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Original Research Article

To study indication's outcomes and complications of non-invasive ventilation in acute respiratory failure

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ABSTRACT

Background: Failure of respiratory system in one or both of its gas-exchanging functions- oxygenation of pulmonary arterial blood and carbon-dioxide elimination from mixed venous blood. Non-Invasive Ventilation is an alternative to invasive ventilation in many conditions it is a valuable component in patient management. Its use in acute respiratory failure is widely accepted and well known.
Aim: To Study the indications, outcomes, and complications of NIV.
Materials and Methods: This is a prospective observational study conducted on 100 patients admitted with either Type-I or Type -II respiratory failure.
Results: Various common indications for use of NIV in acute Respiratory Failure are COPD, ILD, Bronchiectasis, Pneumonia, Pulmonary Thromboembolism, Kyphoscoliosis, and Pulmonary Tuberculosis in that order. The overall success rate of NIV is 84%.
Conclusion: NIV helps in improving gas exchange in acute respiratory failure irrespective of its type, reduces intubation and length of hospital stay hence, its use as the first modality of treatment in patients without overt contraindications is recommended. Overall, NIV is safe and effective in patients with acute respiratory failure as there are no major complications associated with its use.

1. Introduction

Failure of respiratory system in one or both of its gas-exchanging functions- oxygenation of pulmonary arterial blood and carbon-dioxide elimination from mixed venous blood. Hence, respiratory failure is a syndrome rather than a disease.

The normal partial pressure reference values are: oxygen PO2 > 80 mmHg (11 kPa), and carbon dioxide PCO2 < 45 mmHg

Respiratory failure is defined when the mechanism of gas exchange at the lungs is sufficiently impaired to cause + decrease in blood levels of oxygen (hypoxemia); this may occur with or without an increase in carbon-dioxide levels. The definition of respiratory failure is PO2< 7kPa (55mmHg). Respiratory failure is divided as:

1. Type I - involves low oxygen, and normal or low carbon dioxide levels.
2. Type II - involves low oxygen, with high carbon-dioxide i.e. PCO_2 > 45mmHg.

It may be acute or chronic. Acute respiratory failure is characterized by life-threatening deranged arterial blood gases and acid–base status whereas Chronic respiratory failure is more indolent and may be clinically inapparent.[1]

Noninvasive ventilation (NIV) is a type of artificial ventilation in which the ventilatory support is administered without using an invasive artificial airway (endotracheal tube or tracheostomy tube). It is now used as a replacement for invasive ventilation in various conditions, it also has a

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valuable component in patient management. Its use in acute hypoxemic/hypercapnic respiratory failure is now well known and widespread. However, its role in patients with chronic respiratory failure is not as clear and remains to be defined. Guidelines suggest more favorable outcomes when used in patients with chronic obstructive pulmonary disease (COPD) and cardiogenic pulmonary oedema,[2] The use of NIV in treatment of patients with neuromuscular disease is so successful that it has now became standard of care and is widely accepted as the standard method of non-invasive ventilation in patients with chronic hypercapnic respiratory failure caused by chest wall deformity, neuromuscular disease, or impaired central respiratory drive.[3,4]

The advantages of Non-invasive ventilation over endotracheal intubation are well known. Speech, airway defense mechanisms and swallowing functions remain intact. Limitations are- lack of direct access to airway for removal of secretions, need for patient cooperation, facial trauma and discomfort related to the mask and the potential for abrupt respiratory deterioration if patient breathing is not synchronous with the ventilator or the mask becomes dislodged.[5] With NIPPV, the need for intubation was reported to decline and also the respiratory rate and gas exchange showed rapid improvements.[5] Literature has many articles including Randomized Controlled Trials (RCTs) and meta-analyses on non-invasive ventilation in patients with acute respiratory failure with various etiology. In these studies, NIV was associated with a reduced need for invasive mechanical ventilation, better patient tolerance, decreased mortality and shorter length of hospital stay.[6,7]

2. Materials and Methods

This is prospective observational study conducted on 100 patients admitted under Department of Pulmonary Medicine of tertiary care of hospital. Patients presenting with both Type-I and Type-I respiratory failure were included in the study.

2.1. Inclusion criteria

Acute Respiratory failure with underlying Lung condition.

Age between 17-70 years.

2.2. Exclusion criteria

Any contraindication for NIV[8] i.e.,

1. Patient's inability to protect airway.
2. Systolic blood pressure < 90 mmHg or use of vasopressors.
3. Electrocardiogram instability with evidence of ischemia or ventricular arrhythmias;
4. Agitation, lack of cooperation, facial trauma, burns, or facial surgery.

The demographic characteristics, detailed history including the relevant past and personal history was noted. All the relevant investigations including ABG were sent and the reports noted. All patients received optimum medical management for the underlying disease. Initial NIV settings were noted for every patient and the subsequent changes in the settings with reference to the clinical and/or ABG parameters were noted. The final outcomes like discontinuation of NIV either with improvement or failure requiring invasive ventilation was noted along with the duration of the NIV.

Success of NIV- Improvement in ABG or when NIV was no more needed.[9]

Failure of NIV- Patient condition deteriorated even after NIV on appropriate medical support[10] or if patient was shifted to invasive ventilator[11,12] for example- non-improvement of ABG parameters, patients developing loss of consciousness, or worsening of clinical parameters like Heart Rate and Respiratory Rate.

The data was analyzed using SSPS 2016 software.

Machine used for NON-INVASIVE VENTILATION- Stellar 150 (RESMED).

All patients were administered NIV support system, using full face mask or nasal mask. The initial settings (in spontaneous timed mode) were 10 cmH2O of IPAP and 5 cmH2O of EPAP. Both the parameters were titrated as per patient's comfort. Both IPAP as well as EPAP were changed as per the patients' clinical status and ABG parameters. FiO2 requirement was assessed by monitoring SpO2 and frequent ABG analysis. NIV was applied to patients in bed in propped-up position by face mask. Mask and tubings were disinfected/sterilized as per standard disinfection protocol.[12] Pressures, both IPAP and EPAP were gradually increased by 2 - 5 cmH2O every 10-15 minutes as per requirement to maintain Spo2 >94%. Patients were assessed every 15 min for initial 2 hours for pulse rate, respiratory rate, GCS, blood pressure, level of co-operation, mental status, oxygen saturation, signs of air leakage around the mask. Appropriate medical management like bronchodilators, nebulized corticosteroids, intravenous corticosteroids, intravenous antibiotics, methyl-xanthines were also given along with NIV. ABG values were obtained prior to application of NIV, after 1 hour of application of NIV, on stabilization of the patients on NIV settings and prior declaring outcome; however, it was also done whenever required to assess the adequacy of ventilation. Initially NIV was given continuously for 24 hours and then depending on response, NIV was given intermittently or continuously. Once adequate response was achieved, the duration of NIV was reduced gradually. Once patient was weaned off from NIV, daily clinical assessment, ABG were done to assess improvement. Outcome of NIV usage was measured in terms of number of patients treated successfully by NIV and those who failed on NIV. Outcome for existing

pulmonary disease was corelated with type-I or type-II respiratory failure.

3. Observation and Results

Table 1: Type of respiratory failure in patients

	Type	
	Type-I	**Type-II**
No. of patients (N)	47	53
N %	47.0%	53.0%

Table 2: Diagnosis and type of respiratory failure

		Type			
		Type-I		**Type-II**	
		No. of patients (N)	**N %**	**No. of patients (N)**	**N %**
Diagnosis	Bronchiectasis	1	2.1%	10	18.9%
	COPD	14	29.8%	40	75.5%
	ILD	18	38.3%	0	0.0%
	Kypyhoscoliosis	1	2.1%	1	1.9%
	Pneumonia	11	23.4%	1	1.9%
	PTB	1	2.1%	0	0.0%
	PTE	1	2.1%	1	1.9%

Total patients were: COPD-54, ILD-18, Broncietasis-11, Pneumonia-12, Pulmonary Thromboembolism-2, Kyphoscoliosis-2, Pulmonary tuberculosis-1.

Table 3: Outcome analysis after application of NIV

	Improved	**Failure**
Outcome	84	16

Table 4: Type of respiratory failure and outcome

	Type-I		**Type-II**	
	No. of patients (N)	**N %**	**No. of patients (N)**	**N %**
Improved	36	76.6%	48	90.6%
Failure	11	23.4%	5	9.4%
Total	47	100.0%	53	100.0%

Chi-square test: p-value 0.057

Interpretation: p-value greater than that of 0.05, hence it can be said that application of NIV is helpful irrespective of type of respiratory failure.Table 4

Interpretation: p-value less than that of 0.05 indicates that patients with bronchiectasis, COPD, ILD are more likely to improve after application of NIV.Table 5

Interpretation: p-value less than 0.05 indicates that patients with COPD and ILD with Type-I respiratory failure are more likely to improve with NIV application as compared to other diagnosis in which p-value is not significant, likely due to small sample population.Table 6

Table 5: Diagnosis and outcome

	Improved	**Failure**	**Total**
Bronchiectasis	9	2	11
COPD	49	5	54
ILD	16	2	18
Kypyhoscoliosis	1	1	2
Pneumonia	6	6	12
PTB	1	0	1
PTE	2	0	2

Chi-square test: p-value 0.022

Interpretation: p-value less than 0.05 indicates that patients with COPD and with Type-II respiratory failure are more likely to improve with NIV application as compared to other diagnosis in which p-value is no significant, likely due to smaller sample population.Table 7

Interpretation: p-value greater than that of 0.05 indicates that irrespective of type of respiratory failure, patients of COPD may improve on NIV and there is no statistical significance between the type of respiratory failure and outcome.Table 8

Interpretation: p-value less than that of 0.05 indicates that patients with bronchiectasis, COPD, ILD are more likely to improve after application of NIV.Table 9

Interpretation: p-value greater than that of 0.05 indicates no significance of association between PAH and Outcome.Table 10

Interpretation: p-value greater than that of 0.05 indicates no significance of association between Type and Outcome within PAH.Tables 11 and 12

Most common complication found in present study was dryness of mouth followed by aerophagia and non-compliance.

All the patients who were non-compliant to NIV were counselled and NIV was applied.Table 13

4. Discussion

NIV has many advantages like patient comfort, ability to eat and speak, maintenance of airway defenses, also avoiding complications of endotracheal intubation. Disadvantages are slow improvement non-applicability to unconscious or hemodynamically unstable patients.

This study was conducted in the Pulmonary Medicine ward of our Tertiary Health Care Institute.

100 consecutive patients with acute respiratory failure were enrolled in our study with almost equal distribution of patients with Type-I (47) and Type-II (53) respiratory failure (Table 1).

Patients with different diagnoses were COPD (54), ILD (18), Bronchiectasis (11), Pneumonia (12), Kyphoscoliosis (2), Pulmonary Thromboembolism (2), Pulmonary Tuberculosis (1). Patients with these diagnoses who presented with both Type-I and Type -II respiratory failure

Table 6: Outcome in patients of Type I respiratory Failure with different diagnosis:

	Type-I Outcome					
	Improved	**%**	**Failure**	**%**	**p-value**	**Interpretation**
Bronchiectasis	1	2.13%	0	0.00%	0.32	NS
COPD	12	25.53%	2	4.26%	0.01	Sig
ILD	16	34.04%	2	4.26%	0.00	Sig
Kypyhoscoliosis	0	0.00%	1	2.13%	0.32	NS
Pneumonia	5	10.64%	6	12.77%	0.76	NS
PTB	1	2.13%	0	0.00%	0.32	NS
PTE	1	2.13%	0	0.00%	0.32	NS

Table 7: Outcome in patients of Type II respiratory Failure with different diagnosis

	Type-II Outcome					
	Improved	**%**	**Failure**	**%**	**p-value**	**Interpretation**
Bronchiectasis	8	15.09%	2	3.77%	0.06	Not Significant
COPD	37	69.81%	3	5.66%	0.00	Significant
ILD	0	0.00%	0	0.00%	NA	
Kypyhoscoliosis	1	1.89%	0	0.00%	0.32	Not Significant
Pneumonia	1	1.89%	0	0.00%	0.32	Not Significant
PTB	0	0.00%	0	0.00%	NA	
PTE	1	1.89%	0	0.00%	0.32	Not Significant

Table 8: Outcome in COPD with Type-I and Type-II Failure:

	Improved No. of patients (N)	**Failure No. of patients (N)**	**Total No. of patients (N)**
Type-I	12	2	14
Type-II	37	3	40

Chi-square test: p-value 0.451

Table 9: Diagnosis and final outcome

		Final Outcome					
		Discharged		Died			
		Count	**Column N %**	**Count**	**Column N %**	**p-value**	**Interpretation**
Diagnosis	Bronchiectasis	10	11.6%	1	7.1%	0.006656	Significant
	COPD	50	58.1%	4	28.6%	0.0000	Significant
	ILD	16	18.6%	2	14.3%	0.000967	Significant
	Kypyhoscoliosis	1	1.2%	1	7.1%	1.00	Not Significant
	Pneumonia	6	7.0%	6	42.9%	1.00	Not Significant
	PTB	1	1.2%	0	0.0%	0.317311	Not Significant
	PTE	2	2.3%	0	0.0%	0.157299	Not Significant

Table 10: PAH and outcome

	Improved		**Failure**		**Total**	
	No. of patients (N)	**N %**	**No. of patients (N)**	**N %**	**No. of patients (N)**	**N %**
Yes	26	83.9%	5	16.1%	31	100.0%
No	58	84.1%	11	15.9%	69	100.0%

Chi-square test- p-value 0.981

Table 11: PAH with type of respiratory failure and outcome

			Outcome					
			Improved		Failure		Total	
			No. of patients (N)	N %	No. of patients (N)	N %	No. of patients (N)	N %
Yes	Type	Type-I	11	78.6%	3	21.4%	14	100.0%
		Type-II	15	88.2%	2	11.8%	17	100.0%
No	Type	Type-I	25	75.8%	8	24.2%	33	100.0%
		Type-II	33	91.7%	3	8.3%	36	100.0%

Pearson Chi-Square Tests:

Table 12:

			Outcome
Yes	Type	Chi-square	.530
		Df	1
		Sig.	.467
No	Type	Chi-square	3.252
		Df	1
		Sig.	.071

Table 13: Complications of NIV

Complication	Number of Patients
Aerophagia	5
Dryness of mouth	8
Facial oedema	2
Nasal bridge ulceration	4
Non-Compliance	5
Total	24

were COPD (Type-I 14, Type-II 40), Bronchiectasis (Type-I 1 and Type-II 10), Kyphoscoliosis (Type-I 1 and Type-II-1), Pneumonia (Type-I 11 and Type-II 1), Pulmonary Thromboembolism (Type-I 1 and Type-II 1). Patients with ILD and Pulmonary Tuberculosis presented with only Type-I respiratory failure. (Table 2).

Patients were monitored with ABG's every 12 hourly after 1^{st} hour of NIV application and Respiratory Rate, Heart Rate. pH, PO2, PCO2 were analyzed at the time of NIV application (baseline/0^{th} hour), after 1 hour and prior to declaring outcome (PDO) individually for Type-I as well as for Type-II respiratory failure.

In our study, of 100 patients, 84 patients improved after applying NIV, however 16 patients were intubated and shifted on mechanical ventilation (Table 3) George I. et al stated that, success rate with NIPPV was (85%) in patients of acute respiratory failure admitted to intensive care unit.[6] In a study by Ventrella F. et al NIV was successful in (81%) of patients of hypercapnic respiratory failure.[13]

Out of 100 consecutive acute respiratory failure patients enrolled in this study, 47 were in Type-I and 53 were in Type-II respiratory failure and we found that NIV successfully improved gas exchange and V/Q mismatch in both Type-I (76.6%) and Type-II (90.6%) however there was no significant association between type of respiratory failure and outcome (Table 4). Thus, NIV was effective irrespective of type of respiratory failure. In a study by George I. et al overall success rate in the patients with Acute respiratory failure who were treated with NIV was 85 which is comparable to the current study.[6] Whereas Kramer N. et al reported 69% patients in their study of acute respiratory failure improved with NIV.[5] In a study by Ventrella F. et al NIV was successful in (81%) patients of hypercapnic respiratory failure.[13]

Among the various diagnoses, 9 out of 11 Bronchiectasis, 49 out of 54 COPD, 16 out of 18 ILD, 1 out of 2 Kyphoscoliosis, 6 out of 12 Pneumonia, 1 out of 1 Pulmonary Tuberculosis, 2 out of 2 Pulmonary Thromboembolism patients improved on NIV (Table 5). It was found COPD, ILD or Bronchiectasis requiring NIV had significant improvement (Table 5). The result was not significant for other diagnoses, likely due to small sample size.

We also studied outcome in individual diagnosis with type of respiratory failure and concluded that there are significant chances of improvement in patients with COPD and ILD with Type-I respiratory failure (Table 6), however no significant association was seen in rest of the diagnoses may be due to small sample size. COPD (Table 7) with Type-II respiratory failure was significantly

associated with success of NIV whereas type-II respiratory failure in patients with ILD, bronchiectasis, pulmonary tuberculosis, pneumonia, pulmonary thromboembolism or kyphoscoliosis has no significant association with outcome.

As COPD patients presented with both Type-I and Type-II respiratory failure, we also analyzed outcome with type of respiratory failure in COPD and it was observed that there is no significant association (Table 8) between type of failure and outcomes in COPD patients hence it was concluded that COPD has better outcome in Acute Respiratory failure irrespective of type of respiratory failure. In a study by Ritesh Agarwal et al NIV is more effective in preventing endotracheal intubation in Acute respiratory failure due to COPD than any other causes of respiratory failure, and therefore the etiology of ARF is an important predictor of NIPPV failure.[14] De Mi chelis et al. and Raghavan et al in their study showed a significant reduction in ICU admissions, length of hospital stay, increase in survival rates, and decrease in the number of tracheostomies related to COPD exacerbations.[15,16] Therefore, NIV is effective in management of acute exacerbation of chronic obstructive pulmonary disease along with antibiotics and bronchodilators.

In Current study we found that patients with COPD, ILD and bronchiectasis had better outcomes overall, as compared to the patients with other diagnosis (Table 9). However, further study with larger sample size needs to be conducted to ascertain such correlation between other diagnosis and final outcome.

Pulmonary artery hypertension is defined as mean pulmonary artery pressure >/=20 mmHg. We could not find statistically significant association between patients with pulmonary artery hypertension and outcome (Table 10). Also, there was no significant association between type of respiratory failure and PAH (Tables 11 and 12), hence PAH was not a predictor of outcome of NIV, we could not find any study showing PAH as a predictor of NIV outcome, though larger study on PAH as a predictor of NIV should be done.

24% of patients in current study had minor complications due to NIV. Complications noticed during the study were Aerophagia, Dryness of Mouth, Facial Oedema, Nasal Bridge Ulceration, Non-Compliance (Table 13). The most common complication was dryness of mouth, followed by aerophagia. 5 patients were not compliant to NIV due to claustrophobia, however after proper counselling, NIV was applied successfully. As per study by Nicolini A et al 132 patients out of 1809 had complications related to NIV and most common complication found in their study was skin breakdown followed by eye irritation and gastric distension.[17]

5. Limitations

We had a sample size of 100. We recommend similar study to be conducted with larger sample size and different age groups including pediatric patients which may also help in deriving clinical predictor scores for NIV outcome.

6. Conclusion

The commonest indications for NIV in acute Respiratory Failure are COPD, ILD, Bronchiectasis, Pneumonia, Pulmonary Thromboembolism, Kyphoscoliosis and Pulmonary Tuberculosis in that order. COPD and Bronchiectasis may present with either Type I or Type II Respiratory Failure without significant difference. ILD most commonly presents with Type-I respiratory failure. Patients in Acute Respiratory Failure with COPD, Bronchiectasis and ILD managed with NIV have better prognosis.

Overall success rate of NIV is 84%. Optimum medical management of the underlying disease condition along with NIV as a supportive measure can decrease intubation rates, mortality, reduces length of hospital stay and morbidity.

NIV in acute respiratory failure, irrespective of type of respiratory failure helps in improving gas exchange, reduces intubation and length of hospital stay hence, its use as a first modality of treatment in patients without overt contraindications is recommended. Overall, NIV is safe and effective in patients of acute respiratory failure as there are no major complications associated with its use.

7. Source of Funding

None.

8. Conflict of Interest

None.

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