Comparison of the Single-Use Laryngeal Mask Airway Supreme with the Reusable Laryngeal Mask Airway Proseal in Emergency Appendectomy

Tek Kullanımlık Süprem Laringeal Maskesi ile Çok Kullanımlık Proseal Laringeal Maskesinin Acil Apendektomide Karşılaştırılması

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ABSTRACT Objective: Both ProSeal and Supreme laryngeal mask airways increase protection by separating the respiratory and gastro-intestinal tracts during general anaesthesia. We planned to compare the efficacy of these devices in 6 hour fasted adult patients undergoing emergency appendicectomy. **Material and Methods:** Seventy patients aged from 18 to 64 years, ASA physical status I-II were enrolled in this study. After standard monitoring and anesthesia induction, one of these airway devices was inserted and ease of insertion, oropharyngeal leak pressures during the procedure 10 minutes intervals, ease of nasogastric tube insertion, ventilation parameters, need of rocuronium supplementation, hemodynamic parameters, minor complications, preoperative and postoperative cuff volumes were recorded. **Results:** Demographic characteristics of patients were similar in both groups. There were no differences in first insertion success rates, ease of nasogastric tube insertion, ventilation parameters, rocuronium supplementation and postoperative minor complications between groups. Both ProSeal and Supreme laryngeal mask airways provided oropharyngeal leak pressures of more than 26 cmH_2O during the procedure. Both ProSeal laryngeal mask airway and Supreme laryngeal mask airways were statistically significantly decreased the heart rate after insertion (p=0.001 vs p=0.02, respectively). Additionally both airway devices decreased the mean arterial pressure significantly after insertion when compared to the postinduction values (p=0.000). When cuff volumes at the beginning and at the end of the surgery were compared with in-groups; it was seen that postoperative cuff volumes were increased in each group (p<0.001). **Conclusion:** Both Supreme laryngeal mask airway and ProSeal laryngeal mask airway can be a safely alternative to endotracheal tube because of their ability to facilitate high pressure ventilation in 6 hours fasted patients during emergency appendectomy.

Key Words: Appendectomy; laryngeal masks

ÖZET Amaç: Hem ProSeal hem de Süprem Laringeal Maskeleri genel anestezi sırasında gastrointestinal yol ile solunum sistemini birbirinden ayırdıkları için korumayı arttırırlar. Bu iki havayolu aracının etkinliğini, 6 saatlik açlığa sahip acil apendektomiye alınacak erişkin hastalarda karşılaştırmak istedik. **Gereç ve Yöntemler:** Bu çalışmaya, 18 ile 64 yaş arası, ASA I-II fiziki duruma sahip, acil apendektomiye alınacak 70 hasta dahil edildi. Standart anestezi monitörizasyonunu ve indüksiyonunu takiben bu iki havayolu aracından biri yerleştirildi ve yerleştirme kolaylığı, işlem sırasındaki orofaringeal kaçak basınçları 10 dakikalık aralıklarla, nazogastrik yerleştirme kolaylığı, ventilasyon parametreleri, ek roküronyum gereksinimi, hemodinamik parametreler ve minor komplikasyonlar, preoperatif kaf hacimleri ile postoperatif kaf hacimleri kaydedildi. **Bulgular:** Hastaların demografik verileri iki grupta da benzerdi..İlk yerleştirme başarı oranları, nazogastrik tüp yerleştirme kolaylıkları, anestezi sırasında ventilasyon parametreleri, roküronyum ek gereksinimleri ve postoperatif minor komplikasyonlar açısından iki grup arasında fark yoktu. Hem ProSeal hem de Süprem Laringeal Maskeleri operasyon boyunca 26 cmH_2O üzeri orofaringeal kaçak basıncı sağladılar. Hem ProSeal hem de Süprem Laringeal Maskeleri yerleştirme sonrası istististiksel açıdan belirgin olarak kalp hızını düşürdü (p=0,001 ve. p=0,02, sırasıyla). Ek olarak iki havayolu aracı da yerleştirme sonrası indüksiyon sonrası değerlere göre ortalama arter basıncını belirgin azaltmışlardır (p=0,000). Grup içi postoperatif kaf volümleri ile başlangıçtaki kaf volümleri karşılaştırıldığında her iki grupta da postoperatif kaf volümlerinin arttığı gözlendi (p<0,001). **Sonuç:** Hem Süprem hem de ProSeal Laringeal Maskeleri yüksek basınçlı ventilasyona olanak sağlayabilmeleri nedeniyle 6 saatlik açlığa sahip acil apendektomiye alınacak hastalarda entübasyona alternatif olarak güvenle kullanılabilirler.

Anahtar Kelimeler: Apendektomi; laringeal maskeler

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ProSeal laryngeal mask airway (LMA ProSeal; Laryngeal Mask Company, Henley-on-Thames, UK) is a reusable latex free device with a gastric drain tube and an inflatable cuff.[1]

Supreme laryngeal mask airway (LMA Supreme; Laryngeal Mask Company, Henley-on-Thames, UK) is a new designed single-use polyvinylchloride airway device (like LMA Unique) that provides the features of LMA ProSeal with a gastric drain tube and an inflatable cuff, a rigid curvature of the Intubating Laryngeal Mask Airway (ILMA; Fastrach; Laryngeal Mask Company, Henley-on-Thames, UK).[2]

LMA ProSeal and LMA Supreme were compared with each other in different surgical procedures such as; laparoscopic surgery, gynaecological surgery with or without neuromuscular blockade.[3-6] And their role in difficult airway algorithm and resuscitation have validated.[7,8] But we are not aware of any comparative studies in appendectomy.

MATERIAL AND METHODS

Following approval by the Local Research Ethics Committee and written informed patient consent was obtained from all patients; we studied 70 adult, aged 18 to 64 years, American Society of Anesthesiologists (ASA) physical status I-II, 6 hours fasted patients who were scheduled for emergency appendectomy. Patients were randomly allocated to either LMA ProSeal or LMA Supreme group using a sealed envelope technique. An active respiratory infection (cough, fever, rhinorrhoea) or a potentially difficult airway, full stomach were excluded from the study. Patients with gastroesophageal reflux, pregnancy, body mass index >35, ASA III-IV were also excluded. We documented the demographic variables like; age, sex, weight, ASA status. Patients were premedicated with intravenous (iv) midazolam 0.03 mg/kg after iv access was administered. Standard monitoring included; ECG, non-invasive blood pressure, pulse oximetry, heart rate and end-tidal carbon dioxide. Anaesthesia was induced with 3 mg/kg propofol (calculated according to the lean body weight) and 1 μg/kg fentanyl then iv rocuronium 0.3 mg/kg was administered and added when needed. After that, anaesthesia was maintained with Sevoflurane in a mixture of 60% nitrous oxide and oxygen. LMA ProSeal was inserted with the index finger technique. LMA Supreme was inserted like the ILMA, according to the manufacturer's recommendations. Each device was inserted when fully deflated and the dorsal surface lubricated with a lidocaine based agent and inflated with the maximum volume of air according to the manufacturer's recommendations. The investigators experienced in using both devices (over 500 successful insertions with both of the device) performed all the insertions in the neutral position of the head. Parameters were measured and recorded (ease of device insertion, ease of adequate ventilation, ease of gastric tube placement, oropharyngeal leak pressures, gastric insufflations, preoperative ventilatory parameters, preoperative and postoperative cuff volumes, postoperative minor complications (sore throat and blood staining) by an independent unblinded observer. The ease of laryngeal mask insertion was assessed using a subjective scale of 1-3 (1=easy, 2=difficult, 3=impossible). The insertion was recorded as a failure if the placement of the device required more than three attempts, or there was lack of a square-wave capnography tracing, evidence of airway obstruction (SpO_2 <90) or inadequate ventilation (inability to generate 6 ml/kg tidal volume). If the insertion of the device was impossible then the other device was used. All devices were fixed with a banned routinely. To determine the oropharyngeal leak pressure; the expiratory valve was closed and the fresh gas flow was set to 3 l/min and pressure was slowly increased (airway pressure was not allowed to exceed 40 cmH_2O), and then released completely. Gastric insufflation was performed with the auscultation with a stethoscope over the epigastrium during the oropharyngeal leak pressure testing. 14 FG nasogastric tube was placed on a subjective scale; (1=easy, 2=difficult, 3=impossible). Insertion of the gastric tube into the stomach was confirmed by aspiration of gastric contents or insufflation of air heard on auscultation over the epigastrium while 20 ml of air was injected into the tube. Volume control mode ventilation was used for maintenance

of anaesthesia. The lungs were ventilated using volume-controlled ventilation with a FiO_2 of 0.40 and a tidal volume (V_T) of 8 ml/kg at a respiratory rate (RR) of 12 per minute and with an inspiration/expiration ratio of 1:2 and 3 lt/min of a fresh gas flow. If the end-tidal carbon dioxide ($ETCO_2$) increased above 40 mmHg, RR was first increased to 14 per minute and then V_T increased to 10 ml/kg. Ventilation considered to have failed if the SpO_2<90 and $ETCO_2$ > 50 mmHg and the patient excluded from the study. Hemodynamic parameters including heart rate (HR), mean arterial blood pressure (MAP), pulse oximetry (SpO_2), peak airway pressure (Ppeak), $ETCO_2$, inspiratory (insp V_T) and expiratory (exp V_T) tidal volume were also recorded. The number and type of airway manipulations (gentle advancement, withdrawal of the device without removal, jaw thrust and head extension) required to maintain airway patency during the case were also recorded. All devices were removed under deep anaesthesia without deflation. Then cuff volumes were detecting by aspirating the air from the cuff and recorded. Postoperative complications such as; sore throat, tongue, lip and dental damage, coughing, laryngospasm, dysphasia, stridor, bronchospasm, desaturation (SpO_2 <90), aspiration, blood staining on the device after the removal were recorded by a blinded observer. All patients received iv atropine and neostigmine to reverse the neuromuscular blockage. The drainage tube was removed before discontinue of anesthesia. Tramadol 1 mg/kg and ondansetron 4 mg iv were given to all patients for postoperative analgesia.

Statistics; using this size, an alpha of 0.05 and a desired power of 0.9, we estimated that 35 patients per device would be required to detect a difference of 5 ml for the preoperative and the postoperative cuff volume (the minimum difference that is considered clinically significant) between these two devices. Statistical analysis was made with Statistical Package of Social Science 17 (SPSS Inc., Chicago, IL, USA). Statistical comparisons between the devices were made using Chi-square test for categorical data, Student t-test and Mann Whitney U test for continuous data. Paired sample-t test and Wilcoxon Signed Ranks test for comparison within groups for the cuff volumes and the hemodynamic parameters. A value of $p<0.05$ was considered statistically significant.

RESULTS

Demographic variables such as; age, gender, weight, ASA physical status of patients were comparable between the groups (Table 1). Both LMA ProSeal and LMA Supreme were easily inserted and ventilated adequately at the first attempt without the need of any manipulation. Nasogastric insertion was easy and successful (gastric insufflations was detected by auscultation from the epigastrium) in most of the patients. Oropharyngeal leak pressures were similar. Need for rocuronium supplementation was similar among groups (Table 2). We could not be able to detect a statistical difference in ventilation parameters between the groups (Table 3). When compared with in-groups; HR decreased (p=0.02 vs. p=0.001, respectively), the MAP significantly decreased too ($p<0.001$) and the cuff volumes increased postoperatively ($p<0.001$) (Table 4). None of the patient was excluded from the study. Devices were comparable regarding postoperative minor complications such as; blood staining and sore throat either. No aspiration was detected in any patient.

DISCUSSION

The main result of this study was LMA ProSeal and LMA Supreme were comparable regarding ease of insertion, first insertion success rates, ease of ventilation, ease of gastric tube placement, per-operative ventilatory parameters, hemodynamic changes and postoperative minor complications.

According to previous literature, first attempt insertion success rates were similar

TABLE 1: Demographic characteristics of patients.

	LMA ProSeal (n=35)	LMA Supreme (n=35)	p
ASA I/II	30/5	27/ 8	0.4
Age; years	33.3±11.4	31.1±13.9	0.1
Weight; kg	71.3±15.8	65.1±12.8	0.8
Gender Male / Female	18/17	15/20	0.5

Values are mean ± SD or as number (n).

TABLE 2: Insertion characteristics for the LMA ProSeal or LMA Supreme.

	LMA ProSeal (n=35)	LMA Supreme (n=35)	p
Ease of LMA insertion			
Easy/Difficult/Impossible	32/3/0	34/1/0	0.6
Number of insertion attempts			
I/II/III	31/3/1	33/1/0	0.4
Ease of nasogastric insertion			
Easy/Difficult/Impossible	34/0/1	33/1/1	0.6
Ease of adequate ventilation			
Easy/Difficult/Impossible	34/1/0	35/0/0	0.3
Gastric insufflations			
Yes/No	22/12	26/9	0.4
Need for rocuronium supplementation			
Yes/No	14/21	11/24	0.5
Postoperative sore throat			
Yes/No	3/32	1/34	0.3
Blood staining on the device after removal			
Yes/No	1/34	3/32	0.3

Values are as number (n).

TABLE 3: Ventilation parameters and cuff volumes of the patients.

	LMA ProSeal (n=35)	LMA Supreme (n=35)	p
SpO_2 (%)	99.1±0.9	99.1±0.8	0.6
Inspired VT (ml)	588±120	581±79	0.6
Expired VT (ml)	540±133	546±91	0.4
$ETCO_2$ (mmHg)	31.7±4.1	32.3±3	0.5
Ppeak (cmH_2O)	16.6±4.3	16.1±4.1	0.5
Oropharyngeal leak pressure (cmH_2O)	26.8±7.4	28±6.3	0.6

Values are mean ± SD.

TABLE 4: Hemodynamic parameters of the patients groups in itself.

	LMA Supreme (n=35) p	LMA ProSeal (n=35) p
HR_{basal}-$HR_{1\ min}$	90.4±19.8-85±15.6*	90.4±15.2-81.5±14.1†
$HR_{1\ min}$-$HR_{10\ min}$	85±15.6-81.4±13.6	81.5±14.1-74.5±15.4*
$HR_{10\ min}$-$HR_{20\ min}$	81.4±13.6-78.5±14	74.5±15.4-75.4±12
MAP_{basal}-$MAP_{1\ min}$	90.5±9.4-70.5±13.2†	98±15.3-82.4±14.2†
$MAP_{1\ min}$-$MAP_{10\ min}$	70.5±13.2-86±15.3†	82.4±14.2-89.2±13.4†
$MAP_{10\ min}$-$MAP_{20\ min}$	86±15.3-89.4±16.4	89.2±13.4-94.2±16.8
Cuff $volume_{pre}$-Cuff $volume_{post}$	33±8-35±7.1†	30.8±5.6-36±7.2†

Values are mean ± SD.
†: p< 0.001; *: p< 0.05.

between the groups and ranged from 90-98% for the LMA Supreme and 83-97% for the LMA ProSeal.[3-5,9-12] First attempt insertion success rates were 89% for LMA ProSeal and 94% for LMA Supreme in our study. In contrary with our findings, some authors found higher insertion success rates with the LMA Supreme than that with the LMA ProSeal.[13,14]

Consistent with our findings, published reports mentioned that orogastric tube placement was

successful in nearly 100% of patients in both groups.[3-5,13,15] Another study showed higher success rates of orogastric tube placement with a low rate of gastric insufflations with LMA Supreme than LMA ProSeal.[9] A cadaveric study and ours, detected gastric insufflations nearly in 100% of patients with both of the devices even high rates of successful gastric tube placement.[16] Another study marked that, even a good fiberoptic view from the LMA ProSeal it did not prevent oesophageal insufflations.[17]

Our results indicated that, oropharyngeal leak pressures were comparable between these two devices in concordant with the previous published literature.[3,9,11,12,18] In contrary to our findings, some authors found higher oropharyngeal leak pressures associated with the LMA ProSeal than that with the LMA Supreme.[4,5,10,13-15] We think that, this could be a result of not fastening the devices. Fixation the devices with a band could probably prevent malposition of LMA Supreme and increase the leak pressures. Some authors attributed this situation to movement of the semi-rigid curved airway tube of the LMA Supreme.[19]

A study which investigated the emergency appendectomy cases managed with LMA ProSeal found high rates of first insertion of the device and the gastric tube, with adequate ventilation with a low minor complication approximately in 3% of the 102 cases. Peak airway pressures were similar to this study (16±3 cmH_2O).[20]

Mucosal injury was detected in ranged from 3 to 28% (blood recognised on the device after removal) in previous trials with LMA ProSeal and LMA Supreme.[4,5,9-11,13] In this study bloodstaining after removal was detected in 3% of LMA ProSeal and 9% in LMA Supreme cases. As described earlier, we did not find any significant difference with respect to sore throats and ventilator parameters between groups too.[4,10,13,14,16]

LMA ProSeal and LMA Supreme have similar hemodynamic responses with a maximum 20% increase in heart rate and a decrease in MAP.[1,2] According to our results both of the devices decreased the HR and MAP after insertion.[3]

In consistent with the previous reports, our results indicated that nitrous oxide diffused into both LMA ProSeal and LMA Supreme and increased the cuff volumes.[21]

The major limitations of this study were, we did not investigate neither the fiberoptic view of the larynx from these devices and nor the insertion times. Other limitations of this study were; not blinding the operators to the devices being used and the preoperative data collection. We excluded morbidly obese, expected difficult intubation or ventilation cases or ASA III-IV patients. We maintained a deep level of anaesthesia in our patients and administered low doses of rocuronium. In this study we did not apply cricoid pressure before or during device insertions because it would lead to improper insertion of the LMA ProSeal.[22] Our data can not be attributed to the satiated patients. Experienced users inserted these devices, our results may not be applied to inexperienced users.

LMA ProSeal can be malpositioned because of its soft structure. On the other hand, LMA Supreme has advantages of having a rigid curvature but it would lead to nerve damage and may apply pressure to cervical vertebraes.[23] LMA Supreme can also protect from prion diseases.[24] Avoiding tracheal intubation has several advantages. These include; risks of oesophageal intubation, improved mucosiliary clearance and reduced airway resistance.[25]

We conclude that, LMA ProSeal and LMA Supreme probably be used in starved patients of more than 6 hours during anesthesia by experienced users and with a careful patient selection. We discouraged the use of LMA devices if fasting is less than 6 hours because of the increased risk of aspiration of gastric contents. Tracheal intubation is still the first choice in such procedures.

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