Comparison of new generation baska mask with i-gel and classical laryngeal mask in outpatient urological interventions

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ABSTRACT

الأهداف: لمقارنة الأداء السريري لقناع الباسكا، وآي جل والقناع الحنجري لمجرى الهواء الكلاسيكي (cLMA) في المرضى البالغين الذين يخضعون لعلاج المجاري البولية بالعيادات الخارجية.

الطريقة: تم تسجيل 150 مريضًا ضمن التصنيف I–III للحالة الصحية للجمعية الأمريكية للتخدير خلال الفترة من يناير 2017م وسبتمبر 2017م في مستشفى يوكسيك احتيساس للتعليم والأبحاث، أنقرة، تركيا لإجراء جراحة المسالك البولية الاختيارية لهذه التجربة العشوائية المضبوطة ذات الشواهد. كان هناك 50 مريضا في كل مجموعة من المجموعات التالية: قناع الباسكا®، آي جل، و cLMA. في كل مجموعة، تم تقييم أوقات الإدراج، وأوقات التهوية، ومعدلات النجاح «المحاولة الأولى»، ومضاعفات ديناميات مجرى الهواء والمتغيرات الدورة الدموية.

النتائج: لم يلاحظ أي قيم ذات دلالة إحصائية في متوسط البيانات الديموغرافية، وديناميات مجرى الهواء، والمضاعفات، ومتغيرات الدورة الدموية. كانت أوقات الإدراج والتهوية مختلفة بين المجموعات (p<0.001 لكل منهما). في مجموعة cLMA، وجد أن أوقات الإدخال والتهوية أقصر من المجموعات الأخرى (أوقات الإدراج 5.78±1.72 ثانية ومرات التهوية 11.72±4.72 ثانية). وقد لوحظت أطول فترات للتهوية والإدخال في قناع البسكا مع 12.04±6.25 و 21.26±8.53 ثانية. كانت معدلات نجاح "المحاولة الأولى" 98% بالنسبة لـ cLMA، و92% للآي جل، و 88% بالنسبة لقناع باسكا. كانت متطلبات المناورة الإضافية في مجموعة قناع باسكا 20% (10/40).

الخاتمة: عند مقارنة آي جل، و cLMA، و قناع الباسكا فيما يتعلق بأوقات الإدراج والتهوية، ومعدلات نجاح المحاولة الأولى، والمناورات الإضافية، يعد cLMA و آي جل® متفوق على قناع الباسكا® في الحالات الجراحية الإسعافية للمسالك البولية.

Objectives: To compare the clinical performance of the baska mask (PTY Ltd, Australia), i-gel (Intersurgical Ltd, UK) and classic laryngeal mask airway (cLMA) in adult patients undergoing outpatient urologic interventions.

Methods: One hundred fifty patients with American Society of Anesthesiologists I-III physical status were enrolled between January 2017 and September 2017 in Yuksek Ihtisas Research and Educational Hospital, Ankara, Turkey for elective urological surgery for this prospective randomized controlled trial. There were 50 patients in each of the following groups: baska mask, i-gel, and cLMA. In each group, the insertion times, ventilation times, 'first attempt' success rates, airway dynamics-complications and hemodynamic variables were evaluated.

Results: No statistically significant values were observed in means of demographic data, airway dynamics, complications, and hemodynamic variables. Insertion and ventilation times were different between groups (p<0.001 for each). In cLMA group, insertion and ventilation times were found to be shorter than others (insertion times 5.78±1.72 seconds and ventilation times 11.72±4.72 seconds). The longest insertion and ventilation times were observed in baska mask with 12.04±6.25 and 21.26±8.53 seconds. The 'first attempt' success rates were 98% for cLMA, 92% for i-gel, and 88% for baska mask. The addition maneuvering requirements in baska mask group was 20% (40/10).

Conclusion: When cLMA, i-gel and baska mask are compared regarding insertion and ventilating times, first attempt success rates, and additional maneuvers, cLMA and i-gel are superior to baska mask in urological ambulatory surgical cases.

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Extraglottic airway management, which started with the introduction of the classical laryngeal mask (cLMA) in clinical practice, has been a great innovation for anesthesia. Since the first-generation supraglottic airway devices (SADs) were introduced, new features for increasing the safety of patients have been incorporated; most notably, gastric drainage has been attempted to prevent aspiration. In addition to increase the safety of SADs, researchers have attempted to minimize device-related complications. For this purpose, non-inflatable cuffs have replaced inflatable cuffs that may cause damage to the oropharyngeal tissues. A second generation device, i-gel (Intersurgical Ltd, UK), has a non-inflatable head structure that features thermoplastic elastomer. With its soft gel-like head structure and gastric drainage pipe, the i-gel was introduced to clinical use in 2007.[1] Baska mask (PTY Ltd, Australia) is a novel SAD designed by Australian anesthetist Kanag and Baska. Its non-inflatable silicone cuff which takes shape of the airway by positive pressure ventilation, prevents oropharyngeal tissue, and nerve damage.[2]

The objective of this study was to compare the clinical performance in outpatient urologic surgery of the last-generation baska mask with the seconds generation i-gel, and first-generation cLMA. We compared 3 different generation SADs for insertion and ventilation times, the 'first attempt' success rates, the additional maneuvering requirements, and complications developed after intervention. The secondary objective of the study was to evaluate all 3 SADs for airway pressures and hemodynamic parameters.

Methods. After receiving approval from the ethics committee from Ankara Numune Research and Education Hospital, Ankara, Turkey, Clinical Researchers Ethics Committee, we then obtained a written consent from 150 patients scheduled for elective cystoscopic and transurethral urologic surgery. The study was conducted according to the principles and requirements of the Declaration of Helsinki. The study was conducted between January 2017 and September 2017 in Yuksek Ihtisas Research and Educational Hospital, Ankara, Turkey. Adult (>18 aged) and American Society of Anesthesiologists (ASA) I-III patients were included in this prospective double-blind, randomized, controlled study. Patients who underwent outpatient urological interventions (ureterorenoscopy, transurethral prostatectomy, transurethral tumor resection, cystoscopy and retrograde intrarenal surgeries, varicocele) constituted the study population.

The randomization was provided with the closed envelope method. The following were defined as the exclusion criteria: emergency surgery, body mass index ≥35 kg.m^{-2}, head-neck-airway problems, upper gastrointestinal system problems, pregnancy, risk of aspiration of gastric contents, history of previous difficult intubation, mouth opening less than 2.5cm, and muscle relaxants.

During the preanesthetic visit, independent anesthetist evaluated patients for their demographics, tiromental and strenomental distances, interincisor distance, and Mallampati score. Using manufacturer recommendations, the size of the SAD was determined based on ideal weight. Then the body of the SAD was lubricated with a water-based gel. Fitting to the airway in the first trial was assessed as the 'first attempt success rate'. Insertion time was measured with a chronometer. After the patient was positioned and the SAD handled, the chronometer was started. As soon as the SAD was correctly inserted into the oropharynx, the chronometer was stopped. 'Ventilation time' was accepted as the duration between the beginning time of SAD insertion and the time when end-tidal carbon dioxide plateaued. These factors were defined for successful insertion: bilateral chest raising, a satisfactory plateau end-tidal carbon dioxide pressure, and percentage of low leakage heard. When effective ventilation could not be achieved, SADs were subjected to manipulations such as pushing, rotating, or gently pulling to increase the depth of the device. These maneuvers were recorded as additional manipulation requirements. The patients with whom 3 attempts failed were excluded from the study. We recorded the number of the properly inserted SADs and the manipulation required for each. The interventions were performed by 2 researchers, who have performed at least 50 insertions for MA, i-gel, and baska mask. Peak airway pressure and plateau airway pressures were recorded every 10 minutes from the beginning of anesthesia for 90 minutes.

Before planning this study, we conducted a standard search for prior related research in PubMed, clinical trials registers, conference proceedings, and the reference lists of retrieved articles.

Perioperative anesthesia and airway management. Non-invasive blood pressure, electrocardiogram, pulse

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oximeter, and end-tidal carbon dioxide monitoring were included in the standard general anesthesia monitoring for all patients. Patients were placed in the supine position with neutral head position with a pad of about 8-10 cm in thickness under the head. Following preoxygenation for 3 minutes, anesthesia was initiated with lidocaine 40 mg, propofol 2-4 mg kg^{-1}, and fentanyl 2 μg kg^{-1}. The lungs were ventilated by a face mask and oral airway was inserted, if deemed necessary. While the patient was manually ventilated with the mixture of 2% sevoflurane and oxygen, the jaw was allowed to loosen. When needed, additional propofol of 0.5 mg kg^{-1} was administered. No muscle relaxant was used. Following sufficient sedation, SAD was inserted by pushing with the index finger or the erotation technique recommended by the manufacturer for the product being used. Inflatable cuff of cLMA was inflated with air. Anesthesia was maintained with 1-1.5 minimum alveolar concentration sevoflurane in 3 liters oxygen/air mixture. The anesthesia machine was set to 6 ml kg^{-1} tidal volume, 10-14 breaths min^{-1} (this was carried out so that the end tidal CO_2 would be 35-40 mmHg). The maximum allowed airway pressure was 35 mmHg. At the end of the surgical procedure, anesthetics were stopped, adequate spontaneous breathing was observed, and SAD was removed. Anesthesia duration was recorded. Bloodstain examination was performed on the mask when SAD was removed.

In the postoperative recovery unit 2 hours after the operation, patients were examined for tongue, lip, palate, and tooth injuries, sore throat, dysphagia, hoarseness, desaturation, laryngospasm, and regurgitation/aspiration complications.

Statistical analysis. Normality of the variables were analyzed with visual (histogram and probability graphs) and analytical (Kolmogorov-Smirnov/Shapiro-Wilk tests) methods. Descriptive statistics are expressed as mean±standard deviation for continuous statistics and number (percentage) for categorical variables. Differences between the 3 defined groups were compared using Chi-square test for the nominal variables and Kruskal-Wallis test for the non-normally distributed variables and ordinal variables. Comparisons of 2 groups were made using Chi-square and Mann-Whitney U test and were assessed using Bonferroni correction ($p<0.017$). Total type-1 error level was used as 5% for statistical significance. The power of study according to the 'insertion time' parameter was determined. Three groups were compared in the sample size study. It was found that when effect size was considered as moderate (Cohen f=0.25), 80% power would be obtained by including 128 patients in the study (α=0.05) (G.Power version 3.15, Germany). After this preliminary analysis, it was decided to include a total of 150 patients in the study, with 50 patients in each group. Statistical analysis was performed using Statistical Package for Social Sciences, version 15 (SPSS Inc, Chicago, USA).

Results. A total of 150 patients were included in the study. Demographics and airway characteristics are given in **Table 1**. Many parameters were similarly distributed between the 3 groups as a success of the randomization. Insertion times and ventilation times of the cLMA, i-gel, and baska mask were different in the 3 groups (**Figure 1, Table 2**). Both insertion and ventilation times of cLMA were shorter than the others (5.78±1.72 secondsonds and 11.72±4.72 secondsonds). Insertion and ventilation times were 7.28±2.66 secondsonds and 15.38±6.7 secondsonds in the i-gel group. The longest insertion and ventilation times with the baska mask were 12.04±6.25 secondsonds and 21.26±8.53 secondsonds.

The rates of first attempt success for SAD insertion were 98% (49/1) for cLMA, 92% (46/4) for i-gel, and 88% (44/6) for baska mask (p=0.155, **Figure 2**). The rates of additional maneuvering requirements such as

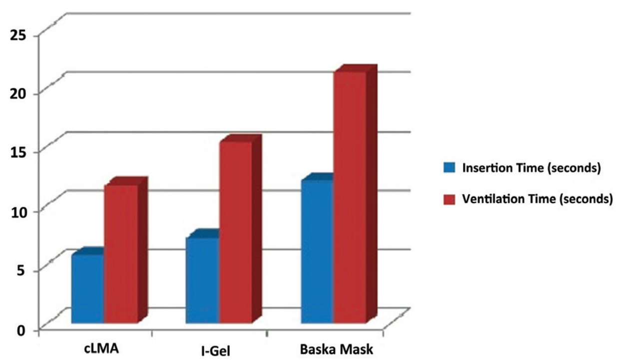

Figure 1 - Insertion versus ventilation time of all the airway devices.

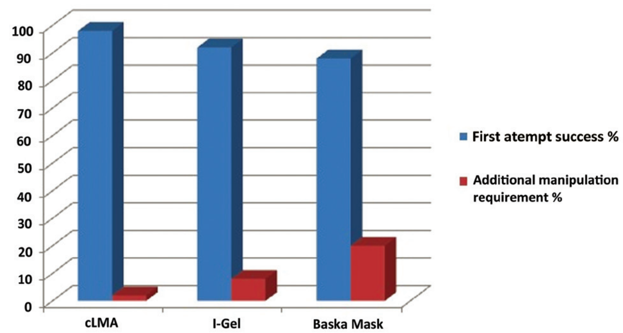

Figure 2 - The first attempt success versus manipulation requirements in of all the airway devices.

Table 1 - Demographic data, and airway characteristics (N=150).

Parameters	cLMA (n=50)	I-Gel (n=50)	Baska mask (n=50)	*P*-value
Age (years)	57.24±14.43	54.34±15.95	48.60±17.62	0.034
Gender (F/M)	13/37 (26/74)	13/37 (26/74)	13/37 (26/74)	1.000
ASA				
1	11 (22)	23 (46)	29 (58)	
2	35 (70)	24 (48)	21 (42)	0.072
3	4 (8)	3 (6)	0	
Body mass index	26.58±4.35	27.53±3.84	26.79±4.17	0.380
Smoking	18 (36)	15 (30)	11 (22)	0.368
Hypertension	15 (30)	9 (18)	12 (24)	0.307
Diabetes	13 (26)	10 (20)	5 (10)	0.118
Chronic obstructive pulmonary disease	6 (12)	4 (8)	3 (6)	0.557
Coronary disease	9 (18)	7 (14)	6 (12)	0.690
Mallampati scores				
I	28 (56)	34 (68)	37 (74)	
II	19 (38)	16 (32)	13 (26)	0.107
III	3 (6)	0	0	
Tiromental distance (cm)	7.04±1.31	6.82±1.19	6.80±0.99	0.323
Sternomental distance (cm)	13.48±1.74	13.49±1.76	13.49±1.43	0.985
Interincisor distance (cm)	4,.2±1.32	4.47±1.43	4.63±1.29	1.000

Values as presented as number and percentage (%). ASA - American Society of Anesthesiologists, F/M - female/male, cLMA - classical laryngeal mask

Table 2 - Parameters, regarded airway devices attempt, and airway related complications.

Parameters	cLMA (n=50)	I-Gel (n=50)	Baska mask (n=50)	*P*-values
First attempt success	49/1 (98)	46/4 (92)	44/6 (88)	0.155
Insertion time (seconds)	5.78±1.72	7.28±2.66	12.04±6.25	cLMA-IGel p=0.001 cLMA-Bska p<0.001 IGel-Bska p<0.001
Ventilation time (seconds)	11.72±4.72	15.38±6.7	21.26±8.53	cLMA-IGel p<0.001 cLMA-Bska p<0.001 IGel-Bska p<0.001
Additional manipulation requirement	1 (2)	4 (8)	10 (20)	cLMA-Iel p=0.169 cLMA-Bska p=0.004 IGel-Bska p=0.084
Bloodstain of the mask	3 (6)	3 (6)	3 (6)	1.000
Dysphagia				
No	45 (90)	46 (92)	48 (96)	
Mild	1 (2)	2 (4)	1 (2)	0.491
Yes	4 (8)	2 (4)	1 (2)	
Tongue injury	1 (2)	1 (2)	0	0.602
Lips injury	0	1 (2)	0	0.365
Teeth injury	0	1 (2)	0	0.365
Palate injury	0	1 (2)	1 (2)	0.551
Sore throat				
No	46 (92)	45 (90)	46 (92)	
Mild	1 (2)	3 (6)	3 (6)	0.924
Yes	3 (6)	2 (4)	1 (2)	
Hoarseness-desaturation laryngospasm regurgitation/aspiration	0	0	0	-

Values are presented as number and percentage (%). cLMA - classical laryngeal mask rotation, pushing forward, and pulling back during insertion were 2% (49/1) for cLMA, 8% (46/4) for i-gel, and 20% (40/10) for baska mask (cLMA-i-gel, *p*=0.169; cLMA-Bska, *p*=0.004; i-gel-Bska, *p*=0.084) (**Figure 2, Table 2**).

No significant difference was found between the groups in terms of bloodstain on the mask, dysphagia, tongue-lips-teeth-palate injuries, sore throat, hoarseness, desaturation, laryngospasm, and regurgitation/ aspiration complications (**Table 2**). No statistically significant difference was found between the groups with the airway pressures and hemodynamic parameters (*p*>0,05) (**Table 3**). Airway pressures of cLMA, i-gel, and baska mask groups are given in **Figure 3**.

Discussion. Baska Mask, which is a novel SAD, was compared with I-Gel and cLMA in patients undergoing elective outpatient urologic surgery. We compared the first attempt success rates, insertion and ventilation times, additional manipulation requirements, and complications of 3 different generation SADs. Significantly, we found that the classical LMA patient group had the shortest insertion and ventilation times.

When inserting classical LMA, the cuff is not completely deflated and it is inserted with the cuff slightly inflated. This eliminates extra cuff inflation requirement and shortens insertion time. In this study, we found insertion and ventilation times were significantly shorter in the i-gel group compared to the baska mask group. There are studies in the literature that argue that insertion and ventilation times of I-Gel are shorter compared to classical LMA. Ari et al[3] reported the insertion time as 21.0 seconds for I-Gel and 30.4 seconds for cLMA. Whereas, Pratheeba at al[4] reported these times as 15.92 seconds for i-gel and 26.06 seconds for cLMA. These studies used different definitions for insertion time and ventilation time, but both studies argued that i-gel was inserted faster. Whereas, in our

Table 3 - Intraoperative variables of hemodynamic parameters in all airway devices.

Minutes	SAP (i-gel)	DAP (i-gel)	HR (i-gel)	SAP (cLMA)	DAP (cLMA)	HR (cLMA)	SAP (baska mask)	DAP (baska mask)	HR (baska mask)
0 min	108.1±19.0	62.2±13,5	70.9±14.5	110.0±23.0	62.6±13.3	68.7±11.4	112.9±19.2	64.8±12.8	69.0±12.0
10 min	100.0±14.1	56.7±9.9	69.7±13.4	102.3±14.4	59.9±10.3	66.9±12.7	104.9±16.6	60.8±12.1	68.6±12.0
20 min	104.3±15.3	58.6±12.4	68.0±13.7	109.3±20.3	62.6±12.7	66.7±12.8	107.2±17.3	60.5±10.8	66.0±11.6
30 min	102.±19.2	58.2±15.8	70.4±15.0	109.9±16.6	62.9±13.9	68.9±12.4	102.9±16.2	59.0±14.0	66.4±11.0
40 min	101.5±17.8	57.4±12.9	69.6±12.7	107.1±13.9	61.7±10.7	68.4±13.4	102.5±14.1	59.2±12.0	66.8±13.7
50 min	105.2±19.0	59.6±14.0	64.1±10.4	108.3±14.3	62.2±9.4	66.3±10.6	107.2±15.2	60.3±10.1	67.3±15.0
60 min	102.8±20.7	57.3±14.7	64.8±11.7	107.1±15.7	65.2±6.6	72.8±13.0	100.0±13.0	55.9±9.8	68.8±14.5
70 min	105.6±20.0	59.1±18.7	67.0±8.9	106.0±13.4	65.2±5.9	75.2±13.6	98.6±11.6	56.5±8.7	71.4±16.3
80 min	112.8±16.2	64.0±14.0	69.6±9.8	108.5±11.7	64.8±6.7	71.5±13.3	106.8±21.8	62.3±14.3	65.0±10.0
90 min	111.0±19.7	66.7±8.4	72.7±6.4	127.0	68.0	61.0	104.5±2.1	82.5±7.8	66.5±3.5

Min - minutes, cLAM - classical laryngeal mask, SAP - systolic arterial pressure, DAP - diastolic arterial pressure, HR - heart rate

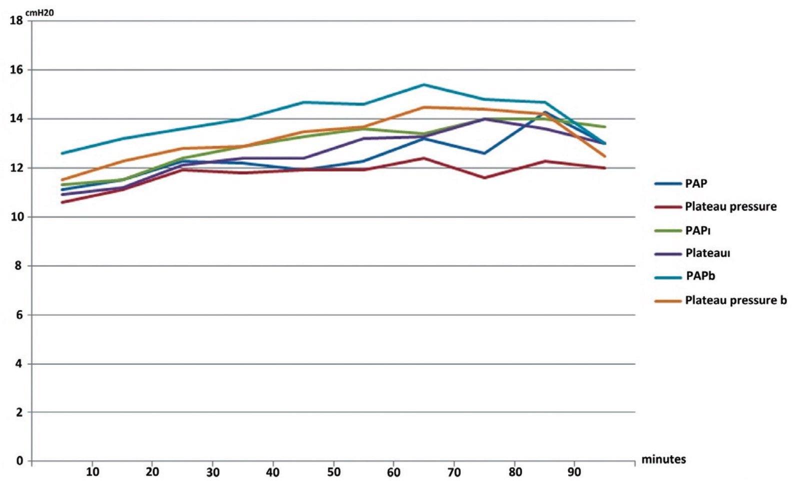

Figure 3 - Peak airway and plateau pressures for classical laryngeal mask, I-gel, and baska mask (PAP - peak airway pressure, PAPı - pear airway pressure for I-gel, Platauı - plateau pressure for I-gel, PAPb - peak airway pressure for baska mask, Plateau b - plateau pressure fro baska mask).

study insertion times were found as 7.28 seconds for i-gel and 5.78 seconds for cLMA. According to these results, all 3 SADs were inserted in a shorter time than in the other studies. Similarly, insertion time of baska mask are also shorter in our study compared with the other studies. We found insertion times 12.04 seconds for baska mask. Other studies found longer baska mask insertion times as 19,6 seconds and 12.33 secondsconds.[2,5] In addition, other studies used different definitions for insertion times.

In our study, cLMA was successfully inserted in the first attempt by 98%, followed by i-gel by 92%, and baska mask by 88%. Although no difference was found between the groups in this respect, success rate at first attempt was higher with cLMA. Conversely, in a study first attempt success rates with Baska Mask were found as 90% when compared to i-gel 83,5 and in an another one for I-gel 92% and for baska mask 88% similar to our study.[2,6] Insertion of baska mask, which has a softer and indented structure, at the first attempt takes time and the success of fitting on the first attempt is decreased. The first attempt success rate for i-gel was 97% according to Park et al.[7] Therefore, both cLMA and I-Gel can be inserted on the first attempt at a high rate of over 90%; however, baska mask lags behind cLMA and i-gel in this respect.

Baska mask has the highest need for additional manipulation at 20%. In the light of these results, it was found that baska mask had significantly longer insertion and ventilation times in clinical practice, lower insertion success at first attempt, and higher additional manipulation requirement. Although these results related to initial parameters are highlighted as disadvantages of baska mask, SAD did not show any difference from the other generation SADs in terms of producing sufficient tidal volume during anesthesia.

In our study, bloodstains were observed in 3 patients (6%) across all 3 groups in the mask examination carried out after removal of SAD at the end of the operation. Furthermore, rates of bloodstain on the mask vary depending on the number of interventions and cuff structure. It is claimed that more blood stains are seen in LMAs with inflatable cuffs due to compression; however, studies[2,6,7] also reported similar rates of bloodstain in SADs with non-inflatable cuff structure. In this regard, we observed no superiority of any of the SADs over the others. Incidence of bloodstain has been reported between 2-6% for I-Gel in the literature.[2,6,7] These rates were found as 12-36% for cLMA[3,8] and 8–18% for baska mask.[1,8] In the literature, the highest rate of bloodstain on the mask is reported with baska mask and this is attributed to the higher requirement of additional maneuvering. In the literature, bloodstain rates were reported between 5-10% for these 3 SADs.[1,2,4,5,7]

Although, no significant differences were found among the groups in terms of dysphagia and sore throat in the postoperative period, severe dysphagia (8%) and severe sore throat (6%) were more common in the cLMA group. Severe dysphagia and severe sore throat were found in 4% and 4% in the i-gel group and in 2% and 2% in the baska mask group. The non-inflated and soft cuff structure of baska mask may have prevented serious complications. When tongue-lips-teeth-palate injuries are evaluated together, these complications were observed in 4 patients in the i-gel group and one patient in each of the other 2 groups. In the study population, none of the patients had hoarseness, desaturation, laryngospasm, and regurgitation/aspiration complications. In a study comparing baska mask and cLMA, these complications were found as 1% for baska bask and 3% for cLMA,[8] whereas, in another study comparing cLMA and i-gel, these complications occurred at 4% for i-gel and 4% for cLMA.[4]

No significant difference was found among the 3 SADs in terms of hemodynamic parameters and airway pressures. Heart rate and systolic and diastolic blood pressures were similar throughout the operation among groups. Oxygen saturation and end-tidal carbon dioxide levels were stable and within the normal range. Peak and plateau airway pressures did not differ in the cLMA, i-gel, and maska Mask groups throughout the operation. Similarly, no significant differences were observed in the studies, comparing baska mask-cLMA and comparing i-gel-cLMA.[4,8]

There are some limitations of the study. First, the leak pressures of SADs were not evaluated, but the primary endpoint was the clinical performance of SADs. Thus, it should be evaluated in further studies. Another limitation were the insertion and ventilation times, first attempt success rate, and addition maneuvering requirements were subjective data, which can vary with the experience of the operator, although we tried to standardize with the same operator .

In conclusion, considering insertion times, ventilation times, first attempt success rates, and additional maneuvering of cLMA, i-gel, and baska mask in outpatient urological surgery, cLMA and i-gel were found to be superior to baska mask. Complications were not different in the 3 airway devices. Our study findings suggest the 3 airway devices are similarly effective in terms of providing sufficient tidal volume and appropriate options for outpatient urological surgery.

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