BRIEF RESEARCH COMMUNICATION

Impact of Prophylactic Noninvasive Ventilation on Extubation Outcome: A 4-year Prospective Observational Study from a Multidisciplinary ICU

Supradip Ghosh[1], Sonali Ghosh[2], Amandeep Singh[3], Ripenmeet Salhotra[4]

Abstract

Introduction: With emerging evidence supporting other interventions, there is a need to re-examine the safety and efficacy of postextubation noninvasive ventilation (NIV) support in high-risk patients.

Methods: Data were collected over 4-year period from a multispeciality ICU. High-risk criteria were uniform, and the application of NIV was protocolized. Successful extubation was defined as the absence of both reintubation and NIV support at 72 hours postextubation.

Results: Extubation success was achieved in 79.6%. At extubation, more patients in the failure group had chronic neurological or kidney diseases, longer days of invasive ventilation, higher sequential organ failure assessment score, and more positive fluid balance. Significant differences were also observed in the indications for prophylactic NIV between the two groups. However, in logistic regression analysis, none of these differences observed in univariate analysis was independently associated with extubation outcome. Failure of postextubation NIV was associated with higher hospital mortality (67.7 vs 10.7%, p <0.001) and longer ICU/hospital length of stay (median 10 vs 6 days, p <0.001 and 13 vs 10 days, p <0.01, respectively). No differences were observed in extubation outcomes between 2016 to 2017 and 2018 to 2019 cohorts.

Conclusion: High rate of extubation failure and worse patient-centric outcomes associated with prophylactic NIV calls for a relook into the current recommendation of NIV for this indication.

Keywords: Efficacy of prophylactic noninvasive ventilation, High risk of extubation failure, Weaning.

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Introduction

A recent guideline from the European Respiratory Society and American Thoracic Society had given a conditional recommendation to postextubation noninvasive ventilation (NIV) support in high- risk patients.[1] However, the guideline accepted low certainty of evidence supporting this recommendation. Several factors could contribute to this uncertainty, including variable criteria used to define high-risk patients, substantial variations observed in rates of reintubation and time to reintubation in NIV arms, and absence of uniform reintubation criteria in many of these studies.[2-4] Perhaps this uncertainty around the evidence is responsible for the failure of this strategy to gain widespread acceptance in clinical practice.[5] To complicate the matter further, failure of prophylactic NIV is demonstrated to be associated with worsening of organ dysfunction, more adverse events, and an increase in-hospital mortality.[6] More recently, high flow nasal oxygenation (HFNO) is gaining popularity as postextubation respiratory support with noninferiority of HFNO (vs NIV) demonstrated in preventing postextubation respiratory failure.[7,8] Combining HFNO and NIV is found to be even better than HFNO alone.[9]

We conducted a prospective observational study of patients at high risk of postextubation respiratory failure and in whom prophylactic NIV support was applied postextubation. The aims of our study were to document extubation outcome in high-risk patients on postextubation NIV in real-world scenario, to identify subgroups of patients who might be benefited specifically by this strategy, and to determine the potential impact of the experience of the team on extubation outcome. To test the latter hypothesis, we planned to compare extubation data from two different study periods: 2016 to 2017 and 2018 to 2019.

[1,3,4]Department of Critical Care Medicine, Fortis-Escorts Hospital, Faridabad, Haryana, India

[2]Department of Paediatric Critical Care, QRG Medicare, Faridabad, Haryana, India

Corresponding Author: Supradip Ghosh, Department of Critical Care Medicine, Fortis-Escorts Hospital, Faridabad, Haryana, India, Phone: +91-9818590021, e-mail: intensivist1972@gmail.com

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Methods

The study was conducted in the 18-bed multidisciplinary ICU of Fortis-Escorts Hospital, Faridabad, India. Patients' data were collected prospectively for a period between January 1, 2016, and December 31, 2019. Part of these data were reported in two earlier publications.[6,10] Institutional ethics committee approval was obtained for both studies and consents of patients' relatives were obtained before enrolment. Inclusion criteria for study entry were consenting adult (>18 years) patients who had planned extubation following invasive ventilation for at least 24 hours and who were put on NIV support postextubation for any one of the following high-risk criteria: underlying chronic obstructive airway disease (COAD) with $PaCO_2$ >45 mm Hg at extubation,

age >65 years, history of chronic heart failure (New York Heart Association class II-IV) or left ventricular ejection fraction <40%, prior failed spontaneous breathing trial or two or more organ system failure other than chronic respiratory or heart failure. Only the first episode of extubation was included for analysis. Patients were excluded from the study if they have any of the following conditions: contraindications to NIV application (example: craniofacial trauma or surgery, ongoing upper gastrointestinal bleeding, excessive respiratory secretions or inability to handle secretion, recurrent vomiting, recent gastric or esophageal surgery, tracheostomized, etc) or patients who are already on home NIV or patients with the decision to limit therapeutic intervention or refusal to consent.

Procedure

The weaning process of the unit has already been described earlier.[10] Prophylactic NIV support was started immediately postextubation. Protocol for NIV application has been published previously.[6] Initially NIV support was applied almost continuously for 6 to 12 hours except for 15 to 20 minutes periods to allow the patient to drink fluids or receive nursing care. Unassisted periods of breathing were allowed for a gradually increasing period following initial 6 to 12 hours of NIV support; provided the patient was comfortable and was able to maintain adequate oxygenation and pH remained >7.35. Either a need for reintubation within 72 hours or a continued requirement of NIV at 72 hours postextubation was categorized as extubation failure. Criteria for reintubation broadly followed international guidelines.[11] However, the final decision regarding both discontinuation of NIV and reintubation was left to the discretion of the attending intensivist.

Data Collection

The data collection process was uniform and was described in our previous publication.[6] All relevant data were collected both at intubation and at the time of extubation. Time to reintubation (from the time of extubation) and indications for reintubation were recorded for patients requiring reintubation. Following outcome data were recorded at hospital discharge: total duration of prophylactic NIV, the outcome of extubation (success or failure), adverse effects of NIV (intolerance to mask, conjunctival irritation, pressure effect, abdominal distension, or agitation), and ICU or hospital length of stay (LOS). The outcome of hospitalization was recorded as survival or death, and the worst possible outcome (death) was recorded as the hospital outcome for patients in whom family wished to discontinue further treatment.

Statistical Analysis Plan

Data were summarized and an appropriate statistical test was applied based on the type and distribution of data. The level of statistical significance was fixed as two-tailed *p*-values of <0.05. For univariate analysis, patients with extubation success and failure (from the whole cohort) were compared for variables both at intubation and at the time of extubation. Conditional stepwise multivariable logistic regression analysis was performed to identify independent factors related to extubation outcome. Patient-centric outcomes were also compared between failure and success groups.

To evaluate the effect of experience in using NIV on extubation outcome, baseline variable at the time of intubation and at extubation was compared for two different time periods—period 1 (between January 1, 2016, and December 31, 2017) and period 2 (between January 1, 2018, and December 31, 2019). Logistic regression analysis was performed to negate the effect of any difference in baseline variables. To assess the time to reintubation and cumulative hazard of reintubation between two time periods, Kaplan–Meier curve was plotted. Data were compared using a log-rank test. For statistical analysis, SPSS software version 22.0 (SPSS, Chicago, Illinois) was used.

Results

At Intubation

A total of 152 patients were eligible for data analysis. Of 152 patients, 121 (79.6%) had successful extubation at 72 hours by study definition. The median time to reintubation was 24.5 hours [interquartile range, Q1, Q3, 7.1, 36.5 hours]. Reasons for reintubation were refractory hypoxia (11, 36.7%), worsening hypercapnia (8, 26.7%), airway issues (6, 20%), extreme agitation (4, 13.3%), and refractory hypotension (1, 3.3%). More patients in the failure group had underlying chronic kidney and neurological conditions, higher sequential organ failure assessment score at intubation, longer time on invasive ventilation, and higher fluid balance at extubation. A significant difference was observed in indications for NIV. Table 1 compares baseline parameters between extubation success and failure groups. However, in logistic regression analysis, none of these variables were found to be independently associated with extubation outcomes.

Clinical Outcome

Table 2 shows the comparison in clinical outcome between successfully extubated patients and patients with extubation failure. Patients with extubation success spent more time on NIV (median 26 vs 19 hours, p <0.01). The success group also had lower hospital mortality compared to the failure group (10.7 vs 67.7%, p <0.001). Extubation success was also associated with shorter ICU, as well as hospital LOS. A higher incidence of adverse effects was observed in the extubation failure group (45.2 vs 9.9%, p <0.001) and was mostly related to extreme agitation.

Extubation Success in Two Different Time Periods

Numerically higher percentage of patients had extubation success in 2018 to 2019 cohort compared to 2016 to 2017 cohort, but the difference did not meet statistical significance (84.7 vs 76.3%, $p = 0.21$). In univariate analysis, significant differences were observed in baseline and at extubation parameters between two cohorts—gender, chronic cardiac/respiratory disease, on admission APACHE II, intubation indication, mean arterial pressure, pH, $PaCO_2$, and fluid balance at extubation (Table 3). However, the difference in extubation success between two cohorts remained statistically nonsignificant even after adjustment for differences observed in univariate analysis. The cumulative hazard of reintubation was not different between the two cohorts in Kaplan–Meier analysis ($p = 0.19$) (Fig. 1).

Discussion

From this relatively large cohort, we observed that in high-risk patients extubation failure rate remains high despite the use of prophylactic NIV in a protocolized manner. We did not observe any subgroup of patients who might be particularly benefited from prophylactic NIV. Extubation failure is shown to be clearly associated with worse patient outcomes. With no significant difference in extubation outcome observed in two consecutive study periods, it is unlikely that outcome of prophylactic NIV would improve further with experience beyond the basic level of training.

Table 1: Variables at initial intubation and extubation in extubation success and failure groups

Parameter	*Total (N = 152)*	*Success (N = 121)*	*Failure (N = 31)*	*p value*
Age in years (mean ± SD)	64.54 ± 14.09	63.98 ± 13.71	66.71 ± 15.52	0.33
Female sex, no. (%)	67 (44.1%)	50 (41.3%)	17 (54.8%)	0.09
Source of admission				0.17
Emergency department, no. (%)	121 (79.6%)	100 (82.6%)	21 (67.7%)	
Operation theater, no. (%)	2 (1.3%)	2 (1.7%)	0	
Wards, no. (%)	29 (19.1%)	19 (15.7%)	10 (32.3%)	
Admission category				0.66
Medical, no. (%)	147 (96.7%)	117 (96.7%)	30 (96.8%)	
Postoperative, no. (%)	3 (2%)	2 (1.7%)	1 (3.2%)	
Trauma, no. (%)	2 (1.3%)	2 (1.7%)	0	
Chronic cardiac disease, no. (%)	24 (15.8%)	17 (14%)	7 (22.6%)	0.24
Chronic respiratory disease, no. (%)	107 (70.4%)	86 (71.1%)	21 (67.7%)	0.71
Chronic kidney disease, no. (%)	13 (8.6%)	7 (5.8%)	6 (19.4%)	0.01
Chronic neurological disease, no. (%)	13 (8.6%)	6 (5%)	7 (22.6%)	<0.01
APACHE II score on day of intubation (median, IQR)	18 (14, 25)	18 (13.5, 24)	20 (16,26)	0.21
Indications for intubation, no. (%)				0.1
Poor GCS, no. (%)	9 (5.9%)	6 (5%)	3 (9.7%)	
Hypoxemic respiratory failure, no. (%)	34 (22.4%)	31 (25.6%)	3 (9.7%)	
Hypercapnic respiratory failure, no. (%)	95 (62.5%)	75 (62%)	20 (64.5%)	
Worsening shock, no. (%)	8 (5.3%)	5 (4.1%)	3 (9.7%)	
Postoperative, no. (%)	5 (3.3%)	4 (3.3%)	1 (3.2%)	
Airway issues, no. (%)	1 (0.7%)	0	1 (3.2%)	
Invasive ventilation days before extubation (median, IQR)	2.5 (1.75, 4)	2.25 (1.75)	3.25 (2, 6)	<0.01
SBT—PS/CPAP, no (%)	137 (90.1%)	110 (90.9%)	27 (87.1%)	0.5
SOFA score on day of extubation (median, IQR)	3 (2, 5)	3 (2,4)	5 (3, 6)	<0.001
Heart rate/minute at extubation (mean ± SD)	97.89 ± 16.62	96.92 ± 16.45	101.71 ± 17.01	0.16
Respiratory rate/minute at extubation (mean ± SD)	24.03 ± 4.33	23.97 ± 4.21	24.29 ± 4.85	0.73
Mean arterial pressure at extubation (mean ± SD)	89.28 ± 15.35	88.60 ± 15.34	91.90 ± 15.35	0.29
pH at extubation (mean ± SD)	7.39 ± 0.05	7.39 ± 0.05	7.40 ± 0.05	0.9
$PaCO_2$ in mm Hg at extubation (mean ± SD)	48.46 ± 11.78	49.16 ± 12.21	45.72 ± 9.63	0.1
PaO_2/FiO_2 ratio at extubation (median, IQR)	212 (186, 264.5)	212 (184, 256)	220 (195, 300)	0.19
Lactate in mmol/L at extubation (median, IQR)	0.9 (0.7, 1.2)	1 (0.7, 1.2)	0.8 (0.6, 1.2)	0.08
Cumulative fluid balance in mL (median, IQR)	2731.5 (1009.25, 4820)	2307 (1018.5, 4063.5)	4855 (1000, 7123)	0.01
Indications for prophylactic NIV, no. (%)				<0.01
COAD with $PaCO_2$ >45 mm Hg at extubation, no. (%)	61 (40.1%)	54 (44.6%)	7 (22.6%)	
Age >65 years with or without chronic cardiac or respiratory illness, no. (%)	30 (19.7%)	27 (22.3%)	2 (20%)	
History of CHF or LVEF <40%, no. (%)	13 (8.6%)	12 (9.9%)	1 (3.2%)	
Prior failed SBT, no. (%)	13 (8.6%)	7 (5.8%)	6 (19.4%)	
Two or more organ system failure other than chronic respiratory or heart failure, no. (%)	35 (23%)	21 (17.4%)	14 (45.2%)	

ICU, intensive care unit; IQR, interquartile range; GCS, Glasgow Coma Scale; SOFA, sequential organ failure assessment; SD, standard deviation; $PaCO_2$, partial pressure of carbon dioxide; PaO_2/FiO_2, a ratio of partial pressure of oxygen and fractional inspiratory oxygen; NIV, noninvasive ventilation; COAD, chronic obstructive airway disease; CHF, congestive heart failure; LVEF, left ventricular ejection fraction

Table 2: Patient outcome

Parameter	*Total (N = 152)*	*Success (N = 75)*	*Failure (N = 10)*	*p value*
Duration of NIV support in hours (median, IQR)	24.5 (18, 38)	26 (18, 38)	19 (6, 30)	<0.01
Adverse effects, no (%)	26 (17.1%)	12 (9.9%)	14 (45.2%)	<0.001
Extreme agitation requiring sedation, no (%)	17 (11.2%)	3 (2.5%)	14 (45.2%)	
Conjunctival irritation, no (%)	3 (2%)	3 (2.5%)	0 (0%)	
Mask intolerance, no (%)	3 (2%)	3 (2%)	0 (0%)	
Nasal bridge ulceration, no (%)	2 (1.3%)	2 (1.7%)	0 (0%)	
Abdominal distension, no (%)	1 (0.7%)	1 (0.8%)	0 (0%)	
In-hospital mortality, no (%)	34 (22.4%)	13 (10.7%)	21 (67.7%)	<0.001
ICU length of stay in days (median, IQR)	6 (4.25, 9)	6 (4, 8)	10 (7, 21)	<0.001
Hospital length of stay in days (median, IQR)	10 (8, 15)	10 (8, 13)	13 (8, 21)	0.01

Table 3: Comparison between 2016 to 2017 and 2018 to 2019 cohort

Parameters	*Total (N = 152)*	*2016–2017 (N = 93)*	*2018–2019 (N = 59)*	*p value*
Extubation success, no (%)	121 (79.6%)	71 (76.3%)	50 (84.7%)	0.21
Age (mean ± SD)	64.54 ± 14.09	63.46 ± 15.40	66.24 ± 11.65	0.21
Female sex, no (%)	67 (44.1%)	49 (52.7%)	18 (30.5%)	<0.01
Source of admission				0.44
Emergency department, no. (%)	121 (79.6%)	72 (77.4%)	49 (83.1%)	
Operation theater, no. (%)	2 (1.3%)	2 (2.2%)	0 (0%)	
Wards, no. (%)	29 (19.1%)	19 (20.4%)	10 (16.9%)	
Admission category				0.19
Medical, no (%)	147 (96.7%)	88 (94.6%)	59 (100%)	
Postoperative, no (%)	3 (2%)	3 (3.2%)	0 (0%)	
Trauma, no (%)	2 (1.3%)	2 (2.2%)	0 (0%)	
Chronic cardiac disease, no (%)	24 (15.8%)	19 (20.4%)	5 (8.5%)	0.04
Chronic respiratory disease, no (%)	107 (70.4%)	55 (59.1%)	52 (88.1%)	<0.001
Chronic kidney disease, no (%)	13 (8.6%)	7 (7.5%)	6 (10.2%)	0.57
Chronic neurological disease, no (%)	13 (8.6%)	11 (11.8%)	2 (3.4%)	0.07
APACHE II score on the day of intubation (median, IQR)	18 (14, 25)	21 (15.5, 27)	14 (10, 21)	<0.001
Indication for intubation, no (%)				0.01
Poor GCS, no (%)	9 (5.9%)	7 (7.5%)	2 (3.4%)	
Hypoxemic respiratory failure, no (%)	34 (22.4%)	25 (26.9%)	9 (15.3%)	
Hypercapnic respiratory failure, no (%)	95 (62.5%)	48 (51.6%)	47 (79.7%)	
Worsening shock, no (%)	8 (5.3%)	7 (7.5%)	1 (1.7%)	
Postoperative, no (%)	5 (3.3%)	5 (5.4%)	0 (0%)	
Airway issues, no (%)	1 (0.7%)	1 (1.1%)	0 (0%)	
Parameters at extubation				
Invasive ventilation days (IQR)	2.5 (1.75, 4)	2.5 (1.75, 4.25)	2.5 (1.75, 3)	0.32
SBT—PS/CPAP, no (%)	137 (90.1%)	86 (92.5%)	51 (86.4%)	0.22
SOFA on day of extubation (median, IQR)	3 (2, 5)	3 (2, 5)	3 (2, 4)	0.08
Heart rate/minute (mean ± SD)	97.89 ± 16.62	98.74 ± 17.82	96.56 ± 14.58	0.41
Respiratory rate/minute (mean ± SD)	24.03 ± 4.33	24.17 ± 4.78	23.81 ± 3.54	0.59
Mean arterial pressure (mean ± SD)	89.28 ± 15.35	92.10 ± 15.49	84.83 ± 14.14	<0.01
pH (mean ± SD)	7.39 ± 0.05	7.39 ± 0.05	7.40 ± 0.05	0.02
$PaCO_2$ in mm Hg (mean ± SD)	48.46 ± 11.78	46.91 ± 11.81	50.90 ± 10.52	0.04
PaO_2/FiO_2 ratio (median, IQR)	212 (186, 264.5)	210 (181, 288)	212 (193, 250)	0.61
Lactate in mmol/L (mean ± SD)	1 ± 0.56	1.08 ± 0.63	0.88 ± 0.41	0.11

Contd...

Table 3: (*Contd...*)

Parameters	*Total (N = 152)*	*2016–2017 (N = 93)*	*2018–2019 (N = 59)*	*p value*
Cumulative fluid balance in mL (median, IQR)	2731.5 (1009.2, 4820)	2924 (1139, 5454.5)	1923 (945, 3835)	0.03
Indications for prophylactic NIV, no. (%)				<0.001
COAD with $PaCO_2$ >45 mm Hg at extubation, no. (%)	61 (40.1%)	24 (25.8%)	37 (62.7%)	
Age >65 years with or without chronic cardiac or respiratory illness, no. (%)	30 (19.7%)	20 (21.5%)	10 (16.9%)	
History of CHF or LVEF <40%, no. (%)	13 (8.6%)	12 (12.9%)	1 (1.7%)	
Prior failed SBT, no. (%)	13 (8.6 %)	9 (9.7%)	4 (6.8%)	
Two or more organ system failure other than chronic respiratory or heart failure, no. (%)	35 (23%)	28 (30.1%)	7 (11.9%)	
Outcome of extubation				
Duration of NIV support in hours (median, IQR)	24.5 (18, 38)	24 (17, 37.5)	26 (17, 37.5)	0.1
Adverse effects, no (%)	26 (17.1%)	15 (16.1%)	11 (18.6%)	0.5
In-hospital mortality, no (%)	34 (22.4%)	28 (30.1%)	6 (10.2%)	<0.01
ICU length of stay in days (median, IQR)	6 (4.25, 9)	6 (4, 9)	6 (4,9)	0.95
Hospital length of stay in days (median, IQR)	10 (8, 15)	10 (8, 14)	10 (8, 14.5)	0.82

GCS, Glasgow Coma Scale; SBT, spontaneous breathing trial; SOFA, sequential organ failure assessment; SD, standard deviation; $PaCO_2$, partial pressure of carbon dioxide; PaO_2/FiO_2, a ratio of partial pressure of oxygen and fractional inspiratory oxygen; NIV, noninvasive ventilation; COAD, chronic obstructive airway disease; CHF, congestive heart failure; LVEF, left ventricular ejection fraction

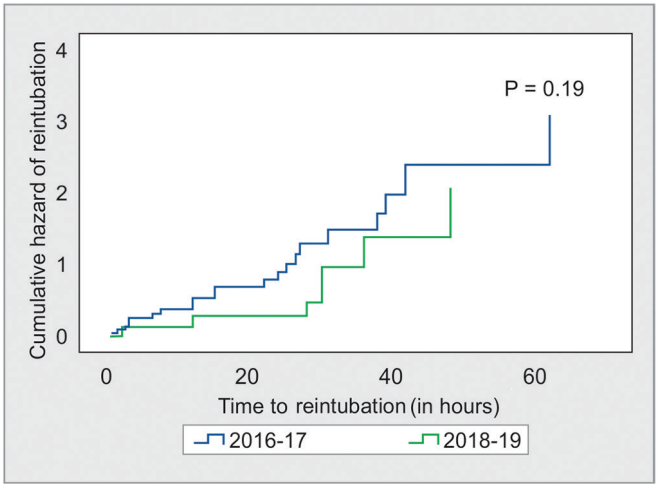

Fig. 1: Cumulative hazard of reintubation after 72 hours, by using the Kaplan–Meier curve. *p* value obtained with the log-rank test

Experience from Randomized Studies

Nava and colleagues randomized 97 high-risk patients to either NIV or low flow oxygen.[2] NIV was applied 1 hour after successful extubation.[2] Rate of reintubation and ICU mortality were lower in the NIV group. This result, however, was not replicated in the study by Ferrer and colleagues with similar reintubation rate and ICU or 90-day mortality observed between NIV and control groups.[3] Interestingly, mortality benefit was observed in a subgroup of patients with underlying chronic respiratory disease and hypercapnia at extubation.[3] This latter observation was tested in a subsequent study by the same group.[4] In 102 patients with chronic respiratory disease and hypercapnia at extubation, application of prophylactic NIV was associated with higher extubation success.[4] Lower 90-day mortality observed in the NIV group despite no difference in short-term ICU or in-hospital mortality, however, remains unexplained.[4]

In cardiac surgery patients, Stephan and colleagues compared NIV with HFNO for mixed indications (including facilitating extubation, as prophylaxis, and as a management strategy for respiratory failure postextubation) and demonstrated HFNO to be noninferior to NIV in preventing extubation failure.[7] In the study by Hernandez and colleagues, the rate of reintubation was similar between HFNO and NIV groups in high-risk patients.[8]

Comparison of RCT Data with Present Study

We used uniform criteria to define high risk, based on earlier published data.[2,12] Rate of extubation failure (20.4%) in our patients was higher compared to NIV arms of studies comparing NIV with low flow oxygen (8% in Nava study,[2] 16% in the first study by Ferrer,[3] and 15% in the second study by Ferrer[4]). However, our extubation failure rate is comparable with more contemporary studies comparing NIV with HFNO (21.9% in Stephan study[7] and 19.1% in Hernandez study[8]).

Patients who failed extubation attempts had significantly higher in-hospital mortality. One reason for this higher mortality could be potential delay in reintubation in patients on NIV.[13,14] However, the median time to reintubation in our study (24.5 hours) was comparable to earlier studies that reported this parameter (41 hours in the first Ferrer study,[3] 29 hours in the second Ferrer study,[4] and 21.5 hours in study by Hernandez[8]).

Conclusion

High rate of extubation failure and associated worse patient outcomes observed in our study raises concerns about the use of prophylactic NIV support in high-risk patients. In light of our findings, the current recommendation for prophylactic NIV for patients at high risk of extubation failure needs to be revisited.[1,15] In view of recent evidence showing encouraging result of a

combination of NIV support alternated with HFNO in preventing extubation failure, we suggest a future randomized study comparing NIV against combination strategy of NIV plus HFNO on extubation outcome in high-risk patients.

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Individual Author Contribution

- Dr. Supradip Ghosh. Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Roles/Writing—original draft; Writing—review and editing.
- Dr. Sonali Ghosh. Formal analysis; Writing—review and editing.
- Dr. Amandeep Singh. Data curation; Writing—review and editing.
- Dr. Ripenmeet Salhotra. Data curation; Writing—review and editing.
- All authors take complete responsibility for the accuracy and integrity of all parts of the work.

Orcid

Supradip Ghosh https://orcid.org/0000-0002-7892-2078
Sonali Ghosh https://orcid.org/0000-0002-2130-0630
Amandeep Singh https://orcid.org/0000-0001-5399-4801
Ripenmeet Salhotra https://orcid.org/0000-0001-8987-6102

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