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Original research article

A Prospective Study is to Evaluate the Efficacy of two Types of Supraglottic Airway Devices- I-gel and cLMA.

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Abstract

One of the major responsibilities of an anesthesiologist is to provide adequate ventilation to the patient. Difficult airway has been responsible for as many as 30% of deaths attributable to anesthesia. The I-gel is the most recent development in supraglottic airway devices. The I-gel is a new single use non inflatable supraglottic airway device. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation. The Laryngeal Mask Airway (LMA) is extremely useful when used conservatively and has proved valuable as a rescue device in both elective and emergency situations, obviating the need for laryngoscopy and virtually requiring minimal training in its use.

Methodology: A study was conducted on 60 adult patients, of both sexes in a randomized prospective manner undergoing elective surgery belonging to ASA physical status I and II.

Group I (30 patients) for I-gel insertion

Group II (30 patients) for classic LMA insertion

Both the devices were compared in relation to the hemodynamic changes, ease of insertion and post-operative sore throat with classic LMA and I-gel in patients undergoing elective surgeries with spontaneous ventilation.

Results: There was no statistically significant difference between the two groups in terms of ease of insertion, number of attempts, hemodynamic changes andpostoperative sore throat and other complications.

Conclusion: Both I-gel and cLMA are easy to insert and provide an effective airway during spontaneous ventilation.

Keywords: Laryngeal mask airway, I-gel, Supraglottic airway device.

Introduction

The first successful supraglottic airway device, the laryngeal mask airway (LMA) classic became available in 1989, first described by Dr.Archie Brain[1] LMA are being used in spontaneous and controlled ventilation. Apart from anaesthesia, various variants of LMA can potentially be useful in other clinical situations i.e. cardiopulmonary resuscitation (CPR) [2,3,4,5]pre-hospital emergency use, and management of a difficult airway[6]. Inspite of this LMA are contraindicated in situations like low pulmonary compliance[7], high airway resistance or conditions where there is increased risk of regurgitation. It is also contraindicated in patients with pregnancy of greater than 14 weeks, morbid obesity, hiatus hernia or any factor associated with delayed gastricemptying careful observations and clinical experience have led to several refinements of Brian's original prototype leading to the development of newer supraglottic airway devices with better airway maintenances such as ProsealLMA, combitube and I- gel LMA. The primary limitation of the LMA is that it does not reliably protect the lungs from regurgitated stomach contents, although it may act as a barrier at the level of the upper oesophageal sphincter if it is correctly positioned.

The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation in elective patients[8]. The I-gel is the most recent development in supraglottic airway devices. Great contribution in the development of this device was made by Dr. Mohammad Aslam Nasir in January 2007[9].The I-gel is a truly anatomical device. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces[9,10]. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation. A drain tube is placed lateral to the airway tube which allows insertion of the gastric tube[11]

Materials and Methods.

The present study from April2021 to January2022 ,Department of anaesthesia ,Dr. N.D. Desai FMSR, Dharmasinh Desai University, College Road, Nadiad, Gujrat After obtaining written informed consent, 60 adult patients of both sexes belonging to ASA Grade I and II planned various elective procedures lasting for 45min to 1 hour duration, were randomly selected.

The study group was divided in two groups of 30 each (n=30):

Group I (30 cases where I- gel was used)

Group II (30 cases where cLMA was used).

Inclusion criteria were

- ASA Grade I & II patients
- Age between 18 to 55 years of both sexes
- Planned for elective surgical interventions where spontaneousventilation is ideal.

Exclusion criteria were

- Patients' refusal
- ASA Grade III & IV patients
- Mouth opening< 2.5 cm
- Obese patients with BMI > 28kg/m2
- Emergency surgical interventions
- Patients with history of allergy or sensitivity to latex or egg
- History of Gastroesophageal reflux disorder

Results

Descriptive and inferential statistical analysis has been carried out in the present study.
The results were analysed by using SPSS version 18 (IBM Corporation, SPSS Inc., and Chicago, IL, USA)**.** Results on continuous measurements were presented on Mean±SD (Min-Max). Significance was assessed at 5% level of significance. Normality of the data was assessed using Kolmogorov Smirnov test. Independent t- test was used to find the significance difference of study parameters between the groups. All results were compared, compiled and statistical analysis was carried out to reach the conclusion. Sample size calculation was based on the previous study on LMA and I-gel.

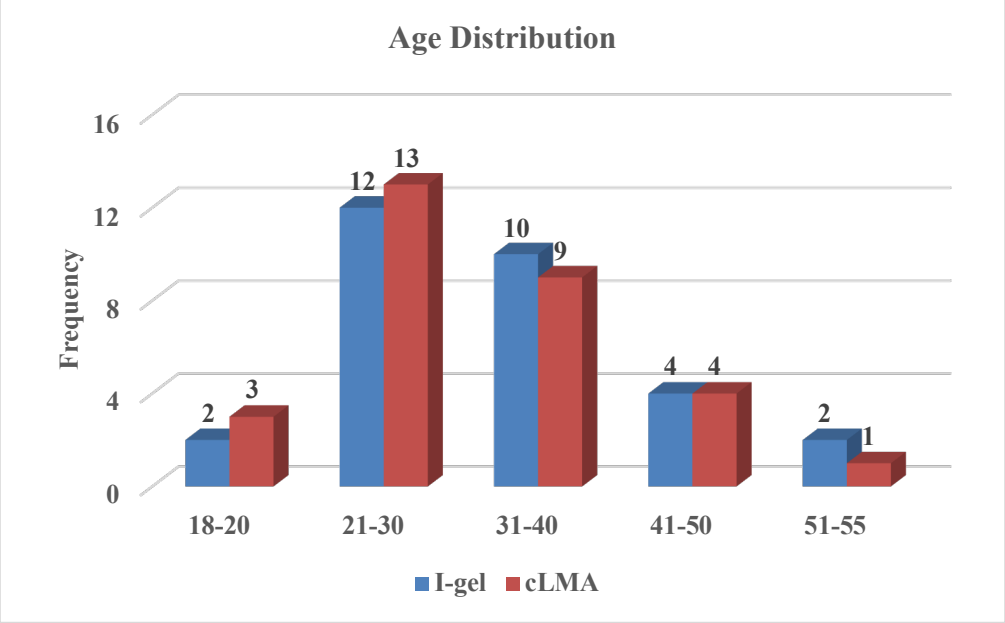
Table 1: Age distribution of patients studied in both the groups

Age in years	**I-gel**		**cLMA**	
	No	**Percentage**	**No**	**Percentage**
18-20	02	6.7%	03	10%
21-30	12	40%	13	43.4%
31-40	10	33.3%	09	30%
41-50	04	13.3%	04	13.3%
51-55	02	6.7%	01	3.3%
Total	30	100%	30	100%
Mean±SD	33.37±10.19		31.73±8.98	

P=0.513

Inference: Both groups are homogeneous.

There was no significant difference between the age groups of the patient (p=0.513)

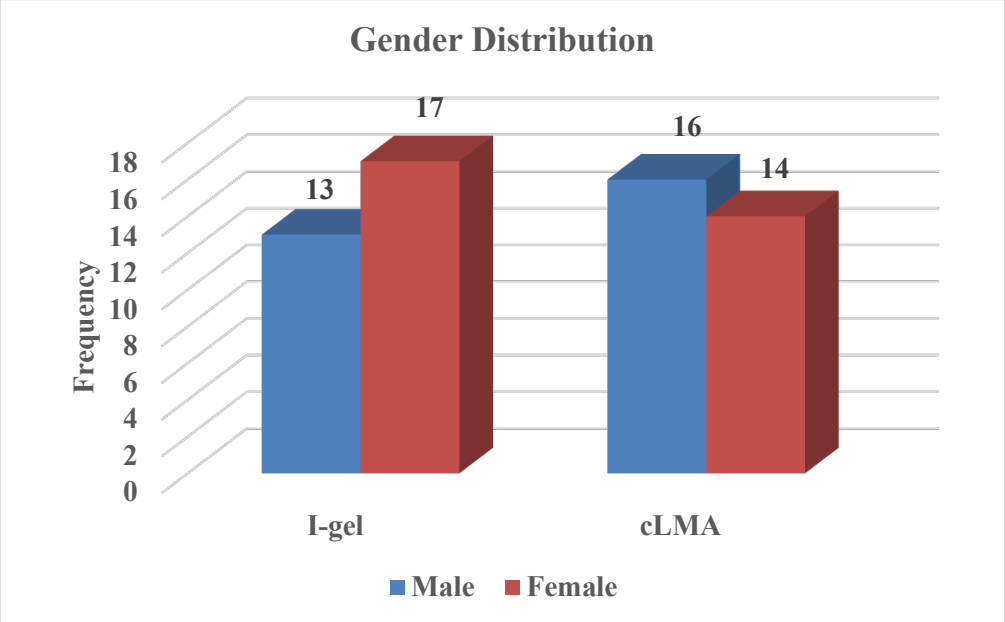


Graph 1

Table 2: Gender distribution of patients studied

Age (years)	I-gel		cLMA	
	No	Percentage	No	Percentage
Male	13	43.4%	16	53.4%
Female	17	56.6%	14	46.6%
Total	30	100%	30	100%

Interpretation: There was no statistical significant difference in gender distribution between the two groups.



Graph 2

Table 3: BMI (kg/m^2)

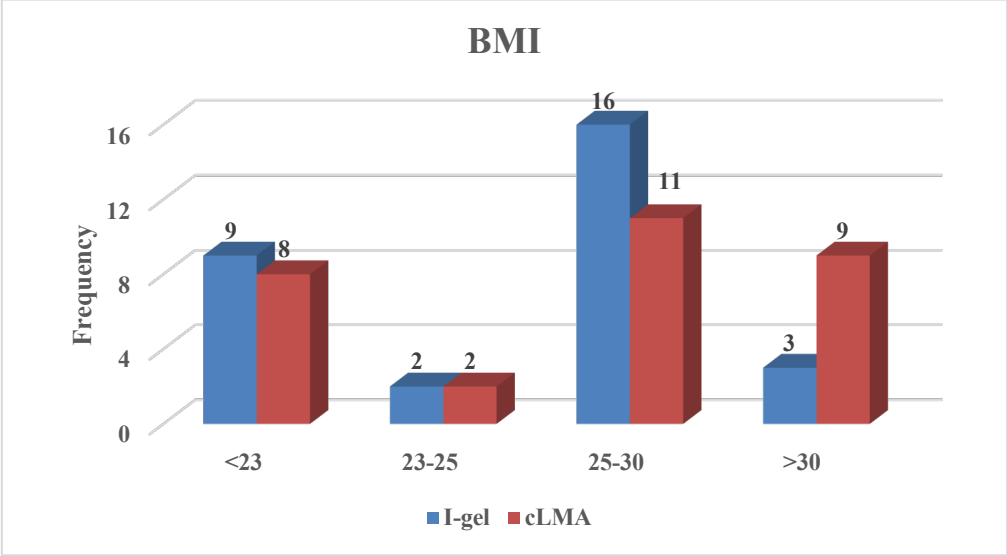
BMI (kg/m^2)	I-gel		cLMA	
	No	Percentage	No	Percentage
<23	09	30.0%	08	26.6%
23-25	02	06.6%	02	06.6%
25-30	16	53.4%	11	36.8%
>30	03	10.0%	09	30.0%
Total	30	100%	30	100%
Mean ± SD	26.10±3.95		26.54±5.35	

P=0.719

Inference: Both groups are homogeneous.

The mean BMI of both groups I and II were 26.10±3.95 and 26.54±5.35 respectively.

There is no significant differences in the BMI of both groups (p=0.719).

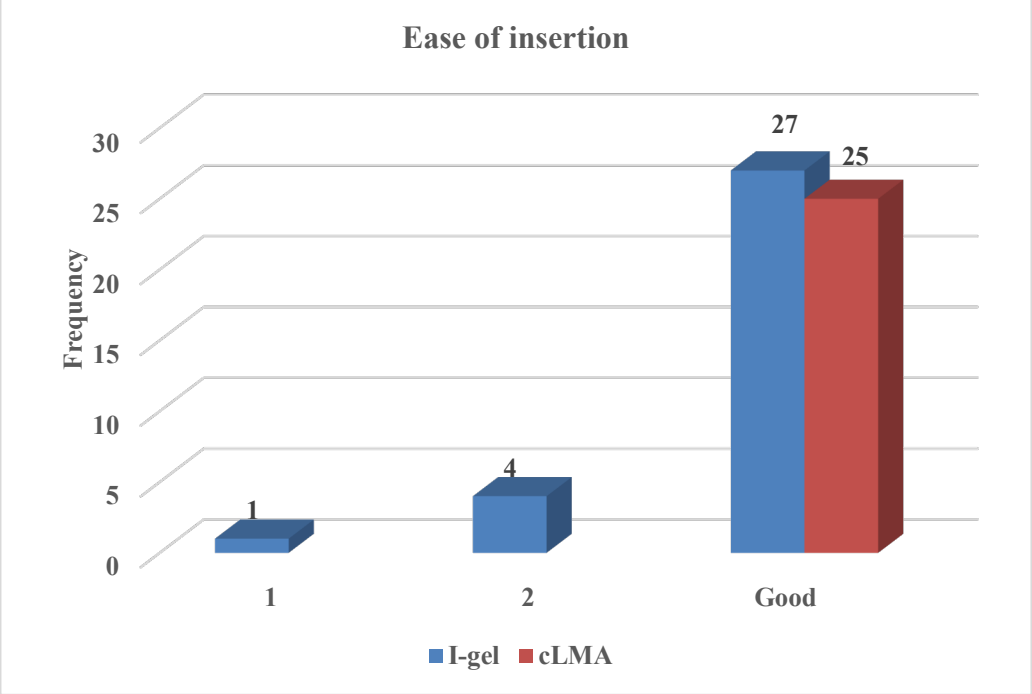


Graph 3

Table 4: Ease of Insertion

Ease of insertion (secs)	I-gel		cLMA	
	No	Percentage	No	Percentage
Poor	01	03.4%	01	03.4%
Fair	02	06.6%	04	13.3%
Good	27	90.0%	25	83.3%
Total	30	100%	30	100%

Interpretation: The ease of insertion was found to be statistically similar in two groups.

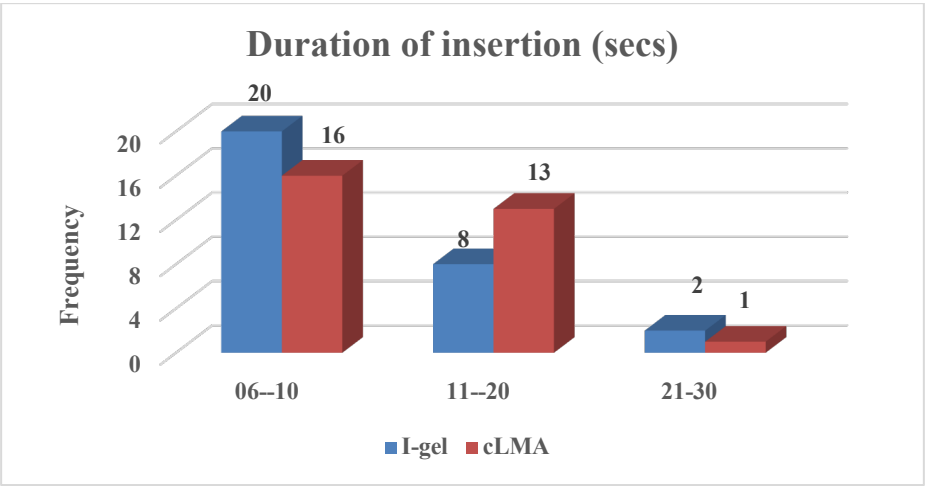


Graph 4:

Table 5: Duration of insertion (secs)

Duration of insertion (secs)	I-gel		cLMA	
	No	Percentage	No	Percentage
6-10	20	66.8%	16	53.3%
11-20	08	26.6%	13	43.3%
21-30	02	06.6%	01	03.4%
Total	30	100%	30	100%
Mean±SD	11.13±4.38		11.83±4.01	

P=0.521**Inference:** There is no significant difference between the groups

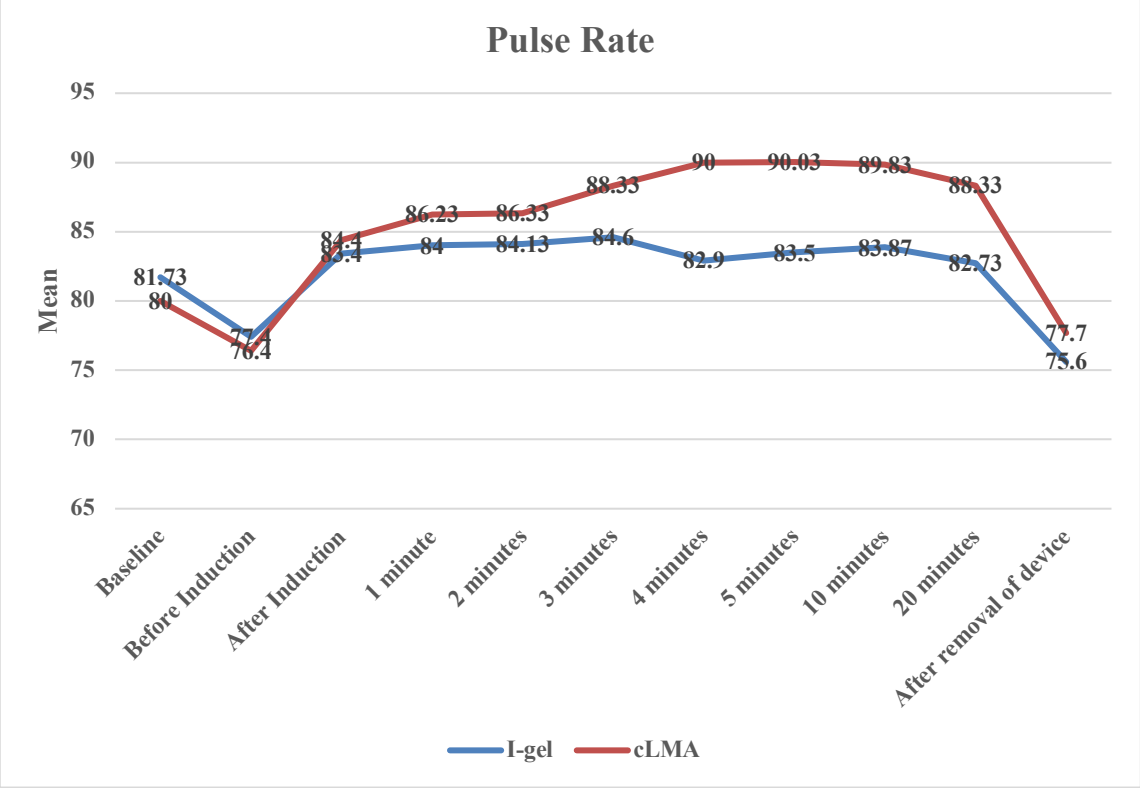


Graph 5

Table 6: Comparison of Pulse rate in two groups studied

Pulse rate	I-gel	cLMA	P value
Baseline	81.73±8.57	80±9.58	0.46
Before Induction	77.40±5.58	76.40±6.79	0.53
After Insertion	83.40±5.53	84.40±3.57	0.41
1 minute	84±4.16	86.23±4.19	**0.04**
2 minutes	84.13±3.74	86.33±4.22	**0.03**
3 minutes	84.60±4.36	88.33±3.90	**0.001**
4 minutes	82.90±5.76	90±3.23	**<0.001**
5 minutes	83.50±5.00	90.03±3.27	**<0.001**
10 minutes	83.87±5.75	89.83±3.40	**<0.001**
20 minutes	82.73±5.72	88.33±3.18	**<0.001**
After removal of device	75.60±4.89	77.70±5.36	0.12

Interpretation: In the above table pulse rate has been compared in both the groups and the difference is found to be statistically significant after the insertion of devices.



Graph 6

Discussion

In the past, choice of airway device was either facemask or endotracheal tube. British anesthesiologist, Dr. Archie Brain in 1981invented the LMA[12], thedevice that could easily and atraumatically be inserted in order to open the obstructed airway rapidly.

LMA came into practice in 1983, since then many families of supraglottic devices were developed. Some are still in use and some had dwindled into oblivion. LMAs are used to ventilate patients lung's during anaesthesia but maybe associated with a less effective seal compared with the traditional tracheal tubes. The I-gel (Intersurgical Ltd, Wokingham, UK) is a novel supraglottic airway device, made of thermoplastic elastomer which is soft, gel-like and transparent.

It wasintroduced for clinical practice by Dr. Mohammed Aslam Nasir in 2007. Unlike the conventional LMA, it does not have an inflatable cuff. Cadaveric studies have shown that I-gels effectively conformed to the perilaryngeal anatomy and consistently achieved proper positioning for supraglottic ventilation. Many studies have been done to compare I-gel with ProsealLMA, but not many studies have been done to compare the clinical uses ofI-gel and cLMA. The aim of undertaking the present study was to compare the I-gel and cLMA in terms of various parameters as ease of insertion, hemodynamic parameters and post-operative sore throat (if any). The original LMA, also called the cLMA, looks like an ETT equipped with an inflatable, elliptical, silicone rubber collar (laryngeal mask) at the distal end. The laryngeal mask component is designed to surround and cover the supraglottic area, providing upper airway continuity. Two rubber bars cross the tube opening at themask end to prevent herniation of the epiglottis into the tube portion of the LMA.

The I-gel is a newly developed single usesupraglottic device with a non-inflatable cuff, devoid of the complications of inflatable cuffs. Levitan RM et al[13], Jolliffe L et al [14]& Jindal P et al[15] observed that the I-gel airway has a sophisticated three dimensional bowl structure intended to mirror perilaryngeal anatomy providing a snug fit onto the glottis. A prospective randomized controlled study of 60 patients was conducted to compare the cLMA and I-gel with respect to the ease of insertion, hemodynamic parameters andpost-operative complication. The patients chosen for the study included all those who were to undergo surgeries, where supraglottic devices were used in supine position.

Conclusion

Classic LMA and I-gel can be used safely and effectively during general anesthesia with spontaneous ventilation in selected patients. Both devices are easy to insert with adequate premedication. The durations of insertion and number of attempts at insertion was less with I-gel as compared to cLMA, though not statistically very significant. I-gel thus, proved to be better and efficient than cLMA in this regard. The time of insertion was, also, considerably less for the I-gel highlighting its efficacy in controlled & spontaneous ventilation conditions and also in resuscitative scenarios.

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