Original Article

Proseal laryngeal mask airway and endotracheal intubation in lower abdominal gynecological surgeries for perioperative gastric volume assessment and assessing postoperative recovery of gastrointestinal functions: A randomized controlled trial

ABSTRACT

Background: In the context of perioperative care, the concern of gastric content aspiration during surgical procedures is crucial, though relatively rare. Supraglottic devices after the creation of pneumoperitoneum and positive pressure ventilation may cause gastric insufflation. This study explores the unique aspects of antral cross-sectional area (CSA) measurement as a novel indicator in comparing the use of ProSeal laryngeal mask airway (LMA) and endotracheal intubation in airway management during lower abdominal surgeries and assessing postoperative recovery in both the groups.

Methods: The study commenced after obtaining approval from Institutional Ethical Committee (IEC number-AIIMS/IEC/22/251 Date: 27/05/2022) and after registration in Clinical Trials Registry - India (CTRI) (CTRI/2022/07/044102 Registered on: 18/07/2022) and was conducted from August 2022 to August 2023. A total of 72 ASA I and II participants were included in two groups: endotracheal tube (ETT) (Group E) and PLMA (Group P). The primary outcome was the antral CSA, and secondary outcomes included hemodynamic and respiratory parameters, time to start clear fluid, light diet, and length of stay.

Results: Our results showed that there was no statistically significant difference between the two groups in antral CSA at various time intervals. The hemodynamic variables were significantly higher in the endotracheal tube group ($P < 0.0001$). The absence of significant differences in time to start clear liquids, time to start a light diet, and time to achieve bowel movements between the ETT and PLMA groups suggested that both airway management techniques are equally safe in facilitating postoperative recovery concerning gastrointestinal functions.

Conclusions: Patients who underwent minimally invasive lower abdominal surgeries, choice of airway management technique, whether ETT or PLMA, did not substantially impact antral CSA, vital parameters, respiratory parameters, or postoperative recovery.

Key words: Antral cross-sectional area, endotracheal intubation, gastric insufflation, laparoscopic surgery, proseal laryngeal mask airway, supraglottic airway devices, ultrasound

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Introduction

In the context of perioperative care, the concern of gastric content aspiration during surgical procedures is crucial, though relatively rare. Traditionally, cuffed tracheal tubes have been the primary method to reduce this risk.[1,2] However, there is a shift toward using supraglottic airway devices (SADs) because of their versatility and ease of use. The second-generation SADs have an added feature of gastric channels, which allow the placement of a nasogastric tube for venting stomach contents.[2,3] The LMA-ProSeal, in particular, can withstand higher airway pressures with minimal gas leakage due to its unique design. It also has a gastric drainage tube that separates the respiratory tract from the esophagus and helps remove gastric fluids, reducing the risk of aspiration.[2–5] Despite the advantages, there are problems about using SADs in certain surgical positions, like the Trendelenburg position, used in laparoscopic surgeries. This position can lead to increased airway pressures due to the effects of pneumoperitoneum, and if SADs leak air, it can inflate the stomach excessively, increasing the risk of aspiration.[3,4,6,7] This study compared the use of ProSeal laryngeal mask airway (LMA) and endotracheal intubation to assess the risk of gastric aspiration during lower abdominal operations. We primarily measured the antral cross-sectional area (CSA) of the stomach using ultrasound to understand the extent of stomach inflation during these surgeries.[4,7] This approach provides a direct and noninvasive method to understand stomach inflation during laparoscopic surgeries, offering precise data on gastric volume and its relationship with different airway management techniques. This research sought to provide insights into the impact of airway management choices on gastric volume during surgery, helping to understand the associated aspiration risk and improve patient safety and postoperative recovery in lower abdominal surgeries.

Materials and Methods

A prospective, randomized controlled trial was conducted in the Department of Anesthesiology at All India Institute of Medical Sciences, Rishikesh, over a 1-year period. The clinical research was conducted in accordance with the Ethical Principles for Medical Research involving Human Subjects, as outlined in the Helsinki Declaration of 1975 (revised 2013). Eligible participants included patients aged between 18 and 65 years with ASA I and II classifications, undergoing elective minimally invasive lower abdominal procedures. The study was started after obtaining approval from the Institutional Ethical Committee (IEC number-AIIMS/IEC/22/251 Dated 27/05/2022) and after registration in Clinical Trials Registry - India (CTRI) (CTRI/2022/07/044102 dated 18/07/2022.

A sample size of 72 patients, with 36 in each group, was determined based on a two-tailed alpha error (α) of 0.05, a power of 80%, and a projected difference of 20% in antral CSA, with calculations assuming a 30% difference in standard deviation using OpenEpi, Version 3. This aligns with a similar study by Qiuping Ye *et al*. in 2020[7] to provide adequate statistical power for assessing differences in antral CSA between the groups.

Methodology: Before arrival at the operating room, the patient was assessed preoperatively in the preoperative room; antral CSA was calculated using ultrasound. The stomach of the patient in a supine position was imaged, and the antral CSA of the stomach was measured by an experienced anesthesiologist with a curved array transducer of a SonoSite 21 EDGE II Ultrasound System using a curvilinear probe (2–5 MHz). Between the left liver lobe in the anterior position and the pancreas in the posterior position in a sagittal or parasagittal scanning plane in the epigastrium, the antrum was located superficially. Important landmarks including, the inferior vena cava (IVC) and the superior mesenteric vein, were marked in the standard plane of the antrum [Figure 1 and Supplementary Figure 1]. The antrum cross-sectional diameter was measured by using two perpendicular planes of diameters, that is, anteroposterior diameter and craniocaudal diameter.[7–10] As the cross-section of the antrum of stomach is elliptical, the area was determined in all patients using the following formula: Antral area = $\pi \times D1 \times D2/4$. To determine the relaxed breadth of the stomach antrum, measurements were taken between antral contractions. The person doing ultrasonography of the stomach was blinded to the placement of the airway device.

Upon arrival in the operating theater, all patients enrolled in the trial were placed in a supine posture and given an advanced multipara monitor, which includes an electrocardiogram, blood pressure, and peripheral saturation. An appropriate-size intravenous catheter was inserted preferably in an upper extremity vein, and hemodynamic parameters were noted. Premedication with midazolam 1 mg was done in every patient. General anesthesia was induced with fentanyl 2 μg/kg, propofol 1–2.5 mg/kg, and vecuronium 0.1 mg/kg. The patient was mask venilated for 3 minutes using the anesthesia machine, with controlled ventilation set to a tidal volume of 7 ml/kg, a frequency of 12–16 breaths per minute, and an inspiratory:expiratory ratio of 1:2 to maintain an end-tidal carbon dioxide of 35–45 mmHg. Patients were assigned randomly according to a computer-generated random table into one of the two groups as follows:-

Group E *(Endotracheal intubation)*- Direct laryngoscopy was performed with a Macintosh blade size 3 or 4 as appropriate

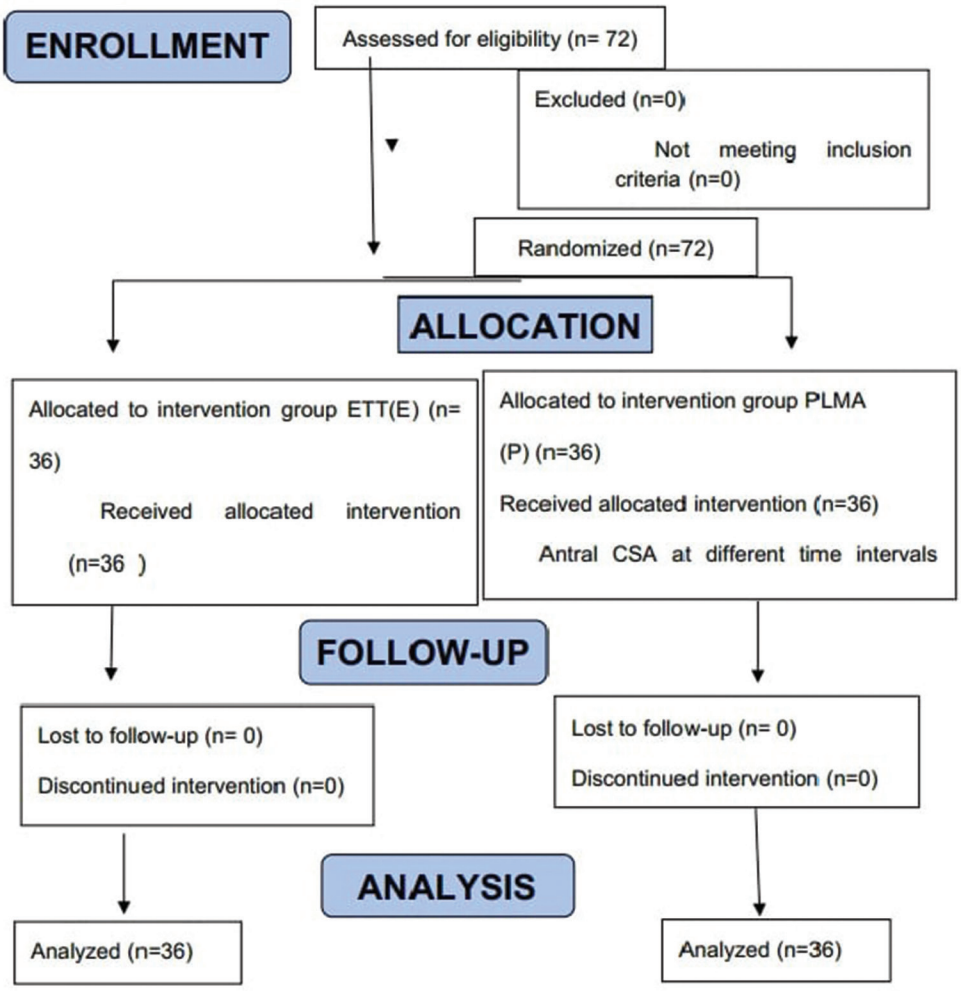

Figure 1: CONSORT diagram

in the supine position. The trachea was intubated with an Endotracheal (ET) tube (ETT) of appropriate size (7 in females and 8 in males) by an experienced anesthesiologist who has experience of putting at least 50 ETTs. The ETT was then connected to the anesthesia workstation with previously assigned settings. The tracheal position of the ETT was confirmed by 5-point auscultation, chest rise, and end tidal carbon dioxide readings. The cuff pressure of the ETT was maintained at 25 cmH_2O by a handheld aneroid pressure gauge.[11-13]

Group P *(ProSeal laryngeal mask airways)*: The appropriate size of proseal LMA device (size 3 or 4 ProSeal LMAs in patients weighing 30–50 and 50–70 kg, respectively, in adult males and females) was chosen, and an experienced anesthesiologist who has an experience of putting at least 50 Proseal LMA inserted the device. The cuff of ProSeal LMA was inflated to a pressure of 60 cmH_2O. The confirmation of placement of ProSeal LMA was confirmed by resistance to further distal movement, end tidal carbon dioxide readings, and effective chest wall movement. If satisfactory insertion of proseal LMA is not achieved with three attempts, or there is respiratory embarrassment, the patient was removed from the study after being intubated via direct laryngoscopy.

The ventilation was set to the volume control mode delivering air:oxygen mixture (2:1) at a frequency of 12–16 breadths/min, TV of 7 ml/kg, and an inspiratory:expiratory (I:E) ratio of 1:2 to maintain end tidal carbon dioxide at 35–45 mmHg, by adjusting the respiratory rate. Anesthesia was maintained with sevoflurane at a minimum alveolar concentration (MAC) of 1.0 initially and titrated further to keep the mean arterial pressure and heart rate within ±20% of the baseline values. Muscle relaxation will be achieved with vecuronium 1 mg intermittently according to neuromuscular monitoring monitoring. Intra-abdominal pressure (IAP) was maintained around 14–16 mmHg, and Trendelenburg tilt was maintained between 30 and 45 degrees as per need of the surgeon. On insertion of the laparoscope, the surgeon was asked to check for any gastric distension and grade it on a Likert scale of 7. The difference between inspired tidal volume (ITV) and ETV was used to calculate leak volume (LV), that is,

LV = inspired tidal volume – expired tidal volume. The leak fraction is defined as leak volume divided by ITV (i.e., leak fraction = LV/ITV).[14] At the conclusion of the surgical procedure, anaesthesia adminstration of gases was stopped, and the reversal of muscle relaxation was achieved using neostigmine and glycopyrrolate. The removal of the tracheal tube, specifically the ProSeal LMA, occurred upon the patient's ability to breathe spontaneously and respond to commands by opening their mouth. Any instances of blood staining on the laryngoscope, tracheal tube, or ProSeal LMA were also recorded. The individual conducting stomach ultrasonography was blinded to the positioning of the airway device. Measurements of the antral CSA were taken at distinct time intervals: T1 at baseline, T2 immediately post induction, T3 at 1 hour, T4 at the surgery's conclusion, and T5 1 hour post surgery. Patients and nurses in the post-anesthesia care unit (PACU) were not informed about the type of airway device used. A single observer, trained and unaware of the airway device, documented postoperative events at 2, 6, and 24 hours after surgery. Patients were queried about symptoms like nausea, vomiting, sore throat, dysphonia, and dysphagia, and their anesthesia and surgical times were recorded. Cardiorespiratory parameters were monitored every 5 minutes, noting any episodes of bradycardia, tachycardia, systolic hypotension, or hypoxia. Discharge from the PACU was contingent upon patients being awake, hemodynamically stable, free from pain/nausea/vomiting, and achieving a SpO2 of 95% on ambient air. Both patients and PACU nurses were kept unaware of the specific airway device utilized. The study's endpoint was the patient's discharge from the hospital.

Statistical analysis was analyzed using IBM SPSS for Windows (version 25). A sample size of 72 patients (36 in each group) was decided based on results from OpenEpi, Version 3, an open-source calculator, considering the alpha error of probability as 0.05 and the power required as 80%, to detect a projected difference of 20% between the groups for the antrum CSA and a 30% difference of standard deviation. Demographic data will be presented as a mean (n) and standard deviation (SD). Parametric primary (antral CSA of the stomach) and secondary outcomes (leak volume, leak fraction, tidal volume, peak airway pressure, mean airway pressure, length of stay, and days to discharge) were presented as mean ± SD and was compared using the T-test. The Chi-square test or Fisher's exact test was used to compare categorical data when appropriate. A P value < 0.05 was considered statistically significant.

Results

The study included patients with comparable demographic profiles, including age, sex, height, weight, and BMI, across both study groups (Group E - Endotracheal Tube and Group P - ProSeal LMA), as shown in Table 1. The study compared the mean antral CSA between Group E (ETT) and Group P (PLMA) at different time points, revealing no significant differences in CSA values: Baseline ($P = 0.075$), at induction ($P = 0.082$), at 1 h interval ($P = 0.094$), at end of surgery ($P = 0.091$), and at 1 h post-surgery ($P = 0.114$). The mean antral CSA values for each group at different time intervals were as follows: Group E: ranged from 2.45 cm^2 to 2.86 cm^2 at different time points, suggesting that the mean antral CSA remained relatively consistent regardless of the airway device used [Table 2]. The study compared various respiratory parameters including measures such as leak volume, leak fraction, tidal volumes (both inspired and expired), peak pressure, plateau pressure, and end-tidal CO2 levels. Specifically, there were no significant differences in leak volume, leak fraction, tidal volumes, peak pressure, and plateau pressure between Group E and Group P at any of the time points. In both Group E (ETT) and Group P (PLMA), the surgeons assessed gastric distension on insertion of the laparoscope using a Likert scale of 7. The results showed comparable findings between the two groups, with no significant differences in the Likert scale ratings for gastric distension observed ($P = 0.583$). The hemodynamic parameters and respiratory parameters were comparable in both groups except for the heart rate (HR) systolic blood pressure (SBP) and diastolic blood pressure, which showed significant differences after induction of anesthesia ($P < 0.0001$) [Tables 3 and 4] The postoperative parameters such as duration of surgery, mean time to

Table 1: Baseline demographics

Parameters	Group: Means±SD		*P* value
	Endotracheal tube (Group E) (*n*=36)	Proseal LMA (Group P) (*n*=36)	
Age (yr)	34.92±9.25	38.44±10.35	0.132
Weight (kg)	57.89±7.02	60.19±6.71	0.161
Height (cm)	158.50±3.76	159.92±3.17	0.090
BMI (kg/m²)	22.35±2.78	22.38±2.91	0.925

Values are presented as mean±SD or number (%). BMI=Body mass index, LMA=Laryngeal mask airway

Table 2: Antral CSA at different time intervals: Primary outcome

Antral CSA (cm^2)	Group: Means±SD		*P* value
	Group E (ETT) (*n*=36)	Group P (PLMA) (*n*=36)	
Baseline	2.45±0.60	2.52±0.71	0.075
At induction	2.78±0.63	2.70±0.71	0.082
At 1 h interval	2.76±0.81	2.84±0.73	0.094
At end of surgery	2.86±0.85	2.95±0.77	0.091
At 1 h post-surgery	2.59±0.83	2.79±0.66	0.114

Where, 1=Baseline, 2=At induction, 3=At 1 hour interval, 4=At end of surgery, 5=At 1 hour post surgery. Values are presented as mean±SD or number (%). LMA=Laryngeal mask airway

start clear fluids, light diet, mean time to achieve bowel function, and mean length of stay were comparable in two groups [Table 5].

Discussion

Laparoscopy has emerged as a popular and minimally invasive surgical technique offering numerous advantages, such as reduced postoperative pain and shorter hospital stays. Nevertheless, it introduces a unique challenge related to the insufflation of carbon dioxide (CO2) into the peritoneal cavity. This insufflation raises concerns about complications, including air leakage, insufficient ventilation, and gastric insufflation.[1-4] In this study, we aimed to compare the antral CSA of the stomach at different time points in patients undergoing minimally invasive lower abdominal surgeries using two different airway management methods, namely, ETT and PLMA. Antral CSA is a crucial parameter to monitor during these procedures as it provides insight into the risk of aspiration, particularly when creating pneumoperitoneum.[7–10] By employing ultrasound, a cost-effective and noninvasive technique, we measured antral CSA along its length, breadth, and overall area at various time intervals. The two perpendicular diameters, anteroposterior and craniocaudal, were used to calculate the CSA.[7–10] Our findings indicated that the mean antral CSA in the group E exhibited values of 2.45 ± 0.60 cm^2 at baseline, 2.78 ± 0.63 cm^2 at induction, 2.76 ± 0.81 cm^2 at the 1-hour interval, 2.86 ± 0.85 cm^2 at the end of surgery, and 2.59 ± 0.83 cm^2 at 1 hour postsurgery. In contrast, group P displayed mean antral CSA values of 2.52 ± 0.71 cm^2 at baseline, 2.70 ± 0.71 cm^2 at induction, 2.84 ± 0.73 cm^2 at the 1-hour interval, 2.95 ± 0.77 cm^2 at the end of the surgery, and 2.79 ± 0.66 cm^2 at 1-hour postsurgery [Table 2]. Our results demonstrated that there was no statistically significant difference between the two groups in antral CSA at various time intervals. This lack of significant variance was evident at baseline ($P = 0.07$), induction ($P = 0.08$), the 1-hour interval ($P = 0.09$), the end of surgery ($P = 0.09$), and 1-hour post-surgery ($P = 0.11$). These findings align with a randomized observational trial conducted by Ye and colleagues.[7] Their study included 100 ASA I-II female patients undergoing laparoscopic gynecological surgery. Using ultrasound, they measured antral CSA as the primary outcome and similarly found no substantial difference in antral CSA across three airway management methods before induction ($P = 0.451$), during induction ($P = 0.456$), and at the end of the operation ($P = 0.195$). Their research demonstrated that antral CSA remained consistent regardless of whether the patients were intubated with the LMA Supreme, I-gel, or ETT ($P = 0.814$). The consistency of antral CSA measurements in our study and the study by Ye *et al*.[7] suggest that this parameter remains relatively stable in patients undergoing lower abdominal laparoscopic surgeries, regardless of whether ETT or PLMA is employed as the airway management method. Consequently, the risk of aspiration appears to be similar in both groups, indicating that both airway devices are equally suitable for use in these surgical procedures.

In addition to antral CSA, our study evaluated secondary outcomes related to respiratory parameters and hemodynamic responses. We observed comparable inspired and expired tidal volumes, leak volumes, and leak fractions between the ETT and PLMA groups, indicating that both airway management methods maintain stable respiratory parameters during surgery. The higher although nonsignificant end-tidal CO2 levels observed in the PLMA group could be attributed to factors such as increased dead space within the device, differences in ventilation distribution or efficiency compared to ETTs, variations in patient positioning or lung mechanics, and potential fluctuations in CO2 elimination rates influenced

Table 3: Hemodynamic parameters

Parameters (mean±SD)	Baseline	Induction	At 1 h	End of procedure	1 h post op
SBP (mmHg)					
Group E	124.56±14.13	136.19±10.75	116.46±13.48	116.83±13.64	122.34±8.61
Group P	123.31±13.51	106.64±14.28	116.75±13.02	118.33±13.59	120.78±9.91
P	0.701	<0.001	0.932	0.644	0.485
DBP (mmHg)					
Group E	76.14±12.44	79.47±6.98	71.77±9.99	71.77±14.25	76.00±9.15
Group P	73.86±9.48	64.05±11.81	68.31±9.56	71.67±9.73	73.33±8.19
P	0.391	<0.001	0.145	0.977	0.202
Heart Rate (bpm)					
Group E	82.42±12.57	92.31±15.61	72.97±9.82	73.80±9.20	79.20±14.74
Group P	80.75±15.60	68.75±11.51	74.92±13.43	79.36±12.90	79.08±12.01
P	0.625	<0.001	0.494	0.652	0.971

Values are presented as mean±SD or number (%). LMA=Laryngeal mask airway. SBP=Systolic Blood pressure, DBP= Diastolic Blood Pressure

by the PLMA's design and placement; however, no clinical differences were observed. Furthermore, our study noted transient increases in heart rate (HR) and systolic blood pressure (SBP) during induction in the ETT group compared to the PLMA group. However, these differences did not persist throughout the surgery, suggesting that both airway devices have similar effects on cardiovascular responses once surgery is underway. These findings align with existing literature on airway management techniques and their impact on respiratory and hemodynamic parameters. Studies by D. Ozdamar, Handan Gulec, and others[9,10,13] have also reported comparable respiratory outcomes and hemodynamic stability between different airway devices, supporting the safety and efficacy of both ETT and PLMA in surgical settings.

Table 4: Respiratory parameters

Group	At induction	At 1 h	At end of Surgery
Leak volume (ml)			
Group E	2.92±7.50	2.06±10.75	5.11±6.76
Group P	3.89±6.97	6.08±9.71	8.31±3.66
P value	0.574	0.085	0.237
Leak fraction (%)			
Group E	0.00±0.10	0.44±2.61	1.30±3.66
Group P	0.01±0.02	1.46±2.45	2.20±1.73
P value	0.355	0.094	0.301
Inspired tidal volume (ml)			
Group E	403.69±5.47	400.14±5.37	400.17±5.13
Group P	411.11±7.76	410.01±7.71	409.14±7.16
P value	0.454	0.272	0.271
Expired tidal volume (ml)			
Group E	406.86±5.39	389.17±5.99	389.17±5.99
Group P	406.39±38.86	403.75±39.16	402.72±36.72
P value	0.972	0.214	0.175
Peak pressure			
Group E	15.64±3.16	21.20±3.21	17.03±3.19
Group P	15.56±2.84	20.75±2.63	17.50±2.58
P	0.911	0.522	0.504
Plateau pressure			
Group E	14.67±3.13	20.23±3.21	16.03±3.17
Group P	14.58±2.84	19.72±2.58	16.50±2.52
P value	0.916	0.471	0.525
$EtCO_2$			
Group E	36.56±4.16	39.74±2.79	36.91±2.44
Group P	37.00±1.72	41.42±2.57	38.22±2.19
P value	0.592	0.051	0.052

Values are presented as mean±SD or number (%). LMA= Laryngeal mask airway, $EtCO_2$=End tidal carbon dioxide

In both Group E (ETT) and Group P (PLMA), the surgeons assessed gastric distension on insertion of the laparoscope using a Likert scale of 7. The results showed comparable findings between the two groups, with no significant differences in the Likert scale ratings for gastric distension observed ($P = 0.583$). This indicates that both ETTs and PLMAs were similarly effective in maintaining gastric integrity during the surgical procedure, supporting their suitability for use in lower abdominal surgeries. Our study also examined postoperative recovery parameters, including time to start clear liquids, time to start a light diet, time to achieve bowel movements, and length of hospital stay. We found no significant differences between the ETT and PLMA groups in these recovery metrics, indicating similar postoperative outcomes regardless of the airway management technique used. These discoveries have significant ramifications for surgical procedures and patient care.

The comparable postoperative recovery times suggested that both ETT and PLMA are equally suitable in facilitating recovery and optimizing patient outcomes following minimally invasive lower abdominal surgeries.

The study's strengths lie in its comparative analysis of ETT and PLMA, objective measurement of gastric distension, by inclusion of CSA assessment, using a Likert scale, measuring leak fraction, evaluation of postoperative recovery parameters, adequate sample size, blinding, statistical analysis, and clinical relevance, enhancing the credibility of the findings in assessing gastric integrity and overall perioperative outcomes during lower abdominal surgeries., However, it is essential to acknowledge the limitations of our study, such as the relatively small sample size, single-center nature, and focus on short-term outcomes.

Conclusion

In conclusion, our study contributes to the growing body of evidence supporting the safety and efficacy of both

Table 5: Postoperative parameters

Parameters	Groups		*P* value
	Group E (*n*=36)	Group P (*n*=36)	
Mean duration of surgery (min)	117.35±35.44	118.61±36.28	0.584
Mean time to start clear fluids (h)	204.00±96.75	193.33±104.53	0.667
Mean time to start light diet (h)	397.91±122.69	418.33±141.61	0.514
Mean time to achieve bowel movements (h)	1083.43±458.	1205.56±372.07	0.223
Mean time to length of stay (days)	2.40±0.91	2.36±0.93	0.675

Values are presented as mean±SD or number (%). LMA=Laryngeal mask airway

endotracheal intubation and proseal LMA in minimally invasive lower abdominal surgeries. In patients undergoing minimally invasive lower abdominal surgeries, the choice of airway management technique, whether endotracheal intubation of proseal LMA, did not substantially impacted antral cross sectional area, vital parameters, respiratory parameters, or postoperative recovery. While there were slight differences observed at certain time intervals, they were not statistically significant, indicating the comparability of both techniques. These findings suggest that both ETT and PLMA can be considered safe and suitable for use in such surgical procedures.

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Conflicts of interest
There are no conflicts of interest.

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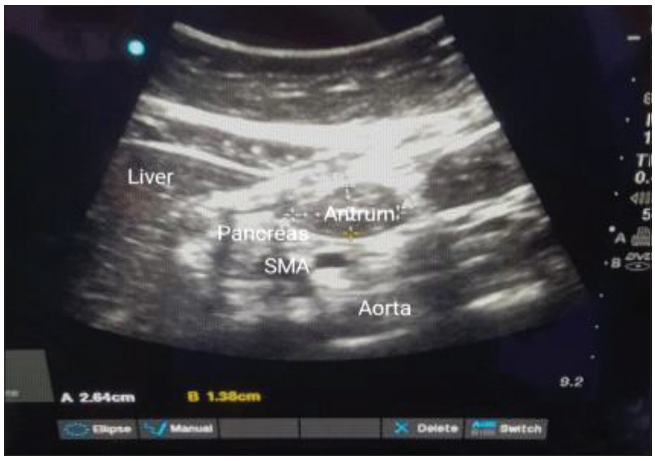

Supplementary Figure 1: Ultrasound image of antral CSA located between left lobe of liver anteriorly, and the pancreas posteriorly