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Original Research Article

CLINICAL EVALUATION AND INTRACUFF PRESSURE MONITORING OF LMA PROSEAL VERSUS LMA SUPREME DURING ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY

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Abstract

Background: Tracheal intubation and controlled ventilation is the gold standard for the anaesthetic management of patients undergoing laparoscopic cholecystectomy. Creating pneumoperitoneum during laproscopy raises intra-abdominal pressure and increases risk of regurgitation and pulmonary aspiration. LMAs allow easy placement without the use of laryngoscope and hence fewer hemodynamic alterations as compared to tracheal intubation and extubation. LMA ProSeal and LMA Supreme are effective ventilatory devices for laparoscopic cholecystectomy. In this study we compared LMA Supreme with LMA ProSeal in laparoscopic cholecystectomy with respect to, oropharyngeal seal pressure and intracuff pressures. **Materials and Methods:** This prospective randomized study was conducted in sixty adult patients of American Society of Anaesthesiologists's Grade I and Grade II, weighing between 30 to 70 kg, scheduled to undergo elective laparoscopic cholecystectomy. Patients with age<30 years, weight <30kg, obese, difficult airway, edentulous, mouth opening <2.5cm, history of upper respiratory tract infections in the last 10 days, pregnant patients and patients with spine, esophageal and intestinal pathology were excluded from the study. All patients received a standard general anaesthetic and either LMA Supreme or LMA ProSeal was inserted. Assesssment of insertion time, ease of insertion, fiberoptic view and, oropharyngeal seal pressure was done. Intracuff pressure was assessed repeatedly and the cuff was deflated at regular intervals to maintain the cuff pressures at 60cm of H2O. **Result:** Oropharyngeal Seal Pressure was LMA Proseal (30.37cm of H2O at 1 min and 30.10 cm of H2O at 60 min) and LMA Supreme(24cm of H2O at 1 min and 25.03cm of H2O at 60 min). A statistically significant difference was found in the intracuff pressure between the two groups 2 mins after the LMA placement, at the time of pneumoperitoneum, during positioning and 30 mins and 1 hour after LMA placement. **Conclusion:** We recommend monitoring of the intracuff pressure of both the device and maintain the cuff pressure at 60 cm of H2O by repeated deflation of the cuff.

INTRODUCTION

Tracheal intubation and controlled ventilation is considered as the gold standard for the anaesthetic care of patients undergoing laparoscopic cholecystectomy.

Pneumoperitoneum during laproscopy increases the risk of pulmonary aspiration and regurgitation while also raising intra-abdominal pressure. Therefore we need to ensure patent airway, adequate ventilation and isolation of respiratory and alimentary tract which can be achieved by the introduction of new generation supraglottic devices, that have been added to the anaethesiologist's armamentarium.[1]

LMA is the first supraglottic device invented by Archie Brain in 1981, which became commercially available in UK in 1988 and in US in 1991. The LMA ProSeal is a modification of LMA Classic. It is a reusable device, made up of silicon and has an additional dorsal cuff designed to provide more effective seal around the glottis, a drain tube that acts as a bypass channel for regurgitated gastric contents and an integrated bite block.[2,3]

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LMA Supreme, launched in March 2007, is a single use device made of Polyvinyl chloride. It has a fixed curved shaft which allows easy insertion and oesophageal tube access to prevent aspiration. A double reinforcement of the tip of the cuff prevents kinking and folding.[3,4]

These LMAs allow easy placement without the use of laryngoscope and hence fewer hemodynamic alterations as compared to tracheal intubation and extubation. LMA ProSeal and LMA Supreme have been used as effective airway management devices for laparoscopic cholecystectomy. The silicon cuff of LMA ProSeal, is highly permeable to diffusion of nitrous oxide which increases the intracuff pressure during nitrous oxide anaesthesia. Excess intracuff pressure is transmitted to pharyngeal mucosa which when exceeds tissue capillary perfusion pressure of mucosa, can lead to post-operative complications such as sore throat and dysphagia. Increased intra-abdominal pressure due to carboperitoneum and reverse Trendelenberg during laparoscopic cholecystectomy can cause increase in intracuff pressure of endotracheal tube and sore throat in post operative period.[5,6]

Measurement of intracuff pressure is a simple and inexpensive procedure and it should be applied in all patients undergoing surgery to decrease post-operative complications. Few anaesthetists in clinical practise use this straightforward technique to repeatedly deflate the cuff and stabilise the cuff pressure at 60 cm of water.[7]

In this study we compared LMA Supreme with LMA ProSeal in laparoscopic cholecystectomy with respect to, oropharyngeal seal pressure and intracuff pressures. We monitored intracuff pressure of two LMAs during surgery and maintained cuff pressure at 60 cm of water by removal of air whenever required. This topic has been chosen as we could find very few studies comparing the two LMA devices in patients undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS

The study was conducted in the Department of Anaesthesia and Intensive Care, xxx Hospital, after obtaining the hospital review committee approval and written consent from all patients.

This prospective randomized study was conducted in sixty adult patients of American Society of Anaesthesiologists's Grade I and Grade II, weighing between 30 to 70 kg, scheduled to undergo elective laparoscopic cholecystectomy. They were randomly allocated to two groups:

Group I - LMA ProSeal(ProSeal) (n = 30) and

Group II - LMA Supreme(Supreme) (n = 30)

Randomization was performed using a sealed envelope method. Anaesthetists experienced in the use of LMA ProSeal and LMA Supreme participated in the study. Blinded trained observer collected the data post-operatively during post-operative follow-up and unblinded trained observer collected the data during anaesthesia.

Patients with age<30 years, weight <30kg, obese, difficult airway, edentulous, mouth opening <2.5cm, history of upper respiratory tract infections in the last 10 days, pregnant patients and patients with spine, esophageal and intestinal pathology were excluded from the study.

Preoperative Preparation

All the patients were made to fast overnight and received Tablet Alprazolam 0.25 mg orally a night before surgery. On the morning of surgery Tablet Metoclopramide 10 mg and Tablet Ranitidine 150 mg was given orally 2 hours prior to the surgery. Inter-incisor gap, Mallampati score and thyromental distance was noted.

Anaesthesia Technique

Patients were taken to operation theatre and standard monitoring was attached before induction of anaesthesia. Basal parameters such as heart rate, blood pressure, Sp02 and ECG was recorded. Intravenous line was secured using 18 gauge cannula and intravenous premedication with Midazolam 0.02 mg per kg and Glycopyrrolate 0.2 mg was given.

Induction and Maintainence

Patient was oxygenated for 3 minutes with bag and mask. Induction of general anaesthesia was performed using Fentanyl 2 mg per kg intravenous and Propofol 2 - 2.5 mg per kg intravenous, till loss of verbal command and, vecuronium bromide 0.1mg per kg intravenous. Haemodynamic parameters, Sp02 and EtCO2 was monitored. Face mask ventilation was done with 100% oxygen and Isoflurane (0.6 - 0.8%). According to manufacturer's recommendation LMA size was selected (according to the weight of the patient). Airway device was lubricated. After 3 minutes of Intermittent Positive Pressure Ventilation (IPPV), either LMA Supreme was inserted using single hand rotation technique or LMA ProSeal was inserted using an introducer tool technique as suggested by manufacturer. Depth of anesthesia was assessed using jaw thrust before insertion of LMA.

During insertion intra-operative events like bucking, coughing, body movement, laryngospasm and fall of SpO2 was noted. Using a 50 ml syringe, the device's cuff was inflated with air. The amount of air needed to achieve an intracuff pressure of 60 cm of water was recorded. Manometer (cuff pressure gauge, swlz, Germany) was used for achieving intracuff pressure of 60cm of water and intracuff pressure was recorded repeatedly. Effective airway was judged by bilateral chest movement, bilateral equal air entry on auscultation, square wave capnograph tracing with value, lack of gastric insufflation and no audible leak at peak airway pressures less than 20 cm of water during gentle manual ventilation. Preloading of LMA was done using orogastric tube French Gauge No. 12 before insertion of LMA and later on it was slided down into the stomach and correct placement was confirmed by injection of air

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and epigastric auscultation. In the event of failure of insertion of device or complete airway obstruction or a significant leak, mask was removed and re-insertion was attempted. Two attempts will be allowed before the device was considered a failure and endotracheal intubation was done thereafter. Once the effective airway was maintained and intracuff pressure was maintained at 60 cm of water, oropharyngeal seal pressure was determined.

After first reading of intracuff pressure, patient was ventilated with tidal volume of 8 ml/kg, adjusting the respiratory rate to maintain end tidal CO2 of 30-35 mmHg using closed circle breathing system with sodalime. Fresh gas flow of 3 l/min [N2O-2l/min, O2-1l/min] with isoflourane (0.4-0.6%) and I:E ratio of 1:2 was maintained. Supplementation of vecuronium bromide intravenously was given whenever needed. Ventilatory parameters like inspiratory tidal volume, expiratory tidal volume, EtCO2 and peak airway pressure was noted. Intra-operative monitoring was continued every 15 minutes throughout the operation. In all the cases an intra-peritoneal insufflation pressure of 12mm of Hg was maintained. Deflation of cuff was done and volume was noted at every 30 minutes, if required, to maintain intracuff pressure at 60 cm of water. Anatomical position of LMA was determined by fibre-optic view and scoring was done. Inj. Diclofenac 3 ml (75 mg) for pain relief was given intramuscularly and anti-emetic Ondensetron 4 mg was given intravenously.

Insertion time was noted from removal of face mask to first capnograph reading.[3]

Ease of insertion was graded using following score:

- Score 1: Easy
- Score 2: Difficult
- Score 3: Not possible.[4]

Anatomical position of airway device in relation to glottic opening was assessed by passing fibre-optic bronchoscope (paediatric) through the airway tube keeping the tip of the bronchoscope just proximal to its end. The view will be graded by following score:

- Score 1: Full view of cords
- Score 2: View of cords partially blocked by epiglottis
- Score 3: Only arytenoids visible
- Score 4: No laryngeal structure visible.[2,3]

Deflation volume was noted half hourly to maintain the intracuff pressure of 60 cm of water with the use of 10 ml syringe.

By closing the circular system's expiratory valve at a set gas flow of 3 litres per minute, measuring the pressure at which an audible leak occurs at the mouth, and listening over the trachea, the oropharyngeal leak pressure was determined.[3,4]

Reversal

At the end of surgery all patients were reversed with intravenous Neostigmine (0.05mg/kg) and intravenous Glycopyrrolate (0.01 mg/kg). Ryles tube suction was done and it was removed. The device was removed when the patient is awake and opens mouth on command. The device was inspected for blood stain.

Patients were questioned at 1hr and 24hr post operatively regarding sore throat, dysphagia, dysphonia and hoarseness of voice.

Statistical Analysis

Data was presented in frequency (percent) for qualitative variable, and mean + standard deviation for quantitative variables. The statistical significance of qualitative variable of the two groups was determined by chi-square/Fisher exact test, and the statistical significance of quantitative variables was determined by unpaired t-test/non-parametric Mann-Whitney test. The level of statistical significance was taken as $p <= 0.05$. The data was analysed using SPSS (version 16.0).

Assuming $\alpha = 0.05$ and power = 80% the minimal sample size in each group was 30.

RESULTS

The two groups were statistically comparable with regards to the demographic data like distribution of Age, Sex, Height, Weight and BMI

Insertion time for ProSeal group was 19.033±4.34 seconds and for Supreme group it was 17.233±3.64 secs. Both the groups were comparable with regard to insertion time as p value was 0.087.

In our study no statistical difference was found between the two groups with regard to ease of insertion as p value > 0.05. [Figure 1]

Oropharyngeal Seal Pressure was LMA Proseal (30.37cm of H2O at 1 min and 30.10 cm of H2O at 60 min) and LMA Supreme(24cm of H2O at 1 min and 25.03cm of H2O at 60 min). The two groups was statistically comparable at 1min and 60 min with p value 0.778 and 0.698.

Fibreoptic bronchoscopic score was comparable between both the groups with p value of 0.432 [Table 1].

There was no statistical significant difference in intracuff pressure measurement in both the groups at the time LMA placement but a statistically significant difference was found between the two groups 2 mins after the LMA placement, at the time of pneumoperitoneum, during positioning and 30 mins and 1 hour after LMA placement. [Table 2]

There was no significant difference in the deflation volume at LMA placement between two groups (p value > 0.05) but a statistically significant difference was noted in the deflation volume at 30 mins and at 60 min between the two groups. [Table 3]

Intraoperative and postoperative complication

- In the study there was no intra-operative complications and no case of dysphonia and hoarseness of voice and the two groups were comparable with regards to sorethroat and dysphagia at 1 hr and 24 hrs postoperatively.

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Table 1: Fiberoptic score

Fiberoptic bronchoscopic score	LMA Proseal	LMA Supreme
1	27(90%)	24(80%)
2	3(10%)	5(16.7%)
3	0(0%)	1(3.3%)
4	0	0

Table 2: Intracuff presssure (in cm of H2O)

Intracuff pressure	LMA proseal	LMA supreme	P value
At LMA placement	60.67±1.516	60.13±0.507	0.184
2 mins	69.80±2.250	62.53±1.570	0.001
At pneumoperitoneum	77.27±3.342	66.20±2.592	0.001
At reverse trendelenberg	82.67±3.095	68.93±3.921	0.001
30 min	89.67±4.334	73.00±5.139	0.001
1 hour	71.67±3.754	62.67±2.987	0.001

Table 3: Deflation volume

Deflation volume(ml)	LMA Proseal	LMA Supreme	P value
At LMA placement	0.083±0.189	0.007±0.036	0.076
At 30 min	2.8917±0.392	1.295±0.544	0.001
At 60 min	1.155±0.390	0.33±0.350	0.001

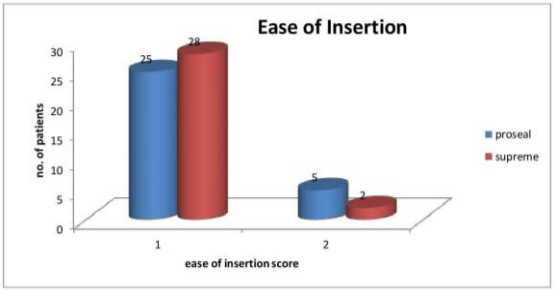

Figure 1: Comparison of ease of insertion

DISCUSSION

Over a period of time supraglottic airway devices have emerged as new airway devices in the anaesthesiologist's armamentarium. The Proseal is one of such new devices which was introduced in 2000. It is preferable to the LMA Classic for providing positive pressure ventilation because it improves glottic seal at lower mucosal pressures because of he presence of an additional posterior cuff and isolates the digestive tract from the respiratory tree due to a drainage tube, which lowers the risk of aspiration.[1,2,8]

The LMA Supreme was launced in March 2007,with design superior to its counterparts larger precurved cuff for optimal positioning and easy insertion, a double reinforcement of the tip to prevent kinking, and the epiglottic fins to prevent the epiglottis from folding over.[2,4]

Laparoscopic surgery is an upcoming subspeciality. The issue that plagues all such treatments is: a) intraperitoneal or extraperitoneal carbon dioxide insuffilation in the body; b) elevated abdominal pressure; and c) the risk for regurgitation and pulmonary aspiration. Till date the cuffed tracheal tube was considered as ideal for providing a safe glottic seal especially for laparoscopic procedures under GA but it was found that LMA Supreme and LMA ProSeal can be used safely in laparoscopic cholecystectomy with suitable patient and experienced users.[1,9,10]

In the present study we have compared LMA Proseal and LMA Supreme in anaesthetized patients on controlled ventilation undergoing elective laparoscopic cholecystectomy

The mean insertion time in our study was 19.033 seconds (range 11-30) for LMA ProSeal group and 17.233 seconds (range 10-24) for LMA Supreme group, which was statistically comparable as p value was 0.087. This is in accordance with the insertion time found by Hosten T and Gurkan Y,[3] which was 17.2 seconds for LMA ProSeal and 16.4 seconds for LMA Supreme.

Both the devices are comparable with regard to ease of insertion (p value = 0.424). Insertion was easy in 83.3% cases of LMA ProSeal and in 93.33 % cases of LMA Supreme. Insertion in first attempt was achieved in 90% (27) cases of LMA ProSeal and 96.66% (29) cases in LMA Supreme (p value= 0.612). In a study conducted by Hosten et al,[3] comparing LMA Supreme with LMA ProSeal in different types of surgery insertion at first attempt was 83.3% (25/ 30) for LMA ProSeal and 90% (27/3) for LMA Supreme, very similar to our study. Another study conducted by Hosten,[10] comparing LMA ProSeal and LMA Supreme in Cholecystectomy, insertion on first attempt was 93% for LMA ProSeal and 93% for LMA Supreme which was also comparable with our study

The mean Oropharyngeal seal pressure at 1 minute was 30.37 ± 3.409 cm of H2O for LMA ProSeal group and 24±2.483 cm of H2O for LMA Supreme group and the mean for 60 mins was 30.10 ± 3.872 cm of H2O for LMA ProSeal group and 25.03±2.141 for LMA Supreme group. The difference in pressure between the two groups was statistically significant (p value= .001) at both 1 min and 60 minutes and pressure of Supreme was lower to that of ProSeal. Whereas the difference in the oropharyngeal seal pressure within the group at 1 min and 60 mins in LMA ProSeal group (p value =

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0.7781) and LMA Supreme group (p value = 0.6982) was statistically comparable.

Our study is in accordance to the study conducted by Lee AK et al in which mean oropharyngeal seal pressure was 31.7± 6.3 cm of H2O for ProSeal and 27.9±4.7 cm of H2O for Supreme.[11] The pressure in Supreme was significantly lower (p value= 0.007) than that in ProSeal.

The study of Hosten,[10] comparing the OLP intraoperatively found that the Oropharyngeal seal pressure did not changed significantly during the induction and throughout the pneumoperitoneum within the group, there result was in support of our study.

In our study flexible fibreoptic bronchoscopy of LMA ProSeal group revealed score 1 view in 90%(27/30) of cases and LMA Supreme group revealed score 1 in 80%(24/30) of cases, score 2 view in 10 % of cases of LMA ProSeal group and 16.7% of cases of LMA Supreme group, 1 case in LMA Supreme group and none case in LMA ProSeal group showed score 3 view. None of the two groups showed score 4 views. The groups were statistically comparable with regard to fibreoptic bronchoscopic score (p =0.432). Our result is supported by a study done by Verghese and Ramaswamy,[12] in which Fibreoptic bronchoscopic scores 1-2 were recorded 29/36 in both groups (LMA Supreme and ProSeal) and the group was statistically comparable.

The cuff of the LMA is manufactured from silicon-based rubber, a substance known to permit the rapid diffusion of volatile anesthetics and nitrous oxide. So during general anaesthesia, nitrous oxide is expected to diffuse into the air filled cuff of the LMA more rapidly than nitrogen in air can diffuse out, thus cuff pressure would be expected to temporarily increase.[13,14]

The cuff pressure of the two groups were similar at the time of LMA insertion (p = 0.184) but the difference in the cuff pressure between the two group at 2 mins, at pneumoperitoneum, at reverse trendlenberg position, at 30 mins and at 1 hr was statistically significant (p = 0.001), the cuff pressures in LMA ProSeal group was greater than that of LMA Supreme group in each timeline. The Cuff pressure at 2 mins was 69.80±250 cm of H2O for LMA ProSeal group and 62.53±1.570 cm of H2O for LMA Supreme group and at 30 mins was 89.67±4.334 cm of H2O for LMA ProSeal group and 73.00±5.139 cm of H2O for LMA Supreme group. At 1 hr it was 71.67±3.754 cm of H2O for ProSeal and 62.67±2.987 cm of H2O. The cuff pressure in both the group increased statistically significantly with time (p=0.001). The decrease of the pressure at 1 hr was due to the deflation done at 30 mins.

According to a study conducted by Lee AK et al,[11] the cuff pressure after 60 mins was significantly (p < 0.001) higher in the PLMA (110±21 cm of H2O) than LMA Supreme (57± 8) which was in accordance to our study. Our cuff pressure for LMA ProSeal is slightly lower than the that found by Lee which might be due to the deflation of the cuff to the pressure of 60 cm of H2O at 30 mins and the cuff pressure of LMA Supreme corresponds there study.

The result of our study clearly demonstrated that the cuff pressure did not stabilize within 15 minutes as Gursoy et al,[15] reported, but continued to increase beyond that period.

In our study deflation of cuff upto the pressure of 60 cm of H2O was done just after LMA Placement, at 30 mins and at 1 hr and the volume of air deflated was noted. Negligible deflation was required just after LMA placement in the two group (p = 0.076). Deflation volume measured at 30 mins was 2.8917±0.3922 ml for LMA ProSeal and 1.295±0.54446 ml for LMA Supreme. The deflation volume between two groups was statistically significant (p= 0.001), suggesting that more air deflation was required to maintain the cuff pressure at 60 cm of H2O in LMA ProSeal group.

Similarly more air deflation was required at 1 hr in LMA ProSeal group (1.155±0.39048) than LMA Supreme group (0.33±0.3505), the difference here was also statistically significant (p =0.001).

There was no case of intraoperative complications like bucking, coughing, body movement, laryngospasm and fall in SpO2. There was also no case of Dysphonia and Hoarseness. There was 2 cases of Sore throat at 1 hour postoperative in each group and 2 cases of Sore throat at 24 hour postoperative. There was 1 case of Dysphagia in LMA Proseal group at 1 Hr and 24 Hrs and 2 cases of Dysphagia in LMA Supreme group at 1 hr and 24 Hrs. The two groups were statistically comparable(p=1) with regard to intraoperative and postoperative complications. Hosten,[3,10] in a study comparing LMA ProSeal and LMA Supreme group found similar intraoperative and postoperative complications between the two groups. There was no intraoperative complication in both groups, similar to our study. The use of these devices for administering general anaesthesia during laparoscopic cholecystectomy cannot be generalised for patients who weigh more than the study's study population of 30 to 70 kg, especially in obese individuals.

CONCLUSION

We strongly recommend the use of LMA ProSeal and LMA Supreme for controlled ventilation in adults undergoing laparoscopic cholecystectomy. Its negligible hemodynamic response, ease of insertion and design helping to form a seal around glottis to reduce the risk of aspiration favors its use in elective surgery. We also recommend monitoring of the intracuff pressure of both the device and maintain the cuff pressure at 60 cm of H2O by repeated deflation of the cuff.

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