Original Research Article

Indian Journal of Anesthesia and Analgesia
2019; 6(1) (Part - 1): 144-150
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.6119.20

The Evaluation of Proseal Laryngeal Mask Airway as an Alternative to Endotracheal Intubation in Patients Undergoing Laparoscopic Cholecystectomy

Sonal Gohel[1], Sandhya MK[2]

[1]Former Resident, Department of Anaesthesiology, Government Medical College, Surat, Gujarat 395001, India. [2]Assistant Professor, Department of Anaesthesiology, Kanachur Institute of Medical Sciences, Mangalore, Karnataka 575018, India.

Abstract

Context: Proseal laryngeal mask airway is a supraglottic airway device with an additional drainage tube and a dorsal cuff which provides better seal and prevents aspiration. *Aims:* 1) tocompare the efficacy of PLMA with standard intubation in patients undergoing laparoscopic cholecystectomy. *Methods and Material:* After approval from institutional ethical committee a prospective randomized controlled study was conducted in sixty ASA class 1 and 2 patients. After induction Proseal LMA was introduced in group P and endotracheal tube was introduced in group E. Details of insertion, haemodynamic parameters, ventilatory performance were recorded. During surgery, oxygenation and ventilation variables were adjusted to maintain SpO_2 > 95% and $EtCO_2$< 45 mmHg. *Statistical analysis used:* Data was analysed using computer statistical software system openepi (open source epidemiological statistics for public health). The two tailed students t test was for unequal variance was used for intergroup comparisons except where specified. Probability values $p < 0.05$ were considered significant and $p < 0.001$ were considered highly significant. *Results:* There was no failed insertion of devices. The mean time of insertion of Proseal (80+43.56 seconds) was greater than conventional intubation (23+17.71 seconds). The difference was statistically highly significant ($p<0.01$). There were no statistically significant differences in oxygen saturation (SpO2) or end-tidal carbon dioxide ($EtCO_2$) between the two groups before or during peritoneal insufflation. There was no case of inadequate ventilation, regurgitation, or aspiration recorded. *Conclusions:* Proseal provides a safe alternative to endotracheal intubation for airway management in patients undergoing laparoscopic cholecystectomy.

Keywords: Proseal LMA; supraglottic airway device; alternative to endotracheal intubation.

How to cite this article:

Sonal Gohel & Sandhya M K. The Evaluation of Proseal Laryngeal Mask Airway as an Alternative to Endotracheal Intubation in Patients Undergoing Laparoscopic Cholecystectomy. Indian J Anesth Analg. 2019;6(1):144-50.

Introduction

Proseal LMA is a modification of classic LMA. It has a drain tube lateral to the ventilatory tube which helps in drainage of the regurgitated gastric secretions. When properly placed the drain tube separates the alimentary and the respiratory tracts completely [1]. In addition to the peripheral cuff PLMA has a dorsal cuff, which improves the seal around the glottic aperture and permits high airway pressures without leak [7]. Endotracheal intubation is considered the gold standard for laparoscopic surgeries. This study was designed to compare PLMA with endotracheal intubation in terms of efficacy and safety.

Corresponding Author: Sandhya M K, Assistant Professor, Department of Anaesthesiology, Kanachur Institute of medical sciences, Mangalore, Karnataka 575018, India.

E-mail: sandhyamohanmk@gmail.com

Received on 28.09.2018, **Accepted on** 16.10.2018

Materials and Methods

After approval from institutional ethical committee of this study was conducted in government medical college, New Civil Hospital Surat. Sixty ASA physical status 1 and 2 patients aged between 18 to 60 years posted for laparoscopic cholecystectomy were included in the study. Patients were divided into two groups of 30 patients each using a computer generated table of random numbers. The patients with anticipated difficult airway, obesity, oropharyngeal pathology, trismus, cardiopulmonary disease, cervical spine fracture, gastro oesophageal reflux disease and risk of aspiration were excluded from the study.

After obtaining informed consent all patients were premedicated with injection glycopyrolate 0.04 mg/kg IV, injection ranitidne 50 mg IV and inj metaclopramide 10 mg IV thirty minutes before shifting the patient to the operating room. On arrival to the operating room routine monitors were attached and baseline values for heart rate, blood pressure were recorded. All patients were preoxygenated with 100% oxygen for 3-5 minutes [7]. Inj midazolam 0.02 mg/kg IV and fentanyl 2mcg/kg IV was given 3 minutes before induction of anaesthesia. All patients were induced with inj lignocaine 20 mg+ inj propofol 2-3 mg/kg IV and succinylcholine 2 mg/kg IV. No intermittent positive pressure (IPPV) was applied before securing the airway.

In group P PLMA size 3 or 4 were chosen depending on the weight of the patient. The cuff was fully deflated and the posterior aspect was lubricated using clear water based jelly. With the patients head on the pillow, the PLMA was introduced using the introducer tool pushing it slowly against the posterior pharyngeal wall. After insertion up to the integral bite block, cuff of PLMA was inserted with 25 or 30 ml of air (size 3 and 4 respectively). In case of group E patients endotracheal intubation was done with endotracheal tube size 7.5 or 8.5 by performing conventional laryngoscopy using Macintosh blade. All patients were ventilated the with same parameters VT-8 ml/kg, Fio2-0.33%, RR- 12/min, I: E ratio 1:2.

Correct placement of the device was confirmed by the following methods: 1) adequate chest rise, 2) square ETCO2 waveform, 3) expired tidal volume of 7-8 ml/kg 4) Silent epigastrium on auscultation 5) No audible leak from drain tube 6) gel displacement test- a drop of gel is placed on the drain tube of PLMA and if the drop moved out with ventilation the device position was considered improper. (5 and 6 were performed in case of PLMA) [5].

The time between picking up of airway device and establishment of adequate airway was recorded in both the groups. The number of attempts and ease of insertion were recorded as 1) easy: at first attempt with no resistance, 2) at second attempt or insertion with resistance, 3) failed: insertion not possible or three or more attempts required. The following parameters were recorded 1) haemodynamic variables: pulse, mean arterial blood pressure 2) ventilation variables - oxygen saturation, end tidal carbon dioxide $ETCO_2$ and peak airway pressure. All haemodynamic variables, $ETCO_2$ and oxygen saturation were recorded before induction, and 5 minutes after induction, before and after achieving carboperitoneum, after desufflation of carboperitoneum and at extubation. Peak airway pressure was recorded before and after achieving carboperitoneum.

Oxygenation and ventilation was aimed to maintained SPO_2 > 95% and $ETCO_2$< 45 mm of hg, by adjusting Fio 2, respiratory rate and tidal volume. If SpO_2 falls below 97% FIO2 was increased to 50 per cent, when saturation failed to improve tidal volume was increased to 10 ml /kg, then to 12 ml/kg. Oxygen saturation between 90-94 per cent was considered suboptimal and saturation <90% was considered failed. An increase in $ETCO_2$ above 45% was managed by increase in RR to 14 and then to 16 per minute.

A lubricated nasogastric tube was inserted in both groups, in group P nasogastric tube size 12 and 14 were used in PLMA size 3 and 4 respectively, in Group E size 14 or 16 nasogastric tubes were used. Ease of insertion was noted in both groups. Adequacy of ventilation and oropharyngeal seal provided by both devices was assessed by grading of stomach size from0 to 10, where grade 0 is deflated and grade 10 is fully distended. This was assessed by the surgeon by laparoscopy.

Anaesthesia was maintained with sevoflurane or isoflurane as maintenance agent along with long acting muscle relaxant.

Complication of aspiration and regurgitation was detected by litmus test, where a litmus paper was applied to the secretions on the dorsal aspect of PLMA and on the cuff of endotracheal tube in group E. If blue litmus turns red then the reaction is acidic indicating a regurgitation of acidic stomach contents. Any other complications like hypoxia, hypercarbia, laryngospasm, emphysema were noted.

After completion of the surgery, residual neuromuscular block was reversed with adequate dose of neostigmine and glycopyrolate. After regain of consciousness and return of protective airway refluxes, airway device was removed after gentle suction of the oral cavity. After transferring the patient to recovery room, heart rate and blood pressure was monitored at regular intervals. Patients were asked about soreness of throat after 24 hours.

Data was analysed using computer statistical software system openepi (open source epidemiological statistics for public health). All data was presented as mean and standard deviation (SD), except where specified. The two tailed students t test was for unequal variance was used for intergroup comparisons except where specified. Probability values $p < 0.05$ were considered significant and $p < 0.001$ were considered highly significant.

Results

There was no significant difference in age, sex, weight, between the two groups (Table 1). It was observed that the mean time of insertion of the airway device was greater in group P (80±43.56) seconds compared to group E (23±17.71 seconds. The difference was statistically highly significant ($p<0.01$). The baseline heart rate was comparable in both groups (Figure 1). The mean heart rate after 1 minute of insertion of the airway device was 96.67±12.00 in group P and 105.76±13.29 in group E and the difference was statistically significant ($p<0.05$). The mean heart rate was comparable in both the groups during the rest of the study (Table 2). The baseline mean arterial blood pressure was comparable in both the groups (Figure 2). The mean arterial blood pressure was 75.87±5.41mm of

Table 1: Demographic Profile

	Group P	Group E	p Value
Age (years)	35.33+11.13	38.53+9.46	p>0.05
Sex (M/F)	3/26	5/25	
Weight (KGS)	51.58+3.48	51.33+3.56	p>0.05

Table 2: Heart rate

	Heart Rate		
Time Interval	Group P	Group E	p value
Baseline	102.34+13.33	95.56+15.66	p>0.05
I minute after insertion	96.67+12.00	107.76+13.29	p<0.05
5 min after insertion	93.72+13.24	97.73+13.29	p>0.05
Before carboperitoneum	89.41+16.26	89.83+111.82	p>0.05
After carboperitoneum	90.82+16.17	86.53+11.82	p>0.05
Before desufflation	85.17+12.99	83.36+11.94	p>0.05
After extubation	91.86+11.69	91.60+11.57	p>0.05

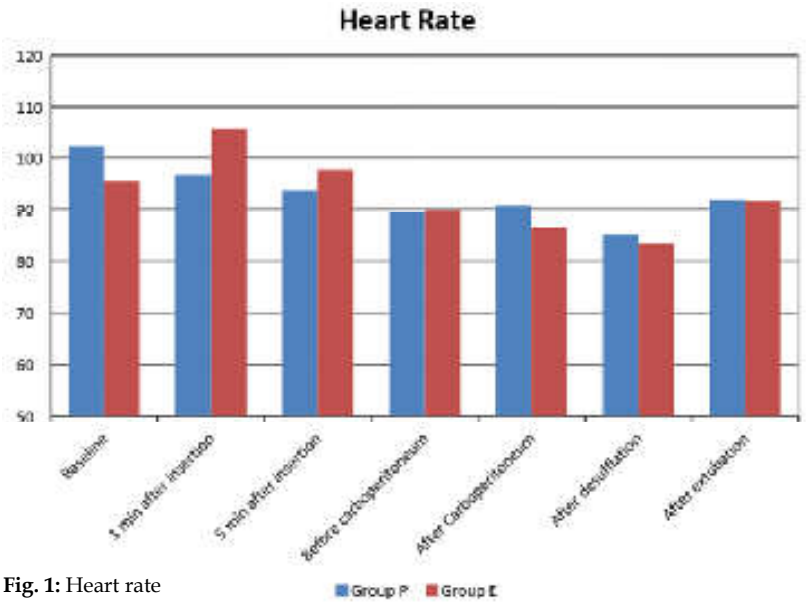

Fig. 1: Heart rate

Hg and 74.20±5.83 mm of Hg in group P at 1 and 5 minutes respectively after insertion of PALMA, 89.34±8.53 mm of Hg and 82.33±7.72 mm of Hg at 1 and 5 minutes respectively after insertion. The differences were statistically highly significant (Table 3). It was observed that the mean SpO_2 was comparable in both groups and it was never below 97% in both groups. The baseline $ETCO_2$ was comparable in both the groups at all times except for 5 minutes after insertion of the airway

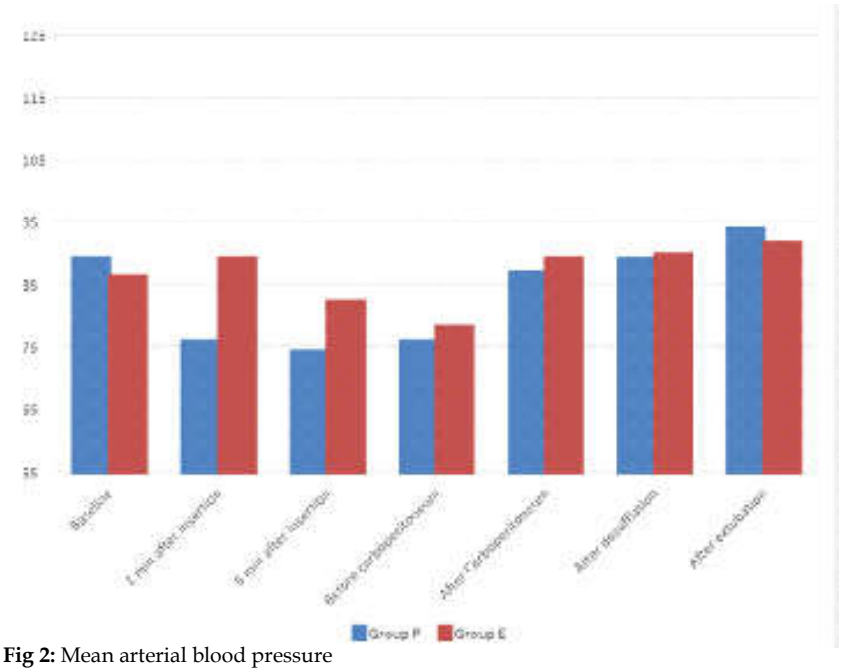

Fig 2: Mean arterial blood pressure

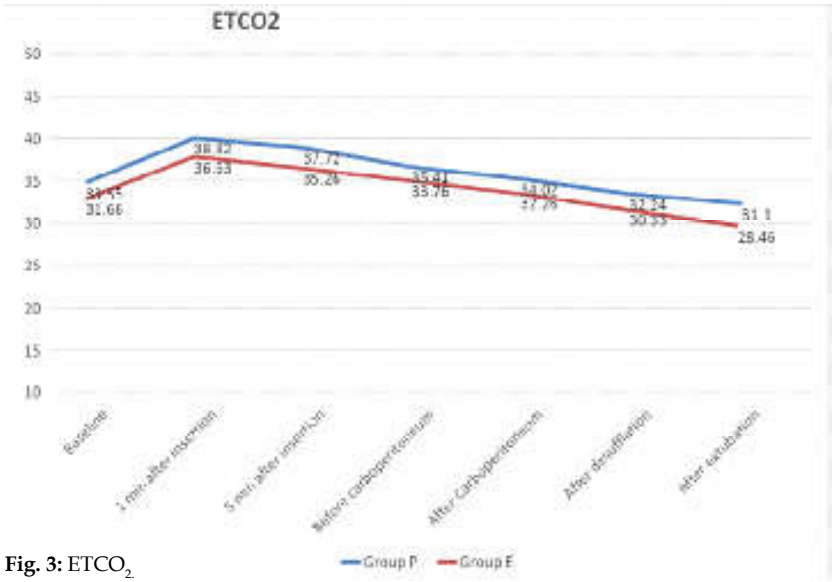

Fig. 3: $ETCO_2$

Table 3: Mean arterial blood pressure

Mean Arterial Blood Pressure			
Time Interval	**Group P**	**Group E**	**P value**
Baseline	89.33+5.99	86.34+8.29	P>0.05
I minute after insertion	75.87+5.41	89.34+8.53	P<0.01
5 min after insertion	74.20+5.83	82.33+7.72	P<0.01
Before carboperitoneum	75.89+5.95	78.17+6.96	P>0.05
After carboperitoneum	86.90+0.66	89.33+7.94	P>0.05
Before desufflation	89.05+5.80	89.92+5.29	P>0.05
After extubation	94.02+3.97	91.75+5.23	P>0.05

device where it was significantly higher (p<0.05) in group P (Table 4) (Figure 3). The mean peak airway pressure was comparable throughout the study except for after carboperitoneum (Table 5). After carboperitoneum there was significant rise in peak airway pressure in group E (Figure 4). Ease of Ryles tube insertion was comparable in both the groups (Table 6). The gastric insufflation was graded by the surgeon on a scale of 0 to 10, where 0 stands for fully deflated stomach and 10 for a stomach inflated to obstruct laparoscopic view. The mean value of stomach size grading was higher in group P (6.24±3.22) compared to group E (3.96±3.10) and the difference was statistically significant (p<0.05).

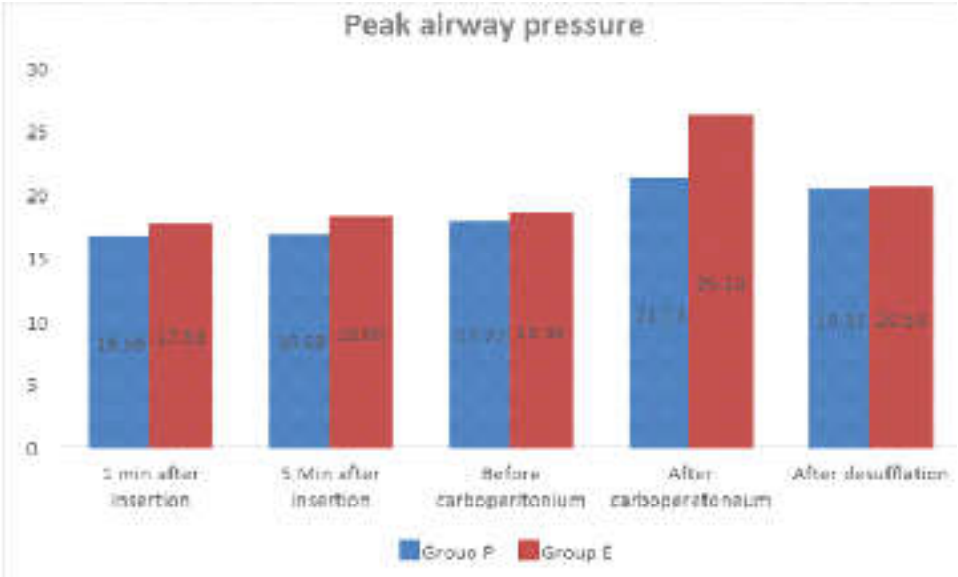

Fig. 4: Peak Airway Pressure

Table 4: $ETCO_2$

	$ETCO_2$		
Time Interval	**Group P**	**Group E**	**p>0.05**
Baseline	33.55	31.66	p>0.05
1 min after insertion	38.82	36.63	p>0.05
5 min after insertion	37.72	35.26	p<0.05
Before carboperitoneum	35.41	33.76	p>0.05
After Carboperitoneum	34.02	32.26	p>0.05
After desufflation	32.24	30.33	p>0.05
After extubation	31.1	28.46	p>0.05

Table 5: Peak Airway Pressure

	Peak Airway Pressure		
	Group P	**Group E**	
1 min after insertion	16.56	17.53	p>0.05
5 Min after insertion	16.69	18.06	p>0.05
Before carboperitoneum	17.72	18.36	p>0.05
After carboperitoneum	21.13	26.13	p>0.05
After desufflation	**20.31**	**20.53**	**p>0.05**

Table 6: Ease of Ryles tube insertion.

	Ease of Ryles tube insertion		
	Group P	**Group E**	**p value**
Easy	27(90%)	28(93.33%)	>0.05
Difficult	2(6.66%)	2(6.66%)	>0.05
Failed	1(3.33%)	0	

Blood staining of the device was noticed in 1 patient in group P (3.44%) and 6 patients in group E (20%). Trauma to the oropharyngeal structures were seen in 1 patient (3.44%) in group P and 2 patients (6.8%) in group E. The differences were not statistically significant. None of the patients developed aspiration or regurgitation. After 24 hours 2 patients (6.8%) in group P and 13 patients in group E (43.33%) complained of sore throat. The difference was statistically significant.

Discussion

Proseal LMA is a supraglottic airway device with drain tube, integral bite block and different cuff design, increased depth of the bowl to improve the seal with the larynx and helps to deliver positive pressure ventilation. When inserted properly it separates the alimentary tract from the respiratory tract, provides adequate seal around the glottic aperture. Endotracheal intubation is considered the gold standard for airway management in laparoscopic surgeries. However it is not devoid of complications like presser response to laryngoscopy and intubation, damage to the oropharyngeal structures during rigid laryngoscopy and sore throat. The use of Proseal LMA instead of conventional laryngoscopy and intubation may overcome these problems [8]. A Ryle's tube can also be passed through the drain tube for aspiration of the gastric secretions. In this study we compared Proseal LMA with endotracheal intubation in terms of ease of insertion, haemodynamic response to insertion, efficiency in delivering positive airway pressure and incidence of complications like aspiration, regurgitation and post-operative sore throat.

In our study there was no failed insertion, however the time taken for insertion of PLMA was greater than endotracheal intubation and the difference was highly significant. This can be attributed to the fact that our anaesthesiologists had lesser exposure to PLMA. Previous studies conducted by anaesthesiologists who had more experience with LMA, concluded that time of insertion of LMA was greater that time required for endotracheal intubation however the difference was not statistically significant [3,7].

The haemodynamic response to PLMA was minimal compared to endotracheal intubation. This can be attributed to the fact that PLMA insertion was relatively easy and does not involve rigid laryngoscopy therefore does not invoke a sympathetic response.

The Proseal drain tube allows the passage of a gastric tube which helps in drainage which helps in emptying gas or gastric secretions from the stomach [1,2]. A lubricated nasogastric tube was inserted in both groups, in group P nasogastric tube size 12 and 14 were used in PLMA size 3 and 4 respectively, in Group E size 14 or 16 nasogastric tubes were used. Ease of insertion of Ryles tube was comparable in both the groups.

Both groups maintained oxygen saturation above 97 per cent throughout the surgery. Following peritoneal insufflation, CO_2 is absorbed transperitoneally and the rate at which it occurs depends on gas solubility, perfusion of peritoneum and duration of pneumoperitoneum [7]. $ETCO_2$ levels were within normal limits in both the groups.

Adequacy of ventilation and oropharyngeal seal provided by both devices was assessed by grading of stomach size from 0 to 10, where grade 0 is deflated and grade 10 is fully distended in our study the stomach was more deflated in group E.

There was no intraoperative displacement of the device. There was no aspiration on regurgitation in any patients.

After 24 hours nine of the patients in group E had sore throat, and 1 patient in group P developed sore throat. The absence of sore throat could be because LMA is a supraglottic airway device and mucosal pressures achieved are usually below pharyngeal perfusion pressures [7].

Conclusion

Proseal LMA can be used as an effective alternative to endotracheal intubation, without increasing the incidence of complications in patients undergoing laparoscopic surgeries.

Acknowledgement

We thank Dr Harsha patel, Professor Department of anaesthesiology GMC Surat for her support.

Conflict of Interest: Nil

References

1. Brain AIJ, Verghese C, Strube PJ. The LMA 'ProSeal': A laryngeal mask with an oesophageal vent. Br J Anaesth 2000;84:650-4.

2. Cook TM, Nolan JP, Verghese C, et al. Randomized crossover comparison of the ProSeal with the classic laryngeal mask airway in unparalysed anaesthetized patients. British Journal of Anaesthesia 2002;88: 527–33.
3. Lalwani J, Dubey KP, Sahu BS, Shah PJ. ProSeal laryngeal mask airway: An alternative to endotracheal intubation in paediatric patients for short duration surgical procedures. Indian Journal of Anaesthesia. 2010;54(6):541-5.
4. Lim Y, Goel S, Brimacombe JR. The ProSeal laryngeal mask airway is an effective alternative to laryngoscope-guided tracheal intubation for gynaecological laparoscopy. Anaesth Intensive Care. 2007;35:52–6.
5. Maltby JR, Beriault MT, Watson NC, Liepert D, Fick GH. The LMA-ProSeal is an effective alternative to tracheal intubation for laparoscopic cholecystectomy. Can J Anaesth. 2002;49:857–62.
6. Mansour SA, Ahmed WG, Azzam KA, EL. Sai TM. Safety and efficacy of ProSeal laryngeal mask airway versus classic laryngeal mask airway and endo tracheal tube during elective surgery. Egypt J Hospital Med 2005;21:82–94.
7. Saraswat N, Kumar A, Mishra A, Gupta A, Saurabh G, Srivastava U. The comparison of Proseal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia. Indian Journal of Anaesthesia. 2011;55(2):129-34.
8. Sharma B, Sehgal R, Sahai C, Sood J. PLMA vs. I-gel: A Comparative Evaluation of Respiratory Mechanics in Laparoscopic Cholecystectomy. Journal of Anaesthesiology, Clinical Pharmacology. 2010;26(4):451-7.
9. Sharma B, Sood J, Sahai C, Kumra VP. Efficacy and safety performance of Proseal™ laryngeal mask airway in laparoscopic surgery: Experience of 1000 cases. Indian J Anaesth. 2008;52:288–96.