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Agreement between two methods for assessment of maximal inspiratory pressure in patients weaning from mechanical ventilation

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Background: Respiratory muscle strength in patients with an artificial airway is commonly assessed as the maximal inspiratory pressure (MIP) and is measured using analogue or digital manometers. Recently, new electronic loading devices have been proposed to measure respiratory muscle strength. This study evaluates the agreement between the MIPs measured by a digital manometer and those according to an electronic loading device in patients being weaned from mechanical ventilation.

Methods: In this prospective study, the standard MIP was obtained using a protocol adapted from Marini, in which repetitive inspiratory efforts were performed against an occluded airway with a one-way valve and were recorded with a digital manometer for 40 seconds (MIP_{DM}). The MIP measured using the electronic loading device (MIP_{ELD}) was obtained from repetitively tapered flow resistive inspirations sustained for at least 2 seconds during a 40-second test. The agreement between the results was verified by a Bland-Altman analysis.

Results: A total of 39 subjects (17 men, 55.4 \pm 17.7 years) was enrolled. Although a strong correlation between MIP_{DM} and MIP_{ELD} (R=0.73, P<0.001) was observed, the Bland-Altman analysis showed a high bias of -47.4 (standard deviation, 22.3 cm H₂O; 95% confidence interval, -54.7 to -40.2 cm H₂O).

Conclusions: The protocol of repetitively tapering flow resistive inspirations to measure the MIP with the electronic loading device is not in agreement with the standard protocol using one-way valve inspiratory occlusion when applied in poorly cooperative patients being weaned from mechanical ventilation.

Key Words: agreement; biomedical technology assessment; mechanical ventilation; respiratory muscles; respiratory system diagnostic technique

INTRODUCTION

Respiratory muscle strength (RMS) is one of the parameters associated with successful

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Subsequently, Truwit and Marini observed no significant differences between coached and non-coached MIP maneuvers when the airway pressure generated during first 100 ms of inspiratory effort ($P_{0.1}$) was greater than 2 cm H₂O during non-coached MIP maneuvers. Thus, those authors concluded that MIP can be reliably measured in critically ill patients independent of coaching using valve occlusion for 20–25 seconds, supporting the use of the method in poorly cooperative or uncooperative patients [7]. Studies of occlusion times of 40 to 60 seconds later demonstrated higher MIP values after 40 seconds of valve occlusion in poorly cooperative subjects and showed a coefficient of variation of 10% in heterogeneous populations [10-12].

Recently, a new electronic inspiratory muscle training device using automatically controlled valves is also capable of evaluating RMS as recommended by the ATS [13,14]. The device generates MIP measurements dynamically through a mathematical algorithm embedded in its software. It measures inspiratory pressure of breathing against resistance based on the volume and flow generated during every breath [15].

Faced with this new technology, idealized for training the respiratory muscle, there is a tendency for its use to be extended to RMS evaluation in patients under weaning from MV [16]. After reflecting on the heterogeneous profiles of critically ill patients, including those poorly cooperative in performing volitional maneuvers for inspiratory muscle strength assessment, we decided to evaluate the agreement between MIPs using a digital manometer (MIP_{DM}) and those from the electronic

KEY MESSAGES

- Maximal inspiratory pressures (MIPs) derived from oneway valve inspiratory occlusion and a digital manometer and those from repetitively tapered flow resistive inspirations and an electronic loading device are discordant.
- MIP assessment using repetitively tapered flow resistive inspirations and an electronic loading device is not reliable in uncooperative patients being weaned from mechanical ventilation.

loading device (MIP $_{\mbox{\tiny ELD}})$ in poorly cooperative patients being weaned from MV.

MATERIALS AND METHODS

Design and Location of Study

This was a prospective study conducted in the intensive care unit (ICU) of a public hospital. It was performed according to the Helsinki Declaration and approved by the Research Human Research Ethics Committee of the Federal University of Pernambuco (protocol: 79233017.7.0000.5208). Written informed consent was given by the legal representatives of all participants.

Sample Size

The sample size required for a Bland-Altman analysis was calculated using MedCalc statistical software version 18.11.6 (Ostend, Belgium). An expected mean difference of 5 cm H_2O , standard deviation of differences of 5 cm H_2O , and maximum allowed difference between methods of 20 cm H_2O were adopted between the MIP_{DM} and MIP_{ELD} variables, and an alpha of 0.05 for the two-tailed test and a beta of 0.90 were set. The sample estimate calculated required 34 pairs of measurements, so to account for losses, 39 volunteers were evaluated to test the study hypothesis.

Eligibility Criteria

Subjects of both sexes, aged 16–89 years, with an artificial airway by orotracheal tube or tracheostomy cannula, and fulfilling the following MV weaning criteria were eligible: respiratory rate (RR) \leq 35/min, heart rate (HR) \leq 140/min, systolic blood pressure (SBP) \geq 90 and \leq 180 mm Hg without the use of or minimal need for vasoactive drugs, PaO₂ \geq 60 mm Hg with FiO₂ \leq 40%, PEEP \leq 8 cm H₂O, PaO₂/FiO₂ \geq 150, SpO₂ \geq 90%, and no or minimal alterations in the acid–base balance (maintaining pH

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 \geq 7.32) in pressure support ventilation (PSV) mode [10,11]. The subjects were poorly cooperative, with a modified Glasgow coma scale (GCS) score ranging from 8 to 10 points, disregarding the "verbal response" component of the scale because the artificial airway was a communication barrier. Subjects with cranial hypertension, chest wall instability, bronchial-pleural or tracheal-esophageal fistulae, alveolar hemorrhage, known coronary artery disease, or upper airway leakage even after cuff hyperinsufflation were excluded from the study population [8].

Data Collection

Clinical information (age, sex, GCS, Simplified Acute Physiology Score 3, diagnosis upon ICU admission and duration of MV) were extracted from medical records. Subjects were classified into one of the following diagnostic categories as the primary cause for ICU admission: (1) respiratory disease, (2) sepsis, (3) post-operative abdominal surgery, (4) leptospirosis, (5) metabolic disease, (6) obstetrical or gynecological disease, and (7) others. Arterial blood gas values were also recorded.

In addition to the patient demographics and diagnoses, level of consciousness was assessed using a modified GCS reported in other studies [16,17] to assess motor, eye, and verbal responsiveness. The previous studies reported that the verbal component of the GCS can be omitted (because the participants were on MV) without compromising the reliability of the score. The presence of spontaneous breaths during PSV mode, along with the criteria given above for MV weaning, was considered a crucial predictive factor of successful weaning that was required to begin the MIP measurement protocols.

Protocols

The subjects were screened daily in the ICU for eligibility. The assessment protocols were performed on a single day by a trained evaluator with a mean washout period of 10 minutes between the two MIP measurement protocols to prevent clinical instability in the hemodynamic and respiratory variables (RR, HR, SpO₂, and SBP).

In a previous pilot experiment to test interference between the MIP assessment methods for randomization, using the digital manometer before using the electronic loading device produced signs of increased work while breathing and required a longer washout time (10–20 minutes). Therefore, we followed a fixed assessment sequence of (1) MIP by electronic loading device (MIP_{ELD}) and (2) MIP by digital manometer (MIP_{DM}).

Prior to the evaluation procedures, pulmonary bronchial

hygiene was performed with tracheal suctioning and preoxygenation at FiO_2 1.0. As soon as the post-aspiration vital signs stabilized, the minute volume during spontaneous breathing disconnected from the mechanical ventilator was measured for 60 seconds with a spirometer (Wright MK20; Ferraris Medical Ltd., Hertford, England) connected to the artificial airway. Then that minute volume was divided by the RR to obtain the spontaneous tidal volume in liters to calculate the rapid shallow breathing index.

Subsequently, a stabilization period of 10 minutes was provided before the start of the evaluation protocol. During that period, the subjects were connected to the ventilator. Both protocols were performed with 45° of bed head elevation, oxygenation at FiO₂ 1.0 for 1 minute, and hyperinflation of the endotracheal tube cuff to prevent air leakage during forced efforts (maintaining the cuff pressure between 25 and 30 cm H₂O). First, the assessment procedures were explained to the subjects, who were told that the strength of their respiratory muscles would be assessed. Therefore, they would be disconnected from the mechanical ventilator for 10 seconds and would breathe directly into the manometer. Each patient was warned that, during the test, it might feel "difficult to breathe for a while" [7], i.e., the non-coached MIP maneuver was performed. For both tests, patients received the same explanation [7]. By the end of the 40-second period, two measurements were accepted with variation of up to 20% between them, and the highest peak value was used for the analysis [4,8,18].

The MIP_{ELD} assessment was conducted using a POWER-Breathe KH2 (POWERbreathe International, Warwickshire, UK), an electronic inspiratory muscle assessment and training device [13] that includes a stationary first valve plate with at least one opening for the passage of air and a second valve plate rotatable relative to the first plate with at least one opening for the passage of air, which generates a tapered flow resistance to inhalation. The MIP_{ELD} was performed using the "MIP test mode analysis" function of the device, which offers different MIP values: the best maximum inspiratory pressure value (with 20% variation between measurements), the average MIP (average inspiratory pressure), and the peak pressure (peak pressure reached during the test) [14].

For this evaluation, the protocol described in the equipment user manual was adapted. All subjects were breathing through the system using a heat and moisture exchanger during the test. The device software (BreathLink, POWERbreathe International) was initially set with patient data (name, height, age, weight, and sex), and MIP Test was selected. For the MIP_{ELD}

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to be detected during the 40-second test period, inspiration should be sustained for at least 2 seconds and followed by complete expiration. We considered the highest pressure value recorded during each session to be the most representative MIP_{ELD} value because it was generated during the best maneuver, and we allowed a 20% variation between measurements to minimize the operator effect (Figure 1A) [1].

MIP_{DM} was assessed after disconnecting the patient from MV for 10 seconds. The orotracheal connection was attached to the manometer with an occluded one-way valve for 40 seconds of unencouraged inspiratory efforts. The MVD 300 digital manometer (Microhard System; Globalmed, Porto Alegre, Brazil) measures respiratory pressures using a digital transducer with a resolution of 1 cm H₂O and has a valid calibration certificate. The equipment uses specific software to provide instantaneous pressure, graphical presentation, and predicted values for each patient according to sex, age, weight, and height norms for the Brazilian population [11]. According to the operating system, pressure with a minimum duration of 1 second was recorded. The equipment emits a beep indicating that a peak pressure has been obtained, and a new alarm is sounded only if a pressure higher than one of the three previous recorded peaks is obtained (Figure 1B).

For both the MIP_{DM} and MIP_{ELD} , instructions were given before the test started, and no verbal encouragement was given to the patient during the test. During all the tests, subjects were monitored through a multiparametric monitor (echocardiogram, RR, HR, SpO₂, and blood pressure). The test was interrupted if two or more of the following occurred: $SpO_2 < 90\%$, RR >40/min, HR >140/min, mean arterial pressure 120 mm Hg. Subjective symptoms (agitation, sweating, increased rate of breathing, signs of discomfort or intolerance) were also monitored by the examiners for possible test interruption.

Data collection involved three examiners simultaneously: examiner 1 responsible for the execution of the tests. Examiner 2 in the role monitoring respiratory and hemodynamic variables during the tests and examiner 3 with function to read and register in real time the values measured by software of each instrument. So, the same trained examiner performed both tests for the same patient and was blind to the results of the test.

Statistical Analysis

The statistical analysis was performed using IBM SPSS software version 23 (IBM Corp., Armonk, NY, USA). For the MIP_{DM} and MIP_{ELD} variables, we applied the following analyses: Bland-Altman plot with description of the mean of measures, bias (difference between the measurements of the two methods and the limit values of clinically acceptable differences), standard deviation, and upper and lower limits of agreement. All the tests reported 95% confidence intervals [CIs], and P-values <0.05 were considered to be statistically significant.

RESULTS

We evaluated 254 subjects for eligibility, and 52 met the cri-

Figure 1. Recording of maximal inspiratory pressure by maximal inspiratory pressure by electronic loading device (MIP_{ELD}) and digital manometer (MIP_{DM}). (A) Recording of MIPELD. This recording was performed using POWERBreathe Breathe-Link 1.0 software (POWERBreathe Holdings, Southam, UK). (B) Recording of MIP_{DM} . The arrow indicates the peak MIP value at approximately 40 seconds. This recording was performed using MVD300 digital manometer software version 1.5 (Microhard System; Globalmed, Porto Alegre, Brazil). The numerical data are shown on the device's display and the equipment's software screen.

teria. Figure 2 provides the flowchart for subject selection. Eight subjects were unable to perform the MIP_{ELD} test because their short inspirations were not sustained for 2 seconds. In addition, data from five patients were not analyzed due to a technical error in measuring the MIP_{ELD} value. The valve plates got stuck during the test, and the patients were unable to open the valve (similar to a "sustained occlusion method, with no opening to exhale"). When that occurred, the MIP_{ELD} values were much higher than the MIP_{DM} values, so we excluded those cases due to uncertainty about their reliability. In the five excluded cases, clinical symptoms of desaturation, increased respiratory effort, restlessness, and appearance of distress were observed during the MIP_{ELD} test. The clinical characteristics of the 39 subjects whose data were analyzed are shown in Table 1.

The median MIP_{DM} was 75.0 cm H₂O (interquartile range [IQR], 55.0–103.0 cm H₂O), and the median MIP_{ELD} was 27.2 cm H₂O (IQR, 20.7–36.0 cm H₂O), with a good correlation (Rho=0.73, P<0.001) between the measures (Figure 3A). The intraclass correlation coefficient using two-way mixed effects and the absolute agreement between MIP_{DM} and MIP_{ELD} and Cronbach's alpha are shown in Table 2. The Bland-Altman plot (Figure 3B) shows a large disagreement between the MIP_{DM} and MIP_{ELD} variables, with a bias of –47.4 cm H₂O (standard deviation, 22.3; 95% CI, 54.7 to –40.2). It should be noted that the difference varied across the range of measurements, becoming larger for higher pressures.

Figure 2. Flowchart of subjects. MIP: maximal inspiratory pressure; MIP_{ELD}: maximal inspiratory pressure by electronic loading device.

DISCUSSION

The main findings of this study are that a digital manometer with a one-way valve generated the highest MIP values; there was a large disagreement between the pressures measured by the digital manometer and those from the electronic loading device; and that disagreement became larger at higher MIP values. The MIP_{DM} protocol adopted in this study follows the methodological standardization suggested by Marini et al. and ATS/ERS [4,6,8] but with the valve occlusion time modified to 40 seconds. This protocol is widely used in clinical practice and is considered the most appropriate method for assessing MIPs in MV patients [6,7]. Marini et al. [6] initially described the ma-

Table 1. Clinical characteristics of patients (n=39)

Variable	Value
Age (yr)	55.4±17.7
≤60	20 (51.3)
61–80	16 (41.0)
>80	3 (7.7)
Women	22 (56.4)
Glasgow coma scale (point)	9.6±0.7
SAPS 3 (point)	63.1±13.5
ICU admission reason	
Respiratory disease	16 (41.0)
Sepsis	9 (23.1)
Postoperative abdominal surgery	4 (10.3)
Leptospirosis	3 (7.7)
Metabolic diseases	3 (7.7)
Obstetrical & gynecological diseases	1 (2.6)
Others	3 (7.7)
Time of MV (day)	8.7±6.0
≤3	4 (11.4)
≥4 to ≤6	9 (25.7)
≥7	22 (62.9)
рН	7.4±0.1
PaO ₂ (mm Hg)	80.1±19.2
PaCO ₂ (mm Hg)	37.9±8.1
PaO_2/FiO_2	303.9±91.2
RR/VT (bpm/L)	48±16.3
MIP_{DM} (cm H_2O)	75.0 (55.0–103.0)
MIP_{ELD} (cm H_2O)	27.2 (20.7–36.6)

Values are presented as mean±standard deviation, number (%), or median (interquartile range).

SAPS: Simplified Acute Physiology Score; ICU: intensive care unit; MV: mechanical ventilation; pH: hydrogen ionic potential; PaO_2 : partial arterial oxygen pressure; $PaCO_2$: partial arterial pressure of carbon dioxide; FiO₂: inspired fraction of oxygen; RR: respiratory rate; VT: tidal volume; MIP_{DM}: maximal inspiratory pressure by digital manometer; MIP_{ELD}: maximal inspiratory pressure by electronic loading device.

Figure 3. Main results of the study. (A) Linear correlation between maximal inspiratory pressure by digital manometer (MIP_{DM}) and maximal inspiratory pressure by electronic loading device (MIP_{ED}). (B) Bland-Altman diagram between MIP_{DM} and MIP_{ED} variables plotted for the whole sample and measured in cm H₂O. SD: standard deviation.

Table 2	 ICCs 	of MIP _D	_м and	MIPELD
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Variable	ICC (95% CI)		Divoluo	Cronbach's
Variable	Single measure	Average measure	r-value	alpha
MIP _{DM}	0.98 (0.61–0.99)	0.99 (0.76–0.99)	<0.001	0.99
MIP _{ELD}	0.85 (0.37–0.95)	0.92 (0.54–0.97)	< 0.001	0.95

ICC: intraclass correlation coefficient; MIP_{DM} : maximal inspiratory pressure by digital manometer; MIP_{ELD} : maximal inspiratory pressure by electronic loading device; CI: confidence interval.

neuver for MV patients with a 25-second occlusion time, but subsequent studies indicated that that time was insufficient to reach peak pressure values [10-12]. Caruso et al. [19] observed that MIP values were increased by 30% with the use of a unidirectional valve because the constant airway blockage boosted the respiratory center chemical stimulus and improved respiratory muscle work efficiency. Therefore, the use of a unidirectional valve is indicated to measure the MIP. Discussion about the best protocol has continued, and although some authors consider 20 seconds to be long enough, others argue that 40 to 60 seconds of unidirectional valve occlusion are required for MIP measurement [9,17].

According to the Bland-Altman analysis, the MIP_{DM} and MIP_{ELD} values for subjects with an artificial airway were not in agreement when no verbal encouragement was provided during the measurement of either method. The MIP_{DM} values were significantly higher than the MIP_{ELD} values, and that discrepancy increased with pressure. According to Giavarina [20],

an ideal agreement model between two measures should have all differences equal to zero. However, degrees of error at any measurement should be considered as long as the gauge imprecision or variability is within acceptable limits.

Bland and Altman proposed an analysis of the limits of agreement to verify whether differences between methods are clinically acceptable [21]. In our study, the ranges of the upper and lower limits of agreement and their respective CIs indicate a significant difference between the pressure values obtained by the two protocols. Furthermore, the disagreement between the MIP values obtained by the two methods was not constant; we observed greater disagreement at higher MIP values. We found no previous studies with which to compare our findings about the validity of the electronic loading device for non-volitional RMS measurement in MV patients.

We attribute our results to the following methodological differences between the tests (Figure 4), which result in clinically unacceptable limits of agreement in patients on MV. First, the unidirectional characteristic of the MIP_{DM} valve results in inspiratory attempts from progressively lower lung volumes, and the MIP_{DM} values were higher than those acquired with the electronic loading device protocol. The MIP_{ELD} measurement did not use a unidirectional valve, and lung volume did not decrease during repetitive attempts. Because lung volume affects the length-tension relationship between the inspiratory muscles and chest wall and the lungs' elastic properties [4,22,23], the peak pressure at the end of the 40-second occlusion period

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Digital manometer	Electronic loading device
model MVD 300	POWERBreathe® KH2
 One-way single valve Manual occlusion method Resistance/load: isometric/constant 	 Orifice valve system with 2 plates, stationary and rotary Automatic occlusion method Resistance/load: dynamic/tapering off

Figure 4. Characteristics of the digital manometer and electronic loading device used to measure maximal inspiratory pressure in this study.

of the MIP_{DM} test was generated at or close to the residual volume, but that was not the case with the MIP_{FLD} measurement.

Second, the valve diameter of the tapered flow resistive loading device implies a different mechanical load from that in the occluded valve. The occlusion method in the MIP_{DM} evokes an isometric contraction, whereas the MIP_{ELD} method evokes a dynamic contraction. An isometric contraction induces higher muscle force than a dynamic contraction [12,13,23,24].

Third, the respiratory drive responds differently to the two MIP assessment methods. Occlusion with a one-way valve will not allow ventilation, which increases drive, whereas the MI- P_{ELD} allows volume displacement during the inspiratory efforts. Although our subjects were disconnected from the ventilator for 10 seconds prior to the start of both assessment methods to stimulate an automatic response and increase their respiratory drive by interrupting the positive airway pressure [18], the subject level of cooperation was very low, which reduced the drive [8,12].

Respiratory drive regulates respiratory muscle activity and correlates with an increase in intrinsic factors (mechanical properties and respiratory muscle function) or extrinsic factors, such as increased mechanical load. A respiratory response that changes during loading is known as a *neural response*, which seems to occur in the graph produced during MIP_{DM} testing, in which the mechanical load is maximal. In contrast, the variable respiratory drive seen in the MIP_{ELD} results could be explained by the lower mechanical load, which was influenced by the patients' poorly collaborative inspiration [5,22,23,25].

All the subjects in this study presented poor collaboration (GCS 8–10 points: at least eye opening to pain and normal flexion as the best motor response), and we assessed them with no encouragement during the MIP testing. The procedures were explained before the assessment for both methods to ensure that the degree of collaboration or understanding did not bias the results. This choice did not affect the MIP values generated by the digital manometer protocol with a unidirectional valve because that method is not much influenced by verbal commands or encouragement. Occluded successive inspiratory efforts generate peak pressures, and at the end of the occlusion period, the highest value is assumed to be the maximum inspiratory pressure [26].

In contrast, verbal commands or encouragement are key points for measuring MIP with the electronic loading device. The device was originally designed for volitional measurements in cooperative patients who are able to provide pressure generation in the early inspiratory phase, not for conditions in which such instructions cannot be followed [27]. In our poorly cooperative subjects, the inspiratory pressures measured with the electronic loading device were produced by non-encouraged breaths, which were measured dynamically with less resistance due to the automatic valve opening and closing and thus produced smaller pressure peaks.

We argue that the bias was not constant because the patients who presented less deterioration in their respiratory muscle performance in a quasi-static evaluation were able to achieve residual volume and more greatly activate their respiratory muscle fibers, which produced higher values in the MIP_{DM} test. However, because they were not encouraged to perform fast or deep inspirations and the resistance offered by the equipment in the MIP_{ELD} assessment was low, the MIP_{ELD} values remained below the value expected for patients with this profile.

Our central idea for this study was to assess the agreement between methods for measuring MIP in poorly cooperative patients being weaned from MV, especially to determine whether the strength of the respiratory muscles can be measured by both static and dynamic inspiratory maneuvers [28]. We raised the question because the electronic loading device developed for collaborative patients is being used for inspiratory muscle training in intensive care [29] and has an MIP test mode integrated into the device. Healthcare professionals tend to incorporate new devices into their clinical practice without proper technology assessment. Thus, recognizing that MIP_{DM} represents a quasi-static measure, and that MIP_{ELD} has a more dynamic character, we wondered whether these measures of inspiratory force would be interchangeable. Our data reveal that the MIP_{ELD} method has clinically unacceptable disagreement with the MIP_{DM} method for this population group.

According to our findings, the MIP_{ELD} values might not represent the maximum inspiratory effort because the device uses a dynamic valve-opening mechanism and estimates RMS us-

ing an algorithm derived from variables such as pressure, flow, and volume over time, which depend on patient cooperation to achieve optimal values. The methodological differences inherent to the equipment seem to have contributed strongly to the lower values obtained with the MIP_{ELD} method. Our results do not support application of the electronic loading device as a substitute for conventionally measured MIP in these patients.

A limitation of this study stems from the levels of understanding and cooperation required from the patients because our objective was to assess the agreement between methods among poorly cooperative subjects. Ethically, the procedure was explained to the patients, but no encouragement was given to simulate a situation of low collaboration. If the maneuvers were repeated randomly with and without encouragement, we could more clearly understand the role of encouragement on the MIP in this population being weaned from MV.

Future studies comparing dynamic RMS measurement protocols for standardized use of an electronic loading device should be conducted to meet the emerging need for reliable measurements within physiological and clinical tolerances. We also suggest that clinical trials and studies be conducted to accurately assess the role of dynamic RMS measured by electronic loading devices in estimating MV weaning success and making reliable decisions.

In conclusion, the MIP values generated by the different protocols adopted in this study were not in agreement in patients with a poor level of cooperation being weaned from MV. The use of repetitively tapered flow resistive inspirations instead of inspiratory occlusions to measure respiratory pressures is unsuitable for poorly cooperative patients with an artificial airway because it underestimates their MIP.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

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