www.jmscr.igmpublication.org
Impact Factor 5.84
Index Copernicus Value: 83.27
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v5i8.123

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

**Original Research Article**

# Proseal Laryngeal Mask Airway versus Endotracheal Intubation for Laparoscopic Surgery: A Randomized Controlled Study

Authors
**Basavaraj Padara[1], Maya Jamkar[2]**
[1]Assistant Professor Department of Anaesthesia, Gadag Institute of Medical Sciences, Gadag
[2]Associate Professor Department of Anaesthesia B J Medical College Pune

**ABSTRACT**

**Context:** *Proseal LMA (laryngeal mask airway) is an useful modification of the classical LMA, which provides better hemodynamic stability and protection against intra operative as well as postoperative complications when used in laparoscopic procedures.*

**Aims:** *To compare the efficacy of Proseal laryngeal mask airway (LMA) and endotracheal tube (ETT) in patients posted for laparoscopic surgery under general anaesthesia.*

**Settings and Design:** *This prospective randomized comparative study conducted in collaboration with a tertiary care level hospital. study was conducted on 100 ASA I-II class patients posted for laparoscopic surgery under general anaesthesia*

**Methods and Material:** *A total of 100 patients posted for various laparoscopic surgeries were allocated into 2 groups of 50 each. After preoxygenation and induction, Proseal LMA was inserted in group A patients and patients in group B were intubated with ETT. Attempts for successful insertion, time taken for successful insertion, hemodynamic variations at various events and protection provided against both intra operative and postoperative complications were studied Statistical analysis used: Qualitative data was analysed using chi-square test or Fischer analysis and quantitative data analysed using paired or unpaired t test.*

**Results:** *First attempt insertion success rate was 84% for PLMA insertion as compared to 76% for endotracheal intubation, Time for successful insertion was 15.54 sec in PLMA group and 20.20 sec in ETT group. Mean heart rate changes during PLMA insertion and removal were 5.52 and 7.10 respectively, and 9.56 and 11.46 at the same events with ETT. Mean systolic blood pressure changes during PLMA insertion and removal were 3.76 and 3.92 respectively and 13.92 and 23.20 at same events with ETT. No events of gastric regurgitation or pulmonary aspiration observed in both groups. PLMA provided better protection against postoperative complications like cough (6%) and sore throat (6%) as compared to ETT with 44% and 24% incidence respectively.*

**Conclusions:** *Proseal LMA can be considered as a safe and effective alternative to endotracheal intubation in patients undergoing various laparoscopic procedures under general anesthesia.*

**Keywords:** *Proseal LMA, endotracheal tube, hemodynamic stability, pulmonary aspiration.*

## Introduction

Laparoscopic surgery is an evolving sub speciality used for many gastro intestinal, urologic and gynaecologic conditions. At the same time it is associated with some peculiar complications related to carbon dioxide insufflation, raised intra abdominal pressure and potential danger of regurgitation and pulmonary aspiration. Till date the cuffed ETT was considered as gold standard for providing a safe glottic seal during

laparoscopic surgery under general anaesthesia. New device Proseal LMA has gained wide acceptance, proved and documented to be safe and effective for laparoscopic surgery[1,2]. Proseal LMA has many desired modifications over classic LMA like a drain tube in addition to reinforced airway tube which prevents inadvertent gastric inflation and aids to nasogastric tube insertion[3] Proseal LMA which is a supraglottic device and less invasive is considered to cause less hemodynamic response[4,5,6]. In this study we aimed to evaluate and compare use of Proseal LMA in patients undergoing laparoscopic procedures under general anaesthesia with conventional endotracheal tube with respect to the ease of insertion, hemodynamic stability, and protection against both intraoperative and post-operative complications peculiar to laparoscopic surgery

**Subjects and Methods**

After approval of the study protocol by our institutional ethics committe, written informed consent was obtained from each patient. 100 ASA I-II patients, of either sex, aged 1875 years, weighing 35-80 kg and undergoing various laparoscopic procedures were included in the present study. Patients with a known difficult airway, BMI >30 kg/m2, mouth opening <2.5 cm, full stomach and those having hiatus hernia, gastroesophageal reflux disease (GERD) were excluded from the study On arrival to the operation theater, an 18-G venous cannula was inserted and Standard monitors like electrocardiography (ECG), non-invasive blood pressure (NIBP) and pulse oximetry (SpO2) were attached and the baseline parameters were recorded. Using a computer-generated randomization schedule, the patients were randomly divided into 2 groups . In group A (n-50) patients PLMA was inserted and in group B (n-50) patients airway was secured with ETT. After preoxygenation with 100% O2 for 3 minutes patients in both the groups were induced with inj. propofol 2 mg/kg I.V. Succinyl choline in the dose of 2 mg/kg was used as muscle relaxant. After confirming the depth of anaesthesia, proper sized Proseal LMA was inserted in group A patients after deflating cuff and applying lubricant over dorsal surface. Mouth opened with the help of left hand and Proseal LMA held in right hand. The index finger is placed in the retaining strap and the Proseal LMA is pressed against the hard palate and advanced into the hypopharynx until resistance is felt. The finger in the retaining strap is pushed towards the occiput, while the other hand exerts counter-pressure to maintain the 'sniffing' position'. Cuff inflated and Position confirmed by auscultation, chest expansion, Spo2 level and Etco2 levels. Similarly appropriate sized ET tubes were used for endotracheal intubation in group B patients. Patients in both groups were maintained on O2:N2O= 50:50, propofol infusion at the rate of 100 mcg/kg/min as anaesthetic agents and vecuronium (0.02 mcg/kg) as muscle relaxant with positive pressure ventilation on Bain's circuit.

Pre induction values of the Heart Rate (HR), Systolic Blood Pressure (SBP), Saturation of O2 (SpO2) were noted. At 1st min and 5th min after PLMA insertion or ET intubation these vital parameters were once again recorded along with recording End Tidal Carbon Dioxide (ETCO2) levels. All these parameters were observed every 10 min intra operatively. Number of attempts required for successful insertion of device and also the time taken for correct insertion/intubation were recorded. Ease of placement of Ryle's tube noted. Episodes of gastric inflation were noted by asking surgeon. After confirming the respiratory attempts on bag reversal was done with, Inj Glycopyrrolate 10 mcg/kg, IV and, Inj Neostigmine 0.05 mg/kg, IV. Thorough oropharyngeal suctioning done, spontaneous eye opening confirmed, tone, power, reflex noted and air blast checked. Thorough Oropharyngeal suctioning done once again, Cuff deflated and Patient extubated at deep inspiration.

Postoperatively values of PR, SBP and Spo2 were noted, device checked for presence or absence of blood, Presence or absence of secretions, events like coughing, nausea and vomiting were noted if

any, patients were followed up till further for 24 Hrs, for sore throat or any other postoperative morbidity. Post op follow up was done to see any postoperative aspiration and was decided to get chest X-ray done for symptomatic patients.

The detailed data was entered into the Microsoft excel sheet and subsequently analyzed by using appropriate statistical tests. Statistics were analyzed as mean, S.D, minimum, maximum and 95% of confidence interval. Graphical display was done for visual inspection. For the analysis of qualitative data, either chi-square test or Fischer analysis was used, whereas quantitative data was analyzed using paired or unpaired t test.

**Results**

The demographic profiles of the patients among the groups were comparable with regards to age, gender and weight (table 1). In present study, the distribution of type of surgery was also comparable between both the groups. Majority of cases studied included laparoscopic cholecyste-ctomy followed by laparoscopic appendicectomy, laparoscopic inguinal hernia repair and diagnostic gynaecologic laparoscopy.

To decide the ease of insertion and to compare it with that of an endotracheal tube we studied the number of attempts taken for successful insertion and also the time required for successful insertion of device or intubation with the ETT. First attempt insertion success rate was 76% in ETT group and 84% in Proseal group (table 2). In the present study the mean time taken for successful insertion (picking up of device to checking ventilation) was also less in Proseal LMA group as compared to that of ETT group. Mean time for successful intubation was 20.20 seconds for endotracheal group and that for Proseal LMA insertion was 15.54 seconds (table 2) Mean heart rate per minute changed from 77.46 at pre induction to 87.02 at 1st min, 82.74 at 5 th min,81.04 at 30 th min and 92.86 at the time of extubation in ETT group (table 3) . In Proseal group the mean heart rate varied from 74.64 at pre induction to 80.16 at 1st min, 77.16 at 5th min, 73.94 at 30th min and 81.04 at extubation (table 3) .The mean heart rate change from pre induction level to that at 1st and 5th min was more in ETT group as compared to that of Proseal group and the difference was statistically significant (graph 1). Similarly the mean heart rare change at the time of extubation was also more in the former group with statistical significance.

Mean systolic blood pressure changed from 118.36 mmHg at pre induction level to 132.28 mmHg at 1st min after the intubation in ETT group which was statistically significant. The change in Proseal group at same event was from 120.32 mmHg to 124.08 mmHg which is not statistically significant (table 4).

At the time of extubation the mean change in systolic blood pressure in ETT group was 23.20 as compared to that of 18.48 in Proseal group (graph 2)) Values of oxygen saturation (spo2) and end tidal co2 (Etco2) were recorded continuously, the oxygen saturation values were 99±1 in both the groups. Intra operatively after achieving pneumoperitoneum the mean Etco2 values were 30.48 and 30.38 in ETT and Proseal group respectively and there was no statistical significance.

In present study gastric insufflations as noted by asking surgeon intra operatively after creating pneumoperitoneum were noted. Only three patients in Proseal LMA group (table 5) had gastric distention without any regurgitation (visible from nasogastric tube) and aspiration which was statistically not significant when compared with endotracheal tube Postoperatively the patients were observed for any complications like nausea, vomiting, cough, sore throat (table 6)). In present study 3 out of 50 and 5 out of 50 patients experienced nausea in Proseal and ETT groups respectively this was a statistically insignificant finding. In the present study none of the patient had vomiting in both the groups. In present study there were significant number of patients who had cough in immediate postoperative period in ETT group (22 out of 50) with about 44% of incidence of postoperative

coughing, whereas it was only 6% (3 out of 50 patients) in Proseal LMA group (table 6) In present study, the incidence of sore throat (constant pain, independent of swallowing) after extubation was noted and similar enquiry was done after 24 hours. 3 out of 50 patients in Proseal group and 12 out of 50 patients in ETT group had sore throat (graph 3). In present study the incidence of sore throat in ETT group was statistically significant when compared with that of Proseal group, 24% and 6% respectively (table 6). In the present study blood on device (which indicates airway trauma) was found in 3 out of 50 patients in endotracheal group and no such case reported in Proseal group.

**Table 1:** patient characteristics

| variables | Group PLMA | Group ETT |
|---|---|---|
| Age (years) | 43.72 +/- 11.48 | 44.88+/-10.49 |
| Weight (kgs) | 59.42 +/- 6.89 | 56+/-8.05 |
| Sex (male:female) | 27:23 | 28:22 |

**Table 2:** Comparison of the number of attempts taken and time for successful insertion/intubation

| variables | | PLMA group | ETT group |
|---|---|---|---|
| attempts | 1 st | 42 | 38 |
| | 2 nd | 8 | 12 |
| Time taken | | 15.54+/-5.47 | 20.20+/-4.84 |

**Table 3:** Mean heart rate variations at different intervals

| Events | Number of patients | Heart rate (mean+/-SD) | Heart rate (mean+/-SD) | P value |
|---|---|---|---|---|
| | | ETT | PLMA | |
| Preinduction | 50 | 77.46 +/-8.50 | 74.64+/-7.43 | 0.08 |
| 1st min | 50 | 87.02+/-10.32 | 80.16+/-7.27 | <0.001 |
| 5th min | 50 | 82.74+/-7.09 | 77.16+/-7.15 | <0.001 |
| 30th min | 50 | 81.40+/-5.80 | 73.94 +/-6.52 | <0.001 |
| At extubation | 50 | 92.86+/-9.13 | 81.04 +/-6.88 | <0.001 |

**Table 4:** Mean blood pressure variation at different intervals

| SBP at | Number of patients | SBP (mean+/-SD) | | P Value |
|---|---|---|---|---|
| | | ETT | PLMA | |
| Preinduction | 50 | 118.36+/-6.97 | 120.32+/-6.81 | 0.127 |
| 1st min | 50 | 132.28+/-8.69 | 124.08+/-5.88 | <0.001 |
| 5th min | 50 | 115.44+/-6.63 | 115.72+/-7.11 | 0.775 |
| 30th min | 50 | 105.52+/-6.82 | 105.52+/-6.50 | 0.857 |
| At extubation | 50 | 128.72+/-7.32 | 124.24+/-6.29 | 0.001 |

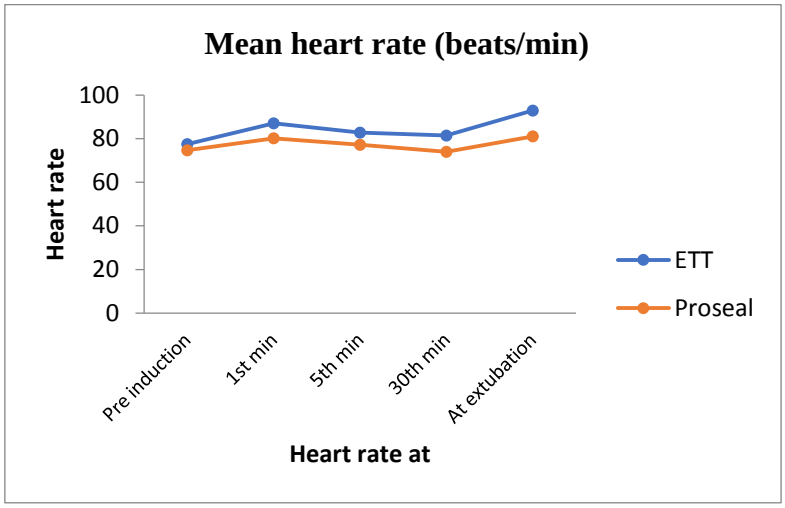
**Table 5:** Comparison of the incidence of intra operative complications

| Complications | ETT GROUP (50) | PMLA (50) | P value |
|---|---|---|---|
| Gastric inflation | 0 | 3 | 0.242 |
| Regurgitation | 0 | 0 | |
| aspiration | 0 | 0 | |

**Table 6:** Comparison of incidence of postoperative complications between the two groups

| Postoperative complications | | Group | | P value |
|---|---|---|---|---|
| | | ETT | PLMA | |
| cough | Present | 22 | 3 | <0.001 |
| | Absent | 28 | 47 | |
| Sore throat | Present | 12 | 3 | 0.022 |
| | Absent | 38 | 47 | |
| nausea | Present | 5 | 3 | 0.714 |
| | absent | 45 | 47 | |

**Graph 1:** Graph showing mean heart rate variations between both the groups at different intervals.




**Graph 2:** Graph showing mean systolic blood pressure variations at different intervals

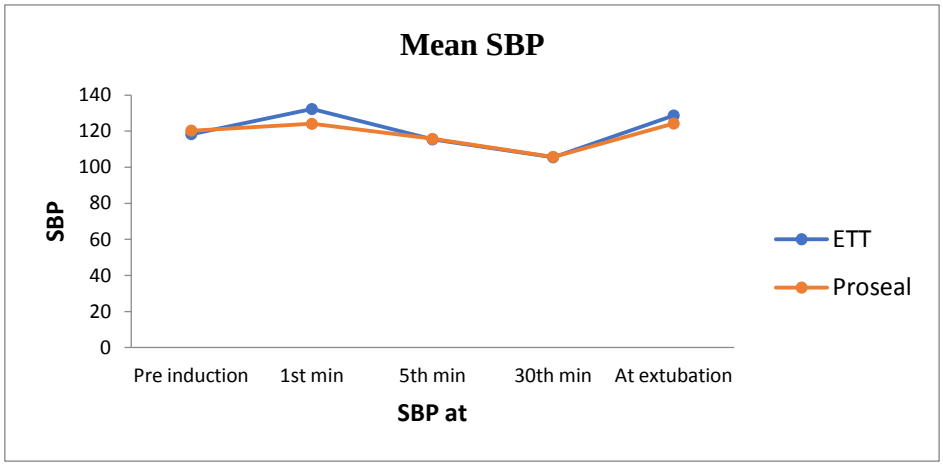
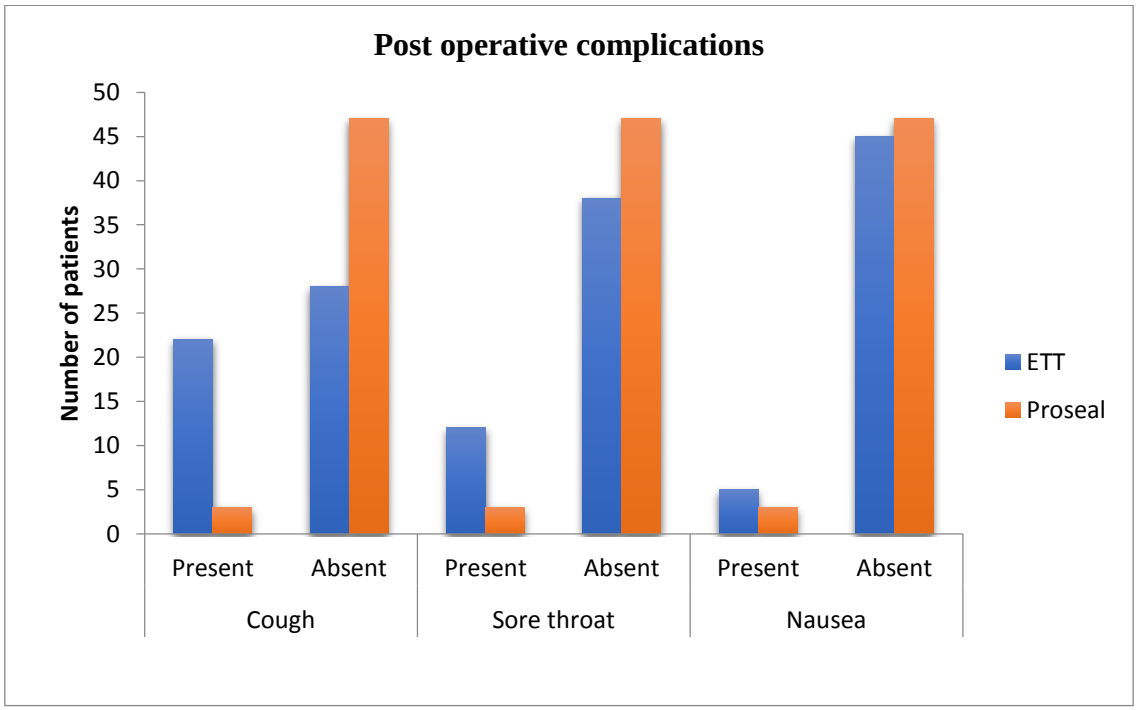



**Chart 3:** Chart showing the incidence of postoperative complications in both the groups



**Discussion**

Till date the cuffed endotracheal tube was considered as gold standard for providing a safe glottic seal during laparoscopic surgery under general anaesthesia. But over a period of time new devices like Proseal LMA, LMA supreme have been added to anesthesiologist's armamentarium and have gained wide acceptance, proved and documented to be safe and effective for laparoscopic surgery from good number of studies [1,2]. To decide the ease of insertion and to compare it with that of an endotracheal tube we studied the number of attempts taken for successful insertion and also the time required for successful insertion of device or intubation with the ETT. First attempt insertion success rate was 76% in ETT group and 84% in Proseal group. Sharma B, Sahai C, Sood J et al[1] observed the similar (80%) first attempt success results for Proseal LMA. Cook TM and Gibbison B[7] observed 84.5% (845/1000) first attempt insertion success rate with PLMA.

Mean time for successful intubation was 20.20 seconds for endotracheal group and that for Proseal LMA insertion was 15.54 seconds. Shroff P, Kamath S [4] noted the similar observations (26 sec for ETT and 15 sec for Proseal insertion) in their study. Because of the quicker insertion and high first attempt insertion success rate, Proseal LMA has a special role in difficult airways and airway rescue, in particular during rapid sequence induction.

Laryngoscopy and endotracheal intubation are associated with hemodynamic response manifesting as an increase in the heart rate and blood pressure, as the Proseal LMA is a supraglottic device and there is no need of laryngoscopy during its insertion it was assumed at the onset of study that the hemodynamic response will be less with Proseal LMA as compared to endotracheal intubation. Mean heart rate per minute changed from 77.46 at pre induction to 87.02 at 1st min ,82.74 at 5 th min,81.04 at 30 th min and 92.86 at the time of extubation in ETT group(table 3) . In Proseal group the mean heart rate varied from 74.64 at pre induction to 80.16 at 1st min, 77.16 at 5th min, 73.94 at 30th min and 81.04 at extubation. The mean heart rate change from pre induction level to that at 1st and 5th min was more in ETT group as compared to that of Proseal group and the difference was statistically significant. Similarly the mean heart rare change at the time of extubation was also more in the former group with statistical significance. Sharma B, Sahai C, Sood J et al [1] observed similar results.

In the present study another important hemodynamic parameter, blood pressure was also measured as the change in mean systolic blood pressure at various intervals. Mean systolic blood pressure changed from 118.36 mmHg at pre induction level to 132.28 mmHg at 1st min after the intubation in ETT group which was statistically significant. The change in Proseal group at same event was from 120.32 mmHg to 124.08 mmHg which is not statistically significant. At the time of extubation the mean change in systolic blood pressure in ETT group was 23.20 as compared to that of 18.48 in Proseal group. Similar results were observed by Sharma B, Sahai C, Sood J et al [1] and Shroff P, Kamath S [4]. Significant hemodynamic response as noted by increase in heart rate and blood pressure at intubation and extubation can be well tolerated by otherwise healthy patients but is not desirable and can be detrimental in patients with hypertension or ischemic heart disease. Proseal LMA by providing better hemodynamic stability during these situations is a better alternative to endotracheal intubation in patients with cardiac comorbidities.

In present study, intra -operatively the values of oxygen saturation (spo2) and end tidal co2 (Etco2) were recorded continuously, the oxygen saturation values were 99±1 in both the groups at all intervals and although statistically significant, there were no events of desaturation to significant extent in both the groups. . Sharma B, Sahai C, Sood J et al [1] found similar results in their study. Intra operatively after achieving pneumoperitoneum the mean Etco2 values were 30.48 and 30.38 in ETT and Proseal group respectively and

there was no statistical significance. Similar findings were found by Sharma N, Kumar A, Mishra A et al[8].

Patients undergoing laparoscopy are considered to be at risk of developing the acid aspiration syndrome as described by piper j et al[9]. Mullet et al [10] In their study ‘’Pulmonary CO2 elimination during surgical procedures using intra or extraperitoneal CO2 insufflation found that, end-tidal CO2 and pulmonary CO2 elimination increased between the eighth and tenth minutes, regardless of site and duration of insufflations . The CO2 absorption is more following extra peritoneal rather than intra peritoneal insufflation. Increasing the minute ventilation by 15-25% is necessary to maintain normocarbia under well functioning physiological mechanisms as described by Joris et al[11].

In present study gastric insufflations as noted by asking surgeon intra operatively after creating pneumoperitoneum were noted. Only three patients in Proseal LMA group had gastric distention without any regurgitation (visible from nasogastric tube) and aspiration which was statistically not significant when compared with endotracheal tube. Postoperatively the patients were observed for any complications like nausea, vomiting, cough, sore throat. In present study 3 out of 50 and 5 out of 50 patients experienced nausea in Proseal and ETT groups respectively this was a statistically insignificant finding. Similar results were found by Hohlrieder M, Brimacombe J et al [12]. In the present study none of the patient had vomiting in both the groups. Hohlrieder M, Brimacombe J et al[12] found 2% incidence of vomiting in Proseal group as compared to 12% in ETT group.

In present study there were significant number of patients who had cough in immediate postoperative period in ETT group (22 out of 50) with about 44% of incidence of postoperative coughing, whereas it was only 6% (3 out In present study there were significant number of patients who had cough in immediate postoperative period in ETT group (22 out of 50) with about 44% of incidence of postoperative coughing, whereas it was only 6% (3 out of 50 patients) in Proseal LMA group. Maltby JR, Michel T et al [13] in their study found, 87% incidence of coughing associated with ETT use and 8% incidence with Proseal LMA use.

In present study, the incidence of sore throat (constant pain, independent of swallowing) after extubation was noted and similar enquiry was done after 24 hours. 3 out of 50 patients in Proseal group and 12 out of 50 patients in ETT group had sore throat. In present study the incidence of sore throat in ETT group was statistically significant when compared with that of Proseal group, 24% and 6% respectively. Hohlrieder M, Brimacombe J [12] et al found about 10% and 4% incidence of sore throat in ETT and Proseal group respectively in their study Proseal LMA is a supraglottic device and its insertion does not require laryngoscopy, also cuff in the pharynx is less stimulating than the cuff of endotracheal tube in the larynx[14], because of these reasons the vomiting centre and centre for pain are less stimulated with Proseal LMA, leading to less incidence of post operative complications like nausea, vomiting, cough and sore throat with its use. Patients were followed up till the time of discharge and recovery profile as noted by time taken for observation in recovery room till stabilization, any post operative morbidity and complications was noted. There was no significant difference observed in the recovery profile of patients between both the groups. Also the average duration of hospital stay for respective surgery in both the groups was studied and did not show any prolongation of hospital stay in both the groups.

Proseal LMA insertion was easier than endotracheal intubation, with high rate of first attempt insertion success and quicker insertion time. It provided better hemodynamic stability than the endotracheal tube. Proseal LMA provided protection against intra operative complications of laparoscopic surgery and it also provided significant protection against post operative

complications like cough and sore throat as compared to that of an endotracheal tube. Recovery profile and hospital stay were not affected with the use of either Proseal LMA or endotracheal tube. Hence it can be concluded that Proseal LMA can be considered as a safe and effective alternative to endotracheal intubation in patients undergoing various laparoscopic procedures under general anesthesia.

**References**


1. Sharma B, Sahai C, Bhattacharya A, Kumra V, Sood J: Proseal LMA: a study of 100 consecutive cases of laparoscopic surgery. Indian J. Anaesth.2003; 47(6): 467- 472.
2. Maltby JR, Beriault M T, Watson NC, Liepert DJ, Fick GH. The Proseal LMA is an effective alternative to tracheal intubation for laparoscopic cholecyste-ctomy. Can J. Anaesth, 2002; 49(8): 857-862.
3. Cook T, Lee G, Nolan J P. The Proseal LMA a review of literature. Can J. Anaesth,2005; 52(7) : 739- 760.
4. Shroff P, Kamath S: Randomized comparative study between the Proseal laryngeal mask airway and endotracheal tube for laparoscopic surgery. The internet journal of anesthesiology. 2006; volume 11: number 1
5. Mishra MN, Ramamurthy B.TheProseal LMA and tracheal tube; A comparison of events at insertion of airway device. Internet J Anaesth. 2008;vol 16.
6. Handan Güleç, TürkayÇakan et al. Comparison of metabolic and hemodynamic stress response caused by Proseal laryngeal mask and endotracheal tubes in patients undergoing laparoscopic surgery. Journal of research in medical science. Feb 2012; 148-152
7. Cook T M, GibbisonB .Analysis of 1000 consecutive uses of the Proseal Laryngeal mask airway by one anesthetist at a district general hospital British J Anaesth. 99 ;(3): 436-439.
8. Sharma N, Kumar A et al. Comparison of Proseal laryngeal mask airway and endotracheal tubes in patients undergoing laparoscopic surgery. Indian J Anaesth. Vol 55 issue 2: 129-133
9. Piper J: Physiological equilibria of gas cavities in the body. In: Fenn WO, Rahn M, eds. Handbook of Physiology. Section: Respiration. Washington,
10. Mullet CE, Jean PV, Pierre E, Charles CM, Luc GR et al. Pulmonary CO2 elimination during surgical procedures using intra or extraperitoneal CO2 insufflation. AnaesthAnalg 1993; 76: 622-626
11. Joris JL. Anesthesia for Laparoscopic Surgery. In: Miller RD, editor. Anesthesia, 5th edn. Philadelphia, Churchill Livingstone, 2000; 2016 DC: American Physiological Society, 1965; 1205-1220
12. Hohlrieder M, BrimacombeJ , et al :A study of airway management using Proseal LMA compared with tracheal tube on postoperative analgesia requirements following gynecological laparoscopic surgery, Anaestheia;2007: 913-918
13. Maltby JR, Beriault MT, Watson NC, Liepert DJ, Fick GH. LMA Classic and LMA-Proseal are effective alternatives to endotracheal intubation for gynecologic laparoscopy. Can J Anaesth 2003; 50: 717.
14. Kelly DJ, Ahmad M, Brull SJ. Preemptive analgesia I: physiological pathways and pharmacological modalities. Can J Anaesth 2001; 48:1000–10.