

Comparison of LMA Supreme and Endotracheal tube in Laparoscopic Cholecystectomy

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Abstract

Background: Second generation Supraglottic airway devices such as LMA-S have enhanced features to answer some of the concerns raised due to laparoscopic abdominal procedures. The present study was undertaken to compare the efficacy and safety of LMA-Supreme (LMA-S) and Endotracheal Tube (ETT) in patients undergoing laparoscopic cholecystectomy in general anesthesia. **Subjects and Methods:** 60 patients were randomly allocated into two groups of 30 each. In group 1 & 2, we have used LMA-S and ET tube for securing airway. We have assessed time used in device insertion, difficulty in insertion, heart rate, MAP, SPO₂, intraabdominal pressure variation, ventilatory parameters and side effects. **Results:** We had found significant difference of heart rate and MAP between the groups at different times ($p < 0.05$). Time taken for insertion of device was significantly less in group 1 than group 2 (14 ± 2 vs 18.2 ± 2 , $p < 0.001$). Side effects were found comparable between the groups. **Conclusion:** LMA-S and Endotracheal Tube (ETT) both of them show similar efficacy during laparoscopic surgery under general anaesthesia and controlled ventilation. So LMA-S can be used as an effective alternate to ET tube.

Keywords: Endotracheal intubation, Fiber optic intubation, Conventional nasal intubation, Mean arterial pressure.

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Introduction

Traditionally Endotracheal Tubes (ETT) had always been a cornerstone for securing airway during laparoscopic surgical procedures under general anesthesia. This was largely due to its ability to provide effective positive airway ventilation under high airway pressures and to avoid gastric distension and pulmonary aspiration. The disadvantages of tracheal intubation involved use of rigid laryngoscopy that may lead to altered hemodynamic responses, situations of failed intubations and damage to the oropharyngeal structures at insertion with added concerns about postoperative laryngo-pharyngeal complications.

Laparoscopic cholecystectomy poses additional challenges to the anesthesiologists in the form of increased intra-abdominal pressure caused by abdominal distension due to pneumoperitoneum, compromised ventilation due to distended abdomen pushing the diaphragm into the thoracic cavity and unfavorable hemodynamic responses due to systemic absorption of carbon dioxide.

Laryngeal mask airway-supreme (LMA-S) is an innovative sterile single use Second Generation Supraglottic Airway Device (SAD). The LMA-S provides access to and functional separation of respiratory and digestive tracts. Second generation SAD such as LMA-S have enhanced features to answer some of the concerns raised due to laparoscopic abdominal procedures.^[1] They have improved pharyngeal seal enabling controlled ventilation at higher airway pressures, increased esophageal seal which lessens the likelihood of regurgitated fluids entering the pharynx leading to aspiration, a drain tube which lies over the top of the esophagus when the LMA-S is correctly positioned. The drain tube may be used to assist insertion, confirm correct device positioning, enable access to the stomach, alert the user to the presence of regurgitation, enable gastric contents to safely bypass the oropharynx and exit the patient. Decreased manipulation of laryngo-tracheal airway, leads to decreased hemodynamic stress response and post-operative laryngo-pharyngeal morbidity of the patient.^[2,3]

The present study was undertaken to compare the efficacy and safety of LMA-Supreme (LMA-S) and Endotracheal Tube (ETT) in patients undergoing laparoscopic cholecystectomy in general anesthesia using neuromuscular blockage with positive pressure ventilation.

Subjects and Methods

After obtaining the Institutional Ethics Committee approval, written and informed consent was taken from the patient and their attendants. This prospective randomized study was conducted on 60 patients who underwent laparoscopic cholecystectomy under general anaesthesia with neuromuscular blockade and positive pressure ventilation. The patients were of either sex belonging to ASA physical status grade 1 and 2; aged 20 years to 65 years and body weight 50 kg to 70 kg. Patients with anticipated difficult airway, obesity (body mass index more than 35 kg/m²), oropharyngeal pathology, cardiopulmonary disease, cervical spine fracture or instability or at increased risk of aspiration (gastro- esophageal reflux disease, hiatus hernia, pregnant patients etc.) were excluded from the study. Patients were randomly allotted in two groups of 30 patients each using a random number table.

Group 1: LMA-Supreme (LMA-S) (size 3 for patient weight 30-50 kg, size 4 for patient weight 50-70 kg) was the device chosen for airway management.

Group 2: Endotracheal Tube (ETT) (size 7.0/7.5 for females, 8.0/8.5 for males) was considered for airway management of the patients.

Patients were advised nil per orally after midnight. Patients were premedicated with oral alprazolam 0.5 mg and ranitidine 150 mg night before surgery. After intravenous (I.V.) access was obtained, ranitidine 50 mg IV and metoclopramide 10 mg IV were administered 30 min before surgery. In the operation theatre, standard monitors were attached which included pulse oximetry (SPO₂), electrocardiography (ECG), non-invasive blood pressure monitoring, capnography and temperature. Baseline parameters were recorded. The airway device to be used was prepared for insertion with the cuff completely deflated and shaped, and its dorsal/external surface lubricated with a water-soluble jelly. The manufacturers recommended insertion technique was strictly adhered for LMA-S (without using fingers in the patient's mouth to facilitate insertion). Cuff deflation, inflation and device fixation for LMA-S was also in strict adherence to the manufacturer's recommendation. Injection Midazolam 0.02 mg/kg, glycopyrrolate 0.2 mg, fentanyl 2 µg/kg were administered as a part of premedication in operation theatre. After preoxygenation with 100% oxygen for 3 minutes, propofol 1-2.5 mg/kg was administered slowly until adequate loss of verbal commands with adequate facemask ventilation followed by administration of Inj. vecuronium 1.0 mg/kg to facilitate device placement (LMA-S

in group 1 and ETT in group 2). After adequate paralysis, ETT was placed in group 2 with standard laryngoscopy. In group 1, patient's head was positioned in neutral or 'slight sniffing' position for insertion of LMA-S. Following head positioning, lubricated LMA-S was grasped along the integral bite block and was introduced into the mouth in the direction towards the hard palate and was glided downwards and backwards along the hard palate until definite resistance was felt. The time interval between holding the airway device to placement to confirmation of correct placement by bilateral air entry in chest auscultation was noted. Correct placement of device was confirmed by adequate chest movement on manual ventilation, capnography, no audible leak from the drain tube with peak airway pressure less than 20 cm of water. A leak below 20 cm of water was taken as significant and suggested a malposition. The gel displacement test, done by placing a blob of gel at the tip of drain tube (DT). In a properly placed mask, there should be slight up-down meniscus movement of the lubricant jelly following the application and release of gentle pressure. The last two tests were specific for LMA-S.

A well lubricated gastric tube (16Fr) was passed through the nasopharyngeal route in ETT group and via DT in LMA-S group. Correct placement was confirmed by air injection and epigastric stethoscope. Anesthesia was maintained with oxygen 50%, air 50%, isoflurane, boluses of 50 µg fentanyl and vecuronium bromide. Pneumoperitoneum was established with the introduction of Varese Needle in the abdominal cavity and the desired intrabdominal pressure (12-16 mm Hg) was set manually on the electronic variable flow Karl Storz insufflators, which terminates flow automatically when a preset intraabdominal pressure is reached. There was a continuous display of intraabdominal pressure and the volume of CO₂ insufflated on the monitor of insufflators. After completing the surgery, neuromuscular blockade was antagonized with neostigmine and glycopyrrolate. The device was removed when patient was able to open mouth on command.

We had assessed and recorded hemodynamic responses (heart rate and mean arterial blood pressure), pulse oximetry (SPO₂) and end tidal carbon dioxide (EtCO₂) preoperatively, pre induction, at the time of insertion of device, 1, 2 and 5 min after insertion of device, before pneumoperitoneum and at 5 min interval till 30 min after pneumoperitoneum. The aim was to maintain target SPO₂ (>95%) and EtCO₂ (< 45 mm Hg) by adjusting the FiO₂, respiratory rate and tidal volume. When SPO₂ was 94% - 90% the oxygenation was graded as suboptimal and failed if it was less than 90%. We also assessed time taken for insertion of device, type of insertion as follows - Easy insertion – insertion at first attempt with no resistance; difficult insertion – insertion with resistance or at second attempt and failed insertion – insertion not possible even after two attempts. Manipulations were done in the form

of increasing the depth of insertion; giving jaw thrust or chin lift or changing size of the device. Oropharyngeal seal pressure was determined by closing the expiratory valve at a fixed gas flow of 5 l/min and recording the airway pressure at which equilibrium was reached. The airway pressure was not allowed to exceed 40 cm of water. The peak airway pressure (PAP) was recorded when intraabdominal pressure (IAP) reached 16 mm Hg. For standardization IAP was maintained at 12 - 16 mm Hg. Airway Pressure before pneumoperitoneum and after pneumoperitoneum was recorded. We also assessed Intraabdominal Pressure (IAP), Ventilatory rate, Initial Inspired tidal volume, Expired tidal volume, Inspired Expired tidal volume difference, Nasogastric tube insertion time, Incidence of Gastric distension / Regurgitation / Aspiration / Intra and postoperative Laryngo-Pharyngeal morbidity (pain in throat / change of voice / difficulty in swallowing) / Cough any lip, tongue and dental injury.

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean±SD. To test the significance of two means the student's 't' test was used. To compare the change in a parameter at two different time intervals paired 't' test was used.

Results

A total of 60 patients scheduled to undergo laparoscopic cholecystectomy and fulfilling the inclusion criteria were enrolled in the study and were randomly divided into one of the two groups (n=30). Demographic and baseline general characteristics of patients in two groups like age, sex, BMI (body mass index), MPG (Mallampatti grading) and ASA status of patients in the two groups were matched and showed no significant statistical difference between two groups. Both the groups were matched for baseline hemodynamic and airway parameters and did not show a statistically significant difference between two groups (p>0.05).

As shown in Figure 1, at baseline, mean heart rate in Group I was 68.6±9.9 beats per minute (bpm) as compared to 71.6±11.1 bpm in Group II, thus showing no statistically significant difference between two groups (p=0.279). No significant difference between two groups was observed at pre-intubation interval too. However, at intubation and thereafter till 5 min interval (post intubation -pi), mean difference between two groups was statistically significant with mean value of Group II patients being significantly higher as compared to that of Group I. However, at subsequent time intervals, statistically no significant difference was observed between two groups. At 30 min pneumoperitoneum (pp) interval mean heart rate in Group I was 76.0±17.0 bpm as compared to 81.0±18.6 bpm in Group II, statistically not showing a significant difference between two groups

(p=0.281).

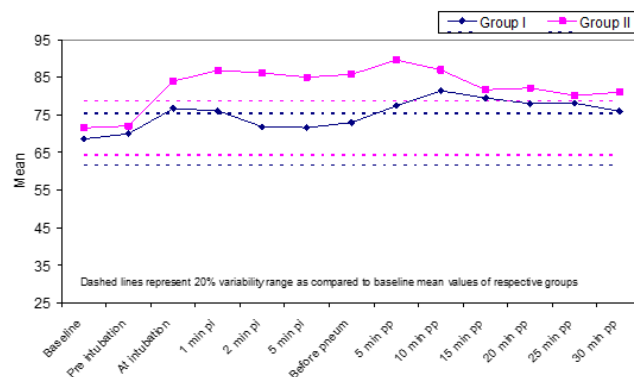


Figure 1: Evaluation of Change in Heart rate at different time intervals

In Group I, mean heart rate was higher as compared to baseline at all the time intervals, and the difference from baseline was statistically significant at all the time intervals except at pre-intubation, from 2 min post intubation (pi) to before creating pneumoperitoneum and 30 min pp intervals respectively. At intubation and 1 min pi change and from 15 min pp interval till the end of study period, mean change crossed the upper limit of 10% variability. In LMA-S group heart rate showed a slight increase at the time airway device insertion which lasted for about 2 minutes, and a similar increase was noted at the time of creation of pneumoperitoneum. In Group II, mean heart rate at different time intervals was higher as compared to baseline values and the difference from baseline was significant statistically at all the time intervals except pre-intubation. During post-intubation period at most of the times, mean values were higher than 10% baseline variability range at all the intervals starting from induction.

Figure 2 shows that at baseline, mean MAP in Group I was 73.6±7.6 mmHg as compared to 71.1±6.4 mm Hg in Group II, thus showing no statistically significant difference between two groups (p=0.162). At subsequent intervals too, there was no significant difference between group except for intubation and at 5- and 20-minute pp intervals. At intubation, Group II had higher mean value as compared to Group I whereas at both pp intervals, mean value in Group II was significantly higher as compared to that in Group I (p<0.05).

In Group I, as compared to baseline, mean values were lower at all time intervals. The change from baseline was statistically significant at 5 min pp till 30 min pp intervals. In Group II, as compared to baseline, mean values were higher at all time intervals but the change was statistically significant only at intubation and 1 min pi interval (p=0.041). In both the groups mean values at different time intervals were well within 10%

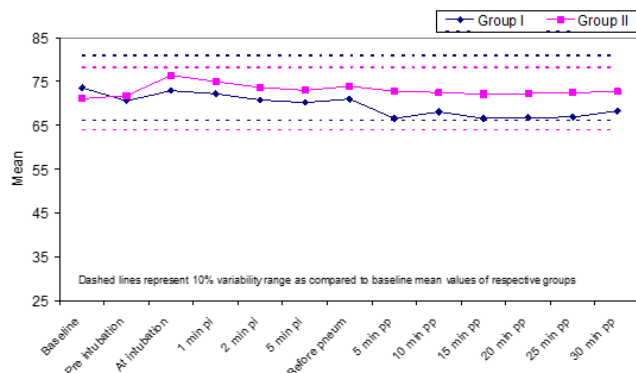


Figure 2: Evaluation of Change in Mean arterial blood pressure (MAP) at different time intervals

baseline variability range.

At baseline, mean Oxygen Saturation in Group I was $98.5 \pm 0.7\%$ as compared to $98.4 \pm 0.8\%$ in Group II, thus showing no statistically significant difference between two groups ($p=0.606$). At all-time intervals, in both the groups, mean oxygen saturation was maintained above 98%. In both the groups, mean oxygen saturation at different time intervals did not show a significant difference from baseline. At all-time intervals, mean oxygen saturation values were within 5% baseline variability range.

At baseline, mean Carbon dioxide Concentration in Group I was $27.9 \pm 2.2\%$ as compared to $28.0 \pm 2.6\%$ in Group II, thus showing no statistically significant difference between two groups ($p=0.894$). At subsequent intervals too, there was no statistically significant difference between groups. At all-time intervals, in both the groups, mean end tidal carbon dioxide concentration was maintained below 35mmHg.

At both the time intervals, no statistically significant difference was observed between two groups. However, in both the groups a significant change in airway pressure was observed ($p < 0.001$). In both the groups all the airway devices were inserted in first attempt. In both the groups all the airway devices were inserted easily without any difficulty or failed attempts.

Side effects were evaluated for distension, regurgitation, aspiration, throat pain, change of voice, difficulty in swallowing, cough, lip/tongue or dental injuries, visible blood or other complications. None of the patients, in either of two groups had distension, aspiration, change of voice, lip/tongue or dental injury or other complications. In Group I, only complication encountered was pain in throat which was observed in 1 (3.3%) patient only and no other complaint was recorded in any of the patients. However, in Group II, pain in throat was reported by 4 (13.3%) patients, difficulty in swallowing by 1 (3.3%)

patient, cough (10%). However, for none of the complications, the difference between two groups was significant statistically ($p > 0.05$).

Discussion

The widespread use of supraglottic airway devices has revolutionized some clinical scenarios in modern anaesthetic practice. The LMA-Supreme (LMA-S) is a new entrant to the family of LMAs, and has some added features over previous all other LMAs. We aimed to compare the safety and efficacy of the LMA-S and ETT in laparoscopic cholecystectomy. Pneumoperitoneum results in hemodynamic changes, ventilatory and respiratory changes, decrease in thoracopulmonary compliance and increase in pulmonary resistance. Although there are comparative studies on the safe usability of LMA-S in gynecological laparoscopy, studies on laparoscopic cholecystectomy are quite few in number. We found the first attempt success rate was 100% for both LMA-S and ETT insertion. In the literature, the first attempt success rates were reported to be between 90%-100% for LMA-S. In both the groups all the devices were inserted easily without any difficulty or failed attempt. The mean airway insertion time was shorter with LMA-S (14.0 seconds) than with ETT (18.2 seconds) ($p < 0.001$) respectively. Studies by Verghese et al (2008) 15 seconds, Teoh et al (2009) 14.3 seconds, Hosten et al (2009) 12.5 seconds corroborated with our study findings.^[4-6] A nasogastric tube was inserted in all the patients. The mean time taken to insert nasogastric tube through LMA-S was significantly less (10.4 seconds) than via nose in intubated patients (14.1 seconds) ($p = 0.677$) respectively. Fernandez et al.^[7] (2009) reported mean nasogastric insertion time through LMA-S to be 9.5 seconds. Similar results were shown by Teoh et al. (2009) 9.0 seconds, and Hosten et al. (2012) 9.0 seconds.^[8]

There was minimum hemodynamic stress response with LMA-Supreme (LMA-S) when compared with endotracheal tube (ETT). Mean heart rate at the time of airway device insertion was 76.7 per minute in LMA-S group and 84.0 per minute in ETT group, respectively. Mean change in heart rate at the time of airway device insertion in LMA-S group was 8.10 ($p = 0.001$), and in ETT group was 12.40 ($p < 0.001$).

Mean arterial blood pressure (MAP) at the time airway of device insertion in LMA-S group was 72.9 mm of Hg and in ETT group was 76.4 mm of Hg, respectively. Mean change in MAP at the time of airway device insertion in LMA-S group was -0.77 ($p = 0.719$) and in ETT group was 5.30 ($p = 0.001$). The increase in heart rate and mean arterial blood pressure (MAP) during intubation in ETT group is attributed to sympathetic stimulation during laryngoscopy and the passage of ETT through the vocal cords. The LMA-S being a supraglottic device does not require laryngoscopy, hence

Table 1: Comparison of Airway Pressure (mm of Hg) before and after the pneumoperitoneum

| SN | Time interval | Group I (n=30) | | Group II (n=30) | | Statistical significance | |
|----|-------------------------------|------------------|------|------------------|------|--------------------------|-------|
| | | Mean | SD | Mean | SD | "t" | "p" |
| 1. | Before pneu- moperitoneum | 17.4 | 1.0 | 17.7 | 1.1 | -1.237 | 0.221 |
| 2. | After pneumoperi- toneum | 24.3 | 1.2 | 24.6 | 0.9 | -1.264 | 0.211 |
| | Change | 6.91 | 1.60 | 6.94 | 1.28 | | |
| | Statistical signifi- cance | t=23.68; p<0.001 | | t=29.72; p<0.001 | | | |

Table 2: Comparison of different outcome parameters between two groups

| SN | Parameter | Group I (n=30) | | Group II (n=30) | | Statistical significance | |
|----|---|----------------|------|-----------------|------|--------------------------|--------|
| | | Mean | SD | Mean | SD | "t" | "p" |
| 1. | Time taken (sec- onds) | 14.0 | 2.0 | 18.2 | 2.0 | -8.293 | <0.001 |
| 2. | Intra Abdominal Pressure (mmHg) | 12.0 | 0.0 | 12.0 | 0.0 | 0.255 | 0.800 |
| 3. | Ventilatory rate(VR)(per minute) | 12.0 | 0.0 | 12.0 | 0.0 | 0.041 | 0.967 |
| 4. | Initial inspired tidal volume (IITV)(ml) | 527.7 | 20.4 | 526.3 | 22.0 | -0.855 | 0.396 |
| 5. | Expired tidal vol- ume(ETV)(ml)Diff | 552.3 | 19.0 | 552.0 | 21.9 | -10.116 | <0.001 |
| 6. | Inspired expired tidal tidal vol. difference (ml) | 24.6 | 5.6 | 25.7 | 4.6 | -2.486 | 0.016 |
| 7. | Oropharyngeal Seal Pressure (mm Hg) | 28.0 | 1.4 | 34.0 | 2.9 | -11.081 | <0.001 |
| 8. | Per Abdominal Pressure(mmHg) | 24.9 | 1.2 | 25.7 | 1.2 | 0.091 | 0.928 |
| 9. | Nasogastric Tube Insertion Time (sec) | 10.4 | 1.2 | 14.1 | 1.3 | -0.419 | 0.677 |

does not evoke a significant laryngoscopy response.

Following peritoneal insufflations, carbon dioxide is absorbed transperitoneally and the rate at which this occurs depends on gas solubility, perfusion of the peritoneal cavity, and duration of the pneumoperitoneum. Both groups maintained adequate oxygenation and ventilation preoperatively. At baseline, mean oxygen saturation in LMA-S was 98.5% as compared to 98.4% in ETT group (p = 0.606). Throughout perioperative period, in both the groups, mean oxygen saturation was maintained above 98%. Similarly, end tidal carbon dioxide was maintained within physiological limits throughout the perioperative period, and did not cross 10% of base line values in either group (27.9 mm of Hg in LMA-S group and 28.0 mm

of Hg in ETT groups) (p = 0.894).

In our study, the mean oropharyngeal seal pressure in LMA-S group was 28.0 cm of water and in ETT group was 34.0 cm of water (p < 0.001) respectively, and was maintained throughout the perioperative period. Belena et al.^[9] (2012) in their study found that oropharyngeal seal pressure was 28.2 cm of water that is similar to our study. Hosten et al (2012) in a study of LMA-S in laparoscopic cholecystectomy also reported oropharyngeal seal pressure to be 27.8 cm of water, and it did not change throughout pneumoperitoneum. In another study conducted recently by Belena et al.^[10] (2013) to compare the efficacy and safety of the LMA-S versus the LMA Prosily (LMA-P) in laparoscopic cholecystectomy, the

Table 3: Comparison of side effects between groups

| SN | Parameter | Group I (n=30) | | Group II (n=30) | | Statistical significance | |
|----|-----------------------------|----------------|-----|-----------------|------|--------------------------|-------|
| | | No. | % | No. | % | χ^2 | p |
| 1. | Distension | 0 | 0 | 0 | 0 | - | - |
| 2. | Aspiration | 0 | 0 | 0 | 0 | - | - |
| 3. | Pain in throat | 1 | 3.3 | 4 | 13.3 | 1.964 | 0.161 |
| 4. | Change of voice | 0 | 0 | 0 | 0 | - | - |
| 5. | Difficulty in swallowing | 0 | 0 | 1 | 3.3 | 1.017 | 0.313 |
| 6. | Cough | 0 | 0 | 3 | 10.0 | 3.157 | 0.076 |
| 7. | Lip/Tongue or Dental injury | 0 | 0 | 0 | 0 | - | - |
| 8. | Others | 0 | 0 | 0 | 0 | - | - |

primary outcome measure was oropharyngeal leak pressure. The mean oropharyngeal leak pressure in LMA-P group (30.7 cm of water) was significantly higher than in the LMA-S group (26.8 cm of water). The silicone cuff of LMA-P is permeable to nitrous oxide, and intracuff pressure can increase when nitrous oxide is used, the cuff of LMA-S is made of polyvinyl chloride is less elastic and less permeable to nitrous oxide.^[11] We maintained the cuff pressure at 60 cm of water throughout the operative procedure. Peak airway pressure before pneumoperitoneum were 17.4 cm of water and 17.7 cm of water in LMA-S and ETT group ($p = 0.221$) respectively, and after insufflations of carbon dioxide were 24.3 cm of water and 24.6 cm of water ($p = 0.211$) respectively in LMA-S and ETT groups. These findings are consistent with those of Belena et al (2012), who evaluated the role of LMA-S in laparoscopic gynecological surgery, and they found mean peak airway pressure was 17.0 cm of water before pneumoperitoneum and 22.1 cm of water after pneumoperitoneum. We observed difference between expired and inspired tidal volumes after creation of pneumoperitoneum, and we noted it to be 24.6 ml in LMA-S group and 25.7 ml in ETT group ($p = 0.016$) respectively. Teoh et al also found the similar difference between expired and inspired tidal volume with LMA-S to be 21.5 ml. In LMA -S group only complication encountered was pain in throat which was observed in 1 (3.3%) patients and no other complaint was recorded in any of the patients. However in ETT group, pain in throat was reported by 4 (13.3%) patients, difficulty in swallowing by 1 (3.3%) patient, cough by 3 (10%) and visible blood in 2 (6.7%) patients. The virtual absence or decrease in occurrence of postoperative laryngo-pharyngeal co morbidities in supraglottic airway device (SAD) groups such as LMA-S in our study, is consistently the finding of almost all the studies conducted so far since the advent of first LMA in early eighties, which makes the supra glottic devices, especially the newer second generation supra glottic

airway devices such as the LMA-S, most attractive to the Anesthesiologists worldwide.

Our study has a few limitations. We did not use fibrotic bronchoscope to assess the anatomical position of LMA-S and ETT in relation to the vocal cords. It was not clinically and logistically feasible to perform endoscopy in all cases. We only studied non obese patients and the results cannot be directly extrapolated to other types of patients. Finally our data only apply to the use of the size 3 and 4 LMA-Supreme, however it is likely that similar results would be obtained when comparing the size 5 or other sizes LMA-S in the patients, as this has been the pattern in all previous studies.

Conclusion

LMA-S and Endotracheal Tube (ETT) both of them show similar efficacy during laparoscopic surgery under general anaesthesia and controlled ventilation. Both the devices are easy to insert without need of many manipulations for maintenance of airway. Thus LMA-S may offer a reliable and significant airway management option owing to its ease of insertion, less hemodynamic changes, its separation of alimentary and respiratory tracts and a better patient compliance due to reduced postoperative laryngo-pharyngeal morbidities. However more studies with large number of patients are required to further validate our results.

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