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EVALUATION OF PERFORMANCE AND SAFETY OF I- GEL A NEW SUPRAGLOTTIC AIRWAY DEVICE FOR GENERAL ANAESTHESIA WITH CONTROLLED VENTILATION IN SHORT SURGICAL PROCEDURES

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ABSTRACT

Background: I-gel supraglottic airway device is used widely in anaesthesia practice. Aim of study was to find safety of I-gel for general anaesthesia in short surgical procedures. **Methods:** This was prospective study with 50 patients of ASA I-II. I-gel was inserted. Insertion time, ease of insertion, number of attempts, and complications were recorded. **Results:** Majority of patients pertained to 21 to 30 years (36%). Involvement of females(68%) was more as compared to males(32%). 74% cases had physical status ASA grade-1. Single attempt insertion was observed in all cases with 98% ease of insertion. Mean time for Insertion was 18.2±2.6 seconds. Audible Airway Leak was present in 4%. Maximum patients(94%) had easy insertion of gastric tube. Tongue/Lip/Dental Trauma were complications(6%). There was significant increase in HR, SBP, DBP and MAP at Insertion, 1-min after insertion and at removal and 1-min after removal compared to baseline values.(p-values<0.05). **Conclusion:** I-gel can be used safely in patients undergoing short-duration elective surgery.

INTRODUCTION

Airway management is a fundamental aspect of anaesthetic practice, both in the operating room and in emergency or critical care settings. Ensuring a patent airway is a core competency for anaesthetists. Among the most common and life-threatening complications associated with general anaesthesia is upper airway obstruction. This typically arises from the transient loss of protective airway reflexes, which can lead to the inadvertent aspiration of gastric contents into the tracheobronchial tree.[1] Airway management techniques have significantly evolved over time, transitioning from the routine use of endotracheal intubation (ETT) to the adoption of less invasive supraglottic airway devices such as the laryngeal mask airway (LMA).[2] ETT remains a rapid, effective, and non-surgical method of securing the airway; however, it can provoke undesirable reflex responses due to neuromuscular blockade and carries a risk of vocal cord trauma. In contrast, laryngeal mask airways (LMAs), while less invasive, may present challenges in patients with certain facial features-such as the presence of facial hair or absence of teeth-leading to difficulties in achieving an adequate seal and operator fatigue when used for prolonged durations.[2,3] A wide array of supraglottic airway devices (SADs) has been developed to address these limitations and to provide reliable airway protection in both elective and emergency settings.[4] Second-generation SADs, such as the ProSeal™ LMA (PLMA), i-gel™, and Laryngeal Tube Suction-D™, offer enhanced features including improved sealing, integrated gastric access, and reduced aspiration risk.[5,6]

The i-gel™ is a second-generation, supraglottic airway device made from soft, medical-grade thermoplastic elastomer called Styrene Ethylene Butadiene Styrene (SEBS).[7] Its non-inflatable, gel-like design conforms to the perilaryngeal anatomy, providing effective airway sealing and separation of the oropharynx from the laryngeal inlet.[8] The integrated buccal cavity stabilizer aligns with the oropharyngeal curvature, enabling easy insertion and stable positioning.[9] A built-in gastric channel allows for suctioning, leak detection, and confirmation of placement. With pharyngeal seal pressures ranging from 30–40 cm H_2O, the i-gel™ offers ventilation performance comparable to endotracheal tubes.[8,9] This study focuses on its safety and efficacy during general anaesthesia with controlled ventilation in short surgical procedures.

METHODOLOGY:

Study design and setting

This was a single-centre, prospective observational study conducted over 24 months (June 2023-June 2025) in the Department of Anaesthesiology at a tertiary care hospital in central India. The study protocol received approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrolment.

Eligibility Criteria

A total of 50 patients, aged 18 to 60 years, of either sex, classified as American Society of Anaesthesiologists (ASA) physical status I or II, and scheduled for short-duration elective surgeries under general anaesthesia in the supine position were enrolled. Exclusion criteria included patients at increased risk of regurgitation, those with known cardiac or pulmonary disease, abnormal or distorted pharyngeal anatomy, airway obstruction distal to the larynx, a history of difficult intubation, or anatomical predictors of difficult airway (e.g., mouth opening <40 mm, thyromental distance <65 mm, Mallampati grade III or IV). Morbid obesity (BMI >30 kg/m²) was also considered an exclusion criterion.

Study Procedure

Preoperative assessment was conducted the evening before surgery. Premedication included IV glycopyrrolate (0.2 mg) and ondansetron (4 mg), administered 30 minutes prior to induction. Standard monitoring like ECG, non-invasive blood pressure (NIBP), pulse oximetry, and capnography was applied upon arrival in the operating room. Induction was performed in the supine position with the head supported on a 7–10 cm pillow. Patients received IV midazolam (0.02 mg/kg) and pentazocine (0.3–0.6 mg/kg), followed by preoxygenation for 3 minutes. Anaesthesia was induced with IV propofol (2–2.5 mg/kg) over 30–40 seconds, targeting loss of eyelash reflex and jaw relaxation. Mask ventilation with 100% oxygen was initiated, and a size-appropriate i-gel™ was inserted after loss of ciliary reflex. Proper placement was confirmed by a stable capnographic waveform and absence of leak. Atracurium (0.5 mg/kg IV) was administered, and patients were manually ventilated. Ventilation parameters included tidal volume of 7 mL/kg, respiratory rate of 12/min,

without PEEP. Anaesthesia was maintained with 50:50 oxygen-nitrous oxide, sevoflurane (4–5%), and supplemental atracurium as needed. At the end of surgery, ease of i-gel™ removal was noted. Neuromuscular blockade was reversed with IV neostigmine (0.05 mg/kg) and glycopyrrolate (4 mcg/kg). Patients received 100% oxygen during emergence. The oral cavity and device were inspected for trauma or blood staining, and the i-gel™ was removed once protective reflexes returned. Postoperative analgesia included IV paracetamol (1 g) and tramadol (100 mg).

Statistical Analysis

The data was analysed with SPSS (IBM, Armonk, NY, USA) version 23.0 for windows. Continuous and categorical variables were represented in terms of mean ± standard deviation and frequency, respectively. Association between continuous and categorical variables was assessed with independent sample t-test and Chi-Square test, respectively. A p-value of < 0.05 was considered as statistically significant.

RESULTS

Table 1 Baseline Patient Characteristics (n=50)

Characteristics	Number	Percentage (%)
Age (years)		
<20 years	11	22.0%
21 to 30 years	18	36.0%
31 to 40 years	7	14.0%
41 to 50 years	8	16.0%
>50 years	6	12.0%
Mean ± SD	33.6 ± 15	--
Sex		
Male	16	32.0%
Female	34	68.0%
Mean + SD	52.8 + 8	--
ASA Grade		
1	37	74.0%
2	13	26.0%

SD – Standard deviation, ASA- American Society of Anaesthesiology

Majority of the patients (37%) pertained to the age group of 21 to 30 years (36%). Mean age was 33.6 ± 15 years. Both males and females were included in study. Involvement of females (68%) was more as compared to males (32%). Mean weight of subjects in the study was 52.8 ± 8 kgs. 74% cases had physical status ASA grade 1 and 26% had ASA grade 2. (Table 1)

Table 2 I-gel And Parameters (n=50)

Size of I-gel		Count	Percentage
i-3		18	36.0%
i-4		32	64.0%
Ease of insertion		**Count**	**Percentage**
Grade I		49	98.0%
Grade III		1	2.0%
Audible airway leak		**Count**	**Percentage**
Absent		48	96.0%
Present		2	4.0%
Ease of insertion of gastric tube		**Count**	**Percentage**
Difficult		3	6.0%
Easy		47	94.0%
Complications of I-gel insertion		**Count**	**Percentage**
Tongue/Lip/Dental Trauma	Nil	47	94.0%
	Present	3	6.0%
Sore Throat	Nil	50	100.0%
Hoarseness	Nil	50	100.0%
Dysphagia	Nil	50	100.0%

I-3 gel was used in 36% and i-4 gel was used in 64% and single attempt insertion was observed in all cases (100%) with 98% ease of insertion was Grade I and Grade III in 2%. Mean time required for Insertion of I-gel was 18.2 ± 2.6 seconds. Audible Airway Leak was present in 4% and absent in 96%, which is clinically significant. 6% had difficult gastric tube insertion and 94% had easy insertion, which is clinically significant. Tongue/Lip/Dental Trauma was only noticed as a complication (6%). (table 2)

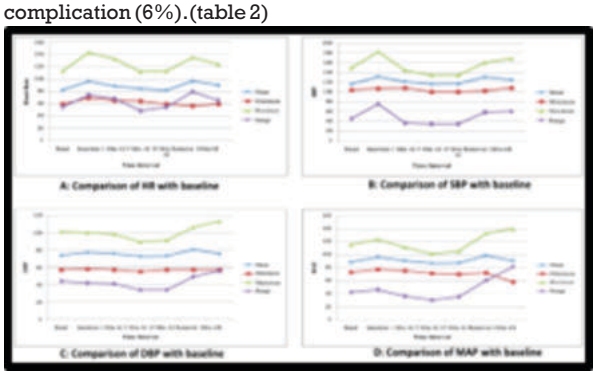

Figure 1 Line Diagram Comparing Hemodynamic Parameters With Baseline Values (n=50)

HR- heart rate, SBP- systolic blood pressure, DBP- diastolic blood pressure, MAP-mean arterial pressure, AI- after insertion, AR- After removal

There was significant increase in heart rate at Insertion, 1 min after insertion, at removal and 1 min after removal compared to baseline values. (all p-values <0.001) There was significant increase in systolic blood pressure at Insertion, 1 min after insertion, at removal and 1 min after insertion compared to baseline values. (p-values - <0.001, 0.031, <0.001, 0.004 respectively). There was significant increase in diastolic blood pressure at removal compared to baseline values. (p-value <0.001). There was significant increase in mean arterial pressure at Insertion, 1 min after insertion and at removal compared to baseline values. (p-values - <0.001, 0.03, <0.001 respectively) (figure 1)

DISCUSSION:

The i-gel™ is a relatively recent, single-use supraglottic airway device designed to provide an effective seal of the laryngopharyngeal space. Published literature reports a high first-attempt success rate and ease of insertion with minimal training, often requiring less time compared to other devices. Additional advantages include high oropharyngeal seal pressures and improved positional stability, attributed to its anatomically contoured, non-inflatable cuff.[1] This study aimed to evaluate the ease of insertion, number of attempts, insertion time, audible airway leak, gastric tube insertion attempts, hemodynamic changes, and adverse events associated with i-gel™ use in 50 ASA I–II patients undergoing short surgical procedures (≤60 minutes). Procedures included fibroadenoma excision, breast lump removal, tubectomy, lipoma excision, upper limb fracture fixation, inguinal hernia repair, scalp papilloma removal, and femoral osteomyelitis surgery. The majority of patients were aged 21–30 years (36%), with a mean age of 33.6 ± 15 years and mean weight of 52.8 ± 8 kg. ASA I patients comprised 74%, while ASA II accounted for 26%. i-gel sizes 3 and 4 were used in 36% and 64% of cases, respectively. In our study, the mean time for I-gel insertion was 18.2 ± 2.6 secs. Several studies have evaluated the insertion time of the i-gel™ airway device in comparison to other supraglottic devices. Weber et al. reported a mean insertion time of 18.3 ± 6.5 seconds when comparing the i-gel™ with the LMA-Unique in patients undergoing elective short-duration surgery.[12] Uppal et al., in a randomized crossover study involving anesthetized and paralyzed adults induced with propofol, fentanyl, and rocuronium, observed a shorter mean insertion time of 12.2 seconds (range 9.7–14.3 seconds) for the i-gel™.[13] Chauhan et al. found that the i-gel™ insertion time (11.12 ± 1.81 seconds) was significantly lower than that of the ProSeal LMA (15.13 ± 2.91 seconds) in elective surgical cases.[14] In a prospective observational study of 60

gynecological laparoscopic procedures, Choudhary et al. reported an average i-gel™ insertion time of 6.5 seconds.[15] Bamgbade et al. described rapid insertion times, with 290 out of 300 insertions completed within 5 seconds, although the exact definition of insertion time was not specified. Conversely, other studies have documented median i-gel™ insertion times of approximately 15 seconds, highlighting some variability in reported values.[16]

Patwa et al. compared the clinical performance of the i-gel™ and ProSeal LMA (PLMA) in adult patients undergoing elective surgeries under general anaesthesia, reporting that insertion was easy in 93.3% of i-gel™ cases versus 90% for PLMA, with difficult insertions occurring in 6.7% and 10% of cases, respectively-a difference that was statistically significant.[17] Park et al. evaluated the i-gel™ and LMA Supreme in laparoscopic cholecystectomy and observed audible air leaks in 5 of 90 patients with the i-gel™ and 8 with the LMA Supreme ($p = 0.39$), findings consistent with the present study.[18] Multiple investigations comparing airway seal pressures have demonstrated that the i-gel™ provides sealing pressures comparable to the ProSeal LMA and superior to Classic LMA and LMA Unique, supporting its safe use for positive pressure ventilation with a low risk of aspiration.[12-14]

In the current study, gastric tube insertion via the i-gel™ was easy in 94% of cases and difficult in 6%, aligning with findings by Pratibha et al., who reported minimal difficulty with gastric tube placement in the i-gel™ group compared to PLMA, with no significant difference between groups.[19] Chavan et al. found significantly higher ease of gastric tube insertion with the i-gel™ ($p = 0.001$), while Singh et al. and Kini et al. reported no statistically significant differences ($p > 0.05$ and $p = 0.230$, respectively).[14,20,21]

Hemodynamic parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP), showed significant increases at insertion, one minute post-insertion, removal, and one minute post-removal compared to baseline, consistent with previous studies.[19,22-23]

Regarding airway trauma, lip, tongue, and dental injuries were observed in 3 of 50 patients, with no blood staining on devices in our study. Sahi et al. reported airway trauma incidences of 5% with Fastrach and 3.33% with i-gel™, with oral trauma more frequent with Fastrach.[24] In this study, no patients reported sore throat, dysphagia, or hoarseness, findings corroborated by other reports.[25] No nerve injuries were observed, although isolated cases of nerve damage have been documented. Lu et al. described a case of bilateral lingual nerve injury following i-gel™ use, which resolved with conservative treatment over eight weeks.[26]

CONCLUSION:

We thus conclude that I-gel is a simple and safe supraglottic airway device made up of a soft gel like material. It is easier to insert with a more rapid time to insert and high success rate with least audible airway leak. Gastric tube insertion is significantly easy and there are almost no any complications involved. Hence, I-gel is a good device for maintenance of airway for short surgical procedures.

Conflict of Interest: None declared.

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