Original Article

Effect Of Delirium Care Bundle On ICU Acquired Delirium Patients With A Mechanical Ventilator. A Randomized Controlled Trial (RCT)

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Abstract

Introduction

Delirium is frequently unrecognized or missed despite of it's high incidence and prevalence that leads to poor clinical outcomes and an enormous rise in cost by ameliorating morbidity, mortality, and hospital and ICU length of stay. Delirium bundle care (ABCDEF bundle) finds to be an evidence-based effective strategy for health care professionals to manage and enhance patient recovery and health outcomes related to delirium in ICU.

Objective

The primary aim of the study is to determine the effectiveness of a delirium care bundle among 56 mechanically ventilated ICU acquired delirium patients with routine care in intensive care units at selected hospitals in Kerala, India.

Materials and methods

A randomized controlled trial was conducted to implement a delirium care bundle intervention. Total fifty-six mechanically ventilated ICU acquired delirium patients were recruited using inclusion and exclusion criteria. The ABCDEF bundle has been implemented every day for the first seven days of ICU admission, and patient delirium status was assessed using the Confusion Assessment Method for The Intensive Care Unit (CAM-ICU). Statistical analysis was done by using SPSS 20.0 version.

Results

Delirium care bundle intervention has been marked to have a significant effect on patient delirium status. It has been manifested that number of days with delirium was significantly dwindled by 2.3 days (4.1 ± 2.1, p=0.001), duration of patients stay with mechanical ventilation was declined by nearly 2.12 days, patients aided on ventilation were a minimum of 3 days and a maximum of 5 days (4.01 ± 0.83, p=0.001), length of ICU stay was decreased nearly 2.41 days (7.31 ± 2.71, p=0.001). The length of hospital stay was curtailed by nearly 2.54 days (10.78 ± 3.87, p=0.001) compared with the control group.

Conclusion

Implementing a standard delirium care bundle among mechanically ventilated patients with ICU acquired delirium has notably condensed the adverse effects of delirium, and it's risk factors, alongside it also turned down the patient morbidity and mortality rate

Keywords ICU acquired delirium, delirium bundle care, Intensive care unit, mechanically ventilated patients.

Background

Delirium is defined by an interruption in consciousness as well as a disturbance in cognition. Delirium commonly develops as a group of symptoms with a sudden onset and a fluctuating duration (1). The prevalence of delirium has been estimated to be as high as 60%–80% in mechanically ventilated ICU patients and 20%–50% in non-ventilated ICU patients (2). As evaluated in a medical ICU, the two most common types of delirium found among patients were mixed one with 54.9 percent and hypoactive with 43.5 percent. Hypoactive delirium is distinguished by slower development and maturation, lethargy, and reduced mobility. It is more frequent in the elderly, with age above 65 years being an independent risk factor (3, 4)

Globally, the incidence of delirium emerging during a hospital stay ranges from 6% to as high as 56% (5). This incidence is even higher when more-specialized populations are considered, including those in postoperative, intensive care, sub acute palliative-care settings. Postoperative delirium occurs in 15–53% of surgical patients over the age of 65 years, and among elderly patients admitted to an intensive care unit (ICU), the delirium incidence can more up to 70–87% (6). Several international studies have demonstrated incidence from 25% to 87% among critically ill patients. Delirium is potentially modifiable depending on the individual patients' circumstances (7).

Delirium is prevalent among critically ill patients admitted to the intensive care unit (ICU) and has a negative long-term prognosis. Long-term effects, such as depression and anxiety, are also the risk for family members. Pain, agitation, confusion, weakness, and sleep deprivation are all common symptoms among critically ill patients during their hospital stay (8). Because of the complexities of care among ICUs these symptoms are frequently addressed by keeping patients highly sedated, immobile, and socially isolated. The ABCDEF bundle is a multidisciplinary, evidence-based approach to the comprehensive treatment of critically ill patients, with the goal of optimizing patient recovery, minimising iatrogenesis, and engaging and empowering the patient and family during their hospitalization. This bundle's performance would decrease mortality, ventilator days, critical care readmissions, delirium, coma, restraint usage, and facility discharge in a dose-dependent manner (9).

The research evidence has suggested that a well-planned and comprehensive delirium management can minimize the adverse effects on ICU acquired delirium. These organized interventions do promote awareness among health care professionals to provide therapeutic attention for early detection and management of ICU acquired delirium (10, 11). Countless research surveys from national and international areas have emphasized the importance of early recognition of delirium in ICU and treatments. Most of the surveys show a disconnection between delirium's perceived importance and the accuracy of diagnosis, implementation of medical management, and comprehensive treatment techniques (12).

Few studies have particularly evaluated integrated, interprofessional methods to symptomatic treatment during critical illness, to our knowledge. The team-based ABCDEF bundle strategy is particularly unusual in that and its ultimate objective is to generate patients who are more alert, intellectually engaged, and physically active, which helps patients to express unsatisfied physical, emotional, and spiritual demands and promote patients autonomy. Present study objectives were to determine the effectiveness of a delirium care bundle among mechanically ventilated ICU acquired delirium patients with routine care in intensive care units. We used the Confusion Assessment Method for The Intensive Care Unit (CAM-ICU) scale to assess the patient delirium status daily basis (1 day of ICU acquired delirium to 7 days of ICU admission).

Methods and materials

A randomized control trial was conducted at a multi-specialty hospital with 20-bedded ICU, and study participants were 56 mechanically ventilated patients diagnosed to be with ICU acquired delirium. The delirium bundle care was implemented to organize daily processes performed by the staff. Confusion Assessment Method for The Intensive Care Unit (CAM-ICU) standardized research instrument was used to assess the patient delirium status on daily basis. The scoring was given as per the following categories. 0 to 2 - no delirium, 3 to 5 - mild to moderate delirium, and 6 to 7 - severe delirium. The ABCDE bundle was performed daily (usually during morning rounds). We have conducted a thorough chart review for each patient admitted to the medical ICU. The study included areas of time that each patient spent receiving MV, 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 was obtained using a standardized research instrument, namely CAM-ICU, data were organized using Microsoft Excel, and statistical analysis done using the SPSS program version 20.0. We have measured the rate of staff compliance with the ABCDE bundle, a number of ventilator days, length of ICU stay, length of hospital stay, and mean days of delirium after implementation of the intervention. A 2-tailed t-test and repeated measures of ANOVA test were computed to determine the daily improvement of patient delirium status. P values less than .05 were considered statistically significant.

Results

Table 1. Frequency and percentage distribution of baseline variables (N= 56)

Sample characteristics	**Experimental group (n=28)**		**Control group (n=28)**	
	Frequency(f)	**Percentage (%)**	**Frequency(f)**	**Percentage (%)**
Age in Years				
50 to 60 years	4	14.2	3	10.8
61 to 70 years	4	14.2	5	17.8
71 to 80 years	11	39.4	11	39.2
81 to 90 years	9	32.2	9	32.2
Gender				
Male	19	67.8	19	67.8
Female	9	32.2	9	32.2

Table 1 revealed that most of the sample 11 (39.4%) belongs to 71 to 80 years of age in both experimental and control groups, majority of sample 19 (67.8) males and 9 (32.2%) of the sample were females in both experimental and control groups (Represented in Table 1).

Table 2. Frequency and percentage distribution of clinical variables (N= 56)

Clinical variables	**Experimental group (n=28)**		**Control group (n=28)**	
	Frequency (f)	**Percentage (%)**	**Frequency (f)**	**Percentage (%)**
APACHE II Score/Predicted mortality				
15-10 (25%)	0	0	1	3.57
20-24 (40%)	2	7.14	5	17.85
25-29 (55%)	11	39.28	8	28.57
30-34 (75%)	12	42.85	10	35.71
>34 (85%)	3	10.71	4	14.28
q SOFA Score				
<2	13	46.42	14	50
>2	15	53.57	14	50
Central venous catheter				
Present	28	100	28	100
Indwelling urinary catheter				

Present	28	100	28	100

Table 2 shows that the majority 12 (42.85%) of the sample had an APACHE -II score of 30-34 with a predicted mortality of 75%, and in the control group10 (35.71%) had an APACHE -II score of 30-34 that is 75% of predicted mortality. Most of sample 15 (53.57 %) had a qSOFA score of >2 scores in the experimental group, whereas, in the control group, 14 (50%) sample were > 2 scores and 14 (50%) sample were had < 2 scores. Both the experimental and control group 28 (100%) patients had a central venous catheter and indwelling urinary catheter.

Figure 1 and 2. Description of the level of delirium among mechanically ventilated patients admitted to critical care units in experimental and control groups.

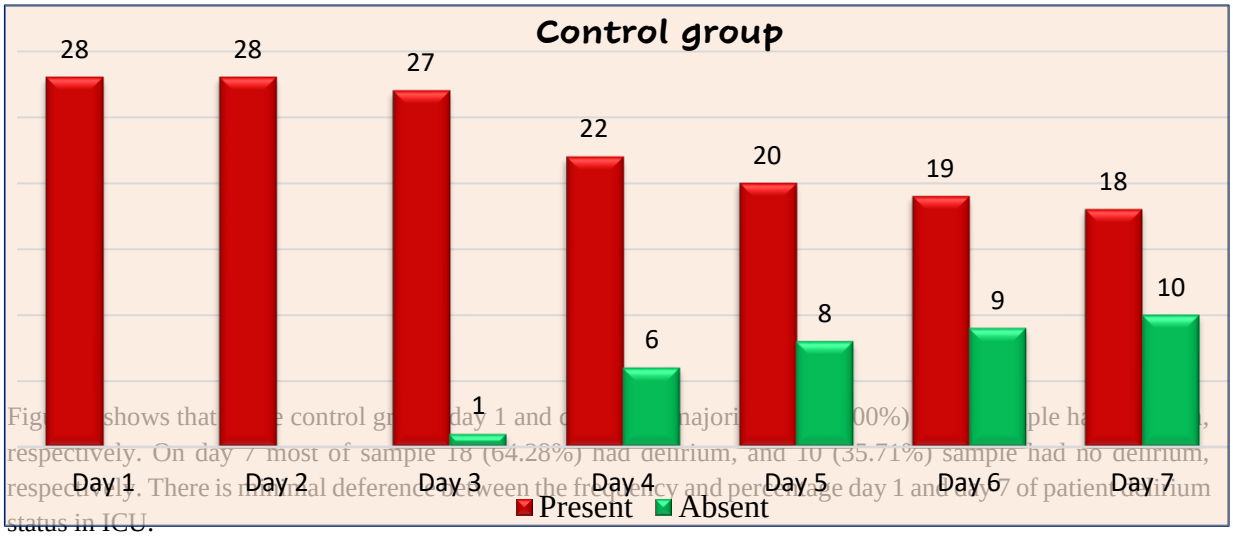

Figure 1 shows that in the control group, day 1 and day 2 the majority (100%) sample had delirium, respectively. On day 7 most of sample 18 (64.28%) had delirium, and 10 (35.71%) sample had no delirium, respectively. There is minimal deference between the frequency and percentage day 1 and day 7 of patient delirium status in ICU.

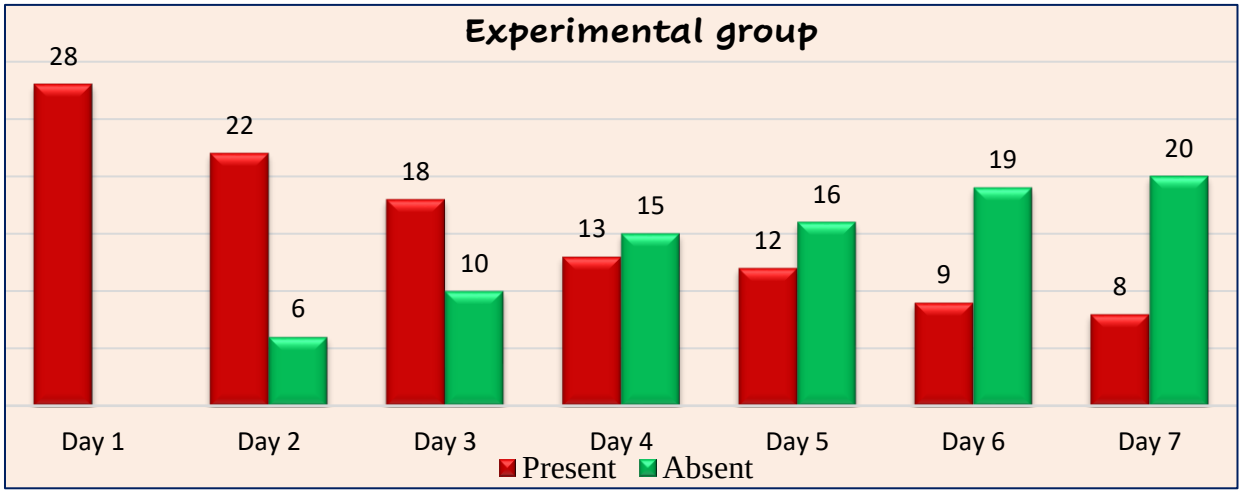

Figure 2 shows that in the experimental group, day 1, the majority of 28 (100%) of the sample had delirium. On day 7 most of the sample 20 (71.42%) had no delirium, and 8 (28.57%) sample had delirium. There is significant deference between the frequency and percentage of day 1 and day 7 of patient delirium status in ICU.

Table 3. Comparison of delirium scores between experimental and control groups.

(N=56)

Performance status	**Days**	**Mean ± SD**	**Repeated Measures ANOVA**		
			df	**F**	**P-value**

Control group (n=28)	Day 1	1.00 ± 0.00	6	9.600	0.001* S
	Day 7	1.21 ± 0.41			
Experimental group (n=28)	Day 1	1.00 ± 0.00	6	86.055	0.001* S
	Day 7	2.00 ± 0.00			
Comparison of means	**Days**	**Mean ± SD**	**Independent sample 't' test**		
			df	**'t' value**	**P-value**
Control group (n=28)	Day 7	1.21 ± 0.41	54	9.950	0.001* S
Experimental group (n=28)	Day 7	2.00 ± 0.00			

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

The data presented in table 3 revealed that there is a significant difference between control group mean scores and standard deviation (F (6,162) = 9.600, p=0.001*) and experimental group mean scores and standard deviation (F (6,162) = 86.055, p=0.001*) on level delirium from day 1 to day 7 of hospital admission. The independent sample 't' test results ($t_{(54)}$=9.950, p=0.001*) shows that there is an overall effect of delirium care bundle intervention on minimizing ICU acquired delirium incidence and improving patient condition among mechanically ventilated patients admitted in ICU. The data revealed that there is a significant effect of delirium care bundle intervention on decreasing ICU acquired delirium symptoms among the interventional group than the control group.

Table 4. Outcome parameters of ICU acquired delirium patients with mechanical ventilation support in experimental and control groups. (N=56)

Parameters	**Experimental group (n=28) Mean ± SD**	**Control group (n=28) Mean ± SD**	**'t' value**	**P-value**
Number of days with delirium (Mean± SD)	4.1 ± 2.1	6.4 ± 3.1	9.950	0.001
Delirium – Free Days in ICU (Mean± SD)	3.7 ± 1.8	2.1 ±1.4	5.129	0.001
Duration of mechanical ventilation (Mean± SD)	4.01 ± 0.83	6.13 ± 2.38	4.193	0.001
Duration of mechanical ventilation– median (Min-Max)	3 days – 5 days	6 days – 8 days	-	-
ICU LOS (Mean ± SD)	7.31 ± 2.71	9.72 ± 3.21	6.920	0.001
Length of hospital stay	10.78 ± 3.87	13.32 ± 4.72	8.612	0.001

Data presented in table 4 represents that post-implementation of intervention mean scores of numbers of days with delirium were significantly decreased nearly 2.3 days comparing to the control group (4.1 ± 2.1, p=0.001). Duration of patients with mechanical ventilation was decreased nearly by 2.12 days, in experimental group, patient with ventilation support were at a minimum of 3 days and a maximum of 5 days (4.01 ± 0.83, p=0.001). Length of stay in ICU was decreased nearly by 2.41 days (7.31 ± 2.71, p=0.001). Length of hospital stay was almost reduced 2.54 days (10.78 ± 3.87, p=0.001). However, this finding was significant (Represented in Table 3). Post-intervention phase of the study suggests that out of 28 participants, none of the participants were reintubated and readmitted to the ICU after shifting to other wards in the hospital.

Discussion

The purpose of this study was to compare the efficiency of a delirium care bundle with routine treatment in critical care units among mechanically ventilated ICU-acquired delirium patients. The association between ABCDEF bundle performance and patient-centered outcomes from a varied group of ICUs that took part in the ICU Liberation Collaborative we wanted to see if the bundle benefits reported in other, smaller randomized control trials could be replicated in this more extensive and more diverse research, which included multiple ICU types (medical, surgical, neurological, and trauma) and academic, community, and federal hospitals. These findings are based on information gathered from more than 56 patients. The ICU patients demonstrated a consistent indication of improved outcomes. Patients who got more ABCDEF bundle pieces each day had a considerable and significantly enhanced chance of improved health outcomes such as reduced ICU acquired delirium, duration of mechanical ventilation support, length of ICU stays, and length of hospital stay.

Study results revealed that delirium care bundle intervention has an overall effect on minimizing ICU acquired delirium and improving patient condition among ICU patients with mechanical ventilation. The data relating to outcome parameters were collected from day 1 to day 7th of ICU admission. The results significantly show that there exists a significant difference between the experimental group and control group mean scores and standard deviation of the following outcome parameters.

A number of days with delirium in the experimental group on an average was 4 days (p=0.002), and the control group was 6.4 days (P=0.13). On average, delirium–Free Days in ICU in the experimental group was 4 days (P=0.001) and control group 2 days (p=0.75). The experimental group's average duration of mechanical ventilation was 4 days (p=0.005), and the control group was 6 days (p=0.90). The experimental group's average length of ICU stay was 7 days (p=0.004), and the control group was 10 days (p=0.53). Similar randomized control trial findings support present study outcomes, and it is reported that during the study total of 420 patients were assessed; out of that total of 53.8% were identified to be with delirium. Patients with delirium were more likely to be male (p=0.005), delirium patients had a higher duration of ventilation (p=0.001), and ICU stays (p=0.001) (13).

The current study reported that the mean duration of mechanical ventilation in the experimental group was a minimum of 3 days, a maximum of 5 days. In the control group, the minimum days were 4, and the maximum days were 8. However, In contrast, an RCT conducted (14) on the effect of delirium prevention bundle has revealed that the mean average days of mechanical ventilation were 12 to 14 days. Still, it is absorbing to note that the number of days with delirium was found to be 2-4 days which is congruent with the present study which had delirium–Free days in ICU in the experimental group with an average of 4 days (P=0.001) in the experimental group.

An observational survey conducted in Punjab, India supported the present study findings. Most of the 64.5% of patients were above 30 years old and male (51.6%). Most of the sample APACHE score was >35 (70% of predicted mortality). Similarly, cohort study results reported that the mean age group of patients presenting with delirium was more significant (p=0.001), with higher APACHE II scores (p=0.001). The age (p=0.019) and physical restraint (p=0.001) variables are related to delirium. At every increased year of life, the chance for the patient to have delirium increases by 4%, whereas the presence of physical restraint increases by 44.3 times the patient's chance of having delirium (p=001), and length of ICU stay was longer (p=0.001) (15).

Prospective quality improvement trial, the implementation of a multiple components bundle has shown a significant improvement in the reduction in the days of delirium in ICU patients (16). Moreover, it is evident from the research studies that mechanical ventilation is one of the highest risk factors for the development of delirium, and the duration of mechanical ventilation is independently associated with the increased incidence of mechanical ventilation among critically ill patients (17, 18)

Thus, this present study accords with the majority of the studies that well-organized and structured coordination of ABCDE bundle components had produced effective outcomes among mechanically ventilated patients in ICUs such as Spontaneous breathing, awakening, reduction in mechanical ventilation duration, usage of sedation, and length of stay in ICU.

Relevance to clinical practice

The intensive care unit provides extensive medical and nursing services, raising the expectations of parents and family members (19). These research findings have suggested that a well-planned and comprehensive delirium management can minimize the adverse effects upon ICU acquired delirium. These organized

interventions will promote awareness among health care professionals to provide therapeutic attention for early detection and management of ICU acquired delirium (10,11).

Conclusion

This study highlighted that implementing a standard delirium care bundle among mechanically ventilated patients with ICU acquired delirium has significantly reduced the adverse effects of delirium risk factors and minimized patient morbidity and mortality. The statistical data revealed a significant effect of the delirium care bundle on ICU acquired delirium among mechanically ventilated patients admitted to intensive care units in the experimental group. The control group did not signify positive outcomes among patients. However, the research studies have emphasized an effect of ABCDEF bundle care among mechanically ventilated patients. This study also reported and supported the existing research evidence to implement the delirium bundle care by the health care professionals in any health care institution to improve the patient, positive health outcomes, and minimize patient morbidity and mortality.

Limitations

The study enrolled specially ventilated patients with ICU acquired delirium. However, our findings should be interpreted in light of 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 study design. Our study included only adults, and the results should not be extrapolated to children.

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.

Conflict of interest

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

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References

1. Cavallazzi R, Saad M, Marik PE. Delirium in the ICU: an overview. Ann Intensive Care. 2012 Dec 27;2(1):49.

2. Shehabi Y, Riker RR, Bokesch PM, Wisemandle W, Shintani A, Ely EW, et al. Delirium duration and mortality in lightly sedated, mechanically ventilated intensive care patients*. Crit Care Med. 2010 Dec;38(12):2311–8.

3. Regier DA, Kuhl EA, Kupfer DJ. The DSM-5: Classification and criteria changes. World Psychiatry. 2013 Jun;12(2):92.

4. Hayhurst CJ, Pandharipande PP, Hughes CG. Intensive Care Unit Delirium: A Review of Diagnosis, Prevention, and Treatment. Anesthesiology. 2016 Dec 1;125(6):1229–41.

5. Fong TG, Tulebaev SR, Inouye SK. Delirium in elderly adults: diagnosis, prevention and treatment. Nat Rev Neurol. 2009 Apr;5(4):210–20.

6. Reddy SV, Irkal JN, Srinivasamurthy A. Postoperative delirium in elderly citizens and current practice. J Anaesthesiol Clin Pharmacol. 2017;33(3):291–9.

7. Johnson K, Fleury J, McClain D. Music intervention to prevent delirium among older patients admitted to a trauma intensive care unit and a trauma orthopaedic unit. Intensive Crit Care Nurs. 2018 Aug 1;47:7–14.

8. Marra A, Pandharipande PP, Patel MB. ICU Delirium and ICU-related PTSD. Surg Clin North Am. 2017 Dec;97(6):1215–35.

9. Pun BT, Balas MC, Barnes-Daly MA, Thompson JL, Aldrich JM, Barr J, et al. Caring for Critically Ill Patients with the ABCDEF Bundle: Results of the ICU Liberation Collaborative in Over 15,000 Adults. Crit Care Med. 2019 Jan;47(1):3–14.

10. Ely EW, Inouye SK, Bernard GR, Gordon S, Francis J, May L, et al. Delirium in mechanically ventilated patients: validity and reliability of the confusion assessment method for the intensive care unit (CAM-ICU). JAMA. 2001 Dec 5;286(21):2703–10.

11. Page VJ, Navarange S, Gama S, McAuley DF. Routine delirium monitoring in a UK critical care unit. Crit Care. 2009 Feb 9;13(1):R16.

12. Selim AA, Ely EW. Delirium the under-recognised syndrome: survey of healthcare professionals' awareness and practice in the intensive care units. J Clin Nurs. 2017 Mar;26(5–6):813–24.

13. Mehta S, Cook D, Devlin JW, Skrobik Y, Meade M, Fergusson D, et al. Prevalence, Risk Factors, and Outcomes of Delirium in Mechanically Ventilated Adults*. Crit Care Med. 2015 Mar;43(3):557–66.

14. Malik AK, Baidya DK, Anand RK, Subramaniam R. A New ICU Delirium Prevention Bundle to Reduce the Incidence of Delirium: A Randomized Parallel Group Trial. Indian J Crit Care Med Peer-Rev Off Publ Indian Soc Crit Care Med. 2021 Jul;25(7):754–60.

15. Mori S, Takeda JRT, Carrara FSA, Cohrs CR, Zanei SSV, Whitaker IY. Incidence and factors related to delirium in an intensive care unit. Rev Esc Enferm USP. 2016 Aug;50:0587–93.

16. Barnes-Daly MA, Phillips G, Ely EW. Improving Hospital Survival and Reducing Brain Dysfunction at Seven California Community Hospitals: Implementing PAD Guidelines Via the ABCDEF Bundle in 6,064 Patients*. Crit Care Med. 2017 Feb;45(2):171–8.

17. Arumugam S, El-Menyar A, Al-Hassani A, Strandvik G, Asim M, Mekkodithal A, et al. Delirium in the Intensive Care Unit. J Emerg Trauma Shock. 2017;10(1):37–46.

18. Lobo-Valbuena B, Gordo F, Abella A, Garcia-Manzanedo S, Garcia-Arias M-M, Torrejón I, et al. Risk factors associated with the development of delirium in general ICU patients. A prospective observational study. PLoS ONE. 2021 Sep 2;16(9):e0255522.

19. Aagaard H, Uhrenfeldt L, Spliid M, Fegran L. Parents' experiences of transition when their infants are discharged from the Neonatal Intensive Care Unit: a systematic review protocol. JBI Database Syst Rev Implement Rep. 2015 Oct;13(10):123–32.