J Bras Pneumol. 2020;46(6):e20180053
http://dx.doi.org/10.36416/1806-3756/e20180053

ORIGINAL ARTICLE

Noninvasive ventilation in a pediatric ICU: factors associated with failure

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Submitted: 20 February 2018.
Accepted: 20 August 2019.

Study carried out in the Hospital de Clínicas, Universidade Estadual de Campinas, Campinas (SP) Brasil.

ABSTRACT

Objective: Evaluate the efficacy of Noninvasive Mechanical Ventilation (NIV) in preventing Endotracheal Intubation (ETI) in a heterogeneous pediatric population and identify predictive factors associated with NIV failure in Pediatric Intensive Care Unit (PICU). **Methods:** Prospective non-randomized clinical trial conducted with patients aged 0-10 years, hospitalized in a PICU with NIV indication, who presented acute or chronic respiratory failure. Demographic data and clinical and cardiorespiratory parameters were evaluated, and patients who did not progress to ETI in 48 h after withdrawal of NIV were classified as "success group", whereas those who progressed to ETI were included in the "failure group". Multivariate logistic regression was performed to identify the predictive factors of failure to prevent ETI. **Results:** Fifty-two patients, 27 (51.9%) males, with median age of 6 (1-120) months were included in the study. When evaluating the effectiveness of NIV, 36 (69.2%) patients were successful, with no need for ETI. After analyzing the predictive factors associated with failure, patients with tachypnea after 2 h of NIV were 4.8 times more likely to require ETI in 48 h. Regardless of outcome, heart (p<0.001) and respiratory (p<0.001) rates decreased and oxygen saturation (p<0.001) increased after 2 h of NIV. **Conclusion:** We concluded that use of NIV was effective in the studied population, with significant improvement in cardiorespiratory parameters after 2 h of NIV, and that tachypnea was a predictive factor of failure to prevent ETI.

Keywords: Noninvasive ventilation; Intensive care units; Children, Pediatric; Artificial ventilation.

INTRODUCTION

Noninvasive mechanical ventilation (NIV) is defined as a ventilatory support that does not require endotracheal intubation (ETI) or tracheostomy.[1-3] It is used through an interface with the aim of promoting adequate ventilation, reducing respiratory work, preventing respiratory muscle fatigue, increasing alveolar ventilation and improving gas exchange, thus preventing intubation and promoting, in some cases, early extubation.[1-3] The use of NIV can also decrease complications associated with the use of invasive mechanical ventilation and, consequently, the morbidity and mortality rates associated with the latter.[2,3]

Currently, NIV is considered an alternative ventilatory support in Pediatric Intensive Care Unit (PICU), with good acceptability and high success rates, being indicated in the presence of acute or chronic respiratory disorders, neuromuscular diseases, central nervous system disorders and obstructive sleep apnea, as well as in the postoperative and post-extubation periods and in early extubation.[1-7] The use of NIV in adults is widely established and recommended; however, due to the great variability of low quality studies, heterogeneity of diseases found in PICU, and the low availability of trained professionals, it is important to conduct new studies addressing the use of NIV in pediatrics.[4,8-10]

There has been an increase in the success rates of the use of NIV in various diseases over time.[7-9] In the beginning, these rates ranged from 5 to 40% and, currently, they can reach 80%.[7-9] NIV has been increasingly used both in our institution and in other centers that utilize it in the pediatric population, and we hypothesize that its success rates, defined as to prevent ETI, vary between 60 and 80% according to the literature.[7-9] However, it is necessary to carry out complementary studies in multi-professional centers in order to improve and disseminate knowledge on the subject, in addition to establishing protocols for the application of NIV.[4,8-14]

Thus, the objective of this study was to evaluate the effectiveness of NIV in preventing ETI in a heterogeneous population of pediatric patients and identify the predictive factors associated with its failure in a PICU at the *Clinical Hospital* (CH) of the *University of Campinas* (Unicamp).

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Financial support: None.

METHODS

A prospective non-randomized clinical trial was carried out with infants, preschoolers, and schoolchildren aged 0-10 years, of both genders, admitted to the PICU of CH - Unicamp between November 2015 and December 2016.

Upon consensus among the professionals working in the PICU, the following inclusion criteria were adopted for all patients with indication for NIV: presence of type I and II acute respiratory failure (ARF), chronic respiratory failure (CRF) with signs of exacerbation and signs of respiratory distress (RD) as a rescue technique against dyspnea, tachypnea and use of accessory muscles, as well as being or in the post-extubation period. Other factors for indicating NIV were presence of hypoxemia and/or PaO_2/FIO_2 ratio <300 and/or hypercapnia with pH >7.20 and/or $PaCO_2$ >45 mmHg in patients with acute diseases and $PaCO_2$ >60 mmHg in diseases chronic diseases.[2]

The same factor considered for contraindication of NIV were used as exclusion criteria, namely, hemodynamic instability, arrhythmia, Glasgow Coma Scale (GCS) score adapted for the pediatric population <10, presence of facial or airway deformity injuries, previous trauma and/or craniofacial surgery, undrained pneumothorax, active bleeding in the upper gastrointestinal tract, and/or cardiorespiratory arrest.

As hemodynamic instability, the following symptoms were considered: altered level of consciousness, filiform pulses, important tachycardia, skin pallor, sweating, slow or extremely fast capillary filling, arterial hypotension, and oliguria.

The choice of ventilation mode between Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP) was based on the patient's clinical condition, and included respiratory work, presence of signs of RD, gas exchange, and tolerance to the selected ventilation mode. BiPAP was the initial ventilation mode for children with signs of RD and/or with hypercapnia in gas exchange, whereas CPAP was the ventilation mode initially used for patients with signs of mild-to-moderate RD and without hypercapnia in gas exchange. Initial Expiratory Positive Airway Pressure (EPAP) between 5-7 cmH_2O was used in CPAP, whereas Inspiratory Positive Airway Pressure (IPAP) between 8-12 cmH2O with EPAP between 5-7 cmH_2O were applied in BiPAP (see Figure 1).

Figure 1 shows a flowchart with information on the indications and contraindications for NIV in the present study, in addition to the protocol established for the therapeutic follow-up of patients.

After the child's adaptation to NIV, pressures were adjusted according to the clinical evaluation and reassessed throughout the process. The following signs or parameters were monitored: RD, respiratory rate (RR), heart rate (HR), tidal volume (TV) between 6-8 ml/Kg according to the child's real weight or weight inferred by the parents, as well as patient tolerance to NIV. In both cases, the initial fraction of inspired oxygen (FiO_2) was 50%, which was adjusted to maintain peripheral oxygen saturation (SpO_2) between 92-95%. Flow sensitivity was adjusted between 0.5-1 L/min, with an apnea alarm set between 10-15 s^2.

Noninvasive machanical ventilation was performed using the following mechanical ventilators: RTC E360Br (Newport Medical Instruments, Brazil), MV Drager EVITA 4 (Dräger Medical AG & Co. KGaA, Germany), and BiPAP® Focus™ (Respironics Inc., California, USA).

The choice of the interface between the Philips Respironics Wisp nasal mask (Philips Medical Systems Ltda., Brazil) or the Babyflow® System - nasal mask or cannula (Dräger Medical GmbH, Germany) was based on the size, age and shape of each patient's face, aiming to minimize air leakage and provide the best comfort and patient-mask adaptation (Figure 2).

For assessing continuity, making adjustments, or interrupting NIV, cardiorespiratory parameters such as HR, RR, SpO_2, presence of signs of RD, TV (6-8 ml/kg), and arterial blood gas (ABG) before and after 2 h of NIV placement were evaluated. In addition, information on sex and diagnostic hypotheses was collected.

Subsequently, patients were classified according to efficacy of NIV use into "success group" -patients who did not progress to ETI or required it in 48 h after withdrawal of NIV and the "failure group" -patients who needed ETI.

Throughout the study, patients were continuously monitored every two hours using oximeters, thermometers, electrocardiograms, HR, RR, TV and systemic blood pressure monitors, pulmonary auscultation, ABG analysis, GCS adapted for pediatric population, presence of signs of RD, abdominal distention and lesions on the face, adequate humidification of the system, and leakage of the interface.

The following criteria were considered for interrupting NIV with immediate need for ETI:[2] FiO_2 >60%; progressive increase in ventilatory parameters; continuous dependence on NIV after 24 h, with no tolerance to remain short periods outside the device; no improvement in gas exchange (hypercapnia with major respiratory acidosis and/or severe hypoxemia, with PaO_2/FiO_2 ratio <100 in the first 2 h); GCS adapted for pediatric population <10; patient intolerance or agitation with the use of NIV.

Data obtained were processed using the SPSS 16.0 for Windows (Statistical Package for the Social Sciences; SPSS Inc., Chicago, IL; USA).

Statistical descriptive analysis was performed with categorical variables expressed in absolute and relative frequencies and continuous variables expressed in mean, standard deviation, median, minimum and maximum.

Unadjusted Odds Ratio (OR) values, 95% CI, and *p*-value were determined for "failure to prevent ETI" in relation to each predictor variable by Univariate Logistic Regression (Enter method). Cardiorespiratory parameters was classified for each age, with RR in eupnea and tachypnea and HR in sinus rhythm and

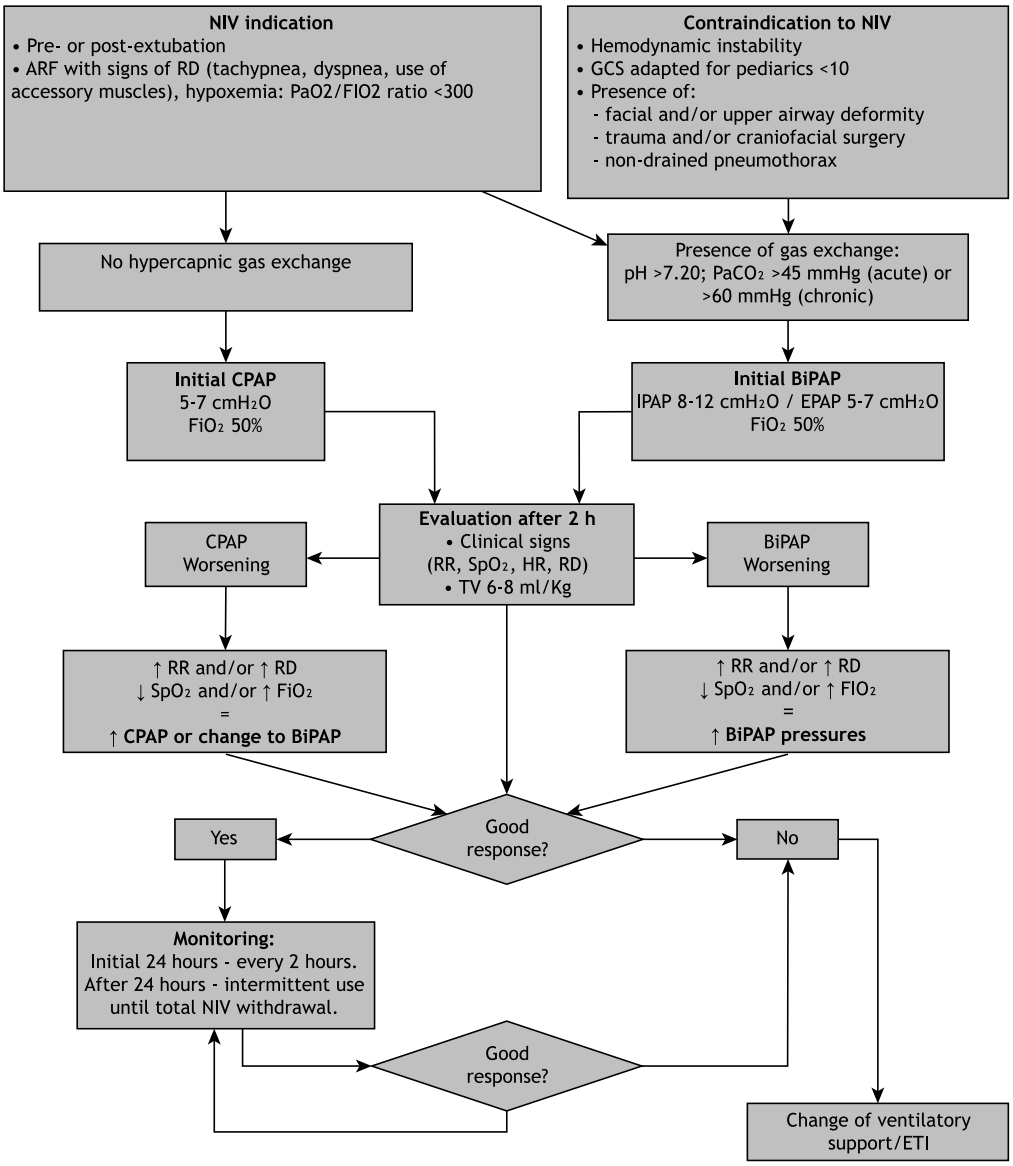

Figure 1. Flowchart of indications, contraindications, and therapeutic follow-up throughout the study. NIV: non-invasive mechanical ventilation; ARF: acute respiratory failure; PaO_2: arterial oxygen pressure; FIO_2: fraction of inspired oxygen; $PaCO_2$: blood pressure carbon dioxide; GCS: Glasgow Coma Scale; RD: respiratory distress; CPAP: Continous Positive Airway; BiPAP: Bi-level Positive Airway Pressure; IPAP: Pressure Inspiratory Positive Airway Pressure; EPAP: Pressure Expiratory Positive Airway Pressure; RR: respiratory rate; HR: heart rate; SpO_2: peripheral oxygen saturation; TV: tidal volume; ET: orotracheal tube.

tachycardia, according to the normality values found in the literature.[15]

Subsequently, the predictor variables with $p<0.200$ in the univariate analysis were selected to compose the multivariate logistic model. The Forward Selection (Wald) method was used with 0.05 and 0.01 inclusion and exclusion *p*-value steps, respectively.

Comparison between the means of the two paired groups was performed by the Student's *t*-test for parametric samples and the Wilcoxon test for non-parametric samples. A significance level of 5% ($p<0.05$) was adopted for statistical analyses.

This study was submitted and approved by the Research Ethics Committee of the College of Medical Sciences of Unicamp under protocol no. 1.313.165. All parents and/or legal guardians signed the Free and Informed Consent Form (FICF) prior to study commencement and those whose children were photographed signed a term allowing the use of the images.

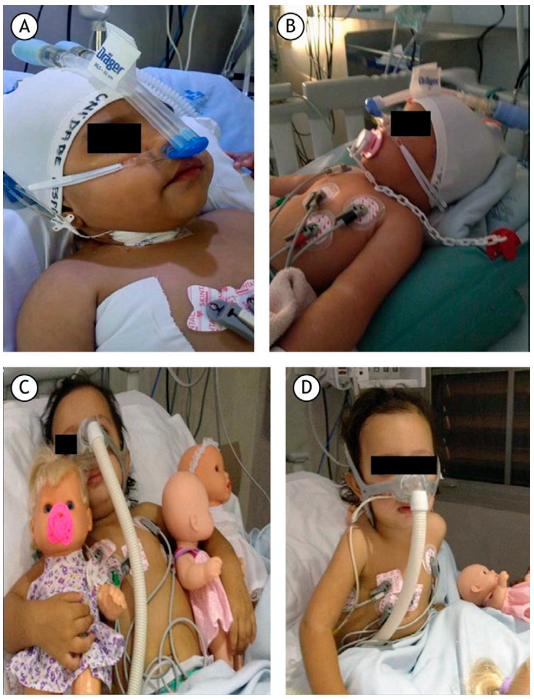

Figure 2. Patients with appropriate interfaces for the age and shape of the face. A: infant in CPAP with nasal cannula; B: infant in BiPAP with unventilated nasal mask; C and D: child in BiPAP with ventilated nasal mask.

RESULTS

The initial study sample comprised 532 infants, preschoolers and schoolchildren admitted to the PICU of CH-Unicamp between November 2015 and December 2016. After application of the inclusion and exclusion criteria, 52 patients were selected to participate in the study.

The study sample consisted of 52 patients, 27 (51.9%) males, with median age of 6 (1-120) months. Among them, there were 41 (78.8%) infants including preterms according to chronological age, four (7.7%) preschoolers, and seven (13.5%) schoolchildren.

All participants presented some type of respiratory failure with indication of NIV. The basic diseases that led to PICU admission were acute viral bronchiolitis (AVB), (19 patients; 36.5%) and pneumonia (9 patients; 7.3%). Some children presented associated comorbidities such as 3 (5.8%) with history of prematurity with bronchopulmonary dysplasia, 4 (7.7%) with cystic fibrosis,3 (5.8%) with laryngitis, 1 (1.9%) with asthma and 8 (15.4%) with basic diagnoses of non-respiratory origin such as Down Syndrome, traumatic brain injury, epilepsy and septic shock, and progressed to NIV as a result of type I ARF.

No adverse effects associated with the use of NIV, such as skin or mucosal lesions due to interface pressure, abdominal distension or eye irritation, were observed throughout the study period.

When assessing the effectiveness of using NIV, 36 (69.2%) patients were successful and 16 (30.8%) failed with need for ETI, 12 of them due to the presence of hemodynamic instability such as decreased SpO_2, RD, tachycardia or tachypnea, two because of decreased level of consciousness with absence of respiratory drive; one as a result of cardiopulmonary arrest; one due to poor adaptation and acceptance to the NIV interface. These signs were identified within the first two hours of NIV placement.

Table 1 shows the demographic and clinical characteristics of the participants in addition to the NIV parameters.

After analyzing the variables that represented predictive factors of "failure to prevent ETI", patients with signs of RD after 2 h of NIV were 3.79 times more likely to require ETI in 48 h (OR: 3.79; 95% CI, 1.10-13.03; p=0.035). In addition, patients with presence of tachypnea after 2 h of NIV were 4.80 times more likely to require ETI in 48 h (OR: 4.80; 95% CI, 1.12-20.48 ; =0.034) (Table 2).

Analysis of the multivariate logistic regression, with inclusion of the predictor (presence of RD and altered RR after 2 h of NIV) and confounding (history of previous mechanical ventilation, type of ARF, pH <7.35, $PaCO_2$ >45 mmHg, and altered initial SpO_2) variables, only RR remained in the multivariate model (OR: 4.80; 95% CI, 1.12-20.48; p=0.034). Therefore, patients with tachypnea after 2 h of NIV present 4.80 fold chance of requiring EDI in 48 h.

Table 1. Demographic and clinical characteristics and initial NIV and cardiorespiratory parameters of the patients included in the study.

	Total (N = 52)
Gestational age	**N (%)**
Preterm	19 (36.5)
Term	33 (63.5)
ARF	**N (%)**
Type I	27 (51.9)
Type II	25 (48.1)
Previous MV	**N (%)**
Yes	23 (44.2)
No	29 (55.8)
Modality	**N (%)**
CPAP	17 (32.7)
BiPAP	35 (67.3)
Initial RD	**N (%)**
Yes	38 (73.1)
No	14 (26.9)
Days in NIV	**Median (min-max)**
Success group	2 (2-6)
Failure group	1 (0-1)

N: Number of cases; %: Relative percentage of cases; min: Minimum; max: Maximum; MV: History of previous mechanical ventilation; ARF: Acute respiratory failure; RD: Presence of respiratory distress; NIV: Noninvasive ventilation.

Table 2. Univariate logistic regression with the predictive variables for failure to prevent ETI in 48 h after placement of NIV.

	Failure Group		p	OR	95% CI
	N (%)	Total			
Gender					
Male	8 (29.6)	27	0.853	0.89	0.27-2.91
Female	8 (32.0)	25		1.00	
Gestational age					
Preterm	7 (36.8)	19	0.473	1.55	0.46-5.20
Term	9 (27.3)	33		1.00	
Current age					
Infant	11 (26.8)	41	0.241	0.44	0.11-1.73
Pre-schooler and schoolchildren	5 (45.5)	11		1.00	
Previous MV					
Yes	10 (43.5)	23	0.082	2.95	0.87-9.98
No	6 (20.7)	29		1.00	
ARF					
Type I	6 (22.2)	27	0.170	0.43	0.13-1.44
Type II	10 (40.0)	25		1.00	
Modality					
CPAP	4 (23.5)	17		1.00	
BiPAP	12 (34.3)	35	0.433	1.70	0.45-6.35
Initial RD					
Yes	13 (34.2)	38	0.380	1.91	0.45-8.06
No	3 (21.4)	14		1.00	
Initial RR					
Eupnea	9 (31.0)	29		1.00	
Tachypnea	7 (30.4)	23	0.963	0.97	0.30-3.18
Initial HR					
Sinus rhythm	6 (31.6)	19		1.00	
Tachycardia	10 (30.3)	33	0.924	0.94	0.28-3.19
Initial SpO_2					
>92%	11 (25.6)	43		1.00	
≤92%	5 (55.6)	9	0.088	3.64	0.83-16.01
pH gasometria inicial					
<7.35	5 (55.6)	9	0.144	0.300	0.06-1.51
7.35-7.45	6 (27.3)	22		1.00	
>7.45	4 (26.7)	15	0.967	1.03	0.23-4.53
Initial $PaCO_2$					
<35 mmHg	2 (16.7)	12	0.290	0.40	0.73-2.18
35-45 mmHg	10 (33.3)	30		1.00	
>45 mmHg	3 (75.0)	4	0.141	6.00	0.55-65.29
RD after 2 h					
Yes	10 (47.6)	21	0.035	3.79	1.10-13.03
No	6 (19.4)	31		1.00	
RR after 2 h					
Eupnea	10 (23.8)	42		1.00	
Tachypnea	6 (60.0)	10	0.034	4.80	1.12-20.48
HR after 2 h					
Sinus rhythm	11 (33.3)	33		1.00	
Tachycardia	5 (26.3)	19	0.598	0.71	0.20-2.50
SpO_2 after 2 h					
>92%	14 (28.0)	50		1.00	
≤92%	2 (100.0)	2	0.999	-	-

N: Number of cases; %: Relative percentage of cases; OR: Odds ratio; 95% CI: 95% confidence interval; MV: History of previous mechanical ventilation; ARF: Acute respiratory failure; CPAP: Continuous Positive Airway Pressure; BiPAP: Bilevel Positive Airway Pressure; RD: Presence of respiratory distress; RR: Respiratory rate; HR: heart rate; SpO_2: Peripheral oxygen saturation.

Table 3. Comparison of heart rate, respiratory rate, and peripheral oxygen saturation before and two hours after NIV placement.

	Moment	Average	SD	Minimum	Median	Maximum	p
HR	Before NIV	151.35	28.24	83	153	220	<0.001[a]
(bpm)	After NIV	135.57	24.65	83	137	185	
RR	Before NIV	49.58	17.40	20	50	87	<0.001[a]
(ipm)	After NIV	38.96	12.92	15	38	78	
SpO_2	Before NIV	96.42	4.35	87	98	100	<0.001[b]
(%)	After NIV	98.25	3.02	82	99	100	

SD: Standard deviation; HR: Heart rate; bpm: Beats per minute; RR: Respiratory rate; ipm: Incursions per minute; SpO_2: Peripheral oxygen saturation; NIV: Noninvasive ventilation. Statistical Tests: [a]Paired Student's *t*-Test; [b]Wilcoxon Test. p-value <0.05 with statistical significance.

Table 3 shows the comparison of cardiorespiratory values (HR, RR and SpO_2) before placement and after 2 h of NIV for all study participants. Significant differences were observed in all parameters analyzed, with increased values of HR, RR and SpO_2 after placement of NIV.

No statistically significant differences were observed between the failure and success groups when comparing variation in HR, RR and SpO_2 pre- and post-NIV placement.

DISCUSSION

To date, there are no Brazilian studies that have developed and applied an NIV protocol to infants, preschoolers and/or schoolchildren hospitalized in PICU to evaluate prevention of ETI, NIV success rate, and predictive factors of NIV failure. The present study identified a success rate of 69.2% with significant improvement in cardiorespiratory parameters 2 h after placement of NIV, and that tachypnea was a predictive factor of failure and an indication for ETI.

Use of NIV in the pediatric age group has been significantly increasing worldwide;[16,17] however, in a systematic review, Castro-Codesal et al. concluded that, despite the fact that most of the existing studies have low methodological quality, 73% of them have reported benefits regarding its use7. Therefore, NIV is an important therapeutic resource in pediatrics.[2,18]

Presence of respiratory failure was the indication criterion for the use of NIV in this study, and preventing the clinical worsening of patients with ARF is an important goal to be established, since it is considered the main cause of cardiorespiratory arrest in the pediatric age group, and is estimated that over 2 million children progress to death due to ARF every year.[18,19]

In ARF due to AVB, NIV presents recommendation A, since it assists with the upkeep of airways, improves expiratory flow and lung compliance, enables adequate gas exchange, decreases partial pressure of carbon dioxide ($PaCO_2$) and, thereby, minimizes the patient's ventilatory effort and signs of RD.[2,20]

Noninvasive mechanical ventilation provides early improvement in most patients with hypercapnic ARF, with some studies associating low GCS scores, absence of cough, poor adherence to NIV, and presence of bronchiectasis and pneumonia as predictive factors for late failure and consequent intubation.[21] In adults, Holanda et al., carried out a study with the objective of determining the efficacy of noninvasive positive pressure ventilation (NIPPV) in ARF and observed success in 62% of the evaluated patients. In addition, they concluded that failure in NIPPV is associated with high mortality, especially in more severe patients who do not respond as expected to its use.[12]

Presence of reintubation is often associated with increased morbidity, hospital costs and risks of hospital readmissions; therefore, knowledge of the predictive factors associated with extubation failure should be investigated.[22] In this study, patients with presence of tachypnea after 2 h of NIV were 4.8 times more likely to require ETI in 48 h. In a longitudinal study conducted with children admitted to PICU, the need for mechanical ventilatory support and Comfort sedation scale score <26 were factors associated with extubation failure.[22]

Tachypnea in the pediatric population indicates presence of respiratory difficulty or dysfunction, which is present in the conditions of hypoxia and hypercapnia and is one of the most frequently found in emergency services.[23] Persistence of tachypnea, even after placement of NIV, indicates greater severity of the disease, and suggests a failure of this resource and the need for ETI.

Improvement in cardiorespiratory parameters with the use of NIV is due to the presence of positive pressure in the airways, which can be achieved using one or two pressure levels, CPAP and BiPAP, respectively. NIV can improve oxygenation, functional residual capacity, ventilation/perfusion ratio, gas exchange, lung compliance, cardiac output, fatigue, and respiratory work, in addition to assisting with reducing collapsed areas.[2,6,24,25]

The use of NIV is increasingly frequent in PICU in type 1 and 2 ARF and in neuromuscular disorders; however, in order for NIV to be successful, it is necessary to have adequate equipment, patient acceptance, and a trained and prepared multi-professional team.[26-30] Moreover, it is emphasized that NIV should be considered an option for early treatment in children at risk for acute

respiratory distress syndrome (ARDS), provided that it is performed in an appropriate environment and monitored by a specialized multidisciplinary team 24 hours.[27-31]

As study limitations, we can mention that, despite the large number of patients evaluated, the number of participants who met the inclusion and exclusion criteria was substantially small, as it is a reference service, with wide variability in age range and clinical situation. Thus, we were able to evaluate the use of NIV in several diseases, such as AVB, cystic fibrosis, bronchopulmonary dysplasia, Down syndrome, among others. We would also like to point out that, despite the statistically significant differences found in the HR and SpO_2 values pre- and post-NIV placement, these values are not clinically significant.

Another limitation regards the diversity of sizes and shapes of the participants' faces, which hindered the adjustment and adequate adaptation of the interfaces and, consequently, caused failure in the use of NIV. Mortamet et al. conducted a review in order to describe the different types of interfaces for the pediatric age group in acute conditions and concluded that, despite the increased use of NIV and the availability of interfaces, there are no recommendations for choosing the most appropriate interface in this population.[32]

The choice of the ideal NIV interface is still considered challenging, since its adjustment to the child's face must be carried out in appropriately aiming to minimize air escape and leakage, ensure stability, and prevent interface moving and displacements, thus maximizing synchronization between patient and ventilator and increasing the chance of success.[32]

Finally, this study evaluated the response to NIV after 2 h of its placement; however, we suggest that further research be carried out to assess whether response in the cardiorespiratory parameters can occur in a shorter or longer time compared with that observed in the present study, as well as to identify the best period for conducting NIV response assessments.

The 2-hour period after placement of NIV is reported within the concept of "golden two hours", which is described as essential in monitoring patients.[3] Children treated with NIV require very careful observation during the first 2 h, because they need continuous reassessment to verify the indication of maintenance or interruption of its use, thus avoiding delaying intubation in cases of non-improvement of the condition.[3]

Furthermore, periodic assessment of ABG, despite being mentioned in the literature, presents difficulties to be carried out in practice, a situation that is quite often observed in our service. There is indication for first ABG measurement within the first 30 min of NIV, and every hour thereafter. Nevertheless, in most cases, it is decided to monitor vital signs and maintain the patient without painful components, which can cause confusion in the data collected.[3]

We emphasize that there is a precariousness of studies addressing the use of NIV in South America and a systematic review found only five studies in this region.[7] Thus, we emphasize the importance of carrying out this study with the application of NIV in the pediatric population in a Brazilian, reference, multidisciplinary, public hospital, since the results can provide more information on this type of ventilatory support for our population in the different diseases studied.

We conclude that the use of NIV was effective in infants, preschoolers and schoolchildren admitted to PICU with a success rate of 69.2%, and that presence of tachypnea after NIV placement is a predictive factor of failure to prevent ETI. In addition, when using the "golden two hours" concept, we consider this time safe to assess the success or failure of NIV, thus avoiding unfavorable consequences for the patient.

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