Preliminary Evaluation of a New Index to Predict the Outcome of a Spontaneous Breathing Trial

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BACKGROUND: The available predictors of spontaneous-breathing-trial (SBT) success/failure lack accuracy. We devised a new index, the CORE index (compliance, oxygenation, respiration, and effort). OBJECTIVE: To compare the CORE index to the CROP index (compliance, rate, oxygenation, and pressure), airway-occlusion pressure 0.1 s after the start of inspiratory flow ($P_{0.1}$), and rapid shallow breathing index (RSBI) for predicting SBT success/failure in a critical care environment. METHODS: With 47 mechanically ventilated patients recovering from respiratory failure, of various causes, we prospectively examined the SBT success/failure prediction accuracy and calculated receiver operating characteristic curves, sensitivity, specificity, and likelihood ratios of CORE, CROP, $P_{0.1}$, and RSBI. RESULTS: The specificities were CORE 0.95, $P_{0.1}$ 0.70, CROP 0.70, and RSBI 0.65. The sensitivities were CORE 1.00, CROP 1.00, $P_{0.1}$ 0.93, and RSBI 0.89. The areas under the receiver operating characteristic curve were CORE 1.00 (95% CI 0.92–1.00), CROP 0.91 (95% CI 0.79–0.97), $P_{0.1}$ 0.81 (95% CI 0.67–0.91), and RSBI 0.77 (95% CI 0.62–0.88). The positive likelihood ratios were CORE 20.0, CROP 3.3, $P_{0.1}$ 3.1, and RSBI 2.5. The negative likelihood ratios were CORE 0.0, CROP 0.0, $P_{0.1}$ 0.1, and RSBI 0.2. CONCLUSIONS: The CORE index was the most accurate predictor of SBT success/failure. *Key words: mechanical ventilation; spontaneous breathing trial; CROP index; $P_{0.1}$, rapid shallow breathing index.* [Respir Care 2011;56(10):1500–1505.

Introduction

Mechanical ventilation is commonly used in the intensive care unit (ICU) to sustain lung function and protect the airways of critically ill patients. Determining which patients will tolerate removal of respiratory support and extubation is difficult. Unsuccessful weaning from mechanical ventilation often results in respiratory-muscle fatigue[1,2] and re-intubation.[3,4] Unsuccessful extubation is associated with higher mortality, prolonged mechanical ventilation, longer ICU and hospital stay, and transfer to a long-term-care facility.[5,6] Traditionally, discontinuation of mechanical ventilation and extubation were carried out after the attending clinician's evaluation, arterial blood gas analysis, and observation of the patient's clinical condi-

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tion.[7,8] This method requires clinical experience and it is nearly impossible to replicate the results and assess muscle fatigue.[7,8]

Several predictors of successful termination of ventilatory support have been validated.[9] In predicting a successful weaning, these predictors have good sensitivity but low specificity.[9] Yang and Tobin[10] proposed the CROP index:

$$CROP = [C_{dyn} \times P_{Imax} \times (P_{aO_2}/P_{AO_2})]/f$$

in which C_{dyn} is dynamic compliance, P_{Imax} is maximum inspiratory pressure, P_{AO_2} is alveolar partial pressure of oxygen, and f is respiratory rate. The CROP index has the same specificity as the individual predictors.[10] Some studies have found a high specificity for the ratio of airway-occlusion pressure 0.1 s after the start of inspiratory flow ($P_{0.1}$) to P_{Imax} to predict a successful spontaneous breathing trial (SBT).[3,11] We previously found $P_{0.1}$ to be a valuable index of respiratory-center output,[12] and it has a high enough sensitivity and specificity to contribute to better guidance of weaning from mechanical ventilation.[13] We devised the CORE index:

$$CORE = [C_{dyn} \times (P_{Imax}/P_{0.1}) \times (P_{aO_2}/P_{AO_2})]/f$$

The objective of this preliminary study was to compare the capacity of CORE, CROP, $P_{0.1}$, and rapid shallow breathing index (RSBI) to predict SBT success/failure. We hypothesized that adding $P_{0.1}$ to the CROP index would improve SBT success/failure prediction, which would decrease the number of failed SBTs and help screen patients earlier for SBT. We did not study the impact of CORE, CROP, $P_{0.1}$, or RSBI on extubation success.

Methods

This study was approved by our institution's ethics committee, and we obtained written informed consent from each patient's surrogate.

Patients

We studied 47 adult patients recovering from respiratory failure, of various causes, in our academic mixed medical/surgical ICU at Hôpital du Sacré-Coeur, Montréal, Québec, Canada. All the patients were orotracheally intubated (7.0–8.0 mm inner diameter endotracheal tube), mechanically ventilated (Evita 2 or Evita 4, Dräger, Lübeck, Germany), and monitored with electrocardiography, radial artery indwelling catheter, and pulse oximetry. All the patients were on pressure support ventilation before study inclusion and data collection.

Patients were enrolled when the underlying cause of respiratory failure had improved and all the following inclusion criteria were met: $S_{pO_2} \geq 90\%$, $P_{aO_2} \geq 60$ mm Hg, $F_{IO_2} \leq 0.4$, PEEP ≤ 5 cm H_2O, respiratory rate ≤ 35 breaths/min, rectal temperature $< 38°C$, hemoglobin ≥ 8 g/dL, no continuous intravenous sedation/analgesia (benzodiazepines, opioids, propofol, or barbiturates) for at least 48 hours, good patient cooperation, and no inotropes or vasopressors. We excluded patients with tracheotomy or hypertensive intracerebral hemorrhage. We calculated Acute Physiological and Chronic Health Evaluation (APACHE II) score for each patient.[14]

Protocol

Pressure support was initially set at 8 cm H_2O and PEEP at 4 cm H_2O, for 30 min, during which we continuously recorded vital signs. If the patient's vital signs were stable during those 30 min, we measured the required respiratory variables and arterial blood gas values to calculate CORE, CROP, $P_{0.1}$, and RSBI. The RSBI was calculated during the last minute without pressure support. Then the SBT was performed, with a T-piece and F_{IO_2} of 0.4, for 30 min. At any time during the pressure support period or the T-piece trial, if vital signs deteriorated the patient was returned to their initial ventilation mode and the SBT was deemed a failure. Figure 1 depicts the procedure algorithm. The SBT was considered successful if all following criteria were met at the end of the 30 min: respiratory rate ≤ 35 breaths/min, $P_{aO_2} \geq 60$ mm Hg, $S_{pO_2} \geq 90\%$, P_{aCO_2} variation ≤ 5 mm Hg, heart rate increase ≤ 20 beats/min, systolic blood pressure increase ≤ 30 mm Hg or decrease ≤ 20 mm Hg, and diastolic blood pressure variation ≤ 20 mm Hg. All data analysis was performed afterward so that the attending physicians were blinded to the weaning predictors, and the decision for extubation was based solely on the physician's evaluation.

We obtained $P_{0.1}$ from the ventilator. Following a passive expiration, the inspiratory valve closes and a transducer measures the airway pressure during the first 0.1 s following a patient effort; this is referred as P1.[15] The 0.1 s time interval starts when a negative pressure of -0.5 cm H_2O is measured as a result of the inspiratory effort. A second pressure reading (P2) is taken after 0.1 s. Simultaneously, the inspiratory valve opens to resume breathing. The occlusion pressure after 0.1 s ($P_{0.1}$) is defined as the difference between P2 and P1. The mean $P_{0.1}$ is calculated from 3 consecutive measurements.

Maximum inspiratory pressure was defined as the most negative pressure recorded during 20 seconds of airway occlusion.[16] C_{dyn} was calculated as the expired tidal volume (V_T) divided by the peak airway pressure minus PEEP.[17] Maximum inspiratory pressure was measured with

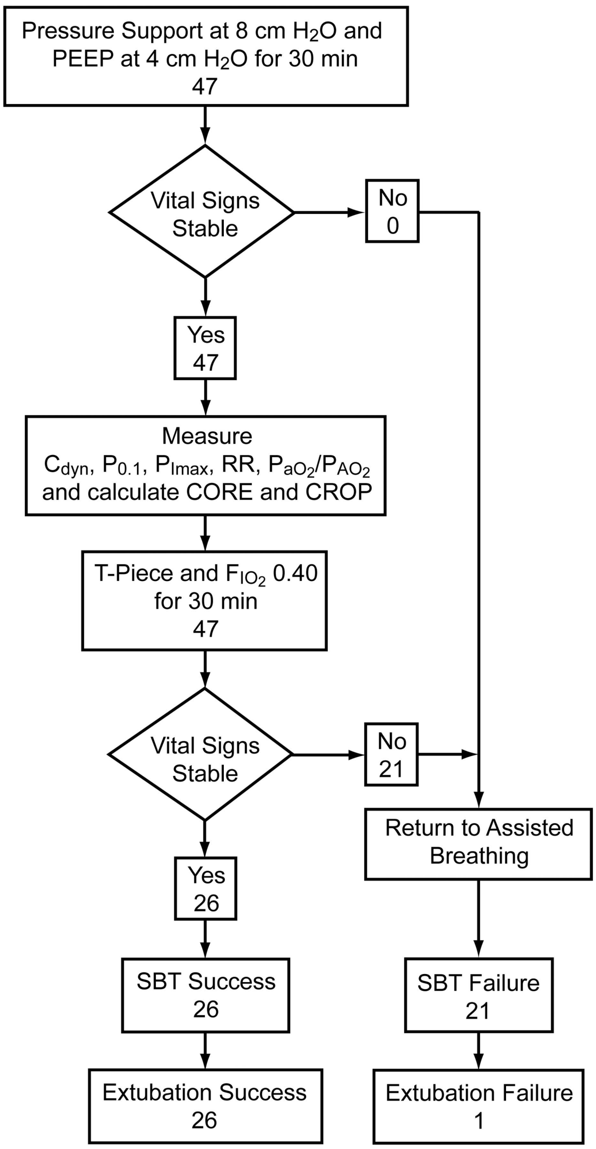

Fig. 1. Flow chart of pressure support test and spontaneous breathing trial (SBT). The rapid shallow breathing index (RSBI) was calculated on PEEP of 4 cm H_2O and without pressure support, over one minute, after the initial 30 min with pressure support of 8 cm H_2O. The extubation decision was solely with the physician, who did not know the result of the calculated indexes. The physicians decided to extubate the 26 patients who successfully completed the SBT, and also one of the 21 patients who failed the SBT. That patient failed extubation due to acute respiratory distress, hypoxemia, and hypercapnia. C_{dyn} = dynamic compliance. P_{Imax} = maximum inspiratory pressure. f = respiratory rate. P_{AO_2} = alveolar partial pressure of oxygen.

a calibrated differential pressure transducer (S&M Instruments, Doylestown, PA) and a unidirectional valve that allows expiration but not inspiration. RSBI was calculated following a continuous positive airway pressure of 4 cm H_2O and without pressure support, for one minute at the end of that 30 min.[18] Minute ventilation and respiratory rate were measured by the ventilator. V_T was obtained by dividing the minute ventilation by the respiratory rate. An arterial blood gas sample was taken while the patient was on mechanical ventilation and oxygenation status was assessed with P_{aO_2}/P_{AO_2}.[19-23]

Statistical Analysis

Values are presented as mean ± SD unless otherwise specified. For variables that had a statistically significant difference between the 2 groups, the predictive performance of the chosen variable was evaluated by calculating the area under the receiver operating characteristic curve (AUC), calculated with MedCalc 8.0 (2005 Frank Schoonjans, Belgium).[24]

To construct receiver operating characteristic curves for each variable, we varied the threshold values for predicting SBT outcome and plotted the relationship between the calculated true positive and false-positive values for each cut-off point. The AUC provides an independent discriminator at the selected threshold value.[25,26] For each variable the threshold values we used were those that resulted in the lowest false-positive and false-negative values. The comparison of the AUC values and 95% confidence intervals was via a non-parametric Wilcoxon approach.[27] $P < .05$ was considered significant. According to one arbitrary guideline,[28] a non-informative predictor has an AUC of < 0.5, a low-accuracy predictor has an AUC of 0.5–0.7, a moderately accurate predictor has an AUC of > 0.7–0.9, and highly accurate predictor has an AUC of > 0.9. Perfect prediction accuracy is an AUC of 1.[28]

Results

Table 1 describes the 47 subjects. There were 4 patients with COPD among the 12 acute-respiratory-failure patients. The mean age was 57.2 ± 18.5 years (range 22–83 y). The mean APACHE II score was 15.4 ± 4.2. The APACHE II score was not associated with the weaning variables or SBT outcomes. The mean days on mechanical ventilation before inclusion was 5.6 ± 6.1 days (range 2–18 d).

Twenty patients (43%) did not tolerate SBT (Table 2) and none of those patients could be liberated from mechanical ventilation within 48 hours. Thirteen patients had more than one reason for SBT failure. Patients who failed SBT were mechanically ventilated for longer than those who successfully completed the SBT (9.0 ± 2.6 d vs 7.1 ± 2.8 d, $P = .03$).

Twenty-six patients (55%) were successfully liberated from mechanical ventilation after the 30 min T-piece SBT, but one patient required re-intubation and mechanical ventilation within 48 hours. Individual data of the indexes and T-piece outcomes are available in the supplementary material at http://rcjournal.com.

Table 1. Subjects ($n = 47$)

Age (mean ± SD y)	57.2 ± 18.5
Male, no.	26
Female, no.	21
APACHE II (mean ± SD score)	15.4 ± 4.2
Mechanical Ventilation Days, no.	
2–3	5
3–4	8
5–6	14
> 7	20
Indication for Intubation, no.	
Trauma	12
Acute respiratory failure	12
Congestive heart failure	11
Neurological disorder	4
Others	8

APACHE = Acute Physiology and Chronic Health Evaluation

Table 2. Reasons for Spontaneous Breathing Trial Failure

Reason	No.
Tachypnea (> 35 breaths/min)	9
Hypertension (increase of > 30 mm Hg systolic or 10 mm Hg diastolic)	9
Hypercapnia (P_{aCO_2} increase of > 5 mm Hg)	7
Tachycardia (heart rate increase of > 20 beats/min)	4
Hypoxemia (P_{aO_2} < 60 mm Hg)	2

We determined the threshold value for each variable with the receiver operating characteristic curve (Fig. 2). Table 3 shows the threshold values, sensitivities, specificities, positive predictive values, negative predictive values, and AUCs. The specificity was highest for CORE (0.95), and the positive likelihood ratio was highest for CORE (20.0). The P values for the AUC comparisons are: $P = .001$ for CORE versus RSBI, $P = .003$ for CORE versus $P_{0.1}$, $P = 0.03$ for CORE versus CROP, and $P = .64$ for $P_{0.1}$ versus RSBI. All the AUCs were significantly greater than an arbitrary test that has no discriminatory value (ie, AUC < 0.5).

Discussion

The CORE index was the most powerful SBT predictor, with an AUC of 1.00 (95% CI 0.92–1.00) and had the highest sensitivity and specificity. A major difficulty for predictors of SBT is their low specificity. A low specificity favors false-positive results, which can lead to premature SBT, which could cause harmful muscle fatigue.[3,4] Unsuccessful extubation is associated with higher mortality, prolonged mechanical ventilation, longer ICU and hospital stay, and transfer to a long-term-care facility.[5,6]

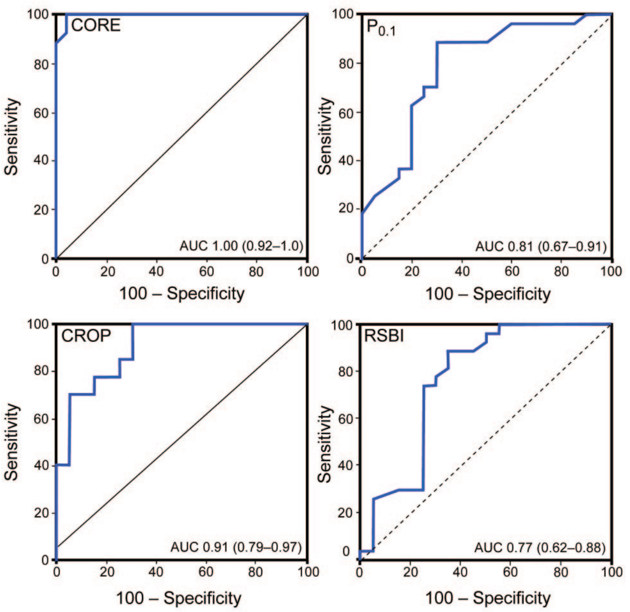

Fig. 2. Receiver operating characteristic curves for the CORE (compliance, oxygenation, respiration, and effort), the CROP index (compliance, rate, oxygenation, and pressure), airway-occlusion pressure 0.1 s after the start of inspiratory flow ($P_{0.1}$), and rapid shallow breathing index (RSBI). The threshold values that provided the fewest false positives and false negatives were: CORE > 8, CROP > 25.2, $P_{0.1} \leq 3.8$ cm H_2O, RSBI ≤ 69 breaths/min/L. The area-under-the-curve values are shown with their 95% CIs.

RSBI is the most commonly used predictor of weaning outcome. However, RSBI has low accuracy for predicting SBT outcome.[9] Comparable to what we found in the present study, the average reported sensitivity and specificity of RSBI are reported to be 0.87 ± 0.14 and 0.52 ± 0.26, respectively.[29] During the SBT the RSBI was also found to stay within the normal range even though the repeated measurements in the esophageal pressure swings showed an increase in respiratory effort and weaning failure.[30] In a recent study,[31] the use of the RSBI did not improve weaning outcome, and it delayed weaning for 2–3 days. Muscle fatigue during an SBT is a complex process that obviously cannot be well predicted based solely on respiratory rate and V_T.

We incorporated $P_{0.1}$ in the CORE index for several reasons. $P_{0.1}$ reliably reflects respiratory-center output and is not influenced by the patient's airway resistance or lung compliance.[12] In patients with acute respiratory failure, $P_{0.1}$ has a specificity of 1.00 and a sensitivity of 0.78 with a threshold 4.2 cm H_2O.[13] $P_{0.1}$ also correlates with work of breathing[32] and with the adjustment of the pressure support level.[33] We therefore feel that $P_{0.1}$ is very informative and reliable in the weaning process.

The CROP index was found to be a better predictor than RSBI in a pediatric study,[34] but CROP is less often used than RSBI, mainly because of CROP's complexity. The

Table 3. Accuracy of 4 SBT Prediction Indexes

Index	Threshold	Sensitivity (CI 95%)	Specificity (CI 95%)	Positive Predictive Value	Negative Predictive Value	Area Under the Curve (CI 95%)	Likelihood Ratio	
							Positive	Negative
CORE	> 8	1.00 (0.87–1.00)	0.95 (0.75–0.99)	0.96	1.00	1.00 (0.92–1.00)	20.0	0.0
CROP	> 25.2	1.00 (0.87–1.00)	0.70 (0.46–0.88)	0.82	1.00	0.91 (0.79–0.97)	3.3	0.0
$P_{0.1}$	≤ 3.8	0.93 (0.76–0.99)	0.70 (0.46–0.88)	0.81	0.88	0.81 (0.67–0.91)	3.1	0.1
RSBI	≤ 69	0.89 (0.71–0.98)	0.65 (0.41–0.85)	0.77	0.81	0.77 (0.62–0.88)	2.5	0.2

SBT = spontaneous breathing trial
CORE = compliance, oxygenation, respiration, and effort index
CROP = compliance, rate, oxygenation, and pressure index
$P_{0.1}$ = airway-occlusion pressure 0.1 s after the start of inspiratory flow
RSBI = rapid shallow breathing index

CORE index expresses the respiratory effort with the $P_{Imax}/P_{0.1}$ ratio, whereas the CROP index expresses it only with P_{Imax}. By further analyzing the results of the CORE index, we found that when using only $P_{0.1}$ we had to use the $1/P_{0.1}$ ratio to express a variable positively related to C_{dyn} and P_{aO_2}/P_{AO_2}. When using only the $1/P_{0.1}$ variable, without association with P_{Imax}, we obtained a specificity of 0.90, which is better than the specificity of the CROP index (0.70) and worse than that of the CORE index (0.95).

We feel this association demonstrates that the validity of the CORE index is not a matter of coincidence but truly reflects a strong predictive outcome assessment of the patient's neuromuscular ability to support spontaneous breathing without assistance. In fact, the CORE index had approximately 6 times more predictive power than $P_{0.1}$, CROP, or RSBI in the patients who tolerated SBT. Based on $P_{0.1}$, CROP, and RSBI, 13–15% of the patients in this study would not have been eligible for SBT but did successfully complete the SBT. On the other hand, based on the CORE index, only 2% of the patients would not have been eligible for SBT but did successfully complete the SBT.

The strengths of this study include that the attending physicians were blinded to the results and their patient evaluations were based solely on their judgment. The patients we studied were representative of the usual population in our medical/surgical and trauma ICU and in many similar tertiary-care centers. We believe that in the weaning process we must look at more variables than V_T and respiratory rate—variables such as amount of secretions, patient cooperation, and the level of support during the SBT—to accurately predict SBT outcome and thus to facilitate and objectively standardize the weaning process.

We specifically examined SBT success/failure, but did not study extubation as an outcome. Whether the CORE index accurately predicts extubation success/failure also remains to be determined.

Limitations

Though the statistical analysis showed highly significant differences, this study included only 47 patients, similar to other weaning studies,[4,34-36] and our results need validation in a prospective multicenter study. Our screening criteria were conservative in order to tightly control the protocol and therefore allow a better comparison of the 4 SBT predictors. However, our results might have been different with more liberal screening criteria. We focused on short-term (48 h) SBT outcome. Future studies of the CORE index should evaluate longer-term outcomes for SBT and extubation. Also, calculating the CORE index requires measurements that may limit its use in daily practice, though those measurements are already available in some ICUs. It may be possible to gather those data from a mechanical ventilator and advise the clinician about the patient's weaning status.

Conclusions

The CORE index was the most accurate predictor of SBT success/failure. If a future study confirms our results, the CORE index may help clinicians screen more patients faster and earlier in the weaning process and avoid inappropriate SBTs. Further studies are required to evaluate the CORE index in the ICU.

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