



Use of Noninvasive Ventilation in Respiratory Failure After Extubation During Postoperative Care in Pediatrics

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Abstract

The purpose of this study was to determine the rate of failure of noninvasive ventilation (NIV) after cardiac surgery in pediatric patients with respiratory failure after extubation and to identify predictive success factors. This was a prospective cohort study of pediatric patients diagnosed with congenital heart disease who underwent heart surgery and used NIV. Data were collected from 170 patients with a median age of 2 months. No patient presented cardiorespiratory arrest nor any other complication during the use of NIV. The success rate for the use of NIV was 61.8%. Subjects were divided for analysis into successful and failed NIV groups. Statistical analysis used Chi-square, Mann–Whitney, and Student's *t* tests, which were performed after univariate and multivariate logistic regression for $p < 0.05$. In the multivariate analysis, only the minimal pressure gradient (OR 1.45 with $p = 0.007$), maximum oxygen saturation (OR 0.88 with $p = 0.011$), and maximum fraction of inspired oxygen (FiO₂) (OR 1.16 with $p < 0.001$) influenced NIV failure. The following variables did not present a statistical difference: extracorporeal circulation time ($p = 0.669$), pulmonary hypertension ($p = 0.254$), genetic syndrome ($p = 0.342$), RACHS-1 score ($p = 0.097$), age ($p = 0.098$), invasive mechanical ventilation duration ($p = 0.186$), and NIV duration ($p = 0.804$). In conclusion, NIV can be successfully used in children who, after cardiac surgery, develop respiratory failure in the 48 h following extubation. Although the use of higher pressure gradients and higher FiO₂ are associated with a greater failure rate for NIV use, it was found to be generally safe.

Keywords Noninvasive ventilation · Heart surgery · RACHS-1 · Risk factors · Extubation · Pediatrics

Introduction

Among the various postoperative complications of cardiac surgery in children, the most frequent are respiratory stridor secondary to glottal edema, atelectasis, pulmonary edema, pleural effusion, chylothorax, diaphragmatic dysfunction,

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and pneumonia associated with mechanical ventilation. These and other complications can lead to respiratory failure (RF) [1–3], which is treated with invasive or noninvasive ventilatory support. Invasive mechanical ventilation (IMV) protects the airways against aspiration or obstruction, creates positive pressure ventilation, and provides optimal airway control, allowing diagnostic or therapeutic interventions. However, IMV exposes patients to important complications, due to causes such as the trauma caused by intubation and the presence of the endotracheal prosthesis, and the reduction of the natural defense mechanisms of the respiratory system, which may lead to ventilator-associated pneumonia [1, 4] These complications associated with IMV increase the chance of extubation failure, which increase the mortality rate and increase hospital stay duration [4, 5].

Noninvasive ventilation (NIV) has demonstrated its efficacy in the treatment of several causes of RF in the postoperative period of cardiovascular surgeries, both in children and, especially, in adults [6, 7]. As in the adult environment, the use of NIV in neonatology and pediatrics has been gaining acceptance [6, 8–10]. However, despite growing interest, few studies have been conducted on this topic. The indication of NIV for pediatrics in different clinical settings is controversial. Existing studies were either performed in single centers or with a small number of patients, or without taking into account the parameters used for mechanical ventilation (ventilatory variables), which are highly relevant for identifying factors prognostic of success or failure. Conventionally, acute RF in postoperative cardiac surgery children is treated with orotracheal reintubation and invasive ventilatory support [6–9, 11]. The use of NIV in this population as an alternative ventilatory support is not well established, in contrast to studies in adults where its use is already consolidated [9, 10].

Thus, this multicentric study aimed to observe, in a statistically relevant sample, the outcomes for children who used NIV for RF within 48 h after extubation and who had undergone corrective or palliative cardiac surgery after diagnosis of congenital heart disease, to determine the success rate of NIV and identify factors predictive of NIV success in this population.

Methods

This was a prospective cohort study conducted in three different centers in São Paulo, Brazil: Hospital Sírio Libanês (HSL), Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (InCor) (the Heart Institute of the University of São Paulo School of Medicine Clinics Hospital), and Hospital do Coração

(HCor). The study received the approval of the research ethics committees of all participating hospitals.

We evaluated consecutive pediatric patients under 18 years of age with a diagnosis of congenital heart disease who underwent corrective or palliative heart surgery, presented RF within 48 h after extubation, and were treated with NIV. Exclusion criteria included those cases in which it was impossible to acquire complete data; tracheostomized patients; and cases where the parents, legal guardians, or responsible physician refused to sign the informed consent form.

This study was a collaboration among three Brazilian tertiary hospitals, two of which are cardiac surgery reference centers, and all of which have medical and multi-professional staff who are highly qualified in postoperative care of pediatric cardiac surgery. The team identified indications for NIV using the Brazilian Consensus of Mechanical Ventilation in pediatrics and neonatology, as these three institutions recommend. The same consensus supported the choices regarding reintubation and ventilatory parameters, which should be sufficient to allow adequate thoracic expandability and an oxygen saturation (SpO_2) between 90 and 95%, except for cyanogenic cardiopathies, for which each surgical team determined the SpO_2 value, usually around 85%.

Ventilation devices used in all three centers were similar, usually the Servo i® (Maquet, Solna, Sweden) or Bipap Vision® (Respironics, Pittsburgh, PA, USA). The interfaces used were also similar in all centers.

A single researcher collected the variables from the medical records of each patient and transferred them to a standardized spreadsheet. Data collection started at NIV establishment and continued daily until termination of NIV use, regardless of success or failure. Success was defined as a patient requiring no orotracheal reintubation, whereas patients needing orotracheal reintubation within 48 h after the end of NIV were scored as failures. Reintubation was decided by team consensus using the absolute criteria cardiorespiratory arrest, hemodynamic instability, and lowering of consciousness level. Relative indications for reintubation were refractory hypoxemia, persistence of respiratory acidosis upon arterial gasometry examination, and clinical signs of respiratory fatigue. The following variables were considered as primary: reintubation, risk-adjusted classification for congenital heart surgery (RACHS-1) score, age, NIV duration, and duration of extracorporeal circulation (ECC). Secondary variables were gender, presence of genetic syndromes, pulmonary hypertension, type of congenital heart disease, surgery performed, inspired fraction of oxygen (FiO_2) used, maximum and minimum pressure gradient, maximum and minimum positive end expiratory pressure (PEEP), type of ventilator, interface used, use of sedatives, complications, total time of IMV, and pre-existing respiratory diseases. Several of these variables displayed

no variation among groups and thus their results are not reported here.

Statistical Analysis

The demographic and clinical quantitative data of the patients were described with the use of centralization and dispersion measures and the qualitative data were described using absolute and relative frequencies. The success or failure of NIV was described according to each characteristic of interest. Chi-square tests were used to assess the association of success or failure for the qualitative characteristics and Mann–Whitney or Student's *t* tests for the quantitative characteristics. Simple logistic regression was employed to estimate the odds ratios (OR) of each variable of interest with the occurrence of failure, with 95% confidence intervals (CI).

A multiple logistic regression model was estimated to identify the factors that jointly influence the occurrence of NIV failures, select the variables that in the bivariate tests presented levels of significance below 0.10 ($p < 0.10$), and use only variables with a significance level lower than 0.05 ($p < 0.05$) in the final model.

All tests were performed with a significance level of 5%. The software packages used were Excel 2003 and SPSS 20.0. To calculate the sample size, a 5% single-tailed alpha error and a 20% beta error were considered, without taking dropouts into account. The rate of NIV failure considered was 40%. Thus, the calculated sample size was 170 subjects.

Results

In the period from 2011 to 2014, 186 patients who used NIV for RF within 48 h after extubation and who had undergone corrective or palliative heart surgery due to diagnosis of congenital heart disease were recruited. However, 16 patients were excluded, 5 for refusal to sign the consent form and 11 due to incomplete data collection. Of the 170 patients analyzed, 68 (40%) were treated at HCor, 94 (55.3%) at InCor, and 8 (4.7%) at HSL.

No patient presented cardiorespiratory arrest during the use of NIV. Thirteen patients died, corresponding to 7.6% of the sample. All were on IMV with orotracheal intubation at the time of death.

Only 12 children presented skin lesions due to the use of NIV, and they required only interface changes without impairing the continuity of NIV support. No patient presented gastric distension that interfered with the use of NIV, nor did any develop pneumothorax due to the use of NIV.

Of the patients using NIV, 61.8% were successful (requiring no reintubation), with newborns representing 36% of

Table 1 Demographic data, surgical characteristics, and variables related to IMV and NIV

Variable	Description (n = 170)
Sex, n (%)	
Male	86 (50.6)
Female	84 (49.4)
Age (months)	
Mean (SD)	5.7 (12.9)
Median (min; max)	2 (0; 108)
Interface, n (%)	
Face mask	71 (41.8)
Nasal cannula	99 (58.2)
Sedation, n (%)	
No	41 (24.1)
Yes	129 (75.9)
Genetic syndrome, n (%)	
No	137 (80.6)
Yes	33 (19.4)
PH, n (%)	
No	145 (85.3)
Yes	25 (14.7)
ECC (min)	
Mean (SD)	85.8 (6.24)
Median (min; max)	95.0 (0; 215)
IMV duration (days)	
Mean (SD)	11.5 (26.1)
Median (min; max)	4 (0; 211)
NIV duration (h)	
Mean (SD)	65 (70.6)
Median (min; max)	47,5 (1; 402)
ReIOT, n (%)	
No	105 (61.8)
Yes	65 (38.2)
Death, (%)	
No	157 (92.4)
Yes	13 (7.6)
RACHS-1, n (%)	
1	3 (1.8)
2	40 (23.5)
3	42 (24.7)
4	51 (30)
5	4 (2.4)
6	30 (17.6)

PH pulmonary hypertension, ECC extracorporeal circulation, IMV invasive mechanical ventilation, NIV noninvasive mechanical ventilation, REIOT reintubation, RACHS-1 risk-adjusted classification for congenital heart surgery score, SD standard deviation, min minimum, max maximum

Table 2 Demographic, surgical, and ventilation-related characteristics of patients according to outcome (success and failure groups)

Variable	Outcome of NIV		<i>p</i>
	Success (<i>n</i> = 105)	Failure (<i>n</i> = 65)	
Sex			0.013
Male	61	25	
Female	44	40	
Age (Months)	2 (0; 108) ^a	1 (0; 36) ^a	0.098**
Interface			0.714
Face mask	45	26	
Nasal cannula	60	39	
Sedation			0.084
Yes	75 (71.4%)	54 (83%)	
Genetic syndrome			0.342
Yes	18 (17.1%)	15 (23%)	
Pulmonary hypertension			0.254
Yes	18 (17.1%)	7 (10.7%)	
ECC (min)	86.1 (64.7) ^b	85.1 (58.8) ^b	0.669*
IMV duration (days)	3 (0; 211) ^a	5 (0; 139) ^a	0.186*
NIV duration (h)	46 (3; 402) ^a	48 (1; 286) ^a	0.804**
RACHS-1 (N)			0.097*
1	3 (2.8%)	0 (0)	
2	20 (19%)	20 (30.7%)	
3	24 (22.8%)	18 (27.7%)	
4	34 (32.4%)	17 (26.1%)	
5	3 (2.8%)	1 (1.5%)	
6	21 (20%)	9 (13.8%)	

ECC extracorporeal circulation, IMV invasive mechanical ventilation, NIV noninvasive mechanical ventilation, RACHS-1 risk-adjusted classification for congenital heart surgery score

^aMedian (min; max)

^bMean (SD)

Chi-square test, *Mann–Whitney test, **Student's *t* test

this success rate. Table 1 describes the demographic data of the patients, including their surgical characteristics and variables related to IMV and NIV.

Most demographic, surgical, and ventilation-related characteristics had no effect on success or failure rates (Table 2), with the exception of sex, as there were significantly fewer failures in male patients.

Conversely, univariate analysis (Table 3) indicated that all ventilatory parameters influenced the occurrence of failures ($p < 0.05$). However, after adjustment for covariates in the multiple analysis (Table 4), only a few ventilatory parameters had an influence on the occurrence of NIV failure: the minimum pressure gradient, the maximum SpO₂, and the maximum FiO₂. The analysis indicates that a higher minimum pressure gradient, maximal FiO₂, and a lower SpO₂ were associated with reintubation.

Table 3 shows the NIV results in relation to ventilatory parameters with univariate analysis, whereas Table 4 presents only the ventilatory parameters with $p < 0.05$ after multivariate analysis.

Discussion

The aim of this study was to determine the success rate and the factors predicting success or failure of NIV for the treatment of RF that presents within 48 h after extubation in children after cardiac surgery. This therapy prevented reintubation in approximately two-thirds of the patients, thus decreasing the risks of airway injury and pneumonia associated with mechanical ventilation. Moreover, NIV was not associated with any relevant complication, showing it to be safe and viable.

The success rates reported here are similar to those reported in other NIV studies of the pediatric population, including patients after cardiac surgery and patients with noncardiac procedures; these studies report success rates around 70% [1, 6, 8, 9, 11–16]. Lafever et al. [15],

Table 3 Univariate analysis of the association of ventilatory parameters and success/failure of NIV

Variable	NIV success		OR (unadjusted)	95% CI		<i>p</i> ^a
	Yes (<i>n</i> = 105)	No (<i>n</i> = 65)		Inferior	Superior	
Pressure gradient min–max	11.8–12.8 (1.8–1.9) ^b	13.9–15.1 (2.1–2.3) ^b	1.78	1.44	2.20	<0.001**
Peep min–max	5.6–5.9 (0.7–0.8) ^b	6–6.5 (0.9–0.9) ^b	1.78	1.17	2.72	0.006**
SpO ₂ min–max	90.4–96.8 (1.9–4.2) ^b	82.5–92.5 (6.8–5.5) ^b	0.87	0.82	0.92	0.001**
FiO ₂ min–max	33.8–37.4 (5.8–7.6) ^b	47.9–59.2 (10–14.5) ^b	1.25	1.17	1.33	<0.001**
FiO ₂ decrease	11.4 (9.8) ^b	13.9 (12.6) ^b	1.02	0.99	1.05	0.172**

PEEP positive end expiratory pressure, SpO₂ oxygen saturation, FiO₂ fraction of inspired oxygen, min minimum, max maximum

^aChi-square test

^bMean (SD)

*Mann–Whitney test, **Student's *t* test

Table 4 Patient data regarding ventilatory parameters with multivariate analysis and patients divided between groups

Variable	NIV success		OR (adjusted)	CI (95%)		<i>p</i> ^a
	Yes (n = 105)	No (n = 65)		Inferior	Superior	
Minimum pressure gradient	11.8 (1.8) ^b	13.9 (2.1) ^b	1.45	1.11	1.91	0.007
Maximum SpO ₂	96.8 (4.2) ^b	92.5 (5.5) ^b	0.88	0.80	0.97	0.011
Maximum FiO ₂	37.4 (7.6) ^b	59.2 (14.5) ^b	1.16	1.10	1.23	<0.001

SpO₂ blood-oxygen saturation level, FiO₂ fraction of inspired oxygen, *min* minimum, *max* maximum

^aChi-square test

^bMean (SD)

in a retrospective study performed in a single center with 200 children in the postoperative period of cardiac surgery, showed a high success rate of NIV. However, that study was retrospective and did not record ventilatory parameters. To fill this gap, this prospective study recorded the ventilatory parameters used in NIV, and gathered data from three different centers, thus increasing the external validity of the results.

A limitation of this study was the lack of a control group with patients who suffered RF after extubation to whom NIV was not offered to avoid reintubation. These data would have allowed us to determine whether there is a group of patients who do not require reintubation even without NIV. However, our goal was to assess the frequency of success, and its predictive factors, for NIV, rather than for all cases of respiratory failure.

Our study analyzed the largest and smallest pressure gradient values, PEEP, and FiO₂ used, and observed that the smaller the pressure gradient, the greater the probability of NIV success. Studies of patients under IMV have verified the association between the pressure gradient value and mortality and lung injury induced by mechanical ventilation, emphasizing the importance of using low pressure gradients [17]. In NIV, the team usually determines the pressure gradient value based on a tidal volume test performed by the patient and/or the appropriate thoracic expandability. The present study points to the use of lower pressure gradient values as a predictive factor for the successful use of NIV.

In a study by Odena et al. [1] of a similar population of patients, NIV was successful in 69% of the cases, and success was related to the duration of NIV: those who failed stayed on NIV longer than those who achieved success (158 h vs. 59 h, *p* < 0.05). In contrast, in our study, which had a larger number of participants (170 vs. 29), the median NIV durations were very similar between the success and failure groups (*p* = 0.804). However, the NIV durations were also much lower than those presented in the aforementioned article (48 h and 46 h for failure and success groups, respectively), despite similar success rates. This leads us to believe that if, after about 50 h on NIV, the patient has not shown signs of improvement, reintubation should be considered.

Another study performed only with children with cardiomyopathies [11] reported an association between greater disease severity and failure of NIV, which differed from what we observed in this study. Gupta et al. [11] divided their patients into two groups according to RACHS-1 score: RACHS-1 of 1 to 3 and RACHS-1 of 4 to 6. In their sample, the most severe group (RACHS-1 4 to 6) presented the highest incidence of NIV failure; in our sample, there was no statistically significant difference among the different levels of the surgical complexity classification, despite half of our sample of children having RACHS-1 scores of 4 to 6 [15, 18]. We believe this is due to the fact that RACHS-1 only takes into account the surgical complexity and not the severity of the patient's condition before surgery.

A major factor in the successful application of NIV as a ventilatory support in children is the commitment of the entire multidisciplinary team to NIV success [1, 8–11, 14]. The importance of training the team in the management of these patients cannot be overstressed, to maintain adequate positioning of both the child and the interface, avoid skin lesions associated with the use of NIV, and prevent airway obstruction and interface displacement. Other critical actions include watching for the presence of pulmonary secretions, to rapidly eliminate them; monitoring the level of awareness of the child and trying to calm the child or administer sedation in case of agitation or, in cases of lethargy, re-evaluating the therapy; and making the appropriate choices of interface and supply fan. This is the opinion of the authors of this work, but it has corroborated by several other groups, including Harrison et al. [3], Essouri et al. [19], Ódena et al. [1], Lum et al. [8], and Gupta et al. [11].

Essouri et al. [20], Lum et al. [8], Mayordomo-Colunga et al. [16], James et al. [20], and Fedor [14] all stated that the lower the FiO₂ used value, the greater the chances of success of NIV. However, all these studies were carried out with mixed populations of children with a variety of diagnoses. In our study, which included only children in the postoperative stage after cardiac surgery, the difference in the maximal FiO₂ used between the success and failure groups was just over 20%, with *p* < 0.001. This is a clinically relevant difference, as it shows the effectiveness of NIV in hypoxemic

patients, similar to what was previously demonstrated for other groups of patients.

The SpO₂ level was also a predictor of success in our study, with higher values associated with a higher success rate ($p=0.01$). However, this result is not clinically relevant because this is a group of subjects in the postoperative period of corrective or palliative heart surgery. In subjects who underwent palliative cardiac surgeries, the value of SpO₂ expected postoperatively is lower than that for corrective surgeries.

The use of high-flow nasal cannula (HFNC) has increased significantly in recent years, with several studies showing its safety and some demonstrating its superiority over conventional oxygen therapy, with HFNC achieving results similar to those of NIV [21]. Initial studies were done with a variety of patients with respiratory failure. Recently, some authors, such as Hernandez [22], in a study comparing the use of HFNC with NIV after extubation in patients at high risk of extubation failure, showed that NIV was not superior to HFNC in preventing reintubation. However, the definition of high risk of failure in that study was quite broad. Despite the promising results of the HFNC, this therapy costs more than NIV, which can be performed with the same ventilators that are already present in intensive care units. In developing countries, this cost factor is critical in choosing the therapeutic method to be used.

At the time of data collection in this study, HFNC was not yet being used in Brazil, and its use was started the following year. If this study were replicated this year, we believe that HFNC would be indicated for some of the patients included in our study, as they presented a milder respiratory discomfort that had a favorable resolution after a few hours of NIV.

Conclusions

Based on the findings of this study, we can conclude that.

1. NIV can be used successfully in children who, after heart surgery, develop RF within 48 h after extubation.
2. Use of a higher pressure gradient and higher oxygen concentrations are factors associated with greater risk of NIV failure.
3. Use of NIV is safe for the sample evaluated, without adverse events that would make it impossible to use this therapy.

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Compliance with Ethical Standards

Conflict of interest Author Denise S Rolim declares that she has no conflict of interest. Author Filomena RB Galas declares that she has no conflict of interest. Author Lucilia S Faria declares that she has no conflict of interest. Author Erica F Amorim declares that she has no conflict of interest. Author Marisa M Regenga declares that she has no conflict of interest. Author Eduardo J Troster declares that he has no conflict of interest.

Ethical Approval This study received the approval of the Research Ethics Committees of all participating hospitals.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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