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Out-of-the-ICU Mobilization in Critically Ill Patients: The Safety of a New Model of Rehabilitation

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OBJECTIVES: Early mobilization of ICU patients has been reported to be safe and feasible. Recently, our ICU implemented out-of-the-ICU wheelchair excursions as a daily rehabilitation practice. The aim of this study is to investigate the safety of participation in the out-of-the-ICU program for early mobilization.

DESIGN: Retrospective cohort study.

SETTING: Single general ICU in a tertiary teaching hospital.

PATIENTS: Adult patients who were admitted to the ICU and underwent the out-of-the-ICU program as an early mobilization intervention was investigated.

INTERVENTIONS: The out-of-the-ICU activities include visiting indoor area, visiting our outdoor garden, and bathing.

MEASUREMENTS AND MAIN RESULTS: Medical records of ICU patients who participated in the out-of-the-ICU program were reviewed. The primary outcome was the occurrence rate of physical safety events, defined as unintentional removal of medical devices, patient agitation, a fall, or an injury. The secondary outcome was the occurrence rate of adverse physiologic changes, defined as hypotension, hypertension, bradycardia, tachycardia, desaturation, bradypnea, tachypnea, an increase in F_{IO_2}, or an increase in doses of vasoactive drugs. In total, 99 adult patients participated in the program, comprising a total of 423 out-of-the-ICU sessions. Among them, one session resulted in a physical safety event, the dislodgement of a tracheostomy tube. In 23 sessions, one or two adverse physiologic changes occurred. None of these events required additional treatment nor resulted in serious sequelae.

CONCLUSIONS: An out-of-the-ICU program can be provided safely to adult ICU patients, provided that it is supervised by a dedicated intensivist with an appropriately trained multiprofessional staff and equipment on-site. It appears to contribute to the promotion of humanizing intensive care.

KEY WORDS: bathing; early mobilization; humanization of intensive care; interdisciplinary team; visitation

The implementation of early mobilization to critically ill patients in the ICU has been recommended (1–3) for its potential benefits on patient outcomes (4–9). A common physical therapy protocol, early progressive mobilization (4, 7, 10, 11), focuses on whether patients achieve the maximum exercise goal for the day; if so, they proceed to the next step. However, it is not uncommon for patients to refuse physical therapy, causing the rehabilitation program to stall. Thus, instead of targeting the intensity or progress of physical activity, focusing on other assets of mobilization may be more meaningful to serve critically ill patients. In fact, mobilization intervention is one of the nonpharmacological strategies that has been receiving increased attention due to its positive effect on delirium (12–14) and mental outcomes (15).

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Family participation is another important intervention (3, 13, 14, 16) that is likely to mitigate the stress of both patients and family members (3, 14, 17). From the viewpoint of patient well-being and humanity in the ICU, expanding patients' spheres of activity to outside of the ICU and enabling them to see family members are indeed invaluable (18, 19).

In 2014, we supplemented our physical therapy protocol with patient excursions out-of-the-ICU, whether for a visit to our outdoor garden, for a bath, or simply for a trip through the hallways. Family members can join the patients for parts of these excursions. Since then, we have implemented the out-of-the-ICU program as a part of daily routine care for patients with extended ICU stays. Although we conduct these excursions very cautiously with well-trained multiprofessional personnel and the appropriate equipment, nonnegligible concerns about patients' safety do arise from the transport of severely ill patients outside the critical care environment (20–22). Therefore, we conducted an investigation of patient safety in the out-of-the-ICU program.

MATERIALS AND METHODS

In this single-center, retrospective cohort study, we reviewed the electronic medical records for adult patients who were admitted to the general ICU (four beds) at the Nagoya City University West Medical Center (a 500-bed tertiary teaching hospital in Nagoya, Japan) from January 1, 2015, to December 31, 2020, and identified patients who participated in the out-of-the-ICU program for early mobilization during their ICU stay. We manually reviewed the comments and documentation sections of each electronic medical record thoroughly, in order to check for the occurrence of any physical safety events, including the unintentional removal of a medical device, an episode of patient agitation requiring the discontinuation of the session, a fall, or an injury. We also obtained physiologic data, the amount of oxygen and vasoactive agents administered before and after the rehabilitation session, and devices and catheters in situ during the session from the clinical flow sheet of the patient's electronic medical record.

This study was approved, and the informed consent requirement was waived by the Institutional Review Board of the Nagoya City University East and West Medical Center (approval no. 20-04-372-26).

Intervention

The out-of-the-ICU rehabilitation program that is provided to patients who are expected to stay in the ICU for at least several days is carried out as follows. In the morning meeting, held on a weekday basis, we assess each patient's condition based on their hemodynamic and respiratory stability evaluated by blood pressure (BP), heart rate (HR), arrythmia, dose of vasoactives, respiratory rate (RR), Spo_2, FIo_2, and body temperature. Patients with elevated intracranial pressure, spinal instability, neuromuscular paralytics, active bleeding, bed-rest order, or a score on the Richmond Agitation-Sedation Scale of +2 or higher are excluded from the out-of-the-ICU activities. Accordingly, we discuss whether the patient can participate in out-of-the-ICU activity. Then, we decide the type of rehabilitation intervention for the day. Based on the patient's ability to hold his or her head and neck or torso, we select the type of wheelchair: regular wheelchair, reclining wheelchair, or wheelchair that converts to a gurney and has a built-in conveyer belt for transferring the patient from bed to the wheelchair, which allows us to take a barely awake or markedly incapacitated patient.

The out-of-the-ICU program includes visiting the outdoor garden, visiting indoor areas, and bathing. We encourage the patient's family members to join the session, if possible. The outdoor garden is located on the fourth floor, which is on the rooftop of the third floor where the ICU is located. As for visiting indoor areas, we go to a hallway, the rehabilitation room, or the ward where the patient was previously admitted, if any. For bathing, we provide a whole-body shower with the patient lying on a mesh bed using a shower-type bath system that covers the patient from neck to toe, which is located in a special bathroom on the eighth floor.

The patient's vital signs are monitored by a transport monitor throughout the session, except for during the bath. We use a transport ventilator for patients who are mechanically ventilated.

The out-of-the-ICU activity is provided by a multiprofessional team, comprised an ICU intensivist, an ICU nurse, and a physical therapist. A clinical engineer accompanies the team when the patient is mechanically ventilated.

Outcome Assessments

The primary outcome was the occurrence rate of physical safety events, which included the unintentional

removal of medical devices, patient agitation requiring the discontinuance of the session, falling, and injury requiring medical treatment. The medical devices of concern included endotracheal tubes, tracheostomy tubes, drainage tubes, IV catheters, arterial catheters, nasogastric tubes, and urinary catheters.

The secondary outcome was the occurrence rate of adverse physiologic change, defined as the occurrence of the following after the mobility session: hypotension (systolic BP [sBP] less than 80 mm Hg), hypertension (sBP greater than 200 mm Hg), bradycardia (HR less than 40 beats/min), tachycardia (HR greater than 140 beats/min), desaturation (Spo_2 less than 88%), bradypnea (RR less than 8 breath/min), tachypnea (RR greater than 40 breath/min), an increase in oxygen dose, and an increase in the dosages of vasoactive agents. sBP, HR, Spo_2, and RR were measured by bedside monitor, and the values were automatically transmitted to the clinical flow sheet of the electronic medical record every 5 min for sBP, HR, Spo_2, and every 15 min for RR. With regard to the continuously measured physiologic data, that is, sBP evaluated by invasive BP measurement, HR, Spo_2, and RR, an average of three consecutive data measured immediately after the session was used for analysis in order to minimize any possible technical misreading of physiologic values that might have happened due to factors such as patient movement. If the physiologic values were not obtained within 10 min after the session, the values were treated as missing data.

Statistical Analysis

Descriptive statistical analysis was performed, including the count and proportion of binary or categorical valuables, and median and interquartile range (IQR) for continuous valuables. Categorical valuables are presented as numbers and percentages. The physical safety event rates were calculated by dividing the number of sessions in which an event occurred by the total number of out-of-the-ICU rehabilitation sessions. Missing physiologic data were treated as missing observations. Adverse physiologic change event rates were calculated by dividing the number of sessions in which an event occurred by the total number of valid sessions, excluding any sessions with missing data. CIs were calculated and presented with event rates.

Statistical analyses were performed using R 4.0.5 (The R Foundation, Vienna, Austria).

RESULTS

Baseline Characteristics

During the study period, 1,821 adult patients were admitted to the ICU. Among them, 99 patients participated in the out-of-the-ICU mobilization. Their characteristics are presented in **Table 1**. Of the 99 patients, 59 were men (60%), and the median age was 73 yr (IQR, 66–77.5 yr). The most frequent primary diagnosis on ICU admission was respiratory failure (52.5%), followed by sepsis (26.3%), cardiac failure (13.1%), and gastrointestinal disease (6.1%). The median score of the Acute Physiology and Chronic Health Evaluation II on ICU admission was 22 (IQR, 16–27). Ninety-four patients (94.9%) received mechanical ventilation, the median length of which was 8 d (IQR, 4–14.5). The initiation of the out-of-the-ICU program was conducted at a median (IQR) of 4 days (2–6 d) after ICU admission.

A total of 423 out-of-the-ICU sessions were performed as follows: 275 sessions of visiting the outdoor garden (65.0%), 101 sessions of visiting indoor areas (23.9%), and 47 sessions of bathing (11.1%). The patient was accompanied by family members in 96

TABLE 1.
Baseline Characteristics of the Patients

Characteristics	*n* = 99
Age, median (IQR), yr	73 (66–77.5)
Male, *n* (%)	59 (60.0)
ICU admission diagnosis, *n* (%)	
Respiratory failure	52 (52.5)
Sepsis	26 (26.3)
Cardiac failure	13 (13.1)
Gastrointestinal disease	6 (6.1)
Other	2 (2.0)
Acute Physiology and Chronic Health Evaluation II score on ICU admission, median (IQR)	22 (16–27)
Mechanically ventilated, *n* (%)	94 (94.9)
Length of mechanical ventilation, median (IQR), d	8 (4–14.5)
Initiation of out-of-the-ICU session, median (IQR), d[a]	4 (2–6)

IQR = interquartile range.
[a]Days after ICU admission.

sessions (22.7%). The median times of participation per patient was 3 (IQR, 2–5).

Of the 423 sessions, the patient was mechanically ventilated either through an oral endotracheal tube in 153 sessions (36.2%) or through a tracheostomy tube in 68 sessions (16.1%). One or more vasoactive agents were administered during 56 of those sessions (13.2%). The details of the sessions are presented in **Table 2**.

In total, 153 endotracheal tubes, 131 tracheostomy tubes, 256 central venous catheters, 320 peripheral IV catheters, 282 arterial catheters, 456 drainage tubes (73 in the chest, 353 in the abdomen, and 30 in other areas), 403 nasogastric tubes, 403 urinary catheters, for a total of 2,404 medical devices, were in situ during the 423 sessions. The median number of devices in situ was 5 (IQR, 4–7).

TABLE 2.
Details of the Activities and Patients' Conditions During the Sessions

Characteristics of the Activities and Patients' Conditions	*n* (%); Out of 423 Sessions
Types of activities	
Visiting outdoor garden	275 (65.0)
Visiting indoor area	101 (23.9)
Bathing	47 (11.1)
Family presence	
Yes	96 (22.7)
No	327 (77.3)
Respiratory support	
Mechanically ventilated through an oral endotracheal tube	153 (36.2)
Mechanically ventilated through a tracheostomy rube	68 (16.1)
Spontaneous breathing through a tracheostomy tube	63 (14.9)
Noninvasive positive pressure ventilation	7 (1.7)
High-flow nasal cannula oxygen therapy	15 (3.5)
Supplemental oxygen through a face mask or a nasal cannula	108 (25.5)
No support	9 (2.1)
Cardiovascular support	
One vasopressor or one inotrope	40 (9.4)
Two of vasopressors and/or inotropes	3 (0.7)
One vasodilator	13 (3.1)
No support	367 (86.8)

Potential Safety Events

During the 423 out-of-the-ICU activity sessions provided to the 99 patients, a total of 27 potential safety events were detected in 24 sessions across 14 patients (**Table 3**).

Regarding physical safety events, one event (0.2%; 95% CI, 0.006–1.3%) of dislodgement of a tracheostomy tube occurred when the patient transitioned to sitting on the edge of bed. None of the other medical devices were removed. There were no falls, episodes of agitation requiring discontinuation of the session, or injuries that required medical treatments (**Table 4**).

The adverse physiologic changes are shown in **Table 5**. Seventeen sessions lacked one or more physiologic values after the session, resulting in their being excluded from the analysis. As a result, 406 sessions were examined for adverse physiologic changes.

In 23 sessions (5.7%; 95% CI, 3.6–8.4%) out of the 406 sessions, 26 adverse physiologic changes occurred among 13 patients (Table 3). The frequent events were respiratory-related, including 15 events of increase in oxygen dose, three events of tachypnea, and one event of desaturation. Regarding hemodynamic instability, there were three events of an increase in vasopressor dosage, two events of hypertension, and two events of hypotension. The entire physiologic abnormal values were transient, and the incremental doses of oxygen and vasopressors were all minimum and temporary. There were no events of bradypnea, tachycardia, bradycardia, or increase in vasodilator dosage (Table 5).

There was no documentation of severe deterioration in physiologic parameters or equipment problems during the sessions.

DISCUSSION

This study demonstrated that the potential safety events related to the out-of-the-ICU activities occurred in 24 of a total of 423 sessions (5.7%; 95% CI, 3.6–8.3%), none of which required additional treatments or resulted in immediate sequelae. Therefore, taking patients out-of-the-ICU for early mobilization rehabilitation can be safely performed.

Previous studies have demonstrated that early mobilization of critically ill patients is feasible and safe, with

TABLE 3.
Occurrences of Potential Safety Events in Respective Sessions and Patients

Patient	Removal of Tracheostomy Tube	Increase in Oxygen	Tachypnea	Desaturation	Increase in Vasopressor	Hypotension	Hypertension
A	✓						
B		✓		✓			
C		✓					
		✓					
		✓	✓				
D		✓					
E		✓					
F		✓					
		✓					
		✓					
					✓		
G		✓					
		✓					
H		✓					
I		✓					
J		✓					
		✓					
K			✓				
			✓				
L					✓		
					✓	✓	
M						✓	
N							✓
							✓
No. of events	1	15	3	1	3	2	2

Each row represents one session of out-of-the-ICU mobilization intervention.

potential safety event rates of 0–5% (4–6, 23–32); however, these figures are difficult to directly compare with our results for several reasons. First, the definitions of safety events are considerably different. Second, the types of physical interventions administered vary significantly across studies. The studies that investigated mobility interventions limited to out-of-bed activities reported less than 1–5% potential safety event rates (29–31). Third, physiologic data were obtained after the sessions in our study, whereas previous studies investigated them during the sessions.

In our study, there was only one physical safety event: namely, one dislodgement of a tracheostomy tube, which was immediately corrected. This incident happened when the patient sat up on the edge of bed in the ICU without the intensivist's direct supervision; consequently, no physical adverse event happened outside the ICU during any session. Previous studies have reported a tracheostomy tube removal (29) or an endotracheal tube self-removal (30, 32) during a rehabilitation session. Removal of the other medical devices did not occur in our study, which was consistent with the very low occurrence rate (0–0.6%) in previous studies (4, 5, 25, 28, 29, 31, 32).

The risk of unintentional removal of medical devices is likely to be highest when a patient sits up or stands up (29), as the devices can become caught on a stationary object. Accordingly, once a patient sits in a

TABLE 4.
Types and Occurrences of Physical Safety Events

Type of the Event	No. of Occurrence
Removal of medical device, *n* (total[a])	1 (2,404)
Endotracheal tube, *n* (total[a])	0 (153)
Tracheostomy tube, *n* (total[a])	1 (131)
Central venous catheter, *n* (total[a])	0 (256)
Peripheral IV line, *n* (total[a])	0 (320)
Arterial catheter, *n* (total[a])	0 (282)
Drainage tube, *n* (total[a])	0 (456)
Nasogastric tube, *n* (total[a])	0 (403)
Urinary catheter, *n* (total[a])	0 (403)
Agitation	0
Fall	0
Injury	0

[a]Total number of such devices in situ during the 423 sessions.

TABLE 5.
Types and Occurrences of Adverse Physiologic Changes

Type of the Event	No. of Occurrence[a]
Respiratory change	
Desaturation	1
Tachypnea	3
Bradypnea	0
Increase in dose of oxygen	15
Δ FIO_2 5%	4
Δ FIO_2 10%	9
Δ Oxygen flow rate 0.5 L/min	1
Δ Oxygen flow rate 1 L/min	1
Hemodynamic change	
Hypotension	2
Hypertension	2
Tachycardia	0
Bradycardia	0
Increase in dose of a vasopressor	3
Δ noradrenaline ~0.04 μg/kg/min	1
Δ noradrenaline 0.04–0.07 μg/kg/min	2
Increase in dose of a vasodilator	0

Δ = increased amount.
[a]During a total of 406 sessions excluding 17 sessions with missing data, which included 11 sessions lacking respiratory rates and six sessions lacking systolic blood pressures.

wheelchair and the devices are well arranged, the risk of unintentional removal of medical devices is likely to be very low, as our study demonstrated.

Physiologic safety events were also reported to be related to changes in position and exertion (28, 29), which can cause orthostatic hypotension, hypertension, and arrhythmia due to stress and increased oxygen demand. In this regard, it is important to assess the patient's hemodynamic and respiratory condition while the patient sits on the edge of the bed and in the wheelchair, and to evaluate whether the patient is stable enough for the excursion out-of-the-ICU.

It is noteworthy that our patient population is markedly older (a median age of 73) than those in other reports (mean or median ages in their fifties or sixties), probably because of the super-aging society in Japan and our institute's lack of a trauma center. Older adults suffer from serious physical and cognitive declines following critical illness (33). This out-of-the-ICU program in which a patient sits in a wheelchair does not require much effort, and thus is easier for older and/or debilitated patients to participate in. Only 5.4% (99 out of 1,821 patients) participated in the out-of-the-ICU activities because the vast majority of the patients in our ICU are postelective surgery patients staying in the ICU overnight, resulting in fewer critically ill patients who are eligible for this program. In addition, only 22.7% of sessions were accompanied by family members. Better arrangement of the session to a more suitable time for family members' convenience may have helped increase this opportunity.

It is now well known that many ICU survivors suffer long from serious physical, mental, and psychologic impairment, and hence reduced quality of life (34). Guidelines and studies endorse the importance of early mobilization (1–3, 7, 9, 35). Common early mobilization therapies progress from passive to active physical movement and to higher intensity activities, which patients sometimes refuse. We implemented this out-of-the-ICU activity program as a way to make rehabilitation sessions more enjoyable and meaningful. This strategy allows us to connect patients to the outside environment and their family members, and gives patients cognitive stimulation and reorientation. During each excursion, they leave the ICU, pass

through a hallway, get on an elevator, and then go outside with their family members. Patients can feel the sunlight and breeze, noticing that it is daytime. They see other patients walking in the garden or exercising in the rehabilitation room. Finally, they retrace the exact same pathway back to the ICU. We strongly believe that these experiences reorient patients to their situation and that this approach can help restore their self-worth and desire to recover and return home with the help of their family.

Outdoor gardens have been reported to have a beneficial impact on the well-being of patients, visitors, and healthcare professionals, providing a relaxed and enjoyable environment (18, 36, 37) and humanistic care (19). Shower bathing is another pleasant stimulation for the ICU patients, who often request it. It is also favorable to the visiting family members and to the healthcare professionals working at the bedside, as the patient's skin is soft and clean and smells pleasant as a result.

In a previous study, we gave a questionnaire to our healthcare professionals including physicians, nurses, physical therapists, and clinical engineers who had participated in the activity, and obtained favorable opinions with very few negatives toward the out-of-the-ICU activity (38). We believe that this approach is an important innovation toward the ultimate goal of patient- and family-centered care (16, 17), not only for ICU survivors but also for those patients who do not survive and their bereaved family members. Furthermore, this expands to human-centered care including healthcare professionals (19).

For this program to be successful, interprofessional collaboration is essential, and strong leadership is a key component. Furthermore, an ICU culture where every member of the team is committed to the program, pursuing the humanization of intensive care, needs to be fostered.

This out-of-the-ICU program is a routine clinical practice at our hospital; hence, this retrospective cohort study demonstrates actual clinical data and reflects true occurrence rates of a real daily practice without any strict study inclusion and/or exclusion criteria or heightened attention to safety.

Limitations

This study has some limitations. First, this is a single-center project and may not be generalizable to all ICUs, since the available resources, including personnel and equipment, vary considerably across facilities. Second is that it being a retrospective cohort study with a relatively small sample size may have introduced biases. Third, we demonstrated physiologic data immediately after the session. Although we monitored the patients' vital signs during the sessions and did not detect any abnormalities in physiologic parameters that resulted in session discontinuation, we cannot deny any possible undetected deterioration that might have occurred during the session. Finally, although we completely inspected their medical records, the possibility of undocumented safety events cannot be excluded.

Future Directions

There has been vigorous research examining the benefits of early mobilization of critically ill patients. As a result, a paradigm shift away from "resting in bed" toward "mobilizing in the ICU" has now been established. In the near future, the paradigm of mobilization may shift from "inside the ICU" toward "outside the ICU." Further studies are needed to investigate the efficacy of this approach.

CONCLUSIONS

The out-of-the-ICU program as an early mobilization intervention for ICU patients can be implemented safely, provided that it is supervised by a dedicated intensivist with an appropriately trained multiprofessional staff and equipment on-site. It appears to contribute to the promotion of humanizing intensive care.

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The authors have disclosed that they do not have any potential conflicts of interest.

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