



"A COMPARATIVE EVALUATION OF LARYNGEAL MASK AIRWAY AND I-GEL DURING GENERAL ANAESTHESIA WITH CONTROLLED VENTILATION IN PAEDIATRIC PATIENTS"

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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 anaesthesia. 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 60mins) 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 stastically 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 :

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 allow 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,, sorethroat, Lip & 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 glycopyrolate 0.01mg/kg, injection fentanyl 2 µg/kg through intravenous route.
- All patients were monitored with pulse oxymeter, 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 5mg/kg and
- 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, appropriate sized I-gel was chosen based upon the weight of the children 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 itrous oxide(N₂O), oxygen(O₂), sevoflurane and intermittent doses of 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 0.05mg/kg IV and Injection glycopyrolate 0.01mg/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, sorethroat, 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

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

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.

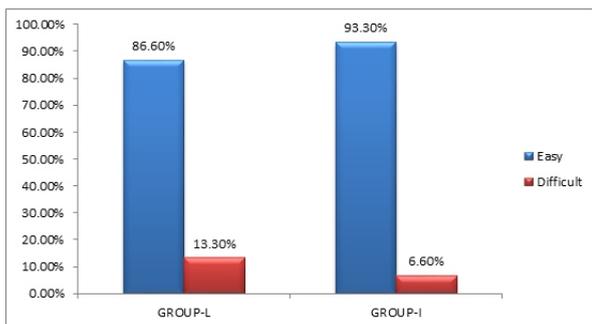
Ease of insertion:

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

Ease of insertion	GROUP-L	GROUP-I	P value
Easy	86.67%	93.34%	0.389
Difficult	13.33%	6.66%	
Impossible	0%	0%	

$\chi^2=0.74, p=0.389$ (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.

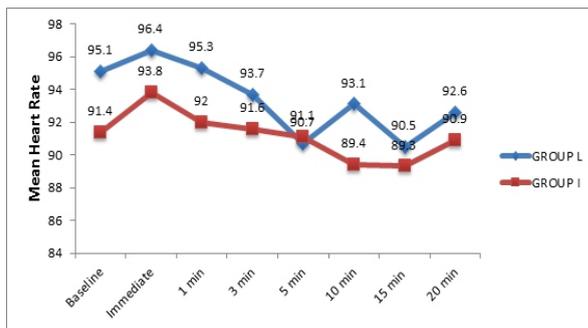
Table 5- Number of attempts in placement:

	Group-L	Group-I	p-value
1 st attempt	83.34%	93.34%	0.227
2 nd attempt	16.66%	6.66%	

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

**HEMODYNAMIC CHANGES
HEART RATE:**

Changes in heart rate in two groups are statistically insignificant



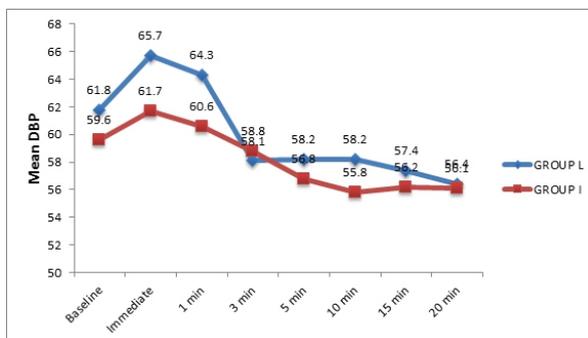
SYSTOLIC BLOOD PRESSURE:

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:

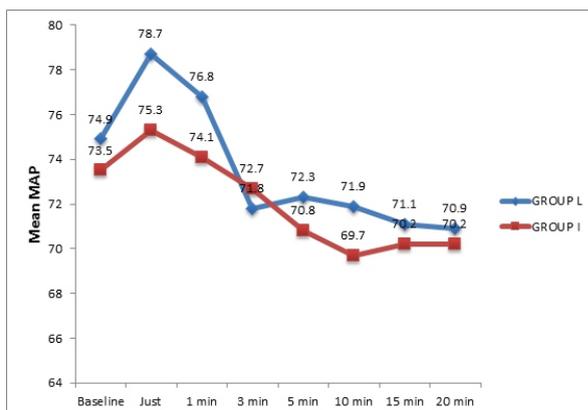
Changes in DBP in two groups were statistically insignificant



MEAN ARTERIAL PRESSURE:

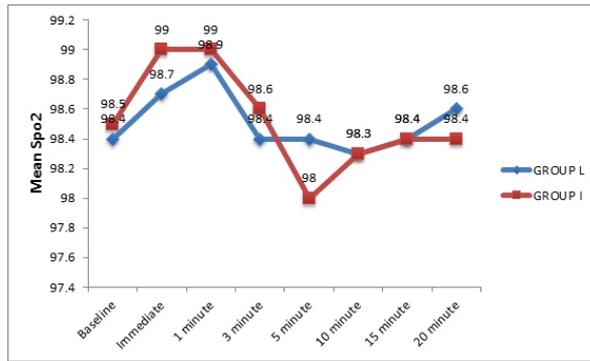
The mean arterial pressure in both groups when compared was statistically insignificant with p value >0.05.

Figure-17: Changes in MAP in two groups



SATURATION OF HEMOGLOBIN (SpO₂):

The Sp₂ Saturation of haemoglobin in group L compared with group I was statistically not significant with p value >0.05.

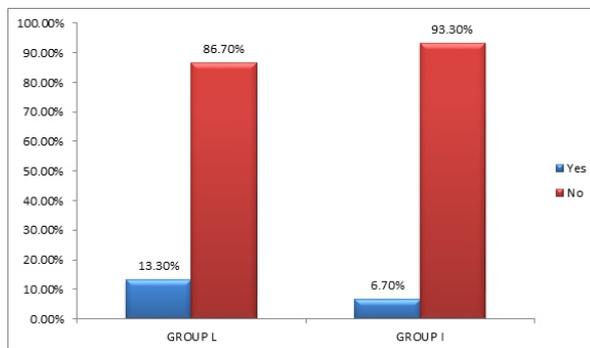


Post removal complications:

TABLE-11: Post removal cough

Cough	GROUP L	GROUP I
	n(%)	n(%)
Yes	4(13.3%)	2(6.7%)
No	26(86.7%)	28(93.3%)
Total	30	30

Figure - 19: Post removal cough



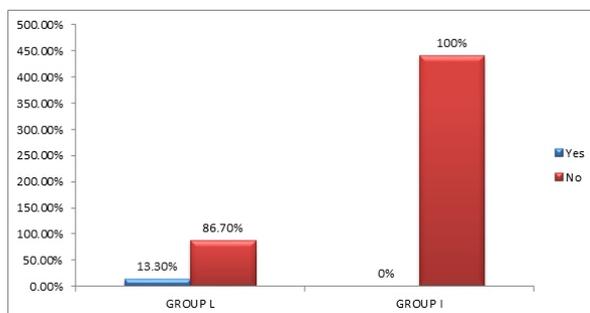
In group L post removal cough was 13.3%, in group I post removal cough was 6.7%, with p value of 0.38, which is more than 0.05 with no statistical significance.

TABLE - 12: Post removal sore throat

Sorethroat	GROUP L	GROUP I
	n(%)	n(%)
Yes	4(13.3%)	-
No	26(86.7%)	30(100%)
Total	30	30

X²=4.28;p=0.03

Figure - 20: Postremoval sore throat



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 less than 0.05 with statistical significance.

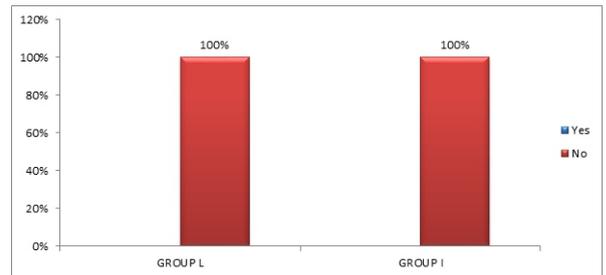
TABLE - 13: Post removal spasm

Spasm	GROUP L	GROUP I
Yes	0	0
No	30(100%)	30(100%)
Total	30	30

	n(%)	n(%)
Yes	-	-
No	30(100%)	30(100%)
Total	30	30

X²=0;p=1

Figure - 21: Post removal spasm



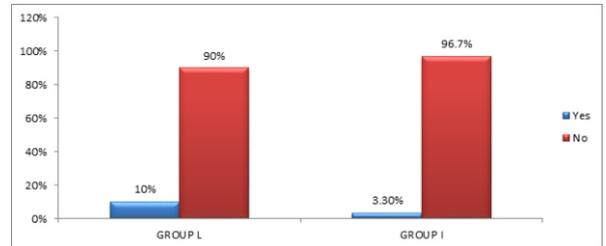
In group L post removal spasm was 0%, in group I post removal spasm was 0%, with P value of 1 which is more than 0.05, which is statistically insignificant.

TABLE - 14: Post removal lip/dental injury

Lip/dental injury	GROUP L	GROUP I
	n(%)	n(%)
Yes	3(10%)	1(3.3%)
No	27(90%)	29(96.7%)
Total	30	30

X²=1.071;p=0.3006

Figure - 22: Post removal lip/dental injury



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 insignificant.

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 I-gel was inserted easily in 93.3% of patients, this can be attributed to easy application of I-gel.
- Ease of insertion was comparable in both groups and the difference was statistically insignificant with p=0.389, our study results are in accordance with Ali A et al, Haq Dad Durrani et al studies.
- In our study, LMA was placed correctly in the 1st attempt in 83.3% & 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 & Siddiqui 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/ bronchospasm 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/bronchospasm 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

1. Lopez-Gil M, Brimacombe J, Alvarez M. Safety and efficacy of the laryngeal mask airway: a prospective survey of 1400 children. *Anaesthesia*. 1996;51(10):969-972.
2. Brain AJ. The laryngeal mask airway (Review article). *Current opinion in Anaesthesiology* 1995;8:478-484.
3. i-gel® user guide. Intersurgical Complete Respiratory Systems. <http://media.intersurgical.com/igel.com/assets/userguide.pdf>. Accessed May 27, 2015
4. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. *Anaesthesia* 2005;60:1022-1026.
5. Singh I, Gupta M, Tandon M. Comparison of clinical performance of i-gel® with LMA Proseal® in elective surgeries. *Indian J Anaesth* 2009;53(3):302-305.
6. Durrani HD, Butt KJ, Sadaf S, Rehan A, Khan AM, Umar A. Comparison of LMA Classic and i-gel in anesthetized, spontaneously breathing patients during elective surgical procedures. *Anaesth Pain & Intensive Care* 2013;17(3):274-278.
7. Michalek P, Hodgkinson P, Donaldson W. Fiberoptic intubation through an I-gel supraglottic airway in two patients with predicted difficult airway and intellectual disability. *Anesth Analg*. 2008;106:1501-1504
8. Ali A, Sheikh NA, Ali L, Siddique SA. Comparison of i-gel supraglottic airway device with laryngeal mask airway. *Professional Med J* 2010;17(4):643-647.
9. Acott CJ. Extraglottic airway devices for use in diving medicine – part 3: The i-gel. *Diving Hyperbaric Med*. 2008;38:124-7.
10. Jindal P, Rizvi A, Sharma JP. Is I-gel a new revolution among supraglottic airway devices? A comparative evaluation. *Middle East J Anesthesiol*. 2009;20:53-58.
11. Keijzer C, Buitelaar DR, Efthymiou KM, Sranek M, Ten cate J, Ronday M, Stopa T, Huitink JM, Schutte P f. A comparison of post operative sore throat and neck complaints after the use of the I-gel and the La premiere disposable laryngeal mask. A double blinded randomized, controlled trial. *Anesth Analg*. 2009;109(4):1092-1095.
12. Comparison of i-gel™ and laryngeal mask airway Classic™ in terms of ease of insertion and hemodynamic response: A randomized observational study N. Pratheeba, G. S. Ramya, 1 R. V. Ranjan, 1 and R. Remadevi *Anesth Essays Res* 2016 Sep-