

Spontaneous Breathing Trial with Pressure Support-Ventilation versus “T-Tube” for Head Trauma Patient: A Randomized Controlled Clinical Trial

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Abstract

Background: Assessing patients' readiness for weaning through spontaneous breathing trial (SBT) is a reliable method for weaning and extubation of patients. Until now, there are controversies regarding the best SBT method.

Objective: This study sought to compare the clinical outcomes of the T-piece and pressure support ventilation (PSV) SBT methods among patients with traumatic brain injury.

Methods: In this randomized controlled trial, 72 patients under mechanical ventilation were recruited from the intensive care unit of Shahid Rajaei hospital, Qazvin, Iran, and randomly allocated to an intervention or control group. SBT was conducted in the study group. In the control group, it was done through the T-piece and PSV (with pressure support of less than 8 cm H₂O), respectively. The groups were compared with each other respecting weaning outcomes, extubation success, length of mechanical ventilation, length of hospital stay, and mortality rate. Data were compared using the Chi-square and the independent-sample *t*-tests.

Results: Weaning success rate in the T-piece group was significantly greater than the PSV group ($P=0.024$), while the post-weaning length of hospital stay in the T-piece group was significantly shorter than the PSV group ($P=0.05$). There were no significant differences in extubation success rate and length of mechanical ventilation between the groups ($P>0.05$).

Conclusion: The T-piece method for SBT could be better tolerated by patients with traumatic brain injury compared with PSV.

Keywords: Spontaneous breathing trial, Mechanical ventilation, Weaning, Traumatic brain injury.

Introduction

Traumatic brain injury (TBI) is one of the major health challenges in the world.¹ It is among the common causes of hospitalization in an intensive care unit (ICU) and use of mechanical ventilation (MV).² Every year, 200,000 people need the MV due to secondary neurological problems.³

Generally, TBI causes an inflammatory response, which results in the migration of inflammatory cells to the lung tissue, where they cause an inflammatory response and respiratory problems.⁴ TBI can also aggravate respiratory problems through altering consciousness, reducing respiratory rate, increasing airway pressure, and reducing lung compliance.

Because of different respiratory problems, patients with TBI generally need respiratory support through MV.⁵ MV for these patients is used to prevent aspiration, hypoxia, and

hypercapnia² as well as reduce brain metabolic activity.^{6,7} MV for patients with hypercapnia and hypoxia helps reduce respiration workload, control minute volume, promote gas exchange in the alveoli, and correct ventilation-perfusion imbalance.⁸ Nonetheless, MV is associated with some complications such as parenchymal lung injury, ventilator-associated pneumonia, respiratory muscle weakness, sinusitis, gastrointestinal bleeding, neurological disorders, prolonged hospital stay, increased treatment costs and mortality rate.⁹

Timely weaning from MV is a key factor in preventing MV-associated complications¹⁰ and improving patient outcomes.¹¹ Weaning is the process of a gradual decrease in MV¹² and delegating respiration from a ventilator to the patient.¹³ Weaning is among the major challenges for healthcare providers in ICU.¹⁴ The weaning of patients with

TBI is more difficult and more prone to failure¹⁵ due to risk factors such as altered consciousness, alterations in brain stem reflexes such as gagging, coughing, swallowing, and muscular disorders such as weakness or paralysis.¹⁶

One of the determining factors in weaning success is the use of weaning readiness assessment protocols¹⁷ to find patients who are ready for spontaneous breathing trial (SBT).¹³ The American Thoracic Society recommended the use of weaning protocols for all patients.¹⁸ Therefore, daily screening of patients under MV is essential for successful weaning.¹⁹ SBT is the simplest way to assess patients' readiness for weaning.²⁰ It provides more accurate information about patients' probable conditions after extubation.²¹ SBT is the most recent weaning policy in more than 60% of ICUs in Europe.²²

Considerable controversies exist over the best SBT method and time.²³ In recent years, new ventilation modes were proposed for weaning, including synchronized intermittent mandatory ventilation (SIMV), automatic tube compensation, and mandatory minute ventilation. The most commonly used SBT methods are the T-piece and pressure support ventilation (PSV) because these methods are associated with higher weaning success.^{24,25} PSV is an assisted MV mode²⁰ in which a preset value of pressure is delivered to the patient during inspiration, resulting in decreased airway pressure and reduced respiration workload.²¹ The T-piece and PSV are used in more than 30%–50% of cases of SBT.²² So far, there is no clear consensus over the best method for SBT.²⁶

Comparisons show that the weaning success rate of the T-piece is two times greater than PSV, probably due to the fact that in the T-piece, respiration is based on patients' own physiological conditions and hence, healthcare providers can more easily judge about weaning and extubation.²⁷ Similarly, a study reported that the weaning success rates of the T-piece and the PSV methods were 76% and 14%, respectively.²⁸ Another study also showed that two-hour use of the T-piece was associated with a greater weaning success rate than its intermittent thirty-hour use.²⁹ On the other hand, the T-piece is associated with a higher risk of post-MV left ventricle failure than PSV, probably due to the higher workload of the respiratory muscles and the greater likelihood of cardiopulmonary edema.¹⁴ Due to the lack of firm evidence regarding the PSV and the T-piece methods, the present study was conducted to compare the clinical outcomes of these two methods among patients with TBI.

Materials and Methods

This randomized controlled trial was conducted in 2019 in the ICU of Shahid Rajaei hospital, Qazvin, Iran. The study population consisted of adult patients with head trauma under mechanical ventilation in the study setting. The number of samples for each group was calculated according to the following equation:

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)}{(d)^2} = \frac{(2.57 + 2.32)^2 (2.29^2 + 2.93^2)}{(4.01)^2} = \sim 27$$

In total, 536 patients were hospitalized during the study in the study setting. Participants were 72 patients with TBI who were under MV. They were selected purposively. Inclusion criteria were having received MV for at least 48 hours and at most two weeks, an age of more than 80 years,³⁰ no chronic cardiopulmonary problem,³¹ a Glasgow Coma Scale (GCS) score of more than nine, normal electrolyte levels, no intake of vasoactive medications, a hemoglobin level of more than 8 (mg/dL), a body temperature of less than 38.5°C,²⁰ and no spinal cord injury, convulsion, or poisoning-induced altered consciousness.² Exclusion criteria were one unsuccessful weaning, transfer to other clinical settings, need for surgery,³² central nervous system infection, and spontaneous extubation.² Participants were randomly classified into an intervention and a control group through block randomization with four-person blocks.

Patients were daily assessed for weaning criteria, namely the availability of the coughing reflex, airway secretions, a positive end-expiratory pressure (PEEP) of less than 8 cm H₂O,¹⁴ a maximum inspiratory pressure of less than –25 cm H₂O, a vital capacity of more than 10 cc/kg, and arterial oxygen saturation of more than 90% with a fraction of inspired oxygen (FiO₂) of 40%. Patients who fulfilled all these criteria were subjected to SBT with the approval of an anesthesiologist.²⁰ Before the beginning of the weaning process, all patients were ventilated using the SIMV mode. To begin the weaning process, patients in the intervention group were placed on the T-piece for two hours. Patients who did not tolerate spontaneous breathing were reconnected to MV,³³ and considered as unsuccessful weaning.³⁴ These patients were subjected to another weaning attempt 24 hours after the first attempt. Spontaneous breathing toleration criteria were the respiratory rate of fewer than 35 per minutes, heart rate of less than 140 beats per minute, arterial oxygen saturation of more than 90%, arterial partial oxygen pressure of more than 60 mm Hg, and no symptom of

increased respiration workload such as sweating, dyspnea, and use of accessory respiratory muscles.³⁵ Patients who fulfilled the criteria of spontaneous breathing for two hours were considered as successful weaning and were subjected to extubation. After extubation, patients who did not need re-intubation for 48 hours were considered as successful extubation.³⁶ In the control group, patients who fulfilled weaning criteria were placed on PSV with pressure support of less than 8 mm Hg. If patients tolerated spontaneous breathing for two hours were considered as successful weaning and were subjected to extubation; otherwise, they were considered as unsuccessful weaning and placed on SIMV. Patients with successful weaning and extubation were considered as successful extubation if they did not need re-intubation during the first 48 hours after extubation.³⁶ Extubation in both groups was conducted using the same method. Before extubation, the cuff leak test was done and a corticosteroid agent was administered in order to respectively assess laryngeal edema³⁷ and reduce laryngeal edema and the need for re-intubation.³⁸ Moreover, before the beginning of the weaning process, sedation was gradually reduced until it was completely discontinued 24 hours before weaning. Patients who needed tranquility received an intravenous bolus injection of a tranquilizer. All participants in both groups were followed up to hospital discharge for clinical outcomes namely weaning outcomes, extubation success, length of MV, length of hospital stay, and mortality rate.

Data were analyzed via the SPSS software (Version 23.0). Normality testing was performed using the Kolmogorov-Smirnov test, and the data were described using the measures of descriptive statistics such as frequency, mean, and standard deviation. Between-group comparisons respecting weaning success, length of MV, and length of hospital stay were conducted using the Chi-square and the independent-sample *t*-tests. 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.1398.388 and registration code: IRCT20171212037848N3). Moreover, the current study was conducted after obtaining written permission 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.

Results

In total, 72 patients were recruited for the study. Eight patients from the intervention group and four from the control group (twelve in total) were excluded due to death or transfer to other clinical settings (Figure-1). Study groups did not significantly differ from each other respecting participants' age, gender, the reason for hospitalization, and GCS score ($P > 0.05$; Table-1).

The rates of successful weaning in the intervention and the control groups were respectively 88.3% and 56.6%, with a statistically significant between-group difference ($P = 0.024$; Table-2). Moreover, the rates of successful extubation in the intervention and control groups were 80% and 63.3%, respectively. The between-group difference was not statistically significant ($P=0.252$; Table-2). On average, the length of MV in the intervention and control groups was 7.5 and 8.7 days, respectively. No statistically significant difference was observed between the groups ($P=0.3$; Table-3). Moreover, the length of hospital stay in the intervention and control groups was 19.9 and 28.9 days, respectively. The between-group difference was statistically significant ($P = 0.05$; Table-3). In the intervention group, the rates of hospital discharge and death were 86.6% and 13.3%, respectively and were 73.3% and 26.6% in the control group, respectively. The between-group difference respecting death rate was not statistically significant ($P = 0.3$; Table-2).

Discussion

This study compared the clinical outcomes of the T-piece and PSV among patients with TBI. Findings revealed that compared with PSV, the T-piece was associated with a significantly greater weaning success rate. Contrarily, two studies reported that PSV-associated weaning outcomes were better than the weaning outcomes of the T-piece,³⁹ while a review study on nine clinical trials showed no significant difference between the outcomes of PSV and the T-piece.²¹ The contradiction between our findings and the findings of these studies is probably due to the difference among the samples of the studies. Our participants were TBI patients who are often younger than patients with medical-surgical conditions, and suffer from no serious underlying condition. Hence, they could tolerate the T-piece better than other patients.

Table-1. Between-group comparison regarding participants' characteristics

Characteristics	Group	Intervention		Control		P value*
		N	%	N	%	
Gender	Female	11	36.6	10	33.3	0.9
	Male	19	63.3	20	66.6	
GCS score	9	18	60	22	73.3	0.69
	10	11	36.6	7	23.3	
	11	1	3.33	1	3.33	
Reason for hospitalization	Road accident	28	93.3	26	86.66	0.7
	Fall	1	3.33	2	6.66	
	Hit on the head with heavy object	1	3.33	2	6.66	
Age		Mean	SD	Mean	SD	P value[^]
		42.3	18.4	44.3	19.6	

*. The results of the Chi-square test

[^]. The results of the independent-sample *t* test

Table-2. Between-group comparisons regarding weaning and extubation success rates and hospitalization outcome

Outcomes	Group	Intervention	Control	Test results*
Weaning	Successful	25 (83.3)	17 (56.6)	$\chi^2 = 5.07$ P = 0.024
	Unsuccessful	5 (16.6)	13 (43.3)	
Extubation	Successful	24 (80)	19 (63.3)	$\chi^2 = 2.05$ P = 0.252
	Unsuccessful	6 (20)	11 (36.6)	
Hospitalization outcome	Discharge	26 (86.6)	22 (73.3)	$\chi^2 = 1.66$ P = 0.16
	Death	4 (13.3)	8 (26.6)	

*. The results of the Chi-square test

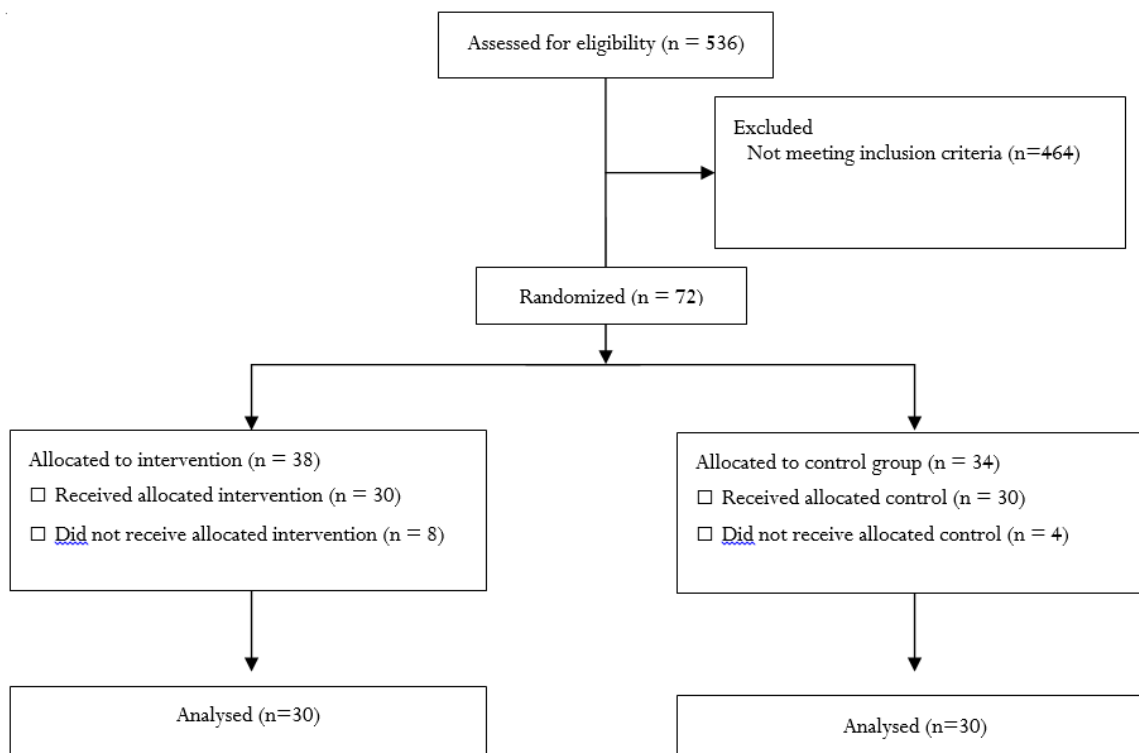


Figure-1. The flow diagram of the study

Although one-hour use of the T-piece is considered a good test for assessing patients' readiness for extubation,²⁰ our findings indicated no significant between-group difference regarding extubation outcomes. A former study also reported the same finding.²⁰ This insignificant difference between the extubation outcomes of the T-piece and PSV may be due to the fact that many different factors can affect extubation success during the process of weaning. Contrary to our findings, a study showed that the extubation outcomes of PSV were better than the T-piece.²⁸ This contradiction can also be due to the difference in the samples of the studies; while our participants were patients with TBI, the sample of that study consisted of patients with chronic obstructive pulmonary disease.²⁸

The findings of the present study also showed no statistically significant difference between the T-piece and PSV regarding the length of MV. In contradiction with this finding, three former studies reported that compared with the T-piece, PSV was associated with shorter MV length.^{10, 22} The insignificant difference in MV length between the T-piece and PSV in the present study may be due to the fact that the decisions about weaning and extubation in the present study were made by physicians without using any clear guideline.

In our study, the length of hospital stay in the T-piece group was shorter than the PSV group. In contradiction, a study reported shorter ICU stay in the PSV group,²⁸ and another study demonstrated no significant difference between the T-piece and PSV regarding ICU stay.²⁰ This contradiction may be attributed to the study of the length of ICU stay in the mentioned study, while in the present study we assessed the length of hospital stay.^{20, 28} Compared with the length of ICU stay, the length of hospital stay is affected by a wider range of factors.

We also found no significant difference between the PSV and the T-piece groups in terms of the death rate. This is in line with the findings of a former study,⁴⁰ while another study found a lower death rate in the PSV group.²³ Death rate among hospitalized patients is affected by numerous factors.

We could not control the effects of factors such as the type of intracranial hemorrhage, intracranial pressure, and the lack of clear clinical guidelines for weaning and extubation. Moreover, this study was conducted on patients with GCS scores of more than nine and hence, its findings may not

easily be generalizable to other patients with lower levels of consciousness.

Conclusions

This study concludes that compared with PSV, MV weaning through the T-piece is better tolerated by patients with TBI, while there are no significant differences between the T-piece and the PSV methods respecting extubation outcomes, length of MV, length of hospital stay, and death rate.

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Authors' Contribution

All authors pass the four criteria for authorship contribution based on the International Committee of Medical Journal Editors (ICMJE) recommendations.

Conflict of Interests

None is declared.

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