# RESEARCH

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# NIV failure in respiratory failure: an analysis

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# Abstract

**Objective** Noninvasive ventilation (NIV) has become an increasingly accepted mode of treatment for acute respiratory failure. Concept of NIV has revolutionized the treatment of acute respiratory failure in terms of the spectrum of diseases that can be successfully managed, the locations of its application, and achievable goals. The study was aimed at analyzing various aspects of NIV failure.

**Material and methods** In this prospective observational study, all patients who underwent NIV therapy for acute respiratory failure from September 2019 to June 2020 were recruited. The clinical, radiological, laboratory and other relevant data from patients satisfying inclusion criteria were collected and analyzed using appropriate statistical tools.

**Results** Out of the 96 NIV applications, 19 (19.8%) failed NIV application in the form of intubation in 12 and inhospital mortality in 8 (8.3% of the total group). A total of 73.7% (14/19) had an early failure, and 26.3% (5/19) had late failure. The median length of hospital stay was significantly higher in NIV failure group compared to NIV success group (p < 0.001). NIV outcomes like failure rate, in-hospital mortality, and length of hospital stay did not have any difference between type 1 and type 2 ARF (p > 0.05). NIV failure and in-hospital mortality were found to be higher in patients with pneumonia and ILD group, respectively (p < 0.05). A baseline respiratory rate of more than 37 per minute, pH < 7.28, and pCO2 > 77 mm Hg measured 1–2 h after NIV initiation, hyponatremia, and prior NIV failure history were identified as the independent predictors of NIV failure. Using NIV as a treatment modality in respiratory failure second-ary to pneumonia has more chances of failure (p < 0.05).

**Conclusion** Though NIV is the preferred initial tool in the management of respiratory failure, it should be judiciously used when risk factors for failure are present. Early escalation or upfront use of invasive mechanical ventilation should be considered in such scenario to prevent undue mortality and morbidity in respiratory failure patients.

# Main points

• Key point behind successful expansion of NIV is its capacity to achieve the same clinical outcomes as invasive ventilation with the avoidance of the complications associated with it.

• Delay in identifying the patients who are likely to fail NIV can cause undue delay in intubation; this can lead to clinical deterioration and increased morbidity and mortality.

• Predictors of NIV failure deciphered from this study are prior history of invasive mechanical ventilation following NIV failure, higher baseline respiratory rate, hyponatremia, low pH, and hypercapnia despite 1–2 h of NIV.

**Keywords** Noninvasive ventilation, NIV failure, Acute respiratory failure, COPD, Acute cardiogenic pulmonary edema, Acute hypercapnic respiratory failure

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# Introduction

Noninvasive ventilation (NIV) has been in use since many years, but its value has become increasingly recognized in the last two decades. The concept of NIV has revolutionized the treatment of acute respiratory failure in terms of the spectrum of diseases that can be successfully managed, the locations of its application, and





achievable goals [1-3]. It is the upfront ventilation technique of choice in certain specific aetiologies of acute respiratory failure (ARF) such as acute acidotic exacerbation of chronic obstructive pulmonary disease (COPD), acute cardiogenic pulmonary edema (ACPE), severe hypoxemia in immunosuppressive conditions and facilitation in transition following extubation from invasive mechanical ventilation (IMV) [3-6]. Over the past two decades, there has been a significant shift towards greater use of NIV in place of invasive mechanical ventilation (IMV) in this group of patients. The key point behind this successful expansion of NIV is due to its capacity to achieve the same clinical outcomes as IMV while avoiding the complications associated with it. Nevertheless, the use of NIV to support in other causes of ARF like communityacquired pneumonia and acute respiratory distress syndrome (ARDS) remains controversial [7, 8].

The reasons for NIV failure are most often related to the inability to improve oxygenation capacity, inability to reduce dyspnea, mask discomfort, agitation, anxiety, hemodynamic instability, and progression of ARF [9]. Use of NIV for conditions which do not have strong evidence for recommendation for its use also hikes the failure rate. Delayed identification of patients who are likely to fail on NIV may result in late entry into invasive mechanical ventilation. This delay is crucial as it may result in otherwise avoidable morbidity and mortality [3]. Therefore, it is imperative to identify the variables that may predict NIV failure [8]. NIV should be considered as a rational art, rather than an advancement in technology, which requires the aptitude of the clinicians to both choose case by case the best "ingredients" for a "successful recipe" (like patient selection, interface) and to avoid delayed intubation if the noninvasive attempt fails. In this context, a prospective observational study was conducted to analyze different aspects of NIV failure and decipher early predictors of NIV failure in patients with respiratory failure.

## **Materials and methods**

In this prospective observational study conducted in a tertiary care center in South India, all patients who were treated with NIV for respiratory failure between September 2019 and June 2020 were recruited. Institutional ethics committee approval (dated 02/01/2020) was taken for the study. Patient who had severe encephalopathy or hemodynamic instability, and those initiated on NIV for palliative purposes, were excluded. NIV initiated as a preemptive therapy to prevent post intubation respiratory failure were also not included in the study. An informed consent was taken either from the patient or from the caregiver if the patient was unable to give a consent due to severe distress. The clinical, radiological, laboratory and other relevant data from patients satisfying inclusion criteria were collected from direct interaction with patient as well as from medical records using a structured study proforma. This patient data was entered into study proforma, along with the details of ventilatory settings and interface used. Sequential ABG reports were taken especially baseline, after 1-2 h, 4-6 h, and later if needed until NIV is weaned off. The patients were followed up until death/discharge from the hospital. The primary outcome measured was the number of patients failing NIV in respiratory failure and the predictors for the same. The secondary outcomes were in-hospital mortality and length of hospital stay. NIV failure was defined by the need for endotracheal intubation/tracheostomy or

those succumbing to death after a DNI (do not intubate)

#### Institutional NIV protocol

order.

After clinical assessment and an initial ABG, standard medical therapy was administrated. If the patient was not improving and the criteria of NIV trial were met, NIV was initiated after properly counselling the patient. NIV was delivered through the following critical care ventilators: ICU Savina 300 classic (Drager Medical, Lubeck, Germany) and ICU Carina (Drager Medical, Lubeck, Germany). The interface used was silicon oronasal mask. In patients on home mechanical ventilation, patient's own NIV machine was at times used depending on the clinical scenario. NIV was started at an IPAP of 6-8 cm H20 and EPAP 3-4 cm H2O and was gradually increased by 2-cm H2O in next 10-15 min; titrating with the clinical response, in the form of relief of dyspnea, reduction of respiratory rate, and effort or SpO2 above 92%, was achieved. A difference of 4-10 cm H20 between IPAP and EPAP was maintained. Patients were attended by doctors and staff experienced in handling NIV in a highdependency unit until they became clinically stable. During the initial 24 h, disconnection of NIV was allowed only for intake of food and to clear oral secretions. Thereafter, depending upon the clinical response, the NIV was gradually weaned off. If worsening of clinical status happened, a shift of ventilatory support to invasive mechanical ventilation was done.

#### Statistical methods

Data collected was tabulated using MS Excel and analyzed using SPSS version 16.0. Results of continuous measurements were represented using mean $\pm$ standard deviation or median (interquartile range), and results of categorical measurements were represented using frequencies and percentages. Categorical variables were compared with chi-square test or Fisher exact test when appropriate. Continuous variables were compared with independent *t*-test or Mann–Whitney *U*-test in non-normal distribution. Univariate and multivariate regression analysis were conducted on the various causes of NIV failure to evaluate the statistically significant predictors among various etiologies. A *p*-value < 0.05 was considered to be statistically significant.

# Results

In the study period of 10 months, there were 119 patients who presented with acute respiratory failure in our hospital. Out of this, 12 patients were intubated upfront and initiated on invasive mechanical ventilation before an NIV trial as per protocol. And after excluding 14 patients initiated on NIV for palliative purposes, there were 93 patients who fulfilled inclusion criteria and were included in the study. Overall, 93 patients received a total 96 NIV applications with 22 (22.92%) and 74 (77.08%) for hypoxemic and hypercapnic acute respiratory failure, respectively. There were 48 males (51.61%) and 45 females (48.38%), with a mean  $\pm$  SD age of 66.9 $\pm$  10.6.

NIV application was success in 80.2% (77/96) applications and failure in 19.8% (19/96). Comparison of various demographic variables, comorbidities, and other relevant data between NIV success and failure group is as shown in Tables 1 and 2.

Previous history of NIV failure, high initial heart rate, high initial respiratory rate, low initial pH, low pH at 1-2 h, low pH at 4-6 h, high pCO<sub>2</sub> at 1-2 h, high pCO<sub>2</sub> at 4-6 h, low initial sodium level, high initial severity scores like APACHE II score, Charlson index, and SAPS II score were found to be significantly different in failed group compared to success group.

A univariate and multivariate logistic regression analysis was done including all parameters having significant p-value < 0.05 to obtain an adjusted odd's ratio with 95% confidence interval and to define variables which are independently associated with NIV failure. Previous history of NIV failure, high initial respiratory rate, low pH, and high pCO2 recorded at 1–2 h after initiation of NIV and low initial sodium level were found to be independent predictors of NIV failure (Table 3).

# Secondary outcomes

# In-hospital mortality

Out of the 96 applications, 19 failed NIV application in the form of intubation in 12 and in-hospital mortality in 8 (8.3% of the total group). Five patients who succumbed to death were not intubated as a decision for DNI was taken initially, whereas 3 patients who got intubated succumbed to death despite all resuscitative measures. NIV failure and in-hospital mortality according to etiology are shown in Table 4.

Table 1	Comparison	of demo	graphic	variables	between	success
and failu	re group					

	Success n (%)	Failed n (%)	p
Sex			
Male	41 (82.0)	9 (18.0)	0.646
Female	36 (78.3)	10 (21.7)	
Smoking status			
Smoker	29 (82.9)	6 (17.1)	0.622
Nonsmoker	48 (78.7)	13 (21.3)	
Respiratory failure			
Туре 1	15 (75.0)	5 (25.0)	0.511
Туре 2	62 (81.6)	14 (18.4)	
Pulmonary hypertension	26 (72.2)	10 (27.8)	0.128
Diabetes mellitus	48 (77.4)	14 (22.6)	0.354
Systemic hypertension	49 (77.8)	14 (22.2)	0.409
Coronary artery disease	25 (71.4)	10 (28.6)	0.102
Home NIV use	15 (83.3)	3 (16.7)	0.712
Home oxygen use	18 (78.3)	5 (21.7)	0.788
Past history of NIV failure	3 (33.3)	6 (66.7)	<i>p</i> < 0.01

OSA Obstructive sleep apnea, NIV Noninvasive ventilation

#### Length of hospital stay

The median length of hospital stay among the entire study group is 7 (5–10). The median length of hospital stay is significantly higher in NIV failure group compared to NIV success group (p < 0.001) and among those whose had mortality in the hospital (p < 0.05) as shown in Table 5.

## NIV failure prediction score

A new score is being proposed based on the independent predictors from various parameters after multivariate analysis.

NIV failure prediction score =  $[pCO2 \ 1-2 \ h \ (mm \ Hg) \times 0.05] + [initial sodium level (mEq/L) \times 0.15] - [respiratory rate <math>\times 0.14] + [pH \ 1-2 \ h \times 34.57] - [past history of mechanical ventilation (if present = 1, no = 0) \times 2.79].$ 

The NIV failure prediction score cut off is 270. A score less than 270 has high chances for NIV failure and vice versa. The AUC value for the prediction score in 0.913 (0.832–0.993) is as shown in Fig. 1. Validation using the

	Success (n = 77)	Failure ( <i>n</i> = 19)	<i>p</i> -value
	Mean $\pm$ standard deviation	Mean $\pm$ standard deviation	
Age (years)	67.9 <b>±9.3</b>	65.8± 15.0	0.446
BMI (kg/m²)	26.0±5.0	24.3 ± 5.2	0.195
Initial heart rate (per minute)	102.5 ± 17.9	116.3 ± 20.0	0.004
Initial respiratory rate (per minute)	28.0 ± 6.4	34.3 ± 8.5	<i>p</i> < 0.01
GCS score	14.8± 0.6	14.5 ± 0.9	0.058
Initial SpO <sub>2</sub> (%)	81.0± 13.1	74.3 ± 17.2	0.062
Initial pH	7.3 ± 0.1	7.3 ± 0.1	0.032
pH at 1–2 h	7.3 ± 0.1	7.2 ± 0.1	<i>p</i> < 0.01
pH at 4–6 h*	7.3 ± 0.1	7.2 ± 0.1	<i>p</i> < 0.01
pCO <sub>2</sub> — initial (mm Hg)	67.1 <del>±</del> 19.4	69.4 <del>±</del> 22.8	0.655
pCO <sub>2</sub> at 1–2 h (mm Hg)	64.1 <del>±</del> 17.3	76.9 ± <b>25.7</b>	0.011
pCO <sub>2</sub> at 4–6 h* (mm Hg)	60.0 <del>±</del> 16.6	74.4 <b>± 33.1</b>	0.012
$PaO_2$ initial (mm Hg)	85.3 ± 47.7	65.8 <del>±</del> 22.8	0.088
Bicarbonate level (mEq/L)	29.5 ± 6.7	27.6 ± 6.3	0.276
Sodium (mEq/L)	135.9± 5.7	129.2 ± 8.8	<i>p</i> < 0.01
CRP (mg/L)	34.6 ± 46.7	61.6 <del>±</del> 80.1	0.057
APACHE II score	14.1 ± 4.3	19.2 <del>±</del> 4.4	<i>p</i> < 0.01
Charlson index	5.0 ± 1.7	6.7 ± <b>2.1</b>	<i>p</i> < 0.01
SAPS II score	22.0 ± 4.8	27.6 <b>± 5.6</b>	<i>p</i> < 0.01

# Table 2 Comparison of various parameters among success and failure group

BMI Body mass index, GCS Glasgow Coma Scale, CRP C-reactive protein, APACHE Acute Physiology and Chronic Health Evaluation, SAPS Simplified acute physiology score

 Table 3
 Independent predictors of NIV failure in patients with acute respiratory failure

	Best cutoff	Beta coefficient	Standard error	Significance	Odds (95% Cl)
Past history of NIV failure	Present	2.79	1.16	.0163	16.22 (1.67–157.51)
Initial respiratory rate	37/min	0.14	0.06	.0175	1.15 (1.03–1.3)
pH at 1–2 h	7.28	- 34.57	11.17	.0020	0 (0–0)
pCO <sub>2</sub> at 1–2 h	77 mm hg	- 0.05	0.03	0.1350	0.95 (0.89–1.02)
Sodium	131.5 mEq/L	-0.15	0.05	.0043	0.86 (0.77–0.95)

NIV Noninvasive ventilation, Cl Confidence interval

**Table 4** Percentage distribution of study population according to in-hospital mortality

Etiology	Total NIV applications	NIV failure	In-hospital mortality
COPD	42	6 (14.3%)	1 (2.4%)
Asthma	10	0	0
ACPE	13	1 (7.7%)	0
OSA/OHS	12	2 (16.7%)	0
ILD	5	3 (60%)	3 (60%)
Neuromuscular diseases	5	2 (40%)	1 (20%)
Bronchiectasis	4	1 (25%)	1 (25%)
Pneumonia	5	4 (80%)	2 (40%)
	96	19	96

NIV Noninvasive ventilation, COPD Chronic obstructive pulmonary disease, ACPE Acute cardiogenic pulmonary edema, OSA Obstructive sleep apnea, OHS Obesity hypoventilation syndrome, ILD Interstitial lung disease

 Table 5
 Length of hospital stay according to outcomes

	Length of hospital stay — median (IQR)	<i>p</i> -value
NIV success group ( $n = 77$ )	6 (5–8)	< 0.00001
NIV failure group ( $n = 19$ )	12 (8–22)	
In-hospital mortality ( $n = 8$ )	18.5 (8.25–32)	0.0032
Survived patients ( $n = 88$ )	7 (5–9)	

IQR Interquartile range, NIV Noninvasive ventilation

existing sample showed a significant specificity of 89.6% and sensitivity of 84.2% as shown in Fig. 2.

## Discussion

NIV has become an increasingly accepted mode of treatment for acute respiratory failure. With its popularity, it has attracted the eyes of many researchers leading to extensive studies regarding its various aspects. The current landscape of NIV literature has an increased focus on determining predictors of NIV failure. The intention of the current study was also the same. Estimating predictors of NIV failure is crucial in the management as delay in identifying patients who are likely to fail NIV can lead to inappropriate delay in intubation and thereby leading to clinical deterioration with increased morbidity and mortality [10].

The primary outcome measured in this study was NIV failure and the predictors of NIV failure. We found a failure rate of 19.8% and an in-hospital mortality of 8.3% in our study population. This figure is at the lower end of the ones reported in other studies where the failure rates range from 9 to 60% [11, 12].

The independent predictors for NIV failure form the current study were high initial respiratory rate, low pH

recorded at 1-2 h, high pCO<sub>2</sub> recorded at 1-2 h, low initial sodium, and past history of NIV failure. Higher respiratory rate at admission and its improvement following NIV administration are associated with successful outcome of NIV [13]. An increase in respiratory rate 1 h after NIV initiation is a risk factor of NIV failure in postoperative ARF and ARF due to hematological malignancies [14, 15]. The current study had derived a cutoff of 37 per minute for baseline respiratory rate above which chances of NIV failure is high with an odd's ratio (OR) of 1.15. A similar finding was obtained by Confalonieri, Garuti, Cattaruzza, Osborn, Antonelli, and Conti (2005) when they studied 1033 COPD patients where a respiratory rate of  $\geq$  35/min at admission lead to respiratory failure with OR of 2.66 [16]. Respiratory rate is also a parameter in the HACOR score for predicting NIV outcome, developed by Duan, Han, Bai, Zhou, and Huang [17]. Rapid shallow breathing index > 105, commonly used to guide weaning from mechanical ventilation, has also been demonstrated to be an independent predictor for endotracheal intubation [18].

The pH level is one of the prime parameters assessed as an indicator in most of the prior studies. pH, being an indicator of severity of hypercapnia, has been reported to be a critical factor in determining the success of NIV. Most studies highlighted a lower baseline pH to be a risk factor for NIV failure [13, 16, 19]. In our study, baseline pH was significantly lower in the failure group compared to success group; however, it did not pass the regression analysis to be an independent predictor. Instead, pH value 1 to 2 h after the application of NIV was shown to be a strong predictor of NIV failure, with good sensitivity of 84.2%. Confalonieri, Garuti, Cattaruzza, Osborn, Antonelli, and Conti (2005) pointed out a similar finding that pH < 7.25 after 1 h of NIV use was a predictor of failure, and the risk of failure was even greater than when the pH levels were < 7.25 at admission [16]. The current study validated the same point that a pH of <7.28 after 1 h of NIV use was associated with increased risk of failure than a similar pH value at admission. The 2017 Official ATS/ERS clinical practice guidelines on NIV point the fact that there is no lower limit of pH below which a trial of NIV is appropriate; however, the lower the pH, the greater is the risk for failure [4]. Several studies have also found the improvement in pH, and pCO<sub>2</sub> and level of consciousness within 1 or 2 h of NIV are strong predictors of success [20, 21]. Agarwal et al. (2008) in a comparative study of NIV in COPD versus other causes identified improvement in pH after 1 h of NIV application, female gender, and etiology of acute respiratory failure to be an independent predictor of successful NIV outcome [22]. Similarly, Bhattacharyya, Prasad, Tampi, and Ramprasad (2011) also concluded in their study that



Fig. 1 ROC curve for the new NIV prediction score

there was improvement in heart rate, respiratory rate, pH, and  $pCO_2$  within the first hour in the success group, and they continued to improve even after 4 and 24 h of NIV application in the success group [22].

The current study highlighted the fact that NIV failure as well as in-hospital mortality was associated with increased length of hospital stay (p < 0.05). Messer et al. (2012) in an integrative review search study had similar conclusion where length of stay was found to be predictive determinant for in hospital mortality [23]. Other determinants predictive of NIV failure in the study were low Glasgow Coma Scale (GCS) on admission to ICU, cardiorespiratory arrest prior to ICU admission, cardiac dysrhythmia prior to ICU admission, and higher values of acute physiology scoring systems. Similarly, Correa et al. (2015) in a prospective single-center cohort study among 85 patients found median length of hospital stay was higher in NIV failure patients. The same study identified age and APACHE II score as predictors of NIV failure [24]. The severity of the underlying illness measured through severity scores like APACHE II score, SAPS score, qSOFA score, and Charlson comorbidity score was commonly identified as predictors of NIV failure; however, there are few studies which counter the observation like the present study [25]. Likewise, our study did not demonstrate any correlation between age, comorbidities, GCS score, bicarbonate level, or CRP with NIV failure, which some of the prior studies have shown [19, 21, 26]. The current study found history of invasive mechanical ventilation (for reasons other than for general anesthesia) as a unique predictive factor for NIV failure, which was not specified in similar studies during our literature search.

The strength of this study lies in its prospective nature. The study had fair number of patients which is comparable with many other similar publications. Robust statistical methods were used in the study which enabled us to interpret results with confidence. Multivariate regression analysis used in the study to identify predictors of failure is a powerful statistical tool which enhances significance by considering effect of confounders. The study



Fig. 2 Diagnostic accuracy of new NIV failure prediction score

also puts forward a new prediction score for predicting NIV failure.

The current study is not claimed to be devoid of limitations. This was an observational, prospective singlecenter study for a period of 10 months. The last 3 months of our study period had comparatively lesser subjects recruited due to the global pandemic of COVID-19. Although institutional protocol was followed for management of acute respiratory failure, identification of NIV failure and the indication for endotracheal intubation were based on attending physician's judgement. Even though most of the patients who were recruited for the study were initiated on critical care ventilator as an initial approach, some patients who were already on domiciliary device were continued on the same, but the advantage of critical care ventilator over a home NIV was not taken into consideration in the analysis. Differentiating between the correct etiology was problematic at times when the cause of respiratory failure was multifactorial, for example, in a COPD patient, the trigger for respiratory failure might be a pneumonia. In such clinical scenario, the most clinically feasible diagnosis which explained the respiratory failure was considered.

# Conclusions

Judicious use of NIV can prevent its failure in selected conditions. In patients with predictors like high initial respiratory rate, worsening ABG parameters after 1–2 h of NIV, electrolyte imbalance, and previous history of an NIV failure, NIV should be continued with caution. Early escalation of support to invasive mechanical ventilation in such patients can prevent associated mortality and morbidity.

#### Abbreviations

APACHE II	Acute Physiology and Chronic Health Evaluation II
ARDS	Acute respiratory distress syndrome
COPD	Chronic obstructive pulmonary disease
ICU	Intensive care unit
IMV	Invasive mechanical ventilation
NIV	Noninvasive ventilation
PaO2	Arterial oxygen partial pressure
PaCO2	Arterial carbon dioxide partial pressure
PaO2/FiO2	Ratio of the arterial oxygen partial pressure to the fraction of
	inspired oxygen
SOFA score	Sequential Organ Failure Assessment score
SpO2	Peripheral oxygen saturation

# **Supplementary Information**

The online version contains supplementary material available at https://doi.org/10.1186/s43168-023-00203-8.

Additional file 1. Supplementary material. MASTER CHART.

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#### Authors' contributions

SVA, conception, design, data collection and processing, analysis and/or interpretation, literature review, and writing. AKA, conception, supervision, data collection, literature review, and critical review. AP, design, supervision, analysis, writing, literature review, and critical review.

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#### Availability of data and materials

All data generated or analyzed during this study are included in as Supplementary information files.

#### Declarations

#### Ethics approval and consent to participate

Protocol of the study was presented in front of institutional scientific committee and ethical committee. Approval was taken from both committees. Consent to participation to the study was taken from all subjects.

#### **Consent for publication**

Consent to publication was taken from all subjects.

#### **Competing interests**

The authors declare that they have no competing interests.

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