

A comparison of two supraglottic airway devices in general anaesthesia: baska mask® vs. I-gel®

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Abstract

Objective: The aim of this was to compare the Baska® mask and the I-gel® airway in paralyzed patients during general anaesthesia in terms of clinical performance, the risk of aspiration, and intraoperative and postoperative characteristics.

Material and Methods: The two devices were compared in 100 paralyzed anesthetized adult patients. Primary outcomes of the study were to evaluate the characteristics of the airway devices within respect to the success of first insertion attempt, the insertion time, the ease of insertion, leak volume, and peak airway pressure. The blood staining on the mask, and the presence of gastric reflux or sore throat two hours postoperatively were evaluated. Hemodynamics, end-tidal CO₂ and the peripheral oxygen saturation measurements were secondary outcomes.

Results: No statistically significant difference was observed between the groups in the criteria of first attempt success rate, ease of insertion, blood staining upon removal of the masks, gastric regurgitation, or sore throat two hours after the procedure. The insertion time was significantly longer for the Baska® mask compared with the I-gel® airway. The leak volume was significantly higher in the Baska® mask patients throughout the surgical procedure. The heart rate and mean arterial pressure measurements were significantly higher in the Baska® mask patients.

Conclusions: Both the Baska® mask and the I-gel® device can be used effectively for selected paralyzed patients under general anaesthesia. The insertion time was significantly longer for the Baska® mask compared with the I-gel® device.

Keywords: Airway management, Baska, I-gel, Laryngeal mask, gastric regurgitation

Introduction

Since Archie Brain introduced the LMA-Classic® (Teleflex Medical Europe Ltd., Westmeath, Ireland) to anaesthesia practice, many supraglottic airway devices (SADs) have been produced. Following the first-generation devices with only a breathing lumen, second-generation SADs with an additional lumen for gastric drainage became available in the market (1). The I-gel® airway (Intersurgical Ltd., Wokingham, Berkshire, UK) is a second-generation SAD with a medical-grade, thermoplastic, elastomeric, soft gel-like structure. It has a non-inflatable cuff designed to fit over the pharynx, larynx and perilaryngeal structures (2). More recently, Australian anesthetists Kanag and Meena Baska designed a new third generation device called the Baska® mask (Logical Health Products PTY Ltd., Morisset, NSW, Australia). This mask brings together clinical characteristics of the LMA-ProSeal®, the LMA-Supreme® (Teleflex Medical Europe Ltd., Westmeath, Ireland), the I-gel® and the SLIPA® device (SLIPA Medical Ltd., London, UK). It has a cuffless membranous bowl, which inflates and deflates with positive pressure

ventilation improving the seal, an inbuilt “tab” permitting ease of placement and allowing control of the degree of flexion, a dual drainage system for the prevention of the aspiration of gastric contents, and a bite block to reduce the risk of patients’ biting down on and blocking the airway(3). The structures of two devices are shown in Figure 1.

Since the introduction of Baska® mask many studies have been published that compare the Baska® mask with other airway devices in different patient populations (4-9). The efficacy of this mask has been demonstrated in both spontaneously breathing and paralyzed patients (10-12).

In this study, the aim was to compare the performance of the Baska® mask and the I-gel® airway in paralyzed patients during general anaesthesia in terms of clinical performance, the risk of aspiration, and intraoperative and postoperative characteristics. The secondary objectives were to assess hemodynamic parameters, peripheral oxygen saturation, and end-tidal CO₂ variability induced by intraoperative mask placement.



Material and Methods

The study was conducted according to the ethical principles outlined in the Helsinki Declaration and the Guideline of Good Clinical Practice. After obtaining approval from the Ethics Committee (decision no: 2018/514/124/9) and written informed consent, the study was conducted with 100 patients of American Society of Anesthesiologists (ASA) physical status I-II and aged 18 years or older of either genders. (Figure 2) The patients were not assessed to be at risk for a difficult airway in the preanaesthetic evaluation and were scheduled for an elective, flexible ureterorenoscopy in the supine position for which a no 4 size Baska® mask (Group B) or I-gel® (Group I) was suitable for airway management. Patients were randomly assigned to either Baska® mask (Group B; n=50) or I-gel® (Group I; n=50) by a computer-generated randomization method (13).

Exclusion criteria included obese patients (Body mass index ≥ 30 kg/m²), patients with known gastrointestinal reflux or, upper respiratory tract infections, planned surgical duration of ≥ 2 hours, patients with neck pathology and patients with oral or dental deformities. The patients fasted for at least eight hours prior to the surgical procedure, including both solids and clear liquids.

All of the patients were premedicated intravenously with 0.03 mg/kg midazolam about 30 minutes before the induction of anaesthesia. Prior to the operation, standard monitoring included a 3-lead electrocardiogram (ECG) with continuous ST-segment analysis, and evaluation of peripheral oxygen saturation (SpO₂) and intermittent non-invasive blood pressure. Following preoxygenation with 100% oxygen for three minutes, general anaesthesia was induced with propofol (3mg/kg) a few minutes after a fentanyl (2µg/kg) injection. Neuromuscular paralysis was achieved with rocuronium (0.5 mg/kg) in all patients. In the event of coughing, gagging, or body movement, an additional dose of propofol was administered. Mask ventilation was continued with 100% oxygen until the adequate jaw relaxation was confirmed. The patient's head was placed on a silicone pillow in the sniffing position. All device insertions were performed by personnel with significant experience in laryngeal mask insertion.

The standard pre-use test was performed to check structural integrity. A well-lubricated size- 4 Baska® mask or I-gel® airway device was chosen according to the prior randomization protocol. According to the manufacturer-recommended approach, the mask size was based on the patient's weight. When the adequate depth of anaesthesia and jaw relaxation were achieved, the mask was held away from the airway tube with the dominant hand facing the cuff outlet anteriorly and pushed against the hard palate until encountering resistance. The non-dominant hand was used to extend the inter-incisor distance and compress the tongue while the device was advanced into the mouth. A maximum of three attempts per patient was permitted to determine successful placement. In the event of a failed insertion, another SAD or endotracheal intubation was used and the patient was excluded from the study. Successful insertion was confirmed with the inspection of bilateral

chest movements, auscultation of both lungs and a capnography interpretation. After successful ventilation was ascertained, the mask was connected to a breathing circuit and fixed by taping the device in place. Anaesthesia was maintained with sevoflurane of 1 to 2% volume with a mixture of 50% oxygen-air in a fresh gas flow of 2 L/minute.

All patients received 1 gr paracetamol and 1 mg/kg tramadol for postoperative analgesia. At the end of the surgery, the anesthetic gas mixture was replaced with 100% oxygen and the neuromuscular block was reversed using a neostigmine (0.05 mg/kg)-atropine (1mg) combination. After adequate ventilation, protective airway reflexes and the patients' response to verbal commands were established, the mask was removed. Immediately after removal, the pH of the posterior surface of the mask was measured with a pH indicator strip (DIRUI H11, DIRUI Industrial Co., Ltd. Changchun, China) and the pH ≤ 6 (the normal pH of saliva is 6.2-7.6) was accepted as evidence of gastric regurgitation. Any blood staining on the mask was recorded.

Data collection: The patients' characteristics including age, gender, body weight, Mallampati score, American Society of Anesthesiologists (ASA) classification of physical status and the duration of anaesthesia were recorded. The insertion time (the time between picking up the mask by the anesthesiologist and successful placement), number of attempts needed for correct placement of the mask, the ease of insertion (very easy, easy, difficult), the leak volume (calculated by the difference between inspiratory and expiratory volume), peak airway pressure, the presence of blood staining on the mask, whether or not there was gastric reflux in the oral cavity, and a sore throat were the primary outcome measurements of this study. The presence of a sore throat was determined by another blinded observer 2 hours after the operation.

Secondary outcomes included the end-tidal CO₂ (EtCO₂), peripheral oxygen saturation (SpO₂) and the hemodynamic variability throughout the surgical procedure.

Statistical analysis: The statistical analysis was performed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean \pm SD while frequency and percentage was computed for gender, ASA status, Mallampati score, insertion attempts, ease of insertion and postoperative outcomes. The Kolmogorov-Smirnov test was used to test for a normal distribution of data. Student's t-test was used to compare the differences in quantitative measurements between groups. A chi-square and Fisher's exact test were used to evaluate the between-group differences in categorical variables. The Mann-Whitney U-test was applied to unpaired and independent observations. A value of $p < 0.05$ was considered significant in this study.

For two independent and continuous group comparisons with 0.05 confidence level (Type I error) and 0.80 power (Type II error), the sample size was calculated to be at least 17 for each group. However, in order to make the study more reliable, 50 patients for each group were included in the study.

Results

The analysis of patients' characteristic indicated that there was a statistical significance in gender representation due to randomization ($p=0.016$).

However, the mean body length and weight of the patients in the groups were similar. The majority of patients in both groups had an ASA II score; the figure was significant in Group I ($p=0.002$).

There was no between-group difference in the Mallampati scores (Table 1). The duration of surgery was 55.80 ± 21.10 minutes and 47.20 ± 15.65 minutes respectively in Group B and Group I ($p=0.023$).

The number of mask insertion attempts was similar in both groups. The insertion time was significantly longer in Group B ($p < 0.001$). One patient in each group was defined as a case of difficult insertion. No blood staining, gastric reflux, or sore throat was recorded two hours after the procedure (Table-2).

Analysis of intraoperative variables revealed that the heart rate and the mean arterial pressure measurements were significantly high until the 60th minutes of surgery in Group B.

The EtCO₂ variables were similar in the groups. There was small but significant decline in the SpO₂ value after the insertion of the mask in Group I patients, but there was no significant difference between groups during the remainder of the procedure (Figure 3).

The peak airway pressure difference was comparable in both groups but the leak volume was significantly greater in Group B patients ($p < 0.001$) (Figure 4).

No untoward effect was recorded throughout the study period.

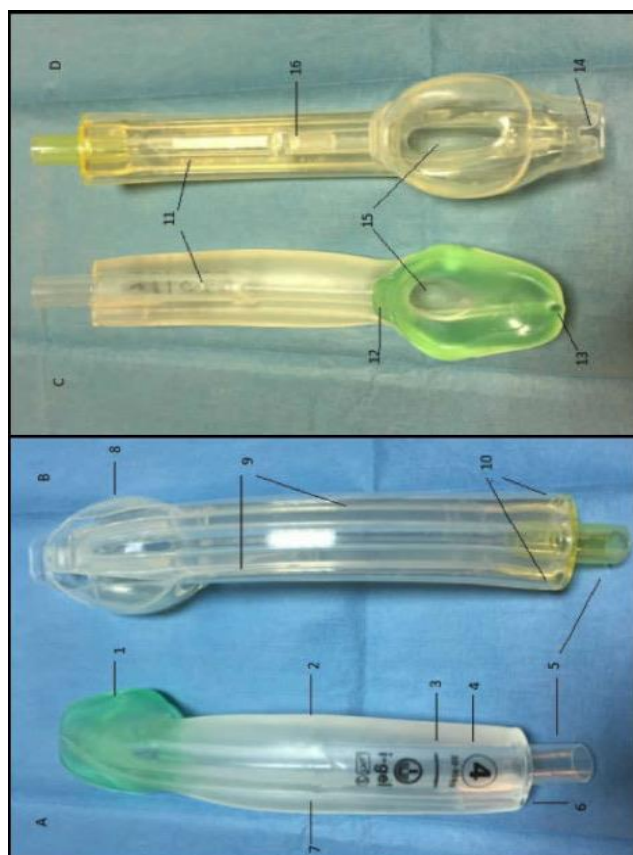


Figure 1. The structural characteristics of the I-gel® airway (A,C) and Baska® mask (B, D). Posterior aspect of the I-gel® device demonstrating the non-inflatable cuff made from a soft gel-like material (1), buccal cavity stabilizer eliminating the potential for rotation (2), position guide for confirmation of the depth of insertion (3), the size and weight guide for the mask (4), proximal end of the gastric channel (6) and the gastric channel (7). The standard connector of both masks is suitable for circle-system connection and catheter mount (5). The cuffless, membranous bowl of the Baska® mask (8) with 2 gastric channels (9) and 2 openings to the atmosphere (10). An anterior aspect view, illustrating the integral bite block to reduce airway occlusion (11), the epiglottic rest of the I-gel® device to prevent the epiglottic “down fold” and airway obstruction (12), the distal ends of the gastric channels (13,14), the airway orifice of both masks (15) and the insertion “tab” of the Baska® mask to ease the manual curve during insertion (16).

Table 1. The demographics of the study groups

Variable		Group B	Group I	Test Statistics	P value
Gender ¹	Female	32 (64)	20 (60)	Pearson Chi-square:5,769 df:1	0.016*
	Male	18 (36)	30 (40)		
Age (years) ²		47.32±13.82	51.16±13.77	Independent sample t test:0.167 df:98	0.167
Body length (cm) ²		166.36±7.76	164.76±7.22	Independent sample t test:-0,167 df:98	0.288
Body weight (kg) ²		76.16±15.15	72.34±13.31	Independent sample t test:-1,339 df:98	0.184
ASA class ¹	I	14 (28)	2 (4)	Fisher's exact test	0.002*
	II	36 (72)	48 (96)		
Mallampati score ¹	I	22 (44)	30 (60)	Pearson Chi-square:2,564 df:1	0.109
	II	28 (56)	20 (40)		

Table 2. Device characteristics

Variables	Group B	Group I	P Value
Number of attempts ¹	1	47(94)	0.617
	2	3(6)	
Insertion time (sec) ²	27.97± 12.97	12.73 ±2.01	<0.001* 95% Confidence Interval of the Difference Lower -18,68170 Upper -10,92710
Blood staining ¹	+/- 0/50 (100)	0/50 (100)	---
Sore throat after 2 hrs ¹	+/- 0/50 (100)	0/50 (100)	---
Gastric reflux ¹	0/50 (100)	0/50 (100)	---

Data are expressed as 1 the number of the patients (n) and the percentage (%) or 2 (mean± SD). * p<0.001, statistically highly significant

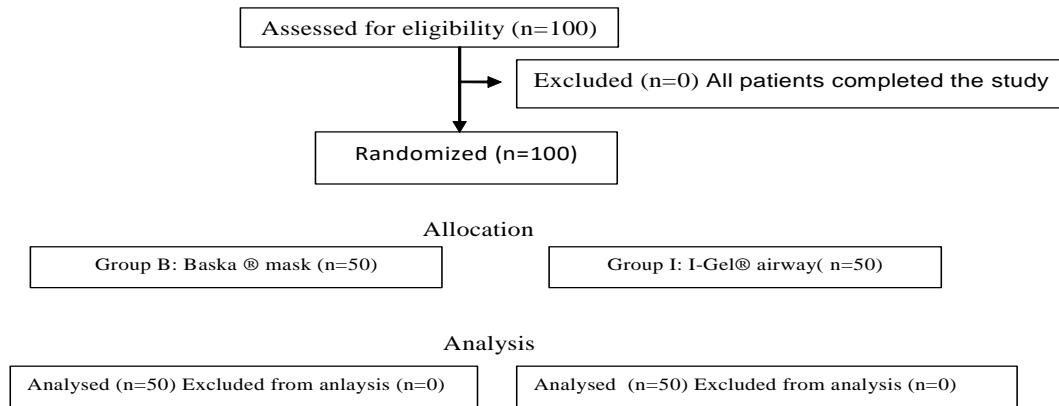


Figure 3. Intraoperative variables of the study groups. A. Heart rate (HR), B. Mean arterial pressure (MAP), C. Peripheral oxygen saturation (SpO2), D. End-tidal carbondioxide (EtCO2) Group B: Baska® mask; Group I: I-gel® airway

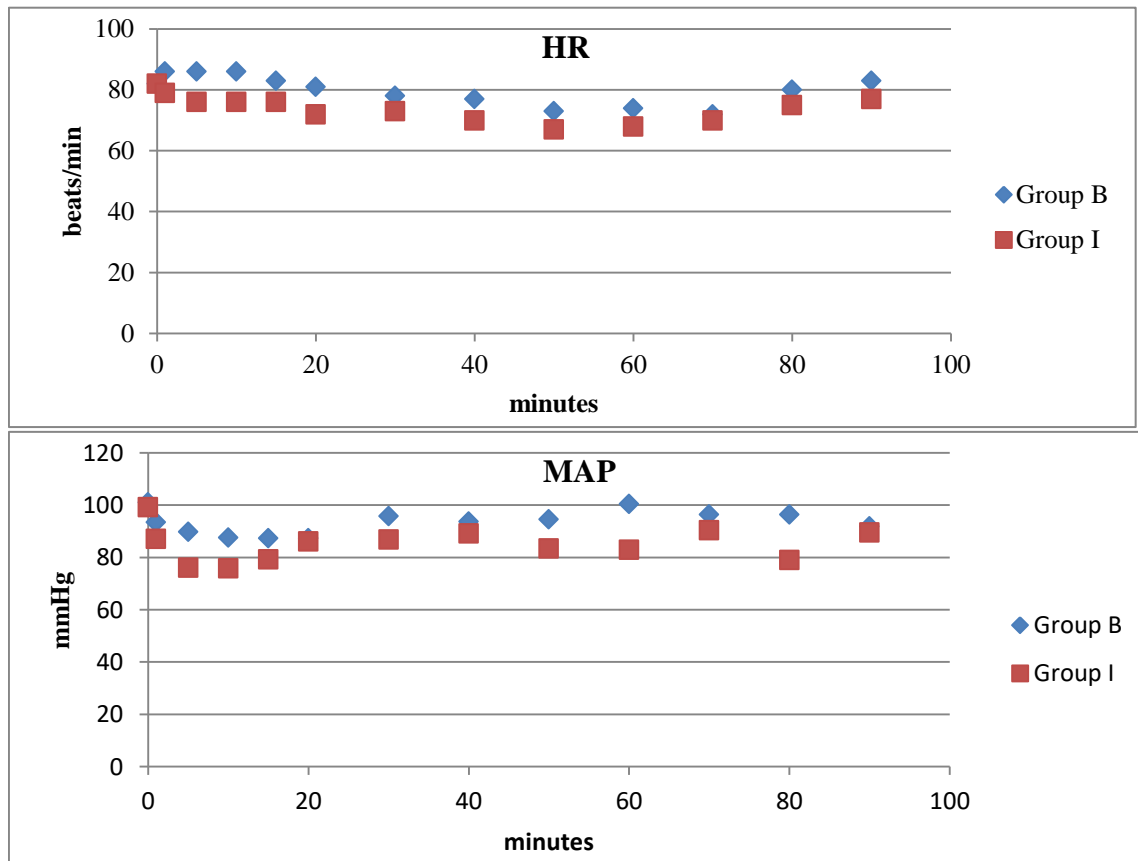


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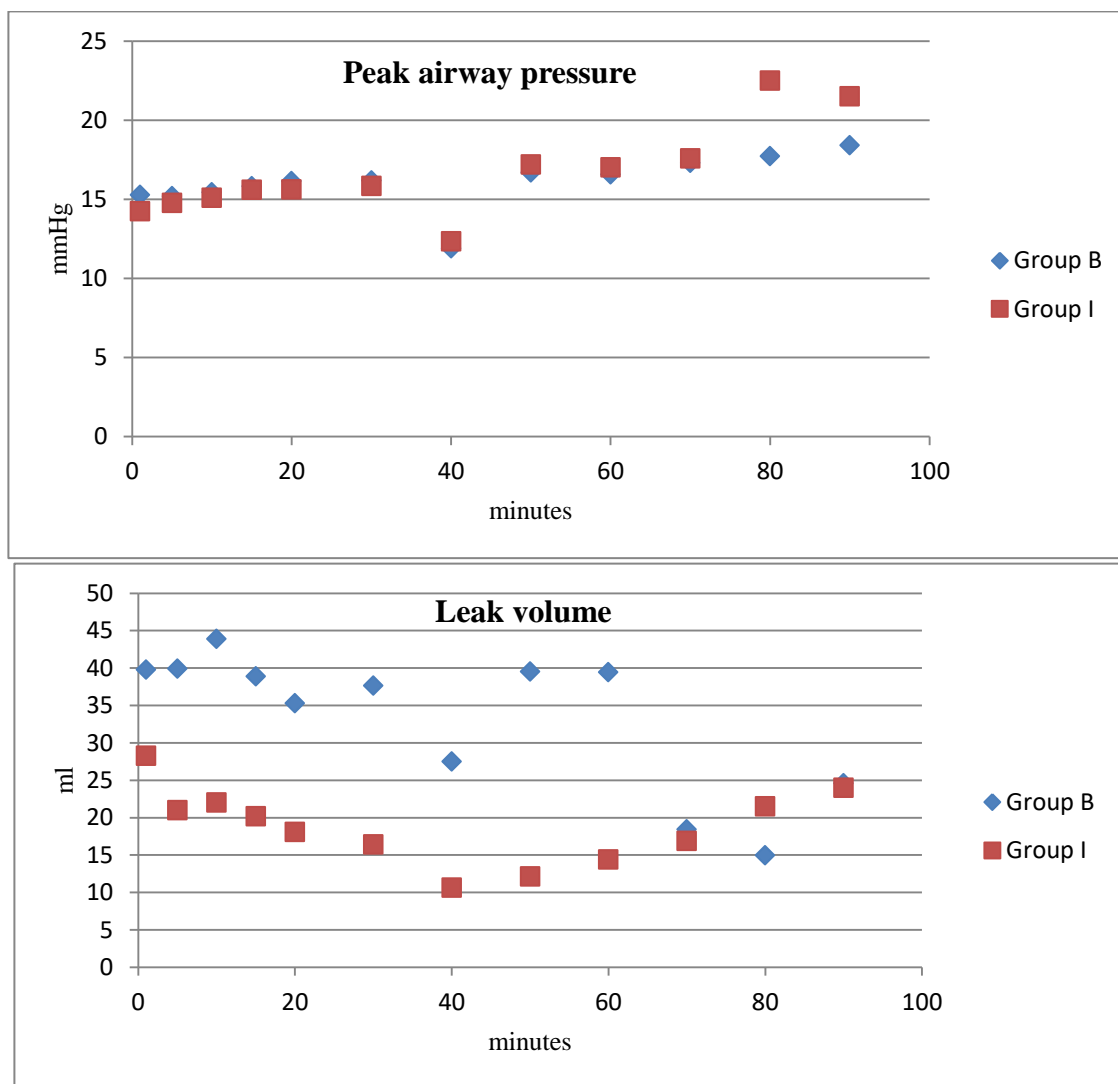


Figure 4. The measurements of peak airway pressure (A) and leak volume (B). Group B: Baska® mask; Group I: I-gel® airway

Discussion

This study indicated that results obtained using the I-gel® mask were superior to those using the Baska® mask in paralyzed patients during general anaesthesia in terms of a lower leak volume and more stable intraoperative hemodynamic characteristics. The I-gel® device provided easier and faster airway management than the Baska® mask. There was no significant difference regarding blood staining, regurgitation, or a sore throat after the operation. Both devices provided a safe airway management under positive pressure ventilation.

According to the earliest data published related to the Baska® mask, the first-time insertion success rate was reported to be 73%, 76.7% and 88% (6,11,12). In a recent study, the percentage was reported as 92.5% (10). This may be explained by increasing experience with the device over time. Studies comparing the Baska® mask to other SADs have yielded varied results.

Aziz et al. (5) reported that first-attempt insertion of the Baska® was better than that of I-gel® (90% vs 83.3%). Shanmugavelu et al. (4) demonstrated in an observational study that the first attempt success rate was comparable between the Baska® mask and the I-gel® airway. The results were similar to those seen with the ProSeal® laryngeal mask (7). In our study, the difference in the success rate for insertion on the first attempt was insignificant, with 94% for the Baska® mask and 98% for the I-gel® airway ($p=0.617$).

The insertion time has been a controversial issue. Some earlier studies found the Baska® mask to be difficult to insert and suggested that it was time-consuming (4,6,9,10,12). Yet a comparative analysis of the Baska® mask with the I-gel® and the ProSeal® devices indicated superiority of the Baska® mask (5,7). Our results revealed that the insertion time was significantly shorter in the I-gel® group ($p=0.000$); however the Baska® mask device is a new device for us so the insertion time may improve over time with clinical practice.

The one of the primary outcomes of this study was to compare the leak volume and peak airway pressure created by both devices. Aziz et al. (14) suggested that the head and neck position reflected no significant changes in respect of oropharyngeal leak and peak airway pressure with the Baska® mask in a comparative clinical trial. The Baska® device was also demonstrated to be a suitable airway device for positive pressure ventilation with a minimum leak even in the event of increased intra-abdominal pressure (4,5,15). Alexiev et al. (6,12) emphasized the importance of anaesthesia depth during mask insertion and suggested that the leak amount showed parallelism to the depth of anaesthesia. They reported that positive pressure ventilation had a positive effect on the leak around the mask secondary to cuff-seal improvement with each inflation. Our results demonstrated indicated a significantly higher leak volume in patients enrolled in the Baska® mask group.

The analysis of intraoperative hemodynamics revealed a significant difference in favor of the I-gel® group in heart rate and mean arterial pressure. This result contradicted some previous reports. Fotedar et al. (9) demonstrated that the I-gel® and the Baska® devices provided similar intraoperative hemodynamics. In a comparative study with a single-use laryngeal mask airway (LMA), the Baska® mask demonstrated no significant hemodynamic differences (6). Nonetheless, in the literature, many authors have concentrated the characteristics of the Baska® mask and the data concerning the effects on the perioperative hemodynamic parameters are limited. Our results may be re-evaluated in subsequent clinical trial with a larger sample size. This may be more beneficial to understanding whether or not the Baska® mask has a negative effect on intraoperative hemodynamics. As in some previous reports, the SpO₂ and EtCO₂ results were comparable in our study (5,9).

Pharyngolaryngeal morbidity is a frequent postoperative adverse outcome associated with patients' satisfaction and delayed post-operative discharge. The larynx has a mucosal structure covered by a cartilaginous framework and can be easily damaged during endotracheal intubation or placement of a SAD. Fotedar et al. (9) reported a 5% occurrence of a sore throat and cough that resolved within 6 hours of postoperatively in spontaneously breathing patients after Baska® mask insertion during anaesthesia. In order to decrease the incidence of sore throat after SADs use, lubrication of the posterior aspects of the mask with a water-soluble jelly is the preferred method. Alternative techniques, including a cuff wash, lidocaine gel and washing the mouth with saline before the mask removal have showed no benefit (16). It has been reported that the use of lidocaine may result in a delay in recovering the protective reflexes or may trigger the allergic reactions (17). In our clinical protocol, we use a water-soluble lubricant to ease the insertion of SADs. No blood staining or a sore throat was recorded two hours after the operation in either study groups in this trial.

Despite its many advantages, positive pressure ventilation with an LMA is considered by many authors as a risk factor for pulmonary aspiration, as well as gastric insufflations (18-22). Second generation SADs with a gastric lumen

were introduced to decrease this risk. The suction port of the device can be helpful throughout the procedure or during the removal of the mask in the risk of gastric regurgitation. This port may also be used for the placement of a gastric tube to empty the stomach (11). In a comparative study with an LMA, the incidence of gastric insufflation was significantly lower in I-gel® patients (23). In a recent study of a geriatric population, the I-gel® had superior results in terms of gastric insufflation when compared with the LMA-Supreme™ (24). A cadaver study demonstrated that an inspiratory pressure of 20 mbar is a safe airway pressure to prevent gastric insufflation during SADs insertions (25). Saracoglu et al. (26) reported that the I-gel device can be used safely in both the supine and lateral positions. In our study, the mean peak airway pressures throughout the procedure was 16.04±1.63 mmHg in Group B and 16.60±2.89 mmHg in Group I (p<0.05). There was no instance of gastric reflux with either device at these pressure levels.

The sample size may be a limitation of this study. As previously mentioned, the I-gel airway has been used in our clinical practice for a long time but the Baska® mask was a new device for us. Those participating in this research had no prior training with the Baska® mask before the trial. This was a randomized clinical study designed to provide information about the Baska® mask and its' clinical characteristics. Both airway devices have been introduced by the investigators. So, the study was not blinded for researchers; there is a risk of bias in subjective measures. All of the researchers had similar experience with other SADs.

Another limitation is that we enrolled only Mallampati I and II patients in this study. The effectiveness of both masks in an airway predicted to be difficult was not observed. Furthermore, neither mask was used in high-risk patients. These points may be the subjects of new clinical trials in the future.

Conclusion

In our opinion, the Baska® mask demonstrated clinical utility as a useful supraglottic airway device. Both the Baska® and the I-gel® device provided a safe airway management in paralyzed patients under positive pressure ventilation. The observed difference in insertion time may reflect a required-learning period with the Baska® mask. Although the leak volume in the Baska® mask was significantly greater than that of the I-gel®, this did not create an untoward clinical effect in our study. This subject requires further evaluation, but these results may re-enforce new clinical studies.

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Author's contributions: OS; Research concept and design; patient examination, data collecting, analysis and interpretation of data, preparation article and revision.

Ethical issues: Author declare, originality and ethical approval of research. The study was conducted under defined rules by the Local Ethics Commission guidelines and audits.

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