Effect of Implementing Delirium Prevention Bundle on Clinical Outcomes of Critically Ill Patients

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Abstract

Background: *Although delirium during critical illness is a common health problem with a high prevalence rate in mechanically ventilated patients, it is always under recognized and under treated by critical care nurses. Studies have proven that delirium is associated with short and long-term disabilities, complicating the course of critical illness and impairing post discharge quality of life. Since delirium prevention is better than cure, it is imperative to adopt the ABCDEF bundle and incorporate it as part of routine care within the Intensive Care Unit (ICU) to prevent and treat delirium in critically ill patients.* ***Objective:*** *To investigate the effect of implementing delirium prevention bundle on clinical outcomes of critically ill patients.* ***Settings:*** *This study was conducted in five general ICUs at Alexandria Main University Hospital, namely: unit I, unit II, unit III, Unit IV and El-Mowasaat general ICU.* ***Subjects:*** *A convenience sample of at least 100 critically ill patients were randomly assigned in to 50 control group and 50 intervention grou).* ***Tools:*** *Three tools were used to conduct this study and include Confusion Assessment Method for the ICU-7 (CAM-ICU-7) Delirium Severity Scale, Mini-Mental state Examination (MMSE) and Assessment of Clinical Outcomes.* ***Results:*** *The percentage of delirium occurrence in the control group was twice as high as in the intervention group with the most severe and durable form noted in the control group. Moreover, a statistically significant difference was found between the intervention and control groups regarding the level of cognitive impairment and clinical outcomes. In other words, impaired cognition, prolonged mechanical ventilation, longer length of stay, constant use of physical restraints and anti-delirious drugs and occurrence of adverse events were noticed more in the control group unlike the intervention group.* ***Conclusion:*** *ABCDEF bundle use in critically ill patients was found significantly effective in mitigating the effect of delirium and improving patients' clinical outcomes.* ***Recommendations:*** *More attention should be directed toward delirium management by critical care nurses to prevent occurrence and avoid related complications. Adoption of systems of care that incorporate the ABCDEF bundle as part of routine care should be emphasized. Teaching and training about delirium significance and presentation as well as the importance of ABCDEF bundle should be taught to nursing students as well.*

Keywords: Critically ill Patients, Delirium Prevention Bundle, Patients' Outcomes

Introduction

Increasingly, delirium has been recognized as a serious complication of critical illness, occurring in 30-60% of critically ill patients with higher rates of 60–80% observed in mechanically ventilated patients. The American Psychiatric Association's fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) revised the diagnostic criteria for delirium and defined it as an acute disturbance in attention and awareness coupled with a change in baseline cognition that develops over a short period of time and fluctuates in both presence and severity of symptoms. (Deng, Cao, & Zhang, 2020; Zhang, Han, Xiao, Li, & Wu, 2021)

Due to that fluctuation and changes in mental status, it is difficult to detect delirium. It has been noted that delirium is overlooked during bedside assessment by nurses. Clinically, delirium has three main domains in symptom presentation: cognitive function, higher order thinking and circadian rhythm. (Yunker & Michael, 2021)

All these symptoms are often reported to be caused by a complex interplay of risk factors and noxious insults. Given that high prevalence of delirium in critically ill patients and its adverse outcomes which do not appear to be modified with treatment, critical care nurses should address delirium and apply the necessary measures to prevent it. (Wilson et al., 2020)

Traditionally, delirium management is presented into non-pharmacological and pharmacological approaches. The non-pharmacological approach is a multi-domain approach that focuses on the identification and correction of underlying causes. Such an approach is provided by the ABCDEF bundle which should be applied as a bundle and established as part of routine nursing care, not a standby physician order. (Wilson, et al., 2020)

Critical care nurses play a unique role in successful bundle implementation as they have direct close contact with the patients. They lead all the bundle-related efforts and constitute a communication link between all specialties. Decisions to advance to subsequent steps of the ABCDEF bundle are dependent upon their assessment. Furthermore, critical care nurses understand the local context and can provide critical insights into the resources and training required for bundle implementation. (Stollings et al., 2019)

Aim of the study

This study aims to investigate the effect of implementing delirium prevention bundle on clinical outcomes of critically ill patients.

Research hypothesis

Patients who are subjected to delirium prevention bundle exhibit positive clinical outcomes than those who are not subjected.

Materials and Method

Materials

Design: A Quasi experimental research design was used to conduct this study.

Settings: This study was conducted in five general ICUs at Alexandria Main University Hospital. These ICUs receive patients with a variety of disorders in the acute stage of illness admitted directly from the emergency department or transferred from any hospital department.

Subjects: A convenience sample of at least 100 critically ill patients admitted to the previously mentioned settings. They were randomly assigned in two equal groups (30 patients each). **Group A** (control group) received the standard routine care that is regularly provided within the ICUs. **Group B** (intervention group) received the ABCDEF bundle. Epi-Info program 7 was used to estimate the critically ill patients sample size applying this information (population size = 135, Expected frequency = 50 %, Acceptable error = 5 %, Confidence coefficient = 95 %, Minimum sample size = 100).

Tools: Three tools were used to conduct this study.

Tool 1: CAM-ICU-7 Delirium Severity Scale to diagnose and assess the severity of delirium in ICU patients. The tool consists of four features; acute onset or fluctuating course, inattention, altered level of consciousness, disorganized thinking and specific points were assigned for each feature. Patient must have features 1 and 2 and either 3 or 4 to be considered delirious. Then severity was scored as follows; from 0–2 for no delirium; 3–5 for mild to moderate delirium; and 6–7 for severe delirium.

Tool 2: Mini-Mental State Examination to assess the patient's level of cognitive impairment. This tool consists of five items (orientation, registration, attention and calculation, recall, language, coping) with a 30 points questionnaire. A score of 24 or more indicates a normal cognition. Below this, scores indicate severe (≤9 points), moderate (10–18 points) or mild (19–23 points) cognitive impairment.

Tool 3: Assessment of Clinical Outcomes Tool to record patients' demographic and clinical data plus clinical outcomes.

It consists of two parts:

Part I: Patient's demographic and clinical data: This part includes patient's demographic (hospital number, age, gender) and clinical data (date of admission, diagnosis, medications, past medical/ surgical history and Acute Physiology and Chronic Health Evaluation-II (APACHE II) score).

Part II: patient's clinical outcomes: This part includes the variances from the following aspects: Incidence/ severity/ duration of delirium, days on mechanical ventilation, use of physical restraints and anti-delirious drugs, length of stay, adverse events (falls, reintubation, removal of catheters, pressure ulcers, pneumonia, behavioral disturbance, cardiac dysrhythmias, death).

Method

Approval from the ethical committee of Alexandria Faculty of Nursing was obtained. An official permission to conduct the study was obtained from the administrative authorities after explanation of the aim of the study. Content validity of the tools was done by five experts in the field of study. A pilot study was carried out on 10 patients (10%) from the sample to assess the clarity and applicability of the tools and the necessary modifications was done. A training session was provided to the research assistants about how to implement the bundle and document the findings.

Newly admitted patients to the ICU were screened by the researcher considering the inclusion and exclusion criteria. Then the eligible patients were assigned randomly to the control and intervention group.

Participants in the intervention group received the delirium prevention bundle during his/her stay in the ICU, whereas the control group received the routine care only.

The study was conducted in three phases:

Phase I: Assessment phase

Both control and intervention groups were assessed using part I of tool three to collect demographic and clinical data.

Phase II: Implementation phase

Control group: in which the patients received the standard medical, nursing, and allied care that is regularly provided within the ICUs. Standard care includes decisions made on daily basis without protocols, spontaneous breathing and awakening trials as determined by the consultant physician on duty, temporary management of pain and delirium and daily active and passive exercise as determined by the physician of the day with patients generally remaining in bed if they are ventilated.

Intervention group: here, ABCDEF bundle was implemented with the eligible patients as follows;

- Assess, prevent and manage pain

  Pain was assessed using 1–10 Numerical Rating Scale (NRS) in patients who were able to report their pain and Critical-Care Pain Observation Tool (CPOT) in patients who weren't able to report their pain. For CPOT, each component was scored from zero to two. Zero score representing the lowest expression observed and score two representing the extreme expression observed with a possible total score ranging from zero to eight. Significant pain was

assumed and treated if the NRS was greater than four or the CPOT was greater than three.

When significant pain was identified, first-line pain management was intravenous opioids. Adjunctive methods including non-steroidal anti-inflammatory drugs also were considered in addition to non-pharmacologic measures.

- Both spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs)

At first, each patient was tested for the ability to tolerate removal of sedatives and narcotics. Those who passed the safety screen, sedatives and opioids were discontinued for them for a period of time each day and they were allowed to wake up spontaneously. Who failed the test, no further steps were taken with them, and sedatives were restarted at half the prior dosage and titrated up as necessary and then rescreening took place the following day.

Secondly, after passing the SAT, a SBT safety screen was performed. Those who passed, their ventilator settings were reduced to minimum support, and they were allowed to breathe spontaneously and assessed for readiness to extubate. Those who failed resumed their previous ventilator settings.

- Choice of analgesia and sedation

In coordination with the physician, a light level of sedation was maintained for all ventilated patients guided by RASS to assess the adequacy of analgesia and to measure quality and depth of sedation. It was done by keeping the RASS between light sedation (−2) to restless (+1) unless deemed not appropriate.

Before the addition of sedating agents, pain control was considered the first-line therapy. Further addition of sedatives was considered for either patient comfort or for clinical indication.

- Delirium assessment and management

Delirium screening was regularly performed with CAM-ICU 7 at least once per nursing shift. After that, modifiable risk factors were addressed, non-pharmacologic strategies implemented, and then pharmacologic intervention was considered.

- Early mobility and exercise

Early progressive mobility protocol was used to move the patients starting with a series of planned movements and build up to the goal of returning the patient to the previous level of functioning.

At first, the safety screening was done and those who passed started the protocol starting with active resistance physical therapy and high fowler position on the bed. Then further progression to sitting on the side of the bed and transferring out of the bed to a chair.

- Family engagement and empowerment

Family members involved in the multi-professional decision making and treatment planning in order to identify patients' preferences, lessen anxiety and increase feelings of inclusion and respect. This was all done through family conferences; share in care and liberalizing family visits.

Phase III: Evaluation phase

Clinical outcomes of both groups were assessed using tool one, tool two and part II of tool three and then documented. These clinical outcomes

include incidence/ severity/ duration of delirium, level of cognitive impairment, days on mechanical ventilation, use of physical restraints and anti-delirious drugs, length of stay and adverse events (falls, reintubation, removal of catheters, pressure ulcers, pneumonia, behavioral disturbance, cardiac complications and death). Then the collected data was analyzed and compared using the appropriate statistical tests.

Ethical considerations

Written informed consent was obtained from the patients after explanation of the aim of the study. Witness consent was obtained from the guardians to observe pain in patients who couldn't report. Patients' privacy was maintained during study implementation. The confidentiality of the collected data was ascertained. The right to refuse to participate in the study was emphasized to conscious patients or guardians and the right to withdraw from the study at any time was emphasized as well.

Results

Table 1 represents the distribution of the study groups according to demographic and clinical data. It shows that 64% of the intervention group patients were males compared to 68% of the control group. Concerning the age, it was ranging between 18 and 62 years with a mean age of 45.84 ± 11.24 and 46.80 ± 13.49 for the intervention and control group respectively with no significant difference (P= 0.70).

Following, the most encountered primary diagnoses were sepsis and respiratory problem with percentages of 24% and 28% compared to 28% and 30% for the intervention and control groups respectively with no significant difference (P=0.11). Moreover, 76% of patients in the intervention group had co-morbidities compared to 80% of the control group with no significant difference (P=0.28). In relation to APACHE II score, the mean scores were 16.36 ± 4.03 and 17.34 ± 3.96 for the intervention and control groups respectively with no significant difference (P= 0.22).

Table 2 depicts comparison between the study groups according to the occurrence, severity and duration of delirium. It can be noted that 38% of the intervention group had delirium compared to 76% of the control group with a significant difference (P=0.00). In the intervention group, the number of patients with severe delirium was lower significantly than those in the control group (P=0.00). In the same context, the mean duration of delirium was 2.58 ± 3.44 and 5.14 ± 3.15 for the intervention and control groups respectively with a significant difference (P=0.00).

Table 3 shows comparison between the study groups according to clinical outcomes. A significant difference between the intervention and control groups regarding the level of cognitive impairment (P=0.03). In other words, 8% of the intervention group had severe cognitive impairment compared to 20% of the control group. Also, this table shows that 26% of the intervention group received prolonged mechanical ventilation (more than 6 days) compared to 52% of the control group with a significant difference (P=0.01).

Regarding length of stay, 14% of the intervention group stayed in the ICU more than 10 days compared to 22% of the control group with a significant difference (P=0.04). As for physical restraints, 34% of patients in the intervention group were restrained compared to 50% in the control group with no significant difference (P=0.10). Similarly, 14% of patients in the intervention group who had delirium received anti-delirious drugs compared to 40% of those in the control group with a significant difference (P=0.00).

Table 4 shows comparison between the intervention and control groups according to the occurrence of adverse events. It can be observed that

there was no significant difference between the two groups regarding events of falls, reintubation, pneumonia, behavioral disturbance and death (P=0.49, 0.44, 0.66, 0.06 and 0.42 respectively).

Unlike, there was a significant difference between the two groups regarding events of removal of catheters, pressure ulcers and cardiac dysrhythmias (P=0.03, 0.00 and 0.03 respectively).

Discussion

Delirium is a major health problem and a serious complication of critical illness, impacting a huge percentage of critically ill patients. Delirium itself is a disturbing, dangerous experience and a potential risk factor for complications. The growing awareness of the seriousness of delirium, coupled with the fact that delirium is potentially preventable resulted in many ways for prevention and treatment. Obviously, interdisciplinary delirium prevention bundles are the most effective evidence-based approaches to achieve that goal.

ABCDEF bundle is an interprofessional, six-step approach which represents an evidence-based guide for n to optimize performance and improve outcomes. It should be established as a vital part of routine nursing practice and acknowledged that its benefits can be maximized only when applied consistently as an entire bundle. (M. F. Mart, Williams Roberson, Salas, Pandharipande, & Ely, 2020)

Briefly, the main results of the current study complement the growing literature that demonstrates the benefits of ABCDEF bundle. A consistent signal of improved outcomes in terms of reduction of delirium, cognitive impairment, mechanical ventilation days, use of physical restraints and anti-delirious drugs and occurrence of adverse events.

This conclusion is consistent with what Hanson, L. (2019) concluded in a literature review about the efficacy of ABCDEF bundle in the ICU. He highlighted the findings of the most cited research articles in that topic. Then proposed that the consistent use of the bundle was associated with obvious reduction in delirium rates, number of days spent in a delirious state, days of coma, length of stay, mechanical ventilation days and mortality risk with a statistical significance. (Hanson, 2019)

Similarly, Ebrahim, A. et al (2021) examined the effectiveness of the ABCDEF bundle on delirium and weakness among mechanically ventilated patients in surgical ICU at Menoufia university hospital. They found a statistically significant reduction in the mean score of delirium features in the intervention group in which the bundle was implemented compared to the control group (p=0.001). (Ebrahim, El Mokadem, Abd-Elhy, & Ibrahim, 2021)

In this study, several observations can be drawn from the results. Regarding demographic and clinical data, no statistically significant difference was found between the intervention and control groups. This similarity can protect against selection bias. Therefore, regardless of which group we choose, the observations within both groups have a normal distribution with a common variance; accordingly the homogeneity of variance assumption is imposed.

After applying the ABCDEF bundle, the clinical outcomes were investigated starting with the occurrence, severity and duration of delirium. It was reported that 38% of the intervention group had delirium compared to 76% of the control group with a significant difference. Likewise, a reduced severity and duration of delirium was observed with the bundle use. A more likely explanation for this discrepancy is the difference in care provision between the two groups which was significant.

Many studies reinforced that conclusion. Rangappa, R. et al (2021) conducted a study in the India Institute of Medical Sciences applying ICU delirium

prevention bundle and the results showed 20% reduction in the incidence of delirium in the intervention group compared to the control group (36% vs 56% respectively). Differently, Roth, A. (2019) applied the ABCDEF bundle in a neurological ICU and reported that delirium percentage did not significantly differ between both groups (p=0.677). (Rangappa, 2021; Roth, 2019)

Another outcome explored in this study is the level of cognitive impairment. All delirious patients exhibited impaired cognitive function with the worst cognition in between patients under routine care. This could likely be attributed to patients' advanced age and communication difficulties. And further that difference might be related to the positive effects of the ABCDEF bundle.

To address this problem, Dean, A. et al (2021) mentioned that from 20% to 40% of ICU survivors experience cognitive impairment after critical illness in terms of executive function, attention, and memory. They also informed that ICU liberation bundles as ABCDEF bundle found viable in managing delirium and could be employed to improve patients' cognitive function. (Dean, Biehl, Bash, Weleff, & Pozuelo, 2021)

Concerning mechanical ventilation outcomes, longer durations of mechanical ventilation were observed in delirious patients particularly in the control group. To illustrate, the duration ranged from 2 to 9 days with mean durations of 5.54 ± 3.10 and 6.42 ± 3.02 for the intervention and control group respectively. This might be explained by the difference in care provision between the two groups.

In this regard, Veneman, W. et al (2019) and Hseih, J. et al (2019) proposed that the durations of mechanical ventilation were significantly shorter with the use of ABCDEF bundle. While Rangappa, R. et al (2021) reported that the duration of mechanical ventilation was not different between the intervention and control group after bundle application. (Hsieh et al., 2019; Rangappa, 2021; Veneman et al., 2019)

As for length of stay, a decrease in the number of days patients stayed in the ICU within the intervention group was observed. This decrease was probably because of the early preventive interventions provided to the intervention group which reduced the need for ICU support and speed up discharge.

Bulic, D et al (2021) reinforced this finding and reported that patients with delirium had a longer duration in the ICU than others. As well as Veneman, W. et al (2019) reported that the ICU length of stay decreased from 9.2 to 6.4 days after bundle application (p=0.005). In contrary, no difference in ICU length of stay was reported by Collinsworth, W. et al (2020) while studying the impact of ABCDEF bundle on patients' outcomes. (Bulic, 2021; Collinsworth, Priest, & Masica, 2020; Veneman, et al., 2019)

As for the use of physical restraints and anti-delirious drugs, it was noticed that most of the studied patients were restrained. This might be explained by the fact that physical restraint is reportedly common and standard practice for agitated patients in hospitals. Besides, anti-delirious drugs were used more often in the control group which might be related to the greater percentage of delirious patients in that group and the poor intervention provided to them in terms of pain management, physical restraints, limited mobility, interrupted sleep, poor communication and social isolation.

Along with these findings, Mart, F. et al (2019) and Hseih, J. et al (2019) stated that the proportion of ICU patient-days in restraints decreased after complete implementation of the ABCDEF bundle in the ICU. Additionally, Veneman, W. et al (2019) and Lee, Y. et al (2020) noticed a reduction in continuous sedation while studying the effect of ABCDEF bundle.

(Hsieh, et al., 2019; Lee, Kim, Lim, & Kim, 2020; M. Mart, Brummel, & Ely, 2019; Veneman, et al., 2019)

In contrast, Hseih, J. et al (2019) informed that during the partial implementation of the ABCDEF bundle, the proportion of ICU days in restraints increased from 50% to 54% compared to complete bundle implementation. (Hsieh, et al., 2019)

In relation to the occurrence of adverse events, a significant difference between the intervention and control group was found. Patients under routine ICU care encountered more adverse events than others. This might be related to the positive effect of the ABCDEF bundle on the intervention group in terms of improving cognitive and physical functioning, increasing ventilator free days, sedation free days, coma free days and preventing complications.

Also, it is also noteworthy that all patients who died in both groups had delirium. This finding confirms the seriousness of delirium as a serious problem and indicates that those who died were affected surely by the negative consequences of delirium, which contributed to the increase in disease severity and mortality.

This is in agreement with Veneman, W. et al (2019) and Hseih, J. et al (2019) who proposed that ventilator acquired pneumonia and pressure ulcers decreased after implementation of the full bundle in the ICU ($p=0.005$, $p<0.001$ respectively). Contradictory to these findings, Zerfas, I. et al (2022) found no significant difference in pressure ulcers prevalence and hospital mortality. (Hsieh, et al., 2019; Veneman, et al., 2019; Zerfas et al., 2022)

Conclusion

Delirium between critically ill patients was found common and significantly and independently associated with negative clinical outcomes calling for the use of preventive measures. Following, ABCDEF bundle use was found significantly effective in improving patients' clinical outcomes. This evidence concurs with the existing literature and further supports the use of ABCDEF bundle in practice and research collaborative aimed at reducing the overall impact delirium has on critically ill patients.

Recommendations

Based on the findings of the current study, it can be recommended that:

- More attention should be directed toward delirium assessment. It should be assessed on a regular basis using reliable tools once the patient is admitted to the ICU.
- Teaching and training opportunities should be provided to critical care nurses and nursing students to address risk factors, best assessment tools, prevention and treatment strategies.
- ABCDEF bundle should be incorporated in the ICU system of care and adopted as part of daily routine care.

Table (1): Distribution of the study groups according to demographic and clinical data (n=50)

Demographic data	Intervention group (n=50)	Control group (n=50)	Test of Sig.	P
	No. (%)	No. (%)		
Gender				
Male	32 (64.0)	34 (68.0)	χ^2= 0.1	0.67
Female	18 (36.0)	16 (32.0)		
Age (years)				
18 – 40 years	10 (20.0)	9 (18.0)		
40 - < 50 years	17 (34.0)	16 (32.0)	χ^2= 5.9	0.21
50 - < 60 years	19 (38.0)	13 (26.0)		
> or equal 60 years	4 (8.0)	12 (24.0)		
Min. – Max.	18.0 – 62.0	20.0 – 62.0	t= 0.4	0.70
Mean ± SD.	45.84 ± 11.24	46.80 ± 13.49		
Primary diagnosis				
Sepsis	12 (24.0)	14 (28.0)		
Cardiovascular	4 (8.0)	5 (10.0)		
Gastrointestinal	4 (8.0)	3 (6.0)	χ^2= 6.1	0.11
Metabolic	2 (4.0)	2 (4.0)		
Neurological	2 (4.0)	2 (4.0)		
Respiratory	14 (28.0)	15 (30.0)		
Renal/ trauma	12 (24.0)	9 (18.0)		
Comorbidities				
Yes	38 (76.0)	40 (80.0)	χ^2= 2.8	0.28
No	12 (24.0)	10 (20.0)		
APACHE II score				
10-14	18 (36.0)	12 (24.0)	χ^2= 1.9	0.39
15-19	20 (40.0)	22 (44.0)		
20-24	12 (24.0)	16 (32.0)		

APACHE II score: Acute Physiology and Chronic Health Evaluation II score

SD: Standard deviation χ2: Chi square test t: Student t-test

* Statistically significant at $p \leq 0.05$

Table (2): Comparison between intervention and control groups according to the occurrence, severity and duration of delirium (n=50)

Delirium parameters	Intervention group (n=50)	Control group (n=50)	Test of Sig.	P
	No. (%)	No. (%)		
Occurrence of delirium				
Yes	19 (38.0)	38 (76.0)	χ^2= 14.7*	0.00*
No	31 (62.0)	12 (24.0)		
Severity of delirium				
No delirium	31 (62.0)	12 (24.0)		
Mild to moderate delirium	10 (20.0)	22 (44.0)	χ^2= 14.9*	0.00*
Severe Delirium	9 (18.0)	16 (32.0)		
Duration of delirium (days)				
Zero	31 (62.0)	12 (24.0)		
1-6 days	6 (12.0)	12 (24.0)	χ^2= 14.7*	0.00*
More than 6 days	13 (26.0)	26 (52.0)		
Min. – Max.	0 .0 – 8.0	0.0 – 8.0	U= 781.5*	0.00*
Mean ± SD.	2.58 ± 3.44	5.14 ± 3.15		

SD: Standard deviation χ2: Chi square test U: Mann Whitney test

*Statistically significant at $p \leq 0.05$

Table (3): Comparison between intervention and control group according to clinical outcomes (n=50)

Clinical outcomes	Intervention group n= (50) No. (%)	Control group n= (50) No. (%)	Test of Sig.	P
Cognitive impairment				
Normal cognition	19 (38.0)	10 (20.0)		
Mild impairment	14 (28.0)	8 (16.0)	9.1*	0.03*
Moderate impairment	6 (12.0)	11 (22.0)		
Severe impairment	4 (8.0)	10 (20.0)		
Not evaluated	7 (14.0)	11 (22.0)		
Mechanical ventilation				
1-3 days	16 (32.0)	10 (20.0)		
4-6 days	21 (42.0)	14 (28.0)	χ^2= 7.1*	0.03*
More than 6 days	13 (26.0)	26 (52.0)		
ICU length of stay				
1-5 days	28 (56.0)	22 (44.0)	χ^2= 6.4*	0.04*
6-10 days	15 (30.0)	17 (34.0)		
More than 10 days	7 (14.0)	11 (22.0)		
Physical restraint				
Yes	17 (34.0)	25 (50.0)	χ^2= 2.6	0.10
No	33 (66.0)	25 (50.0)		
Anti-delirious drugs				
Yes	7 (14.0)	20 (40.0)	χ^2= 8.5*	0.00*
No	43 (86.0)	30 (60.0)		

ICU LOS: Intensive Care Unit Length of Stay SD: Standard deviation

χ^2: Chi square test U: Mann Whitney test *: Statistically significant at $p \leq 0.05$

Table (4): Comparison between intervention and control groups according to the occurrence of adverse events (n=50)

Adverse events	Intervention group (n=50)	Control group (n=50)	χ^2	P
	No. (%)	No. (%)		
Falls				
Yes	0 (0.0)	2 (4.0)	2.0	$^{FE}p=$ 0.49
No	50 (100.0)	48 (96.0)		
Reintubation				
Yes	2 (4.0)	5 (10.0)	1.4	$^{FE}p=$ 0.44
No	48 (96.0)	45 (90.0)		
Removal of catheter				
Yes	13 (26.0)	25 (50.0)	5.8*	0.03*
No	37 (74.0)	25 (50.0)		
Pressure ulcers				
Yes	20 (40.0)	36 (72.0)	10.4*	0.00*
No	30 (60.0)	14 (28.0)		
Pneumonia				
Yes	14 (28.0)	16 (32.0)	0.2	0.66
No	36 (72.0)	34 (68.0)		
Behavioral Disturbance				
Yes	16 (32.0)	25 (50.0)	3.3	0.06
No	34 (68.0)	25 (50.0)		
Cardiac dysrhythmias				
Yes	6 (12.0)	15 (30.0)	4.9*	0.03*
No	44 (88.0)	35 (70.0)		
Death				
Yes	7 (14.0)	11 (22.0)	0.6	0.42
No	43 (86.0)	39 (78.0)		

χ^2: Chi square test FE: Fisher Exact * Statistically significant at $p \leq 0.05$

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