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Original Article / Özgün Araştırma

Comparison of the Supraglottic Airway Devices Classic, Fastrach and Supreme Laryngeal Mask Airway: A Prospective Randomised Clinical Trial of Efficacy, Safety and Complications

Supraglottik Hava Yolu Aletlerinin; Laringeal Maske Klasik, Fastrach ve Supreme'in; Kullanım Kolaylığı, Güvenlik ve Komplikasyonlar Açısından Karşılaştırılması; Prospektif, Randomize, Klinik Araştırma

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Abstract / Öz

Objective: This prospective randomised study was designed to compare the Laryngeal Mask Airway (LMA) Classic, LMA Fastrach and LMA Supreme regarding ease of insertion and insertion time as primary outcomes and reposition, success rate of trials, effects on haemodynamic parameters, provision of an adequate and safe airway, amount of leakage and oropharyngeal and systemic complications as secondary outcomes.

Methods: In this clinical trial, 90 patients aged 18–70 years of American Society of Anesthesiologists (ASA) group I-II were randomised into three groups as providing airway via LMA Classic, LMA Fastrach or LMA Supreme instead of tracheal intubation. No muscle relaxant was used. The allocated LMA was inserted by the same anaesthetist; bispectral index (BIS) was between 40% and 60%.

Results: There was no statistical difference among the groups regarding the ease of insertion and insertion time as primary outcomes; the incidence of repositioning during placement was significantly higher in the LMA Classic group than that in other groups ($p<0.05$) and the rates of bloodstain on the device as well as oropharyngeal mucosal oedema were higher in the LMA Fastrach group than those in other groups ($p<0.05$) as secondary outcomes.

Conclusion: We suggest that LMA Classic, LMA Supreme and LMA Fastrach had similar effectiveness regarding efficiency and airway safety. However, LMA Supreme seems to be more advantageous as it is more appropriate for fewer oropharyngeal complications and there was no repositioning.

Keywords: Laryngeal masks, airway management, efficacy

Amaç: Prospektif ve randomize olarak yapılan bu çalışmada; birincil olarak yerleştirme kolaylığı ve yerleştirme zamanı, ikincil olarak repozisyon gereksinimi, denemelerdeki başarı oranı, sPO_2, $EtCO_2$ ve hemodinamik parametreler üzerine etkileri, yeterli ve güvenli havayolu sağlayabilme ve orafaringeal ve sistemik komplikasyonları açısından, laringeal maske (LMA) Klasik, LMA Klasik, LMA Fastrach and LMA Supreme'in karşılaştırılması amaçlandı.

Yöntemler: Yaşları 18-70 arasında değişen, American Society of Anesthesiologists (ASA) I-II, doksan hasta randomize olarak 3 gruba ayrılarak havayolu sağlamak için LMA Klasik, LMA Fastrach ve LMA Supreme kullanıldı. Nöromüsküler bloker kullanılmadı. Belirlenen LMA aynı anestezist tarafından bispektral index %40-%60 arasındayken yerleştirildi.

Bulgular: Gruplar arasında birincil sonuç olarak belirlenen yerleştirme kolaylığı ve yerleştirme zamanı açısından istatiksel olarak fark yoktu. İkincil sonuç olarak yerleştirme sırasında repozisyon gerektirme oranı LMA klasik grupta diğer gruplara göre belirgin olarak yüksek ($p<0,05$), alet üzerinde kan lekesi varlığı ve mukozal ödem varlığı LMA Fastrach grubunda diğer gruplara göre yüksekti ($p<0,05$).

Sonuç: LMA Klasik, LMA Fastrach ve LMA Supreme araçlarının tümünün etkinlik ve güvenli havayolu sağlama açısından benzer olduğunu düşünmekteyiz. Fakat LMA Supreme; repozisyon gerekmemesi ve daha az orafaringeal komplikasyona yol açmasından dolayı daha avantajlı görülmektedir.

Anahtar kelimeler: Laringeal maske, havayolu yönetimi, etkinlik

Introduction

As a result of studies regarding the provision of an airway that is less invasive than intubation but safer than mask to maintain the patency of airway after anaesthesia induction in brief surgical interventions, supraglottic airway devices have been introduced into practice (1). They are inserted into glottic entry via the oral route and can be used in emergency conditions when tracheal intubation and mask anaesthesia are challenging (1).

Classic Laryngeal Mask Airway (LMA) was first introduced by Archie Brain, MD, in 1988; it consists of a mask with a surrounding inflatable bag compatible with the shape of the hypopharynx and a tube that has a 30° angle with a mask (2, 3).

Fastrach LMA (LMA Fastrach: LMA; North America. Inc., San Diego, CA) was first introduced in 1997 and has features similar to the LMA Classic, but it is designed to provide a secure upper airway during intubation via blind intubation or

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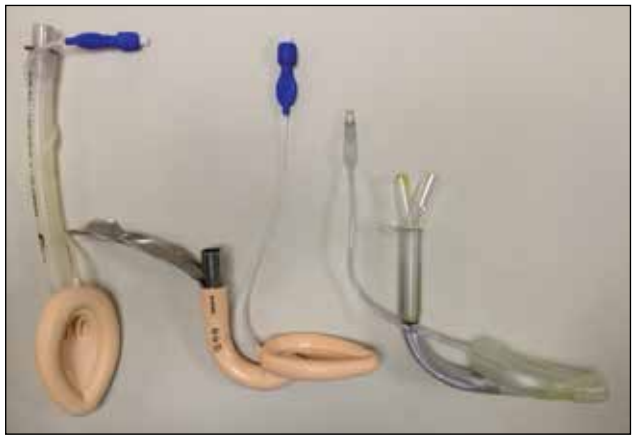

Figure 1. LMA Classic (# 5), LMA Fastrach (# 4) and LMA Supreme (# 5)

fiberoptic assistance (4, 5). It has a rigid handle that allows one-handed insertion, removal or adjustment (Figure 1).

Supreme LMA, first introduced in April 2007, is a novel, sterile, single use, new generation supraglottic airway device that provides more rapid and higher volume gas passage through the airway and can be inserted in a rapid and safe manner because of the advanced cuff and airway tube design (Figure 1). The integrated gastric canal facilitates gastric aspiration (6, 7).

Supraglottic airway devices seem to have more advantages than other devices in different aspects owing to their distinct features. In the literature, there are studies comparing various types of LMA devices for different features. However, to the best of our knowledge, there is no study comparing the three above-mentioned types of LMA regarding these parameters (7, 8). This is the main difference of our study from the studies in the literature.

This study aimed to compare the advantages and disadvantages of LMA Supreme, LMA Classic and LMA Fastrach regarding ease of insertion, repositioning, insertion time, effects on haemodynamic parameters, provision of adequate and safe airway and oropharyngeal and systemic complications.

Methods

This was a single centre, randomised and prospective study conducted at the Anaesthesia Clinic of the Ümraniye Training and Research Hospital in Istanbul. Ninety patients aged 18-70 years with ASA physical status I-II who were scheduled for brief elective surgical interventions, were recruited into the study after obtaining the approval of the local Ethics Committee of the Ümraniye Training and Research Hospital and after obtaining informed consent from the patients.

Normotensive patients with mouth opening of >3 cm, thyromental distance of >6 cm, sternomental distance of >12.5 cm and body mass index of <35 kg m^{-2} were included in the study.

Patients with ASA III-IV; those with a history of gastroesophageal reflux, pregnancy, cardiovascular and central nervous system diseases; those with difficulty in cooperation and those undergoing intracranial, intra-abdominal and ear-nose-throat surgeries were excluded from the study. None of the methods changed after the commencement of the study.

Randomisation was performed by simple randomisation procedures using computer-generated random numbers. Patients were assigned to one of the three groups according to the LMA type used with 1:1:1 allocation using a group size of 30 patients. Preparation of random numbers list, assigning random number list to groups, insertion of LMA and evaluation of complications were undertaken by different persons.

The patients arriving in the operating room were placed in the supine position and monitored by electrocardiography (ECG; standard DII lead by Datex Ohmeda), mean arterial pressure (MAP), heart rate (HR), oxygen saturation (SpO_2) and bispectral index (BIS; vista medical systems) by an electrode placed on the forehead.

Premedication (0.03 mg kg^{-1} IV midazolam) was administered to all patients at 5-10 min before induction, which was achieved using 1.5 μg kg^{-1} IV fentanyl and 1-2 mg kg^{-1} IV propofol. Anaesthesia was maintained using 1%-2% sevoflurane and 50%-50% mixture of O_2 air with a fresh gas flow of 5 L min^{-1}. No muscle relaxant was used.

The appropriate deflated LMA was placed when values between 40% and 60% were seen on the BIS monitor. The same anaesthetist performed LMA placement. The manufacturer's recommendations were followed based on the body weight of the patients for the selection of the tool size.

After achieving adequate airway, cuffs were inflated to pressure levels that allowed minimum air leakage. Ease of insertion was rated using a 4-point scale (4: success at the first attempt without tactile resistance, 3: success at the first attempt with tactile resistance, 2: success at the second attempt, 1: failure at the second attempt). Time to successful insertion and effective airway was defined as the time to observation of three consecutive correct end-tidal CO_2 ($EtCO_2$) waves after insertion and was recorded.

If the inserted device failed to provide adequate ventilation, the device position was changed within the oral cavity; this was then defined as repositioning. If adequate ventilation was not provided despite repositioning, the device was removed from the mouth and changed with the different sizes of the device. This was defined as the success rate of trials and was recorded. If the second attempt to place the device failed (i.e. removal of the device from the mouth), these patients were intubated and excluded from the study. Other parameters assessed included demographic data, $EtCO_2$, amount of leakage [difference between inspiration tidal volume (VTI) and expiration tidal volume (VTE)] and oropharyngeal and systemic complications.

Measurements were taken at the following time points: T1=before premedication, T2=before induction, T3=after induction, T4=insertion, T5=1 min after insertion, T6=5 min after insertion, T7=10 min after insertion, T8=20 min after insertion, T9=before extubation, T10=1 min after ex-

tubation, T11=5 min after extubation. An otolaryngologist who was blinded to the group assignment examined the patients preoperatively (baseline) and at 12 h postoperatively for complications.

After the completion of surgery, devices were removed when the patients achieved adequate spontaneous ventilation and were able to open his/her mouth on verbal command. No intraoral aspiration was performed during extubation; the presence of blood spots on the cuff was recorded. Complications were recorded during perioperative and postoperative periods.

Different persons performed the insertion of LMA and evaluation of complications. However, as the device can be seen in the mouth, it has no importance whether or not the same clinician who inserted the device performed perioperative measurements.

Statistical analysis

A pilot study was conducted to determine the sample size. In the power analysis, according to the results of this pilot study assessing insertion times, a sample size of 30 patients in each group was calculated to be sufficient to achieve 80% power and an α value of 0.05 by taking a delta value of 3.5 and a standard deviation of 4.8 into consideration. Number Cruncher Statistical System 2007, (NCSS; Utah, USA) software was used for statistical analysis. Descriptive statistics (mean, standard deviation and frequency) were used in the study. One-way ANOVA was used to compare normally distributed parameters among groups. Tukey HDS test was used to identify the source of the difference. To compare quantitative data, chi-square test was used. The results were expressed in 95% confidence interval. A value of $p<0.05$ was considered to be statistically significant.

Results

A total of 90 patients were evaluated in the study. There were no exclusions from the study. The demographic characteristics were similar among the groups (Table 1).

Heart rate values after induction during and after 5 min of insertion were found to be significantly higher in the LMA Fastrach group than those in the LMA Classic group ($p<0.05$), whereas HR values after 10 and 20 min of insertion and before and after 1 min of extubation were significantly lower in the LMA Classic group than those in the Fastrach and Supreme groups ($p<0.01$; Figure 2).

Men arterial pressure, SpO_2 and $EtCO_2$ values were within the normal range in all patients, although significant differences were observed among the groups in some measurements of SpO_2 (only after extubation; $p<0.01$) and $EtCO_2$ values (after 1, 5, 10 and 20 min of insertion; $p<0.05$).

No statistical difference was observed among the LMA Classic, LMA Fastrach and LMA Supreme groups regarding the number of trials, ease of insertion (there was no failure during the second attempt in all the three groups, thereby there was no scoring of 1 point; p=0.294), insertion time (p=0.206) and number of times a particular device size was used (#4 and #5 were more common for all devices; p>0.05; Table 2, 3).

Table 1. Patient demographics

(n=90)		Classic Mean±SD	Fastrach Mean±SD	Supreme Mean±SD	p
Age (year)		44.60±13.79	46.17±14.81	49.30±17.28	0.486
Height (cm)		171.43±8.45	169.47±8.93	169.63±10.10	0.657
Weight (kg)		75.77±8.05	75.10±7.20	7700±7.70	0.623
BMI (kg m^{-2})		26.00±0.00	26.25±1.50	28.50±4.95	0.647
		n (%)	n (%)	n (%)	
[a]Sex	Female	9 (30)	8 (26.7)	8 (26.7)	0.946
	Male	21 (70)	22 (73.3)	22 (73.3)	
[a]ASA	I	19 (63.3)	18 (60.0)	16 (53.3)	0.725
	II	11 (36.7)	12 (40.0)	14 (46.7)	

One-way ANOVA; achi-square test; n: patient number; ASA: American Society of Anesthesiologists; SD: standard deviation; BMI: body mass index

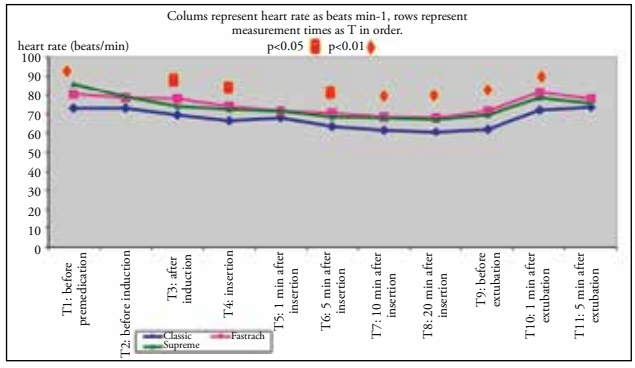

Figure 2. Heart rate variations according to groups (mean)
Heart rate variations according to groups (mean). Columns represent heart rate as beats min–1 and rows represent measurement times as T in order.

The incidence of repositioning was significantly higher in the LMA Classic group than that in the LMA Fastrach and LMA Supreme groups (Table 3).

There was no significant difference among the groups regarding the amount of leakage. The minimum and maximum values can be seen in Table 4.

Among the oropharyngeal complications, there was a significant difference among the groups regarding the presence of bloodstain on the device. The rate of bloodstain on the device was 63.6% (n=7) and the rate of mucosal oedema was 60% (n=9) in the LMA Fastrach group that were higher than those in the other groups ($p<0.05$; Table 5).

There was no significant difference between the groups regarding sore throat, dysphagia, hoarseness and voice alteration (Table 5).

When systemic complications were considered, no significant difference was seen in slight desaturation, cough and hiccup among the groups. No systemic complications such as laryngospasm, bronchospasm, hypercapnia, vomiting or aspiration were observed (Table 5).

Discussion

In the present study, in which the clinical effects of three different types of LMA were compared, it was found that LMA Classic and LMA Supreme were more advantageous than LMA Fastrach because of the presence of blood spots on the cuff and lack of mucosal oedema.

In this study, the more common use of LMA number #5 in all the groups was attributed to demographic characteristics (Table 1).

One of the most important components of haemodynamic response to intubation is elevation in blood pressure and HR, which is considered to be an undesirable event (9).

In previous studies, it has been reported that Classical, Fastrach and Supreme LMAs do not cause marked variation in MAP and HR when compared against each other or with endotracheal intubation (7, 8, 10-14).

At some measurement points, HR values were significantly lower in the LMA Classic group than in other groups of this study. The smaller extent of elevation in HR in LMA Classic can be explained by a lesser degree of stimulation in the receptors at the base of the tongue and pharynx resulting from the more elastic structure of the LMA Classic. All measured values were statistically significant, but these values that were in the normal range had no clinical significance (min: 60.53±8.21; max: 86.10±2.22).

In previous studies, SpO_2 and $EtCO_2$ values were found to be within the normal range in patients for whom LMA Classic was used (14, 15).

In this study, when $EtCO_2$ distribution graphic was assessed, it was seen that baseline values remained within normal ranges by decreasing during surgery and became closer to baseline values at the end of surgery by increasing at the same rate. The effects of Classic Supreme and Fastrach LMAs on oxygenation and $EtCO_2$ were found to be similar; hence, this result facilitated the interpretation that all the three devices are safe and effective in providing an airway.

The airway is considered safe and effective when a tidal volume (TV) of 6 mL kg^{-1} and peak airway pressure of 15 cm H_2O are provided as well as when normal square-shaped $EtCO_2$ traces

Table 2. Insertion time

	Insertion time (s)		
	Min-Max	Mean±SD	p
Classic	18–44	27.10±7.09	0.206
Fastrach	20–47	28.83±7.10	
Supreme	18–46	25.83±5.11	

One-way ANOVA; Min: minimum; Max: maximum; SD: standard deviation

Table 3. Results of assessment of the success rate of trials, LMA numbers and ease of insertion

		Classic n (%)	Fastrach n (%)	Supreme n (%)	p
Success rate of trials	1st attempt	27 (90)	26 (86.7)	29 (96.7)	0.383
	2nd attempt	3 (10)	4 (13.3)	1 (3.3)	
LMA number	4	11 (36.7)	12 (40)	15 (50)	0.553
	5	19 (63.3)	18 (60)	15 (50)	
Ease of insertion	2	3 (10)	4 (13.3)	1 (3.3)	0.294
	3	4 (13.3)	8 (26.7)	4 (13.3)	
	4	23 (76.7)	18 (60)	25 (83.3)	
Reposition		6 (75)	2 (25)	0 (0)	0.021*

Chi-square, p<0.05; n: patient number

Table 4. Amount of leakage

Time (min)	Classic (mL) Mean±SD	Fastrach (mL) Mean±SD	Supreme (mL) Mean±SD	p
1 min after placement	76.67±17.51	74.30±12.58	79.47±15.20	0.425
5 min after placement	78.20±18.01	74.90±13.11	81.30±15.94	0.302
10 min after placement	78.57±18.67	73.57±14.96	82.57±16.29	0.119
20 min after placement	77.87±19.99	75.37±13.78	80.37±15.34	0.508
Before extubation	77.10±18.37	76.73±14.00	81.43±15.74	0.458

One-way ANOVA. SD: standard deviation

Table 5. Assessment of complications

Complications	Classic n (%)	Fastrach n (%)	Supreme n (%)	p
Oropharyngeal complications				
Redness of the tip of the tongue	2 (22.2)	6 (66.7)	1 (11.1)	0.075
Mucosal erosion on the soft palate	1 (11.1)	6 (66.7)	2 (22.2)	0.081
Bloodstain on the device	4 (36.4)	7 (63.6)	0 (0)	0.022*
Oropharyngeal mucosal oedema	4 (26.7)	9 (60)	2 (13.3)	0.044*
Mucosal redness	5 (25)	10 (50)	5 (25)	0.200
Hypopharyngeal complications				
Sore throat				
1.No pain	5 (29.4)	7 (41.2)	5 (29.4)	0.748
2.Pain less than that experienced in common cold	1 (100)	0 (0)	0 (0)	0.364
3.Pain similar to common cold	6 (40)	7 (46.7)	2 (13.3)	0.186
4.Very severe pain	0 (0)	1 (100)	0 (0)	0.364
Dysphagia	3 (50)	3 (50)	0 (0)	0.200
Systemic complications				
Mild desaturation (90%–95%)	2 (66.7)	1 (33.3)	0 (0)	0.355
Cough	1 (50)	1 (50)	0 (0)	0.600
Hiccup	2 (40)	2 (40)	1 (20)	0.809

Chi-square, *p<0.05; comparison among three groups

on the capnogram are observed (16). The LMA manufacturers recommend a cuff pressure of <60 cm H_2O. When the cuff is inflated to a volume higher than the recommended maximum volume, there is a risk of mucosal ischaemia because of compression because pressure applied to the pharynx mucosa by the cuff is higher than the capillary perfusion pressure (17).

In this study, the amount of leakage allowed to maintain a cuff pressure of <60 cm H_2O, airway pressure of <20 mmHg and SpO_2 of >95%. The amount of leakage was recorded within normal SpO_2 and airway pressure after the observation of square-shaped $EtCO_2$ traces by setting TV to 7 mL kg^{-1}. It was measured as 70-80 mL in all patients. This mean value was considered safe because it provided TV within the normal range.

All three airway devices were found to be similar in terms of providing an effective airway and amount of leakage (Table 3).

In this study, there was a significant difference between groups in repositioning rates at the time of insertion (Table 3). The repositioning rate was significantly higher in the LMA Classic group than that in the other groups. The higher repositioning rates in the LMA Classic group were linked to the elastic structure of the tube that can be easily rotated on itself and to the fact that a guide was not used in this group. Lack of repositioning in the LMA Supreme was attributed to the thicker and more rigid structure of the tube that does not allow rotation.

No statistical difference was detected between the study groups when primary outcome measures including ease of insertion and insertion times were assessed (Table 2, 3). However, the shortest insertion time was detected in the LMA Supreme group (25.83±5.11 s) and the rate of success at the first attempt was also highest in the LMA Supreme group, although neither of these was statistically significant (Table 3). It can be suggested that insertion was easier in the LMA Supreme group than that in the other groups because of the structural features of LMA Supreme. This could be elucidated by future studies with larger series. The following are the insertion time reported in some studies: 20±11 s and 23±2 s for LMA Classic; 26 s, 25±22 s and 34±12 s for LMA Supreme and 100 s (min-max: 74-121 s) for LMA Fastrach (11, 14, 18-20). This variation in insertion times can be considered to result from demographic differences in study populations.

In the intraoral complications of the current study, there was a significant difference with respect to the presence of blood spots on the cuff. The rate of blood spots on the device was significantly higher in the LMA Fastrach group (63.6%; n=7) than that in the other groups. The rate of mucosal oedema was also found to be significantly higher in the LMA Fastrach group (60%) than that in the other groups. These findings were attributed to the more rigid structure of LMA Fastrach (Table 5).

No significant difference was found among the groups regarding hypopharyngeal and systemic complications.

In this study, LMA Classic, LMA Supreme and LMA Fastrach were found to be similarly effective in terms of efficiency and airway safety in selected patients undergoing brief surgical interventions at equivalent anaesthesia depths based on BIS values. In conclusion, LMA Supreme may be preferred to a greater extent because of the repositioning risk in LMA Classic and higher rates of oropharyngeal complications in LMA Fastrach. LMA Supreme seems to be more advantageous regarding the ability of aspiration and the number, ease and times of insertion, although there was no statistical difference. Further studies with larger series are required for greater clarification on this topic**.**

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Ümraniye Training and Research Hospital.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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