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Effect of manual hyperinflation with versus without positive end-expiratory pressure on dynamic compliance in pediatric patients following congenital heart surgery

A randomized controlled trial

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Abstract

Background: We aimed to compare the effect of manual hyperinflation with versus without positive end-expiratory pressure (PEEP) on dynamic compliance of the respiratory system in pediatric patients undergoing congenital heart surgery; to assess the safety of the technique in this population.

Methods: This was a randomized controlled trial conducted at the pediatric intensive care unit (PICU) of a tertiary-care hospital. Patients admitted to the PICU following cardiac surgery and receiving postoperative mechanical ventilation were randomized to the experimental or control group. Patients in the experimental group (n = 14) underwent manual hyperinflation with a PEEP valve set at 5 cm H_2O, once daily, during the first 48 hours after surgery. Patients allocated to the control group (n = 16) underwent manual hyperinflation without PEEP, at the same time points. Lung mechanics was assessed before (T0) and 5 minutes (T5) after manual hyperinflation. The primary endpoint was dynamic compliance. Secondary outcomes included oxygen saturation index, duration of mechanical ventilation, length of stay, 28-day mortality and safety.

Results: Demographic and clinical characteristics were comparable in both groups. There was no significant difference in dynamic compliance between times in each group (Day 1: (mean) 0.78 vs 0.81 and 0.70 vs 0.77; Day 2: 0.85 vs 0.78 and 0.67 vs 0.68 mL/kg/cm H_2O, in experimental and control groups, respectively; $P > .05$). Mean deltas of dynamic compliance were not significantly different between groups. The proportion of patients extubated <72 hours after surgery was similar in experimental and control groups (43% vs 50%, respectively; $P = .73$). Oxygen saturation index, length of stay, and 28-day mortality were not significantly different between groups. None of the patients had hemodynamic instability.

Conclusions: Manual hyperinflation was safe and well tolerated in pediatric patients following surgery for congenital heart disease. No significant change in dynamic compliance of the respiratory system or in oxygenation was observed with the use of manual hyperinflation with or without PEEP in this population.

Abbreviations: FiO_2 = fraction of inspired oxygen, PEEP = positive end-expiratory pressure, PICU = pediatric intensive care unit, SpO_2 = oxygen saturation measured by pulse oximetry, STAT = the Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery score, T = time.

Keywords: congenital heart disease, dynamic compliance, physiotherapy, positive pressure ventilation, postoperative

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The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

This study was approved by the Research Ethics Board of Hospital das Clínicas, Ribeirão Preto Medical School, University of São Paulo (#19390819.0.0000.5440) and written informed consent was obtained from the patients' parents.

Clinical Trial Registration Number: ReBEC #RBR-5c2qxsr

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1. Introduction

Congenital heart diseases cause changes in the structure of the heart that result in modified cardiac performance. Approximately 25% of infants with congenital heart malformations have a critical disease, which usually requires surgery within the first year of life.[1] Postoperative respiratory complications are mainly caused by decreased lung compliance resulting from sternotomy, anesthesia, cardiopulmonary bypass and mechanical ventilation with low tidal volumes and low values of positive end-expiratory pressure (PEEP).[2]

In the critical care setting, physiotherapy is important for promoting airway permeability and lung re-expansion in patients on mechanical ventilation. Several techniques have been used to promote airway clearance, including patient positioning, chest wall compression/vibration and manual hyperinflation followed by aspiration of oropharyngeal and endotracheal secretions.[3]

Manual hyperinflation has been used for more than 50 years, with the goals of mobilizing excess airway secretions and re-expanding collapsed lung areas.[4] This technique involves a slow and deep inspiration, followed by an inspiratory pause and a rapid release of pressure, which produces a high expiratory flow. As a result, it contributes to oxygenation improvement.[4,5] Manual hyperinflation can also be performed using a PEEP valve to minimize the deleterious effects caused by disconnection of the patient from the ventilator.[6]

A systematic review that included 6 studies with pediatric patients receiving invasive mechanical ventilation mainly for respiratory failure concluded that the use of the expiratory flow increase technique and chest physiotherapy, especially manual hyperinflation and vibrations, were useful for secretion clearance.[3] Also, a study that evaluated the effects of manual hyperinflation in preterm newborns under mechanical ventilation showed increased lung volumes after manual hyperinflation with and without the PEEP valve.[6] A previous study in adults showed that the use of manual hyperinflation associated with a PEEP valve provided benefits in increasing lung volumes and static compliance in the postoperative period of myocardial revascularization surgery.[7] However, there are no data in the pediatric population after surgery for congenital heart disease. Thus, the objective of this study was to compare the effect of manual hyperinflation with versus without a PEEP valve on dynamic compliance of the respiratory system in pediatric patients undergoing surgery for congenital heart disease. We also aimed to evaluate the safety of the technique, by the occurrence of hemodynamic instability associated with manual hyperinflation in this population.

2. Methods

This was a prospective, randomized, controlled, open trial conducted in the pediatric intensive care unit (PICU) of Hospital das Clínicas of Ribeirão Preto Medical School, University of São Paulo, Brazil, from November 2019 to November 2021. The study was approved by the Institutional Research Ethics Board (#19390819.0.0000.5440) and written informed consent was obtained from the patients' parents. The study was registered at the Brazilian Registry of Clinical Trials (http://www.ensaiosclinicos.gov.br/) under the number RBR-5c2qxsr. All children aged 0 to 18 years with congenital heart disease consecutively admitted to the PICU after cardiac surgery over the study period and receiving mechanical ventilation postoperatively were eligible for the study. Exclusion criteria were preoperative mechanical ventilation, rib cage abnormality such as scoliosis or open chest, postoperative hemodynamic instability, chest radiograph showing a pneumothorax and refusal to participate.

Patients were evaluated by the physiotherapist and the attending physician, and after obtaining the signed informed consent form, those considered eligible for the study were randomized to the experimental group or the control group by means of a list generated by a computerized system that uses a random number generator to produce customized sets of random numbers (www.randomizer.org). Patients allocated to the experimental group underwent manual hyperinflation with a PEEP valve set at 5 cm H_2O, once a day, during the first 48 hours after surgery. Patients allocated to the control group underwent manual hyperinflation without PEEP, once a day, during the first 48 postoperative hours. Usually, the initial ventilator settings for patients on mechanical ventilation following cardiac surgery in our institution are: assist-control mode/pressure-controlled, with peak inspiratory pressure of 10 to 14 cm H_2O (resulting in an exhaled tidal volume of 6 to 8 mL/kg) and PEEP of 5 to 7 cm H_2O.

A highly skilled physiotherapist specialized in pediatric respiratory physiotherapy with a master degree in science and a 12-year experience working in the PICU (THS) performed manual hyperinflation as previously described.[4] The technique consists of applying high tidal volumes, using a slow inspiratory flow through slow compression of a self-inflating bag connected to oxygen flow at 8 L/min, followed by an inspiratory pause of 2 to 3 seconds to distribute the inflated air to the lungs and, finally, a fast decompression of the manual resuscitator bag to promote a high peak expiratory flow. The maneuver was repeated 6 consecutive times and had a duration of 2 to 3 minutes. Subsequently, suctioning of the tracheal tube and upper airways was performed for an average of 3 times, as there is displacement of secretions with the technique.

Lung mechanics was assessed before (T0) and 5 minutes (T5) after manual hyperinflation in both groups. Dynamic compliance of the respiratory system was calculated as tidal volume/ peak inspiratory pressure—PEEP. Oxygen saturation index was calculated as mean airway pressure × FiO_2 × 100/SpO_2, where FiO_2 indicates fraction of inspired oxygen and SpO_2 indicates oxygen saturation measured by pulse oximetry.[8] Hemodynamic variables, including systemic arterial pressure and heart rate, were also recorded before and 5 minutes after manual hyperinflation in control and experimental groups. The criteria for interrupting the procedure were any changes in hemodynamic variables (bradycardia and/or hypotension), drop in SpO_2 >10 points and signs of respiratory distress (tachypnea, chest retractions, nasal flaring) or pneumothorax. All patients were given a bolus dose of fentanyl (1–2 mcg/kg) and midazolam (0.1–0.2 mg/kg) prior to manual hyperinflation. During ICU stay, all patients remained in the supine position, with the head of the bed elevated to 30 degrees, at all times.

Demographic and clinical data were collected from patients' health records. Chest radiographs alterations including atelectasis and increased pulmonary blood flow were recorded. An adapted inotropic score was calculated as: doses of dopamine + dobutamine + milrinone × 10 + epinephrine × 100 + norepinephrine × 100.[9] The complexity of the surgical procedure was stratified according to the Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery score.[10] Disease severity was assessed by Pediatric Risk of Mortality between 8 and 24 hours after PICU admission.[11] Organ dysfunction was assessed by Pediatric Logistic Organ Dysfunction score.[12] Patients were followed up to postoperative day 28, hospital discharge or death, whichever occurred first.

The primary endpoint was dynamic compliance of the respiratory system. Secondary outcomes were oxygen saturation index, duration of mechanical ventilation (categorized as > or < than 72 hours post-operatively), PICU length of stay, hospital length of stay, 28-day mortality, and safety.

2.1. Statistical analysis

Analysis was made using SAS 9.4 software (SAS institute, Cary, NC). Data were expressed as median (range), mean (standard deviation) or number (%). The sample size calculation was based on a previously published study with pediatric patients after cardiac surgery.[13] Considering a mean dynamic compliance of 0.67 mL/kg/cm H_2O with zero PEEP (control group) and an increase of 20% after manual hyperinflation with PEEP of 5 cm H_2O (experimental group), and a standard deviation of 0.12, $\alpha = 5\%$ and $\beta = 10\%$, a sample size of 15 patients per group was obtained. Continuous variables between groups were compared by Mann–Whitney *U* test and categorical variables, by Fisher exact test. Mean values of dynamic compliance, oxygen saturation index, heart rate and mean arterial pressure between times in each group were compared by a linear mixed effects model. Mean values of differences (T5-T0) in dynamic compliance, oxygen saturation index, heart rate and mean arterial pressure between groups were compared by a linear regression model. Kaplan–Meier curves were constructed and log-rank test or proportional risk Cox model were used to compare duration of mechanical ventilation, PICU length of stay and hospital length of stay between groups. A 5% significance level was considered.

3. Results

From November 2019 to November 2021, 72 patients with congenital heart disease were admitted to the PICU of Hospital das Clínicas of Ribeirão Preto Medical School, University of São Paulo, following cardiac surgery; 30 patients were included in the study. Participants were randomly assigned to the control group (n = 16) or the experimental group (n = 14). Forty-two patients were excluded for the following reasons: extubation in the operating room or during the immediate post-operative period (n = 35) and severe hemodynamic instability (n = 7). Figure 1 shows the flow diagram of the study. All patients from both groups underwent manual hyperinflation followed by endotracheal suctioning on the first post-operative day. Seven patients from the experimental group and 10 patients from the control group underwent the maneuver on the second post-operative day, because 13 patients (7 from the experimental group and 6 from the control group) were extubated before 48 hours following surgery.

Baseline demographic and clinical characteristics were comparable in both groups, which shows that the groups were homogeneous and patients were adequately randomized (Table 1). Most patients were younger than 1 year in both groups (11 (79%) vs 12 (75%) in the experimental group and in the control group, respectively; *P* = 1). One patient (7%) in the experimental group and 5 patients (31%) in the control group had Down syndrome (*P* = .17). Chest X-ray showed atelectasis in 4 patients (29%) in the experimental group and 1 patient (6%) in the control group (*P* = .16), and increased pulmonary blood flow was observed in 6 patients (43%) in the experimental group and 8 patients (50%) in the control group (*P* = .73).

The results of the linear mixed effects model did not show significant differences in mean values of dynamic compliance, oxygen saturation index, heart rate and mean arterial pressure between times in each group (Table 2). Furthermore, the linear regression model did not show significant differences in mean values of deltas (T5-T0) of dynamic compliance, oxygen saturation index, heart rate and mean arterial pressure between groups (Table 3).

The proportion of patients extubated <72 hours after surgery was similar in both groups (43% in the experimental group vs 50% in the control group; *P* = .73).

Analysis by Kaplan–Meier curves are shown in Figures 2, 3, and 4. There was no significant difference between groups in duration of mechanical ventilation, length of ICU stay and length of hospital stay. Moreover, 28 day-mortality was comparable in both groups (2/14 (14.3%) in the experimental group vs 3/16 (18.8%) in the control group; *P* = 1).

4. Discussion

In the present study, no significant changes in dynamic compliance or in oxygen saturation index were observed with manual hyperinflation with or without PEEP. In addition, there was

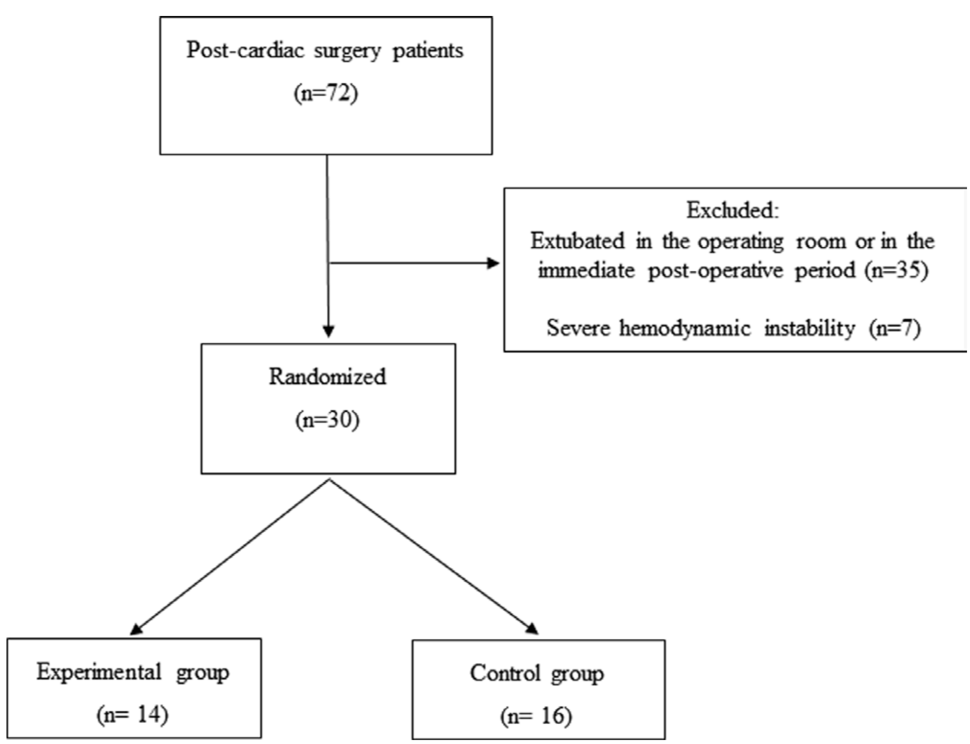

Figure 1. Flow diagram of the study.

no significant difference between groups in deltas of dynamic compliance between times (T5-T0) over the study. The proportion of patients who were extubated <72 hours after surgery was similar in both groups and no significant differences were observed between groups in duration of mechanical ventilation, length of ICU stay or length of hospital stay. Moreover, 28-day mortality was not significantly different in both groups. Manual hyperinflation with or without the use of a PEEP valve was safe and well tolerated as hemodynamic instability was not observed in any group.

Studies evaluating the manual hyperinflation technique in the pediatric population are scarce.[14] A prospective study with pediatric patients following surgery for congenital heart disease showed a significant increase in dynamic compliance and in PaO_2/FiO_2 ratio with the use of an alveolar recruitment maneuver associated with PEEP of 8 cm H_2O compared to mechanical ventilation with 0 cm H_2O PEEP or 8 cm H_2O PEEP without the alveolar recruitment maneuver, which consisted of 5 consecutive mechanical breaths with peak airway pressure of 40 cm H_2O, PEEP of 8 cm H_2O and inspiration/expiration ratio of 1:1.[13] In addition, a study with pediatric patients with congenital heart disease who had upper lobe atelectasis after surgery showed a significant improvement in arterial oxygenation and resolution of alveolar collapse after manual hyperinflation performed with 4 sets of 8 bag compressions, with pressure of approximately 40 cm H_2O and inflation rate of 10 breaths per minute, with a PEEP valve in the circuit for patients who were treated with PEEP during mechanical ventilation.[15]

In adults with ventilator-associated pneumonia, there was a 22% increase in static compliance and a 21% decrease in airway resistance up to 30 minutes after manual hyperinflation associated with endotracheal suctioning, but there was no change in respiratory mechanics with endotracheal suction only.[16] Although in our study endotracheal tube suctioning was performed after manual hyperinflation in both groups, we did not observe a significant change in dynamic compliance after manual hyperinflation with or without the use of a PEEP valve. It should be pointed out that the necessity to disconnect the patient from the mechanical ventilator and the high expiratory flow may promote lung de-recruitment, despite the additional PEEP. This could explain the lack of efficacy of the maneuver. However, there is evidence of short-term improvements in lung compliance and oxygenation with the use of manual hyperinflation with a PEEP valve in adults[17] and children.[15]

There is evidence of changes in dynamic compliance related to the type of heart disease and the use and duration of cardiopulmonary bypass. A decrease in total respiratory resistance after surgery that corrected excessive pulmonary blood flow and a reduction in dynamic compliance in infants with heart defect associated with decreased pulmonary blood flow were observed following surgery with cardiopulmonary bypass.[18] However, in our study, there was no significant difference in the proportion of patients undergoing cardiopulmonary bypass, in cardiopulmonary bypass time or in daily fluid balance between the groups.

Another factor that can reduce lung compliance is bed positioning, as observed in a study with anesthetized infants undergoing surgery to correct congenital clubfoot. The study evaluated lung mechanics sequentially in the supine and prone position, using a pulmonary function monitor, which showed significantly lower values of static and dynamic compliance in the prone position compared to the supine position.[19] However, in the present study, all patients remained in the supine position during surgery and postoperatively, throughout the study.

An experimental study carried out with healthy animals found deleterious hemodynamic effects of manual hyperinflation,

Table 1

Demographic and clinical characteristics of study groups.

Characteristics	Experimental group (n = 14)	Control group (n = 16)	*P*
Age (d)	204 (16–2585)	135 (1–5189)	.92
Male gender	11 (78.5)	9 (56)	.26
Weight (kg)	5.2 (2.5–23)	5.5 (3.15–57.9)	.82
Length/height (cm)	61.8 (44–119)	60 (49–170)	.79
STAT	2 (1–4)	2 (1–4)	.47
PRISM	10 (2–16)	11 (6–21)	.19
PELOD	11 (1–22)	11 (1–22)	.90
Use of cardiopulmonary bypass	13 (93)	12 (75)	.33
Cardiopulmonary bypass time (min)	80 (35–220)	107 (45–275)	.42
Aortic cross clamp time (min)	53 (19–126)	55 (20–137)	.81
Previous surgery	2 (14)	4 (25)	.66
Inotropic score at PICU admission	10 (0–70)	12 (0–55)	.47
Fluid balance on Day 1 (mL/kg)	14 (−23 to 52)	7 (−44 to 40)	.18
Fluid balance on Day 2 (mL/kg)	4 (−41 to 62)	−3 (−33 to 47)	1

Data are expressed as median (range) or n (%).

STAT = the Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery score, PRISM = Pediatric Risk of Mortality, PELOD = Paediatric Logistic Organ Dysfunction, PICU = pediatric intensive care unit.

Table 2

Comparisons of mean values of dynamic compliance (mL/kg/cm H_2O), oxygen saturation index, heart rate (bpm) and mean arterial pressure (mm Hg) between times in each group by the linear mixed effects model.

		Day 1					Day 2				
Variable	Group	Mean T0 (SD)	Mean T5 (SD)	Difference between means (T5-T0)	95% CI	*P*	Mean T0 (SD)	Mean T5 (SD)	Difference between means (T5-T0)	95% CI	*P*
Dynamic compliance	E	0.78 (0.27)	0.81 (0.21)	0.03	−0.07 to 0.12	.60	0.85 (0.42)	0.78 (0.29)	−0.07	−0.19 to 0.06	.29
	C	0.70 (0.24)	0.77 (0.29)	0.07	−0.02 to 0.17	.11	0.67 (0.12)	0.68 (0.15)	0.01	−0.09 to 0.13	.75
Oxygen saturation index	E	4.84 (3.08)	4.81 (2.87)	−0.03	−0.71 to 0.64	.92	5.53 (3.67)	5.43 (3.50)	−0.10	−0.80 to 0.60	.77
	C	5.74 (3.40)	5.60 (3.12)	−0.15	−0.77 to 0.48	.63	4.94 (2.74)	4.81 (2.82)	−0.13	−0.72 to 0.46	.64
Heart rate	E	138.7 (19)	139.5 (20)	0.79	−4.31 to 5.88	.75	138.3 (16)	137.7 (17)	−0.57	−7.15 to 6.01	.86
	C	132.5 (26)	131.9 (29)	−0.56	−5.33 to 4.20	.81	139.5 (23)	142.3 (15)	2.80	−2.70 to 8.30	.30
Mean arterial pressure	E	52.4 (6.2)	54.1 (10.2)	1.79	2.70 to 6.27	.42	65.4 (10.3)	64.3 (17.4)	−1.14	−9.22 to 6.93	.76
	C	59.7 (13.1)	56.6 (13.6)	−3.06	−7.26 to 1.14	.15	57.1 (10.7)	60.5 (10.7)	3.40	−3.36 to 10.16	.30

C = control, CI = confidence interval, E = experimental, SD = standard deviation, T0 = before manual hyperinflation, T5 = 5 minutes after manual hyperinflation.

Table 3

Comparisons of mean values of deltas (T5-T0) of dynamic compliance (mL/kg/cm H_2O), oxygen saturation index, heart rate (bpm) and mean arterial pressure (mm Hg) between the experimental and the control group by the linear regression model.

		Day 1				Day 2			
Variable	Group	Mean of deltas (SD)	Difference between means (E-C)	95% CI	*P*	Mean of deltas (SD)	Difference between means (E-C)	95% CI	*P*
Dynamic compliance	E	0.03 (0.20)	−0.04	−0.19 to 0.09	.50	−0.07 (0.21)	−0.08	−0.24 to 0.08	.33
	C	0.07 (0.16)				0.01 (0.10)			
Oxygen saturation index	E	−0.03 (1.21)	0.11	−0.80 to 1.03	.80	−0.10 (1.11)	0.03	−0.88 to 0.94	.94
	C	−0.15 (1.24)				−0.13 (0.67)			
Heart rate	E	0.79 (6.66)	1.34	−5.63 to 8.32	.69	−0.57 (2.70)	−3.37	−11.95 to 5.21	.42
	C	−0.56 (11.11)				2.80 (10.32)			
Mean arterial pressure	E	1.79 (7.18)	4.84	−7.26 to 1.13	.14	−1.14 (10.06)	−4.54	−15.07 to 5.98	.37
	C	−3.06 (8.99)				3.40 (10.00)			

C = control, CI = confidence interval, E = experimental, SD = standard deviation.

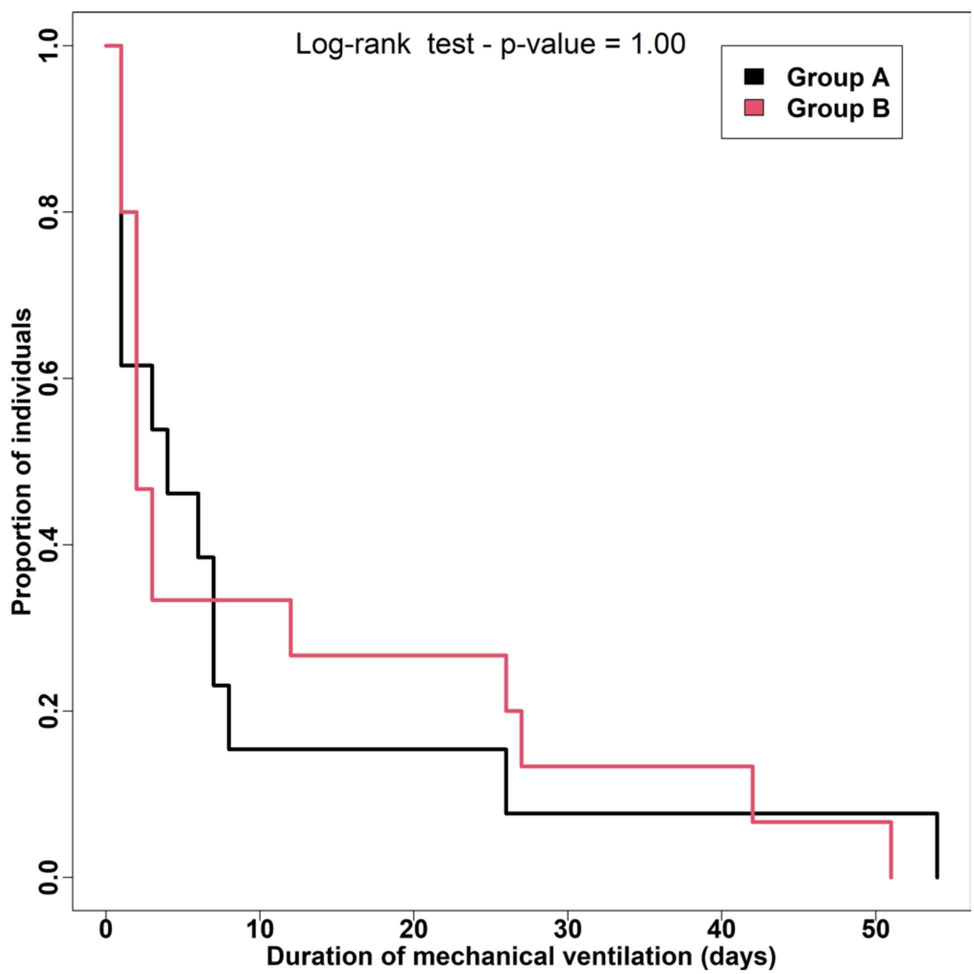

Figure 2. Duration of mechanical ventilation in the experimental group (A) and in the control group (B).

including reduced cardiac output related to the application of positive pressure during the maneuver.[20] In addition, a previous study with ventilated patients showed an increase in diastolic blood pressure and in systemic vascular resistance sustained for 20 minutes after manual hyperinflation.[21] However, among the patients who participated in our study, no significant changes were observed in hemodynamic variables after manual hyperinflation in any group.

A randomized controlled study in adults undergoing mechanical ventilation showed that the manual hyperinflation technique combined with expiratory chest compressions was associated with a higher weaning success rate and a shorter ICU length of stay.[22] In contrast, in our study, the proportion of patients who were extubated within 72 hours, duration of mechanical ventilation and length of ICU stay were not significantly different between the groups.

Although large variations in delivered tidal volumes and peak airway pressures during manual hyperinflation have been reported depending on the health professional who performed it (nurses vs physiotherapists), a good intra-physiotherapist consistency has been observed for the application of manual hyperinflation.[23,24] Indeed, in our study,

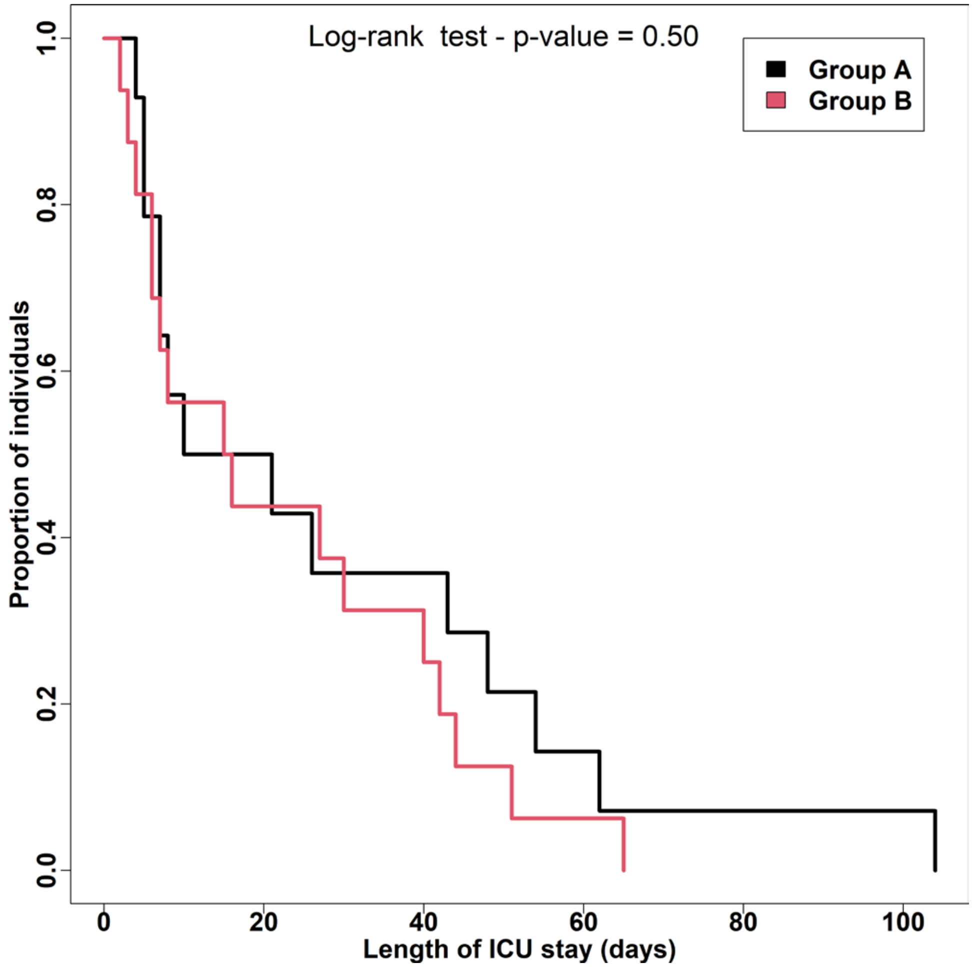

Figure 3. Length of ICU stay in the experimental group (A) and in the control group (B).

the maneuver was performed by a single highly skilled physiotherapist.

The strength of this study is that it is the first randomized controlled clinical trial of pediatric patients undergoing surgery for congenital heart disease to assess the effect of manual hyperinflation associated or not with the use of a PEEP valve on respiratory mechanics and patients' outcomes. Additionally, this study showed that there was no hemodynamic instability after manual hyperinflation, which indicates that the technique is safe in the pediatric population following surgery for congenital heart disease. The main limitation of this study is a relatively small sample size. As the sample size calculation for this study considered a 20% difference in dynamic compliance between the groups, a larger sample size would be required to detect smaller differences. However, because the confidence intervals of the mean deltas (T5-T0) of dynamic compliance (mL/kg/cm H_2O) are narrow, it is possible that a larger sample size would not result in significant differences between the groups. In addition, we did not measure the tidal volume delivered during manual hyperinflation. Usually, the technique provides a tidal volume 50% greater than the delivered by the ventilator.[23] In conclusion, manual hyperinflation was safe and well tolerated in pediatric patients following surgery for congenital heart disease. Hemodynamic instability did not occur in any patient. No significant change in dynamic compliance of the respiratory system or in oxygenation was observed with the use of manual hyperinflation with or without PEEP in this population.

Author contributions

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Writing—review & editing: Jéssica Câmara Guimarães, Thalis Henrique da Silva, Davi Casale Aragon, Cintia Johnston, Ada Clarice Gastaldi, Ana Paula de Carvalho Panzeri Carlotti.

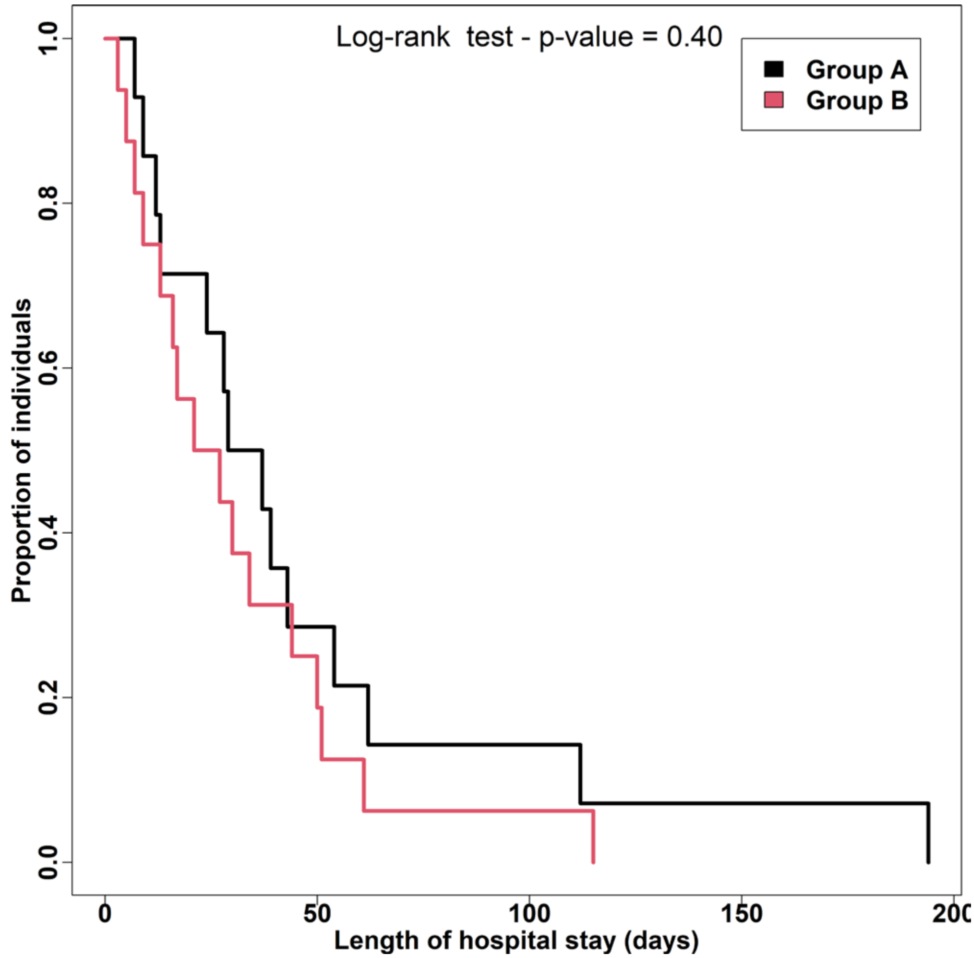

Figure 4. Length of hospital stay in the experimental group (A) and in the control group (B).

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