



Perceived and Observed Side Effects of Noninvasive Mechanical Ventilation in Patients at a Tertiary Care Center: A Prospective Observational Study

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[Visual Abstract](#)

ABSTRACT

Objectives: To evaluate the perceived and observed side effects of noninvasive ventilation (NIV) in patients at a tertiary care hospital and to assess their correlation with inspiratory positive airway pressure (IPAP) levels and duration of NIV.

Materials and methods: This prospective observational study was conducted in the Department of Respiratory Medicine, LTMMC and GH, Sion, Mumbai, over a 1-year period. A total of 300 patients receiving NIV were screened; 241 with complete datasets were included. Demographic and clinical details were recorded. Patient-reported (subjective) and clinician-observed (objective) side effects were documented. Fear and pain were assessed using a 10-point scale. Correlations between average IPAP, NIV duration, and side effects were analyzed using logistic regression and Pearson's correlation, with $p < 0.05$ considered significant.

Results: Among 241 patients (mean age 52.4 ± 13.9 years; 47.3% male), oral dryness (79.7%), fear (74.7%), disturbed sleep (74.3%), and pain (74.3%) were the most common side effects, while abdominal distension was the least frequent (15.3%). Overall, mean IPAP showed no significant association with side effects; however, in chronic obstructive pulmonary disease (COPD) patients, higher IPAP correlated significantly with oral dryness ($p = 0.003$) and skin irritation ($p = 0.029$). Longer NIV duration was significantly associated with abdominal distension, skin irritation, nasal bridge injury, and pain ($p < 0.05$). Subgroup analysis revealed distinct patterns between COPD and post-tuberculosis obstructive airway disease (post-TB OAD) groups.

Conclusion: NIV is associated with frequent subjective and objective side effects, predominantly oral dryness, fear, disturbed sleep, and pain. While IPAP influenced certain complications in COPD, duration of use emerged as the key determinant of adverse events. Routine monitoring, preventive measures, and patient education are essential to improve tolerance and adherence to NIV therapy.

Keywords: Duration, Noninvasive ventilation, Side effects.

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- To correlate the perceived and mechanical side effects with the average inspiratory positive airway pressure (IPAP) received during the NIV.
- To correlate the perceived and mechanical side effects with the duration of NIV.
- Noninvasive ventilation failure was defined as the need for endotracheal intubation due to worsening respiratory failure, hemodynamic instability, deteriorating mental status, or intolerance to NIV.

Statistical Analysis

Statistical analysis was performed using SPSS version 29 (IBM Corp., USA). Descriptive statistics were used to summarize demographic and clinical variables. Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median (IQR), while categorical variables were presented as frequencies and percentages. Appropriate inferential statistical tests (e.g., Chi-square test, t -test, logistic regression) were used, with a p -value < 0.05 considered statistically significant. NIV-related adverse effects such as skin irritation, abdominal distension, nasal bridge injury, eye irritation, and sleep disturbance were treated as binary variables (present = 1, absent = 0) for regression analysis. Variables with $p < 0.2$ in the univariate analysis were included in the multivariate logistic regression model.

INTRODUCTION

The invention of noninvasive ventilation (NIV) dates back to the eighteenth century where the "iron lung" was the first prototype ever used with dramatic results. Over the past century, NIV usage has become a standard of care across the world for both respiratory and cardiac patients. It alleviates the need for invasive ventilation, especially in patients with type 2 respiratory failure, and thus provides protection from ventilator-associated complications whilst providing robust ventilatory support. However, over time, it has been recognized that this "wonder device" is also associated with a spectrum of adverse effects. Many of these complications may contribute to NIV intolerance, treatment failure, or reduced adherence. Careful recognition and monitoring of these side effects may improve patient comfort, compliance, and overall treatment outcomes. A better understanding of these side effects may help improve

patient compliance, minimize discomfort, and ultimately enhance treatment outcomes. We observed and studied the side effects of NIV both subjectively perceived by the patients and also observed if we could clinically come across any side effects. We further tried to analyze whether there was any correlation between the pressures received and the duration of NIV and any of the side effects.

MATERIALS AND METHODS

The study was a prospective single-center observational study conducted after approval from the Institutional Ethics Committee [IEC Number: IEC/15/24] at the Department of Respiratory Medicine, LTMMC and GH, Sion, Mumbai, over a period of 1 year. A total of 300 patients admitted and receiving NIV in the intensive respiratory care unit were included.

Aims and Objectives

- To study the perceived and mechanical side effects of noninvasive ventilation.

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RESULTS

A total of 300 subjects were enrolled; 59 subjects were excluded from the study due to incomplete data. Therefore, the total number of subjects in the study was 241. There were 114 males and 127 females. The average age of the study population was 52.39 years with an SD of 13.87 years. The most common addiction was smoking, found in 85 (35.26%) individuals. The average pack-years among smokers was 6.6 pack-years. There was a previous history of tuberculosis among 124 (51.4%) patients. All these patients had received NIV during the course of their stay in the hospital. The average days of NIV received were 5.56 days with an SD of 6.4 days. The average NIV IPAP was 19.9 ± 1.77 cmH₂O and was normally distributed. NIV intolerance leading to discontinuation due to side effects occurred in 8 patients (2.67%). The most common causes were severe mask discomfort, persistent nasal bridge pain, and anxiety related to mask intolerance.

The side effects perceived by the patients and noted by us were documented. The following is the frequency table (Table 1).

The most common reported side effect was oral dryness seen in 192 (79.67%), followed by fear in 180 (74.69%), disturbed sleep in 179 (74.27%), and pain in 179 (74.27%). The least common reported side effect was abdominal distention (15.35%). Abdominal distention was assessed clinically based on the patient's complaint of bloating or visible abdominal fullness during NIV therapy and was recorded as present or absent. Objective abdominal circumference measurement was not performed.

To study the relationship between the dependent variable, i.e., patient-reported adverse effects of NIV, and the average IPAP pressure, we performed logistic regression. We noticed that the relationship between the dependent and the independent variables was not statistically significant. Fear and pain

were subjectively evaluated on a scale of 1–10 for severity. The presence or absence of NIV-related discomforts and conditions was coded as 1 (present) and 0 (absent). The continuous data (fear score and pain score) in the study were found to be normally distributed with the help of Q–Q plots (Figs 1 and 2). Q–Q plots were generated for fear and pain scores to assess normality. They were all normally distributed.

As the data were normally distributed, Pearson's correlation coefficient was calculated for average IPAP, fear score, and pain score:

- For the average IPAP and fear scale: The correlation coefficient is 0.01. This was negligible.
- For the average IPAP and pain scale: The correlation coefficient is -0.02 . This was negligible.

As the majority of patients were post-TB OAD, overlap syndrome, and chronic obstructive pulmonary disease (COPD), others were clubbed into other diseases due to lower numbers (Table 2).

Therefore, we further did a subgroup analysis of patients with COPD and post-TB OAD.

The relationship between the IPAP and the patient-reported symptoms was not statistically significant in the case of post-TB OAD.

In cases of COPD, the complaints of skin irritation and oral dryness correlated significantly with the average IPAP pressure.

- There was a modest positive correlation between average IPAP and outcome (skin irritation) ($R = 0.229$, $SE = 0.492$). The correlation is statistically significant ($p = 0.029$). The coefficient was 0.069, suggesting that for every 1-unit increase in IPAP, there was a 0.069-unit increase in the probability of skin irritation.
- There is a moderate positive correlation between average IPAP and complaints of oral dryness ($R = 0.301$, $SE = 0.338$). This correlation is statistically significant (0.003). The coefficient was 0.065, suggesting that for every 1-unit increase in IPAP pressure, there was a 0.065-unit increase in the probability of oral dryness.

Table 2: Underlying diseases in the analytical cohort ($n = 241$)

Diseases	Frequency	Percentage
Post-TB OAD	101	41.90%
Overlap syndrome	39	16.18%
COPD	76	31.53%
Other diseases	25	10.37%
Total	241	

* $p < 0.05$, statistically significant. aOR, adjusted odds ratio; CI, confidence interval

The relationship between the duration of NIV days and NIV-related side effects was also studied by logistic regression (overall).

- The relationship between Abdominal distension and NIV duration was found to be statistically significant. The coefficient was 0.0127. For every additional day of NIV, abdominal distension is associated with increased odds by 0.013 units (p -value 0.000159, $R = 0.058$, $SE = 0.3513$).
- The relationship between Skin irritation and NIV duration was found to be statistically significant. The coefficient was 0.0125. For every additional day of NIV, skin irritation is associated with increased odds by 0.0125 units (p -value 0.0077, $R = 0.0293$, $SE = 0.0046$).
- The relationship between Nasal bridge injury and NIV duration was found to be statistically significant. The coefficient was 0.01258. For every additional day of NIV, nasal bridge injury is associated with increased odds by 0.0126 units (p -value 0.0046, $R = 0.0330$, $SE = 0.0044$).
- The relationship between pain and NIV duration was found to be statistically significant. The coefficient was 0.00922. For every additional day of NIV, the reported pain is associated with increased odds by 0.0092 units (p -value 0.025, $R = 0.0208$, $SE = 0.00409$).

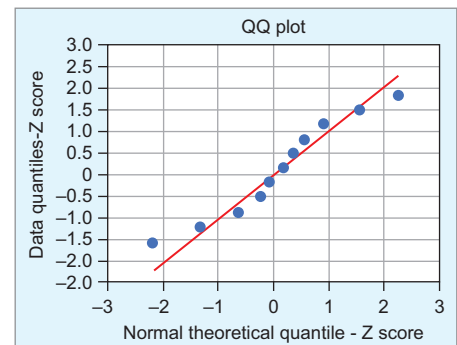


Fig. 1: Q–Q plot showing the normal distribution of fear

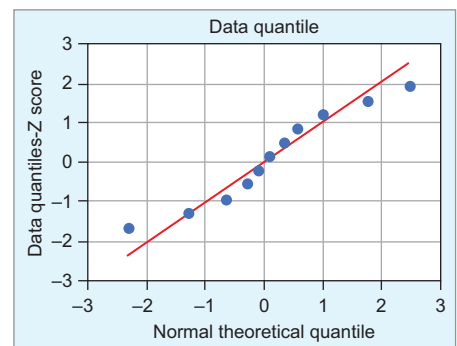


Fig. 2: Q–Q plot showing the normal distribution of pain

Table 1: Frequency of NIV-related side effects ($n = 241$)

Side effects	Frequency	Percentage
Disturbed sleep	179	74.27%
Nasal congestion	152	63.07%
Oral dryness	192	79.67%
Abdominal distention	37	15.35%
Skin irritation	115	47.72%
Nasal bridge injury	82	34.02%
Eye irritation	72	29.88%
Face injury due to mask	70	29.05%
Fear	180	74.69%
Pain	179	74.27%

Table 3: Multivariate logistic regression for skin irritation and oral dryness

Variable	Skin irritation (aOR, 95% CI)	p-value	Oral dryness (aOR, 95% CI)	p-value
Age	1.01 (0.99–1.03)	0.21	1.00 (0.98–1.02)	0.78
Female gender	1.12 (0.68–1.85)	0.64	1.25 (0.74–2.10)	0.39
Smoking	1.45 (0.82–2.56)	0.19	1.62 (0.90–2.91)	0.10
COPD	1.88 (1.05–3.36)	0.03*	2.15 (1.18–3.91)	0.01*
Post-TB OAD	1.22 (0.70–2.13)	0.47	1.31 (0.73–2.35)	0.36
Average IPAP	1.07 (1.01–1.14)	0.02*	1.06 (1.02–1.11)	0.003*
Duration of NIV	1.01 (1.00–1.02)	0.01*	1.01 (0.99–1.02)	0.12

* $p < 0.05$, statistically significant. aOR, adjusted odds ratio; CI, confidence interval

Table 4: Multivariate logistic regression for nasal bridge injury and abdominal distension

Variable	Nasal bridge injury (aOR, 95% CI)	p-value	Abdominal distension (aOR, 95% CI)	p-value
Age	1.02 (1.00–1.04)	0.04*	1.01 (0.98–1.03)	0.32
Female gender	1.38 (0.81–2.34)	0.22	0.92 (0.48–1.76)	0.80
Smoking	1.31 (0.72–2.38)	0.36	1.78 (0.88–3.59)	0.10
COPD	1.42 (0.78–2.57)	0.24	1.67 (0.81–3.44)	0.16
Post-TB OAD	1.19 (0.65–2.17)	0.56	1.08 (0.51–2.29)	0.83
Average IPAP	1.04 (0.99–1.09)	0.08	1.02 (0.96–1.08)	0.42
Duration of NIV	1.01 (1.00–1.02)	0.004*	1.02 (1.01–1.03)	<0.001*

* $p < 0.05$, statistically significant. aOR, adjusted odds ratio; CI, confidence interval

The duration of NIV was correlated with NIV-related side effects in COPD patients.

- A statistically significant association was observed between NIV duration and abdominal distension. The coefficient was 0.0207. For every day increase in the NIV duration, predicted abdominal distension by 0.0207 units ($R = 0.056$, $p = 0.0237$, $SE = 0.008971$).
- The relationship between Nasal bridge injury and NIV duration was found to be statistically significant (COPD). The coefficient was 0.0397. For every day increase in the NIV duration, predicted nasal bridge injury by 0.0398 units ($R = 0.1451$, $p = 0.0002$, $SE = 0.010286$).

The duration of NIV was correlated with NIV-related side effects in post-TB OAD patients.

- The relationship between Skin irritation and NIV duration was found to be statistically significant. The coefficient was 0.012111 units. For every day increase in the NIV duration, predicted skin irritation by 0.01211 units ($R = 0.045$, $p = 0.02439$, $SE = 0.005306$).
- The relationship between eye irritation and NIV duration was found to be statistically significant. The coefficient was 0.011471 units. For every day increase in the NIV duration, predicted eye irritation by 0.011471 units ($R = 0.0477$, $p = 0.020675$, $SE = 0.00488$).

A multivariate logistic regression analysis was performed to identify independent predictors of NIV-related adverse effects after adjusting for demographic and clinical variables.

Higher IPAP and longer duration of NIV were independently associated with increased odds of skin irritation and oral dryness. The duration of NIV was also independently associated with nasal bridge injury and abdominal distension. COPD patients had higher odds of developing skin irritation and oral dryness (Tables 3 and 4).

Noninvasive ventilation failure, defined as the need for endotracheal intubation after initiation of NIV, occurred in 36 patients, corresponding to a failure rate of 12% in the study population.

DISCUSSION

In this prospective observational study of 241 patients receiving NIV in a tertiary respiratory unit, we found that oral dryness, fear, disturbed sleep, pain, and skin/nasal bridge injury were among the most commonly perceived side effects, whereas abdominal distension was relatively uncommon. We also observed statistically significant associations of side effects with duration of NIV, especially nasal bridge injury, skin irritation, pain, and abdominal distension, and in COPD patients, higher IPAP correlated significantly with skin irritation and oral dryness. These results corroborate several recent studies on NIV use and are relevant, particularly in an Indian, post-TB-affected population. Impaired sleep quality has been reported in previous studies with NIV. Shah et al. found poor sleep quality among chronic NIV users, with mouth dryness, mask leak, aerophagia, and mask-related pain identified as contributors.¹ Similarly, a 2025 study on

nocturnal home NIV (without PSG guidance) reported that side effects like dry mouth, hoarseness, mask- or harness-related pain, pressure sores, and leaks were significantly associated with poor sleep quality.² These findings align with the high prevalence of disturbed sleep, pain, and oral dryness in our study. In our study, ~34% had nasal bridge injury, ~48% had skin irritation, ~29% had eye irritation, and ~29% had facial injury. These numbers are comparable to recent reports: A systematic review in 2025 reported the incidence of facial pressure injuries in adults receiving NIV to be ~25%, depending on mask interface, duration, and preventive measures.³ Other studies emphasize that risk increases with device duration, mask tightness, and lack of protective dressings.^{4,5} Prospective and retrospective cohorts have shown pressure injuries in 20–30% of patients on NIV, with the nasal bridge being the most vulnerable site.^{6,7} Nasal bridge injuries in patients receiving NIV are not an uncommon site in critical care settings, and despite protective measures applied, remain a cause of discomfort and concern. In multivariate analysis, duration of NIV emerged as the most consistent independent predictor across multiple adverse effects.

In the HAPPEN trial (2024), which compared high- vs low-intensity NIV in acute COPD, abdominal distension occurred significantly more frequently in the high-intensity group (37.4%) than in the low-intensity group (25.5%).⁸ This aligns with our finding of a statistically significant association between longer NIV duration (and in COPD, higher

IPAP) and abdominal distension, confirming aerophagia remains a relevant adverse event. Our observation that IPAP was significantly correlated with oral dryness and skin irritation in COPD patients is consistent with reports that higher pressure settings increase the risk of interface intolerance.^{9,10} Facial pressure injuries are also reported to rise with longer mask use, higher strap tension, and absence of protective interfaces.^{6,7} While objective mechanical side effects are often emphasized, subjective perceptions such as fear, pain, and anxiety were highly prevalent in our cohort (~74%). Studies underline that discomfort, claustrophobia, and anxiety can drive NIV intolerance and failure.^{11,12} Patient-reported side effects have also been shown to negatively impact adherence to long-term home NIV.¹³ During NIV therapy, several preventive measures were routinely implemented to reduce mask-related complications. These included periodic mask repositioning, adjustment of strap tension, application of protective gauze or hydrocolloid dressings over the nasal bridge, and intermittent breaks from NIV when clinically feasible. In patients experiencing oral dryness, humidification and adequate hydration were encouraged. These measures are recommended in previous studies to reduce NIV-related pressure injuries and improve patient tolerance.

Possible Mechanisms and Clinical Implications

- **Dryness:** NIV delivers dry air; mouth leaks and higher flows exacerbate oral dryness.^{1,2} Humidification, lower flows, and ensuring adequate hydration may help mitigate the oral dryness due to NIV.
- **Skin/nasal bridge injury:** Interface pressure and strap tension at bony prominences lead to injury.^{4,6,7} Softer interfaces and intermittent breaks can be attempted to reduce the incidence of nasal and skin injuries.
- **Abdominal distension:** Aerophagia from higher IPAP levels has been documented in COPD NIV trials.⁸ Mouth breathing can be discouraged, and a Ryle's tube insertion can be used to decompress the stomach to reduce abdominal distention.
- **Pain, fear, disturbed sleep:** Claustrophobia, mask leaks, airflow noise, and inability to speak/eat contribute.^{11,12} Patient education, counseling, and gradual increment of pressures might ease the patient's anxiety and fear over a period of time.
- **Duration effects:** Longer exposure to NIV increases the risk of both mechanical and subjective side effects.^{3,5,9} Addressing the underlying pathology mandating the

requirement of NIV should be optimized to ensure that the duration can be reduced as early as possible.

Our Findings Stress the Need for

- Routine side effect monitoring (skin checks, oral dryness, sleep disturbance).^{7,9}
- Preventive strategies: mask rotation, protective dressings, humidification.^{4,5}
- Patient education to reduce fear and improve adherence.^{12,13}
- Customized pressure titration and mask selection in vulnerable subgroups such as COPD.^{8,10}

The observed NIV failure rate in our cohort was 12%, which is comparable to previously reported rates of 10–20% in acute COPD exacerbations and higher rates in hypoxemic respiratory failure. NIV intolerance due to discomfort, anxiety, mask pressure injury, and aerophagia may contribute to early discontinuation and treatment failure. Recognition and early management of these complications may therefore improve NIV success. Although some correlations reached statistical significance, the magnitude of correlation coefficients was weak, suggesting limited clinical significance. These findings indicate that NIV-related side effects are likely influenced by multiple factors, including mask interface, patient tolerance, airflow leak, and duration of therapy, rather than pressure settings alone.

LIMITATIONS

This study has several limitations. First, it was a single-center study conducted at a tertiary respiratory care unit, which may limit generalizability to other settings. Second, several side effects, such as fear, pain, and sleep disturbance, were based on patient-reported measures and may be subject to reporting bias. Third, objective sleep assessment (such as polysomnography) and objective measurement of abdominal distension were not performed. Finally, mask interface type and humidification settings were not separately analyzed, which may influence the occurrence of NIV-related adverse effects. Multivariate analysis was limited by the lack of adjustment for mask type and humidification settings, which may act as confounders.

CONCLUSION

Our study demonstrates that although NIV remains an essential modality in respiratory care, it is associated with a substantial burden of both mechanical and subjective side effects. Longer duration of NIV appears to be an important determinant of these complications,

while higher pressures contribute to certain adverse effects in COPD patients. Recognition of these side effects, along with early preventive strategies and individualized NIV settings, may improve patient comfort, adherence, and overall success of NIV therapy.

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