Original Article

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Internal Medicine Section

Comparative Study on Outcome of Non-invasive Ventilation in Patients with Acute Exacerbation of COPD Admitted in General Ward vs. High Dependency Unit

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ABSTRACT

Introduction: Non-Invasive Ventilation (NIV) is getting popularity in management of acute exacerbation of COPD with hypercapnic respiratory failure because of its effectiveness. However, there is still a dilemma regarding the site of initiation of NIV. There are several publications comparing outcome of NIV in highly sophisticated Intensive Care Units (ICU) and general ward in western literature, there is paucity of data from this part of the world. Considering unavailability of beds in highly monitored ward, the studies related to feasibility and acceptability of using NIV in general ward might be helpful in reducing suffering of distressed COPD patients.

Aim: To assess the outcome and relative feasibility of NIV use in general ward and High Dependency Unit (HDU) in hypercapnic respiratory failure due to Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD) in a tertiary care hospital.

Materials and Methods: It was a prospective observational study. Patients admitted with AECOPD in HDU and general ward, satisfying all inclusion and exclusion criteria, over a period of six months were recruited as study population. All the patients received NIV along with other conventional treatment protocol. The outcome of NIV was noted in terms of frequency of complications, duration of hospital stay and need for mechanical ventilation. The statistical analysis was done using SPSS Minitab software version 15.1.0.

Results: A total of 70 patients, age ranging from 45-89 years, were included. A 32 patients were put on NIV in general ward while 38 in HDU, depending on availability of bed. There were no significant differences in the clinical parameters at the time of initiation of NIV between the two subsets except the total leukocyte count and the frequency of occurrence of exacerbation in last one year. The outcome of NIV use as analysed found no significant difference in average duration in hours 'on NIV' (p=0.088) among patients who were successfully treated with NIV. Similarly the complication profile and overall failure rate comparable was (p=0.515) between the two subsets.

Conclusion: The NIV is as effective in management of AECOPD with hypercapnic failure in HDUs and less monitored general medical ward in face of non-availability of ICU beds, particularly in a resource constrained setting.

Keywords: Dilemma, Hypercapnic respiratory failure, Leukocyte count

INTRODUCTION

The use of NIV in patients hospitalised with AECOPD with respiratory failure is an accepted initial mode of ventilation that improves patient outcome in terms of need for tracheal intubation, hospital stay and complications of mechanical ventilation [1]. The early initiation of NIV improves the outcome even better [2-5]. There is still controversy regarding site of initiation of NIV, whether in emergency setting or ICU or step-down unit or general ward or even pre-hospital setting [6-9]. However, there is paucity of data in Indian scenario regarding the use of NIV, site of initiation and monitoring compared to other parts of the world. A recent study from Northern India by Sharma S et al., have showed that COPD is one of the most common causes of non-invasive ventilation use in hypercapnic respiratory failure [10]. A nation-wide questionnaire based survey was conducted by Chawla R et al., almost a decade back, comparing NIV use pattern among Indian physicians which showed that the use of NIV was quite popular in their clinical practice (72.4%) though response rate was only 21%, and COPD was the most common indication for its initiation; deployed mostly in the ICU setting (68.4%) [11]. NIV use in general ward has increased substantially in recent years with shortage of ICU bed and HDU; however due to non availability of house staff especially during night shift, the chances of detecting adverse events related to NIV may not be guaranteed in general ward particularly overnight [3]. The identification of the patient subgroup to be benefited most by early initiation of NIV in general ward, causes of NIV failure or reasons for hesitation in its use in unmonitored ward is mostly underexplored compared to similar studies in ICU or HDU setting and demands extensive research work in future [3].

The aim of the present study was to assess the outcome and relative feasibility of NIV use in general ward and HDU in hypercapnic respiratory failure due to AECOPD in a tertiary care hospital.

MATERIALS AND METHODS

It was a prospective observational study, conducted for a period of six months from January 2016 to June 2016 in general ward and HDU of R.G. Kar Medical College, Kolkata, West Bengal, India. The total number of HDU beds available in the present facility was 10 as compared to 60 in general ward. The nurse/patient ratio and doctor/patient ratio in HDU were as 1:3 and 1:5 respectively; whereas in general ward it was 1:10 to 1:12 for nurse and 1: 20 for doctor. The HDU was equipped with continuous cardiac monitor, portable X-ray machine, Arterial Blood Gas (ABG) test machine, defibrillator in HDU and availability of mechanical ventilator. The pulse monitor was present in both the wards. The Institutional Ethics Committee has approved the study and informed consent was taken from every patients.

Study Population

The patients attending the Emergency Department or Outpatient Department (OPD) with clinical features of AECOPD, who fulfill the criteria for hospital admission as per GOLD guideline were

examined clinically and initial investigations were done that included oxygen saturation, chest radiograph, and ABG analysis [1]. The patients were allotted HDU beds preferably over general ward beds depending on availability and grouped accordingly at the point of entry. The patients were supposed to remain in the same subgroup throughout the treatment period as per study protocol. The study protocol was explained to the patient and those who gave consent for the same were included as study population.

Inclusion and Exclusion Criteria

All consecutive patients admitted with hypercapnic respiratory failure, defined as pH <7.35 and/or $PaCO_2$ >55 mmHg, or $PaCO_2$ more than 45 mmHg with respiratory rate >30 breaths/minutes using accessory respiratory muscles, due to AECOPD, age more than 40 years and those who opted for "Do Not Intubate" (DNI), irrespective of present smoking status, extent of chest X-ray abnormality and comorbid conditions were included as the study population. Those who satisfied criteria for mechanical ventilation at the time of admission with severe acidosis and consented for invasive ventilation, those with impaired mental status, somnolence, inability to cooperate, cardiovascular instability (hypotension, arrhythmias, recent myocardial infarction), copious and/or viscous secretions with high risk of aspiration, and craniofacial trauma and/or fixed nasopharyngeal abnormality, cardiac or respiratory arrest and those who did not consent for the study were excluded. Also, those who took Discharge on Own Risk Bond (DORB) were excluded from the study.

Study Protocol

All the patients admitted in general ward or HDU with hypercapnic respiratory failure due to AECOPD were offered non-invasive ventilation along with standard management with bronchodialators, antibiotics, systemic corticosteroids and supplemental oxygen as needed. Routine blood investigations including complete haemogram, blood glucose, urea, creatinine, and electrolytes and electrocardiography were done. NIV was applied using best fitted oronasal mask and a bi-level ventilator (Philips Respironics V60 ventilator). The initial ventilator set-up was Inspiratory Positive Airway Pressure (IPAP): Expiratory Positive Airway Pressure (EPAP) ratio of 10:4, which was gradually increased to IPAP of 16-18 and EPAP was increased gradually to 6-8 cm of H_2O and supplemental oxygen. The patients were monitored clinically (respiratory rate, movement of accessory muscles, blood pressure, level of consciousness) and ABG parameters (pH, $PaCO_2$, PaO_2, HCO_3) at 0 hour, 1 hour, 2 hour, 24 hours, and then daily, and before discontinuation of NIV. The patients were monitored for any unwanted complications throughout the period. In the general ward, the patient relatives were trained and given instruction to handle the machine as well as patient care under supervision of medical team. Repeat chest radiography and ABG analysis, if needed other than in the study protocol, were obtained as appropriate. Initially the patient was on NIV for most of the day except during clearing of airways, feeding and half an hour following feeding. As the patient improved clinically, day-time 'off-ventilator' period was increased first while still on overnight NIV support and finally overnight support was stopped with further improvement of clinical parameters with reduced work of breathing maintaining SpO_2 ≥90% with FIO_2 30% and respiratory rate <24 breaths/minute. The total number of hours on NIV needed for clinical stabilisation and duration of hospital stay was noted as primary end-point of the study. The decision for intubation was taken depending on the following criteria: clinical deterioration, worsening ABG parameters, intolerance to oronasal mask and/or development of any complications. The patients were shifted to ICU by ICU physician after consultation with respiratory physician.

Success was defined as clinical stabilisation of patient with conventional management along with NIV support, so that patient could be discharged home successfully with/without Long Term Oxygen Therapy (LTOT). NIV failure was defined as: 1) need for mechanical ventilation due to deterioration of ABG parameters (pH and/or Pco; 2) haemodynamic instability, deteriorating level of consciousness or inability to tolerate NIV for reasons like claustrophobia, massive leak and lack of co-operation; 2) those who died during course of treatment due to any cause.

Delayed response to NIV was defined as persistence of respiratory acidosis (pH <7.3) even 2 hours after initiation of NIV in AECOPD with respiratory failure, even though there is significant clinical improvement [12].

STATISTICAL ANALYSIS

The statistical analysis was done using Minitab software (version 15.1.0.0; Minitab, State college, PA). The data was summarised as mean±SD for normally distributed data and the median (5^{th} and 95^{th} percentile) for non-parametric data. The Pearson's Chi-square test was used to analyse categorical data.

RESULTS

A total of 56 (80%) male and 14 (20%) female, ages ranging from 45-89 years, were included in the study as per inclusion-exclusion criteria. Out of them 32 (45.7%) were admitted in general ward and rest in HDU. The demographic and clinical profile of the two groups at the time of admission is shown in [Table/Fig-1].

Demographic/Clinical parameters	General ward (n=32)	HDU (n=38)	Significance
Age (years) mean±SD	61.28±8.07	64.58±9.28	0.12
BMI § (kg/cm^2)	19.8 (17.2, 27.3)	19.9 (17.6,26.9)	
Smoking history			
Current	11	14	0.626
Former	8	11	
Ex-smoker	4	7	
Never smoked	9	6	
Prior Hx PTB	8	9	0.918
Rate of occurrence of exacerbations in previous year (number of events/year)	0.78	1.29	0.035*
mMRC§	4	4	0.596
Initial respiratory rate§ (per minute)	32	32	0.473
Duration of present exacerbation§ (days)	5	6	0.220
Rate of occurrence of prior NIV use	12.5 per 100 patients	18.4 per 100 patients	0.527
Comorbidity			
IHD	3 (9.3%)	4 (10.5%)	0.872
HTN	8 (25%)	10 (26.31%)	0.9
DM	4 (12.5%)	10 (26.3%)	0.134
Cor pulmonale	5 (15.62%)	6 (15.79%)	0.985
Dyselectrolytemia			
Na§ (mEq/L)	136	134.5	0.130
K§ (mEq /L)	4	3.95	0.710
TLC	8899±2548	10595±3522	0.023*
Initial ABG			
pH	7.30±0.05	7.30±0.07	0.857
$PaCO_2$ §	64.5	72.5	0.187
PO_2 §	67	67.5	0.283
HCO_3	34.9±5.96	36.7±4.79	0.174
Starting SpO_2 § (%)	87	82.5	0.0609
Ending SpO_2§ (%)	95	95	0.3498

[Table/Fig-1]: Demographic and clinical profile of the two groups at the time of admission.
§ Median; *significant at 0.05 level of significance
BMI: Body mass index; PTB: Pulmonary tuberculosis; IHD: Ischaemic heart disease; HTN: Hypertension; DM: Diabetes mellitus; TLC: Total leukocyte count; ABG: Arterial blood gas analysis

Though most of the patients in general ward used metered-dose inhaler either with spacer 16 (50%) out of 32 or without spacer 6 (18.75%) out of 32 and in HDU subset, 17 (44.74%) out of 38 and 18 (47.37 %) out of 38 respectively, only 17 (53%) out of 32 in General ward and 21 (55%) out of 38 in HDU subset were using it in correct technique (p=0.353). There were no significant difference in the demographic parameters between the two subsets except the total leukocyte count and the frequency of occurrence of exacerbation in last one year, which were found to be significantly higher in HDU subset (p=0.023 and 0.035 respectively).

The change in ABG parameters over time among the two subgroups, particularly pH, $PaCO_2$ and HCO_3 level is shown in [Table/Fig-2]. Contrary to the general trend of ABG parameters, the p-values of HCO_3 level and $PaCO_2$ at 1 hr were obtained as 0.035 and 0.0439 respectively. These two isolated observations may be considered under the cloud of noise. The clinical outcome in patients treated in general ward and HDU are shown in [Table/Fig-3]. Seven patients showed delayed response to NIV (2 in general ward, rest 5 in HDU subgroup) (p=0.507). The failure rate though high in HDU, 4 out of 38 versus 2 out of 32 in General ward was not significantly different among both groups (p=0.515). All the patients who failed NIV trial were more than 55 years of age. All of them were suffering from increased cough with mucopurulent or purulent expectoration for more than 5 days before seeking medical advice and 3 (50%) out of these 6 patients had multiple exacerbations in last one year. The causes of discontinuation of NIV was aspiration pneumonia (n=3), severe hypotension (n=1), severe intolerance to mask (n=2) and thus NIV was discontinued within first 2 hours of initiation, and one had clinical deteriorations along with deteriorating ABG parameters despite conventional supportive management. This included one patient who died in general ward due to development of aspiration pneumonia after an initial improvement in ABG parameters. He refused intubation and mechanical ventilation as ABG parameters started worsening at 24 hours. The complication range was not significantly different in the two groups. The most common complications observed among both the groups were nasal or oral dryness (37.1%) and irritation in the eyes (24.3%). The average duration of hours on NIV in general ward versus HDU were 65.67±27.3 and 77.23±26.04 hours respectively among those who were successfully managed with NIV (p=0.088); whereas the same were 17±18.4 and 10±13.5 hours respectively among those who failed NIV trial (p=0.615).

DISCUSSION

The present study has compared the use of NIV in management of AECOPD with hypercapnic respiratory failure in general ward and HDU in a resource constrained setting. There are several studies that have discussed successful use of NIV in general ward in face of shortage of more monitored ward like ICUs and HDUs in western literature [3,4,9]. However, there is paucity of data from this part of the world. The total duration of NIV used by patients in general ward and HDU were 62.6±29.2 and 70.2±31.2 hours respectively, whereas there was no significant difference in failure rate {2 (6.25%) versus 4 (10.53%) respectively} and complication pattern among the two groups. The mask was well tolerated by most of the patients. Only two of the patients had to discontinue NIV due to severe claustrophobia with the available oronasal mask. The patient care including mouth care, nebulisation and fitting the mask properly each time after it is taken off for feeding purpose was done by nursing staff in HDU; whereas the same task is done by patient attendants supervised by the ward nurse. The records of vitals were maintained by the nursing staff in both the wards. Thus, overall NIV was found safe even in a general ward. The observation in the present study was in concurrence with Yalcinsoy M et al., they concluded that patients of COPD with both mild and moderately severe exacerbation and respiratory acidosis with pH between 7.2-7.3 can be effectively managed in ward with NIV [7]. The dryness of oronasal cavity and irritation of eyes were found to be among the most common minor complications, and aspiration pneumonia and hypotension were reported as major complications in both the subgroups. Gay PC et al., compared an extensive list of randomised controlled trials on NIV; most of the studies on hypercapnic respiratory failure included in the report were done in ICU setting; NIV was found to be well accepted mode of treatment for hypercapnic of respiratory failure in most of the studies, particularly in do-not-intubate patients, despite the fact that NIV has some innate minor and major complications [13]. In present study, three patients with >7.25 pH >7.15 and $PaCO_2$ <100, at presentation with otherwise

		At 0 hour		At 1 hour		At 2 hour		At 24 hour	
		mean±SD	p-value	mean±SD	p-value	mean±SD	p-value	mean±SD	p-value
pH	Gen	7.306±0.054	0.857	7.343±0.033	0.754	7.3794±0.0483	0.781	7.402±0.09	0.929
	HDU	7.309±0.072		7.339±0.0596		7.376±0.0479		7.403±0.049	
HCO_3 (mEq/L)	Gen	34.90±5.96	0.174	34.2±4.6	0.035	34.73±4.1	0.136	34.84±5.01	0.606
	HDU	36.70±4.79		36.76±5,3		36.56±5.85		35.56±6.29	
$PaCO_2$ (mmHg)	Gen	70.01±11.08	0.1443	66.28±8.15	0.0439	61.27±10.43	0.245	57.39±20.23	0.792
	HDU	74.65±14.57		72.11±14.2		64.7±13.51		58.43±12.34	
Po_2 (mmHg)	Gen	74.7±34.1	0.09	88.6±39.3	0.265	90.3±36.1	0.568	86.7±26.2	0.327
	HDU	93.2±54.6		99.5±42.0		94.7±24.2		94.1±34.4	

[Table/Fig-2]: ABG parameters over time in general ward and HDU.
Gen: General ward; HDU: High dependency unit

	General ward	HDU	p-value
Failure n (%)	2 (6.25%)	4 (10.53%)	0.515
Duration in NIV support (in hours) mean±SD	62.6±29.2	70.2±31.2	0.3
Complications			
Facial erythema	8	9	0.957
Nasal congestion	6	7	0.980
Nasal bridge ulceration	1	2	0.647
Abdomen distension	3	3	0.859
Nasal/oral dryness	11	15	0.598
Hypotension	1	1	0.921
Aspiration pneumonia	2	2	0.886
Eye irritation	6	11	0.295
Thick secretions	2	1	0.496

[Table/Fig-3]: The clinical outcome of NIV among the two subgroups.
HDU:High dependency unit; NIV: Non-invasive ventilation

unaltered sensorium, who did not consent for invasive ventilation. So, we considered these patients for NIV trial. Two of them were managed successfully with NIV while one succumbed to death due to aspiration pneumonia and severe hypotension after 4 hours of initiation of NIV. Carron M et al., concluded after reviewing the complications of NIV use as reported in several randomised trials that these patients should better be monitored in ICUs or step-down units until stabilised adequately; nose lesions, eye lesions and gastrointestinal insufflations were common minor complications whereas aspiration pneumonia, hypotension and barotraumas were the major complications responsible for failure of NIV in the majority of cases; gave emphasis on skilled team, adequate ventilator management, and proper choice of device for minimising risks of complications of NIV use [14]. However, in the present study, the authors had to depend on patient attendants, often patient relatives for continuous monitoring of the patient to a great extent. Even with this limited resource and not-so-expert support team, the overall success rate of NIV was 69.9% in the present study. The complication profile and success rate is comparable in general ward and HDU; an observation supported by Patel SP et al., where the authors have concluded that it is cost effective to treat COPD patients with respiratory failure in ward by NIV in India where ICU facility is not available [15]. The patients successfully managed with NIV actually used it for longer duration than those who failed NIV trial ($p < 0.001$); however there was no significant difference in duration of NIV use in hours when analysed separately for the two subgroups (successful outcome in general ward vs. HDU, p-value=0.088 and NIV failure in general ward vs. HDU, p-value=0.615). The overall success rate of NIV was 69.9% which is in accordance with previous studies [4,16].

Though there was significantly high total leukocyte count with history of higher rate of prior NIV use among HDU patients that made no significant difference in clinical outcome among the two subgroups at the end of the study. Though the total number of patients who failed NIV was double in HDU subset, it was not statistically significant (p=0.515), may be because of small number of patients. The factors associated with failure of NIV in the present study were elderly age, longer time before seeking medical facility and multiple prior hospitalisations in last one year. Joves-Sević B et al., found that presence of consolidation in two or more quadrant on chest radiograph (55% vs. 29%, $p<0.001$) and patients treated with NIV in general ward had higher rate of NIV failure (28/52 vs. 20/86, $p<0.001$) [17]. Low serum albumin and high APACHE II score were suggested as predictors of successful NIV in severe hypercapnic acute respiratory failure due to COPD [16]. The low pH at the time of initiation of NIV, response in first 2 hours of initiation, respiratory rate, serum creatinine level, presence or absence of concomitant cardiac illness are all determinants of successful outcome of NIV [7].

LIMITATION

The present study is not sufficiently powered for subgroup analysis for identification of predictors of NIV failure. The study may be repeated with a larger sample size along with considering other probable prognostic factors of successful outcome with NIV e.g., PaO_2/FiO_2 at one hour, APACHE score, serum albumin level, pH at admission, pH after one hour of initiation of NIV, and severity of underlying disease along with standard conventional treatment as suggested in several previous reports [16,18]. All the patients were provided with oronasal mask; whereas choice of interface would have improved compliance even more. The cost-benefit analysis needs to be assessed considering Indian standards.

CONCLUSION

In the present study, the authors would like to conclude that NIV is as feasible and effective in patients presenting with hypercapnic respiratory failure due to acute exacerbation of chronic obstructive pulmonary disease in general ward as in more monitored ward in a low resource setting, even in hands of trained non-medical support team when more monitored ward cannot be offered due to shortage of beds and health care providers.

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