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Risk Factors of Non-Invasive Ventilation Failure in COPD Patients Presenting with Acute Exacerbation

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ABSTRACT

Background: Non-invasive ventilation (NIV) is the first-line management for acute exacerbation of COPD (AECOPD), but some patients don't improve and need invasive ventilation, leading to high mortality. We conducted a study to determine risk factors associated with NIV outcomes in these patients. Identifying predictive parameters of NIV failure could help timely intervention and prevent mortality.

Methods: A Quasi Single Arm study was conducted at a tertiary care Hospital, in Karachi, from July to December 2022. We studied 170 COPD patients admitted to Medicine Department and Medical ICU with acute respiratory failure, among those 170 patients 80 were male and 90 were female, aged above 40 and below 80 years.

Results: Among 170 AECOPD patients studied, 38% experienced NIV failure, while 61% had NIV success. In the NIV failure group, 38.46% of patients died in hospital. Most factors like quadrant infiltrate, weak cough reflex, low consciousness level, more requirements of oxygen, low pH, more respiratory rate, and positive blood cultures (p-value <0.001) were significantly associated with NIV failure and mortality, while others with no significant association still contributed towards NIV failure, like co-morbidities. Out of the 66 patients with NIV failure, 56% experienced immediate failure, 33% had early NIV failure, and 11% had late NIV failure.

Conclusion: Most identified risk factors significantly predicted NIV failure, suggesting they may serve as useful early indicators to guide intervention. Even non-significant factors still exhibited some association with NIV failure. Further research exploring additional predictors could optimize NIV outcomes and reduce mortality from AECOPD.

Keywords: COPD, Hospital mortality, Non-invasive Ventilation, Risk factors, Symptom Exacerbation.

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a frequently avoidable and manageable condition. It leads to respiratory symptoms and persistent airflow restrictions caused by airways and alveoli abnormalities. These abnormalities are primarily the result of significant exposure to harmful particles or gases[1]. As per the guidelines established by GOLD (Global Initiative for Chronic Obstructive Lung Disease), an Acute Exacerbation of COPD (AECOPD) refers to a sudden decline in respiratory function that necessitates additional therapeutic intervention. This added need for treatment places a financial strain on the patient. Furthermore, repeated exacerbations of COPD not only increase the risk of mortality and medical complications but also contribute to a decline in lung function, ultimately diminishing the individual's quality of life. Additionally, the utilization of healthcare services further adds to the financial burden[2-3]. Frequent occurrences of Acute Exacerbation of COPD (AECOPD) episodes lead to a decline in lung function among patients and significantly heighten the risk of mortality[4]. Non-invasive ventilation (NIV) has proven to be a beneficial treatment option for respiratory failure as it improves the survival rate and is also highly recommended for managing acute respiratory failure (ARF) in patients with COPD[5-6]. NIV in ARF reduces breathing effort, and respiratory muscle workload, and improves the respiratory rate, decreasing intubation needs. This helps avoid complications linked to invasive mechanical ventilation (IMV)[7-8]. Management with NIV needs little to no sedation, and have lesser chances of developing ventilator-acquired pneumonia as compared to IMV and it gives larger morbidity and mortality benefit by avoiding prolonged IMV, tracheostomy, and prolonged weaning procedures, and their complications. NIV improves the consciousness level of the patients by reducing the partial pressure of carbon dioxide ($PaCO_2$), which normalizes the arterial pH, and subsequently normalizes the cerebrospinal fluid pH[9-10]. NIV is effective for AECOPD, but some patients don't achieve the desired outcomes. Failure rates range from 15 to 24%. Transitioning to IMV after NIV failure increases in-hospital mortality compared to elective intubation before NIV failure[11]. Recognizing factors causing NIV failure is crucial. Take measures to overcome them or consider IMV before NIV failure. NIV failure is defined as emergency endotracheal intubation (ETI) or death[12]. Prior studies displayed inconsistent failure rates, making outcome prediction and identification of contributing factors challenging. Discrepancies may stem from variations in NIV failure timing, acidosis severity, and overall patient disease severity, including multi-organ failure[13-14]. This study identified factors causing NIV failure, and increasing mortality. By utilizing these predictors, we can reduce mortality in COPD patients with ARF. This study aimed to identify factors contributing to NIV failure in COPD patients with acute exacerbation. Therefore, by utilizing these risk factors we can decide to switch from NIV to IMV before the patient's condition worsens.

METHODS

A Quasi Single Arm study was conducted in the Medicine Department and Intensive Care Unit (ICU) of a tertiary care hospital in Karachi, after approval from the ethical research committee of the institution (4930222YAMED). The calculated sample size was 170 via the WHO calculator, with a 95% confidence interval. The absolute precision required was 0.07. Anticipated population proportion 1 was 0.115 and anticipated population proportion 2 was 0.119.

The inclusion criteria of the cases comprise of the COPD patients admitted to the Medicine Department and Medical ICU with ARF, aged above 40 and below 80 years, of either gender. Cases were labeled as COPD if i) they have a history of smoking at least 20 packs for years, ii) having difficulty in breathing, chronic cough, production of sputum, and/or a medical history of environmental exposure linked to COPD, iii) Patients diagnosed as COPD based on spirometry, iv) Patients previously treated as COPD or currently being treated as COPD by attending physician. Cases were excluded from the research if i) Patients were below 40 or above 80 years of age, ii) If patients/family refused to participate in the study, iii) If patients/family signed do-not-attempt-resuscitation orders, iv) If patients diagnosed other than COPD or not fit in above criteria of COPD. Informed consent was signed by either the patient or the next of kin.

The application of NIV was performed according to the hospital's set criteria. ETI was performed if respiratory failure worsened. When intubation or mortality happened, it was recorded as NIV failure. The time duration in which NIV failure happened and the risk factors present in such patients were noted in the proforma used for data collection.

SPSS version 27 was used for data analysis. Shapiro Wilk test checked the normality of continuous variables (like age). Mean and standard deviations were calculated for normally distributed variables (like age in our data), while the median (IQR) was reported for non-normality distributed ones. Mann-Whitney U test compared continuous data. Percentages and frequencies measured qualitative variables like gender, weak cough reflex, non-invasive ventilation failure, and in-hospital mortality.

RESULTS

A total of 170 patients were included in this study, the mean age was 66 ± 12 years ranging from 40–80 years, 21 patients between 40-49 years, 40 patients

between 50-59 years, 60 patients between 60-69 years, and 49 patients between 70-80 years.

We found a highly significant association of quadrant filtration, weak cough reflex, excessive secretions, hypercapnic encephalopathy, poor Arterial Blood Gases (ABGs), severity of illness, disruption of circadian sleep cycle, and blood cultures with the non-invasive ventilation status (p<0.001). There is an insignificant association of non-invasive ventilation status was found with gender (p=0.541), diabetes (p=0.441), hypertension (p=0.263), chronic kidney disease (p=0.308), ischemic heart disease (p=0.303) and increased expired tidal volume (p=0.561). We also found a significant association of intolerance (p=0.018), agitation (p=0.018), and hospital-acquired pneumonia (P=0.019) with the non-invasive ventilation status (Table 01).

Table 1: Association of different characteristics with non-invasive ventilated status.

Characteristics		NIV Failure		p-value
		Failure (n=66)	Success (n=104)	
Gender	Male Female	33 (50%) 33 (50%)	47 (45.2%) 57 (54.8%)	0.541
Diabetes	Yes No	42(63.6%) 24(36.4%)	60(57.7%) 44(42.3%)	0.441
Hypertension	Yes No	31(47%) 35(53%)	58(55.8%) 46(44.2%)	0.263
Chronic kidney disease	Yes No	12(18.2%) 54(81.8%)	13(12.5%) 91(87.5%)	0.308
Ischemic heart disease	Yes No	6(9.1%) 60(90.9%)	15(14.4%) 89(85.6%)	0.303
Quadrant Infiltration	Positive Negative	64 (97%) 2 (3%)	51 (49%) 53 (51%)	<0.001
Weak cough Reflex	Positive Negative	50 (75.8%) 16 (24.2%)	13 (12.5%) 91 (87.5%)	<0.001
Excessive Secretions	Positive Negative	49 (74.2%) 17 (25.8%)	14 (13.5%) 90 (86.5%)	<0.001
Hypercapnic Encephalopathy	Positive Negative	55 (83.3%) 11 (16.7%)	5 (4.8%) 99 (95.2%)	<0.001
Intolerance	Positive Negative	16 (24.2%) 50 (75.8%)	11 (10.6%) 93 (89.4%)	0.018
Agitation	Positive Negative	16 (24.2%) 50 (75.8%)	11 (10.6%) 93 (89.4%)	0.018
Poor ABGs	Positive Negative	66 (100%) 0 (0%)	19 (18.3%) 85 (81.7%)	<0.001
Severity of illness	Positive Negative	66 (100%) 0 (0%)	25(24%) 79(76%)	<0.001
Disruption of the circadian sleep cycle	Positive Negative	3(4.5%) 63(95.5%)	28(26.9%) 76(73.1%)	<0.001
Blood Cultures	Positive Negative	61(92.4%) 5(7.6%)	25(24%) 79(76%)	<0.001
Hospital-acquired Pneumonia	Positive Negative	9(13.6%) 57(86.4%)	4(3.8%) 100(96.2%)	0.019
Increased expired tidal volume	Positive Negative	2(3%) 64(97%)	1(1%) 103(99%)	0.561[1]

**Statistically significant values <0.05 by Chi-square or Fisher Exact test*

There was a significant association of quadrant filtration, weak cough reflex, excessive secretions, hypercapnic encephalopathy, poor ABGs, severity of illness, blood cultures, and non-invasive ventilation status with mortality. (p<0.001). There is an insignificant association of mortality was found with gender (p=0.949), diabetes (p=0.460), hypertension (p=0.287), chronic kidney disease (p=0.952), ischemic heart disease (p=0.412), intolerance (p=0.415), agitation (p=0.415), and hospital-acquired pneumonia (P=0.081) and increased expired tidal volume (p=0.555). We also found a significant association between disruption of the circadian sleep cycle the mortality (p=0.003) (Table 02).

Table 2: Association of different characteristics with mortality.

Characteristics		Mortality		p-value
		Yes (n=40)	No (n=130)	
Gender	Male	19(47.5%)	61(46.9%)	0.949
	Female	21(52.5%)	69(53.1%)	
Diabetes	Yes	26(65%)	76(58.5%)	0.460
	No	14(35%)	54(41.5%)	
Hypertension	Yes	18(45%)	71(54.6%)	0.287
	No	22(55%)	59(45.4%)	
Chronic kidney disease	Yes	6(15%)	19(14.6%)	0.952
	No	34(85%)	111(85.4)	
Ischemic heart disease	Yes	3(7.5%)	18(13.8%)	0.412[!]
	No	37(92.5%)	112(86.2%	
Quadrant Infiltration	Positive	39(97.5%)	76(58.5%)	<0.001
	Negative	1(2.5%)	54(41.5%)	
Weak cough Reflex	Positive	37(92.5%)	26(20%)	<0.001
	Negative	3(7.5%)	104(80%)	
Excessive Secretions	Positive	36(90%)	27(20.8%)	<0.001
	Negative	4(10%)	103(79.2%)	
Hypercapnic Encephalopathy	Positive	38(95%)	22(16.9%)	<0.001
	Negative	2(5%)	108(83.1%)	
Intolerance	Positive	8(20%)	19(14.6%)	0.415
	Negative	32(80%)	111(85.4%)	
Agitation	Positive	8(20%)	19(14.6%)	0.415
	Negative	32(80%)	111(85.4%)	
Poor ABGs	Positive	40(100%)	45(34.6%)	<0.001
	Negative	0(0%)	85(65.4%)	
Severity of illness	Positive	40(100%)	51(39.2%)	<0.001
	Negative	0(0%)	79(60.8%)	
Disruption of the circadian sleep cycle	Positive	1(2.5%)	30(23.1%)	0.003
	Negative	39(97.5%)	100(76.9%)	
Blood Cultures	Positive	38(95%)	48(36.9%)	<0.001
	Negative	2(5%)	86(63.1%)	
Hospital-acquired Pneumonia	Positive	6(15%)	7(5.4%)	0.081[!]
	Negative	34(85%)	123(94.6%)	
Increased expired tidal volume	Positive	1(2.5%)	2(1.5%)	0.555[!]
	Negative	39(97.5%)	128(98.5%)	
Non-invasive ventilation failure	Yes	40(100)	26(20)	<0.001
	No	0(0)	104(80)	

**Statistically significant values<0.05 by Chi-square or [!]Fisher exact test.*

The comparison of respiratory rate, pH, and PCO_2 at the time of admission among non-invasive ventilation status was presented in Table 3. The median respiratory rate at the time of admission for the NIV failure group was 24 with an IQR of 6, while it was 22 with an IQR of 4 for the NIV success group. The p-value <0.001 suggested a statistically significant difference in the respiratory rate between the two groups at the time of admission. The median pH at the time of admission for the NIV failure group was 7.1 with an IQR of 0.2, while it was 7.3 with an IQR of 0.1 for the NIV success group. The p-value <0.001 suggested a statistically significant difference in the PH between the two groups at the time of admission. The median PCO_2 at the time of admission for the NIV failure group was 67.5 with an IQR of 29, while it was 41 with an IQR of 8 for the NIV success group. The p-value <0.001 suggested a statistically significant difference in the PCO_2 between the two groups at the time of admission.

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Table 3: Comparison of respiratory rate, pH, and PCO2 at admission among NIV status.

Variables	NIV Failure	NIV Success	p-value
	Median (IQR)	Median (IQR)	
Respiratory rate at admission	24(6)	22(4)	<0.001
pH at admission	7.1(0.2)	7.3(0.1)	<0.001
PCO_2 at admission	67.5(29)	41(8)	<0.001

**Statistically significant values <0.05 by Non-parametric Mann-Whitney U test*

Out of 170 cases, 66 (38%) experienced NIV failure while 104 (61%) had NIV success, and 40 (23.5%) participants died in hospital. Figure 1 shows NIV failure concerning timings that are immediate, early, or late.

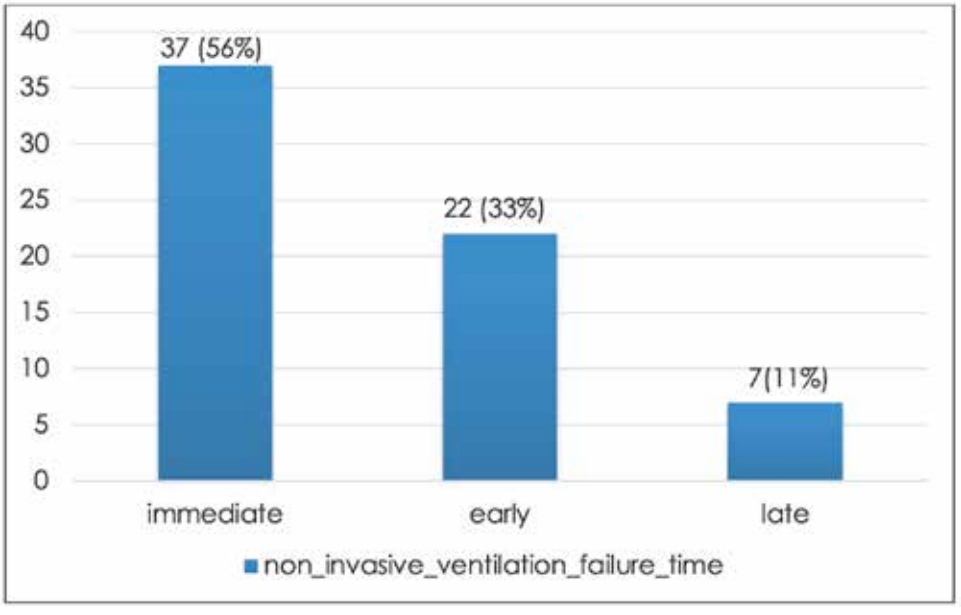

Figure 1: Non-invasive ventilation time in NIV Failure (n=66).

DISCUSSION

In this study, we focused on the parameters that can predict NIV failure in less than 1 hour of admission, between 1 to 48 hours of admission, and after 48 hours of admission of NIV. These three temporal moments are based on randomized control trials (RCTs) 1) immediate failure (within minutes to <1 hour), 2) early failure (1 to 48 hours), and 3) late failure (after 48 hours) [12,15-17]. We studied 170 COPD patients who presented with acute respiratory failure. Of these patients 80 (47%) were male and 90 (53%) were female. The ages of the patients were above 40 and below 80 years. Out of 170 patients, 66 (38%) experienced NIV failure while 104 (61%) experienced NIV success. Out of 66, 37 were immediate, 22 were early and 7 were late NIV failure. In those who experienced NIV failure 40 (38.46%) patients died in hospital. In the NIV success group, there were 33 males (50%) and 33 females (50%) while in the NIV failure group, there were 47 males (45%) and 57 females (55%), shows there is no significant association of gender with NIV failure. In the NIV failure group, 64 patients (97%) had quadrant infiltration, while only 2 patients (3%) did not. The association of quadrant infiltration with NIV failure is proven in previous studies, it was a major complication at the time of admission which led to NIV failure in our study [18-20]. Quadrant infiltration was also significantly associated with mortality after NIV failure. Factors present upon admission - especially quadrant infiltration, low Glasgow Coma Scale (GCS), reduced oxygenation, and higher Fraction of Inspired Oxygen (FiO_2) needs - indicated heightened risk of NIV failure. GCS remained a robust predictor over the next 48 hours. Moreover, weak cough reflex, excessive secretions, hypercapnic encephalopathy (more specifically with 1 hour of NIV), Intolerance (especially mask intolerance), Agitation, and Poor ABGs are also significantly associated with NIV failure in our study as well as in previous studies [21-23]. Research has shown that the outcome of NIV is favorable in acute hypercapnic encephalopathy as compared to other causes of encephalopathy [24-26]. However, in our study, NIV is more successful in cases with higher GCS regardless of hypercapnia. The respiratory rate at the time of

presentation was higher in patients who developed NIV failure. Respiratory failure was also significantly associated with mortality. Low pH and higher PCO_2 at the time of presentation were also significantly associated with NIV failure and mortality. Hospital-acquired respiratory infections, septicemia, and positive cultures were responsible for poor outcomes and potentially associated with mortality. An increase in PO_2 after 1 hour of administration of NIV and reduced requirements of oxygen is associated with favorable outcomes.

Our study results showed that factors at admission predict NIV failure low GCS, weak lungs, and high oxygen needs. Places with fluid in the lungs correlated with failing non-invasive ventilation within 48 hours, as did poor response of blood gases to treatment. Thirteen was the minimum GCS score for success. Factors like struggling to breathe, extreme secretions, and confusion often meant non-invasive ventilation failed. However, higher GCS scores meant non-invasive ventilation worked better. Infections and severe illness correlated with death. Factors like gender, diabetes, hypertension, chronic kidney disease, ischemic heart disease, intolerance, agitation, hospital-acquired pneumonia, and increased expired tidal volume were not significantly associated with NIV failure. Hospital-acquired pneumonia and co-morbidities can still contribute towards NIV failure and mortality with other factors.

The NIV failure rate of our study was 38.8% and mortality was 38.6%. Only 7 patients among 66 patients in the NIV failure group, developed NIV failure after 48 hours, this limits our study in evaluating risk factors associated with late NIV failure. This study provides us information that admission exam findings especially low Glasgow Coma Scale, increased respiratory rate, poor oxygenation, high oxygen demands, and weak cough reflex and a few investigations like ABGs and chest x-rays can be useful in predicting NIV failure among COPD patients presenting with acute respiratory failure. If this kind of study is ever conducted on a larger scale, including more hospitals, it will provide us with more useful information about NIV failure and risk factors.

Late NIV failure risk factors were under-reported due to low cases developing failure after 48 hours. If this study is expanded in the future to encompass a broader range of hospital setups, we can delve deeper into additional risk factors, particularly those linked to late-onset NIV failure.

CONCLUSION

Quadrant infiltrate, diminished consciousness, heightened oxygen needs, low pH levels, and elevated respiratory rates strongly correlate with NIV failure and subsequent mortality. These risk indicators can be identified through basic clinical examinations or straightforward tests such as ABGs and chest radiographs. Our findings emphasize that despite an initially positive response, patients might still encounter NIV failure, warranting ongoing monitoring. In cases of non-improvement, prompt endotracheal intubation (ETI) is advisable, as mortality and complications escalate following unsuccessful NIV treatment.

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CONFLICT OF INTEREST

There is no conflict of interest between the authors.

ETHICAL APPROVAL

Approval from the Ethical Review Committee of the relevant institution. (Reference Code: 4930222YAMED).

PATIENT CONSENT

Written informed consent was obtained from all the patients.

AUTHORS CONTRIBUTIONS

YA apprehended the idea of the research, did the relevant literature search, and drafted the manuscript, HA helped in the literature search, and NA, and QU authors participated in data acquisition. YA also provides clinical support to the patients who participated in this study.

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