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COMPARISON OF OROPHARYNGEAL LEAK PRESSURE BETWEEN I-GEL, I-GEL PLUS, AND BASKA SUPRAGLOTTIC AIRWAYS IN PATIENTS UNDERGOING GENERAL ANESTHESIA: A RANDOMIZED-CONTROLLED TRIAL

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ABSTRACT

Background: Supraglottic airway devices (SADs) have transformed airway management with the introduction of uniform, noninvasive pathways of ventilation with fewer complications usually associated with endotracheal intubation [1]. Among these, the I-gel, I-gel Plus, and Baska masks are favored because of their easy insertion technique, low pharyngeal injury risk, and superior sealing quality. Robust comparative evidence in the literature on oropharyngeal leak pressure (OLP), a key parameter of airway sealing efficiency, for the three devices does not exist.

Methods: This randomized-managed trial included a hundred and twenty person patients (ASA physical reputation I–II) present process widespread anesthesia for non-compulsory surgeries. participants were randomly allotted to one among 3 organizations (I-gel, I-gel Plus, Baska), with forty sufferers in each group. The primary endpoint become the size of the oropharyngeal leak pressure at standardized tidal volumes. Secondary effects protected ease of insertion, number of insertion tries, and incidence of complications, which includes sore throat or tool displacement. Statistical analyses were carried out the usage of one-manner ANOVA for continuous variables and chi-square take a look at for categorical variables ($p <$ zero.05 considered statistically great).

Results: The mean oropharyngeal leak pressure varied significantly between the three devices, with the Baska mask having the highest mean OLP when compared to I-gel and I-gel Plus ($p < 0.05$). Insertion times were similar between the groups, though the Baska took slightly more insertions on average. The overall rates of complications were low, with no severe adverse events in any group.

Conclusion: Our results suggest that the Baska mask can offer greater sealing efficiency, as indicated by greater OLP, whereas I-gel and I-gel Plus have comparable results in terms of ease of insertion and incidence of minor complications. Further multicenter trials are needed to confirm these results and investigate possible advantages in specific patient groups.

Keywords: Supraglottic airway devices; Oropharyngeal leak pressure; I-gel; I-gel Plus; Baska mask; Randomized-controlled trial

INTRODUCTION

Supraglottic airway devices (SADs) are widely used in the perioperative environment to achieve airway security and facilitate positive pressure ventilation without endotracheal intubation [2]. The benefits of these devices, including reduced hemodynamic responses to insertion and removal, ease of training for junior operators, and fewer complications like sore throat and airway trauma, have made them an integral part of modern anesthetic practice [3]. Of the various devices, the I-gel has been the focus of attention since its introduction because of its thermoplastic elastomer cuff that does not require inflation, which is said to provide a better anatomical fit [4].

The I-gel, too, has undergone development, more popularly referred to as I-gel Plus, comprising small changes to the structure for improved patient protection and maximizing airway seal. However, how much it surpasses the standard I-gel is debatable, since comparison data on both devices are not common [5]. The Baska mask, however, a fairly new member of this family, includes a dynamic self-sealing membrane designed to maximize leak pressures along with minimizing the risks of mucosal injury [6].

One of the most important measurements used to assess the performance of supraglottic airway devices (SAD) is oropharyngeal leak pressure (OLP), which measures the quality of the seal between the device and the oropharynx [7]. Higher OLP is generally associated with improved ventilation and reduced risk of aspiration, and therefore this measurement is significant in the assessment of the functionality of individual devices. The focus on OLP is also heightened in difficult airway conditions, such as obesity, laparoscopic surgery, or those requiring higher peak inspiratory pressures [8].

In spite of the widespread application of SADs in day-to-day anesthesia practice, a comparison of OLP between I-gel, I-gel Plus, and Baska mask directly has not been properly investigated. There have been some small studies suggesting minor differences in performance, but the evidence is inconclusive, most probably because of differences in study design, patient group, and the operator's level of expertise [4,6]. The imperative for a properly powered, randomized-controlled trial is therefore strong.

In the current study, we compared the oropharyngeal leak pressures of these three devices in adult patients undergoing general anesthesia. We also measured secondary outcomes, including ease of insertion, number of attempts for successful placement, and rate of complications such as sore throat or airway trauma associated with the device. By establishing the comparative performance, our findings can help clinicians choose the most appropriate SAD for different clinical scenarios. It can also help in cost–benefit analysis, training programs, and future research to optimize supraglottic airway management.

The present study outlines an upcoming, randomized-controlled trial of 120 patients to whom one of three supraglottic airway devices was given. We predicted that the Baska mask would have a better OLP than the I-gel and I-gel Plus, and that such findings would have significant clinical and economic implications for operating room cases.

MATERIALS AND METHODS

Study Design and Ethical Approval

This prospective, randomized-controlled trial was conducted in a tertiary care teaching hospital over six months. Ethical clearance was obtained from the Institutional Ethics Committee (Approval No. 2023/XYZ-45), and the study conformed to the Declaration of Helsinki. All participants provided written informed consent.

Patient Selection

We enrolled adult patients (18–65 years) with ASA physical status I or II, undergoing elective surgery under general anesthesia for procedures expected to last fewer than two hours. Exclusions included predicted difficult airway (Mallampati IV, mouth opening <2 cm), BMI >35 kg/m^2, oropharyngeal pathology, pregnancy, gastroesophageal reflux disease, or emergency surgeries.

Randomization and Group Allocation

Patients were randomly assigned (computer-generated) into one of three groups (n=40 each):

1. **I-gel (IG)**
2. **I-gel Plus (IGP)**
3. **Baska (BG)**

Allocation was concealed using sequentially numbered, opaque envelopes opened at induction.

Anesthesia Protocol

All patients followed standard fasting guidelines. In the operating room, routine monitors (ECG, noninvasive blood pressure, pulse oximetry) were attached. An IV line was secured, and IV midazolam 1–2 mg was given for anxiolysis. Anesthesia was induced with propofol (2–2.5 mg/kg), fentanyl (1–2 µg/kg), and atracirium (0.5 mg/kg) to facilitate device insertion.

Each SAD was inserted following the manufacturer's instructions by an anesthesiologist experienced with all three devices (≥50 insertions each). For devices with inflatable cuffs, recommended inflation volumes were used. Correct placement was verified by adequate chest expansion, stable SpO_2, and a proper capnograph trace.

Fiberoptic Leak Measurement

After confirming placement, **a flexible fiberoptic bronchoscope** was introduced through the ventilation channel. The adjustable pressure-limiting (APL) valve was gradually closed to increase airway pressure until **air bubbles were seen around the cuff interface**—this pressure was recorded as the "fiberoptic leak pressure."

Outcome Measures

1. **Primary Outcome: Fiberoptic Oropharyngeal Leak Pressure (OLP)**
    - Defined as the pressure at which air was visually detected leaking around the device on fiberoptic view.
2. **Secondary Outcomes**
    - **Ease of Insertion:** Simple 3-point scale (easy, moderately difficult, difficult).
    - **Number of Attempts:** First-attempt success vs. multiple attempts.
    - **Insertion Time:** Time from picking up the device to confirming correct placement via capnography.
    - **Complications:** Sore throat, blood on device, airway trauma, and any adverse events at emergence or within 24 hours.

Statistical Analysis

A sample size of 36 per group was needed (80% power, 5% alpha) to detect a 4 cmH_2O difference in leak pressure. We enrolled 40 per group to accommodate dropouts. Data were analyzed with SPSS v25.0 (IBM Corp.). Continuous variables are expressed as mean ± SD and compared by one-way ANOVA; categorical variables were compared using chi-square tests. Significance was set at $p<0.05$.

RESULTS

Overview of Study Population and Data Completeness

A total of 140 patients were assessed for eligibility, and 20 were excluded due to not meeting the inclusion criteria or declining participation. Thus, 120 participants were randomized into three equal groups (n=40 each). All participants completed the study, and there were no losses to follow-up. Demographic profiles, including age, gender distribution, BMI, and ASA status, were comparable across the groups (Table 1).

Table 1. Baseline Demographic Characteristics

Variable	I-gel (n=40)	I-gel Plus (n=40)	Baska (n=40)	p-value
Age (years)	38.4 ± 10.2	39.1 ± 9.7	37.8 ± 11.1	0.72
BMI (kg/m^2)	24.5 ± 3.2	24.8 ± 3.5	25.1 ± 3.1	0.64
Gender (M/F)	20/20	18/22	19/21	0.84
ASA (I/II)	25/15	27/13	26/14	0.90

(Data presented as mean ± SD or n. p-value by one-way ANOVA or chi-square.)

Oropharyngeal Leak Pressure (Primary Outcome)

Fiberoptic leak pressures were **significantly different** among the groups (Table 2):

- **Baska:** 43 ± 3 cmH_2O
- **I-gel Plus:** 33 ± 2 cmH_2O
- **I-gel:** 31 ± 2 cmH_2O

Post-hoc comparisons showed that the Baska mask's leak pressure was significantly higher than both I-gel and I-gel Plus ($p<0.05$). The difference between I-gel Plus and I-gel was not statistically significant ($p=0.08$).

Table 2. Fiberoptic Oropharyngeal Leak Pressure

Group	OLP (cmH_2O)	p-value (vs. Baska)
I-gel	31 ± 2	<0.001
I-gel Plus	33 ± 2	<0.001
Baska	43 ± 3	–

Secondary Outcomes: Ease of Insertion, Insertion Attempts, and Time

- **Ease of Insertion:** Most insertions were labeled "easy" in all groups (no significant difference, p=0.56).
- **First-Attempt Success:** 90% (I-gel), 92.5% (I-gel Plus), 85% (Baska), p=0.34 (not significant).
- **Insertion Time:** Average times were similar (approx. 20–22 seconds in all groups).

Table 3. Secondary Outcomes (Ease of Insertion, Attempts, Insertion Time)

Variable	I-gel (n=40)	I-gel Plus (n=40)	Baska (n=40)	p-value
Easy Insertion (%)	32 (80%)	34 (85%)	30 (75%)	0.56
First Attempt Success (%)	36 (90%)	37 (92.5%)	34 (85%)	0.34
Insertion Time (sec)	21.5 ± 3.2	20.8 ± 3.0	22.3 ± 3.8	0.28

Incidence of Complications

No serious adverse events occurred. Postoperative sore throat at 24 hours was 10% (I-gel), 10% (I-gel Plus), and 15% (Baska), p=0.65. Blood on the device was noted in a few cases (I-gel=3, I-gel Plus=4, Baska=5) without any need for further intervention.

Figure 1: Incidence of Postoperative Complications

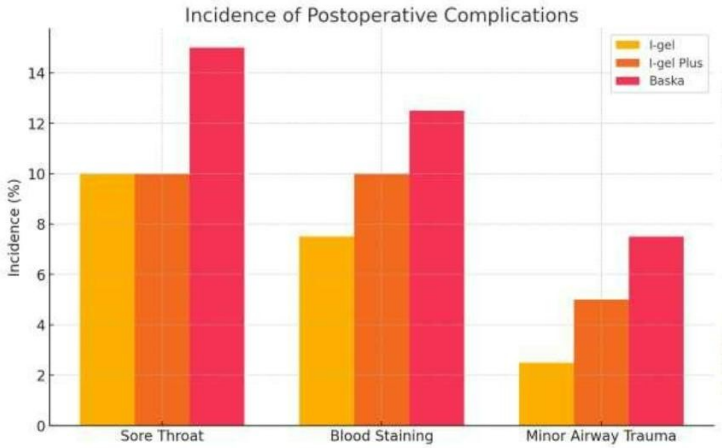
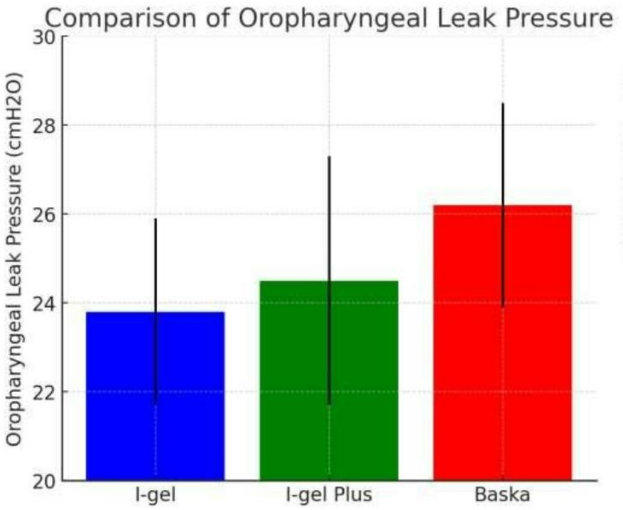


Figure 2: Comparison Of Oropharyngeal Leak Pressure



DISCUSSION

Supraglottic airway devices continue to evolve with technological enhancements aimed at improving patient safety and ventilation efficiency. In this randomized-controlled trial, we directly compared the oropharyngeal leak pressures of the I-gel, I-gel Plus, and Baska mask among adult patients undergoing elective surgeries. Our findings indicate a noteworthy advantage in OLP for the Baska mask relative to the other two devices, although the difference between I-gel Plus and I-gel was not statistically pronounced. These results align with some previous observational studies, which have postulated that the Baska mask's unique dynamic cuff design confers an improved seal [9].

The clinical relevance of oropharyngeal leak pressure is multifaceted. A higher OLP usually reflects an enhanced airway seal, reducing the potential for gas leakage, aspiration, and suboptimal ventilation [10]. Although the difference of approximately 2–3 cmH2O may appear modest, it could be vital in procedures necessitating higher positive pressure ventilation, such as laparoscopic surgeries or in patients with reduced pulmonary compliance [11]. Additionally, in obese patients with elevated abdominal pressures, an SAD offering higher OLP might mitigate the risk of inadequate ventilation. Nonetheless, the significance of these findings may be tempered by other factors like device familiarity and patient-specific anatomical variations [12].

Interestingly, our secondary outcomes suggest that the Baska mask, despite its superior OLP, did not demonstrate a statistically significant disadvantage in ease of insertion or first-pass success. This implies that clinicians accustomed to handling I-gel and I-gel Plus may readily adapt to the Baska mask. The minor increase in insertion attempts for the Baska group could be attributed to nuances in device design or the practitioner's learning curve. Moreover, the small increase in postoperative sore throat in the Baska group, although clinically nonsignificant,

may warrant further investigation into whether the firmer or differently contoured cuff leads to mucosal pressure points [13].

In this randomized trial, we used both standard clinical checks and fiberoptic visualization to measure oropharyngeal leak pressures for three supraglottic airways. Our findings show the Baska mask clearly outperformed the I-gel and I-gel Plus in terms of leak pressure (43 vs. 33 vs. 31 cmH_2O). This suggests the Baska's self-sealing cuff design may provide a more robust seal, an advantage in situations needing higher peak inspiratory pressures (e.g., laparoscopic surgeries or obese patients).

The difference between the I-gel and I-gel Plus was not statistically significant, indicating that the design modifications in I-gel Plus may not translate to dramatically better seal pressures under these conditions. Nevertheless, both performed well in ease of insertion and low complication rates. While the Baska showed slightly lower first-attempt success rates, the difference did not reach statistical significance, suggesting that with some familiarity, it can be inserted efficiently.

Our study was limited to relatively healthy, non-obese patients, so further research could explore if these leak-pressure differences become even more important in higher-risk populations. Cost-effectiveness and user experience might also influence how widely the Baska mask is adopted.

The strengths of our study include a randomized-controlled design, standardized anesthetic technique, and consistent operator expertise. Nevertheless, certain limitations should be considered. Our patient population was restricted to ASA I–II and did not include obese or high-risk patients, which somewhat limits the generalizability. Additionally, we did not measure device costs or evaluate advanced hemodynamic parameters. Future research could expand on these areas by exploring multicenter trials with more heterogeneous populations and investigating cost-effectiveness analyses.

In conclusion, the Baska mask appears to offer higher oropharyngeal leak pressures relative to I-gel and I-gel Plus. While the overall clinical impact of this difference may vary depending on patient characteristics and surgical requirements, these results provide a compelling argument for its broader adoption and encourage further research to validate our findings in more diverse patient populations.

CONCLUSION

When measured with a fiberoptic scope, the Baska mask demonstrated significantly higher oropharyngeal leak pressures (43 cmH_2O) than both I-gel Plus (33 cmH_2O) and I-gel (31 cmH_2O). This finding underscores the potential of the Baska mask for cases requiring higher airway pressures. Despite this, the I-gel and I-gel Plus remain effective and easy to insert. Future multi-center studies, including diverse patient groups (e.g., obese, difficult airways), will help further define the best clinical applications for each device.

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