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Pressure versus volume-controlled ventilation with BASKA mask airway in laparoscopic cholecystectomy: A randomized clinical study

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ABSTRACT

Background: The best ventilation mode that suits with LMAs is still unclear. In this study, we investigated the ventilatory performance of Baska masks in patients who underwent elective laparoscopic cholecystectomy under general anaesthesia and pneumoperitoneum with either volume-controlled ventilation (VCV) or pressure-controlled ventilation (PCV) mode.
Methods: Fifty-Six patients with ASA I – II, who underwent laparoscopic cholecystectomy, were randomly classified into VCV ($n = 28$) and PCV ($n = 28$) groups. The lung was ventilated with a tidal volume of 8 ml/kg in the VCV group. It was ventilated initially using an inflating pressure that delivered a tidal volume of 8 ml/kg with a maximum of 35 cmH2O in the PCV group. The primary outcome was the intraoperative oropharyngeal leak pressure (OLP) of the Baska mask. Secondary outcomes were intraoperative lung mechanics, arterial carbon dioxide levels, and perioperative adverse effects.
Results: After pneumoperitoneum inflation, the OLP, peak inflation pressure (PIP), mean pressure (Pmean), $PaCO_2$, and end-tidal CO_2 significantly increased, and the calculated dynamic compliance significantly decreased in both ventilation modes. All variables partially returned to baseline after pneumoperitoneum deflation. Patients ventilated with PCV mode demonstrated significantly lower PIP and $PaCO_2$ levels but higher dynamic compliance with statistically comparable OLP-PIP difference and higher leak fraction.
Conclusion: In this study, Patients ventilated with PCV mode showed lower PIP and $PaCO_2$ but higher dynamic compliance, and higher leak fraction. However, both modes investigated provided effective Baska mask ventilation and maintained the OLP throughout the procedure with a statistically comparable OLP-PIP difference.

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Cholecystectomy; laparoscopic; laryngeal masks; laryngeal mask airway BASKA; ventilation

1. Introduction

Supraglottic airway devices (SADs) are a suitable alternative to endotracheal intubation because of the noninvasive, easy, rapid insertion, stable hemodynamics, and fewer pharyngolaryngeal complications. In addition, they can provide sufficient ventilation during laparoscopic surgery with high peak airway pressure (PAP) [1].

The Baska mask is one of the third-generation SADs, characterized by a self-sealing silicone variable pressure cuff. It makes an oropharyngeal seal which increases proportionately with increased PAP. Its self-retracting cuff contains a dorsal slit enabled by prepared flaps maintaining it semi-inflated at rest. The mask inflates, increasing the pharyngeal seal during the positive pressure ventilation, and deflates partially to the rest when the pressure is released. It possesses a gastroesophageal reflux drainage system with a wide distal opening in the upper oesophagal part that opens into a built-in sump reservoir on its cuff dorsal side that drains into bilateral suction channels. The oval flexible airway aperture at the distal end ensures the seal patency against the gastric overflow [2].

Pneumoperitoneum during laparoscopic surgery is associated with an upward shift of the diaphragm, increased intrathoracic pressure, stiffness of the abdominal part of the chest wall, and restricted lung expansion. Consequently, pulmonary dynamic compliance significantly decreases, and the PAP increases with an added risk for pulmonary barotrauma [3,4]. This PAP increase is managed by respiratory rate or tidal volume adjustments or by shifting from volume-controlled ventilation (VCV) to pressure-controlled ventilation (PCV) [5].

Recent literature ensures the safety and efficacy of Baska masks in short-term laparoscopic procedures [6–8]. However, the best ventilation mode that suits the device during laparoscopy is still unclear.

This research investigated the Baska mask ventilatory performance in patients who underwent elective laparoscopic cholecystectomy under general anaesthesia and

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pneumoperitoneum with either pressure-controlled or volume-controlled ventilation modes. The primary outcome was the oropharyngeal leak pressure (OLP) changes with both modes. Secondary outcomes were intraoperative lung mechanics, arterial carbon dioxide levels, and perioperative adverse effects.

2. Patients and method

2.1. Ethical considerations

This randomized prospective Study was approved by the Medical Ethics Committee, faculty of medicine, Assiut University, Assiut, Egypt (IRB: 17300212, date: 3 July 2018) and was registered on the clinical trial.gov. (ID: NCT03610126) before patient enrollment. The study followed the declarations of Helsinki. All patients provided written consent to participate. This study comprised 56 ASA class I or II patients aged 18–60 years with a BMI ≤35 kg/m^2 who were scheduled for elective laparoscopic cholecystectomy under general anaesthesia and positive pressure ventilation. Patients who refused to participate were excluded. In addition, we excluded patients with respiratory or cardiac disease history, high regurgitation or aspiration risk, diabetes, hiatus hernia, neck pathology, and difficult airway (inter-incisor distance <20 mm, mouth opening <2.5 cm, cervical spine pathology, thyromental distance <65 mm, or modified Mallampati class III/I).

2.2. Study groupings

Patients were randomly classified using this website (http://www.random.org/) into two groups, the pressure-controlled ventilation (PCV) group ($n = 28$) and the volume-controlled ventilation (VCV) group ($n = 28$). Baska laryngeal mask airway was used to anesthetize all patients. The mask size was determined following the manufacturer's weight-based guidelines.

2.3. Study protocol

All patients were premedicated with ranitidine 150 mg orally two hours before surgery and 2 mg IV midazolam administered on arrival to the operating room. Monitoring included electrocardiogram (ECG), non-invasive blood pressure, pulse oximetry, end-tidal CO_2 by capnography, and train-of four (TOF) for neuromuscular monitoring.

2.4. Anesthesia technique

Anesthesia was induced using fentanyl 1–1.5 µg/kg, lidocaine 1–2 mg/kg, propofol 2–3 mg/kg, and cis-atracurium 0.15 mg/kg. The Baska mask was inserted, and the successful mask insertion was confirmed during manual ventilation by bilateral chest wall movement, chest auscultation, and the presence of a square wave trace on the capnograph. If effective manual ventilation after inserting the mask was not achieved, the mask was moved up and down with neck extension and flexion, and then the mask was removed and reinserted. If all these maneuvers failed, an endotracheal tube was inserted, and the patient was excluded from the study. The mask insertion duration (the period between the beginning of insertion till sufficient ventilation) and the number of insertion trials were recorded. Anesthesia was maintained with isoflurane 1–1.5 minimum alveolar concentration, additional dose of cis-atracurium 0.03 mg/kg was used to keep the neuromuscular blockade of < 1 twitch of a train-of four (TOF). 1 gm IV paracetamol was given to all patients after induction. At the end of surgery, the residual neuromuscular blockage was assessed by TOF and reversed with 20 µg/kg atropine and 50 µg/kg neostigmine. When the patient could react to verbal orders, the mask was removed. A blood-stained mask was recorded, and any perioperative adverse effects were also treated and recorded, including gastric distention, cough, bronchospasm, vomiting, and postoperative sore throat.

2.5. Ventilator settings in the VCV group

After the insertion of the mask in the VCV group, the lung ventilation was done with volume-controlled ventilation with an 8 ml/kg tidal volume and 12 breaths/min respiratory rate. Initially, the respiratory rate was set to 12 breaths per minute and changed throughout laparoscopy to keep a 35–40 mmHg end-tidal carbon dioxide pressure and a ½ I/E ratio

2.6. Ventilator settings in the PCV group

In the PCV group, the lung ventilation was done with pressure-controlled ventilation, initiated with an inflation pressure that provided an 8 ml/kg tidal volume with a maximum of 35 cm H_2O. The respiratory rate was set to 12 breaths per minute and changed throughout laparoscopy to keep a 35–40 mmHg end-tidal carbon dioxide pressure and a ½ I/E ratio.

After stabilizing controlled ventilation in both groups, a carbon dioxide pneumoperitoneum was induced with a maximal intra-abdominal pressure of 12–15 mmHg while placing the patient in a head-up "Anti-Trendelenburg" position with a maximum of 15°.

2.7. Data collected

The oropharyngeal leak pressure (OLP) was obtained by setting the gas flow at 3 L/min and the electronic APL valve at 30 cm H_2O. The airway pressure increased (not allowed to increase more than 40 cm H_2O) until it reached a plateau equal to the entire Baska mask leak pressure when an audible leak occurred over the mouth and auscultated by placing the stethoscope over the patient's neck just lateral to the thyroid cartilage. This pressure was recorded as OLP [9].

Intraoperative lung mechanics included the inspired tidal volume (ITV), expired tidal volume (ETV), exhaled minute ventilation, PIP (peak inflation pressure), Pmean, and plateau pressure. The leak volume (LV) was calculated as the ITV and ETV difference. Leak fraction (LF) was calculated as LF = LV/ITV [10]. The dynamic compliance (Cdyn) was calculated as Cdyn = V_T/(PIP-PEEP) [5]. The OLP and the lung mechanics parameters were recorded after insertion of the Baska mask, after pneumoperitoneum inflation, at 15, 30, 45, and 60 min. Intraoperatively, and after pneumoperitoneum deflation.

Three arterial blood gas (ABG) samples were obtained to measure PaO_2, $PaCO_2$, and PH. Sample I was obtained 5 min. after stabilization of controlled ventilation. Sample II was obtained 15 minutes after pneumoperitoneum insufflation. Sample III was obtained 15 minutes after pneumoperitoneum deflation.

3. Statistics

3.1. Sample size

The primary outcome of this study was intraoperative Oropharyngeal Leak Pressure (OLP). Secondary outcomes were intraoperative lung mechanics, arterial carbon dioxide levels, and perioperative adverse effects. The OLP measured in Sachidananda et al. [11] Study was 28.9 ± 3.5 cmH2O. We assumed that a difference in the mean OLP of 3 cmH2O (10%) change is a clinically meaningful difference. Calculation of the effect size was done by the G power 3.1.9.7 that yielded an effect size of 0.825 (~0.8). We used this value to calculate our sample size using the t-test with a two-tailed p-value <0.05, confidence level 0.95 and 80% power, a sample size of 26 patients for each group is needed (G*Power 3.1.9.7). To overcome patients' dropouts and protocol violation, we enrolled 29 patients in each group.

3.2. Statistical analysis

Data entry and analysis were done using SPSS version 22 (Statistical Package for Social Science). Data were presented as numbers, percentages, mean (SD), and median (range). Continuous data were checked for normality by visual inspection of histograms and by the Shapiro – Wilk test. In the case of parametric data, independent samples t-test was used to compare quantitative variables between the two groups. While in the case of non-parametric data, Mann-Whitney test was used to compare quantitative variables between the two groups and Wilcoxon Signed Rank Test was done to compare quantitative variables between different times in each group. Chi-square and Fisher Exact tests were used to compare qualitative variables. The P-value was considered statistically significant when $P < 0.05$.

4. Results

Fifty-eight patients were enrolled in this study, and two patients were excluded due to failure of ventilation with the Baska mask and ETT insertion. Fifty-Six patients were enrolled and analyzed (28 in each group) (Figure 1). No significant differences were observed in demographic data or operative details, including operative time, pneumoperitoneum time, anaesthesia time, and insertion time) (Table 1).

The baseline mean OLP after Baska mask insertion was 32.29 ± 4.05 cmH_2O vs. 30.96 ± 4.30 cmH_2O in the VCV and PCV groups, respectively ($P = 0.242$). Compared to its baseline, the mean OLP significantly increased after peritoneal insufflation and during the operative procedure in both groups ($P = 0.001$) and partially returned to baseline after pneumoperitoneum deflation. There were no significant differences between the two groups throughout the study (Figure 2A).

After Baska mask insertion, the mean PIP was 19.68 ± 4.62 cmH_2O vs. 17.89 ± 3.76 cmH_2O in the VCV and PCV groups, respectively ($P = 0.119$). Compared to its baseline, the mean PIP significantly increased after peritoneal insufflation and during surgery ($P = 0.0001$) and minimally decreased after pneumoperitoneum deflation in both groups. The mean intraoperative PIP was significantly higher in the VCV group than in the PCV group after pneumoperitoneum insufflation ($P = 0.012$), at 30 min. ($P = 0.016$), and 45 min. ($P = 0.027$) intra-operatively (Figure 2B). There were no significant differences between groups in the mean P mean pressure throughout the study (Supplemental online only: S-Figure 1).

Throughout the study, the mean OLP was higher than the PIP except in two patients (one in each group), in whom ventilation was further adjusted. The median OLP-PIP difference after mask insertion was 13.0 (2.0–25.0) cmH_2O vs. 12.0 (−2.0–26.0) cmH_2O in the VCV and PCV groups, respectively ($P = 0.651$). It showed a small decrease after insufflation and during surgery in both groups compared to its baseline, with no significant intergroup differences (Figure 2C). The median leak fraction was significantly higher in the PCV group than in the VCV group throughout the study ($P < 0.001$) (Figure 3).

Intergroup comparisons revealed higher mean calculated dynamic compliance in the PCV group after Baska mask insertion ($P < 0.001$), after inflation ($P =$

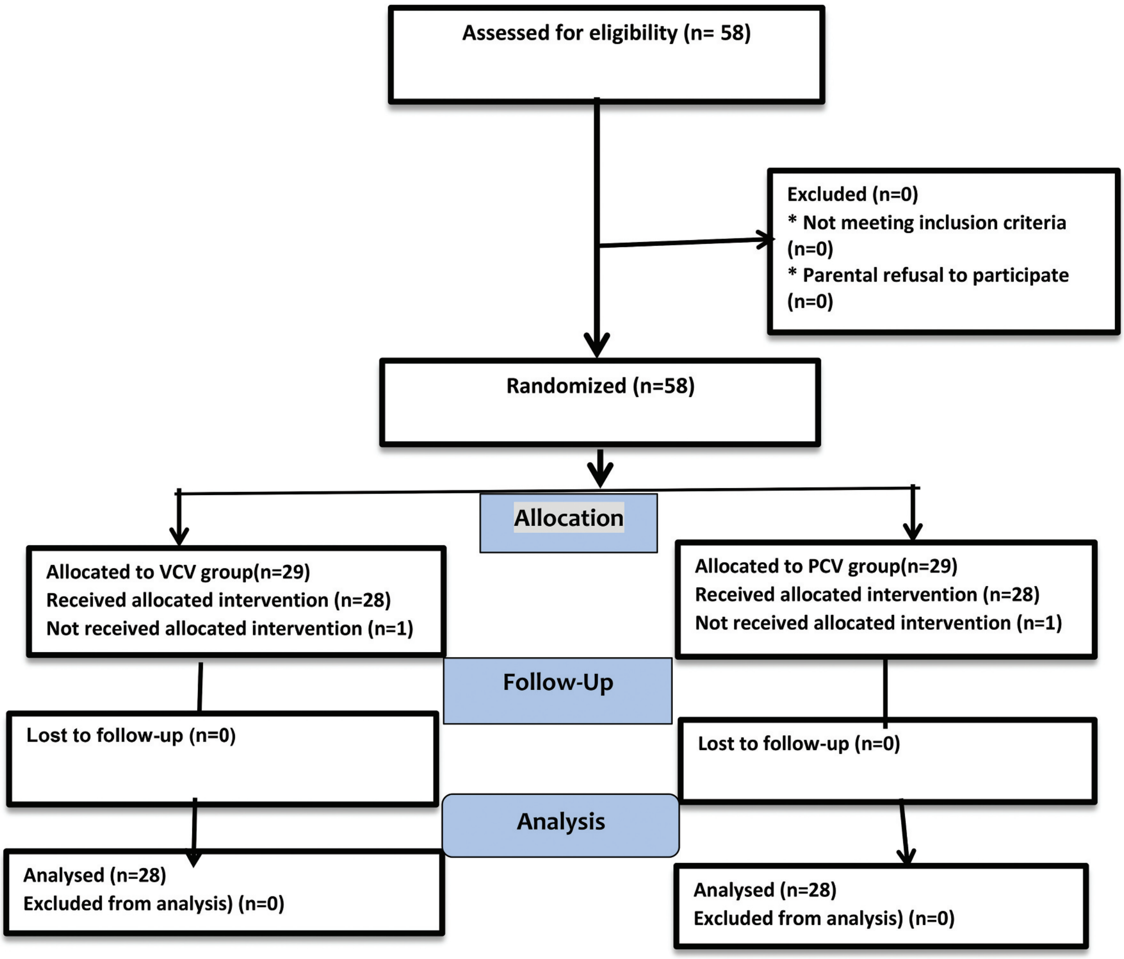

Figure 1. Participant flow diagram.

Table 1. Demographic data and operative details.

Baseline data	VCV (*n* = 28)	PCV (*n* = 28)	P-value
Age (years)	34.68 ± 10.94	31.43 ± 1.21	0.256
Sex: No. (%)			
Male	3 (10.7%)	2 (7.1%)	1.000
Female	25 (89.3%)	26 (92.9%)	
Weight (Kg)	77.54 ± 11.54	72.18 ± 11.54	0.088
Height (meter)	160.57 ± 4.36	158.89 ± 6.16	0.244
BMI (kg/m2)	30.11 ± 4.58	28.53 ± 3.85	0.169
ASA: No. (%)			
I	26 (92.9%)	25 (89.3%)	1.000
II	2 (7.1%)	3 (1.7%)	
Operative time (min.)	46.68 ± 11.40	43.32 ± 1.15	0.250
Pneumoperitoneum time (min.)	39.71 ± 10.27	36.89 ± 1.25	0.308
Anesthesia time (min.)	57.75 ± 12.53	53.25 ± 11.75	0.171
Insertion time (sec.)	40.61 ± 12.24	39.00 ± 12.05	0.623
Attempt no. (1/2)	21/7	22/6	1.000

Data are expressed as Mean ± SD, number, and percentage. ASA; American society of anesthesiologists, VCV=Volume controlled ventilation, PCV=Pressure controlled ventilation. $P < 0.05$.

0.017), and after pneumoperitoneum deflation ($P <$ 0.001) (Figure 4).

Arterial blood gas analysis showed significantly lower mean PaCO2 in the PCV group at 15 minutes after insufflation ($P = 0.010$) and after pneumoperitoneum deflation ($P = 0.009$) compared with the VCV group. In addition, the mean end-tidal CO_2 was significantly lower in the PCV group after Baska mask insertion ($P = 0.043$) but higher at 60 min intraoperatively ($P = 0.019$), with no significant differences between the two studied groups at other time points (Supplemental online only: S-figure S2). No significant intergroup differences were reported in the PH or the PaO2 throughout the study (Table 2). We did not report any perioperative adverse effects in either group.

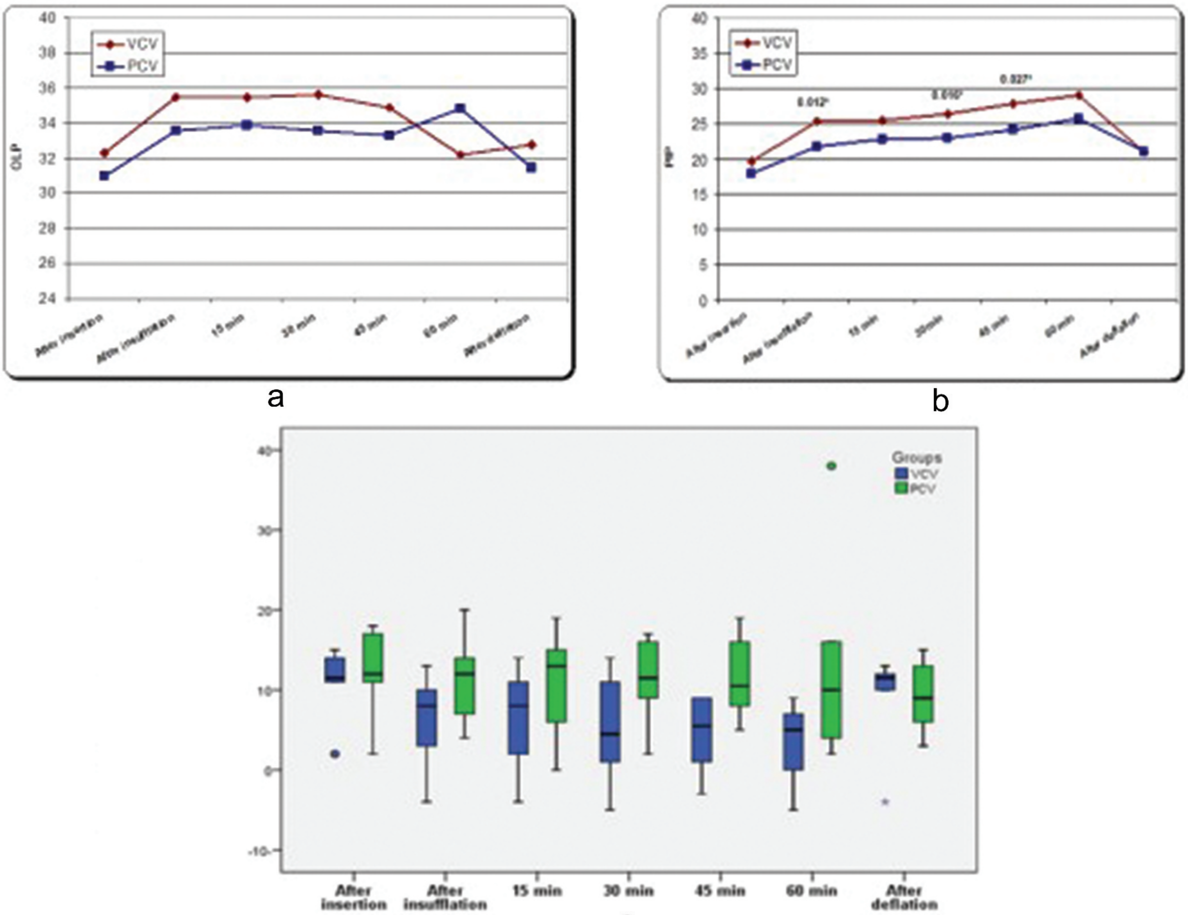

Figure 2. (a) the oropharyngeal leak pressure (OLP) between groups (Mean±sd), P < 0.05 significant difference. (b) the peak inflation pressure (PIP) between groups (Mean±sd), P < 0.05 significant difference. (c) the oropharyngeal leak pressure and Peak inflation pressure difference (OLP-PIP).

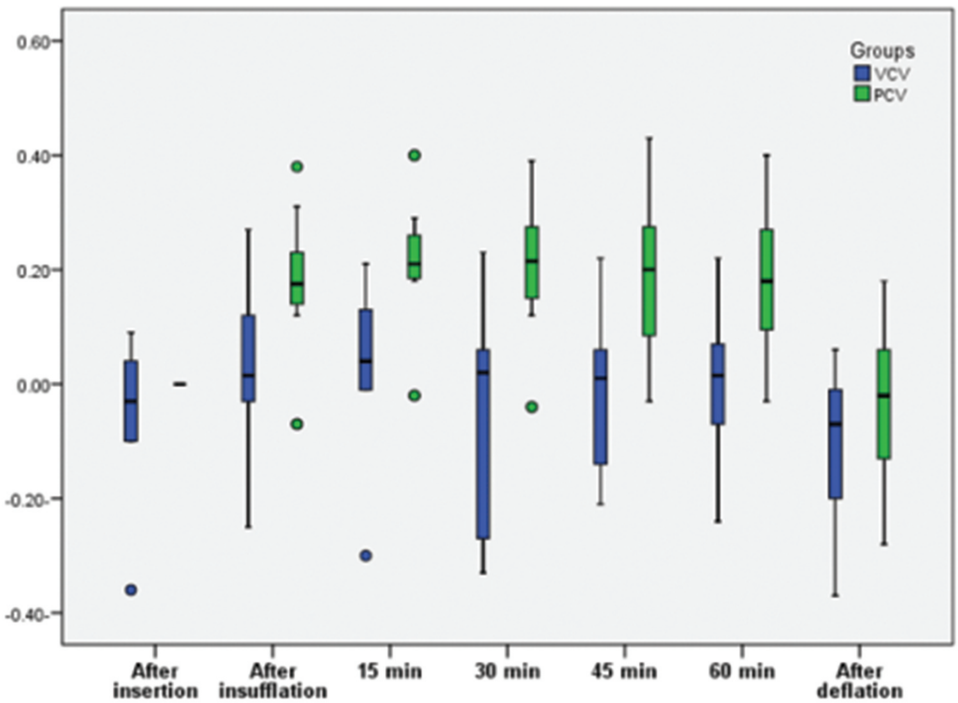

Figure 3. Calculated Leak Fraction (LF) in the two groups (Median and range), $P < 0.05$ significant difference.

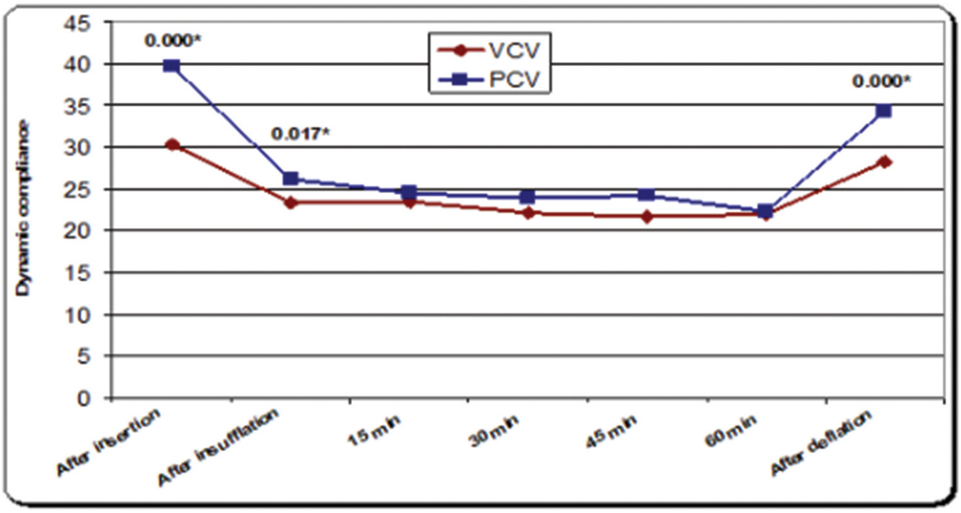

Figure 4. Calculated dynamic compliance (Cdyn) in the two groups (Mean±sd) $P < 0.05$ significant difference.

Table 2. Arterial blood gas analysis (ABG) in the two studied groups.

ABG	VCV ($n = 28$)	PCV ($n = 28$)	P-value[1]
PH:			
Sample I	7.48 ± 0.06	7.50 ± .04	0.091
Sample II	7.43 ± 0.05	7.44 ± .09	0.686
P-value[2]	0.001	0.000	
Sample III	7.41 ± 0.05	7.42 ± .08	0.642
P-value[2]	0.000	0.000	
PaO_2:			
Sample I	372.96 ± 67.48	417.61 ± 97.00	0.051
Sample II	369.75 ± 103.36	361.04 ± 113.70	0.765
P-value[2]	0.875	0.038	
Sample III	363.07 ± 98.92	382.54 ± 93.89	0.453
P-value[2]	0.626	0.139	
$PaCO_2$:			
Sample I	27.36 ± 7.42	25.29 ± 6.49	0.271
Sample II	31.61 ± 6.17	26.64 ± 7.68	0.010
P-value[2]	0.009	0.354	
Sample III	31.86 ± 5.66	27.21 ± 7.14	0.009
P-value[2]	0.011	0.238	

Data are expressed as Mean ± SD, VCV=Volume controlled ventilation, PCV=Pressure controlled ventilation. Sample I; 5 min. after stabilizing of controlled ventilation, Sample II; 15 minutes after pneumoperitoneum insufflation, and sample III; 15 minutes after pneumoperitoneum deflation. P-value[1] < 0.05 significant difference between groups.
P-value[2] < 0.05 significant difference inside each group.

5. Discussion

In this study, we investigated the performance of the Baska mask device in VCV versus PCV in patients undergoing laparoscopic cholecystectomy. After inflation of the pneumoperitoneum, the OLP, PIP, P mean, $PaCO_2$, and end-tidal CO_2 significantly increased, and the calculated dynamic compliance significantly decreased in both ventilation modes. All variables partially returned to baseline after pneumoperitoneum deflation. Patients ventilated with PCV mode demonstrated lower PIP and PaCO2 but higher dynamic compliance with statistically comparable OLP-PIP difference and higher leak fraction.

Laparoscopic surgeries are associated with increased airway pressure by 50% and a 25% decrease in lung compliance [12,13]. Previous studies report an increase in OLP ranging from 29.6 to 38.3 cmH_2O [6,7,14,15]. These findings agree with the current study, which reported that OLP increased similarly in the VCV and PCV groups. This increase in OLP is due to the flexible membranous self-inflating cuff connected to the central channel of the Baska mask, which inflates with the increase in the airway pressure during inspiration enabling the Baska mask to be a suitable airway device for laparoscopic surgeries [6,16]. The Baska mask protects the airway and prevents gastric aspiration [17,18].

In laparoscopic surgeries, if the PIP is high during the VCV mode of ventilation, shifting to the PCV may offer increased tidal volume at a lower PIP because of the increased gas flow earlier in the inspiratory phase [19]. The PCV can improve lung compliance (Cdyn) in cases associated with low Cdyn, as in pregnancy, laparoscopic procedures, morbid obesity, ARDS, and in the presence of a leak in the breathing system (uncuffed ET tube or LMA) [20].

In this study, lung compliance decreased, and the PIP increased in both groups, with a notable increase in the VCV group. These respiratory mechanics were associated with more increase in $PaCO_2$ in the VCV group than in the PCV group. In agreement, Jeon WJ et al. [21] state that PCV using LMA effectively eliminates CO_2 while minimizing the increase in the peak airway pressure after pneumoperitoneum. Also, Jarahzadeh et al. [22] indicate that PCV is suitable for patients undergoing gynecological laparoscopy to reduce airway pressures.

There was no significant difference between the two groups in the P mean, which is an image of the alveolar pressure [23]. All patients in this study were healthy and had no pulmonary disease. In line with previous studies, the P mean increased in the two groups after pneumoperitoneum [23–25].

In contrast to the current study, Balick-Weber et al. (5) state that PCV is not superior to VCV during laparoscopic surgery regarding the respiratory mechanics and gas exchange. Also, Movassagi R et al. and De Baerdemaeker et al. (26, 27) declare that PCV is similar to VCV for laparoscopic surgeries in morbidly obese patients. Moreover, CO2 elimination is better in VCV due to the differences in minute ventilation, physiologic dead space, or CO2 production. However, these studies used the endotracheal tube as an airway device. Future studies using LMAs as airway devices with either mode of ventilation are needed to confirm our results.

In this study, oxygenation was well maintained in the two groups because it depends on the FiO_2, alveolar ventilation, and intrapulmonary shunts [26], and we used a constant Fio_2 in both groups. Alveolar ventilation was not affected in our patients (detected by Pmean). Strang et al. [27] and Andersson et al. [28] report that after pneumoperitoneum, perfusion is redistributed from the atelectatic area to the compliant units resulting in a better V/Q match. Subsequently, oxygenation might be well maintained in healthy adults.

This study has some limitations. The attending anesthesiologist was not blind to the ventilation mode investigated, which may be a source of bias. Nevertheless, most studies on LMAs were open-labelled. In addition, we randomized patients with BMI ≤30 kg/m^2 undergoing laparoscopic cholecystectomy in the anti-Trendelenburg position. Further studies on patients with higher BMI and different laparoscopic procedures and positions are needed. Moreover, the small sample size and female predominance (due to the high prevalence of chronic calculous cholecystitis in females) in this study advocate the need for future studies with larger sample sizes and both sexes.

6. In conclusion

In this study, Patients ventilated with PCV mode showed lower PIP and PaCO2 but higher dynamic compliance, and higher leak fraction. However, both modes investigated provided effective Baska mask ventilation and maintained the OLP throughout the procedure with a statistically comparable OLP-PIP difference. Further studies of larger sample sizes are needed to confirm these results.

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Disclosure statement

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Authors' contributions

1-Amani H. Abdel-Wahab: Conducted the study and collected data. Excel sheet preparation, and initial draft writing.
2- Radwan A. Torky: Conducted the study and collected data.

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