Success of NIV in Acute exacerbation of COPD and Factors Associated with Failure- A Cross Sectional Study in a Tertiary Care Centre

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Abstract
Background: Non invasive ventilation has been helpful in managing COPD patients presenting with Acute exacerbations. This study tries to find out the success rate and factors associated with failure of NIV in AECOPD with Acute or chronic respiratory failure.

Methods: COPD Patients admitted with acute or chronic respiratory failure to the Intensive respiratory care unit started on NIV BiPAP mode using ICU ventilator were enrolled into the study. Patients were followed up till either they were weaned off NIV or ended up with intubation. Patients were followed up with serial ABGs and intense clinical monitoring according to Department protocol.

Setting: Department of Pulmonary Medicine, Govt Medical College Thiruvananthapuram.

Result: NIV was successful in 72% of patients with Acute exacerbation of COPD. Patients with an initial low respiratory rate, high GCS score ans less severe airflow obstruction had a better outcome with NIV. An improvement in the blood gas values within the first 1 hr of initiating NIV contributed to a successful final outcome.

Conclusion: When initiated sufficiently early Non Invasive ventilation is a better choice in acute exacerbations of COPD with respiratory failure. Carefull patient selection leads to better outcome and reduces complications.

Keywords: Chronic Obstructive Pulmonary Disease, Acute Exacerbation, Non invasive ventilation, Respiratory failure.

Introduction
Exacerbations in COPD are defined as acute worsening of respiratory symptoms that result in additional therapy[1]. Each exacerbation leads to significant morbidity and mortality[2].

A considerable number of COPD exacerbations result in acute on chronic respiratory failure that may end up in endotracheal intubation and mechanical ventilation. Early initiation of NIV can improve the condition of the patient and prevent intubation associated complications[3]. This study
tried to find out the success rate and factors associated with failure of NIV in Acute Exacerbation of COPD.

Materials and Methods
The study was conducted in the Intensive Respiratory care Unit of Dept of Pulmonary Medicine, Government Medical College Thiruvananthapuram for a period of 1 year. All consecutive COPD patients admitted in the IRCU with Acute exacerbation and acute on chronic respiratory failure were recruited into the study. 60 patients were enrolled in the study. Patients who had Acute Hypercapnoeic respiratory failure as per ABG, Conscious and cooperative, Hemodynamically stable, with good cough reflux were included. Patients who had a pH < 7.1, with history of recent Myocardial Infarction, Uncooperative or unconscious, hemodynamically unstable patients, those with copious secretion and facial injuries were excluded from the study. Demographic and clinical details were collected using a structured questionnaire soon after admission. Old records were scrutinized in case of patients previously treated at our facility. Vitals and Arterial Blood Gas was analysed during admission and patients with Respiratory Acidosis were started on BIPAP mode of ICU Ventilator following hospital protocol. Vitals and ABG were reassessed after half an hour, 1 hour and 6 hours of initiating NIV. Clinical condition of the patient was also assessed periodically. Those patients who tolerated NIV and showed improvement clinically and in the blood gases were continued on NIV. Those who did not tolerate NIV or clinical condition worsened were intubated according to standard procedure. Those patients who tolerated NIV or survived on NIV were considered as success. Those patients who could not tolerate mask or worsened clinically or showed worsening of acidosis leading to intubation were considered as failures.

Analysis
Data was coded & entered in Microsoft Excel & statistical analysis was done, using statistical software SPSS version 15.0. Quantitative variables were summarized as Mean & Standard deviation. 95% Confidence Interval was estimated. Qualitative variables were summarized as frequency & Percentage. Univariate analysis was done to find the association of each parameter to the final outcome. Multivariate analysis was performed to find association with outcome when all the parameters were combined together.

Ethical Issues
The study was initiated after obtaining clearance from The Institutional Ethics Committee. Informed consent was obtained from relatives prior to recruitment to the study. Control group could not be kept as depriving seriously ill patients of the accepted treatment protocol would be against Medical Ethics.

Results
60 patients were recruited into the study of which 78% were males and 22% females. NIV was successful in 43(72%) while 17(28%) failed on NIV. Mortality was 18% among those intubated. The mean age of patients in whom NIV was successful was 60.95 yrs and 65.94 yrs in failure group. The difference in the mean age was statistically significant (p=0.02). 45% of recruited patients belonged to the age group of 60-69yrs. Univariate analysis was done to check association of individual parameters to success of NIV. Intubated patients had a mean respiratory rate of 37.88 breaths per minute. A respiratory rate less than 35 breaths per minute was associated with successful outcome. (p=<0.001). Patients with a GCS score of >12 had a successful outcome (p<0.001). Patients with serum albumin level <3gm/dl had a worse outcome when compared to those with higher levels and the difference was statistically significant (p<0.001). Patients who had improvement in the arterial pH after 1 hr had a better success rate when compared to those whose value did not change or decreased while on NIV (p<0.001). Similarly, patients who recovered on NIV had a significant drop in the PCO2 values after 1 hr of initiation of
NIV(p<0.001). Patients who had mild to moderate severity of disease had a better chance for success on NIV(p<0.001).

However on multivariate regression analysis, GCS, severe airflow limitation, initial pH, PCO2 and change in pH and PCO2 after 1 hour of NIV showed significance (p<0.05).

Table-1 Age distribution

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>No of Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>40-49</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>50-59</td>
<td>19</td>
<td>31.7</td>
</tr>
<tr>
<td>60-69</td>
<td>27</td>
<td>45</td>
</tr>
<tr>
<td>70-79</td>
<td>11</td>
<td>18.3</td>
</tr>
<tr>
<td>≥80</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

Table-2 Multivariate analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>Std error</th>
<th>F test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR</td>
<td>0.146</td>
<td>0.090</td>
<td>2.62</td>
<td>0.1112</td>
</tr>
<tr>
<td>Albumin</td>
<td>0.021</td>
<td>0.081</td>
<td>0.06</td>
<td>0.7961</td>
</tr>
<tr>
<td>GCS</td>
<td>0.308</td>
<td>0.109</td>
<td>8.01</td>
<td>0.0065</td>
</tr>
<tr>
<td>PFT</td>
<td>-0.221</td>
<td>0.088</td>
<td>6.35</td>
<td>0.0147</td>
</tr>
<tr>
<td>pH</td>
<td>0.236</td>
<td>0.097</td>
<td>5.96</td>
<td>0.0179</td>
</tr>
<tr>
<td>dPCO2</td>
<td>-0.025</td>
<td>0.002</td>
<td>13.4</td>
<td>0.0000</td>
</tr>
<tr>
<td>d pH</td>
<td>0.221</td>
<td>0.095</td>
<td>5.37</td>
<td>0.0242</td>
</tr>
</tbody>
</table>

p<0.05

Discussion

Acute exacerbation of COPD in patients who are having chronic respiratory failure can be fatal if not intervened early enough. Even in patients with less severe disease, the rapid decline in lung function during an exacerbation along with other comorbidities may precipitate a life threatening event [1,2]. Stratifying our patients based on their initial presentation during an exacerbation can help clinicians to decide on their further effective management [3]. This study was conducted to find out the success rate of NIV in AECOPD and also to find out the factors contributing to failure of non invasive ventilation.

72% of our study population showed a successful outcome after initiation of NIV. The results are comparable with the already available studies [3-5]. Mortality among patients who were initiated on NIV was 18%. Results were similar in study by Putinati et al [7,10].

The mean age of patients who had a successful outcome with NIV in our study group was 60.95 years whereas it was 65.94 years in patients who failed on NIV. A younger age group had a higher chance of successful outcome similar to previous studies by Confalonieri et al [9].

A lower respiratory rate at presentation improved the chances of success of NIV. The difference in mean initial respiratory rate among the intubated and non intubated patients was statistically significant (p<0.001). The earlier respiratory failure is identified and started on NIV, the better is the outcome.

This study group showed improvement in respiratory failure in patients who had a higher level of GCS score. 92.5% of patients who improved on NIV had a GCS of >12. An initial GCS of >12 was associated with a better outcome (p<0.001). Confalonieri et al and few others found that a GCS <11 was associated with failure of NIV [9,20].

Nutritional status of a patient has an important role in deciding the outcome of exacerbation in COPD. Hypoproteinemia affects the respiratory muscle strength and the ventilatory drive. Patients with a low serum albumin level had an adverse outcome in our study. S.Alb level of <3gm/dl was associated with an unfavourable outcome (p<0.001). Antonio et al in their study observed that a higher level of albumin was associated with a successful outcome using NIV [18].

Arterial blood gas values at the time of presentation to the hospital affects the outcome of NIV. An initial low pH and high PCO2 values were associated with a high failure rate. The mean pH of patients who failed NIV was 7.25 (p<0.001). McLaughlin et al in their study found that a mean pH of <7.25 was associated with failure of NIV [17]. Several studies by Putinati et al [7] and Antonio et al [18] and many others showed a similar result [20,21].

An improvement in the pH and PCO2 values after 1 hr of initiation of NIV also contributed to an improved outcome. The results were comparable to many previous studies [7,17,18,23].

Our study included patients who were previously diagnosed as COPD according to GOLD guidelines.
and so the Severity of disease was also taken into consideration during analysis. Patients with mild to moderate COPD showed a better outcome with NIV when compared to patients with more severe disease. The results were comparable with results of the study by Antonio et al\[18\].

**Conclusion**
The observations from this study suggest that when initiated early enough Non Invasive Ventilation can avoid invasive ventilation in acute exacerbations of COPD. Patients should be selected based on the initial clinical presentation and the Blood gases so that seriously ill patients are not deprived of their time into invasive ventilation. Aggressive monitoring during initial hours of therapy with NIV is necessary to avoid complications and mortality.

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**References**
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Abbreviations
COPD-Chronic Obstructive Pulmonary Disease, AECOPD-Acute Exacerbation of COPD,NIV-Non Invasive Ventilation, BIPAP-Bi level Positive Airway Pressure, IRCU-Intensive Respiratory Care Unit, ABG-Arterial Blood Gas, GCS-Glasgow Coma Scale