EASE OF INSERTION OF LARYNGEAL MASK AIRWAY BY CLASSIC AND I GEL SUPRAGLOTTIC AIRWAY DEVICES- A COMPARATIVE STUDY

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ABSTRACT

BACKGROUND: Laryngeal mask airway is a supraglottic airway device with an inflatable cuffforming 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 conventional LMA, it does not have an inflatable cuff.The present study was undertaken to compare the performance oftwo supraglottic airway devices classic laryngeal mask airway and i-gel in anesthetized,paralyzed adult patients posted for elective surgeries under general anesthesia.

METHODS : One hundred patients, scheduled for various elective surgical procedures undergeneralanesthesia 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 gelsupraglottic airway device was used and Group 2 (n=50) classic laryngeal maskairway was used. Both the devices were compared concerning the ease of insertion, the number of insertion attempts, time of insertion, airway leak pressure, hemodynamic changes, intraoperative and postoperative complications.

RESULTS : There was no statistically significant difference between the devices concerning ease of insertion and the number of attempts of insertion. The mean airway leak pressurewith i-gel was significantly higher as compared with c-LMA 26.38±2.76 and19.7±2.10 cm H_2O, respectively. The mean time of insertion for i-gel was17.12±3.42 secs which was significantly shorter compared to c-LMA with a meaninsertion time of 25.62±5.28 secs. There were no statistically significantdifferences in hemodynamic changes and the postoperative complications between thedevices.

CONCLUSION : Both i-gel and c-LMA are easy to insert and provide an effective airway during positive pressure ventilation, with i-gel providing a better airway sealing pressure as compared to c-LMA.

KEYWORDS: Laryngeal mask airway; i-gel; supraglottic airway device

Introduction

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. It is designed to be positioned around the laryngeal inlet that could overcome thecomplications associated with endotracheal intubation, and it is simple andatraumatic to insert [1].There are a large number ofsupraglottic airway devices, some of which appear similar to the LMA family andothers that work under a different concept.Laryngoscopy and endotracheal intubation produce reflex sympatheticstimulation and are associated with raised levels of plasma catecholamines,hypertension, tachycardia, myocardial ischemia, and depression of myocardialcontractility, ventricular arrhythmias and intracranial hypertension [2]. Transitory hypertension and tachycardia are probably of no consequence in healthyindividuals but may be hazardous to those with hypertension,myocardial insufficiency or cerebrovascular diseases [3].This laryngoscopic reactionin such individuals may predispose to the development of pulmonary edema,myocardial insufficiency and cerebrovascular accident [4, 5].

Supraglottic airwaydevices are now widely used for surgery requiring general anesthesia, toavoid the complications associated with tracheal intubation [6].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 the insertion of the gastric tube [6].The primary limitation of the laryngeal mask airway (LMA) is that it doesnot reliably protect the lungs from regurgitated stomach contents, although it mayact as a barrier at the level of the upper oesophageal sphincter if it is correctlypositioned. The incidence of aspiration with the LMA has been estimated at0.02%, which is similar to tracheal intubation in elective patients [7].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 laryngopharyngeal space without any air beinginsufflated and additionally has an oesophageal lumen. It can be assumed thatairway 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 [9]. Not many studies have been done to compare the clinical uses of the two supra glottis airway devices namely i-gel and classic-LMA. Hence, this study was undertakenin Prathima Institute of Medical Sciences, to compare these two supraglottic airway devices in relation tothe ease of insertion, number of insertion attempts, time of insertion, airwayleak pressure, haemodynamic changes, intra and postoperative complicationsin anaesthetized, paralyzed adult patients posted for elective surgeries under general anesthesia.

Material and Methods

This cross-sectional study was conducted in the Department of Anesthesia, Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Institutional Ethical Committee clearance was obtained for the study as per protocol. Written consent was obtained from all the patients of the study. A total of n=100 patients scheduled for various elective surgical procedures under general anesthesia belonging to ASA class I and II were included in the study. Inclusion criteria were; Adult normotensive patients aged between 18 and 50 years of both sex, Mallampatti grade I and II, Elective surgeries under general anesthesia with controlled ventilation, Duration of surgery less than 60 minutes. Exclusion criteria were; ASA class III and above, Mallampatti grade

III and above, Emergency surgeries, Head and neck surgeries, Patients with decreased compliance of the lungs, Obese patients with BMI >28 kg/m2. The patients were randomly allotted to Group I i-gel group (n=50), Group 2 – classic LMA group (n=50). A pre-anesthetic evaluation was done on the evening before surgery. All the required investigations were obtained before surgery.

All patients included in the study were premedicated with tablet alprazolam0.5 mg and tablet Ranitidine 150 mg orally at bedtime the previous night beforesurgery. On arrival of the patient in the operating room, an 18-gauge intravenouscannula was inserted under local anesthetic infiltration and an infusion of normalsaline was started. The patient wasconnected to a multiparameter monitor (Starplus of Larson and Toubro), whichrecords heart rate, non-invasive measurements of SBP, DBP, MAP, CO2, 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 the anesthetist based on the patient's body weight and the manufacturer's recommendation. 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 before insertion. After recording the baseline reading, the patient was premedicatedwith injection Midazolam 0.02 mg/kg body weight. Then the patient waspre oxygenated with 100% oxygen for 3 minutes via a face mask with Bain'scircuit. Once an adequate depth of anesthesia wasachieved, the patient was paralyzed by giving intravenous Succinylcholine (1.5 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. The lubricated c-LMA was introduced in the classic method introduced byDr. 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 effectiveairway was confirmed by bilateral symmetrical chest movement, the square waveformon capnograph, normal end-tidal CO2 and stable SpO2 (>95%). The device wassecured with adhesive tape. Bite block was kept in the case of c-LMA and securedalong with it with adhesive tape.

Anesthesia was maintained using 66% nitrous oxide and 33% of oxygenwith 0.6% halothane. After the patient recovered from succinylcholine furtherneuromuscular blockade was maintained with vecuronium 0.05 mg/ kg bodyweight. At the end of the procedure, the 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 neuromuscular blockade.The patient was inspected for any injury of the lips, teeth or tongue and the devicefor bloodstain. 18-24 hours after surgery, the patient was interviewed for any post-operative complications like sore throat, dysphagia, and hoarseness.

Results

The demographic profile of the patients in both groups has been shown in table 1. The minimum age inboth groups was 18 years. The maximum age in bothgroups was50 years. The mean age in groups 1 and 2 was 36.9±10.21 and 36.52±10.60 years respectively. There was no significant difference in the age of the patients between Group 1 and Group 2(p=0.84).The minimum body weight in groups 1 and 2 were 32 Kgs and 30 Kgs respectively. The maximum bodyweight in

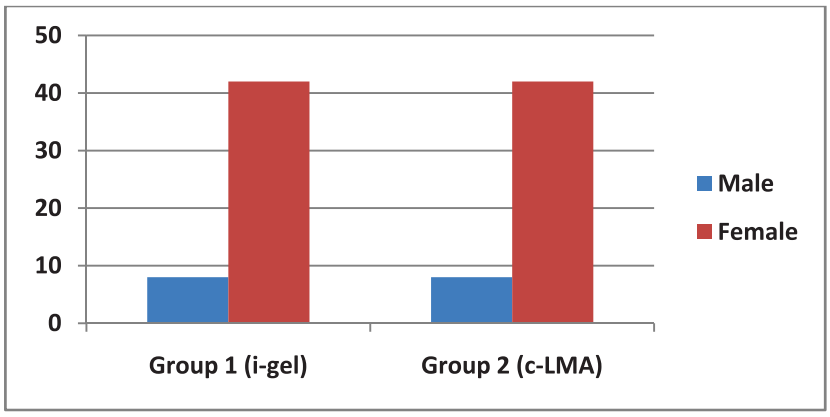
groups 1 and 2 were 85 Kgs and 82 Kgs respectively. The mean body weight in Group 1 was 54.94±13.68 Kgs and in Group 2 it was 56.34±14.16 Kgs. There was no significant difference in the bodyweight of patients between Group 1 and Group 2.In group 1 the mean duration of surgery was 30.08±10.7 minutes and in group 2 it was 43.92±11.8 minutes which was statistically not significant (p=0.078)

Table 1: 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		50	
Mean age in years ±SD	36.9±10.21		36.52±10.60	
t-value	0.091			
p-value	0.84 (NS)			

NS – Not significant

Graph 1: showing the sex-wise distribution of cases in the study



The insertion of i-gel in group n=1 patients were graded very easy in n=49 patients and was difficult in n=1 patient. The insertion of c-LMA in group 2 patients were graded very easy in n=42 patients, easy in n=3 patients and difficult in n=5 patients. The ease of insertion was not statistically significant between the two groups. (p=0.079).N=49(98%) of n=50 insertions in group 1 were in the first attempt and only 1 patient required 2nd attempt. N=45 (90%) of 50 in the group 2 required only one attempt and n=5 patients required 2nd attempt. In 2nd attempt for insertion, airway manipulation with jaw thrust was required in both the groups.

Table 2: Showing the type of surgery performed in two groups of patients

Type of surgery	Group 1 (i-gel)	Group 2 (c-LMA)
Inguinal hernia	5 (10%)	2 (4%)
Carcinoma Breast	23 (46%)	16 (32%)
Fibroadenoma breast	10 (20%)	17 (34%)
Lipoma upper limb	4 (8%)	1 (2%)
Tubectomy	3 (6%)	1 (2%)
Hydrocele	2 (4%)	3 (6%)
Appendicectomy	3 (6%)	8 (16%)
Epigastric hernia	0 (0)	2 (4%)
Total	50 (100%)	50 (100%)

The mean duration of insertion of i-gel in group 1 patients and c-LMA in group 2 patients were 17.12±3.42 and 25.62±5.28 seconds respectively and was statistically highly significant ($p<0.001$). The mean airway leak pressure with i-gel in group 1 patients was 26.38±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 ($p<0.01$).

Table3: Heart Rate (bpm) changes in response to the insertion of i-gel in group 1 and c-LMA in group 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)

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

The mean SBP was comparable in both groups ($p=0.75$). Statistical evaluation between the groups showed no significant difference in SBP changes between group 1 and group 2 during the insertion of i-gel or c-LMA respectively and also after 1 min, 3 min and 5 min of insertion. There were also no significantchanges in SBP during removal and 1 min after removal of the devices in both the group shown in table 4.

Table 4: SBP (mm of Hg) changes in response to the insertionof i- gel in group 1 and c-LMA in group2 patients

Time	Group 1 (i-gel)	Group 2 (c-LMA)	p-value
Basal	117.34±10.74	117.98±9.30	0.7508 (NS)
During insertion	132.36±14.05	131.9±9.42	0.8480 (NS)
1 min-AI	123.10±11.29	120.12±11.72	0.1985 (NS)
3 min-AI	117.78±10.45	115.20±9.06	0.1904 (NS)
5 min-AI	112.98±8.58	117.78±8.84	0.07 (NS)
During removal	133.68±11.83	129.68±11.31	0.0872 (NS)
1 min-AR	126.22±14.27	121.3±10.84	0.0552 (NS)

The mean basal DBP was comparable in both groups (p=0.5686). The mean DBP changes at the time of insertion of the device were not statistically significant. Statistical evaluation between the groups showed no significant difference in DBP changes between group 1 and group 2 during 1 min, 3 min, and 5 mins after insertion. There were also no significant changes in DBP during removal and 1 min after removal of the devices between the groups table 5.

Table 5: DBP (mm of Hg) changes in response to the insertion of i-gel in group 1 and c-LMA in group 2 patients

Time	Group 1 (i-gel)	Group 2 (c-LMA)	p-value
Basal	75.66±10.30	76.78±9.24	0.5686 (NS)
During insertion	78.20±10.91	81.16±12.02	0.08 (NS)
1 min-AI	78.86±11.03	78.98±9.21	0.9531 (NS)
3 min-AI	75.24±8.60	76.02±7.34	0.6271 (NS)
5 min-AI	74.28±9.75	75.12±8.13	0.6410 (NS)
During removal	81.20±13.73	82.70±11.77	0.5591 (NS)
1 min-AR	80.36±15.34	75.68±9.88	0.0730 (NS)

The mean basal MAP was comparable in both groups (p=0.88). Statistical evaluation between the groups showed no significant difference in MAP changes between group 1 and group 2 during the insertion of i-gel or c-LMA and also after 1 min, 3 min and 5 mins of insertion. There were also no significant changes in MAP during removal and 1 min after removal of the devices in between the group table 6.

Table 6: Showing the intergroup comparison of mean arterial blood pressure MAP (mm of Hg) changes in response to the insertion of i-gel in group 1 and c-LMA in group2 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)

The mean SpO2 was comparable in both groups. Statistical evaluation between the groups showed no significant difference in arterial SpO2 between group 1 and group 2 during the insertion of i-gel or c-LMA respectively and also after 1 min, 3 min and 5 mins of insertion. There were also no significant changesin SpO2 during removal and 1 min after removal of the devices in between the groups table 7.

Table 7: SpO2 changes in response to insertion of i-gel in group 1 and c- LMA in group 2 patients

Time	Group 1 (i-gel)	Group 2 (c-LMA)	p-value
Basal	99.98±0.14	100±0.00	>1.0(NS)
During insertion	99.96±0.19	99.98±0.1414	0.5624 (NS)
1 min-AI	99.98±0.14	100±0.00	>1.0 (NS)
3 min-AI	99.98±0.14	100±0.00	>1.0 (NS)
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)

Lip injury was noted in n=3 patients in group 1 (i-gel) out of 50 and in n=4 patients out of 50 in group 2 (c-LMA). However, the incidence was not statistically significant (p=0.695). Only 1 patient in group 1 had developed sore throat postoperatively compared to 4 patients in group 2. The incidence was not statistically different (p=0.169) when compared between the groups. The sore throats in all the 5 cases were mild requiring no treatment.

Table 8: Showing the occurrence of postoperative tongue/lip/tooth injury

Postoperative complications	Group 1 (i-gel)		Group 2 (c-LMA)		p-value
	No. of patients	Percentage	No. of patients	Percentage	
Tongue/Lip/ Tooth Injury	3	6	4	8	0.695 (NS)
Sore Throat	1	2	4	8	0.169 (NS)

Discussion

The i-gel is a novel supraglotticairway device (SAD) made of thermoplastic elastomer which is soft, gel-like, andtransparent. Cadaver studies have shown that i-gels effectively conformed to the perilaryngealanatomy and consistently achieved proper positioning for supraglotticventilation [10].In the study both the groups were comparable and there was no statistically significantdifference with regards to mean age, weight, sex, duration, and type of surgery. 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 Siddiqui et al; [11] 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 forproper device insertion).

In our study, the ease of insertion of i-gel was very easy (score 1) in n=49(98%) patients and difficult (score 3) only in n=1 (2%) patients. In group 2 insertionof c-LMA was very easy (score 1) in n=42(84%) patients, easy (score 2) in n=3 (6%)patients and difficult (score 3) in n=5 (10%)

patients. There was no statisticallysignificant difference between the two groups concerning ease of insertion. The insertion of i-gel was found comparatively easier and required lessskill as compared to LMA. Thei-gel having a noninflatable cuff and firm in consistency is much easier forinsertion as compared to LMA.Ali A et al; [12]Siddiqui et al; [11]Janakiram et al; [13] also did not find any statistically significant difference.In our study, the time for insertion of i-gel (17.12s) was shorter compared to c-LMA (25.6s) was significant statistically. 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 as compared to c-LMA which has a cuff to be inflated after its insertion. Helmy AM et al; [2]Uppal V et al; [11]Jindal Pet al; [14] have also found a significant difference in the insertion times. In Franksen H et al; [15]Amini S et al; [16] Ali A et al; [17] studies, though the meantime for an i-gel insertion was clinically shorter as compared to c-LMA, it was not statistically significant.

Airway leak pressure detection was performed in a similar manner done byUppal V et al; [11] The difference in the leak pressures between i-geland c-LMA were statistically significant in our study similar to theprevious studies of Janakiram et al; [13]Franksen H et al;[15]Amini S et al; [16] andHelmy AM et al; [2].During the insertion of LMA, pressor response 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 [14]. During the removal of LMA, thehemodynamic response is probably triggered by pharyngeal stimulation duringreverse rotation of the cuff [14]. The same thing can also occur with the insertion andremoval of i-gel.In our study, there was no statistically significant difference between i-gel and c-LMA concerning heart rate, systolic, diastolic and mean blood pressure, and arterial saturation (SpO2). The results of our study were similar to the studies done 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 about heart rate, arterial BP, SpO2, and end-tidal CO2. Jindal P et al; [14]in their study observed that i-gel produced fewer hemodynamic changes compared to other SADs.

In our study, the patients were inspected for any injury of the lips, teeth ortongue and the device for bloodstain after its removal at the end of the surgerysimilar to study done by Siddiqui AS et al; [11] Lip injury was noted in n=3 patients ingroup 1 (i-gel) out of n=50 and in n=4 patients out of n=50 in group 2 (c-LMA). Similar results have been observed in studies done byHelmy AM et al; [2].In the study conducted by Siddiqui AS et al; [11] blood on the 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. Postoperative sorethroat graded as nil, mild, moderate and severe [15, 16].Only 1 patient in group 1 had developed sore throat postoperativelycompared to n=4 patients in group 2. The incidence was not statistically different. When compared between the groups. The sore throat in all the n=5 cases was mild requiring no treatment. None of the patients in both the groups developed postoperative hoarseness or

dysphagia. Our results were consistent with the studies done by Siddiqui AS et al;[11]Helmy AM et al; [2]Fanksen H et al; [15]where the difference between LMA and i-gel regarding postoperative complications was not statistically significant except nausea and vomiting which was significantly higher in LMA due to high incidenceof gastric insufflation [2].

Conclusion

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

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