

Current State of Ventilator Setting and Their Relationship with Mortality Rate in Patients under Mechanical Ventilation: A Cross-Sectional Study

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ARTICLE INFO

Article history:

Received 04 July 2023

Revised 29 July 2023

Accepted 15 August 2023

Keywords:

Ventilator;

Parameters;

Lung protective strategies;

Mortality;

Rate

ABSTRACT

Background: Given the importance of implementing lung protective strategies to prevent lung injury caused by ventilators and death of patients, it is necessary to monitor the current condition of hospitals and examine the relationship between the parameters set on the ventilators and patient mortality. This study conducted to determine the current state of ventilator setting and their relationship with mortality rate in patients under mechanical ventilation: a cross-sectional study.

Methods: This is a cross-sectional study that was conducted between June to December 2020 in one of the hospitals affiliated to Tehran University of Medical Sciences. The initial tidal volume set on the ventilator was recorded for 304 patients under mechanical ventilation and then, their heights were measured and their tidal volumes were determined based on the standard formula. Other parameters set on the ventilator as well as systolic and diastolic blood pressures of patients were also recorded and their survival rate was investigated. The data was analyzed by SPSS software, using descriptive statistics and logistic regression model.

Results: Among patients, who were under mechanical ventilation, 77.6% were hospitalized in intensive care units and the rest were hospitalized in general wards. The mean adjusted tidal volume for patients was 472.91 ± 32.13 ml. The mean peak inspiratory pressure and plateau pressure were 28.00 ± 6.98 and 13.88 ± 4.93 CmH₂O, respectively. Also, 37.2% of patients died during the hospitalization. The results of adjusted odds ratio based on multivariate logistic regression model for predictors of mortality rate showed that the variables of patients' age [OR=1.040 (1.019-1.062)], the hospital's general ward in comparison with the ICU [OR=11.379 (5.130-25.240)] and the peak inspiratory pressure [OR=1.072 (1.007-1.141)] had a direct and significant relationship with mortality rate (in all cases $P < 0.05$). Meanwhile, the plateau pressure [OR=0.886 (0.808 -0.972)] had an inverse and significant relationship with mortality rate ($P < 0.05$).

Conclusion: Despite the recommendations regarding lung protective strategies, in some cases, some parameters set in the ventilator are outside the recommended levels, which can effect on patients mortality. So monitoring and controlling the implementation of lung protective strategies and paying attention to controlling pressures set on the ventilator are among measures that should be taken in medical centers in order to prevent lung injuries and maintain patient safety.

The authors declare no conflicts of interest.

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Introduction

Patients under mechanical ventilation are exposed to complications caused by ventilators. Lung injury would occur in patients if the ventilator settings are not appropriate to the characteristics of patients and their underlying diseases. These injuries are called ventilator-associated lung injury (VALI) or ventilator-induced lung injury (VILI) [1-4]. In order to prevent and minimize these complications in patients, protective ventilation strategies have been formulated, such as lowering tidal volume (V_t), applying/reviving Recruitment manoeuvre to prevent pulmonary collapse and atelectasis, limiting plateau pressure (Pplat) to reduce over-distension and volume trauma, and increasing positive end-expiratory pressure (PEEP) to prevent atelectotrauma [2, 5]. Regarding V_t , these strategies recommend that ventilation should be started with a V_t of 8 ml/kg based on the predicted body weight (PBW) and gradually decrease to 6 ml/kg [4, 6]. It should be noted that the V_t should be calculated based on the patient's PBW and also PBW should be determined based on the patient's height, age and gender [7-8].

Since the formulation of these strategies, several studies have been conducted in order to investigate the implementation of these strategies and its consequences. However, despite the development of clinical guidelines to support these strategies, many studies indicate the low adoption of these strategies in clinical setting [9]. Studies have shown that the use of lung protective strategies leads to a decrease in VALI and mortality rate [10-11]. Comparing the results of studies conducted over 14 years (from 2002 to 2016) we can see that the V_t , the peak inspiratory pressure (PIP) and Pplat have decreased by 12.6% 20.6% and 17.1%, respectively. Also, the pressure decrease of 26% (from 20 to 14.8 cm H₂O) has led to decreased mortality rate from 52% to 35.5%, while being associated with a decrease in ventilator-related pulmonary complications [12]. V_t less than 10 ml/kg/PBW, the Pplat of less than 20 cm H₂O, and the PEEP of 5 cm are recommended for mechanically ventilated patients with healthy lungs [12]. In a study by Sjoding et al. (2019), who examined the effect of V_t on patient's clinical outcomes, V_t of 1905 patients hospitalized in 6 ICUs were analyzed, and the results showed that 40% of patients were receiving a V_t of higher than 8 ml/kg/PBW, and being exposed to high V_t (more than 8 ml/kg/PBW) during the first 24 hours of admission was associated with increased mortality [13]. Another study was conducted in 2017 to investigate the relationship between hospital mortality and V_t , PEEP, Pplat, and driving pressure by examining the ventilator settings for 478 patients with acute respiratory distress syndrome. The results of this study showed that V_t and PEEP had no effect on mortality rate, but the Pplat of

higher than 29 cm H₂O was associated with an increased risk of mortality [14]. The results of these studies show the importance of taking measures, such as monitoring and controlling the ventilator settings, implementing lung protective strategies and measuring the mortality rate of patients following ventilator setting. Although the specialized settings of the ventilator are done by physicians, in many cases in teaching hospitals, after intubation of the patient, the initial settings of ventilator are done by physicians and with the cooperation of nurses. In addition, nurses always note down the parameters of the ventilator in the nursing reports and special charts in their round-the-clock care of these patients and take it into consideration. They must evaluate and control the correctness of the set parameters because they are responsible for reporting issues or problems that could endanger patient safety. One of the ethical duties of nurses is to support patients and maintain a high level of care in patients and make sure that high standards of care are met in order to prevent side effects. This role is more important in situations where patients, such as patients under mechanical ventilation, are unable to speak due to their special conditions or do not have a sufficient level of consciousness [15]. Nurses have a vital role in the safety of patients and a potential role in detecting errors, negligence and risks before harm and mortality occur [16-17].

Despite the importance of these issues and conducting numerous studies in order to controlling the implementation of protective ventilation strategies and subsequent mortality in advanced countries, only a few studies has been conducted in Iran. This study conducted to determine the current state of ventilator setting and their relationship with mortality rate in patients under mechanical ventilation: a cross-sectional study. This is while investigating this issue can clarify the status quo of Iran's medical centers and help health policy makers and managers to improve patient safety.

Objectives

This study was conducted to determine the current state of ventilator setting and their relationship with mortality rate in patients under mechanical ventilation: a cross-sectional study.

Methods

Study design and participants

This cross-sectional study was conducted between June to December 2020, following another study [18] where ventilator setting parameters, demographic and clinical information, and height of patients were determined. The setting of this study was a 800-bed general Teaching Hospital in Tehran, Iran. The study population included 304 patients under mechanical ventilation. The inclusion criteria were; age of over 18 years, mechanical

ventilation with volume-cycled ventilation, no hand and arm injury, and hospitalization in any of the general wards, emergency department (ED) or intensive care units(ICU). In cause of patient death within the first 24 hours of hospitalization, the deceased patient was excluded from the study. All patients who were under volume-cycled mechanical ventilation during the study period were included in the study.

Data collection method

The initial Vt set on the ventilator was recorded in 304 patients under mechanical ventilation. Patients heights and then ideal or Predicted Body Weight (PBW) were measured; and finally their Vt were determined based on the standard formula. In this study, height was determined based on the length of the ulnar. For this, first, the length of the ulna was measured using a tape measure and the height of the patients was determined based on the patient length of the ulna, gender and age [19]. Then, using the formula and determined height, the patients' ideal or Predicted Body Weight (PBW) was calculated [8]. In order to determine Vt per kg of PBW, the Vt in the ventilator was divided by PBW.

The data collection tools in this study included patients' demographic and clinical information form, a registration form for ventilator parameters, and the patient mortality rate form. The patients' demographic and clinical information along with the values of ventilator parameters were collected from the patients' medical records. Demographic and clinical information included age, sex, ulna length, admission department, systolic blood pressures (SBP) and diastolic blood pressures (DBP). Parameters related to ventilator settings such as Vt, respiratory rate(RR), flow trigger, flow, PEEP, PIP, Pplat, pressure support (PS), Fio2%, and ventilator mode were also recorded in a separate form. It should be noted that the ventilator settings were based on the initial settings of the ventilator that were set when patient was connected to ventilator. Also, the patients' survival or death was determined based on the patient's hospital record.

Ethical considerations

This study is the result of a registered research project (no. 98-3-160-45748) approved by Tehran University of Medical Sciences on 29.04.2020. (No: IR.TUMS.FNM.REC.1399.017). The information of all patients was confidential and the code used instead of the names of the patients.

Data analysis

Data summarized and reported for qualitative variables with frequency and percentage and for quantitative variables with mean and standard deviation. The relationship between each of the independent variables and the dependent variables determined by logistic regression model. The logistic regression model with Backward LR strategy used to determine the independent predictors of mortality. Finally, the findings presented

with unadjusted and adjusted odds ratio. Data analysis was done by SPSS-16 software at a significance level of less than 0.05.

Results

From patients participated in this study, 236 patients (77.6%) were hospitalized in ICUs and 68(22.4%) were hospitalized in general wards. The mean age of the patients was 56.53 ± 16.41 years. The mean PBW of patients was 61.63 ± 8.80 kg. The ventilation mode of 289 patients (95.1%) was SIMV. The mean Vt of patients was 472.91 ± 32.13 ml and the mean Vt adjusted based on PBW was 7.80 ± 1.01 ml, ranging from 5.6 to 11.2 ml/kg PBW. Also, 113 (37.2%) patients died during the hospitalization (Table 1).

The results of unadjusted odds ratio based on univariate logistic regression model for predictors of mortality showed that, the variables of patients' age [OR=1.048 (1.031-1.066)], and the hospital general ward in comparison with the ICU [OR=6.931 (3.794-12.660)] had a direct and significant relationship with the mortality rate (in all cases $P < 0.05$). Meanwhile, the tidal volume set on ventilator [OR=0.990 (0.983-0.998)], and PEEP [OR=0.785 (0.661-0.931)] had an inverse and significant relationship with mortality rate ($P < 0.05$, Table 2).

The results of adjusted odds ratio based on multivariate logistic regression model for predictors of mortality showed that after adjusting other variables in the model, the variables of patients' age [OR=1.041 (1.019-1.062)], the hospital's general ward in comparison with ICU [OR=11.379 (5.130-25.240)] and PIP [OR=1.072 (1.007-1.141)] had a direct and significant relationship with mortality rate (in all cases $P < 0.05$). Meanwhile, the Pplat [OR=0.886 (0.808-0.972)] had an inverse and significant relationship with mortality rate ($P < 0.05$, Table 3).

The results of adjusted odds ratio based on multivariate logistic regression model with Backward LR strategy for predictors of mortality showed that, the variables of patients' age [OR=1.039 (1.019-1.059)], the hospital's general ward in comparison with the ICU [OR=10.341 (4.856-22.024)] and PIP [OR=1.069 (1.005-1.137)] had a direct and significant relationship with the mortality rate (in all cases $P < 0.05$). Meanwhile, the Pplat [OR=0.896 (0.820- 0.979)] had an inverse and significant relationship with the mortality ($P < 0.05$, Table 4).

Table 1- Demographic and clinical characteristics of patients and the ventilator parameters

Variables	N(%)or Mean±SD	Min- Max
Demographic and clinical characteristics of patients		
Age (year)	56.53±16.41	19-96
Gender	Male	176(57.9)
	Female	128(42.1)
Height based on ulna length (Centimeters)	167.5±7.48	149-184
PBW based on ulna length (Kilograms)	61.63±8.80	41.91-78.76

Ward	EM & General Wards	68(22.4)	
	ICU	236(77.6)	
SBP (mmHg)		118.31±23.17	59-200
DBP (mmHg)		70.55±16.79	40-123
Mortality	Died	113(37.2)	
	Survived	191(62.8)	
Ventilator parameters			
Vt (ml)		472.91±32.13	400-600
Vt (ml/kg PBW)		7.80±1.01	5.6-11.2
Flow trigger		3.63±0.94	2-6
Flow (L/min)		56.23±11.39	35-90
PEEP(cmH2O)		5.26±1.40	2-10
PIP(cmH2O)		28.00±6.98	16-46
Pplat (cmH2O)		13.88±4.93	5-29
PS(cmH2O)		11.76±2.39	1-17
Fio2%		54.29±10.08	35-100
Mode	CMV	5(1.6)	
	SIMV	289(95.1)	
	AC/VC	10(3.3)	

Table 2- The results of unadjusted odds ratio based on univariate logistic regression analysis for the predictors of mortality

Variable	OR	95% CI		P value
		Lower	Upper	
Age (year)	1.048	1.031	1.066	<0.001
Gender (female versus male)	1.025	0.640	1.641	0.919
PBW based ulna length (Kilograms)	0.977	0.952	1.004	0.091
Vt (ml)	0.990	0.983	0.998	0.012
Vt (ml/kg PBW)	1.057	0.841	1.328	0.637
RR	0.949	0.815	1.105	0.500
Fio2 %	0.989	0.965	1.012	0.346
Flow trigger	0.937	0.731	1.202	0.609
Flow (L/min)	0.993	0.973	1.014	0.502
PEEP (cmH2O)	0.785	0.661	0.931	0.006
PS (cmH2O)	1.058	0.956	1.172	0.276
Patient's SBP	0.999	0.989	1.009	0.823
Patient's DBP	1.000	0.987	1.012	0.958
PIP(cmH2O)	1.021	0.987	1.056	0.232
P _{plat} (cmH2O)	1.004	0.957	1.053	0.879

Wards (General versus ICU)	6.931	3.794	12.660	<0.001
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Table 3- Results of adjusted odds ratio based on multivariate logistic regression analysis for the predictors of mortality

Variable	OR	95% CI		P value
		Lower	Upper	
Age (year)	1.040	1.019	1.062	<0.001
Gender (female versus male)	1.485	0.777	2.841	0.232
Vt (ml)	0.998	0.987	1.009	0.769
RR	0.848	0.700	1.026	0.089
Fio2 %	0.987	0.954	1.020	0.426
Flow trigger	0.925	0.673	1.270	0.629
Flow (L/min)	1.010	0.983	1.037	0.465
PEEP (cmH2O)	0.923	0.736	1.157	0.487
PS (cmH2O)	1.069	0.935	1.221	0.328
Patient's SBP	1.003	0.989	1.017	0.701
PIP(cmH2O)	1.072	1.007	1.141	0.030
Pplat(cmH2O)	0.886	0.808	0.972	0.011
Wards (General versus ICUs)	11.379	5.130	25.240	<0.001

Table 4- The results of adjusted odds ratio based on logistic regression model with backward LR strategy for the predictors of mortality

Variable	OR	95% CI		P value
		Lower	Upper	
Age (year)	1.039	1.019	1.059	<0.001
PIP (cmH2O)	1.069	1.005	1.137	0.034
Pplat (cmH2O)	0.896	0.820	0.979	0.015
Wards (General)	10.341	4.856	22.024	<0.001

Discussion

The results of this study showed that 77.6% of patients were hospitalized in ICU and 22.4% in general wards. In Japan, a study found that 53.6% of ventilated patients were hospitalized in ICU and 46.4% of ventilated patients were treated in non-ICU departments [20]. This problem can be due to the lack of beds in ICUs and the forced hospitalization of critically ill patients who need mechanical ventilation in general wards. It should be mentioned that the lack of beds and ICU facilities can be different in developing and developed countries.

The mean adjusted Vt based on PBW was 7.80±1.01 ml, ranging from 5.6 to 11.2 ml. Lung protective strategies recommend that ventilation should start with a Vt of 8 ml/kg/PBW and gradually decrease to 6 ml/kg [4,

6]. Low V_t is a strategy that reduces plateau and driving pressures and therefore, reduces the excessive expansion of alveoli [21]. In the present study, the mean adjusted V_t was somewhat consistent with the lung protective strategies, although the high range of adjusted V_t of up to 11.2 ml/kg was also observed.

The range of PIP was between 16 and 46 CmH₂O. In another study, the PIP range was from 2.29 to 27.87 CmH₂O [22]. This is while in vivo study of ventilator-induced lung injury; the high PIP, especially with 0 PEEP can lead to respiratory swings in right ventricular (RV) filling and pulmonary perfusion, pulmonary edema due to increased permeability, and pulmonary microvascular injury and acute cor pulmonale [23]. This is despite the fact that the upper limit of PIP in this study reached to 46 CmH₂O, which can lead to pulmonary complications. The results also showed that the range of Pplat was between 5 to 29 cm H₂O. In some studies, it is recommended to keep the Pplat below 30 cm H₂O to prevent complication [21, 24]. It has also been recommended that maintaining the Pplat of below 30 cm H₂O is more important than low V_t , which can also be effective in reducing lung injury. Meanwhile in ventilator settings, the flow volume should be adjusted based on the airway pressure, especially the Pplat [25]. What is obvious is that in the present study, the Pplat was consistent with the lung protective strategies; and it has been an expression of attention to this issue from everyone who did the ventilator settings.

The results also showed that the patients' age and hospitalization in the general ward had a significant relationship with the patient mortality, so that increasing age was associated with a higher risk of mortality. The results of a study in which the data of 149 patients with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) under mechanical ventilation were analyzed showed that patient age was significantly correlated with mortality [24]. The results of another study in which patients with ALI who were under lung protective ventilation were examined showed that age (>63 years) is one of predictors of hospital mortality at 90 days [26]. In current study, hospitalization in general wards was associated with a higher risk of mortality. The results of a study aimed at comparing the survival of patients who had newly deteriorate and were admitted to ICU or outside ICU showed that the sooner the patients with decompensated conditions were admitted to the ICU, the more benefit they received. ICU patients had better early survival in regard to out of the ICUs [27]. Another study in which the survival rate of 99 ventilator patients in ICU and general wards was compared showed that in-hospital survival rate in ICU was 38% while in medical wards was 20% [28]. ICUs has more advanced equipment than the general wards. In addition, they have specialized and experienced staff and the ratio of nurses to patients in ICUs is higher than in general wards. It is

obvious that ICUs is a more appropriate place for caring for patients who need mechanical ventilation, because it provides a better management condition for patient care and treatment. As a result, hospitalization of ventilated patients in ICUs can reduce their mortality rate [29].

Although there was a relationship between the patient mortality and adjusted V_t , multiple regression analysis did not show a relationship between the patient mortality and V_t set on the device. Another study has reported that high V_t is harmful and increases patient mortality as it leads to VALI [7]. In addition, the survival of patients after two years has also been investigated in this regard. A study was conducted to determine the relationship between V_t and two-year survival rate of patients with acute lung injury (in which three tidal volumes were set at less than 6.5, V_t between 6.5-8.5 and greater than 8.5 ml/kg). The results of this study showed that an increase of one ml/kg/PBW in the current volume was associated with a relative increase of 18% in patient mortality rate [8]. However, in the present study, the V_t was not significantly correlated to in-hospital patient mortality, which could be due to the setting of V_t at low level.

PIP also had a direct and significant relationship with patient mortality in the present study. Other studies have also shown that PIP was higher in ventilated patients who died. With the increase of PIP, the risk of mortality increases continuously, and this is especially true with the PIP of greater than 40 cm H₂O [30]. In the present study, the mean PIP was 28.00 ± 6.98 CmH₂O with the range of between 16 and 46, which is high. An increase in PIP along with a reduced or low Pplat can increase large-airway resistance. Also an increase in PIP along with elevated Pplat can lead to a decrease in pulmonary compliance, and this in turn can lead to patient complications such as pneumothorax [31]. The results of a study showed that the initial setting of ventilator with high V_t and high PIP (>30 cm H₂O) is associated with the occurrence of acute respiratory distress syndrome (ARDS) in patients who are under ventilation for reasons other than acute respiratory failure [32]. In another study conducted in 2017, the results showed that PIP was higher in patients who the non survivors in hospital [30].

The results of present study also showed that Pplat had an inverse and significant relationship with patient mortality. It should be noted that the mean adjusted Pplat in the present study was 13.88 ± 4.93 CmH₂O with the range of between 5 and 29. Studies have shown that the reduction of Pplat from 55 to 45 CmH₂O is associated with an absolute decrease in mortality of about 15%. But in the conditions where Pplat is between 18 and 28 CmH₂O, has relatively no effect on mortality [33]. In other words, reduction of Pplat for more than 30 cm H₂O does not have a significant effect on patient survival. In other studies, the mean Pplat of between 22.3 and 26.8 CmH₂O in first day of ventilation did not make a difference in patient mortality rate and in fact, this

pressure level may be the safety level for ventilator settings [33-34]. In the present study, it can be said that Pplat was lower than the determined confidence limit. Another important point that has been mentioned in other studies is that in most cases, physicians focus more on limiting the Pplat and pay less attention to limiting the Vt in ventilator settings [25].

Although the pressure and volume parameters set in this study were somewhat consistent with the lung protective strategies, the upper range of parameters set on the ventilator was very high some times. Therefore, teaching medical staff about lung protective strategies as well as monitoring and controlling parameters set on the device, especially pressure parameters, is one of the factors that should be considered in medical centers. Implementation of lung protective strategies in ICUs for patients under mechanical ventilation can be effective in reducing patient mortality. Although ventilator settings are mostly done by physicians, it is obvious that due to the educational nature of many hospitals, most of the time these settings are done by interns or residents of the lower years. Because nurses, especially in the ICUs, must record ventilator parameters in special sheets; therefore, the nurses can emphasize on adjusting the parameters and play their supporting role for the patients safety.

It is necessary to reducing the mortality rate of patients under mechanical ventilation who have been hospitalized in the general wards of hospitals. Training of medical staff specially nurses by trained care teams who can teach the staffs of general wards how to effectively care for these patients and adjust ventilator parameters is one of the important measures that should be considered by the health policy makers and managers.

Limitations

In this study, only the initial parameters set on the ventilator examined. Obviously, the process of adjusting ventilator parameters is dynamic and can be changed in different shifts. Changes in ventilator settings were not investigated in this study. The probability of death and risk of mortality different from patient to patient, and therefore, it was better that assessed by tools such as Acute Physiology and Chronic Health Evaluation (APACHE), Mortality Prediction Models (MPM) and Simplified Acute Physiology Score (SAPS). In this study, these tools were not used due to the problems of recording patients' information.

This study conducted only in one hospital and it is not possible to generalize it to all hospitals. It is suggested to conduct multi-center studies in order to determine the status of lung protective strategies and ventilator parameters.

Conclusion

The results showed that still some of the parameters set in the ventilator are outside the recommended ones in protective ventilation strategies. This issue is especially important in setting of PIP and Pplat due to their relationship with patient mortality. Monitoring and controlling the implementation of lung protective strategies and paying attention to controlling the pressure parameters while setting ventilators should also be considered in medical centers in order to prevent lung injuries and maintain patient safety.

Acknowledgment

This study was part of a research supported by Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran (Grant No: 98-3-160-45748).

Financial support and sponsorship

Tehran University of Medical Sciences.

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