**Scholars Journal of Applied Medical Sciences (SJAMS)** **ISSN 2320-6691 (Online)**
**Sch. J. App. Med. Sci., 2015; 3(6B):2238-2243** **ISSN 2347-954X (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublisher.com

**Research Article**

# Comparative Study between LMA Classic and I-Gel in Spontaneously Breathing Patients Posted For Elective Breast Surgeries

**Dr. Souvik Saha[1], Dr. Debabanhi Borua[2]**
Calcutta National Medical College, Kolkata 700014, India

***Corresponding author**
Dr. Souvik Saha
Email: souviksh@gmail.com

**Abstract:** Supraglottic airway devices are very useful devices in short duration surgeries with or without muscle relaxants with lesser hazards of intubation reflexes. This prospective, randomized study was conducted in 60 spontaneously breathing patients undergoing for breast surgery[Group I - I-gel insertion(n = 30) and Group L - LMA insertion (n =30)] of ASA grades I/II, in the age group of 18-60 years, body weight 30-50 kg. Both groups were compared with respect to insertion time, insertion attempts, insertion failure and hemodynamic parameters (pulse, blood pressure, sp02) and peri operative complications. On the night prior to the operation all patients received Tab. Alprazolam 0.5 mg and Tab. Ranitidine 150 mg. Hemodynamic parameters recorded 5 min before induction. All patients were given Inj. Glycopyrrolate 0.2 mg, Inj Fentanyl 2mcg/kg and then induction was done with Inj Propofol 2mg/kg body weight. The I-gel size3 were used in Group I patients and LMA classic size 3 were used in Group L patients. After confirming the correct placement, LMA-C or I-gel was connected to breathing system and maintenance were done with nitrous oxide, oxygen and isoflurane. After completion of the surgery, anesthetic agents were discontinued allowing smooth recovery of the patient. The devices was removed after the patient regained consciousness spontaneously and responded to verbal command to open the mouth .Chi-square test and independent t-test used for statistical analysis. Mean insertion time for the I-gel (8.810 ± 0.1914,sec)was lower than that of the LMA (10.66 ± 0.1894sec) ($P < 0.0001$).No. of insertion attempts are similar in both groups(p value = 0.7282].There is no statistical difference in pulse rate, blood pressure and spo2 during insertion time of both groups. No peri operative and postoperative complications regarding insertion and post removal was reported during the study.
**Keywords:** Airway sealing, cuff pressure, I-gel, insertion, leak, laryngeal mask airway.

## INTRODUCTION

Laryngoscopy and endo tracheal intubation is the gold standard of airway management. It has the potential risk of precipitating intubation reflexes, due to manipulation of glottic and infra glottic structures, resulting in gross changes in hemodynamic parameters. Laryngeal mask airway (LMA) is a supraglottic device, very useful in short duration surgeries with or without muscle relaxants with lesser hazards of intubation reflexes. Laryngeal mask airway has an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. I-gel is a newly developed Supraglottic device with non-inflatable cuff, composed of soft gel like transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures so that to provide pharyngeal seal without cuff inflation. A passage is placed lateral to the airway tube to allow insertion of a gastric tube for gastric contents suctioning. In 2009 Uppal V *et al.*; [1] found no significant difference between the airway leak pressure of two devices (p=0.083), insertion time with I-gel group was significantly less than LMA ( p=0.007). The number of manipulations required after insertion to achieve a clear airway was same. There were no statistically significant differences in leak volumes or leak fractions during controlled ventilation. They concluded I- gel provides a reasonable alternative to LMAc for controlled ventilation during anesthesia. In 2010 S. Amini *et al.*; [2] compared the performance of the Intersurgical Solus TM laryngeal mask airway (LMA) with that of the I-gel in 120 patients during general anaesthesia with respect to oropharyngeal leak pressure, peak airway pressure, airway manipulation, insertion time, fibreoptic view, ventilatory parameters, and peri-operative complications. Both devices have good performance with very low peri-operative complications. However, the Solus LMA provides a better oropharyngeal seal, provides a better fibreoptic view, and requires less manipulation to secure the airway than the I-gel. In 2009 Jindal P *et al.;* [3] conducted a study to compare the hemodynamic effects of three Supraglottic devices I-gel, SLIPA (stream lined integrated pharyngeal airway) and LMA. Numbers of insertion attempts was similar among groups, but

intubation time was significantly longer in LMA group. I-gel produced less hemodynamic alterations in comparison with LMA and SLIPA. We compared the clinical performance of I-gel and LMA in terms of insertion time, insertion attempts, insertion failure, hemodynamic parameters and peri operative complications.

## MATERIAL AND METHODS

After obtaining ethical committee clearance and informed consent from all the patients, 60 female patients of ASA status 1 and 2, age 18-60 years, body weight 30-50 kg, scheduled for elective breast surgeries under general anaesthesia with spontaneous ventilation were allocated randomly for this study. Exclusion criteria was anticipated difficult airway, Mouth opening < 2cm,acute or chronic lung disease, pathology of the neck or upper respiratory tract, upper respiratory tract infections, patients at increased risk of aspiration, pregnancy, duration of surgery less than 30 min or more than 90 min, patients having sensitivity to latex or eggs, failure of insertion after two re-insertion attempts**.** On the night prior to the operation, all the patients were received Tab Alprazolam 0.5mg and Tab Ranitidine 150mg.In the operation theatre after recording the baseline hemodynamic readings 5 mins prior induction of anesthesia all the patients were pre-medicated with injection Inj. Glycopyrrolate 0.2 mg, Inj. Fentanyl 2mcg/kg and then induction were done with Inj Propofol 2mg/kg body weight. On loss of verbal contact, hand ventilation with face mask was checked. Both LMAc size 3 and I-gel size 3 was used which were prior lubricated using water based jelly on the tip and posterior surface as recommended by the manufacturer. Insertion was attempted at 1 min interval from loss of verbal response by a single experienced anesthesiologist who has the experience of more than 100 LMA and I-gel insertions. The insertion technique of the devices and cuff inflation of LMA was per manufacturer recommendations. Time taken for insertion of the device, total number of attempts required and failure of insertion were noted. During device insertion changes in pulse rate, systolic, SpO2, any ECG changes were recorded during insertion, 3 min, 5 min and 10 min post insertion. Time taken for insertion was defined as the time from picking up the device to time at first manually ventilated breath. Adequate placement of the device was assessed by gently squeezing the breathing bag and observing the end tidal CO2 waveform and movements of the chest wall. If judged inadequate, manipulations were done and number of insertion attempts was recorded. A 'failed attempt' was defined as removal of the device from mouth before re-insertion. A total of three attempts were allowed before considering it as failure. After confirming the correct placement, LMAc or I-gel was connected to breathing system and maintenance were done with nitrous oxide, oxygen and isoflurane. Standard monitoring was continued throughout the surgeries. After completion of the surgery, anesthetic agents were discontinued allowing smooth recovery of the patient. The devices were removed after the patient regained consciousness spontaneously and responded to verbal command to open the mouth. Patients were kept under monitoring for 10 mins and any post removal breath holding, cough, sore throat, dysphasia, dysphonia, laryngospasm, pain on jaw movement, nausea, vomiting, lip and dental injury and presence of blood in LMA/ I- gel were recorded. Then patients were shifted to post operative recovery room, vital signs were monitored. 18 – 24 hours after surgeries they were interviewed for any postoperative complications.

## RESULTS AND DISCUSSION

There was no statistical difference between the two groups with respect to age, height and weight.

**Table 1: Mean, standard deviation and P-value: AGE, Weight and Height**

| | **Age (Years)** | **Weight (Kgs)** | **Height (cms)** |
|---|---|---|---|
| **Group L** | 26.10 ± 0.8190 | 40.28 ± 1.191 | 140.3 ± 1.611 |
| **Group I** | 26.20 ± 0.8142 | 38.07 ± 1.250 | 141.0 ± 1.174 |
| **P-value** | 0.9549 | 0.7308 | 0.1147 |

The mean insertion time of Group L was 10.66 ± 0.1894, n=30 and Group I was 8.810 ± 0.1914, n=30. Difference between means was -1.850 ± 0.2693. 95%Confidence Interval was -2.389 to -1.311. R squared - 0.4486, t=6.869, df=58 and P-value was (< 0.0001). Group I required less Insertion time than Group L.

**Table 2: Unpaired t- test values of Insertion times**

| | **Group L** | **Group I** |
|---|---|---|
| **Mean & SD** | 10.66 ± 0.1894, n=30 | 8.810 ± 0.1914, n=30 |
| **t** = 6.869,**df** = 58 | **Difference between means** -1.850 ± 0.2693 | **P- value <0.0001** |

The insertion attempts table has shown that mean of insertion attempts in group L was 1.103 ± 0.05755 and Group I was 1.133 ± 0.06312, P- value was 0.7282 which is not significant**.** A 'failed attempt' was

defined as removal of the device from mouth before re-insertion. A total of three attempts were allowed before considering it as failure. If ventilation is not adequate even after 2 re-insertion attempts, endo-tracheal intubation was done and the patient was excluded from the study there was not a single attempt which was fitted to the criteria to the 'failed attempts'.

**Table 3: Unpaired t-test and F test to compare variances of Insertion attempts**

| | |
|---|---|
| Mean ± SEM of Group L | 1.103 ± 0.05755, n=29 |
| Mean ± SEM Of Group I | 1.133 ± 0.06312, n=30 |
| Difference between means | 0.02989 ± 0.08558 |
| 95% confidence interval | -0.1415 to 0.2013 |
| t,<br>df | t=0.3492<br>df=57 |
| P value | 0.7282 |
| P value summary | **Not significant** |
| F, DFn, Dfd | 1.244, 29, 28 |

**Table 4: Table showing numbers of attempts of insertion**

| **Insertion attempts** | **Group L** | | **Group I** | |
|---|---|---|---|---|
| | **No. of patients** | **Percentage** | **No. of patients** | **Percentage** |
| First attempts | 27 | 90 | 26 | 86.2 |
| Second attempts | 3 | 10 | 4 | 12 |
| Third attempts | 0 | 0 | 0 | 0 |
| Total | 30 | 100 | 30 | 100 |

There was no statistically significant changes in basal systolic blood pressure were occurred during the insertion of both the devices. There is no significant changes of systolic blood pressure in SBP 1( SBP 5mins pre insertion), SBP 2( SBP 3mins post insertion), SBP 3( SBP 5mins post insertion), SBP 4 (SBP 10 mins post insertion) as p- value of each reading was greater than 0.05.

**Table 5: Mean and standard deviation chart of recorded systolic blood pressures**

| **Mean & sd** | **Group L** | **Group I** |
|---|---|---|
| SBP 1 | 115.6 ± 2.405 | 115.7 ± 2.264 |
| SBP 2 | 112.2 ± 2.309 | 111.6 ± 2.054 |
| SBP 3 | 111.4 ± 2.252 | 112.8 ± 1.988 |
| SBP 4 | 112.8 ± 2.124 | 112.9 ± 1.900 |

**Table 6: Difference between Means**

| **SBP** | **Difference between means** |
|---|---|
| SBP 1 | 0.1333 ± 3.303 |
| SBP 2 | 0.5333 ± 3.090 |
| SBP 3 | 1.333 ± 3.004 |
| SBP 4 | 0.1667 ± 2.850 |

**Table 7: T-value and Degree of freedom**

| **SBP** | **t- value** | **df** |
|---|---|---|
| SBP 1 | 0.04037 | 58 |
| SBP 2 | 0.1726 | 58 |
| SBP 3 | 0.4439 | 58 |
| SBP 4 | 0.05849 | 58 |

**Table 8: P-value of unpaired t- test (Systolic blood pressure)**

| SBP | p- value |
|---|---|
| SBP 1 | **0.9679** |
| SBP 2 | **0.8636** |
| SBP 3 | **0.6588** |
| SBP 4 | **0.9536** |

Both pre and post insertion records noted that during and after insertion of either LMA or I–gel did not cause any significant difference in basal pulse rate as all the p- values were >0.05.

**Table 9: Mean and Standard deviation of recorded pulse rate**

| Pulse rate | Group L | Group I |
|---|---|---|
| **PR 1** | 86.63 ± 2.115 | 81.43 ± 2.574 |
| **PR 2** | 82.23 ± 2.094 | 78.40 ± 2.507 |
| **PR 3** | 80.47 ± 1.878 | 76.93 ± 2.333 |
| **PR 4** | 80.83 ± 1.890 | 77.69 ± 2.536 |

**Table 10: Difference between means**

| Pulse rate | Difference between means |
|---|---|
| **PR 1** | -5.200 ± 3.332 |
| **PR 2** | -3.833 ± 3.267 |
| **PR 3** | -3.533 ± 2.995 |
| **PR 4** | -3.138 ± 3.162 |

**Table 11: T-value and Degree of Freedom**

| Pulse rate | t- value | df |
|---|---|---|
| PR 1 | 1.561 | 58 |
| PR 2 | 1.173 | 58 |
| PR 3 | 1.180 | 58 |
| PP 4 | 0.9923 | 58 |

**Table 12: P-value of unpaired t- test (Pulse rate)**

| Pulse rate | P- value |
|---|---|
| **PR 1** | **0.1240** |
| **PR 2** | **0.2454** |
| **PR 3** | **0.2428** |
| **PR 4** | **0.3253** |

There was no changes in 5mins after the insertion of the both the devices. Spo2 records of 5mins prior insertion, 3 mins post insertion and 10 mins post insertion showed no significant alterations. Statistical evaluation showed that no significant changes of Spo2 during post insertion 3mins, 5mins and 10 mins as calculated p- value was found > .05.

**Table12. Mean and standard deviation of recorded SPO2**

| SPO2 | Group L | Group I |
|---|---|---|
| **SPO2 1** | 99.70 ± 0.1601 | 99.83 ± 0.09689 |
| **SPO2 2** | 100.0 ± 0.0 | 99.97 ± 0.03333 |
| **SPO2 3** | 99.93 ± 0.04632 | 100.0 ± 0.0 |

**Table13: Difference between means**

| SPO2 | Difference between means |
|---|---|
| SPO2 1 | 0.1333 ± 0.1871 |
| SPO2 2 | 0.03333 ± 0.03333 |
| SPO2 3 | 0.06667 ± 0.04632 |

**Table14: P value of unpaired t test of recorded SPO2**

| SPO2 | P - value |
|---|---|
| SPO2 1 | 0.4790 |
| SPO2 2 | 0.3215 |
| SPO2 3 | 0.1555 |

**Table15: t – value and degree of freedom**

| SPO2 | t-value | df |
|---|---|---|
| SPO2 1 | 0.7125 | 58 |
| SPO2 2 | 1.000 | 58 |
| SPO2 3 | 1.439 | 58 |

There were no significant ECG changes recorded during data collection. There was no signs of tachycardia (pulse rate more than 100), no signs of arrhythmia; ischemia or any other abnormality in ECG was recorded during insertion of both the groups. During study all the patients and the devices were examined for any signs of injury, distortion of the devices and presence of blood in the mouth, lips or tongue. Presence of blood on devices was thoroughly ruled out. There was not a single case of peri operative complications reported during the study. Both the devices showed excellent tolerance among the patients during anesthesia.

| |
|---|
| Presence of blood on airway device -N |
| Lip and/or dental injury - N |
| Post removal cough - N |
| Sore-throat - N |
| Dysphagia and/or dysphonia - N |
| Laryngospasm - N |
| Pain on jaw movement - N |
| Nausea and/or vomiting - N |
| Others |

**(N – Not present)**

Adult female patients, each group (group L or group I) consisting of 30 patients each, fulfilling the inclusion criteria were scheduled for breast surgeries and planned for spontaneous breathing during anesthesia. Both group L and group I were comparable. There was no statistical difference in regards to mean age, weight, height, type and duration of the surgeries.

One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study conducted by Siddiqui *et al*.; [4] where insertion of device was recorded as; very easy (when assistant 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 this study, the ease of insertion was evaluated by experienced anesthetists in terms of- insertion time, numbers of attempts and failure of insertion. . Time for insertion of I-gel was 8.81± 1.04860 seconds and for $LMA_C$ 10.66± 1.03744 seconds which is statistically highly significant. The p- value of our study was $< 0.001$. In our study, insertion of I-gel was successful in first attempt in 86.2% patients as compared to 90% patients with LMA which is consistent with the following study. Airway manipulation like jaw thrust was required during second attempt in 4 patients in I-gel group and in 3 patients during insertion of LMA. The p-value was 0.73 which not statistically significant. There was not a single incidence of failure of insertion in either noted during our study. In this study we found no statistically significant changes with regard to systolic blood pressure, pulse rate , saturation of oxygen and electrocardiogram. These results are similar to the studies done by Helmy AM *et al.;* [5] Franksen H *et al*.; [6] who in their studies found no significant hemodynamic alteration between I-gel and $LMA_C$ During our study all the patients were inspected just after removal as well as interviewed before discharge from operation theatre and also in PACU and wards in search of any signs and symptoms of injury to the lips or tongue and oropharyngeal tissue, discomfort, dysphagia, dysphonia, nausea , vomiting, sore throat. Both the devices were postoperatively inspected to find out any distortion of the mask or tube or any other parts or presence of blood. There was no reported case of peri and postoperative complication was recorded during the study in comparison to both the groups even after 18 – 24 hours of post operative evaluations.

## CONCLUSION

Classic LMA and I-gel can be safely and effectively used during general anesthesia in spontaneously breathing patients posted for short

duration surgeries such as breast surgeries. The insertion time of I-gel is less compared to LMA Classic, with both devices having the ability to keep the patients hemo dynamically stable during their insertions. Comparison between both the devices regarding the number of insertion attempts was not significant. I-gel required less insertion time which infers that I-gel may be easier to insert as compared to LMA Classic.

**REFERENCES**

1. Uppal V, Gangaiah S, Fletcher G, Kingsella J; Randomized crossover comparison between the I-gel and the LMA-Unique in anaesthetized, paralyzed adults. Br J Anaesthesia 2009; 103(6): 882-5.
2. Amini S, Khoshfetrat M; Comparison of the Inter surgical Solus laryngeal mask airway and the I- gel supra laryngeal device. Anaesthesia 2010; 65(8): 805-9.
3. Jindal P, Rizvi A, Sharma JP; Is I-gel a new revolution among Supraglottic airway devices? A comparative evaluation. MEJ Anesth, 2009; 20(1): 53-8.
4. Siddiqui AS, Raees US, Siddiqui SZ, Haider S, Raza SA; Comparison of performance and safety of I-gel with laryngeal mask airway (classic) for general anaesthesia with controlled ventilation. Anaesth, Pain and Intensive Care, 2010; 14(1): 17-20.
5. Helmy AM, Atef HM, El-Taher EM, Henidak AM; Comparative study between I-gel, a new supra glottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients, Saudi J Anaesth, 2010; 4(3): 131-6.
6. Franksen H, Renner J, Hanss R, Scholz J, Doerges V, Bein B; A comparison of the I-gel™ with the LMA-Unique in non-paralyzed anaesthetized adult patients, 2009; 64(10): 1118-1124.