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Comparative Evaluation of The Efficacy and Outcomes of The Proseal Laryngeal Mask Airway Versus The Endotracheal Tube Under Low Flow Anaesthesia

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Abstract

Introduction: Low-flow anaesthesia is becoming more popular due to its benefits, including lower costs, reduced atmospheric pollution, and improved conservation of heat and airway humidity. To create a leak-free semi-closed circuit system in low-flow anaesthesia, achieving an airtight seal between the airway device and the patient's airway is crucial. Our study aimed to compare the safety and efficacy of two airway maintenance devices, P-LMA (ProSeal laryngeal mask airway) and ETT (Endotracheal tube), within the context of low-flow anaesthesia.

Materials and methods: A prospective randomised, doubleblind study was conducted on 60 ASA grade I/II patients aged 20-50 and weighing 40-70 kg who underwent surgery with general anaesthesia. They were assigned to two groups: Group L used P-LMA, and Group ET used ETT.

Oropharyngeal leak pressure, tidal volume, peak and plateau pressure, Fraction of inspired oxygen, End Tidal carbon dioxide, inspiratory as well as expiratory concentrations of Nitrous Oxide and Isoflurane, hemodynamic parameters, and complications were analysed statistically using Student's t test.

Results: The oropharyngeal leak pressure measured 29.46 ± 1.1 cm H2O in the P-LMA group, compared to 31.3 ± 0.5 cm H2O in the ETT group ($P < 0.0001$). Additionally, the expired nitrous oxide and isoflurane concentrations were considerably lower in the P-LMA group than in the ETT Group ($P < 0.0001$). While these differences were statistically significant, they were clinically insignificant.

Conclusion: Low-flow anaesthesia is safe when using the ProSeal laryngeal airway or an endotracheal tube, but the ProSeal laryngeal mask results in fewer postoperative complications.

Keywords: Endotracheal tube, Low Flow Anaesthesia, ProSeal Laryngeal Mask Airway

Introduction

Low flow and closed system anaesthesia have considerable economic advantages, limiting atmospheric pollution and maintaining airway humidification and body temperature.

F. Foldes et al. performed anaesthesia in 1952 with a fresh gas flow of 1.0 L/min and introduced the term Low Flow Anaesthesia.

Baker, in 1994, suggested the following classification of flow rates of gases: Minimal flow = 0.5 L or less FGF (fresh gas flow)/ minute.

Low flow = ≥ 0.5 - 1 L/minute.

Medium flow = ≥ 2 - 4 L/minute.

Very high flow = ≥ 4 L/minute.

breathing system should be as low as possible. An airtight seal between the airway device and the patient's airway is essential to establish a leak-free, semi-closed circuit system during controlled lung ventilation [1] and for the safe and effective conduction of low-flow anaesthesia.

An endotracheal tube is always considered the gold standard for maintaining an airway during controlled ventilation under general anaesthesia due to its inherent ability to provide positive pressure ventilation. However, haemodynamic responses, coughing, bronchospasm, failed intubation, and postoperative sore throat due to intubation are also concerns.

These problems led to the invention of newer airway devices, such as Supraglottic devices like LMA (laryngeal mask airway), which Dr. Archie Brain designed in 1981. The advantages of LMA are speed and ease of placement, improved oxygen saturation during emergence, reduced anaesthetic requirement for airway tolerance, lower frequency of coughing during emergence, and lower incidence of sore throat. [2]

The only drawback of LMA compared to intubation is an inadequate seal and the risk of gastric insufflations. This issue can be addressed with a modified version known as the Proseal Laryngeal Mask Airway (P-LMA).

Introduced by Dr Brain in 2002 and updated in 2004, PLMA provides a sufficient seal and safeguards against regurgitation aspiration and gastric insufflation. [3] Zeinab Ahmed El Seify et al. 's 2010 studies tested the feasibility of LMA under low-flow conditions and proved that it could be safe and effective in establishing an airtight seal during controlled ventilation under a low fresh gas flow of 1 L /minute. Considering the advantages of P-LMA over LMA, we have compared PLMA to ETT under low-flow techniques. Our study comprises a comparative evaluation of the efficacy and outcome of P-LMA versus ETT under low-flow anaesthesia.

The primary Aim was to compare the safety and efficacy of P-LMA versus ETT using ventilatory and respiratory parameters to assess the feasibility of airway devices during low-flow anaesthesia. Ventilatory parameters include oropharyngeal leak pressure, inspired and expired tidal volume, and their differences. Respiratory parameters include FiO2 (fraction of inspired oxygen), continuous EtCO2 (End-tidal carbon dioxide) monitoring, and inspired and expired concentrations of Isoflurane and Nitrous oxide. The Secondary Aim was to observe for hemodynamic changes and postoperative complications of any device.

Method

In this study, 60 patients were enrolled from April 2014 to October 2014, scheduled for planned general surgical procedures. The study was a Prospective, randomised, double-blind clinical comparative study to compare the efficacy and outcome of proseal laryngeal mask airway and cuffed endotracheal tube under low-flow anaesthesia. For sample size estimation, the mean and standard deviation for the parameter "Difference between inspiratory & expiratory level of Isoflurane concentration is taken from the reference study, with α error of 0.01and β error of 0.1, using Medcalc software, a sample size of 30 per group was derived. [4]

Inclusion criteria were ASA I/II patients aged between20-50 years, weighted 40- 70kgs, undergoing elective surgery under general anaesthesia with duration of surgery between 45 minutes-120 minutes. Types of surgery included Simple mastectomy, lumpectomy of breast, Upper abdominal surgeries like upper ureterolithotomy, feeding jejunostomy, cyst-jejunostomy, ovarian cyst removal, ovarian mass removal, inguinal hernia repair, incisional hernia repair. Exclusion criteria were difficult airway patients, Patients with Gastroesophageal reflux disease or full stomach, patients with a known allergy to latex, patients with a recent history of sore throat or common cold within the last 10days, and patients not willing to participate in the study.

The patients were randomly assigned to one of two groups of 30 patients, each using computer-generated numbers (www.randomiser.org). They were to receive an airway proseal laryngeal mask (group L) or a cuffed endotracheal tube (group ET). The anaesthesia technique was standardised.

Group L (p-LMA): 1-30, Group L: patients in whom proseal laryngeal mask airway was inserted (N=30) Group ET (ETT):31-60, Group ET: patients in whom endotracheal tube was inserted. (N=30)

All the patients underwent a detailed pre-anaesthetic checkup. Routine investigations, such as haemoglobin, random blood sugar, blood urea, serum creatinine, chest x-ray (if indicated), and ECG (if indicated), were performed for each patient. All the patients were kept nil by mouth from 10 PM. The night before surgery, Ranitidine 150 mg and Diazepam 10 mg were given orally.

This is a double-blind study; the patient and fellow anesthesiologists who collected the Data were blinded to the study group. Unblinding was done after 24 hours. On the day of surgery, Airway devices and an anaesthesia machine with a Gas analyser (Dragger Fabius Plus) were checked before commencing anaesthesia for each case. All the patients were premedicated with Glycopyrrolate 5µg/kg IV for 30 minutes and Ondansetron 4mg IV 15 minutes before induction. Multipara Monitor (Infinity Vista 2000) was attached, and baseline parameters like pulse rate, blood pressure, oxygen saturation and Et CO2 were noted.

Before insertion, P-LMA was inspected for any damage, leak, foreign body, or bolus of lubricant obstructing the distal opening of the airway or gastric channel. The cuff was deflated entirely with a 50-cc syringe. P-LMA was removed from the cradle and grasped along the integral bite block for pre-insertion preparation. Then, the cuff's back, front, and sides were lubricated with water-based lubricant. ETT was inspected for any damage, leak, foreign body, or lubricant bolus obstructing the distal airway opening. The cuff was deflated entirely with a10cc syringe. For Pre-insertion preparation under all aseptic precautions, ETT has lubricated the cuff's back, front and sides with water-based lubricant.

Preoxygenation was done for 5 minutes with 100%oxygen in all the patients using a closed circuit and facemask ventilation. Fentanyl 1 mcg /kg IV was given, and Thiopentone sodium 5mg/kg IV was used as an induction agent, followed by Succinylcholine 1.5 – 2mg/kg IV as a muscle relaxant. In our study, we inserted proseal laryngeal mask airway size No.3 for female patients andNo.4 for male patients in group L. In contrast, cuffed endotracheal tubes No.7-7.5 for female patients andNo.8-8.5 for male patients in group ET were inserted as per the group selected.

Proper placement of P-LMA / ETT was confirmed by square waveform capnography, bilateral equal chest movement and air entry, absence of audible leak on gentle intermittent positive pressure ventilation / oropharyngeal leak pressure, absence of gastric insufflations by auscultation over epigastrium, passing of oro-gastric tube effortlessly through drain tube in case of P-LMA.

After the correct placement of the device was confirmed, it was fixed and attached to a closed circuit. It was then put on controlled mechanical ventilation with a respiratory rate of 12/Minute, tidal volume of 8 ml/kg, and PEEP of 3 cm of H_2O. Vecuronium bromide was injected as a muscle relaxant to maintain neuromuscular blockade as and when required.

Anaesthesia was maintained with 2-2.5 % Isoflurane in a 50:50 Oxygen: nitrous oxide ratio in fresh gas flow at 6 L/minute for 10 minutes (Wash-in period). After 10 minutes, the fresh gas flow was reduced to 1 L/minute while maintaining the oxygen: nitrous oxide ratio at 50:50; the isoflurane vapour setting was 1.0 - 1.5 Volume %.

At the end of surgery, Isoflurane was discontinued 10minutes before the expected end of surgery to wash out the anaesthetics. All anaesthetic gases were discontinued, and fresh gas flow was increased to 6 L / minute; only100% O_2 was given. Neuromuscular blockade was reversed after the return of spontaneous respiration using an intravenous Injection of Neostigmine 50 µg/kg +Glycopyrrolate 10 µg/kg. Intravenous fluid was administered as required. The patient was extubated after all criteria for extubation were achieved.

Intra-operatively, all the patients were monitored according to AAGBI standards. After 5 minutes of insertion of the airway device, oropharyngeal leak pressure was measured in all the patients. Oropharyngeal leak pressure was measured by giving a fresh gas flow of3L/minute, closing the expiratory valve of the circuit, and noting the pressure at which there was an audible leak. The oropharyngeal pressure was not allowed to exceed40 cm H_2O to avoid barotrauma. In our study, we monitored oropharyngeal leak pressure at 5-minuteintervals, then at 15 minutes and 30 minutes later. I inserted all the Airway devices and was trained after 20insertions of both devices. In our study, all airway devices were inserted on the first attempt. We did not observe any failure while inserting it or any changeover of the airway device.

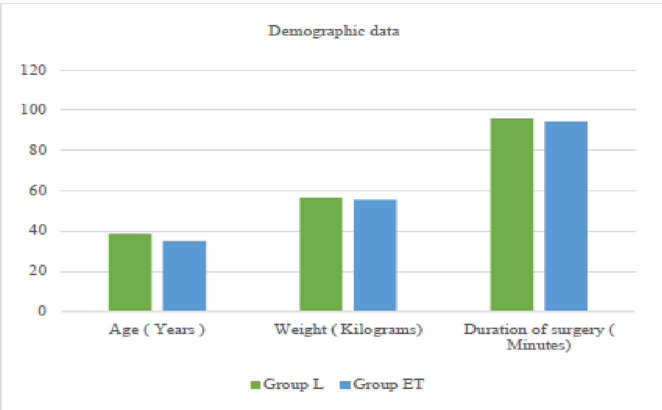
We have observed ventilatory and respiratory parameters, such as the difference between inspiratory and expiratory tidal volume, inspiratory Oxygen concentration (FiO_2), inspiratory concentration of CO_2, inspiratory and expiratory isoflurane concentration, and inspiratory and expiratory N_2O concentration, which were monitored continuously but only recorded afterinduction,5, 10, 20, 30, 40, 50, 60, 80, 100, and 120minutes later.

Intra-operative complications such as the occurrence of leaks, regurgitation, arrhythmias, tongue, lip, dental trauma during insertion of airway device, hypoxia ($SpO_2 < 95\%$), bronchospasm, and laryngospasm were noted.

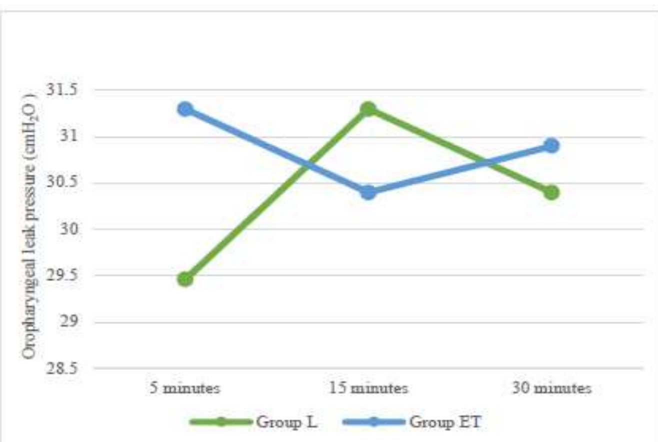
All the patients were monitored postoperatively for vital parameters like heart rate, blood pressure, SpO_2, and$EtCO_2$ and assessed for postoperative complications like blood staining of the device, cough, sore throat, and difficulty swallowing. Observed data was expressed in MEAN±SD form in the table and graphs. Qualitative variables were determined using a paired t-test, and qualitative variables were determined using a chi-square test. The test for significance was done using Medcalc statistical software. The analysis of their significance was done by using the P value. A P value less than 0.05 was considered significant. A P value less than 0.001 was considered highly significant. A P value of more than 0.05 was considered insignificant.

Results

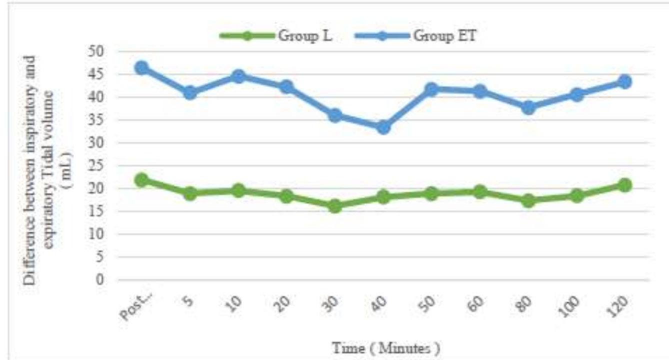
Demographic data regarding age, gender, weight, duration of surgery, and types of surgery were similar in both groups, showing no statistically significant differences. [4] [5] [6]



An oropharyngeal leak pressure below 20 cm H2O indicates significant leakage. Our study measured pressures at 29.46 ± 1.1 cm H2O in Group L and 31.3 ± 0.5 cm H2O in Group ET at 5-minute intervals. While the difference was statistically significant, it lacked clinical significance. At 10 and 30 minutes, pressures were 31.3±2.16, 30.4±1.6 cm H2O for Group L and 30.4±1.8, 30.9±2.4 cm H2O for Group ET, respectively, both statistically insignificant.



Leakage is also assessed as the difference between inspired and expired tidal volumes. Carrier gas flow leakage of more than 100 mL/minute suggests leakage.[4] In our study, the intergroup comparison showed no statistically significant difference; both groups provided adequate air seals.



In low-flow anaesthesia, the oxygen concentration rises but gradually declines due to the body's continuous oxygen consumption. In our study, the oxygen levels initially ranged from 53.6 ± 1.33% to 52.46 ± 1.27%.Over time, these levels decreased to 49 ± 0.5% and 49.25± 0.7% in groups L and ET, respectively. EtCO2 was maintained within the normal range (35-45 mm of Hg) in both groups, with no statistically significant difference in the intergroup comparison. Inspired carbon dioxide was maintained within the normal range of less than 5 mmHg. No incidence of rebreathing was noted.

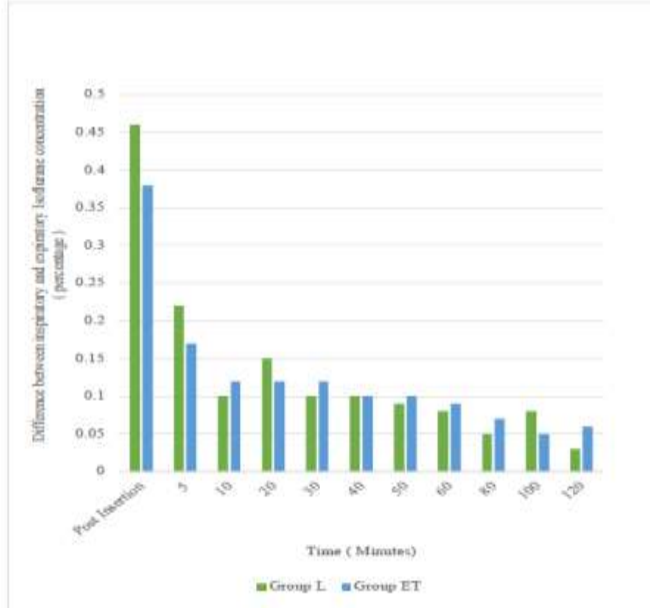
	F_iO_2		E_tCO_2		
Time	Group L	Group ET	Group L	Group ET	Intergroup P value
Post Insertion	53.6±1.33	52.46±1.27	35.56±2.0	36.3±1.7	>0.05
5 mins	52.26±0.9	52±0.99	36.36±1.11	35.7±3.0	>0.05
10 mins	51.9±0.88	51.73±1	36.0±1.2	35.8±2.6	>0.05
20 mins	51.43±1.35	51.1±1.32	35.6±1.52	35.4±2.92	>0.05

30 mins	50.9±1	50.56±0.77	35.8±1.57	36.0±3.26	>0.05
40 mins	50.8±0.95	50.33±0.66	36.0±1.0	36.2±3.36	>0.05
50 mins	50.3±0.59	50.2±0.61	34.9±1.53	36.0±3.51	>0.05
60 mins	49.96±0.18	50.0±0.36	35.7±1.41	35.9±3.38	>0.05
80 mins	49.83±0.75	49.7±0.44	35.4±1.14	36.61±4.19	>0.05
100 mins	49.8±0.41	49.6±0.5	35.5±1.41	35.5±5.0	>0.05
120 mins	49±0.5	49.25±0.7	36.88±0.92	35.4±13.0	>0.05

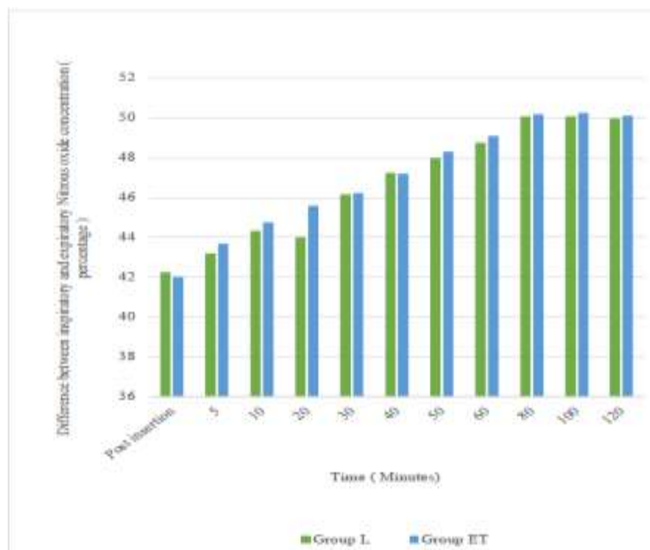
*Table 1: Changes in FiO2 and EtCO2 throughout the study. Values are in Mean ± Standard Deviation (SD) %for FiO2 and Mean ± Standard Deviation (SD) mm Hg for EtCO2.

After inserting the airway device, we observed the inspiratory and expiratory concentrations of isoflurane and N_2O and then at 5, 10, 20, 30, 40, 50, 60, 80, 100, and 120 minutes later.

Isoflurane concentrations were similar in both groups. At20 minutes, the expiratory Isoflurane concentration was0.97±0.03% for P-LMA and 01±0.02% for ETT. While statistically significant, this difference was clinically insignificant since the minimum expiratory concentration exceeded 0.8 times MAC. Combined with nitrous oxide MAC, this results in 1.3 MAC, ensuring sufficient anaesthetic depth for 95% of patients to tolerate noxious stimuli without movement.



At 20 minutes, expiratory nitrous oxide concentrations were 44±1.1% for P-LMA and 45.6±1% for ETT. The difference was statistically significant but clinically insignificant. Tanuja Malik (2012) reported end-tidal nitrous oxide concentrations of 41.90±4.62% to 60. 40±4.83%.



The concentration of anaesthetic agents was maintained at 1 MAC or more. Before leaving the recovery room, the patient was asked for any history of awareness. None of the patients complained of awareness. Moreover, throughout the study, hemodynamic parameters remained stable, indicating a proper level of depth of anaesthesia.

Changes in mean heart rate, systolic blood pressure, mean blood pressure, and SpO2 were comparable in intra-group and group comparisons, with statistically insignificant differences between the two groups. All patients maintained SpO2 levels of more than 95% throughout the study.

We observed intra- and post-operative complications, such as blood staining of devices, hypoxia (SpO2), regurgitation, arrhythmias, bronchospasm, laryngospasm, cough, difficulty swallowing, and sore throat. In our study, the incidence of sore throat was 1.66% in group ET compared to nil in group L.

Discussion

Since the introduction of new inhalation anaesthetics and gas monitoring devices in the anaesthesia machine, low flow anaesthesia has significantly grown in acceptance. Anaesthesia with low flow improves the flow dynamics of inhaled air. [7] It also increases mucociliary clearance, maintains body temperature, and reduces fluid loss. [8] When used routinely, Low-flow anaesthesia can save upto 75% in anaesthesia gas consumption. [9] Moreover, it helps reduce atmospheric pollution in terms of ozone depletion by anaesthetic gas and prevents the greenhouse effect. Effective use of these low-flow anaesthesia techniques requires minimising breathing system leakage; an airtight seal between the airway device and the patient ensures a leak-free, semi-closed circuit during ventilation. [1]

The endotracheal tube is standard for adults under general anaesthesia. Laryngeal mask airway (LMA)provides benefits like faster placement, improved hemodynamic stability, less coughing during emergence, and greater patient satisfaction by minimising postoperative sore throat and voice changes. [10] After a decade of trials, the U.S. FDA approved the Laryngeal Mask Airway (LMA) in 1991 as an alternative to facemasks for elective anaesthesia. [11] By 1998, Rosenblatt et al. reported more cases being managed with the LMA. No gastric distension episodes occurred when used correctly with positive pressure ventilation under 10mL/ kg. [12]LMA inserted in the proper position allows flow reduction in patients.[6] LMA safely establishes an airtight seal during controlled ventilation at a low fresh gas flow of 1 L/minute, causing less coughing and sore throat postoperatively than ETT.[4] Like the PLMA, the second-generation LMA offers adequate seal and protection against regurgitation, aspiration, and gastric insufflation.

Oropharyngeal leak pressure remained above 20 cm H2O, ensuring an airway seal. Hönemann et al. (2001) reported12% leakage with LMA and 1.7% with ETT, while Zeinab Ahmed El-Seify (2010) noted 6.9% initial leakage. Both studies support the efficacy and safety of LMA.

The difference in inspired and expired tidal volume was similar in both groups, with no statistically significant difference. No leakage incidents occurred. Peak airway pressure above 20-30 cm H2O significantly affects air leaks from LMA. [13] In our study, we kept airway pressure below 20 cm H2O for a proper seal. Peak and plateau pressures were comparable in both groups with no significant difference. D. Frohlich et al. (1997) reported similar peak pressures: 1.74±0.19 kPa in the TT group and 1.72±0.20 kPa in the LMA group.

Oxygen concentration was consistent throughout the study, with no patient experiencing hypoxia (FiO2 <40%, SpO2 < 95%) during anaesthesia; thus, no flow changes were necessary. Tanuja Malik (2012) et al. compared desflurane and isoflurane in minimal flow anaesthesia, finding oxygen concentration ranged from34.56±2.89% to 45.80±4.14%.

As flow reduction progresses, the difference between the gas concentration in the breathing system and that in the fresh gas flow increases. [14] Consequently, the composition of the anaesthetic gas cannot be reliably assessed from the composition of the fresh gas. Therefore, continuous gas monitoring is advisable, which we implemented in our study.

The initial wash concentration for Isoflurane is 1-1.5% at4 L/min. [28] With lower gas flow, the vaporiser setting increases during maintenance to maintain adequate anaesthesia. Our study maintained isoflurane at 2-2.5%with a flow of 6 L/min to reduce the wash-in period. After 10 minutes, we lowered the concentration to 1-1.5% and flow to 1 L/min to avoid overdose. Consumption of isoflurane is only partially influenced by fresh gas flow. [15]

Zeinab Ahmed El Seify et al., 2010, found a higher incidence of cough and sore throat in intubated patients. In our study, 13.3% of ETT patients had a cough, and 20% had a sore throat, compared to 0% and 3.4% in LMA patients. The postoperative period was uneventful for all patients.

Conclusion

Conducting low-flow anaesthesia with a fresh gas flow of 1 L/min with oxygen and nitrous oxide is a safe and effective method with mandatory continuous monitoring of parameters like airway pressure, inspired and expired gas volume, carbon dioxide concentration and oxygen saturation. During low-flow anaesthesia, P-LMA and ETT effectively maintain airway seals without altering ventilatory parameters like leak pressure, tidal volume, or peak and plateau pressure. They preserve normal respiratory parameters (concentration of O2, nitrous oxide, CO2, isoflurane), showing minor differences in nitrous oxide and isoflurane at 20-minute intervals, with negligible impact on vital signs. However, the ProSeal laryngeal mask airway is safer than the Endotracheal tube for low-flow anaesthesia, experiencing fewer postoperative complications.

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