RESEARCH PAPER

# Predictors of Outcome of Non-Invasive Ventilation in Patients with Acute Hypoxemic Respiratory Failure - A One Year Hospital Based Observational Study

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**ABSTRACT:**

**Background and objective:** NIV (Noninvasive Ventilation) is one of the most important modality of ventilation which reduces the need for intubation and complications associated with it. However, NIV can not be used in all patients with acute respiratory failure. Hence there is a need to analyse the incidence of failure of NIV and various factors that predict the success and failure of NIV.

**Methods**: The patients of acute hypoxemic respiratory failure (AHRF) who received NIV were included in study and various parameters such as PaO2/FiO2 ratio, A-a O2 gradient, APACHE II score, SAPS II score, qSOFA score, CURB 65 score were analysed within first 24 hours of admission.

**Results:** Among 97 patients 53 had favourable outcome and 44 had unfavourable outcome, the incidence of NIV failure was 45.4%. The baseline mean PaO2/FiO2 ratio and A-a O2 gradient was 158.71 and 298.99 respectively. Among those with favourable outcome the mean values were 193.08 and 196.38 and among those with unfavourable outcome the mean values were
117.32 and 422.59 respectively. This was statistically significant. The various other predictors which were studied were APACHE II, SAPS II, CURB 65 and qSOFA scores whose baseline mean values were 17.29, 39.46, 1.83, 1.46 respectively. Among those with favourable outcome the mean values were lower i.e, 13.30, 32.32, 1.77, 1.17 and among those with unfavourable outcome the mean values were higher i.e, 20.59, 49.14, 2.43, 1.70 respectively and this was statistically significant.

**Conclusion**: This study concludes that one has to have a high index of suspicion of failure of NIV among patients of acute hypoxemic respiratory failure with low Pao2/Fio2 ratio, high alveolar arterial gradient (A-a O2), high APACHE II, SAPS II, CURB 65 and qSOFA scores, as they determine poor prognosis.

**KEY WORDS:** NIV, AHRF, ARF, PREDICTORS, APACHE II, SAPS II

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# Predictors of Outcome of Non-Invasive Ventilation in Patients with Acute Hypoxemic Respiratory Failure - A One Year Hospital Based Observational Study

## INTRODUCTION

**Acute hypoxemic respiratory failure (AHRF)** is a clinical condition characterized by severe hypoxemia that is refractory to supplemental oxygen (PaO2 < 60 mmHg, PaO2/FiO2 <300 mmHg ). [1]

Acute respiratory failure (ARF) is a life-threatening condition caused by either impaired function of the respiratory muscle pump or lung dysfunction[1]. Respiratory failure is a clinical condition that occurs when the respiratory system fails to perform its primary function of gas exchange, resulting in PaO2 less than 60 mmHg and/or PaCO2 greater than 50 mmHg. **Type 1 respiratory failure** has a PaO2 < 60 mmHg with normal or subnormal PaCO2. **Type 2 respiratory failure** has a PaCO2 > 50 mmHg.[2] The incidence of respiratory failure is approximately 137.1 per 100,000 individuals in the United States and the mortality rate is approximately 29%-42%. The etiology of respiratory failure can either be due to involvement of nervous system (lack of ventilatory drive or defects in neural transmission or neuromuscular diseases affecting the respiratory muscles) or due to involvement of respiratory system ( thoracic cage abnormalities or airway diseases or parenchymal diseases.Noninvasive ventilation (NIV) provides positive pressure airway support without the use of an endotracheal tube and is used as the first line of treatment for acute hypoxic respiratory failures (AHRF). The benefits of NIV include the elimination of the need for endotracheal intubation (ETI), which reduces the risk of ventilator-associated pneumonia, the duration of stay in the ICUs, and hospitalization costs. Several studies have been published on the use of NIV in AHRF over the last two decades and still there is a debate over whether NIV is appropriate in all forms of AHRF.[3]Hence NIV cannot be used in all patients with acute respiratory failure. As a result, there is a need to identify the incidence of NIV failure as well as various prognostic indicators determining NIV success or failure.

Noninvasive ventilation (NIV) represents one of the most important advances in the field of pulmonary and critical care medicine of the last 30 years. The efficacy of NIV in appropriately selected patients with acute respiratory failure (ARF) has been widely confirmed by several randomized controlled trials and meta-analyses. Strong evidence supports the application of NIV as a first-line treatment in patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) and acute cardiogenic pulmonary edema (ACPE). Moreover, NIV has also been proven to be beneficial in patients with respiratory failure following solid organ transplantation and in those who are immunocompromised and to wean chronic obstructive pulmonary disease (COPD) patients from invasive ventilation[2] The treatment of respiratory failure ranges from nasal prongs, oxygen mask , rebreathing mask , venturi mask, HFNC ,NIV to intubation based on the etiology and severity . Doshi et al[3] published a randomized noninferiority trial of 204 subjects that compared HFNC with NIV and found HFNC to be noninferior for the treatment of acute respiratory failure. While NIV also has its own problems such as difficulties in patient ventilator synchrony, mask tolerance, humidification, air leaks, pressure difficulties Use of NIV in COPD has become a standard of care setting[4,5]Two recent meta-analyses did not find any strong evidence to support the role of NIV in AHRF and acute lung injury/acute respiratory distress syndrome (ALI/ARDS)[6,7].However, in a few randomized controlled trials of NIV in AHRF patients of pneumonia in immunocompromised hosts and in patients of AHRF post lung-resection surgery, NIV was found to reduce the need for intubation and even mortality.[8–10] In AHRF due to cardiogenic pulmonary edema, use of NIV has been shown to reduce mortality in meta-analysis. [11]

## MATERIALS AND METHODS:

### Source of data

Patients admitted at KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi.

### Method of collection of data

**STUDY DESIGN: AN OBSERVATIONAL**

**STUDY STUDY PERIOD:** JANUARY 2021 TO DECEMBER 2021.

**SAMPLE SIZE**: Sample size was estimated by using the incidence of NIV failure in acute respiratory failure patients at 30.6% from the study by Thiago Domingos Corrêa et al. using the formula

$$\text{Sample size} = \frac{Z_{1-\alpha/2}{}^2 p(1-p)}{d^2}$$

Here

$Z_{1-\alpha/2}$ = Is standard normal variate (at 5% type 1 error ($P<0.05$) it is 1.96 and at 1% type 1 error ($P<0.01$) it is 2.58). As in majority of studies $P$ values are considered significant below 0.05 hence 1.96 is used in formula.
p = Expected proportion in population based on previous studies or pilot studies.
d = Absolute error or precision – Has to be decided by researcher.

P = 30.6,q = 69.4,d = 10%

Using the above values at a 95% Confidence level a sample size of 82 subjects with acute respiratory failure and critically ill will be included in the study. Considering 10% Nonresponse a sample size of 82 + 8.2 ≈ 90 subjects will be included in the study.

**SAMPLE METHOD:** In an observational study, the acute hypoxemic respiratory failure patients who fulfill the inclusion criteria will be included in the study. Data will be entered into a Microsoft excel datasheet and will be analysed using SPSS 22 version software. Categorical data will be represented in the form of Frequencies and proportions. Chi- square will be used as a test of significance. Continuous data will be represented as mean and standard deviation. An Independent t-test will be used as a test of significance to identify the mean difference. Pearson's Correlation will be used to correlate between two quantitative variables. P-value <0.05 will be considered statistically significant.

### INCLUSION CRITERIA

**All patients with acute hypoxemic respiratory failure with:**

- The partial pressure of oxygen (PaO2) in the arterial blood < 60mmHG
- PaO2/FiO2<300 mmHg
- RR >24cpm
- Age >18 years

### EXCLUSION CRITERIA

- Need for emergency intubation
- Recent esophageal, facial, or cranial trauma or surgery
- Severely decreased consciousness (Glasgow Coma Score of 11 or less)Recent esophageal, facial, or cranial trauma or surgery
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## RESULTS

**Table 1: Baseline demographic characteristics of the patients:**

| Parameter | Mean | SD | Median | Minimum | Maximum | Range |
|---|---|---|---|---|---|---|
| Age (years) | 58.13 | 17.83 | 62 | 18 | 90 | 73 |
| HR | 104.62 | 22.09 | 106 | 60 | 210 | 150 |
| RR | 32.31 | 4.23 | 32 | 18 | 44 | 26 |
| SBP | 123.70 | 29.71 | 120 | 50 | 210 | 160 |
| DBP | 77.63 | 22.72 | 80 | 0 | 120 | 120 |
| SPO2 | 90.87 | 7.77 | 90 | 50 | 99 | 49 |
| PaO2/FiO2 | 158.71 | 59.39 | 165 | 59 | 358 | 299 |
| GCS | 14.86 | 0.41 | 15 | 13 | 15 | 2 |
| CURB 65 | 2.07 | 1.06 | 2 | 0 | 5 | 5 |
| qSOFA | 1.41 | 0.67 | 1 | 0 | 3 | 3 |
| A-aO2(mmHg) | 298.99 | 153.34 | 270 | 19 | 578 | 559 |
| pH | 7.29 | 0.12 | 7.30 | 6.90 | 7.50 | 0.60 |
| PO2 | 78.8 | 29.9 | 75 | 30 | 230 | 200 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 2 | 6 | | | | |
| HCO3 | 23.25 | 10.79 | 21 | 7 | 98 | 91 |
| SO2 | 88.95 | 9.73 | 92 | 52 | 100 | 48 |
| APACHE II | 16.61 | 6.92 | 17 | 06 | 34 | 28 |
| SAPS II | 39.90 | 14.69 | 38 | 18 | 98 | 80 |
| LOS(Total) in days | 12.11 | 9.24 | 9 | 1 | 42 | 41 |
| LOS(NIV) in days | 5.14 | 5.53 | 3 | 1 | 37 | 36 |
| LOS(ICU) in days | 7.09 | 6.70 | 5 | 1 | 42 | 41 |

A total of 97 patients were included in the study. There were 62 male patients and 35 female patients and the mean age was 58.13±17.83 years.
PaO2/FiO2 – Ratio of arterial oxygen partial pressure (PaO2 in mmHg) to fractional inspired oxygen
GCS- Glassgow coma scale
APACHE II – Acute physiological and chronic health evaluation score SAPS II – Simplified acute physiological score
qSOFA- quick sequential organ failure assessment score LOS(total)-total length of stay in hospital
LOS(ICU)- Length of
stay in ICU LOS(NIV)-Length of NIV usage
A-a – Alveolar arterial oxygen gradient

## OUTCOME

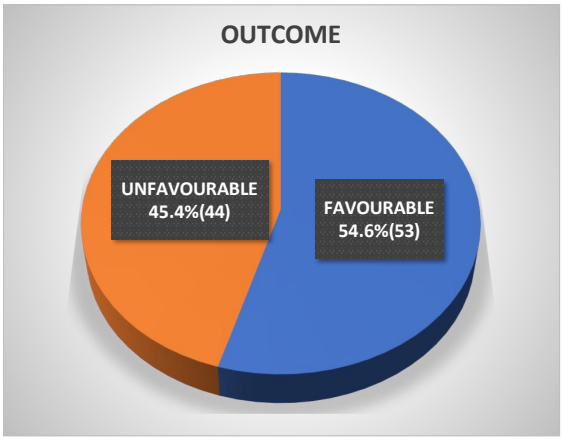
1) Favourable outcome (Success) –

- Discharged from the hospital

2)Unfavourable outcome (Failure)-

- Intubated
- AMA
- Death

**Graph 1: A pie diagram showing outcome among patients with acute hypoxemic respiratory failure on NIV**




Among 97 patients of acute hypoxemic respiratory failure who were put on NIV, 53 had a favourable outcome and 44 had an unfavourable outcome.

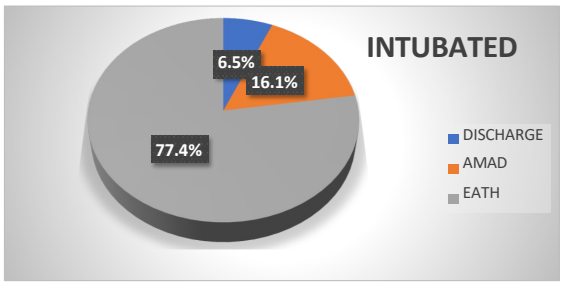
**Table 2: Showing outcome among patients with acute hypoxemic respiratory failure on NIV**

| Outcome | N (N%) |
|---|---|
| Favourable | 53 (54.6) |
| Unfavourable | 44 (45.4) |
| Total | 97 (100) |

**Table 3: Showing the various causes for unfavourable outcome:**

| Unfavourable outcome | N (N%) |
|---|---|
| Discharged(but were intubated) | 2 (4.5) |
| AMA(Against medical advice) | 9 (20.5) |
| Death | 33 (75) |

Among 44 patients with unfavourable outcome 2 patients were discharged (considered unfavourable since they were intubated and recovered and intubation was considered as unfavourable outcome in the study) and 9 patients went against medical advice (AMA) and 33 patients expired.



### Graph 2: A pie diagram showing the outcome of intubated patients

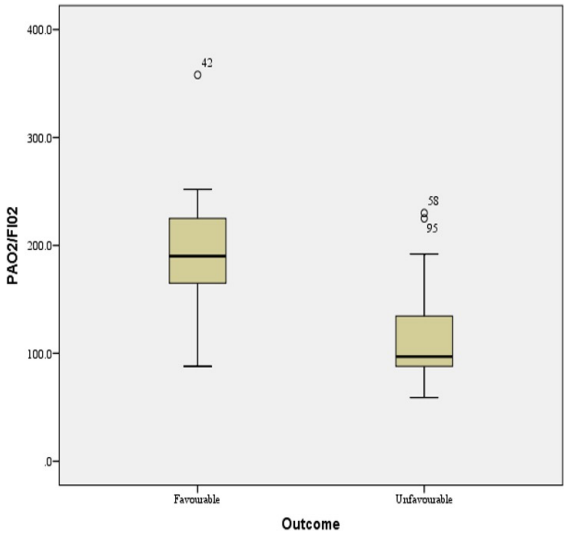
A total of 31 patients were intubated of which only 2 (6.5%) patients were discharged, 5(16.1%) went against medical advice and 24 (77.4%) patients expired.

### Table 4: Comparison of parameters with respect to outcome

| | Outcome | | | | | | P value |
|---|---|---|---|---|---|---|---|
| | Favourable | | | Unfavourable | | | |
| | Mean | SD | Median | Mean | SD | Median | |
| HR | 99.66 | 18.81 | 102.00 | 110.59 | 24.40 | 110.00 | 0.014* |
| RR | 30.64 | 3.35 | 32.00 | 34.09 | 4.44 | 34.00 | <0.001* |
| SBP | 129.60 | 28.12 | 130.00 | 116.59 | 30.32 | 115.00 | 0.031* |
| DBP | 82.26 | 14.09 | 80.00 | 72.05 | 29.22 | 80.00 | 0.027* |
| SPO2 | 93.23 | 3.89 | 93.00 | 88.02 | 10.07 | 90.00 | 0.001* |
| PAO2/FI02 | 193.08 | 47.02 | 190.00 | 117.32 | 44.62 | 97.00 | <0.001* |
| GCS | 14.92 | 0.33 | 15.00 | 14.77 | 0.48 | 15.00 | 0.071 |
| CURB65 | 1.77 | 0.97 | 2.00 | 2.43 | 1.07 | 3.00 | 0.002* |
| Q-sofa | 1.17 | 0.51 | 1.00 | 1.70 | 0.73 | 2.00 | <0.001* |
| PH | 7.31 | 0.07 | 7.30 | 7.26 | 0.16 | 7.25 | 0.062 |
| PO2 | 87.19 | 32.67 | 83.00 | 68.75 | 22.86 | 65.00 | 0.002* |
| PCO2 | 46.36 | 18.25 | 44.00 | 39.11 | 19.78 | 34.00 | 0.064 |
| HCO3 | 26.15 | 12.42 | 24.00 | 19.75 | 7.10 | 19.50 | 0.003* |
| SO2 | 92.58 | 5.58 | 94.00 | 84.57 | 11.74 | 87.50 | <0.001* |
| APACHEII | 13.30 | 5.64 | 11.00 | 20.59 | 6.24 | 20.50 | <0.001* |
| SAPS II | 32.23 | 10.11 | 30.00 | 49.14 | 14.09 | 48.00 | <0.001* |
| LOS(Total) | 12.81 | 8.85 | 9.00 | 11.27 | 9.72 | 9.00 | 0.417 |
| LOS (NIV) | 4.13 | 3.04 | 3 | 6.36 | 7.36 | 4 | 0.047* |
| LOS (intubated) | 0.00 | 0.00 | 0 | 3.93 | 4.11 | 3 | <0.001* |
| Time to NIV | 1.00 | 0.00 | 1.00 | 0.98 | 0.15 | 1.00 | 0.275 |
| A-a | 196.38 | 89.79 | 210.00 | 422.59 | 118.89 | 435.00 | <0.001* |
| LOS(ICU) | 4.43 | 3.00 | 3.00 | 10.30 | 8.37 | 9.00 | <0.001* |

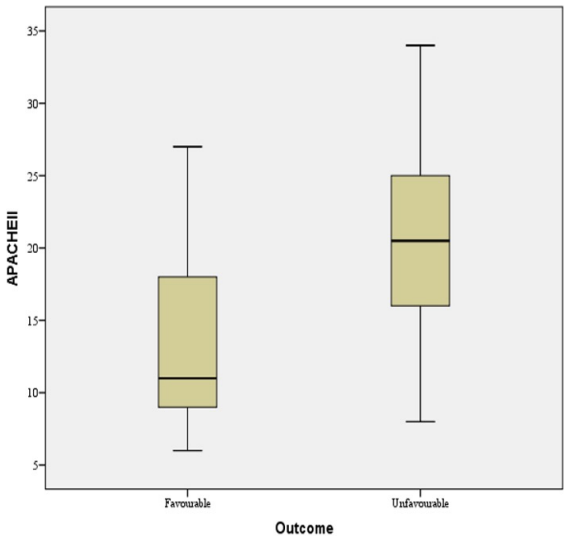
*PaO2/FiO2 – Ratio of arterial oxygen partial pressure (PaO2 in mmHg) to fractional inspired oxygen*
*GCS- Glassgow coma scale*
*APACHE II – Acute physiological and chronic health evaluation score SAPS II – Simplified acute physiological score*
*qSOFA- quick sequential organ failure assessment score LOS(total)-total length of stay in hospital*

*LOS(ICU)- Length of stay in ICU LOS(NIV)-Length of NIV usage*
*A-a – Alveolar arterial oxygen gradient*




### Graph 3: A simple bar diagram showing Pao2/FiO2 with respect to outcome

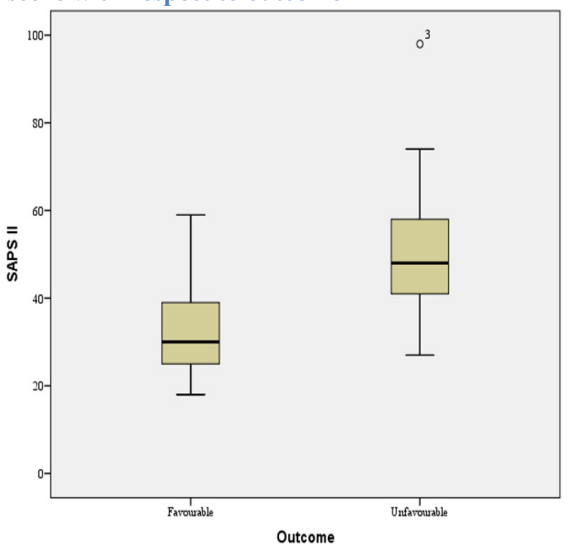
Among the patients with favourable outcome the mean PaO2/FiO2 was 193.08 and the mean PaO2/FiO2 among unfavourable outcome was 117.32 and this was statistically significant with p value <0.001.



**Graph 4: A Simple bar diagram showing APACHE II score with respect to outcome**

Among the patients with favourable outcome the mean APACHE II score was 13.30 and the mean APACHE II score among unfavourable outcome was 20.59 and this was statistically significant with p value <0.001

**Graph 5: A simple bar diagram showing SAPS II score with respect to outcome**




Among the patients with favourable outcome the mean SAPS II score was 32.23 and the mean SAPS II score among unfavourable outcome was 49.14 and this was statistically significant with p value <0.001

**DISCUSSION:**

NIV (Noninvasive ventilation) stands for usage of various noninvasive interfaces for administration of positive pressure ventilation ( nasal mask , nasal plugs , face mask ). Patients with either acute or chronic respiratory failure may benefit from NIV as ventilatory support. In the last two decades, one of the most significant advancements in the field of mechanical ventilation has been the use of NIV.

**Incidence of failure of NIV in AHRF:**

The present study included total of 97 patients of acute hypoxemic respiratory failure of various causes.

Among 97 patients 53 (54.6%) had a favourable outcome and 44(45.4%) had an unfavourable outcome. Among 44 patients with unfavourable outcome 2 patients recovered ,9 patients went AMA and 33 patients expired. The 2 recovered patients were considered unfavorable as intubation was considered as unfavourable outcome in the study.

In a similar study conducted by Agarwal et al[12] , among 40 patients with AHRF on NIV. NIV success was seen in 52.5% (21) of patients with acute hypoxemic respiratory failure. These results were similar and comparable with present study where NIV success was 54.6%.In a study done in South Paulo Brazil conducted by Correa et al [13] , total of 85 patients were included in the study and NIV success was seen in 59 (69.4%) and NIV failure in 26 (30.6%) patients. Compared to present study this study had higher success and it was found

that this study had a lower mean APACHEII score and higher PaO2/FiO2 ratio compared to the present study.

In another Indian study conducted by Kshatriya et al [14] 110 patients of acute respiratory failure who received NIV were included. NIV success was seen in 81 (74%) and failure in 29(26%). This study has a higher rate of NIV success compared to the present study and this study differs from the present study in the baseline patient subgroups as this study has higher number of patients with obstructive airway disease 78(70%) compared to the present study.

In a study conducted in Spain by Ferrer et al[15] , among 51 patients of AHRF who were on NIV, NIV success was seen in 38 (74.5%). The success in this study to was relatively higher compared to the present study and it was found that the mean SAPS II score was lower in this study than the present study (34 vs 40)

**Table 6: Comparing the incidence of success and failure of NIV in various studies**

| Study | Total patients | Group of patients | Prevalence of success n(N%) | Prevalence of failure n(N%) |
|---|---|---|---|---|
| Present study | 97 | Overall | 53(55) | 44(45) |
| | | COPD | 12(92) | 1(7.7) |
| | | ACPE | 13(72) | 5(28) |
| | | Pneumonia | 2(13) | 13(87) |
| | | Covid | 5(29) | 12(71) |
| | | Others | 21(62) | 13(38) |
| Correa et al [13] | 85 | Overall | 59(69) | 26(31) |

| | | | | |
|---|---|---|---|---|
| | | COPD<br>ACPE<br>Pneumonia<br>ARDS<br>Others | 7(70)<br>15(79)<br>20(67) | 3(30)<br>4(21)<br>10(33) |
| Kshatriya et al 14 | 110 | Overall<br><br>COPD<br>Other | 81(74)<br><br>58(85)<br>23(55) | 29(26)<br><br>10(15)<br>19(45) |
| Ferrer et al [15] | 51 | Overall | 38(74.5) | 13(25.5) |

**CONCLUSION:**

In the present study among 97 patients 53 had favourable outcome and 44 had unfavourable outcome and NIV failure rate was 45.4%.The patients with low Pao2/Fio2 ratio and high APACHE II , SAPS II ,CURB65 and qSOFA scores and high alveolar arterial (A-a O2) gradient had higher incidence of NIV failure and are predictors for unfavourable outcome.The patients with increased length of stay in ICU , increased length of usage of NIV are independent predictors for unfavourable outcome.

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