**ABSTRACT**

Aims and Objectives: The aim of this study is to compare insertion parameters, ventilatory parameters, hemodynamic parameters and post-removal complications that occur during laryngeal mask airway insertion and I-gel insertion in paediatric patients for surgical procedures under general anesthesia with controlled ventilation.

Methodology: The present clinical study was undertaken to compare various parameters with laryngeal mask airway and I-gel in pediatric patients. The study was conducted in 60 pediatric patients aged between 2-10 years undergoing elective surgeries under general anesthesia. After institutional ethical committee approval and with informed parental consent, 60 ASA I & II patients of either sex between 2-10 years of age, undergoing various elective short surgeries (duration less than 60 mins) under general anesthesia were selected. The study population was randomly divided into two groups with 30 patients each.

Observations and Results: Our results suggested that the insertion parameters, ease of insertion and number of attempts are statistically insignificant. The hemodynamic response comparable in both the groups. Post removal complications like cough, laryngospasm and lip/dental injury is also statistically not significant in both the groups. Post operative sore throat was the only parameter that was significantly higher in the LMA group.

Conclusion: In conclusion, we can say that routine use of I-gel in pediatric patients is comparable to c-LMA in terms of ease of insertion, hemodynamic response and post removal complications. I-gel is equally safe and efficient compared with LMA.

**KEYWORDS:**

- Ease of insertion
- Number of attempts
- Heart rate
- Systolic blood pressure
- Diastolic blood pressure
- Mean arterial pressure
- Oxygen saturation
- Cough
- Laryngospasm
- Sore throat
- Lip and dental injury

**INTRODUCTION**

Supraglottic Airway Devices (SGD) ventilate patients by delivering anesthetic gases/oxygen above the level of the vocal cords. SGD are designed to overcome the disadvantages of endotracheal intubation. The laryngeal mask airway (LMA) invented in 1983 by Archie Brain, consists of an inflatable silicon mask and a connecting tube. LMA is inserted blindly into the pharynx, forming a low pressure seal around laryngeal inlet and allows gentle positive pressure ventilation. I-gel, is a novel SGD with an anatomically designed mask made of a gel like thermoplastic – elastomer. I-gel has features designed to separate gastro-intestinal and respiratory tract and allows aspiration of gastric contents through gastric tube.

**AIMS & OBJECTIVES OF THE STUDY:**

- The aim of this study is to compare insertion parameters, ventilatory parameters, hemodynamic parameters and post-removal complications that occur during LMA & I-gel insertion in paediatric patients for surgical procedures under general anesthesia with controlled ventilation.
- The parameters compared are:
  - Ease of insertion, Number of attempts, Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), Oxygen saturation (SpO2), Cough, Laryngospasm, Sore throat, Lip and dental injury.

**METHODOLOGY:**

- It is a prospective randomised control study.
- 60 patients, either sex, ages 2 – 10 years, ASA grade I and II undergoing elective short surgeries under general anesthesia were selected.
- The study population were randomly divided into two groups with 30 patients each.
- Study group L: LMA of appropriate size.
- Study group I: I-gel of appropriate size.
- Preanesthetic Evaluation:
  - A thorough preanesthetic evaluation was done for all patients a day before the proposed surgery.
- Procedure:
  - After securing an IV line, all children were premedicated with Injection glycopyrrolate 0.01 mg/kg, injection fentanyl 2 μg/kg through intravenous route.
  - All patients were monitored with pulse oximeter, non invasive blood pressure.
  - Base line values of HR, SBP, DBP, MAP, SpO2 were recorded.
  - Patients were pre-Oxygenated with 100% oxygen.
  - All patients were induced with injection thiopentone sodium 5 mg/kg and reversed with injection neostigmine 0.05 mg/kg IV and injection atropine 0.01 mg/kg IV.
  - Intubation done with injection succinylcholine 2 mg/kg after achieving full relaxation, for the group L, the appropriate sized LMA was chosen based upon the weight of the children as follows:
    - Size 1.5 for 5-10 kgs,
    - Size 2 for 10-20 kgs,
    - Size 2.5 for 20-30 kgs and inserted by the classical approach and once LMA is in position, air was injected to provide adequate seal.
  - For the group I, the appropriate sized I-gel was chosen based upon the weight of the child as:
    - Size 1.5 for 5-12 kgs,
    - Size 2 for 10-25 kgs,
    - Size 2.5 for 25-35 kgs

Position of LMA/I-Gel was confirmed with bilateral chest lift and auscultation of breath sounds. Anesthesia was maintained with intravenous non depolarizing muscle relaxant vecuronium.

**Ease of insertion and number of attempts for insertion** of LMA and I-gel were noted. 

**Hemodynamic changes in HR, BP, MAP and changes in SpO2** were monitored just before induction (baseline), just after intubation/insertion, and then at 1, 3, 5, 10, 20, 30 minutes.

At the end of surgery, residual neuromuscular blockade was reversed with Injection neostigmine 0.05 mg/kg IV and Injection glycopyrrolate 0.01 mg/kg IV. After return of adequate muscle power and spontaneous breathing, in the group L, LMA was removed after deflating the cuff, when the patient became fully awake and responded to commands and in group I, I-GEL was removed after the child became fully awake.

Post-removal complications like cough, laryngospasm, sore throat, lip or dental injury if any were noted.
STATISTICAL ANALYSIS:
- All the values observed were analysed and were expressed as mean ± SD.
- Statistical comparisons were performed by students' t' test.
- A probability value (P) less than 0.05 was regarded as statistically significant.

Level of significance:
P>0.05 - statistically not significant.
P<0.05 - statistically significant.

OBSERVATIONS AND RESULTS

DEMOGRAPHIC DATA:
The demographic data is given in the below table. The data was comparable between the two groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Particulars</th>
<th>Group-L</th>
<th>Group-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age(years)</td>
<td>Mean±SD</td>
<td>4.3±1.8</td>
<td>3.9±1.3</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>2-10yrs</td>
<td>2-8yrs</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Weight (Kgs)</td>
<td>Mean±SD</td>
<td>16.9±4.2</td>
<td>16.8±3.8</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>10-24 kgs</td>
<td>11-23 kgs</td>
</tr>
</tbody>
</table>

Age distribution:
The minimum age of the patient was 2 years and maximum age was 10 years in the study group. Both LMA and I-gel groups were comparable with regard to age and the p value derived equal to 0.21 was not statistically significant.

Ease of insertion:
In both groups, the ease of insertion is statistically comparable and p=0.389 which is not significant.

<table>
<thead>
<tr>
<th>Ease of insertion</th>
<th>GROUP-L</th>
<th>GROUP-I</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy</td>
<td>86.67%</td>
<td>93.34%</td>
<td>0.389</td>
</tr>
<tr>
<td>Difficult</td>
<td>13.33%</td>
<td>6.66%</td>
<td></td>
</tr>
<tr>
<td>Impossible</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

\(X^2=0.74, p=0.389\) (Not Significant)

Figure-13: Ease of insertion of LMA/I-GEL:

Number of attempts in placement of LMA or I-GEL:
In the LMA group, LMA was placed correctly in the first attempt in 83.3% patients and was placed correctly in the 2nd attempt in 16.6%. The I-Gel was placed in the first attempt in 93.3% patients and in both groups the number of attempts in placement of LMA/I-GEL was statistically comparable i.e., p=0.227 which is not significant.

<table>
<thead>
<tr>
<th>Table 5- Number of attempts in placement:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group-L</td>
</tr>
<tr>
<td>1st attempt</td>
</tr>
<tr>
<td>2nd attempt</td>
</tr>
</tbody>
</table>

\(X^2=1.45, p=0.227\) (Not Significant)

HEMODYNAMIC CHANGES

HEART RATE:

SYSTOLIC BLOOD PRESSURE:
The rise in systolic blood pressure in group L was 4% and in group I was 1.8%. The systolic blood pressure in both groups when compared was statistically not significant with p value 0.19 (>0.05).

DIASTOLIC BLOOD PRESSURE:
Changes in DBP in two groups were statistically insignificant.

MEAN ARTERIAL PRESSURE:
The mean arterial pressure in both groups when compared was statistically insignificant with p value >0.05.

SATURATION OF HEMOGLOBIN (SpO2):
The Spo Saturation of haemoglobin in group L compared with group I was statistically not significant with p value >0.05.
Post removal complications:

<table>
<thead>
<tr>
<th>TABLE - 1: Post removal cough</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cough</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

In group L post removal cough was 13.3%, in group I post removal cough was 6.7%, with p value of 0.38, which is more than 0.05 with no statistical significance.

<table>
<thead>
<tr>
<th>TABLE - 12: Post removal sore throat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sore throat</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

In group L post removal sore throat was 13.3%, in group I post removal sore throat was 0%, with p value of 0.03 which is more than 0.05 with statistical significance.

<table>
<thead>
<tr>
<th>TABLE - 13: Post removal spasm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spasm</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

X²=0;p=1

In group L post removal spasm was 0%, in group I post removal spasm was 0%, with p value of 1 which is more than 0.05, which is statistically insignificant.

<table>
<thead>
<tr>
<th>TABLE - 14: Post removal lip/dental injury</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lip/dental injury</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

X²=1.071;p=0.3006

In group L post removal lip/dental injury was 10%, in group I post removal lip/dental injury was 3.3%, with P value of 0.3 which is more than 0.05, which is statistically significant.

DISCUSSION

- The I-gel is a new supraglottic device without an inflatable cuff, designed for use during anaesthesia.
- It is latex free, disposable device, made of a medical grade thermoplastic elastomer. I-gel is anatomically preformed to mirror the perilaryngeal structures.
- The device contains an epiglottic blocker, which helps to prevent epiglottis from downfolding or obstructing laryngeal inlet.
- The soft non-inflatable cuff seals anatomically against perilaryngeal structures. Furthermore, the I-gel has a gastric channel allowing venting of the air and gastric contents or insertion of gastric tube.
- In our study we found that LMA was inserted easily in 86.7% of patients, whereas LMA was inserted easily in 93.3% of patients.
- In our study, LMA was placed correctly in the 1st attempt in 83.3% and in 2nd attempt in 16.6% of patients. The I-Gel was placed in the 1st attempt in 93.3% patients.
In both groups the number of attempts in placement of LMA/I-GEL was statistically comparable i.e., p=0.227 which is not significant, this is in correlation with singh et al & siddqui et al studies.

In our study results of hemodynamic changes like heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure through out the surgery after LMA and i-gel insertion were comparable and statistically insignificant, this is in accordance to Acott study.

In our study saturation of hemoglobin was greater than 97% in all the patients whether ventilated with LMA or i-gel throughout the surgery, in accordance with Pratheeba et al & many other studies.

One of the most important parameters to be compared between both supraglottic devices was postoperative complications.

In this study the postoperative complications that were compared are postremoval cough, post removal sore throat, laryngospasm/brochospsm and lip/dental injury.

It was found that 4/30 patients of LMA group have postremoval cough and 2/30 patients of i-gel group had cough which is statistically not significant this is correlating with siddique et al study.

No postoperative laryngospasm/brochospsm was reported in any of the case in our study, this is in accordance to Ishwarsingh et al study.

Post removal sore throat was found in 4 of 30 patients in Group L where as no incidence of post operative sore throat was found in the I-gel group. Statistically significant difference is there in both the groups with a p value 0.03 (<0.05), our result is comparable to study done by Keijzer C et al.

Lip/dental injury was compared between the two groups, it was found in 3 of 27 patients in group L and 1 of 29 patients in the i-gel group with a p-value of 0.32 (>0.05) which is statistically insignificant in accordance to Haq dad Durrani et al study.

CONCLUSION

Routine use of i-gel in pediatric patients is comparable to c-LMA in terms of ease of insertion, hemodynamic response and post removal complications.

I-gel is safe and efficient compared with LMA.

The hemodynamic response comparable in both the groups. Post removal complications like cough, laryngospasm and lip/dental injury is also statistically not significant in both the groups.

Post operative sore throat was the only parameter that was significantly higher in the LMA group.

Reference