THE RELATIONSHIP BETWEEN DAILY SEDATION INTERRUPTION AND SELECTED PATIENT OUTCOMES AMONG MECHANICALLY VENTILATED PATIENTS

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Abstract

Background: Mechanically ventilated patients are a risk group whose outcomes are negatively affected by many factors. Among these factors is sedation because it is a cornerstone therapy for critically ill patients

Aim: This study aimed to assess the relationship between daily sedation interruption and selected patient outcomes among mechanically ventilated patients

Design: a descriptive correlational research design was utilized to carry out this study

Setting: The study was conducted at ICUs of Shebin El Qanater Central Hospital

Sample: A purposive sample of (68) patients from both gender was included in the study.

Tools: data were collected through using four tools,

Tool (I) patient's structured interview questionnaire that included two parts, part I patient's demographic characteristics of the studied patients and part II: patients medical data.

Tool (II) Richmond agitation section scale (RASS)

Tool (III): Behavioral pain scale (BPS).

Tool (IV): Daily sedative interruption outcomes assessment tool

Results: the study results revealed that 67.7% of the studied patients were in the age group from 56-65 years old, with a mean of age was 60.87± 9.35. 57.4% of them were male **.**44.1% of the studied patients were sedated with fentanyl and 36.8% of the studied patients were on SIMV mode. There were a high statistically significant difference regarding Richmond agitation sedation scale of the studied patients through 5 days from admission (p-value=0.000*).

Conclusion: a highly statistically significant difference regarding Richmond Agitation Sedation scale of the studied patients through 5 days from admission. A highly statistically significant relation among studied patients Richmond Agitation sedation scale, length of ICU stay, and duration of MV

Recommendation: Sedation protocol should be standardized in every critical care unit and every health care person working in the ICU should be made aware of the protocol used.

Keywords: *Mechanical ventilation – Outcomes of mechanically ventilated patient – Sedation*

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Introduction

Mechanical ventilation is a crucial life support system for critically ill patients in the intensive care unit (ICU). However, in these patients, ICU agitation and patient–ventilator dyssynchrony are common problems, potentially related to a prolonged mechanical ventilation duration and ICU stay length as well as elevated tracheostomy and mortality risks and medical burden ***(Kanamor et al., 2023).***

Sedation is an important procedure of intensive care practice at the time of intubation to minimize oxygen consumption and facilitate mechanical ventilation comfortably. Over the past two decades, deep sedation has been reported to be associated with adverse outcomes, such as delayed weaning, increased lengths of intensive care unit (ICU) stay and increased hospital mortality. Especially, early deep sedation during the initial mechanical ventilation period worsens the outcomes ***(Tapia et al .,2022).***

Daily sedation interruption (DSI) has been proposed to reduce the potential excessive sedation risk and excessive sedative agent use DSI has been routinely used in mechanically ventilated adults in the ICU according to the recommendation of the clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the Intensive Care Unit ***(Simpson et al.,2023).***

Daily sedation interruption was a daily stopping of sedative agent for 60 min at 10:00 am (according to the setting where the study was performed to reduce expose to sedative agent allow to assessment of neurological status ,assess readiness for extubation and reduce duration of mechanical ventilation . patient outcomes in this study was noninvasive hemodynamic parameters (temperature ,heart rate ,blood pressure, oxygen saturation, length of ICU stay ,duration of MV,fate of weaning ***(Palakshappa et al.,2022)***

Significance of the study:

Mechanically ventilated patients are a risk group whose outcomes are negatively affected by many factors. Among these factors is sedation because it is a cornerstone therapy for critically ill patients. According to WHO statistics Over the 3 years, total ICU patients ranged from 57.4% to 82.1% and the number of beds filled with mechanically ventilated patients ranged from 20.7% to 38.9% **(WHO., 2021).**

In Egypt, 65% from patients in intensive care are connected to mechanical ventilation. Therefore, there is a need to evaluate the patients' outcomes of sedated mechanically ventilated patient to assess the effect of daily sedation interruption, type of sedation, dose of sedation level of sedation on patients' outcomes ***(Ministry of Health MOH., 2020).***

Aim of the study:

The aim of this study was to :

Assess the relationship between daily sedation interruption and Selected Patient Outcomes among mechanically ventilated patients.

Research Question:

What is the relationship between daily sedation interruption and Selected Patient Outcomes among mechanically ventilated patients?

The subjects and methods for this study were portrayed under the four main items as follows:

I-Technical items II-Operational items
III- Administrative items IV- Statistical items

I- Technical item:

The technical items included the research design, setting, subjects and tools which were used for data collection in the study.

Research design:

A descriptive correlational research design was utilized in the current study. Descriptive correlational researches are utilized to describe the relationships among variables rather than to support inferences of causality and also can be used as a starting point to develop new theories or hypothesis. The descriptive correlational researches are considered a non-experimental study which is concerned with the observation and description rather than the intervention ***(Siedlecki et al., 2020)***

Research Setting:

This study was conducted at ICUs and of El Qanater Central Hospital, Shebein El Qanater, and Kaliobeya, Egypt.

Research Subjects:

A purposive sample of (68) patients from both gender and from the previously mentioned departments was included in the study.

Inclusion criteria:

Patients on mechanical ventilation from 1 to 5 days, Patient on sedation with mechanical ventilation, patient with acute respiratory distress syndrome.

Tool for data collection:

Data were collected using the following tools:

Tool (I): Patient's structured interview questionnaire:

This tool was developed based on review of related literature, It was filled in by the investigator included the following two parts:

Part I: Patient's demographic characteristics:

It included demographic data of the patients as: age, gender, marital status, educational level.

Part II: patient's medical data:

It included data regarding medical diagnosis, co-morbidity diseases, and allergy history, surgical history, previously hospital admission, previously ventilated.

Tool (II): Richmond agitation section scale (RASS)

It is a medical scale used to measure the agitation or sedation level of a patient. It was adopted from ***(Sesslet, et al., 2002)*** The RASS can be used in all hospitalized patients to describe their level of alertness or agitation. It is however mostly used in mechanically ventilated patients in order to avoid over and under sedation.

Tool III: Behavioral pain scale (BPS)

It is a medical scale used to measure the pain level of a patient. It was adopted from **(Payen et al.,2001)** The BPS was based on a sum of three subscales: facial expression, upper limb movements, and compliance with mechanical ventilation.

Tool IV: Daily sedative interruption outcomes assessment tool

It was adopted from ***(Chen etal .,2022)*** it covered data such as sedative agent, MV mood, MV parameter, sedative dose ,length of ICU stay ,mortality rate, duration of MV and hemodynamic parameters (temperature heart rate, respiratory rate, and blood pressure), saturation, and weaning was successful or not.

II -Operational item:

It included preparatory phase, content validity and reliability, pilot study and field work.

Preparatory phase:

Preparatory phase included reviewing of current and past, local and international related literature and theoretical knowledge of various aspect of the study

using books, articles, periodical magazines and internet to modify tool for data collection. This phase also involved construction and preparation of data collection tools. Approval was obtained from the administrative authorities of Shebin El Qanater Central hospital .The investigator obtained a list of patients who admitted to the critical care unities and were connected with mechanical ventilator and undergoing sedation interruption who met the inclusion criteria. Patients or responsible person who are agreed to participate in this study were interviewed individually by the investigator to explain the nature of the current study.

Validity:

Face validity aimed to determine whether the tools measure what were supposed to measure ***(Mueller and Knapp, 2018).*** Content validity was conducted to determine whether the tools covered the aim, test its appropriateness, comprehensiveness, accuracy, correction, clearance, and relevance through a jury of 5 experts (assistant professors and lecturers of medical surgical nursing) from the Faculty of Nursing- Helwan University. Their opinions were elicited regarding tools consistency, rephrasing for some statements and Ethics, values, culture, and beliefs were respected.

Reliability:

Reliability refers to the stability of the measuring instrument used and its consistency over time. In other words, Reliability is the ability to measure instruments to give similar results when applied at different times. However, a strong positive correlation between the results of the measuring instrument is an indication of reliability **(Sürücü & Maslakçi, 2020).** Cronbach's Alpha was used to determine the internal reliability of the tools. Reliability of the questionnaire normally ranges between 0 and 1. Higher values of Cronbach's alpha (more than 0.7) denote acceptable reliability. **Reliability of RASS** Reliability of RASS was tested using Cronbach's Alpha. Its value (0.747) **(Ely et al., 2003)**. **Reliability of BPS** Reliability of BPS was tested using Cronbach's Alpha. Its value (0.826) ***(Wandrey et al., 2023).*** **Reliability of daily sedative interuption outcomes assessment** Reliability of daily sedative interuption outcomes assessment was tested using Cronbach's Alpha. Its value (0.730) ***(Mehta et al., 2012).***

A pilot study was carried out on 10% (7 patient of the study sample) to test the applicability, feasibility clarity of questions and time needed to complete the study tools. Based on the results, no corrections and omissions of items were performed, so the patients were included in the study sample.

Field work included the following:

- An approval was obtained from the scientific ethical committee of Faculty of Nursing- Helwan University and the study subjects.
- Purpose of study was simply explained demographic characteristics and medical data
- Data collection of the study was started and completed within six months in the period from beginning of April 2022 to the end of September 2022.
- The investigator visited the intensive care unit three days per week during the morning shifts (10:00 am to 2:00 pm). The patients were selected according to inclusion criteria. Each day the investigator assessed 1or 2 patients.
- Data were collected through assessed patients to fill data collection tools by the investigator.
- At the beginning the investigator obtained the patients data from medical files, which include demographic characteristics and medical data.
- The investigator utilized the daily sedative interruption assessment sheet (sedative agent dose, patient vital signs, length of icu stay, duration of mechanically ventilated,) then the investigator observed if the weaning was successful or failed.
-The study tools were completed and filled in by the investigator within an average time of 60-120 minutes as following : Structured interviewing questionnaire for collecting data regarding demographic characteristics of patients and medical data ; it took 10 - 20 minutes. The Richmond agitation section scale (RASS) was used to measure the agitation or sedation level of a patient it took about 20 - 35 minutes. The Behavioral pain scale (BPS) was used to measure the pain level of a patient, about 15 – 35 minutes. The daily sedative interruption assessment sheet, took about 15- 25 minutes.

III- Administrative item:

Approval letter included aim of the study was obtained from the dean of the faculty of nursing Helwan University to the director of the previously mentioned setting. An official agreement was obtained from hospital manager and to get approval to conduct the study.

Ethical considerations:

An official permission to conduct the proposed study will be obtained from the scientific research ethics committee of the faculty of Helwan University. Participation in the study is voluntary and subjects will be given complete full information about the study and their role before signing the informed consent. The ethical considerations will include explaining the purpose and nature of the study, stating the possibility to withdraw at any time, confidentiality of the information where it will not be accessed by any other party without taking permission of the participants. Ethics, values, culture, and beliefs will be respected.

IV-Statistical item:

Upon completion of data collection, data were computed and analyzed using Statistical Package for

the Social Science (SPSS), version 24 for analysis. The P value was set at 0.05. Descriptive statistics tests as numbers, percentage, mean standard deviation (SD), were used to describe the results.

The observed differences were considered as follow:
P value < 0.001, highly significant (HS).
P value < 0.05, significant (S).
P value > 0.05, non-significant (NS).

Results:

Table (1): Frequency & percentage distribution of demographic characteristics of the studied patients (n=68).

Items	Studied patients (n = 68)	
	N	%
Age: Mean ± SD	60.87± 9.35	
Age group:		
35 yrs to less than 45yrs	5	7.4
45 yrs to less than 55yrs	17	25
55yrs to 65	**46**	**67.7**
Gender		
Male	39	**57.4**
Female	29	42.6
Marital status:		
Married	41	**60.3**
Divorced	12	17.6
Widow	15	21.1
Level of education		
No read and write	18	26.5
Read and write	28	**41.2**
Highly educated	22	32.4

Table (1) shows that, 67.7%of the studied patients aged from 56-65years old, the mean and standard deviation of age was 60.87± 9.35. Concerning gender, 57.4% of them were male, 60.3% of them were married and 41.2% of the studied patients were read and write.

Table (2): Frequency and percentage distribution of the studied patient regarding Richmond agitation sedation scale (RASS) through 5 days (n=68)
***: Significant At P ≤ 0.05**

Items		Studied patient (n = 68)										
		Day1		Day2		Day3		Day4		Day5		Anova, P-value
		N	%	N	%	N	%	N	%	N	%	
+4	Combative	27	**39.7**	24	**25.3**	12	17.6	1	1.5	2	2.9	19.849, 0.000*
+3	Very agitated	18	26.5	17	25	16	**23.5**	18	**26.5**	4	5.9	
+2	Agitated	10	14.7	6	8.8	14	20.6	11	16.2	13	**19.1**	
+1	restless	3	4.4	8	11.8	9	13.2	6	8.8	2	2.9	
0	Alert and calm	0	0	5	7.4	7	10.3	10	14.7	3	4.4	
-1	Drowsy	4	5.9	6	8.8	6	8.8	0	0	1	1.5	
-2	Light sedation	5	7.4	2	2.9	2	2.9	1	1.5	1	1.5	
-3	Moderate sedation	1	1.5	0	0	0	0	0	0	0	0	
-4	Deep sedation	0	0	0	0	0	0	0	0	0	0	
-5	Unarousable	0	0	0	0	0	0	0	0	0	0	

Table (2) 39.7% & 25.3% of the studied patients were combative in the first day and second day respectively. While 23.5% &26.5% and 19.1% were very agitated and agitated in the third, fourth, fifth day respectively .

Also, there was a highly statistically significant difference regarding Richmond agitation sedation scale of the studied patients through days from

admission (p-value=0.000*

Table (3): Frequency and percentage distribution of the studied patients regarding Behavioral Pain Scale (BPS) through 5 days (n=68)
Significant at P ≤ 0.05

Items		Studied patient (n = 68)										
		Day1		Day2		Day3		Day4		Day5		Anova, P-value
		N	%	N	%	N	%	N	%	N	%	
Facial expression	Relaxed	6	8.8	13	19.1	21	31.8	17	36.2	5	19.2	13.611, 0.000*
	Partially contracted	21	30.9	18	26.5	17	2.8	13	27.7	10	38.5	
	Completely contracted	15	22.1	18	26.5	16	24.2	7	14.9	10	38.5	
	Facial grimacing	26	38.2	19	27.9	12	18.2	10	21.3	1	3.8	
Upper limbs	No movment	6	8.8	19	27.9	19	28.8	12	25.5	4	17.4	
	Partially bent	23	33.8	13	19.1	17	25.8	16	23.5	6	26.1	
	Fully bentwith finger flexion	15	2.1	15	22.1	18	27.3	10	14.7	12	52.2	
	Permanently retracted	24	35.3	21	30.9	12	18.2	9	13.2	1	4.3	
compliance with ventilation	Tolerating movement	8	11.8	17	25	23	34.8	18	38.5	6	23.1	
	Coughing but tolerating ventilation for most of the time	30	44.1	25	36.8	22	33.3	16	34	10	38.5	
	Fighting ventilator	19	27.9	15	22.1	13	19.7	11	23.4	9	34.6	
	Unable to control ventilation	11	16.2	11	16.2	8	12.1	2	4.3	1	3.8	

Table (3): shows that, there was a high statistically significant difference regarding behavioral pain scale of the studied patients through 5 days from admission (p-value=0.01*)

Table (4): relations between the studied patient's type of sedation and length of ICU stay, Duration of MV, Weaning from MV
Table (4) reveals that, there was a highly statistically significant relation among studied patients regarding type

Items	Type of Sedation							
	Fentanyle (n=30)		Dormicum (n=17)		Propofol (n=21)		X2	P-value
	N	%	N	%	N	%		
Length of ICU stay:							7.430	0.03*
4 - 7 days	22	73.3	10	58.8	3	61.9		
7-10 days	8	26.7	3	17.6	4	19		
10-13 days	0	0	4	23.5	4	19		
Duration of MV							4.831	0.248
1-3	12	40	2	11.8	7	33.3		
4 - 7	16	53.3	12	70.6	11	52.4		
>8	2	6.7	3	17.6	3	14.3		
Weaning from mechanical ventilator							3.580	0.167
Weaning	12	40	10	58.8	6	28.6		
Non weaning	18	60	7	41.2	15	71.4		

of sedation and length of ICU stay with p-value = 0.03*, while there was no statistically significant

relation among studied patients regarding type of sedation, duration of MV, and weaning from MV with p-value =(0.248, and 0.167).

Table (5): Relations the studied patient's Richmond agitation sedation scale, and patient's outcomes: *: Significant at P ≤ 0.05

Items	Richmond agitation sedation scale				X2	P-value
	Light sedation		Agitation			
	N	%	N	%		
Sedative agent						
Fentanyle	4	30.8	26	47.3		
Dormicum	3	23.1	14	5.5	1.887	0.183
Propofol	6	46.2	15	27.3		
Sedation Dose						
Low	9	69.2	43	78.2	0.468	0.487
High	4	30.8	12	21.8		
Mortality rate						
Died	2	15.4	6	10.9	0.203	0.643
Not died	11	84.6	49	89.1		

Table (5) shows that, there was no statistically significant relation among studied patients Richmond Agitation Sedation Scale, mortality rate of patients, sedative agent and sedation dose with p-value =(0.643, 0.183, and 0.487 respectively)

Table (6): correlation between Richmond agitation sedation scale and patients' outcomes

Items	Rass	P value
	Correlation coefficient (r)	
Type of sedation	0.310	0.01*
Mechanical ventilation Mode	0.091	0.460
Length of ICU stay	0.099	0.420
Duration of MV	0.051	0.682
Weaning From Mechanical Ventilation	-0.044	0.721
Mortality rate	-0.131	0.286

*: **Significant at P ≤ 0.05**

Table (6) Shows that, there was a high statistically significant positive correlation between studied patient's Richmond agitation sedation scale and type of sedation with p-value = (0.01), while there was no statistically significant negative correlation between studied patient's Richmond agitation sedation scale and length of ICU stay, duration of MV, weaning from MV, outcome of patients, and mechanical ventilation mode with p-value =(0.420, 0.682, 0.721, 0.286, and 0.460 respectively).

Discussion:

Regarding to demographic characteristics of the

studied patients: the results of the present study revealed that more than two thirds of the studied patients were in the age group from 56 to 65years. This result is in agreement with **Estep&parthasarathy.,(2022)** who applied their study entitled with assess relationship between mechanical ventilation and sleep in critical illness: physiology, assessment, and its importance to ICU Care and showed that more than half of studied patients were in the age group 50-77 years.

Considering gender, the present study clarified that more than half of studied patient were males. This result is congruent with **Luz et al.,(2022)**.who studied Practices in sedation, analgesia, mobilization, delirium, and sleep deprivation in adult intensive care units and mentioned that more than two thirds of studied subjects were males.

This study results showed that less than two thirds of studied patients were married. This may be due to that most of the study patients were within 56 – 65 years and usually by this age they are married, according to the Egyptian society culture years. This result disagrees **Graham et al.,(2022)**, who explored a systematic review and critical appraisal of guidelines and their recommendations for sedation interruptions in adult mechanically ventilated patients and stated that more than half of studied patients were single. **Concerning level of education** of the studied patients, this study revealed that less than half of them read and write. This result is agrees **Dzierba, et al.,(2021),**who mentioned that half of patient read and writing.

According to Richmond scale, The present study revealed that more than one third of the studied patients combative in the first day while one fourth of the studied patients were combative in second day and less than one third of studied patients agitated in third and fourth day while the minority of studied patients had agitations in fifth day, also there was a highly statistically significant difference regarding Richmond agitation sedation scale of the studied patients through days from admission, From the investigator point of view Richmond agitation scale effective method to monitor critical ill patients under sedation also while making daily sedation interruption.

This study disagree with **Gitti etal.,(2022)** who study titled in " seeking the light in intensive care unit sedation: the optimal sedation strategy for critically ill patients" and showed that the majority of the studied patients agitated in the first day while the minority of studied patients had combative in fifth day and also no significant difference regarding Richmond agitation sedation scale of the studied patients through days from admission.

Concerning behavioral pain scale, The present study revealed that there was a high statistically significant difference regarding behavioral pain scale of the studied patients through 5 days from admission, From investigator point of view, pain during mechanical ventilation period is one of the most common signs to be measured so applicable of behavioral pain scale very important withe intubated patient.This study agree with **Mitting et al.,(2021),** whose study aimed to assess the sleep cycle in adult with severe acute bronchopneumonia during mechanical ventilation at different depths of sedation and showed that, there was a high statistically significant difference regarding behavioral pain scale of the studied patients through 7 days from admission.

While, the results are not supported by **Zhao etal., (2022),** in their study about the invasive mechanical ventilation for acute viral bronchiolitis: retrospective multicenter cohort study" and showed that no statistically significant difference regarding behavioral pain scale of the studied patients through 10 days from admission.

According to relation between patient's Richmond agitation sedation scale, and mortality rate, sedative agent and sedation dose. This study showed that there was no statistically significant relation between studied patient's Richmond agitation sedation scale and mortality rate of patients, sedative agent and sedation dose. From the investigator point of view to achieve optimal sedation management continues measurement of patient level of sedation at regular intervals is imperative; using these measures like RASS to avoid both over sedation and under sedation have the potential reduce morbidity and mortality. This study similar to **Bardwellet al.,(2020),** who studied " Implementing the ABCDE bundle, critical-care pain observation tool, and Richmond agitation-sedation scale to reduce ventilation time "and showed that there was no statistically significant relation between studied patient's Richmond agitation sedation scale and mortality rate of patients.

This study is congruent with ***Su etal.,(2020)***, entitled as " Implementing the Richmond agitation-sedation scale in a respiratory critical care unit" and clarified that there was a relationship between Richmond agitation sedation scale and mortality rate of patients.

Concerning the correlation between patient's Richmond agitation sedation scale and type of sedation the finding showed that, there was a high statistically significant positive correlation between studied patient's Richmond agitation sedation scale and type of sedation .This study agree's with ***Rashidi et al.,(2020),*** who studied " The effect of using Richmond agitation and sedation scale on hospital stay, ventilator dependence, and mortality rate in ICU inpatients " and found that there was a high statistically significant positive correlation among studied patient's regarding Richmond agitation sedation scale and type of sedation.

In the same perspective, the study results

illustrated that there was no statistically significant negative correlation between studied patient's Richmond agitation sedation scale and length of ICU stay, duration of MV, weaning from MV, outcome of patients, and mechanical ventilation mode This finding goes in the same line with **Thomas, etal.,(2022)** who implemented their study to examine effect of selected nursing procedures on pain and hemodynamic parameters in patient with mechanical ventilator. And revealed that there was no statistically significant negative correlation between studied patient's Richmond agitation sedation scale and length of ICU stay, duration of MV, weaning from MV, outcome of patien ts, and mechanical ventilation mode.

Conclusion:

Based on the findings of the present study, it can be concluded that:

The current study clarified that there was a high statistically significant difference regarding Richmond agitation sedation scale of the studied patients through 5 days of the study. A significant statistically difference regarding behavioral pain scale of the studied patients through 5 days of the study. Also there was a high statistically significant difference regarding hemodynamic parameters of the studied patients through 5 days. A high statistically significant relation between studied patient's Richmond agitation sedation scale, length of ICU stay, duration of MV and behavioral pain scale. Moreover, there was a high statistically significant positive correlation between studied patient's Richmond agitation sedation scale and type of sedation.

Recommendations:

Based on the findings of the study results, the following recommendations were suggested:

- Establish a documentation system for nursing and medical records of the ICU patient to facilitate calculating the dose of sedation
- Availability of update guidelines and evidence-based clinical skills to facilitate the work of the multidisciplinary team who can provide the optimum care for the mechanically ventilated sedated patients utilizing the evidence –based guidelines (pain and agitations) guidelines.
- Provide update guidelines related to weaning from mechanical ventilation to maximize the patient opportunity to be weaned without further complication
- Sedation protocol should be standardized in every critical care unit and every health care person working in the ICU should be made aware of the protocol used.

Recommendation for further research:

- Replication of the study on larger probability sample selected from different geographical areas in Egypt is recommended to obtain more generalized data
- Further studies have to be carried out in order to assess the relation between the daily sedation interruption and more mechanically ventilated patients outcomes such as the developing of ventilator associated pneumonia and the psychological problem**.**

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