

# An Interventional Randomized Study to Evaluate a new Supraglottic Airway Device (I-gel) in Comparison with the Classical LMA

Rachana A Chandura<sup>1</sup>, Bansari Naresh Kantharia<sup>1</sup>, Prachi Kunal Shah<sup>1</sup>

<sup>1</sup>MD Anaesthesiology . Govt. Medical college. Surat, Gujarat, India.

Institute at which research was conducted: Govt. Medical College, Surat, Gujarat, India.

University Affiliation of Thesis: Veer Narmad South Gujarat University, Surat, India.

Year of Acceptance: 2012

## Address of Correspondence

Dr. Prachi Kunal Shah

301, Kasturi Park, New Maneklal Estate, S.N. Mehta Marg, Ghatkopar (west), Mumbai-400086, Maharashtra, India.

E mail: rachana.chandura@gmail.com

**Abstract:** Background: This prospective, randomized controlled clinical trial was done to compare the newer supraglottic airway device(SGD) I-gel with the LMA-classic.

Materials and methods: Sixty adult patients of 18-60 years age group were enrolled. The patients were randomly divided in to two groups, in group 1, I-gel and in group 2, LMA-C was inserted. Both group evaluated regarding the hemodynamic stability, ease of insertion, number of attempts and airway manipulations required during insertion, time required for insertion of the SGD and adverse events occurring intra-operatively and post-operatively.

Result: I-gel is better than LMA in all parameters measured with fewer complications.

Conclusion: I-Gel can be used as a better alternative to the LMA-C.

**Keywords:** Randomized controlled trial, I-Gel, LMA-Classic, supraglottic airways

## THESIS SUMMARY

### Introduction:

Supraglottic devices are useful advent in the airway management, filling a niche between the facemask and tracheal tube in terms of both the anatomical position and the degree of invasiveness. It is easy to insert them blindly in to the hypopharynx to form a seal around the larynx and has an important role in the management of difficult intubation and failed intubation. Laryngoscopy and muscle relaxation are not necessary for the insertion of supraglottic device. As it avoids invasion of vocal cords, incidence of injury inside the oral cavity and the occurrence of sore throat also decreases. These devices are better tolerated than the tracheal tube at 'lighter' levels of anaesthesia and have minimal cardiovascular

response. They can be inserted in awake as well as anaesthetized patients with or without using muscle relaxant. The I-Gel is a new, single use, non-inflatable supraglottic airway for use in anaesthesia during spontaneous or intermittent positive pressure ventilation. The shape, softness and contours accurately mirror the perilaryngeal framework itself and create the perfect fit. As it has no inflatable cuff, it has several potential advantages including easier insertion, minimal risk of tissue compression, stability after insertion and an integrated gastric channel is provided for gastric suction for passage of nasogastric tube to empty the stomach. The objective of our study was to compare two supraglottic devices, classic LMA and I-Gel for ease of insertion, position within the airway, ease

during mechanical ventilation, hemodynamic parameters before, during and after insertion and postoperative complications in anaesthetised patients undergoing elective surgical procedures.

### Materials and methods:

Sixty patients of either sex in the age group of 18-60 years were selected randomly. Patients were divided into two groups comprising of thirty patients each and comparison was made between LMA-C Classic and I-Gel supraglottic device. In group 1, I-gel and in group 2, LMA-C was inserted. The hemodynamic stability, ease of insertion, number of attempts & time required for insertion and airway manipulation required for insertion were

noted. After insertion, pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, SpO<sub>2</sub> & EtCO<sub>2</sub> were noted at different time intervals. Anesthesia was maintained with 66% N<sub>2</sub>O with O<sub>2</sub> and Isoflurane 0.5 -1% and muscle relaxation was provided with vecuronium. Insertion of nasogastric tube was done through the gastric channel of the I-gel using appropriate size of nasogastric tube.

Adequacy of oxygenation was determined as SpO<sub>2</sub> >95% and adequacy of ventilation was defined as EtCO<sub>2</sub> between 30-40 mmHg. At the end of surgery, neuromuscular blockade was reversed with Neostigmine 50 mcg/kg and Glycopyrrolate 8 mcg/kg IV. After suctioning from the hypopharynx and once the consciousness was regained, patients were asked to open their mouth and device was removed after the protective reflexes had returned.

The devices were examined for the presence of blood on it and any adverse events occurring post-operatively were noted. The statistical analysis was done using EPI INFO software using the "two tailed students' 't' test for unequal variance." the difference was considered to be statistically significant when  $p < 0.05$  and highly significant when  $p < 0.01$ .

### Results:

The demographic data of both the groups was comparable. In both the groups pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure remained below the baseline values and remained lower in the I-Gel group compared to the LMA-C group throughout the observation period.

A significantly higher pulse rate was noted in LMA-C group at 3 min following insertion as compared to the I-Gel group ( $p < 0.05$ ). 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 ( $p < 0.05$ ), where it was higher for the LMA-C group. The MAP was comparable in both the groups throughout the observation period ( $p > 0.05$ ).

There was no statistically significant difference in SpO<sub>2</sub>, EtCO<sub>2</sub> and they remained within normal limits ( $p > 0.05$ ), chest compliance and ease of IPPV were adequate in both the groups.

The insertion of the I-Gel required less attempts and less airway manipulation as compared to LMA-C. Insertion of I-gel was possible in single attempt in all 30 patients whereas, in the LMA-C group it was possible in 27 patients while 2 patients required 2 attempts and 1 patient required 3 attempts for insertion. Manoeuvres for airway manipulation like jaw lift, adjusting head and neck position and twisting, rotating or reinsertion of the device were not needed in 20 patients of I-Gel group and one manoeuvre was needed in remaining 10 patients. In the LMA-C group, 6 patients did not require any airway manipulation, 17 patients needed one, 2 patients needed two and 1 patient needed three manoeuvres. I-Gel was easy to insert in 100% patients as compared to 73.33% patients in LMA-C. I-Gel required less time for insertion ( $8.26 \pm 2.88$  sec) as compared to the LMA-C ( $25.13 \pm 31.71$  sec).

One patient of the I-Gel group developed bradycardia (pulse < 60/min) intra operatively. I-Gel insertion was associated with less post-operative complications like sore throat (3.33%) as compared to the LMA-C (20%). I-Gel did not show staining of device with blood and tongue, lip or dental trauma whereas; it was seen in 13.33% and 10% of the patients of the LMA-C group respectively. None of the patients in the I-Gel group experienced cough, hoarseness of voice and vomiting whereas, it was seen in 6.66%, 3.33% and 6.66% of the patients of the LMA-C group respectively.

### Conclusion:

Thus it can be concluded from the study that the I-Gel is easy to insert with less airway manipulations, requiring less time and attempts for insertion, maintaining better hemodynamic stability following insertion and causing less post-operative complications compared to the LMA-C.

The I-Gel can be used as a better alternative to the LMA-C.

### Key Words:

randomized controlled trial, I-Gel, LMA-Classic, supraglottic airways

### Bibliography

1. Al Ali Muneer Is the I-Gel airway device as safe and effective as the standard LMA IZ Leuven Belgium, 2009.
2. Ali Sarfarazsiddiqui, Ummesumayyah, SafiaZafarSiddiqui et al Comparison of performance & safety of I-Gel with LMA-C for general anaesthesia with controlled ventilation Anaesthesia pain and intensive care; 2010; 14(1):17-20.
3. Amr M. Helmy, Hossam M. Atef, Ezzat M. El-Taher Comparative study between I-Gel, a new supraglottic airway device, and classical laryngeal mask airway in anaesthetized spontaneously ventilated patients Saudi journal of anaesthesia vol 4, issue 3, September-December 2010.
4. Ansar Ali, Naseem Ali Sheikh and Liaqat Ali et al Comparison of I-Gel supraglottic with laryngeal mask airway Professional Med J Dec 2010; 17(4): 643-647.
5. AshishKannaujia and Uma srivastava et al A preliminary study of I-Gel: a new supraglottic airway device Indian Journal of Anaesthesia 2009; 53 (1):52-56.
6. Atkinson, Rashman and Davis Lee's Synopsis of Anaesthesia, 11th edition.
7. Ayedi M., Zouari J., Smaoui M. The performance of the I-Gel in comparison with the LMA classic 2010; airway management; page 233.
8. B D Chaurasia's human anatomy 5th edition, volume 3: 237-240.
9. Benumof Jonathan l Laryngeal mask airway, indication and contraindication Anaesthesiology, 1993; 77; 843- 846.
10. Bimla Sharma and RaminderSehgal et al PLMA vs. I-Gel: a comparative evaluation of respiratory mechanics in laparoscopic cholecystectomy Anaesthesia Clinical Pharmacology, 2010; 26(4): 451-457.
11. Carin A. Hagberg Comparison of I-Gel to the laryngeal mask airway Clinical trials.gov, university of Texas medical school at Huston, 2011.
12. Gray's anatomy: the anatomical basis of clinical practice Chapter 34, 40th edition.
13. Intersurgical: User guide: I-Gel supraglottic airway, adult and pediatric sizes. Intersurgical, Wokingham, Berkshire, United Kingdom 2010.
14. Ishwar Singh, Monika Gupta and Mansi Tondon: Comparison of clinical performance of I-Gel with LMA Proseal in elective surgeries Indian Journal of Anaesthesia 2009; 53 (3): 302-305.
15. Joshi Girish P et al Use of LMA as an alternative to the tracheal tube during ambulatory anaesthesia Anaesthesia Analgesia 1997, 98, 573-7.
16. Keerthi Kumar S, Lt.Col. Roman Naik The History of Evolution of Laryngeal Mask Airway Indian Journal of Anaesthesia 1999, 43, 22.
17. L. Gasteiger and J. Brimacombe et al: Comparison of guided insertion of the LMA Prosealvs the I-Gel; Anaesthesia, 2010, 65, pages 913-916.
18. Lorenz G. and Theiler et al Crossover comparison of the laryngeal mask supreme and the I-Gel in simulated difficult airway scenario in anaesthetized patients Anaesthesiology, V 111, No 1, July 2009: 55-62.
19. Miller's Anaesthesia, 7th edition.
20. Mohamed Z. Ali and Reeham S. Ebied et al Controlled mechanical ventilation with

- LMA Supreme versus I-Gel in anaesthetized adult patients *Journal of the Egyptian Society of Parasitology*, Vol. 41, no. 2, August 2011.
21. Parul Jindal, Aslam Rizvi and JP Sharma Is I-Gel a new revolution among supraglottic airway devices *M.E.J. Anaesth* 20(1), 2009.
22. Theiler and Lorenz G. et al Performance of the pediatric sized I-Gel compared with the Ambu AuraOnce laryngeal mask in anaesthetized and ventilated children *Anaesthesiology*, V 115: no 1, July 2011: 102-110.
23. *Understanding anaesthesia equipment* Jerry M. Dorsch and Susan E. Dorsch; 5<sup>th</sup> edition: page 462-466.
24. V. Uppal, S. Gangaiah, G. Fletcher, and J. Kinsella Randomized crossover comparison between I-Gel and the LMA Unique in anaesthetized, paralyzed adults *British Journal of Anaesthesia* 103(6): 882-5 (2009).
25. William Donaldson and Alexander Abraham et al I-Gel vs. AuraOnce laryngeal mask for general anaesthesia with controlled ventilation in paralyzed patients *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub.* 2011 Jun; 155(2): 155-164.
26. Wylie & Churchill- Davidson's *A Practice of Anaesthesiology* 1995, 6<sup>th</sup> edition.
27. Zouche I., Ayedi M., Smaoui J., Abidi S. Comparison of two supraglottic devices: I-Gel and LMA-classic in Pediatric anaesthesia 2010; airway management; page 233.

Conflict of Interest: Nil  
Source of Support: None

Full Thesis and Master Chart available on  
[www.journalmedicalthesis.com](http://www.journalmedicalthesis.com)

#### How to Cite this Article:

Chandura RA, Kantharia BN, Shah PK. An Interventional Randomized Study to Evaluate a new Supraglottic Airway Device (I-gel) in Comparison with the Classical LMA. *Journal Medical Thesis* 2013 July-Sep; 1(1):17-19