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**Original Article** 

# The effects of a tailored postoperative delirium prevention intervention after coronary artery bypass graft: A randomized controlled trial

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#### ABSTRACT

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#### Introduction

Delirium is an acute course of neuropsychiatric syndrome described by disturbance of consciousness, awareness, attention, and other cognitive and perceptual functions, which alters during the day and tends to get worse over time (1). It is recognized as the most common surgical complication among older adults (2), occurring in 10% to 30% after moderate risk and 30% to 50% after high-risk surgeries (3). After cardiac surgery, the frequency of delirium is estimated from 23% to 47% in Iran (4, 5). The most common factors associated with delirium are older age,

**Background & Aim:** Delirium is a frequent complication in patients hospitalized in the intensive care unit following cardiac surgery. This study aimed to assess the effect of a tailored delirium preventive intervention on postoperative delirium and agitation reduction and length of intensive care unit stay in patients who underwent coronary artery bypass graft.

**Methods & Materials:** In this single-blinded, single-center, randomized controlled design, 60 patients from a hospital in Qom, Iran, were randomly allocated to an intervention or a control group. In the control group, patients received routine care. In the intervention group, patients received routine care, a video tutorial, and the Hospital Elder Life Program. Outcomes were measured using the Confusion Assessment Method for the intensive care unit, Richmond Agitation-Sedation Scale, and length of intensive care unit stay in the second and third days after coronary artery bypass graft.

**Results:** There were no significant differences in the rate of delirium episodes and mean scores of RASS between both groups in the second (P=0.301; P=0.125) and third days (P=0.389; P=0.057) after surgery, respectively. However, the mean duration of intensive care unit stays after surgery was significantly lower in the intervention group compared with the control group (P=0.042).

**Conclusion:** This study indicated the tailored delirium prevention intervention could reduce the length of intensive care unit stay. However, the intervention did not reduce postoperative delirium episodes, nor did the intervention improve the RASS scores in the second and third days after coronary artery bypass graft. A future large multicenter trial with long-term follow-up is needed to assess further the effect of such an intervention.

dementia, co-morbid illness, malnutrition, polypharmacy, infection, use of urinary catheters, sensory deprivation, immobility, and electrolyte imbalance (6).

The coronary artery bypass graft (CABG) is a procedure performed to improve symptoms and survival in patients with coronary heart disease (7). Delirium is an important complication after cardiac surgery because it can initiate a cascade of detrimental clinical events, including longer intubation times, prolonged hospitalization, prolonged intensive care unit (ICU) stay (8), and increased morbidity and mortality (9). Due to the high complications of delirium

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and the little effects of post-episode treatment, its prevention is more important (10). Delirium is preventable in 30–40% of cases, highlighting the importance of prevention in this disease (2).

Delirium is often multifactorial in elderly people. The risk factors which nonpharmacological methods can modify are psychoactive drugs, acute medical issues infection, metabolic disorders. (e.g., dehydration, malnutrition, and hypoxia, sensorv impairments, disorientation, immobilization, and sleep deprivation) (2). Despite the introduction of these risk factors, many healthcare centers have not designed and implemented preventive programs based on these risk factors worldwide (11). This may be related to the inconsistency of the results of various studies in this field.

The Hospital Elder Life Program (HELP) is the most widely used evidencebased model to prevent delirium (12). The HELP model of care was originally presented to preserve older hospitalized patients' physical and cognitive functioning (13). A modified HELP version was developed to assist patients in preventing delirium and functional decline (12). The HELP aims to identify the delirium risk profile of a patient and assign the individualized and tailored interventions to each patient considering their abilities and preferences by collaboration within an interdisciplinary team (11, 12).

Patients undergoing cardiac surgery are at high risk for developing delirium. Being in an unfamiliar environment (e.g., ICU) can expose patients to stress and anxiety (14). Severe anxiety can lead to agitation and may result in delirium (15). There is limited evidence from nonpharmacological interventions in preventing delirium, indicating both the effectiveness and ineffectiveness of these interventions on delirium reduction (16, 17). A Cochrane review has highlighted the need for further nursing interventions to prevent delirium (18). Patient education regarding surgery and the environments of the ICU and operating room (OR) can reduce the risk of delirium by reducing the anxiety and stress of patients. Hence, this study aimed to investigate the effect of a tailored delirium

preventive intervention, using a video tutorial and the HELP on postoperative delirium and agitation reduction and length of ICU stay in patients who underwent CABG.

# Methods

# Study design and setting

This study was a single-center, singleblinded, parallel randomized controlled study conducted from September to December 2019. The study setting included a department of cardiac surgery in a university hospital in Qom, Iran. The department of cardiac surgery comprises a 12-bed preoperative ward, an OR, and a 5-bed Cardiac Surgery ICU (CS-ICU).

# **Participants**

The participants were recruited from the study setting who met the inclusion criteria. The inclusion criteria were age over 18 years, being a candidate for CABG, and being alert at the time of admission (orientation to time, place, and persons). The exclusion criteria included being admitted due to emergency heart surgery, isolation due to infectious deterioration of the patient's disease. condition after surgery (e.g., bradycardia, cardiac dysrhythmia, hypotension, excessive hypoxemia, chest drainage. prolonged anesthesia, and prolonged intubation), having a history of previous major surgery (e.g., cardiac surgery, major vascular surgery, spine surgery), and a lack of consent. The participants who met the inclusion criteria and agreed to participate in the study were consecutively enrolled in the trial. These participants were randomly allocated to an experimental group or a control group using the R package 'randomizeR.' The software had provided a list of numbers from 1 to 60 that were allocated randomly to two equal columns A and B. Before randomization, column A was considered the experimental group and column B the control group. The participants were blinded to whether they had been assigned to the intervention or control group throughout the study. The participant's recruitment and allocation to an experimental group or a control group carried out during hospitalization in the surgery ward before going to the operation room for CABG.

The study sample size was calculated based on a previous study's results that the proportion of delirium in the intervention and control group was 7% and 35%, respectively (19). With a type I error probability of 0.05 and a power of 0.80, the sample size was determined to be 30 patients for each group.

### **Outcome measurements**

The study instrument comprised three parts, including a demographic and clinical characteristics questionnaire, Confusion Assessment Method for the ICU (CAM-ICU), and Richmond Agitation-Sedation Scale (RASS). The demographic and clinical characteristics questionnaire included age, gender, marriage, educational status, left ventricle ejection fraction (LVEF), and length of ICU stay in days. The CAM-ICU is a brief tool to quickly identify delirium by nonclinicians psychiatric using а 4-item algorithm, including acute onset and fluctuating course, inattention, disorganized thinking, or altered consciousness level. The CAM-ICU algorithm requires the presence of both the first and the second items and either one of the third or the fourth item (20). The CAM-ICU is a valid and reliable scale with a sensitivity of 83% and a specificity of 100% (21). RASS is a 10-point scale ranged from -5 (unarousable) to +4 (combative); (alert: 0, agitated: +1 to +4, sedated: -1 to -5) to measure levels of sedation and agitation of a nonverbal patient (22). RASS > 0 or < 0 has 84.0% sensitivity and 87.6% specificity for delirium (23).

# Intervention

In the department of cardiac surgery, patients who are candidates for CABG are initially admitted to the preoperative ward and sent to the OR after receiving preoperative care. After surgery, the patients are transferred to the CS-ICU for recovery. The CS-ICU had two separate parts; in one part, the samples of the intervention group, and in the other part, the samples of the control group were hospitalized, and the study was conducted in parallel. All CS-ICU staff were aware of the type of study and study groups. The ICU nurses who took care of the intervention group were provided training in an hour using the protocol including material. prevention and management of delirium using HELP. The ICU nurses monitored the patients for delirium using CAM-ICU and checked the RASS score regularly every 2 hours when checking for vital signs. One of the researchers in the ICU recorded the mean scores of RASS and checked if patients reported having delirium according to CAM-ICU daily at 18:00.

In the control group, patients received routine care, including early mobilization (e.g., walking once a day in the second and third days of surgery), avoiding dehydration, and if necessary, provision of glasses and hearing aids.

In the intervention group, patients received a delirium prevention protocol consisting of a video tutorial before surgery and the HELP after surgery during ICU hospitalization. A 10-minute educational video, called Cardiac Surgery, was produced by the authors of this study. Its content was reviewed by a panel of experts, including a cardiac surgeon and two CS-ICU nurses. The video was played the day before surgery in the face-to-face educational session and explained in detail by the first author, MA. The video illustrated the conditions before (e.g., preoperative care), during (e.g., OR environment) and after surgery (e.g., being intubated, having chest tubes, connected to monitors).

The HELP included reorientation, therapeutic activities, reduced use and doses of psychoactive drugs, early mobilization, promotion of sleep, maintenance of adequate hydration and nutrition, and provision of vision and hearing adaptations (Table 1). Patients in the intervention group received HELP after surgery during their stay in the CS-ICU. Patients were oriented to place, person, and time using clocks and calendars. Patients' condition and the reason why they were in the ICU were explained to them. Family members visited patients two times daily. ICU nurses were instructed to avoid sedative and psychoactive drugs if possible or at least reduce the dosage. Early mobilization was encouraged in the second and third days of surgery. To improve sleeping conditions, a quiet room at night with low-level lighting was provided. Patients were discouraged from napping and encouraged exposure to bright light during the day. A nutritional balance was maintained. Dehydration was avoided, and the medical team corrected any fluid or electrolyte imbalance. If necessary, personal glasses and/or hearing aids were provided.

Table 1. Hospital Elder Life Program (HELP)
The clocks and calendars were used, ICU nurses explained the l

Reorientation strategies	The clocks and calendars were used, ICU nurses explained the hospital's spatial arrangement and talked with patients about their current situation. Family members visited two times daily.			
Therapeutic activities	Cognitive stimulation activities were done three times daily (e.g., discussion of current events and reminiscence).			
Reduced use and doses of psychoactive drugs	Avoided sedative and psychoactive drugs as much as possible or at least reduced the dosage.			
Early mobilization	Patient was encouraged to move their upper and lower limbs (arms and legs) in range-of-motion on the second and third days of surgery. Patient walked twice a day with the help of a nurse.			
Promotion of sleep	Discouraged napping and encouraged exposure to bright light during the day. Tried to provide an uninterrupted period for sleep at night. A quiet room at night with low-level lighting was provided.			
Maintenance of adequate hydration and nutrition	Avoided dehydration, feeding started immediately after the extubation, and relieving nausea.			
Provision of vision and hearing adaptations	Patient was reminded of the use of their glasses and hearing aids.			

#### Data analysis

The data were analyzed by using SPSS version 24.0 (SPSS Inc., Chicago, IL, USA). Frequency and percentage distributions were reported for categorical variables, and the mean and standard deviation were reported continuous data. Moreover. for we employed the chi-square test and independent-samples t-test to compare the study outcomes in two groups. The level of significance was set at below 0.05.

#### Ethical considerations

This study was performed in accordance with the Declaration of Helsinki (1964) and approved by the Research Ethics Committee of Qom University of Medical Sciences (no: MUQ.REC.1394.136). The study also was registered in the Iranian registration centre of clinical trials (no: IRCT20150724023314N2). A written informed consent was obtained before CABG from the patients after they

were informed about the aim and the process of the study, being free to withdraw from the study at any stage, and the confidentiality of personal information.

#### Results

In this study, 30 patients in the control group and 30 patients in the intervention group were studied and analysed (Figure. 1). The mean age of the patients in the control and intervention groups was 58.93±10.57 and 56.46±9.89 years, respectively. The LVEF was 44.83% and 42.33% in the control and intervention groups, respectively. Men comprised 56.7% of the patients in the control group and 53.3% of the intervention group's patients. Most of the patients were married, 86.7% in control and 90% in intervention groups. Table 2 shows the demographic and clinical traits of the study sample. There significant differences were no in demographic or clinical characteristics between the two groups.

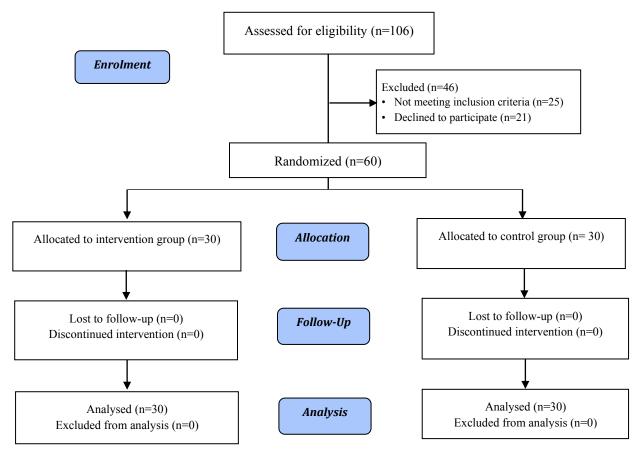


Figure 1. The study consort flow diagram

The rate of delirium episodes was lower in the intervention group compared with the control group on the second day (3.3% vs. 10%) and third day (6.7% vs. 13.3%) after surgery; however, the chi-square test showed no significant differences between the groups following the second (P=0.301) and third days (P=0.389) after surgery (Table 3). The mean scores of RASS were lower in the intervention group compared with the control group on the second day (0.03 vs. .023) and third day (0.06 vs. 0.36) after surgery; however, the independent t-test showed no significant differences between the groups following the second (P=0.125) and third days (P=0.057) after surgery (Table 3). In addition, the mean duration of ICU stays after surgery was significantly lower in the intervention group ( $3.53 \pm 0.57$  days) compared with the control group ( $4.06 \pm 1.28$  days, P = 0.042, Table 3).

Intervention group $(N = 30)$ $56.46 \pm 9.89$ $42.33 \pm 5.20$	Control group (N = 30) 58.93 ± 10.57	x2/t	<b>P</b> 0.355*
	$58.93 \pm 10.57$	0.993	0.255*
$42.33 \pm 5.20$			0.333*
	$44.83 \pm 8.25$	1.403	0.166*
16 (53.3)	17 (56.7)	0.067	0.795**
14 (46.7)	13 (43.3)		
3 (10)	4 (13.3)	0.162	0.688**
27 (90)	26 (86.7)		
9 (30)	6 (20)	0.800	0.371**
21 (70)	24 (80)		
	16 (53.3)         14 (46.7)         3 (10)         27 (90)         9 (30)	16 (53.3)       17 (56.7)         14 (46.7)       13 (43.3)         3 (10)       4 (13.3)         27 (90)       26 (86.7)         9 (30)       6 (20)	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

SD, standard deviation; LVEF, left ventricle ejection fraction

\* The results of the independent-samples t-test \*\* The results of the chi-square test

Table 3. Study outcomes in the intervention and control groups.								
Variables	Intervention group (N = 30)	Control group (N = 30)	x2/t	Р				
Episodes of delirium; N (%)								
Second day of surgery	1 (3.3)	3 (10)	1.071	0.301*				
Third day of surgery	2 (6.7)	4 (13.3)	0.741	0.389*				
RASS Score; mean ± SD								
Second day of surgery	$0.03 \pm 0.18$	$0.23 \pm 0.67$	1.558	0.125**				
Third day of surgery	$0.06 \pm 0.25$	$0.36\pm0.80$	1.939	0.057**				
ICU length of stay; mean ± SD	$3.53 \pm 0.57$	$4.06 \pm 1.28$	2.078	0.042**				

RASS, Richmond agitation-sedation scale; SD, standard deviation; ICU, Intensive care unit

\* The results of the chi-square test

\*\* The results of the independent-samples t-test

#### Discussion

Our findings indicated that the tailored delirium prevention intervention did not significantly reduce postoperative delirium episodes, nor did the intervention improve the RASS scores. However, the intervention reduced the length of ICU stays in the intervention group.

Previous studies on applying delirium prevention intervention to reduce delirium have shown varying results. In some studies, the intervention was found to be effective in reducing the incidence of delirium in general patients (16) and after cardiac surgery (24). Other studies have reported no significant effects of delirium prevention intervention on reducing the incidence of delirium in the patients hospitalized in ICU (17) and after surgery (25). In the present study, an insignificant reduction of postoperative delirium episodes in the intervention group was shown. One possible explanation might be related to the appropriate routine care for preventing delirium in the control group. Some delirium prevention intervention components early mobilization, (e.g., provision of vision and hearing adaptations, and maintenance of adequate hydration) were included. Another possible explanation might be the low mean age of our participants (< 60years). Older age has been reported as a predictor of postoperative delirium (26) as delirium incidence increases to 52% over the age of 60 years in cardiac surgical patients (27). In addition, the onset of delirium was mostly reported on the fourth postoperative day in cardiac surgical patients (26). However, after the third day in our study, we could not assess delirium because patients

routinely were discharged from CS-ICU on the fourth day after surgery.

In our study, there were no significant differences in the RASS scores between both groups following the second and third days after cardiac surgery. Our study's RASS scores were very close to the target RASS score (0=alert), which indicates meticulous monitoring of the sedation and agitation status of the patients in the study setting. A RASS> +1 or < -1 is reported to be a very high positive likelihood ratio for diagnosing delirium (23), which is consistent with the low rate of postoperative delirium in our sample. Delirium and agitation level are associated with a high incidence of of unintentional removal catheters. endotracheal tubes, and urinary catheters (28). Delirium was also associated with higher mortality, longer duration of mechanical ventilation, prolonged length of ICU and hospital stay, long-term cognitive impairment (8, 9), and higher cost of care (29).

In the present study, the mean length of ICU stay was significantly lower in the intervention group. Similarly, previous studies showed that delirium preventive interventions can decrease the length of ICU stays (30). In contrast, a study that applied a perioperative psycho-educational intervention to reduce postoperative delirium incidence found no significant difference in the mean length of ICU stay between the intervention and control groups in cardiac surgical patients (24). Moreover, a 6-month nursing intervention in patients with acute brain injury did not significantly reduce ICU stayICU stay length (17).

The results of the present study must be considered with some limitations. The mean age of patients in this study was<60 years. Since delirium incidence increases over the age of 60 years in cardiac surgical patients, our results should be generalized with caution to patients >60 years old. Moreover, the studv evaluated the short-term postoperative delirium outcomes and did not follow up on the patients after ICU discharge to the general wards. The short period of observation is indeed a shortcoming that might have led to a certain proportion of undetected cases of delirium. Accordingly, a large multicentre trial with long-term follow-up in older age is recommended.

# Conclusion

This study indicated no significant differences in the rate of delirium episodes and RASS scores between the intervention and control groups. However, the intervention by adding a video tutorial and the HELP to the routine care reduced the length of ICU stays in the intervention group. Future research should focus on a large multicentre trial with longterm follow-up to better address the of postoperative effectiveness delirium prevention intervention in the patients who underwent CABG.

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# **Conflict of interest**

The authors declared no potential conflicts of interest.

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