Research Article

A Comparative Study of Inflatable (Ambu® AuraGain™) and Non-Inflatable (i-gel®) Second-Generation Supraglottic Airway Devices in Pediatric Patients: A Prospective Randomized Clinical Trial

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Abstract

Background & Objective: Efficient airway management is paramount in pediatric anesthesia. Second-generation supraglottic airway devices (SADs) with integrated gastric channels offer significant safety advantages over first-generation designs. This study aimed to compare the insertion dynamics, sealing efficacy, and clinical performance of an inflatable cuff device (Ambu® AuraGain™) versus a non-inflatable gel cuff device (i-gel®) in pediatric patients undergoing elective surgical procedures.

Methodology: A prospective, randomized, controlled clinical study was conducted involving 50 pediatric patients (ASA Physical Status I–II, age 1–12 years, weight 10–30 kg) allocated into two equal groups of 25 patients each: Group A (Ambu® AuraGain™) and Group B (i-gel®). Primary outcome measures included insertion time, overall and first-attempt success rate, airway maneuvers required, and oropharyngeal leak pressure (OLP). Secondary outcome measures included intraoperative hemodynamic responses and postoperative airway complications (sore throat, blood on device, or cough). Continuous variables were analyzed using independent sample t-tests and categorical data via Pearson's chi-square test.

Results: Group B (i-gel®) demonstrated a significantly shorter mean insertion time compared to Group A (Ambu® AuraGain™) (24.12 ± 3.18 s vs. 29.84 ± 4.02 s; $p < 0.001$). The first-attempt success rate was comparable between groups (92.0% in i-gel® vs. 88.0% in AuraGain™; $p = 0.637$), with overall insertion success reaching 100% in both cohorts without device failure. However, Group A achieved a significantly higher mean OLP than Group B (19.24 ± 2.45 cmH_2O vs. 17.68 ± 2.11 cmH_2O; $p = 0.021$). Patients in Group A required significantly more supplementary airway manipulations to achieve adequate ventilation (48.0% vs. 20.0%; $p = 0.037$). Both groups demonstrated stable hemodynamic profiles with negligible postoperative complications.

Conclusion: Both second-generation supraglottic devices provide safe and reliable airway preservation in pediatric patients. The non-inflatable i-gel® offers faster placement and requires fewer positioning maneuvers, making it exceptionally well-suited for brief elective procedures. Conversely, the inflatable Ambu® AuraGain™ achieves higher airway sealing pressures, making it the preferred choice when superior mucosal seal is needed, such as in laparoscopic procedures or controlled positive-pressure ventilation.

Keywords: Pediatric Anesthesia; Supraglottic Airway Devices; Ambu AuraGain; i-gel; Oropharyngeal Leak Pressure; Airway Management.

1. Introduction

Pediatric airway management remains one of the most vital, demanding, and technically complex domains in modern anesthesiology [1]. Children possess distinct anatomical, physiological, and pharmacological vulnerabilities that set them apart from the adult surgical population [1, 4]. Anatomically, pediatric patients exhibit a proportionately larger tongue, a higher and more anterior glottic orifice (typically at the level of the C3-C4 cervical vertebrae compared to C5-C6 in adults), an elongated, soft, floppy, omega-shaped epiglottis, and a shorter neck with narrow subglottic dimensions at the level of the cricoid cartilage [1, 9]. Physiologically, pediatric patients display significantly higher baseline oxygen consumption rates (6–8 mL/kg/min compared to 3–4 mL/kg/min in adults) paired with a lower functional residual capacity (FRC) [1, 4]. Consequently, any acute airway interruption or delay in securing effective ventilation rapidly leads to profound arterial desaturation, severe hypoxemia, bradycardia, and catastrophic cardiac arrest [1].

For decades, direct laryngoscopy followed by endotracheal intubation represented the undisputed gold standard for securing the airway during pediatric surgical procedures requiring general anesthesia [1, 3]. However, endotracheal intubation is intrinsically invasive and carries an appreciable spectrum of mechanical, physiological, and reflex complications [1, 3]. Direct view laryngoscopy requires forceful elevation of the epiglottis and axis alignment, invoking intense sympathetic reflex surges that induce transient tachycardia, arterial hypertension, elevated

intraocular pressure, and raised intracranial pressure [1]. Furthermore, passing a rigid cuffed or uncuffed endotracheal tube past the delicate, highly vascularized subglottic mucosa risks local mucosal abrasion, post-extubation subglottic edema, post-operative sore throat, stridor, laryngospasm, and post-procedural bronchospasm [1, 3]. In small pediatric patients, improper insertion depth or patient movement can easily result in unintentional endobronchial intubation or accidental extubation [1, 5].

The development and clinical introduction of supraglottic airway devices (SADs) over the past three decades marked a revolutionary milestone in pediatric anesthesia practice [1, 3, 4]. SADs provide a reliable, non-invasive conduit for both spontaneous and mechanical positive-pressure ventilation without crossing the vocal cords or directly instrumenting the trachea [1, 4, 8]. By avoiding direct laryngoscopy and glottic traversal, supraglottic devices substantially dampen the sympathetic cardiovascular response during airway placement, drastically decrease the incidence of postoperative sore throat and hoarseness, and significantly lower the threshold for perioperative respiratory adverse events such as coughing and laryngospasm upon emergence [1, 3].

First-generation supraglottic airway devices, epitomized by the classic Laryngeal Mask Airway (LMA Classic™), demonstrated excellent utility for routine elective short surgical cases [3, 4]. However, first-generation devices exhibited key inherent safety limitations [1, 3]. They possessed relatively low mucosal sealing capability (typically yielding oropharyngeal leak pressures of 14–18 cmH_2O), which constrained their effectiveness during controlled mechanical ventilation with high peak airway pressures [3, 4, 8]. More critically, first-generation devices lacked an isolated gastric drainage channel [1, 2]. In the event of inadvertent gastric inflation, elevated peak airway pressure, or unrecognized gastric regurgitation, there was no physical barrier separating the respiratory tract from the gastrointestinal tract, leaving the pediatric patient vulnerable to pulmonary aspiration of acidic gastric contents [1, 2, 6].

To address these anatomical and functional drawbacks, second-generation supraglottic airway devices were engineered with built-in safety enhancements [1, 2]. The defining architectural hallmark of a second-generation SAD is the incorporation of an independent gastric drain tube running parallel to the central airway conduit [1, 2, 8]. This esophageal channel isolates the alimentary tract, providing a direct exit path for escaping gastric gases, allowing passage of a nasogastric/orogastric tube to decompress the stomach, and venting passive regurgitant fluids away from the laryngeal inlet [1, 2, 6]. Additionally, second-generation devices feature structural modifications designed to achieve higher mucosal sealing pressures, enabling safe positive-pressure ventilation under controlled mechanical ventilation and in laparoscopic procedures where intra-abdominal insufflation increases airway resistance [1, 6, 8].

In modern pediatric practice, two main second-generation supraglottic airway devices are widely deployed: the Ambu® AuraGain™ and the i-gel® [1, 2, 8]. Despite sharing the second-generation classification, these two devices reflect fundamentally divergent structural concepts regarding mucosal sealing and cuff mechanics [1, 3, 7].

The Ambu® AuraGain™ features an inflatable cuff constructed from high-grade silicone, molded with a pre-formed anatomical curve that mirrors the natural architecture of the human airway [1, 5, 7]. It incorporates an integrated, dedicated gastric drainage conduit alongside a broad central airway lumen [1, 7]. The inflatable cuff allows the operator to adjust intracuff pressure dynamically using a pressure manometer, aiming to maintain intracuff pressure within safe mucosal capillary perfusion limits (40–60 cmH_2O) [1, 5]. The anatomical shape is engineered to facilitate rapid, friction-free insertion while establishing a high-pressure seal against the perilaryngeal structures [1, 7, 8].

In stark contrast, the i-gel® incorporates an innovative non-inflatable cuff composed of a soft, gel-like thermoplastic elastomer (styrene-ethylene-butadiene-styrene) [1, 3, 4]. The profile of the i-gel® is precisely contoured to mirror the intricate anatomy of the supraglottic, hypopharyngeal, and peri-laryngeal structures without requiring an inflatable air bladder [1, 3]. Because it lacks an inflatable cuff, the i-gel® completely eliminates the clinical step of cuff inflation, avoids the requirement for intracuff pressure monitoring, and inherently guards against tissue trauma or mucosal ischemia caused by hyperinflation [1, 3, 9]. Furthermore, it incorporates an epiglottic rest to prevent epiglottic fold-down and a broad, rigid stem with an integrated ridge to prevent accidental rotational displacement or user biting [1, 3, 4].

While both the Ambu® AuraGain™ and the i-gel® are routinely utilized in pediatric clinical practice, comparative clinical evidence regarding their relative insertion speed, single-attempt placement efficiency, requirement for corrective airway manipulations, sealing capacity (measured via oropharyngeal leak pressure), and post-operative complication profiles remains actively discussed in pediatric literature [1, 4, 8]. High sealing pressures are particularly advantageous in pediatric laparoscopic procedures or when mechanical ventilation requires high peak pressures to prevent tidal volume leakage [1, 6]. Conversely, rapid insertion speed and low maneuvering demands are ideal for short daycare surgical procedures where minimizing anesthesia depth fluctuations and procedural time is paramount [1, 3, 5].

Therefore, this prospective, randomized, comparative clinical study was undertaken to evaluate and compare the clinical performance, insertion characteristics, sealing efficacy, and safety profiles of the inflatable Ambu® AuraGain™ versus the non-inflatable i-gel® second-generation supraglottic airway devices in pediatric patients undergoing elective surgical procedures under general anesthesia [1].

METHODOLOGY

Ethics Committee Approval and Trial Registration

This prospective, randomized, comparative clinical study was conducted in the main operating theater complex of the Department of Anaesthesiology at D.Y. Patil Medical College, Hospital and Research Institute, Kolhapur, Maharashtra, India [1]. Institutional Ethics Committee (IEC) review and formal ethical approval were granted prior to participant enrollment (Protocol Approval No. DYPMC/IEC/2025/114) [1]. The trial was conducted in full accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments, as well as Good Clinical Practice (GCP) guidelines [1]. Written informed consent was obtained from the parents or legally authorized guardians of every participating child after providing thorough, comprehensible explanations regarding the study scope, surgical protocol, anesthetic techniques, and device characteristics in their native language [1].

Study Eligibility Criteria

Pediatric surgical patients presenting for elective minor-to-moderate surgical procedures under general anesthesia were systematically screened for study eligibility during preoperative evaluations [1, 5]. The specific inclusion and exclusion criteria were established as follows [1]:

Inclusion Criteria: Elective surgical candidates aged between 1 and 12 years; body weight ranging between 10 kg and 30 kg; classification as American Society of Anesthesiologists (ASA) Physical Status I or II; and documented written parental/guardian consent [1].

Exclusion Criteria: Refusal of parental/guardian consent; anticipated or known difficult airway based on physical markers (e.g., retrognathia, micrognathia, limited mouth opening [< 2.0 cm], cervical spine instability, severe facial dysmorphism, or history of difficult intubation); active upper or lower respiratory tract infection, acute coryza, or active bronchial asthma; documented high risk of pulmonary aspiration or full stomach status; emergency surgical procedures; patients scheduled for gastrointestinal or intra-abdominal emergency surgery; severe thoracic cage deformities; and known hypersensitivity to device materials [1].

Randomization and Allocation Concealment

Eligible pediatric patients (total N = 50) were randomly allocated into two equal, parallel study arms (n = 25 per group) using a computer-generated simple randomization schedule created via standard randomizer software (GraphPad QuickCalcs) [1]. Allocation concealment was maintained using sequentially numbered, opaque, sealed

envelopes prepared by an independent research assistant not involved in patient recruitment or intraoperative management [1].

• Group A (Ambu® AuraGain™ Group, n = 25): Pediatric patients assigned to receive airway management using the inflatable second-generation supraglottic device Ambu® AuraGain™ [1].

• Group B (i-gel® Group, n = 25): Pediatric patients assigned to receive airway management using the non-inflatable second-generation supraglottic device i-gel® [1].

The sealed randomization envelope designated for each patient was opened inside the operating theater by the attending anesthesia technician immediately prior to patient arrival and induction of general anesthesia [1].

Preoperative Assessment and Premedication

All enrolled children underwent standardized preoperative clinical evaluation, including detailed clinical history, physical examination, baseline vital signs recording, airway assessment, and basic laboratory investigations [1]. Fasting guidelines were strictly enforced in accordance with standard pediatric guidelines: 6 hours for solid food and infant formula, and 2 hours for clear fluids [1]. In the preoperative holding area, under continuous pulse oximetry monitoring, children received intravenous premedication consisting of glycopyrrolate (0.004 mg/kg IV) to decrease airway secretions, midazolam (0.05 mg/kg IV) for anxiolysis, and ketamine (1.0 mg/kg IV) to facilitate smooth, non-distressful separation from parents [1].

Intraoperative Anesthetic Protocol

Upon transfer to the operating theater, patients were positioned supinely on the operating table with a small shoulder roll positioned under the upper chest when appropriate to maintain a neutral head-and-neck alignment [1]. Standard multiparameter monitoring was applied, including continuous electrocardiogram (ECG, Lead II), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), and side-stream end-tidal capnography ($EtCO_2$) [1].

Preoxygenation was conducted for 3 minutes using 100% medical oxygen via a tight-fitting face mask connected to a pediatric Jackson-Rees or Mapleson F breathing system until an end-tidal oxygen concentration (EtO_2) > 90% was established [1]. General anesthesia was induced intravenously using propofol (2.0–2.5 mg/kg IV) titrated until loss of palpebral reflex was achieved [1]. Neuromuscular blockade was facilitated using intravenous succinylcholine (2.0 mg/kg IV) [1]. Following administration of succinylcholine, manual bag-valve-mask ventilation was delivered with 100% oxygen, and complete muscle relaxation was verified by the disappearance of muscular fasciculations and absence of response to peripheral nerve stimulation [1].

SAD Selection and Insertion Technique

The appropriate size of the supraglottic device was selected according to patient body weight in strict compliance with the respective manufacturer guidelines [1]:

Ambu® AuraGain™ Selection: Size 1.5 for weight 5–10 kg; Size 2.0 for weight 10–20 kg; Size 2.5 for weight 20–30 kg [1, 5].

i-gel® Selection: Size 1.5 for weight 2–5 kg / 5–12 kg; Size 2.0 for weight 10–25 kg; Size 2.5 for weight 25–35 kg [1, 4].

All insertions were performed by an experienced consultant anesthesiologist who had previously performed more than 50 successful clinical insertions with both study devices in pediatric patients [1].

For patients allocated to Group A (Ambu® AuraGain™), the posterior surface and tip of the cuff were lubricated with sterile water-soluble gel [1]. The device was introduced into the oral cavity with the cuff fully deflated, guided along

the hard palate following the natural anatomical curvature, and advanced until firm resistance was felt at the hypopharynx [1, 7]. Following placement, the inflatable cuff was inflated with room air using a calibrated handheld cuff manometer to establish an intracuff pressure within the safe range of 40–60 cmH_2O [1, 2].
For patients allocated to Group B (i-gel®), the leading tip and posterior bowl of the non-inflatable cuff were lubricated with a thin layer of sterile water-soluble jelly [1]. The device was advanced smoothly along the hard palate toward the pharynx until definitive resistance was met, placing the leading tip into the upper esophageal sphincter [1, 3]. No cuff inflation step was required [1].

Evaluation of Primary and Secondary Study Outcomes

Insertion Time (seconds): Defined as the precise time elapsed in seconds, measured using a digital stopwatch, from the instant the operator picked up the lubricated device until the appearance of the first continuous, regular, square-wave capnogram trace on the patient monitor, accompanied by visual chest rise upon manual ventilation [1].
Number of Insertion Attempts: Evaluated on a scale of 1, 2, or failure (>2 attempts) [1]. An attempt was defined as the insertion of the device into the oral cavity and its subsequent withdrawal [1]. If effective ventilation (defined as square-wave capnography and bilaterally equal chest movement without major air leak) was not achieved after two placement attempts, the case was recorded as a SAD failure, and the airway was secured via direct laryngoscopy and endotracheal intubation [1].

Required Airway Maneuvers: Any corrective physical maneuver required by the operator to obtain an unobstructed airway, establish effective ventilation, or eliminate audible oropharyngeal gas leakage [1]. These maneuvers included chin lift, jaw thrust, head extension, neck flexion, or gentle pushing/pulling adjustment of insertion depth [1, 5].

Oropharyngeal Leak Pressure (OLP, cmH_2O): Measured intraoperatively under stable neuromuscular blockade and controlled mechanical ventilation [1]. Fresh gas flow was adjusted to 3 L/min, and the adjustable pressure-limiting (APL) valve on the anesthesia delivery system was set to 30 cmH_2O [1]. The mechanical ventilator was switched to manual mode, and gas flow was maintained until airway pressure plateaued at an equilibrium value [1]. The maximum peak airway pressure displayed on the system pressure gauge at which equilibrium was reached (or at which an audible air leak escaped from the mouth) was recorded as the OLP [1]. For patient safety, maximum circuit pressure was capped at 30 cmH_2O [1].

Hemodynamic Responses: Heart rate (HR, beats per minute) and mean arterial pressure (MAP, mmHg) were recorded at predefined time intervals: T0 (baseline pre-induction), T1 (immediately post-insertion), T2 (3 minutes post-insertion), T3 (5 minutes post-insertion), T4 (10 minutes post-insertion), and T5 (15 minutes post-insertion) [1].

Postoperative Complications: Following SAD removal at the conclusion of surgery, the device was inspected visually for presence of blood staining [1]. Postoperative adverse events, including coughing upon emergence and sore throat complaints, were assessed in the recovery room at 1 hour and 24 hours post-extubation [1, 3].

Anesthesia Maintenance and Recovery Protocol

Anesthesia was maintained with sevoflurane (1.0–1.5 MAC) delivered in a 50:50 mixture of oxygen and medical air under controlled mechanical ventilation (Volume-Controlled Mode; tidal volume 6–8 mL/kg, respiratory rate adjusted to maintain $EtCO_2$ between 35 and 40 mmHg) [1]. Intermittent intravenous vecuronium bromide (0.1 mg/kg loading, 0.02 mg/kg top-ups) was administered for intraoperative muscle relaxation [1]. Postoperative analgesia was provided using intravenous paracetamol (15 mg/kg) or rectal paracetamol suppositories (30–40 mg/kg) [1]. At the end of surgery, residual neuromuscular blockade was antagonized using intravenous neostigmine (0.05 mg/kg) and

glycopyrrolate (0.008 mg/kg) [1]. The supraglottic device was removed when the patient was fully awake, displaying purposeful movement, and maintaining spontaneous respiration [1].

Sample Size Calculation

The sample size calculation was derived based on primary data from published clinical trials regarding mean Oropharyngeal Leak Pressure (OLP) in pediatric SAD evaluations [1]:

• Mean ± SD OLP using Ambu® AuraGain™: 18.6 ± 4.2 cmH_2O [1]

• Mean ± SD OLP using i-gel®: 23.3 ± 4.6 cmH_2O [1]

Applying the standard statistical formula for comparing two independent sample means [1]:

Z_{1-alpha/2} = 1.96 (for a two-tailed 95% confidence interval, alpha = 0.05); Z_{1-beta} = 1.65 (for 95% statistical power); sigma = combined standard deviation; d = expected mean difference (4.7 cmH_2O) [1]. The calculation yielded a minimum requirement of 23 patients per study group [1]. To account for potential dropouts, protocol deviations, or procedural conversions (~10%), a final sample size of 25 patients per group (total N = 50 patients) was established [1].

Statistical Analysis

All collected demographic and clinical data were compiled into a master spreadsheet using Microsoft Excel 2016 and analyzed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp., Armonk, NY, USA) [1]. Continuous variables (age, body weight, insertion time, OLP, HR, MAP) were checked for normality using the Kolmogorov-Smirnov test and expressed as Mean ± Standard Deviation (SD) [1]. Categorical variables (gender, ASA status, success rates, maneuver frequency, complication rates) were expressed as absolute frequencies and percentages [1]. Intergroup comparisons for continuous variables were analyzed using the independent sample Student's t-test [1]. Categorical data were compared using Pearson's Chi-square test or Fisher's Exact test where cell frequencies were less than 5 [1]. A two-tailed p-value < 0.05 was considered statistically significant [1].

Results

A total of 50 pediatric patients fulfilling all eligibility criteria were successfully enrolled and randomized into two study groups (Group A: Ambu® AuraGain™, n = 25; Group B: i-gel®, n = 25) [1]. All 50 enrolled patients completed the study protocol without dropouts, procedural protocol deviations, or device failures requiring endotracheal intubation [1].

Baseline Demographic and Patient Characteristics

The baseline demographic profiles, physical parameters, and surgical distributions were comparable across both study groups [1]. There were no statistically significant differences between Group A and Group B with respect to age distribution, gender breakdown, body weight, or ASA physical status (p > 0.05 for all parameters), confirming successful randomization and group comparability [1].

Table 1: Detailed Baseline Demographic Data and Patient Characteristics (N = 50)

Parameter	Group A: AuraGain™ (n=25)	Group B: i-gel® (n=25)	p-value
Age (years, Mean ± SD)	5.68 ± 2.42	5.84 ± 2.51	0.821

Gender (Male / Female, n [%])	14 / 11 (56.0% / 44.0%)	15 / 10 (60.0% / 40.0%)	0.774
Body Weight (kg, Mean ± SD)	17.44 ± 4.82	17.92 ± 5.10	0.736
ASA Physical Status (I / II, n [%])	19 / 6 (76.0% / 24.0%)	20 / 5 (80.0% / 20.0%)	0.733
SAD Size Used (1.5 / 2.0 / 2.5, n)	3 / 14 / 8	2 / 15 / 8	0.882

Primary Airway Performance Outcomes and Insertion Mechanics

Primary airway metrics, including insertion time, placement success rates, maneuver requirements, and sealing pressure capabilities, are summarized in Table 2 [1].

The mean insertion time was significantly shorter in Group B (i-gel®) compared to Group A (Ambu® AuraGain™) (24.12 ± 3.18 seconds vs. 29.84 ± 4.02 seconds; $t = 5.58$, $p < 0.001$) [1]. This represents a statistically significant 5.72-second (19.2%) reduction in placement duration in favor of the non-inflatable i-gel® device [1].

First-attempt insertion success was achieved in 22 out of 25 patients (88.0%) in Group A and in 23 out of 25 patients (92.0%) in Group B [1]. The remaining patients in both groups (3 patients in Group A, 2 patients in Group B) were successfully fitted on the second insertion attempt, resulting in an overall success rate of 100% across both study arms [1]. There was no statistically significant difference between the two devices regarding first-attempt or overall placement success rates ($p = 0.637$) [1]. Zero cases of device failure or conversion to endotracheal intubation were recorded [1].

Regarding intraoperative airway adjustments, patients in Group A (Ambu® AuraGain™) required a significantly higher proportion of supplementary airway maneuvers (such as chin lift, jaw thrust, or device depth manipulation) to achieve satisfactory ventilation waveforms compared to Group B (i-gel®) (48.0% [12/25] vs. 20.0% [5/25]; $\chi^2 = 4.34$, $p = 0.037$) [1].

With respect to mucosal seal strength, Group A (Ambu® AuraGain™) demonstrated a statistically significantly higher mean Oropharyngeal Leak Pressure (OLP) than Group B (i-gel®) (19.24 ± 2.45 cmH_2O vs. 17.68 ± 2.11 cmH_2O; $t = 2.41$, $p = 0.021$), establishing superior sealing capacity under positive-pressure ventilation [1].

Table 2: Comparison of Primary Airway Insertion Characteristics, Maneuvers, and OLP (N = 50)

Parameter	Group A: AuraGain™ (n=25)	Group B: i-gel® (n=25)	Statistical Analysis
Mean Insertion Time (seconds ± SD)	29.84 ± 4.02	24.12 ± 3.18	$t = 5.58$, $p < 0.001$*
First-Attempt Success Rate (n [%])	22 (88.0%)	23 (92.0%)	$\chi^2 = 0.223$, $p = 0.637$
Second-Attempt Success Rate (n [%])	3 (12.0%)	2 (8.0%)	$\chi^2 = 0.223$, $p = 0.637$

Overall Failure Rate (n [%])	0 (0.0%)	0 (0.0%)	N/A
Airway Maneuvers Required (n [%])	12 (48.0%)	5 (20.0%)	$\chi^2 = 4.34$, $p = 0.037$*
Mean OLP ($cmH_2O \pm SD$)	19.24 ± 2.45	17.68 ± 2.11	$t = 2.41$, $p = 0.021$*

Hemodynamic Parameters and Postoperative Adverse Events

Hemodynamic monitoring values (Heart Rate and Mean Arterial Pressure) across baseline (T0), post-insertion (T1), and subsequent intraoperative time intervals (T2–T5) are presented in Table 3 [1]. Both devices maintained excellent hemodynamic stability throughout the perioperative monitoring period [1]. Minor, transient increases in HR and MAP were observed immediately following SAD placement in both groups, but these returned to baseline values within 3 to 5 minutes without clinical consequences [1]. There were no statistically significant intergroup differences in HR or MAP at any measured time point ($p > 0.05$) [1].

Table 3: Perioperative Hemodynamic Trends (Heart Rate and MAP) (N = 50)

Time Interval	Group A: AuraGain™ (n=25)	Group B: i-gel® (n=25)	p-value
Baseline (T0) - HR (bpm) / MAP (mmHg)	112.4 ± 10.2 / 74.2 ± 6.1	110.8 ± 9.8 / 73.8 ± 5.9	0.572 / 0.814
Post-Insertion (T1) - HR / MAP	118.6 ± 11.4 / 78.6 ± 6.8	116.2 ± 10.6 / 77.4 ± 6.2	0.446 / 0.518
3 min Post-Placement (T2) - HR / MAP	114.2 ± 9.8 / 75.4 ± 5.8	112.6 ± 9.2 / 74.8 ± 5.4	0.551 / 0.708
5 min Post-Placement (T3) - HR / MAP	110.6 ± 8.8 / 73.6 ± 5.2	109.8 ± 8.4 / 73.2 ± 5.0	0.744 / 0.783
10 min Post-Placement (T4) - HR / MAP	108.4 ± 8.2 / 72.8 ± 4.8	107.8 ± 8.0 / 72.4 ± 4.6	0.795 / 0.764
15 min Post-Placement (T5) - HR / MAP	106.8 ± 7.8 / 72.0 ± 4.5	106.2 ± 7.5 / 71.8 ± 4.2	0.782 / 0.871

Postoperative complication rates were exceptionally low across both cohorts [1]. Zero cases of visible blood staining on the device upon removal were observed in either group [1]. In Group A (Ambu® AuraGain™), 1 patient (4.0%) experienced mild coughing during emergence, and 1 patient (4.0%) complained of mild sore throat at 1 hour postoperatively, which resolved completely by 24 hours [1]. In Group B (i-gel®), zero cases of cough or sore throat were recorded [1]. The overall complication rates showed no statistically significant difference between groups ($p > 0.05$) [1].

DISCUSSION

The primary goal of modern pediatric anesthesia is to provide smooth, uncomplicated general anesthesia while securing an effective, non-traumatizing airway [1]. Supraglottic airway devices have revolutionized this arena by providing a clinical bridge between basic face-mask ventilation and invasive endotracheal intubation [1, 3, 4]. Second-generation SADs represent a major evolutionary step forward, incorporating gastric drainage channels that mitigate pulmonary aspiration risks while improving airway sealing mechanics [1, 2, 8]. The present prospective randomized study offers a comprehensive comparison between the inflatable Ambu® AuraGain™ and the non-inflatable i-gel® second-generation supraglottic devices in 50 pediatric patients [1].

Our primary findings demonstrate that both the Ambu® AuraGain™ and the i-gel® are highly safe, effective, and reliable devices for pediatric airway maintenance under controlled mechanical ventilation, with both devices achieving a 100% overall placement success rate and zero procedural failures [1, 3, 8]. However, statistically significant differences were revealed regarding insertion dynamics, positioning maneuvers, and mucosal sealing pressures [1].

With respect to insertion velocity, the non-inflatable i-gel® exhibited a statistically significant advantage over the inflatable Ambu® AuraGain™, achieving a mean insertion time of 24.12 seconds compared to 29.84 seconds for the AuraGain™ ($p < 0.001$) [1]. This 5.72-second difference represents a 19.2% reduction in total placement time [1]. This insertion time superiority is clinically explained by the structural characteristics of the i-gel® [1, 3]. Because the i-gel® features a pre-formed gel cuff manufactured from a soft thermoplastic elastomer, it completely bypasses the clinical requirement for manual cuff inflation and pressure adjustment using a manometer [1, 3]. Once the device glides past the hard palate into position, instant ventilation can commence [1]. Conversely, placement of the Ambu® AuraGain™ requires the operator to connect a cuff pressure manometer and inject air to achieve a precise intracuff pressure of 40–60 cmH_2O [1, 2]. In pediatric anesthesia, where functional residual capacity is limited and desaturation can occur rapidly, saving procedural seconds during airway placement provides a meaningful clinical buffer [1, 4].

Our finding of faster placement times with the i-gel® aligns with clinical observations reported by Kim et al. in a randomized trial comparing AuraGain™ and i-gel® in young children, where the i-gel® consistently demonstrated faster insertion times due to the absence of a cuff inflation step [1]. Similar observations were documented by Hemlata et al. and Shiveshi et al., who confirmed that non-inflatable gel-cuff devices streamline insertion workflows in pediatric daycare settings [3, 4].

First-attempt insertion success rates were high in both cohorts (92.0% in i-gel® vs. 88.0% in AuraGain™), with no statistically significant difference between devices [1]. All remaining patients in both arms were successfully fitted on their second attempt [1]. This high single-attempt efficiency reflects the refined anatomical contours engineered into both second-generation devices [1, 7]. The pre-formed anatomical curvature of the AuraGain™ and the pre-contoured gel bowl of the i-gel® both match the supraglottic geometry of pediatric patients, minimizing resistance during blind insertion [1, 5, 7].

However, a notable statistical difference emerged regarding the frequency of required airway maneuvers [1]. Patients in the Ambu® AuraGain™ group required significantly more manipulative adjustments (such as chin lift, jaw thrust, neck extension, or depth adjustment) to achieve an unobstructed capnography trace compared to patients in the i-gel® group (48.0% vs. 20.0%; $p = 0.037$) [1]. The higher maneuver requirement in the AuraGain™ cohort may be attributed to its inflatable cuff bulk and firm silicone structure, which can occasionally cause epiglottic fold-down or minor tissue displacement during advancement prior to cuff inflation [1, 5, 7]. Conversely, the slim, semi-rigid stem and soft gel bowl of the i-gel® allow it to self-align against the laryngeal inlet with minimal tissue disruption, as highlighted in studies by Behera et al. [5]

Regarding airway sealing capacity, the Ambu® AuraGain™ achieved a statistically significantly higher mean Oropharyngeal Leak Pressure (OLP) than the i-gel® (19.24 ± 2.45 cmH_2O vs. 17.68 ± 2.11 cmH_2O; $p = 0.021$) [1]. OLP is a critical surrogate marker for supraglottic device performance, representing the maximum airway pressure at

which gas escapes around the cuff [1, 8]. A higher OLP ensures superior positive-pressure ventilation, prevents tidal volume loss during changes in lung compliance, and reduces gas leakage into the esophagus [1, 6, 8]. The superior sealing performance of the Ambu® AuraGain™ stems from its inflatable silicone cuff [1, 7]. When inflated to recommended pressures (40–60 cmH_2O), the pneumatic cuff expands symmetrically to conform dynamically to subtle individual variations in perilaryngeal tissue, establishing a tight, high-pressure mucosal barrier [1, 2, 7]. While the i-gel® gel cuff warms to body temperature and molds against hypopharyngeal structures, its non-inflatable nature means its seal relies strictly on fixed device dimensions, resulting in slightly lower peak sealing pressures [1, 3, 4].

These OLP results accord with previous pediatric evaluations by Joshi et al. and Raman et al., who demonstrated that inflatable second-generation SADs consistently achieve higher sealing pressures than non-inflatable designs [2, 8]. Higher sealing pressure makes the Ambu® AuraGain™ particularly advantageous during pediatric laparoscopic procedures—where pneumoperitoneum and steep Trendelenburg positioning increase intra-abdominal pressure and airway resistance—or in pediatric patients with reduced pulmonary compliance requiring higher peak inspiratory pressures [1, 6, 8].

Both devices displayed outstanding safety profiles in our trial [1]. Hemodynamic parameters (heart rate and mean arterial pressure) remained remarkably stable pre- and post-insertion in both groups, avoiding the hyperdynamic surges typical of endotracheal intubation [1, 3]. Furthermore, postoperative adverse events were minimal: zero cases of visible blood trace on device removal, zero cases of severe sore throat, and only isolated minor transient events in the AuraGain™ group (1 case of emergence cough, 1 case of mild 1-hour sore throat) [1]. The low incidence of mucosal trauma confirms that maintaining controlled cuff pressure (40–60 cmH_2O) in inflatable devices and utilizing soft thermoplastic elastomer in non-inflatable devices effectively protects pediatric perilaryngeal mucosa from ischemic injury [1, 3].

Clinical Practice Summary: The decision between the Ambu® AuraGain™ and the i-gel® should be tailored to the surgical scenario [1]. For routine, short elective daycare procedures where rapid placement, ease of insertion, and minimal airway manipulation are prioritized, the non-inflatable i-gel® represents an outstanding choice [1, 3, 5]. Conversely, for longer surgical cases, procedures conducted under controlled mechanical ventilation, or laparoscopic surgeries requiring high airway sealing capabilities, the inflatable Ambu® AuraGain™ is preferred due to its superior oropharyngeal leak pressure [1, 6, 8].

CONCLUSION

Both the inflatable Ambu® AuraGain™ and non-inflatable i-gel® second-generation supraglottic airway devices provide reliable, safe, and effective airway maintenance under controlled mechanical ventilation in pediatric patients undergoing general anesthesia [1]. The non-inflatable i-gel® offers distinct clinical advantages in terms of significantly faster insertion times and a lower requirement for corrective airway positioning maneuvers, making it exceptionally well-suited for brief elective daycare surgical procedures [1, 3, 5]. Conversely, the inflatable Ambu® AuraGain™ achieves significantly higher oropharyngeal leak pressures, establishing a superior airway seal that is highly desirable during laparoscopic procedures, controlled positive-pressure ventilation, or cases requiring higher airway pressure thresholds [1, 6, 8]. Both devices maintain excellent perioperative hemodynamic stability and demonstrate negligible postoperative complication rates [1].

DECLARATIONS

Ethics Approval & Consent: Institutional Ethics Committee (IEC) approval was obtained prior to study initiation (Protocol Approval No. DYPMC/IEC/2025/114). Written informed consent was obtained from parents or legal guardians of all participating pediatric patients prior to enrollment [1].

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