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Comparison of the clinical performances of i-gel and baska mask

Süheyla Abitağaoğlu[1]✉, Ceren Köksal[2], Güldem Turan[3], Arzu Yıldırım Ar[4], Fatma Nur Akgün[5], Dilek Erdoğan Arı[6]

Background: **Various types of supraglottic airway devices (SGAD) have been developed so far. Baska mask and I-gel are two different SGADs used in daily anesthesia practice. The purpose of this study is to compare the ease of use of Baska Mask and I-gel regarding insertion duration, success and complication rates.** ***Methods*****: 30 patients with ASA I-II were enrolled in this randomized clinical study. Heart rate (HR), mean arterial blood pressure (MAP), oxygen saturation (SpO2) and integrated pulmonary index (IPI) were monitored. SGAD insertion duration, success in the first insertion attempt, total insertion success, gastric drainage tube insertion duration, leak pressures and IPI values were recorded. Perioperative and postoperative complications were evaluated.** ***Results:*** **Insertion duration was significantly longer in Baska mask group compared to the I-gel group (61.2 ± 43.4 sec vs 20.9 ± 13.8 sec; p = 0.012). Success rate in the first insertion attempt and leak pressures were similar. The gastric catheter insertion duration, ease and IPI values were similar. There was no difference in terms of complications.** ***Conclusions:*** **Even though higher insertion duration, Baska mask may be an alternative to I-gel in positive pressure ventilation.**

INTRODUCTION

After the laryngeal mask airway was first introduced in 1981, supraglottic airway devices came into use in anesthesia practice, accompanied with a progressive expansion in the clinical use of these devices (1). Various types of supraglottic airway devices (SGAD) have been developed so far. Devices with gastric tube are more advantageous in positive pressure ventilation.

Baska mask and I-gel are two different SGADs used in daily anesthesia practice. They are equipped with a gastric tube, non-inflatable cuff and integrated bite-block (2, 3). Integrated bite-block reduces the risk of blocking the airway by patients' bite. Baska mask fits the anatomy of the supraglottic area through the self-inflation of its cuff during positive pressure ventilation. Non-inflatable cuff of Baska mask is continuous with the central channel of the device (3). I-gel provides thermal adaptation to the airway through its thermoplastic elastomeric composition (4). Hence, they reduce potential oropharyngeal tissue and/or nerve damage. While these devices reduce the risk of pulmonary aspiration through the gastric tube available, Baska mask is equipped with side channels that provides aspiration of the secretions and gastric content that accumulates in the supraglottic area (5, 6, 19). The extended hand-tab on the Baska mask helps to control the flexion of the device during insertion (3).

While there are plenty of studies exploring the clinical performance and safety of I-gel and comparing it to other supraglottic airway devices, there is no study comparing it to the relatively new Baska mask. The purpose of this study is to compare the ease of use of Baska mask and I-gel regarding the success rate, performance and complication rates.

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MATERIALS AND METHODS

After receiving the approval of Ethical Board (FSMEAH-KAEK 2016/13) and written informed consent of patients, 30 male and female patients from ASA I-II group, aged between 20 and 80, who were to be operated under general anesthesia during March 2016 - September 2017 period were enrolled in this randomized clinical study. Subjects scheduled for a planned laparoscopic surgery, who currently had a pulmonary disease, airway abnormality, pre-surgical aphonia, obesity (BMI >35 kg/m2), gastric reflux, suspected for difficult tracheal intubation (Mallampati score >2, mouth opening < 2.5 cm, cervical vertebra pathology, sternomental distance < 12.5 cm) were excluded.

Patients were randomized into 2 groups; Grup-B and Grup-Igel, by the sealed envelope technique. Age, gender, body mass index (BMI), mouth opening and sternomental distance of the patients were recorded.

A 20G intravenous catheter was inserted on the hand of patients admitted to the operating room to start 10ml/kg/hr Ringer Lactate infusion. Heart rate, noninvasive blood pressure, oxygen saturation (SpO2) via pulse oximeter, and bispectral index (BIS) were monitored.

[1]Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, Istanbul, Turkey; [2]Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, Istanbul, Turkey; [3]Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, Istanbul, Turkey; [4]Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, Istanbul, Turkey; [5]Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, Istanbul, Turkey; [6]Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, Istanbul, Turkey;
✉*Corresponding author:* Süheyla Abitağaoğlu; Anesthesiology and Reanimation Department, University of Health Sciences Fatih Sultan Mehmet Health Research and Application Center, E-5 Highway İçerenköy Street 34752 Ataşehir İstanbul, Turkey. Phone number: +905325267656 (mobile); E-mail address: suheylaatay81@gmail.com

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Integrated Pulmonary Index (IPI) was also monitorized. The IPI algorithm is a mathematical model that helps to assess the efficiency of ventilation and oxygenation by reducing the combination of SpO_2, respiratory rate, HR and $EtCO_2$ into a single value that is between 1 and 10 (Table I) (7) In our study, we assessed the respiratory condition of patients by IPI monitorization. IPI values between 7-10 were determined as targeted level.

Table I Evaluation of IPI monitorization

IPI	Clinical Assessment
10	Normal
8-9	Close to normal range
7	Close to normal range; requires attention
5-6	Requires attention and may require intervention
3-4	Requires intervention
1-2	Requires immediate intervention

IPI: integrated pulmonary index

After preoxygenation for 3 minutes with 100 % O_2, anesthesia induced with 2 - 2,5 mg/kg propofol, 2 mcg / kg fentanyl and 0.3 mg / kg rocuronium. Patients were ventilated with 100 % O_2 via balloon-valve-mask system for 2 minutes. Then, one anaesthesiologist who have experience with both devices inserted I-gel (Intersurgical Ltd, Wokingham, Berkshire, UK) or Baska mask (PROACT Medical Systems, French Forest NSW, Australia) of appropriate size. Masks were chosen based on manufacturers' recommendations by weight. Imaging bilateral chest movements during manual ventilation was accepted as a sign of effective ventilation. In case of partial or complete airway obstruction or severe air leak, insertion attempt was considered to have failed. If the first insertion attempt failed, a second attempt was conducted as accompanied with the 'jaw-thrust maneuver'or by altering the head position. At the third attempt, the same supraglottic airway device was switched to a different size. In case of failure, airway was established via an endotracheal tube. Mechanical ventilation was applied with the following settings: fresh gas flow of 3 L / min (with 50 % oxygen in air), tidal volume 8 ml / kg, 10-12 breaths/minute in order to maintain end-tidal CO_2 ($ETCO_2$) between 30-36 mmHg. Anesthesia administration was continued with 1-2 % Sevoflurane inhalation and remifentanil infusion to keep BIS values between 40-60 %. A 12 Fr nasogastric catheter was inserted through gastric access port of SGAD to drain the gastric contents.

One anaesthesiologist inserted SGADs and one blinded anaesthesiologist collected the data during insertion and perioperative period. SGAD insertion time, success at the first attempt, number of insertion attempts, gastric drainage tube insertion time and difficulty level, and presence of gastric distension were recorded. Heart rate (HR), mean arterial pressure (MAP), SpO_2, $ETCO_2$ and IPI levels were recorded at baseline (before oxygen supplement), at the time when SGAD was inserted and subsequently at minutes 10, 20, 30 and 45, and then every 15 minutes, at the time when SGAD was removed, and at the 5^{th} and 30^{th} minutes in PACU. Leak pressure was measured after SGAD was inserted. Leak pressure of supraglottic airway device was determined by setting the pop-up valve to 40 cm H_2O, providing fresh gas flow of 3 l/min until reaching a stable airway pressure. The pressure of audible gas leak was defined as leak pressure. Peak inspiratory pressures (PIP), minute ventilation and leak volume (difference between inspired and expired tidal volume) were recorded after SGAD insertion, subsequently at min 10, 20, 30 and 45, and every 15 minutes thereafter. Duration of surgery was recorded and at the end of the surgery 0.05mg/kg neostigmine and 0.01mg/kg atropine were administered for reversal of neuromuscular blockage. SGAD was removed after patients returned to spontaneous respiration.

Patients were assessed for presence of blood on SGAD, laryngospasm and bronchospasm after removal of SGAD and further for postoperative complications in terms of sore throat, aphonia, cough, dysphagia, nausea for 30 minutes in PACU by an anaesthesiologist who was blind to groups.

The primary outcome of the study was insertion duration. Data from the pilot study [mean (B)=76 (sd=48), mean (i-gel)=31 (sd=17)] showed that 9 patients were required in each group, but 15 were included to compensate for possible dropouts.

For analysis of data SPSS Statistics 22 (IBM SPSS, Turkey) programme was used. Normal distribution of values was assessed with Shapiro Wilks test. Student t test was used to compare the numerical values consistent with normal distribution and Mann Whitney U test was used to compare numerical values inconsistent with normal distribution. Categorical variables were compared using Pearson's chi-squared test, Fisher's exact test and Continuity (Yates) correction. In-group evaluations Paired samples test was used for values consistent with normal distribution and Wilcoxon sign test was used for values inconsistent with normal distribution. A p-value < 0.05 was considered as significant.

Table II Demographical data of the patients

		Group B	Group IGEL	p
		Mean±SD	Mean±SD	
Age (years)		48.47±13.68	47.53±13.38	[1]0.852
Gender n(%)	Male	10 (66.7%)	6 (40%)	[2]0.272
	Female	5 (33.3%)	9 (60%)	
BMI (kg/m^2)		25.47±2.04	25.1±2.73	[1]0.680
SM distance (cm)		14.69±1.35	14.8±1.75	[1]0.844
Mouth opening (cm)		5.35±0.92	5±0.87	[1]0.296
Duration of surgery (min)		58.25±28.58	39.43±21.63	[1]0.068
Surgery type n(%)				
General		7 (46,6)	7 (46,6)	[3]0,849
Gynaecology		1 (6,6)	2 (13,3)	
Orthopaedic		4 (26,6)	4 (26,6)	
Urology		2 (13,3)	0 (0)	
Vascular		1 (6,6)	1 (6,6)	
Ophthalmologic		0	1 (6,6)	

[1]Student t Test, [2]Continuity (Yates) correction, [3]Fisher's exact test

RESULTS

There was no difference between groups in terms of age, gender, body mass index, mouth opening, sternomental distance, surgery type and duration of surgery (Table II).

Insertion duration was significantly longer in Baska mask group (61.2 ± 43.4 s) compared to the I-gel group (20.9 ± 13.8 s) (p = 0.012). There were no significant difference between two groups in terms of success in the first insertion attempt and number of attempts. Intubation was necessary for 3 patients in Baska mask group and 1 patient from I-gel group (p = 0.330). Gastric catheter insertion duration was similar (Table III). No gastric distension was observed in any of the patients.

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Table III Data of Baska Mask and I-gel insertion, leak pressure and gastric catheter insertion

		Group B	Group IG	*p*
Insertion duration (sec)		61.2±43.4	20.9±13.8	[1]**0.012***
Number of insertion attempts	**1**	6	10	[2]0.116
	2	4	4	
	3	5	1	
Success in the first attempt	**Yes**	6	10	[3]0.272
	None	9	5	
Leak pressure (cmH_2O)		32±2	30±4	[2]0.252
Gastric catheter insertion duration (sec)		29.1±43	20.5±12.7	[1]0.252
Ease of inserting gastric catheter	**Very easy**	8	6	[2]0.252
	Easy	3	5	
	Difficult	1	2	
	Very difficult	0	1	

[1]Student t Test, [2]MannWhitney U Test, [3]Continuity (Yates) correction

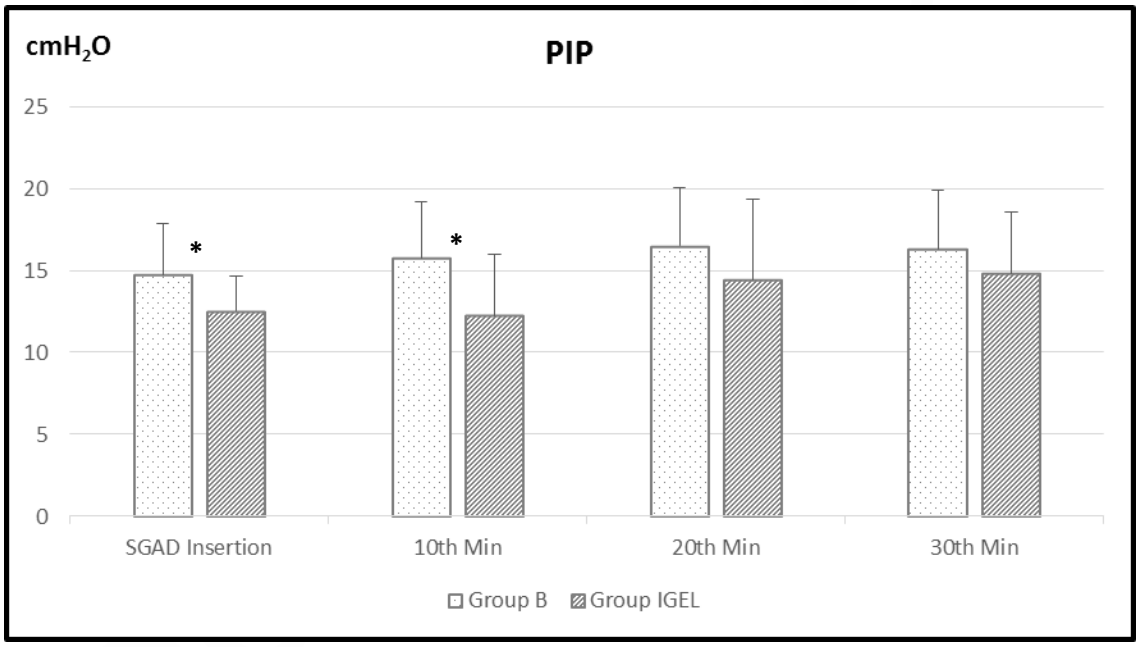

Figure 1 Comparison of Peak Inspiratory Pressures (PIP) between groups
Student t test, * p<0.05

Table IV Comparison of IPI values between groups

IPI	Group B	Group IG	*p*
	Mean ± SD (median)	Mean ± SD (median)	
Baseline	9.91±0.3 (10)	9.75±0.45 (10)	0.325
LMA insertion	9.33±0.78 (9.5)‡	9.29±0.83 (9.5)	0.911
10th Min	9.42±0.67 (9.5)‡	8.79±0.97 (8)‡	0.083
20th Min	9.08±0.67 (9)‡	9±0.96 (9)‡	0.827
30th Min	9.27±0.79 (9)‡	8.92±0.79 (9)‡	0.280
Postoperative	9.4±0.52 (9)‡	9.36±0.74 (9.5)	0.948
Postoperative 30th Min	9.7±0.48 (10)	9.64±0.63 (10)	0.971

Mann Whitney U Test; ‡ Wilcoxon Sign Test

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Leak pressure in Baska mask group was similar to I-gel group (Table III). While PIP levels were higher in Baska mask group immediately after insertion ($p = 0.041$) and at min 10 ($p = 0.022$), they showed a similar trend on subsequent follow-ups (Figure 1). There was no significant difference in leak volumes between groups.

MAP, HR, SpO_2 and $ETCO_2$ values of the patients' were similar. In both groups, IPI values were in between targeted levels without any significant difference between groups. In-group evaluations, in perioperative and early postoperative period IPI values were lower than basal values in Baska Mask group; it is also lower at 10^{th} min, 20^{th} min, 30^{th} min of perioperative period in I-gel group (Table IV).

None of the patients had laryngospasm, bronchospasm, aphonia and dysphagia. After the removal of the Baska mask, presence of blood, sore throat and postoperative nausea were observed in two patients, however such complaints were not observed in I-gel group. In 2 patients from I-gel group, cough was observed within 30 minutes postoperatively. No statistically significant difference was observed in terms of complications.

DISCUSSION

This is the first study in the literature to compare Baska mask, a novel supraglottic airway device, to I-gel. The primary outcome of our study was insertion duration. Insertion duration of Baska mask was found to be longer compared to I-gel (61.2 sec vs 20.9 sec). One study comparing the Baska mask and the disposable LMA reveals a longer time for inserting Baska mask (8). Alexiev et al., reported the mean duration of the successful insertion attempt of Baska mask was 23.9 seconds (3). In their study Liew et al., reported the insertion duration of I-gel was 23 sec and Arı et al., found I-gel insertion duration as 21 seconds (2, 4). In our study while the I-gel insertion duration found similar to data reported in previous studies, Baska mask insertion time was found to be relatively longer. The success rate in the first insertion attempt with Baska mask and I-gel were similar in our study. There were a few studies in the literature on Baska mask. In their study, Alexiev et al., (3) reported a success rate of 76.7 % in inserting Baska mask in the first attempt and two other studies reported 73 % and 88 %. (6, 8) In our study, success rate in the first insertion attempt was 40 %. Such a long insertion duration and a low ratio of success rate in the first attempt is attributable to the necessity to position the cuff opening in the glottis due to the specific nature of Baska mask, leading to a potential insertion difficulty to a particular extent. Also, the leaflet structure of non-inflating cuff of Baska Mask that can contact to teeth during insertion might be creating difficulty in the course of oral passage. In a study comparing Baska mask and the conventional LMA, success of inserting Baska mask in the first insertion attempt was found to be lower and the authors suggested that this difference was attributable to fact that optimal approach to sizing of Baska Mask is not clear (8). Various studies on I-gel reveal first-attempt success rates from 54 % to 90 %, respectively (1,2,4,9,10). In our study, it was found as 66.7%. Despite the higher success rate of inserting I-gel in the first attempt, no statistical difference was found between groups.

We were not able to insert SGAD in 3 patients from Baska mask group and one patient from I-gel group, and patients were intubated. While total success rate of inserting Baska mask was 80 %, it was 93.3 % for I-gel. No difference was found between the two groups in terms of insertion success ($p > 0.05$). One study reported a Baska mask insertion success of % 96.7 (3). In our study, it is lower. In their study, Radhika et al. reported I-gel insertion success of 85.7 %, while Das et al reported 100 % success in their study (1,11). The I-gel insertion success in our study is similar to the rates reported in the literature.

Though the presence of a cuff in SGAD seems to be a factor reducing the leak volume, studies on I-gel have shown no increase in leak volume, and there are some other studies even reporting lower leak volume than cuffed SGADs (1,4,12) Likewise, in their study, Alexiev et al., found no difference between Baska mask and conventional LMA in terms of leak volume (8). In our study, Baska mask that have self-inflating cuff was compared to I-gel, uncuffed device, and no difference was found regarding leak volumes. I-gel with its thermoplastic elastomeric structure, adapts to supraglottic area by bending with body temperature and Baska mask with its self-inflating cuff fits the anatomy of the supraglottic area during positive pressure ventilation and create low leak volumes.

There was no difference between Baska mask and I-gel in terms of leak pressures. In a study authors showed that leak pressure in I-gel group is higher compared to the LMA supreme group (1). Mishra et al., found a lower leak pressure in I-gel group compared to Proseal LMA group (9). In another study, a comparison carried out immediately after insertion revealed a higher leak pressure in I-gel group compared to LMA supreme group (13). One comparison between Baska mask and the disposable LMA revealed higher leak pressures in Baska mask group (8). In our study, leak pressure of Baska mask and I-gel were similar (32 ± 2 vs 30 ± 4 cmH_2O); suggesting safety in posive pressure ventilation. In our study, PIP values were found higher at the time of insertion and min 10 in Baska mask group, however all PIP values were lower than leak pressures in both groups. In recent publications it has been reported that the use of I-gel in laparoscopic surgery is safe (14,15). Also in a case report Baska mask was described as a promising alternative to intubation in laparoscopic surgery (16). With high leak pressures of both Baska Mask and I-gel; our findings supports these previous data.

During the follow-up of patients, IPI monitorization as well as standard monitorization was performed. A similar trend of IPI values between the two groups suggests that both SGADs provide sufficient ventilation. In-group evaluations, even though all values obtained were within targeted limits, IPI values were lower than basal values in all perioperative period in Baska Mask group and perioperative 10^{th} min, 20^{th} min, 30^{th}min in I-gel group. Since IPI algorithm combines different vital parameters, this decrease in IPI values during perioperative period can be attributable to combination of minimal changes in SO_2, CO_2 and HR values. This is the first study evaluating IPI monitorization in the comparison of SGAD effectively.

In both of the airway devices, gastric tube insertion ease and duration were similar (29.1 ± 43 sec vs 20.5 ± 12.7 sec) While both devices are equipped with ports allowing gastric access, Baska mask has side channels that provides aspiration of the secretions and gastric content that accumulates in the supraglottic area. This is considered to be an advantage of Baska mask, however no significant secretion was aspirated by the suction from supraglottic area during the follow-up of the patients.

Postoperative oropharyngeal trauma and postoperative complications are likely to develop after SGAD use. In our study, there was no difference in complications such as oropharyngeal injury, laryngospasm, bronchospasm, blood presence in SGAD and nausea between the groups during the postoperative period. When comparing I-gel and LMA Supreme, Beleña et al., showed that frequency of coughing and visible blood after removal of the device were low and comparable; and also there were no differences relating to the incidence of sore throat, dysphagia or hoarseness (17). In their study on the

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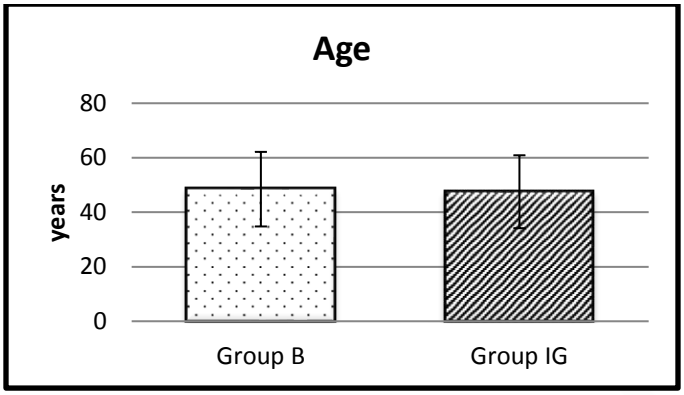
comparison of I-gel and LMA proseal, Chauhan et al., reports less postoperative complications when using I-gel (18). In our study no difference between the two groups in terms of complications is attributable to the fact that both SGADs have no inflatable cuffs.

Limitations of our study are lack of an assessment of the anatomic positions of I-gel and Baska mask by means of fiberoptic bronchoscopy. And the study was not conducted in the patients undergoing a specific type of surgery.

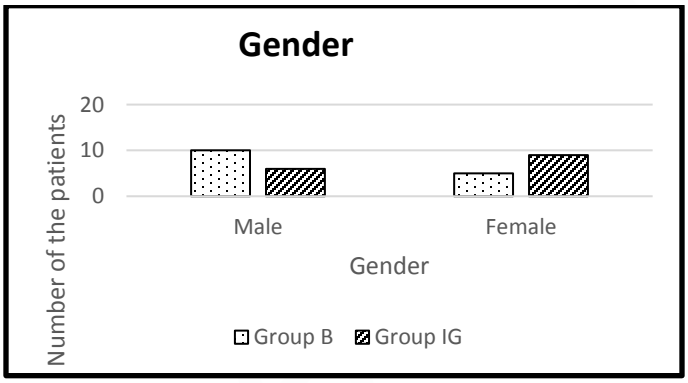
CONCLUSION

Baska mask, even though having a longer insertion time, with a similar leak pressure, similar IPI values during the follow-up and again similar complication rates, may be an alternative to I-gel in positive pressure ventilation.

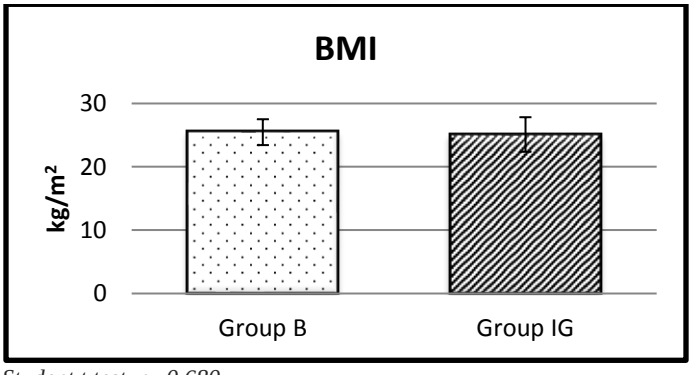
Annexure



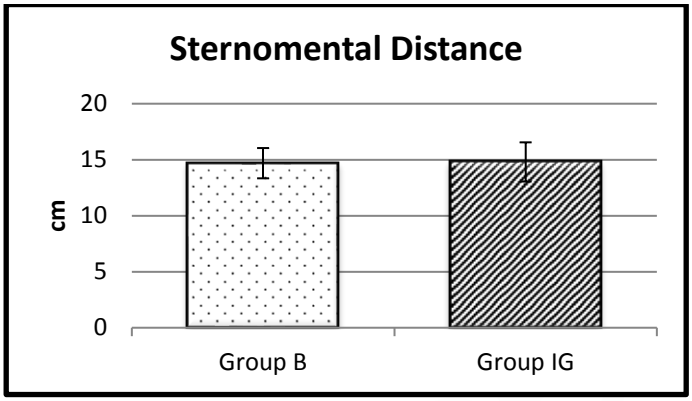
Student t test, p=0,852



Continuity (Yates) correction, p=0,272



Student t test, p=0.680



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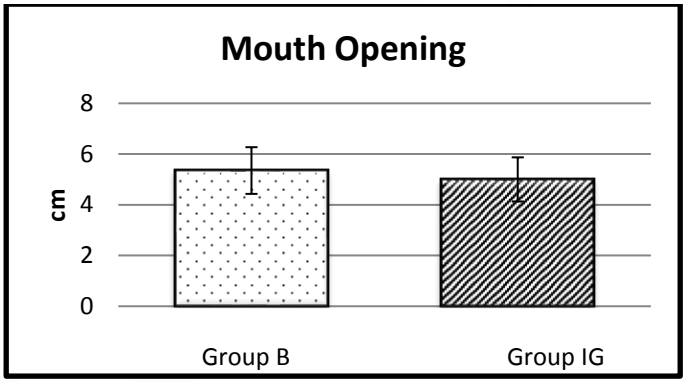
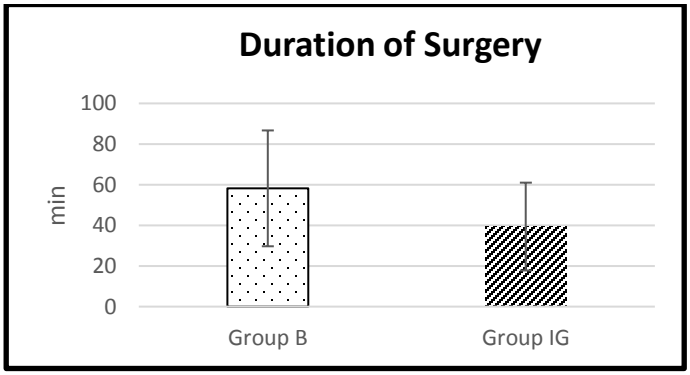
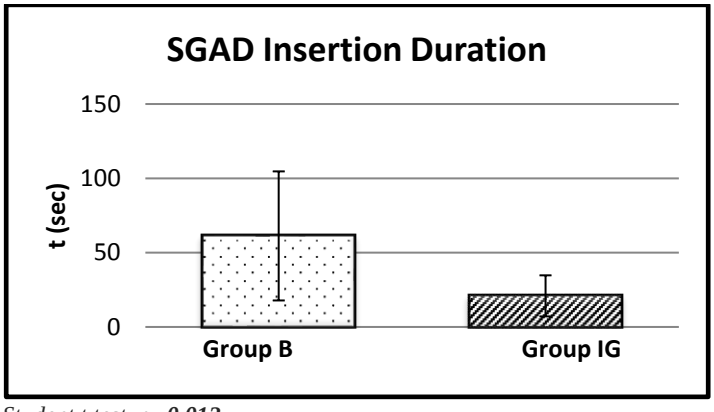


Student t test, p=0,296



Student t test, p=0,068



*Student t test, p=**0,012***

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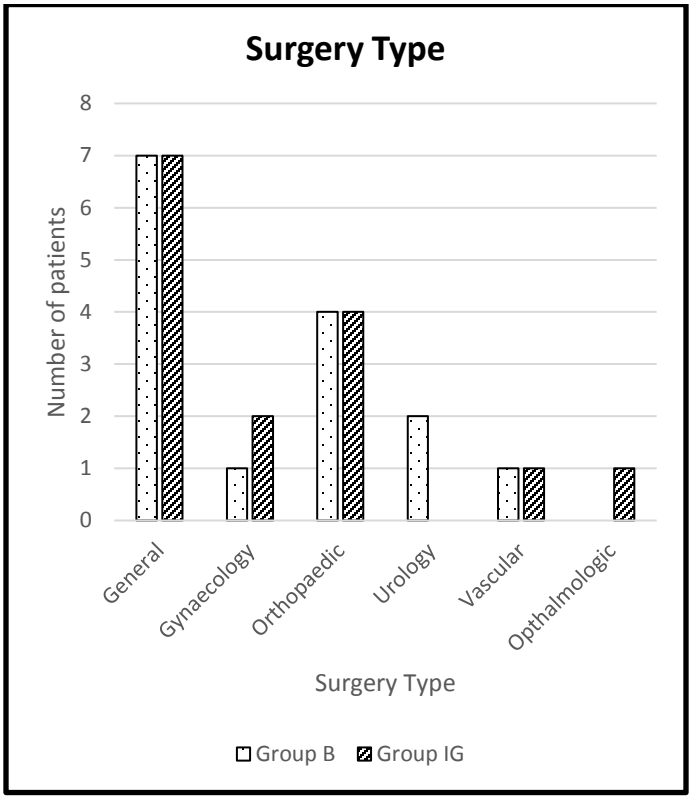
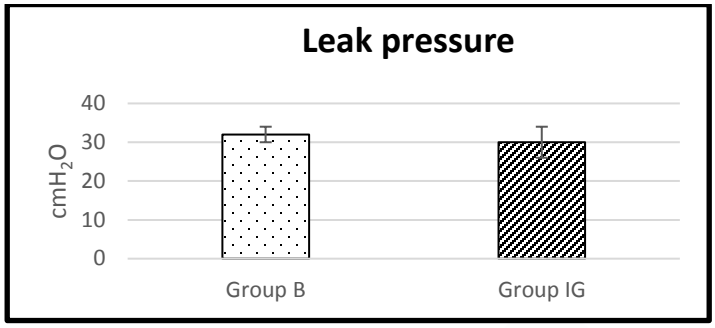
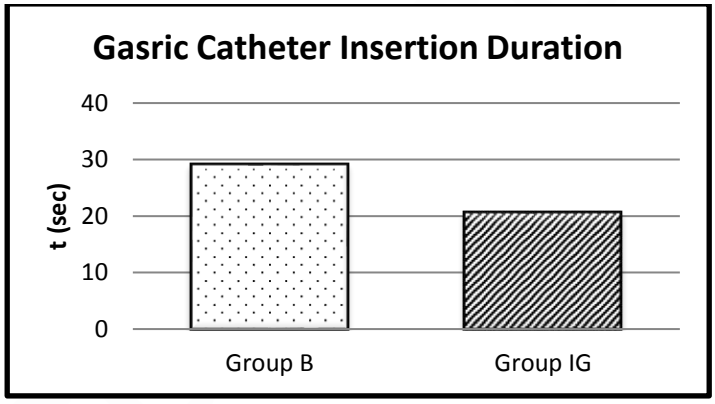


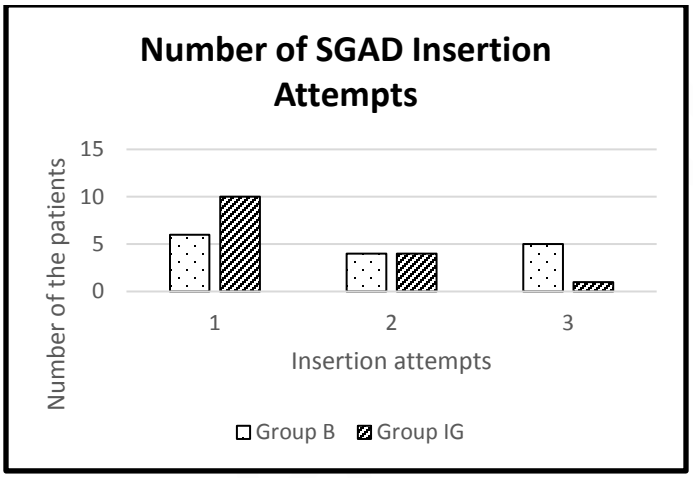
Fisher's exact test, p=0,849



Mann Whitney U test, p=0,252



Student t test, p=0,252



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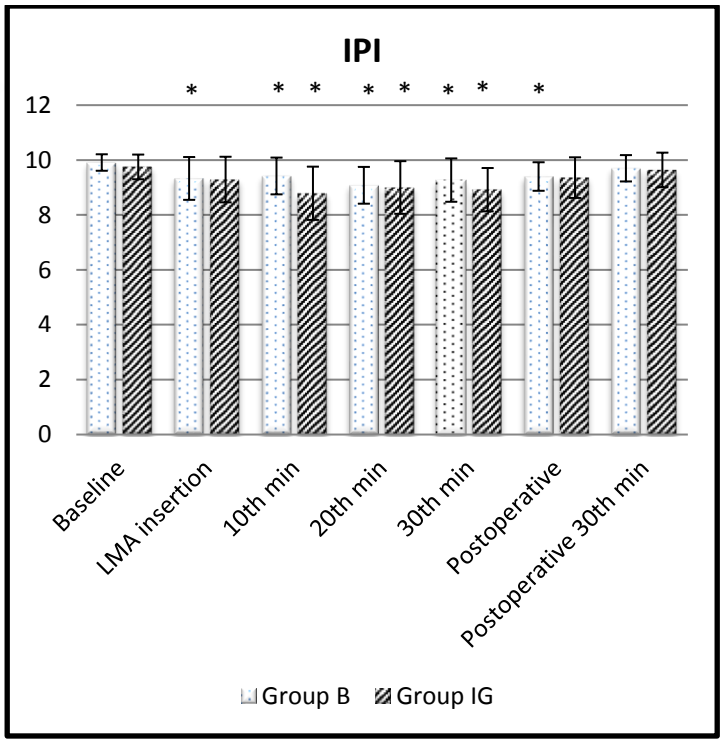
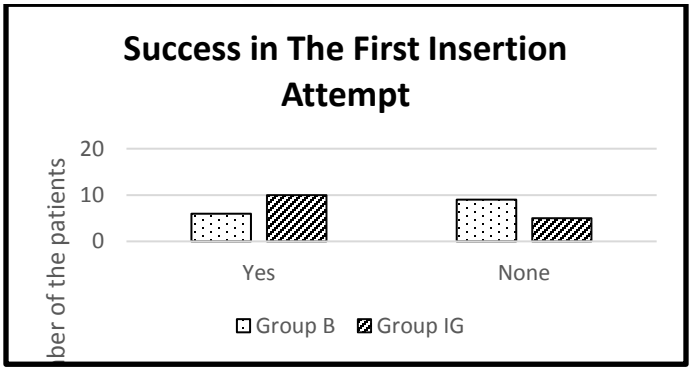


*Mann Whitney U Test, *p<0,05 in-group evaluations, Wilcoxon Sign Test*



Continuity (Yates) correction, p=0.272

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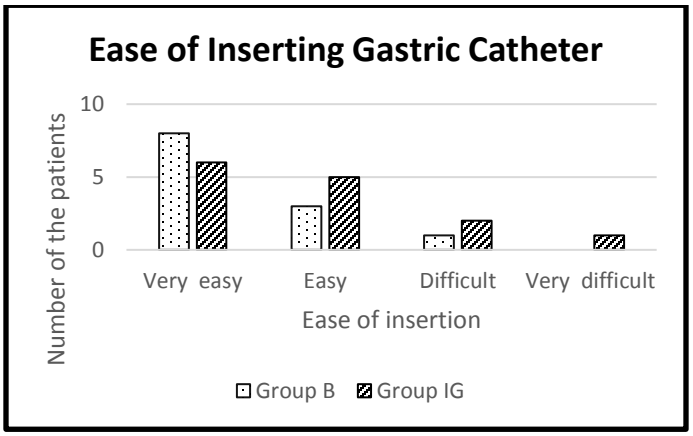

Mann Whitney U Test, p=0,252

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Author Contributions
Süheyla Abitağaoğlu: Study conception and design, acquisition of data, analysis and interpretation of data, drafting of manuscript.
Ceren Köksal: Acquisition of data, drafting of manuscript.
Güldem Turan: Study conception and design, analysis and interpretation of data, critical revision.
Arzu Yıldırım Ar: Acquisition of data, analysis and interpretation of data.
Fatma Nur Akgün: Study conception and design, drafting of manuscript
Dilek Erdoğan Arı: Analysis and interpretation of data, critical revision, language.

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List of Abbreviations
BIS: Bispectral index
Group B: Group Baska mask
Group IG: Group I-gel
HR: Heart rate
IPI: Integrated pulmonary index
MAP: Mean arterial pressure
SGAD: Supraglottic airway device
SpO_2: Oxygen saturation

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