Effect of Nursing Care Protocol daily Interruption of Sedation on Mechanical Ventilated Patients 'Outcome

Mervat Anwar Abdel ElAziz[(1)], Mona Aly Mohammed[(2)], Khalid Mohamed Morsy[(3)], Mona AbdElaziem[(4)]
(1) Assistant Professor of Critical Care and Emergency Nursing, Faculty of Nursing, Assiut University, Egypt
(2) Assistant Professor of Critical Care and Emergency Nursing, Faculty of Nursing, Assiut University, Egypt
(3) Department of Anesthesia Technology,Colleg of Applied Medical Sciences in Jubail,Imam Abdulrahman bin Faisal
(4) Lecture of Critical Care and Emergency Nursing, Faculty of Nursing, Assiut University, Egypt

Abstract

Nursing care protocol daily sedation is very important to optimize sedation for patients on mechanical ventilators, these requires nursing staff is very crucial in this aspect to avoid complication of sedation and earlier extubation. **Aim:** This study was aimed to identify effect of nursing care protocol for daily interruption sedation on mechanical ventilation patients outcome. **Design**: a quasi-experimental design. **Setting**: Carried at ICU at Assiut university hospital. **Subjects**: A purposive sample of 70 adults patients. Sample was assigned to two equal groups (study and control). **Tools**: Four tools were utilized to collect data of study, tool I: Patient assessment sheet. Tool II: Interruption and infusion sedation assessment scales tool. Tool III: Intensive Care Delirium Screening Checklist. Tool IV:patients outcome tool. **Results**: the present study revealed that there was a statistical significant differences (P<0.001**) between study and control groups in relation to sedative complication, Delirium , ICU stay, and Duration of mechanical ventilation. **Conclusion**: Patient who received nursing care protocol during daily interruption of sedation leading to improve outcome and reduce complication. **Recommendation:** Provide in-service education and training program for critical care nurses regarding applying daily interruption of sedation and how managed these patients.

Key words: Daily interruption of sedation, Nursing care protocol, Mechanical ventilation, Patients outcome

Introduction

Interrupting continuous sedation with regular daily breaks, together with assessing the level of sedation, allows clinicians and nurses to target the minimal sedation necessary to keep the patient comfortable. There are a strong association between interventions designed to optimize sedation and reduced duration of mechanical ventilation and length ICU stay. Interventions included regular assessment of the level of sedation, choice of sedative drugs and daily sedation breaks **(Mauro. et al., 2016)**.

Nursing care protocol daily interruption of sedation reduce the incidence of several adverse outcomes, and the influence of sedatives on the development of delirium or the duration of mechanical ventilation, weaning, hypoxemia, wake up and breathe, may reduce length of stay in ICUs (**Klompas, et al., 2015**)

Sedation management is a multidisciplinary process, in which nurses adjust sedation according to a wide range of information, including subjective assessments of patients' consciousness and comfort needs, need to prevent self-injury by patients, efficiency of care, and the nurses' own beliefs and interactions with patients' families (**Brian et al., 2018).** Critical care nurse should include assessment of patient comfort, conscious level, use caution in renal and liver failure, use spontaneous breathing, unless contra-indicated **(Cameron. et al., 2018).**

Appropriate sedation management of critically ill MV patients is imperative for the ventilator synchrony, toleration of the endotracheal tube, immobility, toleration of procedures, oxygenation optimization, and to ensure safety. Adequate levels of sedation are challenging, and if done inappropriately expose patients to stress, anxiety, delirium, and increased risk of post-traumatic stress disorder (**Kress et al., 2002; Schulingkamp, Woo, Nguyen, Sich, & Shadis, 2016)**. Oversedation can result in difficulty weaning from MV

which may coincide with a higher risk of developing short and long-term complications and delirium.

Supporting daily interruption of sedation (DSI) may be confusing, so keeping nurses up-t;o-date on continuous sedation in mechanically ventilated patients is a priority. Mechanically ventilated patients often experience neurologic status, from endotracheal suctioning, mechanical ventilation, indwelling catheters, (Kress, and et al., 2002) the discomfort from these factors results in patients requiring I.V. continuous sedation which includes analgesia. DSI is needed so that you can assess the patient's neurologic status and determine the necessity for continuation of sedation.

The nurse evaluates the patient's hemodynamic status, the settings and functioning of the mechanical ventilator. Assessment also addresses the patient's neurologic status and effectiveness of coping with the need for assisted ventilation and the changes that accompany it. The nurse should assess the patient's comfort level and ability to communicate as well **(Kitty, 2016).**

Significant of study:

Nursing care protocol provide noted using continuous infusion of sedation. Their use are associated with both short and long-term negative patient outcome, including prolonged mechanical ventilation, disturbed level of conscious delirium and cognitive dysfunction. Under and over sedation can lead to complications.

Providing appropriate sedation is currently one of the most important aspects of nursing care for patients receiving mechanical ventilation in the ICUs. Nurses' understanding of patients' clinical conditions may influence the level of sedation and lead to deep or inadequate sedation so we apply this study.

In 2017, the number of patients admitted in critical care and emergency ICU was about (300) patients, about more than 50% of them connected to MV (**Assuit university hospital records, 2017**).

Aim of the study:

To assess effect of Nursing Care Protocol for daily Interruption of Sedation on Mechanical Ventilated Patients' Outcome.

Hypothesis:

- To fulfill the aim of this study the following research hypothesis is formulated.
- Nursing care protocol daily interruption of sedation will be improved Patients' outcome who receiving mechanical ventilated.

Patient and Method

Research design:

- Quasi experimental research design was used to apply this study.

Variables:

- Independent variable: is implementing nursing protocol for patients of daily interrupted sedation.
- Dependent variable: Patient outcome.

Setting:

- This study was applied in general Intensive care units at Assiut university hospital.

Subjects:

Purposive sampling of 70 adult's critical ill patients aged from (20-60 years old) who admitted to previous mentioned setting who were eligible for inclusion in the subject. Subject was assigned to two equal groups each group consist of 35 patients. Control group who was received continuous sedation infusion, study group who was received daily interruption of sedation.

Inclusion criteria:

Subject who met the following criteria was included in the study:

- Recent admission.
- Age 20-60years.
- Patients connected with mechanical ventilator for more than 12 hours and received continuous infusions of sedation for at least 24 hours.

Exclusion criteria:

The study excluded patients who had the following criteria:

- End stage of diseases, Head injury, shocked patients, burned patients, neurological or neurosurgical diagnosis, pregnancy, addict patient, transfer to ICU after resuscitation following cardiac arrest and initiation of sedative infusion in another hospital.

Tools of data collection:

Four tools were used to collect the necessary information for the study, the following tools were used**:**

Tools:

Tool one: Patient assessment sheet:

- The tool was developed by the researcher after review of literatures **(Gholam et al., 2018)**,This tool used to assess patient condition, and divided into four parts as hemodynamic state and mechanical ventilation data:-

Part I: Bio-socio demographic data and clinical data assessment sheet:

- Bio-socio demographic data includes patient's name, age and sex. Clinical data as diagnosis, length of stay in ICU and APACHE II score(Acute Physiology And Chronic Health Evaluation) that it is considered as method of measuring disease severity .

Part II: Assessment of respiratory and hemodynamic state:

- This part was developed by the researcher after review of literatures**.**
- This part used to assess respiratory rate, rhythm, breathing sounds, presence of secretions, oxygen saturation, pulse, and mean arterial blood pressure and central venous pressure (CVP)which this part covered (8) items. **In addition to Mechanical ventilation data. covered (6) items**

Part III: Medication:-

- This part was developed by researcher. This part used to assess
- Medication that includes name of sedative agent, time of administration,
- Duration of infusion, total doses of sedative and analgesic drugs, monitor duration of interruption of sedative infusions per day.

Part IV: FOUR score scale: -

- This tool was adopted from "FOUR" is acronym for "Full Outline of UnResponsiveness".This tool used to assess neurological state**.** This score comprises four main items (Eye response (0-4), Motor response (0-4), Brain stem reflexes (0-4) and Respiration (0-4) where total score of this tool are 16 items.

Tool two: - Interruption and infusion sedation assessment tool:

- This tool was adopted from **(Yeganeh et al., 2018) (Justin et al., 2018).**
- Used to assess anxiety and agitation for both groups (study and control) and consist of two parts:

Part I: Richmond Agitation Sedation Scale (RASS):

- This tool was adopted from **(Yeganeh et al., 2018)** and used to assess patient's level of sedation which consist of a ten point. Three sequential steps are used: observation, response to verbal stimulation and response to physical stimulation.

Items	Score
Combative	+ 4
Very agitated	+ 3
Agitated	+ 2
Restless	+ 1
Alert and calm	0
Drowsy	-1
Light sedation	-2
Moderate sedation	-3
Deep sedation	-4
Unarousable	-5

Part II: Warning signs for Daily Interruption of Sedation failure:

- This part was developed by the researcher after review of literatures**,** and used to assess patients failure to sustain interruption of sedation and the need to immediately inform physician for recommend to return infusion of sedation.

- These warning signs covered (8) items that are:
  - Excitation
  - Inconvenience
  - Hemodynamic instability (mean arterial blood pressure and pulse increase more than 20%prevous level)
  - Respiratory distress it include
  - Signs of neurological deterioration (suspected or diagnosed deteriorated cerebral edema or hemorrhage).
  - Positive end-expiratory pressure (PEEP) ≥15 cmH_2O were observed
  - Rapid Shallow Breathing Index (RSBI): is defined as the ratio of respiratory frequency to tidal volume (F/V_t). People on a ventilator who cannot tolerate independent breathing tend to breathe rapidly (high frequency) and shallowly (low tidal volume), and will have a high RSBI **(Schmidt et al., 2017)**

Tool Three: Intensive Care Delirium Screening Checklist

- It is adopted from **(Mehta. et al., 2015),** used to assess delirium
- This Checklist comprises eight-item-based for delirium .The patient is evaluated for inattention, disorientation, hallucination, delusion or psychosis, psychomotor agitation or retardation, inappropriate speech or mood, sleep/wake cycle disturbance, and fluctuation of the above symptoms.
- Each item is scored as absent or presents (0 or 1, respectively) and summed. A score ≥ 4 indicates delirium (Present), while 0 indicates no delirium (not present). Patients with scores between 1 and 3 are considered to have subsyndromal delirium. Patients with subsyndromal delirium have some but not all features of delirium and have outcomes that are in between those of patients with and without delirium.

Tool four: patient Outcome tool.

- This tool was developed by the researcher after review of literatures **(Brian. et al., 2018)**, and used to assess primary and secondary outcome.
- Primary outcome which include duration of mechanical ventilation and ICU stay
- Secondary outcome which include delirium, respiratory complication.

Method

- **The study was conducted throughout four main phases**, which were preparatory phase, assessment phase, implementation phase and evaluation phase:

1. Preparatory phase for both control, and study groups:-

- Permission to conduct the study obtained from the hospital responsible authorities in critical care units of anesthesiology department, after explaining the aim and nature of the study.
- The tools (I and II) developed by the researcher based on the relevant literature reviewing.

Content validity: The developed tools (I and II) were tested the content validity by a jury of (7) experts (5) from specialists in the field of critical care nursing and (2) from intensive care medical, the necessary modification was done .

Reliability: The study tools were tested for its reliability by using Crombach's Alpha Co-efficient test, it was efficient and test, was **(α= 0.729)**

A pilot study: -was carried out to assess tool clarity, and applicability of the tools and the necessary modifications were done. The tools were applicable, the pilot study was done on 7 patients were excluded from the study.

Ethical consideration:

1- Research proposal was approved from Ethical Committee in the Faculty of Nursing.

2- There was not risk for study subject during application of the research.

3- The study was following common ethical principles in clinical research.

4- Written consent was obtained from parents that are willing to participate in the study, after explaining the nature and purpose of the study.

5- Parents assured that the data of this research used only for the purpose of research.

6- Confidentiality and anonymity was assured.

7- Parents had the right to refuse to participate and or withdraw from the study without any rational any time.

2. Assessment phase for control and study group:

- During this phase the researcher assessed patient from the first day.
- Of admission starting sedation and record patient socio demographic and clinical data before any data collection by taking this information from his/her sheet using tool 1 (part 1).
- The researcher assessed patient from the second morning of mechanical ventilation and at least 24hours of sedative infusion (first day of intervention) and record respiratory and homodynamic state of patient before starting sedation and during and after withdrawal from sedation by using tool 1 (part II) every 15 minutes for the first two hours of interruption daily on the same time for both groups.
- The researcher assessed patient from the first day of intervention and record mechanical ventilation data tool 1 (part II) Also, assessing level of consciousness by using four score scale tool 1 (part III) one time daily at the same corresponding time for both groups.
- The researcher assessed patient from the first day of intervention and record level of sedation (RASS) daily tool 2 (part I) by using three sequential steps: observation, response to verbal stimulation and response to physical stimulation.

1. Observe patient
   a. Patient is alert, restless, agitated or combative (score 0 to +4)
2. If not alert, state patient's name and say to open eyes and look at speaker
   b. Patient awakens with sustained eye opening and eye contact (score –1)
   c. Patient awakens with eye opening and eye contact, but not sustained(score –2)
   d. Patient has any movement in response to voice but no eye contact (score –3)

When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum

e. Patient has any movement to physical stimulation (score –4)

f.Patient has no response to any stimulation (score –5)

- The researcher assessed patient from the first day of intervention and record Intensive care delirium screening checklist daily by using (tool 3)
- The researcher assessed primary and secondary outcome by using (tool 4)

4. Implementation phase for study group:

Data collection:

- Data were collected in nine months from,(January to September 2018)
- The data were collected from the first day of admission after stabilization of the patient's condition tool 1 (part 1) and collect data from the second morning of mechanical ventilation and at least 24hours of sedative infusion according to inclusion criteria for seven consequent days, every day and every morning shift then the data were recorded in the developed tools.

The researcher assigned study sample (70 patients) to two groups (Control group, Study group):

- For the control group: The researcher assessed patients who were receiving the continuous infusion of sedation.
- For study group: The researcher assessed patients who were receiving the continuous infusion of sedation then applying daily interruption of sedation.

The researcher applied nursing care protocol regarding daily interruption of sedation for study group after 24 hours of sedative infusion and 12hours of mechanical ventilation for seven consequent days, every day and every morning shift if sedative infusion continue as the following:

- Sedation (midazolam or fentanyl) that are routinely used in the selected setting was stopped in the morning as doctor order, but timing was depend on practicalities such as daily rounds, procedures, and travel outside the

ICU. Interruption occur one time every morning shift for seven consequent days if sedative infusion continue.

- Then, assess patients for warning signs of daily interruption of sedation by using tool 2 (part II),if present warning signs indicated failure of trial and the need to immediately inform physician for recommend to return infusion of sedation.

4. Evaluation phase:

This phase was done to evaluate effect of nursing care protocol daily interruption of sedation on outcome of mechanically ventilated patients by using four tools, **Tool I**: Patient assessment sheet. **Tool II:** Interruption and infusion sedation assessment scales tool. **Tool III**: Intensive Care Delirium Screening Checklist. **Tool IV**: patients outcome tool.

Statistical analysis:

Data entry and data analysis were done using SPSS version 20 (Statistical Package for Social Science). Data were presented as number, percentage, mean and standard deviation. Chi-square test and Fisher exact test were used to compare qualitative variables. Mann-Whitney test was used to compare quantitative variables between groups in case of non-parametric data. Wilcoxon Signed Rank Test was done to compare quantitative variables between different times. Spearman correlation was done to measure correlation between quantitative variables. P-value considered statistically significant when $P < 0.05$.

Limitation of the study:

Warning signs for daily interruption of sedation contain eight items but applied items present in my result ex (Excitation, Inconvenience, Respiratory distress and rapid shallow breathing index) while others items not presented in my result because duration of interruption for sedation was not very long to cause this complication.

Results

Table (1): Distribution of study and control groups related to socio demographic and clinical data

Socio demographic and clinical data	Control (n= 35)		Study (n= 35)		P-value
	No.	%	No.	%	
Age: Mean ± SD	38.12 ± 16.14		42.48 ± 15.17		0.338
Gender:					
Male	27	77.1	22	62.9	0.269
Female	8	22.9	13	37.1	
Setting:					
General ICU	35	50	35	50	-
Diagnosis:					
Respiratory diseases	20	57.1	22	62.9	
Cardiovascular diseases	3	8.6	2	5.7	0.949
Gastrointestinal diseases	3	8.6	3	8.6	
Other diseases	9	25.7	8	22.9	
APACHE II Score on admission	17.88 ± 4.23		17.60 ± 4.31		0.781
APACHE II Score at last day	16.47 ± 6.21		15.48 ± 4.48		0.335

Independent T-test for quantitative data between the two groups

Table (2): Distribution of study and control groups in relation to hemodynamic

	Control(n=35)	Study(n=35)	P. value
Temperature			
1st day	37.4±0.79	37.69±0.62	0.088
2nd day	37.94±0.64	37.67±0.63	0.083
3rd day	37.75±0.73	37.67±0.65	0.629
4th day	37.95±0.72	37.62±0.61	0.056
5th day	37.98±0.58	37.78±0.68	0.374
6th day	38.25±0.9	37.61±0.68	0.017*
7th day	38.05±0.73	37.63±0.43	0.013*
Pulse			
1st day	110±16.09	108.57±15.93	0.710
2nd day	112±16.23	110.29±13.82	0.636
3rd day	108.29±17.9	108±14.1	0.941
4th day	104.24±18.71	102.93±14.44	0.759
5th day	104.81±18.68	99.23±18.53	0.280
6th day	107.83±19.99	100.56±17.98	0.235
7th day	106.25±16.28	102.94±16.49	0.566
Mean Blood Pressure			
1st day	93.43±11.87	96±13.11	0.393
2nd day	94.86±15.79	96.57±13.71	0.629
3rd day	95.71±13.35	100.29±17.06	0.216
4th day	104.85±10.64	99±12.69	0.051
5th day	97.41±12.28	100.38±12.8	0.391
6th day	96.52±16.41	101.11±13.23	0.340
7th day	99.38±16.92	95.29±13.75	0.451
Central Venous Pressure:			
1st day	8.4±3.91	9.11±3.9	0.447
2nd day	10.77±4	11.09±4.08	0.746
3rd day	11.04±5.44	12.96±3.45	0.132
4th day	10.78±5.71	11.89±3.51	0.475
5th day	9.94±3.11	11.71±3.73	0.035*
6th day	9.64±3.92	11.87±3.94	0.028*
7th day	9.25±3.73	12.29±3.92	0.029*

Independent T-test for quantitative data between the two groups
***Significant level at P value < 0.05**

Table (3): Distribution of study and control groups in relation to mechanical ventilation parameters

	Control (n=35) Mean ± SD	Study(n=35) Mean ± SD	P. value
Respiratory rate			
1st day	22.14±6.04	25.11±7.14	0.064
2nd day	22.94±7.36	25.91±6.07	0.070
3rd day	21.46±6.96	25.46±7.13	0.020*
4th day	23.86±7.25	28.4±7.53	0.018*
5th day	23.64±9.15	26.77±5.85	0.145
6th day	23.66±7.88	29±7.29	0.032*
7th day	23.25±6.82	25.76±2.10	0.041*
Tidal Volume/litre			
1st day	0.46±0.15	0.42±0.15	0.275
2nd day	0.45±0.11	0.45±0.17	0.932
3rd day	0.49±0.08	0.47±0.12	0.558
4th day	0.49±0.14	0.49±0.11	0.926
5th day	0.51±0.12	0.49±0.12	0.628
6th day	0.52±0.15	0.44±0.14	0.068
7th day	0.53±0.16	0.46±0.1	0.204
Fio2			
1st day	48.44±9.71	52.19±16.01	0.262
2nd day	45.63±11.2	47.73±9.28	0.412
3rd day	42.88±10.16	49.88±13.6	0.022*
4th day	44.17±13.6	49.53±16.11	0.173
5th day	47.31±18.77	43.4±8.63	0.347
6th day	43.01±15.45	49.1±7.97	0.041*
7th day	40.07±7.93	52±12.79	0.005**
SPO2			
1st day	98.29±1.9	97.31±2.58	0.077
2nd day	97.94±1.97	97.83±1.84	0.803
3rd day	97.57±2.03	98±2.07	0.386
4th day	97.01±2.2	98.23±1.59	0.009**
5th day	94.65±2.72	96.38±4.10	0.041*
6th day	95.5±6.66↑	98.43±1.85	0.014*
7th day	95.81±3.06	97.47±1.87	0.007**
PEEP (Positive End Expiratory Pressure)			
1st day	6.31±2.13	7.63±2.81	0.040*
2nd day	7±3.01	7.67±2.9	0.366
3rd day	7.79±2.91	7.88±3.02	0.906
4th day	7.76±3.23	8.3±3.2	0.520
5th day	7.65±2.46	8.16±3.34	0.540
6th day	7.73±2.16	8.67±4.01	0.363
7th day	8.33±2.23	9.8±4.3	0.250
Pressure Support ventilation			
1st day	17.22±10.54	15.84±6.99	0.541
2nd day	18.91±11.38	16.03±6.7	0.217
3rd day	18.27±10.1	14.78±6.09	0.098
4th day	14.34±7.54	15.1±4.89	0.649
5th day	13.35±6.04	15.96±7.74	0.184
6th day	13.73±6.4	21±11.13	0.016*
7th day	11.22±2.11	17.33±3.33	0.001**

Independent T-test for quantitative data between the two groups
***Significant level at P value < 0.05**
****Significant level at P value < 0.01**

Table (4): Distributions of study and control groups in relation to Four Score Scale to assess level of consciousness

	Control (n=35)	Study(n=35)	P. value
	Mean ± SD	Mean ± SD	
Four Score Scale			
Before sedation 1st day	2.57±3.04	3.74±2.89	0.103
During sedation 2nd day	2.54±2.82	5.54±3.74	<0.001**
3rd day	3±3.81	5.86±3.69	0.002**
4th day	3.48±4.09	6.83±4.02	0.002**
5th day	2.78±2.97	7.08±4.18	<0.001**
6th day	3.48±3.78	8.61±4.33	<0.001**
7th day	3.13±2.9	8.53±4.42	<0.001**

Independent T-test for quantitative data between the two groups Study
****Significant level at P value < 0.01**

Table (5): Distribution of study and control groups in relation to Richmond Agitation Sedation Scale (RASS during sedation)

Richomond Agitation Sedation Scale, during sedation	Control (n=35)	Study (n=35)	P. Value
1st day	-4.05±0.87	-3.46±1.93	0.098
2nd day	-4.08±0.78	-3.4±1.9	0.052
3rd day	-4.34±1.08	-3±2.2	0.002**
4th day	-4.06±1.32	-3.03±1.88	0.014*
5th day	-4.44±1.01	-3.15±1.41	<0.001**
6th day	-4.09±1.2	-2.67±1.61	0.002**
7th day	-4.19±0.83	-2.71±1.65	0.003**

Independent T-test for quantitative data between the two groups
***Significant level at P value < 0.05-Study**
****Significant level at P value < 0.01**

Table (6): Distribution of study groups in relation to duration of interruption for sedative infusion every day related to warning signs

Duration of interruption for sedative infusion per hours in the Study group	Mean ±SD
1st day	1.09±1.13 /hours
2nd day	1.54±1.26 /hours
3rd day	2.36±1.43 /hours
4th day	2.65±1.78/hours
5th day	2.71±1.69/hours
6th day	2.81±1.81/hours
7th day	3.55±1.12/hours

Table (7): Distribution of study and control groups according to Warning signs for Daily interruption of sedation

as a warning signs for Daily interruption of sedation	Control (n= 35)		Study (n= 35)		P-value
	No.	%	No.	%	
A-Excitation					
1st day	15	42.86	22	62.86	0.150
2nd day	13	37.14	28	80.00	<0.001**
3rd day	15	42.86	28	80.00	0.003**
4th day	10	28.57	24	68.57	0.001**
5th day	9	25.71	20	57.14	0.015*
6th day	8	22.86	13	37.14	0.297
7th day	5	14.29	12	34.29	0.094
B-Inconvenience					
1st day	6	17.14	9	25.71	0.560
2nd day	5	14.29	9	25.71	0.370
3rd day	5	14.29	9	25.71	0.370
4th day	4	11.43	7	20.00	0.511
5th day	3	8.57	6	17.14	0.475
6th day	1	2.86	3	8.57	0.607
7th day	1	2.86	3	8.57	0.607
C-Respiratory distress					
1st day	3	8.57	10	28.57	0.065
2nd day	3	8.57	16	45.71	0.001**
3rd day	2	5.71	17	48.57	0.001**
4th day	4	11.43	14	40.00	0.013*
5th day	2	5.71	12	34.29	0.007**
6th day	2	5.71	9	25.71	0.048*
7th day	2	5.71	8	22.86	0.087

Independent T-test for quantitative data between the two groups
***Significant level at P value < 0.05**
****Significant level at P value < 0.01**

Table (7): Con… Warning signs for Daily interruption of sedation

Rapid shallow breathing index	Control	Study	P. value
	Mean ±SD	Mean ±SD	
1st day	46.89±18.63	55.91±19.88	0.066
2nd day	51.85±23.51	57.4±18.8	0.296
3rd day	45.02±16.41	53.94±17.78	0.040*
4th day	49.55±26.59	58.72±22.17	0.188
5th day	49.64±31.8	57.8±16.55	0.385
6th day	49.57±18.26	62.63±24.53	0.024*
7th day	46.83±17	66.38±21.3	0.004**

Independent T-test for quantitative data between the two groups
***Significant level at P value < 0.05**
****Significant level at P value < 0.01**

Table (8): Comparison between Studied group According to primary outcome (Duration of mechanical ventilation)

	Control(n=35)		Study(n=35)		P.value
	N.	%	N.	%	
Duration of mechanical ventilation					
<4 days	9	25.7	19	54.3	0.014*
>4 days	26	74.3	16	45.7	
Mean±SD	6.91±2.56		5.43±1.91		0.008**

Chi square test for qualitative data between the two groups
***Significant level at P value < 0.05, **Significant level at P value < 0.01**

Table (9): Distribution of study and control groups according to secondary outcome (Respiratory complication)

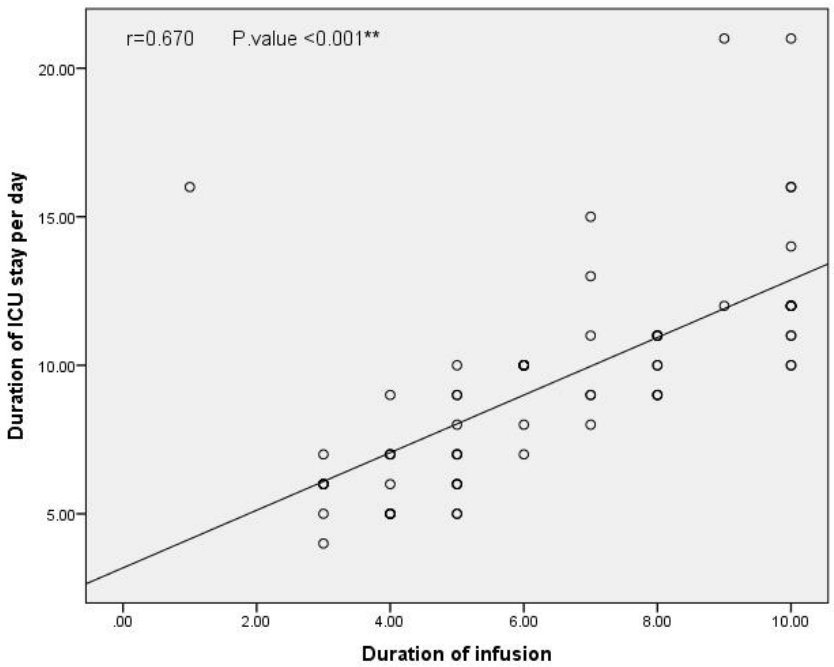
Respiratory complications	Control		Study		P. value
	No.	%	No.	%	
Reintubation	13	37.14	3	8.57	0.010*
Chest trauma:					
Pneumothorax	14	40.00	5	14.29	0.031*
Hemothorax	10	28.57	2	5.71	0.026*
Pleural effusion	6	17.14	3	8.57	0.475
Chest infection	13	37.14	4	11.43	0.025*

Chi square test for qualitative data between the two groups
***Significant level at P value < 0.05**

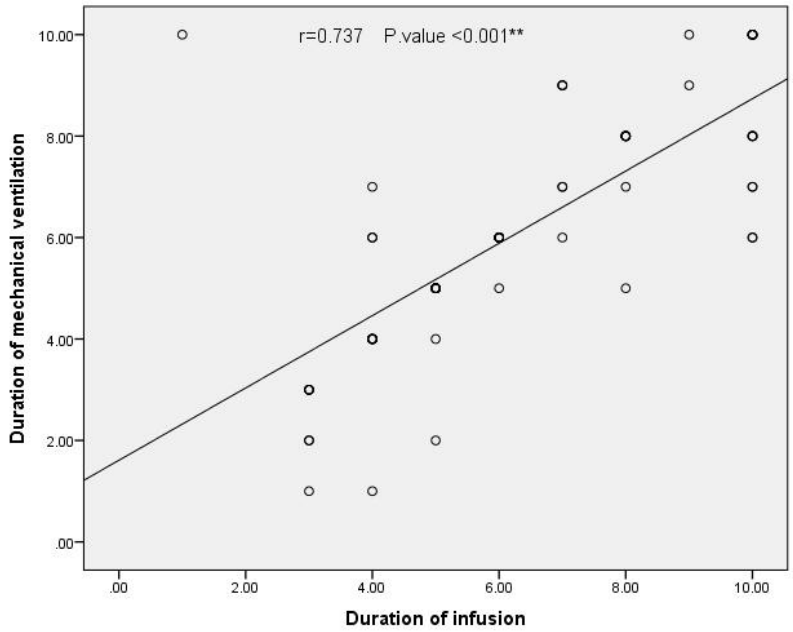
Table (10): Distribution of study and control groups according to Intensive Care Delirium Screening Checklist

Intensive care delirium checklist	Control (n= 35)		Study (n= 35)		P-value
	No.	%	No.	%	
Before starting Nursing care protocol of sedation	4		3		
1st day		11.43		8.57	0.999
During 1st day	4	11.43	2	5.71	0.668
3rd day	4	11.43	2	5.71	0.668
4th day	5	14.29	3	8.57	0.706
5th day	9	25.71	2	5.71	0.048*
6th day	12	34.29	4	11.43	0.046*
After sedation 7th day	13	37.14	4	11.43	0.025*

Chi square test for qualitative data between the two groups
***Significant level at P value < 0.05**



Figures (1): Correlations of duration of sedative infusion with duration of ICU stay per day



Figures (2): Correlations of duration of mechanical ventilation with duration of sedative

Table (1): This table illustrates **socio demographic and clinical data** of study and control groups. Regarding to age, it was noticed that the main age in study and control groups (42.48 ± 15.17and 38.12 ± 16.14) respectively Related to gender, it was the majority of patients were male in control groups and study groups (77.1% and62.9%) respectively. According to APACHE II score, it was found that there was no a statistical significant difference between study and control groups (P value > 0.05).

Table (2): This table shows **hemodynamic status** of the study and control groups. As regard to temperature, results revealed that there was a statistical significant difference between study and control groups in6th and 7th day (P=0.017*& P=0.013*). According to central venous pressure, results revealed that there was statistical significant differences between study and control groupsin5th,6thand 7th days post intervention (P= 0.035*&P=0.028* &P=0.029*) .

Table (3): This table shows distribution of study and control groups in relation to mechanical ventilation parameters. According to respiratory rate, it was observed that there was not statistical significant difference in first days of Nursing care Protocol but there was a statistically significant differences in following days of intervention in, 6th and 7th days (P=0.032&P=0.041*. Regarding to fraction of inspired oxygen (FiO2), results revealed that there was a statistically significant difference between study and control groups in 6th and 7th days (p=0.041*&P= 0.005**) post intervention. According to Spo2, it was found that there was statistical significant differences between study and control groups from4th, to 7th days (p= 0.009**&P=0.041*&P= 0.014* & P=0.007) post nursing care protocol.

Table (4) illustrates Four Score Scale of study and control groups. it was observed that there was not statistical significant difference before interruption of sedation while It was found that there was statistical significant difference between study and control groups post intervention(P= 0.001**).

Table (5): This table shows **Richmond Agitation Sedation Scale** (RASS). it was observed that Distribution of study and control groups according to **Secondary outcomes Table (6):** This table shows **duration of interruption** for sedative infusion in the Study groups, per hours every day,. Results revealed that the highest duration of first day interruption in the study groups were in 7th day (3.55±1.12) hrs. post intervention . While in control groups, sedative infusion was continue 24hrs per day without interruption.

Table (7): This table shows warning signs for Daily interruption of sedation. Regarding to excitation and respiratory distress: results revealed that that there was not statistical significant difference before interruption of sedation while there was statistical significant differences between study and control groups in all days(P= 0.000*) post intervention.

Table (8): This table shows comparison between studied groups according to **Primary Complication (duration of mechanical ventilation).** It was noticed that there was a statistical significant difference between study and control groups in<4 days and>4 days (P=0.014*) & (P=0.008*).

Table (9): Distribution of study and control groups according to **Secondary outcomes (Respiratory complication): I**t was noticed that there were a statistical significant differences between study and control groups regarding to reintubation (P value = 0.010*), pneumothorax (P value = 0.031*), hemothorax (P value = 0.026*) and chest infection (P value = 0.025*).

Table (10): Distribution of study and control groups according to **Secondary outcomes (intensive care delirium checklist)** It was found that there was not statistical significant difference before interruption of sedation while It was noticed that there was statistically significant difference between study and control groups post intervention (P= 0.001**).

Figure (1): Distribution of study and control groups according to **Secondary outcomes (ICU stay)** This figure presented that there was significant positive correlation between duration of sedative infusion with duration of ICU stay per day (P<0.001*) respectively.

Figure (2): This figure presented that there was significant positive correlation between duration of mechanical ventilation with duration of ICU stay per day (P<0.001*) respectively.

Discussion:

Nursing care protocol of daily sedation interruptions should be titrated to maintain a light Sedative rather than a deep level of sedation in adult ICU patients, unless contraindicated, keep patients comfortable and safe using the minimum possible amount of sedation, use protocolized care with sedation score monitoring **(Lynelle, 2015).**

Daily sedation interruptions may not be necessary in ICUs with protocolized sedation, review infusion rates at least daily, and after any procedures, with boluses of analgesics (e.g. IV morphine or fentanyl), only make minor increases in basal infusion rates, avoid prolonged deep coma whenever possible, use caution in renal and liver failure, use spontaneous breathing, unless contra-indicated and dexmedetomidine is increasingly preferred in delirious patients requiring ongoing sedation **(Cameron. et al., 2018)**

According to hemodynamic status

The recent study showed that study groups suffer from tachypnea in first days of interruption sedation and increase in mean blood pressure but improved post intervention. This might be attributed that deep sedation decreased forearm vascular resistance, norepinephrine and further decreased mean arterial blood pressure, so the researcher noticed a significant increase in respiratory rate and mean blood pressure during trial of interruption. **This on according with (Kitty, 2016)** who keep attention to hemodynamic monitoring during moderate to deep sedation especially for treatment of hypotension.

The present study show there was not statistical significant difference before interruption of sedation while It was found that there was a significant improvement of oxygen saturation post intervention **.**This could be interpreted by the fact that every conscious level of patients improve, patients can take spontaneous breathing and improve oxygen saturation. This is agree with **(Mauro. etal, 2016)** who found that there was gradual improvement in hemoglobin saturation of oxygen as recorded by pulse oximetry (SPO2) during daily interruption of sedation, supported hypothesis of the study.

The finding of this study revealed that there were some criteria of weaning from mechanical ventilation available in study groups more than that in control groups such as improve thermodynamic stability, patients can follow simple command for example spontaneous cough and general improve ABG parameters in fourth day and fifth day, supported hypothesis of the

study. The explanation was that repeated trials of sedation interruption every day increase. Opportunity in improvement of weaning readiness criteria. The study of spontaneous-awakening trials with showed that daily sedation interruptions improved the time to extubation majority of patients by approximately two days which reduced the total admission time to the ICU by three and half days **(Grensemann. et al., 2018)**.

According to level of consciousness

The present finding indicated that there was a statistical significant difference between study and control groups regard to **Four Score Scale** (FSS) post intervention .There is evidence that there is a negative correlation between consciousness level of the patients and deep sedation. This is agree with **(Abou-Chebl. et al., 2018)** who found that the intervention group had higher consciousness compared to the control group supported hypothesis of the study.

Regarding sedation

Sedation is recommended to allow patients the ability to tolerate unpleasant diagnostic or surgical procedures and to relieve anxiety and discomfort. Ideal **sedation level** should be neither deep nor inadequate. Planning and intervention of the medical team are essential in this regard.

In the current study, it was noticed that there was a statistical significant difference between study and control groups related to RASS in most day. This may be due to level of sedation was better controlled in the study group that led to improve the quality of sedation in ICU patients .**This is agreeing with (Chris Nickson , 2016)** who found that patients on sedative infusion were minimally arousal or non-arousal. **On the other hand with (Aliye. et al., 2017)** who suggested that using daily interruption of sedation does not have much effect on the ICU patients' sedation level.

The finding of this study revealed that there was a significant positive correlation between duration of sedative infusion and duration of mechanical ventilation. **In this result**, daily sedation interruption and targeting light sedation levels are safe and proven to improve oxygenation. **This in according with** (**Ahmed. etal, 2015)** who found that daily interruption of sedation is safe and practical approach to treating patients who are receiving mechanical ventilation.

Regarding patients outcome

It was noticed that there were a statistical significant differences between study and control groups regarding to **Secondary outcome (respiratory complication).** This may be attributed to the fact that daily interruption of sedation has more improvement than heavy sedation on outcome of mechanically ventilated patients supported hypothesis of the study.

The use of sedation has several disadvantages. Sedation eliminates the possibility to clinically observe the cerebral function of patients and complicates the ability to detect delirium since Richmond Agitation-Sedation Scale (RASS) needs to be at least -3 or above to use Intensive Care Delirium Screening Checklist to detect delirium **(Engstrom. et al., 2016).**

In my results found that there is difference between two groups related to presence of delirium **(Secondary outcome**) post intervention. **This is in line with** (**Fabio and Ary, 2016)** who found that midazolam was associated with significantly increased risk of delirium.

On the other hand, (**Devlin. etal, 2018)** who presents no difference in delirium between two groups**.**

The finding of this study revealed that there was significant positive correlation between duration of sedative infusion and duration of mechanical ventilation. Also between duration of sedative infusion and duration of ICU stay.In my opinion, daily sedation interruption and targeting light sedation levels are safe and proven to improve outcomes, supported hypothesis of the study. **This in according with (Nagaraj,et al., 2017)** who found that daily interruption of sedation is safe and practical approach to patients who are receiving mechanical ventilation.

Finally, the major finding of this study was that nursing care protocol Sedation breaks or DIS, which make the patients conscious, cause their earlier separation from the ventilator and decrease their duration of ICU stay, while reduction in the consciousness level of the patients caused by deep sedation can have many risks such as delayed separation from the ventilator, increased duration of ICU stay days.

Conclusion

- Based on the results of this study, it could be concluded that Nursing care protocol daily interruption of sedation improved outcome for Patients who receiving mechanical ventilator through decreases the duration of mechanical ventilation, the length of stay in the intensive care unit, and has the potential to reduce excessive sedation ,improving conscious level, respiratory complication.

Recommendation:

1- Emphasize the importance of the role of the nursing staff that is very crucial in this aspect to assess the level of sedation in adult ICU patients, unless contraindicated.

2- Reapply this research on a larger probability sample acquired from different geographical areas in Egypt for generalization.

3- Nursing guidelines routine use of sedation to fully prevent patients from exposure to these adverse effect.

4- There were some barriers face researcher during data collection need to overcome in the future application of daily interruption of sedation in all ICUs

- Health care team should supported protocol of sedation interruption for patients in all ICUs to improve of outcomes of this protocol.

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