The Promise and Opportunity Costs of New Rehabilitation Technology in the ICU*

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ICU survivors are at risk of important disability, which can last up to 8 years post-critical illness (1). The COVID-19 pandemic saw a marked increase in critically ill patients, and subsequently an increase in ICU survivors at risk of post-ICU disability (1). While rehabilitation in ICU may help improve patient outcomes, delivery became particularly complex during the pandemic given staff shortages and increased infection prevention and control measures. Technology has the potential to offload some demands from clinicians, potentially increasing capacity to provide rehabilitation treatments to critically ill patients, particularly when capacity is strained.

TRIAL SUMMARY

In this issue of *Critical Care Medicine*, Lorenz et al (2) conducted a single-center, four-ICU, 20-patient pilot randomized controlled trial (RCT) to evaluate the feasibility of robotic-assisted mobility activities in mechanically ventilated patients with COVID-19. The authors used new technology that combines three types of equipment in critical care: a motorized tilt table (3), multimodal in-bed cycling (passive or active-assisted, actuated by the patient) (4), and hospital beds that facilitate verticalization. The intervention was planned for two sessions per day for a total of 5 days, for a duration of 20 minutes or more. If a patient was extubated, the intervention was stopped. The comparison group received usual care rehabilitation. Coprimary outcomes were maximum and mean ICU Mobility Scale (IMS) (5) and Surgical ICU Optimal Mobilization Score (SOMS) (6) measured during rehabilitation sessions for the maximum 5-day treatment period.

The authors randomized 20 patients (10 robot-assisted, 10 usual care) across four ICUs in Germany. Patient characteristics were similar across groups, with a median age greater than 55 years, and most participants were male (75%). Patients had a median Acute Physiology and Chronic Health Evaluation II score of 17.5 (intervention) and 20.5 (usual care). Patients received mechanical ventilation for a median of 29 (intervention) and 32 (usual care) days and had an ICU length of stay (LOS) for 42.5 and 33 days, respectively. Five patients (two intervention, three usual care) died in ICU (25% mortality). The remaining 15 survivors had a median of 38 (intervention) and 39 days (usual care) hospital LOS.

Implementation of the robotic-assisted mobilization intervention was feasible, with 80 of 90 planned sessions delivered (89% fidelity). Following extubation, 10 sessions did not occur as per protocol. The time for equipment set up for the first intervention treatment was a median of 30 minutes (range,

*See also p. 683.

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27–53 min) and 12 minutes (range, 10–23 min) thereafter. The intervention and usual care groups received 232.5 and 147.5 minutes of therapy across 5 days, with 85 minutes more in the intervention group. Treatments occurred across 8.5 total sessions per patient in the intervention group (median 25 min/session) and 4.5 in the usual care group (median 33 min/session). Intervention delivery required two people per session, whereas usual care required one. Four safety events occurred across the 80 intervention sessions (two altered blood pressure, two increased agitation), while none occurred during usual care. There were no differences in coprimary outcomes at either timepoint (absolute maximum and mean values 0 [IMS, passive movement] and 1 [SOMS, passive range of motion]).

The study by Lorenz et al (2) has several important strengths and addresses contemporary clinical issues in the ICU. First, the authors successfully conducted a pilot RCT during the height of the COVID-19 pandemic. The study team modeled study team dedication to completing the trial with a physician and a research assistant directly involved in mobilization sessions. In both groups, randomized treatments started within the first 3 days of ICU admission. This very early treatment delivery is likely due in part to use of a deferred consent model. The authors clearly reported and contextualized safety events for both the intervention and comparison groups. Of note, there were no safety events during usual care.

CONSIDERATIONS FOR FUTURE RESEARCH

The Role of Pilot and Feasibility Studies

The study by Lorenz et al (2) provides an example of the importance of pilot and feasibility studies to optimize intervention implementation before evaluation. If an intervention cannot be successfully implemented, it is impossible to determine its impact on patient outcomes. Pilot and feasibility studies assess implementation success, which is particularly relevant for complex rehabilitation interventions where there are multiple interacting components (7). From a feasibility standpoint, there are several critical design considerations before proceeding with a larger RCT. The inclusion criteria may need to be broadened to achieve adequate recruitment in a timely manner. Investigators may consider leveraging the expertise of allied health professionals and research personnel to support the refinement of trial design and conduct. Given the unanticipated increase in clinical staff required for the intervention compared with usual care, investigators will need to consider the staffing requirements to deliver the intervention in a larger RCT.

Comparator Groups

Comparator groups are critical to establishing the safety and feasibility of new interventions. The authors used an unrestricted usual care comparison group. This was an appropriate choice given the lack of known best practice treatments for patients with COVID-19 at the time of study design (8). The authors reported patients in the usual care group received passive mobilization, and acknowledged that these passive activities required further description. The Rehabilitation Treatment Specification System (RTSS) could facilitate more detailed reporting (9). The RTSS is a tool to guide the description of rehabilitation treatments at the level of individual sessions, according to their relationship with patient outcomes (10). Given the previously documented heterogeneity and international practice variation (11), granular documentation and reporting of usual care characteristics will enhance our understanding of rehabilitation treatments, particularly in unique patient groups such as those with COVID-19.

Opportunity Cost of New Rehabilitation Technology in the ICU

Introducing technology into the ICU comes at an opportunity cost. The authors hypothesized that use of the robotic technology would decrease human resources required for ICU-based rehabilitation. In contrast, more clinical staff were required to provide a similar amount of therapy per treatment session. Rehabilitation interventions in the ICU may seem simple—many patients receive similar interventions, including range of motion activities, muscle strengthening and mobility activities. However, complex decision-making and just-in-time personalization underlies each rehabilitation treatment session in the ICU, especially in the earlier phases of critical illness before the patient stabilizes.

Rehabilitation technologies in the ICU still require real-time supervision by an individual with critical

care knowledge. This supervisory time could come at a therapeutic opportunity cost, particularly if there is a mismatch between the patient's current physical capacity and the technology capabilities. The time required for setup and takedown of a new technology is another consideration. In the study by Lorenz et al (2), equipment setup was a median of 30 minutes for the first session and 12 minutes for each subsequent session. With two sessions per day in the intervention group, this preparation time equates to the duration of one additional usual care session.

CONCLUSIONS

We applaud the authors for conducting this complex intervention as a pilot RCT during the COVID-19 pandemic. The authors demonstrated the feasibility and safety of introducing robotic rehabilitation technology into the ICU environment. While technology may augment rehabilitation treatments, it will never replace the humanistic, thoughtful, and complex decision-making made by clinicians caring for critically ill patients. We are excited to see the next phase of this research program.

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Evolving Understanding of Patients' Experiences in Acute Care Trials Without Prospective Consent*

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Challenges related to informed consent have plagued clinical trials in critical care because patients are acutely ill, study interventions must be delivered quickly, and appropriate decision-makers are often unavailable in the necessary timeframe. Importantly, regulatory provisions in most countries exist that allow research to occur in this context without prospective consent (1). In European Union countries, these regulations typically use a deferred consent model. U.S. regulations permit an exception from informed consent (EFIC) for clinical trials in emergency settings that meet certain criteria (2, 3). The most notable difference between deferred consent and EFIC regulations

***See also p. 694.**

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