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Robot-assisted early mobilization for intensive care unit patients: Feasibility and first-time clinical use

Angelika Warmbein [a,*], Lucas Hübner [b], Ivanka Rathgeber [a], Amrei Christin Mehler-Klamt [c], Jana Huber [c], Ines Schroeder [b], Christina Scharf [b], Marcus Gutmann [d], Johanna Biebl [d], Kirsi Manz [e], Eduard Kraft [d], Inge Eberl [c], Michael Zoller [b], Uli Fischer [a]

[a] Department of Clinical Nursing Research and Quality Management, University Hospital, LMU Munich, Munich, Germany
[b] Department of Anaesthesiology, University Hospital, LMU Munich, Munich, Germany
[c] Professorship of Nursing Science, Faculty of Social Work, Catholic University of Eichstätt-Ingolstadt, Eichstätt, Germany
[d] Department of Orthopaedics and Trauma Surgery, Musculoskeletal University Center Munich (MUM), University Hospital LMU Munich, Munich, Germany
[e] Institute for Medical Information Processing, Biometry, and Epidemiology, Ludwig-Maximilians-University, Munich, Germany

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ABSTRACT

Background: Early mobilization is only carried out to a limited extent in the intensive care unit. To address this issue, the robotic assistance system VEMOTION® was developed to facilitate (early) mobilization measures more easily. This paper describes the first integration of robotic assistance systems in acute clinical intensive care units.
Objective: Feasibility test of robotic assistance in early mobilization of intensive care patients in routine clinical practice.
Setting: Two intensive care units guided by anesthesiology at a German university hospital.
Participants: Patients who underwent elective surgery with postoperative treatment in the intensive care unit and had an estimated ventilation time over 48 h.
Methods: Participants underwent robot-assisted mobilization, scheduled for twenty-minute sessions twice a day, ten times or one week, conducted by nursing staff under actual operational conditions on the units. No randomization or blinding took place. We assessed data regarding feasible cutoff points (in brackets): the possibility of enrollment ($x \geq 50$ %), duration (pre- and post-setup ($x \leq 25$ min), therapy duration ($x = 20$ min), and intervention-related parameters (number of mobilizing professionals ($x \leq 2$), intensity of training, events that led to adverse events, errors or discontinuation). Mobilizing professionals rated each mobilization regarding their physical stress ($x \leq 3$) and feasibility ($x \geq 4$) on a 7 Point Likert Scale. An estimated sample size of at least twenty patients was calculated. We analyzed the data descriptively.
Results: Within 6 months, we screened thirty-two patients for enrollment. 23 patients were included in the study and 16 underwent mobilization using robotic assistance, 7 dropped out (enrollment eligibility = 69 %). On average, 1.9 nurses were involved per therapy unit. Participants received 5.6 robot-assisted mobilizations in mean. Pre- and post-setup had a mean duration of 18 min, therapy a mean of 21 min. The robot-assisted mobilization was started after a median of 18 h after admission to the intensive care unit. We documented two adverse events (pain), twelve errors in handling, and seven unexpected events that led to interruptions or discontinuation. No serious adverse events occurred. The mobilizing nurses rated their physical stress as low (mean 2.0 ± 1.3) and the intervention as feasible (mean 5.3 ± 1.6).
Conclusions: Robot-assisted mobilization was feasible, but specific safety measures should be implemented to prevent errors. Robotic-assisted mobilization requires process adjustments and consideration of unit staffing levels, as the intervention does not save staff resources or time.
Registration: clinicaltrials.org TRN: NCT05071248; Date: 2021/10/08; URL https://clinicaltrials.gov/ct2/show/NCT05071248.
Tweetable abstract: Robot-assisted early mobilization in intensive care patients is feasible and no adverse event occurred.

* Corresponding author at: Department of Clinical Nursing Research and Quality Management, University Hospital, LMU Munich, Marchioninistr. 15, 81377 Munich, Germany.
E-mail address: angelika.warmbein@med.uni-muenchen.de (A. Warmbein).

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What is already known

- Early mobilization has positive effects on intensive care patients like preventing the loss of muscle strength.
- Manual early mobilization in intensive care patients represents a high physical strain for mobilizing professionals.
- Robotic assistance systems for mobilization are increasingly being developed, but studies focus mainly on patient outcomes and safety.

What this paper adds

- This study addressed the feasibility of robot-assisted early mobilization in critically ill patients and the implementability in settings such as intensive care units.
- Robot-assisted early mobilization has a comparable risk profile to conventional early mobilization, with an adverse event rate of 1.8 %.
- The load on the mobilizing staff was appropriate, but introduction of robotics cannot counteract intensive staff retention and is time consuming.

1. Background

Early mobilization might have positive effects on the cognitive and functional health of patients in the intensive care unit (ICU) (Thomsen et al., 2008; Bailey et al., 2007; Morris et al., 2008; Burtin et al., 2009; Schweickert et al., 2009; Connolly et al., 2016; Reid et al., 2018; Beyer and Seidel, 2017; Luca et al., 2022). Mobilization helps to prevent the loss of muscle strength (Burtin et al., 2009) and can prevent functional disorders (Thomsen et al., 2008; Bailey et al., 2007; Fichtner et al., 2017; Fuest and Schaller, 2019). Patients in the intensive care setting may benefit from mobilization, in terms of shorter hospitalization (Morris et al., 2008; Schweickert et al., 2009) or faster recovery (Eggmann et al., 2018).

In most cases, nurses or physical therapists in intensive care units carry out mobilization therapy manually. Usually, at least two specialists are involved for the duration of the intervention (Bein et al., 2015), so the therapy is staff-intensive. In this context, it is problematic that the current shortage of qualified staff, especially nurses, also affects intensive care in Germany. According to the S2e guideline ("Positioning therapy and early mobilization for prophylaxis or therapy of pulmonary dysfunctions") (Bein et al., 2015), patients with pulmonary disease should undergo the first early mobilization 72 h after admission to the intensive care unit at the latest, if there is no medical reason indicating otherwise (Fichtner et al., 2017; Kumpf et al., 2018). Regarding the guideline, mobilization should be performed twice daily for 20 min. The recently revised iteration, embodied in the S3 guideline (Deutsche Gesellschaft für Anästhesie und Intensivmedizin, 2023), softened these criteria, emphasizing the central role of the patient's condition in determining the extent and frequency of mobilization. If patients are still sedated or ventilated (Barber et al., 2015), they lack the muscle tone to cooperate during mobilization therapy. Consequently, there is an increased physical and time burden on the mobilizing professionals, which can lead to the widely prevalent problem of back pain (Gilchrist and Pokorná, 2021) and other musculoskeletal disorders (Da Costa and Vieira, 2010; Ellapen and Narsigan, 2014) due to the heavy lifting work. In daily practice, this can result in reduced or less intensive mobilization (Hodgson et al., 2015).

Over the past few years, technology and robotics developers have addressed this issue (Yakub et al., 2014). Currently, there are several robotic assistance systems that can support (early) mobilization (Huebner et al., 2022; Klamt et al., 2021) and can physically relieve nurses (Bohlen et al., 2020; Brinkmann et al., 2022; Hegewald et al., 2018). These systems, which are technically adapted to the patient population, are already being tested and implemented in some hospitals (Dieterich et al., 2022; Calabrò et al., 2015; Charite University, n.d.; Peper et al., 2022). Studies have focused more on safe handling and feasibility concerning patient outcomes (Just et al., 2022), and less on implementation and feasibility in the context of intensive care units concerning aspects such as staff retention or time and effort.

For this purpose, a three-year research project was initiated. Prior to that, a comprehensive preliminary study was carried out, which focused on the current state of early mobilization in intensive care units and the experience gained to date with the implementation of robotic systems (Huebner et al., 2022; Klamt et al., 2021; Warmbein et al., 2023; Mehler-Klamt et al., 2022a).

The aim of this study was to investigate whether robotic assistance systems are feasible for mobilization of surgical patients in the intensive care unit. For this purpose, we examined to what extent robot-assisted early mobilization can be carried out in a homogenous patient population, whether patient safety incidents[1] (Larizgoitia et al., 2013) occur that cause harm (ICH Harmonised Tripartite, 1994), interruption or discontinuation, and how mobilizing nursing professionals assess this form of mobilization.

2. Methods

2.1. Study design and setting

This was a monocentric feasibility study with standardized observations (Thierbach and Petschick, 2019). The evaluation was part of a multi-thematic study design within the MobiStaR (mobilization of intensive care patients by a new standard in adaptive robotics) project (Warmbein et al., 2022). The overall study represented the first implementation of the robotic system VEMOTION® into the practical setting of acute clinical intensive care units. It included three study arms, which deal with feasibility, the experience of the mobilizing professionals (Mehler-Klamt et al., 2022b), and the effects on patient outcomes. Since these data were collected using various assessment methods and time points from different institutions, this article solely presents the thematic focus of the feasibility. Based on the development model of complex interventions of the Medical Research Council (Craig et al., 2019), the study took place in the feasibility phase. The study was registered on clinicaltrials.org (TRN: NCT05071248; Date: 2021/10/08). Reactive Robotics GmbH, Munich, Germany, developed the VEMOTION® system, which is CE certified and approved for intensive care patients. This was the only robot used in this study.

The study was conducted in two interdisciplinary intensive care units, guided by anesthesiology, at the university hospital in Munich, Germany. There were up to sixty nurses working in each ICU, so there was high staff rotation from shift to shift and between the caretaking of individual patients. The intervention took place from September 2021 to March 2022 during a peak phase of the COVID-19 pandemic, which restricted conditions during the study. Since the conventional mobilization therapy carried out in the two ICUs differed significantly from the planned robot-assisted intervention in terms of frequencies, durations, and intensity, no comparison was made in this study.

2.2. Participants

Robot-assisted mobilization was performed with adult patients who underwent scheduled surgery and planned postoperative treatment in an interdisciplinary ICU. The patients had given informed written consent to the study physicians prior to the procedure (ICH Harmonised Guideline Integrated Addendum to ICH E6(R1), n.d.). Postoperative treatment included an expected ventilation time of more than 48 h. As prerequisites for VEMOTION® training, patients had to weigh between 45 and 135 kg and be between 1.50 and 1.95 m tall. These criteria primarily applied to patients requiring a (lung) transplant operation. During the transplantation

[1] A Patient Safety Incident is defined as "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. A patient safety incident can be a reportable circumstance, a near miss, a no harm incident or a harmful incident (adverse event)" (Larizgoitia et al., 2013).

informed consent discussion, the study physicians approached them regarding their potential participation in the study. Patients were excluded if they were chronically ventilated or bedridden, had a clinical frailty scale score of ≥7 (Tipping, 2016), were at risk for or had elevated intracranial pressure, had a recent cerebral hemorrhage, or had pre-existing neuromuscular disease resulting in chronic limitation of strength and performance. An estimated sample size of at least 20 patients had been calculated, which can be found in the study protocol (Warmbein et al., 2022; Tabachnick and Fidell, 2014; Kinney et al., 2020).

Nursing professionals had to work in an anesthesiology intensive care unit and be trained in robot-assisted mobilization on this specific device. Nurses got detailed information about the study and its evaluation as part of the training (see Fig. 1). Participation in the study was voluntary. Since no personal data were collected, no additional written consent was obtained in this study arm besides that of the study arm evaluating behavior and experiences (Warmbein et al., 2022).

2.3. Description of materials

For enrollment eligibility, data was collected on the number of patients meeting the inclusion criteria, the number of patients included, and the number of dropouts. Regarding interventions, data collection included the frequency of robot-assisted and conventional mobilization in each shift. This involved documenting the duration, pre- and post-preparation time, and the number of personnel involved in mobilization. For robot-assisted mobilization, we recorded the degree of verticalization, duration at the highest level of verticalization, step count per minute, and total step count. We also documented all kind of patient safety incidents (Larizgoitia et al., 2013) that led to any kind of harm, f. e. adverse events (AEs) (ICH Harmonised Tripartite, 1994), or reasons for discontinuation. After completing robot-assisted mobilization, the performing nurses were asked to rate the feasibility and physical exertion of the mobilization on a Likert scale ranging from 0 to 7. The data collection forms were discussed with the mobilizing nurses. During the discussion, the target values for assessing the overall feasibility (≥4.0) and physical stress (≤3) were jointly established.

2.4. Clear descriptions of all processes, interventions, comparisons

The study covered the period of robot-assisted early mobilization of patients who met the inclusion criteria. The intervention was planned for twice a day for 20 min, for at least 10 times or for 7 days, beginning in the first 72 h after admission to the ICU (Bein et al., 2015). Data collection took place every day during the morning and afternoon shifts, if it was deemed safe following the recommendations and criteria of the Consensus Conference, decided by the responsible unit physicians and nurses (Hodgson et al., 2014). Recommendations followed the traffic light system (Rocca et al., 2016). In order to implement the intervention in the unit, a new process for the robot-assisted mobilization was established, and 10–12 nurses per unit were instructed on the use. During training sessions lasting 1.5 h, a manufacturer trainer instructed 3–4 nurses at a time in the device. The training followed the manufacturer's best practice training regimen, which encompassed not only the fundamental application, but also demonstrated modifications based on patients' needs and included emergency training. To facilitate the learning process, a healthy volunteer would lie in the patient bed, and the nurses would learn the procedure through hands-on practice. Follow-up training sessions were held as real mobilizations of patients. Once nurses were confident in using the robot, they were authorized to instruct other nurses.

After surgery, included patients were placed in special study beds that were compatible with the adaptive robotic system. For the intervention, the patient was secured in the study bed; the robotic system was connected to the bed and the patient with a belt system. The device moved the legs according to gait patterns and offered the possibility to raise the patient up to 70°, allowing passive and passive-assistive walking in bed.

Fig. 1. Training session with the robotic system.

After regaining consciousness, patients could determine the intensity of motion and verticalization of the bed. If the patient was not conscious, nurses performed mobilization carefully and with lower intensity. During the intervention as well as pre- and post-processing, members of the research team were present to support the nurses and collect data. The technical developers were available for additional training and refresher sessions in the introductory phase, and spontaneous requests for assistance during mobilizations were answered throughout the whole integration.

2.5. Statistical analysis

Data were collected on standardized forms and managed using Research Electronic Data Capture (REDCap) tools (Harris et al., 2009; Harris et al., 2019), maintained and secured by IT specialists. REDCap is a secure web-based software platform designed to support data capture for research studies. The data were pseudonymized using randomly assigned three-digit IDs and analyzed descriptively using R software (*R: A Language and Environment for Statistical Computing*, 2022). We described continuous variables as median and minimum/maximum values or mean and standard deviation, as appropriate. Categorical variables were described as frequency and percentage. In this study, robot-assisted mobilization was rated as feasible when a minimum amount of such mobilizations (i.e., 50 %) could be performed, no serious adverse events occurred, and it was judged acceptable by the users.

2.6. Enrollment eligibility

Every patient who met the inclusion criteria was included in the assessment of enrollment eligibility, which is where the potential of the intervention should be derived. We recorded the number of screened patients who were not included in the study. It was determined that at least 50 % of the patients should be included to consider the enrollment eligibility feasible, and the retention rate (number of patients who discontinued the intervention or had AEs) should be below 10 %.

2.7. Negative incidents and reasons for discontinuation

We systematically documented all patient safety incidents (Larizgoitia et al., 2013) or reasons for discontinuation within robot-assisted mobilization. These were categorized as follows:

(1) Serious adverse events (SAEs) ("any untoward medical occurrence that at any dose results in death or is life-threatening" (ICH Harmonised Tripartite, 1994)), adverse events (AEs) ("unfavorable changes in health, including abnormal laboratory findings, that occur in trial participants during the clinical trial or within a specified period following the trial" (ICH Harmonised Tripartite, 1994; U.S. National Libary of Medicine, n.d.).
(2) errors ("a broader term referring to any act of commission (doing something wrong) or omission (failing to do the right thing) that exposes patients to a potentially hazardous situation" (Patient Safety Network, 2019))

Furthermore, we created a classification for events that led to interruptions and discontinuations of the intervention but did not result in a (serious) adverse event or harm, nor occurred due to an error.

(3) unexpected events or experiences/organizational issues that did not result in any (potential) harm but led to an interruption or discontinuation of the intervention.

2.8. Intervention-related feasibility

To assess intervention-related feasibility, the duration and setup time should both be less than a mean of 25 min. To assess staff retention, the number of mobilizing professionals had to be less than two (compared with the recommendation of two professionals in the S2e guideline (Bein et al., 2015)). We also documented the degree of verticalization, minutes at the highest degree of verticalization, steps per minute, and total minutes of intervention (mean of 20 min). The mobilizing professionals rated their own physical stress (target value: a maximum mean of 3) and feasibility (target value: a minimum mean of 4) of every robot-assisted mobilization on a 7-point Likert scale.

2.9. Ethics approval and consent to participate

The study was approved by the Ethics Committee of Ludwig-Maximilians-University, Munich, Germany (21-0355). Patients consented to participate in written form.

3. Results

3.1. Enrollment eligibility

During the recruitment period, 525 patients were treated in the two ICUs. Thirty-two patients met the prerequisites for participation in the study and were screened for enrollment (see Fig. 2). Because of the restrictions imposed by the COVID-19 pandemic, there has been a reduction in the number of elective procedures performed. Consequently, this has led to a decrease in the pool of eligible patients available for screening, as emergency patients were unable to give informed consent. Nine eligible patients could not be enrolled for logistic reasons (e.g., patient

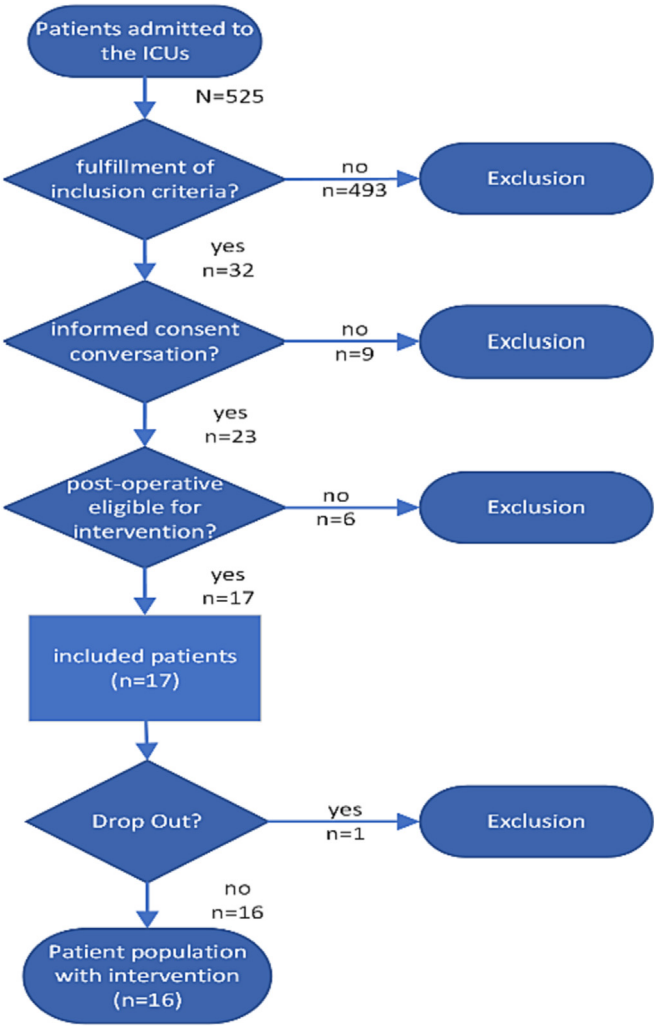

Fig. 2. Selection and inclusion/exclusion process of the study population.

Table 1
Overview of patient characteristics. Normally distributed data are shown as mean ± SD and non-normally distributed data as median (IQR). Categorical data are summarized as frequency (percentage). SD = standard deviation, IQR = interquartile range.

	All (n = 23)	Intervention (n = 16)	Dropout (n = 7)
Male sex	12 (52 %)	8 (50 %)	4 (57 %)
Age in years	58 ± 8.8	58 ± 8.4	56 ± 10.3
Height in cm	170 ± 6.9	169 ± 7.1	172 ± 6.2
Weight in kg	66 ± 11.1	67 ± 11.9	67 ± 9.8
BMI[a] in kg/m^2	23 ± 4.2	23 ± 4.3	22 ± 4.2
Length of ICU stay in days	14 (25)	14 (19)	23 (21)
Length of invasive ventilation (in h)	191 (653)	126 (501)	524 (435)
No. robot-assisted mobilizations	–	6 (4.5)	–
Pre-op. FSS ICU[b]	35 (0)	35 (0)	35 (0)
SAPS II[c] (Day 0)	40 ± 10.3	38 ± 8.6	47 ± 12.3
RASS[d] (Day 1)	−5 (0)	−5 (1)	−5 (0)
SOFA[e] (Day 1)	8 ± 3.3	7 ± 2.5	12 ± 2.1

[a] BMI = body mass index.
[b] Pre-op. FSS ICU = pre-operative Functional Status Score for the Intensive Care Unit.
[c] SAPS II = Simplified Acute Physiology Score II.
[d] RASS = Richmond Agitation Sedation Scale.
[e] SOFA = sepsis-related organ failure assessment score.

not available for information and consent preoperatively). The study physicians invited twenty-three patients to participate and were fully informed. All patients consented in writing to participate in the study. Within the study period, one patient withdrew consent postoperatively. The predefined target criterion of study participation of at least 50 % of the potential patients was met, with 69 % (16/23). Of the 23 patients included, 7 patients (30 %) were not able to undergo the intervention due to extracorporeal membrane oxygenation (ECMO) treatment and hemodynamic instability (n = 6) or withdrawal of consent (n = 1). The patient population is described in Table 1.

In total, the nurses carried out 90 robot-assisted mobilizations with 16 patients. In 161 instances, mobilization could not be performed. Medical contraindications (e.g., ECMO therapy) were a factor in sixty-nine cases, organizational reasons such as staffing shortages were mentioned in forty-two cases, patients expressed different preferences in thirty cases, and mobilization was prevented in twenty cases due to (planned) medical treatment (see supplemental material). Using robotic assistance, 70 % of the patients were mobilized. All patients also underwent standard mobilization therapy.

On average, mobilization began after 18 h. Fifteen of the sixteen patients (94 %) were mobilized within the first 72 h from ICU admission. The first robot-assisted mobilization started on average after 26 h. One patient was first mobilized after 115 h (see Fig. 3).

On average, the patients were mobilized using robotic assistance 5.6 (±2.9) times within the one-week period. The number of mobilizations varied between 2 and 10 units. The setup time varied from 9 to 45 min and post-processing time from 3 to 20 min (mean 8 min). With a mean setup time of 18 min and mobilization time of 21 min, the target time of a maximum 25 min was met. There was no observed decrease in setup times throughout the duration of the study.

3.2. Reasons for discontinuation and patient safety incidents

Within the study period, eight discontinuations of the intervention occurred (see Table 2). One discontinuation was due to the indication of pain by the patient. Additionally, one intervention was prematurely terminated due to a user error. These two events present the most important reasons for discontinuation, corresponding to 1.8 % of all interventions. In four cases, patients discontinued the intervention due to short-term exhaustion, wherein one event was classified as patient safety incident. Two discontinuations were unrelated to the intervention (attributed to medical treatment and bowel movement). In summary, there were no serious adverse events and three interruptions with one pain, one exhaustion and one incorrect utilization of the therapy device. Five interruptions were non-critical events such as bowel movement, exhaustion and interruption for medical treatment.

Throughout the entire study period, the researchers documented twenty-two events that posed an impairment factor in the context of the intervention. Among these, fourteen events (64 %) were resolved during the intervention, enabling the completion of the intervention. This included one AE with pain, which the attending nurse successfully addressed with medication administration, and the patient agreed to complete the intervention.

The most frequent events were errors related to robotics handling, such as misses in connecting the adaptive robot to the study bed or entrapment of infusion cables in the robot's fixation system. These events caused no harm but were considered avoidable. No serious adverse event occurred; one incidence of pain was categorized as adverse event.

3.3. Staff deployment and evaluation

Across all mobilizations, the mean number of professionals performing the therapy was 1.9. Thus, the target criterion of <2 individuals was met, but the number could not be reduced to 1. The number of mobilizing

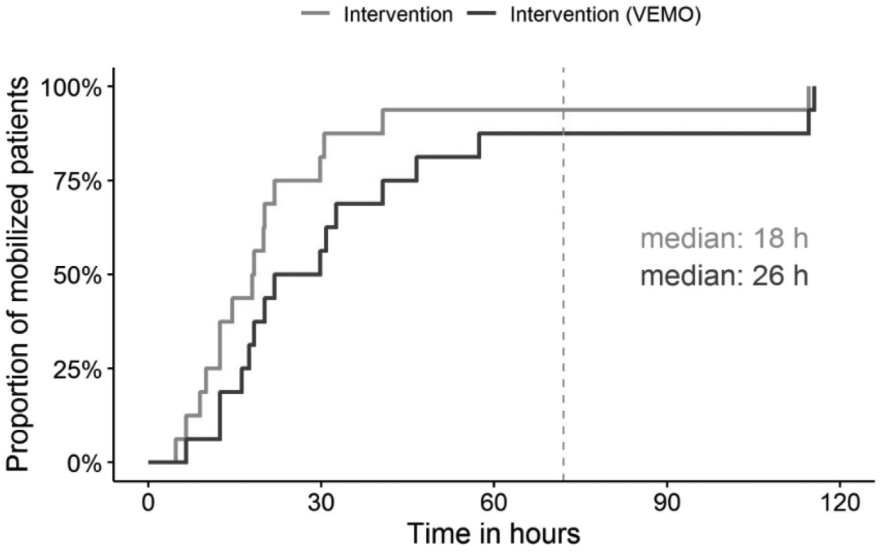

Fig. 3. Kaplan–Meier curve for time to first mobilization. Light gray curve shows time to first mobilization of any type and dark gray curve shows time to first robot-assisted mobilization. Dashed gray line shows 72 h since ICU admission.

Table 2
Reasons for discontinuations and patient safety incidents in robot-assisted mobilization.

	Category	Description	Number (total)	Discontinuations	
				In patient safety incidents	In uncritical events
Patient safety Incidents	SAE[a]	–	–	–	–
	AE[b]	Pain	2	1	–
	Errors	Incorrect utilization of the therapy device	10	1	–
		Lack of workplace monitoring	1	–	–
		Software update error	1	–	–
Other events	Organizational issue	Medical treatment	1	–	1
	Unexpected events/experiences	Bowel movement	2	–	1
		Exhaustion	4	1	3
		Maximum force shutdown of robot by the patient	1	–	–
	TOTAL			3	5
			22	8	

[a] SAE = serious adverse event.
[b] AE = adverse event.

specialists varied between one and four for the individual therapy units (one person, 19 %; two persons, 65 %; three persons, 11 %; four persons, 1 %). This number did not vary in the course of therapy for individual patients.

After each mobilization, the nurses responsible for the mobilization assessed their own physical stress and the feasibility of the training session. On average, physical stress was rated as 2.0 (±1.3) on a scale from 0 (no stress) to 7 (very high stress). The target criterion value of ≤3 was achieved. The assessed physical stress varied according to the number of mobilizations the individual patient received. The mean rating that was above the target criterion was exceeded in five of ten mobilizations (see supplemental material). As a result, the overall physical stress can be considered appropriate, but a general relief of the physical burden could not be confirmed due to the outliers.

General feasibility was assessed by the mobilizing nurses on a scale from 0 (not feasible) to 7 (very feasible). Overall, with an average rating of 5.3 (±1.6), the target criterion of 4.0 was met. Therefore, the mobilizing nurses rated the robotic assistance as feasible. Assessing the different stages of mobilization units, no changes were found (see supplementary material).

3.4. Intervention-related overview

The robot-assisted mobilization parameters were assessed as part of the evaluation. The verticalization of the patient ranged between 14 and 54° (31.0 ± 8.6). For the most part, patients indicated that they did not want further verticalization. The maximum of 70° was not used within the patient cohort. On average, the patients remained at the highest degree of verticalization for 13.3 (±5.2) minutes. With a median of 20 steps per minute (IQR = 0) a range of between 270 and 682 steps (median 407.0, IQR = 38) was documented. The movement of the legs was quite feasible, but the verticalization was used cautiously.

4. Discussion

This study represents the first use of VEMOTION® in early mobilization of critical care patients in acute care hospitals. In here, a 1.8 % rate of adverse events with robotic-assisted mobilization underscores the comparable safety risk of this approach compared to conventional methods, which reported a 2.6 % rate (Nydahl et al., 2017). The contrast becomes even more significant considering that standard care interventions show a 50 % incidence of serious adverse events (Decormeille et al., 2021) while no serious adverse event occurred in our six months trial period. Despite the documented benefits of any kind of mobilization (Burtin et al., 2009) for patient populations such as lung transplant patients (Renner et al., 2023), the observed mobilization rates in other studies remain at 16 % (Hodgson et al., 2015) or range from 8 % to 53 % (Nydahl et al., 2013; Alqahtani et al., 2022). This highlights the need for careful consideration of mobilizing critically ill patients and the importance of transparent communication about potential risks.

Especially in innovations like robotics, detailed examinations about benefits and risks are essential. Calabrò et al. (2015) assessed the acceptability and the risks in patients with aneurysmal subarachnoid hemorrhage using a comparable mobilization robot, Erigo. This robot is very similar to the one used in our study, except for the need to transfer the patient from the bed to the training device. The authors reported no adverse events or discontinuations in this vulnerable patient population. Our study revealed two adverse events in the form of pain, one of which led to discontinuation of the intervention. This reaction was not desirable, but was deemed tolerable due to its short-term occurrence and as an expected risk in view of the temporal proximity to the transplantation procedure (Wickerson et al., 2016). Also exhaustion (or fatigue) has been shown to be a normal response to surgery after less invasive procedures, such as day surgery (Donadello and Gottin, 2020; Mendy et al., 2020). Patients who have undergone lung transplantation continue to experience fatigue one year after surgery (Reinsma et al., 2006). Since the exhaustion experienced by the patients had no influence on patient parameters, condition or medication, it can also be regarded as an undesirable, but tolerable side effect of the training. This contrasts with the case study by Dieterich et al. (2022), in which a patient was successfully guided through the weaning process using the VEMOTION® system, with no mobilization-related incidents reported.

In addition to Serious Adverse Events and Adverse Events, we also focused on all events that interrupted or even led to discontinuation of the intervention, as robotics is a highly complex technology that requires accurate and precise handling (Servaty et al., 2020). Using the robotic system in daily clinical practice during a peak period of the COVID-19 pandemic, characterized by increasing staff shortages and complex patient treatment protocols, was challenging and the goal of ten mobilizations per patient was rarely achieved. In this context, user errors or lapses in attention at the workstation led to longer setup times or discontinuations. Even though these user errors, in their present state, did not result in adverse events, they carried the risk for delays or patient discomfort. The ongoing demand for the designated nurses' presence (Bertelsen et al., 2020) disturbed the nurses' everyday routine, as they typically had to provide care for two patients. These were rarely placed in the same room, requiring the involvement of an additional nurse to assess the condition of the other patient during the intervention. This, coupled with the alignment of setup times with therapy duration (Waibel et al., 2022), occasionally led to the substitution of robotic assistance for more time-efficient conventional mobilization. This differs from other trials in which either nurses or physiotherapists were explicitly assigned to perform the intervention, or the safety of the intervention was tested in feasibility studies (Bertelsen et al., 2020; Gandolfi et al., 2017). To make robot-assisted mobilization an intervention that saves human resources, two other factors should be taken into account: the training of core teams within a unit, indicated in our preliminary

research (Warmbein et al., 2023) as well as the need to develop technology that is easy to use in practice, highlighted by Bertelsen et al. (2020).

However, Brinkmann et al. (2022) observed that the implementation of robotic systems for manual patient handling can alleviate physical workload and musculoskeletal strain for nurses. According to the current S3 guideline (Deutsche Gesellschaft für Anästhesie und Intensivmedizin, 2023), two specialists should be involved in the mobilization. In our study, the average number of people using the robotic system was 1.9, which can be regarded as a positive result when considering the overall staff resources. This presents a chance to provide a health-promoting intervention for nurses by reducing physically demanding tasks (Dieterich et al., 2022), and an opportunity to provide physical support to nurses.

Another study (Grunow et al., 2022) also described a lack of space for handling and storage as a barrier to implementing new robot-assisted therapies. The typically limited space in intensive care units was not a critical issue in our study, although the structural conditions were not designed for the use and storage of mobile robotics.

5. Limitations

The study only focused on the mobilization robot VEMOTION® so the results might vary with other models. While conducting the evaluation, the COVID-19 pandemic was a great burden for the staff in ICUs and influenced the frequency and length of robot-assisted mobilization. Another limitation is that procedures in the interdisciplinary intensive care unit are not schedulable. A comparison with conventional early mobilization could not be implemented, as patients were primarily passively conventionally mobilized. The cutoff points for assessing feasibility and self-perceived physical stress by the users were jointly determined with the nurses to provide a practical assessment. It should be noted that these cut-off points may vary in other healthcare institutions. Real-life conditions are described, but their transferability to other settings is restricted.

6. Conclusions

Robot-assisted early mobilization in ICUs is feasible for nurses mobilizing a pre-defined patient population. However, the study highlighted the need for more comprehensive support and training to reduce errors. Notably, no serious harm to patients was observed during this study, but incorrect usage increases the potential for harm. At the same time, the introduction of robotics cannot counteract intensive staff retention and is time consuming. Further research, in form of a larger randomized trial, is needed on the long-term implementation of robotics and related processes in the ICU setting. Since challenges such as nursing shortages cannot be solved in the near future, increased efforts should be made to support nurses with new technologies such as robotics.

Consent for publication

Not applicable.

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CRediT authorship contribution statement

Angelika Warmbein: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Lucas Hübner:** Writing – review & editing, Writing – original draft, Methodology, Investigation. **Ivanka Rathgeber:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Amrei Christin Mehler-Klamt:** Writing – review & editing, Methodology, Investigation. **Jana Huber:** Writing – review & editing, Methodology, Investigation. **Ines Schroeder:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Christina Scharf:** Writing – review & editing, Methodology, Investigation. **Marcus Gutmann:** Writing – review & editing, Methodology, Investigation. **Johanna Biebl:** Writing – review & editing, Methodology, Investigation. **Kirsi Manz:** Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Formal analysis. **Eduard Kraft:** Writing – review & editing, Funding acquisition, Conceptualization. **Inge Eberl:** Writing – review & editing, Project administration, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Michael Zoller:** Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Uli Fischer:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Data availability

The datasets generated or analyzed during the current study are not publicly available but will be available from the study directors upon reasonable request.

Declaration of Competing Interest

The authors declare that they have no competing interests. The company that manufactures the VEMOTION® system is part of the overall study consortium. However, it was not part of the clinical study or the analysis team.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2024.104702.

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