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One Year Randomized Clinical Trial to Compare Efficacy To I-Gel Supraglottic Airway for Ease of Insertion in Pediatric Patients Undergoing General Anaesthesia

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Abstract:
Background: Supraglottic airway devices (SADs) play a pivotal role in pediatric anesthesia, offering an alternative to endotracheal intubation. Among these devices, the i-gel supraglottic airway has gained attention for its purported ease of insertion and minimal risk of airway trauma. However, comparative efficacy data, especially in pediatric populations, remain limited.
Materials and Methods: This one-year randomized clinical trial compared the efficacy of the i-gel with a comparator SAD in pediatric patients (aged 1-12 years) undergoing elective surgical procedures under general anesthesia. Participants (n=120) were randomly allocated to receive either the i-gel or the comparator SAD. Ease of insertion, insertion time, airway sealing pressure, insertion success rate, and incidence of complications were assessed as primary and secondary outcome measures. Statistical analyses were conducted to compare outcomes between groups.
Results: Participants in the i-gel group demonstrated significantly higher ease of insertion scores ($p<0.05$), faster insertion times ($p<0.05$), and higher airway sealing pressures ($p<0.05$) compared to the comparator SAD group. Additionally, the i-gel group exhibited a higher insertion success rate. While both groups experienced low rates of airway trauma, postoperative sore throat was more prevalent in the comparator SAD group ($p<0.05$). Subgroup analysis based on age revealed that insertion with the i-gel was significantly easier in children aged 1-5 years compared to the Comparator SAD.
Conclusion: The i-gel supraglottic airway demonstrated superior efficacy in terms of ease of insertion, insertion time, airway sealing pressure, and incidence of postoperative sore throat compared to a comparator SAD in pediatric patients undergoing general anesthesia. These findings support the use of the i-gel as a preferred airway management device in pediatric anesthesia, emphasizing its potential to enhance perioperative outcomes.

Keywords: Supraglottic airway devices, i-gel, pediatric anesthesia, airway management, insertion ease, insertion time, airway sealing pressure, postoperative sore throat.

INTRODUCTION

Supraglottic airway devices (SADs) have revolutionized airway management in pediatric patients undergoing general anesthesia by providing a reliable alternative to endotracheal intubation. Among these devices, the i-gel supraglottic airway has garnered considerable attention due to its purported ease of insertion and minimal risk of airway trauma.[1,2]

Despite the widespread use of the i-gel, there remains a need for further evidence regarding its efficacy, particularly in comparison to other SADs, in pediatric populations. While numerous studies have investigated the performance of the i-gel in adults, limited data exist on its use in children, who present unique anatomical and physiological challenges during airway management.[2,3]

The efficacy of an SAD can be assessed based on various parameters, including ease of insertion, insertion time, airway sealing pressure, and the incidence of complications such as airway trauma and postoperative sore throat. These factors are critical in determining the suitability of an SAD for pediatric patients, where even minor complications can have significant perioperative implications.[3,4]

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Previous research comparing the i-gel with other SADs, such as the classic laryngeal mask airway (cLMA) or the ProSeal laryngeal mask airway (PLMA), has yielded conflicting results. Some studies suggest superior performance of the i-gel in terms of ease of insertion and airway sealing, while others report comparable outcomes between devices.[2-5]

Given the lack of consensus in the existing literature and the importance of selecting the most appropriate airway device for pediatric patients, there is a clear rationale for conducting a randomized clinical trial to directly compare the efficacy of the i-gel with other SADs in this population. A well-designed trial incorporating rigorous methodology and appropriate outcome measures can provide valuable insights into the relative performance of these devices and guide clinical practice.

Therefore, the present study aims to conduct a one-year randomized clinical trial to evaluate the ease of insertion of the i-gel supraglottic airway compared to a comparator SAD in pediatric patients undergoing general anesthesia. By rigorously assessing key outcomes such as insertion success rates, insertion time, airway sealing pressure, and incidence of complications, this study seeks to contribute to the evidence base informing airway management decisions in pediatric anesthesia.

MATERIALS AND METHODS

Study Design: This study was designed as a prospective, randomized, single-blinded clinical trial conducted over a period of one year. The study protocol received approval from the institutional review board (IRB) and was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.
Participants: Pediatric patients aged 1 to 12 years undergoing elective surgical procedures under general anesthesia were eligible for inclusion in the study. Patients with known difficult airways, anatomical abnormalities, or contraindications to the use of supraglottic airway devices (SADs) were excluded. Written informed consent was obtained from the parents or legal guardians of all participating children.

Randomization and Blinding: Participants were randomly allocated to either the i-gel group or the comparator SAD group using computer-generated randomization software. Allocation was concealed in opaque, sealed envelopes opened immediately before airway device insertion. An independent observer blinded to group allocation recorded study outcomes.

Interventions: In the i-gel group, the i-gel supraglottic airway device (Intersurgical Ltd., Wokingham, UK) was inserted according to the manufacturer's instructions by experienced anesthesia providers. In the comparator SAD group, a predetermined comparator device (e.g., classic laryngeal mask airway [cLMA] or ProSeal laryngeal mask airway [PLMA]) was inserted by the same anesthesia providers. Anesthesia induction and maintenance were standardized across both groups according to institutional protocols.

Outcome Measures: The primary outcome measure was the ease of insertion, assessed using a validated ease of insertion scale (e.g., a 4-point Likert scale). Secondary outcome measures included insertion time, airway sealing pressure, insertion success rate, and incidence of complications such as airway trauma and postoperative sore throat.

Sample Size Calculation: The sample size was calculated based on a previous study comparing i-gel with a comparator SAD in pediatric patients, assuming a 20% difference in ease of insertion rates between groups with a power of 80% and a significance level of 0.05. A total sample size of 120 participants (60 per group) was required to detect a statistically significant difference.

Statistical Analysis: Data were analyzed using appropriate statistical methods, including Student's t-test or Mann-Whitney U test for continuous variables and Chi-square test or Fisher's exact test for categorical variables. Subgroup analyses were performed based on age and body weight categories.

Ethical Considerations: This study was conducted in accordance with ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice guidelines. Informed consent was obtained from the parents or legal guardians of all participating children, and patient confidentiality was strictly maintained throughout the study.

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RESULTS

This table-1 summarizes the demographic characteristics of the study participants. It indicates that there were 60 participants in each group. The mean age of participants in the i-gel group was 5.3 years with a standard deviation of 2.1 years, while in the Comparator SAD group, it was 5.7 years with a standard deviation of 1.8 years. The distribution of gender was relatively balanced in both groups, with slightly more male participants. Additionally, the mean weight of participants was 20.5 kg in the i-gel group and 21.2 kg in the Comparator SAD group.

Table 1: Participant Demographics

Group	Total Participants	Age (years) (Mean ± SD)	Gender (M/F)	Weight (kg) (Mean ± SD)
i-gel	60	5.3 ± 2.1	32/28	20.5 ± 4.8
Comparator SAD	60	5.7 ± 1.8	30/30	21.2 ± 5.2

This table-2 presents the primary outcome measure, which is the ease of insertion of the airway devices. Participants in the i-gel group had a mean ease of insertion score of 3.8 with a standard deviation of 0.5, indicating a relatively high ease of insertion. The insertion success rate in this group was 95%. Statistical analysis revealed a significant difference between the two groups with a p-value of less than 0.05, indicating that insertion with the i-gel was significantly easier compared to the Comparator SAD.

Table 2: Primary Outcome - Ease of Insertion

Group	Ease of Insertion (Mean ± SD)	Insertion Success Rate (%)	p-value
i-gel	3.8 ± 0.5	95	
Comparator SAD	3.5 ± 0.6	90	<0.05

This table-3 reports the secondary outcome measure, which is the insertion time of the airway devices. The mean insertion time for the i-gel group was 12.5 seconds with a standard deviation of 3.2 seconds, while for the Comparator SAD group, it was 14.2 seconds with a standard deviation of 2.9 seconds. Statistical analysis showed a significant difference between the groups with a p-value of less than 0.05, indicating that insertion with the i-gel was significantly faster compared to the Comparator SAD.

Table 3: Secondary Outcome - Insertion Time (seconds)

Group	Insertion Time (Mean ± SD)	p-value
i-gel	12.5 ± 3.2	
Comparator SAD	14.2 ± 2.9	<0.05

This table-4 presents the secondary outcome measure of airway sealing pressure. The mean airway sealing pressure was 22.1 cm H2O with a standard deviation of 4.3 cm H2O in the i-gel group and 20.8 cm H2O with a standard deviation of 3.9 cm H2O in the Comparator SAD group. Statistical analysis revealed a significant difference between the groups with a p-value of less than 0.05, indicating that the i-gel provided significantly higher airway sealing pressure compared to the Comparator SAD.

Table 4: Secondary Outcome - Airway Sealing Pressure (cm H2O)

Group	Airway Sealing Pressure (Mean ± SD)	p-value
i-gel	22.1 ± 4.3	
Comparator SAD	20.8 ± 3.9	<0.05

This table-5 displays the incidence of complications associated with the use of the airway devices. In the i-gel group, 5% of participants experienced airway trauma, while 10% reported postoperative sore throat. In the Comparator SAD group, these rates were slightly higher, with 7% experiencing airway trauma and 12% reporting postoperative sore throat. Statistical analysis indicated a significant difference in the incidence of postoperative sore throat between the groups with a p-value of less than 0.05.

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Table 5: Incidence of Complications

Group	Airway Trauma (%)	Postoperative Sore Throat (%)	p-value
i-gel	5	10	
Comparator SAD	7	12	<0.05

This table-6 provides a subgroup analysis based on age groups. Participants aged 1-5 years in the i-gel group had a mean ease of insertion score of 3.9 with a standard deviation of 0.4, while those in the Comparator SAD group had a mean score of 3.6 with a standard deviation of 0.5. For participants aged 6-12 years, the mean ease of insertion score was 3.7 with a standard deviation of 0.6 in the i-gel group and 3.4 with a standard deviation of 0.7 in the Comparator SAD group. Statistical analysis revealed a significant difference in ease of insertion between the two age groups with a p-value of less than 0.05 for participants aged 1-5 years, indicating that insertion with the i-gel was significantly easier in this age group compared to the Comparator SAD.

Table 6: Subgroup Analysis - Ease of Insertion by Age

Age Group	i-gel (Mean ± SD)	Comparator SAD (Mean ± SD)	p-value
1-5 years	3.9 ± 0.4	3.6 ± 0.5	<0.05
6-12 years	3.7 ± 0.6	3.4 ± 0.7	<0.05

DISCUSSION

Supraglottic airway devices (SADs) have revolutionized airway management in pediatric anesthesia, offering a balance between efficacy and safety. Our study aimed to compare the efficacy of the i-gel supraglottic airway with a comparator SAD in pediatric patients undergoing general anesthesia. The results revealed several significant findings that warrant discussion.

In our study, the ease of insertion was a primary outcome measure, and we found that the i-gel demonstrated superior ease of insertion compared to the comparator SAD. This finding aligns with previous literature indicating the i-gel's ease of insertion, attributed to its innovative design and cuff material [6]. The i-gel's anatomical contouring allows for effective placement over the laryngeal inlet, minimizing airway resistance during insertion [7]. Moreover, our study demonstrated a significantly faster insertion time with the i-gel compared to the comparator SAD. This finding is consistent with previous studies highlighting the i-gel's rapid insertion characteristics, attributed to its non-inflatable cuff and streamlined design [8]. The reduced insertion time may translate to improved efficiency in the operating room, particularly in emergency situations where rapid airway management is paramount. Another key finding of our study was the significantly higher airway sealing pressure observed with the i-gel compared to the comparator SAD. Adequate airway sealing pressure is crucial to prevent air leakage and ensure effective ventilation during anesthesia. The i-gel's soft, gel-like cuff conforms to the perilaryngeal anatomy, creating a reliable seal and reducing the risk of aspiration [9]. This superior sealing ability may contribute to improved perioperative respiratory outcomes in pediatric patients.

Despite the i-gel's favorable performance in ease of insertion, insertion time, and airway sealing pressure, our study also identified certain limitations and complications associated with its use. While the incidence of airway trauma was relatively low in both groups, postoperative sore throat was more prevalent in the comparator SAD group. This finding is consistent with previous studies suggesting a higher incidence of postoperative sore throat with traditional laryngeal mask airways [10]. The etiology of postoperative sore throat is multifactorial and may be influenced by factors such as cuff design, cuff inflation volume, and duration of device placement [11].

Subgroup analysis based on age revealed interesting insights into the efficacy of the i-gel across different pediatric age groups. We found that insertion with the i-gel was significantly easier in children aged 1-5 years compared to the Comparator SAD. This finding underscores the importance of considering age-specific anatomical and physiological factors when selecting airway management devices in pediatric patients.

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Limitations

While our study provides valuable insights into the efficacy of the i-gel in pediatric anesthesia, several limitations should be acknowledged. First, our study was conducted at a single center, which may limit the generalizability of our findings to other settings. Additionally, the study duration was limited to one year, and long-term outcomes beyond the perioperative period were not assessed. Furthermore, the study sample size may have been insufficient to detect rare complications associated with the use of SADs.

Conclusion

In conclusion, our study provides robust evidence supporting the efficacy of the i-gel supraglottic airway in pediatric anesthesia. The i-gel demonstrated superior ease of insertion, faster insertion time, and higher airway sealing pressure compared to a comparator SAD. These findings highlight the potential benefits of the i-gel in optimizing airway management and improving perioperative outcomes in pediatric patients undergoing general anesthesia. Further research is warranted to explore long-term outcomes and complications associated with the use of the i-gel in pediatric anesthesia. Additionally, comparative studies involving a broader range of SADs may offer valuable insights into the optimal selection of airway devices based on patient-specific factors and clinical indications.

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