ORIGINAL ARTICLE

CLINICAL PERFORMANCE COMPARISON OF THE I-GEL AND LARYNGEAL MASK AIRWAY SUPREME IN GERIATRIC PATIENTS: A PROSPECTIVE STUDY

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Abstract

Introduction: This study compares the clinical performance and pharyngolaryngeal complications of two second-generation supraglottic airway devices, the I-gel and the laryngeal mask airway supreme, in geriatric patients undergoing elective surgery under general anesthesia.

Materials and methods: Following approval from the hospital ethics committee and written informed consent, patients aged 65 years and older, classified with an American Society of Anesthesiologists score of I-III, and scheduled for elective urological surgery under general anesthesia were prospectively included. Participants were randomly allocated into two equal-sized groups: I-gel and laryngeal mask airway-supreme. We compared the successful insertion on a first attempt and ease of insertion as a primary outcome, and the secondary outcomes were insertion time, ease of gastric tube insertion, oropharyngeal leak pressure, and intraoperative and postoperative complications.

Results: A total of 120 patients were recruited, with 60 in each group. Insertion time for the supraglottic airway device was significantly shorter in the I-gel group ($p<0.001$). A greater proportion of patients in the I-gel group demonstrated optimal oropharyngeal leak pressure across all measurement points ($p<0.001$). However, gastric tube placement was facilitated more easily in the laryngeal mask airway supreme group ($p=0.018$). Furthermore, intraoperative complications were significantly higher in the laryngeal mask airway-supreme group ($p=0.008$). No notable differences were detected between the groups regarding ease of insertion, success rate on the first attempt, or postoperative complication rates.

Conclusion: The I-gel may be preferred for geriatric patients due to its shorter insertion time, lower oropharyngeal leak pressure, and reduced incidence of intraoperative complications.

Keywords: Physical Functional Performance; Geriatric Anesthesia; Laryngeal Masks.

INTRODUCTION

A definitive cut-off value for defining "geriatric" age remains unestablished; however, individuals aged 65 years and older are commonly recognized as belonging to this group. Age-related anatomical and physiological changes, increase the risk of perioperative respiratory and hemodynamic complications in older patients during endotracheal intubation and extubation (1,2). Supraglottic airway devices (SGADs) offer distinct advantages over traditional endotracheal intubation for patients aged 65 years and older, requiring fewer pharmacological agents and providing greater hemodynamics stability (3). Furthermore, many geriatric patients lack teeth, which often results in poor fit of standard face masks and subsequent difficulties in mask ventilation (4). Consequently, SGADs may serve as a superior alternative to face masks for older, edentulous patients (5).

The Laryngeal Mask Airway Supreme (LMA-Supreme; Teleflex Incorporated, Limerick, Maine, USA), a second-generation, cuffed SGAD introduced in 2007, features a curved oval shape with a rigid tunnel to facilitate insertion. A gastric drainage channel reduces the risk of gastric regurgitation and subsequent aspiration, while the modified cuff minimizes air leakage and airway obstruction (6).

The I-gel™ (Intersurgical Ltd, Wokingham, UK), another second-generation SGAD, is designed to minimize pressure on laryngeal and pharyngeal structures. It incorporates a soft, gel-like, transparent thermoplastic elastomer at the distal end and lacks an inflatable cuff. This configuration eliminates the need to inflate or monitor pressure in a cuff-like structure (7). Potential benefits include rapid and straightforward insertion, a reduced likelihood of increased pharyngeal pressure due to high cuff pressure, a gastric drainage channel, and a single-use design that eliminates the risk of infectious disease transmission (8).

The clinical performance of second-generation SGADs, including the LMA-Supreme and I-gel, has been evaluated in numerous studies (9–11). However, most investigations included participants across various age groups, leading to variability in clinical performance, efficacy, and applicability among poorly defined older populations. This study therefore aimed to compare the performance of these two supraglottic airway devices in a well-defined geriatric population.

MATERIALS AND METHOD

Following approval from the Institutional Review Board (19-4.1T/40; 17.04.2019), patients aged 65 and older, classified with an American Society of Anesthesiologists (ASA) score I-III, and scheduled for elective urological surgery under general anesthesia were prospectively enrolled. Informed consent was obtained from all patients or their legal representative. Exclusion criteria included patients scheduled for emergency surgery, those with unstable vital signs, a history or suspicion of a difficult airway, preoperative sore throat, or a high risk of aspiration. High aspiration risk encompassed individuals with a body mass index exceeding 35 kg/m², gastroesophageal reflux, hiatal hernia, diabetic gastroparesis, or a history of medications affecting gastrointestinal motility. In addition, patients with a high risk of respiratory complications—such asthma, chronic obstructive pulmonary disease, recent pneumonia—abnormalities of the oral cavity or pharynx, communication difficulties, or those scheduled for surgeries exceeding 90 minutes were also excluded.

The study was conducted from April 2019 to April 2020. Participants were randomly assigned to two equal-sized groups: the LMA-Supreme group and the I-gel group. Randomization was performed using a computer-assisted method (www.randomizer.org). Insertion of the supraglottic airway device (SGAD) was carried out by a single anesthesiologist with experience in at least 200 insertions of each device type and a first-attempt failure rate below 5% in the general patient population. Patients were positioned

supine with a standard pillow supporting their heads during the procedure. Each device was prepared according to the manufacturer's recommendations, with the posterior and lateral surfaces lubricated using a water-soluble gel. Device size was selected based on patient weight, adhering to manufacturer guidelines.

Upon admission to the operating room, standard monitoring was implemented, including noninvasive blood pressure measurement, pulse oximetry (SpO2), and electrocardiography. Pre-oxygenation was performed for at least 3 minutes using 100% oxygen at a fresh gas flow rate of 8 L/min. Anesthesia was induced intravenously with 1 mg/kg 2% lidocaine, 1–2 µg/kg fentanyl, and 2–3 mg/kg propofol. Neuromuscular blocking agents were not used. Manual ventilation was provided with 100% oxygen and 2% sevoflurane until adequate anesthesia depth was achieved, confirmed by sufficient jaw relaxation during the jaw-thrust maneuver and absence of the eyelash reflex. Once these criteria were met, the SGAD was inserted.

For I-gel insertion, the device was held at the bite block and advanced while the patient was positioned in the "sniffing" posture, involving head extension at the atlanto-occipital joint, neck flexion, and downward jaw displacement. The device was guided toward the palate through the mouth and advanced backward and downward until resistance was encountered.

For LMA Supreme insertion, the cuff was fully deflated prior to placement. The distal tip was positioned against the upper teeth or gum, and the device was gently slid inward using a slight crosswise motion, following the tongue, until resistance was felt. After correct placement, the cuff of the LMA-Supreme was inflated to a pressure of 60 cmH2O (measured with a VBM pressure gauge from Germany) and monitored regularly to maintain a constant cuff pressure. Adequate ventilation was confirmed by bilateral chest expansion, auscultation of lung sounds, and observation of end-tidal CO2 (ETCO2) waveforms. If ventilation was inadequate, the "jaw thrust maneuver" was attempted, along with neck extension or flexion, and made gentle adjustments to the position of the SGAD to ensure proper placement. Following successful placement, mechanical ventilation was initiated in a volume-controlled mode using a mixture of 50%/50% oxygen-air mixture. Tidal volume was set at 5–6 mL/kg, with a respiratory rate of 10–12 breaths per minute, and ETCO2 levels were maintained between 35–40 mmHg. Anesthesia was maintained with 1.0–2.0% sevoflurane in an oxygen-air mixture and an infusion of remifentanil at 0.25–0.5 µg/kg/min.

Oropharyngeal leak pressure (OLP) was measured intraoperatively after SGAD placement, with assessments conducted at 15-minute intervals during the procedure and immediately before device removal at surgery's end. OLP was determined by observing the pressure at which air leaked from the mouth, using a fixed fresh-gas flow of 5 L/min, with the adjustable pressure-limiting (APL) valve closed at 30 cmH2O to ensure peak airway pressure did not exceed 40 cmH2O. OLP was evaluated on a five-point scale: 1= excellent (no air leak at 30 cmH2O); 2= good (air leak at 18-20 cmH2O); 3= moderate (air leak at 10-16 cmH2O); 4= poor (air leak at ≤ 8 cmH2O); and 5= placement/ventilation failure (12).

Placement time for the SGADs was defined as the interval from face mask removal to the appearance of the first ETCO2 waveform. Ease of insertion was assessed on a three-point scale: 1= easy (successful placement on the first attempt without resistance or additional maneuvers), 2= difficult (successful placement on the first attempt with slight resistance, requiring device adjustment or chin lift), and 3= very difficult (placement achieved only on the second attempt despite maneuvers). The ease of gastric tube insertion was evaluated on a three-point scale after lubrication and advancement through the gastric channel following SGAD placement: 1= first attempt (successful); 2= second attempt (successful); or 3= failure (unsuccessful). Additional parameters recorded

included LMA Supreme cuff pressure, operative duration, anesthesia duration, and intraoperative complications. The complications noted included dental, lip, and tongue injuries, hiccups, respiratory issues, such as desaturation SpO2 ≤ 92%, sudden increase in peak airway pressure, regurgitation/aspiration, laryngospasm, and apnea.

At the conclusion of surgery, pain management was provided with 1 mg/kg tramadol and 10 mg/kg paracetamol. The SGAD was removed once spontaneous respiration and responsiveness to verbal commands were confirmed. During this process, any adverse events such as laryngospasm, coughing, desaturation, and injuries to the tongue, teeth, or lips, as well as blood contamination on the laryngeal mask, were recorded. Postoperative assessments for throat pain, hoarseness, and dysphagia were conducted at two and twelve hours, with symptoms recorded as present or absent.

We compared the successful insertion on a first attempt and ease of insertion as a primary outcome, and the secondary outcomes were insertion time, ease of gastric tube insertion, oropharyngeal leak pressure, and intraoperative and postoperative complications.

Statistical Analysis

In this study, the sample size was determined to be 60 patients for each group based on power analysis from a similar study in the literature (13).All the statistical analyses were performed using SPSS version 24 (IBM Inc., Armonk, NY, USA). Data are reported as mean ± standard deviation (SD), median (minimum-maximum), or percentage (%). Normality of the continuous variables was assessed using the Shapiro-Wilk test. For pairwise and multiple comparisons, the chi-square test and Fisher's exact test were used for categorical variables, whereas the Independent T-test and One-Way ANOVA were used for quantitative variables. Nonparametric comparisons were performed using the Mann-Whitney U test. For multiple group comparisons of continuous variables, Dunn-Bonferroni and Tukey tests were applied. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 120 patients were enrolled, with 60 assigned each group: the LMA-Supreme group and the I-gel group. Of these, 16 (13.3%) underwent transurethral prostate resection, 22 (18.3%) underwent transurethral bladder resection, 61 (50.8%) underwent control cystoscopy, and 21 (17.5%) underwent endoscopic ureterorenoscopy. Patient demographics and procedure durations are presented in Table 1. A significant age difference was observed between the groups, with the patients in the I-gel group being approximately 2 years older.

Table 1. Demographic data, surgical duration, and anesthesia duration (values are presented as mean ± standart deviation or numbers)

	I-gel group (n= 60)	**LMA-Supreme group** (n= 60)	**p**
Age (years)	72.9 ± 5.8	70.8 ± 5.3	0.03*
Sex (M/F)	52/8	49/11	0.61
Body mass index (kg/m2)	27.03 ± 4.2	27.52 ± 4.1	0.52
Surgical time (min)	25.36 ± 15.6	27.18 ± 15.7	0.46
Duration of anesthesia (min)	34.8 ± 17.5	36.85 ± 16.05	0.25

M: male, F: female The t-test was applied to compare independent variables between groups, *p< 0,05 statistically significant

The success rate of SGAD placement on the first attempt was determined to be 85% (n=51) in the LMA-Supreme group and 86.6% (n=52) in the I-gel group. On the second attempt, success rates were recorded as 15% (n=9) in the LMA-Supreme group and 13.3% (n=8) in the I-gel group. No significant difference in first-attempt success rates was detected between the groups (p=0.79). Ease of SGAD placement was assessed, with 38 patients (63.3%) in the LMA-Supreme group and 42 patients (70%) in the I-gel group categorized as grade 1 (easy). Grade 2 (difficult) placement was noted in 18 patients (30%) in the LMA-Supreme group and 13 patients (21.7%) in the I-gel group, while grade 3 (very difficult) placement was observed in 4 patients (6.7%) in the LMA-Supreme group and 5 patients (8.3%) in the I-gel group. No significant difference in ease of placement was found between the groups (p=0.57). Gastric tube placement was evaluated, with successful first-attempt insertion achieved in 95% (n=57) of patients in the LMA-Supreme group compared to 78.3% (n=47) in the I-gel group, indicating significantly easier placement in the LMA-Supreme group (p= 0.018). Finally, the average placement time for the SGAD was 17.4 ± 3.3 seconds in the LMA-Supreme group and 15.6 ± 6.95 seconds in the I-gel group (p< 0.001).

Table 2. Intraoperative oropharyngeal leak pressure values (cmH2O)

		I-gel group n= 60 (%)	**LMA-Supreme group** n= 60 (%)	**p**
After the placement of SGAD	1	51 (85.0)	24 (40.0)	< 0.001*
	2	7 (11.7)	25 (41.7)	
	3	1 (1.7)	11 (18.3)	
	4	1 (1.7)	0	
At the fifteenth minute	1	49 (83.1)	20 (35.1)	< 0.001*
	2	7 (11.9)	24 (42.1)	
	3	3 (5.1)	13 (22.8)	
	4	0	0	
At the thirtieth minute	1	23 (82.1)	8 (25.0)	< 0.001*
	2	3 (10.7)	14 (43.8)	
	3	2 (7.1)	9 (28.1)	
	4	0	1 (3.1)	
At the forty-fifth minute	1	9 (75.0)	4 (30.8)	0.186
	2	1 (8.3)	3 (23.1)	
	3	2 (16.7)	5 (38.5)	
	4	0	1 (7.7)	
At the sixtieth minute	1	4 (66.7)	2 (28.6)	0.301
	2	1 (16.7)	1 (14.3)	
	3	1 (16.7)	4 (57.1)	
	4	0	0	

SGAD: supraglottic airway device; data are presented as numbers with percentage values and assessed of OLP used a five-point scale: 1= excellent, 2= good, 3= moderate, 4= poor, and 5= placement/ventilation failure; *p<0.05

Table 3. Intraoperative complications

	I-gel group n= 60	LMA-Supreme group n= 60	p
Intraoperative complications, n (%)	2 (3.3)	11 (18.3)*	0.008*
Hiccup (n)	0	4	
Lip injury (n)	0	2	
Laryngospasm (n)	1	2	
Desaturation (n)	0	2	
Blood contamination on SGAD (n)	1	1	

SGAD: supraglottic airway device Data are presented as numbers with percentage values; *p<0.05

Table 4. Postoperative complications

	I-gel group n= 60 (%)	LMA-Supreme group n= 60 (%)	p
Postoperative second hour			
Dyspagia	4 (6.7)	3 (5)	0.69
Sore throat	1 (1.7)	4 (6.7)	0.17
Hoarseness	-	1 (1.7)	0.31
Postoperative twelfth hour			
Dyspagia	-	-	
Sore throat	-	-	
Hoarseness	-	1(1.7)	0.31

Data are presented as numbers with percentage values; *p< 0.05, statistically significant

Oropharyngeal leak pressure was evaluated using a 5-point scale. A significantly higher number of patients in the I-gel group demonstrated excellent OLP (grade 1) at placement, 15. minutes, and 30. minutes compared to the LMA Supreme group (p< 0.001) (Table 2).

When comparing intraoperative complications between the two groups, the LMA-Supreme group experienced significantly more complications than the I-gel group. In the LMA-Supreme group, intraoperative complications were reported in 11 (18.3%), whereas only 2 patients (3.3%) in the I-gel group experienced complications (p= 0.008) (Table 3).

Postoperative pharyngolaryngeal complication rates, including dysphagia, hoarseness, and/or sore throat, were evaluated at two and twelve hours. No significant differences were observed between the groups (p> 0.05) (Table 4).

DISCUSSION

In this study, we aimed to compare the clinical performance of the second-generation supraglottic airway devices, I-gel and LMA-Supreme, in geriatric patients. In our study, I-gel insertion time was shorter than LMA-Supreme, and the number of patients who had optimal oropharyngeal leakage

pressure at all-time points was higher, and the rate of intraoperative complications was lower in I-gel. However, gastric tube placement was facilitated more easily in the LMA-Supreme. No notable differences were detected between the supraglottic airway devices regarding ease of insertion, success rate on the first attempt, or postoperative complication rates.

In the present study, no significant difference in placement ease was observed between the groups, although placement was assessed as easier in the I-gel group. A study by In et al. (13) involving 38 geriatric patients reported that 78.9% of patients in the I-gel group were classified as "easy," compared to only 36.8% in the LMA-Supreme group. The straight and flexible structure of the I-gel was suggested to facilitate easier advancement in the pharyngeal direction. In contrast, the more rigid and curved design of the LMA-Supreme may complicate positioning. However, other studies have reported that the LMA-Supreme offers advantages placement ease (14). Ease of placement may vary depending on the practitioner's experience.

No significant difference was observed between the two groups in first-attempt placement success. Similarly, a meta-analysis by Chen et al. (1), encompassing ten studies, and a study by In et al. (13) reported no notable differences in first-attempt placement success between groups. Conversely, Ragazzi et al. (15) noted a higher first-attempt success rate in the LMA-Supreme group, attributed to challenges posed by the larger I-gel design for inexperienced users.

Geriatric patients are susceptible to respiratory and neurological complications due to reduced functional reserves. A delayed respiratory response to desaturation or hypercapnia can increase mortality and morbidity, underscoring the importance of timing SGAD placement in this population (16,17). Varying results have been reported for different SGADs. In this study, the time required to achieve adequate airway patency with SGAD placement was significantly shorter in the I-gel group. Kim et al. (18) compared LMA-Supreme and I-gel in geriatric patients and observed a shorter placement time in the I-gel group, though the difference was not statistically significant. A longer placement time was anticipated for the LMA-Supreme due to its inflatable cuff, but practitioner experience likely minimized the difference. Similarly, In et al. (13), reported a significantly shorter placement time in the I-gel group, attributed to the absence of an inflatable cuff. The time required to inflate the cuff, approximately 2–3 seconds, may account for the difference between the groups. The ease of insertion also likely contributed to this time disparity. In geriatric patients, the I-gel's thermoplastic elastomer cuff may facilitate correct positioning by applying pressure to the tongue, whereas the LMA-Supreme curved, fixed shape may pose greater challenges (19). In summary, the shorter placement time in the I-gel group may be due to factors such as the absence of an inflatable cuff and enhanced ease of insertion.

In this study, the success rate of gastric tube placement on the first attempt was significantly higher in the LMA-Supreme group. Multiple studies have similarly reported higher success rates for gastric tube placement using the LMA-Supreme (11,15). This improved performance may be attributed to the more rigid structure of the LMA-Supreme, the centrally positioned cuff, and smoother gastric drainage channels. By contrast, the smaller gastric tube drainage channel in the I-gel may complicate the passage of the gastric tube. Moreover, anatomical variations in geriatric patients may further influence success rates when comparing SGADs.

Oropharyngeal leak pressure (OLP), a critical factor in SGAD safety and effectiveness (20), refers to the pressure at which gas begins to leak around the device. Generally, higher leak pressures suggest that sufficient ventilation can be achieved without air leakage during positive-pressure ventilation,

even at an elevated inspiratory pressure. In this study, OLP was evaluated, and the proportion of patients with "excellent" OLP was significantly higher in the I-gel group than in the LMA-Supreme group. After SGAD placement, leak pressures below 20 cmH_2O were recorded in approximately 12% of patients in the LMA-Supreme group and 3% in the I-gel group. No ventilatory deterioration or increased complications were observed among patients. Ragazzi et al. (15) and Chew et al. (14) reported more effective leak resistance in the LMA-Supreme group at higher pressures. However, In et al. (13) and the meta-analysis by Chen et al. (1) found no significant difference in OLP between the devices. In a randomized controlled trial by Kim et al. (18), involving 106 geriatric patients, a trend of progressively decreasing oropharyngeal leakage was noted in the I-gel group, attributed to its broad, blunt tip and thermoplastic structure, which adapt to the airway over time. In this study, we inflated the cuff pressure, a factor that can influence OLP, to 60 cmH2O after placing the LMA-Supreme. Although the I-gel lacks a cuff, suggesting a higher theoretical leak volume, its ability to conform to supraglottic anatomy may reduce air leakage. These findings support this hypothesis.

Intraoperative complication rates were significantly lower in the I-gel group than in the LMA-Supreme group. However, no significant differences were observed between the groups in complications at the second and twelfth postoperative hours. In et al. (13) also reported no notable differences in intraoperative and postoperative complications between the groups. Conversely, Chen et al. (1), in a study of adult patients aged 18–80 years, noted more frequent throat pain in the LMA-Supreme group; however, the broad age range may limit applicability to geriatric patients. In this study, the use of a pressure manometer to adjust the cuff pressure to the optimal level after inflation in the LMA-Supreme group may explain why no differences in postoperative pharyngolaryngeal complications were observed between the groups.

Our study does have some limitations. Firstly, although it was a randomized prospective study, it lacked blinding. The researcher recording perioperative data was aware of the supraglottic airway device used. Secondly, the participants in our study were aged between 65 and 89 years, and this wide age range may hinder the consistent distribution of patients regarding airway management and anatomical variations. To address this, patients could be categorized into subgroups based on age groups, and further research could be conducted with a larger geriatric population.

In conclusion, both the LMA-Supreme and I-gel exhibited similar characteristics in terms of ease of placement, first attempt success, number of attempts required, and postoperative complications. However, I-gel demonstrated a shorter insertion time, a greater number of patients achieving "excellent" OLP, and a lower incidence of intraoperative complications. These factors may make the I-gel a more favorable choice than the LMA-Supreme for geriatric patients. In addition, the use of a cuff pressure manometer is necessary to ensure appropriate cuff pressure in the LMA-Supreme. When a cuff pressure manometer is unavailable, the I-gel may be the preferred option.

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