

## ORIGINAL ARTICLE

# The Safety and Effect of Early Mobilization in the Intensive Care Unit According to Cancellation Criteria

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**Objective:** The aim of this study was to investigate the effect and risk management of early mobilization in the intensive care unit (ICU) with multidisciplinary collaboration and daily goal planning. **Methods:** Rehabilitation of ICU patients in our hospital between April 1, 2019, and September 30, 2019, was investigated retrospectively. The following factors were evaluated: age and sex of the subjects; diseases; the total number of early mobilization therapy sessions done at a lowered goal level; the clinical course of the step-down sessions; reasons for lowering goal levels that corresponded to the cancellation criteria from the officially issued guidelines of the Japanese Association of Rehabilitation Medicine, the expert consensus on ICU, or other reasons for step down; and the rate of planned goals that were achieved. **Results:** Of the 1908 overall rehabilitation sessions carried out during the period of investigation, 9.6% had the planned level lowered; changes in vital signs accounted for 54.6% of the reasons for lowering the level. Of the step-down sessions, 92.3% corresponded with the cancellation criteria of rehabilitation. Early mobilization in the ICU in accordance with daily goal planning via collaboration within the multidisciplinary team during rounds was accomplished in 90.4% of sessions. No serious mobilization-related adverse events were noted during the study period.

**Conclusion:** Early mobilization should be performed with daily goal planning by a multidisciplinary team during rounds and should be governed by the cancellation criteria of rehabilitation.

**Key Words:** early mobilization; ICU; protocol; risk management

## INTRODUCTION

An evidence-based, multicomponent, and interprofessional team management strategy has been developed for optimizing intensive care unit (ICU) recovery and outcomes.<sup>1,2)</sup> The strategy is called the ABCDEF bundle, which is derived from “Assess pain, Both SAT/SBT, Choice of drugs (analgesia and sedation), Delirium monitoring and management, Early mobility and exercise, and Family engagement and empowerment.” This protocol facilitates the adoption of the Pain, Agitation/Sedation, Delirium, Immobility and Disrupted Sleep Guidelines for comprehensive results in ICU

management,<sup>3-5)</sup> recommended by the Society of Critical Care Medicine.

The activities of daily living (ADL) or quality of life of patients after discharge from the ICU remains low, although the survival rate of clinically severe patients in the ICU has increased. Muscle weakness and neuropathy have been recognized as ICU-acquired conditions and are believed to result from sustained immobilization, multiorgan dysfunction, and hyperglycemia, as well as the use of steroids and muscle relaxants.<sup>6,7)</sup> Needham et al. reported that, after patients have had 4 days of bed rest, it is common for critically severe ICU patients worldwide to be under the care of

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a multidisciplinary team focused on reducing heavy sedation. Moreover, increasing ICU staffing to include full-time physical and occupational therapists with new consultation guidelines is not uncommon. Using a quality improvement process, ICU delirium, physical rehabilitation, and functional mobility were markedly improved and were associated with a decreased length of stay.<sup>8)</sup> Schweickert et al. reported that, for patients who started early mobilization within 72 h of intubation in the ICU, the Barthel index score had significantly increased at the time of discharge; they concluded that hyperacute rehabilitation at the ICU was effective in improving ADL function.<sup>9)</sup>

To conduct early mobilization in the ICU, risk management during rehabilitation is considered particularly important. Complications in ICU patients are profoundly serious and potentially life threatening; these complications include acute respiratory distress, acute exacerbation of chronic respiratory distress, acute cardiac failure after major surgery, and post-cardiopulmonary arrest, among others. Consequently, because priority must be given to improving the function of all organs and controlling the general condition of the patient, early mobilization and active exercise during the early phase are sometimes contraindicated. However, excessive bed rest promotes the development of immobilization syndrome and increases the risk for various complications, and in such cases, early mobilization and active exercise during the early phase are advisable. In the ICU, the patient's fundamental condition may change drastically, or the intensive care situation may change suddenly; as result, early mobilization and active exercise during the early phase needs to be carefully assessed.

Bailey et al. reported that less than 1% of patients who were admitted to the respiratory intensive care unit and required mechanical ventilation for >4 days suffered activity-related adverse events. Such events included falling to the knees without injury, feeding tube removal, high systolic blood pressure (>200 mm Hg), low systolic blood pressure (<90 mm Hg), and oxygen desaturation (<80%).<sup>10)</sup> Bourdin reported that an adverse event occurred in 3% of interventions in patients who had been in the ICU for more than 1 week, but none resulted in harmful consequences. These reports gave no clear criteria for starting early mobilization.<sup>11)</sup>

In 2014, Hodgson et al. developed the expert consensus safety standards on active mobilization, and, recently, several protocols and cancellation criteria have been proposed.<sup>12,13)</sup> In 2017 in Japan, development of the expert consensus on early mobilization and active exercise in the early phase was begun by the Japanese Society of Intensive Care Medicine.<sup>14)</sup>

During rehabilitation treatment, the adoption of cancellation criteria is necessary for risk management,<sup>15)</sup> and there are several cancellation criteria for rehabilitation.<sup>16,17)</sup> To effectively and safely execute early mobilization by applying the ABCDEF bundle, setting the protocol for cancellation criteria is fundamental. Multidisciplinary rounds were assumed to be necessary for the ABCDEF bundle and were therefore adopted in our hospital.

Recently, barriers to and strategies for early mobilization in the ICU and analysis of outcomes have been reported.<sup>18–20)</sup> However, to our knowledge, studies with protocol and cancellation criteria in Japan that particularly examined the safety and course of early mobilization and active exercise in the early phase in the ICU are limited.<sup>21)</sup> Consequently, we aimed to investigate the risk management and the specific method for early mobilization and active exercise for ICU patients using protocol and cancellation criteria within multidisciplinary rounds.

## SUBJECTS AND METHODS

### Hospital Setting


Our hospital is an 814-bed acute phase-specific hospital in Tokyo with a 12-bed semi-closed ICU. Admissions to the ICU are either from the emergency room or from hospital wards. All admissions to the ICU result either from unplanned emergency critical illnesses in outpatients or from planned postoperative or unplanned emergency conditions that develop in the wards.

Daily multidisciplinary rounds were performed every morning from Monday to Friday, and the team members consisted of physicians (chief, ICU, and rehabilitation physicians), physiotherapists, nurses, medical engineers, nutritionists, and pharmacists who collaborated to accomplish early mobilization.

During every morning round, the day's specific rehabilitation goals were set using the protocol and with consideration of the patient's condition on that day. Assessment of the patient's condition included the pain level, respiratory or circulatory conditions, and the *scaleRASS* (delirium) or Glasgow scale score indicating consciousness and the level of sedation; these factors were used in association with the day's planned treatments and the previous days' accomplished mobilization goals.

If a patient was unable to follow commands or actively participate in mobilization (RASS score range from –5 to –2 or the Glasgow scale  $\leq 8$ ), the level was set at 1 or 2, according to the patient's general condition. If the patient was sentient

**Table 1.** Early mobilization protocol at the Tokyo Medical and Dental University Hospital

Level 1	Level 2	Level 3	Level 4	Level 5
Unconscious		Awake		
RASS -5/-2 Glasgow $\leq$ 8		RASS -1/+1 Glasgow $>$ 8		
ROM exercise	Verticalization	Sitting on the edge of the bed	Standing	Assisted walking
Passive/active-assisted/active/active-resisted manual mobilization				
Passive				Active
Contraindications of early mobilization (Level 2 to 5) [18] <ol style="list-style-type: none"> <li>1. Cases that physicians do not allow</li> <li>2. Patients that need rest and who do not comply due to excessive excitement (RASS <math>\geq</math>2)</li> <li>3. Severe arousal disorder without cooperation adequate for exercise (RASS <math>\leq</math>-3)</li> <li>4. Unstable hemodynamics requiring mechanical circulatory support such as IABP</li> <li>5. Blood pressure is too low even with a large amount of inotropes</li> <li>6. Blood pressure fluctuates greatly on changing body position</li> <li>7. Untreated aneurysm at risk of impending rupture</li> <li>8. Uncontrolled pain</li> <li>9. Uncontrolled increased intracranial pressure (<math>\geq</math>20 mmHg)</li> <li>10. Unstable head and/or neck trauma</li> <li>11. Unstable fracture</li> <li>12. Active bleeding</li> <li>13. High possibility of accidental removal of lines by early mobilization or active exercise from the early phase due to insufficient fixation of central lines or driplines</li> <li>14. When staff members are not available to ensure safety</li> <li>15. When the consent of the patient or family cannot be obtained</li> </ol>				

ROM, range of motion.

and was able to follow commands (RASS score range from -1 to +1 or the Glasgow scale  $>$ 8), active mobilization at a level of 3–5 (more than sitting on the edge of the bed) was set based on the patient's general condition and on the goal accomplished on the previous day. After the goal of the day was set, the sedation level, respiratory mode, and the time of day for administering other treatments were adjusted as much as possible by members of the multidisciplinary team to facilitate accomplishment of the rehabilitation goal.

To execute early mobilization, the protocol is set in accordance with “the contraindication of early mobilization and active exercises from the early phase” established by the expert consensus of the Japanese Society of Intensive Care Medicine (**Table 1**).<sup>14)</sup> No physical therapists are assigned to the ICU, so they are brought from the rehabilitation center for each therapy session. The early mobilization and rehabilitation sessions are done with consideration of the cancellation criteria. The cancellation criteria were consistent with “the cancellation criteria in the early mobilization and active exercise in early phase in ICU” proposed in the expert con-

sensus of the Japanese Society of Intensive Care Medicine<sup>14)</sup> and Guidelines for Safety Management and Promotion prepared by the Clinical Practice Guidelines Committee of the Japanese Association of Rehabilitation Medicine (**Tables 2, 3**).<sup>17)</sup>

## Patients

To evaluate the effectiveness of early mobilization with daily multidisciplinary rounds in promoting patient recovery after critical illness, all consecutive ICU patients aged at least 18 years who were treated between April 1, 2019, and September 31, 2019, were assessed. We extracted and analyzed the following patient data: age, sex, category of rehabilitation, type of surgery, intubation, assisted circulation [including percutaneous cardiopulmonary support (PCPS), extra-corporeal membrane oxygenation (ECMO), intra-aortic balloon pump (IABP), and ventricular assist device (VAD)], the planned goal of early mobilization established on the round, the current level of early mobilization, the intubation rates for each level, the number of sessions stepped

**Table 2.** Guidelines for Safety Management and Promotion of the Clinical Practice Guidelines Committee of the Japanese Association of Rehabilitation Medicine<sup>17)</sup>

<p><u>Cases in which aggressive rehabilitation should be avoided</u></p> <ul style="list-style-type: none"> <li>• Pulse rate at rest <math>\leq 40</math> beats/min or <math>\geq 120</math> beats/min</li> <li>• Systolic blood pressure at rest <math>\leq 70</math> mmHg or <math>\geq 200</math> mmHg</li> <li>• Diastolic blood pressure at rest <math>\geq 120</math> mmHg</li> <li>• Effort angina</li> <li>• Significant bradycardia or tachycardia in patients with atrial fibrillation</li> <li>• Poor cardiovascular hemodynamics in patients immediately after myocardial infarction</li> <li>• Significant arrhythmia</li> <li>• Chest pain at rest</li> <li>• Presence of palpitations, shortness of breath, or chest pain prior to rehabilitation</li> <li>• Dizziness, cold sweats, nausea, etc., in a sitting position</li> <li>• Body temperature at rest <math>\geq 38^{\circ}\text{C}</math></li> <li>• Oxygen saturation at rest <math>\leq 90\%</math></li> </ul>	<p><u>Cases in which rehabilitation should be canceled</u></p> <ul style="list-style-type: none"> <li>• Higher than moderate degree of shortness of breath, dizziness, nausea, angina pectoris, headache, a strong feeling of fatigue, etc.</li> <li>• Heart rate <math>&gt;140</math> beats/min</li> <li>• Systolic blood pressure on exercise rises by 40 mmHg or more or diastolic blood pressure rises by 20 mmHg or more</li> <li>• Tachypnea (<math>\geq 30</math> cycles/min) or shortness of breath</li> <li>• Increased arrhythmia with exercise</li> <li>• Presence of bradycardia</li> <li>• Worsening level of consciousness</li> </ul>
<p><u>Cases in which rehabilitation should be stopped and may be restarted after recovery</u></p> <ul style="list-style-type: none"> <li>• Heart rate exceeds that before exercise by 30%: cancel or change to very light exercise if it does not return to less than 10% before exercise after 2 min of rest</li> <li>• Heart rate <math>&gt;120</math> beats/min</li> <li>• Ten or more premature ventricular contractions in 1 min</li> <li>• Presence of mild palpitation or shortness of breath</li> </ul>	<p><u>Cases in which other precautions are required</u></p> <ul style="list-style-type: none"> <li>• Presence of hematuria</li> <li>• Increase in amounts of sputum</li> <li>• Increase in body weight</li> <li>• Presence of fatigue</li> <li>• Loss of appetite or fasting</li> <li>• Worsening edema of the lower extremity</li> </ul>

down from the planned goal, the reason why the goal was not achieved, the number of sessions stepped down according to the cancellation criteria, the planned goal for the next day after the step down, the number of stepped-up sessions that needed to be lowered according to the cancellation criteria, the planned goal for the following day after the step down, and the rate of level up for the next day.

### Data Analyses and Statistical Tests

The median age of the step-down patients in each category was assessed (Table 4). The Kruskal-Wallis test was used to compare the ages among the categories. The chi-squared test was used to compare the step-down rates among the categories. The chi-squared test was also used to compare the step-down rates among the planned levels (Table 5).

All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). EZR is a modified version of the R Commander designed to add statistical

functions frequently used in biostatistics.<sup>22)</sup> The level of statistical significance was set at  $P < 0.05$ .

This study was conducted with the approval of the Research Ethics Committee at the Tokyo Medical and Dental University (M2018-073) and in accordance with the World Medical Association Declaration of Helsinki. Written informed consent was obtained from all individual participants included in the study.

## RESULTS

Within the study period, 1908 early mobilization therapy sessions involving 432 patients were investigated (Table 4).

The ages among the disease categories were significantly different ( $P < 0.01$ ). The patients in the cardiovascular surgery group, the liver and gastrointestinal surgery group, and the circulatory category were older than the patients in the brain surgery group. The ages of the stepped-down patients of each category were not significantly different. The step-down rate was significantly different among the disease categories ( $P$

**Table 3.** The Cancellation Criteria for Early Mobilization and Active Exercise in the Early Phase in the ICU proposed by the expert consensus of the Japanese Society of Intensive Care Medicine<sup>14)</sup>

Category	Elements index	Value of decision criteria or condition	Remarks
General Nervous system	Reaction	Occurrence of obvious poor reactions	Drowsiness, stupor in response to call
	Expression	Agony expression, the occurrence of	
	Consciousness	pallor or cyanosis	
	Agitation	The occurrence of mild or more impaired	
	Voluntary movement of extremities	consciousness	
	Posture adjustment	The occurrence of dangerous behavior The occurrence of limb weakness Rapid increase in assistance Posture cannot be held, fall	
Subjective symptoms	Dyspnea	Complaint of sudden dyspnea	Pneumothorax, PTE Modified Borg scale 5–8
	Fatigue	Appearance of forced breathing Unbearable fatigue Patient wants to stop	
	Respiratory rate	<5 per min or >40 per min	
	SpO <sub>2</sub>	<88%	
Respiratory system	Respiration pattern	Appearance of sudden expiratory or inspiratory effort breathing	Except for transient symptoms assess with the findings of airway obstruction, for example by auscultation
	Ventilator	Desynchronization, bucking	
	Heart rate	Decreased heart rate or bradycardia after starting exercise	
Circulatory system	Electrocardiograms	<40 bpm or >130 bpm	Except for transient symptoms
	Blood pressure	New rhythm disorders Suspected myocardial ischemia Systolic blood pressure <65 mmHg or >180 mmHg 20% decrease of systolic or diastolic blood pressure Mean atrial pressure >110 mmHg	
	Artificial airway	Risks or occurrences of accidental removal	
	Nasogastric tube, central venous catheter		
	Chest drain, wound drain, bladder catheter		
Others	Patient refusal	Appearance of drain waste	
	Action for suspension	Risk of wound opening	
	Suggestion of active bleeding		
	Surgical wound condition		

<0.01). The step-down rates of the cardiovascular surgery and the circulatory and respiratory categories were high.

In 1725 sessions (90.4%) the planned goal was accomplished, whereas in 183 sessions (9.6%) the planned level was lowered (**Table 5**). Early mobilization, i.e., more than sitting

up in bed, was accomplished in 630 sessions (33.0%). The step-down rates significantly increased at the higher levels.

The time of step down was decided either at the start of the rehabilitation session or during the session. Judgment of whether to step down was performed at the start of reha-

**Table 4.** Patient characteristics

	Sessions (n)	Patients (n)	Sex	Age (years)	ICU stay (days)	Intubation (n, %)	Assisted circulation (PCPS, VAD, ECMO, IABP) (n, %)	Step-down sessions (n, %)						
									M/F	Median	Range	P <sup>a</sup>	Median	Range
Cardiovascular	691	107	70	37	70	21-89	5	2-117	171	24.7	47	6.80	76	11 <sup>a</sup>
Brain	382	150	80	70	63.5	20-81	2	2-23	133	34.8	0	0	36	9.4
Liver/gastrointestinal	227	60	49	11	74.5	42-89	3	2-19	95	41.9	0	0	20	8.8
Surgery	64	22	18	4	68.5	46-81	2	2-38	37	27.8	0	0	4	6.2
Others (orthopedic, urologic, gynecologic, vascular)	122	34	21	13	69	33-88	2	2-28	55	45.1	0	0	7	5.8
Total	1486	373	238	135	69	21-89	3	2-117	491	33.0	47	3.16	143	9.6
Circulation	143	31	19	12	74	31-86	3	2-31	74	51.8	17	11.9	19	13.2
Respiratory	83	6	5	1	66.5	51-79	6	2-34	30	36.1	2	2.4	12	14.5
Others (e.g., gastrointestinal, collagen, renal, neurological, blood)	196	22	12	10	69	19-83	7	3-29	81	41.3	0	0	9	4.6
Total	422	59	36	23	70.5	19-86	4.5	2-34	185	43.8	19	4.50	40	9.5
Total	1908	432	274	158	70	19-89	3	2-117	686	40.0	66	3.46	183	9.6

<sup>a</sup>Kruskal-Wallis test to compare the ages among disease categories

<sup>b</sup>Chi-squared test to compare the step-down rates among disease categories

\*Significantly different among disease categories



**Table 5.** The course of early mobilization

	Level 1	Level 2	Level 3	Level 4	Level 5	Total	P
Planned sessions (n)	848	379	197	222	262	1908	P<0.01 <sup>a</sup>
Patients accomplished the planned level (n (%))	848 (100)	334 (89.1)	162	184	196	1725	
Sessions actually done <sup>b</sup> (n)	901	388	(82.2)	(82.9)	(74.8)	(90.4)	
Intubation (n)	450	80	178	246	196	1908	
Assisted circulation (PCPS, VAD, ECMO, IABP, etc.) (n)	70	30	10	35	43	188	
Time of decision of step down	Level 1	Level 2	Level 3	Level 4	Level 5	Total	
Sessions (n (%))		45	35	37	66	183	
At the start of rehabilitation (n (%))		45 (100)	28 (80)	15 (40.5)	10 (15.2)	98 (53.6)	
During rehabilitation (n (%))		0 (0)	7 (20)	22 (59.5)	56 (84.8)	85 (46.4)	
Reason for step down under criteria	Level 1	Level 2	Level 3	Level 4	Level 5	Total	
Sessions (n (%))		42 (93.3)	34 (97.1)	33 (89.2)	60 (90.1)	169 (92.3)	
Vital sign(+)		13	7	14	22	56	
Blood pressure (n)		7	4	3	3	17	
Tachycardia, bradycardia, arrhythmia (n)		3	4	3	0	10	
Respiration (n)		0	7	3	3	13	
O2 saturation (n)		1	0	0	3	4	
Fever (n)		24	22	23	31	100 (54.6)	
Total (n (%))		4	3	3	4	14	
Vital sign(-)		0	0	1	16	17	
Consciousness, delirium (n)		0	0	4	7	11	
General fatigue (n)		8	1	0	0	9	
Nausea, vomiting (n)		3	1	0	0	4	
Convulsion (n)		0	3	0	2	5	
Bleeding risk (n)		3	4	2	0	9	
Chest pain or other pain (n)		18	12	10	29	69 (37.7)	
Device (n)							
Total (n (%))		18	12	10	29	69 (37.7)	

**Table 5.** The course of early mobilization (*continued*)

	Level 1	Level 2	Level 3	Level 4	Level 5	Total	P
<b>Others</b>							
Cerebrospinal fluid leak (n)		2	0	0	0	2	
Graft ischemia (n)		1	1	2	0	4	
Muscle weakness (n)		0	0	2	6	8	
<b>Total (n (%))</b>		<b>3</b>	<b>1</b>	<b>4</b>	<b>6</b>	<b>14 (7.7)</b>	
<b>The level of the previous day</b>							
The average of next day's goal	Level 1 2.65	Level 2 2.61	Level 3 3.58	Level 4 4.57	Level 5 4.93	Total 3.23	
Step-down session (level)	(1-5) 2.02	(1-5) 3.44	(1-5) 3.78	(1-5) 5	(1-5)	(1-5) 3.44	
Next day: level up(+/-)	(1-5) 50/16	(1-5) 7/38	(1-5) 4/14	(1-5) 54/0	(1-5)	(1-5) 156/27	
<b>Total</b>	<b>66</b>	<b>45</b>	<b>18</b>	<b>54</b>	<b>183</b>	<b>183</b>	

<sup>a</sup>Chi-squared test to compare the step-down rate among the levels

<sup>b</sup>At some mobilization levels, the number of sessions actually done was higher than the planned number because drop-down sessions were added.



bilitation for the lower levels, whereas for the higher levels, judgment was done during the session.

Of the step-down sessions, 92.3% were attributed to events corresponding to the cancellation criteria of rehabilitation, and 54.6% of discontinuations were due to vital sign factors. Reasons other than the cancellation criteria accounted for 7.7% of the sessions where step down was deemed appropriate; these reasons included new conditions necessitating immobilization, such as cerebrospinal fluid leakage, graft ischemia, or muscle weakness.

The following day's rehabilitation level was increased based on the current level, and it was increased at all levels, including for the step-down sessions. In this investigation period, no serious adverse events related to rehabilitation in the ICU were reported.

## DISCUSSION

To reduce the incidence of post-ICU syndrome, early mobilization in the ICU is recommended in the ABCDEF bundle, and we attempted to conduct early mobilization in accordance with the cancellation criteria and with team collaboration during the multidisciplinary round.

By setting goals daily, during the 6-month study period, we estimated that most planned rehabilitation sessions (90.4%) in the ICU were accomplished to the level presumed to be possible during the round. Moreover, no serious adverse events occurred during performance of those therapies. However, the planned goal levels were lowered in 9.6% of sessions. Reasonable goals were set during the multidisciplinary round using the protocol according to the condition of the patient on the day, the day's planned treatments, and the previous day's accomplished goals.

Leveling down of the rehabilitation was decided either at the start or during rehabilitation sessions. In some cases, the general condition of the patient had changed between the multidisciplinary assessment in the morning and the time of initiation of rehabilitation. In other cases, the preparations for rehabilitation planned by the multidisciplinary members on the round, such as the reduction of sedation, pain management, or a change of respiratory mode, had to be delayed, and, therefore, the assessment to level down was made at the beginning of the therapy session. Additionally, lowering of the level was decided either according to the cancellation criteria or for other reasons. In six cases, new reasons for immobilization occurred: two cases of cerebrospinal fluid leakage and four cases of graft ischemia. In the other cases, during the rehabilitation therapies, the judgment to discon-

tinue was done according to changes in vital signs or the occurrence of subjective symptoms such as general fatigue or nausea.

The rate of lowered sessions was significantly different depending on the general level. Overall, 92.3% of the reasons for the decision to lower the level of early mobilization were associated with conditions corresponding to the cancellation criteria of rehabilitation. The setting of cancellation criteria is said to be vital in rehabilitation therapy for acute stage patients.<sup>15)</sup> Such criteria are particularly important when determining whether to continue with therapy or whether a step up to the next level is safe and to address risk management against excessive exercise stress during rehabilitation in the ICU.

The level was lowered in nine sessions due to the cancellation criteria associated with newly added devices or delayed removal of devices after the morning round or because treatment did not permit patients to verticalize or to leave the bed because of IABP, ECMO, or continuous hemodialysis from an inguinal blood access. However, it should be noted that in the ABCDEF bundle in the ICU, the patient is not always prohibited to verticalize or to leave the bed, even when supported by PCPS, ECMO, IABP, or continuous hemodiafiltration or if a Swan-Ganz catheter is being used.<sup>23,24)</sup> In patients with implantable VADs, early mobilization is necessary to obtain higher levels of ADL, thereby facilitating the transition to waiting for a heart transplantation when the patient is at home.<sup>25,26)</sup> However, the conditions vary, and individual consideration is necessary for placing or stabilizing blood access to avoid kinking or disconnection. Furthermore, for patients with unstable circulation, conducting early mobilization has negative effects and poses new risks to the patient's general condition and overall treatment.

Additionally, the rehabilitation level should be planned according to the characteristics and posttreatment of the disease. Overall, lowering of the planned level was done based on reasons other than the cancellation criteria in 7.7% of sessions. The levels of six sessions were lowered because bed rest was necessary due to changes in posttreatment for the original disease, such as cerebrospinal fluid leakage or graft ischemia. The posttreatment can also be changed during the course of the disease. Treatments were regularly altered depending on the patient's condition, and judgment was consistently required that not only considered the patient's general condition but also the specific disease symptoms and their corresponding treatments.

Muscle weakness was another reason for lowering the mobilization level. In nine patients at level 4 or 5, standing

or walking was impossible because of muscle weakness, although their general condition was good. Six were post-operative cases (five intestine and one brain surgery), and three were internal medicine cases (one circulation and two others). The step down was appropriate to mitigate against falls or excessive exercise stress. The acute progression of muscle weakness is frequently seen in the ICU, and muscle strength should be considered when deciding whether to level up the day's therapy. Moreover, the judgment for leveling down should be done considering fall risk management in patients whose muscle strength is inadequate for higher level mobilization even with assistance.

A total of 32.5% of early mobilization rehabilitation sessions involved more than sitting up in bed. In general, the rate of early mobilization or its course depends on the severity of the conditions of patients in the ICU and the particular hospital. The levels of the rehabilitation therapies on the following day were increased compared with the previous day even in the step-down sessions. Trials of early mobilization can be planned, performed, and evaluated according to the protocol. Although the progress of the course in early mobilization in the ICU depends on the severity of the patient's condition, we could evaluate early mobilization individually and comprehensively.

This study has several limitations. First, we do not have comparative data for this study, although using the protocol made it easy to set definite, standardized, and appropriate goals via assessment of the patient's level of consciousness or general condition before the rehabilitation therapy and to prepare patients effectively based on their condition before initiation of the actual rehabilitation therapy. These preparations included consideration of pain control, reduction of sedation, time adjustment of other treatments, or even the acquisition of compatible factors to evaluate the rehabilitation therapies themselves. Second, the investigation period was limited and covered 6 months only (from April to October) and did not include the winter or colder seasons. Finally, the diseases included varied widely: further investigation of specific diseases is necessary.

In conclusion, a relatively low number (9.6%) of the overall rehabilitation sessions in the ICU were stepped down during the investigation period, and 92.3% of the reasons for stepping down were associated with the cancellation criteria. Furthermore, all the reasons corresponded to cancellation of sessions during rehabilitation therapy. No serious adverse events were observed during the 6-month study period. Therefore, this study suggests that early mobilization in the ICU can be performed effectively and safely with consid-

eration of the cancellation criteria and in accordance with specified daily goals as determined by collaboration among the multidisciplinary team members in accordance with appropriate protocols.

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## CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this article.

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