

A Prospective Randomized Comparative Study between Baska Mask, Proseal LMA and I Gel During Positive Pressure Ventilation in Laparoscopic Cholecystectomy

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Laparoskopik Kolesistektomide Pozitif Basıncılı Ventilasyon Sırasında Baska Mask, Proseal LMA ve I Gel ile Prospektif Randomize Karşılaştırmalı Bir Çalışma

ABSTRACT

Objective: Supraglottic airway devices with facility for gastric suction such as Proseal LMA and I gel have been successfully used for positive pressure ventilation in laparoscopic surgeries. Baska mask, a novel device with many unique features such as self-sealing membranous cuff and effective sump drainage system was designed in such a way that the perilaryngeal seal increases incrementally with increasing airway pressures. But Baska mask was not extensively evaluated to validate its use in laparoscopic surgeries. The efficiency of Baska mask (B), Proseal LMA (P) and I Gel (I) are compared during positive pressure ventilation in laparoscopic cholecystectomy.

Methods: Ninety patients of ASA physical status I-II planned for laparoscopic cholecystectomy were randomized into three groups (B, I, P) of 30 each. The study was proceeded with 88 (B-30, I-29, P-29) patients. Oropharyngeal leak pressure, insertion time, effective airway time and airway morbidity were assessed and compared between the three groups. Mean, standard deviation, paired sample t-test, one way ANOVA with Tukey's Post-Hoc test was used.

Results: The oropharyngeal leak pressure at insertion time was 38.33±4.353 cm of H₂O for group B, 30.57±2.174 cm of H₂O for group I, 29.36±2.706 cm of H₂O for group P. The leak pressure was statistically significant between group B and other groups.

Conclusions: Baska mask provided higher oropharyngeal leak pressure in comparison to other two supraglottic devices.

Keywords: Baska mask, Proseal LMA, I Gel, oropharyngeal leak pressure, laparoscopic cholecystectomy

ÖZ

Amaç: Proseal LMA ve I gel gibi gastrik aspirasyon avantajı olan supraglottik hava yolu araçları, laparoskopik ameliyatlarda pozitif basınçlı ventilasyonda başarıyla kullanılmaktadır. Kendiliğinden yerleşen membranöz cuff ve etkin sıvı drenaj sistemi gibi pek çok benzersiz özelliğe sahip yeni bir cihaz olan Baska mask, perilarengal yerleşme basıncının, artan hava yolu basınçları ile aşamalı olarak artacağı şekilde tasarlanmıştır. Ancak, Baska maskın, laparoskopik ameliyatlarda kullanımı kapsamlı olarak araştırılmamıştır. Laparoskopik kolesistektomide pozitif basınçlı ventilasyon sırasında Baska mask (B), Proseal LMA (P) ve I Gel (I)'in etkinliği karşılaştırıldı.

Yöntem: Laparoskopik kolesistektomi planlanan ASA I-II 90 hasta, üç gruba (B, I, P) randomize edildi. Çalışma 88 (B-30, I-29, P-29) hasta ile sürdürüldü. Orofarengal kaçak basıncı, yerleştirme zamanı, etkin hava yolu zamanı ve hava yolu morbiditesi değerlendirildi ve üç grup karşılaştırıldı. İstatistiksel analizde; ortalama, standart sapma, paired sample t-testi, Tukey Post-Hoc testi ile tek yönlü ANOVA kullanıldı.

Bulgular: Yerleştirme sırasında orofarengal kaçak basıncı, B grubunda 38.33±4.353 cmH₂O, I grubunda 30.57±2.174 cmH₂O, P grubunda 29.36±2.706 cmH₂O idi. Kaçak basıncı, B grubu ve diğer gruplar arasında istatistiksel olarak anlamlıydı.

Sonuç: Baska mask, diğer iki supraglottik araç ile karşılaştırıldığında daha yüksek orofarengal kaçak basıncı sağladı. Bu çalışmada kullanılan üç farklı ikinci kuşak supraglottik hava yolu aracı arasında, Baska mask, yüksek orofarengal kaçak basıncı ile yeterli ventilasyonun sağlanmasında daha etkin bulunmuştur.

Anahtar kelimeler: Baska mask, Proseal LMA, I Gel, orofarengal kaçak basıncı, laparoskopik kolesistektomi

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INTRODUCTION

Laparoscopic cholecystectomy has become a standard and less invasive technique for cholecystectomy surgeries in gall bladder diseases ^(1,2). Although tracheal intubation is considered as an ideal approach, it has disadvantages like raised respiratory and hemodynamic responses during intubation, pneumoperitoneum and extubation ⁽³⁻⁹⁾. However, supraglottic airway devices (SAD) with facility for gastric suction such as Proseal LMA and I gel have been successfully used in laparoscopic cholecystectomy ⁽¹⁰⁻¹⁶⁾. Initial experience with Baska mask has demonstrated it to be a suitable device ^(17,18) and there are only limited literature comparing these devices, so we decided to assess the efficiencies of Baska mask, I gel and Proseal LMA during laparoscopic cholecystectomy.

MATERIAL and METHODS

After obtaining approval from the hospital ethics committee and written informed consent from the patients, this prospective randomized comparative study was done in 90 ASA (American Society of Anesthesiology) physical status grade I-II patients, aged 18-60 years scheduled for elective laparoscopic cholecystectomy, divided into 3 groups of 30 patients each. The primary objective of this study was to compare the oropharyngeal leak pressure between the three devices. The secondary objectives were to compare the insertion time, number of attempts, and airway-related complications of these three devices in patients.

Based on the pilot study with oropharyngeal leak pressure as the primary outcome with 5 cases in each group to find an effect size of 3 cmH₂O with power of 80% and an alpha error of 0.05, the calculated sample size was 28 cases in each group. Considering the possibility of dropouts from the study, we decided to include 90 patients in the study. Exclusion criteria were patient's refusal, ASA PS III and above, predicted difficult airway as per Benumof's 11 parameter analysis, mouth opening of <2.5 cm, patients at increased risk of aspiration of gastric contents including gastro-esophageal reflux disorders, conversion to open surgery for various reasons, restrictive and obstructive lung disease and BMI >30 kg.m⁻². Randomization was done using com-

puter generated numbers into three groups of 30 each in Group B-Baska mask (Baska Versatile Laryngeal Mask (BVLM) Pty Ltd, Australia), Group I -I gel (Intersurgical Ltd, UK) and Group P-Proseal LMA (PLMA) (Teleflex Medical Europe Ltd, Ireland).

The pre-anesthetic visit of the patient was performed by an anesthesiologist not involved in the study. Size selection was based on the manufacturer's recommendation and weight-based estimate ⁽¹⁷⁻¹⁹⁾. A standard anesthesia technique was followed. On arrival in operating theatre, the patients were connected to standard monitoring devices. After preoxygenation and administration of fentanyl 2 µg kg⁻¹, induction of anaesthesia was done using propofol 2 mg kg⁻¹ and vecuronium 0.1 mg kg⁻¹ was given. Anesthesia was considered adequate for SAD insertion when the patient was unresponsive, had lost the eyelash reflex, and did not respond to anterior jaw thrust ⁽¹⁸⁾. Anesthesia was maintained using sevoflurane 1.5-2.0% in oxygen 40% and air. Analgesia was achieved with additional intermittent boluses of 0.5 µg kg⁻¹ fentanyl every one hour with a margin of not less than 20 minutes prior to extubation and infiltration of the surgical wound with 0.25% bupivacaine. All patients received intravenous paracetamol 1 g intra-operatively. All the devices were inserted by an anesthesiologist who had sufficient experience in the use of all three devices.

The Proseal LMA was introduced by the standard technique without using the introducer and the cuff was inflated with air according to the size used ⁽¹⁹⁾. The I gel and Baska mask are cuffless devices not requiring the same procedure.

The patency of the airway was ascertained and the SAD was connected to the breathing circuit and fixed. An initial assessment of airway patency and the ability to ventilate the lungs was made by gently squeezing the reservoir bag and observing the amplitude of end-tidal carbon dioxide waveforms and the presence of chest movements. Volume-controlled ventilation was used with the tidal volume of 8-10 mL kg⁻¹ and the respiratory rate was 10 to 16 per minute to maintain EtCO₂ between 35-45 cmH₂O. A lubricated orogastric tube was inserted through the gastric channels into the stomach to confirm the correct placement.

Oropharyngeal leak pressure was determined following mask insertion the supine position before development of pneumoperitoneum and at 30 min of surgery in the supine position with pneumoperitoneum by closing the expiratory valve of the circle system at a fixed gas flow of 3 L min⁻¹ and noting the airway pressure when the equilibrium was reached. A maximum pressure of 40 cmH₂O was allowed during measurement⁽¹⁸⁾. The insertion time was taken as the time between picking-up the prepared device and its successful placement⁽¹⁸⁾. The effective airway time is the time between picking-up the prepared device and obtaining the first capnographic trace. The success of insertion was assessed by the number of insertion attempts (counted as an attempt when the SAD is taken in and out of the mouth). Postoperative airway morbidity such as sore throat, dysphagia, dysphonia were graded as none, mild, moderate, or severe at 4th hour postoperatively⁽¹⁸⁾. Intra-operative complications were recorded. If an adequate capnogram and ventilation were not achieved after two insertion attempts, endotracheal tube was used and the patient was excluded from the study. The SAD was removed when protective reflexes returned to normal after reversal of neuromuscular blockade.

Statistical Analysis

The collected data were analysed with IBM.SPSS statistics software 23.0 Version. Descriptive statistics, and frequency analysis were used for categorical variables and the mean, standard deviation were used for continuous variables. To find the significant difference between the bivariate samples in paired groups, the paired sample t-test was used. In order to compare more than two groups in terms of numerical variables, the one way ANOVA with Tukey's Post-Hoc test was used. To find the significance in categorical data, chi-square test was used. In all the above statistical tools, the probability value p<0.05 was considered as the level of significance.

RESULTS

Ninety patients were randomized into three groups as B, I, P, among which 2 patients were excluded from study as laparoscopy was converted to open surgery (Figure 1). The final study groups included 88

patients (B=30, I=29, P=29). The age, gender distribution, BMI and the ASA physical status of the patients were comparable (Table I and II). The insertion time for Group B was 11.47±3.2 minutes (min), Group I - 12.50±2.8 (min) and for group P it was 14.07±3.6 (min). Intergroup difference as for insertion time was not statistically significant. The effective airway time, the maximum ETCO₂ and the duration of anesthesia were not also statistically significant between the groups (Table II).

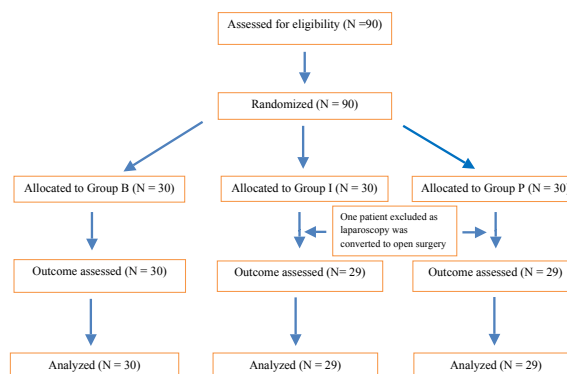


Figure 1. Study flowchart

Table I. Gender distribution and ASA physical status among groups

Parameters	B	I	P	Total	p value	
Sex	Female	22	22	20	64	0.41
	Male	8	7	9	22	
ASA Class	I	18	21	20	59	0.83
	II	12	8	9	29	

B = Baska mask, I = Igel, P = Proseal LMA, ASA = American Society of Anesthesiologist.

Oropharyngeal leak pressure during insertion time and 30 min after insertion was analysed within the group and between the groups. The leak pressure at insertion time was 38.33±4.4 cm of H₂O for Group B, 30.57±2.2 cm of H₂O for Group I, 29.36±2.7 cm of H₂O for Group P. The p value revealed statistical significance between Group B and the other two groups, but p value obtained for Group I and Group P was not statistically significant. The leak pressure after 30 minutes of insertion was 40.00±2.4 cm of H₂O for Group B, 35.14±3.2 cm of H₂O for Group I, 34.36±1.3 cm of H₂O for Group P. The p value was significant for Group B in comparison with other two groups, but insignificant for Groups I and P (Table II). The oropharyngeal leak pressure at insertion and at

30 minutes for Groups I and P was statistically significant when compared to Baska mask (Table III).

Table II. Patient characteristics and SAD placement parameters

S.No	Patient characteristics	Group	n	Mean ± SD	p value
1	Age (Years)	B	30	47.67±8.2	0.951
		I	29	47.71±9.0	
		P	29	46.79±9.2	
2	Height (cm)	B	30	155.20±6.0	0.098
		I	29	160.86±7.4	
		P	29	159.14±7.8	
3	BMI (Kg m ⁻²)	B	30	24.113±2.5	0.173
		I	29	25.600±3.1	
		P	29	25.779±1.9	
4	Insertion Time (Seconds)	B	30	11.47±3.2	0.105
		I	29	12.50±2.8	
		P	29	14.07±3.6	
5	Effective Airway Time (seconds)	B	30	20.00±2.5	0.808
		I	29	20.14±3.7	
		P	29	19.71±2.8	
6	Maximum ETCO ₂ (mm Hg)	B	30	36.00±1.3	0.664
		I	29	35.57±1.7	
		P	29	35.57±1.3	
7	Duration of Anaesthesia (minutes)	B	30	95.07±39.6	0.101
		I	29	127.50±50.5	
		P	29	101.00±33.9	
8	Oropharyngeal Leak pressure at insertion time (cm of H ₂ O)	B	30	38.33±4.4	0.04
		I	29	30.57±2.2	
		P	29	29.36±2.7	
	Oropharyngeal Leak pressure at 30 minutes of insertion (cm of H ₂ O)	B	30	40.00±2.4	0.04
		I	29	35.14±3.2	
		P	29	34.36±1.3	

B = Baska mask, I = Igel, P = Proseal LMA, SD = Standard Deviation, BMI=Body Mass Index, ETCO₂ = End Tidal Carbon dioxide, SPO₂ = Oxygen saturation.

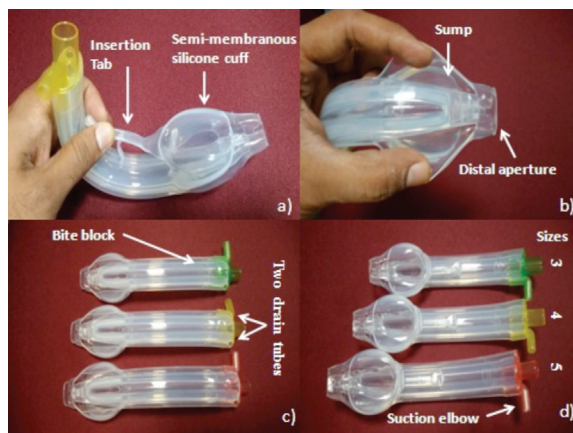


Figure 2. Baska mask. a) Insertion tab for manually curving the tab for easy insertion and self sealing variable pressure semi-membranous silicone cuff, b) Sump for easy drainage of gastric and throat contents, c) Two drain tubes on either side of ventilating tube with bite block, d) Different sizes of Baska mask with detachable suction elbow for attachment of suction tubing

Table III. Within group comparison of oropharyngeal leak pressure.

S.No	Group (n)	At insertion time (cmH ₂ O)	After 30 min (cmH ₂ O)	p value
1	B (30)	38.33±4.4	40.00±2.4	0.07
2	I (29)	30.57±2.2	35.14±3.2	0.0005
3	P (29)	29.36±2.7	34.36±1.3	0.0005

B = Baska mask, I = Igel, P = Proseal LMA

DISCUSSION

This study compared the use of three supraglottic devices in laparoscopic cholecystectomy surgery. The demographic profile and ASA physical status of the subjects in the three groups [B, I, P] were comparable. In our study, Baska mask had the quickest insertion time (11.47±3.2 seconds) when compared to the Proseal LMA (14.07±3.6 seconds) and I gel (12.50±2.79 seconds) (Table II), though the intergroup difference was not statistically significant. This may be due to its anatomical curvature which does not require manual opening of mouth to insert, its non inflatable cuff, shorter time to inflate the cuff and needless volume adjustment as required in PLMA. This demonstrates that a short learning curve is sufficient for the placement of Baska mask. Although statistically non-significant, effective airway time was shorter in PLMA group which would probably attributed to long experience as also reported in another study⁽²⁴⁾. Two male patients in the Baska mask, and one male patient in the Proseal group required two insertion attempts but none of the patients required endotracheal intubations due to failure of device insertion. Oxygenation and ventilation were optimal in all patients throughout the surgery. The end-tidal carbon dioxide levels and duration of anesthesia were comparable in all the three groups (Table II).

The primary objective of this study is to assess the oropharyngeal leak pressure among the three supraglottic devices used in the study. This was assessed during and 30 minutes after insertion in all the subjects. Oropharyngeal leak pressure reveals the degree of airway protection, feasibility for using in positive pressure ventilation and success of the device placement⁽²⁵⁾. High leak pressure was provided by Baska mask (38.33±4.4 cmH₂O) at insertion time was

comparable even 30 minutes after insertion (40.00±2.4 cm of H₂O) which was measured during laparoscopy, and statistically significant in comparison to other devices. Al Rawahi et al. ⁽²⁶⁾ compared the Baska mask with the Proseal LMA and found that the sealing pressure was significantly higher in the Baska group (30±9 vs 24±6 cm of H₂O). Higher sealing pressure achieved with Baska mask over PLMA was also shown in other studies ^(18,19,26,31). In this study Igel and PLMA were comparable in terms of oropharyngeal leak pressure.

The inflatable cuff of SADs has often been held responsible for the device-related complications or laryngopharyngeal morbidity (LPM) ⁽³²⁾. However, in this study, we did not observe any significant dysphagia or dysphonia at extubation and at 4 hours postoperatively between the three devices. However, 8 patients in PLMA group, 2 each in BM and I gel group had mild sore throat at 4 hours postoperatively, which probably can be attributed to cuff pressure in Proseal LMA patients.

The sealing pressure serves as an index of airway and respiratory mechanics ⁽³³⁾. Hence high oropharyngeal leak pressures are necessary to deliver the required increased peak airway pressures without the fear of leak, gastric insufflation and resultant pulmonary aspiration. Despite these issues with pneumoperitoneum, in our study there were no problems of hypoventilation, leak, gastric distension, desaturation and aspiration in any of the groups. Amongst the three groups, Baska mask has higher oropharyngeal leak pressure when compared to the other two devices, proving that Baska Mask is superior to other second generation SADs in terms of higher oropharyngeal leak pressure. Our study had a few limitations. Obese patients and those with restrictive lung disease were not included in the study, which may be evaluated in future for further validation.

CONCLUSION

In this study, Baska mask showed higher mean oropharyngeal leak pressure compared to the other two supraglottic devices, while mean oropharyngeal leak pressures of the other two devices were comparable.

Ethics Committee Approval: Received from SRI Ramachandra Institute of Higher Education and Research Deemed to be University (CSP-MED/16/AUG/30/129).

Conflict of Interest: None.

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Informed Consent: The patient's consent was obtained.

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