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CLINICAL TRIAL REPORT

Pressure-Controlled Volume-Guaranteed Ventilation Improves Respiratory Dynamics in Pediatric Patients During Laparoscopic Surgery: A Prospective Randomized Controlled Trial

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Purpose: Pressure-controlled volume-guaranteed (PCV-VG) combines the characteristics of pressure-controlled ventilation (PCV) and volume-controlled ventilation (VCV). It has been reported that PCV-VG decreases airway pressure and improves oxygenation among the adult group. In this study, the respiratory dynamics of PCV-VG and VCV are compared in pediatric patients ventilated with laryngeal mask airway and underwent laparoscopic hernia of the sac ligation.

Patients and Methods: Sixty-four pediatric patients were included in this prospective, randomized clinical trial. Pediatric patients were randomly allocated to receive VCV and PCV-VG ventilation during the general anesthesia. The hemodynamic and respiratory variables were recorded at the time when laryngeal mask airway was placed, pneumoperitoneum began, 5 mins after pneumoperitoneum began, pneumoperitoneum ended, and the operation ended respectively. The respiratory adverse events were recorded after the operation and on the first day after the operation. In this study, respiratory adverse events are defined as cough, hoarseness, hypoxemia, laryngospasm, bronchospasm, and sore throat.

Results: There was no statistical difference in hemodynamic variables at all time points between the two groups. Compared to the VCV group, peak airway pressure (Ppeak) and plateau airway pressure in the PCV-VG group decreased significantly. Pulmonary dynamic compliance (Cydn) in the PCV-VG group was significantly higher than that in the VCV group. The respiratory adverse events appeared to have no statistical difference between VCV and PCV groups.

Conclusion: PCV-VG provides a lower Ppeak and better Cydn in pediatric patients compared with the VCV group during laparoscopic surgery. The results suggested that PCV-VG may be a superior way of mechanical ventilation for pediatric patients who ventilated with laryngeal mask airway and experienced laparoscopic surgery.

Keywords: pediatric anesthesia, adverse events, mechanical ventilation, pediatric intensive care

Introduction

Pediatric patients have a high oxygen consumption with a low oxygen reservation, and easily occur respiratory complications due to unfitting mechanical ventilation. Thus, a befitting mode of ventilation during general anesthesia is a crucial factor to avoid respiratory adverse events. For the time being, the modes of mechanical ventilation used in pediatric patients include volume-controlled ventilation (VCV) and pressure-controlled

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ventilation (PCV).[1,2] Pressure-controlled volume-guaranteed (PCV-VG) ventilation combines the characteristics of PCV and VCV.[3] PCV-VG provides a stable tidal volume that is not affected by the change of airway pressure while assuring that the airway pressure does not exceed the preset pressure to ensure the ventilation and oxygen supply of pediatric patients. Some researchers have compared the VCV and PCV-VG ventilation among the adult group.[4,5] However, the effect of respiratory dynamics in pediatric patients undergoing VCV and PCV-VG ventilation with laryngeal mask airway is still unclear.

The primary aim of the study is to compare the respiratory dynamics changes of VCV and PCV-VG in pediatric patients ventilated with laryngeal mask airway and experienced laparoscopic hernia of the sac ligation, through real-time continuous airway monitoring of ventilatory pressure, volume, resistance, and lung compliance. Providing a basis for the selection of ventilation strategy under the guidance of respiratory dynamics for pediatric patients, through understanding the mechanical state of lung and airway during operation.

Patients and Methods

Ethics Statement

This prospective, randomized clinical trial was approved by the Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University, Hefei, China (approval number: PJ2020-01-07) and was registered at Chinese Clinical trial Registry (http://www.chictr.org.cn/index.aspx, registration number: ChiCTR2000029932). This study was conducted in accordance with the declaration of Helsinki.

Study Population

Pediatric patients who accepted elective laparoscopic high ligation of the hernia sac under general anesthesia in the First Affiliated Hospital of Anhui Medical University between January 2020 and December 2020 were screened for inclusion. Written informed consent was obtained from the parent/guardian of the pediatric patients. Patients with age 1 to 8 years and American Society of Anesthesiologists (ASA) physical status I or II were considered for enrollment. Patients were excluded if they had a sore throat, enlarged tonsil, cardiopulmonary disease, severe hepatorenal dysfunction, and a history of upper respiratory tract infection 2 weeks before the operation. The pediatric patients were randomly allocated into either VCV or PCV-VG ventilation group, and one researcher who was not involved in the data collection stage was randomly dispatched into every two groups. This manuscript follows the CONSORT Guidelines.

Management of Anesthesia

All the pediatric patients were non-peros according to anesthetic guidelines before the operation. Blood pressure, heart rate, and SpO_2 of pediatric patients were monitored before the anesthesia began. Anesthesia induction was performed with 2–3 mg/kg propofol (AstraZeneca Pharmaceutical Co., Ltd, United Kingdom) or via facemask with sevoflurane (Maruishi Pharmaceutical Co., Ltd, Japan), 0.3 μg/kg sufentanil (Yichang Humanwell Pharmaceutical Co., Ltd, China) and 0.15 mg/kg cis-atracurium (Jiangsu Hengrui Pharmaceutical Co., Ltd, China). Then, an appropriate size of I-gel laryngeal mask airway was chosen according to the patient's weight and was properly fixed after placement. Mechanical ventilation was performed with VCV or PCV-VG mode. Hi-Lo Hand Pressure Gauge (COVIDIEN Ltd, USA) was selected to inflate the laryngeal mask to maintain the cuff pressure in the green area of the pressure gauge. The laryngeal mask airway positioned correctly if the trace of $EtCO_2$ is square, auscultation of bilateral breath sounds is symmetrical and no leaking murmur appears in the anterior cervical region. Remifentanil 0.05–0.2 mcg/kg/min (Yichang Humanwell Pharmaceutical Co., Ltd, China) and propofol 50–120 mcg/kg/min infusion were used for anesthesia maintenance.

Ventilation Protocol

Mindray A7 anesthesia machine (Shenzhen Mindray Biomedical Electronics Co., Ltd, China) was used for mechanical ventilation. Pediatric patients in the VCV group received volume-controlled ventilation, target tidal volume was set at 10 mL/kg, with a respiratory rate of 16 beats/min and a respiratory ratio of 1:2. Pediatric patients in the PCV-VG group were conducted with pressure-controlled volume-guaranteed ventilation, target tidal volume was set at 10 mL/kg, with a respiratory rate of 16 beats/min and a respiratory ratio of 1:2. The upper limit pressure of the airway was preset at 20 cmH_2O.

Measurements

Parameters of respiratory dynamics were taken as the primary outcome measures: peak airway pressure (Ppeak), plateau airway pressure (Pplat), pulmonary dynamic compliance (Cdyn), airway resistance (RAW),

and end-expiratory carbon dioxide ($EtCO_2$). Secondary outcome measures included mean arterial pressure (MAP), heart rate (HR), and postoperative respiratory adverse events such as cough, hoarseness, sore throat, hypoxemia, laryngospasm, bronchospasm. Data were recorded at the following five time-points: laryngeal mask airway was placed (T1), pneumoperitoneum began (T2), 5 mins after pneumoperitoneum began (T3), pneumoperitoneum ended (T4) and the operation ended (T5).

Statistical Analysis

The data obtained were statistically analyzed by using SPSS 19.0 (IBM, Armonk, New York, USA), and presented using the mean ± standard deviation (SD) or median and interquartile range (IQR), as appropriate. The Kolmogorov–Smirnov test with Lilliefors correction was performed to assess the normality and Levene's test was selected to evaluate the homogeneity of the parameters. Independent Samples *T*-test was assigned in a comparison of parameters with normal distribution and Kolmogorov–Smirnov test was used in a comparison of parameters with non-normal distribution. Differences were considered to be significant at a P-value of <0.05.

The sample size was calculated based on the results from the pre-experimental study. The mean Ppeak in the VCV group of pre-experimental study was 16.6±4.3 and we aimed to detect a 20% decrease of Ppeak in the PCV-VG group compared with the VCV group during pneumoperitoneum. At last, a sample of 27 was required in each group (https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html) based on a two-sided alpha level of 0.05 and statistical power of 80%. Considering that a 20% dropout rate, 32 patients in each group were needed.

Results

Of the 123 pediatric patients screened, 64 patients (N=32 in each group) were included and completed the study (Figure 1). Patient characteristics and surgery-related information of 64 pediatric patients are presented in Table 1. The median age of pediatric patients in the VCV group is 2 (1 to 8) years old, and the PCV-VG group is 3 (1 to 8) years old. In the VCV group, 20

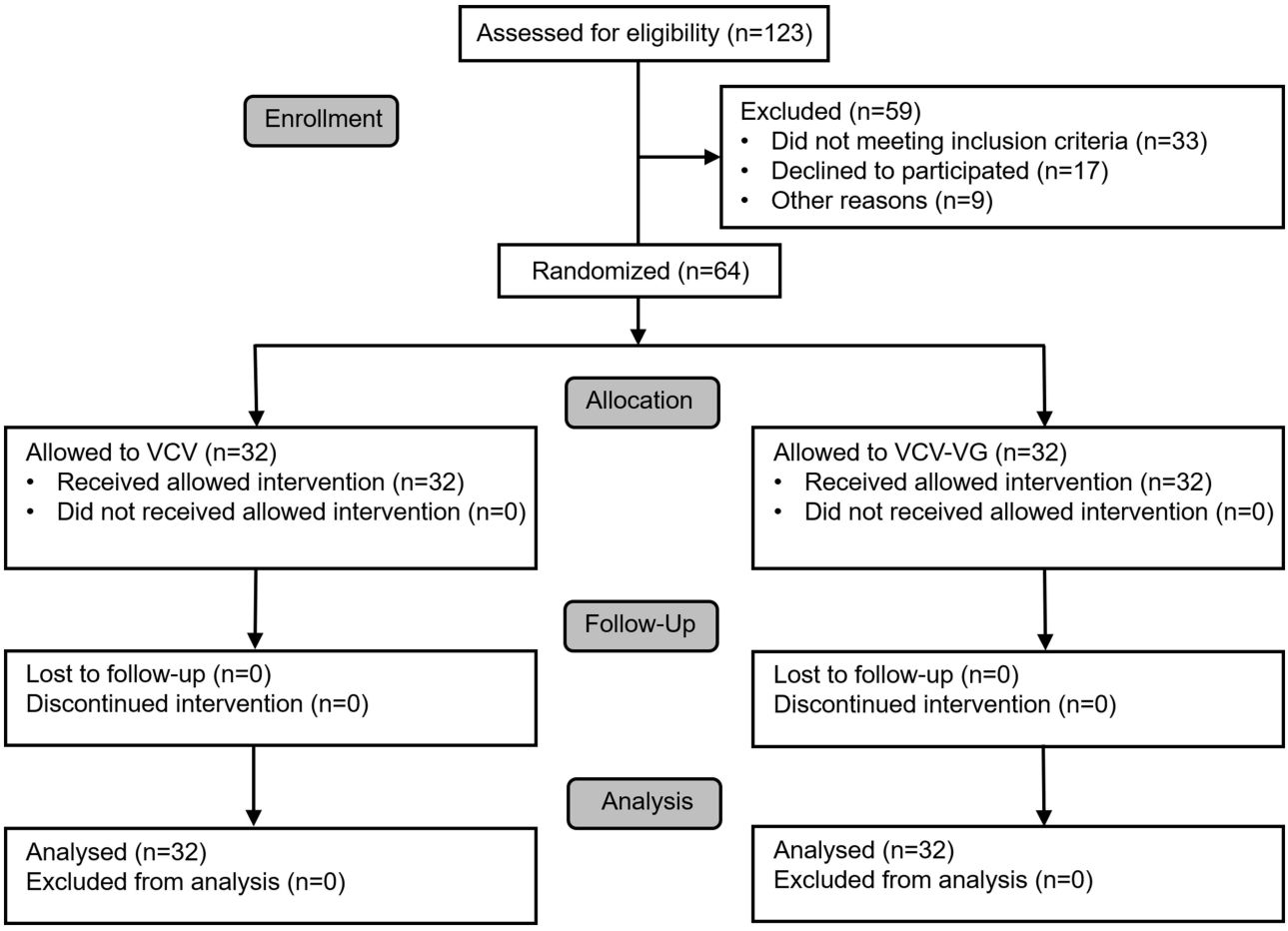

Figure 1 The CONSORT flow diagram.

Table 1 Patient Characteristics and Surgery-Related Information

	VCV (N=32)	PCV-VG (N=32)	P-value
Demographics data			
Female/Male (n)	3/29	4/28	0.689
Age (Year)	2 (1–8)	3 (1–8)	0.830
Weight (kg)	15 (10–37)	14 (9–30)	0.159
Height (cm)	100 (75–139)	90 (50–125)	0.088
Surgical data			
Inhalation/i.v induction induction (n)	20/12	21/11	0.794
Duration, anesthesia (min)	36.19±7.43	36.81±11.10	0.537
Duration, surgery (min)	17.88±6.00	19.78±6.68	0.234

Abbreviations: VCV, volume-controlled ventilation; PCV-VG, pressure controlled-volume guaranteed ventilation; i.v, intravenous.

Table 2 Perioperative Circulatory Parameters

	HR		P-value	MAP		P-value
	VCV Group	PCV-VG Group		VCV Group	PCV-VG Group	
T0	101.91±17.61	108.84±18.16	0.126	71.19±12.19	71.44±10.50	0.93
T1	88.72±18.03	94.47±18.24	0.209	61.09±7.08	58.72±7.88	0.209
T2	85.63±19.85	93.69±17.16	0.087	70.56±13.00	70.94±13.92	0.912
T3	90.34±20.50	98.19±17.61	0.106	73.78±12.97	74.19±12.66	0.9
T4	92.50±23.01	96.38±19.03	0.466	76±11.59	76.81±13.87	0.8
T5	89.56±21.06	94.09±18.19	0.361	72.69±12.15	72.78±14.37	0.978

Abbreviations: VCV, volume-controlled ventilation; PCV-VG, pressure controlled-volume guaranteed ventilation; HR, heart rate; MAP, mean arterial pressure. T0, Before anesthesia; T1, laryngeal mask airway was placed; T2, pneumoperitoneum began; T3, 5 mins after pneumoperitoneum began; T4, pneumoperitoneum ended; T5, the operation ended.

pediatric patients were induced by inhalation anesthesia and 12 pediatric patients were induced by intravenous anesthesia. Inhalation anesthesia induction was performed among 21 pediatric patients and intravenous anesthesia induction was applied among 11 pediatric patients in the PCV-VG group. There were no significant differences between the groups for age, sex, height, weight, and operation time ($P > 0.05$).

Comparison of Hemodynamic Parameters

There was no significant difference in HR and MAP between VCV and PCV-VG group at each time point ($P > 0.05$). Hemodynamic parameters of pediatric patients are presented in Table 2.

Comparison of Intraoperative Respiratory Dynamics

Ppeak and Pplat of pediatric patients in the PCV-VG group were significantly lower than that of in the VCV group ($P < 0.05$, Figure 2A) and Cdyn in the PCV-VG group was higher than that of in the VCV group at each time point ($P < 0.05$, Figure 2B). In addition, RAW in the PCV-VG group was lower than that of in the VCV group, and there was a significant difference at T2 (26.81 ± 4.32 vs 29.94 ± 5.24, $P = 0.012$) and T3 (27.16 ± 5.14 vs 30.09 ± 5.28, $P = 0.028$) during pneumoperitoneum. There was no significant difference in $EtCO_2$ at all time points ($P > 0.05$). Respiratory parameters of pediatric patients are presented in Table 3.

Occurrence of Postoperative Respiratory Adverse Events

There were 1 case of cough and 8 cases of hoarseness in the VCV group; 2 cases of cough and 5 cases of hoarseness in the PCV-VG group after the operation. On the first day after the operation, there were 5 cases of cough and 2 cases of hoarseness in the VCV group patients; 3 cases of cough, 3 cases of hoarseness, and 2 cases of sore throat in the PCV-VG group. There was no significant difference in the incidence of respiratory adverse events

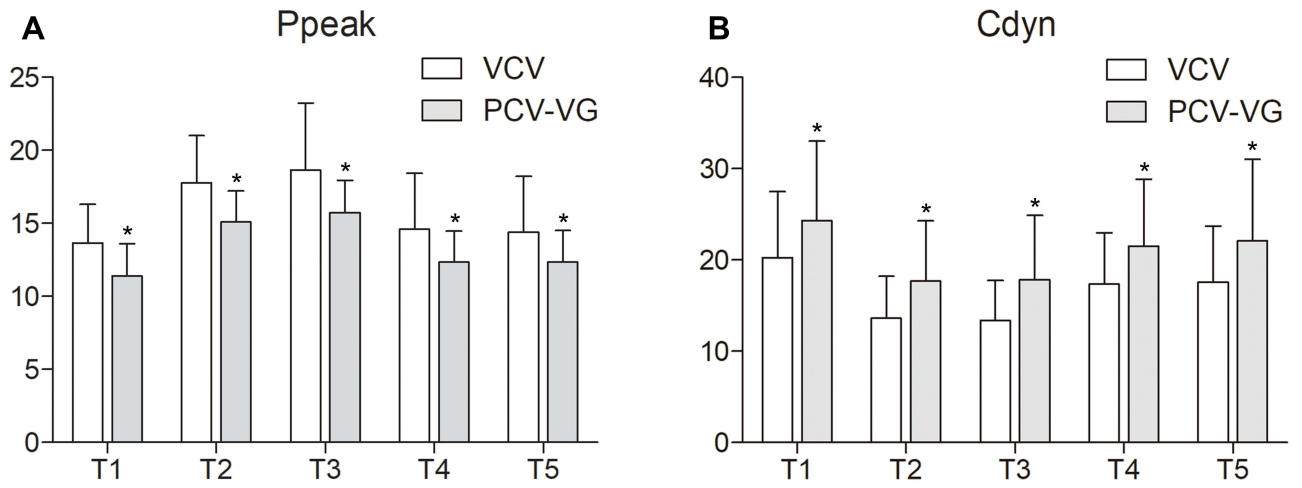

Figure 2 The comparison of Ppeak (**A**) and Cdyn (**B**) at each measurement time point. Data are presented as mean ± standard error of the mean. Ppeak value is higher in the VCV group than that of in the PCV-VG group ($P < 0.05$). Cdyn value is lower in the VCV group than that of in the PCV-VG group ($P < 0.05$). *$P < 0.05$: Compared with the VCV group at the same time point.

Abbreviations: VCV, Volume-controlled ventilation; PCV-VG, Pressure-controlled volume-guaranteed ventilation; T1, Laryngeal mask airway was placed; T2, Pneumoperitoneum began; T3, 5 mins after pneumoperitoneum began; T4, Pneumoperitoneum ended; T5, The operation ended.

between the two groups ($P > 0.05$). Perioperative respiratory adverse events are presented in Table 4.

Discussion

In this prospective randomized clinical trial, there were major differences in the primary outcome. Ppeak was significantly lower and Cdyn was significantly higher in the PCV-VG group than that in the VCV group at all time points among pediatric patients who ventilated with I-gel laryngeal mask airway and experienced laparoscopic high ligation of the hernia sac. RAW in the VCV group was higher than that in the PCV-VG group, but this significant difference only occurred during pneumoperitoneum (T2 and T3 time points). Hemodynamic varieties and respiratory adverse events were not found to show significant differences during the perioperative period.

Table 3 Intraoperative Respiratory Parameters

		T1	T2	T3	T4	T5
Ppeak	VCV	13.66±2.65	17.78±3.22	18.66±4.58	14.59±3.83	14.41±3.81
	PCV-VG	11.41±2.20	15.09±2.13	15.72±2.22	12.34±2.12	12.34±2.18
	P value	0.000	0.000	0.002	0.001	0.002
Pplat	VCV	13.16±2.65	17.31±2.97	17.91±3.95	14.34±3.33	13.97±3.37
	PCV-VG	11.22±2.09	15.03±2.12	15.59±2.20	12.19±2.13	12.22±2.25
	P value	0.001	0.001	0.006	0.002	0.018
Cdyn	VCV	20.25±7.22	13.63±4.60	13.38±4.38	17.34±5.64	17.56±6.17
	PCV-VG	24.31±8.69	17.69±6.60	17.81±7.09	21.50±7.35	22.13±8.92
	P value	0.046	0.017	0.015	0.027	0.020
RAW	VCV	24.50±5.22	29.94±5.24	30.09±5.28	26.13±4.42	26.31±5.08
	PCV-VG	23.13±3.12	26.81±4.32	27.16±5.14	25.00±3.59	24.72±3.83
	P value	0.207	0.012	0.028	0.268	0.162
$EtCO_2$	VCV	37.59±4.76	38.81±6.66	42.59±6.62	42.93±8.40	42.16±8.93
	PCV-VG	35.94±4.83	36.81±4.78	39.91±5.30	41.06±5.93	39.91±5.89
	P value	0.172	0.173	0.078	0.306	0.239

Abbreviations: Pplat, plateau airway pressure; Peak, peak airway pressure; Cdyn, pulmonary dynamic compliance; RAW, airway resistance; EtCO2, end-tidal carbon dioxide; VCV, volume-controlled ventilation; PCV-VG, pressure controlled-volume guaranteed ventilation; T1, laryngeal mask airway was placed; T2, pneumoperitoneum began; T3, 5 mins after pneumoperitoneum began; T4, pneumoperitoneum ended; T5, the operation ended.

Table 4 Perioperative Adverse Events of Respiratory System

		VCV Group	PCV Group	P-value
Post-operation	Cough	1 (3.1%)	2 (6.3%)	0.554
	Hoarseness	8 (25.0%)	5 (15.6%)	0.351
	Hypoxemia	0 (0.0%)	0 (0.0%)	1.000
	Laryngospasm	0 (0.0%)	0 (0.0%)	1.000
	Bronchospasm	0 (0.0%)	0 (0.0%)	1.000
24h after operation	Cough	5 (15.6%)	3 (9.4%)	0.450
	Hoarseness	2 (6.3%)	3 (9.4%)	0.641
	Hypoxemia	0 (0.0%)	0 (0.0%)	1.000
	Sore throat	0 (0.0%)	2 (6.3%)	0.151

Abbreviations: VCV, volume-controlled ventilation; PCV-VG, pressure controlled-volume guaranteed ventilation.

At present, laparoscopic surgery has become a common surgical method in pediatric surgery.[6] Whereas, laparoscopic surgery may lead to increased intra-abdominal pressure and gravely affects the respiratory and circulatory systems of pediatric patients. The laryngeal mask airway is more suitable for ventilation during general anesthesia for pediatric patients, although endotracheal intubation is the most critical way to establish a definite airway. For the time being, there are few studies on PCV-VG ventilation with laryngeal mask airway in pediatric laparoscopic surgery. Accordingly, this study compared the respiratory dynamics of PCV-VG and VCV in pediatric patients who ventilated with laryngeal mask airway and experienced laparoscopic high ligation of the hernia sac to observe the effects of PCV-VG ventilation during pediatric laparoscopic surgery.

VCV is an ordinarily conducted mechanical ventilation in clinical practice.[7,8] The ventilator delivers a desired tidal volume with a constant flow rate and volume increases linearly in VCV.[3] Concerning airway pressure, it increases quasi-linearly during inspiration until a peak is reached.[3] PCV is an extensively applied pressure-targeted ventilation compared with VCV and supports the tidal volume through a decelerating flow under preset pressure, which can vary according to lung compliance.[9] PCV-VG aims to deliver a desired tidal volume at the lower possible inspiratory pressure by decelerating flow and calculating Cdyn at each breath cycle to adjust the inspiratory pressure to get the tidal volume set by the clinician. Barotrauma is inclined to occur when VCV ventilation is performed, in virtue of the high and unstable airway pressure in pediatric laparoscopic surgery. Furthermore, insufficient ventilation tends to occur while PCV ventilation is adopted. Therefore, PCV-VG ventilation is more suitable for laparoscopic surgery in pediatric patients theoretically.

Previous studies had found that PCV-VG improves respiratory dynamics and oxygenation during mechanical ventilation among adults or the elderly, compared with VCV. Kothari et al found that PCV-VG presents lower Ppeak and better lung compliance than VCV during laparoscopic cholecystectomy.[9] It was also observed by lung ultrasound that the lung ultrasound score in the PCV-VG group is better than that of in the VCV group.[10] Lee et al showed that PCV-VG leads to a lower Ppeak and an improved Cdyn compared with VCV, suggesting that PCV-VG may be an available alternative mode of mechanical ventilation in the prone position for patients who accept lumbar surgery.[3] Moreover, PCV-VG improves respiratory dynamics in robot-assisted laparoscopic gynecologic surgery with Trendelenburg position.[11] Importantly, PCV-VG decreases the release of norepinephrine, reduces the inflammatory response and lung injury, protects the lung function of elderly patients with one-lung ventilation in thoracotomy.[12,13] The above results provide a basis for the study of PCV-VG in pediatric laparoscopic surgery.

To the best of our knowledge, many studies are focusing on adult PCV-VG ventilation, but few articles study pediatric PCV-VG. The results of this study are similar to previous research of adults. Respiratory dynamics in the PCV-VG group are significantly improved than that of in the VCV group, Ppeak is lower and Cdyn is higher than that of in the VCV group. What is important is that the present study is the first to observe the application of PCV-VG in pediatric patients who ventilated with laryngeal mask airway and underwent laparoscopic surgery.

As an improvement from previous studies, this study followed perioperative respiratory adverse events in pediatric patients. Although the study results suggest that PCV-VG ventilation can be safely applied in children during

pneumoperitoneum, no significant difference is found between the two groups in perioperative respiratory adverse events. The possible reason is that the operation time of laparoscopic high ligation of the hernia sac is short and the respiratory system is rarely affected by two different modes of ventilation. Hypothetically, it may get a clinically significant result when an operation that takes longer is selected to study in the future.

The present study has several limitations. Pediatric patients under 1-year-old are not included in the study; hence, PCV-VG ventilation for pediatric patients accepted laparoscopic surgery under 1-year-old needs to be further explored. It is difficult to evaluate the oxygenation of pediatric patients accurately during ventilation, because arterial blood gas analysis is not designed in this study considering that operation time is short and arterial puncture is difficult for pediatric patients. In addition, the obtained perioperative respiratory adverse events only rely on the access of medical staff or guardians, due to poor communication and expression of pediatric patients. Thus, there may be some bias in the results of respiratory adverse events.

Conclusion

PCV-VG provides a lower Ppeak and better Cdyn in pediatric patients during laparoscopic surgery. The results suggest that PCV-VG can be selected as an effective alternative mode of mechanical ventilation for pediatric patients, especially for laparoscopic surgery. However, further research is needed to observe the effects of PCV-VG on pediatric patients less than 1-year-old and the incidence of perioperative respiratory adverse events.

Data Sharing Statement

Due to no consent from the study participants to disclose raw data, this data could not be made available to protect the participants' identity.

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Disclosure

The authors report no conflicts of interest in this work.

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