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Original Article / Özgün Araştırma

Comparison of Different Cuff Pressure Use with the Supreme Laryngeal Mask Airway on Haemodynamic Response, Seal Pressure and Postoperative Adverse Events: A Prospective Randomized Study

Farklı Kaf Basıncı ile Kullanılan Supreme Laringeal Maskenin Hemodinamik Cevap, Kaçak Basıncı ve Postoperatif Yan Etkiler Açısından Karşılaştırılması: Prospektif Randomize Bir Çalışma

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Abstract / Öz

Objective: The Supreme™ laryngeal mask airway (SLMA) is a supra glottic airway (SGA) device that is used as an alternative to endotracheal tubes. In the present study, we aimed to compare the use of the SLMA with normal cuff pressure and low cuff pressure, primarily for haemodynamic response.

Methods: In the present study, 120 patients diagnosed with hypertension and scheduled for varicose vein or inguinal hernia operation were enrolled and 99 patients finished. Using randomization, patients were divided into two groups according to cuff pressure as a low-pressure group (Group L, 45 cm H_2O) and a normal-pressure group (Group N, 60 cm H_2O). Demographics, Mallampati score and the type and duration of surgery, heart rate (HR), mean arterial pressure (MAP), percentage of tidal volume leakage, Ppeak, Pmean, $etCO_2$, seal pressure, fibreoptic scores and postoperative adverse effects of all patients were recorded.

Results: MAP and HR values immediately and 2 minutes after SLMA insertion were significantly lower in Group L ($p<0.001$). In Group L and Group N, the seal pressures were 24.1±3.1 cm H_2O and 26.2±3.9 cm H_2O, respectively ($p=0.003$). Also, blood staining and sore throat occurred less frequently in Group L ($p<0.05$). The fibreoptic average score, insertion features and ventilation parameters were similar between the groups ($p>0.05$).

Conclusion: SLMA use with a cuff pressure of 45 cm H_2O significantly decreases haemodynamic response and post-operative side effects compared with a normal cuff pressure. Therefore, except for some specific surgeries that require higher seal pressures, we recommend the use of the SLMA with cuff pressures as low as 45 cm H_2O.

Keywords: Laryngeal mask airway supreme, general anaesthesia, haemodynamic response, cuff pressure, seal pressure.

Amaç: Supreme laringeal maske hava yolu (SLMA), endotrakeal tüpe alternatif olarak kullanılan bir supra glottik hava yolu aracıdır. Çalışmamızda düşük kaf basıncı ve normal kaf basıncı ile kullanılan SLMA'nın öncelikli olarak hemodinamik cevap üzerine etkisini araştırmayı hedefledik.

Yöntemler: Hipertansiyon tanısı olan ve varis veya inguinal herni operasyonu geçiren 120 hasta çalışmaya alındı ve 99 hasta çalışmayı tamamladı. Randomize olarak hastalar SLMA kaf basıncına göre düşük basınç grubu (Grup D, 45 cm H_2O) ve normal basınç grubu (Grup N, 60 cm H_2O) olarak iki gruba ayarıldı. Demografik özellikler, Mallampati skoru, cerrahi türü ve süresi kaydedildi. Ayrıca hastaların kalp atım hızı (KAH), ortalama arter basıncı (OAB), tidal volüm kaçak yüzdesi, Ptepe, Portlama, $etCO_2$, kaçak basıncı, fiberoptik skoru ve postoperatif yan etkiler kaydedildi.

Bulgular: SLMA yerleştirilmesi sonrası hemen ve 2 dk sonra ölçülen OAB ve KAH değerleri Grup L'de anlamlı olarak daha düşük bulundu ($p<0,001$). Kaçak basıncı Grup L'de ve Grup N'de sırası ile 24,1±3,1 ve 26,2±3,9 cm H_2O saptandı ($p=0,003$). Boğaz ağrısı ve LMA üzeri kan sürüntüsü görülmesi Grup L'de daha az görüldü ($p<0,05$). Fiberoptik skor, yerleştirme ile ilgili veriler ve ventilasyon parametreleri gruplar arasında benzer bulundu ($p>0,05$).

Sonuç: SLMA'nın 45 cm H_2O kaf basıncı ile kullanılması normal kaf basıncı ile kullanımına göre anlamlı ölçüde hemodinamik cevabı ve postoperatif yan etkileri azaltmaktadır. Yüksek kaçak basıncı gerektiren cerrahi operasyonlar hariç, SLMA'nın düşük kaf basıncı ile kullanımını önermekteyiz.

Anahtar Kelimeler: Supreme laringeal maske hava yolu, genel anestezi, hemodinamik cevap, kaf basıncı, kaçak basıncı

Introduction

Supraglottic airway (SGA) devices and the models developed for their use have been an alternative to endotracheal tubes for many years in anaesthesia practice (1, 2). The Supreme™ laryngeal mask airway (SLMA) is a relatively new type of SGA device (3, 4). Several studies have indicated that SGA devices, including the SLMA, cause lower haemodynamic responses during intubation and reduce post-operative side effects compared to endotracheal tubes (5, 6). Increases in blood pressure can be dangerous after intubation, particularly in hypertensive patients, and maintaining normal blood pressure provides safer induction of anaesthesia in this patient group. The SLMA and other SGA devices also lead

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to an increase in blood pressure depending on the level of pharyngeal stimulation. Also, there is speculation that high SLMA intracuff pressures reduce mucosal perfusion leading to postoperative complications (7). Many studies indicate that reduction and monitorisation of the intracuff pressure of SGA devices lowers the incidence of postoperative pharyngolaryngeal complications (8, 9). In the literature, there are no studies about the effects of reducing the intracuff pressure of SGA devices on haemodynamic response in hypertensive patients. In addition, the use of SLMAs with lower intracuff pressure than recommended has not been investigated. We hypothesized that the patients' haemodynamic responses to intubation and postoperative side effects can be decreased by using the SLMA with intracuff pressures lower than the manufacturer's recommendation without any negative effect on airway safety.

In the present study, we aimed to compare the use of SLMAs with normal cuff pressure (60 cm H_2O) and low cuff pressure (45 cm H_2O) with haemodynamic response as the primary goal and insertion features (the success of insertion and the time for insertion), seal pressure, fibreoptic score and postoperative side effects as secondary goals.

Methods

Ethics approval

Ethics approval for this study (Ethics Committee N° 2013/1228) was provided by İstanbul University İstanbul School of Medicine on 06 September 2013. Written informed consent was obtained from the patients.

Study design

Using randomization, 120 patients were equally divided into two groups: a low pressure group (Group L) and normal pressure group (Group N) with an equal number of cases. Data collection and ensuring that the cuff was inflated to the appropriate pressure and maintained throughout the operation was done by two different anaesthetists.

Patients

This study included patients who were diagnosed with hypertension and who were administered antihypertensive drugs. The weight range of the patients was 50-100 kg, and they were all status II according to the American Society of Anesthesiologists (ASA). All patients were scheduled for varicose vein or inguinal hernia surgeries at Istanbul Medical Faculty. Patients were excluded if they had pre-existing pharyngolaryngeal symptoms, a recent history of an upper respiratory tract infection, contraindications to the use of a laryngeal mask airway device (e.g. body mass index >40 kg/m^2), a symptomatic hiatal hernia, or severe gastroesophageal reflux disease.

Clinical observations and procedure

A #4 SLMA (The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands) was used for patients weighing <70 kg, and a #5 SLMA was used for patients weighing 70-100 kg to ensure airway patency in all patients. The SLMA was prepared by placing the cuff in such a way that it was completely reduced in all patients, as done in the study by Timmermann et al. (10). The SLMA was inserted using the one-handed rotational technique, with the patient's head in the neutral position (10, 11). The insertion of SLMAs was done by the same anaesthesia resident (with experience of applying more than 200 SLMAs). Demographic parameters (age, height and weight), Mallampati score and the type and duration of surgery were recorded. Patients were monitorised for heart rate (HR) by three-channel electrocardiography, non-invasive blood pressure, peripheral oxygen saturation (SpO_2), entidal CO_2 ($etCO_2$) (Datex-Ohmeda S/5TM Compact Critical Care Monitor), bispectral index (BIS; A-2000 BIS monitoring system, Aspect Medical Systems, BIS XP, Framingham, MA, USA), and neuromuscular transmission (TOF-T1; TOF-Watch SX® Organon Instruments, Boxlet, Netherlands). For anaesthesia induction, 1 mcg kg^{-1} fentanyl and 0.6 mg kg^{-1} rocuronium bromide were administered, and 1% propofol was used until the BIS value was below 60. In order to standardise the patients' condition during SLMA insertion, the insertion was conducted when BIS was between 50 and 60 and T1 was 0. After placing the SLMA, the cuff was inflated until its pressure reached 45 cm H_2O in Group L and 60 cm H_2O in Group N as measured by a cuff pressure manometer (Portex cuff inflator pressure gauge, Smiths Medical International Limited, UK). During the surgery, cuff pressure was monitored, and the target cuff pressure was maintained in all patients. Two attempts were allowed for SLMA insertion in both groups. The SLMA was deemed to be accurately placed in this study, as it was in the previous studies, by the absence of a leaking sound, and it was properly verified by obtaining a capnography curve (10). When the placement was not effective, the position was optimized by gently pushing the SLMA further down the pharynx and/or to the lateral side using the fixation tab until the air leak ceased. In case of failure in Group L, a second attempt was allowed, and after the second attempt the SLMA cuff was inflated up to 60 cmH_2O. However, the patient was intubated if correct placement of the SLMA was still not achieved. In Group N, patients were intubated if a second attempt was unsuccessful. The success rate and duration of SLMA insertion, the number of attempts and the insertion complications were recorded for each group. The time to achieve a successful insertion was defined as the time from removing the face mask from the patient to the first valid capnography reading. After proper placement, a size 14-French gastric tube was inserted through the drain tube. The success rate and duration of insertion were recorded. Following these procedures, fresh gas flow was adjusted to 6 L min^{-1} (a 1:1 mixture of O_2 and air) during the surgery. Sevoflurane was used as an inhalation agent for anaesthesia maintenance. Tidal volume was adjusted to 8 mL kg^{-1} with 12/min respiratory rate by volume-controlled ventilation mechanics (Datex-Ohmeda S/5 Avance).

Table 1. Patient demographic parameters, operation time and Mallampati score

	Group L (n=49)	Group N (n=50)	p
Gender (M/F)	22/27	24/26	0.757
Age (years)	46.4±13.2	44.5±12.5	0.465
Height (cm)	163.2±7.3	163.3±7.1	0.956
Weight (kg)	71.8±12.8	73.6±13.5	0.502
Mallanpati score (I/II/III)	14/29/6	15/30/5	0.936
Type of operation (VV/IH)	30/20	33/17	0.534
Size of SLMA (number 4/number 5)	25/24	28/22	0.619

Data are mean±SD or number of patients. M: male; F: female; VV: varicose vein; IH: inguinal hernia

Table 2. Insertion success and fibreoptic score

	Group L (n=49)	Group N (n=50)	p
SLMA insertion success at first attempt	44 (89.7%)	46 (92%)	0.703
SLMA insertion time (s)	12.3±3.4	11.6±3.1	0.242
Fibreoptic score	3.2±0.8	3.4±0.7	0.119
Gastric tube insertion success	45 (91.8%)	49 (98%)	0.161
Gastric tube insertion time (s)	12.4±3.5	11.6±2.9	0.245

Data are mean±SD or number of patients. M: male; F: female; VV: varicose vein; IH: inguinal hernia

HR, mean arterial pressure (MAP) and peripheral oxygen saturations of the patients were recorded before (after induction) and after insertion of the SLMA (immediately and after 2 min), during the surgery (15th min, 30th min and 45th min), and before and after extubation. During the surgery, the percentage of tidal volume leakage, Ppeak, Pmean, etCO_2, seal pressure and fibreoptic scores of all patients were measured three times, and the mean values were recorded. In order to calculate the percentage of leakage, the expiratory tidal volume was extracted from the inspiratory tidal volume, and the result was proportioned to the inspiratory tidal volume. The seal pressure was determined using a technique similar to the one followed by Keller and Shimbori (12, 13) by closing the expiratory valve of the circle system at a fixed gas flow of 3 L min^{-1} (maximum allowed was 40 cm H_2O) and noting the airway pressure at which equilibrium was reached. At this time, gas leakage was determined at the mouth (audible) and the stomach (epigastric auscultation).

Fibreoptic scores were recorded on a scale of 1 to 4 (4=only vocal cords visible, 3=vocal cords plus posterior epiglottis visible, 2=vocal cords plus anterior epiglottis visible, 1=vocal cords not seen), where a score of 1 was considered the worst and a score of 4 was considered the best (14). During the surgery, patients with an audible air leak and fibreoptic score of 1 were evaluated for SLMA shift, and the number of SLMA shifts in both groups was also recorded. After surgery, all patients were taken to the recovery unit and observed for at least 1 hour. When modified Aldrete scores were 10, the patients were transferred to the ward. Observed adverse effects, such as blood staining of the device, sore throat, hoarseness, aphasia, nausea, vomiting and agitation were recorded in the recovery room period.

Statistical analysis

Sample size was calculated according to the pilot study (including 10 patients per group) and was based on MAP measurement immediately after SLMA insertion. In the pilot study, we found MAP values of 86.3±10.5 mmHg and 93.2±11.3 mmHg for Group L and Group N, respectively. The minimum number of patients needed for both groups was calculated to be 44 patients for a type 1 error of 0.05 and a power of 0.9. Results are expressed as means±standard deviation (SD). All statistical analyses were conducted using Statistical Package for the Social Sciences for Windows version 15.0 (SPSS Inc.; Chicago, IL, USA). Student's t-test and the Mann-Whitney U test were used for comparison of quantitative variables. Qualitative variables were compared using chi-square tests. A p value <0.05 was considered statistically significant.

Results

A total of 120 patients were included at the beginning of the study, but 21 patients were subsequently excluded for various reasons (Figure 1). Forty-nine patients in Group L and 50 patients in Group N completed the study. In terms of demographic data and Mallampati scores, there was no significant difference between the groups (Table 1). The mean durations of surgeries were 58.0±12.2 min and 56.1±10.2 min for Group L and Group N, respectively (p=0.932). Fifteen patients used ACE inhibitors, six patients used diuretics, twelve patients used beta blockers, seven patients used alpha blockers and nine patients used calcium channel blockers preoperatively in Group L. Twelve patients used ACE inhibitors, seven patients used diuretics, fourteen patients used beta blockers, seven patients used alpha blockers and ten patients used calcium channel blockers preoperatively in Group N.

Parameters of laryngeal mask and gastric tube insertion

In Group L, the SLMA was successfully inserted in 44 patients (89.7%) on the first attempt and in all remaining patients on the second attempt. In Group N, the SLMA was successfully inserted in 46 patients (92%) on the first attempt and in all remaining patients on the second attempt. The success rate and duration of insertion were similar in both groups (Table 2). Fibreoptic average score was similar between both groups (Table 2). In both groups, the SLMA was not displaced in any patient during the surgery. The success of gastric tube placement and duration were similar between the groups (Table 2).

Table 3. Ventilation parameters

	Group L (n=49)	Group N (n=50)	p
Airway sealing pressure (cm H_2O)	24.1±3.1	26.2±3.9	0.003*
Leakage percentage (%)	4.7±1.6	4.4±1.3	0.412
P_{peak} (cm H_2O)	16.4 ±2.0	17.1±2.5	0.244
P_{mean} (cm H_2O)	6.7±1.5	7.3±1.8	0.173
$etCO_2$ (mmHg)	34.2±2.6	33.6±3.1	0.320

*p<0.05. Data are mean±SD, $etCO_2$: end-tidal CO_2

Table 4. Adverse effects

	Group L (n=49)	Group N (n=50)	p
Blood staining	3 (6.1%)	10 (20%)	0.041*
Sore throat	1 (2%)	8 (16%)	0.046*
Agitation	7 (14.3%)	9 (18%)	0.616
Nausea and vomiting	6 (12.2%)	10 (20%)	0.295

*p<0.05. Data are numbers of patients and percentage.

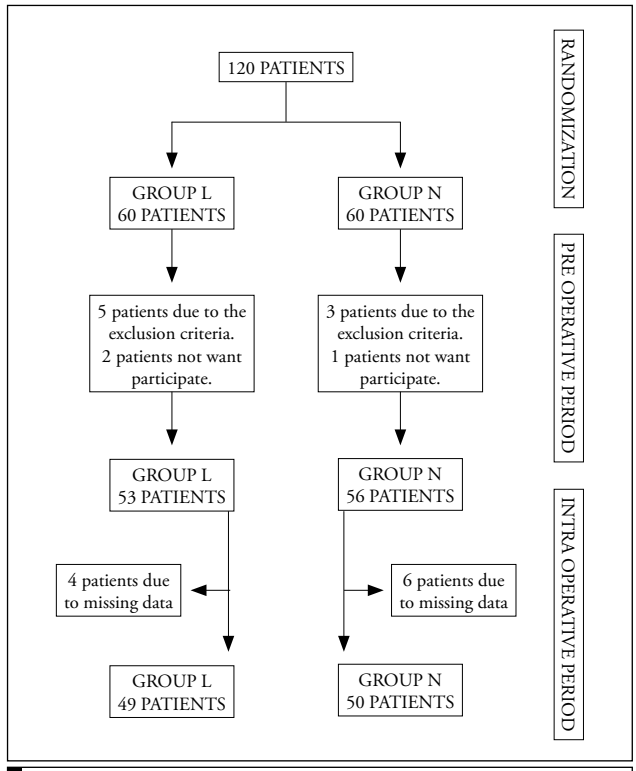

Figure 1. Study flowchart

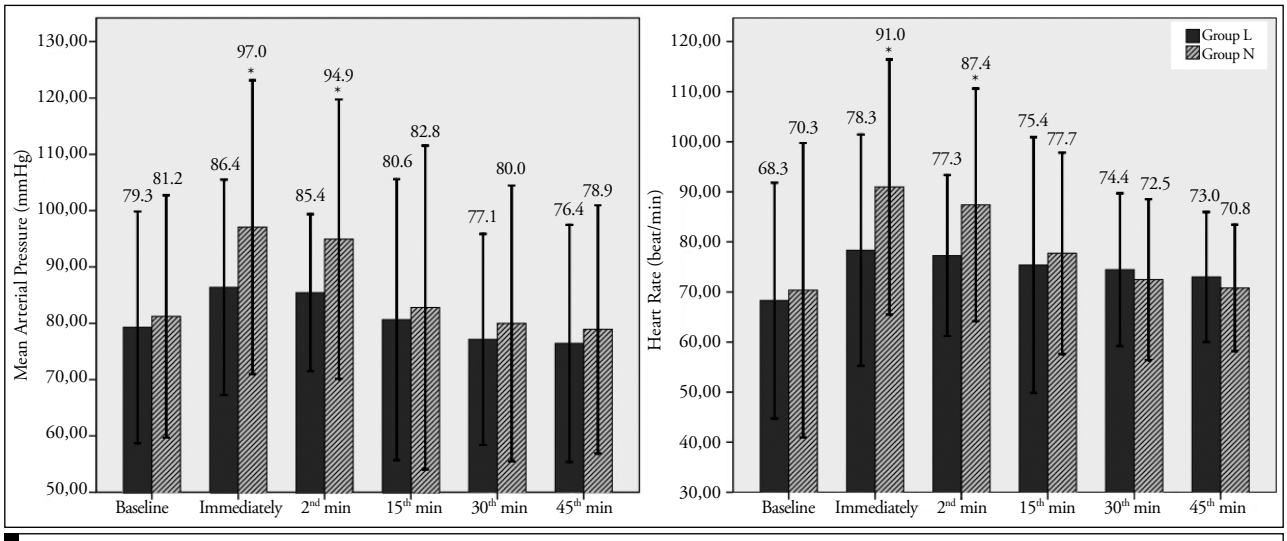

Figure 2. Mean arterial pressure and heart rate
*p<0.001

Parameters of ventilation

There was no difference between the two groups with respect to Ppeak, Pmean, $etCO_2$, or tidal volume leakage percentage values measured by a ventilator. The seal pressure was significantly higher in Group N than in Group L (Table 3).

Haemodynamic parameters

Before the SLMA was placed, MAP and HR values were similar between the groups. However, immediately and 2 min after SLMA placement, MAP and HR values measured in Group L were significantly lower than those in Group N (Figure 2). However, during the rest of the surgery time the MAP and HR were similar between the two groups (Figure 2).

Post-operative complications

None of the patients in either group had dysphagia or dysphonia. The most common complications encountered in both groups were agitation, nausea/vomiting, sore throat and bleeding (Table 4). Blood staining and sore throat were observed less frequently in Group L (p<0.05).

Discussion

In this study, we primarily noted that SLMA use with a low cuff pressure leads to lower haemodynamic response and fewer post-operative side effects compared with a normal cuff pressure. In addition, we determined that the use of a low cuff pressure did not negatively influence insertion success or ventilation parameters.

The SLMA led to a lower haemodynamic response compared with endotracheal intubation to ensure airway patency, which is similar to the findings of other SGA devices (6, 15). Blood pressure and HR increases during airway management because of stimulation of the vocal cords and/or pharynx (16). In our study, we aimed to reduce this undesirable effect by reducing stimulation of the pharynx by using a low cuff pressure. The present study is the first to examine this issue. We maintained the SLMA cuff pressure lower than that recommended in hypertensive patients, whose haemodynamic changes are more unstable than the normal patient population. These severe haemodynamic changes could cause dangerous complications such as acute coronary syndrome in hypertensive patients. With this procedure, we have successfully reduced the stress response to intubation. We noted that MAP and HR values after placement of the SLMA were significantly lower in Group L than in Group N. Haemodynamic response that occurs during intubation is influenced by the depth of anaesthesia (17, 18). In the present study, those effects were standardized by using BIS and TOF monitoring to provide similar conditions during SLMA placement in all patients. The literature contains many studies about the effects of endotracheal intubation compared to SGA devices on haemodynamic responses; however, there are no studies comparing the effect of different LMA cuff pressures on haemodynamic response. Several studies showed the relation between the LMA cuff pressure and post-operative side effects (19). Seet et al. (20), in their study of more than 200 ambulatory surgical patients, used manometry and limit intracuff LMA pressure less than 44 mmHg to decrease pharyngolaryngeal complications by 70% compared with routine care with high cuff pressure. Also, Wong et al. (21) noted that LMA did not cause any episodes of sore throat when cuff pressures of <40 cm H_2O were used for 120 paediatric patients. In the present study, we found similar results showing that the incidences of blood staining and sore throat were <5% in Group L patients. These side effects were observed with incidences >15% in Group N. These results were significantly different between the groups. However, we cannot recommend the use of the SLMA with low-pressure cuff only on the basis of these positive effects. In addition, we need to ensure successful placement, provide airway security and ensure adequate seal pressure. Ferson et al. (22) showed SLMA placement success rates of 98% in their study. In the present study, we also noted a placement success rate of 100% in both groups. Moreover, we noted that the success rate and duration of insertion was similar between the two groups. Zhang et al. (23) used SLMAs with different cuff pressures in 123 cases and noted that a cuff pressure of 40 cm H_2O did not affect the placement success and duration of insertion. In addition, monitoring for BIS and TOF allowed us to obtain similar conditions during insertion of the SLMA in our study (24). In this way, we were able to avoid misleading effects because of the difference in depth of anaesthesia and muscle relaxation.

The fibreoptic score provides more objective information compared with a capnography curve and other data about the accuracy of SLMA placement. In the present study, we used fibreoptic viewing to determine the accuracy of SLMA placement. A low cuff pressure did not cause any negative effect on fibreoptic score. This showed that SLMA positions were similar between the groups.

The seal pressure has also been used to indicate the feasibility of positive-pressure ventilation and the degree of airway protection (12). In previous studies, the SLMA seal pressure has ranged between 20 and 28 cm H_2O when used with a normal cuff pressure (20, 25, 26). Compared with classic LMA, SLMA has a higher seal pressure. Furthermore, the SLMA has a wider range of use based on this feature. In particular, the SLMA can be used as safely as the ProSeal SLMA during laparoscopic procedures. Lee et al.(27) used the SLMA safely on 70 patients undergoing laparoscopic gynaecological surgery. In our study, neither group experienced any problem because of the seal pressure. Seal pressures of >20 cm H_2O are usually adequate in ensuring airway security. However, high seal pressures are required in laparoscopic surgical procedures. Studies have found that the lower cuff pressure can cause reduced seal pressure, but this does not create a clinically significant problem. In the present study, clinically significant seal pressure differences were detected between the groups. We noted an approximate decrease of 2 cm H_2O in seal pressure in Group L. Despite the decrease in seal pressure measuring 24 cm H_2O, this result ensures a safe surgical procedure. Zhang et al. (23) investigated the effects of different SLMA cuff pressures on the seal pressures and detected a lower seal pressure in the group with a cuff pressure of 45 cm H_2O.

Conclusion

Supreme™ laryngeal mask airway use with a cuff pressure of 45 cm H_2O significantly decreases haemodynamic response and post-operative side effects compared with a cuff pressure of 60 cm H_2O. According to our results, a lower cuff pressure has no negative effects on placement success or airway security. An average decrease of 2 cm H_2O in seal pressure was noted only with the use of a lower cuff pressure. Therefore, except for some specific surgeries that require higher seal pressures, such as laparoscopic interventions, we recommend the use of the SLMA with cuff pressures <60 cm H_2O.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of İstanbul University İstanbul School of Medicine (No: 2013/1228).

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

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