Scholars Journal of Applied Medical Sciences (SJAMS)
Abbreviated Key Title: Sch. J. App. Med. Sci.
ISSN 2320-6691 (Online)
ISSN 2347-954X (Print)

A Unit of Scholars Academic and Scientific Society, India
www.saspublishers.com

Anaesthesiolog

Comparative Study of Clinical Performance of the I-Gel with LMA Proseal: A Randomised Control Study

Dr. Ajit Desai[1*], Dr. Varshali Keniya[2], Dr. S. S. Swami[3]
[1]Resident, Department of Anaesthesiology, Bharati Vidhyapeeth Medical College, Pune, India
[2]Associate Professor, Department of Anaesthesiology, Bharati Vidhyapeeth Medical College, Pune, India
[3]Professor and HOD, Department of Anaesthesiology, Bharati Vidhyapeeth Medical College, Pune, India

Original Research Article

***Corresponding author**
Dr. Ajit Desai

Article History
Received: 16.02.2018
Accepted: 26.02.2018
Published: 30.03.2018

DOI:
10.36347/sjams.2018.v06i03.051

Abstract: The major responsibility of anaesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing functional respiration is airway. Supraglottic airway devices have become a standard fixture in airway management, filling a niche between facemask and tracheal tube. To compare clinical performance of two different supraglottic devices. Seventy patients of ASA I and ASA II status with age between 18-65 years were divided into two groups. PLMA group and I-GEL group. PLMA and I-GEL were inserted after anaesthesia and adequate muscle relaxation. The parameters like insertion time for the device, insertion device score, airway sealing pressure, airway sealing quality score (ASQ score), blood staining of devices and post-op complication were recorded. The mean airway sealing pressure was higher with PLMA (28.11 cm of H20) than I-GEL (24.60 cm of H20). The insertion time of I-GEL 12.14 seconds as opposed to PLMA which was 16? 29 seconds. Insertion device score and ASQ score was better with I-GEL than PLMA. Blood staining and post-op complication were seen more in patients with PLMA. Securing airway is comparatively faster and easier in I-GEL which can be advantages in patient with difficult airway and emergency situation. As higher Airway sealing pressure was achieved in patient with PLMA, it can be considered in patients for laparoscopic surgeries.
Keywords: Supraglottic airway, ASQ score, ventilation.

INTRODUCTION

The major responsibility of anesthesiologist is to provide adequate ventilation to patient. The most vital element in providing functional respiration is the airway.

It has been established that inability to successfully manage difficult airway is known to be responsible for majority of deaths totally attributable to anaesthesia [1].

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between facemask and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit over laryngeal opening but provide a hands free means of achieving a gas tight airway [1,2].

The first successful supraglottic airway device, the laryngeal mask airway (LMA) classic became available in 1989, first described by Archie Brain. As the time went on additional devices were added to LMA family to satisfy specific needs [3,4].

The Proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in clinical practice in 2000 with its improved feature of modified cuff to improve the seal around the glottis and a drain tube to provide a bypass channel for regurgitated gastric contents, its seal is more effective than that of classic LMA[2-5]. The drain tube prevents gastric insufflations, allows easy placement of gastric tube. It can also help in placement of mask with the help of Bougie[4].

The I-gel is the most recent development in Supraglottic airway devices. It was developed by Dr. Mohammad Aslam Nasir in January 2007. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work, mirroring the shape of the epiglottis, aeryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces [5-7].

The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation [6].

We have compared the clinical performance of the I-GEL with PLMA in anaesthetized patients on controlled ventilation, undergoing elective surgical procedures with respect to ease of insertion, insertion attempts, airway sealing pressure, ease of gastric tube placement and complications.

MATERIALS AND METHODS

The study was conducted in the tertiary care hospital. After approval by ethical committee, study was conducted at attached teaching hospital from September 2015 till June 2017

- STUDY DESIGN –The study was a Prospective Comparative study.
- CONSENT- A written informed consent was taken from each patient, in the language he or she understands.
- Study population- the study population included 70 patients which were randomly divided in two equal Groups (Group P and Group I) by chit method with 35 patients in each Group.
    - P: LMA Proseal group –with 35 patients.
    - I: I-gel- with 35 patients.

Inclusion criteria

All patients with in age of 18 to 65 years, ASA I/II grades, undergoing elective surgery in supine position under General Anaesthesia with controlled ventilation and duration of surgery less than 3 hrs.

Exclusion criteria

- Patient with anticipated difficult airway.
- Patient at high risk of aspiration eg. full stomach, emergency surgery or GERD.
- Obese patients.
- Cervical spine disease.
- Head and neck surgery.

METHODOLOGY OF STUDY

- All patients were asked to fast overnight.
- Inj. Glycopyrrolate 0.2 mg, inj. Ondensetron 4 mg, inj. Midazolam 0.02 mg/kg was administered intravenous to the patient 20 minutes prior to surgery.
- Baseline parameters like Peripheral oxygen saturation (SpO_2), ECG, heart rate, noninvasive blood pressure was noted.
- Anaesthesia was induced with inj. Fentanyl 1 mcg./kg and inj. Propofol 2-2.5 mg/Kg intravenously. Neuromuscular block was achieved with inj. Rocuronium 0.8 mg/Kg. Both I-gel and PLMA was lubricated with water soluble gel.
- Once adequate depth is achieved, in Group P, Proseal LMA and in Group I, I-GEL was inserted by an experienced anaesthesiologist.
- In Group P, Cuff of LMA Proseal was inflated with air to 60 cm of H_2O pressure and maintained at this pressure throughout anesthesia using a cuff pressure monitor.
- Both the devices were fixed by taping the tube over the chin. A lubricated gastric tube was placed into the stomach through gastric channel.
- Maintenance was achieved by oxygen with Nitrous oxide, Isoflurane and intermittent doses of intravenous Inj. Rocuronium. Intra operative heart rate, noninvasive blood pressure, oxygen saturation and end tidal carbon dioxide was recorded at every 15 minutes till the end of surgery.
- Insertion time was recorded by an independent observer for each device and defined as time interval between picking up the device and securing an effective airway. However if insertion failed at second attempt, the patient was withdrawn from the study and insertion was recorded as failure and a cuffed endotracheal tube of appropriate size was inserted.
- Insertion device score (IDS) for each device was recorded as follows [10].

- **Insertion Device Score**

  3 - Insertion at first attempt without tactile resistance.
  2 - Insertion at first attempt with tactile resistance.
  1 - Insertion at Second attempt.
  0 - Insertion failed at second attempt.

- Airway sealing pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow rate of 3L/min and recording the airway pressure at which equilibrium was achieved. At this stage audible leak at the mouth and stomach was ascertained by placing the stethoscope just lateral to the thyroid cartilage or over stomach.

- Tidal volume loss was detected by inspiratory-expiratory volume on the ventilator display screen. From this tidal volume loss ASQ score was calculated as follows [10].

- **Airway Sealing Quality Score (ASQ)**

  1 - No leak detected.
  2 - Minor leak of TV (TV loss < 20%)
  3 - Moderate leak of TV (TV loss – 20% - 40%)
  4 - Insufficient seal (TV loss > 40%)

- Ease of insertion of the gastric tube was recorded as either successful in first attempt/second attempt/failure. Its correct placement was confirmed by aspiration of gastric contents or by injection of air and auscultation over the epigastrium. Failure is defined as inability to

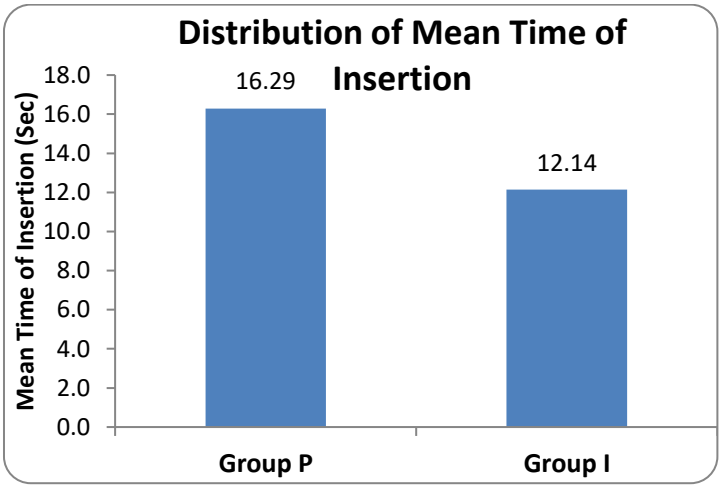
advance the orogastric tube into the stomach with two attempts.

- At the end of surgical procedure anaesthesia was discontinued, neuromuscular blockade was reversed with inj. Neostigmine 0.04 mg/kg and inj. Glycopyrrolate 0.01mg/kg intravenously and the device was removed.

- Blood staining of the device, tongue, lip and dental trauma was recorded.
- Postoperative complications in the form of sore throat, dysphagia or vomiting were assessed immediately after regaining full consciousness and again after 6 hours.

- The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 16.0, IBM Corporation, USA) for MS Windows.
-
- The inter-group comparison of categorical variables is done using Chi-square test.

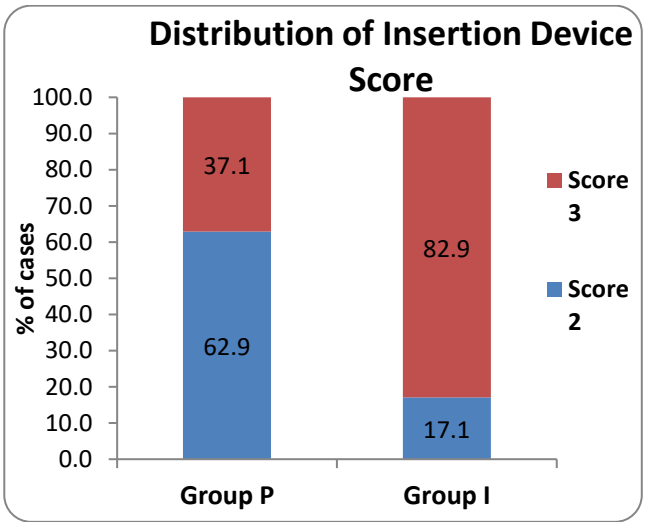
OBSERVATIONS AND RESULTS



Graph-1: The distribution of mean time of insertion of the cases studied across two study groups

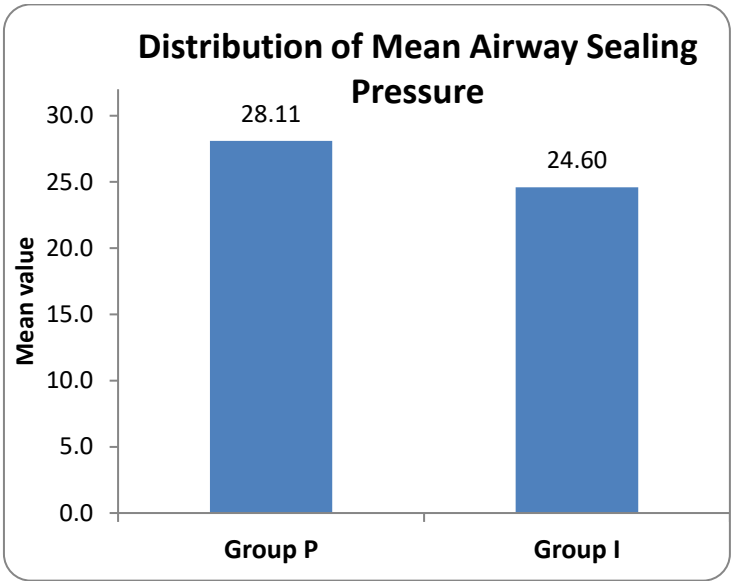
- The **mean insertion time** of I-GEL was 12.14 seconds and of PLMA was 16.29 seconds

- The insertion score was significantly higher in PLMA group by 4 secs compared with I-GEL.(p value<0.001)



Graph-2: The distribution of insertion device score of the cases studied across two study groups

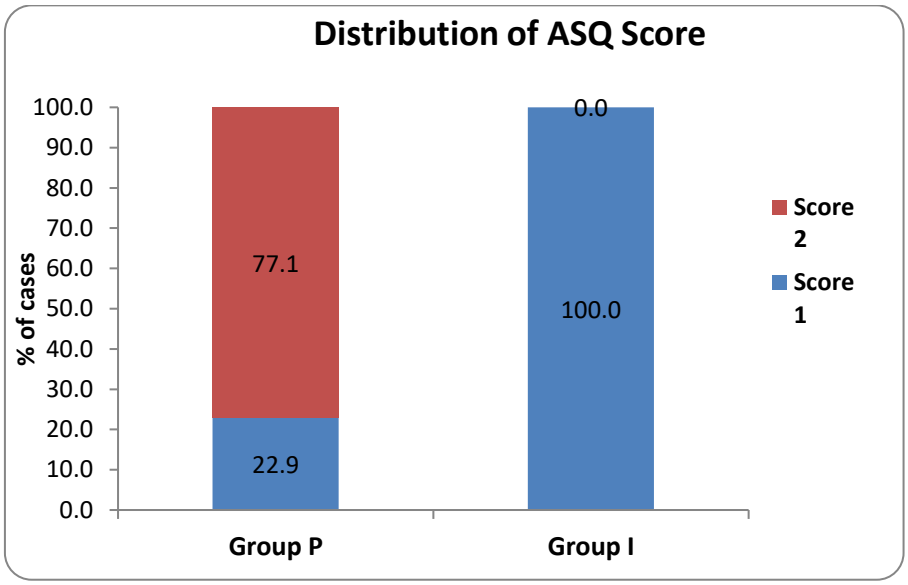
The **insertion device score** for I-GEL was score 3 in 82.9 %, score 2 in 17.1% while that in PLMA was score 3 in 37.1% and score 2 in 62.9% which was statistically significant (p value< 0.001)



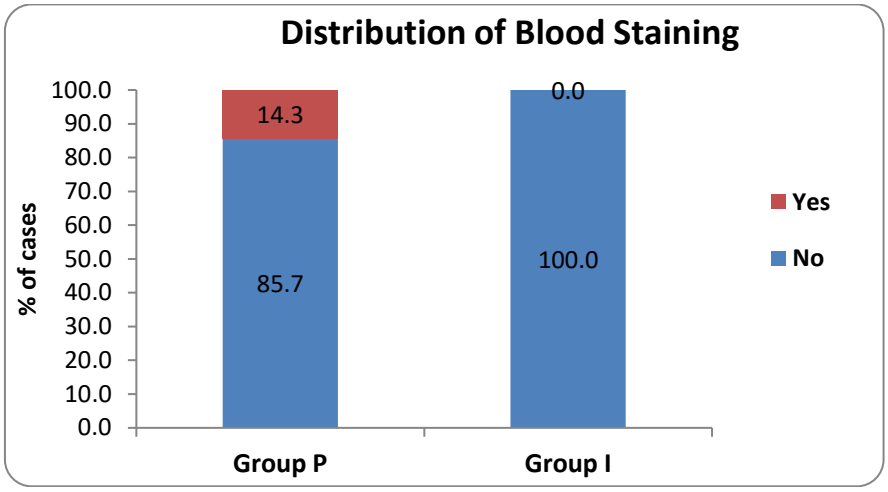
Graph-3: the distribution of mean airway sealing pressure of the cases studied across two study groups.

The mean airway sealing pressure of I-Gel was 24.60 cm of H2O while that of PLMA was 28.11 cm of H2O which was statistically significant (p value<0.0001).

The ASQ score was statistically significant with less tidal volume loss with I-GEL (p value<0.0001)

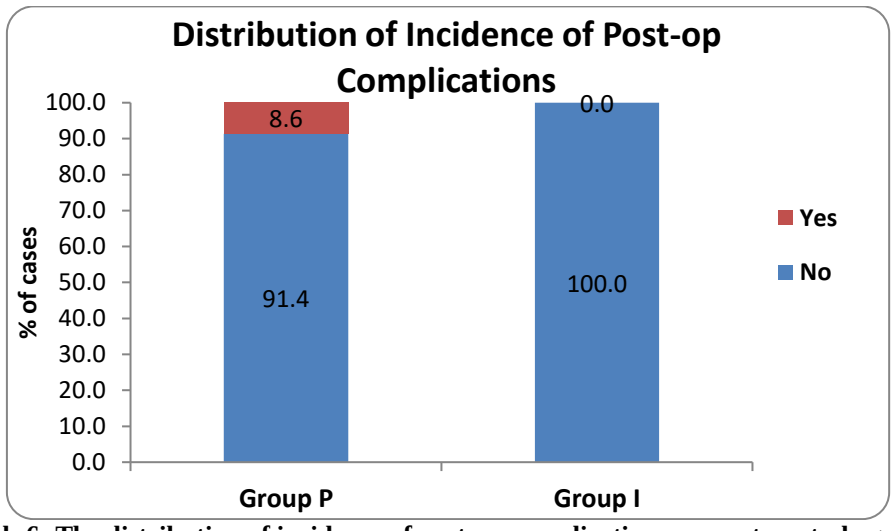


Graph-4: The distribution of ASQ Score of the cases studied across two study groups.



Graph-5: The distribution of blood staining of the cases studied across two study groups

The blood staining of device was 5 cases with PLMA which was statistically insignificant (pvalue>0.05) (Graph-5). The post-op complication was 3 cases with PLMA which was statistically insignificant (p value>0.05) (Graph-6).



Graph-6: The distribution of incidence of post-op complications across two study groups.

DISCUSSION

- The introduction of LMA in clinical practice led to revolution in the airway management.
- The introduction of LMA changed the condition from unable to intubate and ventilate to unable to intubate but able to ventilate.
- The mean insertion time and ease of insertion was better with I-GEL than PLMA, as PLMA required manipulation during insertion and no cuff inflation is required in I-GEL, the same results were obtained by Singh *et al*. The PLMA was having high airway sealing pressure than I-GEL due to inflatable cuff, this finding suggest that, PLMA was better ventilating device in patients requiring high airway sealing pressures. The similar results were obtained by V. Trivedi *et al*. in their study.
- Blood staining of device and post-op were more with PLMA, as device with inflatable cuff has the potential to cause tissue distortion, venous compression and nerve injury. The results were obtained by Singh etal in their study.

CONCLUSION

- I-GEL is comparable with PLMA in securing a patent airway during controlled ventilation.
- I-gel is better than PLMA in terms of faster insertion and ease of insertion with a low incidence of pharyngeal morbidity.
- I-GEL requires less manipulations and no cuff inflation is required so the securing of better airway is rapid.
- PLMA has high airway sealing pressure than I-Gel therefore it is relevant in securing a airway with adequate ventilation in patients requiring high airway sealing pressure like obese patients and patient undergoing intra-abdominal surgery or laparoscopic surgeries

REFFERENCES

1. Misra MN, Ramamurthy B. The Proseal LMA and the tracheal tube: A comparison of events at insertion of airway device. Internet J Anaesth 2003;47:467-472
2. El-Ganzouri A, AvramovMN, BudacS, Moric M, Tuman KJ. Proseal laryngeal mask airway versus endotracheal tube: ease of insertion, hemodynamic responses and emergence characteristics. Anesthesiology 2003; 99: A 571.
3. Lim Y, Goel S, Brimacombe JR. The ProSeal (TM) laryngeal mask airway is an effective alternative to laryngoscope-guided tracheal intubation for gynaecological laparoscopy. Anaesthesia and intensive care. 2007 Feb 1;35(1):52
4. Van Zundert TC, Brimacombe JR, Ferson DZ, Bacon DR, Wilkinson DJ. Archie Brain: celebrating 30 years of development in laryngeal mask airways. Anaesthesia. 2012 Dec 1;67(12):1375-85.
5. Tim Cook, Ben Howes. Supraglottic airway devices: recent advances. british journal of anesthesia .2010.
6. Brain AI, Verghese C, Strube PJ. The LMA 'ProSeal'—a laryngeal mask with an oesophageal vent. British Journal of Anaesthesia. 2000 May 1;84(5):650-4.
7. Cook TM, Lee G, Nolan JP. The ProSeal™ laryngeal mask airway: a review of the literature. Canadian Journal of Anesthesia. 2005 Aug 1;52(7):739.
8. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia. 2005 Oct 1;60(10):1022-6.
9. 7th ed. Wokingham, UK: Intersurgical Ltd; 2009. [accessed 16th Feb 2011] I-gel user guide. www.Igel.com.
10. Singh I, Gupta M, Tandon M. Comparison of Clinical Performance of I-Gel™ with LMA—Proseal™ in Elective Surgeries. Indian journal of Anaesthesia. 2009 Jun;53(3):302
11. Jindal P, Rizvi A, Sharma JP. Is i-Gel a new revolution among supraglottic airway devices?. Department of Anesthesiology American University of Beirut Medical Center PO Box 11-0236. Beirut 1107-2020, Lebanon. 2009 Feb;20(1):53.