Original Article

Delirium Care Bundle On Sedation And Orientation Among Icu-Acquired Delirium A Randomized Controlled Trial

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Abstract

Introduction: Early identification of delirium symptoms and implementation of ABCDEF bundle among mechanically ventilated patients has been demonstrated as feasible, safe, and effective to reduce intensive care unit acquired delirium however it is most effective when it is delivered with the coordination of nursing staff and other health care team members. **Objective:** Aim of the study is to determine the effectiveness of a delirium care bundle on sedation and orientation among ICU-acquired delirium patients with mechanical ventilation. **Materials and methods:** Randomized controlled trial was conducted to implement a delirium care bundle. This intervention has been implemented daily for the seven days of ICU admission. Data were collected using the standardized Richmond Agitation and Sedation Scale to assess the level of sedation. A structured scale was developed by the investigator to assess the level of orientation. Statistical analysis was done by using SPSS 16.0 version. **Results:** The statistical mean scores revealed that there is a significant reduction in the level of sedation from day 1 to day 7 in the experimental group. (0.04 ± 1.42 to 1.00± 0.00) then the control group (7 0.61 ±1.49 to 1.04 ± 0.74). The level of orientation statistical mean scores shows that there is a significant improvement from day 1 to day 7 in the experimental group (1.00 ± 0.00 to 3.71 ± 0.46) than the control group (1.00 ± 0.00 to 2.14 ± 0.44). There is an overall effect of the delirium care bundle intervention on reducing the level of sedation ($t_{(54)}$=-1.900, p=0.001*) and improving the level of orientation ($t_{(54)}$=12.94,p=0.001*) among intubated ICU acquired delirium patients. **Conclusion:** Delirium care bundle intervention has been marked to significantly reduce agitation, and irritability, implementation of non-pharmacological pain management can lead to early orientation and ambulation. Nurses play a significant role in identifying the risk factors, and symptoms of delirium at the initial stage.

Keywords: ICU acquired delirium, delirium bundle care, sedation, level of orientation, Intensive care unit, and mechanically ventilated patients.

Introduction

In the intensive care unit, delirium and weakness are common, typically overlooked, and unappreciated despite decades of studies showing their risks [1]. Delirium is a substantial impairment of awareness and cognitive function that emerges as short-term swings in inattentiveness, cognitive problems, and perceptual disturbance [2]. This process involves the administration of sedative and narcotic medications, mechanical breathing, and immobilization. Any intervention aiming at lowering delirium and weakness would ideally be interprofessional since a clinical team (including nurses, doctors, pharmacists, and respiratory and physical therapists) jointly

supervises these processes [3]. According to a comprehensive study and meta-analysis, delirium affects around one-third of intensive care unit (ICU) patients. Delirium can occur in 20-50 percent of nonventilated patients and 60-80 percent of mechanically ventilated patients, and it is linked to greater mortality and many significant consequences, such as extended ICU admissions and longer hospital stays [4].

Agitation can lead to the unintentional removal of intravascular catheters or endotracheal tubes that are used for monitoring or administering life-saving drugs. As a result, sedatives and analgesics are among the most frequently used medications in ICUs [5]. If reducing the intensity and duration of sedation is seen to be a desired aim, then using a short-acting medication with an impact that can be quickly changed, such propofol or remifentanil, should be preferable to longer-acting medications or medications with active metabolites. Propofol has not been proven to decrease mortality when compared to benzodiazepines, however it may shorten the time of stay in the intensive care unit [6]. Dexmedetomidine, as opposed to benzodiazepines, appears to lessen the likelihood of delirium in the intensive care unit [5].

Critically ill patients frequently require artificial breathing and are frequently given sedatives, principally benzodiazepines and opioids, to assure comfort, reduce discomfort, and make life-saving procedures acceptable [7,8]. The use of early mobilization [9], spontaneous breathing trials [10,11], and spontaneous waking trials [12,13], have all become best practises for patients who are being mechanically ventilated. The most of research, meanwhile, only assessed these treatments as single-pronged ones. A packaged method, known as "Awakening and Breathing Coordination, Delirium monitoring/management, and Early exercise/mobility," or ABCDE, has been shown by current limited evidence to be more beneficial [1]. The existing randomised controlled trial evidence base is founded on protocolized practise, carried out in single locations, and in which each new ABCDE step was evaluated on a foundation of care with nearly uniform application of the prior stages.

Methods and materials

A randomized control trial was conducted at a multi-specialty hospital with a 20-bedded ICU, and study participants were 56 mechanically ventilated patients diagnosed as ICU acquired delirium. The delirium bundle care was implemented to organize daily processes performed by the staff. A standardised Richmond agitation and sedation scale (RASS) research instrument was used to assess the level of sedation. which consists of a 10 – point scale that ranges from a high of 4 (combative) to a low of -5 (deeply comatose and unresponsive). In the RASS system, patients who were spontaneously alert, calm, and not agitated scored at 0 (neutral one).

A self-structured scale was developed by the investigator to assess the level of orientation. Scale was validated with subject experts (SCVI = 0.90) and reliability were assessed with 8 sample (r=0.82). This scale has four items a) Orientation to person, place, time, and situation (Oriented) The patient knows his or her name, location, and time, as well as why they are currently treated. b) Orientation to person, place, and time (Mild Disorientation) The patient knows his or her name, location, and time of the day. c) Oriented to person and place (Moderate Disorientation) The patient knows his or her name as well as the location. d) Oriented to person (Severe Disorientation) The patient knows his or her name. Score Interpretation is Oriented- 4, Mild disorientation -3, Moderate disorientation - 2 Severe disorientation -1. We have conducted a thorough chart review for each patient admitted to the medical ICU. The study included time each patient spent receiving mechanically ventilator, being intubated, and requiring sedation. After gathering all the information from the chart review, comparisons were made with chart data to the data collection sheets completed by ICU staff.

Statistical Analysis

The data were organized using Microsoft Excel, and statistical analysis was done using the SPSS program version 16.0. We have measured the rate of staff compliance with the ABCDE bundle. The mean value of level of sedation and level orientation was calculated from day 1 to day 7 of ICU admission in the control and experimental group. 2-tailed t-test and repeated measures of ANOVA test was computed to determine the daily improvement of patient delirium status. P values less than .05 were considered statistically significant.

Results

A) Demographic variables

In experimental group out of 28 participants, most of the sample 4 (14.2%) belongs to 50 to 60 years, 4 (14.2%) are between 61 to 70 years, 11(39.4%) are between 71 to 80 years and 9 (32.2%) are between 81 to 90 years. Majority of the participants are male 19 (67.8%) and female 9 (32.2%). In control group out of 28 participants 3 (10.8%) belongs to 50 to 60 years, 5 (17.8%) are between 61 to 70 years, 11 (39.2%) are between 71 to 80 years and 9 (32.2%) are between 81 to 90 years. Majority of the participants are male 19 (67.8%) and female 9 (32.2%).

B) Level of sedation among mechanically ventilated patients admitted to ICU

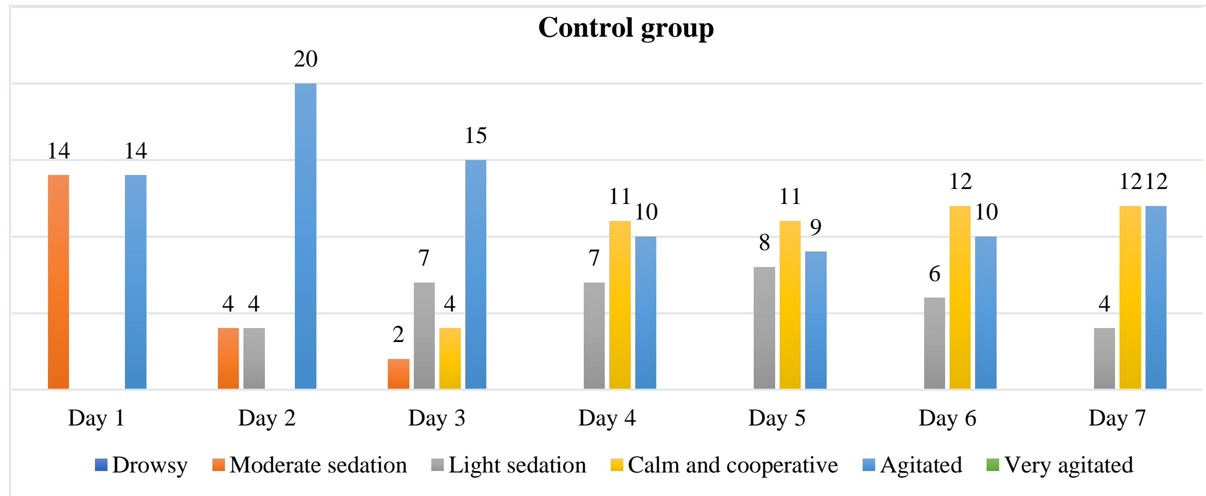

Figure 1 shows that in the control group, day 1 majority 14 (50%) of the sample were moderately sedated, and 14 (50%) samples were agitated. Day 2, most 20 (71.42%) of the sample were agitated, Day 3 majority 15 (53.57%) of the sample were agitated, On day 4, most 11 (39.28%) of the sample were calm and cooperative, Day 5 majority 11 (39.28%) of the sample were calm and cooperative, Day 6, most 12 (42.85%) of the sample were calm and cooperative, Day 7, most 12 (42.85%) of the sample were calm and cooperative, and 12 (42.85%) were agitated.

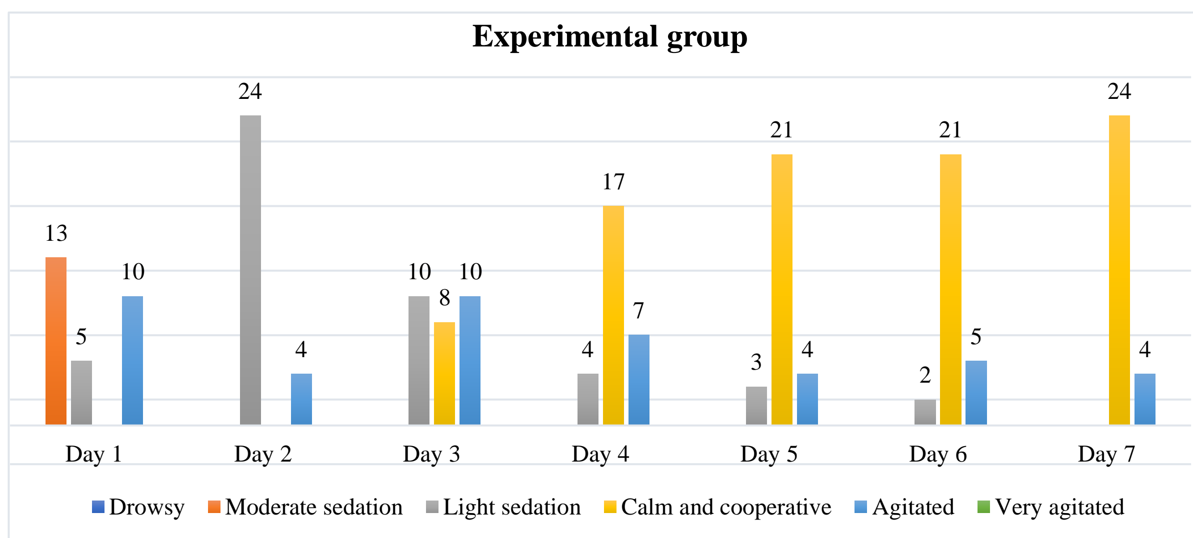

Figure 2. Assessment of level of sedation among mechanically ventilated patients admitted to ICU from day 1 to day 7 in the experimental group.

Figure 2 shows that in the experimental group, day 1 majority 13 (46.42%) of the sample were moderately sedated and 10 (35.71%) were agitated. Day 2, most 24 (85.71%) of the sample were lightly sedated. Day 3 majority of sample 10 (35.71%) agitated and 10 (35.71%) lightly sedated. Day 4, most of sample 17 (60.71%) were calm and cooperative, and 7 (25%) were agitated. Day 5 majority of sample 21 (75%) were calm and

cooperative. Day 6 majority of sample 21 (75%) were calm and cooperative. Day 7, most of sample 24 (85.71%) were calm and cooperative, and 4 (14.28%) were agitated.

Table 1: Comparison of the level of sedation scores between experimental and control groups.
(N= 56)

Performance status	Days	Mean ± SD	Repeated Measures ANOVA		
			df	F-Ratio	P-value
Control group (n=28)	Day 1	0.61 ±1.49	6	27.838	0.001* S
	Day 7	1.04 ± 0.74			
Experimental group (n=28)	Day 1	0.04 ± 1.42	1	35.231	0.001* S
	Day 7	1.00± 0.00			
Comparison of means	**Days**	**Mean ± SD**	**Independent sample 't' test**		
			df	**'t' value**	**P-value**
Control group (n=28)	Day 7	1.04 ± 0.74	54	1.900	0.001* S
Experimental group (n=28)	Day 7	1.00 ± 0.00			

*<p=0.005, S – Significant, NS- Non-Significant

The data presented in table 1 revealed that there is a significant difference was found between control group mean scores and standard deviation (F (6,162) = 27.838, p=0.001*) and experimental group means scores and standard deviation (F (1,27) = 35.231, p=0.001*) on level of sedation from day 1 to day 7 of hospital admission. The independent sample 't' test results ($t_{(54)}$=-1.900, p=0.001*) shows that there is an overall effect of delirium care bundle intervention on decreasing sedation levels among mechanically ventilated patients admitted to ICU.

C) Level of orientation among mechanically ventilated patients admitted to ICU

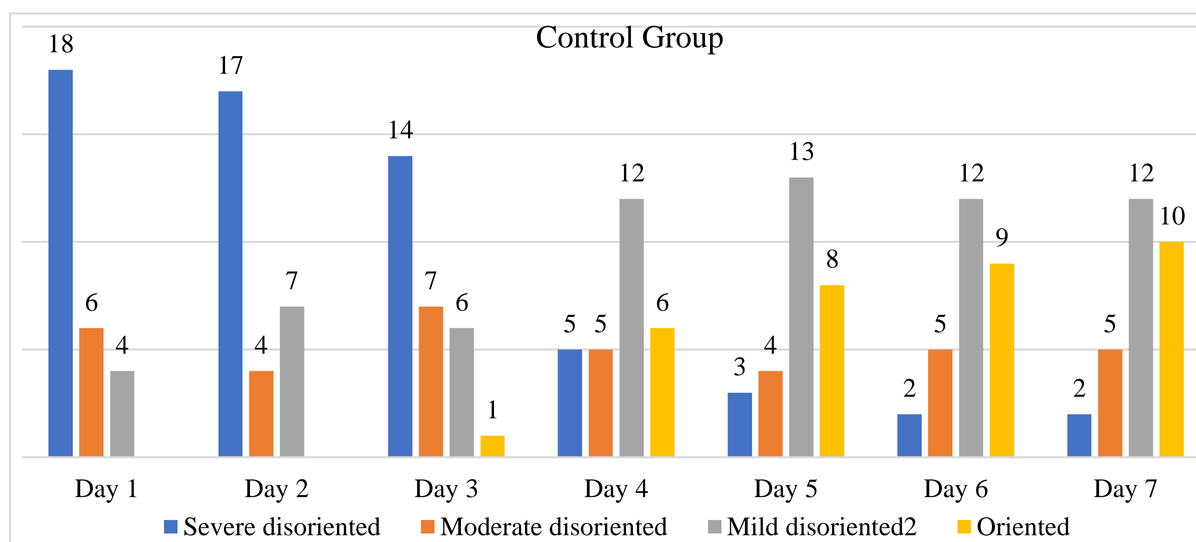

Figure 3: Level of orientation among mechanically ventilated patients admitted to ICU from day 1 to day 7 in the control group.

Figure 3 shows that in the control group, day 1, most of the sample 18 (64.28%) were severe disorientation. Day 2, most of the sample 17 (60.71%) were severely disoriented, Day 3, the majority of the sample 14 (50%) were severely disoriented and 7 (25%) were moderately disoriented. Day 4, most 12 (42.85%) of the sample were mild disoriented and 6 (21.42%) were oriented. Day 5 majority 13 (46.42%) of the sample were mild disoriented and 8 (28.57%) were oriented. Day 6, most 12 (42.85%) of the sample were mild disoriented and 9 (32.14%) were oriented. Day 7, most of the sample 12 (42.85%) were mild disoriented and 10 (35.71%) were oriented.

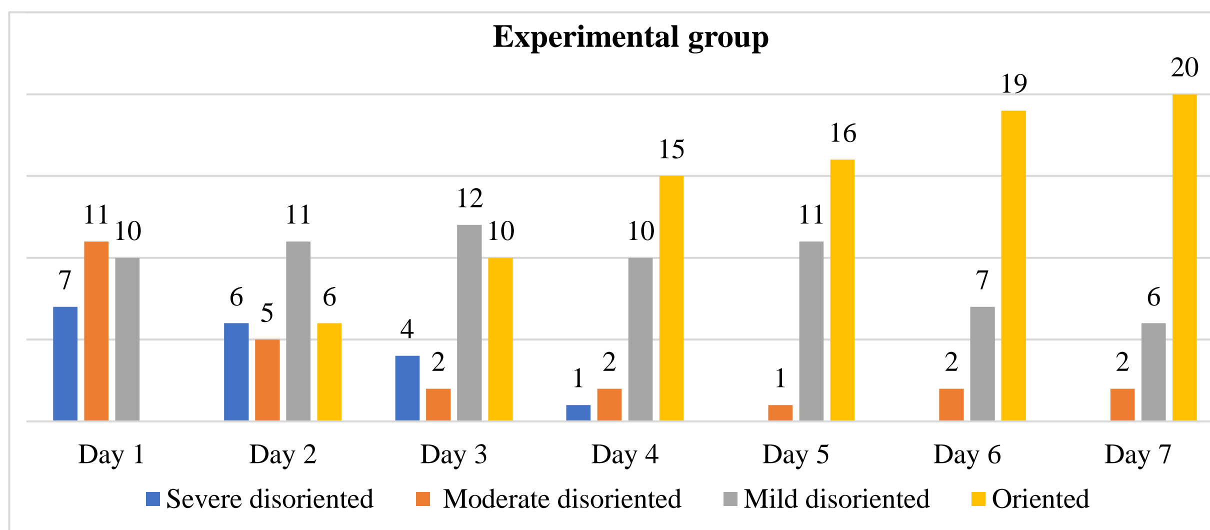

Figure 4: Level of orientation among mechanically ventilated patients admitted to ICU from day 1 to day 7 in the Experimental group.

Figure 4 shows that in the control group, day 1, most of the sample 10 (35.71%) were mild disorientated and 11 (39.28%) were moderately disoriented. Day 2, most of the sample 11 (39.28%) were mild disoriented. Day 3, most of the sample 12 (42.85%) were mild disoriented and 10 (35.71%) were oriented. Day 4, most 15 (53.57%) of the sample were oriented and 10 (35.71%) were mild disoriented. Day 5 majority 16 (57.14%) of the sample were oriented and 11 (39.28%) were mild disoriented, Day 6, most 19 (67.85%) of the sample were oriented and 7 (25%) were mild disoriented. Day 7, 20 (71. 42%) of the sample were oriented and 6 (21.42%) were mild disoriented.

Table 2: Comparison of level of orientation scores between experimental and control group

(N= 56)

Performance status	**Days**	**Mean ± SD**	**Repeated Measures ANOVA**		
			df	**F-Ratio**	**P-value**
Control group (n=28)	Day 1	1.00 ± 0.00	6	33.64	0.001* S
	Day 7	2.14 ± 0.44			
Experimental group (n=28)	Day 1	1.00 ± 0.00	6	166.5	0.001* S
	Day 7	3.71 ± 0.46			
Comparison of means	**Days**	**Mean ± SD**	**Independent sample ‘t’ test**		
			df	**‘t’ value**	**P-value**
Control group (n=28)	Day 7	2.14 ± 0.44	54	12.94	0.001* S
Experimental group (n=28)	Day 7	3.71 ± 0.46			

*<p=0.005, S – Significant, NS- Non-Significant

The data presented in Table 3 shows that there is a significant difference was found between control group mean scores and standard deviation (F (6,162) = 33.64, p=0.001*) and experimental group means scores and standard deviation, (F (6,162) = 92.78, p=0.001*) on level of orientation from day 1 to day 7 of ICU admission. The independent sample 't' test results ($t_{(54)}$=12.94,p=0.001*) shows that there is a significant effect of delirium care bundle intervention on increasing orientation level among mechanically ventilated patients admitted to ICU.

Discussion

Several research evidence supporting, highlighted that routine delirium assessment is most essential and strongly recommended in all critically ill patients throughout the ICU admission [14] . In the present study experimental group, majority 13 (46.42%) of the sample were moderately sedated and 10 (35.71%), half of the papulation sedated due to symptoms of dementia and aggressive behaviour. On day 7th most of sample 24 (85.71%) were calm and cooperative, and 4 (14.28%) were agitated. These findings emphasize the need of standardised interventions to care for delirium patients with comprehensive nursing care. The findings, which corroborated those of other studies, demonstrated that total and average dosages of morphine and midazolam were linked to decreased rates of delirium and shorter durations of mechanical ventilation, ICU care, and total hospital LOS [1].

Present study revealed that there is a significant difference was found between control group mean scores and standard deviation from day 1 to day 7 of hospital admission. The independent sample 't' test results ($t_{(54)}$=-1.900, p=0.001*) shows that there is an overall effect of delirium care bundle intervention on decreasing sedation levels among mechanically ventilated patients admitted to ICU. The present study supported by a prospective cohort study performed delirium assessments before and after sedative discontinuation. It found delirium to be extremely prevalent, with 89% of patients developing delirium, but only a small group of patients (12%) had delirium that abated after sedation interruption (rapidly reversible, sedation-related delirium). Sedation-related delirium had fewer ventilator days (P<0.001), ICU days (P=0.001), and hospital days (P<0.001), was more likely to be discharged home vs. an institution (P<0.001) and had higher survival rates (P<0.001) than those whose delirium persisted [15].

Current study highlighted that day 1, most of the sample 10 (35.71%) were mild disorientated and 11 (39.28%) were moderately disoriented. After implementation of delirium bundle care Day 7, 20 (71. 42%) of the sample were oriented and 6 (21.42%) were mild disoriented. This study revealed that there is a significant difference was found between control group mean scores and standard deviation from day 1 to day 7 of ICU admission. The independent sample 't' test results (t(54)=12.94,p=0.001*) shows that there is a significant effect of delirium care bundle intervention on increasing orientation level among mechanically ventilated patients admitted to ICU. These findings were supported by Schweickert et al. conducted a multi-centre randomised controlled trial among 104 hemodynamically stable medical ICU patients. The early delirium bundle care group had a median of 2 days of ICU delirium, compared to a median of 4 days in the control group (P=0.03). Similar levels of sedation and analgesia were experienced by both groups, although the physical therapy group was awake for an average of longer than the control group [9].

The evidence from various research does not support the routine administration of medication to prevent delirium unless if the patient is agitated [16,17]. Though delirium is a distressing problem, bundle care provides careful attention to prevention, detection and minimizing the long-term impact on patient and their families [18,19]. However, the intensive care community has emphasised the need for higher level evidence in several areas about delirium including pain, agitation, improving sleep quality [21]. Recent studies highlighted that that a significant number of intensive care patients still receive outdated treatment because of inadequate guideline implementation. Researchers require to conduct the clinical trials and implement updated structured delirium care bundle in order to improve patient optimized care and bridge gap between theory and clinical practice [22].

In this prospective before-after trial, patients treated with the ABCDE bundle spent an extra 3 days breathing without the use of a mechanical ventilator compared to patients receiving standard treatment. The ABCDE bundle was shown to be a significant independent predictor of decreased delirium rates and enhanced chance of mobility out of bed after controlling for significant variables. The ABCDE bundle's implementation was likewise determined to be secure and well-tolerated. Despite a lower-than-expected compliance with the ABCDE bundle, these effectiveness and safety outcomes were nonetheless apparent.

Research viewpoint

- ABCDEF bundle is a research-based manual for physicians and other medical professionals to use when integrating multidisciplinary patient care at ICU. It's proven through this randomized control trial that early identification and implementation of ABCDEF bundle care among mechanically ventilated patients has been demonstrated to reduce ICU delirium.
- Non-pharmacological management is the only currently known intervention associated with a decreased delirium. Moreover, it is widely recommended guidelines for implementing non-pharmacological treatment for patients in ICU before and after diagnosis of hospital acquired delirium.
- The type of sedation used in mechanically ventilated patients in the ICU can affect rates of delirium. Currently, it is recommended by the delirium bundle care guidelines to perform analgesia-first sedation followed by non-benzodiazepine medications if needed for sedation in mechanically ventilated patients in the ICU [12].
- This bundle care can progress from passive range of motion to active range of motion, exercise in bed, sitting, standing, walking, and activity of daily living training depending on a patient's sedation level and physical abilities.

Implications for clinical practice

Current study findings and several clinical trials emphasize that nursing staff and other health care members can play a significant role in early identification ICU acquired delirium and prevent. Nursing staff need to be trained on delirium care bundle (ABCDEF) and a firm orientation must be given on the importance of guidelines and implementation procedures. The results of the study highlighting that the nurses and other healthcare professionals can incorporate the early prevention strategies such as implementing non-pharmacological management, minimal sedation, reduction in unit noise, modification of the ICU environment to promote early ambulation, minimize the risk factors for pain and agitation among critically ill patients.

Limitations of the study

The study enrolled specially ventilated patients with ICU acquired delirium. However, our findings should be interpreted considering limitations. The non-controlled design of this study raises the possibility of confounding variables that may have influenced study outcomes. Because our study did not include patients with brain injuries, our findings may not be generalizable to neurological or trauma ICUs that care for patients with these injuries. Furthermore, our study cannot be generalized to long-term ventilator care units. The purpose of this study was to implement a delirium bundle care intervention with ICU acquired studies, so the incidence of delirium could not be assessed, and study sample size was limited due to randomized controlled trial. Our study included only adults, and the results should not be extrapolated to children.

Conclusion

The present study highlighted that treatment of sedation and delirium may have a significant impact on the outcomes of patients receiving care in intensive care units, according to mounting data. According to the data currently available, the best results are obtained when a protocol is followed, in which the level of sedation, the presence of pain, and delirium are routinely monitored, pain is promptly and effectively treated, the number of sedatives administered is kept to a minimum necessary for the patient's comfort and safety, and early mobilisation is attempted whenever possible. Treatment of delirium should focus on identifying and managing the causative medical conditions, providing supportive care, preventing complications, and reinforcing preventive interventions. Preventive interventions such as early identification of delirium symptoms, promoting quality of sleep, non-pharmacological pain management and early and recurrent mobilization have all been shown to reduce the incidence of delirium, regardless of the care environment. Study findings have recommending that health care team members should assess, screen, and diagnose risk factors of delirium every shift and highlighting the delirium care bundle (ABCDEF) have significant effect on prevention of hospital acquired delirium among ICU patients.

Ethical clearance

Ethical clearance was obtained from the institutional ethical committee Pushpagiri Institute of Medical Sciences and Research Centre (PIMSRC/E1/388A/47/2015). Administrative permission was received from the hospital

authority. Confidentiality was maintained by retaining all information properly and excluding their names from the questionnaires.

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Conflict of interest

The author declares no conflicts of interest in this research work.

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