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Evaluation of the effect of ventilation strategies during cardiopulmonary bypass on postoperative pulmonary complication in pediatric cardiac surgery: A randamized prospective study

Mohamed Magdy
Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine Mansoura University, Mansoura, Egypt.
Corresponding author email: dr_mohamedmagdy1988@hotmail.com

Naglaa A. Elnegeery
Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine Mansoura University, Mansoura, Egypt.

Ghada A. El Rahamawy
Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine Mansoura University, Mansoura, Egypt.

Mohamed A. Elgamal
Department of Cardiothoracic Surgery, Faculty of Medicine Mansoura University, Mansoura, Egypt.

Salwa M. S Hayes
Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine Mansoura University, Mansoura, Egypt.

***Abstract*---**Objectives: To compare the effects of three ventilation strategies during cardiopulmonary bypass on postoperative pulmonary complications (PPCs). Design: A prospective, randomized, double blinded study. Setting: Single center hospital. Participants: forty eight pediatric patients undergoing elective repair of congenital heart diseases with cardiopulmonary bypass. Interventions: Patients were randomly assigned into three groups according to ventilation strategy during CPB: (1) low tidal volume (LTV), RR 5 breath ber min, and V_t 2 -3mL/kg of ideal body weight, (2) continuous positive airway pressure (CPAP) of 5-10 cm H2O, (3). no ventilation (NOV). Measurements: and Main Results: postoperative atelectasis. Regarding the frequency of postoperative atelectasis there was statistically

insignificant between the studied groups although the number of patients who developed atelectasis in NVgroup 7 (43.8%) were greater than the number in both LTV group 2 (12.5%) and CPAP group 2 (12.5%) Conclusions: Maintaining ventilation during CPB can reduce the incidence of PPCs in pediatric patients undergoing cardiac surgery.

***Keywords*---**Congenital heart disease, ventilation during cardiopulmonary bypass, pediatric cardiac surgery, postoperative pulmonary complications.

Introduction

Congenital heart disorders (CHDs) are characterised by structural flaws in the heart or blood arteries that start developing at birth [1]. The heart was complex and developed in a dynamic manner during embryological development. This began on day 15 of conception and ends on day 49 with the complete development of the human heart[1].

Cardiopulmonary bypass (CPB) is an essential procedure in cardiac surgery. It permits surgeons to perform their procedures in an environment free of blood while ensuring blood flow and oxygenation[2]. Apnea during CPB ensures the best surgical vision, despite the risk of postoperative atelectasis and pulmonary ischemia-reperfusion injury. [2].

Despite advancements in CPB circuit materials and medication modification, acute lung damage is a frequent consequence of cardiopulmonary bypass (CPB). Clinically meaningful respiratory impairment lasting more than a week was common, even in cardiac surgery patients who did not have severe heart failure. Lung damage caused by CPB is a result of numerous variables. There have been several proposed potential mechanisms for CPB-related lung injury, including pulmonary ischemia due to reduced pulmonary artery and bronchial artery flow, inflammatory reactions following CPB, leukocyte trapping in pulmonary circulation, apnea during CPB, myocardial damage, and hyperoxia [3].

Anesthesiologists can use ventilation techniques like positive end-expiratory pressure (PEEP), continuous positive airway pressure (CPAP), vital capacity manoeuvres (VCMs), and low-volume ventilation on the majority of CPB patients without hindering the surgical procedure[3]. Reduced pulmonary shunt values and improved gas exchange indices assessed after CPB show that the ventilation/perfusion mismatch has improved with the use of CPAP at 10 cmH2O [4]. Low tidal volume (LTV) low frequency breathing may lessen inflammatory reactions and some unfavourable immunological markers, such as interleukin 10 (IL10) and tumour necrotic factor-a (TNF-a), but it may also lessen the frequency of CPB-related lung injury [5].

Aim of the work

The aim of this randomized controlled study was to compare the effects of three different modes of ventilation during CPB in pediatric patients with congenital heart diseases (CHD) undergoing elective cardiac surgery on PPCs.

Materials & Methods

Study design

This prospective, randomised, double-blind trial was approved by the institutional review board. Legal guardians of each patient gave their written, truthful consent prior to surgery. The Declaration of Helsinki's ethical standards and good clinical practise were followed in the conduct of this investigation. 48 children under the age of six, of either sex, were enrolled by the authors for elective CPB repair of congenital heart diseases. Emergency cases, patients who underwent surgery repeatedly, and patients with persistent lung disorders were not included in the study.

Randomization

Patients were divided into one of three groups at random during CPB: (1) The ventilator (Drager, Fabius) was set to a respiratory rate of five breaths per minute, a tidal volume of two to three ml/Kg of ideal body weight, and a positive end expiratory pressure of three to five cmH2O in the low tidal volume (LTV) group. (2) After the ventilator (Drager, Fabius) was turned off, oxygen flow in the continuous positive airway pressure (CPAP) group was kept at 0.5L/min during CPB. The 10 m bar pressure setting on the adjustable pressure limitting valve (APL) was used. (3) The ventilator (Drager, Fabius) was turned off, all fresh air flow was stopped, and (APL) was set to a spontaneous position in the no ventilation (NV) group. The patient's group assignment was revealed by opening sealed, opaque envelopes with the results of randomization.

Anesthetic management

Each patient underwent a thorough clinical, radiological, and laboratory examination prior to surgery. Laboratory studies included testing for the liver and kidney functions as well as the complete blood picture (CBC), arterial blood gas, serum electrolytes, coagulation survey, urine analysis, and blood glucose level. Both a chest x-ray and transthoracic echocardiography were performed. During the preoperative appointment, all were revised. 15 minutes prior to induction, all patients received injectable doses of ketamine (5 mg/kg) and atropine (0.02 mg/kg) at the time of arrival in the preoperative room. The electrocardiogram (ECG), non-invasive blood pressure monitoring (NIBP), and pulse oximetry were started as standard monitors in the operating room. Following anaesthetic induction, oral temperature monitoring, invasive intra-arterial pressure (IBP), and central venous pressure (CVP) monitoring were all connected. With the use of sevoflurane MAC 2 in 50% oxygen, anaesthesia was achieved. Intravenous line was placed when the patient lost consciousness. Rocuronium, 0.9 mg/kg, relaxed the muscles. Then, a properly sized oral endotracheal tube was placed, and

mechanical ventilation was started both before and after CPB using pressure controlled ventilation (PCV). PCV maintains end-tidal CO2 at 35–40 mm Hg while maintaining a 1:2 inspiratory to expiratory ratio and a tidal volume equal to 6–8 the patient's body weight. Then, under strict aseptic circumstances, an arterial line and central venous catheter were placed. Fentanyl was delivered at a dose of 5ug/kg prior to skin incision. Ketamine at 1 mg/kg/h and sevoflurane at MAC 2 were used to maintain anaesthesia. Heart rate and blood pressure were kept within 80% of their baseline values. Patients continued to receive a 1ug/kg/hour fentanyl infusion, which was stopped at the end of operation. Patients in three groups received the same cardioplegia solution throughout the trial to protect the myocardium during cross clamp. We kept our haemoglobin level around 1 0gm% after surgery. Protamine sulphate was used to reverse the effects of the heparin at a ratio of 1:1.5, following hemodynamic stabilisation and weaning the patient off of CPB. The patients' chest X-rays were taken once again the next day till their discharge from the intensive care unit (ICU) under observation following their transfer.

The arterial blood gas (ABG) was drown after induction of anasthesia, during and after CPB and in ICU. In the three group ABG managed to maintain $PaCo_2$ between 35-40 mmHg. In the intensive care unit (ICU), weaning from mechanical ventilation was tested after patients were stabilised, and extubation was performed after 30 minutes of spontaneous breathing.

Outcome measures

Chest x-ray was done to detect atelcasis as the primary out come of the study, the secondary out comes were Pao2/Fio2 (hypoxic index), time needed to extubate patient after surgery ICU stay time and hospital stay time.

Sample size calculation

The Power Analysis and Sample Size software (PASS) version 15.0.5 for Windows (2017) was used to determine sample size using data from a pilot study with the frequancy of postoperative atelacsis as the main outcome. To reach 80% power (1-β or the probability of rejecting the null hypothesis when it is false) a sample size of 14 patients in each group was required. Two patients in each group were expected to drop out, making a total of 48 patients divided into three groups with 16 patients each.

Statistical analysis

The data had been analysed using the Statistical Package of Social Science (SPSS) programme for Windows (Standard version 26). The normality of data had been tested firstly with one-sample Kolmogorov-Smirnov test. The following tests were done: A one-way analysis of variance (ANOVA) when comparing between more than two means Qualitative data had been described using number and percent. Association between categorical variables had been tested using Chi-square test while Monte carlo test and Fisher exact test had been used when expected cell count less than 5. Continuous variables had been presented as mean ± SD (standard deviation) for normally distributed data and median (min-max) for non-

normal data. The three groups had been compared with Student t test for parametric data and Mann Whitney test for non-parametric data. Threshold of significance was fixed at 5% level for all above mentioned statistical tests .The results were considered statistically significant when $p \leq 0.05$.

Result

48 children of either sex who had elective surgical correction of congenital heart diseases using cardiopulmonary bypass (CPB) were enrolled and evaluated for eligibility. Regarding demographic and anthropometric data, between the three groups that were examined there were no statistically significant differences (table 1). Also regarding the type of lesion there were no statistically significant differences between the three groups (table 2). Regarding the frequency of postoperative atelectasis there was statistically insignificant between the studied groups although the number of patients who developed atelectasis in NVgroup 7 (43.8%) were greater than the number in both LTV group 2 (12.5%) and CPAP group 2 (12.5%) as showen in (table 3). Regarding ICU stay time /day ,there were no significant statistical differences between the examined groups, while hospital stay /day showed statistically significantly decreased in LTV group(6.40±0.91) and CPAP group(6.75±0.93) in comparison to (8.25± 2.41) in NV group (table 4). As regard CPB time (min), cross clamp time(min) and time needed to wean patient from CPB(min) there were no statistically significant differences between examined groups(table 5). As regard the duration of surgery /hours and time needed to extubate patients after surgery/hour showed no statistically significant different between the examined groups (table 6). As regard hypoxic index (PaO2/FiO2): shows no statistically significant difference between three groups in the 1st hr. in ICU, 2nd hr and 4th in ICU. Also at 15 mins after CP B and at the end of CPB: There were no significant difference between three groups (table 7).

Discussion

Patients undergoing correction of CHD using CPB can suffer from deterioration of pulmonary functions in the postoperative period. During CPB the lungs are unventilated or deflated Cessation of the pulmonary circulation and ventilation during CPB may lead to atelectasis and may markedly contribute to inflammatory reactions in the lung which lead to postoperative pulmonary complications. The potential mechanisms of CPB related lung dysfunction involve pulmonary atelectasis, intrapulmonary shunt and change in systemic immune and inflammatory status [3].

Although the causes of postoperative hypoxemia after cardiac surgery with CPB are multifactorial, formation of lung atelectasis appear to be the primary factor responsible for increased hypoxemia and intrapulmonary shunt after cardiac surgery. As many as 64% of patients have radiologically confirmed atelectasis after CPB [4].

There have been many approaches investigated to lessen or perhaps entirely eliminate post-CPB injuries. Most of them focus on reducing inflammation by administering drugs to patients like steroids, statins, or heparin. The use of

biocompatible materials, blood filters, and CPB miniaturization are the main non-pharmacological techniques. [5].

A inexpensive and easy technique that can be used to keep patients undergoing cardiac surgery from having long lung deflation is low-tidal, low-frequency mechanical ventilation during CPB [6].The possible benefits of applying CPAP or intermitted ventilation during CPB has been debated with conflicting experimental and clinical [7].

The authors found in this prospective, randomised study that the use of CPAP or LTV during cardiopulmonary bypass can improve post pulmonary complication in children undergoing elective correction of congenital heart disease. Mechanical ventilation has been demonstrated to be safe when used during CPB in adults, while its advantages are still up for debate. In adult patients having heart surgery, the use of ventilation during CPB may improve gas exchange and post-CPB oxygenation, according to a new meta-analysis of 17 trials comprising 1162 adult patients. [8]. There are hardly many published studies in paediatric surgery. Without a clear indication of clinical improvement in patients on ventilation,. [9]

Compared five different forms of mechanical ventilation which used during CPB in 50 children. below the age of 5 years who were having open cardiac surgery with multiple CHD were included in a study by padalino et al 2002 [10] and Assist control ventilation was used with ((V_t) of 4 ml/kg, 10 BPM, (PEEP) of 5 cmH_2O, and FiO_2 0.21). The study found that continuous low-tidal/low-frequency mechanical breathing during CPB was risk-free, easy to use, and did not adversely affect paediatric patients. The duration of the intubation , the duration of the ICU stay, or the expression of inflammation biomarkers in the first 24 hours following surgery did not differ statistically.

In the current study patient demographic and anthropometric measurements provided insignificant statistical differences between groups. Additionally, the current study found no statistically significant differences between groups as regarding type of cardiac operations and duration of surgery. In harmony to our results, Zhang et al 2021 [11] examined 413 adult patients undergoing elective heart surgery with CPB classified into three groups: N V group, LOV group, and HOV group. They found no statistically significant differences between the three groups in terms of (age, gender, BMI, comorbidities), intraoperative factors, and (Surgical type, Anesthetics administration, Duration of surgery).

Moreover , the current study found no statistically significant differences amoung the 3 groups as regarding number of patients developed atelectasis after surgery although number of patients who developed atelectasis in NV group was greater than LTV group and CPAP group. Zhang et al 2021 [11] in his study found no statistically significant differences amoung the 3 groups as regarding number of patients developed atelectasis after surgery (P=0.09) although number of patients who developed atelectasis in HOV group was greater than LTV group and NoV group.

Administration of 100% oxygen during CPB may lead to absorption atelectasis and oxygen toxicity [12]. In a study by Piov et al 2000 [13]lung function improved later post-operatively in patients ventilated with 100% oxygen during CPB.

The current study founded no significant statistical differences between the examined groups as regard ICU stay /day, while hospital stay /day showed significant decrease in LTV group. On the other hand no differences in hospital mortality, early respiratory failure, ventilation support beyond day 2, or re-intubation were observed between the ventilating group and the control group (no ventilation) in the recently published MECANO research, which involved a sizable number of patients (n=1501) [14]. Zhang et al 2021 [11] found no significant difference in surgical site infection, ICU intubation time, ICU stay, hospital stay, and 30-d mortality among the three groups.

Also the current study found no significant statistical differences between groups as regarding time of cross clamp, cardiopulmonary bypass time and time needed to wean patient from CPB. The current study found no significant statistical differences between groups as regarding intraoperative complication, duration of surgery by hours and time needed to extubate patient after surgery. In agree with our study Padalino et al 2022 [10]study found that there were unable to identify any significant differences in lung inflammatory biomarkers, intubation time, or ICU stay.

Moreover, the current study found no statistically significant differences amoung the 3 groups as regarding hypoxic index during CPB or postoperatively in ICU. Hassan et al 2018 [15] in his study on 66 patients found that The application of alveolar recruitment strategy showed short term improvement in the arterial oxygenation and ventilation perfusion mismatch in patients undergoing CABG using CPB. Also Minkovich et al 2007. [4] who showed that application of VCM during and after CPB had an improvement effect on PaO2/FiO2 ratio extended three hours after CPB. Also Tschernko et al. 2002 [16] examined the application of repeated VCM three times before termination of CPB. However, the results of this study couldn't abolish the effect of shunting and hypoxemia after CPB. Also Claxton et al. 2003 [17] investigated the effect of alveolar recruitment strategy on patients undergoing CPB. They attained a significant improvement of oxygenation parameters up to one hour post CPB.

Conclusions

Use of different modes of ventilation during CPB such as low tidal volume ventilation or CPAP at pressure 5-10 mmHg can improve postoperative lung function by decrease incidence of postoperative atelectasis and improve oxygenation.

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Tables :

Table (1): Comparison between different ventilation strategies regarding demographic data and anthropometric measurements

Demographic data	LTV group (n=16)	CPAP group (n=16)	NV group (n=16)	Test of significance		
				P1	**P2**	**P3**
Age (Month) **Median (Min-Max)**	20 (10-72)	18 (10-72)	15 (10-60)	Z=0.58 p=0.56	Z=0.82 p=0.41	Z=0.25 p=0.81
Gender **Male** **Female**	10 (62.5%) 6 (37.5%)	8 (50%) 8 (50%)	8 (50%) 8 (50%)	χ^2 =0.51 P=0.48	χ^2 =0.51 P=0.48	χ^2 =0 P=1.0
Weight **Mean ± SD**	11.72±2.17	11.06±1.69	11.75±2.31	t=0.953 p=0.348	t=0.039 p=0.969	t=0.959 p=0.345
Height **Mean ± SD**	84.37±9.91	79.37±9.44	82.18±11.1	t=1.46 p=0.154	t=0.588 p=0.561	t=0.772 p=0.446
BSA **Mean ± SD**	0.524±0.07	0.494±0.06	0.517±0.08	t=1.21 p=0.237	t=0.262 p=0.795	t=0.828 p=0.414

P1: Comparison between LTV group and CPAP group, P2: Comparison between LTV group and NV group, P3: Comparison between CPAP group and NV group
Data are expressed as mean ± standard deviation or percentage (%) and number (n).

Table (2): Type of lesion among different ventilation strategies

Operations	**LTV group (n=16)**	**CPAP group (n=16)**	**NV group (n=16)**	**Test of significance**		
				P1	**P2**	**P3**
TOF	6 (37.5%)	6 (37.5%)	5 (31.2%)	P=0.865	P=0.688	P=1.0
VSD	2 (12.5%)	3 (18.8%)	4 (25.0%)			
ASD	2 (12.5%)	3 (18.8%)	4 (25.0%)			
DORV	2 (12.5%)	2 (12.5%)	1 (6.2%)			
D.TGA	2 (12.5%)	2 (12.5%)	2 (12.5%)			
VSD,MS	2 (12.5%)	0 (0%)	0 (0%)			

P1: Comparison between LTV group and CPAP group, P2: Comparison between LTV group and NV group, P3: Comparison between CPAP group and NV group
Data are expressed as percentage (%) and number (n).

Table (3): Frequency of atelectasis among different ventilation strategies

Variables	LTV group (n=16)	CPAP group (n=16)	NV group (n=16)	Test of significance		
				P1	P2	P3
Atelectasis **Yes** **No**	2 (12.5%) 14 (87.5%)	2 (12.5%) 14(87.5%)	7 (43.8%) 9 (56.2%)	FET P=1.0	FET P=0.11	FET P=0.11

FET: Fisher exact test
P1: Comparison between LTV group and CPAP group, P2: Comparison between LTV group and NV group, P3: Comparison between CPAP group and NV group
Data are expressed as percentage (%) and number (n).

Table (4): Comparison between different ventilation strategies regarding ICU& hospital stay

ICU& hospital stay	LTV group (n=16)	CPAP group (n=16)	NV group (n=16)	Test of significance		
				P1	P2	P3
ICU stay / d **Mean ± SD**	3.47±0.64	3.44±0.63	4.00±1.03	t=0.128 p=0.899	t=1.71 p=0.097	t=1.86 p=0.073
Hospital stay **Mean ± SD**	6.40±0.91	6.75±0.93	8.25±2.41	t=1.06 p=0.299	t=2.79 p=.009*	t=2.32 p=.027*

P1: Comparison between LTV group and CPAP group, P2: Comparison between LTV group and NV group, P3: Comparison between CPAP group and NV group
*significant p≤0.05
Data are expressed as mean ± standard deviation.

Table (5): Comparison between different ventilation strategies regarding cross clamp time, CPB time and weaning

Variables	LTV group (n=16)	CPAP group (n=16)	NV group (n=16)	Pvalue
Cross clamp time /min **Mean ± SD**	87.25±30.01	87.18±32.29	86.56±27.8	0.979
CPB time/min **Mean ± SD**	115.62±33.6	113.12±33.2	110.94±28.7	0.843
Weaning time/min **Mean ± SD**	28.37±5.12	25.94±3.75	24.37±3.59	0.179

*significant p≤0.05
- Data are expressed as mean ± standard deviation.

Table (6): Comparison between different ventilation strategies regarding intraoperative complication, duration of surgery by hours and time needed to extubate patient after surgery

Variables	LTV group (n=16)	CPAP group (n=16)	NV group (n=16)	Pvalue
Duration of surgery/ hrs	4.81±0.98	4.50±0.89	4.37±0.62	p=0.649
Total extubation time/hrs	18.60±6.02	16.00±6.15	17.56±6.98	p=0.247

*significant p≤0.05
Data are expressed as mean ± standard deviation or percentage (%) and number (n).

Table (7): Comparison between different ventilation strategies regarding to hypoxic index (PaO2/FiO2)

PaO2/FiO2:	LTV group (n=16)	CPAP group (n=16)	NV group (n=16)	P value
Base Line Mean ± SD	394.78+52.72	403.55+42.77	410.78+39.55	0.259
End of CPB Mean ± SD	330.55±70.92	360±52.64	355±64.02	0.337
15 mins after CPB Mean±SD	313.55±67.26	335.23±58.27	331.52±57.89	0.210
1st hr in ICU Mean±SD	404.34±57.17	395.05±46.08	364.29±15.54	0.375
2nd hr in ICU Mean±SD	451.77±47.90	453.41±58.72	415.38±66.51	0.380
4th hr in ICU Mean±SD	441.00±46.51	429.50±54.86	423.76±53.92	0.285

*significant p≤0.05
- Data are expressed as mean ± standard deviation.

This prospective, randomized, double blinded study was approved by institutional review board (code number MD.20.01.266).