



Original Research Article

A comparative study on the performance between I-gel[®] and Classic laryngeal mask airway in anaesthetized spontaneously breathing patients

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ABSTRACT

Context: The classic Laryngeal Mask Airway (c-LMA) is a first generation supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. I-gel is a supraglottic airway device made of thermoplastic elastomer which is soft gel-like and transparent. Unlike the classic LMA(c-LMA), I-gel does not have an inflatable cuff. In view of this, the present study was undertaken to compare the performance of the two supraglottic airway devices in spontaneously breathing adult patients posted for elective surgeries under general anesthesia.

Aims: To compare the ease of insertion, number of insertion attempts, time for insertion, airway leak pressure, hemodynamic changes as well as perioperative complications such as cough sore throat between patients using the two devices.

Materials and Methods: Sixty patients admitted in SRM medical college and research center scheduled for various elective surgical procedures under general anesthesia belonging to ASA class I and II were included in the study. They were randomly divided into two groups of 30 each using a random number generator. In group I, I-gel supraglottic airway device was used and in Group 2 classic laryngeal mask airway was used. Data was collected using a questionair containing socio-demographic details, details regarding performance of the device as well as hemodynamic changes and perioperative complications.

Results: The insertion was easy in 25 patients (83.3%) in group I, while in group II 15 patients (50%) had easy insertion. $P=0.01781$. The mean time of insertion for I-gel was $(20.17 \pm 3.91$ seconds) which was significantly shorter compared to c-LMA (26.80 ± 7.24 seconds) ($P<0.001$).

There was no statistically significant difference between the devices with respect to number of attempts of insertion. Even though the airway leak pressure is not statically significant, the mean oropharyngeal leak pressure for I-gel was 20.40 ± 5.68 (mm Hg), which was higher than c-LMA 18.73 ± 5.06 (mm Hg), which is well within the normal limits to prevent aspiration. There were no statistically significant differences in hemodynamic changes. No Blood staining was seen after removal of device in I-gel group where it was observed in 2 (7%) patients in c-LMA group. Post removal cough was more in c-LMA (13.3%) than I-gel ($P=0.04$ SS*). Pharyngo-Laryngeal morbidity was more with classic LMA. Sore throat was more with the classic LMA (13.3%) when compared to I-gel group (3%).

Conclusion: We conclude that I-gel is a better airway when compared to c-LMA with respect to ease of insertion, shorter duration for insertion, adequate oropharyngeal seal with lesser pharyngo-laryngeal morbidity and less incidence of airway trauma.

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1. Introduction

LMA is extremely useful in both elective and emergency situations. It can be used successfully difficult airway, The

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LMA-classic has been widely used in clinical practice. It provides a perilaryngeal seal with an inflatable cuff. Additional devices were added to the LMA family to satisfy specific needs, and a number of other devices were developed. Problems with use of Classic LMA(c-LMA) include: postoperative sorethroat (POST), aspiration risk, air leak due to inadequate seal, gastric distension and laryngospasm.

A relatively new supraglottic airway I-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) has been introduced recently. Which has many additional features than the c-LMA. I-gel is made of thermoplastic elastomer. It has an anatomically designed mask that allows quick and easy insertion. It can be accurately positioned itself. It provides a reliable perilaryngeal seal without the need for an inflatable cuff. Its distinctive features like non-inflatable cuff, an integral bite block and buccal cavity stabilizer sets it apart from its other competitors. It also has a port for gastric tube placement.

In our study, objective is to compare the clinical performance of I-gel with classic LMA in relation to the ease of insertion, number of insertion attempts, time of insertion, airway leak pressure, hemodynamic changes, intra and Postoperative complications in anaesthetized, adult patients posted for elective surgeries under spontaneous ventilation.

2. Materials and Methods

This study was done as a observational study in a tertiary Hospital in south India. After getting the ethical committee approval 341/IEC/2012 and informed consent, 60 patients posted for elective surgery under GA with spontaneous ventilation, where assigned randomly into two groups. Patients inclusion in the study are American society of anaesthesiologists physical status I/II, aged18-60, weight between 60-90kgs Mallampati classification I and II and Elective procedures.

Obesity (bmi>35kg/m2), pregnancy, any full stomach patients, mouth opening <2.5cm, h/o GERD, asthma, pharyngeal or laryngel pathology, anticipated difficult intubation, emergencies, allergy to any of the study medications where excluded.

60 Patients were randomly allocated into two groups group 1 and group II.

All patients were kept nil orally for a minimum of 8 hours preceding the surgery. They received intravenous injection midazolam 1 mg, glycopyrrolate 0.2 mg and inj ondansetron 4 mg half an hour before surgery in the pre-anaesthetic room. On arrival in the operating room, after the placement of standard minimum monitoring devices, patients were preoxygenated for three minutes with I00% oxygen. All patients were induced with inj Propofol 2.5 mg/kg i/v and fentanyl 2µ/kg i/v.

LMA or I-gel was inserted according to the study group allotted by randomization. Depth of Anaesthesia was considered adequate for device insertion when the patient has lost eyelash reflex. The airway device size 3 or 4 according to the weight of patient was lubricated with 2% lignocaine gel, the device was inserted, bilateral air entry checked and device secured with tape. Anaesthesia was maintained with nitrous oxide and oxygen in a ratio 2:1 along with sevoflurane to attain a MAC of 0.8 to 1.0.

2.1. Insertion time

Insertion time is calculated from the time in minutes taken from picking the airway in hand to the successful placement of airway as confirmed by auscultation and capnography.

If correct placement could not be achieved, the device will be removed and 2 more attempts will be permitted before failure of insertion were recorded. After 3 unsuccessful attempts, the trachea was intubated. Along with insertion time the number of insertion attempts was also recorded.

2.2. Ease of insertion

Ease of insertion was defined in terms of the need of airway manoeuvres as shown in Table 1.

Table 1: Showing easiness of insertion

Easy	No airway manipulation required
Satisfactory	Required less than 2 manoeuvres
Difficult	Required more than 2 manoeuvres

Maneuvers will be neck extension or flexion, chin lift, jaw thrust or gentle pushing or pulling of the device(1).

2.3. Airway leak pressure

Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed fresh gas flow of 3L/min and recording the oropharyngeal leak pressure by detection of an audible noise using a stethoscope placed just lateral to the thyroid cartilage.

At the end of the surgical procedure, anaesthesia was discontinued and the device was removed while the patient was in a deeper plane of anaesthesia.

2.4. Hemodynamic parameters

The following parameters were monitored prior to insertion and at 0, 1,3,5,10,15 min after securing the airway.

1. Heart rate (HR) in beats per minute.
2. Systolic blood pressure (SBP) in mm of hg.
3. Diastolic blood pressure (DBP) in mm of hg.
4. Oxygen saturation (SpO2) in percentage.

2.5. Post-operative complications

Following post operative airway device related complications were looked for

1. Presence of blood on airway device
2. Lip/Dental injury
3. Post removal cough
4. Patients were assessed 18-24 hours post-operatively for
5. Sore throat (constant pain even without swallowing)
6. Dysphagia (difficulty or pain on swallowing)
7. Dysphonia (difficulty or pain on speaking)

3. Results

The prospective, randomized, comparative study compared the clinical performance between-gel and classical laryngel mask airway in anaesthetized spontaneously breathing patients in 60 adult patients. All date were collected, tabulated and expressed as Mean ± Standard deviation. Appropriate statistical analysis was consider using SSPC 21 version. To find association between two variable at 95% open epi software 2.2 version was used. All quantitative date were compared using unpaired student’s test. All qualitative date were compared using Chi square test P values were calculated for all testes. A p value < 0.05 was considered significant.

The summated result are presented below:

Table 2: Showing ASA distribution

ASA Status	ASA I	ASAII
Group I	21	9
Group II	18	12

In group I (I-gel) out of 30 patient 21 patients were under ASA I & 9 by ASA II. In Group II (classic LMA) 18 were ASA I assessed under ASA I & 12 by ASAIL.

Table 3: Showing age, gender, weight

Age	Group I	Group II	
<20	0	1	$X^2_{yates}=6.033$ $df=4$ $P=.01967NS$
21-30	11	8	
31-40	5	12	
41-50	7	6	
51-60	7	3	
Sex	Group I	Group II	$X^2_{yates}=0.1617$ $df=1$ $P=0.6876$
Male	3	4	
Female	27	26	
Weight	Group I	Group II	
31-40	2	0	$X^2_{yates}=5.04$ $P=0.28(NS)$
41-50	11	8	
51-60	13	13	
61-70	2	6	
71-80	2	3	

The minimum and maximum age in c LMA were 19 years and 58 years respectively and that of I-gel group was 22 years and 57 years respectively. The mean age in group I and II were 38.4 and 36.63 years respectively. There was no significant difference in the age of the patients between Group I and Group II. $X^2_{yates}=6.033$. $df=4$, $P=0.1967$. Both the group are statistically comparable with respect to demographic variables likes age, sex and weight

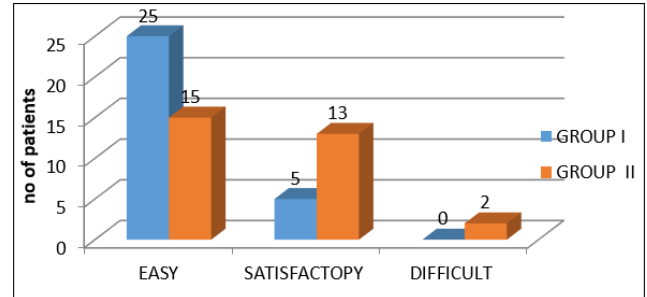


Fig. 1: Showing comparison of ease of insertion

The insertion of I-gel in group I patients was easy in 25(83%) patient satisfactory in 5(16.7%) patients. The insertion of c-LMA was easy in 15 (50%) patients. Satisfactory in 13 (43%) patients and difficult in 2(7%) patients.

$Alph2_{yates}=8.056$, $df=$. $P=0.01781$ *(significant)

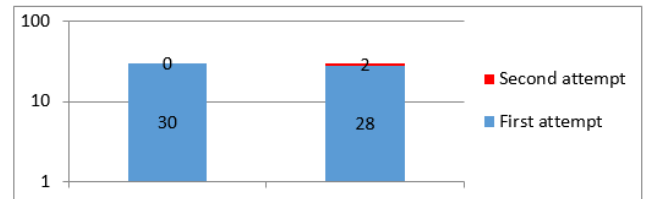


Fig. 2: Showing the comparison of attempts of securing

I-gel insertion was successful in all cases (100%) in first attempt, classic LMA insertion was successful in 28/30(93.3%) in first attempt and 2/30 (7%) patients required additional second attempt. $x^2_{yates}=2.069$, $df=1$, $P=0.1504$ (NS). The difference in successful placement in two groups, though appearing clinically relevant, on statistical analysis did not reveal any difference.

The mean duration of insertion of I-gel is 20.17 ±3.91 seconds and that of c-Lma is 26.80±7.24 seconds respectively the difference in duration is statistically significant $P.000$ *** (highly significant) $t=4.42$.

The mean airway leak pressure with I-gel is 20.40±5.68 (cmH20) and with c-LMA is 18.73±5.06(cmH20). The difference in the airway leak pressure not statistically significant. (P value equals 0.2349).

Heart rate systolic blood pressure, diastolic blood pressure were measured before insertion, then 1 min 3 min,

Table 4: Heart rate, systolic blood pressure, diastolic blood pressure

Time	Parameter	Group-I(I-gel)	Group- II(c-LMA)	p-value
Basal	Herat rate	84.47±12.10	82.97±30.75	0.6554(NS)
	Systolic blood pressure	123±11.57	124.60±15.21	0.6968(NS)
	Diastolic blood pressure	85.04±10	79.47±7.07	0.0103(NS)
During induction	Herat rate	81.40±11.63	78.23±10.85	0.2799(NS)
	Systolic blood pressure	97.63±12.75	97.10±14.91	0.8822(NS)
	Diastolic blood pressure	66.83±11.07	66.60±10.79	0.9344(NS)
During insertion	Herat rate	79.07±12.33	79.10±11.85	0.9914(NS)
	Systolic blood pressure	97.03±10.95	102.03±13.90	0.1272(NS)
	Diastolic blood pressure	65.60±11.07	68.63±10.91	0.2884(NS)
1 min	Herat rate	77.57±10.72	78.67±11.06	0.6971(NS)
	Systolic blood pressure	98.83±11.09	101.80±12.34	0.3427(NS)
	Diastolic blood pressure	67.53±10.51	69.53±11.49	0.4846(NS)
3 min	Herat rate	77.53±10.92	78.30±10.42	0.7818(NS)
	Systolic blood pressure	100.37±9.42	103.67±12.34	0.2489(NS)
	Diastolic blood pressure	66.90±9.77	69.67±9.40	0.3030(NS)
5 min	Herat rate	78.93±10.29	78.70±10.73	0.9381(NS)
	Systolic blood pressure	101.47±9.53	105.60±12.56	0.1565(NS)
	Diastolic blood pressure	69.13±8.07	69.90±9.40	0.7360(NS)
10 min	Herat rate	79.37±10.02	79.33±9.53	0.9895(NS)
	Systolic blood pressure	106.07±13.02	108.83±13.32	0.4192(NS)
	Diastolic blood pressure	73.10±12.07	73.20±11.42	0.9738(NS)
15 min	Herat rate	81.10±12.83	81.13±10.13	0.9911(NS)
	Systolic blood pressure	106.40±9.41	110.43±13.63	0.1875(NS)
	Diastolic blood pressure	73.13±9.19	75.03±11.46	0.4815(NS)

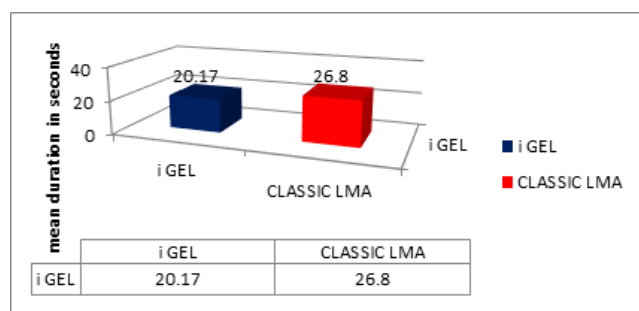


Fig. 3: Showing mean duration of insertion

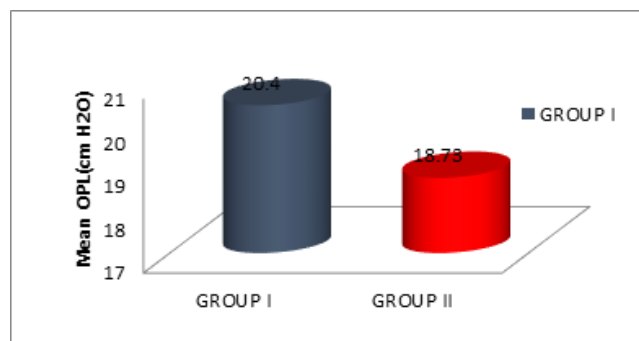


Fig. 4: Showing mean oropharyngeal leak pressure (cmH₂O)

5 min 10 min 15 min after insertion the actual values are documented in the tabular column above statistical analysis by students t test reveals p value which is not significant hence there is no significant hemodynamic responses to insertion in both groups.

3.1. Intraoperative complications

Laryngospasm occurred in one patient in both groups. Both these patients were managed by deepening the plane of anesthesia. However results from both these patients are excluded from the study. Their postoperative period were uneventful.

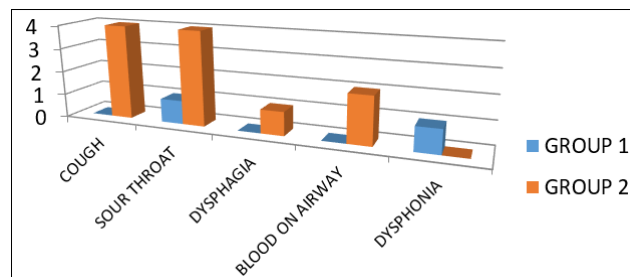


Fig. 5: Showing postoperative complication

Two cases in the classic-LMA group had blood stain on the device on removal while there was no blood staining in any case of I-gel group.

Only 1(3%) patient in group 1(I-gel) had developed sore throat post operatively compared to 4 (13.3%) patients in group 2 (c- LMA). They sore throat in all the 5 cases were mild requiring no treatment.

Dysphagia was observed in one patient of c-LMA while none had in I-gel group.

Cough was observed in 4(13.3%) patients in c- LMA while none of the patients experienced in I-gel group. Which was statically significant ($p=0.04$).

1(3%) patient experienced dysphonia in I-gel group while none of the patients had in Group 2.

4. Discussion

The laryngeal mask airway has been well-established for more than three decades and is often used when endotracheal intubation is not necessary.^{1,2} Nevertheless, utility of the LMA is limited by the potential risk of aspiration.^{1,3,4}

The I-gel supraglottic airway is a 2nd generation supraglottic airway device with a soft anatomically preformed non-inflatable stuff made of a gel like thermoplastic elastomer, containing a gastric port. The tensile properties of the I-gel bowl, along with its shape and the ridge at its proximal end, contribute to the stability of the device upon insertion. The main aim of this study was to compare the clinical performance of I-gel with the c - LMA in terms of the ease of insertion of the device, duration for insertion, leak pressure, and postoperative device related complications.

4.1. Demographic criteria

Both the groups were comparable and there was no statistically significant difference with regards to mean age, weight, sex.

4.2. Ease of insertion

In our study, insertion of I-gel was graded as easy in 25 (83.3%) patients and satisfactory in 5 (16.7%) patients and none of them were difficult insertion of c- LMA was easy in 15(50%) patients, satisfactory in 13 (43.3%) patients and were difficult in 2(7%) patients (X^2 Yates=8.056, $df=2$) $P=0.01781$ *(significant).

Jee-Eun Chang, Hyerim Kim et al. in (2019),¹ Smita R. Engineer, Digant B. Jansari, Saumya Saxena et al (2016).² Vinuth Krishna Murthy, Krishna Prasad Patla et al. (2020)⁵ concluded that I-gel is effective airway which is easier to insert and provides a better airway maintenance even in the scene of a difficult airway. In many studies ease of insertion becomes an important factor when these devices are used by relatively untrained personnel.⁶ The firmness of the tubesection, having a non inflatable cuff and oropharyngeal curvature allows easy insertion of I-gel.

4.3. Time need for insertion

I-gel requires less time for insertion with a preformed mask forming a good around the laryngeal inlet. We found that not only was the I-gel quicker to insert but it required fewer manipulations to facilitate insertion than the c-lma these findings widen the scope of I-gel as an emergency rescue airway devices especially in “cannot ventilate cannot intubate situations.”⁷⁻⁹

Pratibha SD et al (2017),¹⁰ Balasaheb Tukaram Govadane et al (2018)² also found that I-gel is an effective airway which is quicker to insert when compared to C-LMA

4.4. Number of attempts for successful placement

There is a 100% success rate for I-gel when compared to c-LMA(93%) but it was not statically significant. In Janakiram et al¹¹ study, the first attempt success rate with I-gel insertion was only 54% and with c-LMA it was 86%. Which was highly significant this was because during the use of I-gel in 14 patients a larger size had to be used due to the presence of an audible leak and hence required a second attempt. However, in our study we didn't have such problem.

Successful airway management¹² is the first priority in a variety of emergency care and pre hospital scenarios. Supraglottic airway s have provided to be relatively safe and easy to be used by operators with limited airway management experiences. The European Guidelines for resuscitation^{13,14} reduced emphasis on early tracheal intubation in favour of supraglottic airway. Even though it is not statically significant, our study has proven a 100%success rate in first attempt for I-gel.

4.5. Oropharyngeal leak pressure

In our study, the mean OPL is higher in I-gel (20.4mmHg) when compared to classic LMA (18.73) similar to the study conducted by Jeevan Sing, et al in 2012.¹⁵ Though our Leak pressure is not statistically significant, the airway sealing pressure of I-gel Group was very well within the normal limit to prevent aspiration. Thus proving the adequacy of ventilation Srinivas Rao et al in 2016,¹⁶ Gupta P, Kumar A 2015¹⁷ had similar results.

4.6. Hemodynamic

There was no statistically significant difference in hemodynamic response in both groups, similar to studies done by Jee-Eun Chang, Hyerim Kim et al in (2019),¹ Gunaseelan Sivasamy et al. in (2018).¹⁸

4.7. Injuries observed

In our study, patients were inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery. None of the patients had

blood stain in I-gel group and 2(7%) patients in classic LMA had blood on the device. No injuries to lip, teeth or tongue was noted in our study.

Vinuth Krishna Murthy et al. 2020⁵ Syed Amir Raza et al., in 2012¹⁹ in their study observed no blood stain on the device on removal of I-GEL.

Siddiqui AS et al. (2010)²⁰ observed blood on device in 18% patients in c-LMA group and none in the I-gel group.

4.8. Post operative complications

Because of the absence of an inflatable cuff, the authors hypothesized that use of the I-gel produced fewer postoperative throat and neck complaints compared with a c-LMA. In my study only 1 (3%) patient in I-gel group had developed sore throat post operatively compared to 4 (13.3%) patients in (c-LMA). The sore throat in all the 5 cases were mild requiring no treatment dysphagia was observed in one patient of c-LMA while none in I-gel group.

Cough was observed in 4(13.3%) patients in c-LMA while none of the patients experienced in I-gel group, which was statically significant (p=0.04).

1 (3%) patient experienced dysphonia in I-gel group while none of the patients had in c-LMA.

18-24 hours after surgery, patients were assessed for any postoperative complications like sore throat, dysphagia and hoarseness. Postoperative sore throat graded as nil, mild, moderate and severe.^{6,21}

Raajaram Mu, et al. 2016²² in their study they observed no sore throat, Keijzer C et al. in 2009²³ in their study compared the post-operative throat and neck complications between c-LMA and I-gel. There was a higher incidence of sore throat and dysphagia at 1, 24, and 48 h in the LMA group compared with the I-gel group. Neck pain was also more common at 24 and 48 h in the c-LMA group.

5. Conclusion

Hence we conclude that I-gel is a better airway when compared to classic LMA with respect to ease of insertion with shorter duration for insertion. Adequate oropharyngeal seal with lesser pharyngolaryngeal morbidity and less incidence of airway trauma and no significant difference in number of attempts and oropharyngeal leak pressure.

6. Source of Funding

Nil.

7. Conflicts of Interest

There are no conflict of interest.

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