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Original Article

Acupuncture for ventilator-dependent patients at a hospital-based respiratory care center: A randomized controlled trial

Jia-Ming Chen [a], Wan-Li Chiang [a], Bin-Chuan Ji [b,c], Ruei-Jhe Jhang [a], Pei-Hsin Chen [a,d], Ya-Lun Li [a], Che-Ju Chang [a], Sung-Yen Huang [a], Tsung-Chieh Lee [a], Chia-Yun Chen [a], Ching-Hsiung Lin [b,c], Sheng-Hao Lin [b,c,e,f,*]

[a] Department of Chinese Medicine, Changhua Christian Hospital, Changhua, Taiwan
[b] Department of Chest Medicine, Changhua Christian Hospital, Changhua, Taiwan
[c] Respiratory Care Center, Changhua Christian Hospital, Changhua, Taiwan
[d] Department of Chinese Medicine, Yunlin Christian Hospital, Yunlin, Taiwan
[e] Post-Baccalaureate Medicine, National Chung Hsing University, Taichung, Taiwan
[f] Graduate Institute of Genomics and Bioinformatics, National Chung Hsing University, Taichung, Taiwan

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ABSTRACT

Background: In intensive care units, mechanical ventilation is an important therapy to help patients with dyspnea. However, long-term ventilator dependence would consume huge medical resources and increase the risk of morbidity and mortality. The aim of the study was to examine the efficacy of the acupuncture combined with western medical care on ventilator parameters in ventilator-dependent patients.

Methods: In this clinical trial, 80 ventilator-dependent patients aged 20 to 80 years old were randomly assigned to acupuncture group and control group in the respiratory care center (RCC) of Changhua Christian Hospital. Besides regular medical care and therapy, participants in the acupuncture group received acupuncture therapy at the same 17 acu-points for 20 minutes once a day, a total of 12 sessions. The ventilator parameters were recorded to evaluate the respiratory efficiency for all participants. The primary outcome was rapid shallow breathing index (RSBI), and secondary outcomes were respiratory rate (RR), tidal volume (TV) and ventilation per minute (MV),

Results: Though there was no significant difference in the parameter between the acupuncture group and the control group, we found the trend of decreasing RSBI in the acupuncture group. In subgroup analyses, the mean of RSBI significantly decreased 16.02 (with the SD in 60.84) in acupuncture group, while it increased 17.84 (with the SD in 39.38) in control group (p=0.036) after 12 sessions.

Conclusion: Acupuncture treatment can improve breathing ability of patients with respirator dependence in respiratory care center.

1. Introduction

In intensive care units, mechanical ventilation is an important therapy to help patients with dyspnea. However, long-term dependence on ventilators would consume huge medical resources and endanger the patient's physical and psychological state, increasing risk of morbidity and mortality.[1–4] Mechanical ventilation is applied to support the respiratory function of patients with critical dyspnea. Ventilator Weaning refers to the process of patient's breathing state change from depending mechanical ventilation to on their own. Ventilator weaning costs generally 7 days. However, there are 20 %~30 % patients encounter difficulty to detach from ventilation, repeated ventilator weaning failure, and various side effects accompanied by long-term dependence on ventilation.[5] Patients who continuously use ventilation over 21 days will be classified as long-term ventilation-dependent patients. And the situation mentioned above are defined to ventilator weaning failure.[6]

In view of so many complications and trouble from long-term use of ventilation, we hope to promote the combination with western medical care and medical acupuncture therapy on the ventilator parameters in ventilator-dependent patients.

According to ancient Chinese Medicine Books such as Huangdi Neijing (The Yellow Emperor's Internal Classic) and The Great Compendium of Acupuncture, there are numerous theory indicating that acupuncture can be an alternative and adjuvant therapy for complications of lung.[7] Previous retrospective observational study indicate that acupuncture is

* Corresponding author at: Department of Chest Medicine, Changhua Christian Hospital, 135 Nanhsiao Street, Changhua 50006, Taiwan.
E-mail address: 112364@cch.org.tw (S.-H. Lin).

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conducive to wean mechanical ventilation.[8] However, prospective studies on the effect of acupuncture on weaning are still lacking.

Weaning from the ventilator as soon as possible is an issue of great clinical concern. The purpose of this research was to compare the effect of patients who received acupuncture treatment along with regular western medicine treatment and the patients who received only regular western medicine treatment in the RCC of Changhua Christian Hospital.

2. Methods

This study employed a randomized controlled trial design. The study was conducted from January 2020 to December 2020, at the Respiratory Intensive Care Unit (RCC) of Changhua Christian Hospital, Changhua, Taiwan. The reporting of this study followed the CONSORT guidelines.

2.1. Trial design

We recruited volunteers who were eligible for admission from the respiratory care center (RCC) of Changhua Christian Hospital used ventilators. We calculated the sample size of our study by using the software G-Power, and the required sample size of the trial was estimated to be 26 subjects in each group, which was calculated to a controlled experiment with the significance level using a two-tailed test at alpha = 0.05, power = 0.80, and effect size = 0.8.

2.2. Participant

The respiratory care center (RCC) of Changhua Christian Hospital has patients who use or rely on respirators. Before the trial, we discussed with the doctors and nurses in Respiratory Care Center about the trial design including the criteria of the participants and the intervention.

Inclusion criteria: Patients whose age is greater than or equal to 20 years old, and those who are less than or equal to 80 years old, who are receiving care in the RCC due to illness and are dependent on respirators and patients or their family members who have signed the consent form. If the patients' consciousness level was clear, we explained the trial to them and asked them for the willing to join the trial. Otherwise, we asked their family if the patients were in consciousness disturbance.

Exclusion criteria: Patients whose age is younger than 20 years old, or older than 80 years old, patients hospitalized for lung cancer, patients or family members who cannot sign the consent form, those who have been diagnosed by medical staff and found that they have unstable vital signs or have acute symptoms, the life expectancy is less than one month, or there is medical evidence that the disease has progressed to death in the near future Inevitable (e.g., cancer or the eight major non-cancerous end-stages, etc.), subjects who are unable to cooperate with the treatment (such as unconsciousness or restlessness or may remove acupuncture needles by themselves), those who use injections or oral pressure boosters. Patients with confirmed COVID-19 were excluded due to the clinical characteristic of highly infectious ability and rapid progression.

2.3. Intervention

The acupuncture group received regular medical treatment in RCC and acupuncture treatment. Acupuncture treatment was performed at 17 acupuncture points. According to the WHO Standard Acupuncture Point Locations[9] of CV4 (single), LU5, PC6, LI4, ST36, ST37, ST39, SP6, LR3 (bilateral), and no other acupuncture points were used. In traditional Chinese Medicine theory, acupoints CV4, ST36, ST40, SP6 were used to drive out the sputum; LU5, PC6, LI4 were used to drive out the phlegm and heat from lung; and CV4, ST36, ST37, ST379, SP6 were used to nourish the Qi of Lung and Spleen.

The acupuncture needles made of stainless steel (0.25 mm in diameter, 40 mm in length; DONG-BANG, Korea) were inserted to a depth ranging from 15 to 20 mm depending on the thickness of the skin and subcutaneous fatty tissue, and the perception of the Qi was confirmed after the needles were inserted (i.e., the acupuncture therapy operator would observe that the needles were "hold" by patient's skin and muscle). The needles were left for 15 min without manipulation after being inserted. The therapy operators were Chinese Medicine doctors of Department of Chinese Medicine, Changhua Christian Hospital. Each patient in acupuncture group received acupuncture once a day, six times a week for 2 weeks, and a total of 12 sessions of acupuncture.

The control group only received the regular medical treatment in RCC, there was no acupuncture treatment was performed in the control group.

2.4. Outcome measure

The primary outcome was rapid shallow breathing index (RSBI), the ratio of RR/TV of ventilator parameters, and it is a predictor of weaning outcome.[10] Our secondary outcomes were respiratory rate (RR), tidal volume (TV) and ventilation per minute (MV), the parameters to monitor the exchange of air between the lungs and the air. RR is the number of breaths per minute, and TV is the volume of air moving in and out of the lungs in a respiratory cycle. MV is the amount of air that enters the lungs per minute, calculated as RR times TV.[11,12]

In the trial with 12 sessions, the data of RR, TV, MV was recorded after each session of treatment or observation. If the participant completed the trial, the outcome data was the ventilator parameter data collected after the 12th acupuncture treatment or observation. If the participant received less than 12 times of treatment or observation due to weaning of weaning ventilator, transfer to another hospital, dropout due to unstable vital signs or expired, the last data that were recored before the case was terminated would be the endpoint data.

RSBI was recorded before the trial, after the sixth therapy or observation, and after the last therapy and observation. If the participant completed the trial, the RSBI after the last session was the endpoint data; if the participant received less than 12 sessions of treatment or observation, the RSBI recorded after the sixth therapy or observation was the endpoint data.

2.5. Randomization methods

The participants were randomly and equally assigned into two groups by simple randomization. The study code (either the acupuncture group or the control group) was generated in software Excel by the statistician. After excluding the participants that did not meet the inclusion criteria, all participants were randomly enrolled into the acupuncture group and the control group. The eligible participants were assigned to two group according to the code in the sealed envelope by the researchers. The researchers, caregivers in RCC, and participants did not know which group they belong to until the trial began.

2.6. Ethical statement

The study was approved by the Research Ethics Committee of CCHIRB, under protocol No. 200206. This research originated from the program "Multiplex development of Chinese Medicine", a research program initiated by Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare of Taiwan, and conducted by Changhua Christian Hospital.

2.7. Statistical analyses

The ventilator parameters were collected recorded to evaluate the respiratory efficiency for all participants. The data of all 80 participants in our trial, included those patients did not receive complete 12 sessions, would be analyzed. After performing the test of normality, the comparison of ventilator parameters between the two groups was based on independent t-test if the data set was well-modeled by a normal distribution, and on Wilcoxon rank-sum test if the data set was not. The

baseline characters were analyzed by using Wilcoxon rank-sum test and Chi-Square test. "95 % confidence interval" in analyses means 95 % confidence interval of the difference when the data was analyzed based on independent t-test, and 95 % confidence interval of Monte Carlo Significance when the data was analyzed based on Wilcoxon rank-sum test. The Kaplan-Meier method estimator was performed to estimate the cumulative incidence rate of weaning. Survival analysis models factors that influence the time to an event. In our analysis, we see the successful weaning as the "event" in Kaplan-Meier method estimator.

To reduce the interference of comorbidities and complication, we need to focus on the participants with better prognosis and who have received more times of treatment or observation. In subgroup analysis, we analyzed the participants with at least 6 times treatment or observation, and excluded those cases whose ISS score was higher than 16 or was ST-segment elevation myocardial infarction when admitted to hospital, out-of-hospital cardiac arrest, septic shock, or failure of weaning many times during admission. We also estimated the cumulative incidence rate of weaning for the participants in subgroup analysis.

Statistical analyses were performed in SAS 9.4 and IBM SPSS 25.

3. Results

3.1. Subject characteristics

We recruited 96 volunteers who are eligible for admission from the respiratory care center (RCC) of Changhua Christian Hospital used ventilators. After excluding 16 participants who did not meet the inclusion criteria, all 80 ventilator-dependent patients, aged 20 to 80 years old, were randomly assigned to two groups, with 40 in acupuncture group and 40 in control group. After 12 sessions of study, 43 participants (18 in the acupuncture group and 25 in the control group) received 12 sessions of study. 37 participants (22 in the acupuncture group and 15 in the control group) did not receive complete 12 sessions of study because of weaning the ventilator, unstable vital sign and expiration (Fig. 1). Furthermore, in the 37 participants who did not receive complete 12 sessions, there were 12 participants (8 in the acupuncture group and 4 in the control group) received less than 6 sessions of study.

The baseline characteristics of the 80 participants are shown in Table 1. There were no statistically significant differences between the two groups in demographic and ventilation parameters.

3.2. Outcomes

After 12 days of trial, there were no statistically significant differences between the two groups in RR, TV, MV, and RSBI (Table 2).

Although there was no significant difference in the change of RSBI between the acupuncture group and the control group, we found the trend of decreasing RSBI in the acupuncture group (decreased in 0.37 breaths/min/L), while a little increased in the control group (increased in 0.02 breaths/min/L).

3.3. Subgroup analysis

In the subgroup analysis, we focused on the patients with better prognosis. There were 45 participants in the subgroup analysis (24 participants in the acupuncture group and 21 participants in the control group). The mean of RSBI significantly decreased in the acupuncture group, while it increased in the control group, and there were statistically significant differences between the two groups ($P = 0.036$). The changes of mean of RR in the acupuncture group was significantly higher than in the control group ($p = 0.022$). There was no significant difference of change of means in TV and MV between the acupuncture group and the control group (Table 2).

3.4. Cumulative incidence rate

After excluding the participants expired or transferred to another hospital before weaning, there are no statistically significant differences in the cumulative incidence rate of weaning between two groups. All participants in the acupuncture group successfully weaned the ventilator

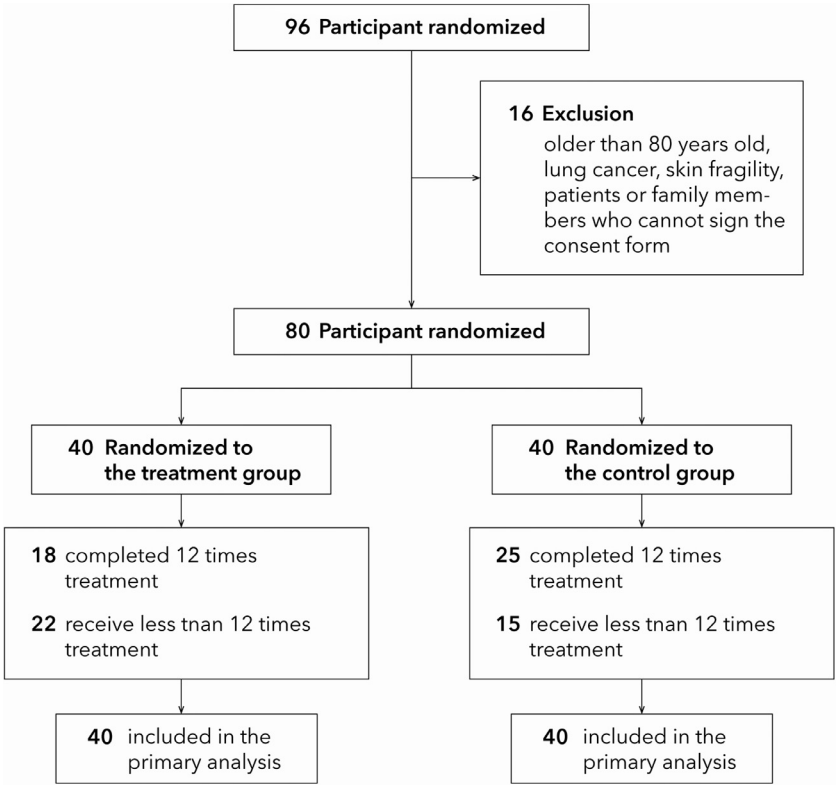

Fig. 1. Flow diagram of enrollment, randomization, and treatment.

Table 1
Baseline characteristics.

	Acupuncture group (N=40)	Control group (N=40)	P-value
Demographics variable			
Age, *year*	59.4 ± 16.3	62.6 ± 13.0	0.567 [W]
Body weight, *kilogram*	61.1 ± 13.2	64.4 ± 23.1	0.954 [W]
Hospital stays before trial, *day*	20.6 ± 16.1	23.5 ± 33.4	0.225 [C]
Gender (Male/Female), *n*	27/13	26/14	0.813 [C]
Smoking (No/Quit/Yes), *n*	23/7/10	28/5/7	0.508 [C]
Ventilator Parameters			
MIP, *cm H_2O*	-20.6 ± 21.5	-20.6 ± 29.6	0.702 [W]
MEP, *cm H_2O*	29.5 ± 15.1	37.2 ± 19.4	0.063 [W]
RR, *breaths/min*	17.0 ± 3.2	16.3 ± 5.0	0.138 [W]
TV, *mL*	589.5 ± 140.7	558.90 ± 104.7	0.544 [W]
MV, *L*	9.79 ± 3.07	9.58 ± 3.22	0.655 [W]
RSBI, *breaths/min/L*	111.4 ± 58.8	91.5 ±52.9	0.159 [W]

Values are expressed as mean ± standard deviations.
No smoking: the participant never smoked. Quit smoking: the participant smoked once but quitted before admission. Yes smoking: the participant still had the habit of smoking.
C: Chi-Square test. T: independent t-test. W: Wilcoxon rank-sum test.
*some patients might have multiple diseases that caused the usage of ventilator.

Table 2
Effects of acupuncture on ventilation outcomes.

Ventilation outcomes	Acupuncture		No treatment		P-value	Acupuncture	No treatment	P-value
	Baseline	Post	Baseline	Post		Change (Post-baseline)	Change (Post-baseline)	
ITT analysis (Baseline n=40, Post n=40 for both groups)								
RSBI, *breaths/min/L*	111.4 ± 58.8	101.99 ± 43.64	91.5 ± 52.9	91.54 ± 45.97	0.342 [T]	-9.37 ± 61.21	0.02 ± 59.63	0.525 [T]
RR, *breaths/min*	17.0 ± 3.2	20.68 ± 5.43	16.3 ± 5.0	18.88 ± 4.83	0.145 [W]	3.65 ± 6.01	2.63 ± 6.32	0.46 [T]
TV, *mL*	589.5 ± 140.7	502.8 ± 156.4	558.90 ± 104.7	485.7 ± 131.9	0.598 [T]	-86.9 ± 165.4	-73.2 ± 124.3	0.682 [T]
MV, *L*	9.79 ± 3.07	9.11 ± 3.77	9.58 ± 3.22	9.15 ± 3.99	0.557 [W]	-0.67 ± 4.63	-0.43 ± 3.47	0.751 [W]
Subgroup analysis* (Baseline n=24, Post n=24 for acupuncture group; Baseline n=21, Post n=21 for no treatment group)								
RSBI	116.88 ± 59.78	100.86 ± 45.21	78.66 ± 38.84	96.51 ± 39.34	0.006 [W]	-16.02 ± 60.84	17.84 ± 39.38	0.036 [T]
RR	17.13 ± 2.85	22.08 ± 5.27	16.38 ± 4.53	17.71 ± 4.15	0.733 [W]	5.13 ± 5.33	1.33 ± 5.31	0.022 [T]
TV	583.87 ± 134.64	516.5 ± 182.26	555.62 ± 90.22	487.1 ± 114.4	0.285 [W]	-69.5 ± 155.6	-68.5 ± 110.1	0.981 [T]
MV	9.42 ± 2.48	8.69 ± 2.77	9.27 ± 2.7	8.64 ± 4.41	0.963 [W]	-0.73 ± 3.73	-0.63 ± 4.16	0.724 [W]

Values are expressed as mean ± standard deviations.
* To reduce the interference of comorbidities and complication, we analyzed the participants with at least 6 times treatment or observation, and we excluded those cases whose ISS score was higher than 16 or was ST-segment elevation myocardial infarction when admitted to hospital, out-of-hospital cardiac arrest, septic shock or failure of weaning many times during admission.CIs: confidence intervals, MD: mean difference, MV: ventilation per minute, RR: respiratory rate, RSBI: rapid shallow breathing index, TV: tidal volume, T: independent t-test, W: Wilcoxon rank-sum test.

in 40 days, and not all participants in the control group did it (Fig. 2A). Furthermore, for the participants in subgroup analysis, the cumulative incidence rate of weaning in the acupuncture group is greater than in the control group (Fig. 2B).

3.5. Adverse events

A total of 80 participants were analyzed in this trial. Only one patient reported pain and refused the acupuncture therapy in the acupuncture group, and we terminated the case. The analysis of adverse events included 12 subjects in our trial. Some adverse events observed during the trail were severe, life-threatening, and are unrelated to the intervention. The serious adverse events observed during the trial included a case of seizure, 3 cases of fever, 4 cases of agitation, one case of respiratory failure, and one case of expire. (Supplementary Table S2)

4. Discussion

4.1. Summary of main findings

To our knowledge, this is the first study on acupuncture evaluated the parameters of ventilator in ventilator-dependent patients in respiratory care center.

Several parameters were used to predict weaning outcomes, including RSBI, age, and maximum inspiratory pressure.[13] RSBI is the one of the most common used parameters for predicting the success rate of weaning. RSBI is the ratio of RR/TV, and it is a predictor of better opportunity of weaning successfully when lower than 105 breaths/min/L.[14]

In our research, the mean of RSBI in the acupuncture group was higher in baseline (111.36 breaths/min/L in the acupuncture group, and 91.52 breaths/min/L in the control group), though there is no statistically significant difference between two groups, it might lead to a poor prognosis. In our trial, the mean of RSBI decrease into 101.99 breaths/min/L in the acupuncture group, and that means the better prognosis of extubation. On the other hand, there has been no significant change in the means of RSBI in the control group.

In subgroup analysis, we found the significant effect on decreasing RSBI in the acupuncture group (p=0.036) and all patients weaned the ventilator in 40 days (Table 2 and Fig. 2B).

4.2. Agreements and disagreements with other studies or reviews

Previous studies indicate that acupuncture and acupressure therapy have benefit on respiratory function. Recent research data and clinical observation demonstrated that stimulating meridian points, including acupuncture and acupressure, could promote successfully weaning off the mechanical ventilator by significantly increasing tidal volume and dynamic lung compliance, as well as significantly decreasing respiratory rate, heart rate, rapid shallow breathing index, dyspnea, and anxiety.[15,16]

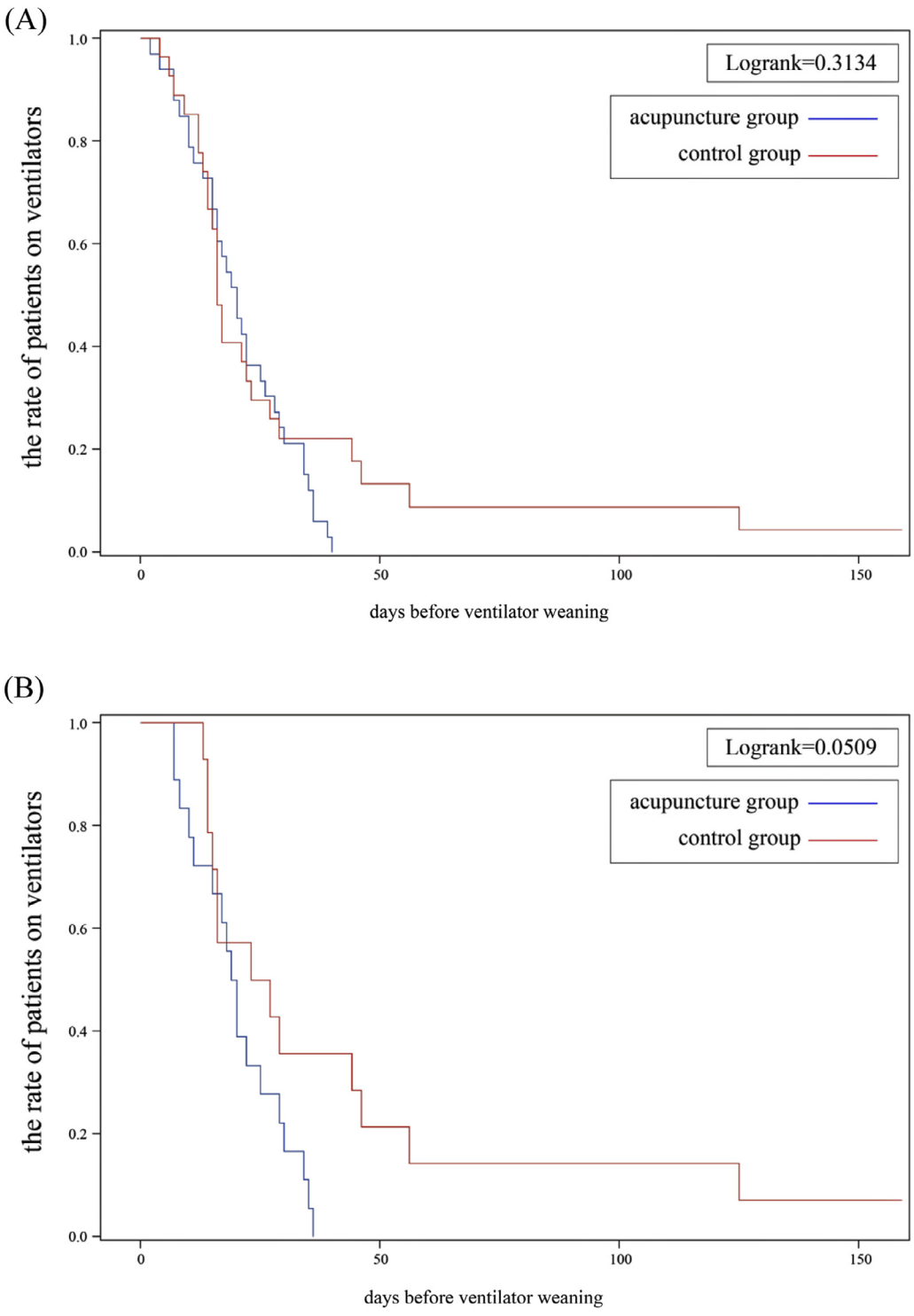

Fig. 2. The cumulative incidence rate of weaning (A) total analysis, and (B) subgroup analysis
In subgroup analysis of cumulative incidence rate of weaning, we analyzed the participants with at least 6 times treatment or observation, and we excluded those cases whose ISS score was higher than 16 or was ST-segment elevation myocardial infarction when admitted to hospital, out-of-hospital cardiac arrest, septic shock, or failure of weaning many times during admission.

Previous studies indicate the effects of improving the lung function by using acupuncture or acupressure therapies. For patients with COPD, acupressure therapy could improve the symptoms of dyspnea and anxiety.[16] Acupuncture may also be effective in improving respiratory function and the score of quality of life, such as COPD Assessment Test (CAT), St George's Respiratory Questionnaire (SGRQ), and 6-minute walking distance (6MWD).[17,18]

Although several evidence-based hypotheses have been reported, the detailed mechanism of acupuncture could not be totally elucidated.[19,20] However, the World Health Organization still recommends acupuncture for more over 100 conditions.[21] Based on available evidence, stimulating acupoint appears to be an effective and safe alternative therapy to improve the prognosis of critical condition, especially acute respiratory failure.[8] The mechanism of acupuncture might be related to the oxygen

saturation and the improvement of the function of muscles of respiration. A previous study showed that acupuncture therapy improved the blood oxygen saturation in patients with a history of respiratory system disorders.[22] Acupuncture therapy might stimulate the nerves that provide routes for somatosensory reflexes and play the role of locomotion, and it might improve voluntary respiration via the pectoralis muscles, and then improve the function of respiratory system.[23]

Previous research has shown that some comorbidities would reduce the probability of weaning. Septic shock is the risk of prolonged mechanical ventilation because of multiple organ failure and weakness.[24] Lung dysfunction might elevate airway resistance and impaired gas exchange increase the work of breathing, and it increase the difficulty of weaning the ventilation machine. Transition from mechanical ventilation to spontaneous breathing imposes an additional load on the cardiovascular system, so patients with cardiac dysfunction such as history of heart disease, heart failure, cardiac arrest and left ventricular heart failure might face the more difficult of weaning.[25,26] Patients with severe trauma severe traumatic brain injury or with poor Glasgow Coma Scale (GCS) score might have higher risk of exhibiting weaning difficulty.[27] In order to focus on those patients with better prognosis and evaluate the effect of acupuncture therapy, we excluded those cases whose ISS score was higher than 16 or was ST-segment elevation myocardial infarction when admitted to hospital, out-of-hospital cardiac arrest, septic shock, or failure of weaning many times after doing the literature review and discussing with the doctors and nurses in respiratory care center.

4.3. Implication in clinical practice

Patients sometimes fail to wean from mechanical ventilator, and prolongedly depend on mechanical ventilation support to survive.[28] Long-term dependence on ventilation also costs huge medical resources. In our study, we found that acupuncture treatment can improve the RSBI in ventilation-depending patients, especially for the patients without severe comorbidities such as heart failure, septic shock, or severe trauma injury. Acupuncture treatment would be helpful to improve the prognosis of the patients with dependence on ventilator and reduce the cost of medical expenses.

4.4. Implication in research

It was the first study on acupuncture evaluated the parameters of ventilator in ventilator-dependent patients in respiratory care center. Furthermore, acupuncture treatment is a safe and acceptable therapy, only one case withdrew because of pain in our study, and the severe adverse events observed during the trail are unrelated to the acupuncture therapy. Our study provides a safe and effective way of intervention of further studies for ventilation-dependent patients.

4.5. Limitations

The limitation of this study is that the 12-time treatment and observation was relatively short. The case size of our trial was insufficient, it was difficult to further analyze the effect of acupuncture therapy in the different types of disease and in the different modes of ventilator. The small case number of our trial and the variation in disease when admission could be the reasons that made the difference for our participant between two groups in baseline of our study. Furthermore, the group of patients with ventilator dependence has many comorbidities and complications, higher mortality, and poor progress, making it difficult to estimate the efficiency of the intervention. To evaluate the long-term effects of acupuncture therapy in those who are receiving care in the Intensive Respiratory Care Center (RCC) due to illness and are dependent on respirators, the longer treatment and follow-up periods are required.

4.6. Conclusion

Compared with the respirator parameters before treatment, the average rapid shallow breathing index (RSBI) of the patients in the acupuncture group which collected closest to the 12th treatment decreased more than the control group. In addition, from the results, we inferred that acupuncture treatment can improve breathing ability of patients with respirator dependence, and further enhance the patient's spontaneous breathing ability helping to get out of the respirator. Therefore, acupuncture combined with western medicine has clinical application value and is worth promoting.

CRediT authorship contribution statement

Jia-Ming Chen: Conceptualization, Writing – review & editing, Project administration. **Wan-Li Chiang:** Writing – review & editing. **Bin-Chuan Ji:** Resources, Writing – review & editing. **Ruei-Jhe Jhang:** Data curation, Writing – review & editing. **Pei-Hsin Chen:** Formal analysis, Writing – review & editing. **Ya-Lun Li:** Data curation, Writing – review & editing. **Che-Ju Chang:** Writing – original draft, Writing – review & editing. **Sung-Yen Huang:** Methodology, Writing – review & editing. **Tsung-Chieh Lee:** Methodology, Writing – review & editing. **Chia-Yun Chen:** Methodology, Writing – review & editing. **Ching-Hsiung Lin:** Resources, Writing – review & editing. **Sheng-Hao Lin:** Conceptualization, Writing – review & editing, Supervision.

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Conflict of interests

The authors declare that they have no competing interests.

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Ethical statement

The study was approved by the Research Ethics Committee of CCH IRB, under protocol No. 200206 in Changhua Christian Hospital, Taiwan. Informed consent was obtained from all participants.

Data availability

The obtained data in the current study are available upon reasonable request from the corresponding author.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2023.100997.

Supplementary Table S1. The reason for ventilation and past history of participants

Supplementary Table S2. Adverse events

Supplementary Table S3. CONSORT checklist

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