

Preoperative physiotherapy in prevention of pulmonary complications in pediatric cardiac surgery

Fisioterapia pré-operatória na prevenção das complicações pulmonares em cirurgia cardíaca pediátrica

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Abstract

Objective: To evaluate the occurrence and risk of pulmonary complications in children who underwent pre- and postoperative physiotherapeutic intervention in cardiac surgeries, as well as to compare these patients to those who underwent only postoperative physiotherapeutic intervention.

Methods: A randomized clinical trial was performed with 135 patients from 6 years of age and younger with congenital heart disease who had undergone cardiac surgery. Patients were randomly assigned to the intervention group (G1) in which they underwent pre- and postoperative physiotherapy, or to the control group (G2) in which they underwent only postoperative physiotherapy. Mann-Whitney and the Chi-square tests were used to compare the variables between the groups. The magnitude of the absolute risk was calculated by the number of patients needing treatment. Statistical significance was set at 5% ($p < 0.05$).

Results: 17 patients (25%) in G1, and 29 patients (43.3%) in G2 presented pulmonary complications ($p = 0.025$). Pneumonia was the most frequent complication, and among the 17 patients in G1, seven (10.3%) developed pneumonia, six (8.8%) developed atelectasis, and four (5.9%) presented complications due to both complications. In G2, 13 patients (19.4%) developed pneumonia, eight (11.9%) developed atelectasis, and eight (11.9%) developed pneumonia associated with atelectasis. Absolute risk reduction for the

primary outcome was of 18.3% and the number of necessary treatments was 5.5.

Conclusion: Preoperative respiratory physiotherapy significantly reduced the risk of pulmonary complications in postoperative pediatric cardiac surgery.

Descriptors: Physical therapy modalities. Cardiac surgical procedures. Child.

Resumo

Objetivo: Avaliar a incidência e o risco de complicações pulmonares em crianças submetidas a intervenção fisioterapêutica pré e pós-operatória nas cirurgias cardíacas, bem como comparar com aquelas submetidas apenas a intervenção fisioterapêutica pós-operatória.

Métodos: Ensaio clínico aleatório, que incluiu 135 pacientes de zero a 6 anos com cardiopatias congênitas, submetidos à cirurgia cardíaca. Os pacientes foram aleatorizados para grupo intervenção (G1), que realizou fisioterapia pré e pós-operatória, ou para grupo controle (G2), somente fisioterapia pós-operatória. Para comparar as variáveis entre os grupos foi utilizado o teste de Mann-Whitney e o Qui quadrado. Foi calculado o risco absoluto e sua magnitude por meio do número necessário para tratar. A significância estatística foi estipulada em 5% ($P < 0,05$).

Resultados: No G1, 17 (25%) pacientes tiveram complicação pulmonar e, no G2, foram 29 (43,3%) ($p = 0,025$).

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A complicação mais frequente foi pneumonia e, dos 17 pacientes do G1 que complicaram, sete (10,3%) desenvolveram pneumonia, seis (8,8%) atelectasia e quatro (5,9%) associação das duas. No G2, 13 (19,4%) pacientes tiveram pneumonia, oito (11,9%), atelectasia, e oito (11,9%), pneumonia associada à atelectasia. A redução do risco absoluto para o desfecho primário foi de 18,3% e o número necessário para tratar foi calculado em 5,5.

Conclusão: A fisioterapia respiratória pré-operatória reduziu significativamente o risco de desenvolvimento de complicações pulmonares no pós-operatório de cirurgia cardíaca pediátrica.

Descritores: Modalidades de fisioterapia. Procedimentos cirúrgicos cardíacos. Criança. Ensaio Clínico Controlado Aleatório.

INTRODUCTION

In general, the incidence of congenital heart diseases is 8 out of every 1000 live births [1]. In most cases, surgical treatment is needed, with total or palliative correction.

Heart surgery was first outlined for just over six decades ago, and since then, the progress has been vertiginous. The first heart surgery was successfully performed in 1938 by Dr. Robert E. Gross to correct persistent ductus arteriosus. The first correction of an intracardiac defect was performed in 1952 by Dr. F. John Lewis in a patient with interatrial communication. In 1951, cardiopulmonary bypass was used for the first time in humans [2].

Pulmonary complications are the most common causes of morbidity and mortality in heart surgery. Its incidence has a wide range of 6% to 76% [3]. There are reports from the 50's from both physiotherapists [4,5] and the surgeons [6] about the important role of pre- and postoperative physiotherapy to avoid complications.

In Brazil, innovative service in pre- and postoperative physiotherapy specifically for heart surgery was established in Curitiba in 1973 [7]. Preoperative intervention in adults showed satisfactory results in the prevention of respiratory complications [8,9]; however, these publications are rare for cases with children.

The aim of this study is to evaluate the effectiveness of preoperative physiotherapy combined with postoperative physiotherapy to reduce pulmonary complications in pediatric heart surgeries.

METHODS

Out of the 153 one-day-old to six-year-old patients with congenital heart disease who underwent heart surgery at Hospital Infantil Sagrada Família in Londrina, Paraná from January 2004 to February 2006, 141 patients were randomized to receive either preoperative physiotherapy associated with postoperative physiotherapy (group 1; n = 71) or only postoperative physiotherapy (group 2; n = 70). One hundred and thirty-five patients completed the study. The exclusion criteria were: patients with respiratory infection or

atelectasis immediately prior to the surgery, and patients who died during the surgical procedure or in the immediate postoperative period (48 hours). The study was approved by the Committee on Bioethics of the aforementioned institution and Informed Consent was signed by those responsible. The study was carried out in accordance with the Consort-Statement norms [10].

Sample size calculation

The calculation was estimated by considering the possibility of a 20% reduction in pulmonary complications in favor of the intervention group compared with the control group. To achieve this, we considered the Type I error (alpha) of 5% and test power of 80% [11]. The estimated total number of participants for each group was 59. 10% were added to this total, due to possible losses; thus, the total was 65 participants per group.

Randomization

The randomization was done in two steps: by first generating numbers (using a table of random numbers) and by then concealing the patients' assignments using opaque sealed envelopes. After signing an Informed Consent, an envelope was opened by an independent professional who declared in which group the patient would be included (I or II). Group I received pre- and postoperative physiotherapy (intervention) and group II received only postoperative physiotherapy (control).

Procedures

After randomization and evaluation, the patients included in Group I underwent at least two sessions of preoperative physiotherapy, including clearance and re-expansive techniques, abdominal support, and guidance for the parents or adult patients.

In the postoperative period, the patients were re-evaluated and the procedure was the same in both groups, emphasizing airway clearance, pulmonary re-expansion and early mobilization. The following techniques were performed: positioning or postural drainage, mobilization, manual hyperinflation, percussion, vibration, drainage,

coughing, breathing and limb exercises [12.13]. The guidance for parents and adult patients was about the importance of physiotherapy in pre- and postoperative period, as well as the purpose of physiotherapy.

The team of physiotherapists, the surgeon, and medical team who followed the patients in the postoperative period did not know who of them had undergone pre-operative physiotherapy. The evaluation of the primary clinical outcomes was hidden from the researcher.

Clinical outcomes

The primary clinical variable was the presence or absence of pulmonary complications (pneumonia and atelectasis). The diagnosis of pneumonia and atelectasis was performed by a physician and confirmed by two other medical officials using radiological and clinical criteria according to established by the Centers for Disease Control and Prevention (CDC) [14].

The secondary variables were: time on mechanical ventilation, time of stay in the ICU, total time of hospital stay, duration of surgery, time of cardiopulmonary bypass (CPB), time of aortic clamping (AC) and other complications (breathing - except pneumonia and atelectasis -, sepsis and surgical site infection).

Statistical analysis

The numerical variables are presented as median and quartiles (25-75). To evaluate the association between the primary variables (pulmonary complications) and categorical variables, Fisher’s exact test or the chi-square test analysis was performed (with or without Yates’s correction). To compare the numerical variables between the groups, the Mann-Whitney test was used. In order to determine whether there was a difference in reducing the risk of developing pulmonary complications between the groups, the absolute risk reduction and its magnitude was calculated by the number needed to treat (NNT) with confidence interval of 95%. All tests were performed using the intent-to-treat principle via the SPSS software (version 11.5). The statistical significance was set at 5% ($p < 0.05$).

RESULTS

153 patients were admitted for heart surgery from January 2004 to February 2006. 135 completed the study (68 in the intervention group (G1) and 67 in the control group (G2)). Figure 1 shows the progression algorithm of patients during the clinical trial.

The two groups were similar in gender, heart disease, associated diseases and pulmonary flow. The data are presented in Table 1. In both groups, the most frequent heart diseases were acyanotic with shunt.

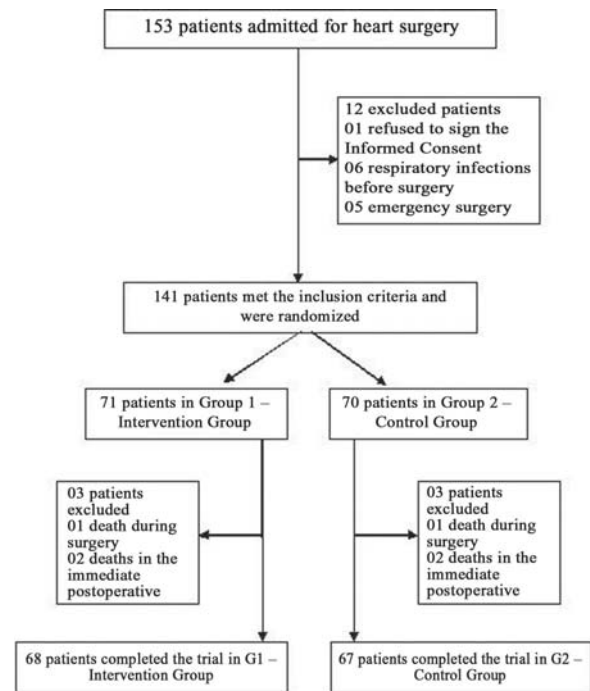


Fig. 1 – Algorithm of progression of patients during the clinical trial

Table 1. Sample characteristics

	G1 n=68	G2 n=67	P
Age (Md; 1° e 3°q) in months	4; 1 e 16	6; 0.7 e 28	0.867
Gender (n; %)			
Male	36 (52.9)	37 (55.2)	0.790
Female	32 (47.1)	30 (44.8)	
Diagnosis (n; %)			
Acyanotic with shunts	40 (58.8)	30 (44.8)	0.426
Acyanotic without shunts	8 (11.8)	12 (17.9)	
Cyanotic	17 (25)	21 (31.3)	
Complex	3 (4.4)	4 (6)	
Type of surgery			
Palliative	6 (8.8)	9 (13.4)	0.357
Septoplasty	26 (38.2)	20 (29.8)	
Ligature of ductus arteriosus	10 (14.7)	6 (9)	
Coartectomy	4 (5.9)	8 (11.9)	
Jatene’s surgery	3 (4.4)	5 (7.5)	
Total correction of Tetralogy of Fallot			
Fallot	5 (7.4)	6 (9)	
Glenn surgery	0	3 (4.5)	
Fontan surgery	1 (1.5)	2 (3)	
Others	13 (19.1)	8 (11.9)	

Most patients did not present associated diseases: 41 (60.3%) in G1 and 46 (68.7%) in G2. Pulmonary hypertension was the most frequent association, presenting in 11 patients (16.2%) in G1 and 11 (16.4%) in G2. Other associated diseases were Trisomy 21, genetic syndromes, other associated

malformations and pericardial effusion, with no statistical difference between the groups. One patient underwent pneumectomy in a previous surgery. As for pulmonary flow, most of patients showed pulmonary hyperflow: 43 (63.2%) in G1 and 31 (46.2%) in G2, followed by pulmonary hypoflow for 17 (25%) in G1 and 20 (29.9%) in G2. In smaller numbers, pulmonary normal flow was observed in eight patients (11.8%) and 16 (23.9%) patients in G1 and G2, respectively.

Regarding the surgical data, there was no statistical significance between groups. The time of surgery was similar between the two groups. G1 presented a median of 142.5 minutes and first and third quartiles (93.7 and 193.7, respectively) and G2 had a median of 140 minutes with first and third quartiles (100 and 240, respectively).

In the most of patients, cardiopulmonary bypass during surgery was used: 52 (76.5%) in G1 and 47 (70.1%) in G2. The two groups presented similar time of cardiopulmonary bypass: a median of 41 minutes (21.5-69.7) in G1 and (0-90) in G2. Aortic clamping was also used in most of the patients: 52 (76.5%) in G1 and 45 (67.2%) in G2. The most used surgical approach was median sternotomy: 54 patients (79.4%) and 49 (73.1%) in G1 and G2, respectively.

There was no statistically significant difference between groups in terms of the time of mechanical ventilation, stay in ICU and in hospital. The G1 presented a median of 35.8 (7-204) hours of mechanical ventilation and G2 of 36 (8-288) hours. The median time of total stay and ICU stay was 13.5 days (7-27.7 days) and 6 days (3-13.7 days) in G1 and 14 days (8-44 days) and 6 days (3-17 days) in G2.

The median number of preoperative sessions for the patients in G1 was 2 (2-4). The median number of postoperative sessions was 13 (8-24) in G1, and 17 (8-44) in G2.

Pulmonary complications were significantly more frequent in G2 (Table 2). The absolute risk reduction for the primary outcome was 18.3%, 95% CI [2.58, 33.99] and the NNT was 5.5, 95% CI [2.94; 38.8].

The difference in incidence of other complications was also statistically significant and is shown in Table 3.

The distribution of patients with pulmonary complications (pneumonia and atelectasis) by type of heart disease showed no statistically significant difference.

When we consider the presence of pulmonary complications associated with other complications related to the time of hospital stay, the patients from G1 presented a lower risk of developing such complications, and, when this occurred, the time of hospital stay was lower than in the control group. In G1, only 23 (33.8%) of patients presented pulmonary complications associated with other complications, and in G2, there were 43 patients (64.2%), with a significant difference ($p < 0.0001$). The median time hospital stay for the 23 patients of G1 who presented

pulmonary complications associated with other complications was 8 days (6;13.5) and for the 43 patients of G2, it was 26.5 days (14; 37.7) with $p < 0.0001$.

Table 2. Pulmonary Complications

	G1 n=68	G2 n=67	P
Pulmonary Complication (n; %)			
Yes	17 (25)	29 (43.3)	0.025*
No	51 (75)	38 (56.7)	
	G1 n=17	G2 n=29	P
Pulmonary Complication (n; %)			
Pneumonia	7 (10.3)	13 (19.4)	0.150
Atelectasis	6 (8.8)	8 (11.9)	
Pneumonia + atelectasis	4 (5.9)	8 (11.9)	

*Chi-square test with Yates's correction

Table 3. Other complications

	G1 n=68	G2 n=67	P
Other Complications (n; %)			
Yes	16 (23.5)	35 (52.2)	0.001*
No	52 (76.5)	32 (47.8)	
	G1 n=16	G2 n=35	P
Other Complications (n; %)			
Sepsis	3 (5.9)	6 (11.7)	0.066
Pleural effusion	2 (3.9)	5 (9.8)	
Pneumothorax	3 (5.9)	4 (7.8)	
Chylothorax	1 (2)	1 (2)	
Surgical site infection	0	2 (3.9)	
Pulmonary hypertension	1 (2)	0	
Pulmonary hemorrhage	0	1 (2)	
Diaphragmatic paralysis	0	1 (2)	
Others	6 (11.7)	15 (29.4)	

*Chi-square test with Yates's correction

DISCUSSION

Although respiratory physiotherapy is widely used to prevent postoperative pulmonary complications [15,16], its benefits may be controversial [17]. There is strong evidence that the therapy is effective in treating atelectasis [18]; however, there are few studies showing reduction in the incidence of pneumonia [19]. A recent study has shown effectiveness in reversal of difficult-to-treat atelectasis in the postoperative pediatric cardiac surgery, using conventional physiotherapy associated with the inhalation of saline solution [20].

There are few prospective studies involving pre- and postoperative physiotherapy in prevention of pulmonary complications with appropriately randomized control group [8, 9, 21]. Additionally, such studies are related to heart surgery in adults.

No randomized clinical trials to analyze preoperative physiotherapy in the prevention of pulmonary complications in children who have undergone surgical correction of congenital heart diseases were found. In relation to postoperative physiotherapy with the same aforementioned purpose, only one randomized clinical trial [22] was found, in which there was an increase of atelectasis in the intervention group which, at first glance, can discredit the procedure.

In this study, pulmonary complications were greater in the group that received only postoperative physiotherapy. The most frequent complication in both groups was pneumonia, which was similar to other studies [23]. Although pneumonia is one of the most common diagnosis in critically ill children, there are few studies to validate the diagnostic criteria [24]. We use the criteria from the CDC to define pneumonia and other hospital infections [14,24].

The main function of respiratory physiotherapy in pediatric patients is to contribute to the removal of tracheobronchial secretions [12] and to obtain better lung expansion, preventing or reversing atelectasis [13], and reducing the risk of lung infections.

Physiotherapy has an important role today, especially in patients on mechanical ventilation [25]. The techniques used in our study are commonly used, especially in ICUs [26], do not cause significant hemodynamic effects [27] and are effective in mobilizing pulmonary secretions, which improves lung function and gas exchange [28].

In this study, the NNT was 5.5; one out of every 5.5 patients who underwent a preoperative physiotherapy did not have pulmonary complications. The NNT shows the magnitude of the absolute risk reduction and allows us to weigh the benefits of prevention of an event in one patient against the costs and risks of a particular therapy [29].

Both the number of pulmonary complications associated with other complications and the time of hospital stay were significantly larger in the group that received only postoperative physiotherapy. There are studies in the literature in which the use of pre- and/or postoperative physiotherapy showed reduction in ICU time and hospital stay [8,9,30]. An analysis of respiratory complications - and not only complications occurred exclusively in the lungs - could be a proposal for new studies.

A limitation of this study was the number of sessions of preoperative physiotherapy. It was not possible to admit children much earlier due to increased hospital costs and mainly due to an increased risk of infection [3,23]. However, other studies also presented good outcomes with a low

number of sessions [16,30]. For the next study, a plan for presurgical outpatient physiotherapy could be created.

CONCLUSIONS

Preoperative physiotherapy associated with postoperative physiotherapy decreased the frequency and risk of postoperative pulmonary complications in pediatric heart surgery when compared to physiotherapeutic intervention in only the postoperative period.

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