

ORIGINAL ARTICLE

Outcomes of Emergency Department Based Ventilatory Management of Adult Patients with Severe COVID-19

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ABSTRACT

Background: Many COVID-19 patients experience acute respiratory distress syndrome. During the second wave of COVID, there was a massive surge in the cases of severe COVID-19, leading to paucity of healthcare resources at all levels. We aimed to assess the outcome of patients with severe COVID-19 on Ventilator.

Method: This prospective study at AIIMS, New Delhi, during the second wave of COVID (4th may to 15th June 2021). 24 AgVa® ventilators were used, adult severe COVID patients saturation was <90% and required NIV or IV were included. All patients were managed on 100% FiO₂ and steroids. No other drugs (except supportive treatment like antibiotics and IV fluids) were given and analysis done using SPSS (p<0.05 considered significant).

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Results: 125 patients were treated for COVID-19. 82 were males and 43 were females. The mean age was 51.29 years. Mean SpO₂ at admission was 93.23% (± 8.06). The median FiO₂ on admission was 75. 43 patients were put on NIV, 82 required IV while 3 were shifted from NIV to IV. The mean duration of ventilator support for survivors was 2.5 days. The mean length of hospital stay for patients discharged was 5.52 days. The overall mortality rate was 34.4%. The difference in mortality rates in NIV and IV modes was not statistically significant, however it approached significance ($p=0.06$).

Conclusion: This Indian study reports outcomes of severe COVID-19 patients requiring NIV or invasive ventilation who were managed in the emergency department using only oxygen and steroids during the second pandemic wave.

KEYWORDS

• COVID-19 • Invasive Ventilation • Mechanical Ventilation • Non Invasive Ventilation

INTRODUCTION

The novel coronavirus now referred to as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused over 4 million deaths worldwide with more than 210 Million cases.¹ India is the second most affected country in terms of number of cases after the United States. Ever since its declaration as a pandemic on March 11, 2020 with more than 11800 cases and 4291 deaths in 114 countries, the whole world is still battling this deadly virus.² The respiratory manifestations due to this virus comprise the COVID-19 as per WHO i.e. coronavirus disease. Due to the immune and inflammatory reactions against this virus there is diffuse alveolar damage leading to acute respiratory distress syndrome (ARDS)³ Mainstay of treatment remains ventilation (NIV or IV) along with supportive treatment with corticosteroids. In low resource settings like India, there has been a shortage of infrastructure and healthcare facilities including mechanical ventilators which lead to a high spike in the number of cases and deaths. As per a study conducted the estimated number of ventilator days required to cater India's condition is 975,000 per patient.⁴ AgVa ventilator is an indigenously made device that significantly reduces the cost of respiratory care in COVID-19 patients by 80% while having a similar efficacy as the standard ventilators. As around 10000 units of AgVa ventilators were deployed all across the country during the pandemic by the Indian government, we tried to assess its utility in the emergency department of a tertiary care hospital during the peak of the second COVID wave in Delhi.

MATERIALS AND METHODS

This was a prospective observational study to assess the management and outcome of patients on AgVa ventilator and was carried out in the emergency department of the All India Institute of Medical sciences, New Delhi from 4th may 2021 to 15th June 2021. Twenty four AgVa ventilators were deployed in the Emergency department (ED) during this second wave of COVID to augment the health infrastructure in the ED. Severe covid patients whose saturation was less than 90% and who required NIV or IV on AgVa Ventilators were included in the study. Data points collected included ventilator parameters, Blood gases and clinical outcomes.

The patients were followed up until recovery/death in the hospital.

Statistical analysis

Following the data procurement, SPSS Software was utilised to perform statistical analysis. student's t test and chi square test were used wherever necessary. A p value <0.05 was considered statistically significant.

RESULTS

A total of 125 patients were treated for COVID-19 in this study period. 82 were males and 43 were females. The mean age was 51.32 with a range of 14-83 years. The mean SpO₂ at admission was 93.23% (± 8.06 SD). The median FiO₂ on admission was 75. 43 patients required noninvasive ventilation (NIV) - bilevel positive airway pressure (BPAP). Of these, 1 patient was initially kept on BIPAP and later on

continuous positive airway pressure (CPAP). 3 patients further required Invasive ventilator (IV) mode. 82 patients required IV ventilation - 5 on assist control ventilation (ACV), 3 on pressure support ventilation (PSV), 1 on pressure-regulated volume control (PRVC), 1 on spontaneous (SPNT) and 72 volume control-continuous mandatory ventilation (VC-CMV). Of these 72 patients, 3 were shifted from VC-CMV to BPAP.

Clinical Performance

The mean length of stay was 6.08 days (± 8 SD). The mean length of stay on the ventilator was 2.62 days (± 1.33 SD). The mean duration of ventilator support for survivors was 2.5 days (± 1.23 SD) (Range: 1–6 days). The mean length of stay for patients discharged alive was 5.52 days (± 7.9 SD) (Range: 1–46 days). The Average PEEP was 7.034 (± 3.88 SD). 46 patients had hypercarbia ($\text{PaCO}_2 > 45$ mm Hg) despite 100% Fio2 while 79 patients had Hypoxia ($\text{PaO}_2 < 80$ mmHg).

Outcome:

A total of 43 (34.4%) patients died. The median time to death after admission was 4 days (range 1-40 days). The mean age of the patients who died was 51.57 years. 80% (n=32) of the patients who could be maintained on NIV had a good outcome and could be discharged from the hospital. Patients on invasive ventilation had a mortality rate of 41.176% (35 out of 85 patients died). Patients on IV mode had nearly double the mortality rate than the patients on NIV mode of ventilation ($p=0.06$). Cause of death in all patients was COVID-19 and related complications.

Table 1: mentions the demographic and clinical details of the included patients in the study

Variable	No. of patients (n)
Mean Age	51.32
Gender	
Male	82
Female	43
Mean SPO2	93.23% (± 8.06 SD)
NIV- BPAP/CPAP	40
IV	82
ACV	5
PSV	3
VC-CMV	72
PRVC	1

Variable	No. of patients (n)
SPNT	1
Both NIV + IV	6
1st NIV then IV	3
1st IV then NIV	3 (included under IV)
Mean PEEP	7 (± 3.76 SD)
Hypercarbia	32
Hypoxia	46
Discharged	82
Died	43

Comparative analysis in the NIV and IV mode:

A comparative analysis between NIV and IV mode revealed that the difference between the mean PEEP of the two groups was statistically significant ($p < 0.001$) with values 5 and 7.98 respectively. The difference between the mortality rates of two groups was not statistically significant, but approached the significance level ($p=0.06$). The difference between the groups in terms of other parameters i.e. Mean length of stay in the hospital and Mean length of stay on the ventilator, was not statistically significant ($p=0.367$, $p=0.406$ respectively). Table 2 mentions the demographics, clinical features and outcome for the NIV and IV mode.

Table 2: Comparative analysis of patients on Non invasive and invasive mechanical ventilation

Parameter	NIV	IV	p value
Total patients	40	79	
Mean age	51.325	50.81	0.869
Mean PEEP	5	7.98 *	<0.001
Mean length of stay (days)	6.8 (SD 7.64)	5.39 (SD 8.81)	0.367
Mean length of stay on ventilator (days)	2.4 (SD 1.13)	2.61 (SD 1.35)	0.406
Survived (n)	32	46	0.06
Died (n), Mortality rate (%)	8, 20%	33, 41.77%	

* Data not available for 4 patients

DISCUSSION

The most severe complication of COVID-19 is ARDS characterised by severe hypoxia. Approximately one third of patients with COVID-19 progress to ARDS.⁵ COVID-19 patients with ARDS have a mortality rate of 52% as observed in Wuhan.⁶ Hence, it's conspicuous that the main aim to treat ARDS

must be to bring back the oxygen levels. This is achieved by mechanical ventilation wherein NIV is a preferred alternative to IV. For patients in low and middle income countries, NIV has proven to be an efficacious approach for being cost effective and easy to use.⁷ This is more relevant since in these countries the burden of illness is exceptionally high which increases with urbanisation, emerging epidemics and expanding access to hospitals.⁷ Increasing burden of COVID-19 consequently led to an urgent requirement of well equipped infrastructure that posed a lot of obstacles to manage this pandemic in not only developing but even developed nations. Not to mention, things worsened when the second wave hit. Already, the resources were scarce and the increasing demand made things more complicated. Conditions had been so unfavourable that ICUs were fully occupied and the patient number even exceeded the beds in the emergency. Philanthropic donation of ventilators and other medical equipment did create a difference. However, due to improper management and unavailability of trained manpower and resources rendered them useless in upto 50% cases.⁸ A study by Reddy et al. found that the median direct medical cost for a median stay of 13 days was as high as INR 202248.5 (\$ 2742.91) per patient.⁹ Undoubtedly, cost effective ventilators are the need for today's pandemic.

This is the first study on the Indian population to report mortality rates of COVID-19 ventilated patients to the best of our knowledge. As per WHO, over 33 million cases have been confirmed in India till now. Despite the fact of being the 2nd most affected country after the United States, there has been no study reported till date to on the outcome of ventilated patients of severe COVID, making this study one of its kind amongst the Indian population.¹ The approved treatment for ARDS in COVID-19 is steroids and oxygen therapy which is accomplished by assisted ventilation. Many FDA unapproved drugs like remdesivir are being prescribed to patients. Additionally, upto 90% of COVID-19 patients received antibiotics while less than 10% required it.¹⁰ However, we adhered to universal guidelines to avoid unnecessary risks and fortunately, 82 patients were successfully recovered and discharged. This is all the more encouraging as all patients had severe Covid and were managed in the ED without any proper ICU

facilities.

40 patients required NIV, 82 were on IV and 3 required both NIV and IV ventilation. In total 68% of the patients needed IV. This is in accordance with a study by Graselli *et al.*, where 72% patients required IV.¹¹ The results were satisfactory wherein 65.6% patients were discharged after full recovery. The overall mortality rate was 34.4% comprising 41.77% of patients in the IV group while mortality was as low as 20% in the NIV group.

King *et al.* reported a mortality rate of 42.7% in the IV mode which was very similar to our results.¹² While a study by Richardson *et al.* in New York had a mortality rate of 88%.¹³

This drastic difference might be because of the exclusion of patients already in the ICU on ventilators by the latter study. Yang *et al.*¹⁴ reported a mortality of 61% (n=36/59) for COVID-19 patients on IV mode. A mortality rate of 68% was seen in Mexican patients (n=6898). However, Ziehr *et al.* conducted a study in 2020 and a striking contradiction was observed in the mortality rate of people on IV ventilation mode. They reported the death of 11 patients out of 66 and hence a mortality rate of 17%.¹⁵ 36.3% patients on IV died as reported in a multicenter study undertaken by COVID-ICU Group on behalf of the REVA Network and the COVID-ICU Investigators.¹⁶

NIV emerged as a successful approach with a success rate of 77.7% in the study by Mukhtar *et al.*¹⁷ Likewise, 80% patients on NIV mode of AgVa ventilator were discharged successfully, which brings out the essence that NIV is feasible and suitable to treat ARDS in COVID-19. Unlike the present study, the success rate of NIV Philips V680™ (Respironics INC®, Pennsylvania, USA) or Hamilton G-5 (Hamilton Medical AG, Bonaduz, Switzerland) was marginally low (48.1%) in a study by Menzella *et al.*¹⁸ 94.7% COVID-19 patients on NIV were discharged in full recovery in a study by Zheng *et al.*¹⁹ While a mediocre percentage of patients (59.2%) on NIV approach recovered from ARDS due to COVID-19 in a multicenter study by Hua *et al.*²⁰ However, the overall mortality rate of patients on mechanical ventilation was high (62.64%) in this study, suggesting the additive higher mortality of patients on IV mode of ventilator. **Table 3** presents a summary of studies evaluating the success rate of COVID-19 patients managed with non-invasive ventilation.

Table 3: Summary of studies evaluating the success rate of COVID-19 patients managed with non invasive ventilation.

Author, year	Patients receiving NIV	Success rate (%)	Ventilator used
Mukhtar <i>et al.</i> , 2020 ¹⁸	30	77.7	Not mentioned
Menzella <i>et al.</i> , 2021 ¹⁹	79	48.1	Philips V680™ (Respironics INC®, Pennsylvania, USA) or Hamilton G-5 (Hamilton Medical AG, Bonaduz, Switzerland)
Zheng <i>et al.</i> , 2020 ²⁰	19	94.7	Not mentioned
Hua <i>et al.</i> , 2020 ²¹	152	59.2	Not mentioned
Present study, 2021	40	80	AgVa

We reported an overall mortality rate of 34.4% (n=43). A comprehensive literature review of studies reported so far on the mortality of COVID-19 patients on MV revealed that most of the studies had a case fatality rate (CFR) almost similar to our results. 35.7% patients out of 165 had already died in the study by Auld *et al.*²¹ Considering the death of patients already on ventilation (n=8), the maximum CFR could be 40.6%. A joint study by COVID-ICU Group on behalf of the REVA Network and the COVID-ICU Investigators reported a mortality rate of 36.75 (n=1053).¹⁶ This was so far the largest study in the group. However Roedl *et al.*²², Hua *et al.*²⁰ and Yang *et al.* reported significantly high mortality rates of 44.31%, 62.64% and 81.08% respectively.²³

Such wide variations in the mortality rates could be due to demographic variations and heterogeneity in the management of patients and reporting of the outcome data. Several reasons could be there for the same. ICUs in the areas not affected much by the pandemic have an advantage of gathering the equipment and resources easily.²¹ Better survival rates are expected when there is closer monitoring and timely intensive care for the patients.²⁴ CFR could also have been affected by the variations in healthcare facilities and indications for ventilation. Table 4 summarises the overall mortality rates of COVID-19 patients on mechanical ventilation in various studies reported so far.

Table 4: Overall mortality rates of COVID-19 patients on mechanical ventilation in various studies

Author	Total patients on MV	Died	Mortality Rate (%)
Auld <i>et al.</i> , 2020 ²²	165	59	35.7*
Hua <i>et al.</i> , 2020 ²¹	265	166	62.64
Roedl <i>et al.</i> , 2020 ²³	167	74	44.31
Yang <i>et al.</i> , 2020 ²⁴	37	30	81.08

COVID-ICU Group 2021 ¹⁷	2865	1053	36.75
Present study, 2021	125	43	34.4

*Excluding the patients still on ventilator, i.e. n=8

COVID-19 pandemic brought out the grave condition of not only the developing but also the developed nations. Due to scarcity of medical infrastructure, personnel and ventilators, the burden of COVID-19 of more than 33 million confirmed cases, has stretched the health resources to unimagined limits. The duration of stay and mortality rate of patients on ventilators is a good indicator to understand the etiology behind death of patients despite getting proper ventilation care. Our study calls for more studies on the Indian population. This study finally adds onto the pool of ventilator mortality studies and presents striking data in front of the world.

CONCLUSION

This is the first study from India to assess the mortality rate of patients with COVID-19 induced ARDS requiring NIV or invasive ventilation and managed in the emergency department purely on oxygen and steroids during the second wave of the pandemic. Despite extreme overcrowding and suboptimal resources, the outcome in an ED can be comparable to the best available across the globe. This study shows that it is possible to provide ICU level outcomes for severe COVID in the ED itself, provided the staff is motivated and competent.

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