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# RANDOMISED COMPARATIVE STUDY BETWEEN CLASSIC LARYNGEAL MASK AIRWAY AND I-GEL FOR ANAESTHESIA WITH CONTROLLED VENTILATION

**Dr. Rihana A. P.** Junior Resident.

**Dr. Priti Devalkar** Additional Professor.

**Dr. Devika Poduval**

**ABSTRACT** A hospital-based, prospective randomized comparative study was conducted for a duration of 1 year to compare Classic Laryngeal Mask Airway with I-gel in adult patients undergoing general surgery with respect to effective airway time, number of attempts, hemodynamic response and associated immediate and delayed complications. A total of 80 patients were randomly allocated into two groups of 40 each: Group A: Classic LMA was inserted and; Group B: I-gel was inserted. Both the groups were comparable with respect to age, gender and ASA distribution (p value>0.05). Mean effective airway time for successful placement of device was significantly more for I-gel as compared to LMA Classic (28.48 seconds vs 16.66 seconds, p<0.01). In LMA Classic group, successful placement was seen in 97.5% patients in the first attempt and in 75% of the patients in I-gel group. No failure was seen in any of the group. Hemodynamic parameters such as heart rate, mean arterial pressure, SPO2 and ETCO2 were comparable between the two groups. Sealing pressure was comparable between the two groups. Incidence of blood staining on device was observed in 5 patients (12.5%) in LMA group as opposed to just 1 patient (2.5%) in I-gel group. There were no late complications in both the groups.

**KEYWORDS :** Classic LMA, I gel LMA

## INTRODUCTION

Airway management has evolved greatly; from the development of endotracheal intubation by Mc Evan in 1880 to the present day use of supraglottic airway device [(1)]. Endotracheal intubation is the proven standard of care for maintaining a patent airway during anesthesia. But this requires skill and has a long learning curve and requires continuous training and practice. Supraglottic airway devices(SADs) are medical devices which are capable of acting as a passageway for ventilation, oxygenation and administering anesthesia gases.

The LMA Classic consists of an inflatable silicone mask with a connecting tube. It is inserted blindly into the pharynx with the index finger. Once inserted, the cuff needs to be inflated forming a low-pressure seal at the laryngeal inlet. The LMA Classic has also found a place in the Difficult Airway Society (DAS) Guidelines and in a Cannot Intubate Cannot Oxygenate situation. On the other hand, once the cuff is inflated, it causes tissue oedema of the perilaryngeal structures, venous congestion and nerve injury. There is also a risk of aspiration due to prolonged use of LMA as there is gastric insufflation with no port for gastric drainage tube [(5)].

Newer generation devices started incorporating gastric channel for gastric drainage tube, elevated leak pressures thus providing more dependable positive pressure ventilation, integrated bite blocks and disposability thus facilitating one-time use.

The I-gel is a second generation supraglottic airway device by Intersurgical launched in 2007. It is made of a soft, gel-like transparent medical grade thermoplastic elastomer. It has a non-inflatable cuff, designed to form an anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures whilst avoiding the compression trauma that can occur with inflatable SADs. We aimed to compare Classic LMA and I gel as an airway device in patients undergoing general surgery.

## MATERIALS AND METHODS:

**Study Design:** This was a single center randomized prospective comparative study done over one year at a tertiary care hospital.

**Sample Size:** Our study was carried out in 80 patients who were randomly allocated into two groups, consisting of 40 patients each, using computer generated sequences.

- Group A – Classic LMA was inserted.
- Group B – I-gel was inserted.

**Inclusion Criteria:**

- Patients of ASA I or ASA II.
- Patients of either sex in the age group 18-65 years.
- Patients posted for elective general surgery in the supine position under general anesthesia with controlled ventilation.

**Exclusion Criteria:**

- Patient's refusal for consent for study
- Anticipated difficult airway - any pathology of the neck and upper respiratory tract, mouth opening <2.5cm, patients with history of obstructive sleep apnea.
- Pregnancy
- Patients at risk of aspiration e.g. full stomach, hiatus hernia or gastro-esophageal reflux disease or those undergoing emergency surgery, BMI >25 kg/m$^2$.

## METHODOLOGY

This was a randomized, prospective, comparative clinical study conducted after obtaining approval from the Departmental Review Board and Institutional Ethics Committee. Written informed consent was obtained from all participants during pre-anesthetic evaluation. Eighty ASA physical status I–II patients scheduled for elective general surgery in the supine position were enrolled. Standard preoperative fasting was confirmed. Upon arrival in the operating room, standard monitors (pulse oximeter, NIBP, ECG, capnograph) were attached and baseline parameters recorded. A 18G IV cannula was secured, and lactated Ringer's solution initiated.

Patients received preoxygenation with 100% oxygen for 3 minutes, followed by IV midazolam (0.03 mg/kg) and fentanyl (2 μg/kg). Anesthesia was induced using IV propofol (2 mg/kg), and mask ventilation confirmed before administering vecuronium (0.1 mg/kg). After 3 minutes, the airway device (I-gel or LMA Classic) was inserted per manufacturer's instructions based on group allocation and patient body weight. The device was connected to a breathing circuit and manual ventilation was initiated. Correct placement was confirmed by square wave capnography and bilateral chest expansion. If gastric insufflation occurred, the device was reinserted.

Insertion time (from device pick-up to effective ventilation) and number of attempts were recorded. A maximum of three attempts were allowed; failure led to endotracheal intubation. Anesthesia was maintained with oxygen, nitrous oxide, and a volatile agent. Hemodynamic parameters were recorded at baseline, and at 1, 5, 10, and 15 minutes post-insertion. Airway sealing pressure was determined by closing the expiratory valve at 3 L/min gas flow and recording the equilibrium pressure where a leak was detected.

At surgery completion, anesthesia was discontinued and neuromuscular blockade reversed with IV neostigmine (0.05 mg/kg) and glycopyrrolate (8 μg/kg). The airway device was removed and complications such as post-extubation cough, breath-holding, laryngospasm, blood staining, or trauma to lips, tongue, or teeth were noted. At 24 hours postoperatively, patients were assessed for sore throat, dysphonia, and dysphagia.

**Monitoring:**

1. Insertion time for effective airway and ease of insertion (no. of insertion attempts)
2. Cardiorespiratory parameters - Heart rate, non-invasive blood pressure, end tidal $CO_2$ tension and oxygen saturation ($SpO_2$)
3. Airway sealing pressure
4. Airway complications

- Post-extubation cough, breath holding or laryngeal spasm
- Blood staining on device, lip and dental injury
- Dysphonia, sore throat, dysphagia

## OBSERVATIONS AND RESULTS

This study included 80 patients which were randomized in two groups, Group A (LMA classic) and Group B (I gel). The demographic data and ASA status was comparable in both the groups. There was statistically significant difference between the insertion time and sealing pressure of the two groups. (Table1). The mean insertion time of LMA Classic was 16.65+/-7.32 secs as compared to I gel 28.48+/-14.51 secs (p value <0.01). The mean sealing pressure was 14.90+/-2.00 with LMA classic as compared to 15.73+/-2.29 with I gel (p value 0.09).

**Table 1: Distribution Of Study Parameters**

| Study Parameter | | Group A (LMA Classic) | Group B (I gel) | p value |
|---|---|---|---|---|
| Sex | Male | 20(50%) | 26(65%) | 0.258 |
| | Female | 20(50%) | 14(35%) | |
| ASA status | ASA I | 40(100%) | 38(95%) | 0.49 |
| | ASA II | 0 | 2(5%) | |
| Mean age (years) | | 35.70±14.68 | 36.63±15.84 | 0.787 |
| Weight (kgs) | | 55.03±7.57 | 57.40±10.83 | 0.259 |
| Insertion time(sec) | | 16.65±7.32 | 28.48±14.51 | <0.01 |
| Sealing pressure (mmHg) | | 14.90±2.00 | 15.73±2.29 | 0.09 |

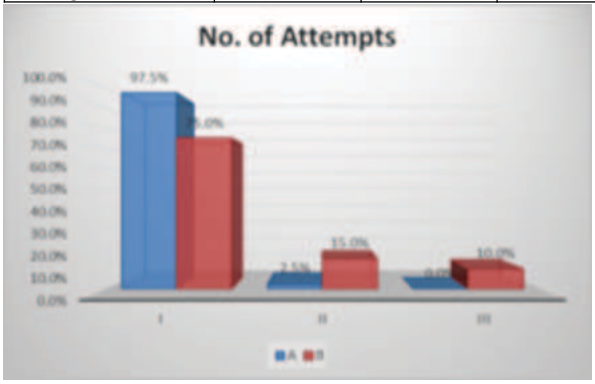


**Fig 1:** Comparison of number of attempts required for successful insertion of LMA Classic and I-gel

In LMA Classic group, successful placement was seen in 97.5% patients in the first attempt and in 75% of the patients in I-gel group. Second attempt was required in 2.5% of patients in LMA Classic group whereas 15% of patients in I-gel group. Third attempt was not required in any patient for LMA Classic and in 10% (four) patients for I-gel group (p- 0.013). No failure was seen in any of the group (**Fig 1**).

The hemodynamic variables and clinical parameters noted at specified time intervals were comparable between two groups as seen in Table 2 and Figure 2.

**Table 2: Clinical Parameters At Specified Time Intervals**

| Time | Groups | HR | MAP | Spo2 | Etco2 |
|---|---|---|---|---|---|
| Pre-insertion | A | 73.13+/-10.50 | 74.63+/-7.82 | 99.98+/-0.16 | 30.63+/-3.22 |
| | B | 73.08+/-9.47 | 78.91+/-14.41 | 99.50+/-0.27 | 29.85+/-3.77 |
| | P value | 0.98 | 0.09 | 0.31 | 0.33 |
| 1 minute | A | 73.08+/-9.34 | 74.05+/-7.02 | 99.98+/-0.16 | 32.28+/-3.91 |
| | B | 72.68+/-9.60 | 78.65+/-12.10 | 99.60+/-0.22 | 33.50+/-3.48 |
| | P value | 0.85 | 0.05 | 0.56 | 0.14 |
| 5 minutes | A | 72.33+/-9.15 | 73.93+/-6.76 | 99.93+/-0.27 | 33.40+/-3.71 |
| | B | 70.05+/-9.33 | 75.03+/-7.83 | 99.60+/-0.27 | 34.70+/-3.61 |
| | P value | 0.27 | 0.50 | 1.00 | 0.12 |
| 10 minutes | A | 72.70+/-8.35 | 73.00+/-6.55 | 99.95+/-0.22 | 34.05+/-3.39 |
| | B | 69.53+/-8.68 | 74.48+/-7.17 | 99.70+/-0.16 | 34.88+/-3.60 |
| | P value | 0.11 | 0.34 | 0.56 | 0.29 |
| 15 minutes | A | 72.15+/-8.48 | 72.68+/-5.95 | 99.95+/-0.22 | 34.45+/-3.58 |
| | B | 68.88+/-8.18 | 75.05+/-8.10 | 99.85+/-0.40 | 35.15+/-3.73 |
| | P value | 0.08 | 0.14 | 0.31 | 0.29 |

## DISCUSSION

Supraglottic airway devices have proved to be one of the major game changers in anesthesia practice and management of airway and because of their ease of insertion, they have been incorporated in the algorithm in the Difficult Airway Society (DAS) guidelines for management of unanticipated difficult intubation.We compared I gel and Classic LMA in our study.

### Insertion Time And Number Of Attempts For Placement

In our study, the success rate for first-attempt insertion was 97.5% for LMA Classic and 75% for the I-gel group. The second attempt was required in 2.5% of LMA insertions and 15% for I-gel, while third attempts were necessary in 10% of I-gel cases. These differences were statistically significant. The mean insertion time was 16.65 seconds for LMA Classic and 28.48 seconds for I-gel, with I-gel requiring more time, likely due to less experience and overlapping sizing guidelines.

Previous studies by Janakiraman et al. reported a first-attempt success rate of 86% for LMA Classic and 54% for I-gel, consistent with our findings. Research by B. Richez et al. showed a 97% insertion success rate for I-gel, with easy insertion regardless of the anesthesiologist's experience. Similarly, Amr M Helmy et al. found I-gel insertion successful in 90% of cases versus 80% for LMA Classic. Reza Hashemian et al. and Dilek Erdogan et al. also reported significantly shorter insertion times for I-gel, attributing this to the absence of an inflatable cuff and the device's ease of insertion.

### Hemodynamic Parameters

In the present study, mean heart rate variations and mean

blood pressure were comparable between the two groups at pre-insertion,1min, 5min, 10min and 15min after insertion of the device. Mean oxygen saturation was comparable among both groups and was maintained above 99% throughout the duration of surgery. $EtCO_2$ was also comparable among both groups.

Revi et al Das et al [4] Smita R Engineer et al [1] Amr M Helmy [3] found no significant difference in the hemodynamic parameters between LMA Classic and I-gel which is in concordance to the results of our study.

N Pratheeba et al [5] Parul Jindal et al Atef et al noted more hemodynamic changes with LMA Classic as compared with I-gel.

Rachana Chandura et al observed a significantly higher pulse rate at 3 minutes after insertion in LMA Classic group. The difference in mean systolic blood pressure was significant at 1 & 3 min after insertion ($p<0.05$) and in mean diastolic pressure, it was significant at 5 min after insertion of LMA Classic.

Reza Hashemian et al [2] reported comparable hemodynamics between the 2 groups. They also noted significant difference in end tidal $CO_2$ from baseline and 10 and 15 minutes after insertion in I-gel group which they suggested was due to the weaker ventilation provided by the I-gel.

### Sealing Pressure

We obtained a mean sealing pressure of 14.90 cms of $H_2O$ for c LMA and 15.73 cms of $H_2O$ for I-gel which was comparable in both the groups. Reza Hashemian et al [2] found no difference in leak pressure between I-gel and LMA-Classic.

V Uppal et al Damodaran S et al also found comparable leak pressures between I-gel and other LMA devices.

Janakiraman C et al Amr M Helmy et al [3] Das et al [4] Priyamvada Gupta et al found I-gel to have a superior sealing pressure than classic LMA.

### Complications

We observed no significant complications in both the groups. There were 5 cases of blood staining on device in the LMA Classic group and 1 case in the I-gel group, but this was not statistically significant.

Reza Hashemian et al [2] observed no significant complications in the 2 groups.

Ali Sarfraz Siddiqui et al noted blood staining on device in 18% of cases in cLMA group and none in I-gel group. They also noted a higher incidence of post removal cough in I-gel group. Smita R Engineer et al [1] noted more complications with cLMA such as coughing after removal of device, numbness of tongue and blood staining on device as compared to I-gel. In their study on I-gel and LMA Proseal, G. Chauhan et al state that those devices with an inflatable cuff have the potential to cause tissue distortion, venous compression and nerve injuries and hence are associated with more postoperative morbidity. Thus I-gel has an advantage in having less postoperative complications due to the absence of a cuff. P. Gupta et al also noted a higher incidence of cough, sore throat, blood on device with cLMA than I-gel.

Haq Dad Durrani et al reported 5 cases of blood staining on device in cLMA group and I-gel, due to the absence of an inflatable cuff, showed no sign of blood.

However, Das et al, [4] in their study of supraglottic devices on children, stated that even though I-gel exerts less pressure on the perilaryngeal tissue, the incidence of sore throat was comparable among I-gel and cLMA.

Rachana Chandura et al reported that incidence of sore throat, blood staining on device, lip or dental trauma, cough, hoarseness of voice and vomiting were noted more in cLMA group than in I-gel group.

Thus, in the present study, LMA Classic was faster and successfully inserted in the first attempt as compared to I-gel.

### Limitations

Our study had a few limitations. Firstly, it was done in a single centre. So, the results cannot be extrapolated to the entire population, for which a larger sample size would be required. We studied only low risk patients (ASA I-II) with normal airways. The performance of these devices need to be assessed in difficult airways. We have not used the flexible fiberscope for assessing the airway placement position. We had less experience in inserting I-gel as compared to Classic LMA. I-gel, owing to its bulky design, requires more time for skill development.

## CONCLUSION

From the results of our study, we conclude that LMA Classic is a better alternative than I-gel in terms of time required and the ease for insertion. We feel that I-gel requires time to learn and is not suitable for novices. We also feel that there is an overlap in the sizing guidelines by the manufacturers, hence has a lower first-time insertion success rate as compared to Classic LMA. However, the I-gel has a potential advantage of causing less pharyngolaryngeal morbidity due to its soft gel-like material. It also has an integral tube through which stomach contents can be aspirated and prevents excessive gastric insufflation.

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