

Original Research Article

A randomized controlled trial to compare the outcome of mechanically ventilated patients between daily interruption of sedation versus continuous sedation

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ABSTRACT

Background: This study is to Compare the Outcome of Mechanically Ventilated critically ill patients by daily interruption of sedation Versus continuous sedation.

Methods: The proposed study was a double-blinded, prospective randomized control trial done in critically ill mechanical ventilator patients in the critical care units, for 14 months. 52 adult patients were equally divided into 26 into each group were receiving mechanical ventilation and continuous infusions of sedative drugs. The interruption Group of Patients are named As Group "I" Patients They Received Injection Midazolam Infusion of 2 mg Per Hour, And the Continuous Group patients named has Group "C" Was Received Injection: Midazolam infusion of 2 mg per hour in continuous infusion during the period of mechanical ventilation. The interruption Group of patients the sedative infusions were interrupted until the patients were awake, daily. Sedative infusions for the continuous group of patients in the intensive care unit were only interrupted at the clinician's discretion.

Results: The mean total duration of mechanical ventilation in hours (Group I) Interruption group is 79.46±28.96 while the mean total duration of mechanical ventilation in hours (Group C) continuous group is 174.26±84.91 The mean total number of hospitals stays in Group I is 16.42±3.12, while in Group C is 23.58±2.97.

Conclusions: Due interruption of sedation infusions helps to periodically evaluate the neurological status and sedation score of the patients, it can able to assess the neurological status of the patient intermittently, and hence extubation can be planned earlier. Therefore, this study concludes that the reduced duration of Mechanical ventilation and length of stay in intensive care units were significantly reduced in interruption group.

Keywords: ICU Sedation infusion, critically ill patients, Mechanical ventilation, Sedation scale, Early outcome

INTRODUCTION

Sedation is routinely administrated to critically ill patients to reduce stress and oxygen consumption, to control agitation, prevent pain and anxiety, and improve synchronicity with mechanical ventilation. Sedation is often used and is frequently associated with worse clinical consequences, such as more time on mechanical ventilation, longer stays in intensive care units, and

elevated cognitive impairment (delirium and coma).^{1,2} Commonly used sedation agents in ICU such as benzodiazepines (midazolam) and opioids are fentanyl, morphine, and adjuvants to anesthesia drugs dexmedetomidine and propofol.³ These agents may be used alone or in combination administered by patients for a sedative infusion. Benefits of sedation in ICU enables patients to endure unpleasant or upsetting treatments or diagnostic procedures (such as invasive lines and endotracheal intubation) optimize mechanical ventilation

to decrease O₂ consumption (e.g., tolerate permissive hypercapnia) in conditions like sepsis decrease ICP in patients undergoing neurosurgery to make cooling (such as therapeutic hypothermia) easier reduce agitation, psychological response to stress.⁴

Goal For Sedation in ICU Prioritize patient comfort and maintain hemodynamic stability to enhance overall well-being. Ensure that nursing management is facilitated to provide responsive and effective care. Deliver optimal analgesia for surgical patients to alleviate pain, prevent self-extubation, safeguarding patient improve the patient's safety and comfort. Sedation and analgesia improve the Patient synchrony with mechanical ventilator. Continuously monitor the patient who are intubated with mechanical ventilator support receiving sedative infusions. Hemodynamic monitors blood pressure, heart rate, saturation, respiratory rate, Neurological assessment Glasgow coma scale Sedation scoring monitoring, Pain score monitoring. Review infusion rates at least daily, and after any procedure Hourly urine output.⁵

Sedation scoring systems enable the assessment of patients' depths of sedation and adjust analgesic and sedative therapies to achieve an optimum level of sedation for the individual patient. In the ICU, sedation assessments evaluate both sedation levels and agitation. This evaluation includes measuring the level of consciousness, pain, and synchrony with the ventilator.⁶ The two most commonly used sedation scoring systems in the ICU are the Ramsay Sedation Scale and the Richmond Agitation-Sedation Scale (RASS).

The RASS is particularly used in critical care settings for patients on mechanical ventilation, as it helps prevent both over-sedation and under-sedation. This scale is crucial for evaluating a patient's level of consciousness, agitation, and neurological activity, which can significantly reduce the risks associated with over-sedation. Common side effects of sedation include respiratory depression, hypotension, and sleep disruption. Therefore, monitoring sedation scores is vital to ensure the safety and comfort of patients in the ICU.^{7,8}

Midazolam is a short-acting hypnotic-sedative drug with anxiolytic, muscle relaxant, anticonvulsant, sedative, hypnotic, and amnesic properties. It belongs to a class of drugs called benzodiazepines. This drug is unique from others in this class due to its rapid onset of effects and short duration of action. Sedation is required in the ICU in order for patients to tolerate noxious stimuli, particularly mechanical ventilation. Under - and oversedation can lead to complications. To sedate patients in the ICU, midazolam is commonly administered via titrated, continuous infusions. The Pharmacological Action of benzodiazepines are mainly acts on CNS reticular activating system producing sedation and hypnosis, reduce anxiety, muscle relaxation, anticonvulsant effects and producing amnesia.⁹ Midazolam used mainly to cause sleep are called hypnotics. The suppression of REM sleep

is very little with benzodiazepines. The quality of sleep resembles natural sleep more closely when compare to other older hypnotics. Sedation and anxiolytic effects of benzodiazepines are reduced anxiety and aggression and produce a calming effect. anxiolytic effect due to their action on limbic system.¹⁰ The muscle relaxant action of the benzodiazepines reduces skeletal muscle tone by a central action. They depress the spinal polysynaptic reflexes which maintain the muscle tone. Generally, anxiety is associated with an increased muscle tone and may responsible for aches and pain in mechanical ventilated patients. The muscle relaxation by benzodiazepines adds to their beneficial effect in mechanical ventilator patient. High dosage also depresses the transmission at the anticonvulsant effects benzodiazepines increase the seizure threshold and act as anticonvulsant. They suppress the development and spread of seizures. Diazepam used intravenously for treatment of status epilepticus. Midazolam suppresses the seizures by increasing the way gamma-aminobutyric acid (GABA) acts in the brain. GABA is a major substance or neurotransmitter in the brain.¹¹ Common Dosage of Injection midazolam initial IV bolus: 0.2–5 mg every 1–5 minutes and continuous infusion at 1–2 mg/hour dosage should be increased by 1–5 mg/hour until adequate sedation is achieved, Rate of infusion in ICU 2 to 5ml/hour. Common side effect of midazolam includes respiratory depression and hypotension.^{12,13}

We hypothesized that due to interruption of sedation. It is able to assess the neurological status of the patient intermittently thereby facilitating earlier extubation. The aim is to assess and compare the outcome of mechanically ventilated critically ill patients by intermittent interruption of sedative infusions versus continuous sedative infusions.

METHODS

Study design and setting

This was a prospective, single-center, parallel-group comparative study conducted over a period of 14 months from 2021 to 2023. The study was carried out in the Medical Intensive Care Unit (MICU), Surgical Intensive Care Unit (SICU), and Neurosurgical Intensive Care Unit of SRM Medical College Hospital and Research Centre, a tertiary care teaching hospital in Kattankulathur, Tamil Nadu, India. The study was initiated after obtaining approval from the Institutional Ethics Committee (IEC Clearance No: 8254/IEC/2022). Written informed consent was obtained from the patients' legally authorized representatives prior to enrollment. Patients were allocated into two groups using a randomization method, and outcome assessment was performed by an assessor who was blinded to the group allocation.

Participants

Inclusion criteria of the Patients aged from 18 to 65 years, Patients who require mechanical ventilator support for

more than 24 hours in MICU, SICU, Neurosurgical ICU, Neurosurgical patients include Decompression craniectomy, cranioplasty, aneurysm coiling, post operative surgical patients like nephrectomy, laparotomy, refractory status epilepticus, traumatic brain injury. We exclude patients from this study patients with Glasgow coma scale less than 8, patients who are receiving paralytic agent, severe hepatic failure, pregnancy patients.

Randomization and blinding

Participants were assigned in a 1:1 ratio to either the Interruption group (Group I) or the Continuous group (Group C). The allocation sequence was generated using a computer-based random number system by an independent individual who had no role in patient management or outcome assessment. Group assignments were concealed using sequentially numbered, opaque, sealed envelopes. After confirming eligibility and enrollment, the next envelope in sequence was opened to determine the assigned intervention.

Methodology

It was a randomized controlled trial involving 52 adult patients equally divided into 26 in each group, they were receiving continuous sedative infusion and mechanical ventilation in critical care units. An Interruption group of patients are named as "I" group patients they will receive inj. midazolam infusion 2 mg per hour, the continuous group patients named has "C" the patients they will receiving inj. midazolam infusion 2 mg per hour in continuous infusion during the period of mechanical ventilation. In the interruption group of patients, the sedative infusions were interrupted on daily basis till the patients were awake or agitated, on a Sedative infusion for the continuous group of patients in intensive care unit were only interrupted at the clinician's discretion.

The daily simultaneous interruption of midazolam infusions in the interruption group was performed by a researcher not directly involved in care of the patients under the guidance of ICU physicians, while sedative infusion Interrupted in group I until the patient might be following the commands while awake, or until they are agitated and needed the sedation to be resumed. Infusions of sedatives were not stopped if a patient was getting a paralytic medication. Throughout the period when infusions were halted and until the patients were either awake or uncomfortable and required the return of sedation, a research nurse who was not directly involved in the care of the patients daily evaluated the patients. The total daily dosages of sedative medicines administered into the Group C patients were recorded while they were being observed by study investigator each day. The staff of the intensive care unit team made the decision as to how much sedative medication should be administered to the group C. All other decisions pertaining to patient care, excluding the daily cessation and restart of sedative medication infusions in the interruption group, were decided by the

intensive care unit personnel. We evaluated each patient's neurological status by observing their Glasgow coma scale (GCS) by 4 hours interval and level of sedation in ICU was assessed in daily basis by using Richmond Agitation Sedation Scale (RASS). The patients will be monitored for at least 5 days or until they are weaned off from ventilator support and followed till, they are discharged from the hospital to record the total number of days in hospital stay. We also assessed the comparison in reduction in total duration of mechanical ventilation in hours among both groups either by interrupting the sedation given to the patients. Intermittently or by providing continuous infusion of sedation on a daily basis from the day of admission. The demographic variables are age, height, weight, BMI, vital signs heart rate (HR), systemic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen arterial saturation (SPO2), neurological status, Glasgow coma scale, sedation scale Richmond agitation sedation scale.

Primary outcomes

Patients in the interruption group showed earlier extubation, improved GCS and RASS scores, and better hemodynamic stability. Patients receiving daily sedation interruption had shorter ventilator duration (72-96 h) and reduced hospital stay (<20 days) compared to continuous sedation (120-140 h; >20 days).

Secondary outcomes

The secondary outcomes indicate that implementing daily sedation interruption is safe and leads to quicker lightening of sedation, accelerated neurological improvement, and minor changes in hemodynamic parameters, while maintaining stable respiratory function.

Sample size calculation

The sample size was calculated with 80% power and 5% alpha error to detect a significant difference between the two groups. A minimum of 25 patients were required in each group; therefore, 52 patients were included in the study.

Statistical analysis

All the statistical analysis was performed using Statistical Package for Social Sciences (SPSS Version 20) for Microsoft Windows. The data were normally distributed and therefore, parametric tests were performed.

Descriptive statistics (mean, standard deviation, median, frequency and percentage) were included. To compare the quantitative data between 2 groups Student Independent 't' test was used. The results were expressed in 95% confidence interval. A value of $p < 0.05$ was considered to be statistically significant. Results were reported with 95% confidence intervals.

Ethical approval and informed consent

The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC No: 8254/IEC/2022). The study was originally approved under the title “A Randomized Controlled Trial to Compare the Outcome of Mechanically Ventilated Patients Between Daily Interruption of Sedation Versus Continuous Sedation.” Written informed consent was obtained from the legally authorized representatives of all patients prior to enrollment.

The study was conducted in accordance with the ethical principles.

RESULTS

A total of 52 patients were included in the analysis, evenly distributed between the Daily Sedation Interruption group (Group I, n=26) and the Continuous Sedation group (Group C, n=26). No participants were withdrawn from the study, and baseline clinical characteristics were comparable between groups.

Table 1: Comparison of demographic, hemodynamic (HR, SBP, DBP, MAP, SPO₂) and neurological parameters (GCS, RASS) between study groups.

Parameter	Group I (n=26)	Group C (n=26)	P value
Demographics			
Age (years)	52.3±14.1	54.8±13.7	0.48
Height (cm)	164.7±6.8	165.3±7.2	0.74
Weight (kg)	65.1±9.4	66.5±10.1	0.63
BMI (kg/m ²)	24.0±2.7	24.4±2.9	0.62
Baseline vital signs			
Heart rate (BPM)	88.2±6.5	89.5±7.1	0.49
SBP (mm Hg)	122.4±8.9	123.8±9.3	0.57
DBP (mm Hg)	76.3±5.6	77.0±5.8	0.66
MAP (mm Hg)	91.0±6.2	91.8±6.5	0.71
SPO ₂ (%)	97.8±1.1	97.6±1.3	0.59
GCS	8.4±1.1	8.3±1.2	0.74
RASS	-3.1±0.4	-3.2±0.5	0.52

Table 2: Day-wise changes in vital signs and neurological scores.

Parameter	Day	Group I	Group C	P value
Heart rate (BPM)	1	88.2±6.5	89.5±7.1	0.49
	3	84.5±6.1	88.9±6.8	0.02*
	5	82.1±5.8	87.2±6.3	0.001*
MAP (mm Hg)	1	91.0±6.2	91.8±6.5	0.71
	3	89.6±5.9	91.7±6.4	0.21
	5	88.4±5.7	91.9±6.1	0.03*
GCS score	1	8.4±1.1	8.3±1.2	0.74
	3	11.2±1.5	9.5±1.3	0.004*
	5	13.5±1.1	10.8±1.4	<0.001*

Note: Values expressed as mean±SD. BPM: Beats per minute; MAP: Mean arterial pressure; GCS: Glasgow Coma scale. P<0.05 significant; and *-Statistically significant.

The demographic and baseline clinical parameters of the study participants are presented in Table 1. Both Group I (n=26) and Group C (n=26) were comparable in terms of age, height, weight, and BMI, with no statistically significant differences (p>0.05). Baseline vital signs, including heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and peripheral oxygen saturation (SpO₂), were similar between groups. Neurological assessments at baseline, including Glasgow Coma Scale (GCS) and Richmond Agitation Sedation Scale (RASS) scores, also showed no significant differences. As shown in Table 2, both groups maintained relatively stable hemodynamic

parameters over the study period; however, notable differences emerged by Day 3 and Day 5. Heart rate in Group I showed a progressive decline from baseline, reaching significantly lower values than Group C on Day 3 (84.5±6.1 vs 88.9±6.8 bpm, p=0.02) and Day 5 (82.1±5.8 vs 87.2±6.3 bpm, p=0.001). MAP values remained comparable until Day 5, when Group I exhibited a modest but statistically significant reduction compared to Group C (88.4±5.7 vs 91.9±6.1 mm Hg, p=0.03). Neurological recovery, as assessed by GCS, improved more rapidly in Group I, with significantly higher scores on Day 3 (p=0.004) and Day 5 (p<0.001).

Table 3: Changes in Richmond agitation-sedation scale (RASS) scores over time between groups.

Time point	Group I (n=26)	Group C (n=26)	P value
Baseline	-3.1±0.4	-3.2±0.5	0.52
6 h	-3.0±0.5	-2.8±0.6	0.18
12 h	-2.9±0.6	-2.6±0.7	0.09
24 h	-2.5±0.7	-2.1±0.8	0.04*
48 h	-2.0±0.8	-1.7±0.9	0.21

Note: Values expressed as mean±SD. RASS: Richmond Agitation-Sedation Scale. P <0.05 significant. *-Statistically significant.

Table 4: Frequency percentage distribution of extubation, total duration of mechanical ventilation in hours and total number of hospital stay on interruption group (n=26).

Variables	Frequency (n)	Percentage (%)
Extubation		
Yes	26	100.0
No	-	-
Total duration of mechanical ventilation (h)		
24-48	1	3.85
72-96	23	88.46
120-144	-	-
>144	2	7.69
Total number of hospital stay (days)		
≤15	10	38.46
16-20	15	57.69
>20	1	3.85

Table 5: Frequency percentage distribution of extubation, total duration of mechanical ventilation in hours and total number of hospital stay on continuous group (n=26).

Variables	Frequency (n)	Percentage (%)
Extubation		
Yes	26	100
No	-	-
Total duration of mechanical ventilation (h)		
24-48	-	-
72-96	6	23.08
120-144	9	34.62
>144	11	42.30
Total number of hospitals stay (days)		
≤15	-	-
16-20	5	19.23
>20	21	80.77

Table 3, at baseline, the sedation depth as measured by RASS was comparable between Group I (-3.1±0.4) and Group C (-3.2±0.5; p=0.52).

Both groups demonstrated progressive reduction in sedation depth over time. By 24 hours, Group I had a significantly higher (less negative) RASS score (-2.5±0.7) compared to Group C (-2.1±0.8; p=0.04), indicating lighter sedation.

No statistically significant differences were observed at 6, 12, or 48 hours. Table 4 shows frequency and percentage distribution of extubation status, total duration of mechanical ventilation, and hospital stay in the

interruption group. Total no of patients was extubated is 26 that is 100%, total duration of mechanical ventilation for 24-48 hours was 1 patient (3.85%). for 72-96 hours were 23 patients (88.46%) and for more than 144 hours was 2 patients (7.69%).

When total number of days in hospital was noted in interruption group, not more than 15 days is 10 patients (38.46%), for 16-20 was 15 patients (57.69%), while more than 20 days was 1 patient (3.85 %). Table 5 shows frequency and percentage distribution of extubation status, total duration of mechanical ventilation, and hospital stay in the continuous group. Total no of patients was extubated is 26 that is 100%.

Table 6: Comparison of total duration of mechanical ventilation in hours and total number of hospitals stay among mechanically ventilated critically ill patients between the interruption and continuous group.

Variables	Group	Mean	SD	Mean difference	Student independent 't' test and p value
Total duration of mechanical ventilation (h)	Interruption	79.46	28.96	94.80	T=5.388, p=0.0001, s***
	Continuous	174.26	84.91		
Total number of hospitals stay (days)	Interruption	16.42	3.12	7.16	T=8.295, p=0.0001, s***
	Continuous	23.58	2.97		

Note: Values expressed as mean±SD; h: Hours; SD: Standard deviation. Independent Student's t test used for comparison. P<0.05 considered statistically significant; ***-Highly significant.

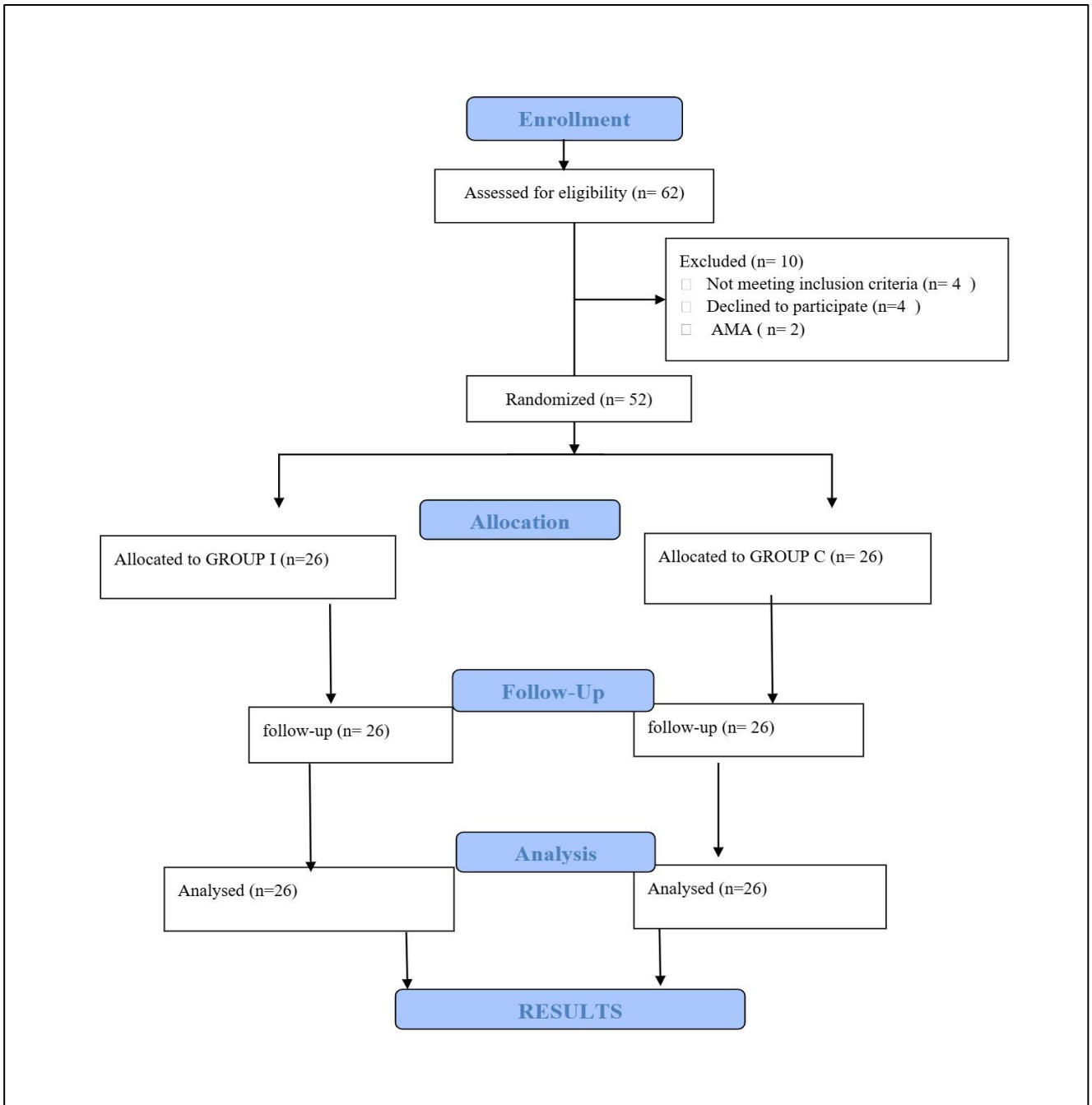


Figure 1: CONSORT flow diagram.

Total duration of patients on mechanical ventilation for 24-48 hours was 0, 72-96 hours was 6 patients (23.6%), 120-144 hours was 9 patients (34.62%), and more than 144 hours was 11 patients (42.30%).

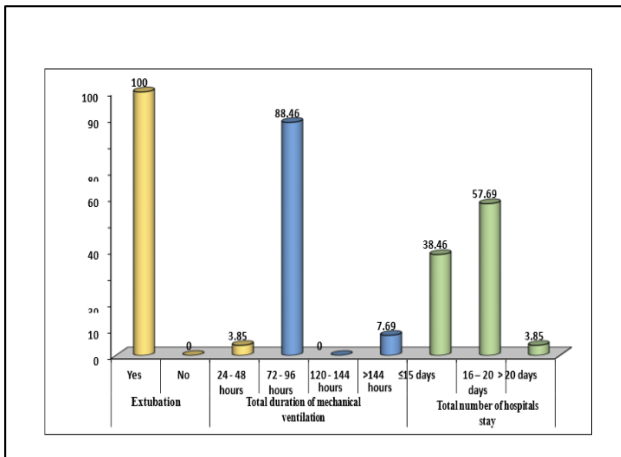


Figure 2: Percentage distribution of extubation, total duration of mechanical ventilation in hours and total number of hospital stays on interruption group.

When total number of days in hospital was noted, 0 patients were stayed <_to 15 days, 5 patients (19.23%) stayed for 16-20 days, while 21 patients (80.77%) stayed for more than 20 days.

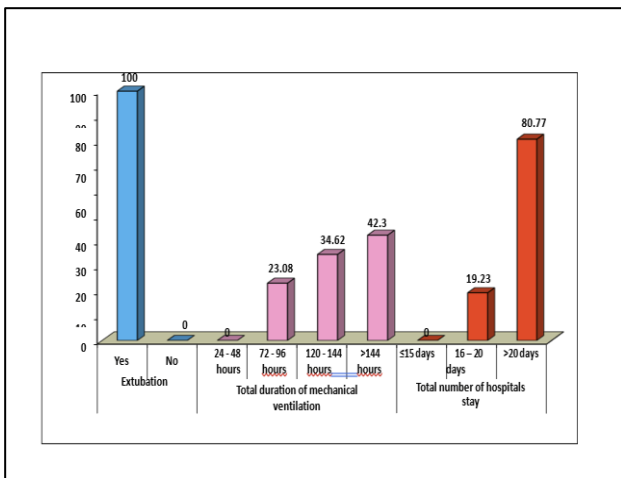


Figure 3: Percentage distribution of extubation, total duration of mechanical ventilation in hours and total number of hospital stays on continuous group.

Table 6 is comparison of total duration of mechanical ventilation and hospital stay between interruption and continuous sedation groups in mechanically ventilated ICU patients. The mean total duration of mechanical ventilation in hours (Group I). Interruption group is 79.46 ± 28.96 , while the mean total duration of mechanical ventilation in hours (Group C). Continuous group is 174.26 ± 84.91 . The mean total number of hospital stays in Group I is 16.42 ± 3.12 , while in group C, it is 23.58 ± 2.97 . After statistical analysis using the student's independent t-

test, it has been found that the values are not comparable and the difference is statistically significant. We conclude that there were variations between the two groups.

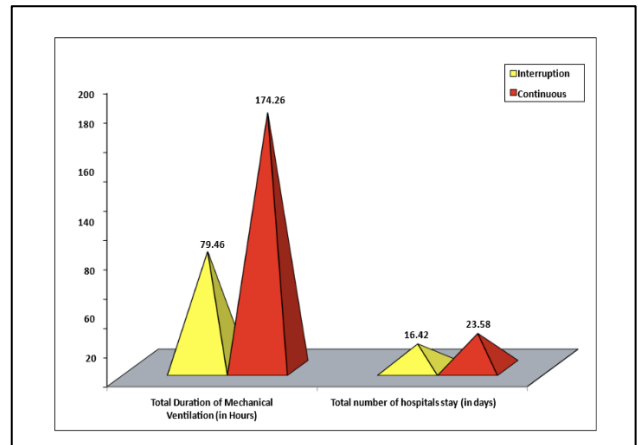


Figure 4: Comparison of total duration of mechanical ventilation in hours and total number of hospital stays between two groups.

DISCUSSION

Patients who are receiving mechanical ventilation frequently get sedatives in order to reduce their anxiety, stress and enhance nursing care. Continuous infusion of these medications provides a more constant dose of sedation than periodical bolus, which may enhance patient comfort. In our experience, intermittent administration of sedation is frequently challenging, and such regimens can be exhausting on nurses and impair other facets of patient care. Continuous infusions may have the potential disadvantage of accumulating medication and delaying the improvement of mental status. We predicted that interrupting the sedative infusion on a regular basis would solve these issues. Benzodiazepines (midazolam) is commonly used for ICU sedation because it is anxiolytic, hypnotic, anticonvulsant, and a muscle relaxant.

We conducted a study on comparing the outcome of mechanically ventilated patients between daily interruption of sedation versus continuous sedation. The total patients included were 52 patients which included 17 female patients (32.6%) and 35 male patients (70%) they received mechanical ventilation support with simultaneous sedative infusion in intensive care unit.

The total patients in this study were divided in two groups of Group I and group C; each group included 26 patients. among the 26 patients in group C, 2 patients were discharged under against medical advice (AMA) as per decision of their relatives. Enhance, we cannot calculate the length of stay for those two patients. The questionnaire form included characteristics of a patient (AGE, SEX, BMI, HR, SBP, DBP, MAP, SPO2, Glasgow coma scale (GCS), Richmond agitation sedation scale (RASS), total duration of mechanical ventilation in hours and total number of days in hospital. Monitoring parameters and

scores were predictive of both groups which determine whether the daily interruption of sedative infusions in mechanically ventilated critically ill patients, would decrease the duration of mechanical ventilation and the length of stay in the intensive care unit. The predictive parameters show that the duration of mechanical ventilation in hours and length of stay in hospital was reduced in interruption group compared to the continuous group. We conducted a randomized controlled trial over a period of one year and six months involving 52 patients aged 18 to 80 years, which compared the outcomes of daily interruption of sedation with continuous sedation in mechanically ventilated patients.

Des Breen et al in 2005 found in their study, remifentanyl-based sedation was well tolerated and improved the weaning process when compared to conventional hypnotic-based sedation regimens in ICUs, which required long-term ventilation for up to 10 days.¹⁴ Curtis et al in their study found that early extubation was more commonly achieved with dexmedetomidine-based sedation than with propofol-based sedation.¹⁵ In our study the mean total duration of mechanical ventilation in hours (Group I) Interruption group is 79.46 ± 28.96 while the mean total duration of mechanical ventilation in hours (Group C) continuous group is 174.26 ± 84.91 . The mean number of days in hospital stay in Group I is 16.42 ± 3.12 , while in Group C is 23.58 ± 2.9 .

After statistical analysis with the Student Independent's t-test, it has been found that both values are not comparable and their difference was noted in both the groups. The results were expressed in a 95% confidence interval, A value of $p < 0.05$ is statistically significant. The p value for the above parameters was < 0.05 and here we conclude that there were variations between the two groups. This shows Group I Patients had reduced duration of mechanical ventilation in hours and length of stay in hospitals, compared to Group C patients. In group I, Total no of patients was extubated is 26 is that 100%, total duration of mechanical ventilation for 24-48 hours was 1 patient (3.85%). for 72-96 hours were 23 patients (88.46%) and for more than 144 hours was 2 patients (7.69%). when total number of days in hospital was noted in interruption Group, not more than 15 days is 10 patients was (38.46%), for 16- 20 was 15 patients (57.69%), while more than 20 days was 1 patient (3.85 %).

In our study the duration of mechanical ventilation in hours is (72-96 hours) and the length of stay in hospital was less than 20 days in interruption groups, while compared to continuous group. In group C, Total no of patients was extubated is 26 is that 100%. Total duration of patients on mechanical ventilation for 24-48 hours was 0 %, 72-96 hours was 6 patients (23.06%), 120-144 hours was 9 patients (34.62%), and more than 144 hours was 11 patients (42.30%) when total number of days in hospital was noted, 0 patients was stayed < 15 days , 5 patients (19.23%) stayed for 16-20 days, while 21 patients (80.77%) stayed for more than 20 days. In our study the average duration of mechanical ventilation in hours is

(120-140 hours) and the length of stay in hospital was more than 20 days in continuous groups, when compared to interruption group.

An-yi Xu et al in 2013, conducted a study in which, patients in the first two groups received a loading dose of propofol or midazolam, then the same medications were continuously infused. Propofol was administered as a loading dose to those in the combination group, and then propofol and midazolam were continued as infusion.¹⁶ In this study, the effectiveness of sedation was assessed using the Ramsay sedation score (RSS). According to the Ramsay score, the patients in three groups were maintained at a depth of sedation level 2-4 and reassessed every one to two hours after the procedure started. According to a 2019 study published by J Caring Sci et al, a sedation protocol based on RASS scores can improve patient sedation, which in turn significantly shortens the length of mechanical ventilation, hospital stays, and maintenance costs.

According to 2013 research by Abdar et al, the mean RASS score of the intervention group was closer to the optimal range of -1 to +1 than the control group (-0.95 vs -1.88). The control group's consciousness level was lower (8.4 vs 8.8) than that of the intervention group. Finally, the control group received larger dosages of midazolam and morphine than the intervention group.¹⁷

In our study we compared Richmond Agitation Sedation Scale (RASS) on Day 1 to 5 among mechanically ventilated critically ill patients between the interruption and continuous Group. The (RASS) was noted from the first 4 hours to 24 hours at every 4 hours' interval. After a statistical analysis, we found that both the values are comparable and the difference is statistically significant. So, there were variations between the two Groups. The score in the Group I lies between (0 to -1) when compare to Group C the lies between (-1 to -2) which increases both duration of mechanical ventilation in hours and total number of hospitals stay when compare to group I.

In our study we also compared Glasgow coma scale (GCS) on Day 1 to 5 in mechanically ventilated critically ill patients between both the interruption and continuous group. The GLASOW COMA SCALE (GCS) was assessed in the 4th hour up to 24th hour, at every 4 hours intervals, after a statistical analysis, we found that both the values are comparable and the difference is statistically significant. So, there were variations between the two groups. Our study shows that GCS was improved in Group I on daily examination of neurological status of patients when compared to group C. GCS did not show any better improvement of neurological status of patient on mechanical ventilator support with continuous infusion of sedation.

Romina E, Aragon et al assessment of sedation depth was carried out in 2019 using a standard measure like GCS. However, there is a significant correlation between the RASS sedation scale and the GCS. Nevertheless, given

how GCS was designed, agitation status would have been underestimated. In our study a Comparison of HR, SBP, DBP, MAP, SPO₂, and variation was noted among mechanically ventilated critically ill patients between the interruption and continuous group. From Day 1 in first 4 hours to 24 hours at every 4 hours of interval. after statistical analysis, it was found that there is no statistically significant and no variation between the two groups. But for Day 2 to day 5 in first 4 hours to 24 hours at every 4 hours of interval, It was found that both values are comparable and statistically significant. So, there were variations between the two groups.

Research was conducted by A. A. Weinbroum et al, to assess the safety and effectiveness of midazolam and propofol, either alone or in combination, in the protracted sedation of a homogenous group of severely injured patients, particularly those with head injuries, were established by a prospective, controlled, randomized research. Midazolam and propofol both provided prolonged, safe, and effective sedation in critically ill, mechanically ventilated medical, post-trauma, and surgical patients. Both medications enabled a quick weaning from mechanical ventilation.¹⁸ Regardless of the duration of sedation, therapy with propofol was linked to a quicker weaning phase than treatment with midazolam, according to Carrasco et al assessment of three sedation periods: short, middle, and protracted. In our study group I, patients were extubated earlier with improved GCS, RASS, and better improvement in the hemodynamic status of the patients in interrupted group when compared to Group C. While patients in Group C were not extubated earlier because of moderate variations in their GCS, RASS and fluctuations in their hemodynamic status.

Limitations

This study was single-centered with a relatively small sample size, which may limit generalizability. Sedative agent choice was standardized, but differences in patient diagnosis, comorbidities, and severity of illness could have influenced outcomes. Additionally, delirium incidence, a key sedation-related outcome, was not assessed and should be addressed in future research. Some patients in the continuous group. Sedative infusion were interrupted intermittently in the intensive care units. we observed Signs of visible physical discomfort during interruption of sedative infusion.

CONCLUSION

Sedation is a safe and practical way to treat mechanically ventilated patients. Daily interruption of sedation infusions helps to periodically evaluate the neurological status and sedation score of the patients, allowing earlier planning of extubation. Therefore, this study concludes that interrupted sedation reduced the duration of mechanical ventilation in hours and length of stay in intensive care units and hospital.

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