



Influence of clinical severity and ventilation time on the use of timed inspiratory effort (TIE) as a predictor of success in ventilatory weaning

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Background: Weaning from mechanical ventilation (MV) is a critical phase in the recovery of patients undergoing prolonged ventilation. Previous studies have suggested the timed inspiratory effort (TIE) index as a potential predictor of weaning success. This study aimed to evaluate the predictive value of TIE and the impact of clinical severity and ventilation time on weaning outcomes.

Methods: A prospective observational study was conducted in patients undergoing prolonged MV. Analysis included TIE measurements, duration of MV, and clinical severity as assessed by the Simplified Acute Physiology Score 3 (SAPS3). Logistic regression and receiver operator characteristic (ROC) curve analyses were performed to determine the predictive value of TIE for weaning success. All statistical tests were performed with a significance level of $P < 0.05$.

Results: TIE showed limited utility as an independent predictor of weaning success, with an area under the ROC curve (AUC) of 0.529 and a non-significant P value ($P = 0.79$). In contrast, clinical severity as measured by the SAPS3 score was a significant predictor of weaning success ($P = 0.01$). Patients with lower SAPS3 scores were more likely to be weaned successfully.

Conclusions: TIE as an isolated tool is limited in predicting successful weaning from MV. Clinical severity, as assessed by tools such as the SAPS3 score, appears to be more relevant. Integrating multiple clinical parameters into decision models may improve weaning outcomes in ventilated patients.

Keywords: Mechanical ventilation (MV); weaning success; prolonged mechanical ventilation (PMV); Simplified Acute Physiology Score 3 (SAPS3); clinical severity

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Introduction

Background

Mechanical ventilation (MV) is a crucial resource in the management of critically ill patients, but the weaning process is particularly challenging, especially in patients undergoing MV for long periods. Patients who remain ventilated for seven days or more are at greater risk of extubation failure and complications such as respiratory muscle weakness. The prognosis of patients submitted to MV for more than 21 days will depend on a series of variables and with measurable losses, and the outcome of weaning is often influenced by factors such as diaphragmatic dysfunction and clinical complexity (1-4).

Rationale and knowledge gap

The implementation of customized strategies for ventilator

weaning has been demonstrated to be imperative for enhancing outcomes in patients undergoing protracted mechanical ventilation (PMV). The implementation of multidisciplinary protocols and advanced ventilatory technologies has had a positive impact on the success rate of weaning. Among the available technologies, neurally adjusted ventilatory assistance (NAVA) has demonstrated efficacy in enhancing patient-ventilator synchrony, reducing weaning duration, and augmenting ventilator-free days in patients experiencing challenging weaning scenarios (5-7). These findings underscore the necessity of customized approaches that integrate evidence-based strategies and innovative technologies to enhance the weaning process in patients with PMV.

Given the multifactorial nature of weaning, especially in patients with PMV, the use of reliable predictive tools is essential to assess readiness for extubation (8). Among the predictors widely used are the rapid and shallow respiration index (RSRI) and maximum inspiratory pressure (MIP), where the RSRI assesses the relationship between respiratory rate and tidal volume, while the MIP measures respiratory muscle strength (9-11). CROP index, a validated integrative index that combines dynamic compliance (C_{dyn}), respiratory rate, oxygenation [ratio of arterial oxygen pressure to alveolar oxygen pressure (P_{aO_2}/P_{AO_2})], and inspiratory muscle strength (MIP). Other indices, such as the integrative weaning index (IWI) and the P0.1/MIP ratio, where P0.1 refers to the airway occlusion pressure measured 100 ms after the onset of inspiratory effort, offer a comprehensive assessment to predict the outcome of weaning more accurately (12-14). The timed inspiratory effort (TIE) index is a recently described tool that shows promise in predicting weaning success from MV. The aim of this study was to evaluate its predictive ability in patients undergoing prolonged MV, to assess whether its accuracy is consistent with the cut-off proposed by de Souza *et al.* (15), and how clinical severity and prolonged weaning affect its effectiveness as a weaning predictor. We present this article in accordance with the STROBE reporting checklist (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-24-1764/rc>).

Methods

This was a prospective, observational study conducted in intensive care units (ICUs) at the Hospital de Clínicas of the State University of Campinas (UNICAMP), which included subjects who had been under MV for seven days or more. Selection and data collection took place between May 2022 and October 2023, with subjects participating

Highlight box

Key findings

- This study demonstrates that the timed inspiratory effort (TIE) index shows limited value as a standalone predictor of successful weaning from prolonged mechanical ventilation (MV). The receiver operator characteristic (ROC) curve analysis yielded an area under the curve of 0.529, indicating low discriminative capacity. Additionally, TIE did not reach statistical significance as a predictor in logistic regression analysis ($P=0.79$). In contrast, clinical severity, measured through the Simplified Acute Physiology Score (SAPS), emerged as a significant factor associated with weaning success ($P=0.01$), emphasizing the need to incorporate multifactorial assessments in clinical practice.

What is known and what is new?

- The TIE index has been proposed in the literature as a potential predictor for successful weaning from MV, particularly in critically ill patients.
- This study adds new evidence suggesting that while TIE can be a useful tool, it may not be reliable when used in isolation. The findings highlight the importance of considering clinical severity and duration of ventilation when predicting weaning outcomes.

What is the implication, and what should change now?

- The results suggest that clinical practice should move towards a more holistic approach in predicting weaning success, incorporating both clinical severity scores like Simplified Acute Physiology Score 3 and other factors alongside TIE. Relying solely on TIE may lead to suboptimal decisions in the weaning process.
- Future weaning protocols should integrate multifactorial assessments that combine physiological indices, clinical scores, and ventilation duration to improve prediction accuracy and patient outcomes.

after signing the informed consent form (ICF). Subjects over the age of 18, without neuromuscular disorders, with a Glasgow Coma Scale ≥ 8 were included, and subjects with hemodynamic instability, defined as mean arterial pressure (MAP) < 65 mmHg, heart rate > 100 or < 60 bpm, or significant variations such as a decrease in MAP of more than 20% or an increase in heart rate of more than 30% compared to baseline values or cognitive impairment were excluded. Clinical and demographic data was collected from electronic medical records, recording information such as diagnosis, gender, age and SAPS3 score. Data relating to the period of hospitalization such as duration of IMV, success and failure of extubation, whether or not a tracheostomy was performed and clinical outcomes were verified during the subjects' hospitalization.

A Globalmed MVD300-U digital manovacuometer, calibrated according to the manufacturer's recommendations, was used to carry out the TIE. The subjects were previously submitted to bronchial hygiene, when necessary, and placed in the supine position with the head elevated to 45 degrees. The cuff balloon was hyperinflated to avoid leaks and the subjects were pre-oxygenated with 100% fraction of inspired oxygen (FiO_2) for 2 min before the test. They were then disconnected from the mechanical ventilator for 10 seconds before the test. A unidirectional valve with 60-second occlusion was used to ensure that the patient inhaled against resistance without the air flow returning, allowing accurate measurement of inspiratory pressure. Throughout the procedure, respiratory and hemodynamic variables were monitored. The test was interrupted if the patient showed signs of intolerance such as pallor, sweating, hemodynamic instability, a 20% increase in baseline respiratory rate (RR), and desaturation [Peripheral oxygen saturation (SpO_2) $\leq 88\%$]. The TIE index was obtained from the ratio between the MIP recorded and the time taken to reach it. Given the potential influence of tracheostomy on weaning outcomes, a subgroup analysis was performed to examine differences in TIE and extubation success between tracheostomized and non-tracheostomized patients. The purpose of this analysis was to assess whether the presence of a tracheostomy could affect the predictive accuracy of the TIE index.

Ethical statement

The study was a prospective, observational study conducted in the ICUs at the Hospital de Clínicas of the State University of Campinas (UNICAMP), involving patients

who had been under MV for 7 days or more. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. Ethical approval was granted by the Ethics Committee of the Clinical Hospital of Unicamp (UNICAMP) (CAAE 37295520.00000.5404), and all participants provided informed consent prior to their inclusion in the study.

Statistical analysis

The statistical analysis included parametric and non-parametric tests, as appropriate. Student's *t* was used to compare variables with a normal distribution and the Mann-Whitney *U* test was applied to variables with a non-normal distribution. Differences in the TIE between diagnosis groups (HD) were analyzed using the Kruskal-Wallis test. The predictive capacity of the TIE was assessed using the ROC curve to determine the area under the curve (AUC). In addition, a Cox regression was performed to identify possible predictors of weaning failure, such as the Simplified Acute Physiology Score 3 (SAPS3) score and ventilation time. All statistical tests were conducted with a significance threshold set at $P < 0.05$. Pearson's correlation was employed to assess relationships between continuous variables, and binomial logistic regression was used to analyze predictors such as TIE values and extubation outcomes. The analyses were performed using Jamovi software (version 2.5) and R software (version 4.4.2), with the ggplot2 and pROC packages used for graphical representations.

The sample calculation used was based on an analysis carried out in a previous study, the aim of which was to detect a 20% difference between the groups. This calculation considered a statistical power of 80% and a significance level of 5%, resulting in a minimum sample of 78 patients. In the present study, this estimate was exceeded, with the inclusion of 81 participants.

Results

The study included 81 ICU patients who had been on MV for 7 days or more. The mean age of the participants was 57.9 ± 16.9 years, and 55% of the sample were male. The duration of MV had a median of 17 days [interquartile range (IQR), 11–30 days], while the median length of ICU stay was 25 days (IQR, 17–39 days). Patients were categorized into eight diagnostic groups, with sepsis being the most prevalent condition (35.9%), followed by respiratory disorders (23.1%). Coronary syndromes and

Table 1 Demographic, functional, and diagnostic characteristics

Variable	Values
Age (years)	57.9±16.9
TIE (cmH ₂ O/s)	1.48 (1.06–2.05)
SOFA	7±3.28
SAPS3	68.2±16.7
Length of MV (days)	17 (11.0–30.0)

Data are presented as mean ± SD or median (interquartile range). Diagnostic distribution: sepsis (35.9%), respiratory disorders (23.1%), coronary syndromes (11.5%), neurological conditions (11.5%), others (~18%). MV, mechanical ventilation; SAPS3, Simplified Acute Physiology Score 3; SD, standard deviation; SOFA, Sequential Organ Failure Assessment; TIE, timed inspiratory effort.

neurological conditions each accounted for 11.5% of cases. Polytrauma, hematologic diseases, postoperative liver transplant, abdominal surgeries, and other miscellaneous diagnoses comprised the remaining, less representative categories. The TIE index showed a median value of 1.48 cmH₂O/s (IQR, 1.06–2.05 cmH₂O/s). The SAPS3 score had a mean of 68.2±16.7, while the Sequential Organ Failure Assessment (SOFA) score averaged 7±3.28 (Table 1).

Of the total sample, 44 patients (54%) were successfully extubated, of whom 13 (16%) required reintubation due to weaning failure. Reintubation was significantly associated with mortality, as 9 of the 13 reintubated patients (69.2%) died ($P<0.01$). In addition, 42 patients (52%) underwent tracheostomy. The overall mortality rate was 34.6%, reflecting the high clinical severity of the sample.

A subgroup analysis was realized: tracheostomized *vs.* non-tracheostomized patients. The analysis included 42 tracheostomized patients (52%) and 39 non-tracheostomized patients (48%). Tracheostomized patients had a significantly longer median duration of MV [23 days (IQR, 15–33 days)] compared to non-tracheostomized patients [12 days (IQR, 9–19 days), $P<0.01$]. The median TIE index was similar between groups (1.50 cmH₂O/s in tracheostomized patients *vs.* 1.46 cmH₂O/s in non-tracheostomized patients, $P=0.68$). However, tracheostomized patients had a lower weaning success rate (38% *vs.* 72%, $P<0.001$) and a higher rate of reintubation was observed in this group. ROC curve analysis showed that the predictive ability of TIE for weaning success was lower in tracheostomized patients (AUC =0.512) compared to non-tracheostomized patients (AUC =0.584), indicating a limited discriminative ability of the index in both groups.

Analysis of the ROC curve indicated an AUC of 0.529, demonstrating the low ability of the TIE index to distinguish between patients with successful and failed weaning. These results suggest that TIE alone is not sufficient to predict ventilatory outcomes, particularly in critically ill patients on prolonged MV.

In addition, a subgroup analysis using the non-parametric Kruskal-Wallis's test was conducted across different diagnostic groups. The χ^2 value was 15.5 ($P=0.08$), indicating no statistically significant differences between the groups in relation to TIE values. However, the ε^2 coefficient of 0.207 suggested that approximately 20.7% of the variability in TIE between patients could be attributed to diagnostic differences, despite not reaching statistical significance.

A binomial logistic regression analysis was performed to assess the influence of TIE, SAPS3, and other clinical variables on extubation success. The regression revealed that TIE was a significant predictor (estimate: -0.58572, $P=0.03$), showing an inverse relationship in which higher TIE values were associated with greater likelihood of successful weaning.

The SAPS3 also showed a significant negative association with weaning success (estimate: -0.04185, $P=0.04$), reinforcing the critical role of clinical severity in determining patient outcomes.

However, other variables such as days on MV, ICU-acquired weakness (ICU-AW), and tracheostomy did not reach statistical significance in the multivariate model. Nevertheless, tracheostomy demonstrated potential clinical relevance due to its association with prolonged MV.

The ROC curve for the final model achieved an AUC of 0.795, indicating good discriminative power for predicting weaning success (Figure 1).

Furthermore, a significant negative correlation was identified between the TIE index and the SAPS3 score ($P=0.02$), indicating that patients with greater clinical severity tend to present lower TIE values.

A Cox proportional hazards regression was conducted to evaluate predictors of weaning success, using days of MV as the time variable and extubation status as the outcome. Among the evaluated predictors, SAPS3 emerged as a significant factor [hazard ratio (HR): 0.97, 95% confidence interval (CI): 0.95–0.99, $P=0.01$], indicating that higher clinical severity was associated with lower chances of successful weaning.

In contrast, TIE (HR: 1.03, 95% CI: 0.79–1.35, $P=0.83$) and age (HR: 1.02, 95% CI: 1.00–1.04, $P=0.11$) did not show statistical significance in predicting weaning outcomes. The Cox model demonstrated moderate discriminatory

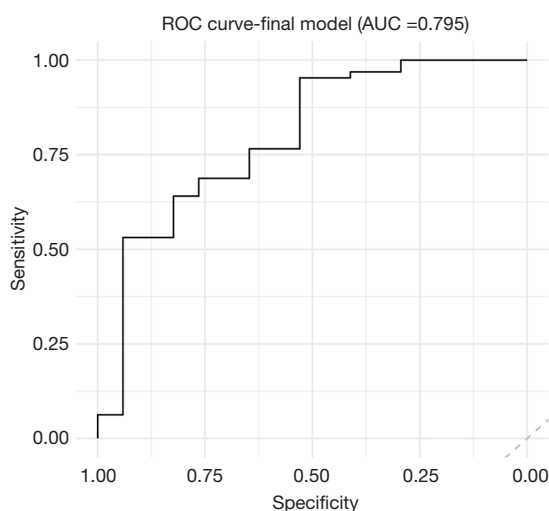


Figure 1 ROC curve for the final model predicting weaning success. The ROC curve illustrates the discriminative ability of the final logistic regression model to predict ventilatory weaning success. The model includes the variables: TIE, SAPS3, MVD, and tracheostomy. The AUC is 0.795, indicating the model's accuracy. The dashed diagonal line represents a random classification (AUC =0.5). Created using R software (version 4.4.2) with the ggplot2 and pROC. AUC, area under the curve; MVD, mechanical ventilation duration; ROC, receiver operating characteristic; SAPS, Simplified Acute Physiology Score; TIE, timed inspiratory effort.

power [Concordance =0.598, standard error (SE) =0.048], reinforcing that clinical severity plays a critical role in determining weaning success (Figure 2).

Discussion

Key findings

This study evaluated the predictive capacity of the TIE index in critically ill patients undergoing PMV. Contrary to the findings reported in studies such as de Souza *et al.* (15), which underscored the TIE index as a reliable predictor of weaning success with an AUC ranging from 0.90 to 0.96, our study observed a more circumscribed predictive capacity (AUC =0.795) (15). Multivariate logistic regression identified SAPS 3 as a significant predictor of weaning success (HR =0.97, $P=0.01$), while TIE demonstrated no significant association ($P=0.83$). These findings imply that clinical severity, as measured by SAPS3, and potentially other multifactorial components, exert a more substantial influence on weaning outcomes compared to TIE alone.

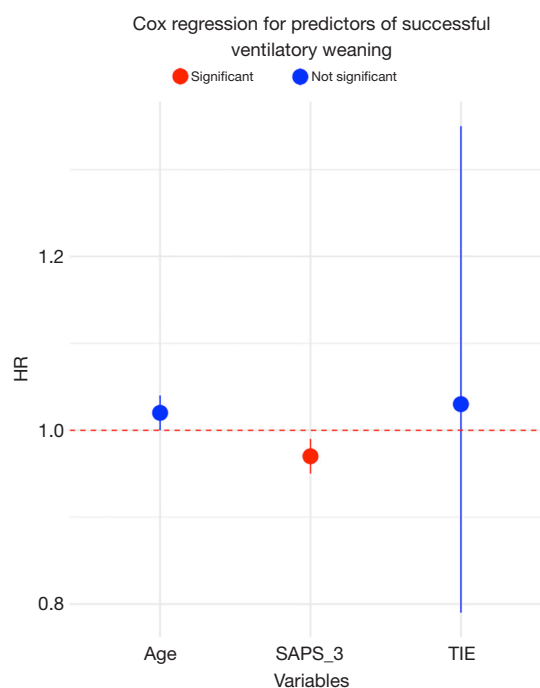


Figure 2 Cox regression analysis for predictors of successful ventilatory weaning. The figure presents the HR and 95% CIs for each variable included in the Cox regression model. The SAPS3 score was the only significant predictor, with an HR of 0.97 (95% CI: 0.95–0.99, $P=0.01$). Created using R software (version 4.4.2) with the ggplot2 package. CI, confidence interval; HR, hazard ratio; SAPS, Simplified Acute Physiology Score; TIE, timed inspiratory effort.

Strengths and limitations

Among the limitations of the study, it is worth noting that the population studied had a longer duration of MV compared to other samples in the literature, which may have influenced the results. Diaphragmatic dysfunction and ventilator-induced muscle weakness may compromise the predictive ability of TIE, which could explain the divergence from other studies. The main strength of the study was the multifactorial approach to evaluating weaning, including the use of comprehensive weaning protocols and consideration of clinical variables.

Comparison with similar researches

The results of this study show that the TIE was not a significant predictor of successful extubation, contrary to what was observed in previous studies that validated the TIE as a robust index for ventilator weaning (15). Although

the study by da Silva Neto *et al.* demonstrated that the TIE has a high accuracy, with an area under the ROC curve ranging from 0.90 to 0.96, our findings do not confirm this effectiveness, since there were no significant differences between the extubated and non-extubated groups based on the TIE value ($P=0.50$) (16). Corroborating the previous findings of the univariate analysis, our multivariate analysis identified SAPS3 as the main predictor of ventilator weaning failure ($HR=0.97$, $P=0.01$), reinforcing that TIE was not a significant predictor of successful ventilator weaning. The impact of MV time and clinical severity seems to play a more decisive role, highlighting the need for a multifactorial approach to adequately predict weaning success (17,18).

In addition, we observed a significant negative correlation between the TIE value and the SAPS3 score ($P=0.02$), suggesting that subjects with greater clinical severity had lower TIE values. This finding reinforces the hypothesis that TIE may be less effective in more severe populations, especially in subjects with complex respiratory failures and muscle impairment.

Previous studies suggest that prolonged MV is associated with diaphragmatic dysfunction and ventilator-induced respiratory muscle weakness, which may compromise the ability to predict TIE (1,3). This aligns with findings from Telias *et al.*, who noted that indices based on inspiratory effort may be less accurate in patients with significant diaphragmatic dysfunction (17). Similarly, studies such have demonstrated that ICU-AW negatively impacts respiratory muscle function, which can influence weaning outcomes. In this sense, MV time may have influenced the rate of extubation failure in our study, corroborating previous findings which indicate that subjects ventilated for prolonged periods are more likely to develop respiratory complications and weaning failure (18-21).

A recent study found that serial weekly measurements of the TIE index can predict successful weaning in patients undergoing prolonged MV. However, these findings were primarily focused on tracheostomized patients, reinforcing the need to consider patient subgroups when evaluating the predictive utility of the TIE index (22).

Although the sample included subjects with different MV times and levels of clinical severity, the statistical analysis showed homogeneity in relation to TIE, indicating a consistent behavior of the index among the subjects evaluated. However, it is important to consider the variability related to other factors, such as tracheostomy, which was performed in more than 50% of the subjects.

The use of tracheostomy in subjects with prolonged ventilation can significantly influence the outcome of weaning, since these subjects tend to face a longer and more complex weaning process (23,24). This suggests that although the TIE was homogeneous, additional factors, such as the presence of a tracheostomy, may have had an impact on the success of weaning from ventilation.

The subgroup analysis revealed that tracheostomized patients had lower weaning success rates and longer MV durations, which may have impacted the predictive capacity of the TIE index. These findings are consistent with previous studies suggesting that tracheostomy is associated with prolonged and more complex weaning processes due to respiratory muscle weakness and higher clinical severity. For example, da Silva Guimarães *et al.* (22) observed that tracheostomized patients are at a higher risk of diaphragmatic dysfunction, which may reduce the effectiveness of inspiratory effort-based indices such as the TIE. Additionally, another study highlighted that predictive indices relying on inspiratory muscle strength may be less accurate in patients with significant diaphragmatic dysfunction, a condition frequently observed in tracheostomized patients (22,25). In our study, the ROC curve analysis showed that the predictive capacity of TIE for weaning success was lower in tracheostomized patients ($AUC=0.512$) compared to non-tracheostomized patients ($AUC=0.584$). These results reinforce that the isolated use of TIE may be limited in more clinically complex populations, suggesting the need for multifactorial approaches to improve the accuracy of weaning predictions. Initially, our binomial logistic regression model included ICU-AW as a potential predictor of weaning success, considering the well-documented association between muscle weakness and prolonged MV. However, the inclusion of this variable did not improve the model's discriminative capacity and worsened its fit [Akaike Information Criterion (AIC)], leading to its exclusion from the final model. These findings align with the study, which reported that ICU-AW is a relevant factor for clinical outcomes, but its isolated impact may be limited in predictive models due to the multifactorial nature of ventilatory weaning. Similarly, Telias *et al.* suggested that diaphragmatic dysfunction, often related to ICU-AW, negatively affects the accuracy of inspiratory effort-based indices (17).

Interestingly, we observed that tracheostomized patients, who are at a higher risk of ICU-AW, had significantly lower weaning success rates. However, clinical severity, as measured by the SAPS3 score, emerged as a more robust

predictor in our model, indicating that global severity assessment may be more relevant than isolated muscle weakness indicators. These findings reinforce that TIE should be used cautiously in tracheostomized patients and those suspected of having ICU-AW. The presence of a tracheostomy may indicate a more severe and complex clinical condition, requiring a more comprehensive approach to predict weaning success. Integrating clinical severity scores such as SAPS3 and other respiratory parameters may improve prediction accuracy and assist in clinical decision-making (26,27).

We conclude that the isolated use of TIE in clinically severe populations, such as tracheostomized patients or those with acquired muscle weakness, may lead to suboptimal weaning decisions. Weaning protocols that integrate multiple predictive factors may offer better clinical outcomes for these patients.

The findings of this study serve to reinforce the significance of multifactorial assessments in predicting the success of ventilatory weaning. TIE emerged as a significant predictor, with an inverse relationship indicating that higher TIE values are associated with reduced success rates, consistent with the initial hypothesis. SAPS3 emerged as another critical determinant, emphasizing that patients with higher clinical severity have lower probabilities of successful weaning. This finding is consistent with the conclusions of previous studies that identified physiological stress and organ dysfunction as critical factors in the process of weaning. Notably, neither the number of days on MV nor the presence of ICU-AW reached statistical significance, although their potential clinical implications merit further investigation. The interaction terms did not demonstrate added predictive value, suggesting that TIE and SAPS3 alone capture the most relevant dynamics for this cohort. The AUC of 0.795 indicates the model's robust predictive performance; however, the relatively low sensitivity underscores the necessity for integrating additional predictors.

Conclusions

It is concluded that the TIE index should not be used as a standalone predictor of successful ventilator weaning in critically ill patients undergoing prolonged MV. Factors such as ventilation duration and clinical severity significantly influence weaning outcomes, highlighting the need for a multifactorial approach that integrates TIE with other clinical parameters to achieve more accurate and reliable predictions.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://jtd.amegroups.com/article/view/10.21037/jtd-24-1764/rc>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. Ethical approval was granted by the Ethics Committee of Hospital de Clínicas of the State University of Campinas (UNICAMP) (CAAE 37295520.00000.5404), and all participants provided informed consent prior to their inclusion in the study.

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