THE EFFECT OF CO-ORDINATED SPONTANEOUS AWAKENING AND BREATHING TRIALS PROTOCOL ON THE DURATION OF VENTILATION AMONG MECHANICALLY VENTILATED PATIENTS

Zeinab Hussein Ali[1], Taisser Zaiton [2],Ekram Mahmoud Shalash[3]

Article History: Received: 20.05.2023 **Revised:** 25.06.2023 **Accepted:** 01.07.2023

ABSTRACT

Background: Mechanical ventilation is a therapeutic modality which is commonly used to support the respiratory function of patients with life-threatening illnesses. Mechanical ventilation is not an intervention without complications. The ventilator management should be aimed at getting the patient off ventilator support as rapidly as possible. Repeated ventilator weaning failure can cause prolonged mechanical ventilation period. **Aim of the study:** To determine the effect of co-ordinated spontaneous awakening and breathing trials protocol on the duration of ventilation among mechanically ventilated patients.

Research design: A quasi experimental design.

Setting: General intensive care units and cardiopulmonary intensive care unit of Damanhur Medical Institute**.**

Methods: A purposive sample of 60 adult mechanical ventilated patients from previously mentioned setting, allocated randomly into two equal groups (30 patients in each). **Tools**: Three tools were utilized, included: Spontaneous Awakening Trial Safety Screen, Spontaneous Breathing Trial Safety Screen, Mechanical ventilation duration measurement record

Results: There was a statistical significant difference between both groups as regarding duration of mechanical ventilation (P-value < .009**).

Conclusion: Application of co-ordinated spontaneous awakening and breathing trials protocol had a positive effect on the duration of ventilation among mechanically ventilated patients.

Recommendations: Apply co-ordinated spontaneous awakening and breathing trials protocol help patients to decrease duration of mechanical ventilation.

Key words: Breathing Trial, Duration of mechanical ventilation, Spontaneous Awakening,

1 Professor of Adult Health Nursing, Faculty of Nursing Helwan University
2 Professor of Critical Medicine, Faculty of Medicine Alexandria University
3 Assistant Lecturer of Critical Care and Emergency Nursing, Faculty of Nursing Tanta University

DOI: 10.48047/ecb/2023.12.Si8.641

1. INTRODUCTION

Mechanical ventilation (MV) is a therapeutic modality which is commonly used to support the respiratory function of patients with life-threatening illnesses. There are numerous indications for MV, but in general MV should be considered for the patient cannot maintain an airway, adequate oxygenation or ventilation. MV should not be delayed until the patient is in extremis. **(Cohen JA, 2015) (Pearson SD ,2020).**

Core principles of critical care to present comfort, improve tolerance of the rough intensive care unit environment, and help to decrease distress. Critically ill patients, especially those who are receiving mechanical ventilation usually have dyspnea, pain, fear, anxiety, and other forms of distress such as disruption, noise, and sleep deprivation that coupled with stress and fear of the critical illness are also culprits**. (Fultz B, 2019)(Hoyer E, 2015).**

Weaning from mechanical ventilation is an essential and universal element in the care of critically ill intubated patients receiving mechanical ventilation. Weaning covers the entire process of liberating the patient from mechanical support and from the endotracheal tube, including relevant aspects of terminal care. There is uncertainty about the best methods for conducting this process, which will generally require the cooperation of the patient during the phase of recovery from critical illness. This makes weaning an important clinical issue for patients and clinicians. Immediate, uncomplicated postoperative extubation is excluded from the scope of the current statement. **(Khalil N, 2018).**

Repeated ventilator weaning failure can cause prolonged mechanical ventilation period which may increase morbidity and mortality of patients. Mechanically ventilated patients experience negative emotions such as anxiety, anger, fear and frustration during mechanical ventilation period because of the intensive care unit (ICU)

environment, invasive monitoring devices, ventilator dyssynchrony, invasive procedures, communication difficulties, and dyspnea**.(Doorduin J,2016).**

The spontaneous awakening and breathing trails coordination protocol incorporates the best available evidence related to sedation and analgesia and ventilator management in ICU. Therefore, critical care nurses, as quality improvement initiatives, play a major role in adherence to evidence based guidelines, vigilant monitoring, astute observation, early intervention, advocacy, interdisciplinary team work and measuring short and long term outcomes for improving quality of care. **(Mcginn K, 2018).**

Significance of the study:

Use of criteria for weaning readiness has been shown to significantly reduce the number of weaning failure among mechanically ventilated patients. However, despite the use of these criteria, over 45% failed at least one attempt. Extubation failure is reported to be as high as 15-18% of planned extubations cause difficult and prolonged weaning. **(Penuelas, Frutos-Vivar, and Fernandez, 2011),(Tobin,2012).**

Controlled trial to assess whether daily coordinated SATs and spontaneous breathing trials (SBTs) might prevent ventilator-associated events (VAEs). 20 units in the Centers for Disease Control and Prevention Epicenters Program participated in the trial. 12 units implemented an opt-out protocol for nurses and respiratory therapists to perform paired daily SATs and SBTs. 8 units only conducted surveillance for VAEs. With significant increases in the performance of SATs and SBTs, there were significant decreases in duration of mechanical ventilation and hospital length of stay. ***(Klompas, 2015).***

Aim of the study:

The aim of the present study is to determine the effect of co-ordinated spontaneous awakening and breathing trials protocol on the duration of ventilation among mechanically ventilated patients through the following objectives:-

- Assess clinical data for mechanically ventilated patients.
- Implement co-ordinated spontaneous awakening and breathing trials protocol for the study group.
- Evaluate the effect of applying co-ordinated spontaneous awakening and breathing trials Protocol on the duration of ventilation among mechanically ventilated patients on the study group.

- **Research Hypothesis:**

At the end of the study the mechanically ventilated patients who exposed to the designated protocol will have less duration on mechanical ventilator than those patients whom will have routine care in the ICU.

- **Theoretical Framework**

The present study employed Orem's Self-care Deficit Nursing Theory (SCDNT) as a theoretical framework of reference in implementing the self-care management program. The theory includes the theoretical constructs of Self-Care, Self-Care Deficits and Nursing Systems (Hartweg DL., 2022).

According to the theory, nursing is required in situations of self-care deficits, which occurs when an individual is unable to fulfill self-care activities. It can encompass limitations in knowledge, the ability to perform actions, or making decisions, and nurses play an essential role in fulfilling the self-care need activities using the theory of the nursing system **(Tanaka M , 2022).**

2. SUBJECT AND METHODS

Research Design:

A Quasi-experimental design was utilized to conduct the study

Setting:

This study conducted in the General intensive care units of Damanhur Medical Institute and cardiopulmonary intensive care unit.

Subject:

A purposive sample of 60 adult mechanically ventilated patients from the above mentioned settings and divided randomly into two equal groups study and control (30 patients for each group). The patients in both groups were selected according to the following criteria: **With Inclusion criteria:** Newly admitted patients (less than 24hrs), Patients who will in need for mechanical ventilation for more than 24 hours on continuous sedation, and$PEEP<8$ cmH_2O, PaO_2/Fio_2 ratio>150-200.**With Exclusion criteria:** Patients who had neuromuscular disorders that may affect respiratory muscles, and ICP or VAP after 48 hours of admission.

Tools of Data Collection:

Tools of data collection that used to achieve the purpose of the current study are three tools:-

1ST tool: "Spontaneous Awakening Trial (SAT) Safety Screen": (Dichotomous questionnaire):

This tool adopted from ***(Girard, 2008)*** with a reliability score (r=0.747). It used to assess patient's readiness and tolerance for SAT. It consists of two parts:Part I: Spontaneous awakening trial safety screen. Part II: Spontaneous awakening trial tolerance screen.

2endtool: "Spontaneous Breathing Trial (SBT) Safety Screen"(Dichotomous questionnaire):

This tool adopted from ***(Kallet , 2018)***with a reliability score (r=0.921).It used to assess patient's readiness and tolerance for SBT. It consists of two parts: Part I: Spontaneous breathing trial safety screen. Part II: Spontaneous Breathing Trial Tolerance Screen.

3rd tool: "Mechanical ventilation duration measurement record for coordinated spontaneous awakening and breathing trial": (Assessment questionnaire):

This tool adopted from **(Hopkins ,2017)** with a reliability score (r=0.821).It used to assess patient's duration on the mechanical ventilation and patient's clinical outcomes.

Ethical considerations:

- An ethical approval to conduct the proposed study was obtained from the Scientific Research, Ethical Committee of the faculty of Nursing, Helwan University.
- The researcher obtained an oral and written consent from the studied patients.
- Participation in the study was voluntary, studied patients were given complete full information about the study and their role before signing the informed consent.
- The ethical considerations include explaining the purpose and nature of the study, stating the possibility to withdraw at any time, confidentiality of data assured by the researcher by using codes to identify participants instead of names or any other personal identifiers.
- **Pilot study:**
- A Pilot study was carried out with 10% (not less than 10 patients) of the sample under study to test the applicability, clarity and efficiency of the tools. Patients who shared in pilot study are excluded from the study sample.
- **Field Work:**
  - Sampling was started and completed within thirteen months from February 2021 to the end of March 2022 and carried out through four phases: assessment, diagnosis, implementing and evaluation.
- **Assessment phase:**
- The researcher collects data regarding to participants' sociodemographic and health history. Data collection was held through structured interviews and medical record chart. Each patient was assessed individually before SAT, SBT co-ordination porotocol, and data collection was filled by the researcher.
- **Second phase (diagnosis phase)** According to Orem's theory diagnosis provides the basis for selection of nursing interventions to achieve outcomes for which the nurse is accountable, actual problems includes: altered breathing pattern, altered level of consciousness. Potential problem: risk for complications as VAP, infection, and delirium.
- **Implementation phase:**
- Newly admitted adult MVPs who met the inclusion criteria will randomly assign through coins toss method into equal groups, study (PG) and control (NPG) (30 patients in each). The PG subjected to spontaneous coordinated awakening and breathing trials protocol and the NPG received the routine nursing care. There are two trials; each one will proceed by screening phase and followed by monitoring phase for tolerance signs.

-For Non Protocolized Group; after assessing SAT safety screen, NPG of patients was subjected to the routine care used in the study settings.

-For Protocolized Group; there are two probabilities. The first one; if the PG of patients did not meet any of SAT safety screen criteria. Thus, they were considered not ready to be awakened and then the researcher reassessed them for the next 24 hours and repeat till safety was considered. The second probability; if SAT safety screen criteria was present. The researcher considered that it is safe to conduct the trial through shutting off all continuous sedatives infusion and / or withholding all sedative bolus. This decision was taken collaboratively with the physician.

-After awakening; both groups of patients were monitored by the researcher for SAT tolerance when patients were awake and calm and there are no signs of intolerance, SBT was considered. However, the NPG of patients in this case were subjected to the study setting' routine care.

-For Protocolized Group; SBT will consider safe to be conducted when all safety screen criteria are present. On the other hand, when PG of patients considered unready to SBT if any of the SBT safety screen criteria was absent, they remained on the same ventilator data in addition to restart the sedatives at half of the previous dose, reassess the next 24 hours for SBT safety screen criteria and repeat till safety was considered.

-For Non Protocolized Group; after screening for the readiness of SBT safety screen criteria, NPG of patients were subjected to the routine care used in the study settings.

-After conducting SBT; both groups of patients monitored the researcher for SBT tolerance If the patients were not developing signs of intolerance from 30 minutes to 120 minutes the patient's physicians notified for possible extubation. But, if any signs of intolerance are present, the previous ventilator support restarted for PG of patients only.

Evaluation phase:

Evaluation was done by using tool (III) used to assess patient's duration on the mechanical ventilation and patient's clinical outcomes. The duration of mechanically ventilation was the primary outcome in this study. Other awakening, weaning outcomes and ventilator associated complications were the secondary outcomes. The collected data were managed in such manners which test the study hypotheses. The study hypotheses propose that, MVSPs subjected to the ABC protocol exhibit more positive awakening and weaning outcomes with lesser ventilator associated complications and duration than those who were not subjected.

Result:

Table (1): Frequency and percentage distribution of sociodemographic characteristics for both Study and control groups (N: 60)**.**

Patient characteristics	Study group 30		Control group 30		Test P value
	N	%	n	%	
Age:					T test
30 - <40	2	6.7	1	3.3	1.890
40 - <50	2	6.7	3	10	>0.05
50 – <60	6	20	5	16.7	
60 or more	20	66.7	21	70	
Mean± SD	63.7 ± 8.94		65.22 ± 7.61		
Gender:					Chi-square
Females	20	66.7	19	63.3	0.924
Males	10	33.3	11	36.7	0.078

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05

Table (1) illustrates that there was no statistically significant difference between study and control groups with p-value >0.05, as regarding socio-demographic characteristics like; age, gender, which indicated proper matching between study and control groups in these variables.

Table 2: Distribution of patients according to past& current medical data in study and control groups (N=60)

Medical data	Study group 30		Control group 30		T Test P value
	N	%	n	%	
Length of ICU stay:					1.261
4 – 8	22	73.3	11	36.6	0.013
9 – 14	6	20	7	23.4	
>14 days	2	6.6	12	40	
Mean± SD	6.5 ± 1.3		12.3 ± 1.71		
APACHE II score on admission:					1.120
7 – 12	12	40	10	33.3	0.057
13 – 18	14	46.7	14	46.7	
19 - 24	4	13.3	6	20	
Mean± SD	13.9 ± 4.0		14.4 ± 3.60		
SOFA score:					
4 – 9	11	36.7	9	30	1.042
10 – 15	16	53.3	16	53.3	0.062
16 - 21	3	10	5	16.7	
Mean± SD	10.85± 2.3		10.14± 2.1		
CAM-ICU score:					
1 – 3	16	53.3	15	50	1.044
4 – 6	14	46.7	15	50	0.062
7 – 9	0	0	0	0	
Mean± SD	4.07 ± 0.9		3.5 ± 0.8		
Duration of continuous sedation in days:					0.980
1 – 5	22	73,3	14	46.7	0.031
6 – 12	6	20	12	40	
13 – 19	2	6.6	4	13.3	
Mean± SD	6.5 ± 1.3		7.2 ± 1.6		

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05

Table (2) shows that the mean length of stay in the study group was 6.5 ± 1.3, while in the control group, it was 12.3±1.71. There was highly significant difference between the two groups, with

a p-value 0.013. Additionally, for the Duration of continuous sedation, there was a significant difference between the study and control groups, with a p-value p ‹0.05 it was (0.031).

Table (4): Frequency and percentage distribution of major health related data for both study and control groups (N:60).

Patient characteristics	Study group 30		Control group 30		Test P value
	N	%	n	%	
Current diagnosis:					
Cardiovascular disorder	5	16.7	6	20	
Renal disorder					Chi-square
Respiratory disorder	3	10	3	10	1.382
Metabolic disorder					0.05
Gastrointestinal disorder	12	40	10	33.3	
	6	20	5	16.7	
	2	6.7	2	6.7	
Co-morbidities:					
Cardiovascular disorder	5	16.7	6	20	
Renal disorder					Chi-square
Respiratory disorder	3	10	3	10	1.382
Metabolic disorder					0.05
Gastrointestinal disorder	12	40	10	33.3	
	6	20	5	16.7	
	2	6.7	2	6.7	

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05

Table (4) shows that 40% of patients in the study group were diagnosed with respiratory disorders, while 33.3% of patients in the control group were diagnosed with respiratory disorders. The difference in the prevalence of respiratory disorders between the two groups was a statistically significant, with a p-value 0.05. Regarding co-morbidities, 16.7% of patients in the study group suffered from cardiovascular disorders. Majority of both control and study group had respiratory disorders co-morbidities. There was no significant difference in the prevalence of co-morbidities between the study and control groups, with a p-value > 0.05.

Table (5): Frequency and percentage distribution of Patient's safety screening criteria for SAT for study and control groups (N:60).

safety screening criteria for SAT	**Study group present**		**Control group present**		**Test P value**
	N	**%**	**n**	**%**	
Signs of increased ICP					
Change in LOC	**0**	**0**	**9**	**30**	**9.776 0.000****
Ocular signs such as diplopia	**0**	**0**	**3**	**10**	**9.896 0.010****
Decrease in motor function	**2**	**6.7**	**11**	**36.7**	**3.500 0.013***
Cushing triad	**2**	**6.7**	**9**	**30**	**4.681 0.011***
Projectile vomiting	**2**	**6.7**	**7**	**23.3**	**4.881 0.021***
Headache	**16**	**53.3**	**21**	**70**	**10.145 0.000****
Signs of myocardial instability					
ECG ischemic changes	**3**	**10**	**21**	**70**	**6.129 0.005****
- HR > 120 b/m	**6**	**20**	**13**	**43.3**	**5.023 0.011***

SBP change 20 % from baseline chest pain elevated biomarkers levels	**0**	**0**	**6**	**20**	**5.000 0.011***
RASS: +2 Agitated +1 Restless 0 Alert and calm -1 Drowsy -2 Light sedation -3Moderate sedation	 **2** **10** **14** **0** **3** **1**	 **6.7** **33.3** **46.7** **0** **10** **3.3**	 **4** **2** **11** **0** **3** **10**	 **13.3** **6.7** **36.7** **0** **10** **33.3**	 **8.711 0.001****
Indication for sedative infusion: Active seizure Agitation Drug withdrawal	 **0** **0** **0**	 **0** **0** **0**	 **0** **3** **15**	 **0** **10** **50**	 **7.661 0.004****
Simple tasks:					
Open eyes	**30**	**100**	**30**	**100**	**3.999 0.014***
Look at caregivers	**30**	**100**	**30**	**100**	
Squeeze the hands	**29**	**96.7**	**17**	**56.7**	
Put out tongue	**30**	**100**	**24**	**80**	
Mean (SD)	**3.96 (0.04)**		**2.93 (0.65)**		

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05
*SAT Spontaneous awakening trial.
Table (5) presents significant findings related to all safety screening criteria for SAT in the study and control groups.

Table (6): Frequency and percentage distribution of Patient's intolerance criteria for SAT for study and control groups (N:60).

Signs of intolerance spontaneous awakening trial	**2** hrs after SAT		**4** hrs after SAT		**6** hrs after SAT		**8** hrs after SAT		**10** hrs after SAT		**12** hrs after SAT	
	Study	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**
Decreased level of consciousness	**0**	**2**	**0**	**3**	**0**	**4**	**0**	**7**	**0**	**6**	**0**	**6**
Chi-square p. value	**3.133 0.034***		**3.560 0.030***		**4.122 0.027***		**7.655 0.006****		**7.234 0.007****		**7.234 0.007****	
Restlessness	**30**	**30**	**10**	**30**	**6**	**30**	**0**	**2**	**0**	**2**	**0**	**2**
Chi-square p. value	---		**9.800 0.000****		**9.761 0.000****		**2.909 0.042***		**2.909 0.042***		**2.909 0.042***	
Agitation/ anxiety	**2**	**8**	**2**	**8**	**2**	**8**	**0**	**2**	**2**	**13**	**2**	**13**
Chi-square p. value	**6.544 0.008****		**6.544 0.008****		**6.544 0.008****		**2.909 0.042***		**9.220 0.000****		**9.220 0.000****	
Pain	**29**	**30**	**12**	**30**	**8**	**30**	**2**	**13**	**2**	**13**	**0**	**2**
Chi-square p. value	**0.982 0.075**		**8.999 0.000****		**10.134 0.000****		**7.891 0.002****		**7.891 0.002****		**2.909 0.042***	
Diaphoresis	**1**	**3**	**1**	**5**	**0**	**5**	**0**	**7**	**0**	**5**	**1**	**4**
Chi-square p. value	**2.444 0.045***		**3.500 0.035***		**5.383 0.011***		**7.655 0.006****		**5.383 0.011***		**4.122 0.027***	
Use of accessory muscles	**15**	**30**	**5**	**16**	**2**	**16**	**0**	**14**	**0**	**13**	**0**	**12**
Chi-square p. value	**11.980 0.000****		**10.234 0.000****		**10.999 0.000****		**11.243 0.000****		**11.001 0.000****		**10.761 0.000****	
SpO_2 < 88 %	**2**	**6**	**3**	**7**	**0**	**5**	**0**	**5**	**0**	**6**	**0**	**6**
Chi-square p. value	**4.512 0.025***		**4.122 0.027***		**5.383 0.011***		**5.383 0.011***		**7.234 0.007****		**7.234 0.007****	

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05 ¶

Table (6) reveals that there was high significant difference in all intolerance criteria for SAT for study and control groups after SAT .

Table (7): Continue table (6): Frequency and percentage distribution of Patient's intolerance criteria for SAT for study and control groups (N:60).

	2 hrs after SAT		**4** hrs after SAT		**6** hrs after SAT		**8** hrs after SAT		**10** hrs after SAT		**12** hrs after SAT	
	Study	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**
Respiratory rate > 35 b/ m for ≥ 5 min.	**5**	**12**	**3**	**11**	**2**	**10**	**0**	**8**	**1**	**8**	**1**	**9**
Chi-square p. value	**7.300** **0.003****		**8.671** **0.001****		**7.590** **0.003****		**8.100** **0.002****		**7.500** **0.003****		**8.455** **0.001****	
Heart rate > 120 b/min or > 20% sustained change from baseline	**1**	**6**	**0**	**5**	**0**	**5**	**0**	**4**	**0**	**4**	**0**	**3**
Chi-square p. value	**5.999** **0.009****		**5.383** **0.011***		**5.383** **0.011***		**4.122** **0.027***		**4.122** **0.027***		**3.145** **0.041***	
Systolic blood pressure > 180 mmHg or < 90 mmHg	**1**	**3**	**1**	**4**	**0**	**3**	**0**	**2**	**0**	**2**	**0**	**1**
Chi-square p. value	**2.677** **0.040***		**3.566** **0.038***		**3.560** **0.030***		**2.909** **0.042***		**2.909** **0.042***		**0.876** **0.234**	
Acute cardiac dysrhythmia	**2**	**5**	**2**	**6**	**0**	**7**	**0**	**10**	**0**	**10**	**0**	**8**
Chi-square p. value	**3.167** **0.020***		**3.400** **0.017***		**6.200** **0.005****		**8.500** **0.001****		**8.500** **0.001****		**8.100** **0.002****	
Total SAT intolerance											**5** **16.6%**	**24** **80%**
Chi-square p. value											**8.455** **0.001****	

*SAT Spontaneous awakening trial. ¶

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05 ¶

Table (7) reveals that there was high significant difference in all intolerance criteria for SAT for study and control groups after SAT.

There was high significant difference p value **0.001**** related SAT intolerance criteria as only 16,6% of the study group showed SAT intolerance 12 hrs after SAT. While 80% of the control group showed SAT intolerance 12 hrs after SAT.

Table (8): Frequency and percentage distribution of Patient's safety screening criteria for SBT for study and control groups (N:60).

Patient's safety screening criteria for SBT	**Study group present**		**Control group Present**		**Test P value**
	n	**%**	**n**	**%**	
Oxygenation parameters					
FiO_2 < 50 %	**12**	**40**	**4**	**13.3**	**9.888** **0.001****
PaO_2/FiO_2 ratio < 240 & no ARDS	**10**	**33.3**	**3**	**10**	**8.700** **0.003****
$SpO_2 \geq 88\%$	**24**	**80**	**20**	**66.7**	**4.056** **0.021***
PH > 7.34	**8**	**26.7**	**2**	**6.7**	**8.364** **0.004****
Ventilation parameters					

PEEP < 8 cmH2o	**25**	**83.3**	**20**	**66.7**	**4.670 0.013***
Sufficient minute volume (4-6 mL/Kg)	**26**	**86.7**	**19**	**63.3**	**6.700 0.007****
Spontaneous inspiratory effort in a 5 minute period	**24**	**80**	**17**	**56.7**	**7.800 0.005****
Neurological parameters					
No agitation	**28**	**93.3**	**23**	**76.7**	**4.612 0.014***
Conscious patient	**30**	**100**	**30**	**100**	**--**
Hemodynamic parameters					
Temperature (normothermic)	**28**	**93.3**	**21**	**70**	**6.537 0.007****
Heart rate < 120 b/m	**27**	**90**	**20**	**66.7**	**8.002 0.005****
Respiratory rate < 35 c/m	**24**	**80**	**18**	**60**	**8.364 0.004****
Systolic blood pressure > 90 mmHg < 180 mmHg	**29**	**96.7**	**22**	**73.3**	**7.612 0.006****
Mean arterial blood pressure ≥ 60 mmHg	**29**	**96.7**	**23**	**76.7**	**8.321 0.002****
Other safety screen criteria					
No significant use of vasopressors or inotropes (dopamine ≥5 μg/kg per min, norepinephrine ≥2 μg/min, or vasopressin or milrinone at any dose).	**30**	**100**	**26**	**86.7**	**6.490 0.009****
No evidence of increased intracranial pressure.	**29**	**96.7**	**21**	**70**	**7.023 0.006****
No evidence of myocardial instability.	**29**	**96.7**	**23**	**76.7**	**6.411 0.009****

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05 ¶

*SBT spontenous breathing trial ¶

Table (8) reveals that there was high significant difference in all safety screening criteria for SBT for study and control groups**.**

Table (9): Frequency and percentage distribution of Patient's intolerance criteria for SBT for study and control groups (N:60).

Patient's intolerance criteria for SBT	30 min. after SBT		60 min. after SBT		90 min. after SBT		120 min. after SBT	
	Study	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**
Abrupt change in mental status	**3**	**8**	**3**	**8**	**4**	**9**	**3**	**7**
Chi-square p. value	**4.981 0.013***		**4.981 0.013***		**5.091 0.011***		**4.100 0.018***	
Restlessness	**26**	**30**	**11**	**19**	**14**	**18**	**1**	**16**
Chi-square p. value	**4.554 0.014***		**6.778 0.007****		**5.224 0.011***		**4.371 0.014***	
Agitation	**1**	**6**	**3**	**5**	**4**	**7**	**5**	**7**
Chi-square p. value	**4.226 0.019***		**1.643 0.052**		**3.997 0.028***		**1.713 0.053***	
Diaphoresis	**2**	**7**	**5**	**8**	**6**	**10**	**3**	**11**
Chi-square	**4.371**		**3.997**		**4.666**		**5.001**	

p. value	**0.014***		**0.028***		**0.011***		**0.010***	
Use of accessory muscles	**11**	**16**	**12**	**17**	**12**	**18**	**1**	**17**
Chi-square p. value	**4.126** **0.018***		**4.222** **0.017***		**6.900** **0.006****		**6.778** **0.007****	
Abdominal paradox	**6**	**10**	**2**	**9**	**6**	**9**	**3**	**9**
Chi-square p. value	**4.100** **0.018***		**7.134** **0.004****		**3.997** **0.028***		**4.226** **0.019***	
SpO_2 < 88 %	**8**	**16**	**7**	**17**	**5**	**15**	**2**	**14**
Chi-square p. value	**7.889** **0.003****		**8.900** **0.000****		**9.102** **0.000****		**8.560** **0.001****	

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not ¶
significant at p>0.05
*SBT spontenous breathing trial ¶

Table (9) reveals that there was high significant difference in all safety screening criteria for SBT for study and control groups**.**

Table (10): Distribution of patients according to Signs of intolerance for Spontaneous breathing Trial in study and control groups (n=60)

Signs of intolerance for SBT	30 min. after SBT		60 min. after SBT		90 min. after SBT		120 min. after SBT	
	Study	**Control**	**Study**	**Control**	**Study**	**Control**	**Study**	**Control**
Respiratory rate > 35 b/ m for ≥ 5 min.	**4**	**11**	**5**	**14**	**4**	**12**	**2**	**13**
Chi-square p. value	**7.800** **0.003****		**8.690** **0.001****		**8.001** **0.002****		**7.650** **0.003****	
Heart rate > 120 b/min or > 20% sustained change from baseline	**4**	**12**	**5**	**12**	**3**	**14**	**3**	**11**
Chi-square p. value	**8.001** **0.002****		**7.546** **0.006****		**9.102** **0.000****		**7.800** **0.003****	
Systolic blood pressure > 180 mmHg or < 90 mmHg	**2**	**11**	**3**	**12**	**4**	**9**	**2**	**8**
Chi-square p. value	**8.900** **0.000****		**8.790** **0.001****		**5.800** **0.009****		**4.100** **0.018***	
Acute cardiac dysrhythmia	**1**	**6**	**2**	**9**	**3**	**8**	**0**	**9**
Chi-square p. value	**4.226** **0.019***		**6.317** **0.007****		**5.091** **0.011***		**5.091** **0.011***	
RSBI = Respiratory Rate/Tidal Volume in liters: Success Failure	**24** **6**	**16** **14**	**24** **6**	**15** **15**	**24** **6**	**16** **14**	**25** **5**	**18** **12**
Chi-square **p. value**	**10.823** **0.000****		**9.700** **0.000****		**10.124** **0.000****		**10.001** **0.000****	
Total SBT intolerance							**5** **16.6%**	**22** **80%**
Chi-square p. value							**8.560** **0.001****	

¶ *Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05
¶ *SBT spontenous breathing trial. * RSBI Rapid shallow breathing index = Respiratory Rate/Tidal Volume in liters.

Table (10) shows a high significant difference in Signs of intolerance for Spontaneous breathing Trial in study and control groups Related SBT intolerance criteria as only 16,6% of the study group showed SBT intolerance 120 minutes after SAT. While 80% of the control group showed SBT intolerance 120 minutes after SBT

Table (11): Relation between SBT attempts before and after implementation of SAT, and SBT co-ordinated protocol among study group and control group (N:60).

Study group	SBT attempt before		SBT attempt after	
	Mean	SD	Mean	SD
Successful SBT in control group	2.8	1.7	2.7	1.6
Failed SBT in control group	11.4	5.7	11,2	5.4
Successful SBT in study group	1.4	0.7	11,4	5.7
Failed SBT in study group	11.7	1,8	2.7	.8
F test	5.1		0.82	
p-value	**0.06**		**0.001***	

*statistical significant difference with p-value <0.05

Table (11) illustrated that there was no statistical significant difference of successful and failed SBT attempts before implementation of SAT, and SBT co-ordinated protocol among study and control group of patients (p-value 0.06). On the other hand there was a high statistical significant difference in successful and failed SBT attempts score after implementation of SAT, and SBT co-ordinated protocol among study group with p-value >0.001.

Table (12): Relation between duration of ventilation and SAT, and SBT co-ordinated among study group and control groups (N:60).

SBT related data	Study group present		Control group present		Chi-Square Test P value
	n	%	n	%	
Duration on mechanical ventilation in days 1 – 3 4 – 6 >6	 20 5 5	 66.7 16.666 16.666	 8 12 10	 26.666 40 33.333	 6.570 0.009**

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05

Table (12) shows that, there was a highly significant difference between the study and control groups concerning the duration of mechanical ventilation, with a p-value of <0.01**

DISCUSSION

The socio-demographic and medical characteristics of subjects in both study and control groups, were not significantly different; this means that the participants were selected from identical population of mechanical ventilated patients with good random allocation obtained. This findings supported with **Batagello, et al. (2022)** who conducted a study carried out in Sao Paulo, Brazil, reported that the baseline prognostic factors were well balanced and as most patients randomly assigned were followed, there was little potential for bias.

The present study findings indicated the mean age of the studied patients in both study and control groups was (63.7 ± 8.94 65.22 ± 7.61) respectively. The increased incidence of weaning failure and re-intubation could be explained as normal physiological changes of aging, and the morphological changes occur inside respiratory system the patients in this age group are more prone to infections, use of invasive procedures, and problems associated with aging process including malnutrition, loss of bone and muscle mass, and therefore decreased pulmonary ventilation and initiation of MV could elevate anxiety and fear levels which may in turn lead to breathing difficulty and greater distress during weaning attempts contributing to weaning failure. This explanation was supported by **Corbellini C, et al (2015)** who reported in the study about "Weaning from mechanical ventilation: a cross-sectional study of reference values and the discriminative validity of aging" revealed that ageing affects distal air space

leading to close the small airways more readily, decrease expiratory flow and gas trapping .

As regards gender, the current study reveals that about more than half of the studied patients were females. It is found that more than three quarters of MVPs experienced weaning failure were females. In this regard the current study reveals also that a positive correlation between MVPs' sex and weaning failure. This finding may be due to more stress and anxiety during weaning process in females than males. This could be attributed to the fact that in Egyptian culture men are not expected to show or express negative emotions like fear and anxiety. These results were congruent with **Chen Y (2017)** who found that females experienced greater level of anxiety and fear during the weaning process in comparison to males.

Females are generally at greater risk of weaning failure. The finding is concorded with **Trowbridge K& Horstman H(2017)** who reported in the study about "The effect of music listening on anxiety and agitation in adult mechanically ventilated patients: A systematic review" reported that more than half of the studied patients were females due to nature of females and stress, and sex hormones.

The result of the current study reveals that the most common encountered diagnosis was respiratory disorders, they constitutes one third of the studied MVPs. This could be related to the old age of MVPs. The current study revealed that a positive correlation between MVPs' diagnosis and weaning failure. This could be due to patients with chronic airflow obstruction increase risk for ventilator re-intubation. This finding was in line with **Ghoneim A& El-Komy H (2017)** who conducted "Assessment of weaning failure in chronic obstructive pulmory disease patients under mechanical ventilation in zagazig university hospitals " reported that nearly fifty percent of all initial weaning trials in mechanically ventilated chronic obstructive pulmonary disease patients failed .

The finding of the present study reveals that more than two thirds of the studied MVPs met the safety screening criteria to SAT from the first attempt. These findings were similar to the findings reported by **Lee Y& Sims K (2017)** who studied "The Combination of SAT and SBT Protocols May Help Reduce the Incidence of Ventilator-Associated Pneumonia in the Burn Intensive Care Unit" and found that about more than half of MVPs met the safety screen criteria to SAT from the first attempt.

As regard SAT safety screening criteria, this study displays that there was a significant statistical difference between both groups of patients related to all safety criteria. It is notable that study group of patients was screened after twenty four hours only of the initiation of sedative infusion and every day till meet the safety criteria. In contrast, most of control group were unsafe for awakening at the time of SAT.

Findings of the present study are in accordance with **Xing, et al (2015)**, concluded through a retrospective study that patients who received sedation have a longer duration of ventilation, a longer hospital and ICU stay and an increased mortality rate compared with the patients who did not receive sedation. Moreover, **Shehabi, et al (2012)** concluded that early deep sedation is an independent predictor of delayed time to extubation and increased long term mortality. The prevalence of early deep sedation presents a modifiable risk factor that is a candidate for future intervention.

The finding of present study reveals that more than half of study group met the safety screen criteria to SBT from the first attempt. This may related to less accumulation of sedative drugs metabolites resulting in faster recovery of mental status essential for weaning and the immediate shift to SBT which reduce the dependence level on mechanical ventilator. The finding of current study shows also that more than three quarters of MVPs proceeded to SBT using CPAP method.

Using such method to conduct SBT in the present study may be attributed to two reasons; first that it contributes to reduce the work of breathing and second, it is easier to back the MVPs to the original mode in case of intolerance. In accordance to this finding, **Yi L& Tian X (2021)** who compared ATC and CPAP during SBT found that two thirds of patients meet the pre-determined screening criteria at the first time using CPAP method. They added that CPAP method is safe and do not hasten liberation from mechanical ventilation, when compared to ATC.

The present study indicates that study group exhibited better weaning outcomes than control group in the form of short period of mechanical ventilation, tracheal intubation and oxygen therapy as well. Additionally, the findings of this study show that a statistical significant difference regarding re-need for mechanical ventilation in which control group had a high percent more than study group with a more incidence of re-intubation.

Additionally, the current study reveals that study group was safer than control group as only one sixth of study group acquired VAP and less one quarter of them experienced PVD during their mechanical ventilation course. This may be due to control group spent more time on mechanical ventilator, with more agitation, fear, and stress responses that may contribute to PVD. All of these events may increase the risk for respiratory muscles weakness, consequently delay in the return of spontaneous breathing and increase VAP incidence.

Similar to the present study, **Saeed F, et al (2023)** Added that patients in the study group are extubated on the day they first passed SBT compared with patients in the control group.

Passing the SBT is interpreted as readiness for discontinuation of ventilator support, whereas

failing the SBT indicates non-readiness. This is the rational make pre-trial screening is an important step to ensure the MVPs safety. Early identification of MVPs who are able to breath spontaneously result in a shorter duration of mechanical ventilation and lower complication rates. Screening criteria for both study and control groups in the current study reveals a significant statistical difference in meeting oxygenation, ventilation, neurological, and hemodynamics related criteria. These findings can highlight the more eligibility of study group to SBT than control group of patients.

In line with **Kress et al (2000)** who conducted a single-center, randomized controlled trial of MVPs comparing usual care to a sedation strategy that involves DIS and analgesic infusion, until patients are awake, or are agitated. Through a retrospective analysis, they found a significant decrease in the duration of mechanical ventilation, indeed significant fewer overall complications especially VAP.

Sedation interruption has been demonstrated as a beneficial ICU intervention as initiated at **(2000) by Kress et al** has been also been paired with a ventilator weaning protocol to improve MVPs outcomes through a study of **Baron, D, (2010)**. **Hooper and Girard (2011)** confirmed benefits of daily SAT and extended by pairing SAT with SBT in a protocol that improved multiple outcomes, fewer hospital days with lesser duration of sedation infusion, and mechanical ventilation period, VAP incidence, ICU days as well as mortality rate.

Conclusion:

Based on the findings of the study, it can be concluded that, aim and hypothesis of the study was achieved, therefore, after implementing co-ordinated spontaneous awakening and breathing trials protocol , there was a positive effect on the patients outcomes among study group as regarding the incidence of complications VAP, and duration of mechanical ventilation compared to control group, as well as there was statistically positive correlation with high significance between co-ordinated spontaneous awakening and breathing trials protocol and duration of mechanical ventilation.

Recommendation:

- Applying the co-ordinated spontaneous awakening and breathing trials protocol, before weaning to facilitate safely weaning process and decrease duration of ventilation.
- Encourage collaboration between CCNs and physicians to decrease factors accelerate complications among MVPs.

Reference:

1. **Baron, D., Metnitz, P. & Gustorff, B (2010).** Sedierung und Analgesie auf der Intensivstation: Physiologie und Anwendung. *Wien Klin Wochenschr* **122**, 455–64 . Available from: https://doi.org/10.1007/s00508-010-1418-x
2. **Batagello C, Vicentini F, Monga M (2022).** Tranexamic acid in patients with complex stones undergoing percutaneous nephrolithotomy: a randomised, double-blinded, placebo-controlled trial. BJU International.129;1: pp: 35-47. Available from:https://doi.org/10.1111/bju.15378.
3. **Chen Y, Li Hwang S, Li C, Yang C, Huang K, ET AL, (2017).**
4. Vagal withdrawal and psychological distress during ventilator weaning and the related outcomes, Journal of Psychosomatic Research,101.,PP: 10-16, Available from : ,https://doi.org/10.1016/j.jpsychores.2017.07.012.(https://www.sciencedirect.com/science/article/pii/S0022399917301800)
5. **Cohen JA, Anthony P, (2015):** Trauma-focused Cognitive Behavior Therapy for Traumatized Children and Families. Child Adolesc Psychiatr Clin N Am. 24(3):PP: 557-70.
6. **Corbellini C, Trevisan C, Villafañe J, Doval da Costa A, Rios Vieira SM, (2015).**Weaning from mechanical ventilation: a cross-sectional study of reference values and the discriminative validity of aging. Journal of Physical Therapy Science.PP: 45-1950. Available from:DOI https://doi.org/10.1589/jpts.27.1945 .
7. **Fultz, B, (2019).** Critical Care Medicine: Principle of Diagnosis and Management in the Adult. *Can J Anesth/J Can Anesth* **66**, PP: 1423–24. Available from: https://doi.org/10.1007/s12630-019-01453-1
8. **Girard TD, Kress JP, Fuchs BD, Thomason JW, Schweickert WD, Pun BT, Taichman DB, Dunn JG, Pohlman AS, Kinniry PA, Jackson JC, Canonico AE, Light RW, Shintani AK, Thompson JL, Gordon SM, Hall JB, Dittus RS, Bernard GR, Ely EW (2008).** Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomised controlled trial. Lancet. 12;371(9607): pp:126-34. Available from: doi: 10.1016/S0140-6736(08)60105-1. PMID: 18191684.
9. **Ghoneim A, El-Komy H, Gad D, Abbas A. (2017).**Assessment of weaning failure in chronic obstructive pulmonary disease patients under mechanical ventilation in Zagazig University Hospitals.Egyptian Journal of Chest Diseases and Tuberculosis,66, 1,PP: 65-74, Available from:

https://doi.org/10.1016/j.ejcdt.2016.01.013.(https://www.sciencedirect.com/science/article/pii/S0422763816300140)

10. **Hartweg DL, Metcalfe SA(2022).** Orem's Self-Care Deficit Nursing Theory: Relevance and Need for Refinement. Nurs Sci Q. Jan;35(1):70-6. Available from: doi: 10.1177/08943184211051369. PMID: 34939484.
11. **Hooper M, Girard T. (2011).**Sedation and Weaning from Mechanical Ventilation: Linking Spontaneous Awakening Trials and Spontaneous Breathing Trials to Improve Patient Outcomes.Anesthesiology Clinics 29(4): PP: 651-61.Available at: DOI:10.1016/j.anclin.2011.09.005
12. **Hopkins J.(2017):** Daily Care Processes Guide for Reducing Ventilator-Associated Events in Mechanically Ventilated Patients . Medicine/Armstrong Institute for Patient Safety and Quality with contract funding provided by the Agency for Healthcare Research and Quality. AHRQ Pub. No. 16(17)-0018-3-EF .
13. **Hoyer E, Brotman DJ, Chan KS& Needham DM.(2015).** Barriers to early mobility of hospitalized general medicine patients: survey development and results. Am J Phys Med Rehabil.
14. **Kallet RH, Zhuo H, Yip V, Gomez A, Lipnick MS (2018).** Spontaneous Breathing Trials and Conservative Sedation Practices Reduce Mechanical Ventilation Duration in Subjects With ARDS. Respir Care. 63(1): pp:1-10. Available at: doi: 10.4187/respcare.05270. Epub 2017 Oct 10. PMID: 29018041.
15. **Khalil NS. (2018).**Critical care nurses' use of non-pharmacological pain management methods in Egypt. Appl Nurs Res. 44: PP: 33-8. doi: 10.1016/j.apnr.2018.09.001. Available from: Epub Sep 18. PMID: 30389057.Accessed in October,2021, 2.00 am.
16. **Klompas M. (2015).**Potential Strategies to Prevent Ventilator-associated Events. Am J Respir Crit Care Med. 15;192(12):pp: 1420-30.
17. **Kress JP, Pohlman AS, O'Connor MF, Hall JB (2000).** Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. N Engl J Med. 18;342(20):1471-7. Available from: doi: 10.1056/NEJM200005183422002. PMID: 10816184.
18. **Lee Y, Sims K , et al (2017).** The Combination of SAT and SBT Protocols May Help Reduce the Incidence of Ventilator-Associated Pneumonia in the Burn Intensive Care Unit, *Journal of Burn Care & Research*, Volume 38, Issue 2, pp: 574–9. Available from: https://doi.org/10.1097/BCR.0000000000000451
19. **McGinn L,MK(2018).** Cognitive Behavioral Therapy of Depression
20. Theory, Treatment, and Empirical Status. Journal of the American Psychiatric Association.PP: 271. Available from: https://doi.org/10.1176/appi.psychotherapy.2000.54.2.257.
21. **Pearson SD, Patel BK (2020).** Evolving targets for sedation during mechanical ventilation. Curr Opin Crit Care. 26(1): pp: 47-52. Available from: doi: 10.1097/MCC.0000000000000687. PMID: 31764193; PMCID: PMC8086012.
22. **Peñuelas O, Frutos-Vivar F, Fernández C, Anzueto A, Epstein SK, Apezteguía C, González M, Nin N, Raymondos K, Tomicic V, Desmery P, Arabi Y, Pelosi P, Kuiper M, Jibaja M, Matamis D, Ferguson ND, Esteban A& Ventila Group.(2011).** Characteristics and outcomes of ventilated patients according to time to liberation from mechanical ventilation. Am J Respir Crit Care Med. 15;184(4):pp: 430-7.
23. **Saeed F, Lasrado S (2023).** Extubation.. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. -. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539804/
24. **Shehabi Y, Bellomo R, Reade MC, Bailey M, Bass F, Howe B, McArthur C, Seppelt IM, Webb S, Weisbrodt L;(2012).** Sedation Practice in Intensive Care Evaluation (SPICE) Study Investigators; ANZICS Clinical Trials Group. Early intensive care sedation predicts long-term mortality in ventilated critically ill patients. Am J Respir Crit Care Med. 15;186(8):724-31. Available at: doi: 10.1164/rccm.201203-0522OC. Epub 2012 Aug 2. PMID: 22859526.
25. **Tanaka M (2022).** Orem's nursing self-care deficit theory: A theoretical analysis focusing on its philosophical and sociological foundation. Nurs Forum. 57(3): pp:480-485. Available from: doi: 10.1111/nuf.12696. Epub 2022 Jan 17. PMID: 35037258.
26. **Tobin MJ, Laghi F, Jubran A (2012).** Ventilatory failure, ventilator support, and ventilator weaning. Compr Physiol. 2012 Oct;2(4):2871-921. Available from: doi: 10.1002/cphy.c110030. PMID: 23720268.
27. **Trowbridge, Kristen M, Horstman, Hailee N.,(2017).** The Effect of Music Listening on Anxiety and Agitation in Adult Mechanically Ventilated Patients: A Systematic Review. *Williams Honors College, Honors Research Projects*. Pp:438. Available from : https://ideaexchange.uakron.edu/honors_research_projects/438
28. **Xing XZ, Gao Y, Wang HJ, Qu SN, Huang CL, Zhang H, Wang H, Xiao QL, Sun KL**

(2015). Effect of sedation on short-term and long-term outcomes of critically ill patients with acute respiratory insufficiency. World J Emerg Med. 6(2):PP: 147-52. doi: 10.5847/wjem.j.1920-8642.2015.02.011. PMID: 26056547; PMCID: PMC4458476.

29. **Yi LJ, Tian X, Chen M, Lei JM, Xiao N, Jiménez-Herrera MF (2021).** Comparative Efficacy and Safety of Four Different Spontaneous Breathing Trials for Weaning From Mechanical Ventilation: A Systematic Review and Network Meta-Analysis. Front Med (Lausanne). Pp: 22;8: Available from: 731196. doi: 10.3389/fmed.2021.731196. PMID: 34881255; PMCID: PMC8647911.