

## A PROSPECTIVE RANDOMISED STUDY COMPARING AMBU LMA AND I GEL IN ANESTHETISED PATIENTS UNDERGOING GYNAECOLOGICAL PROCEDURES

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### Abstract

**Background:** Supraglottic airway devices (SADs) are commonly used in clinical practice to secure the airway, particularly when endotracheal intubation is challenging or impossible. Common types of SADs include laryngeal mask airway (LMA), i-gel, and various other designs. This study compared the clinical performance and advantages of two supraglottic devices, the I gel and Ambu LMA, in anaesthetised patients undergoing gynaecological procedures. **Material & Methods:** This study was conducted in the elective operation theatres of Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, and included 100 patients who had undergone minor gynaecological procedures. I-gel was used in group I (50 patients), and Ambu LMA was used in group A (50 patients). Observations and recordings were performed in both groups for ease of insertion, number of attempts, haemodynamic response, and complications. All results were tabulated and analysed. **Results:** The findings from the present study indicated that the time taken for insertion and several attempts by the I-Gel were less and statistically significant. The incidence of trauma and postoperative airway morbidity was similar in both groups. **Conclusion:** The I-GEL demonstrates easy and rapid insertion as a supraglottic airway device. The I-gel and Ambu LMA showed comparable effectiveness for the number of insertion attempts and ease of insertion. However, the time taken for insertion was significantly shorter with the I-GEL than with the Ambu LMA. Thus, further studies are needed to determine the overall efficacy of one option over another.

## INTRODUCTION

Anesthesia has been administered conventionally for over a decade using the Goldmann dental mask and endotracheal intubation (ETI).<sup>[1]</sup> This method of anaesthesia administration is known as conventional-al mask anaesthesia. Since Dr. Archie Brain created the laryngeal mask airway (LMA) in 1981, supra-glottic airway devices (SADs) have begun to replace ETI for resuscitation and, difficult intubation procedures and general anaesthesia.<sup>[2,3]</sup> SADs can maintain stable haemodynamics even though they require less anaesthetic than ETI.<sup>[3]</sup> Most recently developed medical tools, such as the I-gel and AmbuAuraGain, have become available for use in clinical settings in recent years. The I-gel is one of these second-generation devices. It has a

soft, flexible, and gel-like texture, and it is made of a thermoplastic elastomer non-inflatable cuff to create a seal with the peri-laryngeal structures.<sup>[1,4-8]</sup> Another second generation, the SAD known as the Ambu LMA, AuraGain, was introduced to the market in June 2014.<sup>[1]</sup> It is also a device that can be thrown away because it is composed of polyvinyl chloride. It has a preformed curvature that mimics the shape of the human airway.<sup>[9-11]</sup> These recently released second-generation SADs contain a gastric channel that reduces the risk of aspiration resulting from gastric insufflation. Previous studies indicate that the I-gel demonstrates effective sealing capabilities during anaesthesia for spontaneous breathing and controlled ventilation scenarios.<sup>[3,7,9,11]</sup> However, there is a lack of studies that have specifically compared its performance with the PLA

(Proseal Laryngeal Mask Airway) in the context of laparoscopic surgery. Therefore, we devised this study to determine the clinical effectiveness of I-gel and AmbuAuraGain in adult female patients undergoing general anaesthesia. This study aimed to compare the clinical performance and advantages of two supraglottic devices, I-gel and Ambu LMA, in anaesthetised patients undergoing gynaecological procedures.

## MATERIALS AND METHODS

This prospective randomised controlled study was conducted on ten patients at Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, from April 2021 to November 2022. The study received ethical committee approval and informed consent before the initiation.

### Inclusion Criteria

ASA I and II, who were scheduled for elective gynaecological surgery under general anaesthesia, aged 18–50 years, were included, MPC class I and II, and weighing 30-60 kg.

### Exclusion Criteria

Patients with restricted mouth opening (< 2 cm), anticipated difficulty in the airway, diseased oral cavity, increased risk of aspiration, and a history of symptomatic gastroesophageal reflux were excluded.

Patients were randomised into groups I and A (50 each). Group I received general anaesthesia with I-GEL, while Group A received general anaesthesia with AURA GAIN LMA.

Patients were administered premedication (T. Ranitidine 150 mg and T. Metoclopramide 10 mg) the night before surgery and advised overnight fasting for 8 hours. On the day of surgery, standard monitoring was performed before induction, including ECG, pulse oximetry, capnography, non-invasive blood pressure, and temperature monitoring. The patient was premedicated with intravenous ranitidine 50 mg, intravenous metoclopramide 10 mg, Inj Midazolam 0.02 mg/kg IV, Inj Glycopyrrolate 0.2 mg/kg IV. Pre-oxygenation was performed with 100% O<sub>2</sub>, and the patient was manually ventilated using a face mask. Anaesthesia was induced with Inj Propofol 2 mg/kg IV. After adequate face mask ventilation, an appropriately sized supraglottic airway device was inserted according to randomisation. Correct placement of the Supraglottic device and ventilation adequacy following placement was assessed with bilateral auscultation and visible chest expansion. This was confirmed by good Etco<sub>2</sub> tracing. During this procedure, the time taken for supraglottic device insertion and several insertion attempts, HR, RR, Spo<sub>2</sub> and end-tidal Co<sub>2</sub> concentration monitoring, and intraoperative and postoperative complications were assessed.

## Statistical Analysis

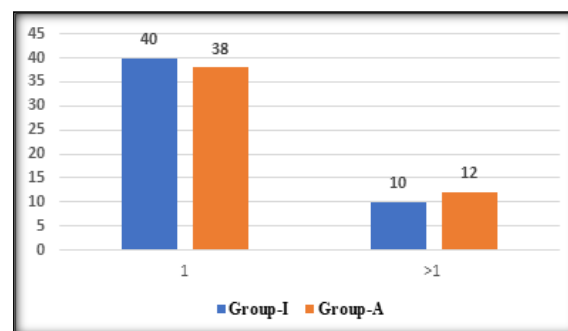
The collected data were entered into Microsoft Excel and analysed using SPSS version 24.0. Categorical data were expressed as frequencies. Descriptive variables were expressed as mean and standard deviation (SD) and compared using Student's t-test. Statistical significance was set at  $p < 0.05$ .

## RESULTS

The mean age and BMI were comparable in both groups, whereas the time taken to insert the device in seconds was significantly different. The time taken for device insertion in group I was less than that in group A, and the association was statistically significant ( $p < 0.05$ ). [Table 1]

The distribution of ASA grading within the study groups indicated that group I comprised 24 participants with grade 1 and 26 with grade 2. Group A comprised 27 participants from Grade 1 and 23 participants from Grade 2. [Table 2]

There were fewer attempts at insertion of the device in group I than in group A, and the association was statistically insignificant ( $p > 0.05$ ). [Figure 1]



**Figure 1: Number of attempts of insertion among study participants**

Regarding complications, the I-GEL group experienced six cases of sore throat and two cases of vomiting, whereas the Ambu LMA group had five cases of sore throat and one case of vomiting. No other complications, such as bronchospasm, laryngospasm, traumatic injury, vomiting, or hoarseness of voice, were reported in either group. [Table 3]

Hemodynamic parameters like heart rate, oxygen saturation and respiratory rate were comparable between both the groups, and there was no statistical difference. [Figures 2, 3 & 4]

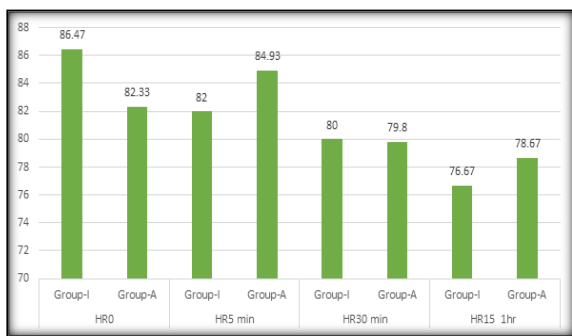


Figure 2: Heart rate among study participants

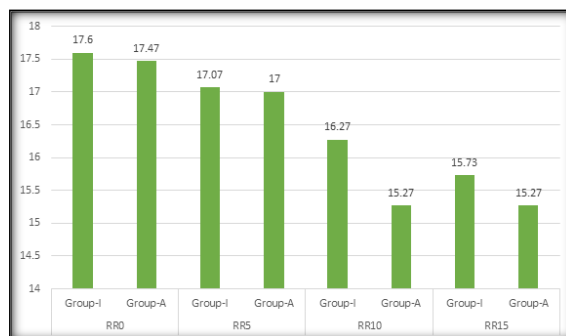


Figure 4: Respiratory rate among study participants

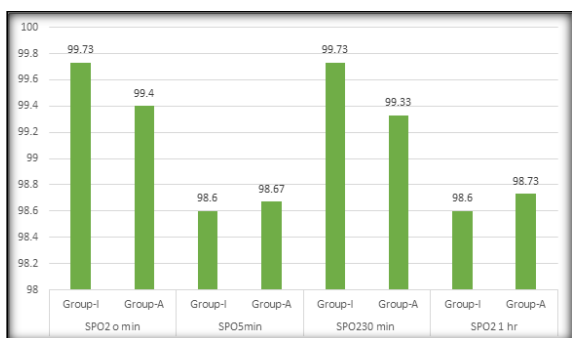


Figure 3: SPO2 among study participants

Table 1: Age distribution, body mass index, and time taken for insertion of device in seconds among study groups

	Group-I	Group-A	P-value
Age	44.28 ± 8.6	46.03 ± 9.2	0.56
Body mass index	24.16 ± 2.21	24.75 ± 2.42	0.42
Time taken for insertion of device in seconds	15.12 ± 1.21	17.06 ± 2.42	0.02

Table 2: ASA grading among study groups

Group	Grade 1	Grade 2
Group-I	24	26
Group-A	27	23

Table 3: Postoperative complications among study participants

Group	Vomiting	Sore throat	Oral Bleeding
Group-I	2	6	Nil
Group-A	1	5	Nil

## DISCUSSION

In our study, the mean age, BMI, and sex ratios between the groups were comparable. Haemodynamic parameters, such as blood pressure, oxygen saturation, and heart rate, were comparable between the groups, and there was no statistical difference. Similarly, there was no difference in hemodynamics in the study by Shetty et al., where they compared the advanced I-GEL with ILMA as a conduit for blind endotracheal intubation for patients posted for elective procedures under general anaesthesia.<sup>[12]</sup>

Our study showed that I-GEL, as a ventilatory device, was as effective as ALMA in maintaining ventilation and oxygenation in anaesthetised patients with normal airways. The mean insertion time for the supraglottic airway device was significantly shorter for the I-GEL than for the ALMA. The I-GEL is an uncuffed peri-laryngeal sealer, and insertion is easy and quick. In addition, it provides a

reliable airway. Both IGEL and ALMA were successfully inserted in all patients. The overall success rate of supraglottic airway device insertion was similar in both groups in our study. In a study conducted by Gatward et al., I-GEL was inserted in the first attempt in 40 patients, and ALMA was inserted in 38 patients, revealing a significant difference.<sup>[13]</sup> Similarly, Jeon et al. conducted a study revealing that successful insertion and mechanical ventilation were achieved on the first attempt in all 30 patients using both supraglottic airway devices. There were no significant differences in insertion time, and leak pressure remained consistent between and within the groups after CO<sub>2</sub> insufflation. Additionally, the groups showed no significant variations in leak volume or fraction. The study concludes that I-gel is a reasonable alternative to PLMA for controlled ventilation during laparoscopic gynecologic surgery.<sup>[14]</sup>

There were 6 cases of I-GEL with a sore throat and 2 cases of vomiting, while Ambu LMA had 5 cases with a sore throat and 1. Other complications, such as bronchospasm, laryngospasm, traumatic injury, vomiting, and hoarseness of voice, did not occur in either group. Similarly, the study done by Jadhav et al. revealed that the I-Gel demonstrated significantly easier insertion compared to LMA-Proseal ( $p < 0.05$ ), with a shorter mean insertion time for Group I. They observed that the success rate of first-attempt insertion was higher in Group I ( $p < 0.05$ ), and there were no instances of airway trauma, regurgitation, or aspiration, whereas sore throat was more prevalent in Group P.<sup>[15]</sup>

A comparison of I-GEL and laryngeal mask airway-Classic in terms of ease of insertion and haemodynamic response performed by Pratheeba et al,<sup>[16]</sup> revealed that I-gel is a suitable alternative to LMA Classic during general anaesthesia because of the successful and shorter duration of insertion, with a less haemodynamic response. Except in our study, there was not much of a difference in haemodynamic response but a shorter duration of insertion, with statistical significance when comparing ALMA. The first-attempt success rate is another important performance indicator of tracheal intubation. Insertion of a supraglottic airway and tracheal intubation may be indicated when conventional laryngoscopy fails. I-GEL, a relatively new device, has some benefits: it is disposable and cheap, and its wide bore facilitates the direct passage of a standard-size tracheal tube. It can be a useful adjunct to tracheal intubation in patients with difficult airways, as documented in several case reports.

## CONCLUSION

The I-GEL aids in easy and rapid insertion as a supra-glottic airway device. Both SADs were equally effective in terms of insertion attempts. The ease of insertion was comparable, but the time taken was significantly less for the I-gel group than for the Ambu LMA group. However, further studies are needed to determine the efficacy of one option over another.

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