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RESEARCH ARTICLE

**TO STUDY THE ROLE OF NONINVASIVE VENTILATION AS A WEANING MODE WHEN
COMPARED TO CONVENTIONAL WEANING**

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ABSTRACT

Background: Noninvasive Ventilation (NIV) delivers mechanical ventilation to the lungs using techniques that do not require an indwelling endotracheal airway. Since it provides partial ventilatory support, NIV is used in preventing reintubation in patients with ARF from COPD, cardiogenic edema. The aim of the study is to evaluate the role of NIV as a weaning mode and to ascertain difference with conventional weaning.

Methods: A randomized prospective study was conducted after getting permission from ethical committee of our university. 40 patients of age group 18-65 years, in ICU who received mechanical ventilation for more than 72 hours were considered and were divided randomly and equally in to 2 groups after satisfying weaning criteria, Group A : Included those patients who were weaned by NIV (using BiPAP mode with Oro nasal interface), Group B: Included those patients who were weaned by conventional methods (Spontaneous mode with pressure support).

Results: Incidence of weaning failure and reintubation was 35% (7 cases) in Group A as compared to none in Group B (p=0.004). Following this, 7 failed cases from Group A were excluded from assessment, and thus the sample size of Group A was reduced to 13. This was done to compare the hemodynamic profile, duration of hospital stay & ventilator use between the patients weaned by NIV and to that of conventional weaning. Now statistically the difference between two groups for the mean Systolic, Diastolic blood pressures and Pulse rate, was significant at all the follow up intervals (p<0.001) with continuous declining trend of all these variables was observed in Group A patients, along with their mean values lesser than that of group B patients throughout the follow up period. Mean duration of hospital stay and ventilator use was significantly lower in Group A as compared to Group B (p=0.002 & p=0.004 respectively). There was no change in outcome of the patients in terms of VAP between the two groups.

Conclusion: NIV does not prevent the need for reintubation, or reduce the incidence of weaning failure. Despite this NIV can be considered as an alternative weaning procedure taking in to consideration of the advantages provided by them, although a judicious clinical decision of when to wean and selection of appropriate patients gives a favourable outcome in patients who are weaned by NIV.

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INTRODUCTION

Patients with acute respiratory failure often require endotracheal intubation and mechanical ventilation to sustain life. Although invasive ventilation is effective, it has been associated with the development of numerous complications leading to increased morbidity and a trend toward increased mortality. So, for these reasons, minimizing the duration of invasive mechanical support is considered an important goal of critical care.¹

Non Invasive Positive Pressure Ventilation (NPPV) or Non Invasive Ventilation (NIV) is the delivery of mechanical ventilation to the lungs using techniques that do not require an indwelling endotracheal airway. It provides partial ventilatory support to patients recovering from respiratory failure and also in patients who require ventilator support, but have regained the ability to breathe spontaneously.

Weaning refers to gradual reduction of mechanical ventilation support, it is reserved for those who still require ventilatory support, but only to some degree. Time spent in the weaning process represents 40–50% of the total duration of mechanical ventilation.² Patients receiving prolonged mechanical ventilation account for 6% of all ventilated patients but consume 37% of intensive care unit (ICU) resources.³ Interest in reducing the duration of weaning by various methods is given prime importance nowadays as it can reduce the time spent in mechanical ventilation.

To counteract the effects of complications associated with prolonged invasive ventilation, the role of NIV in weaning, that is, replacing invasive support with noninvasive support in patients who are on long term mechanical ventilation with respiratory failure of any cause and who are ready to be weaned is explored. To achieve this, the study was conducted with following aim and objectives “To study the role of NIV as a weaning mode over conventional weaning” and to

ascertain difference between strategies in terms of Incidence of weaning failure, Incidence of reintubation, Incidence of ventilator-associated pneumonia, Length of stay in ICU, Total duration of mechanical ventilation, Hemodynamic parameters.

MATERIAL AND METHODS

This randomized and prospective study was undertaken after getting permission from the Institutional Ethics Committee between July 2015 and August 2016. An informed written consent from the parents or guardian of the patient was taken before the study.

Patients are selected on the basis of following criteria. Inclusion criteria includes: Patients between age group of 18 - 65 years and patients receiving Invasive Positive Pressure Ventilation (due to respiratory failure of any cause), for at least 72 hours. Exclusion criteria includes, patients with any of the following feature: patient refusal / intolerance, immediate need for tracheal intubation, unable to fit mask / interface, severe encephalopathy, uncontrolled vomiting, upper gastrointestinal bleeding, upper airway obstruction, facial trauma, agitated, uncooperative, swallowing impairment, excessive secretions not managed by clearance technique, multiple organ failure.

Forty patients who are on mechanical ventilation were included in the study, after satisfying the weaning criteria, randomly 20 patients were weaned by NIV (using BiPAP and oro nasal interface) comprised group A, and 20 patients were weaned by conventional weaning (spontaneous mode with pressure support) comprised group B.

Weaning criteria included, **A) Clinical Criteria:** Initial reason for providing ventilatory support to be resolved or significantly improved, Adequate Haemoglobin (> 8 mg/dl), Stable hemodynamics (systolic BP between 90 to 160 mmHg, diastolic blood pressure between 60 to 90 mmHg with minimal or no vasopressors, and heart rate ≤ 140 beats per minute), No evidence of myocardial ischemia or cardiac arrhythmias, No significant fever or infection, Patient should be arousable, No significant electrolyte abnormality. **B) Ventilatory Parameters:** Stable spontaneous ventilator drive, Tidal volume 4-6 ml/kg. **C) ABG Parameters:** $\text{PaO}_2 > 60$ mmHg on $\text{FiO}_2 \leq 50\%$, $\text{PaCO}_2 < 50$ mmHg on $\text{FiO}_2 \leq 50\%$, $\text{PaO}_2 / \text{FiO}_2$ ratio: > 200 mmHg, pH: 7.35 to 7.45, $\text{HCO}_3^- = 22$ to 26 Meq/l.

The severity of illness is evaluated by APACHE II and GCS score at the time of admission. Blood Pressure, Heart Rate, Arterial Oxygen Saturation (SPO₂) are measured every five minutes from the onset of weaning up to 30 minutes of spontaneous breathing trial (SBT), to quantify hemodynamics. Arterial Blood Gas (ABG) analysis are performed before and after the period of spontaneous breathing trial.

Patients who are on invasive mechanical ventilation are ventilated by Hamilton C1 ventilator using SIMV (synchronized intermittent mandatory ventilation) mode. After satisfying weaning criteria, patients of both the group are taken on spontaneous breathing trial. Patients on group A are extubated and switched over to NIV using Bilevel Positive Airway Pressure (BiPAP) mode and oro nasal interface on RESMED STELLAR, Noninvasive ventilator. An initial ventilatory setup started in spontaneously triggered mode with backup rate and with tidal volume 10 ml/kg is initiated along

with Inspiratory Positive Airway Pressure (IPAP) of 12 cmH₂O, Expiratory Positive Airway Pressure (EPAP) of 6 cmH₂O and Pressure Support (PS) of 6 cmH₂O is used. Both IPAP and EPAP are titrated to achieve patient comfort, adequate exhaled tidal volume, and synchrony with the ventilator. Peak pressures are not allowed to exceed 20 cm H₂O. Straps are readjusted to prevent airleaks. Patients on group B are switched over to spontaneous mode of ventilation using the same Hamilton C1 ventilator with Pressure support of 10 cmH₂O, Fraction of Inspired Oxygen ($\text{FiO}_2 = 40\%$), Positive End Expiratory Pressure (PEEP) = 8 cmH₂O.

Weaning failure is defined when the patient exhibits any of the following feature: Altered sensorium, Abnormal respiratory pattern, Inability to clear secretions, Inability to tolerate interface, SPO₂ $< 90\%$, Heart rate > 140 bpm, Blood Pressure $> 160/100$ mmHg, Respiratory rate > 40 bpm, ABG parameters (pH < 7.3 or pH > 7.5 and $\text{PaCO}_2 > 50$ mmHg on $\text{FiO}_2 40\%$). In such a scenario the patients in either groups are taken in to their previous ventilator settings.

Successfully weaning is said if the patients show following clinical signs over their entire weaning period: Able to follow commands, SPO₂ $> 95\%$, Heart rate < 140 bpm, Respiratory rate < 30 bpm, Blood pressure $< 160/100$ mmHg, Stable ABG with pH 7.3 – 7.5 and $\text{PCO}_2 < 50$ mmHg on $\text{FiO}_2 40\%$.

Patients from both the groups after their successful, stable spontaneous breathing trial for 30 minutes, the pressure support and PEEP is gradually reduced. When a satisfactory recovery has been achieved, either the NIV is stopped in group A patients or endotracheal tube is removed from group B patients, and thereafter oxygen supplementation is provided by means of venturi mask at a oxygen flow rate of 5liters/minute. If at any instance, patient deteriorates when NIV or SBT with PS is interrupted, the therapy (previous ventilator settings) is resumed, but, otherwise, they can be discontinued.

Once the patient is discontinued from the ventilator support, the following variables are noted: Incidence of weaning failure, incidence of reintubation, incidence of ventilator associated pneumonia, total duration of mechanical ventilation, total duration of ICU stay.

Statistical Analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) version 15.0. Comparison between two groups was done using independent samples "t"-test or Chi square test, depending on the normality of distribution. The values were represented in number (%) and mean \pm SD. The student "t" test and analysis of variance (ANOVA) were used for analysis of quantitative parametric data. 'P value' less than 0.05 was considered to be significant.

RESULTS

Demographic data, APACHE II score, GCS score at the time of admission, baseline hemodynamic variables and ABG values were matched statistically between the two groups. Weaning failure and reintubation was 35% (7cases) in Group A as compared to none in Group B. Statistically, the difference was significant ($p=0.004$).

Comparison of weaning status after SBT

SN	Variable	Group A (n=20)		Group B (n=20)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	Incidence of weaning failure/ reintubation	7 (35.0%)		0 (0%)		$\chi^2=8.485$;	p=0.004

Comparison of ABG Profile after SBT

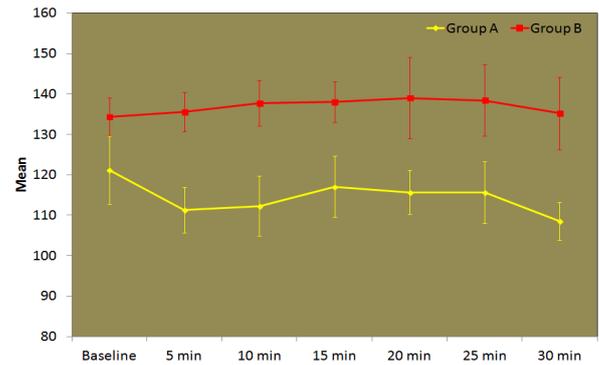
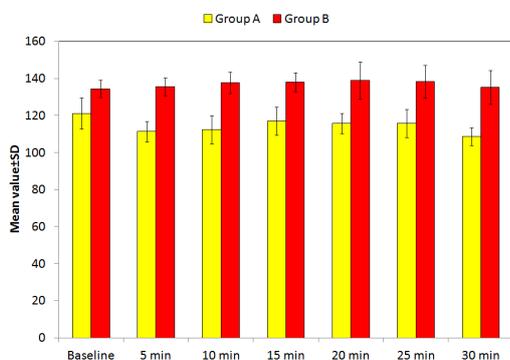
SN	Variable	Group A (n=20)		Group B (n=20)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	pH	7.34	0.08	7.41	0.03	-3.515	0.001
2.	pO ₂ (mmHg)	129.10	46.46	142.55	26.97	-1.120	0.270
3.	pCO ₂ (mmHg)	41.35	8.01	40.05	3.72	0.658	0.514
4.	HCO ₃ (mEq/L)	22.65	3.34	25.90	1.71	-3.867	<0.001

On comparison of ABG Profile between two groups after SBT: Statistically, a significant difference was observed between two groups for pH (p=0.001). Mean pH in group A was 7.34±0.08 and mean pH in group B was 7.41±0.03. This difference accounted because 7 cases which showed weaning failure in group A developed respiratory acidosis, leading to decrease in pH. Statistically significant difference was also observed between two groups for HCO₃ (p=<0.001), probably because the respiratory acidosis developed in 7 cases which failed in group A had raised raised PCO₂ and correcting the raised PCO₂ by our body will promote bicarbonaturia through renal compensation to normalize the pH.

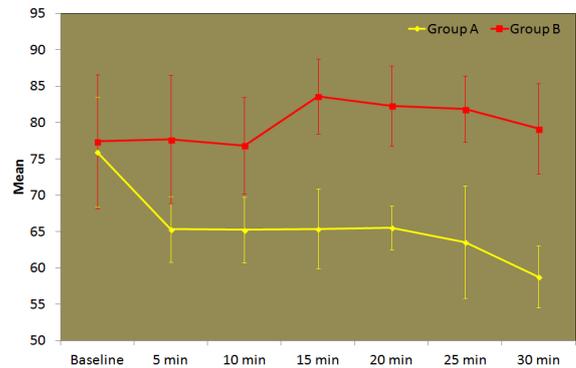
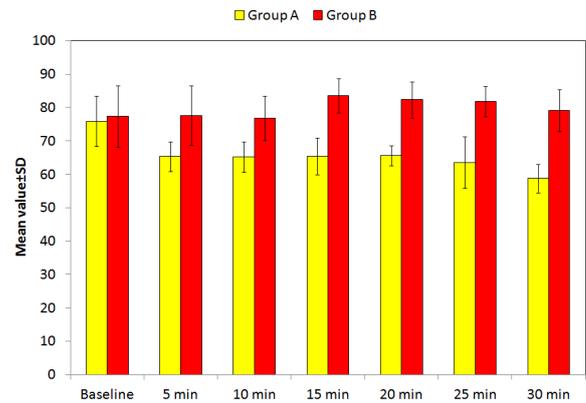
Following weaning failure and reintubation, 7 cases from Group A were excluded from assessment, and thus the sample size of Group A was reduced to 13. Now only the successfully weaned cases of group A (n=13) is compared with group B (n=20) This was done to compare the hemodynamic profile and the hospital stay & ventilator use duration between the patients weaned by BiPAP and to that of conventional weaning.

Statistically the difference between two groups for the mean Systolic, Diastolic blood pressures and Pulse rate, was significant at all the follow up intervals (p<0.001). A continuous declining trend of all these variables was observed in Group A patients, along with their mean values lesser than that of group B patients throughout the follow up period.

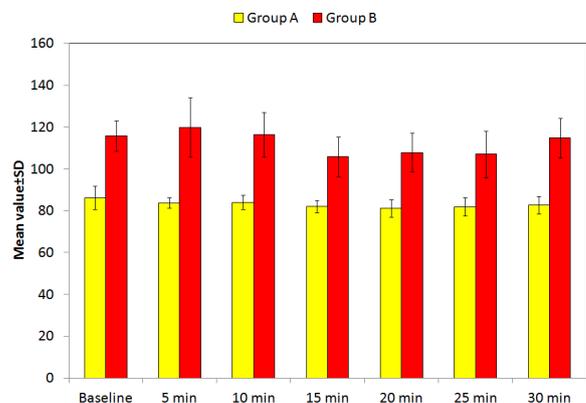
Comparison of Systolic Blood Pressure between two groups at different time intervals



Comparison of Diastolic Blood Pressure between two groups at different time intervals

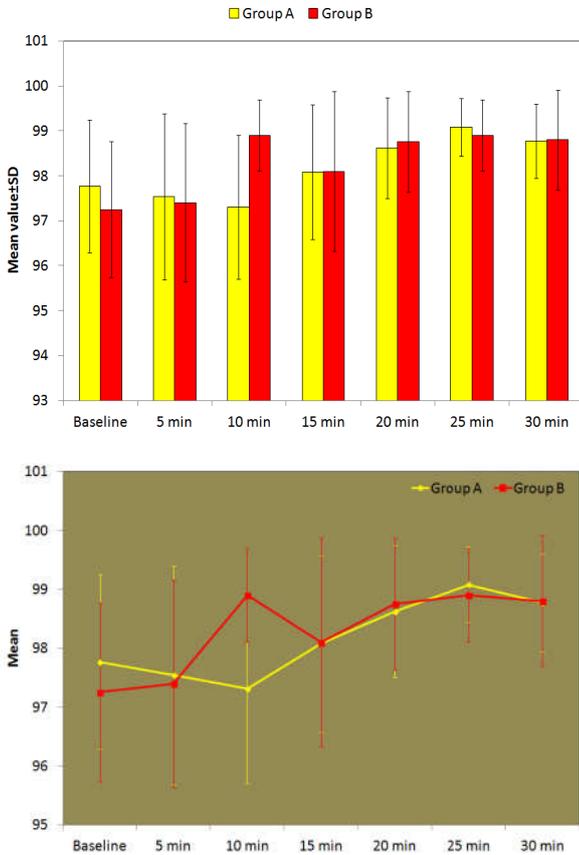


Comparison of Pulse rate between two groups at different time intervals



Mean Oxygen Saturation values in both the groups at different time intervals were found to be statistically insignificant ($p > 0.05$).

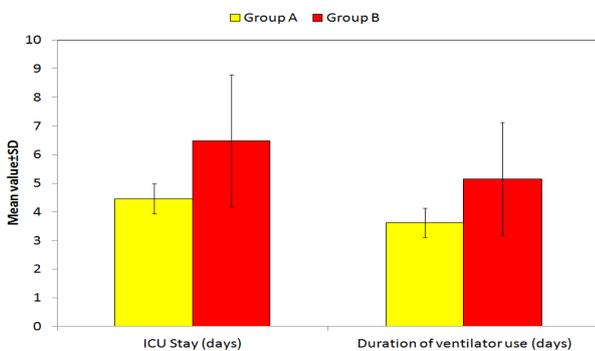
Comparison of Oxygen saturation between two groups at different time intervals



Mean duration of hospital stay and ventilator use was significantly lower in Group A as compared to Group B ($p = 0.002$ & $p = 0.004$ respectively).

Comparison of Different Outcome parameters between two groups

SN	Variable	Group A (n=13)		Group B (n=20)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	ICU Stay (days)	4.462	0.519	6.475	2.30	-3.086	0.004
2.	Duration of ventilator use (days)	3.615	0.506	5.150	1.974	-2.731	0.010



DISCUSSION

In our study we have found 35% of patients who were weaned by NIV had weaning failure and required reintubation and mechanical ventilation. The main reasons for endotracheal

intubation were found to be progression of hypoxemia, hypercapnia, hemodynamic instability, besides patients who failed weaning by NIV were comparatively older and had higher APACHE II scores, suggesting the need for careful selection of patients and the close monitoring in more severe patients during NIV. Those patients who have been successfully weaned by NIV, showed a marked reduction in duration of ICU stay & ventilator use, better hemodynamic profile and reduced incidence of complications when compared to conventional weaning.

In a study conducted by Nava,⁴ to determine whether NIV improves the outcome of weaning from invasive mechanical ventilation (IMV) in intubated patients with COPD, it was found that among patients who received NIV, the probability of survival and weaning during ventilation was higher ($P = 0.002$) and time in the ICU was shorter (15.1 ± 5.4 days compared with 24.0 ± 13.7 days for patients who received IMV; $P = 0.005$), and it was concluded that NIV reduces weaning time, shortens the time in the intensive care unit, decreases the incidence of nosocomial pneumonia, and improves 60-day survival rates. In our study the total duration of ICU stay was 4.46 ± 0.52 compared to 6.48 ± 2.30 days for patients who received IMV; $p = 0.004$.

In the study conducted by Girault,⁵ with the similar aforementioned aim and objective, it was found that 12 of 16 patients (75%) in the conventional group versus 13 of 17 (76.5%) in the NIV group ($p = NS$) were successfully weaned and extubated, the durations of ICU stay and the 3-mo survival were similar in the two groups. But in our study the duration of ICU stay was significantly reduced by NIV.

There were no incidence of VAP in both the groups of our study, but in the study conducted by Chen,⁶ between study group and control group, the incidence of VAP was 0/12 vs 7/12, $P = 0.027$. This proves that NIV is effective in reducing VAP - the most dreaded complication associated with the IMV.

In a study conducted by Ferrer et al.,⁷ Compared with the control group, the NIV group had shorter periods of IMV (9.5 ± 8.3 vs. 20.1 ± 13.1 days, $p = 0.003$) and intensive care unit (ICU) (14.1 ± 9.2 vs. 25.0 ± 12.5 days, $p = 0.002$), but in our study the duration of these periods were reduced to half and Ferrer et al⁷ also proved that earlier extubation with NIV resulted in shorter mechanical ventilation and length of stay, less need for tracheotomy, lower incidence of complications, and improved survival in these patients.

A prospective, randomized controlled study by Wang⁸ included 90 intubated COPD patients with severe hypercapnic respiratory failure triggered by pulmonary infection, it was found that compared with control group, study group had shorter duration of IMV [(6.4 ± 4.4) days vs (11.3 ± 6.2) days, $P = 0.000$], lower rate of (VAP) (3/47 vs 12/43, $P = 0.014$), fewer days in ICU [(12 ± 8) days vs (16 ± 11) days, $P = 0.047$] and lower hospital mortality (1/47 vs 7/43, $P = 0.025$). Thus Wang⁸ concluded that in COPD patients requiring intubation and IMV for hypercapnic respiratory failure, which is exacerbated by pulmonary infection, early extubation followed by NIV, may decrease significantly the duration of IMV, the risk of VAP and hospital mortality. In our study a similar favourable results were obtained when NIV was used in patients with ARF due to different etiologies, indicating that NIV can be used in mixed

respiratory disorders apart from hypercapnic respiratory failure.

Trevisan⁹ experimental randomized clinical trial showed that the percentage of complications in the NIV group was lower (28.6% versus 75.7%), with lower incidences of pneumonia and tracheotomy, and the length of stay in the ICU and mortality were not statistically different when comparing the groups, but in our study the NIV despite decreasing the complications, also reduced the duration of ICU stay among the patients.

In the study conducted by **Prasad**,¹⁰ it was concluded that, NIV is as useful as PSV in weaning and can be better in weaning failure especially in COPD for earlier weaning, decreases ICU stay, complications and mortality. This indicates that the NIV is better among the other newer alternative methods of weaning.

In a Multiple-center, randomized controlled study by **Nava et al.**,¹¹ it was found that, compared with the conventional group, the NIV group had a lower rate of reintubation (4 of 48 vs. 12 of 49; $p = .027$). The need for reintubation was associated with a higher risk of mortality ($p < .01$), but in our study the incidence of reintubation was quite higher (7 of 20 vs 0 of 20).

Our study has limitations. This was prospective, single center study carried out in ICU for a short period and it included very few patients. Since patients on ventilator had ever changing peak pressure, mean airway pressures, tidal volume, respiratory rate and minute ventilation, it was not feasible for us to note and compare these parameters between the two groups and hence these parameters are not presented here.

Besides due to limitation of resources we were not able to estimate, Forced Vital Capacity (FVC), Negative Inspiratory Force (NIF), ratio between dead space volume and tidal volume (V_d/V_t), Rapid shallow breathing index. Analysis of more variables, and implementing a more complex weaning protocols would have been a better predictor in assessing the correct time to start weaning.

More dynamic comparisons could have been done with variables noted at multiple intervals of time and average values obtained, as these would have provided additional support to results that we have obtained from our study. Multicenter trials, more manpower, more sample size and extended duration of study period would have helped us in conducting a better study. Still with these limiting factors, the results obtained from this study will provide valuable insight into the management of critically ill patients, which could be explored more in near future.

One important issue to emphasize in all of the NIV trials there is a mixture of different type of patients and aetiology of the respiratory failure being treated. The evidence for use of NIV in COPD patients and those with hypoxic respiratory failure with concomitant hypercapnic respiratory failure is substantially stronger than in other groups. Careful patient selection is imperative for the use of NIV and for future study design. NIV cannot generally be recommended for any of the specific topics mentioned previously. However, there is promise that for some subgroups (hypercapnic respiratory insufficiency, especially in COPD patients) NIV may be helpful in expediting the weaning process. Clear criteria for usage and discontinuation of NIV must be defined. Positive

effects of, NIV as a weaning mode and prophylactic NIV treatment in patients at risk for reintubation seem likely, but larger studies have yet to confirm this observation.

CONCLUSION

If we can save at least few time period of mechanical ventilation in a single patient, collectively it will be of immense importance in terms of avoiding invasive mechanical ventilation complication, cost of extra ICU stay and ventilator use. In our study we have found that in 65% of the patients the number of days of ICU stay and ventilator use has been significantly reduced by using NIV, so taking in to consideration of this factor NIV can be used as an alternative weaning method in favourable patients.

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