

## Non-invasive versus invasive ventilation in chronic obstructive pulmonary disease patients, with severe acute respiratory failure, meeting the criteria for mechanical ventilation

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### Abstract

**Background:** The aim of this study was to determine whether, non-invasive ventilation (NIV) may be an effective as well as a safe alternative to invasive mechanical ventilation in patients with chronic obstructive pulmonary disease (COPD) with acute severe respiratory failure who meet criteria for mechanical ventilation.

**Methodology:** The sample size was a total of 40 subjects; 20 subjects for each of the two groups. Group 1 was given NIV trial and the group 2 was given Endotracheal Tube Mechanical Ventilation or (ETMV).

**Results:** Mean age of NIV group was  $59.5 \pm 6.25$  years, and ETMV group was  $62.7 \pm 7.3$  years. The mean Respiratory rate of NIV group was  $35.2 \pm 3.4$  breaths per minute and ETMV group was  $37.2 \pm 2.4$  breaths per minute. The mean pH level of NIV group was  $7.2 \pm 0.02$ , and ETMV group was  $7.17 \pm 0.04$ . There was a marked improvement in pH after intubation, but there was not much of a significant change with NIV management. The mean PCO<sub>2</sub> level of NIV was  $69.4 \pm 7.4$  mmHg, and ETMV was  $78.1 \pm 13.12$  mmHg. The mean PaO<sub>2</sub> level of NIV was  $64.3 \pm 13.9$  mmHg, and ETMV was  $75.65 \pm 19.12$  mmHg. In the total of 20 subjects in this group, 8 had recovered from NPPV, and 12 were intubated, in which there were 4 mortalities and 8 had recovered after being intubated. The NIV in this group had failed, was reached. However, the overall complications and outcome had been better resulted than expected, when compared to the ETMV group. The complications in the NIV group were dryness of mouth (10%), Pneumonia (10%), and Multi-organ failure (5%). In ETMV group, in the total of 20 subjects in this group, out of which there were 6 mortalities and 14 recovered.

**Conclusion:** The results of this study show that the NIV trial failed. However, this type of ventilation has an advancement when it is presented in an ICU setup, as complications can be avoided and managed. Even though it is a slightly inconvenient preference, it is preferred over ETMV. This preference comes as an inclination due to its cost effectiveness and fewer complications when compared to ETMV.

### 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 major mode of delivery of Non-Invasive Ventilation. The mention of Non-Invasive Ventilation will refer to Non-invasive Positive-Pressure Ventilation (NIPPV). It is used as an alternative conventional Mechanical Ventilation through an Endotracheal Tube (Endotracheal Tube Mechanical Ventilation or ETMV), in more severe patients deem to require ventilator assistance [1-3].

In patients with COPD and mild to moderate

hypercapnic acute respiratory failure, the adhesion of NIV to the medical treatment has been proven to be effective in relieving dyspnea. [1] It is used as an alternative conventional mechanical ventilation through an end tracheal tube or ETMV, in more severe patients deem to require ventilator assistance. In patients with COPD and mild to moderate hypersonic acute respiratory failure, the adhesion of NIV to the medical treatment has been proven to be effective in relieving dyspnea [4]. NIV was the first choice for ventilatory management in 60% of all COPD patients receiving mechanical ventilation [5].

Respiratory failure is a condition where the respiratory system unable to do one or both gaseous exchange functions, i.e., oxygenation and elimination of carbon dioxide from venous blood. It is conventionally defined as an arterial

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oxygen tension (PaO<sub>2</sub>) of <8.0 kPa (60mmHg), an arterial carbon dioxide tension (PaCO<sub>2</sub>) of >6.0kPa (45mmHg) or both. Failure of pump results in alveolar hypoventilation and hypercapnic (hypercapnic or type 2 respiratory failure). Although there is coexistence hypoxemia, the hallmark of ventilatory failure is the increase in PaCO<sub>2</sub> [6].

By avoiding endotracheal intubation, NIV minimizes complications associated with invasive ventilation like airway problems, ventilator-associated pneumonia (21%) and sinusitis (5-25%). In addition, the patient with an intact upper airway retains the ability to eat, swallow and verbalize.

NIV can facilitate the discontinuous of ongoing ventilatory dependence and treat chronic respiratory failure in COPD. NIV is supportive, corrects pathophysiology rather than etiology in disorders characterized by chronic hypoventilation, nocturnal oxygen desaturation, respiratory muscle fatigue. It provides intermittent rest for respiratory muscles & reduces work of breathing.

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 the sixth leading cause of death in 1990, will become third by the year 2020. 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 3rd by 2030[7].

Epidemiologic studies suggest that respiratory failure will become more common as the population ages, increasing nearly by 80% in the next 20 years [8]. Two recent publications from India suggested that Non-Invasive Ventilation was beneficial in cohorts of patients presenting with COPD, as well as the respiratory failure of varied etiology [9].

The aim of this study was to determine whether, non-invasive ventilation (NIV) may be an effective as well as a safe alternative to Invasive Mechanical Ventilation in patients with chronic obstructive pulmonary disease (COPD) with acute severe respiratory failure who meet criteria for mechanical ventilation.

## Materials and Methods

### Study design: Prospective study

After obtaining institutional ethical committee approval, the study was conducted among 40 patients with COPD with acute respiratory failure, who were admitted under the Department of Respiratory Medicine, Narayana Medical College and Hospital, Nellore, during the period of January 2017 to August 2018.

### Sample and selection of patients

The patients included were those with COPD and hypercapnia acute respiratory failure, who worsened despite medical treatment in the ward and were deemed to require mechanical ventilation. The diagnosis of COPD was based on clinical history, physical examination, and prior pulmonary function tests.

A study of patients with COPD with acute respiratory failure falling in the age group between 40 and 80 years were included, with the below mentioned inclusion and exclusion criteria:

### Inclusion criteria

Acute exacerbation of COPD; pH < 7.25; Respiratory Rate > 30/ min; Partial pressure of Oxygen (PaO<sub>2</sub>) < 60mmHg, Partial pressure of carbon dioxide (PaCO<sub>2</sub>) > 45mmHg; peripheral capillary oxygen saturation (SpO<sub>2</sub>); < 92% with oxygen delivered by mask.

### Exclusion criteria

Predefined exclusion criteria were:

Any kind of ventilatory assistance before admission to the ICU; respiratory or cardiac arrest; unconsciousness; extreme claustrophobia or anxiety despite repeated attempts to facilitate the use of NIPPV; hemodynamic instability: shock (either cardiogenic or septic) with a systolic blood pressure of < 90mmhg despite fluid challenge or need for pressure agents; unstable arrhythmias; recent myocardial infarction; facial surgery/ trauma/ deformity; upper airway obstruction; inability to co-operate 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 included: dyspnea quantitated by modified Medical Research Council (mMRC) dyspnea scale, respiratory rate (RR), heart rate, arterial blood gas (ABG), blood pressure of the patient at admission, ECG, consciousness level and evidence of any comorbid illness. Routine blood investigations were sent for analysis. A chest X-ray was also included.

Written informed consent was obtained from the patient or next of kin. Study protocol was approved by Institutional Ethics Committee, Narayana Medical College & Hospital, Nellore, A.P, India. Baseline evaluation consisting of patient's clinical history and detailed clinical examination was noted.

All eligible patients with all the criteria fulfilled, were then divided into 2 groups. The first group was given the NIV trial and the second group, the ETMV trial.

For the group placed in the NIV trial, the NIV was delivered in the ICU via a facial mask with an inflatable soft cushion seal. The procedure was explained to the patient. The head of the bed was elevated to 45° angle. IPAP was initially set at 8cm of H<sub>2</sub>O and increased by increments of 2cm of H<sub>2</sub>O up to 20cm of H<sub>2</sub>O, based upon clinical response and ABG. The initial EPAP was set at 4cm H<sub>2</sub>O and if required was increased at increments of 1-2cm and titrated between 4-10cm H<sub>2</sub>O 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, oro-nasal mask, was held by hand, over patient's face. IPAP and EPAP were adjusted so that the patient can tolerate it, without any discomfort and to avoid any major air leaks. Head straps were

used along the side of mask, to help secure it, but was taken care to avoid any tightness or discomfort to the patient.

After starting the treatment, each patient was monitored closely for the first hour. Patient's discomfort and intolerance for mask was observed. Continuous pulse-oximetry and ECG monitoring was done. Any difficulty to clear secretions and presence of abdominal distention was observed. NIV was delivered intermittently for at least 18 hours per day. Any disconnection from NIV was allowed for less than 1 hour to permit eating, drinking and expectoration. During these intervals, oxygen supplementation was delivered via a nasal cannula.

Standard pharmacological treatment included bronchodilators (inhaler salbutamol, ipratropium bromide through nebulization) and steroids, (IV hydrocortisone, steroid nebulization) and antibiotics that were given alongside NIV.

Blood pressure, respiratory rate, heart rate, dyspnea by mMRC scale were recorded at baseline.

Once the patient improved clinically and was corroborated by improvements in ABG, weaning was initiated. During the weaning phase, the IPAP was decreased in gradations of 2-3cm until the IPAP was 7-10cms. The applications was then switched over to intermittent use. The time of weaning was different for each patient.

If the clinical features such as Respiratory distress (Tachypnea, Tachycardia), Hypotension, worsening of level on consciousness, or laboratory evidence of worsening ABG or persistent respiratory distress were seen, then the patient is considered to be placed on ETMV, from NIV. Presence of sustained clinical improvement with reduction of RR < 24/min, HR <100/min, and presence of normal pH and O<sub>2</sub> saturation > 90% were required before patients were considered for weaning.

For the second group of patients, ABG, dyspnea, respiratory rate, heart rate, and consciousness, are taken into consideration and those who fit into the group of ICU protocol were given the ETMV trial. Those who fit this protocol were sedated before they were placed on the ETMV in the ICU. The ventilators that are used on this group for ETMV were also used on the NIV group. The pre-set inspiratory pressure was set in such a way where a tidal volume of 6-8ml/kg was reached. The initial PEEP was set at 5cm H<sub>2</sub>O for all the patients. When there was reappearing of spontaneous breathing, PSV mode was initiated, and extubating was planned.

The other variables collected in the study included dyspnea score (RR, HR), ABG parameters (pH, PaCO<sub>2</sub>, PaO<sub>2</sub>), the mean duration of NIV application, ETMV, duration of hospitals stay and any complications relating to the procedures. Any complications developed during the procedures were treated adequately.

Statistical analysis was done by using SPSS statics version 25.

A 'p' value < 0.005 is considered significant and 'p' value < 0.001 is considered extremely significant.

## Results

### Age distributions

The mean age of the study population in NIV group is 59.45 years and 62.75 years in the ETMV group.

The majority of the subjects were in the age range of 60-69 years in both NIV and ETMV groups, consisting of 45% and 50% respectively.

**Table 1:** NIV Group

Age Group	No. of Patients (n=20)	Percentage (%)
40-49	1	5
50-59	7	35
60-69	9	45
70-79	3	15

**Table 2:** ETMV Group

Age Group	No. of Patients (n=20)	Percentage
40-49	1	5
50-59	5	25
60-69	10	50
70-79	3	15
80-89	1	5

**Table 3:** Symptoms at presentation of all enrolled subjects

Symptoms at presentation	Present Study	
	No. of patients (n = 40)	Percentage (%)
Dyspnea	40	100
Cough	22	55
Fever	6	15
Chest pain	5	12.5

The most common symptom on presentation was dyspnea seen in the enrolled subjects. Cough was present in the about 55% of the subjects, fever in 15% and chest pain was present in 12.5% of the subjects. The mean smoking pack years for the NIV group is 17.4 years,

**Table 4:** Smoking pack years in NIV group

Smoking Pack Years	No. of Patients (n=20)	Percentage (%)
10 - 15	8	40
16 - 20	8	40
21 - 25	3	15
26 - 30	1	5

**Table 5:** Smoking pack years in ETMV group

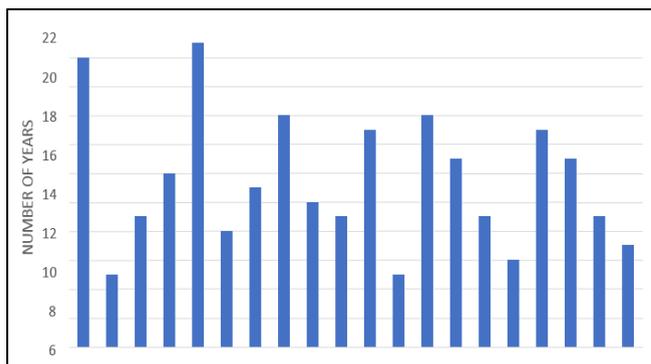
Smoking Pack Years	No. of Patients (n=20)	Percentage (%)
10 - 15	4	20
16 - 20	5	25
21 - 25	3	15
26 - 30	4	20
31 - 35	3	15

The mean smoking pack years in ETMV group is 23.35 years

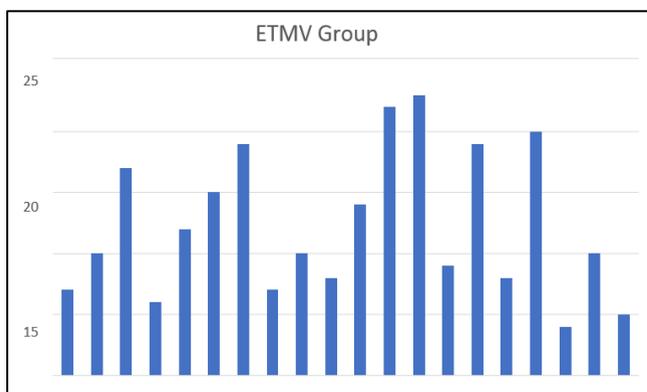
### Duration of disease

COPD is diagnosed by physical examination, chest X-ray, and Spirometry, and symptoms. The duration of disease varies in each individual, and not on the 'smoking pack years.'

The duration of the disease in the NIV group averaged at  $11.45 \pm 4.63$  years, giving a range of 6.82 to 16.08 years in ETMV group.



**Fig. 1:** The duration of the disease in NIV group



**Fig. 2:** The duration of the disease in ETMV group

The duration of disease in the ETMV group averaged at  $12.25 \pm 5.95$  years, giving a range of 6.30 to 18.20 years. The duration of the disease is higher in ETMV group than NIV group. The longer the duration, the higher the risk of exacerbation of COPD and other comorbidities.

### pH Level

The pH level is a maker as to whether the patient requires ventilation. It plays an important role in ABG, which can help determine the type of ventilation required by the patient.

The Mean pH level was  $7.21 \pm 0.03$ .

In the ETMV group, during the subjects' hospitalization. The Mean pH level was  $7.17 \pm 0.04$ . There pH levels showed better improvement after intubation in some patients.

### Respiratory rate

The mean respiratory rate in the NIV group is  $35.95 \pm 4.26$  breaths per minute whereas the mean respiratory rate in the ETMV group is  $37.20 \pm 2.44$  breaths per minute. Higher respiratory rate indicates the severity of dyspnea.

Mean heart rate in NIV is  $96.80 \pm 12.79$  beats per minute and

in ETMV is  $110.05 \pm 18.35$  beats per minute. The rate was higher in ETMV group.

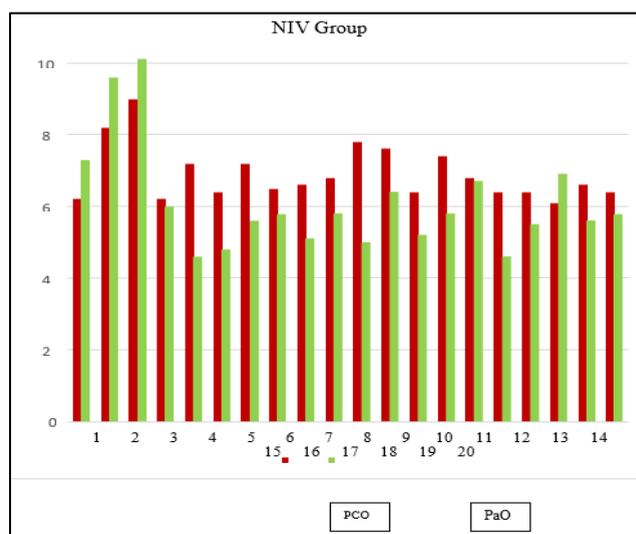
### PCO<sub>2</sub> and PaO<sub>2</sub>

Mean PaCO<sub>2</sub> and mean PaO<sub>2</sub> in NIV group. The mean PaCO<sub>2</sub> value was  $69.10 \pm 7.63$  mmHg and PaO<sub>2</sub> mmHg value was  $61.10 \pm$

$14.73$  mmHg.

### Duration of hospital stay

In the NIV group, the mean duration of hospital stay is  $10.7 \pm 3.73$  days and in the ETMV group it was  $8.15 \pm 3.12$  days. The mean duration of hospital stay was less ETMV group compared to NIV group.



**Fig. 3:** Mean duration of hospital

### Outcome

The total number of patients included in the group were 20, all who were diagnosed with COPD with acute respiratory failure using the symptoms, Chest X-ray, and ABG. These patients in this group were managed by NIV. Out of 20 of those patients 8 (40%) recovered with NIV and remaining 12 (60%) who did not recover on NIV, worsened. These patients were intubated and resulted with 8 (40%) who recovered and 4 (20%) ended with death.

The number of patients included in this group were 20. These patients are intubated and connected to mechanical ventilator. Of these patients, 14 (70%) recovered and 6 (20%) were ended in death. These patients were not given NIV trail.

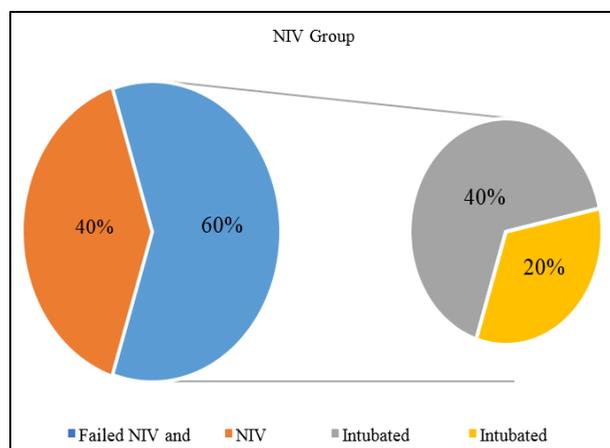


Fig. 4: Outcome

### Complications

There are few complications in NIV group in compared to ETMV group. In NIV group 10% had pneumonia and 10% dryness of mouth and the other 5% had multi organ failure. In those where multi organ failure was seen NIV had failed and were intubated when these complications occurred.

In ETMV group there are more complications compared to the NIV group. The complications are Pneumonia 20%, Multi organ failure is 10%, Pneumothorax 5% and Renal failure is 5%. In this group, it was shown that 60%, did not have any complications.

### Discussion

A significant number of acute exacerbations of COPD are associated with hypercapnia respiratory failure. These patients are managed with both NIV and Invasive mechanical ventilation. Numerous studies have been conducted at many centers in the past and highlighted the benefits of NIV usage in acute exacerbation of COPD in the terms of reduced need of Invasive mechanical ventilation. Patients who received NIV as the first ventilator treatment showed a lowered rate of complications and lean towards a faster weaning process. However, mortality rate, duration of mechanical ventilation and length of ICU and post-ICU hospital stays were different between NIV group and Invasive Mechanical Ventilation group.

Meta-analysis of the trial have also confirmed the benefits of NIV in AECOPD [10]. The results of previously conducted and the rapid nature of most of the episodes of acute decompensation suggests that patients with AECOPD should benefit from NIV. Compared to the studied, where NIV was used at earlier stage to avoid ETMV, rather than as an alternative to it [11-15]. In our study, NIV was prone to a higher rate of failure and produced lesser positive results.

The most common symptom on presentation was breathlessness, seen in all the enrolled 40 patients (100%). Cough was present in a sizable number of patients, i.e. 22 Patients (55%) and a relatively small number of patients had fever at the time of presentation i.e., 6 patients (15%) and Chest pain in 5 patients (12.5%). Chest pain on presentation was clinically diagnosed as Pneumonia.

In the present study, mean respiratory rate of the NIV study group was  $35.2 \pm 3.4$  breaths per minute. In the study, conducted by Rizvi et al study, the mean respiratory rate of their study group was  $32.2 \pm 5.3$  breaths per minute [16]. In another study on NIV by George et al, the mean respiratory rate was  $32.5 \pm 5.5$  breaths per minute. In the study conducted by G. Conti et al study, the mean respiratory rate was  $33 \pm 2.6$  breaths per minute [17]. In the study done by Antonelli et al., the mean respiratory rate was  $39 \pm 4$  breaths per minute. Respiratory rate was reduced after the patients are treated with NIPPV [3].

In the study conducted by Conti et al., the mean respiratory rate in ETMV study group was  $33 \pm 2.4$  breaths per minute [17]. In the study done by Antonelli et al., the mean respiratory rate was  $39 \pm 5$  breaths per minute [3]. Respiratory rate is reduced after patient is managed with Endo tracheal mechanical ventilation in ICU.

In this study the mean age of study population in NIV group is  $59.5 \pm 6.5$ . In the Squadrone et al., study, the mean age of NIV group is  $69 \pm 6$  and in the Conti et al., study, the mean age was  $72.5 \pm 7.7$  years [17]. In the Antonelli et al., study, the mean age was  $52 \pm 19$  years [3].

The mean age in the present study of ETMV group was  $65 \pm 7.3$  years. In the study done by Squadrone et al., the mean age was  $70 \pm 5$  years [18]. In the Antonelli et al., study, the mean age group was  $57 \pm 18$  years and in the G. Conti et al study, the mean age in the ETMV group was  $71.8 \pm 8$  years [3,17].

In this study, pH in NIV patients was  $7.2 \pm 0.002$  and in the mechanically ventilated group, the pH was  $7.17 \pm 0.004$ . In comparison of both the groups, the pH in the mechanically ventilated group was lower than NIV group. But pH started to decline after managing patients with Non-invasive ventilation and endotracheal tube mechanical ventilation.

There was a drastic decrease in the pH level, after the application of conventional mechanical ventilation in the ETMV group compared to the NIV group. The pH in the present study in ETMV group was similar to that of the Squadrone et al., study [18].

The mean PaCO<sub>2</sub> in the present study is  $69.4 \pm 7.4$  mmHg. In Squadrone et al, the mean PaCO<sub>2</sub> is  $104 \pm 14$  mmHg and in G. Conti et al is  $85 \pm 16$  mmHg [18,17]. In these group the PaCO<sub>2</sub> is raised when NIV is failed due to mask intolerance or due to deterioration of mental status or inability to clear secretions.

In the present study the PaCO<sub>2</sub> was  $78.1 \pm 13.2$  mmHg and in Squadrone et al., study, the PaCO<sub>2</sub> was  $100 \pm 13$  mmHg. The G. Conti et al study had a PaCO<sub>2</sub> of  $87 \pm 14$  mmHg in ETMV group.

There is a marked decrease in PaCO<sub>2</sub> levels after managing with conventional mechanical ventilator in ETMV group.

The mean PaO<sub>2</sub> in the present study was  $61.0 \pm 13.9$  mmHg and in Squadrone study the mean PaO<sub>2</sub> was  $64.3 \pm 13.9$  mmHg [18]. Several studies had taken PaO<sub>2</sub>:FiO<sub>2</sub> ratio instead of PaO<sub>2</sub> because oxygen supplementation had to be started immediately before ABG in some instances.

In ETMV group the mean PaO<sub>2</sub> was 75.65 ± 19.12 mmHg (p value 0.001) and in Squadrone et al., study was 44 ± 8 mmHg. The PaO<sub>2</sub> levels are low in NIV group when compared to ETMV group [18].

Total number of deaths was 4 (20%) in NIV group in this study. In the study by Squadrone et al., the number of deaths was 5 (8%) in NIV group [18]. The deaths in this study were those who failed NIV management and went for Endo tracheal mechanical ventilation. The deaths were due to complications like pneumonia.

In the present study the number of deaths in ICU is 6 (30%) in these group the deaths are due to few complications like multi organ failure and ventilator associated pneumonia and even few had renal failure. In Squadrone study the deaths was 11 (17%) [18].

The mean duration of hospital stay in the present study was 10 ± 3.6 days and in Enzo Squadrone et al., study the mean duration of duration of hospital stay is 13 ± 8 days [18]. NIV group took little longer than ETMV group because if NIV was failed then ETMV trail is given.

The mean duration of hospital stay in the present study was 8.15 ± 3 days. In Squadrone et al., study it was 15 ± 3 [18]. Overall duration of hospital stays in NIV and ETMV group didn't show much difference in duration of hospital stay.

Low rate of infectious complications in patients receiving NIV has been confirmed in randomized studies by Brochard et al., [12] and Bott et al., [4]. There are few complications while using NIV in the study group, i.e., dryness of mouth 2 patients (10%), pneumonia 2 patients (10%). Pneumonia was treated with antibiotics and it resolved completely.

In comparison of NIV, ETMV has higher complications. In this study there are few complications such as Pneumonia 4 patients (20%), Pneumonia was treated with antibiotics and it resolved completely, 2 Patients with multi organ failure (10%), 1 patient with Pneumothorax (1%), these patients were treated with inter-costal drain and pneumothorax was resolved in 4 days. Renal failure in 1 patient (5%), Dialysis was done two times and patient was recovered.

Limitation of the present study was that the sample size was considerably small. Therefore, the results of the present study were difficult to generalize. A similar study on larger population is needed to be conducted for a better and clearer outcome.

## Conclusion

In the patients with COPD-AE with severe acute respiratory failure, the modality of management is ETMV, however NIV provides a few advantages over conventional invasive ventilation. Usage of NIV in ventilator required patients had a high rate of NIV failure and got intubated. NIV trial did not produce any significant difference in the mortality rate or in the length of the ICU stay. The use of NIV resulted in fewer serious complications, in the patients who recovered with NIV trail, and in those who did not recover by the NIV, i.e. NIV failure, were mechanically intubated, showed faster weaning off mechanical ventilation.

No harm was noted in those who had NIV failure, due to delayed initiation of management by invasive ventilation. Nonetheless, those who recovered without intubation due NIV trial, had a clear-cut benefit over those in the ETMV group, who were directly intubated.

NIV trial can be given in patients with acute severe respiratory failure due to COPD- AE, who require ETMV but should be given in an ICU set up to avoid complications, failure or mishaps, where it can be dealt immediately.

## Conflicts of interest

None declared

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