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# The ultrasound estimation of extravascular lung water in volume controlled versus pressure controlled ventilation after one lung ventilation in Thoracoscopic surgery. A-comparative study

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**ABSTRACT**

**Background:** Thoracoscopic surgeries are an absolute indication of one lung ventilation OLV, the choice of using volume-controlled ventilation (VCV) or pressure controlled ventilation (PCV) remains controversial. Respiratory complications are major cause of postoperative morbidity which is associated with increased extravascular lung water (EVLW). Assessment of (EVLW) helps in early detection and treatment of respiratory complications. Lung ultrasound (LUS) has been suggested as reliable method of assessment of EVLW. This study was designed to figure out whether there was any difference in OLV by either PCV or VCV on EVLW water in the ventilated lung using LUS score and arterial oxygenation.

**Methodology:** 50 patients were randomly assigned into two groups; Group V: received VCV (Vt 7 ml/kg ideal body weight) Group P: received PCV (To achieve Vt 7 ml/kg ideal body weight, Pmax 30 $cmh_2o$)

**Results:** We found that both techniques PCV and VCV showed no statistically significant differences as regards the ultrasound score at different timings of measurement; (T0) before induction of anesthesia, (T5) immediately at the end of operation after extubation, and (T6) 2 hours after ICU admission. Where P values were 0.525, 0.309, and 0.597 consecutively, we also found there were no statistically significant differences between the two groups regarding hemodynamics, arterial blood gases, ventilatory parameters.

**Conclusion:** We concluded that when utilizing VCV & PCV in OLV in thoracospic surgeries there was no statistically significant difference regarding EVLW score measured by LUS in the ventilated lung.

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Thoracoscopic surgeries; one lung ventilation; volume controlled ventilation; pressure controlled ventilation; extravascular lung water; lung ultrasound

## 1. Introduction

Video-assisted thoracoscopy (VATS) is currently a well-established technique for many surgical procedures [1]. One lung ventilation (OLV) is essential to achieve adequate collapse of the operative lung to facilitate surgery during VATS under general anesthesia [2]. One of the major concerns in OLV for the anesthesiologists is the prevention of acute lung injury (ALI), which is associated with high postoperative mortality and morbidity[3]. The choice of the ventilatory mode during OLV is still controversial between Volume controlled (VCV) and Pressure controlled (PCV) [3,4], (ALI) characterized by an increase in pulmonary capillary permeability to protein leading to extravasation of protein-rich edema fluid known as extravascular lung water (EVLW) into the alveoli [5]. EVLW is a marker for early diagnosis of pulmonary complications, including ALI after thoracic surgery [6]. Post-discharge freedom from pulmonary congestion is associated with a better prognosis. Therefore, the possibility to monitor EVLW at a subclinical stage remains an attractive and elusive goal, Several clinical, radiological, and non-imaging methods are currently used for this goal as physical examination Which is late and inaccurate, chest X-ray which is insensitive and imprecise, computerized tomography which is too complex for real time, repeated measurements in sick patients, and conductance measurements with cardiac devices which is inadequately validated and not widely available LUS assessment of EVLW by B-lines provides a reliable and easy alternative [7].

**2-Aim of the work**: This study was designed to figure out whether there was any difference in one lung ventilation either by pressure controlled mode versus volume controlled mode on the extra vascular lung water in the ventilated lung using lung ultrasound and arterial oxygenation.

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## 2. Patients and methods

This single center study was conducted at cardiothoracic surgery theater Cairo University hospitals, from June 2018 till May 2019. Following written informed consent, 50 patients aged 18 to 60 years, American Society of Anesthesiologists (ASA) I and II, scheduled for elective VATS using OLV with insertion of double lumen tube (DLT), were include in this Randomized comparative study.

Emergency surgeries, Left Ventricular ejection fraction ≤ 40%, patients known to suffer from pulmonary hypertension, liver functions ≥ double the upper reference range, (BMI > 40), creatinine ≥2 mg/dl, forced expiratory volume in first second FEV1 < 60% of the expected, previous thoracic surgery and OLV≥ 2 hours were excluded from the study.

Patients were randomly assigned into two groups: Group V (received volume controlled mechanical ventilation; (VT 7 ml/kg ideal body weight) and Group P: (received pressure controlled mechanical ventilation. To achieve Vt 7 ml/kg ideal body weight, Pmax 30 $cmh_2o$, randomization was done using computer generated number and concealed using sequentially numbered, sealed opaque envelope. The study was an open-label study.

All patients had routine preoperative workup including chest x-ray, lung function tests including spirometer (forced vital capacity (FVC) and (FEV1). Upon arrival to the operating room, patients were monitored with 5 leads electrocardiogram and pulse oximetry and non-invasive blood pressure. IV access and arterial catheters were secured, Arterial blood gases withdrawn. Anesthesia was delivered using anesthesia system (MAQUET FLOW-i 4.1). After pre oxygenation, anesthesia was induced with fentanyl 2 mcg/ kg, propofol 2 mg/kg, and atracurium 0.5 mg/kg. Isoflurane (0.8–1.5%). The trachea was intubated with left DLT.confirmed clinically and by fiberoptic bronchoscope (FOB), An internal jugular central venous catheter was inserted for monitoring in the ipsilateral side, crystalloids were administered at a dose of 3 ml/kg. h . Initially two-lung ventilation with VCV was performed using 0.6 fraction of inspired oxygen concentration ($fio_2$), a TV of 7 ml/kg of ideal body weight, and with initial respiratory rate 12/breaths min, which was adjusted to maintain an end-tidal carbon dioxide concentration ($ETCO_2$) of 35–40 mmHg. After positioning the patient to a lateral decubitus position, the position of the DLT was reassessed with FOB. During OLV, the lumen of the non-ventilated side was left open to the air. Both groups during the OLV period were ventilated using the following variables: inspired oxygen fraction of 0.6 unless saturation ≤ 90%) where it was increased to 1.0 and the incidence of which was reported in the results, peak airway pressure limit was adjusted to give plateau airway pressure ≤ than 30 $cmh_2o$ in both groups.

Patients showing intolerance to OLV with persistent Hypoxemia (saturation <90%) despite correct DLT position, increasing inspired oxygen fraction to 1, or those with P Plateau more than 30 $cmh_2o$, duration of One lung ventilation more than 2 hours, and/or Thoracoscopic procedure converted into open thoracotomy were excluded from the study.

## 3. Lung ultrasound examination (LUS)

LUS was performed with a (2–4)MHz phased array probe of (Philips HD11XE machine, Philips Medical Systems, Bothell, WA) Patients were scanned in supine position by a recording 5 seconds videos. Lung ultrasound was assessed for the presence of B lines.

The B line is the name given to an artifact with seven features: a hydroaeric comet-tail artifact; arising from the pleural line; hyper echoic; well defined; spreading up indefinitely reaching bottom of the screen; erasing A lines; and moving with lung sliding when lung sliding is present. It reflects the coexistence of elements with a major acoustic impedance gradient, such as fluid and air. Fluid at the sub pleural interlobular septum surrounded by air-filled alveoli (ie, septal edema) fulfills this condition [8].

The sum of lung comets produces a score reflecting the extent of lung water accumulation. The (LUS) score was obtained by scanning 12-rib interspaces with the probe longitudinally applied perpendicular to the wall. The dependent lung intraoperative was divided into six areas: two anterior areas, two lateral areas, and two posterior areas. The anterior chest wall (zone 1) was delineated from the parasternal to the anterior axillary line and was divided into upper and lower halves, from the clavicle to the third intercostal space and from the third to the diaphragm. The lateral area (zone 2) was delineated from the anterior to the posterior axillary line and was divided into upper and basal halves. The posterior area (zone 3) was considered as the zone beyond the posterior axillary line. The sum of B-lines on each scanning site.

0 absences

1B7 lines: multiple B-lines 7 mm apart

2B3 lines: multiple B 3 mm apart

3consolidation [9,10] giving Score for the ventilated lung is only from 0–18.

Arterial Pao2, Paco2, arterial blood pressure(mean), heart rate were recorded from (T0 to T6), Peak inspiratory pressure (P peak), and Expired tidal volume, plateau airway pressure (P plateau) were recorded from (TI to T4) and LUS was done in the following time intervals (T0, T5 and T6).

T0before induction of anesthesia

T1during two-lung ventilation using VCV before initiation of OLV in supine position

**Table 1.** Comparison between the two groups regarding the lung ultrasound score.

| | Group v | | | Group p | | | |
|---|---|---|---|---|---|---|---|
| | Median | 1st quartile | 3rd quartile | Median | 1st quartile | 3rd quartile | P value |
| lung us score T0 | .00 | .00 | .00 | .00 | .00 | .00 | 0.525 |
| lung us score T5 | .00 | .00 | 1.00 | .00 | .00 | .00 | 0.309 |
| lung us score T6 | .00 | .00 | 1.00 | .00 | .00 | .00 | 0.597 |

Data expressed in median and interquartile range.
P-values<0.05 considered as statistically significant
(T0) before induction of anesthesia, (T5) immediately at the end of operation (after extubation) and (T6) 2 hours after ICU admission

T2in lateral decubitus 10 minutes after initiation of one lung ventilation

T345 min after initiation of one lung ventilation in lateral decubitus

T410 min after re-establishing two-lung ventilation at the end of surgery

T5immediately at the end of operation (after extubation)

T62 hours after ICU admission

Due to lack of clinical studies for EVLW detection by LUS in comparing VCV versus PCV the sample size to compare between 2 groups was calculated based on previous studies by Song, et al (2014) [11] who studied arterial oxygenation which is the secondary outcome in the current study .The mean ±standard deviation for group (v) was 328.1 ± 123.7 and for group (p): 375.8 ± 145.1, with an expected effect size of approximately (f = 0.2). A total sample size of 42 (21 in each of the two groups) will be sufficient with power of 80%, and 5% significance level. The number is increased to a total sample size of 50 (25 in each of the two groups) to allow for the use of a non-parametric test. Sample size was calculated using G*Power program (University of Düsseldorf, Düsseldorf, Germany).

Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 25. Data was summarized using mean and standard deviation for normally distributed quantitative variables or median and interquartile range for non-normally distributed quantitative variables and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between groups were done using unpaired t test in normally distributed quantitative variables while non-parametric Mann-Whitney test was used for non-normally distributed quantitative variables [12]. For comparison of serial measurements within each group repeated measures ANOVA was used in normally distributed quantitative variables while non-parametric Friedman test and Wilcoxon signed rank tests were used for non-normally distributed quantitative variables. For comparing categorical data, Chi square test was performed. Fisher Exact test was used instead when the expected frequency is less than 5 [13]. P-values less than 0.05 were considered as statistically significant.

## 4. Results

Fifty patients scheduled for elective thoracic surgery with one lung ventilation were included in the study. Patients were randomly allocated into one of two groups:

Group V: received (VCV). (n = 25) and Group P: received (PCV). (n = 25).

All of the patients enrolled in the study completed the procedure uneventfully. No intraoperative complications including severe hypoxemia indicated exclusion from the study.

LUS score were comparable (P value ≥ .05) at T0, T5, and T6 in Table 1, similarly $pao_2$ (Figure 1) shows no evidence of statistically significant difference in arterial oxygenation between two groups at the same time intervals. Both groups were also comparable (P value ≥ .05) regarding their demographic data (age, weight, gender) and operative characteristics (operation time, side of the non-ventilated lung) in Table 2, hemodynamic parameters (heart rate and mean blood pressure) in Table 3, oxygen saturation and $paco_2$ (Table 4) and ventilatory parameters (peak airway pressure, plateau pressure, expired tidal volume and end tidal carbon dioxide) in Table 5.

All patients had an uneventful ICU stay and were discharged from ICU within one day, from the hospital within one week.

## 5. Discussion

In the current study we aimed to evaluate the effect of ventilation by either PCV versus VCV in the ventilated lung on EVLW by LUS and oxygenation. We found no statistically significant differences regarding the (LUS), the change of score between the baseline reading and postoperative readings. Similarly $PaO_2$ did not show statistically significant differences between both groups.

This may indicate that both modes did not impact the amount of EVLW during the times of the study.

The choice between volume and pressure controlled ventilation is an ongoing debate; it is useful to understand the underlying mechanism of lung injury and extravascular lung water formation.

VCV is widely used. However it may increase the incidence of barotrauma and cause the uneven distribution of pulmonary gas when Compared to PCV. On

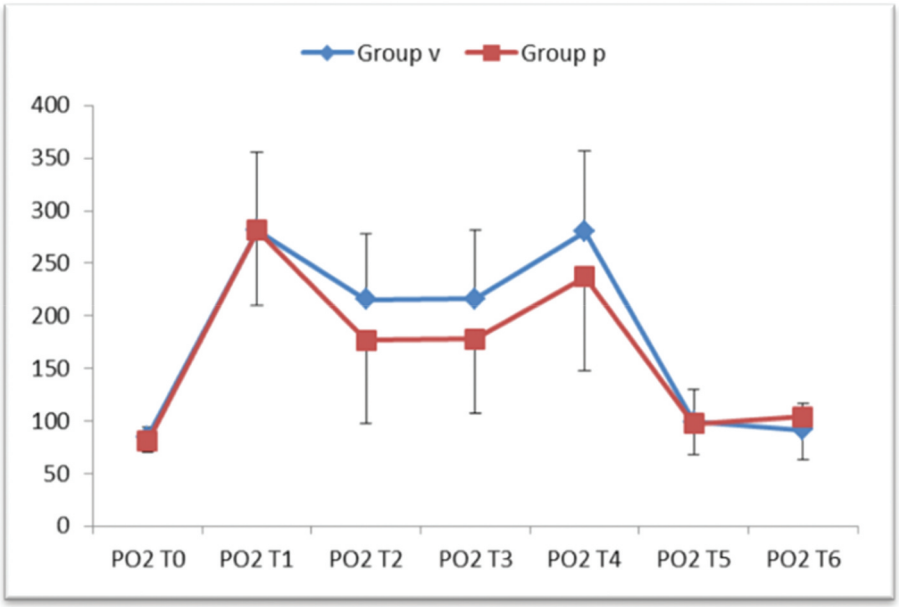


**Figure 1.** Comparing between two groups regarding PaO2.

**Table 2.** Demographic data.

| | | Group V | | Group P | | P value |
|---|---|---|---|---|---|---|
| Age (years) | | 38.88 | ±15.21 | 39.44 | ±14.05 | 0.893 |
| Operation time (hours) | | 2.46 | ±0.56 | 2.44 | ±0.60 | 0.903 |
| Weight (kg) | | 74.40 | ±14.14 | 75.68 | ±11.02 | 0.723 |
| Gender | Male (n, %) | 19 | 76.0% | 15 | 60.0% | 0.225 |
| | Female (n, %) | 6 | 24.0% | 10 | 40.0% | |
| Side | Left (n, %) | 8 | 32.0% | 14 | 56.0% | 0.087 |
| | Right (n, %) | 17 | 68.0% | 11 | 44.0% | |

Demographic data (age, weight, gender) and operative characteristics (operation time, side of the non-ventilated lung) were comparable between both groups.Data expressed as mean ±SD, except for gender and operative side expressed number and percentage

P-values < 0.05 considered as statistically significant

the other hand, PCV offers the advantage of lower airway pressure and less incidence of barotrauma, maintaining adequate distribution of pulmonary gas, and improving oxygenation. However, a drawback of PCV is that VT can change as the patient's lung compliance changes [14–16].

Ventilation-induced lung injury (VILI) is characterized by dysfunction of the surfactant system, alveolar and interstitial edema, leukocyte recruitment, cytokine production and neutrophil dependent tissue destruction [17]. Postoperative acute lung injury, non-cardiogenic pulmonary edema shares clinical, radiological and histopathological characteristics with ARDS [18].

Non-cardiogenic pulmonary edema results from increased permeability of the alveolar capillary membrane, creating a capillary leak syndrome with exudation of water and protein into the alveolar space caused activation of complement and mediators of inflammatory cascade [19].

As with ARDS, the diagnosis of Post anesthesia lung injury is often delayed because clinical signs of pulmonary edema present only once the extra vascular lung water (EVLW) rises over 7 ml/kg (ideal body weight). Therefore, any technique that could assess lung water would not only make the diagnosis of Post anesthesia lung injury early but might better guide fluid management of patients following lung resection [18].

In clinical settings EVLW can be estimated by physical examination, imaging Chest X ray, chest computerized tomography, or (LUS), or by invasive cardiac output monitoring utilizing Trans pulmonary thermo dilution [20].

**Table 3.** Hemodynamic parameters.

| | Heart Rate | | | | | Blood Pressure | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Group v | | Group v | | P value | Group v | | Group v | | P value |
| T0 | 83.48 | ±14.35 | 84.72 | ±18.37 | 0.791 | 87.44 | ±15.85 | 93.04 | ±21.13 | 0.294 |
| T1 | 84.36 | ±14.33 | 87.88 | ±13.05 | 0.368 | 89.56 | ±14.52 | 96.2 | ±17.64 | 0.153 |
| T2 | 87.6 | ±15.52 | 90.2 | ±14.95 | 0.549 | 88.68 | ±15.14 | 94.24 | ±14.59 | 0.192 |
| T3 | 86.64 | ±14.40 | 90.44 | ±16.43 | 0.389 | 89.44 | ±13.33 | 96.52 | ±15.41 | 0.089 |
| T4 | 87.68 | ±18.75 | 88.52 | ±15.45 | 0.863 | 86.6 | ±14.12 | 92.4 | ±13.51 | 0.144 |
| T5 | 85.88 | ±13.26 | 91.12 | ±17.29 | 0.235 | 87.92 | ±15.41 | 90.16 | ±15.39 | 0.609 |
| T6 | 84.4 | ±17.94 | 84.52 | ±16.22 | 0.98 | 88.52 | ±11.89 | 91.36 | ±17.21 | 0.501 |

Heart rate expressed in beat/minute, Mean arterial blood pressure expressed in mmHg, Data expressed as mean ± SD, P-values < 0.05 considered as statistically significant.

(T0) before induction of anesthesia, (T1) during two-lung ventilation using VCV before initiation of OLV in supine position (T2) in lateral decubitus 10 minutes after initiation of one lung ventilation; (T3) 45 min after initiation of one lung ventilation in lateral decubitus; (T4) 10 min after re-establishing two-lung ventilation at the end of surgery. (T5) immediately at the end of operation (after extubation), (T6) 2 hours after ICU admission.

**Table 4.** Oxygen saturation and $PaCo_2$

| | Oxygen saturation | | | | | $PaCo_2$ | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Group v | | Group p | | P value | Group v | | Group p | | P value |
| T0 | 98.68 | ±0.80 | 98.44 | ±2.42 | 0.64 | 34.46 | ±3.59 | 36.35 | ±5.47 | 0.154 |
| T1 | 98.72 | ±0.61 | 98.56 | ±0.92 | 0.472 | 36.74 | ±6.20 | 39.5 | ±9.32 | 0.224 |
| T2 | 98.32 | ±1.46 | 97.92 | ±2.10 | 0.438 | 40.16 | ±9.68 | 42.9 | ±9.87 | 0.327 |
| T3 | 98.12 | ±1.74 | 98 | ±2.04 | 0.824 | 41.42 | ±9.32 | 43.96 | ±12.60 | 0.422 |
| T4 | 98.52 | ±1.56 | 98.28 | ±1.43 | 0.573 | 41.01 | ±10.25 | 44.92 | ±14.66 | 0.279 |
| T5 | 98.8 | ±0.87 | 98.76 | ±0.60 | 0.85 | 41.05 | ±6.93 | 42.16 | ±11.11 | 0.676 |
| T6 | 99.04 | ±0.54 | 98.96 | ±0.45 | 0.573 | 39.76 | ±6.53 | 36.23 | ±6.35 | 0.059 |

Oxygen saturation expressed in percent, PaCO2 expressed in mmHg, Data expressed as mean ± SD, P-values <0.05 considered as statistically significant. (T0) before induction of anesthesia, (T1) during two-lung ventilation using VCV before initiation of OLV in supine position (T2) in lateral decubitus 10 minutes after initiation of one lung ventilation; (T3) 45 min after initiation of one lung ventilation in lateral decubitus; (T4) 10 min after re-establishing two-lung ventilation at the end of surgery. (T5) immediately at the end of operation (after extubation), (T6) 2 hours after ICU admission.

**Table 5.** Ventilator parameter pressure, plateau airway pressure, expired tidal volume and end tidal CO2.

| | Group v | | Group p | | P value |
|---|---|---|---|---|---|
| **P peak T1** | 21.24 | ±3.44 | 22.40 | ±4.85 | 0.334 |
| **P peak T2** | 23.88 | ±4.07 | 23.56 | ±4.44 | 0.791 |
| **P peak T3** | 23.88 | ±4.43 | 24.04 | ±4.67 | 0.902 |
| **P peak T4** | 23.16 | ±4.20 | 23.68 | ±4.36 | 0.669 |
| **P plateau T1** | 19.76 | ±3.19 | 19.32 | ±6.07 | 0.750 |
| **P plateau T2** | 22.28 | ±4.18 | 23.52 | ±4.43 | 0.314 |
| **P plateau T3** | 22.24 | ±4.32 | 24.00 | ±4.64 | 0.172 |
| **P plateau T4** | 21.60 | ±4.22 | 23.64 | ±4.35 | 0.099 |
| **EXP TV T1** | 520.44 | ±98.78 | 528.68 | ±76.67 | 0.743 |
| **EXP TV T2** | 506.68 | ±96.41 | 515.84 | ±73.99 | 0.708 |
| **EXP TV T3** | 502.72 | ±96.44 | 510.52 | ±77.04 | 0.753 |
| **EXP TV T4** | 515.28 | ±95.39 | 523.72 | ±75.67 | 0.730 |
| **EtCO2 T1** | 29.64 | ±4.48 | 30.48 | ±4.12 | 0.494 |
| **EtCO2 T2** | 31.00 | ±4.06 | 32.04 | ±3.42 | 0.332 |
| **EtCO2 T3** | 32.08 | ±3.65 | 32.36 | ±3.07 | 0.770 |
| **EtCO2 T4** | 31.52 | ±3.43 | 31.48 | ±4.47 | 0.972 |

Peak airway pressure, plateau airway pressure expressed in cm/H2o, expired tidal volume in mland EtCO2 in mmhg. Data expressed as mean ± /SD. P-values <0.05 considered as statistically significant. (T0) before induction of anesthesia, (T1) during two-lung ventilation using VCV before initiation of OLV in supine position (T2) in lateral decubitus 10 minutes after initiation of one lung ventilation; (T3) 45 min after initiation of one lung ventilation in lateral decubitus; (T4) 10 min after re-establishing two-lung ventilation at the end of surgery

The B-lines are vertical echoic comet-tail artifacts detected by LUS; they are typically correlated with the loss of pulmonary aeration and an increase in lung water [21]. Ultrasound is available at bedside and is non-invasive [22].

(**Cagini et al 2018)** [23] found that LUS might be useful in better managing postoperative patients. They described the correlation between EVLW increase and impairment of gas exchange, respiratory ratio (pao2/fio2) and fluid retention, measured by brain natriuretic peptide (BNP). They found correlation between LUS interpretation and transpulmonary thermodilution in assessing EVLW.

In two studies (**Anelli et al 2017**) [20] and **(ILIĆ et al 2018)** [24] to evaluate LUS assessment as a tool to estimate the EVLW in critically ill patients Suggested that LUS may be a promising non-invasive method for early detection of EVLW after surgery.

(**Al Shehri et al 2014)** [25] compared Effects of PCV and VCV in thoracotomies During OLV. In agreement with current study they found no statistically significant difference regarding oxygenation in the two modes they concluded that use of PCV offers more improved RV Function than the use of VCV during OLV for open thoracotomy.

For surgeries conducted in the supine position with both lungs ventilated, (**Moningi et al 2017)** [26] found the two modes to be comparable regarding oxygenation. Also In agreement with our results, (**Umari et al 2018)** [27] intrestingly states equivocal results comparing between both modes of ventilation regarding oxygenation during (OLV) in Thoracoscopy.

(**Roze et al 2010**) [28] concluded that during (PCV) for OLV the decrease in peak airway pressure is observed mainly in the respiratory circuit and is probably not clinically relevant in the bronchus of the dependent lung.

In concordance with current study (**Song et al 2014**) [3] found that PCV-VG did not provide significantly improved arterial oxygen tension compared with VCV. However they found that PCV-VG provided attenuated airway pressure despite increased exhaled TV compared with VCV, This contradicts the findings of our study which did not show any statistically differences in airway pressure between the two groups which may be explained by larger TV 8 ml/kg and different times of readings.

(**Zhu et al 2017**) [29] Aimed to detect whether there was any difference between (VCV) and (PCV) on oxygenation and postoperative complications under the condition of protective ventilation (PV) and Concluded that during OLV both modes of ventilation had comparable findings on the intraoperative oxygenation and postoperative complications under the condition of PV.

(**Pu et al 2014**) [16] explored the effects of (PCV-VG) on the inspiratory pressures, oxygenation parameters and hemodynamics of patients during (OLV) for thoracic surgery, compared with (VCV). They found that in PCV-VG P peak, Plateau, and P mean were less and oxygenation was higher versus VCV. That may be due to the study design (crossover) versus controlled randomized in the current study.

Adding lung recruitment maneuver, **(Liu et al 2017)** [30] investigated the effects of two different ventilation modes. They concluded that LRM with

both VCV and PCV not only improved oxygenation during OLV for patients undergoing thoracoscopic lobectomy, but also decreased airway pressure and increased dynamic compliance.

## 6. Limitations and recommendation

Patients included in this study are ASA I& II. Further studies including patients with preexisting comorbidities may be required. We choose patients who underwent OLV ≤ 120 minute longer periods for OLV may be of interest, the follow up of patients in the current study was only done for two hours postoperatively for practical reasons. We recommend LUS after longer durations; LUS could not be assessed intraoperatively in the ventilated lung due to technical difficulty of introducing the probe during the surgery in the lateral decubitus position. Refining lus examination to detect minor changes in EVLW and or using other methods in combination with lus such as mediators from lavage or lung compliance.

## 7. Conclusion

We concluded that when utilizing VCV & PCV in OLV in thoracoscopic surgeries there was no statistically significant difference regarding EVLW measured by LUS in the ventilated lung and arterial oxygenation.

## Disclosure statement

"No potential conflict of interest relevant to this article was reported regarding this article."

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## Previous presentation in conferences

This research has not been previously presented in conferences.

## IRB approval

The approval was provided by the research Ethics Committee of faculty of medicine of Cairo University, Egypt. (No. N-8-2018, University of Cairo, Egypt, on 17 February 2018). The protocol of the study approved by scientific and research committee of department of anesthesia in May 2017. (N 7-2017/M.D).

## Clinical trial

The study was registered at (clinicaltrials.gov Identifier: NCT03514706).

## IRB approval

The approval was provided by the research Ethics Committee of faculty of medicine of Cairo University, Egypt. (No. N-8-2018, University of Cairo, Egypt, on 17 February 2018).

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