Trauma Mon. 2019 September; 24(5):e90398. doi: 10.5812/traumamon.90398.

Published online 2019 September 8. **Research Article**

The Effects of Using the Persian Weaning Tool on Mechanical Ventilation Outcomes Among Patients with Head Trauma: A Clinical Trial

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Received 2019 February 06; **Revised** 2019 April 05; **Accepted** 2019 July 07.

Abstract

Background: Patients with head trauma need mechanical ventilation in order to protect airway and prevent complications. However, due to the lack of well-developed weaning protocols, weaning failure rate among them is high and hence, they may need mechanical ventilation and stay in hospital for long time, resulting in heavy costs on healthcare systems and high risk of death.
Objectives: The aim of the present study was to evaluate the effects of using the Persian weaning tool on patient outcomes among patients with head trauma under mechanical ventilation.
Methods: This clinical trial was conducted in 2018 on sixty patients with head trauma who were receiving mechanical ventilation in the intensive care unit of Shahid Rajaei Hospital, Qazvin, Iran. Participants were randomly allocated to an intervention and a control group. Weaning from mechanical ventilation in these groups was performed using the Persian Weaning Tool and routine physician-directed method, respectively. Groups were compared with each other concerning weaning outcomes through the Mann-Whitney U and the chi-square tests conducted using the SPSS software (version 23.0).
Results: Weaning success rate in the intervention group was significantly greater than the control group (83.3% vs. 56.6%; P = 0.024) and the length of hospital stay in the intervention group was significantly shorter than the control group (19.9 vs. 28.9 days; P = 0.05). However, there were no significant between-group differences concerning extubation success rate (80.0% vs. 63.3%; P = 0.252) and mechanical ventilation duration (7.5 vs. 8.7 days; P = 0.3).
Conclusions: The use of the Persian Weaning tool is effective in increasing weaning success rate and shortening hospital stay but has no significant effects on extubation success rate and mechanical ventilation duration. Specific weaning assessment tools and protocols need to be developed for patients with neurologic conditions.

Keywords: Head Trauma, Brain Injury, Mechanical Ventilation, Weaning, Intensive Care Unit

1. Background

Brain injuries are one of the major health problems in the world (1). The mortality rate of brain injuries is 20% - 50% (2). Head trauma is a major mechanism for brain injuries and is the second leading cause of death in intensive care units in Iran (3). Brain injuries caused by head trauma are among the leading causes of hospitalization in intensive care units (4). Most patients with head injuries need mechanical ventilation to prevent aspiration, hypoxia, and hypercapnia (4) and reduce brain metabolic activity (5). Each year, around 200000 people with neurologic injuries undergo mechanical ventilation (2).

Mechanical ventilation is associated with different problems and side effects (6). It may increase intracranial pressure (7), cause damages to throat, vocal cords, and lung tissue, and result in immobility-related complications such as urinary tract infection, pneumonia, and clot formation in the lower extremities. Therefore, early weaning is of great importance (8). Of course, too early weaning may result in weaning failure, raise the probability of re-intubation, increase the risks of tracheal and pulmonary injuries, aspiration, and pneumonia by eight times, and increase mortality rate by 6 - 12 times (9).

Patients with head trauma usually need mechanical ventilation for longer periods of time compared with other patients hospitalized in intensive care units (10). This is due to risk factors such as altered consciousness, impairments of brain stem reflexes (such as cough, gag, and swallow reflexes), and muscular problems (such as muscular

weakness or paralysis) (11). Therefore, ventilator weaning among these patients is usually difficult so that weaning failure rate among them is relatively high (1). This rate in 55 studies on 33000 patients with head trauma was reported to be as high as 12.5% (12).

Weaning failure refers to a situation in which the patient is unable to successfully pass a trial for spontaneous breathing (13). Extubation failure also refers to the situation in which the patient is re-intubated during the first 24 - 8 hours after extubation (12). Extubation failure increases in-hospital mortality rate by five times, prolongs the duration of mechanical ventilation and hospital stays, and hence, results in adverse functional outcomes among patients with head trauma (14). Contrarily, patients who successfully tolerate the first weaning and extubation trials have better clinical outcomes (15, 16).

The weaning process for patients with head trauma is started through reducing mechanical ventilation parameters after the stabilization of clinical conditions and intracranial pressure (1). The best time for weaning is usually determined based on physicians' judgment and experience. In Iran, weaning from mechanical ventilation is performed based on physicians' personal experiences or medical orders and without using any weaning protocol or weaning readiness assessment tool (17). However, these approaches to weaning may end in weaning failure (4, 18). On the other hand, protocol-based weaning is more successful than physician-directed approaches (19) and shortens the duration of mechanical ventilation and the length of stay in intensive care unit (20). Daily assessment of patient conditions using a well-developed protocol helps identify the best time at which a given patient is able to have spontaneous breathing and can be placed on T-tube (21). There are different tools to facilitate weaning from mechanical ventilation, including acute physiology and chronic health evaluation (APACHE II) system and Burn's and Morganroth's weaning scales. However, none of these instruments specifically evaluate patient readiness for weaning (22) and hence, their use may be associated with the risk of weaning failure particularly among patients with head trauma (4).

In 2014, Bazrafshan et al. introduced a new tool for weaning readiness assessment entitled, the Persian weaning tool (PWT) (23). Its validity and reliability were assessed and confirmed later in another study (24).

2. Objectives

The aim of the present study was to evaluate the effects of using the Persian Weaning Tool on mechanical ventilation outcomes among patients with head trauma.

3. Methods

This clinical trial was conducted from March to September 2018 in the head trauma intensive care unit of Shahid Rajaei Hospital, Qazvin, Iran. Study population consisted of adult patients with head trauma under mechanical ventilation in the study setting. Number of samples for each group was calculated based on formula:

$$\begin{aligned} n &= \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \left(\sigma_1^2 + \sigma_2^2\right)}{d^2} \\ &= \frac{(2.57 + 2.32)^2 \left(2.92^2 + 2.93^2\right)}{4.01^2} \\ &\cong 27 \end{aligned} \quad (1)$$

In total, 536 patients were hospitalized during the study in the study setting. However, only 72 patients met the eligibility criteria of the study, namely hospitalization due to head trauma, an age of more than eighteen (25), altered consciousness due to head trauma with a Glasgow coma scale score of 9 or more (23), mechanical ventilation for at least 48 hours before recruitment to the study, no previous attempt for weaning before the study, no history of convulsion or chronic cardiopulmonary problems, and no spinal cord injury. Patients were excluded if they experienced spontaneous extubation, needed surgery, were transferred to other hospital wards, or experienced death (4). In total, 72 eligible patients were purposefully recruited to the study and randomly allocated to an intervention and a control group through permuted block randomization. Block size was 4.

Study data were collected using a demographic questionnaire, a mechanical ventilation parameter datasheet, and PWT. PWT includes 26 items in three main domains, namely respiratory status (9 items), cardiovascular status (4 items), and general status (13 items). PWT items are scored on a three-point scale as the following: (1) "Critical conditions which need immediate intervention", (2) "Conditions which need usual intensive care", (3) "Good conditions". Moreover, conditions which are not assessable or cannot be firmly answered are responded as "Non-assessable". Some items are scored 1 - 2 and some are scored 1 - 3 and hence, the total score of PWT can range from 26 to 75. The cutoff score of this tool is 57. Accordingly, patients are considered ready for weaning if they obtain scores greater than 57 (24).

Study intervention for participants in the intervention group was weaning from mechanical ventilation using PWT. Accordingly, participants in this group were assessed and scored using the PWT under the supervision of an attending anesthesiologist. Patients who obtained scores more than 57 were weaned and connected to the

T-tube for two hours. Patients were re-connected to ventilator if they showed the symptoms of weaning intolerance (26), i.e. respiratory rate of more than 35 per minute, heart rate of more than 140 per minute, arterial oxygen saturation of less than 90%, arterial oxygen pressure of less than 60 mmHg, and increased workload of the respiratory system characterized by sweating, dyspnea, and the use of accessory muscles of respiration (22). Patients who successfully tolerated weaning and had spontaneous breathing for more than two hours were extubated. If they did not need re-intubation during the first 48 hours after extubation, the extubation was considered successful (17). On the other hand, patients in the control group were weaned using the routine method, in which weaning readiness was determined by an attending anesthesiologist based on parameters such as respiratory rate, arterial oxygen saturation, level of consciousness, and arterial blood gases. If the anesthesiologist decided on weaning, the number of pressure-support mandatory ventilations was gradually reduced and the patient was placed on synchronized intermittent mechanical ventilation. Patients who tolerated synchronized intermittent mechanical ventilation were placed on the spontaneous ventilation mode. After that, patients who did not tolerate spontaneous ventilation were placed back on the synchronized intermittent mechanical ventilation mode, while those who tolerated spontaneous ventilation for two hours were extubated. All patients in both groups were extubated using the same extubation technique. Cuff-leak test was performed for all of them in order to assess pharyngeal inflammation because pharyngeal inflammation is among the common reasons of re-intubation (27). Moreover, an intravenous dose of a corticosteroid agent was given to each of them before extubation in order to reduce pharyngeal inflammation and the risk of re-intubation (28). Patients were monitored until hospital discharge or death. It is noteworthy that the dose of sedative agents in both groups was gradually decreased so that sedation was completely stopped 24 hours before weaning. In case of any need for sedation, an intravenous dose of a sedative agent was given.

Data were analyzed using the SPSS software (version 23.0). Normal distribution of the variables age, mechanical ventilation duration, and length of hospital stay was tested using the Kolmogorov-Smirnov test, the results of which indicated that none of them had normal distribution ($P < 0.05$). Therefore, between-group comparisons concerning these variables were made through the Mann-Whitney U test. Between-group comparisons concerning other study variables were made through the chi-square test.

This study was approved by the Ethics Committee of Qazvin University of Medical Sciences, Qazvin, Iran, and was registered in the Iranian Registry of Clinical Trials (approval code: IR.QUMS.REC.1396.318 and registration code: IRCT20171212037848N1). Moreover, the study was conducted after obtaining written permissions from the authorities of the study setting and making necessary arrangements with the staff of the intensive care unit. In addition, informed consent for participation was obtained from participants or their family members.

4. Results

In total, 72 patients were recruited to the study. However, twelve patients were excluded due to spontaneous extubation, need for surgery, transfer to other settings, or death, and the study was completed with thirty patients in each group (Figure 1). Most participants in both groups were female and all of them were under mechanical ventilation at the time of weaning using the synchronized intermittent mechanical ventilation mode. Age mean in the intervention and the control group was 42.3 ± 18.4 and 44.3 ± 19.6, respectively. Study groups did not significantly differ from each other concerning participants' demographic and clinical characteristics, namely age, gender, smoking, cause of hospitalization, and level of consciousness ($P > 0.05$; Table 1).

The rate of successful weaning in the intervention group and the control group was 83.3% and 56.6%, respectively. The between-group difference was statistically significant ($P = 0.024$). Moreover, the rate of successful extubation in these groups was respectively 80.0% and 63.3%, with no significant between-group difference ($P = 0.252$; Table 2). Respecting treatment outcomes, 86.6% of participants in the intervention group were discharged from hospital and 13.3% of them experienced in-hospital death. These values in the control group were 73.3% and 26.6%, respectively. The between-group difference concerning treatment outcome was not statistically significant ($P = 0.33$). On average, the duration of mechanical ventilation in the intervention and the control groups was respectively 7.5 and 8.7 days, with no significant between-group difference ($P = 0.3$). However, the length of hospital stay in the intervention group was significantly shorter than the control group (19.9 vs. 28.9 days; $P = 0.05$; Table 3).

5. Discussion

This study aimed to evaluate the effects of using PWT on patient outcomes among patients with head trauma under mechanical ventilation. The rate of extubation failure in the control group in this study was 36.6%, while this rate in previous studies had been 2% - 25% (14). The

Table 1. Between-Group Comparisons Concerning Participants' Demographic and Clinical Characteristics[a]

Characteristics	Group		P Value
	Intervention	Control	
Gender			0.9[b]
Female	11 (36.6)	10 (33.3)	
Male	19 (63.3)	20 (66.6)	
Glasgow coma scale score			0.69[b]
9	18 (60)	22 (73.3)	
10	11(36.6)	7 (23.3)	
11	1 (3.33)	1 (3.33)	
Cause of hospitalization			0.7[b]
Traffic injuries	28 (93.3)	26 (86.6)	
Falling (suicide)	1 (3.33)	2 (6.66)	
Heavy objects striking the head (beat)	1 (3.33)	2 (6.66)	
Smoking			0.58[b]
Yes	12 (40)	9 (30)	
No	18 (60)	21 (70)	
Age, y	42.3 ± 18.4	44.3 ± 19.6	0.6[c]

[a] Values are expressed as No. (%) or mean ± SD.
[b] The results of the chi-square test.
[c] The results of the Mann-Whitney U test.

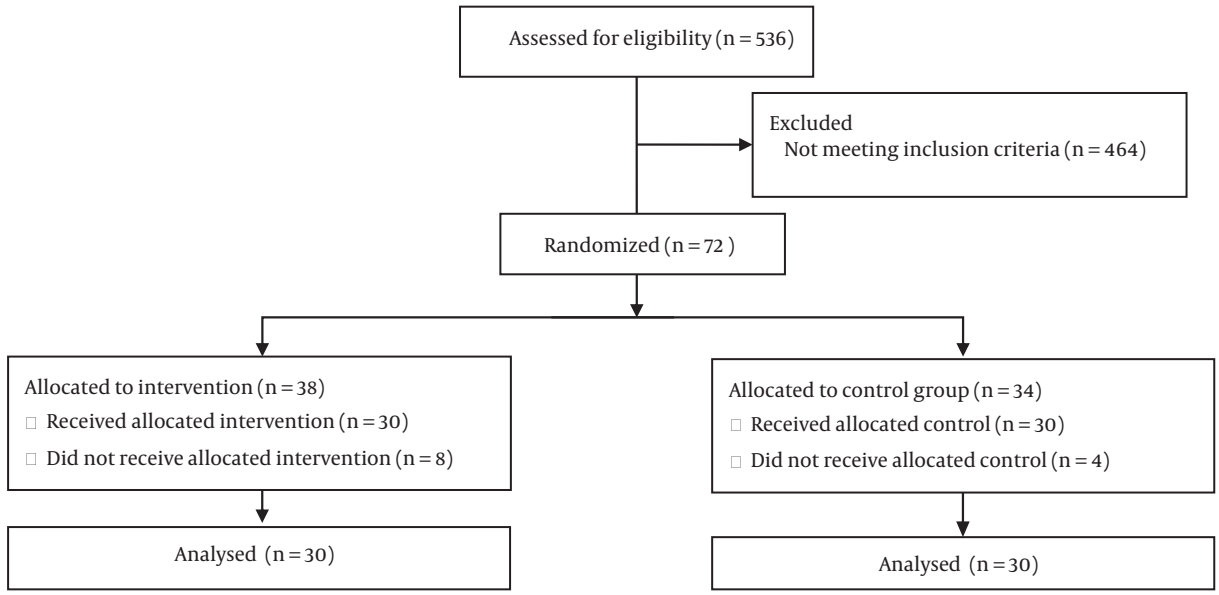

Figure 1. The flow diagram of the study

higher extubation failure rate in the present study can be attributed to the physician-directed approach to weaning used for patients in the control group. An earlier study showed that physician-directed approaches to weaning are less successful than protocol-based weaning approaches (19).

Study findings revealed that the use of PWT significantly increased weaning success rate. Similarly, previous

Table 2. Between-Group Comparisons Concerning Weaning and Extubation Success Rates[a]

Characteristics	Group		Results of the Chi-Square Test	
	Intervention	Control	χ^2	P Value
Weaning				0.024
Successful	25 (83.3)	17 (56.6)	5.07	
Unsuccessful	5 (16.6)	13 (43.3)		
Extubation				0.252
Successful	24 (80)	19 (63.3)	2.05	
Unsuccessful	6 (20)	11(36.6)		

[a] Values are expressed as No. (%).

Table 3. Between-Group Comparisons Concerning Mechanical Ventilation Duration and Hospital Stay

Characteristics	Group		Results of the Mann-Whitney U Test	
	Intervention	Control	Z	P Value
Mechanical ventilation duration, days	7.5 ± 4.2	8.7 ± 4.6	-1.04	0.3
Hospital stay, days	19.9 ± 10.3	28.9 ± 22.1	-1.8	0.05

[a] Values are expressed as mean ± SD.

studies reported that protocol-based approaches to weaning are associated with better weaning outcomes (4, 18, 19). However, our findings revealed that PWT use had no significant effects on extubation success rate. The significant effects of PWT on weaning success rate and its insignificant effects on extubation success rate are attributable to the fact that weaning success is a short-term outcome which is achieved during two hours, while extubation success is a long-term outcome which is achieved in 24 - 48 hours and hence can be affected by a wide variety of factors.

We also found that PWT use did not significantly affect the duration of mechanical ventilation. However, previous studies reported that protocol-based weaning approaches can reduce mechanical ventilation time (17). This contradiction may be attributed to the fact that our participants were patients with brain injuries induced by head trauma, while those studies were mainly conducted on patients with medical or surgical problems. Similarly, a meta-analysis on ten clinical trials reported that patients with neurologic conditions are different from other patients respecting their response to protocol-based weaning approaches (18). Another study also reported that patients with neurologic conditions are affected by a unique series of problems related to airway management and mechanical ventilation (2). For instance, these patients may suffer from intracranial bleeding, cerebral edema, impaired cough reflex, and spinal cord injuries which can dramatically affect not only the weaning process, but also the final prognosis (1, 29). Therefore, further studies are needed to develop specific weaning protocols for patients with neurologic conditions (29).

The other finding of the present study was that PWT use significantly shortened hospital stay. This is in line with the findings of a former study which reported that the use of Burn's weaning scale significantly reduced the length of hospital stay (30). The insignificant effects of PWT use on mechanical ventilation time and its significant effects on hospital stay in the present study may be due to the fact that ventilator weaning among patients with head trauma is affected by numerous factors such as the level of consciousness, intracranial pressure, and the type of intracranial lesion, while PWT does not include items on these factors.

5.1. Conclusions

This study shows the effectiveness of PWT use in increasing weaning success rate and shortening hospital stay and its insignificant effects on extubation success rate and mechanical ventilation duration. Therefore, this tool can be used to facilitate weaning from mechanical ventilation and improve weaning outcomes. However, PWT does not include items on some parameters related to neurologic status such as intracranial pressure, cerebral perfusion pressure, and the level of consciousness which can determine the outcomes of mechanical ventilation and weaning among patients with neurologic conditions. Therefore, specific weaning assessment tools and protocols need to be developed for patients with neurologic conditions.

5.2. Limitations

The number of eligible patients and the number of sampling settings for this study were limited.

Acknowledgments

The authors would like to sincerely thank the authorities of Shahid Rajaei hospital, Qazvin, Iran, the head nurse and the nursing staff of the intensive care unit of the hospital, and the patients and their family members who participated in the study.

Footnotes

Authors' Contribution: Leili Yekefallah: Design of proposal and acquisition of data and analysis of data; Sareh Mohammadi: Interpretation of data and supervise the research team; Siamak Yaghoubi: Writhing and translation of manuscript; Maryam Mafi: Revise and publication of manuscript.

Conflict of Interests: None of the contributors has any conflict of interest.

Funding/Support: No funding source.

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