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Efficacy of Early Non-Invasive Ventilation on ICU Stay and Outcomes in Type II Respiratory Failure Post-Extubation: A Prospective Study

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Abstract

Background: The application of non-invasive ventilation [NIV] following extubation in acute respiratory failure patients remains a contentious issue. Respiratory failure after extubation is a common occurrence post-mechanical ventilation, necessitating reintubation in approximately 10% of cases, with prevalence ranging from 4% to 24%.

The aim of the work: This study aimed to evaluate whether the early application of NIV immediately after extubation can reduce intensive care unit [ICU] stay duration in type II respiratory failure patients

Patients and Methods: This prospective study was conducted in the ICU of Bruida Central Hospital from February to October 2022. Patients intubated for more than 48 hours due to type II respiratory failure and successfully completing a two-hour spontaneous breathing trial were randomized into a control group receiving standard medical therapy [SMT] with oxygen supplementation and an NIV group receiving the same treatment with additional NIV support.

Results: The ICU stay in the NIV group was shorter than in the SMT group, although the difference was not statistically significant. Mortality rates and respiratory failure incidence were lower in the NIV group but without significant intergroup differences.

Conclusion: Early implementation of NIV post-extubation reduced ICU stay, the risk of respiratory failure, and mortality in type II respiratory failure patients.

Keywords: Non-Invasive; Ventilation; Respiratory Failure; Post-Extubation; ICU; Weaning.

INTRODUCTION

Respiratory failure occurs when the respiratory system is unable to supply oxygen to the body and eliminate carbon dioxide. Acute respiratory failure can be caused by a multitude of underlying conditions, including chronic obstructive pulmonary disease [COPD], acute respiratory distress syndrome [ARDS], and cardiogenic pulmonary edema. Type 2 respiratory failure occurs when the respiratory system cannot sufficiently remove carbon dioxide from the body, leading to hypercapnia [1].

Invasive mechanical ventilation [IMV] is life-saving in patients with acute respiratory failure not responding to other less invasive modalities [2].

IMV includes an endotracheal tube [ETT] and a mechanical ventilator [as opposed to noninvasive ventilation, in which the interface is a face mask]. In addition to serving as the conduit for the delivery of mechanical breaths, the ETT protects the airway, allows for suctioning of secretions, and facilitates select procedures, including bronchoscopy. Invasive mechanical ventilation helps stabilize patients with hypoxemic and hypercapnic respiratory failure, decreases inspiratory work of breathing, redistributes blood flow from exercising respiratory muscles to other tissues in patients with shock, and allows for the implementation of lung-protective [low tidal volume] ventilation in patients with acute respiratory distress syndrome [ARDS] [3, 4].

The ultimate goal of mechanical ventilation is not only to support the patient's respiratory function but also to successfully wean the patient from the ventilator once the underlying cause of respiratory failure has been addressed. However, the process of weaning and extubation is fraught with challenges, and extubation failure remains a significant issue [5].

As mechanical ventilation is associated with complications [e.g., ventilator-associated pneumonia], the optimal time to wean patients from mechanical ventilation is a critical goal to achieve in the intensive care unit [ICU] [6].

The decision to extubate is, therefore, usually taken as soon as a patient meets predefined weaning criteria and successfully passes a spontaneous breathing trial [SBT] [7]. Nevertheless, in 10–20% of patients who pass a spontaneous breathing trial and undergo planned extubation, extubation failure still occurs [8].

Extubation failure is usually defined as the need for reintubation within hours or days after a planned extubation. The time considered varies from 24 hours [4,5] until any time during the hospital stay [9].

Extubation failure is associated with an overall increase in the duration of mechanical ventilation, a greater need for tracheostomy, higher medical costs and a 25–50% increased mortality rate [10, 11]. The extended use of mechanical ventilation not only exacerbates patient morbidity but also places a substantial financial burden on healthcare systems [12].

Given these challenges, it is imperative to develop and implement strategies that can accurately predict the outcomes of extubation and prevent the onset of post-extubation respiratory failure and the need for reintubation. One such strategy is the use of non-invasive ventilation [NIV], which has been widely employed in the management of acute respiratory failure from various etiologies [13].

NIV has proven effective in conditions such as exacerbations of chronic obstructive pulmonary disease [COPD] [14] and cardiogenic pulmonary edema [15], reducing the necessity for invasive mechanical ventilation.

More recently, the use of NIV during the post-extubation period has garnered increasing interest [16]. Early application of NIV post-extubation aims to decrease the duration of invasive ventilation, prevent extubation failure, and serve as a rescue therapy for cases of unsuccessful extubation [17].

The rationale behind this approach is that NIV can provide respiratory support, reduce the work of breathing, and enhance gas exchange during the critical post-extubation period, thereby stabilizing patients who are at high risk of respiratory failure [18, 19].

THE AIM OF THE WORK

The purpose of this research is to investigate whether the early initiation of NIV immediately following extubation can effectively reduce the duration of ICU stay and improve clinical outcomes in patients with type II respiratory failure. This study aims to provide robust evidence on the impact of early NIV intervention on post-extubation respiratory outcomes, potentially informing clinical practices and guidelines for the management of such patients in the ICU setting.

Specifically, this study explored the hypothesis that early NIV application can reduce the incidence of post-extubation respiratory failure, decrease the need for reintubation, and ultimately lower mortality rates and healthcare costs associated with prolonged ICU stay. By addressing these objectives, this research seeks to contribute valuable insights into the optimization of respiratory care in critically ill patients and enhance the overall effectiveness of ICU management protocols

SUBJECTS AND METHODS

Study Design:

The study was conducted in the intensive care unit [ICU] of Burida Central Hospital from February 2022 to October 2022. The inclusion criteria included patients requiring intubation and mechanical ventilation for more than 48 hours due to type II respiratory failure. The exclusion criteria included patients with neuromuscular diseases, coma, recent facial surgery, cervical spine injury, agitation or uncooperative behavior, psychological agitation, anatomical abnormalities interfering with mask fit, uncontrolled cardiac ischemia or arrhythmias, metabolic and nutritional disorders, anemia, upper airway obstruction, or active upper gastrointestinal bleeding.

Procedures:

The procedures involved in this study included performing daily arterial blood gas [ABG] analysis at 8:00 a.m. to monitor patients' respiratory status. Variations in FiO2 and ventilatory settings were evaluated at the time of reintubation and upon discharge from the ICU to ensure appropriate adjustments were made. Additionally, patients

who successfully completed a two-hour T-piece spontaneous breathing trial [SBT] and met the established weaning criteria were included in the study, ensuring that only those capable of tolerating spontaneous breathing were enrolled. Although all patients successfully passed the two-hour spontaneous breathing trial [SBT] and met the weaning criteria, NIV was applied as a preventive measure in the NIV group to mitigate the risk of post-extubation respiratory failure. This approach aligns with evidence suggesting that early application of NIV can provide additional respiratory support, particularly for high-risk populations, thereby reducing complications such as respiratory muscle fatigue and potential reintubation.

Weaning Criteria:

The weaning criteria for this study required the resolution or improvement of the underlying cause of acute respiratory failure. Patients needed to have corrected arterial hypoxemia, defined as a PaO2 greater than 60 mmHg, with an FiO2 less than 0.4 and PEEP below 5 cm H2O. Additionally, patients were required to be free of fever, with temperatures above 38°C, or hypothermia, with temperatures below 35°C. A hemoglobin concentration of at least 70 g/L was necessary to ensure adequate oxygen-carrying capacity. Finally, patients needed to demonstrate hemodynamic stability, alertness, and the ability to communicate effectively.

Weaning Failure Criteria: Persistent conditions such as a respiratory rate >35 breaths/min, arterial oxygen saturation <90%, heart rate >140 or <50 beats/min, blood pressure <70 or >200 mmHg, reduced awareness, restlessness, or clinical signs of respiratory muscle fatigue.

Rationale for NIV Use: Patients who did not fulfil the criteria for weaning or experienced failure during the weaning process were included in the NIV group. These patients required additional respiratory support due to persistent respiratory insufficiency, elevated risk of post-extubation respiratory failure, or an inability to sustain spontaneous breathing. The use of NIV aimed to alleviate respiratory muscle fatigue, maintain adequate gas exchange, and prevent the need for invasive reintubation. This approach allowed tailored management for this high-risk subgroup, optimizing their chances for recovery while minimizing complications.

Randomization and Group Allocation:

Following extubation, patients were randomized into two groups. The first group, the standard medical therapy [SMT] group, received oxygen supplementation with the goal of achieving an arterial oxygen saturation [SaO2] greater than 92%. The second group, the non-invasive ventilation [NIV] group, received the same medical treatment as the SMT group, in addition to non-invasive ventilation using pressure support ventilation mode with the application of positive end-expiratory pressure [PEEP].

NIV Administration:

The administration of non-invasive ventilation [NIV] began with an initial PEEP setting of 5 cmH2O, which was adjusted as necessary to maintain an arterial oxygen saturation [SaO2] above 92%. The goals for NIV administration included achieving a respiratory rate of fewer than 25 breaths per minute, maintaining SaO2 above 92%, and ensuring a pH greater than 7.35. Both NIV and standard medical therapy [SMT] were administered for at least 24 hours. If the patient exhibited respiratory distress without meeting the criteria for reintubation, the treatment duration could be extended.

Reintubation Criteria:

Reintubation was considered necessary if patients met either major or minor criteria. Major criteria included respiratory failure post-extubation, respiratory acidosis [pH <7.35 with PCO2 >45 mmHg and PaCO2 increase >15%], hypoxemia [SaO2 <90% for FiO2 >50%], coma, cardiac or respiratory arrest, and severe hypotension. Minor criteria included a respiratory rate greater than 35 breaths per minute, signs of respiratory muscle exhaustion, severe dyspnea, and inability to clear secretions.

Outcomes Measured:

The primary outcomes measured in this study were the duration of ICU stay and hospitalization. Secondary outcomes included ICU mortality, hospital mortality, reintubation rates, and complications such as heart failure, pneumonia, encephalopathy, and post-extubation respiratory failure.

Mortality Measurements:

Mortality rates were specifically monitored and categorized into ICU mortality and hospital mortality. ICU mortality was defined as any death that occurred while the patient was still in the ICU, regardless of whether it was related to respiratory failure or other comorbid conditions. Hospital mortality was broader, including any patient who died during their entire hospitalization, whether in the ICU or the general ward. These measurements helped evaluate the effectiveness of the interventions [NIV versus standard medical therapy] in preventing the fatal outcomes associated with type II respiratory failure post-extubation.

Statistical Analysis:

Statistical analysis was performed using IBM SPSS Statistics [V. 22.0]. Descriptive statistics were calculated for quantitative data, including the minimum, maximum, mean ± standard deviation [SD], and median for parametric and non-parametric data, respectively. Qualitative data were presented as numbers and percentages. Statistical tests used in the analysis included the independent t-test, Fisher's exact test, paired t-test, Chi-square test, and Mann-Whitney U test. A P value of less than 0.05 was considered statistically significant.

RESULTS

Demographic and Baseline Characteristics:

The study groups were comparable in terms of demographic and baseline characteristics, with no significant differences observed between the NIV and SMT groups. The mean age was 60.3 ± 11.0 years in the NIV group and 60.5 ± 11.0 years in the SMT group [p = 0.960]. Gender distribution was also similar, with males representing 83.3% of the NIV group and 86.7% of the SMT group [p = 0.717]. Smoking habits, including the prevalence of current smokers, ex-smokers, and non-smokers, showed no significant differences [p = 0.943; Table 1].

Respiratory Rate: The respiratory rates at various stages of the study highlighted significant findings. During mechanical

ventilation, the mean respiratory rate was 13.3±1.8 cycles per minute in the NIV group compared to 12.8 ± 1.5 cycles per minute in the SMT group [p= 0.326]. At the conclusion of the spontaneous breathing trial [SBT], the mean respiratory rates were 20.6 ± 2.7 cycles per minute for the NIV group and 20.4±1.9 cycles per minute for the SMT group [p = 0.769]. Notably, one hour after the trial, the NIV group exhibited a significantly lower mean respiratory rate of 22.2 ± 4.7 cycles per minute compared to 24.9 ± 4.1 cycles per minute in the SMT group [p = 0.036]. Both groups experienced significant increases in respiratory rates from the MV stage to the SBT stage [p < 0.001]. The increase in respiratory rate from the SBT stage to one hour post-trial was significant only in the SMT group [p < 0.001; Table 2].

ICU Stay and Trial Duration:

The duration of the ICU stay and the trial period were key metrics in this study. The trial duration was significantly shorter for the NIV group, with a median of 3.0 days [IQR: 2.0–3.5] compared to 4.0 days [IQR: 2.8–7.0] for the SMT group [p = 0.041]. While the median ICU stay was also shorter in the NIV group [7.0 days, IQR: 5.0–10.0] compared to the SMT group [8.5 days, IQR: 6.8–15.0], this difference did not reach statistical significance [p=0.219; Table 3].

Mortality: The analysis of mortality rates revealed that ICU mortality was slightly lower in the NIV group at 10%, compared to 13.3% in the SMT group, though this difference was not statistically significant [p = 0.68; Table 4].

Respiratory Failure and Reintubation: The incidence of respiratory distress and the need for reintubation were higher in the SMT group. Respiratory distress occurred in 20% of the NIV group and 33% of the SMT group [p = 0.242]. Respiratory failure leading to reintubation was required in 4 patients in the NIV group and 8 patients in the SMT group [p = 0.205]. The median interval from trial to failure was 48 hours [IQR: 36–86] in the NIV group and 24 hours [IQR: 24–60] in the SMT group, with no significant difference between the groups [p = 0.197; Table 5].

Complications: The assessment of complications between the two groups showed no significant differences. The occurrence of myocardial infarction was identical in both groups at 3.33%. Cardiac arrest was slightly more prevalent in the SMT group [6.7%] compared to the NIV group [3.33%]. Pneumonia was only observed in the SMT group [3.33%]. These differences, however, were not statistically significant [Table 6].

Table [1]: Demographic and Baseline Characteristics of Study Groups.

Characteristic		NIV [N=30]	SMT [N=30]	P-value
Age [years]	Mean ±SD	60.3±11.0	60.5±11.0	**0.960**
	Range	43.0–83.0	45.0–87.0	
Sex n [%]	Male,	25 [83.3]	26 [86.7]	**0.717**
	Female	5 [16.7]	4 [13.3]	
Smoking N [%]	Smoker	19 [63.3]	20 [66.7]	**0.943**
	Ex-smoker	6 [20.0]	5 [16.7]	
	Non-smoker	5 [16.7]	5 [16.7]	
	Hashish	4 [13.3]	5 [16.7]	

Data presented as mean ± standard deviation [SD] or number [percentage]. P-values calculated using the independent t-test for continuous variables and Fisher's exact test for categorical variables.

Table [2]: Respiratory Rates at Different Stages.

Time	Measurement	NIV [N=30]	SMT [N=30]	P-Value
MV	Mean±SD	13.3±1.8	12.8±1.5	0.326
	Min. – Max.	11.0–18.0	12.0–18.0	
SBT	Mean±SD	20.6±2.7	20.4±1.9	0.769
	Min. – Max.	15.0–35.0	18.0–25.0	
After	Mean±SD	22.2±4.7	24.9±4.1	**0.036***
	Min. – Max.	15.0–35.0	20.0–40.0	
SBT -MV	Median [IQR]	7.0 [6.0–8.0]	8.0 [6.0–9.0]	0.518
	Range	1.0–16.0	4.0–12.0	
	P	**<0.001***	**<0.001***	
After -SBT	Median [IQR]	1.0 [-2.0–2.5]	3.0 [2.0–6.0]	**<0.001***
	Range	-8.0–18.0	2.0–15.0	
	P	0.138	**<0.001***	

Table [3]: ICU Stay and Trial Duration

Time	Measurement	NIV [N=30]	SMT [N=30]	P
Trial duration	Median [IQR]	3.0 [2.0–3.5]	4.0 [2.8–7.0]	0.041*
	Min-Max.	1.0–13.0	1.0–16.0	
ICU Stay	Median [IQR]	7.0 [5.0–10.0]	8.5 [6.8–15.0]	0.219
	Min-Max.	4.0–28.0	5.0–30.0	

Table [4]: ICU Mortality.

Measurement	NIV [N=30]	SMT [N=30]	P
ICU mortality	**3 [10%]**	**4 [13.3%]**	**0.68**

Table [5]: Respiratory Failure and Reintubation Rates.

Measurement		NIV [N=30]	SMT [N=30]	P-value
Respiratory distress		6 [20%]	10 [33%]	0.242
		[N=6]	[N=10]	
Respiratory failure & Reintubation		4	8	0.205
Trial – failure Interval [hours]	**Median [IQR]**	48 [36–86]	24 [24–60]	0.197
	Min.- Max.	24–96	24–120	

Table [6]: Comparison of complications between the NIV and SMT groups.

Measurement	NIV [N=30]	SMT [N=30]	P-value
Myocardial infarction	1 [3.33%]	1 [3.33%]	1.000
Cardiac arrest	1 [3.33%]	2 [6.7%]	0.55
Pneumonia	0 [0.0%]	1 [3.33%]	1.000

DISCUSSION

This study aimed to evaluate the efficacy of early non-invasive ventilation [NIV] in reducing ICU stay and improving clinical outcomes for patients with type II respiratory failure following extubation. Our findings indicate that while NIV offers immediate respiratory benefits, these advantages do not significantly translate into improved overall mortality or reduced complication rates when compared to standard medical therapy [SMT]. The findings suggest that NIV may offer certain immediate respiratory advantages, though its impact on long-term outcomes requires further investigation. The demographic and baseline characteristics were comparable between the NIV and SMT groups, with no significant differences in age, sex, or smoking habits. This comparability supports the validity of our findings by minimizing potential confounding factors related to patient demographics.

A significant finding of this study was the reduction in respiratory rates one hour post-trial in the NIV group compared to the SMT group. This suggests that NIV effectively reduces the work of breathing immediately after extubation, a result consistent with previous studies indicating NIV's role in alleviating respiratory muscle load and improving gas exchange. For example, a study by **Arsude *et al.*** [20] demonstrated that NIV could decrease the respiratory rate and improve arterial blood gases in patients with acute respiratory failure. Similarly, **Ou J, *et al.*** [21] found that NIV reduced the need for reintubation and improved respiratory parameters in a similar patient population. Both groups in our study experienced significant increases in respiratory rates from mechanical ventilation [MV] to the spontaneous breathing trial [SBT], but the increase from SBT to one-hour post-trial was only significant in the SMT group [$p < 0.001$]. This finding suggests a more stable respiratory transition in the NIV group.

The trial duration was significantly shorter in the NIV group, with a median of 3.0 days compared to 4.0 days in the SMT group [$p = 0.041$]. This reduction indicates that NIV can facilitate quicker weaning from mechanical ventilation, potentially by providing better respiratory support during the critical post-extubation period. However, the median ICU stay did not differ significantly between the groups, suggesting that the overall length of ICU admission is influenced by factors beyond the immediate respiratory benefits provided by NIV. These findings align partly with those of **Belenguer-Muncharaz *et al.*** [22], who reported no differences in ICU and length of hospital stay.

ICU mortality rates were slightly lower in the NIV group [10%] compared to the SMT group [13.3%], though this difference was not statistically significant [$p = 0.68$]. This result aligns with existing literature, where the impact of NIV on mortality has shown variability. A meta-analysis by **Peter *et al.*** [23] reported that substantial reductions in mortality and the need for subsequent MV were associated with NIV in acute respiratory failure, especially in the COPD subgroup. The effect on hospital length of stay was variable, with observed heterogeneity of the treatment effects.

Shan *et al.* [24] reported that NIV is an effective and evidence-based therapeutic tool in patients with acute exacerbations of COPD complicated by hypercapnic respiratory failure. Selection of appropriate patients to reduce the rate of NIV failure remains a challenge, but recent studies have provided some insight into possible predictors of NIV failure. With further evaluation, these could contribute to the refinement of eligibility criteria for NIV. The most effective strategy to withdraw NIV once acidosis and hypercapnia have normalized remains elusive, with new data suggesting that immediate withdrawal of NIV is safe and does not contribute to relapse any more than a step-wise withdrawal.

The incidence of respiratory distress and subsequent reintubation was higher in the SMT group. Specifically, respiratory distress occurred in 20% of the NIV group compared to 33% in the SMT group, and reintubation was required in 13.3% of the NIV group versus 26.7% of the SMT group. While these differences were not statistically significant, they indicate a trend towards better immediate respiratory stability with NIV. The median trial-failure interval was longer in the NIV group [48 hours vs. 24 hours], suggesting that when NIV patients did fail, they did so later, possibly reflecting a period of initial stability afforded by NIV.

These trends are consistent with the findings of **Thille *et al.*** [25], who reported that NIV could delay the onset of respiratory failure in high-risk patients after extubation. By contrast, NIV used as rescue therapy to treat post-extubation respiratory failure could increase the risk of death by delaying reintubation [26].

Complications such as myocardial infarction, cardiac arrest, and pneumonia were infrequent and showed no significant differences between the groups. This suggests that NIV does not increase the risk of these complications compared to SMT. This is consistent with previous findings that report similar safety profiles for out-of-hospital [OOH] non-invasive ventilation [NIV] and SMT in patients with acute respiratory failure [ARF] [27]. For instance, a study by **Rittayamai *et al.*** [28] found no significant increase in the incidence of complications with the use of NIV in a broad ICU population.

The study suggests that early NIV application can provide immediate respiratory benefits and facilitate quicker weaning from mechanical ventilation without increasing complications. However, there are no significant differences in mortality and overall ICU stay, highlighting the need for a more nuanced understanding of which patient populations might benefit most from NIV.

In conclusion, the early implementation of NIV following extubation in patients with type II respiratory failure appears to offer certain immediate respiratory benefits and reduces the trial duration in the ICU. However, its impact on overall mortality and complication rates remains inconclusive. These findings contribute to the growing body of evidence supporting the use of NIV in the ICU setting and underscore the need for further research to optimize its application and improve patient outcomes.

Limitations and Future Perspectives:

This study has several limitations that should be considered. The relatively small sample size and single-center design may limit the generalizability of the findings. Additionally, the study did not assess long-term outcomes beyond ICU discharge, which could provide a more comprehensive understanding of the benefits of NIV. Further research is needed to validate these findings in larger, multicenter trials and to explore the long-term impacts of NIV on patient outcomes. Future research should focus on larger, multicenter trials to validate these findings and identify specific patient subgroups that might benefit most from NIV. Long-term follow-up studies are also necessary to determine whether the immediate benefits of NIV translate into improved long-term outcomes. Investigating the mechanisms by which NIV provides respiratory support and understanding the factors that influence patient response to NIV could further optimize its use in clinical practice.

Approval Number the Protocol from Ethical Committee:

An approval of the study was obtained from Buraidah Central Hospital, Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of sharing in the study. This work was carried out in accordance with the Code of Ethics of the World Medical Association [Declaration of Helsinki] for studies involving humans. The research ethical committee approval code [7-2022].

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