUPRA GLOTTIC AIRWAY DEVICES IN ANAESTHETIZED, ADULT PATIENTS"- was undertaken inSVRRGGH&SVMedical College, Tirupati during the period January 2017 to May 2018

The study was undertaken after obtaining ethical committee clearance as well asinformed consent from all patients.One hundred patients, scheduled for various elective surgical proceduresunder general anaesthesia belonging to ASA class I and II were included in thestudy.

INCLUSION CRITERIA FOR THE STUDY

1) Adult normotensive patients aged between 18 and 50 years of both sex
2) Mallampatti grade I and II
3) Elective surgeries under general anaesthesia with controlled ventilation
4) Duration of surgery less than 60 minutes

EXCLUSION CRITERIA FOR THE STUDY

1) Age <18 years and > 50 years
2) ASA class III and above
3) Mallampatti grade III and above
4) Emergency surgeries
5) Head and neck surgeries
6) Patients with decreased mouth opening
7) Patients with increased risk of aspiration
8) Patients with abnormal or distorted anatomy of the pharynx
9) Patients with obstruction of the airway beyond the larynx
10) Patients with decreased compliance of the lungs
11) Obese patients with BMI >28 kg/m2

The study population was randomly divided into two groups' with50 patients in each group using sealed envelopes containing the name of the groupand the patient was asked to pick up the envelope. The envelope was opened bysenior anaesthesiologist who was not involved with the study.

Group 1 – i-gel group (n=50)

Group 2 – classic LMA group (n=50)

Pre-anaesthetic evaluation was done on the evening before surgery.A routine pre-anaesthetic examination was conducted assessing;

• General condition of the patient
• Airway assessment by Mallampatti grading and rule of 1- 2- 3
• Nutritional status and body weight of the patient
• A detailed examination of the cardiovascular system
• A detailed examination of the Respiratory system

The following investigations were done in all patients

• Haemoglobin estimation
• Urine examination for albumin, sugar and microscopy
• Standard 12-lead electrocardiogram
• X-ray chest/Screening of chest
• Blood sugar
• Blood urea, Serum creatinine.

All patients included in the study were premedicated with tablet Alprazolam0.5 mg and tablet Ranitidine 150 mg orally at bed time the previous night beforesurgery. They were kept nil orally for solids 10 pm onwards on the previous nightand for clear fluids upto 2 hours before induction.On arrival of the patient in the operating room, an 18-gauge intravenouscannula was inserted and an infusion of normalsaline was started. The patient's head was placed on a soft pillow of 10 cms beforeinduction of anaesthesia with the neck flexed and head extended. The patient wasconnected to multiparametermonitor, whichrecords heart rate, non-invasive measurements of SBP, DBP, MAP, etCO2 andcontinuous ECG monitoring and oxygen saturation. The baseline systolic, diastolicblood pressure, mean arterial pressure and heart rate were recorded.The i-gel supraglottic airway was used in Group 1 patients. The size of thedevice was decided by anaesthetist based on patient's body weight andmanufacturer's recommendation. Size 3 for patients weighing between 30-50 kgs,size 4 between 50-90 kgs and size 5 for patients weighing > than 90 kgs. ClassicLMA device was used in group 2 patients. The size 3 classic-LMA for patientsweighing 30- 50 kgs, size 4 for 50-70 kgs and size 5 for patients of >70 kgs.The standard pre use tests for both devices were performed. Both deviceswere lubricated using Lignocaine jelly on the tip and posterior surface asrecommended by the manufacturer and the c- LMA fully deflated prior toinsertion.After recording the baseline reading, the patient was premedicatedwith injection Midazolam 0.02 mg/kg body weight. Then the patient waspreoxygenated with 100% oxygen for 3 minutes via a face mask with Bain'scircuit. Intravenous lignocaine (2%) 2 ml was given to prevent pain on injection of Propofol. Anaesthesia was induced with Propofol 2 mg/ kg body weight.Induction of anaesthesia was confirmed by loss of verbal communication with thepatient and loss of eyelash reflex. Once an adequate depth of anaesthesia wasachieved, patient was paralyzed by giving intravenous Succinylcholine (2 mg/kgbody weight). The patient was mask ventilated with 100% oxygen for 1 minute.The allotted device was inserted according to the manufacturer's instructions. Thepatient's head was placed in 'sniffing the morning air' position. Insertion of all thedevices was done by the same anaesthesiologist who had an experience ofintroducing successfully more than 400 c-LMA and 20 i-gel.18.The lubricated i-gel was grasped along the integral bite block andintroduced into the mouth in the direction towards the hard palate and glideddownwards and backwards along the hard palate until definite resistance was felt.The device was connected to breathing circuit and patient ventilated manually. 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 waveformon

capnograph, normal end tidal CO2 and stable SpO2 (>95%). The device wassecured with adhesive tape. Bite block was kept in case of c-LMA and securedalong with it with adhesive tape.Anaesthesia was maintained using 66% nitrous oxide and 33% of oxygenwith 1dial setting of Sevoflurone. After the patient recovered from Succinylcholine furtherneuromuscular blockade was maintained with Vecuronium 0.05 mg/ kg bodyweight. At the end of the procedure, patient was reversed with Neostigmine0.05 mg/kg body weight and atropine 0.02 mg/ kg body weight. The patientremained in the supine position and the device removed after the patient was fullyawake and met all the reliable signs of recovery from neuro muscular blockade.The patients were inspected for any injury of the lips, teeth or tongue and the devicefor blood stain. 18-24 hours after surgery, patient was interviewed for any postoperative complications like sore throat, dysphagia and hoarseness.

PARAMETERS STUDIED DURING THE PROCEDURE

1. Ease of insertion:

Graded subjectively on a scale from 1 to 3.

Table 1: Grading of ease of insertion

1	Very easy
2	Easy
3	Difficult

Insertion of device was recorded as; very easy (when assistant help was notrequired), easy (when jaw thrust was needed by assistant) and difficult (when jawthrust and deep rotation or second attempt was used for proper device insertion).[22]

Time of insertion

Time from picking up the device, to the time of confirmation of effectiveventilation by bilateral symmetrical chest movement, square waveform oncapnograph, normal range end tidal CO2 and stable arterial SpO2 (>95%).[2,8,9,15,18]

3. Number of insertion attempts

Number of attempts required for the insertion of each device was noted.

4. **Airway leak pressure**

It is detected by using closed circuit with mechanical ventilation in Drager-Fabius machine. Keeping the flow rate of 3 litres/min and maximum pressure limit of40 cm H_2O, the airway pressure was gradually increased. The pressure at which anaudible noise was detected using a stethoscope placed just lateral to the thyroidcartilage was taken as the airway leak pressure.[17,19,20]

5. Haemodynamic Parameters

The following haemodynamic parameters were recorded in all patients.

- Heart rate [HR] in beats per minute
- Systolic blood pressure [SBP] in mm of Hg
- Diastolic blood pressure [DBP] in mm of Hg
- Mean arterial pressure [MAP] in mm of Hg
- Saturation SpO2

The above haemodynamic parameters were monitored in the followingtime interval –

1. Basal before premedication
2. At the time of insertion
3. 1 minute after insertion
4. 2 minutes after insertion
5. 5 minutes after insertion
6. At the time of removal
7. 1 minute after removal

6. Injuries

The patient was inspected for any injury of the lips, teeth or tongue and thedevice for blood stain after its removal at the end of the surgery.[23]

7. Post Operative Complications

18-24 hours after surgery, patient was interviewed for any post operativecomplications like sore throat, dysphagia and hoarseness. Post operative sorethroat was graded as nil, mild, moderate and severe.[17,23]

STATISTICAL METHODS EMPLOYED AND SAMPLE SIZECALCULATION

Sample size calculation was based on the previous studies on LMA andi-gel[15,23].Accordingly, we calculated the sample size to detect at least thedifference between both the devices which was described previously for theprimary end point (airway leak pressure) with an -error of 0.05 and a power of0.9. For a difference of 6 cm H_2O and a standard deviation of 8 cm H_2O,40 patients per group were needed. Considering some dropouts of patients fromthe study, a sample size of 50 in each group was taken.

IV. Results

Table 2: Showing the age distribution

Age (years)	Group-1 (i-gel)		Group-2(c-LMA)	
	NO OF PATIENTS	PERCENTAGE	NO OF PATIENTS	PERCENTAGE
<20	4	8	6	12
21-30	13	26	10	20
31-40	10	20	11	22
41-50	23	46	23	46
Total	50	100	50	100

Mean age in years ±SD	36.9±10.21	36.52±10.60

t-value	0.091
p-value	0.84 (NS)

Table 2 shows age distribution of the patients in both the groups. Theminimum ages in both groups were 18 years. The maximum age in bothgroups was 50 years. The mean age in group 1 and 2 were 36.9±10.21 and36.52±10.60 years respectively. There was no significant difference in the age of the patients between Group 1 and Group 2 (p=0.84).

Table 3: Showing the sex distribution between Group 1 and Group 2

Sex	Group-1 (i-gel)		Group-2(c-LMA)	
	NO OF PATIENTS	PERCENTAGE	NO OF PATIENTS	PERCENTAGE
MALE	8	16	8	16
FEMALE	42	84	42	84
TOTAL	50	100	50	100

From the above table it is seen that statistically there is no significantdifference in the gender in both the groups.

Table 4: Showing the comparison of ease of insertion in between group 1and group 2

Ease of insertion	Group-1 (i-gel)		Group-2(c-LMA)	
	NO OF PATIENTS	PERCENTAGE	NO OF PATIENTS	PERCENTAGE
Very easy	49	98	42	84
Easy	0	0	3	6
Difficult	1	2	5	10
Total	50	100	50	100

p-value – 0.079(NS)

The insertion of i-gel in group 1 patients was graded very easy in49 patients and was difficult in 1 patient. The insertion of c-LMA in group 2patients was graded very easy in 42 patients, easy in 3 patients and difficult in5 patients. The ease of insertion was not statistically significant between the twogroups. (p=0.079)

Table 5: Showing number of attempts of insertion of devices

Insertion attempt	Group-1 (i-gel)		Group-2(c-LMA)	
	NO OF PATIENTS	PERCENTAGE	NO OF PATIENTS	PERCENTAGE
First attempt	49	98	45	90
Second attempt	1	2	5	10
Total	50	100	50	100

49 of 50 (98%) insertions in group 1 were in the first attempt and only1 patient required 2nd attempt. 45 of 50 (90%) in the group 2 required only oneattempt and 5 patients required 2nd attempt. In 2nd attempt for insertion, airwaymanipulation with jaw thrust was required in both the groups.

Table 6: Showing the mean duration for insertion

	Mean duration of insertion (seconds)
Group-1	17.12±3.42
Group-2	25.62±5.28
p-value	0.000 (HS)

HS-Highly significant

The mean duration of insertion of i-gel in group 1 patients and c-LMA ingroup 2 patients were 17.12±3.42 and 25.62±5.28 seconds respectively and wasstatistically highly significant. (p<0.001).

Table 7: Showing the mean airway leak pressures

	Mean airway leak pressure (cm H2O)
Group-1	26.38±2.76
Group-2	19.70±2.10

p-value – 0.000(HS)

HS-Highly significant

The mean airway leak pressure with i-gel in group 1 patients was26.38±2.76 9 (cm H2O) and with c-LMA in group 2 patients was 19.70±2.10(cm H2O) and was highly significant statistically. (p<0.01).

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

Time	**Group 1 (i-gel)**	**Group 2 (c-LMA)**	**p-value**
Basal	81.24±14.14	84.12±13.80	0.3054 (NS)
During insertion	97.12±15.53	95.36±12.22	0.5304 (NS)
1 min-AI	88.72±12.69	90.60±12.16	0.4515 (NS)
3 min-AI	84.48+10.408	87.66±11.57	0.1518 (NS)
5 min-AI	80.80±10.49	85.54±11.13	0.050 (NS)
During removal	97.08±14.09	96.42±14.22	0.8162 (NS)
1 min-AR	91.52±13.49	94.42±11.67	0.2533 (NS)

p<0.01) – Highly significant (HS); (p<0.05) – Significant (S);

(p>0.05) – Not significant (NS); AI-After insertion; AR-After removal

The basal heart rate was comparable in both groups (p=0.305). Statisticalevaluation between the groups showed no significant difference in HR changesbetween group 1 and group 2 during the insertion of i-gel or c-LMA respectivelyand also after 1 min, 3 min and 5 min after insertion. There were also no significantchanges in heart rate during removal and 1 min after removal of the devices inboth the groups.

Table 9: Showing the intergroup comparison of mean arterial bloodpressure MAP (mm of Hg) changes in response to insertion ofi-gel in group 1 and c-LMA in group 2 patients

Time	**Group 1 (i-gel)**	**Group 2 (c-LMA)**	**p-value**
Basal	92.36±10.12	92.08±9.62	0.8876(NS)
During insertion	97.42±11.26	101.54±10.38	0.0602 (NS)
1 min-AI	94.46±10.51	92.12±9.63	0.2489 (NS)
3 min-AI	88.88±8.25	89.74±7.64	0.5900 (NS)
5 min-AI	87.96±9.22	87.02±8.00	0.5874 (NS)
During removal	98.96±12.89	98.92±9.98	0.9862 (NS)
1 min-AR	94.22±16.33	90.6±9.94	0.4030 (NS)

(p<0.01) – Highly significant (HS); (p<0.05) – Significant (S);

(p>0.05) – Not significant (NS); AI-After insertion; AR-After removal

The mean basal MAP were comparable in both groups (p=0.88). Statisticalevaluation between the groups showed no significant difference in MAP changesbetween group 1 and group 2 during the insertion of i-gel or c-LMA and also after1 min, 3 min and 5 mins of insertion. There were also no significant changes inMAP during removal and 1 min after removal of the devices in between the groups.

Table 10: Showing the intergroup comparison of oxygen saturation (%) SpO2changes in response to insertion of i-gel in group 1 and c-LMA ingroup 2 patients

Time	Group 1 (i-gel)	Group 2 (c-LMA)	p-value
Basal	99.98±0.14	100±0.00	
During insertion	99.96±0.19	99.98±0.1414	0.5624 (NS)
1 min-AI	99.98±0.14	100±0.00	
3 min-AI	99.98±0.14	100±0.00	
5 min-AI	99.98±0.14	99.84±0.46	0.055 (NS)
During removal	99.96±0.28	99.9±0.30	0.3086 (NS)
1 min-AR	100±0.00	99.96±0.2828	0.43 (NS)

($p<0.01$) – Highly significant (HS); ($p<0.05$) – Significant (S);
($p>0.05$) – Not significant (NS); AI-After insertion; AR-After removal

The mean SpO2 were comparable in both groups. Statistical evaluationbetween the groups showed no significant difference in arterial SpO2 betweengroup 1 and group 2 during the insertion of i-gel or c-LMA respectively and alsoafter 1 min, 3 min and 5 mins of insertion. There was also no significant changesin SpO2 during removal and 1 min after removal of the devices in between thegroups.

Table 11: Showing the occurrence of post operative tongue/lip/tooth injury

POSTOPERATIVE COMPLICATIONS	Group 1 (i-gel)		Group 2 (c-LMA)		
	No. of patients	Percentage	No. of Patients	Percentage	p-value
Toungue/lip/tooth injury	3	6	4	8	0.695 (NS)
Sore throat	1	2	4	8	0.169 (NS)

NS-not significant

Lip injury was noted in 3 patients in group 1 (i-gel) out of 50 and in4 patients out of 50 in group 2 (c-LMA). However the incidence was notstatistically significant (p=0.695) when compared between both the groups.Two cases in the i-gel group had blood stain on the device on removal while there was no blood staining in any case of c-LMA group.Only 1 patient in group 1 had developed sore throat post operativelycompared to 4 patients in group 2. The incidence was not statistically different (p=0.169) when compared between the groups. The sore throat in all the 5 caseswas mild requiring no treatment.None of the patients in both the groups developed post operativehoarseness or dysphagia.

V. Discussion

The present prospective, randomized study was undertaken to compare twosupraglottic airway devices i-gel and classic-LMA in anaesthetized patients with respect to ease of insertion, number of attempts of insertion, airwayleak pressure, haemodynamic changes and post operative complications

The study population consisted of 100 patients divided into two groupsrandomly using simple closed envelope method with 50 patients in each group.Group 1 consisted of 50 patients in whom i-gel supraglottic airway device wasused and group 2 consisted of 50 patients in whom classic-LMA was used.

Demographic criteria

Both the groups were comparable and there was no statistically significantdifference with regards to mean age, weight, sex, duration and type of surgery.

Ease of insertion

One of the primary objectives was to compare the ease of insertion betweenthe two devices. The grading of insertion was done similar to the study conductedby Siddiquiet al.[18],where insertion of device was recorded as; very easy (whenassistant help was not required), easy (when jaw thrust was needed by assistant)and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).In our study, the ease of insertion of i-gel was very easy (score 1) in 49 (98%) patients and difficult (score 3) only in 1 (2%) patient. In group 2 insertionof c-LMA was very easy (score 1) in 42 (84%) patients, easy (score 2) in 3 (6%)patients and difficult (score 3) in 5 (10%) patients. There was no statisticallysignificant difference between the two groups with respect to ease of insertion ($p>0.05$). The insertion of i-gel was found comparatively easier

and required lessskill as compared to LMA but the results were not statistically significant. Thei-gel having a non inflatable cuff and firm in consistency is much easier for insertion as compared to LMA.

Insertion of i-gel in our study was similar to Richez B et al.[7],study, whograded insertion of no-4 i-gel as very easy in 93% (66 of 71) patients and easy inremaining 7% (5 of 71) patients. Insertion of c-LMA in our study was comparablewith Janakiram et al.,[14]study where 90% (45 of 50) c-LMA insertions were easyinsertions.In this study, insertion of i-gel was successful in first attempt in 98% patients as compared to 90% first time insertion with c-LMA. Airwaymanipulation like jaw thrust was required during second attempt insertion in onepatient of i-gel insertion and 5 patients with c-LMA insertions. Very similarresults were found in studies conducted by Helmy AM et al.,[2]Uppal V et al.,[13]Franksen H et al.,[15]Amini S et al.[16],Siddiqui AS et al.[18],.In Janakiram et al.[14],study, the success rate with first time i-gel insertionwas only 54%, and with c-LMA of 86% which was statistically highly significant.This was because, during the use of i-gel in 14 patients a larger size i-gel had to beused due to presence of audible leak and hence required 2nd attempt. However, inour study we did not have such problem and hence the success rate of first timeinsertion was comparable between both the devices.The time for insertion was considered according to the study conducted byHelmy AM et al.[2],from picking up the device to confirmation of effectiveventilation by bilateral chest movement, square wave pattern capnography, normalrange end tidal CO2 and stable arterial SpO2 (>95%)[15,16].In our study, the time for insertion of i-gel (17.12sec) was shorter comparedto c-LMA (25.6s) which was highly significant statistically (p=0.000).The i-gel SAD is made of thermoplastic elastomer and has no cuff to beinflated after its insertion, hence requires less time for successful insertion ascompared to c-LMA which has a cuff to be inflated after its insertion.Consistent with our results, Helmy AM et al.[2],Uppal V et al.[13],Parul Jet al.,[12]also significant difference in the insertion times. InFranksen H et al.[15],Amini S et al.[16],Ali A et al.[17]studies, though the mean time for i-gel insertion was clinically shorter as compared to c-LMA, it was notstatistically significant.Airway leak pressure detection was performed in a similar manner done byUppal V et al.,[13]in their study. The difference in the leak pressures between i-geland c-LMA were statistically significant in our study (p=0.000) similar to theprevious studies of Janakiram et al.,[14]Franksen H et al.[15],Amini S et al.[16],andHelmy AM et al.[2],.Airway leak pressure of i-gel in our study was comparable with Uppal Vet al.[13],and Helmy AM et al.[2],studies and of c-LMA with Amini S et al.[16],study.The efficacy of the oropharyngeal seal of the SAD depends on the fitbetween the structures surrounding the glottis and the distal mask of the SAD.With c-LMA, in order to obtain a good seal, the distal cuff has to be inflated. Thei-gel made of thermoplastic elastomer is designed anatomically to fit theperilaryngeal and the hypopharyngeal structures without the use of an inflatablecuff. Its airway seal is likely to be higher than that of the LMA-Classic[24].This maybe the reason for improved seal with the i-gel and hence higher airway leakpressures as compared with the c-LMA.

Haemodynamic changes

During the insertion of LMA, pressor response (i.e. increase in heart rateand arterial pressure), may be induced by the passage of the LMA through the oraland pharyngeal spaces, pressure produced in the larynx and the pharynx by theinflated cuff and the dome of the LMA.[15] During removal of LMA thehemodynamic response is probably triggered by pharyngeal stimulation duringreverse rotation of the cuff.[12]The same thing can also occur with insertion andremoval of i-gel

The following haemodynamic parameters were recorded in all patients.

- Heart rate [HR] in beats per minute
- Systolic blood pressure [SBP] in mm of Hg
- Diastolic blood pressure [DBP] in mm of Hg
- Mean arterial pressure [MAP] in mm of Hg
- Saturation SpO2

The above haemodynamic parameters were monitored in the followingtime interval – Basal before premedication, at the time of insertion, 1 minute afterinsertion, 2 minutes after insertion, 5 minutes after insertion, at the time ofremoval and 1 minute after removal.15In our study, there was no statistically significant difference between i-geland c-LMA with regard to heart rate, systolic, diastolic and mean blood pressure and arterial saturation (SpO2). The results of our study were similar to the studiesdone by Helmy AM et al[2].,Franksen H et al.[15],who in their studies found no significant difference between i-gel and c-LMA with regard to heart rate, arterialBP, SpO2 and end tidal CO2.Jindal P et al.[12],in their study observed that i-gel produced lesshaemodynamic changes compared to other SADs. The authors concluded that i-gel effectively confirms to the perilaryngeal anatomy despite the lack of an inflatablecuff, it consistently achieves proper positioning for supraglottic ventilation andcauses less hemodynamic changes as compared to other supraglottic airwaydevices like c-LMA which because of an inflatable cuff can produce morehaemodynamic changes.

Injuries

The inflatable supra glottis airway devices, during insertion, the deflatedleading edge of the mask can catch the epiglottis edge and cause it to down-fold orimpede proper placement beneath the tongue and can cause pharyngeal injury.[25]Inflatable masks also have the potential to cause tissue distortion, venouscompression and nerve injury.In our study, the patients were inspected for any injury of the lips, teeth ortongue and the device for blood stain after its removal at the end of the surgerysimilar to study done by Siddiqui AS et al.[18]Lip injury was noted in 3 patients ingroup 1 (i-gel) out of 50 and in 4 patients out of 50 in group 2 (c-LMA). Howeverthe incidence was not statistically significant (p=0.695). Two cases in the i-gel grouphad blood stain on the device on removal while there was no blood staining in anycase of c-LMA group. Similar results have been observed in studies done byHelmy AM et a[12].In the study conducted by Siddiqui AS et al.[18],blood on device was notedin 18% patients of LMA group while none in the i-gel group which wasstatistically significant. The authors attributed the cause may be due to inflatablemasks having the potential to cause tissue distortion, venous compression andnerve injury.

Post operative complications

In a time period of 18-24 hours after surgery, patients were interviewed for any post operativecomplications like sore throat, dysphagia and hoarseness. Post operative sorethroat graded as nil, mild, moderate and severe.[16,22]Only 1 patient in group 1 had developed sore throat post operativelycompared to 4 patients in group 2. The incidence was not statistically different(p=0.169) when compared between the groups. The sore throat in all the 5 caseswas mild requiring no treatment. None of the patients in both the groupsdeveloped post operative hoarseness or dysphagia.Our results were consistent with the studies done by Siddiqui AS et al.[18],Helmy AM et al.[2]Fanksen H et al.[15],where the difference between LMA andi-gel regarding post operative complications was not statistically significant exceptnausea and vomiting which was significantly higher in LMA due to high incidenceof gastric inufflation.[2] There was a higher incidence of sorethroat and dysphagia at 1, 24, and 48 h in the LMA group compared with the i-gelgroup. Neck pain was also more common at 24 and 48 hours in the LMA group.Because of the absence of an inflatable cuff, the authors hypothesized that use ofthe i-gel produced fewer postoperative throat and neck complaints compared witha standard LMA.

VI. Conclusion

Classic-LMA and i-gel can be used safely and effectively during generalanaesthesia with positive pressure ventilation in selected patients. Both devices areeasy to insert. The i-gel provides a better airway sealing pressure compared toc-LMA. The i-gel has low pharyngolaryngeal morbidity rate as compared toc-LMA.

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