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REVIEW

Current status and future development of acute and cardiac physiotherapies in Japan

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ABSTRACT. In recent years, the importance of early physiotherapy for rapid mental and physical functional recovery is increasing with the increasing number of older patients and high-risk patients with duplicate disorders. Increasing the effectiveness of acute physiotherapy within a shorter hospital stay is a great challenge. We published the first expert consensus of early rehabilitation in Asia in 2017. Our expert consensus will contribute to the establishment of physiotherapy in intensive care for Asian populations. The minimum standard of clinical practice for physiotherapists working in critical care settings is important to showcase physiotherapists' knowledge and abilities as medical professionals working in the intensive care unit. We are planning to release the minimum standard of clinical practice for Japanese physiotherapists working in critical care settings in 2020. Being in the forefront among nations of aging populations, Japan has a rapidly increasing number of older frail patients with heart failure. Further studies are necessary to confirm the effectiveness of task-specific exercise training considering the characteristics of frailty.

Key words: acute physiotherapy, cardiac physiotherapy, expert consensus, frailty, task-specific exercise training

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On September 26, 2019, the Ministry of Health, Labour and Welfare announced that the estimated medical expense for financial year (FY) 2018 reached a record high of 42.6 trillion yen [1)]. This medical expense increased by 0.8% annually. The medical expense for people aged ≥75 years increased by 2.4%. Japan is the only super-aging society in the world, and medical expenses are expected to increase in the future as the population ages.

In 2025, the baby boomer generation of approximately 8 million people will become older senior citizens (≥75 years old), and the social security costs (those who need medical and nursing care) are expected to increase rapidly. This is called the "crisis of increasing elderly population in 2025." In preparation for 2025, a change in bed classification and further shortening of the length of hospital stay in acute care hospitals are planned. Japan has also the longest length of stay in acute care hospitals among the 35 member countries of the Organization for Economic Cooperation and Development Organization[2)]. Structural reform of medical care in Japan is attracting attention worldwide.

In Japan, among the priority issues of the basic policy of the revision of medical fees for FY2014 are as follows: (1) In the description of functional differentiation, cooperation enhancement of medical institutions, and enhancement of home health care, it was stated that "In addition to early discharge, in order to prevent ADL function decrease, it is also important to enhance the early rehabilitation implementation and support for early discharge and transfer." The enhancement of early rehabilitation became a social proposition in Japan.

The Japan Society of Intensive Care Medicine, organized by the Early Rehabilitation Ad Hoc Committee in 2014, is aimed at establishing the content and system of early rehabilitation in the field of intensive care in Japan. To achieve this aim, "Evidence-based expert consensus for

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Table 1. Contraindication for early mobilization and rehabilitation in the intensive care unit

1) No permission from the attending physician
2) Too agitated (RASS ≧ 2)
3) Severe arousal disorder (RASS ≦ −3)
4) Unstable circulation that requires the use of assistive devices such as IABP or PCPS/ECMO
5) Too low blood pressure with a large amount of vasopressor
6) Unstable blood pressure by only changing body position
7) Untreated aneurysm
8) Uncontrolled pain
9) Neurological instability: intracranial pressure (ICP) ≧ 20 cmH_2O
10) Unstable head and spinal injuries
11) Unstable fracture
12) Active bleeding
13) Insufficient and unstable catheter or infusion line
14) Insufficient staff for safety
15) No informed consent

RASS: Richmond agitation-sedation scale
IABP: intra-aortic balloon pumping
PCPS: percutaneous cardiopulmonary support
ECMO: extracorporeal membrane oxygenation

early rehabilitation in the intensive care unit" was published in February 2017 [3]. In this expert consensus, the following are summarized, including the definition, effectiveness, and contraindications of early rehabilitation; inception and cessation criteria; and the role of the early rehabilitation team. The contraindications (Table 1), inception, and cessation criteria for early rehabilitation (Table 2, 3) indicated by the expert consensus are the first standards in Asia.

Owing to the impact of the announcement of the early rehabilitation expert consensus, "early rehabilitation addition (5,000 yen/patient/day, 14-day upper limit)" was newly established as the additional fee for the specific intensive care unit (ICU) management in the revision of medical treatment fees in FY2018. Until then, medical fees for rehabilitation in the ICU were not paid because patients undergoing intensive care in the ICU were considered not in the physical condition to undergo physical therapy. However, claiming medical fees for rehabilitation in the ultra-acute phase in the ICU became possible owing to this additional fee. This means that early rehabilitation in Japan has made even greater progress since 2018. More than 250 of 650 Japanese ICUs registered as early rehabilitation facilities at the end of 2018.

Development of Sedative Analgesia Management and Early Rehabilitation in Intensive Care

It is not an exaggeration to say that the development of early rehabilitation in intensive care evolved from sedation management. The clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the ICU (PAD guideline) [4] by the American College of Critical Care Medicine, Society of Critical Care Medicine, and American Society of Health-System Pharmacists were revised for the first time in 10 years and became "Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU" (PADIS guidelines) [5]. In the current sedation management, avoiding excessive sedation using a short-acting agent such as midazolam, propofol, and dexmedetomidine in a continuous intravenous administration protocol is common. More recently, further light-sedation management has been performed using sedative-centered hypnotic-based sedation and pain management-centered analgesia-based sedation. This progress in the management of sedative and analgesics has become the source of the Awakening and Breathing Controlled Trial (ABC Trial) [6], which pairs daily spontaneous awakening trials (i.e., interruption of sedatives) with daily spontaneous breathing trials. After that, the ABC trial evolved into an ABCDE bundle (Awakening and Breathing Coordination of daily sedation and ventilator removal trials, Choice of sedative or analgesic exposure, Delirium monitoring and management, Early mobility and Exercise) [7].

The purpose of sedation is to relieve the anxiety and ensure the comfort of the patient, not to induce sleep. In intensive care, rather than deep sedation, the patient will wake up and be able to move the body immediately after a procedure with proper sedation management using the sedation and analgesia scale. The introduction of the sedation management protocol facilitated the introduction of early rehabilitation. The fact that early rehabilitation is now attracting attention in intensive care is clearly a result of the progress of sedation and analgesia management.

Table 2. Inception criteria for early mobilization and rehabilitation

	Index	Range and criteria
Conscious	Richmond agitation-sedation scale (RASS)	−2 ≦ RASS ≦ 1
		No agitation requiring sedation within 30 min
Pain	NRS, VAS, BPS, and CPOT ≦ 2	NRS ≦ 3 or VAS ≦ 3, BPS ≦ 5 or CPOT ≦ 2
Respiration	Respiratory rate (RR)	< 35 breaths/min
	Oxygen saturation (SaO_2)	≧90%
	Fraction of inspiratory oxygen (FiO_2)	< 0.6
	Positive end-expiratory pressure (PEEP)	< 10 cmH_2O
Circulation	Heart rate (HR)	≧50 or ≦120
	Arrhythmia	No new severe arrhythmia
	Ischemia	No ECG changes indicating new ischemia
	Mean blood pressure (MAP)	≧65 mmHg
	DOA or noradrenaline dosage	No increase within 24 hours
Other	Treatment for shock is given, and the condition is stabilized.	
	SAT and SBT are conducted. There is no bleeding tendency.	
	There are no harmful lines when moving.	
	Intracranial pressure (ICP) < 20 cmH_2O	

NRS: numerical rating scale
VAS: visual analogue scale
BPS: behavioral pain scale
CPOT: critical-care pain observation tool
DOA: dopamine
ECG: electrocardiography
SAT: spontaneous awakening trial
SBT: spontaneous breathing trial

Recent Negative Evidence of Early Rehabilitation

In our Japanese Early Rehabilitation Expert Consensus, research papers published from 2000 to 2015 in PubMed, Medline, Cochrane Database of Systematic Reviews, and ICHUCHI from the Japan Medical Abstract Society were systematically reviewed. Twenty-five randomized controlled trials have been conducted since 2016, and some papers do not support the effectiveness of early rehabilitation [8].

For example, the EPICC study published in *Thorax* in 2018 showed that ICU-based physical rehabilitation did not appear to improve physical outcomes at 6 months as compared with the standard physical rehabilitation [9]. They conducted a randomized controlled trial in patients who had received at least 48 hours of invasive or noninvasive ventilation. Participants were randomly divided into two groups, an intervention group (n = 150, 90 min of physical rehabilitation per day) and a control group (n = 158, 30 min of physical rehabilitation per day). The intervention group received a median (interquartile range [IQR]) of 161 min (67-273 min) of physical rehabilitation in the ICU as compared with 86 min (31-139 min) in the control group. They showed no significant difference in the Physical Component Summary (PCS) measure of the 36-item short-form health survey at 6 months.

Morris et al. showed that standardized early rehabilitation for patients hospitalized with acute respiratory failure did not shorten the length of hospital stay as compared with usual care (median [IQR], 10 days [6-17 days] for the rehabilitation group and 10 days [7-16 days] for the usual care group) [10].

In recent years, in-bed cycling exercise and neuromuscular electrical stimulation have been introduced. Fossat and colleagues examined that the effects of in-bed cycling exercise (15 minutes) plus neuromuscular electrical stimulation (50 minutes to quadriceps) added to the standardized rehabilitation program [11]. They showed that adding in-bed cycling exercise and neuromuscular electrical stimulation to the standard early rehabilitation program did not improve overall muscle strength at discharge from the ICU.

These reports do not imply that all early rehabilitation programs are ineffective. In fact, the control group included standardized physiotherapy and standard care, which means that performing physical therapy as usual is important. In addition, there are unstable patients and patients with various conditions in the ICU. These may underestimate the effects of early rehabilitation and may obscure the effects of physical therapy.

Table 3. Cessation criteria for early mobilization and rehabilitation

Category	Items and index	Criteria for determination	Remarks
Nervous system	• Reaction	• Appearance of a clear bad reaction condition	• A state of drowsiness and chaos against a call
	• Facial expression	• Appearance of agonizing expressions, facial paleness, and cyanosis	
	• Consciousness		
	• Agitation		
	• Voluntary movement of the extremities	• Emergence of mild or more consciousness disorders	
	• Postural adjustment	• Emergence of dangerous behavior	
		• Emergence of limb weakness	
		• Rapid increase in the amount of assistance	
		• Emergence of unretained posture	
		• Fall	
Subjective symptoms	• Dyspnea	• Complaint of sudden dyspnea	• Pneumothorax
		• Labored respiration	• Pulmonary thromboembolism
			• Modified Borg scale score of 5-8
	• Fatigue	• Unbearable fatigue	
		• If the patient wants to stop	
		• Complaint of pain	
Respiratory system	• Respiratory rate	• 5 breaths/min or >40 breaths/min	• Except for evanescent increase
	• SpO_2	• <88%	
	• Breathing pattern	• Sudden breathing effort	
	• Mechanical ventilator	• Unsynchronization	• Evaluation of airway obstruction by auscultation
		• Backing	
Cardiovascular system	• Heart rate	• Decreased heart rate and bradycardia	• Except for evanescent increase
		• 40/min or >130/min	
	• Electrocardiography	• New arrhythmia	
		• Suspected myocardial ischemia	
	• Blood pressure	• Systolic blood pressure > 180 mmHg	
		• 20% decrease in systolic or diastolic blood pressure	
		• Average arterial pressure < 65 mmHg	
		• Or >110 mmHg	
Device	• Artificial airway	• Risk of removal (or removal)	
	• Nasogastric tube		
	• Central venous catheter		
	• Chest drain		
	• Wound drain		
	• Bladder catheter		
Other	• If the patient refuses		
	• If the patient asks for cessation		
	• Suspected active bleeding	• Properties of drainage	
		• Risk of wound separation	
	• Surgical wound condition		

Cessation was determined depending on the patient's condition or request to discontinue or resume.

Minimum Standards of Clinical Practice for Physiotherapists Working in Critical Care

Skinner and research colleagues in Australia and New Zealand published "Minimum standards of clinical practice for physiotherapists working in critical care settings in Australia and New Zealand" [12]. By using a modified Delphi technique, they obtained consensus-based minimum clinical practice standards for physiotherapists working in critical care settings in Australia and New Zealand. Minimum standards were defined as the basis of possession of expertise and experience in the practice and teaching of critical care

physiotherapy clinical skills. One hundred ninety-nine items were considered as minimum standards, which included specific areas of practice, skills, and knowledge required by physiotherapists working in critical care in the first-round questionnaire, and 132 items were "essential" items for inclusion in the final framework. Physiotherapists working in critical care settings in Australia and New Zealand are required to have a broad range of knowledge and skills as a minimum standard.

On the other hand, several items that are considered necessary for physiotherapists working in critical care settings in Japan were excluded from the minimum standard consensus as follows:

・A physiotherapist can accurately interpret readings from clinical monitoring, including advanced electrocardiography (ECG; i.e., conduction block, 12-lead ECG) and nutritional status, including feed administration, volume, and type.

・A physiotherapist can accurately interpret findings from laboratory investigations, including albumin level and liver function tests (e.g., alanine transaminase, lactate dehydrogenase, and bilirubin levels).

・A physiotherapist can independently interpret findings from imaging investigations (excluding the imaging report), including computed tomography (brain and chest imaging) and ultrasonography.

・An ability to perform an assessment of sedation levels.

・Ability to perform a delirium assessment (e.g., the confusion assessment method for the ICU).

・A physiotherapist can assess and interpret mechanical ventilation settings/measurements, including maximum inspiratory pressure measurements.

・A physiotherapist can measure peak cough flow on or off mechanical ventilation.

This research paper is also helpful in knowing the occupational description of a physical therapist overseas. The scope of work and role of a physical therapist vary greatly depending on the laws, culture, and history of each country. Awareness of physical therapists' scope of work and role is also necessary when quoting and referring to international research papers. In the fall of 2019, we began to investigate the minimum standard for physical therapists in critical care in Japan as a role of the expert committee of the Japanese Society of Intensive Care Medicine. We plan to publish an international comparative paper with the Australian-New Zealand group's research paper.

We expanded our survey to physicians and nurses specializing in intensive care. Clarifying the minimum standards of clinical practice for physiotherapists working in critical care settings in Japan through international and inter-professional comparisons will deepen the understanding of physiotherapists in the critical care team and clarify the roles of physiotherapists.

Physiotherapy for Older Frail Patients with Heart Failure

In recent years, the number of older frail patients with heart failure has been rapidly increasing in Japan. Older frail patients with heart failure have significantly decreased motor function by even just a short period of bed rest, which increases the degree of care required. Frailty is well known to be a strong factor of heart failure recurrence, rehospitalization, and poor prognosis [13]. The characteristics of frailty patients with heart failure are slowness, low physical fitness, and reduced balance function [14]. Therefore, they need an exercise training program to improve their frailty characteristics, rather than performing a conventional program to gradually extend their walking distance. That is, task-specific training is required, not just low-intensity resistance training.

The percentage of frailty patients with heart failure has been reported to range from 15% to 79% [15]. The reason for the wide range of frailty is the difference in race and research cohort, and the frailty evaluation method used. In general, frailty evaluation includes a wide range of functions such as physical, cognitive, and social functions. Many frailty evaluation methods have been used, but the most reasonable frailty evaluation method for patients with heart failure has yet to be identified. The Short Physical Performance Battery (SPPB) is a common well-established instrument for measuring physical performance. It includes a timed 4-m walk, timed repeated chair sit-to-stand test, and 10-s balance tests (side by side, semi-tandem, and full tandem) [16]. The SPPB can be evaluated in a relatively short period and can evaluate the characteristic motor function degradation (slowness, poor balance function, etc.) in older patients with heart failure.

We have newly developed an in-patient exercise program for older frail patients with heart failure. On the basis of the SPPB score, we plan to create an exercise program to improve the domains with low scores (Table 4).

Physiotherapy for Patients after Transcatheter Aortic Valve Implantation

The use of transcatheter aortic valve implantation (TAVI) has rapidly spread in Western countries since the first TAVI was performed in France by Dr. Alain Cribier in 2002. In Japan, TAVI has been covered by the national insurance since October 2013. After that, TAVI was added as an adaptive disease with cardiac rehabilitation fees in the revision of medical fees in FY2018. As TAVI is minimally invasive, its application has also been expanding to patients with contraindication of surgical valve replacement. Among the comprehensive factors for predicting the prognosis of patients with TAVI, frailty has become a particularly important factor in recent years.

Table 4. Evaluation of motor function for older patients with heart failure

SPPB	BASE	Balance (10-s balance tests)	Ambulation (a timed 4-m walk)	Sit-ups (a timed 5 times-repeated chair sit-to-stand test)	Endurance (maximum walking distance)
4	5	One leg 10s	Less than 4s	<9.2 s	340 m (6 min)
	4	full-tandem 10s	Less than 4.82s	<11.19 s	180 m
3	3	full-tandem 3 ~ 9.99s	4.82 ≦ 6.20s	11.2 ≦ 13.69 s	80-179 m
2	2	semi-tandem 10s	6.21 ≦ 8.70s	13.7 ≦ 16.69 s	40 m
1	1	side-by-side, 10s	More than 8.70s	>16.70 s	15 m
0	0.8	side-by-side, 3 ~ 9.99s	4m with light assistance	>60 s or stand up 2-5 times	4 m
	0.6	broad base 10s (without support)	4m with moderate assistance	Stand up once without support	Wheelchair 30 min
	0.4	Able to stand with support	4m with heavy assistance	Stand up with arm support	Wheelchair 10 min
	0.2	Able to stand with assistance	2.3 steps with heavy assistance	Stand up with assistance	Able to sit on the edge of bed
	0	Unable to stand	Unable to walk	Unable to stand up	Bed rest

SPPB 0-6: low function 7-9: moderate function 10-12: high function

In 2012, the PARTNER trial, which examined the usefulness of TAVI for patients with severe aortic valve stenosis, reported that frailty could be a perioperative risk factor[17]. "Poor activity" as one of the frail assessment items was added in Euro-SCOREII, which is used as a perioperative risk assessment. The American College of Cardiology and American Heart Association Guideline for the Management of Patients with Valvular Heart Disease released in 2014 adds frail assessment (Katz activities of daily living score and walking independence [need assistance, independent, and can walk 5 m within 6 seconds]) to the risk assessment of valve surgery and interventions [18].

From the viewpoint of rehabilitation, a much higher daily life physical function than before TAVI surgery is expected because TAVI surgery is less invasive. TAVI patients are older and often gradually narrow the daily life space from before operation. Low physical function before surgery is also known to strongly affect life prognosis [19].

However, if the life prognosis after a minimally invasive surgery such as TAVI is strongly related to frailty before surgery, after the aortic valve stenosis symptoms have been improved by TAVI surgery, rehabilitation can be started with the aim of overcoming higher body functions and frailty than before surgery. If the life prognosis after a minimally invasive surgery such as TAVI is strongly related to frailty before surgery, cardiac rehabilitation can be started after the aortic valve stenosis symptoms have been improved by TAVI surgery, with the aim of overcoming the physical function and frailty before surgery. In fact, 6-min walking distance and functional independence measure score improved significantly after 19 days of cardiac rehabilitation [20], suggesting the importance of cardiac rehabilitation after TAVI surgery.

Conclusion

The importance of a safe and effective early physiotherapy to minimize the harmful effects of prolonged bed rest is increasing because older patients with comorbidities easily develop a hospitalization-associated disability. Quality assurance is needed to ensure that physiotherapists perform early physiotherapy safely and effectively in the acute care setting.

In the treatment of heart disease, less invasive interventions such as TAVI have been introduced, and their indications are expanding to include older patients. Further studies are needed to identify the optimal physiotherapy, considering frailty characteristics, and thereby improve the prognosis of older patients with heart disease.

Conflict of Interest: The authors disclose no conflicts of interest.

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