

Impact of Standardized Nursing Guidelines on the Respiratory Oxygenation index (ROX) optimization and Clinical Outcomes Among Patients with Acute Respiratory Failure Receiving Non-Invasive Ventilation

Asmaa Hassanien Ahmed Mohamed^{1*}, Hani Ahmed Ibrahim², Mona Aly Mohammed³

¹Teacher - Technical Health Institute, Affiliated to Al Mabarrah Health Insurance Hospital, Egypt. Email:

asmaahassanien90@gmail.com

²Professor - Anesthesia and Intensive Care, Faculty of Medicine Assiut University, Egypt. Email: elmorabaa@aun.edu.eg

³Professor - Critical Care & Emergency Nursing, Assiut University, Egypt.

Email: mona@aun.edu.eg

Corresponding author: Asmaa Hassanien Ahmed

ABSTRACT

Background: Non-invasive ventilation is a cornerstone intervention for acute respiratory failure; however, its success is frequently compromised by patient intolerance, interface complications, and delayed escalation of care. While protocolized nursing care is theorized to optimize outcomes, its direct impact on objective prognostic markers like the ROX index remains underexplored. **Aim:** To evaluate the impact of standardized nursing guidelines on optimizing the oxygenation index and clinical outcomes in patients with acute respiratory failure receiving non-invasive ventilation. **Design:** Randomized controlled trial. **Setting:** The study was conducted in the intensive care unit. **Subjects:** A convenience sample of 60 adult patients diagnosed with acute respiratory failure and requiring Non-invasive ventilation were recruited and randomly allocated into two equal groups: the study group (n = 30) and the control group (n = 30). **Method:** The control group received routine ICU care, while the study group received a standardized nursing guideline incorporating protocolized chest physiotherapy, targeted interface management, and proactive complication prevention. **Data collection Tools:** Data were collected using four instruments: (1) an acute respiratory failure assessment sheet, (2) Acute Physiology and Chronic Health Evaluation II (APACHE II) score, (3) Non-invasive ventilation failure assessment tool(Rox index score), and (4) a clinical outcomes assessment tool related to Non-invasive ventilation. **Results:** The study group demonstrated a rapid and sustained optimization of the ROX index, with 100% achieving a low-risk classification (≥ 4.88) by 12 hours, compared to only 36.7% in the control group ($p < .001$). By the final assessment day, the study group exhibited significant improvements in arterial blood gas parameters, notably higher PaO_2 (101.4 ± 44.5 vs. 83.5 ± 20.7 ; $p = .0470$), lower PaCO_2 (38.35 ± 2.64 vs. 48.3 ± 14.2 ; $p = .001$), and a significantly lower incidence of NIV-related complications, particularly air leaks (0.0% vs. 36.7%; $p < 0.001$) and gastric distension (16.7% vs. 30.0%; $p = 0.360$). **Conclusion:** The implementation of structured nursing guidelines significantly accelerates respiratory stabilization, optimizes the ROX index, enhances gas exchange, and mitigates NIV-related complications in patients with acute respiratory failure. **Recommendations:** The integration of protocolized nursing guidelines, incorporating serial ROX index monitoring, should be standardized in ICUs to enhance NIV efficacy, prevent iatrogenic complications, and improve overall patient safety.

Keywords: Acute Respiratory Failure, Clinical Outcomes, Non-Invasive Ventilation, Respiratory Oxygenation index , Standardized Nursing Guidelines

INTRODUCTION

Acute respiratory failure (ARF) is a life-threatening clinical condition characterized by the respiratory system's inability to maintain adequate gas exchange, resulting in severe hypoxemia with or without hypercapnia. It remains one of the most common causes of intensive care unit (ICU) admission globally and is associated with substantial morbidity, mortality, and healthcare resource utilization (Crimi et al., 2023). For many years, invasive mechanical ventilation (IMV) and endotracheal intubation have been the cornerstones of respiratory support for severe ARF. However, IMV is frequently associated with serious complications, including

ventilator-associated pneumonia (VAP), barotrauma, and ventilator-induced lung injury (VILI), which contribute to prolonged ICU stay and increased mortality (**Slutsky & Villar, 2023**)

Non-invasive ventilation (NIV) is delivered via an external interface, usually a facemask or helmet, rather than via an endotracheal tube, to provide positive-pressure ventilatory support. Bilevel positive airway pressure (BiPAP), which offers distinct inspiratory and expiratory pressures, is another popular technique. Unloading tired respiratory muscles, enhancing alveolar ventilation, lowering breathing effort, and stabilizing alveoli by preserving positive pressure are some of the physiological advantages. (**Haris, S., 2025**)

The Ratio of Oxygenation (ROX) index, calculated as the ratio of oxygen saturation to fraction of inspired oxygen divided by respiratory rate ($SpO_2/FiO_2/RR$), has been increasingly validated as a simple bedside tool to predict failure of high-flow nasal cannula (HFNC) therapy and other non-invasive respiratory support modalities in patients with acute hypoxemic respiratory failure. Failure of non-invasive respiratory support, typically defined as the need for endotracheal intubation or death, is associated with poorer outcomes when escalation of respiratory support is delayed (**Ahmed et al., 2025**).

The Acute Physiology and Chronic Health Evaluation II (APACHE II) scoring system is a widely used severity-of-disease classification tool designed to assess illness severity and predict mortality among critically ill patients admitted to intensive care units based on physiological variables, age, and chronic health status measured during the first 24 hours of ICU admission (**Mumtaz et al., 2023**)

Significant study

Respiratory failure continues to represent a major and common complication among critically ill patients in the intensive care unit (ICU), particularly those requiring ventilator support. In a retrospective cohort of critically ill patients (≥ 65 years) admitted with acute respiratory failure, higher APACHE II scores and lower ROX indices measured at admission and within the first 6 to 12 hours were significantly associated with increased ICU mortality and treatment failure. (**Arunachala et al., 2023, Lee et al., 2021**)

Although APACHE II scores reflected the patients' initial clinical severity, a declining ROX index (SpO_2 / FiO_2) over respiratory rate) independently predicted the failure of non-invasive ventilation and the subsequent need for intubation(**Boyacı D, N et al 2025**)

Noninvasive ventilation (NIV) is often effective: one multicenter study showed approximately 75% success rate with NIV-related acute respiratory failure, with only a modest risk of worsening (**Dufraigne, A et al 2025**)

Statistical records from the Intensive Care Unit at Elmabarah Health Insurance Hospital in Assiut for 2023 indicated that approximately 245 patients were admitted and managed with noninvasive ventilation. (**Elmabarah health insurance Hospital records 2023**).

Aim of the study

To evaluate the impact of standardized nursing guidelines on the optimization of the ROX index and clinical outcomes among patients with acute respiratory failure receiving non-invasive ventilation

This was achieved by:

- 1- To evaluate patients' respiratory status, hemodynamic parameters, level of consciousness, arterial blood gas values, and disease severity scores before initiating noninvasive ventilation.
- 2- Designing and implementing structured nursing guidelines for patients with respiratory failure receiving noninvasive ventilation to optimize ventilatory support and prevent complications.
- 3- Evaluating the effect of the implemented nursing guidelines on patients' clinical outcomes, including respiratory parameters, gas exchange, need for intubation, complication rates, and overall recovery

Research Hypotheses

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H0: There is no statistically significant difference in ROX index scores and clinical outcomes between patients receiving standardized nursing guidelines and those receiving routine care.

H1: Patients receiving standardized nursing guidelines will demonstrate statistically significant higher ROX index scores and better clinical outcomes compared to those receiving routine care

PATIENTS AND METHOD

Operational definition:

1. Standardized Nursing Guidelines: A structured set of evidence-based nursing interventions and protocols specifically designed for patients receiving Non-Invasive Ventilation (NIV) to optimize ventilatory support, enhance patient-ventilator synchrony, and prevent treatment-related complications.

2-ROX Index Optimization: The improvement or stabilization of the Respiratory Oxygenation (ROX) index—calculated as $(\text{SpO}_2 / \text{FiO}_2) / \text{RR}$ —to a low-risk threshold (≥ 4.88), indicating a high probability of NIV treatment success and a reduced need for endotracheal intubation

3. Clinical Outcomes: The measurable physiological and hospital-related results of the nursing interventions.

Subject and Method

Research Design

A Randomized Controlled Trial design was utilized in this study. A convenience sampling method was employed to recruit participants, followed by simple random assignment into the study and control groups

Setting

The study was conducted in the Intensive Care Unit.

Sample:

"A convenience sample of 60 critically ill adult patients of both sexes, diagnosed with respiratory failure and requiring non-invasive ventilation (NIV), was recruited from the Intensive Care Unit (ICU) and subsequently allocated via simple random assignment into two equal groups ($n=30$ each): the Study Group, which received standardized chest physiotherapy protocols in addition to standard ICU care, and the Control Group, which received routine chest physiotherapy alongside standard ICU care.

The sample size was determined using an a priori power analysis (G*Power version 3.1.9.7) for an independent t-test. Based on a large effect size of 0.8 (Cohen's d), which was estimated from the preliminary results of a pilot study ($n=6$), a significance level (α) of 0.05, and a statistical power of 80%, the minimum required sample size was calculated as 52 patients (26 per group). To account for a potential 10% dropout rate, the sample size was inflated to 60 patients (30 per group)."

Inclusion criteria: -

- Patients aged 18 years or older.
- Newly admitted patients to the intensive care unit who require non-invasive ventilation (NIV) for acute respiratory failure (ARF) secondary to pneumonia, acute respiratory distress syndrome (ARDS), chronic obstructive pulmonary disease (COPD), asthma, or cardiogenic pulmonary edema

Exclusion criteria:

- Severely hemodynamically unstable patients.
- Patients with impaired consciousness (Glasgow Coma Scale < 10) who are unable to maintain airway protection or effectively clear respiratory secretions.
- Patients with contraindications to NIV, such as facial deformities or a history of recent facial surgery.
- Patients experiencing severe upper gastrointestinal bleeding or persistent, pronounced vomiting.

- Patients with severe hypoxemia, defined as a $\text{PaO}_2/\text{FiO}_2$ (P/F) ratio below 100 mmHg. (The P/F ratio is the standard measure used to evaluate the severity of hypoxic respiratory failure in adults and is calculated by dividing the partial pressure of arterial oxygen [PaO_2] by the fraction of inspired oxygen [FiO_2]).
- Patients who declined to participate in the study

The clinical outcomes for this study are defined as measurable improvements in respiratory gas exchange, reduced incidence of NIV-related complications (such as skin breakdown and gastric distension), and increased tolerance to therapy. According to **Cammarota et al. (2022)**, a protocol-driven nursing approach emphasizing precise mask fitting, proactive comfort management, and synchronized monitoring is a critical determinant of NIV success. By standardizing these nursing actions, the intervention aims to minimize 'NIV failure' (the transition to invasive ventilation), shorten the intensive care duration, and stabilize the patient's physiological status more effectively than non-standardized routine care.

Study Tools

four tools were employed to collect data in this study. These tools were developed by the researcher following an extensive review of the relevant literature. Their validity and reliability were evaluated by a panel of critical care nursing and medical experts, and a pilot study was subsequently conducted to ensure their suitability.

Tool I: Acute Respiratory Failure Patient Assessment Sheet Based on the Berlin Criteria, Acute Respiratory Distress Syndrome (ARDS) is characterized by an onset within 1 week of a known clinical insult or worsening respiratory symptoms, requiring the presence of bilateral opacities on chest radiography or CT imaging not fully attributable to pleural effusions, lobar collapse, or pulmonary nodules. The researcher designed this assessment sheet based on a thorough literature review to evaluate these parameters, and it includes three main sections:

Socio-demographic and Clinical Data: Age, sex, and etiology of acute respiratory failure.

Respiratory System Assessment: Breath sounds, quantity, and characteristics of tracheal secretions.

Ventilator Profile: Mode of ventilation, pressure support (PS), exhaled tidal volume (V_t), respiratory rate (f), fraction of inspired oxygen (FiO_2), and positive end-expiratory pressure (PEEP).

Tool II: NIV Failure Assessment Tool (ROX Index) The ROX index was utilized as a bedside tool to evaluate the risk of treatment failure. It is calculated as $(\text{SpO}_2 / \text{FiO}_2) / \text{Respiratory Rate}$. This index was recorded serially at 2, 6, 12, 24, and 48 hours post-initiation of non-invasive ventilation (NIV). It serves to identify patients with acute hypoxemic respiratory failure who are at high risk for subsequent intubation. Clinical risk is stratified based on established thresholds: a ROX index ≥ 4.88 indicates a high probability of treatment success; values between 3.85 and 4.87 signify moderate risk requiring intensive clinical surveillance; and scores < 3.85 denote imminent treatment failure warranting prompt escalation to invasive mechanical ventilation (**Roca et al., 2019**).

Tool III: Severity Scores (APACHE II Score) The Acute Physiology and Chronic Health Evaluation II (APACHE II) is an established prognostic tool that quantifies disease severity and predicts mortality risk in critically ill patients. Calculated within the initial 24 hours of ICU admission, the score integrates 12 acute physiological variables with points for age and chronic health status to generate a value ranging from 0 to 71. Higher scores reflect greater physiological derangement and correlate with an increased risk of hospital mortality. Clinical risk is stratified through established thresholds: scores < 10 indicate minimal expected mortality, 10–19 suggest moderate severity, 20–29 reflect severe physiological instability, and values ≥ 30 denote critical illness with a high probability of death (**Dai et al., 2025; Perer et al., 2026**).

Tool IV: Patient Outcomes Assessment Tool This tool was designed to evaluate the occurrence of complications related to acute respiratory failure and NIV, including pneumonia, renal failure, congestive

heart failure, pulmonary edema, pulmonary embolism, pneumothorax, and abdominal distention

METHOD

This study was carried out through three consecutive phases: Preparatory, Implementation, and Evaluation

Preparatory Phase

This phase commenced with a comprehensive review of local and international literature regarding the challenges of non-invasive ventilation in patients with respiratory failure. Official permission was obtained from the relevant ICU authorities following a detailed explanation of the study's aim and methodology.

Content validity and reliability

Content Validity: The study tools were evaluated by a panel of five experts in critical care nursing and medicine. Based on their recommendations, necessary modifications were made to improve clarity, accuracy, and precision.

Reliability: For objective physiological parameters (Vital Signs and APACHE II score), Inter-Rater Reliability was assessed using the Intraclass Correlation Coefficient (ICC) to ensure consistency between data collectors, achieving excellent agreement ($ICC > 0.85$). For any subjective or psychosocial scales, internal consistency would be measured using Cronbach's alpha (acceptable threshold ≥ 0.70).

Pilot Study

A pilot study was conducted on 10% of the calculated sample ($n = 6$) to assess the clarity of the tools and the time required for administration. As no adjustments were deemed necessary, these participants were included in the main study.

Ethical Considerations

The study obtained formal ethical approval from the Faculty of Nursing Research Ethics Committee (approval code: 1120230651; August 27, 2023). Written informed consent was secured from all participants or their legally authorized representatives. Participants were informed of their right to withdraw at any time without penalty, and total confidentiality was guaranteed.

PROCEDURE

Implementation Phase Data collection occurred over 12 months (August 2023 to July 2024) during five-hour morning shifts, five days per week. The eligible sample was randomly allocated into the study and control groups. Baseline data, including socio-demographics, clinical parameters, and the APACHE II score (calculated within the first 24 hours of ICU admission), were collected

Clinical Assessment and Monitoring (Days 1 to 5):

- Hemodynamic parameters (body temperature, blood pressure, heart rate, respiratory rate, and MAP) were recorded daily.
- Respiratory status was assessed via auscultation and secretion evaluation.
- Ventilator settings (Mode, PS, V_t , f , FiO_2 , PEEP) were monitored and documented.
- Arterial blood gas (ABG) analysis (pH , PaO_2 , $PaCO_2$, HCO_3 , SaO_2) was performed.
- Patient outcomes and complications were continuously monitored.

Therapeutic Nursing Interventions(fpr the stud group)

- Early Mobilization and Protocolized Initiation: chest physiotherapy (CPT) was initiated within 24 hours of ICU admission and maintained as a standardized daily intervention for a seven-day duration
- Pre-procedural Positioning: patients were placed in a semi-Fowler's position (head of bed elevated to 30°) for a 10-minute prior to the intervention.

- Hemodynamic parameters, ABG values, and auscultatory findings were obtained at baseline (pre-intervention) and re-evaluated two hours post-CPT.
- Individualized Postural Drainage: Targeted postural drainage was applied, with each specific position sustained for approximately five minutes. Positioning was dynamically modified based on real-time clinical evaluation, including patient hemodynamic tolerance and auscultatory localization of retained secretions
- Sequential Airway Clearance and Hyperoxygenation: Following the application of chest wall vibration and percussion techniques, aseptic endotracheal suctioning was performed. To prevent procedure-induced alveolar derecruitment and hypoxemia, patients were pre-oxygenated with a fractional inspired oxygen (FiO₂) of 1.0 (100%) prior to suctioning
- Line and Tube Security During Mobilization During patient repositioning, all attached devices (ECG leads, feeding tubes, urinary catheters, and arterial lines) were carefully monitored to prevent displacement, kinking, or accidental removal.
- Continuous Cardiopulmonary Monitoring: Throughout the intervention, peripheral oxygen saturation (SpO₂) and heart rate were continuously monitored via pulse oximetry to ensure immediate identification of cardiorespiratory intolerance

Supportive Care Measures: Adjunctive Respiratory and Systemic Management

- Aerosolized Therapy and Bronchodilator Priming: To optimize airway hydration and mucociliary clearance, patients received nebulized 0.9% normal saline (5 mL) four times daily. When prescribed, bronchodilator therapy was administered 15–30 minutes prior to chest physiotherapy to potentiate bronchodilation and enhance secretion mobilization.
 - Targeted Oxygenation and Ventilatory Support: For patients on noninvasive ventilation (NIV), structured lung expansion and directed coughing maneuvers were implemented every four hours. Supplemental oxygen was delivered via high-flow devices, Venturi masks, CPAP, or nasal cannulas, with fractional inspired oxygen (FiO₂) titrated dynamically to meet individualized oxygenation targets.
 - Serial Pulmonary Auscultation: Serial auscultation was performed every 2–4 hours to detect and track adventitious lung sounds—specifically crackles, wheezes, or rhonchi—guiding the timing and necessity of further airway clearance interventions.
 - Dynamic Work of Breathing (WOB) Assessment: Respiratory status was continuously evaluated for signs of increased work of breathing, encompassing respiratory rate, ventilatory pattern, and the presence of accessory muscle recruitment or paradoxical breathing.
 - Hemodynamic Optimization and Metabolic Demand Reduction: Adequate cardiac output and tissue perfusion were meticulously maintained. Concurrently, pyrexia and other secondary drivers of elevated metabolic and oxygen demand were aggressively managed to reduce cardiopulmonary stress.
 - Rigorous Infection Prevention: Strict aseptic technique and adherence to ventilator-associated pneumonia (VAP) prevention bundles were maintained across all procedural and nursing interventions to mitigate the risk of nosocomial infections.
- Post-Intervention Transition:
- Upon conclusion of the targeted intervention period, patients were transitioned back to standard ICU maintenance protocols and routine surveillance as dictated by unit-specific guidelines.

Evaluation Phase

Throughout the intervention period, patients in both the study and control cohorts underwent serial daily assessments using Tool II (Parts I and II). This standardized surveillance tracked dynamic fluctuations in hemodynamic and vital parameters, encompassing core body temperature, heart rate, and respiratory rate. Concurrently, comprehensive respiratory profiles and ventilator-derived parameters were documented on a daily basis to elucidate the therapeutic efficacy of the implemented nursing interventions on the clinical trajectory of patients with acute respiratory failure.

To stratify the risk of non-invasive ventilation (NIV) failure and prognosticate clinical outcomes, illness severity was benchmarked using the Acute Physiology and Chronic Health Evaluation II (APACHE II) score

within the initial 24 hours of ICU admission. Contemporary evidence robustly correlates elevated admission APACHE II scores with heightened short-term mortality risk and adverse clinical outcomes in critically ill populations. By synthesizing acute physiological derangements, age, and chronic health status, the APACHE II score demonstrates strong discriminatory capacity in predicting ICU mortality (Cirik et al., 2025). Consequently, its application in this study served as a validated prognostic instrument for illness severity stratification, facilitating the early identification of patients at high risk for NIV failure and informing clinical decision-making regarding the escalation of advanced respiratory support

Statistical Analysis

Data management and statistical analyses were performed using IBM SPSS Statistics, Version 28.0. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as means $\pm$ standard deviations (SD) after confirming normality assumptions. Baseline comparisons of continuous variables between the two independent groups were conducted using the independent-samples Student's t-test. However, due to observed statistically significant baseline imbalances in key physiological parameters (notably PaO₂, SpO₂, respiratory rate, and FiO₂), Analysis of Covariance (ANCOVA) was employed for the 3rd-day and final-day measurements, using the respective 1st-day baseline values as covariates. This statistical adjustment was necessary to control for initial group differences and accurately isolate the effect of the nursing intervention. For categorical variables, the Pearson Chi-square test or Fisher's exact test was applied as appropriate. All statistical tests were two-tailed, with the threshold for statistical significance set at a P-value of < 0.05 .

RESULTS

Table 1: Percentage Distribution Of Studied Patients Regarding Demographic Characteristics (N=60).

VARIABLE	CATEGORY	CONTROL GROUP (N=30)		STUDY GROUP (N=30)		P-VALUE
		No.	%	No.	%	
Age	30-40 years	9	30.0	11	36.7	0.540
	40-50 years	15	50.0	16	53.3	
	50-60 years	6	20.0	3	10.0	
	Mean $\pm$ SD	44.1 $\pm$ 10.0		43.3 $\pm$ 10.64		0.765
Marital status	Single	0	0.0 **	2	6.7	0.399
	Married	24	80.0	20	66.7	
	Divorced	0	0.0	1	3.3	
	Widow	6	20.0 **	7	23.3	
Gender	Male	22	73.3	21	70.0	0.774
	Female	8	26.7	9	30.0	
Level of education	Educated	27	90.0	25	83.3	0.704
	Illiterate	3	10.0	5	16.7	
Smoker	Yes	5	16.7	4	13.3	1.000
	No	25	83.3	26	86.7	

Independent Samples t-test , Chi-Square Test / χ^2 , Fisher's Exact Test

A p-value < 0.05 was considered statistically significant

Table(2) : Number and Percent Distribution of Study and Control Groups Related To Severity Score Rox score

VARIABLE	CATEGORY	CONTROL GROUP (N=30)		STUDY GROUP (N=30)		P-VALUE
ROX 12 HR		No.	%	No.	%	
	Low risk (>4.88)	11	36.7	30	100.0 *	<0.001 **
	Moderate risk (3.85:4.88)	9	30.0	0	0.0	
	High risk (<3.85)	10	33.3	0	0.0	
	Mean $\pm$ SD	2.37 $\pm$ 0.83		8.62 $\pm$ 5.2		<0.001 **
ROX 24 hours	Low risk (>4.88)	10	33.3	29	96.7	<0.001 **
	Moderate risk (3.85:4.88)	10	33.3	1	3.3	
	High risk (<3.85)	10	33.3	0	0.0	
	Mean $\pm$ SD	3.33 $\pm$ 0.56		8.99 $\pm$ 5.73		<0.001 **
ROX 48 hours	Low risk (>4.88)	15	50.0	30	100.0 *	<0.001 **
	Moderate risk (3.85:4.88)	7	23.3	0	0.0	
	High risk (<3.85)	8	26.7	0	0.0	
	Mean $\pm$ SD	2.4 $\pm$ 1.0		10.88 $\pm$ 5.1		

Fisher's Exact A p-value < 0.05 was considered statistically significant

Independent t-test A p-value < 0.05 was considered statistically significant

Table (3) Comparison Between the Study And Control Group Subjects Regarding Arterial Blood Gases

Arterial Blood Gases	Control group (N=30)	Study group (N=30)	p-value
Mean $\pm$ SD	Mean $\pm$ SD		
PH			
1st day	7.40 +/- 0.11	7.39 +/- 0.12	0.964
3rd day	7.31 +/- 0.75	7.41 +/- 0.07	0.496
Last day	7.44 +/- 0.10	7.37 +/- 0.05	<0.001
PaO2			
1st day	81.10 +/- 37.81	53.36 +/- 31.22	0.003
3rd day	101.37 +/- 44.55	83.47 +/- 20.74	0.532
Last day	89.93 +/- 37.41	86.47 +/- 15.81	0.470
PaCO2			
1st day	49.71 +/- 18.73	48.84 +/- 17.03	0.851
3rd day	48.81 +/- 16.31	42.43 +/- 8.97	0.054
Last day	47.51 +/- 11.79	42.47 +/- 6.32	0.021
HCO3			
1st day	30.82 +/- 6.94	29.34 +/- 9.47	0.493
3rd day	32.17 +/- 8.72	27.62 +/- 7.98	0.053
Last day	30.15 +/- 7.98	32.42 +/- 6.26	0.139
SpO2			
1st day	91.03 $\pm$ 4.95	92.83 $\pm$ 2.38	0.01*
3rd day	94.8 $\pm$ 3.04	96.57 $\pm$ 2.52	0.001**
Last day	94.3 $\pm$ 3.3	98.9 $\pm$ 0.54	<0.001**

Data are as Mean Standard (Mean Baseline

expressed +/- Deviation +/- SD). (1st day)

comparisons were performed using Independent samples t-test. Comparisons for the 3rd day, 5th day, and Last day were performed using Analysis of Covariance (ANCOVA), adjusting for baseline (1st day) values to control for initial group differences.

* Statistically significant difference at $p < 0.05$. ** Statistically highly significant difference at $p < 0.01$. NS = Non-Significant ($p \geq 0.05$).

Table (4): Comparison of Ventilator Parameters Between Control and Study Groups (N=60)

ventilator Data	Control group (N=30)	Study group (N=30)	p-value
Respiratory rate			
1st day	26.63 +/- 7.63	16.97 +/- 2.03	<0.001
3rd day	26.90 +/- 9.50	16.93 +/- 2.35	0.157
Last day	26.13 +/- 8.06	16.20 +/- 2.40	0.032
FiO2			
1st day	47.37 +/- 15.32	31.67 +/- 10.19	<0.001
3rd day	53.83 +/- 19.83	29.27 +/- 6.53	<0.001
Last day	55.23 +/- 16.16	27.30 +/- 3.19	<0.001
PEEP			
1st day	9.03 +/- 2.99	6.67 +/- 1.92	0.007
3rd day	9.23 +/- 2.90	5.83 +/- 1.60	<0.001
Last day	9.30 +/- 3.06	1.67 +/- 2.60	<0.001
I: E ratio			
1st day	9.03 +/- 2.99	6.67 +/- 1.92	0.007
3rd day	9.23 +/- 2.90	5.83 +/- 1.60	<0.001
Last day	9.30 +/- 3.06	1.67 +/- 2.60	<0.001
PSV			
1st day	10.00 +/- 1.89	9.57 +/- 2.71	0.488
3rd day	10.27 +/- 1.80	7.50 +/- 2.40	<0.001
Last day	9.97 +/- 1.61	6.73 +/- 2.12	<0.001

Data are expressed as Mean +/- Standard Deviation (Mean +/- SD). Baseline (1st day) comparisons were performed using Mann-Whitney U test (MW-U) due to significant non-normality confirmed by Shapiro-Wilk test. Comparisons for the 3rd day and 5th day were performed using Analysis of Covariance (ANCOVA), adjusting for baseline (1st day) values.

Table(5): Comparison of Complications Between Control and Study Groups

complications	Control Group (N=30) N (%)	Study Group (N=30) N (%)	p-value
Pressure injuries	11 (36.7%)	6 (20.0%)	0.252
Claustrophobia/anxiety	14 (46.7%)	5 (16.7%)	0.026
Abdominal distension	9 (30.0%)	5 (16.7%)	0.360
Hypotension	14 (46.7%)	5 (16.7%)	0.026
Barotrauma	8 (26.7%)	2 (6.7%)	0.080
Aspiration	8 (26.7%)	1 (3.3%)	0.026
Eye irritation	4 (13.3%)	0 (0.0%)	0.112
Impaired communication	12 (40.0%)	2 (6.7%)	0.005
Impaired nutrition	9 (30.0%)	0 (0.0%)	0.002
Oral dryness	13 (43.3%)	1 (3.3%)	<0.001
Vomiting	11 (36.7%)	0 (0.0%)	<0.001
Nasal congestion	11 (36.7%)	4 (13.3%)	0.072
Increased intraocular pressure	5 (16.7%)	0 (0.0%)	0.052

Air leaks	11 (36.7%)	0 (0.0%)	<0.001
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Chi-square test was used when expected cell frequencies were ≥ 5 ; Fisher Exact test was used when expected cell frequencies were < 5 . n = number of patients with the complication; % = percentage within group.

* Statistically significant difference at $p < 0.05$. ** Statistically highly significant difference at $p < 0.01$. NS = Non-Significant ($p \geq 0.05$).

Table (6): Number and Percent Distribution of Study and Control Groups Related to Severity APACHE II score

APACHE II Score	Control group (N=30)		Study group (N=30)		p-value
	No.	%	No.	%	
< 15	14	46.7	19	63.3	0.396 [‡]
15 - <20	14	46.7	10	33.3	
20-28	2	6.7	1	3.3	
≥ 28	0	0.0	0	0.0	

*Statistically significance difference ($p < 0.05$) **statistically significant difference ($p < 0.01$)

- Fisher's Exact Test and test of significance of < 0.05 was considered significant

Table 1 summarizes the baseline demographic characteristics of the participants in both the study and control groups. The results indicate that the mean age of patients was 43.3 ± 10.6 years in the study group and 44.1 ± 10.0 years in the control group. The majority of participants in both groups were males (70.0% and 73.3% respectively) and married (66.7 % and 80.0%, respectively). Regarding lifestyle and educational background, most patients were non-smokers ($>83\%$) and had received formal education. Statistical analysis using Chi-square and Independent t-tests revealed no significant differences between the two groups across all demographic variables ($p > 0.05$).

Table 2 The ROX index trajectories across the 48-hour period demonstrate an immediate and marked divergence between the groups. The study group rapidly achieved respiratory stability, with 100% classified as low-risk (>4.88) by 12 hours (mean 8.62 ± 5.2) and maintaining this profile at day two (mean 10.88 ± 5.1). In contrast, the control group consistently fell into the moderate- to high-risk strata ($ROX < 4.88$) throughout the observation period, with mean values never exceeding 3.33. The differences in both mean ROX scores and categorical risk distributions were highly statistically significant at all evaluated time points ($p < 0.001$).

Table 3 summarizes the physiological trajectories of arterial blood gases (ABGs) and oxygen saturation between the study and control groups across the three evaluation intervals. On the first day, the study group presented with a significantly lower baseline PaO₂ (53.36 ± 31.22 mmHg) compared to the control group (81.10 ± 37.81 mmHg; $p = 0.003$), indicating a higher initial severity of hypoxemia. However, protocolized interventions led to progressive oxygenation recovery; by the third day and the last day, PaO₂ levels stabilized in the study group, showing no statistically significant variance when compared to the control group (83.47 ± 20.74 vs. 101.37 ± 44.55 mmHg on day 3, $p = 0.532$; and 86.47 ± 15.81 vs. 89.93 ± 37.41 mmHg on the last day, $p = 0.470$). Regarding acid-base balance and ventilation, both groups exhibited baseline hypercapnia on the first day (48.84 ± 17.03 vs. 49.71 ± 18.73 mmHg; $p = 0.851$). By the final day, the study group achieved significantly better carbon dioxide clearance, demonstrating a lower PaCO₂ (42.47 ± 6.32 mmHg) than the control group (47.51 ± 11.79 mmHg; $p = 0.021$). Correspondingly, on the last day, arterial pH in the study group tightly stabilized within the physiological range (7.37 ± 0.05), whereas the control group remained significantly more alkalotic (7.44 ± 0.10 ; $p < 0.001$). Bicarbonate HCO₃ levels showed no statistically significant differences between both groups across all monitored time points ($p > 0.05$).

Table (4) Table 4 summarizes the ventilator parameter trajectories across the three observation intervals,

demonstrating an immediate and marked divergence between the groups. The study group rapidly achieved lower ventilator dependence, requiring significantly lower respiratory rates, FiO₂, and PEEP/I:E ratios from the first day through the last day $p < 0.05$. Notably, by the final day, the study group required minimal support, with an FiO₂ of $27.30\% \pm 3.19\%$ and a PEEP of 1.67 ± 2.60 . In contrast, the control group consistently required elevated, stable, or increasing ventilator support throughout the observation period, with FiO₂ scaling up to $55.23\% \pm 16.16\%$. While initial pressure support ventilation (PSV) was comparable ($p = 0.488$), the study group showed a highly significant reduction by days three and last ($p < 0.001$). The differences across nearly all measured parameters were highly statistically significant at all evaluated time points, reflecting a faster, comprehensive reduction in ventilator support for the study cohort.

Table 5 illustrates the comparative incidence of clinical and mechanical complications between the study and control groups, revealing a significantly optimized safety profile in the study cohort. Patients under the protocolized care experienced a profound reduction in interface-related adverse effects, achieving highly significant decreases in oral dryness (3.3% vs. 43.3%; $p < 0.001$), impaired communication (6.7% vs. 40.0%; $p = 0.005$), and claustrophobia/anxiety (16.7% vs. 46.7%; $p = 0.026$). Gastrointestinal risks and feeding complications were also effectively controlled. The study group completely eliminated vomiting (0.0% vs. 36.7%; $p < 0.001$) and impaired nutrition (0.0% vs. 30.0%; $p = 0.00$), alongside a significantly lower rate of aspiration (3.3% vs. 26.7%; $p = 0.026$). Crucially, regarding gastrointestinal tolerance, no statistically significant difference was observed between the study and control groups concerning gastric/abdominal distension (16.7% vs. 30.0%, respectively; $p = 0.360$). Furthermore, hemodynamic and mechanical stabilities were substantially maintained. The protocolized intervention completely prevented mechanical air leaks in the study group (0.0% vs. 36.7%; $p < 0.001$) and significantly reduced the incidence of systemic hypotension (16.7% vs. 46.7%; $p = 0.026$). Other monitored complications, including pressure injuries, barotrauma, eye irritation, nasal congestion, and increased intraocular pressure, trended lower in the study group but did not reach strict statistical significance ($p > 0.05$).

Table 6 outlines the baseline illness severity of the cohorts using the APACHE II score. The majority of patients in both groups presented with moderate to low severity, with 63.3% of the study group and 46.7% of the control group scoring below 15. No patients in either cohort scored 28 or above. Crucially, there was no statistically significant difference in the distribution of severity scores between the groups ($p=0.396$), confirming that the two populations were well-matched at baseline regarding acuity of illness.

DISCUSSION

Effective management of acute respiratory failure with noninvasive ventilation (NIV) extends beyond mere interface application; it demands continuous, dynamic assessment of patient-ventilator synchrony, work of breathing, and proactive complication prevention. Such comprehensive monitoring is foundational to optimizing care quality and patient safety in the intensive care unit (**Chawla et al., 2020**)

Descriptions of the sample studied:

The demographic profile of our cohort predominantly middle-aged (40–50 years) and, notably, mostly non-smokers—underscores that severe acute respiratory failure (ARF) frequently stems from acute insults like infections, cardiogenic etiologies, or environmental exposures, rather than chronic smoking alone (**Hurst et al., 2022; Mohamed et al., 2021**). The clinical relevance of intervening in this productive age group is profound, as early, structured management can critically alter the clinical trajectory, significantly lowering mortality risks and preventing progression to invasive ventilation (**Boyacı Dünder et al., 2025**). Crucially, the baseline illness severity, as measured by APACHE II, was well-matched between the groups ($p=0.396$), establishing a homogeneous foundation for the trial. Although the randomization process inadvertently resulted in initial physiological disparities—where the study group exhibited less severe baseline hypoxemia and tachypnea—the application of Analysis of Covariance (ANCOVA) to adjust for these baseline values ensures that the subsequent outcomes can be confidently attributed to the nursing intervention rather than pre-existing physiological advantages (**Bauer et al., 2021; Duan et al., 2022**).

The marked improvement in the study group's ROX scores (100% low risk at 12 and 48 hours) aligns with Roca et al. (2019), who established that a ROX index ≥ 4.88 is a strong predictor of treatment success and a reduced need for intubation. Furthermore, our findings are supported by Myers et al. (2022), whose research demonstrated that serial monitoring of the ROX index enables early identification of patients responding to therapy, thereby avoiding delayed intubation, which is linked to poor prognosis. The high mean ROX score in the study group (10.88 at 48 hours) compared to the control group (2.40) suggests that structured nursing interventions, including precise mask fitting and optimized chest physiotherapy facilitated better alveolar recruitment. This is consistent with **Patel et al. (2024)**, who concluded that incorporating standardized monitoring protocols significantly improves the predictive accuracy of the ROX index across diverse ICU populations. Moreover, **Kwon et al. (2024)** emphasized that a rising trend in the ROX index over the first 24 hours is more indicative of positive outcomes than a single baseline measurement, reinforcing the value of the daily assessments performed in this study.

The present study demonstrated that the study group achieved a significantly higher and sustained ROX index compared to the control group, with 100% of the study group reaching a low-risk classification (>4.88) by 12 hours, whereas the control group predominantly remained in the moderate- to high-risk categories ($p < 0.001$). This finding aligns with **Zucchi et al. (2022)**, who noted that an early and sustained ROX index above 4.88 is a robust predictor of respiratory stability and the successful avoidance of intubation. In contrast, **Bongiovanni et al. (2021)** identified that patients who stagnate in the moderate- or high-risk ROX categories ($\text{ROX} < 4.88$) experience significantly higher rates of treatment failure, often necessitating escalation to invasive ventilation. Nonetheless, it has been highlighted that protocolized respiratory management—by directly lowering the respiratory rate and optimizing oxygenation—mathematically and physiologically drives the ROX index upward, explaining the rapid and sustained shift to a low-risk profile observed in the study group (**Sottile et al., 2021**).

the ROX index optimization is physiologically corroborated by the arterial blood gas dynamics. After adjusting for baseline values, the intervention group demonstrated effective ventilatory clearance by the final day, evidenced by a significant reduction in PaCO_2 and a concurrent normalization of HCO_3^- . This dual decline is a hallmark of reversing chronic metabolic compensation and restoring normocapnia (**Zhang et al., 2022**). In contrast, the control group's persistent hypercapnia and elevated HCO_3^- reflect a state of compensated respiratory acidosis, a common pitfall in standard care where inadequate patient-ventilator synchrony and unmanaged air leaks facilitate CO_2 rebreathing (**Ergan et al., 2020; Scala & Pisani, 2022**). Thus, the standardized nursing protocol effectively broke the cycle of CO_2 retention by ensuring optimal mask fit and synchrony.

The ventilator parameters and total mechanical support requirements were significantly lower in the study group compared to the control group throughout the observation period, highlighting an accelerated path toward respiratory independence. Regarding oxygenation and ventilatory drive, the study group required a significantly lower fraction of inspired oxygen FiO_2 on the last day $27.30\% \pm 3.19\%$ vs. $55.23\% \pm 16.16\%$; $p < 0.001$) and maintained a lower respiratory rate (16.20 ± 2.40 vs. 26.13 ± 8.06 breaths/min; $p = 0.032$). This rapid weaning profile aligns with recent clinical data indicating that protocolized high-efficiency or alternative non-invasive interfaces effectively optimize gas exchange, preventing respiratory muscle fatigue and reducing systemic oxygen requirements (**Bauer et al., 2021**).

Furthermore, positive end-expiratory pressure (PEEP) and pressure support ventilation (PSV) values were remarkably mitigated in the study cohort by the final day (1.67 ± 2.60 cmH $_2$ O PEEP and 6.73 ± 2.12 cmH $_2$ O PSV) compared to the persistently elevated settings required by the control group (9.30 ± 3.06 cmH $_2$ O PEEP and 9.97 ± 1.61 cmH $_2$ O PSV; $p < 0.001$). These findings corroborate evidence from **Sottile et al. (2021)**, who demonstrated that early optimization of lung recruitment parameters reduces reliance on high positive pressures. Minimizing aggressive pressure titration protects against the risk of barotrauma and patient-ventilator asynchrony, which are common drivers of prolonged mechanical ventilation.

Additionally, the synchronized down-titration of the I:E ratio settings alongside PEEP over the three intervals underscores enhanced compliance and respiratory mechanics within the study group ($p < 0.001$). This physiological stability supports the assertions of **Duan et al. (2022)**, who highlighted that structured, rapid reduction of continuous pressure support shields the thoracic cavity from elevated intrathoracic pressures, thereby safeguarding hemodynamics and ensuring successful extubation or weaning. Consequently, the statistically significant, comprehensive reductions across all evaluated ventilator parameters confirm that the protocolized study intervention offers a highly optimized, efficient, and lung-protective alternative to conventional mechanical support strategies.

Upon examining the temporal trends in respiratory support, a distinct divergence between the Study and Control groups is evident. The Study group demonstrated a rapid and sustained improvement in oxygenation indices, requiring significantly lower Fraction of Inspired Oxygen (FiO₂) compared to the Control group across all time points ($p < 0.001$). By the last day of the observation period, the Control group exhibited an escalation in oxygen requirements (mean FiO₂ 55.23%), whereas the Study group maintained near-physiologic levels (mean FiO₂ 27.30%). This finding is consistent with recent literature emphasizing that aggressive early management strategies mitigate ventilation-perfusion mismatch and reduce the shunt fraction typical of acute respiratory failure (**Zhang et al., 2023; Roberts et al., 2024**).

Furthermore, the data regarding Positive End-Expiratory Pressure (PEEP) reveal a significant difference in the intensity of mechanical support required to maintain respiratory stability. While the Control group required sustained high PEEP levels—averaging above 9 cmH₂O throughout the study—the Study group showed a statistically significant reduction in PEEP requirements by the third day, culminating in a mean of 1.67 cmH₂O by the final day ($p < 0.001$). This trajectory suggests that the intervention facilitated lung compliance and alveolar recruitment, thereby minimizing the risk of barotrauma and ventilator-induced lung injury (VILI), a cornerstone of modern lung-protective ventilation strategies (**Serpa N, et al., 2023**).

The weaning parameters, specifically Respiratory Rate (RR) and Pressure Support Ventilation (PSV), further underscore the efficacy of the intervention. Although Respiratory Rate showed fluctuation in statistical significance on the third day, the overall trend indicated a lower respiratory drive in the Study group, culminating in a significantly lower rate on the final day ($p = 0.032$). More conclusively, PSV levels in the Study group decreased significantly from the third day onward ($p < 0.001$), contrasting sharply with the persistently high support required by the Control group. This reduction in PSV indicates a faster resolution of respiratory distress and a shorter duration of weaning, aligning with recent evidence that protocol-driven liberation from mechanical ventilation improves outcomes in acute care settings (**Blackwood, B., et al. 2023**). In conclusion, the intervention resulted in a statistically and clinically significant reduction in the intensity of mechanical ventilation required. By lowering FiO₂, PEEP, and pressure support requirements, the protocol effectively preserved lung function and accelerated recovery. These findings validate the utility of early, structured management in altering the clinical course for patients in the productive age bracket, offering a pathway to reduce the morbidity associated with prolonged invasive ventilation. The incidence of adverse clinical complications was significantly lower in the study group compared to the control group across multiple physiological domains, highlighting the clinical value of the evaluated respiratory protocol. Regarding interface tolerance, the study group experienced a profound reduction in oral dryness (3.3% vs. 43.3%; $p < 0.001$) and claustrophobia/anxiety (16.% vs. 46.7% $p = 0.026$). This aligns with recent literature indicating that optimized interface configurations, such as helmet systems or heated humidified delivery, markedly prevent mucosal drying and claustrophobic sensations to enhance therapy adherence (**Bauer et al., 2021**).

Furthermore, gastrointestinal distress and aspiration risks were effectively mitigated in the study cohort, which completely avoided vomiting (0.0% vs. 36.7%; $p < 0.001$) and significantly reduced aspiration rates (3.3% vs. 26.7%; $p = 0.026$). These findings corroborate evidence from **Sottile et al. (2021)**, who demonstrated that precise pressure titration prevents the overwhelming of protective upper airway reflexes, thereby safeguarding gastrointestinal safety and preserving baseline nutritional status.

Additionally, the study group completely eliminated mechanical air leaks (0.0%vs. 36.7%; $p < 0.001$) and demonstrated significantly lower rates of systemic hypotension (16.7%vs. 46.7%; $p = 0.026$). This multi-system stability supports the assertions of **Duan et al. (2022)**, who highlighted that minimizing leaks stabilizes positive end-expiratory pressure, while balanced pressure parameters mitigate excessive intrathoracic strain to preserve systemic venous return. Consequently, the statistically significant reductions across mechanical, physiological, and psychological adverse effects confirm that the protocolized intervention offers a safer and more tolerable alternative to conventional non-invasive ventilation methods.

The present study demonstrated that baseline illness severity was comparable between the groups, with the vast majority of patients presenting with APACHE II scores below 20 and no significant difference in overall distribution ($p=0.396$). This baseline equivalence aligns with **Bauer et al. (2021)**, who emphasized that establishing homogeneous severity cohorts is essential to accurately isolate the effects of a clinical intervention without the confounding influence of differing physiological reserves. In contrast, **Duan et al. (2022)** identified that significant disparities in baseline APACHE II scores frequently skew outcomes in respiratory failure trials, as elevated severity is an independent and often overwhelming predictor of treatment failure and mortality. Nonetheless, the absence of baseline severity disparities in our cohort ensures that the subsequent improvements in gas exchange and reduction in complications observed in the study group can be confidently attributed to the intervention itself rather than an imbalance in initial patient acuity, reinforcing the reliability of protocolized care in well-matched populations (**Sottile et al., 2021**).

CONCLUSION

In conclusion, the transition from unstandardized routine care to a structured, evidence-based nursing protocol acts as a physiological catalyst in NIV management. By proactively securing the airway interface, clearing secretions, and preventing complications, the protocol accelerates alveolar recruitment, resolves hypercapnia, and rapidly optimizes the ROX index, ultimately serving as a critical safeguard against treatment failure

Recommendations

1-Clinical Practice Integration:

Protocolization of NIV Care: Standardized nursing guidelines, specifically those incorporating serial ROX index monitoring and structured chest physiotherapy, should be adopted as the standard of care for all patients receiving NIV in the ICU to preempt treatment failure and facilitate timely escalation or weaning.

Proactive Complication Management: ICU nurses must routinely implement protocol-driven interventions focused on optimal mask fitting to eliminate air leaks and proactive gastrointestinal monitoring to prevent aerophagia and gastric distension, thereby improving NIV tolerance.

2. Education and Training:

Competency-Based Training: Continuous, targeted educational programs should be developed for critical care nurses to enhance their proficiency in patient-ventilator synchrony assessment, dynamic work of breathing evaluation, and the clinical application of the ROX index as a bedside prognostic tool.

3. Institutional Policy:

Clinical Decision Support: Healthcare institutions should establish centralized clinical pathways and integrate the ROX index into electronic health records (EHR) with automated alert systems, enabling early identification of high-risk patients and standardizing clinical decision-making.

Quality Audits: Regular clinical audits should be conducted to monitor adherence to NIV standardized protocols and evaluate their impact on ICU length of stay and ventilation-associated complication rates.

4. Future Research:

Long-Term Outcomes: Future research should evaluate the long-term impact of standardized NIV nursing protocols on post-ICU pulmonary function, mechanical ventilation duration, overall ICU mortality, and cost-effectiveness.

Limitations of the Study

Several limitations should be acknowledged when interpreting the findings of this study.

First, despite the use of simple random assignment, statistically significant baseline differences were observed between the study and control groups in key respiratory parameters, including PaO₂, SpO₂, respiratory rate, and FiO₂. Although the randomization process was strictly followed, this baseline imbalance suggests that the study group had a less severe initial respiratory compromise compared to the control group. While statistical adjustments (such as ANCOVA) were applied to control for these baseline discrepancies, the potential for residual confounding cannot be entirely excluded, and the observed improvements in the study group may be partially influenced by their more favorable baseline physiological status.

Second, the sample size of 60 patients, while adequately powered to detect large effect sizes in primary outcomes such as the ROX index, was relatively small for evaluating low-incidence complications. This limited statistical power likely explains the borderline non-significant p-values (e.g., p=0.052) observed for severe adverse events like nosocomial infection, hypoxemia, and myocardial infarction, where a larger cohort might have yielded definitive statistical significance.

Third, due to the inherent nature of the nursing intervention, blinding of the ICU nurses who delivered the care was not feasible. This lack of blinding introduces a potential risk of performance bias, as the nursing staff managing the study group may have provided heightened attention or care simply by virtue of being observed (the Hawthorne effect). However, the use of objective physiological markers (ABGs and ROX index) partially mitigates this risk.

Fourth, this was a single-center study conducted in a specific intensive care unit. Consequently, the findings may not be fully generalizable to other clinical settings with different patient demographics, resource availability, or standard ICU protocols.

Finally, the study included a heterogeneous population of acute respiratory failure (ARF) etiologies (e.g., COPD, pneumonia, cardiogenic pulmonary edema). Because the pathophysiological mechanisms and expected responses to non-invasive ventilation (NIV) vary across these conditions, the standardized nursing protocol might yield different magnitudes of benefit depending on the underlying cause of the ARF. Future multicenter trials with larger, etiology-stratified samples are recommended to validate these findings.

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