Noninvasive ventilation in pediatric acute respiratory failure by means of a conventional volumetric ventilator

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Background: Acute respiratory failure (ARF) is one of the main causes for admission to pediatric intensive care unit (PICU). This study aimed to evaluate the feasibility and outcome of noninvasive ventilation (NIV) by a volumetric ventilator with a specific mode in pediatric acute respiratory failure.

Methods: A three-year prospective non-controlled study was undertaken in children with ARF who had received NIV delivered by Evita 2 Dura with NIV mode through a nonvented oronasal mask.

Results: Thirty-two episodes of ARF were observed in 26 patients. Pneumonia was observed in most of the children (46.8%). Pediatric logistic organ dysfunction (PELOD) score was 12.4%±24% (range 0-84%). Peak inspiratory pressure was 18.5±2.7 cmH2O, positive end-expiratory pressure 5.7±1.1 cmH2O, pressure support 10.5±2.7 cmH2O, and mean pressure 9.2±2 cmH2O. The clinical score was improved progressively within the first 6 hours. Before the initiation of NIV, respiratory rate was 41.7±16.3, heart rate 131.6±25.8, systolic arterial pressure 108±19.5, diastolic arterial pressure 58.2±13.9, pH 7.33±0.12, pCO2 55.1±20.2, SatO2 87.8±9.9 and FiO2 0.55±0.25. There was a significant improvement in the respiratory rate, heart rate, pH, pCO2 and SatO2 at 2-4 hours. This improvement was kept throughout the first 24 hours. The level of FiO2 was significantly lower at 24 hours. Radiological improvement was observed after 24 hours in 17 out of 26 patients. The duration of NIV was 85.4±62.8 hours. Complications were defined as minor. Only 4 patients required intubation. All patients survived.

Conclusions: NIV can be successfully applied to infants and children with ARF using this volumetric ventilator with specific NIV mode. It should be considered particularly in children whose underlying condition warrants avoidance of intubation.

Key words: acute respiratory failure; children; conventional volumetric ventilator; noninvasive positive pressure ventilation; pneumonia

Introduction

Acute respiratory failure (ARF) is one of the main causes for admission to pediatric intensive care unit (PICU). Children with ARF frequently require endotracheal intubation (ETI) and mechanical ventilation (MV). Despite assuring patient airway and ventilation, this treatment is not free of risks and complications such as nosocomial infection, tracheal and pulmonary injury and the need for sedation.[1-4] Noninvasive ventilation (NIV) or MV without ETI or tracheotomy could minimize these complications[5] and reduce the length of stay in the PICU in patients who do not need airway protection. Thus, this can be a reasonable option for carefully selected patients.[4,6]

The most widely used NIV modality is positive airway pressure ventilation provided by a mask (interface). This modality is mainly indicated for cases of chronic alveolar hypoventilation,[7,8] and has proved useful in cases of chronic respiratory insufficiency (CRI) worsening[9-15] and also in some cases of ARF.[16,19] It is also useful to avoid ETI and shorten invasive ventilation time.[20,21] Furthermore, this technique should be considered especially in patients in whom ETI is not indicated because of their underlying condition.[6,22] There are many studies on NIV effectiveness in adult patients with ARF in order to avoid ETI and reduce mortality.[23,24] However,
its role in pediatric ARF has not yet been conclusively defined.\textsuperscript{[25]}

The major limitation of NIV in pediatric ARF arises when selecting the right device for the application. In pediatrics, specific NIV ventilators are the most commonly used. However, due to their low usage rate specifically in pediatrics, these devices are not always available or are insufficient in number at every PICU. Modern conventional ventilators can provide specific NIV modes with automatic air-leak compensation.\textsuperscript{[26]} They can be an available and efficient alternative for NIV in pediatric ARF. The aim of this study is to evaluate the usefulness of a conventional volumetric ventilator with NIV modes in treatment of pediatric ARF.

**Methods**

A prospective non-controlled clinical study was carried out in children admitted to our PICU who were treated by NIV over a 3-year period. The PICU is a 6-bed multivalent unit at a tertiary university hospital. The study was approved by the Institutional Review Board, and informed written consent was obtained from parents of the children. We applied NIV to pediatric patients with ARF, aged 1 month to 16 years, when the attending pediatric intensive care physician thought that the patient was likely to require ETI.\textsuperscript{[6,27]} ARF was defined by the following clinical and/or gasometric criteria: 1) an increased respiratory rate for age\textsuperscript{[28]} and moderate to severe respiratory distress signs reaching >4 in the clinical score applied (Table 1), and/or 2) hypoxemic ARF (type I): PaO\textsubscript{2} < 60 torr or arterial oxygen saturation (SatO\textsubscript{2}) < 90% with FiO\textsubscript{2} > 0.5\textsuperscript{[29]} and/or 3) hypercapnic ARF or a mixed one (type II): plus pH < 7.35 with PaCO\textsubscript{2} > 50 torr.\textsuperscript{[25,29]} Postextubation ARF was defined as the clinical appearance of ARF immediately after extubation according to the above criteria.

For the diagnosis of acute respiratory distress syndrome (ARDS) and pneumonia, we used the criteria of the American-European Consensus on ARDS\textsuperscript{[30]} and CDC\textsuperscript{[31,32]} respectively. The exclusion criteria for NIV treatment are shown in Table 2.\textsuperscript{[3,26,33-35]}

A volumetric ventilator with specific NIV mode was used (Evita 2 Dura, Dräger Medical, Lübeck, Germany) with active humidification in all cases (Fisher and Paykel Healthcare, Auckland, New Zealand). The ventilator program includes air leakage compensation. The inspiratory trigger was a flow trigger set at the most sensitive value without auto-triggering. Expiration was allowed by decrease of inspiratory flow or after a set inspiratory time. The difference of initial ventilation mode was dependent on the severity of pathology. Continuous positive airway pressure with pressure support (CPAP+PS) was used in postextubation ARF and in type I (mild to moderate), and bi-level positive airway pressure with pressure support (BIPAP+PS) was used in the rest of cases, as well as in patients treated initially with CPAP+PS whose evolution was not favorable. The non-vented oronasal face mask used in the current study was the Mirage model (Resmed, Poway, CA), Perfomatrack (Respironics, Murrysville, PA) or Hans Rudolph masks (Hans Rudolph Inc, Kansas City, Missouri). In order to minimize skin damage, we placed hydrophilic material (Comfeel\textsuperscript{®}, Coloplast, Humlebaek, Denmark) on the bridge of the nose and also over the area most exposed to friction.\textsuperscript{[6,21]} In addition, alternating face mask model was also done to relieve the support area. Dipotassium clorazepate (0.5-1 mg/kg per day) or Midazolam (0.05-0.1 mg/kg per hour) was administered to all patients to improve mask tolerance and adaptation to MV according to medical criteria.

Nasogastric tube (NGT) decompression was used according to attending pediatrician's criteria. Enteral feedings were not commenced until the need for intubation was ruled out. Oral feeding was started when patient improvement made intermittent NIV feasible.

We studied age, sex, underlying condition, cause and type of ARF, pediatric logistic organ dysfunction (PELOD) score\textsuperscript{[36]} and pediatric risk of mortality III

**Table 1. Clinical scores: it was applied a synthesis of Silverman and Wood-Downes test**

<table>
<thead>
<tr>
<th>Clinical signs</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercostal/sternal retractions</td>
<td>0</td>
</tr>
<tr>
<td>Thoraco-abdominal dissociation</td>
<td>1</td>
</tr>
<tr>
<td>Nasal flaring</td>
<td>2</td>
</tr>
<tr>
<td>Expiratory groan</td>
<td></td>
</tr>
<tr>
<td>Cyanosis (SatO\textsubscript{2})</td>
<td></td>
</tr>
<tr>
<td>Consciences level</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Costal</td>
</tr>
<tr>
<td>No</td>
<td>Moderate</td>
</tr>
<tr>
<td>No</td>
<td>Slight</td>
</tr>
<tr>
<td>No</td>
<td>Auscultation</td>
</tr>
<tr>
<td>No</td>
<td>With air</td>
</tr>
<tr>
<td>Normal</td>
<td>Depression/</td>
</tr>
<tr>
<td>Depression</td>
<td>Restlessness</td>
</tr>
<tr>
<td>Depression</td>
<td>Restlessness</td>
</tr>
</tbody>
</table>

Silverman's test was used, unifying the evolution of the costal and sternal retractions as a unique parameter, and we included the evaluation of conscience level and of cyanosis of Wood-Downes score. This last parameter was evaluated by pulse oximetry, instead of PO\textsubscript{2} and clinical evaluation. Score: <4: slight; 4-6: moderate; >6: severe.

**Table 2. Exclusion criteria for noninvasive ventilation treatment**

<table>
<thead>
<tr>
<th>Patients younger than 1 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who need immediate endotracheal intubation</td>
</tr>
<tr>
<td>Inability to protect the airway</td>
</tr>
<tr>
<td>Hemodynamic instability (refractory at volemic expansion &gt;60 ml/kg and dopamine &gt;10 mcg/kg per minute).</td>
</tr>
<tr>
<td>Malformation, traumasisms or facial burns</td>
</tr>
<tr>
<td>Severe digestive hemorrhage</td>
</tr>
<tr>
<td>Undrained pneumothorax</td>
</tr>
<tr>
<td>Severe upper airway obstruction</td>
</tr>
<tr>
<td>Abundant respiratory secretions</td>
</tr>
<tr>
<td>Complete absence of collaboration</td>
</tr>
</tbody>
</table>
score (PRISM III) during the first 24 hours, ventilation mode, and the initial and highest parameter values. The following measures were taken to evaluate the initial evolution in the first 24 hours. First, respiratory work was evaluated based on the clinical score at 0, 2 and 6 hours (Table 1). Respiratory rate, heart rate, and blood pressure data were collected at the beginning and then again after 2-4, 6, and 24 hours.

Second, pH, pCO$_2$, SatO$_2$, and FiO$_2$ were collected at the beginning and then again after 2-4 and 24 hours. Capillary samples were taken (arterialized blood by heating the peripheral extremity) because initial arterial canalization was not performed in most patients. SatO$_2$ was measured by pulse oximetry with Masimo technology (Radical, Datascpe, Irvine, CA). Oxygen was administered by Venturi mask, reservoir mask or nasal prongs before starting NIV. When nasal prongs were used, FiO$_2$ was calculated according to the following formula: FiO$_2$ = 20 + 4 × oxygen flow in L/min. Once NIV is placed, the levels of FiO$_2$ are measured by MV.

Thoracic radiography was performed before and after 24 hours and was evaluated by a pediatric radiologist who was not familiar with the patient's clinical evolution. The duration of NIV, the time in PICU, and technical complications were evaluated. Treatment failure was defined as withdrawal due to poor tolerance and/or inability to stabilize the progression of respiratory failure and requirement of ETI. The maximal inspiratory pressure did not exceed 25 cmH$_2$O. The attending pediatric intensive care physicians indicated ETI when clinical and gasometric stabilization was not achieved despite the increase of respiratory assistance. ETI was also indicated if exclusion criteria emerged during treatment (Table 2).

We compared the evolution of patients with immunosuppression (IS) and psychomotor delay with the whole series, taking into account all the parameters studied.

Statistical analysis
The SPSS statistic package 14.0 for Windows was used. ANOVA designs were used for continuous variables between subjects and t tests for related values. Repeated measures designs were also used. Mauchly's test of sphericity was used in Repeated Measures ANOVA. In case of non-compliance, Pillalai's Trace test was used. In multiple comparisons, the Bonferroni adjustment procedure was used for type I error. The Wilcoxon's matched-pairs ranks test for related values and the Kruskal-Wallis test for group comparison were used to compare ordinal variables. Fisher's exact test was applied to dichotomous variables. A P value less than 0.05 was considered statistically significant.

Results
NIV was used in 32 ARF episodes of 26 patients, 19 boys and 7 girls, aged 1 month to 16 years (7.9±5.2 years on average). Patients' main characteristics are shown in Table 3. NIV was used 3 times in one patient and twice in 4 patients. The most common cause of ARF was pneumonia in 15 patients (46.8%), followed by ARDS in 7 (21.8%), asthmatic episodes in 5 (15.6%), and postextubation ARF in 5 (15.6%). PELOD mortality risk was 12.4±24% (range, 0-84%), and the PRISM III mortality score was 12.4±7.7 (range, 1-28). Initial radiography prior to NIV showed that one quadrant was affected in 1 patient (2.7%), 2 quadrants were affected in 16 patients (50%), 3 quadrants in 2 (5.5%) and 4 quadrants in 7 (21.8%). The results of the radiography were normal in 6 patients (18.7%), 5 suffered from postextubation ARF, and one with bronchiolitis.

Tolerance was good despite initial agitation in the youngest children. Moreover, none of them required withdrawal of the NIV. Anxiolytics or sedatives were given to all patients, Dipotassium clorazepate in 15 patients and continuous perfusion with midazolam in 17. The initial and highest NIV values are listed in Table 4.

A progressive improvement in the clinical score reached significant values between the beginning and after 2 hours of NIV (6.3±1.9 vs. 4.3±1.7, P<0.001), and between 2 and 6 hours of NIV (4.3±1.7 vs. 3.4±1.7, P=0.001). A significant improvement in respiratory and heart rate, pH, pCO$_2$, and SatO$_2$ was found at 2-4 hours after NIV initiation. This improvement was maintained throughout the study (Figs. 1, 2 and 3). FiO$_2$ was significantly lower at 24 hours (Fig. 3). There were no differences in the evolution of arterial pressure.

The radiological evolution of the 6 patients undergoing initial normal radiography did not show any alterations. Radiographic improvement was observed in 17 patients (65%) after 24 hours and none of them required ETI. This improvement was clearer in the upper and front segments but slower in the lower lobes.

Decompressive NGT was used during NIV in 18 patients, subsequently used for enteric feeding in 7. Two patients had gastrostomy. Oral feeding was initiated in 7 cases when intermittent NIV therapy was tolerated. Patients with NGT decompression had a significantly higher mortality risk (PELOD 19±29.6 vs. 3.6±7, P<0.05). No differences were observed in respiratory assistance or in other parameters.

The duration of NIV treatment in all patients was 85.4±62.8 hours (range, 2-216 hours). The patients who developed postextubation ARF had less time for NIV (17.2±14.5 vs. 100.2±59.3 hours, P<0.001). In seven patients, NIV was applied intermittently after initial improvement. Only 2 patients who had previous CRI...
Fig. 1. Respiratory rate (RR) and heart rate (HR) evolution. A significant reduction in both took place at 2-4 hours after beginning NIV treatment. This improvement was maintained throughout the first 6 to 24 hours ($P<0.001$, 0 hours vs. later for both parameters).

Fig. 2. Evolution of pH and pCO$_2$. NIV produced a quick improvement both in pH as well as pCO$_2$ which was maintained throughout the first 24 hours ($P<0.038$, $P<0.016$ respectively, 0 hours vs. later).

Fig. 3. Oxygen saturation (SatO$_2$) and FiO$_2$ evolution. SatO$_2$ showed a quick improvement during the first 2-4 hours. This improvement was maintained throughout the first 24 hours ($P<0.001$, 0 hours vs. later). FiO$_2$ was significantly lower 24 hours after initiating NIV treatment ($P<0.017$, 24 hours vs. previous times).

needed respiratory support after discharge from the hospital. One patient was discharged home with NIV after being readmitted to the hospital. The third ARF episode was successfully treated with NIV by means of our conventional ventilator (Table 3).

Since most complications were minor and related to interface, ventilation withdrawal was not necessary. The most frequent complications were mild erosion and irritative dermatitis on the bridge of the nose (11 patients). Only 1 patient required adhesiolysis and suturing. Three patients suffered from conjunctivitis. No bronchoaspiration, barotrauma or gastric distension was observed in all patients.

Four patients (12.5%) underwent intubation 3, 24, 60, and 83 hours after start of NIV (Table 3). ARF was caused by a serious ARDS (PaO$_2$/FiO$_2$ postintubation: 100.1±16.8 torr). These patients required more ventilatory assistance before and after intubation (Table 4). The time of MV was 15.8±5.1 days.

The mortality risk (PELOD) of the IS group was 27.5±34.5%. The patients in the IS group had significantly higher PRISM III mortality score (17±6.9 vs 10±6.9, $P=0.027$), required more hemodynamic support (8/8 vs. 2/22, $P<0.001$) and ETI (3/8 vs. 1/23,
In patients with psychomotor delay, ARF type II was most frequently seen (9/12 vs. 5/20, P=0.01), and the initial values of pH and pCO₂ were clinically and statistically altered (7.25±0.12 vs. 7.38±0.08, P<0.003 and 71.6±19.1 vs. 44.5±12.3 torr, P<0.002, respectively). These patients required BIPAP+PS more frequently (12/12 vs. 13/20, P=0.029) and had more complications related to interface (8/12 vs. 5/20, P=0.014). No differences were observed in respiratory assistance or in other parameters.

Table 4. Initial and highest assistance

<table>
<thead>
<tr>
<th>Variables</th>
<th>Initial NIV assistance</th>
<th>Highest assistance</th>
<th>All NIV patients</th>
<th>NIV failure patients</th>
<th>Post-intubation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIV mode (n)</td>
<td>CPAP+PS (13) BIPAP+PS (19)</td>
<td>CPAP+PS (7) BIPAP+PS (25)</td>
<td>BIPAP+PS (4)</td>
<td>CMV (4)</td>
<td></td>
</tr>
<tr>
<td>FiO₂</td>
<td>0.5±0.2 (range 0.3-0.9)</td>
<td>0.5±0.2 (range 0.3-1)</td>
<td>0.7±0.2 (range 0.6-0.9)</td>
<td>0.8±0.1 (range 0.75-1)</td>
<td></td>
</tr>
<tr>
<td>PIP (cmH₂O)</td>
<td>16.8±3.0 (range 14-23)</td>
<td>18.5±2.7 (range 15-25)</td>
<td>20.7±1.2 (range 20-23)</td>
<td>35±10.1 (range 28-50)</td>
<td></td>
</tr>
<tr>
<td>PEEP (cmH₂O)</td>
<td>5±0.8 (range 4-6)</td>
<td>5.7±1.1 (range 4-9)</td>
<td>7±2 (range 5-9)</td>
<td>9.8±2.1 (range 8-12)</td>
<td></td>
</tr>
<tr>
<td>PS (cmH₂O)</td>
<td>9.6±2.3 (range 5-15)</td>
<td>10.5±2.7 (range 5-18)</td>
<td>12.3±0.6 (range 10-13)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>MP (cmH₂O)</td>
<td>8.1±1.5 (range 5-11)</td>
<td>9.2±2.0 (range 6-14)</td>
<td>12.3±1.5 (range 11-14)</td>
<td>18.8±2.2 (range 16-21)</td>
<td></td>
</tr>
</tbody>
</table>

CMV: controlled mechanical ventilation; PIP: peak inspiratory pressure; PEEP: positive end-expiratory pressure; PS: pressure support over PEEP; MP: mean pressure; NIV: non-invasive ventilation.
None of these patients died during their hospital stay.

The length of stay in the PICU was 14.2±11 days. The patients who required intubation had a significantly longer stay in the PICU (21.8±5.6 vs. 13.4±11.3, P<0.005). None of these patients died during their hospital stay.

Discussion

Currently, experience in the application of NIV in pediatric ARF is still quite limited. Most papers are retrospective studies[6,27,42-45] and/or short series.[14,46-48] Establishing a selection of patients likely to benefit from this technique has not yet been determined,[33] thus restricting its use. In our opinion, this may be caused in part by a preferential use of NIV specific ventilators with limited availability. Furthermore, many of these devices do not have an inner oxygen mixer, so they are less suitable for hypoxemic ARF. For these reason conventional ventilators with NIV mode could efficiently solve this serious problem. In our series, like in two other recent studies,[27,49] the use of this conventional ventilator has proved its usefulness for pediatric ARF treatment. Our results show a significant improvement in the clinical, gasometrical and radiological evolution, lower rates of complications and a high success rate in the application of NIV. It should be pointed out that both clinical and gasometric improvement took place within initial hours of applying this technique and this improvement was maintained throughout the first 24 hours. Moreover, in our patients the use of NIV did not worsen prognosis in patients who required ETI.

Selection of interface is a key aspect in the overall success of NIV.[35,43] Although a preference for nasal masks has been described for its better tolerance,[25,33,50] We used oronasal masks because they avoid mouth leaks and improve ventilation and pressurization, thus making them more efficient in ARF.[44,50]

We agree with other authors[21] about the importance of having different sizes and models of masks, so as to vary the pressure points as outlined above. In this way, tolerance is improved and the risk of local complications is reduced when the application of NIV extends. Our results show that changing masks are especially important in patients with psychomotor delay. As in other studies,[21,33,49,51] we used sedation to improve tolerance and patients did not experience any complications. According to our results, indication for decompressive NGT depends on the severity of the patient's condition and not on the ventilation assistance since gastric distension is unlikely to occur with pressure less than 25 cmH₂O.[33,34]

According to our experience, the most efficient NIV mode in pediatric ARF is BIPAP + PS and must be tested early before the patient requires intubation. When comparing the ventilatory parameters used by other authors, we observed that PEEP/EPAP used was similar but with slightly higher PIP/IPAP values.[6,27,39,44,52] However more information on the severity of the patient's condition is needed to make a proper comparison. Only the most recent studies provide this information, showing the high mortality risk of our patients.[27,49,53] In addition, data on the severity of ARF are scarcely available. Initial radiological data were not found and only a subjective clinical scoring system[59] or a specific asthma scoring system[54] was applied. Although the synthesis scores of Silverman and Wood-Downes that we propose have not been validated, we believe it can be applied to any type of ARF by using general failure rate parameters of both scores. Likewise, the clinical evolution can be evaluated objectively by considering all the parameters easily evaluated by different observers, therefore making it useful for making comparisons.

The etiology of ARF in our series was similar to that found in other studies. The most frequent cause of ARF was pneumonia[6,39,43,49,52] and ARDS was the main cause of technique failure.[27] Although NIV failed in 4 patients with ARDS, ETI was avoided in 3 other patients. Moreover, NIV time varied greatly in those patients who needed ETI, being more than 24 hours in 3 of them. These patients did not show radiological improvement and required major respiratory assistance and MV time. These facts suggest that intubation was due to disease progression and not to an inappropriate initial indication of NIV. We consider that NIV should be tested early in patients with hypoxemic ARF.[53] This is especially important in IS patients with poor prognosis after ETI and mortality rates ranging from 50% to 100% in adults[16,17,56-58] and children.[47,59-61] Although 3 of the 4 patients who required ETI belonged to this group, intubation could have been avoided in the other 5, all of them survived. In our opinion it is possible that these results are related, in part, to the early respiratory support.

NIV has also proved especially useful in patients with psychomotor delay, mostly with a CRI grade variable. Despite the greater initial respiratory involvement, the evolution was favorable in all patients, including those in whom ETI may not be considered appropriate by family members and physicians.[6]

In conclusion, NIV can be successfully applied to infants and children with acute respiratory failure by this modern conventional ventilator with a NIV mode in a pediatric intensive care unit. It must be considered particularly in children with post-extubation ARF and in patients whose underlying condition warrants avoidance of intubation.

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According to Elliot[62] "there is much to be gained and little to be lost trying NIV, but then again, these patients should be carefully monitored by a motivated and well-trained critical care team because their conditions can deteriorate rapidly, and the risk of a delayed intubation is not acceptable".

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Ethical approval: Ethical approval by the Institutional Review Board.

Competing interest: The authors have not disclosed any conflicts of interest.

Contributors: Muñoz-Bonet JI proposed the study. Muñoz-Bonet JI and Flor-Macián EM wrote the main body of the article. All authors contributed to the intellectual content and approved the final version. Brines J is the guarantor.

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