ISSN 2673-0200 (print) ISSN 2673-0251 (online)

Original article

Development and Validation of the RCC Ventilator Weaning Assessment Checklist in Patients Who Are Ventilator-Dependent

Received: Feb 27, 2019;
Accepted: April 28, 2019;
Published Apr 30,2019

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Abstract

Background: Although a number of clinical weaning profiles have been developed, they are not completely suitable since some items in the profiles are out of date and not used in our practice. Developing a weaning checklist that is applicable and suitable in our practice can help achieve better weaning outcomes. **Purpose**: The purpose of this study was to develop and validate a 26-item respiratory care unit (RCC) ventilator weaning assessment checklist for predicting successful weaning from ventilators in patients with respiratory failure. **Methods**: A retrospective descriptive research design was employed, including two steps. In step 1, a heterogeneous focus group was held with five experts to discuss and finalize the RCC ventilator weaning assessment checklist, which has three domains: physiological function, electrolyte balance, and respiratory function. The content validity index of the new checklist was then assessed. In step 2, a chart review was employed to collect data and test the criterion validity using the RCC ventilator weaning assessment checklist. A total of 180 medical records were reviewed. The patients were those with acute respiratory failure who were admitted to the RCC of a medical center in southern Taiwan between January 2011 and December 2012. Receiver operating characteristic (ROC) curve analysis was used to determine the optimal cut-off point for predicting weaning success using the checklist. Sensitivity, specificity, and positive and negative predictive values were calculated. **Results**: The content validity index of the five experts was 74% to 97% for the 26 items and 90% for the total scale. The mean age of the 180 participants was 74.28 ± 13.29 years old. Of the 180 participants, 80 (44.4%) were successfully weaned. The ROC curve analysis showed that the cut-off point for the checklist score was 67%, and the area under the curve (AUC) was 0.874 ± 0.026 ($p < .001$), with a sensitivity of 88%, a specificity of 79%, a positive predictive value of 77%, and a negative predictive value of 89%. Patients who had a score of 67% or above were 4.1 times more likely to wean successfully than those with a score lower than 67%. **Conclusions**: The 26-item RCC ventilator weaning assessment checklist is a useful tool for predicting successful weaning from ventilators for patients with acute respiratory failure. Further validation of this tool with prospective studies is needed.

Keywords: Ventilator weaning assessment checklist, ventilator-dependent, ventilator weaning, mechanical ventilation, respiratory failure.

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ISSN 2673-0200 (print) ISSN 2673-0251 (online)

Introduction

Clinically, patients with acute respiratory failure undergoing mechanical ventilation should be taken off ventilator support within seven days. However, approximately 20% to 30% of such patients experience repeated ventilator weaning failure and prolonged mechanical ventilation and then need to be transferred to a respiratory care center (RCC) for respiratory training (Lone & Walsh, 2011). Ventilator dependency can cause complications such as ventilator-associated pneumonia (prevalence of 9%-27%; Chastre, Luyt, & Fagon, 2013) and sinusitis (prevalence of approximately 27%; Agrafiotis, Vardakas, Gkegkes, Kapaskelis & Falagas, 2012), increasing the difficulties for ventilator weaning. Ventilator dependency also promotes additional stresses and burden on the patients' families (Pai et al., 2007). The medical costs for this population are gradually increasing annually (Lone & Walsh, 2011). In Taiwan, the number of patients requiring mechanical ventilation was approximately 16,902 in 2016. The annual medical costs for patients using a ventilator for more than 21 days were up to 26 billion Taiwan dollars, which ranked third in total medical expenditures for critical illnesses (Wu & Yang, 2012). Early weaning from mechanical ventilation, therefore, is vital to help patients and their families return to normal life, decrease stress, and reduce medical burden.

Failure to help successfully wean patients from mechanical ventilation may be due to failure to assess the readiness of the patients; therefore, the weaning process is initiated either too early or too late (Liu et al., 2008). Previous studies have found that using key weaning indices, as suggested by the American Chest Task Force group (Macintyre, 2012), or structured assessment tools, such as the Burns Wean Assessment Program (BWAP; Burns, Fahey, Barton, & Slack, 1991), can help practitioners assess the readiness of patients. These indices and assessment tools, however, are not completely suitable since some parameters in the existing profiles are out of date and no longer used in our practice. Therefore, the development of a new weaning checklist that is applicable in our practice in Taiwan is imperative to improve weaning outcomes.

Weaning success refers to patients being able to maintain spontaneous breathing for at least 5 days after extubation, while weaning failure is defined as patients failing to pass a spontaneous breathing trial or needing to be reintubated within 48 hours following extubation (Hayat, Khan, Khalil, & Asghar, 2017).

Ventilator weaning is a complicated process; therefore, using a structured checklist can make it possible to conduct a comprehensive assessment of the spontaneous breathing trial. Among the current existing weaning assessment tools, the BWAP developed by Burns et al. (1991) is the most commonly used. The BWAP comprises 12 items related to general physiological measurements and 14 items related to respiratory function (Burns et al., 1991). A percentage score is calculated by summing up the positive answers and dividing by the 26 items. A BWAP score of 65% or higher indicates being ready for weaning (Burns, Ryan, & Burns, 2010). During a 5-year period, Burns et al. assessed a total of 1,889 weaning attempts and found that 1,669 of these attempts were successful (Burns et al., 2010). The authors concluded that the BWAP is effective in determining weaning outcomes.

However, the BWAP has some limitations, especially with regard to its application among elderly patients. In an Epstein and Peerless (2006) study with BWAP, the authors suggested that maintaining fluid balance might be useful in weaning elderly patients from mechanical ventilation. Assessment of fluid balance, however, is not one of the items in the BWAP (Epstein, & Peerless, 2006). Likewise, some BWAP factors may lack sensitivity in cases with a longer duration of ventilator use, for example, maximal inspiratory pressure (Pimax) and maximal expiratory pressure (Pemax) in Liu et al.'s study (2008) of 319 elderly patients. In their study, these two factors were significantly different between the weaning success and

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

failure groups, which had a mean duration of 41.5 days of ventilator use (Macintyre, 2012). However, no significant between-group differences were found after ventilator use for over 60 days.

On the other hand, other clinical factors should be taken into consideration based on the evidence from previous studies showing a significant association with successful weaning outcomes. These factors are minute ventilation (V_E) (Baptistella et al., 2018; El-Khatib & Bou-Khalil, 2008), heart rate, blood pressure, peripheral capillary oxygen saturation (SpO_2), arterial blood gas, the rapid shallow breathing index (RSBI), and a high partial pressure of oxygen (PaO_2)/fraction of inspired oxygen (FiO_2) ratio (Agarwal, Kachhwah, Thakur, & Narang, 2018).

The purpose of this study was to develop and validate a new weaning assessment checklist to fit the current needs of our practice. By using the BWAP as a starting point, we developed a new RCC weaning assessment checklist. We hypothesized that this checklist could adequately assess the weaning readiness of the patients. Therefore, the predictability of this new checklist was examined with ventilator-dependent patients who had experienced respiratory failure.

Methods.

Research Design

A retrospective descriptive research design was employed, including two steps. In step 1, a heterogeneous focus group discussion was held to develop and test the content validity of the new checklist. In step 2, a chart review was conducted to test the criterion validity (in terms of the prediction ability) of the checklist.

Sample and Setting

Step 1. Five experts in the respiratory care unit were invited: two physicians, one head nurse, one nurse practitioner, and one respiratory therapist.

Step 2. A convenience sample of 180 medical records was used. Participants were patients who were admitted to the respiratory care center of a medical center in southern Taiwan during the period of January 2011 to December 2012. A total of 280 medical records were reviewed. Of them, 180 patients met the inclusion and exclusion criteria and entered this study. The inclusion criteria were as follows: (1) aged 20 years or older, (2) had a diagnosis of respiratory failure due to pulmonary diseases and transfer from the medical intensive care unit (MICU), and (3) had undergone weaning trials for mechanical ventilation. Exclusion criteria included surgical and terminally ill patients (e.g., cancer, severe/decompensated cardiopulmonary failure).

Demographic Data and Disease Characteristics

Demographic data included sex, age, and body mass index (BMI). Disease characteristics consisted of the Glasgow Coma Scale [GCS], APACHE II disease severity score, and the duration of time on the ventilator prior to transfer into the RCC.

The RCC Ventilator Weaning Assessment Checklist

The RCC ventilator weaning assessment checklist was developed based on the BWAP (Hayat et al., 2017) and the literature review. Considering that several items in the BWAP had not been used as weaning indicators in our practice, the five experts suggested that some items, including Pemax, vital capacity (not used clinically), adequate sleep/rest (subjective determination), anxiety and nervousness (subjective determination), should be removed and that items that are commonly used in real practice, including RSBI, the daily routine general pain score, and chest X-ray findings, should be added.

The RCC checklist has three domains: a 7-item physiological function assessment, a 7-item electrolyte balance assessment, and a 12-item respiratory function assessment. The physiological functions are (1) a heart rate of 60-100 beats/min and absence of arrhythmia prior to weaning; (2) a systolic blood pressure of 90-160 mmHg, a diastolic blood pressure 60-100 mmHg, and an absence of vasopressor use prior to weaning; (3) a tympanic temperature of 36-

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

37.5 °C and absence of fever prior to weaning; (4) systemic hydration: intake/output > 1500 ml for the past 3 days; (5) the daily routine general pain score: measured with a visual analogue scale (VAS) ranges between 0 (no pain) and 10 (possible worse pain); (6) absence of bowel problems (diarrhea, constipation); and (7) a chest X-ray indicating no improvement, improvement, or normal.

The 7 items of the electrolyte balance domain are (1) hematocrit > 25%; (2) albumin > 2.5 g/dl; (3) Na: 135~145 meq/L; (4) K: 3.5~5.5 meq/L; (5) Ca: 4.5~5.5 meq/L; (6) Mg: 1.7~2.8 meq/L; and (7) P: 2.5~4.5 meq/L.

The 12-item respiratory function domain consists of (1) the spontaneous respiratory rate (＜30 breaths/min); (2) absence of adventitious breathing sounds (rhonchi, wheezing); (3) sputum (amount, color, character): little, moderate, or a significant amount; color: white, yellow white, or yellow; character: thick or thin; (4) presence of tracheostomy; (5) coughing ability; (6) Pimax □ -20 - -25 cmH_2O; (7) tidal volume (V_T) > 5 ml/kg; (8) RSBI＜105 min/L; (9) V_E＜10 L/min; (10) pH: 7.35-7.45; (11) $PaCO_2$: 35~45 mmHg; and (12) PaO_2□60 mmHg.

Each item is rated on a 2-point scale (1 = yes, 0 = no). The total score ranges from 0 to 26. A percentage score is calculated by summing the number of "yes" responses and then dividing by 26 and multiplying by 100, with a higher score indicating better readiness for ventilator weaning.

Procedures for Data Collection

This study was reviewed by the Institutional Review Board of the study hospital (KMUH-IRB-20120276). We were granted permission to use the BWAP and received permission from the administrators of the hospital to conduct this study. After the checklist development, we explained the purposes and methods of this study to the RCC attending physicians. We also requested permission to access medical records from the medical records department. Then, the primary researcher screened the database for eligible cases based on the inclusion and exclusion criteria and collected data according to the checklist. The data collection period was from March 1, 2013 to July 31, 2013.

Data Analysis

Data were analyzed using SPSS for Windows (SPSS Inc., Chicago, IL), release 18.0. In step 1, the content validity index was calculated. In step 2, descriptive statistics, including the frequency distribution, percentage, mean, and standard deviation, were used to describe the data for all variables. For the criterion validity test, the criterion index was the participants' weaning outcomes. The 180 participants were grouped into either success or failure groups based on their real weaning outcomes. As a result, 80 patients were in the success group, and 100 patients were in the failure group. The differences between the groups were examined with chi-square tests for categorical variables and independent-t tests for continuous factors. The receiver operating characteristic (ROC) curve analysis was utilized to determine the characteristics of different RCC ventilator weaning assessment checklist intervals or cut-off points as a function of the weaning outcomes (success vs. failure). Test characteristics, including sensitivity, specificity, and positive and negative predictive values, were calculated for the cut-off point score.

Results

Content Validity of the RCC Ventilator Weaning Assessment Checklist

In the content validity test, the five experts were invited to evaluate three qualities of each item: importance, clarity, and usefulness. The scale options for each quality were 1 (not relevant), 2 (unable to assess relevance without item revision), 3 (relevant but needs minor alteration), or 4 (very relevant and succinct). By taking the number of items > or = 3, the content validity index (CVI) ranged from

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

74% to 97% for the 26 items and was 90% for the total scale.

The Predictability Analysis of the Checklist Assessed by Weaning Outcomes

The mean age of the 180 participants was 74.28 (SD=13.29) years. Table 1 shows the comparisons of the demographic and disease characteristics between the success group (n = 80) and the failure group (n = 100). The success group had significantly higher GCS scores (9.73 ± 4.23 vs. 7.85 ± 4.26, t = 2.94, p <0 .01) and lower APACHE II scores (15.14 ± 4.92 vs. 19.94 ± 5.84, t = 5.87, p <0 .001) than those of the failure group. The mean percentage score of the 180 participants was 66% (SD = 15%). The success group had significantly higher percentage scores prior to the weaning trials than the failure group (76% ± 9% vs. 57% ± 14%, p <0.001).

Table 1. Differences in Demographic and Disease Characteristics between the Success Group and the Failure Group

	Overall (*N*=200)	Success (*n*=80)	Failure (*n*=100)	*t* /χ^2	*p*
Variables	*M* ± SD	*M* ± SD	*M* ± SD		
Sex[a]				3.68	0.055
Male, *n* (%)	102 (57)	39 (49)	63 (63)		
Female, *n* (%)	78 (43)	41 (51)	37 (37)		
Age	74.28 ± 13.29	74.89 ± 13.87	73.79 ± 12.85	0.55	0.583
BMI	22.94 ± 5.91	23.10 ± 6.62	22.80 ± 5.29	0.34	0.740
GCS	8.68 ± 4.34	9.73 ± 4.23	7.85 ± 4.26	2.94	0.004
APACHE II	17.81 ± 5.94	15.14 ± 4.92	19.94 ± 5.84	5.87	<0.001
Duration on ventilator	19.56 ± 8.72	19.56 ± 8.82	20.01 ± 8.66	-0.77	0.440

Note. [a]χ^2 tests; BMI: body mass index; GCS: Glasgow coma scale; APACHE II: acute physiology and chronic health evaluation II.

Among the 26 items of the checklist (Table 2), significant between-group differences were found in 3 physiological functions, 2 electrolytes, and 8 respiratory variables. In the physiological function domain, the success group had significantly lower heart rates (83.54 ± 13.92 vs. 91.23 ± 18.97, *t* = -3.14, *p* < 0.01), systemic hydration (404.13 ± 616.31 vs. 716.00 ± 741.56, *t* = -3.02, *p* <0.01), and normal or improving chest X-rays (98% vs. 37%, χ^2 = 70.83, *p* < 0.001) than the failure group. They also had higher hematocrit (29.81 ± 5.09 vs. 28.01 ± 4.16, *t* = 2.61, *p* < 0.05) and albumin levels (2.72 ± 0.36 vs. 2.46 ± 0.48, *t* = 4.14, *p* < 0.001) than the failure group in the electrolyte balance domain.

In terms of the respiratory function domain, the success group had significantly lower spontaneous respiratory rates (20.54 ± 4.48 vs. 29.24 ± 6.61, t = -10.49, p <0.001), Pimax (-24.10 ± 8.87 vs. -12.80 ± 9.89, t = -7.96, p < 0.001), RSBI (61.19 ± 25.61 vs. 117.53 ± 42.20, t = -11.05, p < 0.001), and VE (7.76 ± 2.16 vs. 13.29 ± 2.82, t = -14.91, p <0.001) but higher use of tracheostomies (58% vs. 35%, χ2 = 9.09, p <0 .010), coughing ability (82% vs. 47%, χ2 = 22.18, p < 0.001), VT (372.54 ± 124.81 vs. 283.07 ± 105.29, t = 5.12, p < 0.001), and PaO2 (115.92 ± 30.03 vs. 95.80 ± 31.67, t = 4.33, p < 0.001) than the failure group.

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

Table 2. RCC Ventilator Weaning Assessment Checklist between the Success Group and the Failure Group

Variables	Success (*n*=80) *M* ± SD	Failure (*n*=100) *M* ± SD	χ^2/t	*p*
Physiological function				
Heart rate	83.54 ± 13.92	91.23±18.97	-3.14	0.002
Systolic blood pressure	135.85 ± 19.78	130.86 ± 21.30	1.61	0.109
Diastolic blood pressure	71.75 ± 14.36	70.64 ± 14.58	0.51	0.610
Tympanic temperature	36.80 ± 0.54	36.85 ± 0.72	-0.51	0.611
Intake/output balance	404.13 ± 616.31	716.00 ± 741.56	-3.02	0.003
Pain score change	0.38 ± 1.28	0.51 ± 1.51	-0.64	0.524
Absence of bowel problems[a], *n* (%)	68 (85)	75 (75)	5.07	0.226
Chest X-rays improved or normal[a], *n* (%)	78 (98)	37 (37)	70.83	0.001
Electrolytes				
Hematocrit	29.81 ± 5.09	28.01 ± 4.16	2.61	0.010
Albumin	2.72 ± 0.36	2.46 ± 0.48	4.14	0.000
Na	139.53 ± 6.34	141.79 ± 7.01	-2.25	0.056
K	4.00 ± 0.60	4.09 ± 0.69	-0.85	0.394
Ca	4.97 ± 0.51	5.10 ± 0.56	-1.58	0.116
Mg	2.40 ± 0.46	2.33 ± 0.50	0.98	0.327
P	3.39 ± 1.18	3.53 ± 1.03	-0.84	0.402
Respiratory function				
Spontaneous respiratory rate	20.54 ± 4.48	29.24 ± 6.61	-10.49	<0.001
Absence of adventitious breath sounds[a], *n* (%)	6 (8)	2(28)	3.17	0.075
Sputum (amount, color, character)[a]			10.96	0.054
Small, whitish, sticky, *n* (%)	26 (33)	14 (14)		
Moderate, whitish, sticky, *n* (%)	48 (60)	68 (68)		
Significant, yellowish/whitish, sticky, *n* (%)	6 (8)	18 (18)		
With tracheostomy[a], *n* (%)	46 (58)	33 (35)	9.09	0.003
Cough ability[a], *n* (%)	65(82)	47(47)	22.18	<0.001
Pimax	-24.10 ± 8.87	-12.80 ± 9.89	-7.96	<0.001
Tidal volume (V_T)	372.54 ± 124.81	283.07 ± 105.29	5.12	<0.001
Rapid shallow breathing index	61.19 ± 25.61	117.53 ± 42.20	-11.05	<0.001
Minute ventilation (V_E)	7.76 ± 2.16	13.29 ± 2.82	-14.91	<0.001
PH	7.43 ± 0.04	7.39 ± 0.08	3.11	0.125
$PaCO_2$	39.55 ± 7.31	40.07 ± 11.85	-0.37	0.713
PaO_2	115.92 ± 30.03	95.80 ± 31.67	4.33	<0.001

[a] Analyzed with chi-square tests.

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

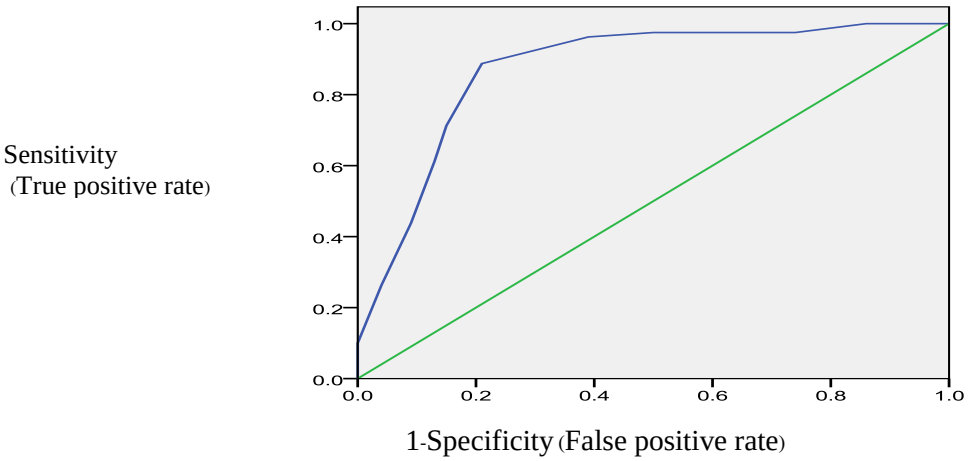

Figure 1. ROC curve of the total score of the RCC Ventilator Weaning Assessment Checklist (n=180); the cut-off point was 67.3%

The ROC results

There were 80 participants who successfully weaned and 100 who failed to wean. As shown in Figure 1, the ROC curve analysis showed that the area under the curve (AUC) was 0.874 ± 0.026 ($p < .01$). The most acceptable cut-off point of the percentage score was 67.3%, with a sensitivity of 88.8% and a 1-specificity of 21%. Table 3 presents a detailed examination of the operating characteristics of different cut-off points from percentage scores of 65% to 70%. The results indicated that scores in the range of 66% to 69% had the same sensitivity, specificity, and likelihood values for predicting weaning outcomes.

Table 3. Operating Characteristics of Different RCC Ventilator Weaning Assessment Checklist Cut points for Diagnosing Weaning Success (N=180)

Checklist score	Sensitivity (%)	Specificity (%)	Likelihood ratio (%)
≧65%	93	66	2.7
≧66%	88	79	4.1
≧67%	88	79	4.1
≧68%	88	79	4.1
≧69%	88	79	4.1
≧70%	71	84	4.4

Table 4. Diagnostic test results of the RCC Ventilator Weaning Assessment Checklist for Weaning Success

Weaning outcomes	≧67%	< 67%	Total
Success	71	9	80
Failure	21	79	100

Sensitivity：88 %（71/80）; Specificity：79%（79/100）;Predictive value（+）：77%（71/92）
Predictive value（-）：89%（79/88）; Positive Likelihood ratio（+）：4.1（0.88/1-0.79）
Negative Likelihood ratio（-）：0.15（1-0.88/0.79）; Overall, correct rate：83%（71+79/180）

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

Discussion

Overall, the results supported the use of this RCC ventilator weaning assessment checklist for determining weaning outcomes. The success group had significantly higher percentage scores prior to the weaning trials than the failure group (76% vs. 57%). The ROC analysis revealed that patients with a percentage score greater than 67% were more likely to be weaned successfully. With a cut-off point of 67%, this checklist demonstrated a sensitivity of 88% and a specificity of 79%.

Although percentage scores of 66% to 69% had the same predictability for weaning success, a percentage score of 67% was identified as the successful weaning score based on the ROC curve analysis result. Likewise, the mean score of the current study was 66%. Previously, the BWAP score was 65% (Boles et al., 2007). The sensitivity, specificity, positive predictive value, and negative predictive value of the RCC ventilator weaning assessment checklist were 88%, 79%, 77%, and 89%, respectively, whereas those of the BWAP were 77%, 60%, 20%, and 95%, respectively. The greatest difference between the BWAP and this RCC checklist was the positive predictive value (20% vs. 77%). This may be because we merely used cross-sectional retrospective data, whereas Burns, Burns, and Truwit (1994) used prospective data to analyze the predictability of the tools.

Regarding the 26 items on the RCC weaning assessment checklist, 13 items showed significant between-group differences. The success group had significantly lower heart rates, better intake and output balance and improved or normal CXR in the physiological function domain and higher hematocrit and albumin levels in the electrolyte balance domain than those of the failure group. These findings support previous studies showing that stable hemodynamics (Boles et al., 2007; Twibell, Siela, & Mahmoodi, 2003), sufficient nutritional status (Macintyre, 2012), and control of pulmonary infection (Boles et al., 2007) are important for improving oxygen delivery and reducing respiratory muscle fatigue, thus increasing the probability of weaning success. Likewise, the success group had higher GCS scores and lower APACHE II scores than those of the failure group, indicating that patients who had a stable condition were more likely to achieve favorable weaning outcomes than those who did not (Islam, 2013), suggesting the need to stablize the patient's condition before iniating the weaning process.

Participants in the weaning success group also had significantly more stable pulmonary function, including spontaneous respiratory rate, spontaneous V_T, higher PaO_2, better coughing ability, lower Pimax, lower RSBI, lower V_E, and fewer endotracheal intubations in the respiratory function domain. The RSBI can be used as an indicator of the tolerance of respiratory muscle (Blumhof, Wheeler, Thomas, McCool, & Mora, 2016), while V_E < 10 L/min can prevent respiratory muscle fatigue (Silva, & Rocco, 2018). When patients have stable and spontaneous respiratory rates, they can reach optimal V_T, retain coughing ability, and maintain a patent airway (Terzi et al., 2018).

The finding that the success group had fewer endotracheal intubations is congruent with the findings of a study by Lee, Lin, and Weng (2008). The participants in the current study were mainly elderly patients who had experienced problems such as ineffective airway protection, poor coughing ability, and ineffective airway clearance. These problems can precipate difficulties in weaning attempts. Therefore, a tracheostomy was recommended to, but commonly refused by, patients and their families the first time. We suggest that in the future, healthcare providers should put more effort into encouraging such patients to undergo a tracheostomy early to improve the success rate of weaning.

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

Limitations

This study only involved patients with pulmonary diseases from a respiratory care center located in southern Taiwan, which limits the generalizability of the study. Future research should include more participants with respiratory failure owing to different causes, such as neurological disorders. Likewise, prospective studies should be conducted to test

The usefulness of our RCC ventilator weaning assessment checklist.

Conclusions

The results supported the prediction ability of the RCC ventilator weaning assessment checklist. A percentage score of ≥ 67% could predict successful weaning with a sensitivity of 88%, a specificity of 79%, a positive predictive value of 77%, and a negative predictive value of 89%. Future studies, however, should be conducted to confirm the applicability and usefulness of the checklist.

ISSN 2673-0200 (print) ISSN 2673-0251 (online)

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