Is an Earlier and More Intensive Physical Therapy Program Better?

To the Editor:

We read with great interest the recent article by Moss and colleagues and appreciated the authors' efforts to determine whether an intensive physical therapy (PT) program improved long-term physical functional performance compared with the standard-of-care PT program (1). However, we would like to point out three concerns regarding this work.

First, as the authors mentioned in the discussion, the timing of the first PT session did not appear to be "early." In a landmark study showing the efficacy of early mobilization in mechanically ventilated patients, Schweickert and colleagues started their intervention within 2 days (2). Therapy was initiated for the patients in the Moss and colleagues study at a median of 8 days after intubation, which was nearly equivalent to that of Schweickert and colleagues' control group. However, regardless of the PT program, a higher percentage (~50%) of this study population was discharged for home care than the control group (24%). We would like to have additional information on the intensity of early exercise/mobility before the patients were randomized and outside of the PT sessions.

Second, the median duration of mechanical ventilation was a little longer than that of Schweickert and colleagues' study, despite a comparable Acute Physiology and Chronic Health Evaluation II score. This suggests that in the Moss and colleagues' study the presence of other factors made ventilator weaning difficult (1). Particularly, delirium affects not only the duration of mechanical ventilation but also long-term cognitive impairment (3). The provision of information regarding the incidence and effects of delirium or other factors, including nutritional status, might help the readers better understand the results.

Third, the short form of the Continuous Scale Physical Functional Performance Test (PFP-10) includes the instrumental activities of daily living (IADL) (4). The present PT program, however, was based on a national survey (5) and did not necessarily include IADL training. Whether a PT program alone could improve the IADL remains uncertain. The PFP-10 score could also be affected by the difference in age between the groups (6). Taken together, the outcome setting on the basis of PFP-10 might not be appropriate for the evaluation of the efficacy of the PT program.

Elucidating the aforementioned factors might help in interpreting the results better and in establishing a better intensive PT program. ■

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Reply

From the Authors:

We appreciate the opportunity to respond to the letter from Taito and colleagues regarding our clinical trial of an intensive physical therapy program for patients with acute respiratory failure (1). Their letter raises several important issues concerning the timing of the intervention, patient characteristics, and the effectiveness of our primary outcome variable. All of these issues are fundamental concerns that were intensely scrutinized during the design of this clinical trial.

For patients with acute respiratory failure, the proper time to start a physical therapy program is currently unknown. Although earlier interventions seem to make sense, muscles can be inflamed and undergo proteolysis early in the course of critical illness. Exercise at this time may be potentially detrimental. Our trial was not designed to study early versus late physical therapy but rather to determine the efficacy of an intensive physical therapy program versus a standard-of-care physical therapy program for patients at high risk of developing intensive care unit-acquired weakness. Because longer duration of mechanical ventilation is associated with the development of intensive care unit-acquired weakness, we deliberately enrolled patients who required mechanical ventilation for 4 or more days. In our trial, no patients received therapy delivered by a physical therapist before enrollment into the trial. Importantly, the intensity of our physical therapy program was greater than the interventions delivered in previously reported trials (2, 3).

The inclusion criteria for our study required mechanical ventilation for more than 4 days. In contrast, the inclusion criteria for the Schweickert and colleagues study required mechanical ventilation for less than 3 days (2). The differences in these inclusion criteria are likely responsible for the longer duration of

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mechanical ventilation between patients enrolled into the two studies. The overall longer total duration of mechanical ventilation for our patients was 10 days compared with 4 to 5 days in the Schweickert and colleagues study (2). In addition, Acute Physiology and Chronic Health Evaluation II scores are not accurate predictors of duration of mechanical ventilation (4). Unfortunately, we did not specifically collect information regarding delirium or nutritional status in our study.

Finally, proper interpretation of a clinical trial requires a complete understanding of the complexities of the primary outcome measure. Our primary outcome measure (Continuous Scale Physical Functional Performance Test short form [CS-PFP-10]) was specifically designed to capture capacity for physical performance with possible scores from 0 to 100. Tasks included on the CS-PFP-10 represent common daily activities that do not require specific training to be completed. At 6 months after hospital admission, the total CS-PFP-10 scores of 39 (intervention) and 44 (control) indicate a substantial degree of functional limitation when compared with average CS-PFP-10 scores of 63 for nondisabled individuals aged 55 to 64 years and 71 for nondisabled individuals aged 45 to 54 years (5).

In summary, we were disappointed that our clinical trial did not demonstrate that an intensive physical therapy program was beneficial for patients with acute respiratory failure. However, we hope the critical care research community learns from this trial and that our findings help frame future physical therapy-based research for critically ill patients. ■

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Daily Home Spirometry: A New Milestone in the Field of Pulmonary Fibrosis

To the Editor:

We read with great interest the article by Russell and colleagues regarding the use of daily home spirometry as a tool for detecting progression in idiopathic pulmonary fibrosis (1). This study shows that home spirometry is highly informative and feasible in patients with idiopathic pulmonary fibrosis (IPF) (1). We believe this article represents another milestone in the rapidly evolving field of IPF. Indeed, our understanding of disease pathogenesis has improved substantially, better-defined diagnostic criteria have been agreed on by the American Thoracic Society/European Respiratory Society/Japanese Respiratory Society/Latin American Thoracic Association, and, perhaps most importantly, two antifibrotic agents have finally become available for patients with IPF (2). Yet, this implies new challenges in clinical trial design and treatment decisions. In fact, placebo-controlled trials will be troublesome, and probably unethical, and new treatment protocols will likely evaluate the efficacy of investigational agents as compared with placebo as add-on with either pirfenidone or nintedanib as background therapy, which is likely to make the window of effect much smaller (3).

In their article, Russell and colleagues show that monitoring patient-administered daily FVC in patients with IPF is feasible and reliable, as the differences generated by less-accurate measurement might be leveled out by the frequency of measurement (1). Although daily home monitoring of FVC appears to provide a better assessment and prediction of disease behavior than traditional periodic hospital-based readings, additional data in larger cohorts are needed before daily home spirometry can be used in routine patient care and early-phase clinical trials. Specifically, more data are needed on optimal strategies to familiarize interstitial lung disease teams with the technique, patient compliance, misperformance, and validation of the quality of individual daily readings. In fact, FVC measurement in patients with IPF is challenging owing to the progressive nature of the disease and the fact that the degree of psychological impairment is strictly linked with perception of dyspnea (4), which, in turn, can influence patient performance, especially if the maneuver is performed without supervision. This is a major challenge and needs special attention and support. Likewise, methods should be developed for handling mental implications of the feedback (e. g., slowly progressive decline) patients receive by measuring their lung function daily. Future studies should also use spirometers with electronic records of results, as manual transcription of daily readings by individual patients may introduce errors. Although daily evaluation of FVC is more sensitive than hospital-based measurements in predicting disease behavior, because of the inability of the latter to capture accurately the variable and unpredictable loss in FVC (5), unsupervised home spirometry appears to underestimate the values obtained when readings are supervised by a respiratory physiologist and obtained on hospital-based lung function equipment (1), although it is unknown whether this underestimate is effort or equipment related. Accordingly, a study comparing unsupervised daily home-based spirometry with hospital-based readings every 3 months as recommended by current guidelines would be valuable. Finally, future studies should explore