ORIGINAL ARTICLE

Comparison of the effects of clinical observation and protocol-based weaning on antioxidant stress factors

Cem Erdoğan, M.D.,[1] Deniz Kızılaslan, M.D.,[1] Burcu Tunay, M.D.,[1] Pelin Karaaslan, M.D.,[1] Gözde Ülfer, M.D.,[2] Türkan Yiğitbaşı, M.D.,[2] Yavuz Demiraran, M.D.,[1] Hüseyin Öz, M.D.[1]

[1]Department of Anesthesiology and Reanimation, İstanbul Medipol University Faculty of Medicine, İstanbul-*Türkiye*
[2]Department of Biochemistry, İstanbul Medipol University Faculty of Medicine, İstanbul-*Türkiye*

ABSTRACT

BACKGROUND: We aimed to compare the effects of observation of the physician (POB) or by adhering to the protocol-based (PB) weaning methods on total antioxidant capacity (TAC) and total oxidative stress (TOS) levels and weaning success levels.

METHODS: Our study was conducted on patients admitted from the emergency department between January 2015 and January 2018 in the intensive care unit of our hospital. During the spontaneous breathing trial (SBT), when one of the criteria specified in developed, SBT was terminated and the previous mechanical ventilator parameters were returned. The patient was planned to be taken to SBT again the next morning. If the SBT was successful, extubation was decided. The extubation decision based on physician observation was made according to the patient's state of consciousness and adequate chest expansion during the daily visit.

RESULTS: The decrease in TAC average value before and after extubation was found to be significant in the POB group patients (p=0.001). The decrease in the average TAC value of the PB group patients before and after extubation was found to be significant (p=0.03).

CONCLUSION: In our study, TAC values were found to be higher in the PB group than in the POB group, and in addition, the reintubation rate was found to be lower. We think that the management of weaning as a PB may contribute to maintaining the balance between TAC and TOS and reduce the rate of reintubation.

Keywords: ICU; oxidative stress index; total antioxidant capacity; total oxidative stress; weaning.

INTRODUCTION

While free oxygen radicals oxidize biological molecules such as proteins, lipids, and DNA, which are the building blocks of the body, they can work against this oxidation as a part of the body's natural antioxidant defense system as well. This situation is balanced under normal physiological conditions. However, if any stress is encountered, oxidative stress increases as a result of increased antioxidant consumption or free radical generation.[1,2] Long intubation periods in intensive care units cause additional problems in patients. Managing this process correctly is important for both the prognosis of the patients and the financial cost. Oxidative stress may increase due to both high concentrations of oxygen and patient incompatibility with the ventilator in patients treated with mechanical ventilators in the intensive care unit. This prolongation of the weaning process may adversely affect the prognosis. The most important goal of the intensive care specialist is to terminate the mechanical ventilator treatment as soon as possible and to ensure that the patient continues her/his life with normal breathing. In intensive care units, the decision of extubation of the patient can be made based on the observation of the physician (POB) or by adhering to the protocol based (PB).[3,4] What is important here is that the patient should be separated from the mechanical ventilator, providing normal breathing (weaning success) and no reintubation. In

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Address for correspondence: Cem Erdoğan, M.D.
İstanbul Medipol Üniversitesi Tıp Fakültesi, Anesteziyoloji ve Reanimasyon Anabilim Dalı, İstanbul, Türkiye
Tel: +90 212 - 460 77 77 E-mail: cerdogan@medipol.edu.tr

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our literature survey, we could not find a study comparing the weaning success of these two weaning methods with total antioxidant capacity (TAC) and total oxidative stress (TOS) levels. There are many antioxidant molecules in the blood to prevent or inhibit the harmful effects of free oxygen radicals. Measurement of total antioxidant and oxidant levels in plasma can be used to determine the oxidative stress reaction of the organism.[5,6] Patients who are ventilated with a high oxygen rate in a mechanical ventilator are exposed to oxidative stress and this disrupts the muscle strength and energy balance and prolongs the extubation period.[7,8] In the light of this information, we aimed to compare the effects of POB and PB weaning methods on TAC and TOS levels and weaning success levels.

MATERIALS AND METHODS

Our study was conducted on patients admitted from the emergency department between January 2015 and January 2018 in the General Intensive Care Unit of School of Medicine, Istanbul Medipol University Hospitals Complex. Ethics Committee of Istanbul Medipol University University Hospital (07.11.2014-30) was included in this prospectively designed study. After obtaining informed consent forms from the relatives of the patients, 64 randomly selected adult patients between the ages of 18 and 65 who were applied Mechanical Ventilation (MV) as orotracheally intubated for at least 48 h were included in the study. Randomization was planned respectively for the patients who were hospitalized in the ICU, the first patient according to POB, and the second patient according to the PB (HGB: 1,3,5,…/PB: 2,4,6,…). Our study was designed as a single blind. The person collecting the data did not know the groups, only collecting data according to their numerical values. Patients with permanent neurological damage, tracheostomy, psychomotor agitation, self-extubation, mental retardation, and morbid obesity were excluded from the study. In our adult general ICU, when the patients who were followed up with a mechanical ventilator through the endotracheal tube between the dates mentioned above, when they successfully completed the spontaneous breathing trial (SBT), it was decided to be extubated according to the protocol-dependent criteria.[9,10] Extubation decision in our intensive care unit; it was applied according to the criteria of PB weaning (Table 1) by a team consisting of bedside nurses, respiratory therapists, assistant physicians, and intensive care specialists.[11,12] The extubation decision based on physician observation is made according to the patient's state of consciousness and adequate chest expansion during the daily visit.

If the patients met the above (Table 1) criteria, they were taken to SBT. A SBT was performed for 120 min by adjusting the pressure support to 7 cm H_2O and PEEP to 6 cm H_2O. During the SBT, when one of the criteria specified in Table 2 developed, SBT was terminated and the previous mechanical ventilator parameters were returned. The patient was planned to be taken to SBT again the next morning. If the SBT was successful, extubation was decided. If extubation did not occur within 21 days, tracheostomy was performed and was excluded from the study. SBTs were stopped if any of these were present in the patient scheduled for PB extubation (Table 2).[13,14]

Study Design and Variables

Our primary aim was to compare the effects of PD and POB extubation on TAC and TOS levels. Our secondary aim was to observe reintubation within 72 h after extubation.

Data Collection

Demographic data of all patients were recorded by one of the researchers. These are age, gender, height, weight, Acute Physiologic Assessment and Chronic Health Evaluation II (APACHE II) score, acute respiratory distress syndrome development, Rapid Shallow Breathing Index, duration of mechanical ventilation, reason for mechanical ventilation,

Table 1. Protocol-based (PB) weaning criteria

1. FiO_2 ≤40, PaO_2 /FiO_2 ≥200 mmHg
2. SpO_2 >90%
3. PEEP ≤6 cm H c
4. Breathing rate per-minute (BRP) <35
5. Heart rate (HR) <120/min
6. Fast superficial breathing index (FSBI) ≤. F
7. Static lung compliance 25 ml/cmH_2O ≤
8. Minute ventilation 10 lt/min ≥
9. Observation of the consciousness of patients who underwent sedation by stopping sedation
10. Electrolyte levels and normal metabolic status
11. No need for continuous vasoactive medication or (dopamine or dobutamine <5 µg/kg/min, noradrenaline <0.05 µg/kg/min)
12. Average arterial pressure 65 mmHg ≤
13. Pressure assistance (7 cm H_2O).

Table 2. Indications for stopping spontaneous breathing trials[13]

1. Breathing rate more than 35/min
2. Under SaO_2 92%
3. Heart rate above 120/min or continuous increase or decrease in heart by more than 20%
4. Systolic blood pressure above 180 mmHg or below 90 mmHg
5. Increased need for vasopressors or inotropic agents

Development of diaphoresis, somnolence, dyspnea, and chest pain

comorbidities diseases, vital parameters before extubation (heart rate, average arterial pressure, and breathing rate), and blood gas values before extubation (pH and PaO_2/FiO_2). In addition, reintubation rate, day of hospitalization in the intensive care unit, and mortality were recorded.

Laboratory Design

Blood samples of the patients were taken 1 h before and 1 h after extubation in the POB and PD weaning groups. Serums were separated from the blood centrifuged at 1500 rpm for 10 min. Serums were stored at −80 degrees to study TAC and TOS. TAC, TOS, and oxidative stress index (OSI) were conducted using a SpectraMax i3 Multimode Microplate reader (Molecular Devices, Sunnyvale, CA, USA).

Total Antioxidant Assay

The TAC value was measured colorimetrically in serum using the method developed by Erel. ABTS [2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid)] (Sigma-Aldrich, Taufkirchen, Germany) reagent is radicalized by hydrogen peroxide (Sigma-Aldrich, Taufkirchen, Germany). When serum is added, antioxidants in the serum neutralize existing ABTS radicals. The absorbance is measured at 658 nm.[15,16]

Total Oxidant Assay

The TOS value was measured colorimetrically in serum using the method developed by Erel. Fe2SO4 dissolves in water, releasing Fe^{2+}. Oxidants found in serum enable Fe^{2+} to Fe^{3+} oxidation. The X-orange (Sigma-Aldrich, Taufkirchen, Germany) reagent used gives a colored complex with Fe^{3+}. The absorbance is measured at 658 nm.[15,16]

OSI is calculated by the formula (TOS/TAC) × 100.[7,8] Blood gas parameters were studied with the radiometer ABL 700 device. In the statistical evaluation of our study; independent samples t-test was used for independent samples, independent samples paired sample t-test and Chi-square test were used for dependent samples. P<0.05 was accepted as the level of significance. Using the power sample size calculator, the sample size was calculated to be 30 for each group with an 80% power (p=0.05), considering the minimal clinically significant change of at least 1% change in measured parameters.

RESULTS

A total of 71 patients were included in the study, including 38 patients in the PD group and 33 patients in the POB group. Three patients in the POB group and four patients in the PD group were excluded from the study because of death. The age range of the patients included in our study was 18–65, and the mean age was 53.5 years (Table 3). There was no significant difference between the PB group and the POB group in TAC values determined before and after extubation (p>0.05) (Table 4). No significant difference was found between the PB group and the POB group in the OSI values determined before and after extubation (p>0.05). The decrease in TAC average value (0.96±0.20–0.81±0.15) before and after extubation was found to be significant in the POB group patients (p=0.001). The decrease (0.89±0.26–0.80±0.18) in the average TAC value of the PB group patients before and after extubation was found to be significant (p=0.03) (Table 5). The decrease in TAC level before and after extubation in the POB group was more distinct than in the PB group.

The decrease in TOS mean value (31±14–27.1±7.8) before and after extubation in the POB group patients was found to be significant (p=0.049). The decrease (34±17.86–28.2±9.6) in the mean TOS value of the PB group patients before and after extubation was found to be significant (p=0.02). The decrease in TOS level in the PB group was more distinct than in the POB group. The decrease in OSI mean values before and after extubation (3.34±1.49–3.42±1.02) in the POB group patients was not statistically significant (p>0.11). The decrease in the average value of OSI (4.1±2.42–3.62±1.28) before and after extubation in PB group patients was not statistically significant (p>0.75) (Table 4).

In both the POB and PB groups, it was found that extubation not only decreased the oxidative stress of the patients but also caused a significant decrease in antioxidant capacity. It was observed that the decrease in TOS values after extubation in the PB group was more significant than the POB group. However, it was observed that the decrease in TAC level after extubation in the PB group was less than in the POB group. Three of 34 patients included in the PB group and 16 of 30 patients included in the POB group were reintubated. A statistically significant difference was observed between the PB group and the POB group in terms of the need for reintubation (p<0.0001). When APACHE II ("Acute Physiology And Chronic Health Evaluation II") scores of the patients included in the study were examined, the APACHE II value of the patients in the POB group was found to be higher than the PB group (p=0.022). When the intubation times of the patients in the groups were compared, although it was not statistically significant, it was seen that the total intubation period (n=30, 196 days) of the patients in the POB group was longer than the PB group (n=34, 178 days).

DISCUSSION

We observed that the rate of reintubation was higher in the POB group compared to the PB group, and the TAC value was lower in the POB group, although it was not statistically significant compared to the PB group. In addition to that, when the TAC and TOS levels of the POB and PB groups before extubation were compared with the TAC and TOS values after extubation, there was no statistically significant difference.

In the study of Miltiades et al.,[17] it was reported that the reintubation rate of ICU patients who were separated from

Table 3. Patient characteristics

	PB (n=34) (OD±BR)	POB (n=30) (OD ±BR)	p-value
Age (year) (average)	51.76	55.53	0.221
Gender (female) (average)	17	12	0.423
APACHE II (average)	15.26	16.9	0.022
RSBI (average)	66.04 (42–82)	73.14 (52–93)	0.686
BR (min) (average)	19.34 (12–24)	20.39 (12–28)	0.377
Heart rate (min) (average)	80.32 (60–102)	87.70 (66–122)	0.408
AAP (mmHg) (average)	76.50 (55–104)	77.93 (53–102)	0.447
Intubation number of days (average)	5	6.5	0.080
Comorbid diseases			
Heart rate	8	11	0.251
CHF	6	10	0.148
DM	7	6	0.800
CRF	2	4	0.349
HT	12	7	0.440
COPD	6	3	0.268
Lung cancer	3	5	0.323
OTI etiology			
Pneumonia	13	11	0.897
CHF	9	6	0.753
Cardiac arrest	6	10	0.247
COPD	2	1	0.911
OVTA	2	2	0.697
ABG values (before extubation)			
pH (average)	7.414	7.389	0.452
$PaCO_2$ (mmHg) (average)	46.88	46.6	0.937
PaO_2/FiO_2 (average)	313.2	301.3	0.080

APACHE II: Acute Physiology and Chronic Health Evaluation II; RSBI: Rapid Shallow Breathing Index; BR: Breathing rate; AAP: Average arterial pressure; HR: Heart rate; CHF: Congestive heart failure; DM: Diabetes mellitus; CRF: Chronic renal failure; HT: Hypertension; OTI: Orotracheal intubation; ARDS: Acute respiratory distress syndrome; COPD: Chronic obstructive pulmonary disease; OVTA: Out-of-vehicle traffic accident; ABG: Arterial blood gas.

mechanical ventilation based on the protocol was approximately 10%. In the same study, a 96 h period interval was determined for reintubation, and the period determined for reintubation in our study was the same. In our study, while the reintubation rate was 53.3% in the POB group, it was 8.8% in the PB group. In our randomized study, the high APACHE II score in the POB group may explain this difference in the rate of reintubation ($p<0.022$). However, the TOS effect caused by long intubation may also contribute to this situation.

Thille et al.[18] determined that 31 (14%) of 225 patients who were intubated for more than 24 h, who were extubated depending on the protocol, needed reintubation within 7 days after extubation. In this study, extubation failure of patients with insufficient cough, mechanical ventilation duration of more than 7 days, and advanced left ventricular dysfunction are reported as stronger indicators than delirium and myopathy. In our study, unlike the study above, we included patients who were intubated for at least 48 h and accepted as reintubated if they were intubated again within 4 days. In our study, reintubation occurred in patients in the PB (8.8%) and POB (53%) groups. We think that the high reintubation rate in the POB group, the high APACE II value in the POB group in our study, and the accompanying comorbid diseases during admission to the ICU may contribute.

In a study by Yin et al.[19] in pigs, oxidative damage and antioxidant response after early weaning were examined. In early weaning, it has been observed that the p53 gene, which increases reactive oxidant derivatives, increases after awakening, and the level of p65, which increases the activation of the antioxidant system and regulates the antioxidant gene, is

Table 4. TAC and TOS parameters in case of before extubation and after extubation

	Before extubation		p-value	After extubation		p-value
	PB	POB		PB	POB	
TAC (mmol Trolox Equivalent/L)	0.89±0.26	0.96±0.20	>0.05	0.80±0.18	0.81±0.15	>0.05
TOS (1 mol H_2O_2 Equiv/L)	34±17.86	31±14	>0.05	28.2±9.6	27.1±7.8	>0.05
OSI (TOS. 1 mol/L)/(TAC. 1 mol Trolox equivalent/L)/100	4.1±2.42	3.34±1.49	>0.05	3.62±1.28	3.42±1.02	>0.05
Reintubation (n)				3/34	16/30	=0.0001

TAC: Total antioxidant capacity; TOS: Total oxidative stress; OSI: Oxidative stress index; PB: Protocol-based; POB: Observation of the physician.

Table 5. Oxidative stress factor and TAC values among POB and PB's themselves

	POB			PB		
	Before extubation Mean±SD	After extubation Mean±SD	p-value	Before extubation Mean±SD	After extubation Mean±SD	p-value
TAC (mmol Trolox Equivalent/L)	0.96±0.20	0.81±0.15	=0.001	0.89±0.26	0.80±0.18	=0.03
TOS (1 mol H_2O_2 Equiv/L)	31±14	27.1±7.8	=0.049	34±17.86	28,2±9.6	=0.02
OSI (TOS, 1 mol/L)/ (TAC, 1 mol Trolox equivalent/L)/ 100	3.34±1.49	3.42±1.02	>0.05	4.1±2.42	3.62±1.28	>0.05

TAC: Total antioxidant capacity; TOS: Total oxidative stress; OSI: Oxidative stress index; PB: Protocol-based; POB: Observation of the physician; SD: Standard deviation.

suppressed. In our study, we also observed that TAC levels decreased in both groups, similar to this study. It was determined that the decrease in TAC in the HGB group with a longer intubation period was statistically more significant (p=0.001) than the PB group (p=0.03). In addition, when we looked at TOS levels, we observed that it decreased more in the PB group than in the POB group after extubation. We think that this is due to the shorter intubation period of the patients in the PB group (Table 4).

Verona et al.[20] obtained similar results in oxidative stress blood measurements of patients in successful or unsuccessful SBT s in their study for blood markers of OS to predict failure to wean from a mechanical ventilator (MV). In our study, it cannot be said that the TOS and TAC values are significant in both groups in evaluating the success of weaning from the mechanical ventilator. However, we think that the high reintubation rate in the POB group may be due to the parameters used in the selection of patients and the higher APACHE II score in the POB group compared to the PB group.

Silva et al.,[21] the relationship between short MV duration and reintubation rate with a special weaning protocol in an intensive care unit was investigated. In a retrospective study performed on 252 patients, the reintubation rate was 12.7% (32 patients). The high rate of reintubation in the POB group (52%) in our study can be attributed to the significantly higher APACHE II score of the patients included in the study in the POB group (p=0.022). Imad BouAkl et al.,[22] regarding weaning from MV, it was stated that intubation should be short term and new methods should be developed to prevent this because prolonged intubation increases complications. In addition, it has been stated that weaning performed by adhering to a specific protocol can reduce the complications of earlier extubation and prolonged extubation. In our study, although earlier extubation was aimed in the POB group, a longer intubation period and an increased reintubation rate were observed compared to the PB group. We think that a two-group study with similar APACHE II scores and higher number of patients is needed to explain the reason for the high reintubation rate in the POB group.

Jaber et al.,[23] although the short and long effects of mechanical ventilation MV on the antioxidant systems of the pig diaphragm do not work; it was stated that prolonged controlled MV caused diaphragmatic oxidative stress, and diaphragm thiobarbituric reagent was found to be significantly higher and SOD activity lower in long MV and short MV. Glutathione peroxidase activity was expected to be lower in animals treated with long MV, but no significant difference was found. Patients who are ventilated with a high oxygen rate in a mechanical ventilator are exposed to oxidative stress and this disrupts the muscle strength and energy balance and prolongs the extubation time.[7,8] When the results of our study

were examined, it was observed that mechanical ventilation caused oxidative stress, with a decrease in TOS after extubation in both groups. Moreover, the decrease in TOS in the POB group compared to the PB group can be explained by the reason of prolonged intubation and is compatible.

The small number of cases and the single-center nature of our study can be counted among the limitations of our study. In addition, one of the limitations of our study is that it was conducted in an ICU with high APACHE II scores.

Conclusion

While the life balance of patients in intensive care units is in a critical process, it is necessary to balance free radicals and keep metabolic problems related to oxidative stress under control. This study is the first known study in the literature that shows that a PB extubation can be beneficial for the metabolic balance of the body as well as reducing the risk of reintubation compared to the POB group. In our study, TAC values were found to be higher in the PB group than in the POB group, and in addition, the reintubation rate was found to be lower. We think that the management of weaning as a PB may contribute to maintaining the balance between TAC and TOS and reduce the rate of reintubation.

Ethics Committee Approval: This study was approved by the İstanbul Medipol University Clinical Research Ethics Committee (Date: 07.11.2014, Decision No: 30).

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ORİJİNAL ÇALIŞMA - *ÖZ*

Klinik gözlem ve protokole dayalı weaning'in antioksidan stres faktörleri üzerindeki etkilerinin karşılaştırılması

Dr. Cem Erdoğan,[1] Dr. Denız Kızılaslan,[1] Dr. Burcu Tunay,[1] Dr. Pelin Karaaslan,[1] Dr. Gözde Ülfer,[2] Dr. Türkan Yiğitbaşı,[2] Dr. Yavuz Demiraran,[1] Dr. Hüseyin Öz[1]

[1]İstanbul Medipol Üniversitesi Tıp Fakültesi, Anesteziyoloji ve Reanimasyon Anabilim Dalı, İstanbul
[2]İstanbul Medipol Üniversitesi Tıp Fakültesi, Biyokimya Anabilim Dalı, İstanbul

AMAÇ: Bu çalışmada, hekim gözlemine (POB) veya protokole bağlı (PB) weaning protokolünün total antioksidan kapasite (TAC) ve total oksidatif stres (TOS) düzeyleri ve weaning başarı düzeyleri üzerindeki etkilerini karşılaştırmayı amaçladık.

GEREÇ VE YÖNTEM: Çalışmamız Ocak 2015–Ocak 2018 tarihleri arasında hastanemiz yoğun bakım ünitesinde acil servisten başvuran hastalar üzerinde yapıldı. Spontan solunum denemesi sırasında, belirtilen kriterlerden biri geliştiğinde, SBT sonlandırıldı ve önceki mekanik ventilatör parametrelerine dönüldü. Hastaların ertesi sabah tekrar SBT'ye alınması planlandı. Spontan solunum denemesi başarılı olursa ekstübasyona karar verildi. Doktor gözlemine dayalı ekstübasyon kararı, hastanın bilinç durumu ve günlük vizit sırasında yeterli göğüs ekspansiyonu durumuna göre verildi.

BULGULAR: POB grubu hastalarda ekstübasyon öncesi ve sonrası TAK ortalama değerindeki düşüş anlamlı bulundu (p=0.001). PB grubu hastalarda ekstübasyon öncesi ve sonrası TAK ortalama değerindeki azalma anlamlı bulundu (p=0.03).

TARTIŞMA: Çalışmamızda PB grubunda TAK değerleri POB grubuna göre daha yüksek bulundu ve ayrıca yeniden entübasyon oranı daha düşük bulundu. Bir PB olarak weaning yönetiminin TAC ve TOS arasındaki dengeyi korumaya ve yeniden entübasyon oranını düşürmeye katkıda bulunabileceğini düşünüyoruz.

Anahtar sözcükler: ICU; oksidatif stres indeks; total antioksidan kapasite; total oksidatif stres; weaning.

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