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A Comparative Study between Proseal Laryngeal Mask Airway and Endotracheal Intubation Using Pressure Controlled Ventilation In Patients With Chronic Obstructive Pulmonary Diseases Undergoing Laparoscopic Cholecystectomy

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Abstract: *Chronic obstructive pulmonary diseases (COPD) carries a risk of bronchospasm and hypoxaemia airway instrumentation. Use of laryngeal mask airway (LMA) is a safe alternative to endotracheal intubation in laparoscopic surgeries. Earlier studies noted that LMA can be used in providing pressure controlled ventilation (PCV). Aim was to evaluate and compare between ProSeal LMA (PLMA) and endotracheal intubation for maintaining adequate oxygenation, using PCV in COPD patients undergoing laparoscopic cholecystectomy.*
60 adult patients with COPD of ASA II, were randomized into two groups to secure airway either using endotracheal tube (Group A) or ProSeal LMA (Group B). Both the groups were put on ventilator using PCV mode and parameters were adjusted to maintain end-tidal CO2 between 35 and 40 mmHg. Arterial blood gas analyses were done at preinduction, 15 minutes after creation of pneumoperitoneum and at 20 minutes interval thereafter till the end of the surgery. Every untoward event was noted. All data were analyzed statistically. Both Groups showed no statistically significant (p > 0.05) difference in PaO2 and PaCO2 level. No patient needed conversion from PCV to volume controlled ventilation (VCV). Incidence of adverse outcome was relatively higher in group A.Thus PLMA is a safe and effective alternative to endotracheal intubation in maintaining adequate oxygenation using PCV in COPD patients undergoing laparoscopic cholecystectomy.

Keywords: *COPD, Laparoscopic cholecystectomy; Pressure controlled ventilation; ProSeal LMA; Endotracheal intubation.*

I. Introduction

Microscopic shear and stress lung injury has changed the whole concept of "safe ranges" of pressure and volume curve in mechanical ventilation [1]. To avoid associated morbidity with mechanical ventilation in patients with chronic obstructive pulmonary disease (COPD), the cornerstone is to prevent dynamic pulmonary hyperinflation by limiting minute ventilation and maximizing time for expiration and by inducing synchronization between the patient and mechanical ventilator[2].

The characteristic of flow and pressure generation with pressure limitation in pressure controlled ventilation (PCV) may diminish the risk of barotrauma in patient with COPD[3].

Previous study comparing PCV with VCV during laparoscopic gastric banding surgery has revealed that PCV improves oxygenation without any side effects[4].

Evidence suggests that laryngeal mask airway (LMA) in laparoscopic surgery is a safe and effective alternative to endotracheal tube (ETT) in controlling the airway without manipulating sensitive larynx and trachea[5]. Earlier study found no difference in SpO_2 and $PEtCO_2$ between PLMA and ETT groups before and after peritoneal insufflations[6].

Considering previous studies, aim of this study was to evaluate and compare between the PLMA and endotracheal intubation for maintaining adequate oxygenation using PCV in patients with COPD undergoing laparoscopic cholecystectomy.

II. Materials and Methods

After obtaining approval of the Institutional Ethics Committee and informed consent from patients this prospective, randomized, open label, parallel group study was undertaken on 60 patients at IPGME&R, Kolkata between April 2008 and March 2009.

Inclusion criteria:

- Maximum medically optimized COPD patients with 60 to 70% predicted forced expiratory volume in one second (FEV1)

- FEV1/FVC (forced vital capacity)
- Mid expiratory flow rate (MEFR) and peak expiratory flow rate (PEFR) >300 ml/min on a well performed test
- ASA grade II
- BMI <30 kg/m2
- Preoperative PaCO2 between 35 and 45 mmHg
- Scheduled for laparoscopic cholecystectomy
- Either sex, aged between 30 and 49 years

Exclusion criteria:

- Patients with upper airway obstruction
- Patients receiving active bronchodilator therapy
- Inability to maintain SpO2 > 95% in room air preoperatively
- Difficulty in intubations, mouth opening < 2.5cm
- Known hypersensitivity to study drugs
- Duration of surgery exceeding 45 minutes following pneumoperitoneum

Sample size calculation: A pilot study involving 10 patients (5 in each group) was performed to determine the difference of mean PaO2 between groups and the within group standard deviation. From this data and assuming a probability of Type I error as 5 %, it was calculated that a minimum of 60 patients would be required for the study to reject the null hypothesis with a power of 80 %.

Following securing arterial and venous accesses, baseline arterial blood gas (ABG) analysis was done. Sixty patients with $PaCO_2$ between 35 and 45 mmHg were selected and randomized into two groups.
Group A (n=30): Airway secured using endotracheal tube (ETT)
Group B (n=30): Airway secured using PLMA

Following fasting for 8 hours, patients received inj. omeprazole 20 mg and inj. metoclopromide 10 mg iv 2 hrs before induction. Inj. glycopyrrolate 0.2 mg and inj. fentanyl 2 µg/kg were given iv 5 minutes before induction. After preoxygenation for 4 minutes, patients were induced with inj. thiopentone sodium 5 mg/kg. After achieving adequate muscle relaxation with inj. rocuronium bromide 0.9 mg/kg, patients of Group A were intubated with cuffed PVC ETT of appropriate size and the airway of patients of Group B were secured using PLMA of appropriate size, inserted using index finger as recommended by the manufacturer[7] by the same experienced anaesthesiologist.

Normal thoraco-abdominal movement with manual ventilation, no audible leak from drain tube at peak airway pressure of 20 cm H_2O and a square wave capnographic trace were considered as signs of effectively secured airway.

5 minutes after establishment of patent airway with PLMA the exact intra-cuff pressure was set and maintained at 60 cm H_2O throughout, using an ergonomic pressure gauge[8] (Hi –Lo Hand Pressure Gauge; MALLINCKRODT Medical, Germany).

Lungs were ventilated with circle breathing system using Penlon Prima SP, AV 800 ventilator to deliver PCV with inspiratory/expiratory ratio of 1:2.5. Airway pressure was set to deliver a tidal volume of 8 ml/kg. Respiratory rate (RR) was set to keep $EtCO_2$ 35-40 mmHg. Anaesthesia was maintained with 50% oxygen in air and sevoflurane 2-3%[9] to keep bi spectral index (BIS) between 40 and 60. Inj. tramadol 2 mg/kg and top up doses of inj. rocuronium bromide 0.08 mg/kg (maintaining < 2 twitches using a train-of-four sequence) were administered.

Continuous changes of pulse rate, NIBP, SpO_2%, RR, $EtCO_2$, ECG, lung compliance, and end tidal anaesthetic gas percentage were monitored and recorded at 5 minutes interval till the end by Datex Ohmeda five Channel Multipara Monitor.

After creation of pneumoperitoneum (intra abdominal pressure 10-12 mmHg) patients were placed in a 25^0 head-up position. Following an increase or decrease in $EtCO_2$, RR was increased or decreased by 2/min every 3 minutes till 20/min or 8/min to achieve the target $EtCO_2$. Patients requiring airway pressure > 35 cm H_2O and RR > 20/min to maintain normocarbia or with I:E < 1:2 were shifted to VCV and dropped from the study.

Cuff pressure in Group B and peak airway pressure in both groups were recorded after insertion of airway devices, 10 minutes after pneumoperitoneum, at 10 minutes interval thereafter, and after desufflation of pneumoperitoneum. ABG was done 15 minutes after establishment of pneumoperitoneum, at 20 minutes interval thereafter till the end of the surgery and 10 minutes after extubation.

Neuromuscular blockade was reversed when train-of-four ratio was ≥ 2 twitches with inj. neostigmine 0.05 mg/kg and inj. glycopyrrolate 0.01 mg/kg. Patients were shifted to recovery room only when they were stable and maintaining SpO_2 > 95% in room air. Humidified oxygen was administered for two hours. HR, NIBP, SpO_2% and RR were monitored. Incidence of peri-operative bronchospasm or other untoward events if any was recorded.

End point of the study: Conversion of ventilator mode from PCV to VCV.

Primary outcome parameters for statistical analyses were: Difference in PaO2 and PaCO2 between the study groups.

Secondary outcome variables: Alveolar arterial oxygen gradient (A-aDO2), all variables pertaining to ventilation like pH, EtCO2, RR, tidal volume, peak airway pressure, SBP, DBP, mean arterial pressure (MAP) were considered for analyses.

III. Statistical analyses

All raw data were entered into an Excel Spreadsheet and analyzed using standard statistical software like 'SPSS and Statistica'. All normally distributed numerical data were analysed using unpaired t-test and all categorical data were analysed using Pearson's chi-square test. Non-normal data between groups were compared using Mann Whitney U test. A p value <0.05 was considered statistically significant.

IV. Results

Table 1: Demographic profile (Mean ± SD)

Characteristics	Group A (n=30)	Group B (n=30)
Age (yr)	44.11 ± 4.60	43 ± 4.65
Weight (Kg)	48.77 ± 7.31	51.12 ± 7.86
Height (m)	1.55 ± 0.06	1.58 ± 0.05
BMI (Kg/m^2)	33.38 ± 1.79	34.09 ± 1.88
Sex (M:F)	16/14	12/18
FEV1	65.16 ± 2.21	65.00 ± 2.03
FEV1/FVC	66.72 ± 2.01	65.70 ± 1.99
PEFR	311 ± 7	309 ± 6

p > 0.05

SD= Standard Deviation. BMI= Body Mass Index.

Table 1 showed that two groups were comparable in terms of demographic profile

Table 2: Duration of surgery, anaesthesia, CO_2 insufflation time, intra-abdominal pressure (Mean ± SD)

Characteristics	Group A (N=30)	Group B (N=30)
Duration of surgery (min)	47.21 ± 8.22	49.13 ± 7.42
Duration of Anaesthesia (min)	54.47 ± 8.34	55.76 ± 9.68
Duration of CO_2 insufflations (min)	36.22 ± 5.12	38.34 ± 5.41
Intra abdominal pressure (mmHg)	10.95 ± 0.65	11.07 ± 0.43

p > 0.05 CO_2 = Carbon dioxide

Table 2 showed that two groups were comparable in terms of duration of surgery, duration of anaesthesia, duration of CO_2 insufflations and the intra-abdominal pressure.

Table 3: Haemodynamic variables (Mean ± SD)

Parameters	**Group A**	**Group B**
Heart rate (min)		
Before induction	79.78 ± 10.69	75.14 ± 19.51
15 mins after pneumoperitoneum	82.77 ± 09.67	79.43 ± 15.69
35 mins after pneumoperitoneum	83.99 ± 10.04	77.73 ± 16.64
Systolic arterial pressure (mmHg)		
Before induction	114.76 ± 12.14	123.27 ± 11.74
15 mins after pneumoperitoneum	118.04 ± 13.41	115.24 ± 13.62
35 mins after pneumoperitoneum.	113.44 ± 11.67	117.72 ± 13.43
Diastolic arterial pressure (mmHg)		
Before induction	78.80 ± 08.63	76.63 ± 08.91
15 mins after pneumoperitoneum	80.12 ± 09.11	78.16 ± 08.88
35 mins after pneumoperitoneum	79.78 ± 10.12	76.63 ± 07.72
Mean arterial pressure (mmHg)		
Before induction	90.71 ± 08.50	92.90 ± 8.93
15 mins after pneumoperitoneum	96.72 ± 09.92	94.95 ± 8.89
35 mins after pneumoperitoneum.	91.78 ± 08.82	90.01 ± 7.66

p > 0.05

Table 3 revealed that there were no statistically significant differences in the two groups in terms of heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure between pre-induction and 15, 35 min after pneumoperitoneum.

Table 4: Ventilatory parameters (Mean ± SD)

Characteristics	Group A (N=30)	Group B (N=30)
RR (per min)		
After intubation	10.03 ± 0.68	10.08 ± 0.55
15 min after pneumoperitoneum	10.06 ± 0.82	11.03 ± 0.12
35 min after pneumoperitoneum	11.07 ± 0.83	12.11 ± 0.44
Tidal Volume (ml)		
After intubation	406 ± 43.03	410 ± 37.08
15 min after pneumoperitoneum	392 ± 39.07	402 ± 41.06
35 min after pneumoperitoneum	397 ± 48.05	401 ± 44.01
Peak Airway Pressure (cm H_2O)		
After intubation	20.7 ±1.1	19.3 ± 1.7
15 min after pneumoperitoneum	19.5 ± 1.2	18.9 ± 1.8
35 min after pneumoperitoneum	18.8 ± 1.7	18.1 ± 2.9
% of patients required conversion to volume control ventilation.	0	0

Table 4 showed that respiratory rate and tidal volumes were required in Group A were comparable to Group B. at preinduction, at 15 and 35 minutes ventilation were required and statistically insignificant ($p > 0.05$) peak airway pressures were generated in both the Group. At 35 minutes after pneumoperitoneum RR required to increase to maintain the saturation but was not statistically significant.

Table 5: SpO_2, pH, EtCO2, $PaCO_2$ and $PaCO_2$-$EtCO_2$, PaO_2 and PAO_2-PaO_2 (Mean ± SD)

Characteristics	Group A n=30	Group B n=30
SpO2%		
Pre-induction	99.06 ± 0.07	99.04 ± 0.13
15 min	99.05 ± 0.76	99.07 ± 0.71
35 min	99.03 ± 0.68	99.06 ± 0.72
After extubation	97.01 ± 0.62	99.05 ± 0.64
pH		
Pre-induction	7.36 ± 0.42	7.38 ± 0.78
15 min	7.38 ± 0.05	7.38 ± 0.88
35 min	7.37 ± 0.75	7.39 ± 0.05
After extubation	7.38 ± 0.33	7.39 ± 0.09
EtCO2 (mmHg)		
Pre-induction	38.82 ± 1.23	38.79 ± 1.33
15 min	39.01 ± 1.41	38.71 ± 1.45
35 min	39.69 ± 1.92	39.52 ± 1.80
After extubation	37.76 ± 2.30	37.78 ± 2.00
$PaCO_2$ (mmHg)		
Pre-induction	43.00 ± 1.77	42.82 ± 1.33
15 min	43.01 ± 1.25	42.80 ± 2.00
35 min	44.52 ± 2.15	44.37 ± 1.78
After extubation	41.89 ± 1.87	42.00 ± 2.73
$PaCO_2$– $EtCO_2$ (mmHg)		
Pre-induction	04.82 ± 0.77	04.76 ± 0.55
15 min	04.99 ± 0.86	04.43 ± 0.68
35 min	05.21 ± 0.93	04.98 ± 0.91
After extubation	05.06 ± 0.54	05.10 ± 0.74

PaO_2 (mmHg)		
Pre-induction	094.30 ± 06.50	093.83 ± 07.41
15 min	278.80 ± 46.67	283.30 ± 55.00
35 min	269.13 ± 56.64	272.62 ± 62.13
After extubation	096.15 ± 08.62	099.22 ± 07.76
PAO_2– PaO_2 (mmHg)		
Pre-induction	011.19 ± 21.00	012.87 ± 43.13
15 min	104.22 ± 32.02	106.91 ± 34.01
35 min	099.51 ± 12.03	102.64 ± 17.31
After extubation	015.64 ± 21.01	014.63 ± 37.02

$p < 0.05$

Table 5 showed no statistically significant difference in pH, $PaCO_2$, PaO2, PAO2 – PaO2, and $PaCO_2$-$EtCO_2$ values in the two groups at preinduction, and at 15, after pneumoperitoneum, PaO2 and PAO_2 – PaO_2 were also comparable in both the groups at pre induction, 15 minutes. But at 35 minutes after pneumoperitoneum, the patients in Group B showed statistically insignificant (p>0.05) higher value of PaO_2 and lower value of PAO_2 – PaO_2 in comparison to the patients in Group A.

IV. Discussion

COPD causes gradual destruction of lung parenchyma (emphysema) or inflammation of small airways (chronic bronchitis) with increased residual volume, air trapping, and hyperinflated lungs.

In these patients hypoxaemia is a serious complication during anaesthesia particularly while undergoing laparoscopic surgery. Bronchospasm may occur on induction, during airway instrumentation or on extubation. Avoidance of endotracheal intubation, if possible, may reduce the risk of bronchospasm.[5]A previous study suggested that LMA in laparoscopic surgery is a safe and effective alternative to ETT in controlling the airway without manipulating the sensitive larynx and trachea[5]. Similarly in the present study it has been found that PLMA is better than ETT in COPD patients to avoid bronchospasm.

Brimacombe JR and Berry A showed that when the drainage tube was closed, PLMA successfully protected the airway from fluid injected up the esophagus until cuff sealing pressures of 63 – 68 cm H_2O had been achieved[10]. In this study regurgitation was not noted through drain tube in any patient of PLMA group keeping the cuff sealing pressures at 60 cm H_2O.

The large tidal volumes used in VCV to maintain normocarbia during laparoscopic surgery in COPD patients lead to over distend normal alveoli leading to rupture[11]. Nichols D and Haranath S. concluded in their study that in patients with obstructive pulmonary disease, pressure limitation might diminish the risk of barotrauma[3]. In our study, we could also maintain normal oxygenation and normocarbia in COPD patients using PCV.

PCV, by virtue of pressure ceiling, is seen as a possible means of avoiding transient high peak alveolar pressures in lung units close to central airways and possessing fast time constants[12]. Pressure limits and decelerating flow profiles are thought to produce more uniform distribution of forces within lungs, possibly reducing the risk of volu–barotraumas and provide better oxygenation than square wave pattern[12].
As per GOLD Classification of COPD[1] this study included 60 patients divided into two groups using ETT or PLMA to receive PCV.

Measurement of arterial blood gas is desirable in these patients to measure arterial O_2 tension to detect more subtle changes in intrapulmonary shunting.[13]

Although monitoring of ET CO_2 is an adequate guide for determining the minute ventilation required to maintain normocarbia, it takes about 15 minutes for $PaCO_2$ to reach a plateau after creation of pneumoperitoneum[15]. High solubility of CO_2 increases systemic absorption by the vasculature of the peritoneum. This, combined with smaller tidal volumes because of poor lung compliance, leads to increased arterial CO_2 levels and decreased pH. Arterial CO_2 measurement is also needed to guide ventilation because increased dead space widens the normal arterial–to-end-tidal CO_2 gradient.

In this study, arterial blood samples were measured at preinduction, 15 minutes after establishment of pneumoperitoneum, at 20 minutes interval thereafter till the end of the surgery and 10 minutes after extubation. Changes in the SpO_2, pH, $PaCO_2$ and $PaCO_2$-$EtCO_2$, PaO_2 and PAO_2-PaO_2 at preinduction, 15 min and 35 min were comparable in both Group A and B. Refer table 5.

Cadi P, Guenoun T, Journois D, Chevallier JM, Diehl JL, Safran D showed that PCV improves oxygenation during laparoscopic obesity surgery compared to VCV[4]. Similar finding related to oxygenation using PCV in COPD patients has been found in this study. Sinha A, Sharma B, Sood J. showed that PLMA and ETT are comparable regarding SpO_2 and $PEtCO_2$ before and after peritoneal insufflations[6]. In terms of PaO_2 and $PaCO_2$, the present study also showed statistically insignificant results with ETT and PLMA using PCV.

The study was designed to convert the ventilator mode from PCV to VCV when it was needed to convert I:E ratio < 1:2 to maintain SpO_2 > 95%, keeping $EtCO_2$ between 35 - 40 mmHg to alleviate the development of auto-PEEP[3]**.** No patient required conversion to VCV.

Although several studies have been performed to determine the optimal ventilatory settings in these patients, the answer is yet to be found. The primary goal of mechanical ventilation is the maintenance of adequate gas exchange which must be achieved with minimum lung injury and the lowest possible degree of haemodynamic impairment, reduction in postoperative ventilatory requirement, prolonged hospital stay and increase in morbidity.

V. Conclusion

PCV may be considered as a suitable mode of ventilation in COPD patients undergoing laparoscopic cholecystectomy as it improves arterial oxygenation and also limits the chance of lung injury. PLMA may be considered as a better alternative to endotracheal tube to secure airway to provide pressure controlled ventilation by reducing peri-operative morbidity and mortality in patients with obstructive airway diseases.

VI. Limitations of the study

Lack of direct measurement of functional residual capacity, lung compliance, trapped air volume, plateau pressure and auto-PEEP.

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