

Pressure-controlled versus Volume-controlled Ventilation during One Lung Ventilation for Empyema Thoracis: A Randomised Control Trial

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ABSTRACT

Introduction: Volume Controlled Ventilation (VCV) is traditionally used during One Lung Ventilation (OLV); however, it is associated with complications such as volutrauma and barotrauma. On the other hand, Pressure Controlled Ventilation (PCV) allows the delivery of a required tidal volume at lower airway pressures, leading to enhanced oxygenation and ventilation.

Aim: To compare VCV and PCV modes for OLV in patients undergoing surgery for empyema thoracis.

Materials and Methods: A randomised controlled trial was conducted among 50 patients requiring OLV. The participants were divided into two groups, namely Group-V and Group-P, with each group receiving VCV and PCV, respectively. The two groups were compared based on the partial pressure of oxygen (during the intraoperative and post-operative period), peak and plateau airway pressures, lung compliance, and complications. The groups were analysed using the Chi-square test, and the threshold of statistical significance was set at a p-value <0.05.

Results: Fifty participants were divided into two groups: VCV (n=25) and PCV (n=25). Both study groups were found to be

comparable in terms of demographic details, haemodynamic parameters, and duration of surgery. The mean age of the patients was 27.80 years in Group-V and 31.04 years in Group-P. The authors observed improved PaO₂ levels, lung compliance, and reduced peak pressures during OLV in the PCV group. After lung isolation, PaO₂ levels of Group-P patients (93.64±5.154 mmHg) were higher compared to Group-V (81.38±7.975 mmHg) at 50% FiO₂ (p-value <0.001). Similarly, post-extubation PaO₂ levels were better in Group-P (99.24±18.58 mmHg) than in Group-V (84.35±7.677 mmHg) at 36% FiO₂ (p-value <0.001). The mean peak pressures were lower in Group-P (25.17±4.34 cm H₂O) than in Group-V (28.22±4.51 cm H₂O). Additionally, there was a statistically significant improvement in lung compliance among Group-P patients (p-value=0.0144).

Conclusion: Thus, it can be inferred that PCV improves oxygenation and reduces airway pressures during OLV. However, there was no significant difference seen between the two modes in terms of post-operative pulmonary complications.

Keywords: Compliance, Haemodynamics, Lung injury

INTRODUCTION

The OLV serves a dual purpose by facilitating surgical access and isolating the non-operative lung, enabling un-hampered ventilation during thoracic surgical procedures. However, OLV is associated with three major complications: arterial hypoxemia, Ventilator-Induced Lung Injury (VILI), and inflammatory injury. Ventilating a single lung unit leads to transpulmonary shunting and widening of the alveolar-to-arterial (A-a) oxygen gradient, eventually causing arterial hypoxemia [1,2]. Hypoxic pulmonary vasoconstriction aids in re-directing this shunted blood to the dependent side. However, as airway pressures of the dependent lung rise during positive pressure ventilation, blood flow is diverted from the dependent lung to the non-dependent lung, offsetting hypoxic pulmonary vasoconstriction and ultimately leading to further widening of the shunt fraction [2,3]. Mechanical trauma of the operated lung, barotrauma, and volutrauma of the dependent lung, atelectasis, and inflammation can further worsen post-operative morbidity and mortality. Nevertheless, reducing airway pressures during OLV can decrease the shunt fraction, enhance oxygenation, and mitigate the risk of Acute Lung Injury (ALI) [3].

Although numerous peri-operative lung protective ventilation strategies such as employing low tidal volume, applying Positive End-Expiratory Pressures (PEEP), reducing peak airway pressures, incorporating intermittent recruitment maneuvers, and utilising goal-directed peri-operative fluid administration strategies have demonstrated their

effectiveness in minimising intra-operative pulmonary complications and improving postsurgical patient outcomes [4], there is still a pressing need for an ideal and secure ventilation strategy that can result in improved oxygenation, decreased peak airway pressures, and reduced risk of VILI. The choice of the most suitable ventilatory mode for OLV remains a subject of controversy, and there is no clear consensus in the existing literature.

Traditional usage has leaned towards Volume Control Ventilation (VCV) for OLV, but it is associated with elevated airway pressures and carries a theoretical risk of VILI and oxygen insufficiency [5]. On the other hand, PCV offers the advantage of maintaining reduced airway pressure while still delivering the required tidal volume. Furthermore, it promotes a uniform distribution of the inspired gas mixture, a factor that is likely to enhance oxygenation [5,6]. Therefore, the authors conducted this study with the objective of comparing VCV and PCV across a range of ventilation parameters, including oxygenation, airway pressures, lung compliance, and post-operative complications. The aim of the present study was to determine which of the two modes (PCV or VCV) is best suited for OLV in patients undergoing surgery for empyema thoracis.

MATERIALS AND METHODS

A randomised controlled, parallel, single-blind trial was designed and conducted in the Department of Anaesthesiology, King George's

Medical University, Lucknow, from March 2021 to March 2022. The study was initiated following approval from the Institutional Ethical Committee (IRB NUMBER-ECR/262/Inst/UP/2013/RR-19) and its subsequent registration on the Clinical Trials Registry of India (CTRI/2021/02/031499).

Sample size calculation: Based on the maximum variation in PaO_2 during the observation time in the two study groups using the formula:

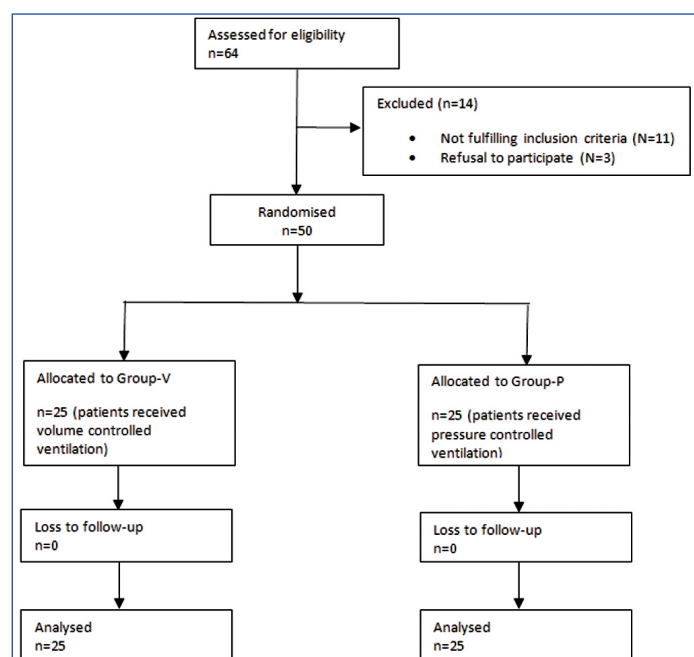
$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 (\sigma_1^2 + \sigma_2^2)}{d^2}$$

Where, $\sigma_1=83.8$ is the maximum Standard Deviation (SD) of PaO_2 during the observation time in the first group, $\sigma_2=82.4$ is the maximum SD of PaO_2 during the observation time in the second group, and $d=\min(\sigma_1, \sigma_2)$ is the minimum mean difference considered to be clinically significant. A total of 50 participants were included, providing a statistical power of 90% and an alpha error of 0.05 [7].

Inclusion criteria: The patients with American Society of Anaesthesiologists (ASA) physical status category I-III, aged between 20-70 years, who were scheduled for decortication surgery for empyema thoracis were included in the study.

Exclusion criteria: Patients with haemodynamic instability, neurological disorders, major organ dysfunction, including severe lung dysfunction (FEV1 30-50%), increased intracranial pressure, a history of chest wall deformity or thoracic surgery that could interfere with lung resection, non-pulmonary deformities that cause severe functional limitation (morbid obesity) or could limit survival (cancer), pulmonary hypertension at rest, and those for whom surgical time exceeded more than two hours.

A total of 64 participants were assessed for eligibility, out of which 50 were enrolled in the study after obtaining written and informed consent. With the help of computer-generated randomisation, study participants were divided into two groups, Group-V (n=25) and Group-P (n=25) [Table/Fig-1].



[Table/Fig-1]: Study flow according to the Consolidated Standards of Reporting Trials (CONSORT) diagram.

Upon the patient's transfer to the operation theatre, monitors as per ASA standards (electrocardiogram, pulse oximeter, non-invasive blood pressure, temperature) were attached, and vitals were recorded. The technique of General Anaesthesia (GA) was standardised for all patients. The patients were pre-medicated with Midazolam (0.05 mg/kg i.v.), Fentanyl (2 mcg/kg i.v.), and Glycopyrrolate

(0.02 mg i.v.). Pre-oxygenation with 100% O_2 for three minutes was followed by induction using Propofol (2 mg/kg i.v.) and Vecuronium (0.1 mg/kg i.v.) for muscle relaxation. Intubation was done with an appropriate size Double Lumen Tube (DLT), and its placement was confirmed by auscultation and fiber-optic bronchoscopy in both the supine and lateral positions. Anaesthesia was maintained with Sevoflurane, Fentanyl infusion @1 mcg/kg/h, and intermittent doses of Vecuronium (0.02 mg/kg i.v.).

The fraction of inspired oxygen (FiO_2) was kept at 50% by admixture of oxygen with medical air. Oxygen Saturation (SpO_2) was maintained >90%, failing which patients were excluded from the study. The tidal volume was targeted at 6 mL/kg predicted body weight, and PEEP of 5 cm H_2O was uniformly set in both groups. The patients in Group-P, who received PCV during OLV, were administered for appropriate positive pressure to receive the set tidal volume.

Haemodynamic and ventilatory parameters, including Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Heart Rate (HR), oxygen saturation, End-tidal Carbon Dioxide (EtCO_2), plateau pressure (Pplat), peak pressure (Ppeak), and lung compliance, were meticulously recorded immediately after DLT confirmation, at five minutes, and thereafter every 15 minutes until the conclusion of surgery. The Pplat and Ppeak were recorded from the ventilator of the Anaesthesia workstation (Dräger Fabius XL), while compliance was calculated as $C=V/(P_{\text{plat}}-\text{PEEP})$ [8].

The ABG analysis was further conducted at three different time points perioperatively: first, a baseline sample (T1) immediately after securing arterial cannula; second, after one hour (T2) following initiation of OLV; and third, after 30 minutes of shifting the patient to the post-operative Intensive Care Unit (T3). All ABG analyses were done within five minutes of sample extraction to ensure accuracy and were corrected to body temperature. After completion of surgery, a thorough assessment was conducted to identify and document post-operative complications, with respect to hypoxemia, bronchospasm, re-intubation, post-operative shifting to mechanical ventilation, and prolonged (more than one-week) post-operative hospital stay duration.

The primary outcome of the study was to determine oxygenation, peak and plateau airway pressures, and compliance of the ventilated lung, while the secondary outcome was to record any complications.

STATISTICAL ANALYSIS

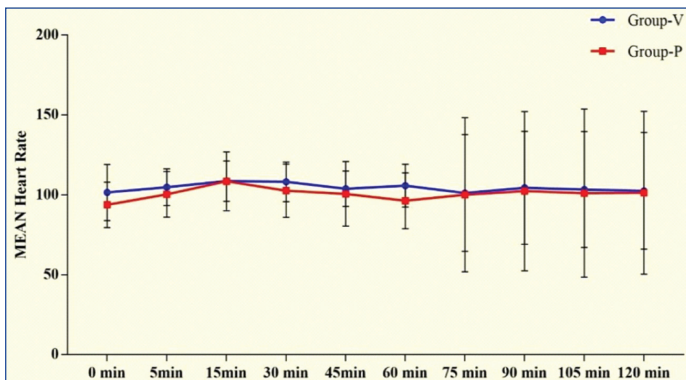
The statistical analysis and correlation were conducted using the Statistical Package for Social Sciences (SPSS) version 21.0 statistical analysis software. The data values were expressed as percentages (%) and represented as mean \pm SD. The student's t-test was used to analyse parametric data, while the Mann-Whitney U test was applied to non-parametric data, and Fisher's test or Chi-square test were used to analyse categorical data. The threshold of statistical significance was set at a p-value <0.05.

RESULTS

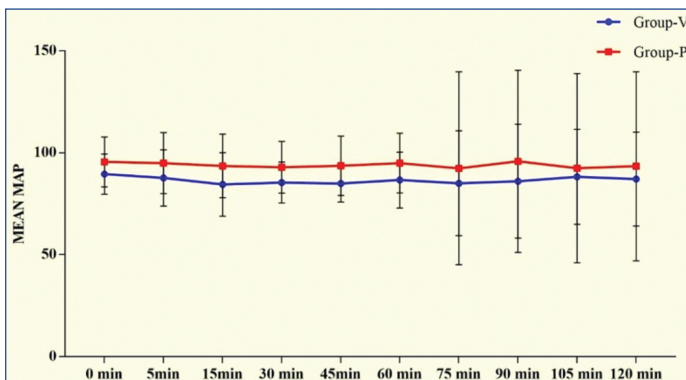
The mean age of the patients was 27.80 years in Group-V and 31.04 in Group-P. Both study groups were found to be comparable in terms of demographic details, haemodynamic parameters, and duration of surgery [Table/Fig-2-4]. The mean preoperative PaO_2 values were comparable in Group-V and Group-P at 21% FiO_2 . However, the mean intraoperative PaO_2 of Group-V patients was lower than that of Group-P patients at 50% FiO_2 . A similar difference was observed in the mean post-operative PaO_2 , with values being lower for Group-V compared to Group-P at 36% FiO_2 [Table/Fig-5,6]. All these differences were statistically significant (p-value <0.001).

	Group-V (n=25)	Group-P (n=25)	
	Mean±SD	Mean±SD	p-value
Age (years)*	27.80 (10.40)	31.04 (9.00)	0.245
BMI (kg/m ²)*	21.51 (2.99)	20.92 (1.71)	0.399
Gender [#]	N (%)	N (%)	1.00
Male	13 (52.00)	14 (56.00)	
Female	12 (48.00)	11 (44.00)	
ASA grade [#]			0.952
ASA grade [#] I/II/III	9/12/4	8/13/4	
Duration of surgery- (Mean±SD)	1.57±0.31	1.49±0.33	t=0.8835 p=0.3814

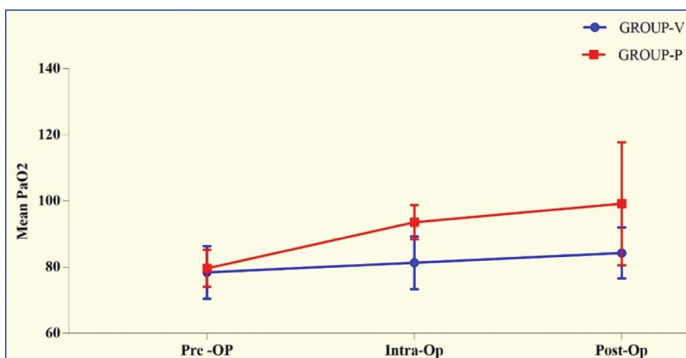
[Table/Fig-2]: Comparison of demographic profile of Group-V and Group-P.
Data represented as Mean±SD (standard deviation), number (N) and percentage (%). *Student t-test, [#]Chi-square test



[Table/Fig-3]: Graphical representation of mean Heart Rate (HR) of Group-V and Group-P patients.



[Table/Fig-4]: Graphical representation of mean MAP of Group-V and Group-P patients.



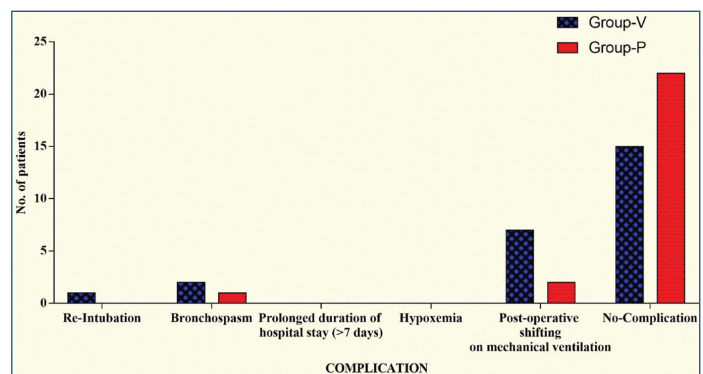
[Table/Fig-5]: Graphical representation of mean PaO₂ of Group-V and Group-P patients.

The peak pressure (Ppeak) and plateau pressure (Pplat) were higher for Group-V than for Group-P. This difference was also statistically significant (p-value=0.0186 and 0.0151, respectively) [Table/Fig-6]. Additionally, the lung compliance values were better in PCV mode compared to VCV mode with statistical significance (p-value=0.0144) [Table/Fig-6].

	Group-V (n=25)	Group-P (n=25)	p-value
Preoperative PaO ₂ (mmHg)*	78.46±7.944	79.72±5.579	0.3675
Intraoperative PaO ₂ (mmHg)*	81.38±7.975	93.64±5.154	<0.001
Post-operative PaO ₂ (mmHg)*	84.35±7.677	99.24±18.58	<0.001
Peak pressure (cmH ₂ O)#	28.22±4.51	25.17±4.34	0.0186
Plateau pressure (cmH ₂ O)#	18.26±3.31	15.84±3.48	0.0151
Lung compliance (ml/cmH ₂ O)#	38.58±2.84	55.35±4.66	0.0144

[Table/Fig-6]: Comparison of partial pressure of oxygen (PaO₂), peak and plateau pressure and lung compliance among groups V and P.
Data represented as mean±SD; *Mann-Whitney U test; [#]Student t-test

When analysing the post-operative complications among the two groups, six patients in Group-V required post-operative mechanical ventilation, and two patients experienced bronchospasm. In contrast, three patients required post-operative mechanical ventilation, and only one experienced bronchospasm. However, the mean difference was statistically in-significant (p-value=0.3902) [Table/Fig-7].



[Table/Fig-7]: Comparison of complications among Group-V and Group-P patients.
Data represented as number (n). Group-V (n=25), Group-P (n=25).

DISCUSSION

Although the baseline parameters and PaO₂ values were comparable between the two groups, the PCV group demonstrated better oxygenation, reduced airway pressures, and improved compliance. There was no significant difference in the complications recorded between the two groups.

Arterial hypoxemia and volume-related lung trauma are serious consequences of OLV [2,6]. While VCV has been popularly used as a ventilatory mode for OLV, it offers some disadvantages. Although the delivery of the set tidal volume and minute ventilation is ensured in VCV mode, it is associated with increased airway pressures. This can subsequently reduce lung compliance, increase resistance, and render the dependent lung more susceptible to volutrauma and barotrauma [3,9]. PCV effectively addresses this issue by imposing a limit on the maximum airway pressure delivered to the dependent lung. During PCV, the ventilator generates a square pressure waveform to deliver the gas mixture, thereby achieving the specified inspiratory pressure and delivering the tidal volume. This approach results in a decelerating flow pattern, which subsequently leads to reduced airway pressures in the dependent lung [5,9]. This reduction in airway pressure results in improved and homogeneous distribution of ventilation, thereby reducing atelectasis and lowering the risk of ALI [3,4]. Moreover, reduced airway pressures in the dependent lung offer the added advantage of a lower shunt fraction. It is worth emphasising that while numerous studies have established the association between PCV and reduced airway pressure during OLV, its superiority over VCV is debatable and a topic of ongoing research [10,11].

The authors observed that the patients in the PCV group had improved arterial oxygenation, reduced peak and plateau airway pressures, and improved lung compliance compared to

the patients in the VCV group. The present study findings align with those made by Lin F et al., who reported similar significant improvements in oxygenation in both intra-operative and post-operative periods among elderly patients who received PCV during OLV [12]. Similarly, Yang M et al., conducted a study comparing VCV with traditional large tidal volumes and PCV with low tidal volume and PEEP. They also concluded that PCV was associated with satisfactory gaseous distribution and a lower incidence of pulmonary complications [13]. According to a study conducted by Gulati K et al., there was a statistically significant lower Peak Inspiratory Pressure (cmH₂O) during PCV compared to VCV, which aligns well with the present study. However, there was no statistically significant difference in Plateau Inspiratory Pressure and Mean Airway Pressure (cmH₂O), which differed from these findings [14].

A systematic review and meta-analysis conducted by Kim KN et al., further support the advantages of PCV during OLV. They concluded that PCV was associated with evidently improved oxygenation and reduced inspiratory pressures [6]. These findings are consistent with several other studies that have also highlighted the importance of PCV mode. These benefits include reduced airway pressures, a lower shunt fraction, decelerating gaseous flow, and better oxygenation [4,5]. The cumulative evidence from these studies indicates that PCV can be advantageous in optimising lung ventilation and oxygenation during OLV.

In studies comparing PCV-VG (volume guaranteed) and VCV ventilation modes during OLV, it was observed that PCV-VG yielded better patient oxygenation, significantly lower peak and plateau airway pressure, and slightly lower mean airway pressure. These findings suggest that PCV-VG, featuring decelerating flow, may outperform VCV in terms of alveolar ventilation and gas distribution. The present study aligns with this observation, albeit with the limitation of not including the PCV-VG mode; instead, the authors utilised conventional PCV. However, in PCV mode, a specific pressure was set to deliver a tidal volume of 6 mL/kg, ensuring a protective ventilation strategy [15,16].

However, it is worth mentioning that while many studies have demonstrated the advantages of PCV during OLV, there are also studies with opposing results. For instance, Song SY et al., found no difference between PCV (volume guaranteed) and VCV except in reducing airway pressures [17]. Similarly, Pardos PC et al., and Unzueta MC et al., also found no substantial advantages of PCV over VCV mode [18,19].

The two groups did not exhibit significant differences in post-operative complications. This finding is consistent with observations made by Pardos PC et al., and Boules NS and Ghobrial HZ in their respective studies [18,20]. Haemodynamic parameters were comparable in both groups, and again, this observation was consistent with that made by Gulati K et al., and Pu J et al., [14,16].

These discrepancies in findings highlight the complexity of the subject and the potential variability in patient population, surgical procedures, and ventilation strategies across different studies. It is important to consider the specific clinical context and patient characteristics when choosing between PCV and VCV.

Based on the present study findings, it appears that PCV may provide advantages during OLV for patients with empyema thoracis, particularly in terms of improved oxygenation and pressure limitation. The decelerating flow pattern during PCV may contribute to these benefits. While the existing literature still may not yet provide conclusive evidence in favour of PCV over VCV, this study, along with others, highlights the potential advantages of PCV and its safe adoption as a ventilation strategy [7,10,11,21]. As the field of

respiratory care continues to evolve, ongoing research may provide further insights into the optimal ventilation approaches targeting specific patient populations and surgical scenarios.

Limitation(s)

The study being performed at a single centre could have been a limitation, and the extent of the disease could have been a confounding factor.

CONCLUSION(S)

In conclusion, it can be inferred that PCV improves oxygenation and reduces airway pressures during OLV. There were no significant differences seen between PCV and VCV modes in terms of post-operative complications. PCV appears to be an effective alternative to VCV in patients requiring one-lung anaesthesia and may be preferable to VCV in patients with respiratory illnesses. Further studies should be conducted, taking into consideration the specific characteristics and severity of respiratory diseases, to enhance our understanding and refine the application of PCV for OLV.

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