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A Study of Role of Noninvasive Ventilation in Patients with Type ii Respiratory Failure

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ABSTRACT

The present study was conducted to understand the role of NIPPV in patients with Type II Respiratory failure. The sample size was 40. In our study cohort, the most common clinical diagnosis included COPD exacerbation, 90% (36/40) with or without associated co-morbidities. The Borg dyspnoea score improved from 5 at baseline to 1.4±0.07 at discharge. ($p < 0.0001$). The mean respiratory rate dropped from 34.8±4.4 before NIV to 13.82±1.96 ($p<0.0001$) at discharge. The mean pH changed from 7.29±0.02 at baseline to 7.4±0.03 at discharge($p<0.0001$).There was also a marked improvement in mean PaCO2 and PaO2 which changed from, 67.3±5.61, 54.6±8.85 at baseline to 50.02±4.08, 75.1±9.71 at the time of discharge respectively($p<0.0001$ for both parameters).Respiratory rate at baseline was significantly higher in the patients who failed to respond to NIV and there was a significant improvement in the clinical and blood gas parameters within the 1st of NIV in the successful group whereas no such improvement was observed in the failure group. In the present study NIPPV was successful in 34 patients (85%) and 6 patients (15%) failed to respond and required intubation. Of them, 2 patients did not consent and left against medical advice. 4 were intubated 2 survived and 2 eventually expired. No mortality was observed in the patients improved and continued on NIPPV. The mean IPAP used in the present study was 16.5±0.9 and mean EPAP used was 5.2±0.52. NIPPV was used for an average of 38.5±13 hrs. The incidence of complications in the present study was 10% which included aspiration pneumonia(2.5%), irritation of eyes (5%) and dryness of mouth (2.5%).The mean duration of hospital stay in the present study was 10.32±3.46 days. Our results strongly support and encourage the use of NIV as a first line ventilatory management in patients with respiratory failure due to acute exacerbations of COPD and the present study showed improvement in both the patients of Kyphoscoliosis and obstructive sleep apnea when put on NIPPV. Thus, NIPPV may be beneficial in these patients when they present with acute on-chronic respiratory failure.

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Key Words
Respiratory failure, borg dyspnoea, respiratory rate, non-invasive ventilation

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INTRODUCTION

The term non-invasive ventilation (NIV) refers to the application of artificial ventilation without any conduit access to the airways i.e., without an endotracheal or tracheostomy tube. Earlier negative pressure ventilation was used but in the modern era positive-pressure ventilation has supplanted negative-pressure ventilation as the dominant mode of delivery of non invasive ventilation and the mention of "non invasive ventilation" will refer to Non Invasive Positive-Pressure Ventilation(NIPPV) delivery in this study. Recently, NIV has assumed a prominent role in the management of acute respiratory failure[1-3]. Respiratory failure is a condition in which the respiratory system fails in one or both of its gas exchange functions, i.e. oxygenation of and/or elimination of carbon dioxide from mixed venous blood. It is conventionally defined by an arterial oxygen tension (PaO2) of <8.0 kPa (60mmHg), an arterial carbon dioxide tension (PaCO2) of >6.0 kPa (45mmHg) or both. In general, failure of the lung caused by a variety of lung diseases leads to hypoxaemia with normocapnia or hypocapnia (hypoxaemic or type I respiratory failure). Failure of the pump results in alveolar hypoventilation and hypercapnia (hypercapnic or type II respiratory failure). Although there is coexistent hypoxaemia, the hallmark of ventilatory failure is the increase in PaCO2[4]. By avoiding endotracheal intubation, NIV prevents complications associated with invasive ventilation like airway problems, nosocomial pneumonia (21%) and sinusitis (5-25%)[5-8]. In addition, the patient with an intact upper airway retains the ability to eat, swallow and verbalise. Mechanical ventilation is more comfortable without a tube in place and can be utilized outside the intensive care setting[9]. NIV can facilitate the discontinuance of ongoing ventilatory dependence and treat chronic respiratory failure in numerous diseases such as chronic lung disease and neuromuscular disorders. NIV is supportive, corrects pathophysiology rather than the etiology in disorders characterized by chronic hypoventilation, nocturnal oxygen desaturation, respiratory muscle fatigue and poor sleep quality. It provides intermittent rest for respiratory muscles and reduces work of breathing . It eliminates auto PEEP[10]. Many underlying causes contribute to Type II respiratory failure. The commonest cause of type II respiratory failure is COPD. COPD is a major health problem with significant medical and financial impact on society. The Global Burden Of Disease study projected that COPD which ranked as sixth leading cause of death in 1990, will become third by the year 2O2O. COPD was ranked 12th-leading cause of disability-adjusted life years (DALYS, defined as “the number of years lost due to ill-health, disability or early death") in 1990 and is expected to become 7th by 2030[11]. Epidemiologic studies suggest that respiratory failure will become more common as the population ages, increasing by as much as 80 percent in the next 20 years[12]. Two recent publications from India suggested that non invasive ventilation (NIV) was beneficial in cohorts of patients presenting with chronic obstructive pulmonary disease (COPD), as well as respiratory failure of varied etiology[13,14]. NIV is becoming the preferred method of treatment for patients with NMD, including daytime ventilator support[15].

Aims and Objectives:

- To study the role of Non invasive positive pressure ventilation in patients with Type II Respiratory Failure.
- To assess and compare the clinical and physiological parameters before and after the application of NIPPV in the study population.
- To determine the outcome of non invasive ventilation in the study population.

MATERIALS AND METHODS

Study Design: A Prospective Observational Study. After obtaining institutional ethical committee approval, the study was conducted among 40 patients with Type II Respiratory failure admitted to The Department of Respiratory Medicine.

Sample and Selection of Patients: A study of patients with type II respiratory failure falling in the age group 40-80 years were included, with the below mentioned inclusion and exclusion criteria.

Inclusion Criteria:

- Moderate to severe dyspnoea lasting <2 weeks plus any two of the following.
- Respiratory rate >25/min.
- pH <7.35-7.25.
- Partial pressure of carbon dioxide (PaCO2) >45 mmHg, PaO2<60mmHg, SpO2<92% with oxygen by mask.

Exclusion Criteria:

- Cardiac/respiratory arrest.
- Extreme claustrophobia or anxiety despite repeated attempts to facilitate the use of NIPPV.
- Severe upper gastrointestinal bleeding.

- **Hemodynamic Instability:** Shock (either cardiogenic or septic) with a systolic blood pressure of <90 mm Hg despite fluid challenge or need for pressure agents.
- Unstable arrhythmias.
- Encephalopathy, Glassgow Coma Score (GCS) <8.
- Recent Myocardial infarction.
- Facial surgery/trauma/deformity.
- Severe co-morbidity.

- Upper airway obstruction.
- Inability to cooperate and need of airway protection because of copious respiratory secretions.
- Seropositive for HIV and active Tuberculosis patients.
- Life threatening hypoxia.

Method of Study: Once eligibility was verified, patients were included in the study. Parameters that were recorded include dyspnoea quantitated by modified Borg dyspnoea score, respiratory rate (RR), heart rate (HR), arterial blood gas analysis(ABG). At admission patients' Blood pressure, ECG consciousness level and evidence of any co morbid illnesses were recorded. Routine blood investigations were sent. A chest X-ray was taken. Written informed consent was obtained from the patient or from his closest relative. Baseline evaluation consisting of patient's clinical history and detailed clinical examination was conducted. All patients were administered NIPPV using the BiPAP ventilatory support system (Respironics Inc). A appropriate size oro nasal mask was used for the study. The procedure was explained to the patient. The head end of the bed was elevated to 45^{o} angle. IPAP was initially set at 8 cm H 2 O and increased by increments of 2 cm of H2O up to 20 cm H2O based on clinical response and arterial blood gases. The initial expiratory positive airway pressure (EPAP) was set at 4 cm H2O and if required was increased by 1-2 cm increments titrated between 4-10 cm H2O to improve triggering and oxygenation. Humidified supplemental Oxygen therapy was administered with NIPPV and titrated to achieve an oxygen saturation of 88-92%. After explaining the procedure to the patient, Oronasal mask as held with hand over patient's face. IPAP and EPAP are adjusted so that patient can tolerate without discomfort and no major air leaks. Now interface was secured with head straps avoiding excessive tightness. After starting treatment each patient was monitored closely for initial one hour. Patient's discomfort and intolerance to mask was looked for. Continuous pulse oximetry and ECG monitoring was done. Any difficulty to clear secretions and abdominal distention was looked for. Once initiated continuous application of NIPPV was encouraged, with intermittent discontinuation for eating and drinking. Standard pharmacologic treatment including bronchodilators [inhaled salbutamol, ipratropium bromide through nebulisation and steroids (IV hydrocortisone)] and antibiotics were given along with NIPPV. Blood pressure, respiratory rate, heart rate, dyspnoea using modified. Borg scale were recorded at the baseline, 1 hr, 6 hrs and daily until discharge. Patients who appear to benefit from NIV during the first few hours of treatment received NIPPV for as long as possible (minimum of 6 hrs) with appropriate breaks for oral intake, nebulisation etc, during the first 24 hours. Once the patient improved clinically and corroborated by improvements in arterial blood gases, weaning was initiated. During the weaning phase, the IPAP was decreased in gradations of 2-3 cm until the IPAP was 7-10 cm. The application was then switched over to intermittent use. The time of weaning, thus, was different for each patient. NIPPV failure was defined as the need for IMV due to worsening of clinical features such as respiratory distress (tachypnea, tachycardia, increased work of breathing) hypotension, worsening of the level of consciousness, or laboratory evidence of worsening ABG or persistent respiratory distress while on NIPPV. If there were clinical and/or laboratory evidence of deterioration at any point during NIPPV intervention, endotracheal intubation was considered. Presence of sustained clinical improvement with reduction of RR <24/min, HR <100/min and presence of normal pH and O 2 saturation >90% on ABG analysis were required before patients were considered for weaning from NIPPV. The outcome of NIPPV usage was measured in terms of:

- **NIPPV Failure:** The need for endotracheal intubation.
- **NIPPV Success:** Improvement of patient condition Successful weaning from the NIPPV.
- Patients taking discharge against medical advice.

The other variables collected in the study included clinical (dyspnoea score, RR, HR), ABG parameters (pH, PaCO2 and PaO2), the mean duration of NIPPV application, duration of hospital stay and any complications related to the procedure. Any complications developed during the procedure were treated adequately. Statistical analysis was done using SPSS statistics version 22. A p value <0.05 is considered significant and p value <0.001 is considered extremely significant.

RESULTS AND DISCUSSIONS

The mean age of the study population is 60.7±7.8 yrs. Majority of them were in the age group of 51-60 yrs and 61-70 yrs each constituting 40%. Out of the 40 patients included in the study 36 (90%) were males and 4 (10%) were females. Sex ratio (M:F) is 9:1. The most common symptom on presentation was breathlessness seen in all the enrolled patients. Cough was present in a sizeable number of patients, i.e., 50%. A relatively small number of patients, 10% and 6% respectively, also had fever and chest pain on presentation, which was clinically diagnosed as pneumonia. In the present study a history of smoking (either active or ex smokers) was obtained in 36 patients (90%). Most of the patients had an average smoking pack years of 11-20 (50%). Most of the patients had an average smoking pack years of about 11-20.

Table 1: Causes Leading to Type II Respiratory Failure

Disease	males	Females	No of patients (n=40)	Percentage
AE COPD	34	2	36	90
Kyphoscoliosis	1	1	2	5
Obstructive sleep apnea	1	1	2	5

In the present study NIPPV was administered to 40 patients. Out of 40, 6 patients deteriorated and required intubation within 6 hrs. 34 patients who remained by the end of 6 hrs continued to receive NIPPV. NIPPV was effective in lessening the dyspnoea score from 5 at baseline to 3.2±0.02 at 1 hr, to 2.32±0.4 at 6hrs, 2.12±0.38 at 24 hrs and 1.4±0.07 at the time of discharge. (p<0.0001 from base line to all 4 measurements). The respiratory rate decreased from 34.8±4.4 at baseline to 26.9±5.66 at 1 hr, to 16.64±1.73 at 6hrs , 15.4±1.2 at 24 hrs and 13.8±1.9 at the time of discharge. (p<0.0001 from base line to 4 measurements). The heart rate reduced from 102.4±10.9 at baseline to 97.2±9.39 at 1hr to 88.2±8.1 at 6 hrs to 77.4±8.6 at 24 hrs and 77.1±9.65 at the time of discharge. (p<0.0001 from base line to 4 measurements).

Table 2: Changes in the ABG Parameters Before, During and After NIPPV

	0hr (n=40)	1hr (n=40)	24hrs (n=34)	Discharge (n=34)
pH	7.29±0.02	7.31±0.02*	7.37±0.02*	7.40±0.03*
PaCO 2mm Hg	67.3±5.61	62.8±5.74 *	51.8±3.7*	50.02±4.08*
PaO2 mm Hg	54.6±8.85	61.7±7.17*	70.3±9.19*	75.14±9.71*

Out of the 40 patients administered NIPPV , 6 patients deteriorated and required intubation and only 34 patients remained by the end of 6 hours. The pH changed from 7.29±0.02 at baseline to 7.31±0.02, 7.37±0.02 and 7.40±0.03 at 1 hr, 24 hrs and at discharge respectively. (p< 0.0001 from baseline to all 3 measurements). PaCO2 decreased with time significantly from 67.3±5.61-62.8±5.74 at 1 hr, 51.8±3.7 at 24 hrs and 50.02±4.08 at discharge (p<0.0001 from baseline to all 3 measurements). A rise in PaO2 was observed from 54.6±8.85 to 61.7±7.17 at 1hr, to 70.3±9.19 at 24 hrs and to 75.14±9.71 by the time of discharge. (p<0.0001 from baseline to all 3 measurements). Graph showing changes in PaCO2 and PaO2 in the study population. There was a significant fall in PaCO2 with NIPPV over time and PaO2 also improved significantly. (p<0.0001 for both PaCO2 and PaO2 from baseline to all measurements).

Table 3: Ventilatory Requirements

	Mean±SD (Range)
IPAP	16.5±0.9 (15-20)
EPAP	5.2±0.52 (5-8)
Duration on NIPPV(hrs)	38.513.1 (24-80)

The mean IPAP used in the present study was 16.41±0.69 The mean EPAP used was 5.11±0.32. NIPPV was used for an average of 38.5±13.1 hrs. Mean duration of hospital stay in our study was 10.32±3.46 days. Majority of patients were discharged within the 2nd week. In the present study NIPPV was successful in 34 (85%) and failed in 6 (15%) patients. RR at baseline was significantly higher in the patients who failed NIPPV (p value 0.03). Although the PaCO2 of patients who failed NIPPV was higher than the patients who succeeded this did not reach statistical significance. (70.3±5.7 vs 67.2±5.8, p 0.19 NS) No other differences were observed in baseline characteristics of patients who failed versus those who succeeded. After 1 hr of NIPPV, pH was significantly higher and PaCO2, was significantly lower in the success group as compared to failed group (7.31±0.01vs 7.29±0.01, 61.2±5.2 vs 73.8±4.6, p<0.0001). When compared to baseline values there was a significant improvement in RR (34.2 ±4.4-25.02±3.1, p<0.001), HR (102.6±11.2-97.8±9.1), pH (7.29±0.02 vs 7.31±0.01, p<0.001), PaCO2 (67.2±5.8 vs 61.2±5.2, p<0.001), PaO2 (54.6±9.1-62.7±6.8, p<0.001) in the success group. There was no change in pH and PaCO2 deteriorated in the failure group. In the present study the success rate with NIPPV was 85%, with 34 patients weaned off successfully and discharged. Of the six patients who failed NIPPV, 2 patients left against medical advice. The other 4 were intubated and mechanically ventilated. Out of these 4 patients 2 patients eventually expired, 1 due to ventilator associated pneumonia, 1 from gram negative sepsis and multi organ dysfunction syndrome. No mortality was observed in the patients improved and continued on NIPPV.

The present study was undertaken to understand the role of NIPPV in patients with Type II respiratory failure and to determine the outcome of such patients attending to our hospital. The current study group comprised of 40 patients who were eligible according to inclusion and exclusion criteria. The mean (SD) age of study group was 60.7±7.8 yrs with an age range of 40-80 years. The present study group has a male preponderance (36/40) of 90% similar to the study of vishal vanani *et al* with a male preponderance (43/50) of 86% and also the study of Lt. Col. *et al.* had a male preponderance of 64%. Soliman et al study group had a male preponderance (23/27) of 85%. However, in a similar study by George *et al.*, females constituted 56% of the total cohort[16-18]. The less number of females in the present study might be attributed as many of the females of COPD had a milder exacerbation and pH and PaCO2 only deviated slightly from normal values at presentation. Two patients didn't give consent to NIV and left against medical advice. Only those females with ABG criteria and other eligibility criteria fitting in were included. The mean heart rate on admission was 102.4±10.9 per min. The mean systolic blood pressure on admission was 138.96 mm Hg with a range of 128-168 mm Hg and the mean diastolic blood pressure was 96.72 with a range of 86-114 mm Hg. The most

common indication of NIV in our Study was acute exacerbation of chronic obstructive pulmonary disease (AE-COPD 90%). Two of the patients in the present study were diagnosed as Kyphoscoliosis with Type II Respiratory Failure. Both patients were put on NIV and both patients survived with significant improvement in PaO2, PaCO2. Verma *et al.* studied 2 patients with kyphoscoliosis presenting as. Type II Respiratory Failure. Both patients put on NIV survived with improvement in PaO2 and PaCO2. In our study a significant improvement was observed in the clinical and the blood gas parameters within 1 hr of application of NIPPV. The dyspnoea score has improved from 5 at baseline to 3.2±0.02($p<0.0001$) at 1 hr. Barbe *et al.* noticed significant decrease in dyspnea during with hospitalization at 72 hrs, 80 hrs and discharge in patients treated with NIV. Keenan[19] observed BORG index at 1hr and day 2 were significantly better in NIV treated group. The RR has fallen from a baseline of 34.8±4.4 to 26.9±5.66 ($p<0.0001$). In the present study further significant improvement was obtained at 24 hrs and it maintained upto the time of discharge. The pH, PaCO2 and PaO2 changed from baseline of 7.29±0.02, 67.3±5.61, 54.6± 8.85-7.4±0.03, 50.02±4.08, 75.1±9.71 at the time of discharge respectively. ±0.08, 66.4±16.24, 53.4±18 to 7.42±0.06, 56±12, 71±24.1 at the time of. The results in the present study indicate that NIV not only relieves respiratory distress and rests fatigued respiratory muscles but also can significantly improve hypercapnia and acidosis in patients with respiratory failure in acute exacerbation of COPD and thus alleviate the need for endotracheal intubation. In the present study it was observed that RR at baseline was significantly higher in the patients who failed NIPPV (34.2±4.4 vs 38.3±2.4, $p<0.05$). Although the PaCO2 of patients who failed NIPPV was higher than the patients who succeeded this did not reach statistical significance. After 1 hr of NIPPV, pH was significantly higher and PaCO2 was significantly lower in the success group as compared to failed group pH. (7.31±0.01vs 7.29±0.01, 61.2±5.2 vs 73.8±4.6, $p<0.0001$). When compared to baseline values there was a significant increase in pH and fall in PaCO2 in the success group, whereas there was no change in pH ,PaCO2 deteriorated in the failure group. These findings suggests that respiratory rate at admission and an improvement in gas exchange parameters within the 1st hour of NIPPV could possibly be used to predict response to NIPPV. However other determinants of success (like comorbidities, BMI etc) NIPPV were not evaluated in the present study. In the current study, the clinical improvement of patients on NIV was corroborated with improvements in the physiological variables. In the present study NIPPV was successful in 34 (85%) and failed in 6 (15%) patients. RR at baseline was significantly higher in the patients who failed NIPPV (p value 0.03)Although the PaCO2 of patients who failed NIPPV was higher than the patients who succeeded this did not reach statistical significance. (70.3±5.7 vs 67.2±5.8, p 0.19 NS) No other differences were observed in baseline characteristics of patients who failed versus those who succeeded. Only 4 (10%) complications occurred in the current study. One is aspiration pneumonia(2.5%) , 2 patients experienced irritation of eyes (5%) and 1 patient experienced dryness of mouth (2.5%) which is very similar to the complication rate in Umberto Meduri *et al.* (12%). NIV was well tolerated by the patients in study group. Reassurance was given and regular mouth care for dryness of mouth was advised. Commercially available oral lubricants can provide temporary relief. Aspiration pneumonia was treated with antibiotics and it resolved completely. This low rate of infectious complications in patients receiving NIPPV has been confirmed in randomized studies by Brochard et al and Bott[20,21]. In the present study the success rate with NIPPV was 85%, with 34 patients weaned off successfully and discharged. Of the six patients who failed NIPPV, 2 patients did not consent and left against medical advice. The other 4 were intubated and mechanically ventilated. Out of these 4 patients 2 patients eventually expired, 1 due to ventilator associated pneumonia,1 from gram negative sepsis and multi organ dysfunction syndrome. No mortality was observed in the patients improved and continued on NIPPV.

CONCLUSION

The study, thus, demonstrated that NIPPV is not only a cost effective ventilatory modality but also a treatment that is associated with significant improvements in clinical and biochemical outcomes. NIPPV with BiPAP was successful in 85% of patients in our study group with 40 patients weaned successfully off NIPPV. NIPPV, thus, circumvents the complications of Invasive Mechanical Ventilation like injury to airways, barotrauma and post-intubation laryngeal and tracheal stenosis while retaining the benefits of positive pressure ventilation. To conclude, the results in the present study showed that NIPPV is a promising therapeutic modality for management of selected patients with exacerbations of COPD who have respiratory acidosis. The protocol is simple to implement and monitor. In the present study a relatively lower respiratory rate at baseline and a significant improvement in clinical and blood gas parameters within the 1st hr of NIPPV indicated a favourable response. However further studies are required to establish this and to evaluate other potential predictors of success for better outcomes

with NIPPV. Proper selection of patients, proper interface, proper monitoring to recognize complications is the corner stone in success of NIPPV.

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