

ORIGINAL RESEARCH

# Construct Validity of the Chilean-Spanish Version of the Functional Status Score for the Intensive Care Unit: A Prospective Observational Study Using Actigraphy in Mechanically Ventilated Patients



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## Abstract

**Objective:** To evaluate the construct validity (hypotheses testing) of the Chilean-Spanish version of the Functional Status Score for the Intensive Care Unit (FSS-ICU) using continuous actigraphy from intensive care unit (ICU) admission to ICU discharge.

**Design:** The Chilean-Spanish version of the FSS-ICU was used in a prospective observational study to mainly evaluate its correlation with actigraphy variables. The FSS-ICU was assessed on awakening and at ICU discharge, while actigraphy variables were recorded from ICU admission to ICU discharge.

**Setting:** A 12-bed academic medical-surgical ICU.

**Participants:** Mechanically ventilated patients (N=30), of 92 patients screened.

**Interventions:** Not applicable.

**Main Outcome Measures:** Construct validity of the FSS-ICU Chilean-Spanish version was assessed by testing 12 hypotheses, including the correlation with activity counts, activity time (>99 counts/min), inactivity time (0-99 counts/min), muscle strength, ICU length of stay, and duration of mechanical ventilation.

**Results:** The median FSS-ICU was 19 points (interquartile range [IQR], 10-26 points) on awakening and 28.5 points (IQR, 22-32 points) at ICU discharge. There was no floor/ceiling effect of the FSS-ICU at awakening (0%/0%) and only a ceiling effect at ICU discharge that was acceptable (0%/10%). Less activity time was associated with better mobility on the FSS-ICU at both awakening ( $\rho = -0.62, P < .001$ ) and ICU discharge ( $\rho = -0.79, P < .001$ ). Activity counts and activity time were not correlated as expected with the FSS-ICU.

**Conclusions:** The Chilean-Spanish FSS-ICU had a strong correlation with inactivity time during the ICU stay. These findings enhance the available clinimetric properties of the FSS-ICU.

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Decreasing mortality rates in the intensive care unit (ICU) have led to survivors who have functional disability even 5 years after hospital discharge.<sup>1</sup> Part of the challenge for clinicians and researchers is to design and use measurement instruments that could detect physical functioning issues early during the ICU stay.<sup>2</sup> In the ICU setting, 60 instruments focused on the measurement of physical functioning have been identified, of which 38 measure

the mobility domain.<sup>3</sup> Based on their clinimetric properties, 4 instruments measuring mobility and designed for the ICU setting have been recommended<sup>4,5</sup>: Chelsea Critical Care Physical Assessment Tool (CPAx),<sup>6</sup> Intensive Care Unit Mobility Scale (IMS),<sup>7</sup> Physical Function in Intensive Care Unit Test-scored (PFIT-s),<sup>8</sup> and Functional Status Score for the Intensive Care Unit (FSS-ICU).<sup>9,10</sup> Of these 4 instruments, FSS-ICU is the only one that assesses the level of physical assistance required by the patient when performing functional activities on the bed, out of bed, and walking.

The FSS-ICU is a widely used instrument because it is available in English,<sup>10</sup> Portuguese,<sup>11</sup> Turkish,<sup>12</sup> and Spanish,<sup>13</sup> and its reliability, validity, responsiveness, and interpretability have been evaluated in multiple studies<sup>10,14,15</sup> although not specifically for the Chilean-Spanish version. The validity of the FSS-ICU has been assessed through correlation analysis against other physical functioning measurement instruments, such as the Medical Research Council Sum Score (MRC-SS) ( $r^2=0.32-0.81$ ), the Activities of Daily Living ( $r^2=0.39-0.86$ ), the Instrumental Activities of Daily Living ( $r^2=0.48-0.57$ ), PFIT-s ( $\rho=0.85-0.87$ ), and the IMS ( $\rho=0.46-0.95$ ).<sup>10,15</sup> However, physical functioning refers to a broad concept, including physiological functions, neuromuscular functions, and mobility.<sup>16</sup> The subjective nature of the assessment of mobility means there is no objective reference standard for its measurement. Therefore, using accelerometer-derived measures of human activity in the ICU could be an alternative to solve this issue.<sup>17,18</sup>

Actigraphy is a noninvasive alternative for quantifying movement continuously<sup>19,20</sup> that has a good correlation with direct observation of human movement,<sup>21</sup> providing that consideration is given to the type of device and wear location for the measurement variable. Actigraphy uses accelerometers and has been validated in a wide variety of admitted and outpatient populations.<sup>22-24</sup> Its use in patients in the ICU is simple because it is a small instrument that does not interfere with clinical procedures and has been used in the ICU setting to measure human activity.<sup>25,26</sup>

The main aim of this study was to assess the construct validity (hypotheses testing) of the Chilean-Spanish version of the FSS-ICU using 3 variables measured through continuous actigraphy (activity counts, activity time, and inactivity time) in mechanically ventilated patients from their admission to ICU discharge. The secondary aim was to test the correlation of the FSS-ICU with MRC-SS, ICU length of stay (LOS), and duration of mechanical ventilation.

#### **List of abbreviations:**

<b>CPAx</b>	<b>Chelsea Critical Care Physical Assessment Tool</b>
<b>FSS-ICU</b>	<b>Functional Status Score for the Intensive Care Unit</b>
<b>ICU</b>	<b>intensive care unit</b>
<b>ICU-AW</b>	<b>intensive care unit—acquired weakness</b>
<b>IMS</b>	<b>Intensive Care Unit Mobility Scale</b>
<b>IQR</b>	<b>interquartile range</b>
<b>LOS</b>	<b>length of stay</b>
<b>PFIT-s</b>	<b>Physical Function in Intensive Care Unit Test-scored</b>
<b>MRC-SS</b>	<b>Medical Research Council Sum Score</b>

## **Methods**

### **Study design**

A prospective observational study was conducted to assess the FSS-ICU clinimetric properties in a 12-bed academic medical-surgical ICU. The clinimetric properties were defined based on the consensus-based standards for the selection of health status measurement instruments.<sup>27</sup> This article followed the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines.<sup>28</sup> This study was reviewed and approved by the research ethics committee of the faculty of medicine of the Clínica Alemana Universidad del Desarrollo (registration no.: 2017-104).

### **Participants**

All patients admitted to the adult ICU were screened consecutively to determine eligibility for this study. The inclusion criteria were mechanically ventilated adult patients older than 18 years. The exclusion criteria were limitation of life-sustaining care, plegia in 1 or more limbs, invasive mechanical ventilation in another center for more than 24 hours, limb amputation, patient readmitted to ICU who was already enrolled in this study, patient awakening in the first 24 hours since ICU admission (to ensure at least 24h of actigraphy recording between ICU admission and awakening), and previous functional dependence (FSS-ICU score < 30 points based on a retrospective proxy interview). Once a patient was identified as eligible, their proxy was contacted at ICU admission to ask for their informed consent to participate. When patients achieved a maximum level of cooperation (defined as the ability to follow 5 simple commands as described below and being delirium-free), they were asked for their consent to participate.

### **Measurements**

Measurements were conducted at 3 time points: (1) ICU admission, defined as within the first 12 hours from admission to the ICU; (2) awakening, defined as the first time a patient responded to 5 simple commands (as per De Jonghe<sup>29</sup> cooperation criteria: [a] open/close your eyes, [b] look at me, [c] open your mouth and put out your tongue, [d] nod your head, and [e] raise your eyebrows when I have counted up to 5); and (3) ICU discharge, defined as the moment when a patient met medical criteria for discharge from the unit.

### **Functional Status Score for the Intensive Care Unit**

Mobility was measured with the FSS-ICU Chilean-Spanish version available at [www.improveLTO.com](http://www.improveLTO.com). The FSS-ICU was designed for the ICU setting to quantify the level of physical assistance required by the patient when performing 5 activities: rolling, transfer from supine to sit, sitting at the edge of the bed, transfer from sitting to stand, and walking. Each activity is scored using an 8-point ordinal scale ranging from 0 (not able to perform) to 7 (complete independence); therefore, the overall score ranges from 0-35 points, with higher scores indicating greater functional independence.<sup>10</sup> The translation and cross-cultural adaptation of the Chilean Spanish version of the FSS-ICU has been published elsewhere.<sup>13</sup> It was conducted following the recommendations of Beaton et al,<sup>30</sup> which includes backward and forward translation, review by an expert committee, and pretesting through cognitive interviews of 30 physiotherapists.

## Actigraphy

Gross motor activity was measured using triaxial accelerometers (GT9X Link<sup>®</sup>) daily for 24 hours from ICU admission to ICU discharge.<sup>31</sup> Accelerometers were fitted to the patient's right ankle with an elastic Velcro strap as used elsewhere<sup>32,33</sup> because it interferes less with clinical procedures and is a valid recording method compared with placing it in the hip or wrist.<sup>34</sup> The time-sampling interval or epoch used was 5 seconds, and the sampling frequency was 90 Hz.<sup>35</sup> The accelerometers were charged at 100% and initialized before being placed on the patient. The accelerometer was never removed from the patient except for out-of-room clinical tests (ie, magnetic resonance imaging, computed tomography, surgical procedures). Twice a day, the patient's skin condition and the battery level and functioning of the accelerometers were checked. To ensure continuous measurement, if the battery level fell below 10% the accelerometer was replaced by a fully charged device. Additionally, care and maintenance instructions of the accelerometer was left in each room for family members and staff members. Once a patient was discharged from the ICU, actigraphy data were extracted using the "Low-frequency extension"<sup>36</sup> function available in the ActiLife software (version 6.13.3).<sup>a</sup> Data were filtered to include recordings from the first installation up to the final removal of the device. To achieve this, data were exported to an Excel spreadsheet where the first and last hour of each device recordings were deleted. Data for activity counts, activity time, and inactivity time were analyzed. For the variable activity counts, the vector magnitude (ie, 3 axes) was used and is reported in counts and counts per recording hour. The variables' activity and inactivity time are reported in minutes and minutes per hour. Freedson et al's<sup>37,38</sup> definition was used, where 0-99 counts per minute are considered inactivity time, while 99 counts per minute or higher are considered activity time. The actigraphy variables reported on ICU awakening correspond to a cumulative measure of counts or minutes from ICU admission to awakening, while those reported at ICU discharge correspond to a cumulative measure of counts or minutes from admission to ICU discharge.

## Medical Research Council Sum Score

The measurement of peripheral muscle strength was performed using the MRC-SS following the method described by Hermans et al.<sup>39</sup> Six muscle groups were assessed bilaterally (ie, shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension, and ankle dorsiflexion). Every muscle group is scored between 0 and 5 points (0=no palpable or visible contraction; 1=visible/palpable contraction but no movement; 2=active movement, gravity eliminated; 3=active movement against gravity; 4=active movement against resistance adjusted for age and sex; 5=active movement against full resistance). The MRC-SS ranges from 0-60 points, with higher scores indicating greater strength and <48 points indicating ICU-acquired weakness.<sup>29</sup>

## Study protocol

Twelve physiotherapists were trained for the FSS-ICU measurement using the documentation available at [www.improveLTO.com](http://www.improveLTO.com) (ie, training video, frequently asked questions, and the pocket card), obtaining an interobserver agreement of intraclass correlation coefficient 0.96 (95% CI, 0.92-1.00).<sup>40</sup> The medical-surgical ICU where data were collected has physiotherapy on-site 24 hours/7 days a week; therefore, patients can receive physiotherapy during weekends and out of usual business hours. This ICU

performs standard ICU care with protocol-guided sedation, weaning, and standard physiotherapy, including chest physiotherapy, passive/active mobilization, out-of-bed and in-bed cycling, tilt table, progressive mobility, and neuromuscular electrical stimulation. The MRC-SS measurement was performed by 1 of 3 expert assessors who have used the scale routinely in their clinical practice for more than 4 years for assessing muscular strength.<sup>41</sup>

Once the patient's proxy signed the informed consent, the patient's demographic, clinical, and anthropometric data were registered in the Research Electronic Data Capture<sup>42</sup> system, and the accelerometer was fitted. The first measurement of the FSS-ICU and MRC-SS were performed within 24 hours of awakening. Before each measurement, clinical stability was assessed using cardiovascular, respiratory, neurologic, and orthopaedic safety criteria<sup>43</sup> so patients could sit on the edge of the bed and at least 3 FSS-ICU activities could be assessed, which are requirements for assessing the FSS-ICU total score. The FSS-ICU and MRC-SS were assessed again when ICU discharge was decided and within 24 hours of leaving the unit. The accelerometer was removed after these assessments.

## Statistical analysis

The sample size was calculated using QFAB Power Calculator web application.<sup>44</sup> For a power of 0.9, an expected correlation between the FSS-ICU and actigraphy of 0.7,<sup>15</sup> and a significance threshold of 0.01, the sample size calculated was 23 patients. An extra 15% was sampled to account for the potential loss of accelerometer recordings; therefore, 27 patients were needed for this analysis. The statistical analysis was performed using Stata/IC 15.0.<sup>b</sup>

## Descriptive statistics

Given that variables did not follow a normal distribution, medians and interquartile range [IQR] are used for numerical variables, while absolute and relative frequencies are used for categorical variables. The data captured through Research Electronic Data Capture was exported to an Excel spreadsheet for their analysis. Floor and ceiling effects for the FSS-ICU were calculated as the percentage of patients obtaining the minimum (0 points) or maximum (35 points) score, respectively. These were interpreted as follows: excellent (no floor or ceiling effects), adequate (floor or ceiling effects <20%), and poor (floor or ceiling effects >20%).<sup>45</sup>

## Hypotheses testing

As there is no criterion standard for measuring mobility, the FSS-ICU construct validity was assessed by testing 12 hypotheses, including the correlation of the FSS-ICU with activity counts, activity time (min), inactivity time (min), MRC-SS (points), ICU LOS (d), and duration of mechanical ventilation (d). All correlations were performed for data on awakening and at ICU discharge. The correlation between the FSS-ICU and activity counts, activity time, and MRC-SS were expected to be positive and at least moderate (>0.7). In the case of inactivity time, ICU LOS, and duration of mechanical ventilation, the correlations were expected to be negative. In addressing the secondary study objective, similar correlations to those reported for the English version of the FSS-ICU were expected for the MRC-SS, ICU LOS, and duration of mechanical ventilation,<sup>10</sup> meaning correlation coefficients in the order of >0.25 (supplemental table S1, available online only at

<http://www.archives-pmr.org/>). The Spearman  $\rho$  correlation coefficient was used to test for the hypotheses. They were interpreted according to Domholdt et al's categories, where 0.00-0.25 was little if any, 0.26-0.49 was weak, 0.50-0.69 was moderate, 0.70-0.89 was strong, and 0.90-1.00 was very strong correlation.<sup>46</sup> Given the number of hypotheses that were tested, the threshold for significance was modified using a Bonferroni correction ( $P < .003$ ). The trend line shown in the plots was constructed using a quantile regression model for the median.

## Results

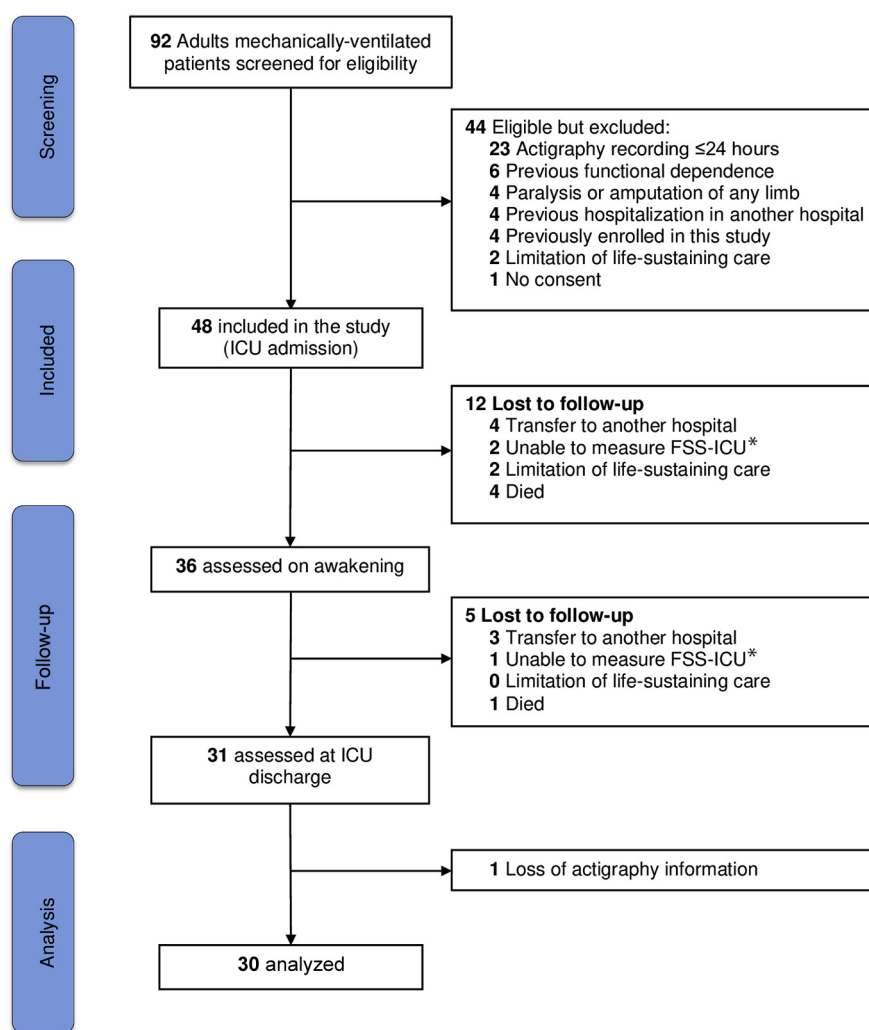
Ninety-two mechanically ventilated adult patients admitted to the ICU were consecutively screened from October 2018 to January 2019. The screening was completed when the number of patients with valid data reached the expected sample size for the analysis. The last enrolled patient was discharged from the ICU in March 2019. Forty-eight patients met the inclusion criteria, but because of loss to follow-up, data from 30 patients were analyzed (fig 1). Baseline demographic and ICU admission characteristics of the study participants are available in table 1.

The descriptive statistics for the FSS-ICU and the actigraphy variables on awakening and at ICU discharge are shown in table 2. The distribution of the FSS-ICU score of the 30 patients showed a floor effect of 0% (0 of 30) on awakening and 0% (0 of 30) at ICU discharge. The ceiling effect observed was 0% (0 of 30) on awakening and 10% (3 of 30) at ICU discharge. The median of the total actigraphy recording time from admission to ICU discharge was 5.48 days (IQR, 3.33-8.56d). Of this recording time, 0.15 days (IQR, 0.06-0.25d) corresponded to activity time, and 5.33 days (IQR, 3.26-8.37d) were inactivity time. This is equal to 2.5% of the time being active and 97.5% of inactive time during the whole ICU stay.

Of all hypotheses tested, 58% were confirmed (table 3). Activity counts and activity time were not correlated as expected with the FSS-ICU score, while inactivity time was negatively correlated on awakening ( $\rho = -0.62$ ,  $P < .001$ ) and at ICU discharge ( $\rho = -0.79$ ,  $P < .001$ ) (fig 2).

## Discussion

This is the first study assessing the validity of a mobility measurement instrument designed for the ICU setting available in Spanish.



**Fig 1** Study flow diagram. \*Include pain, discomfort, and hemodynamic or respiratory instability preventing evaluation.

**Table 1** Baseline characteristics of the study participants (n=30)

Variables	Participants
Age (y), median (25th-75th percentiles)	64.5 (55-74)
Body mass index, median (25th-75th percentiles)*	25.7 (23.7-27.1)
APACHE II score, median (25th-75th percentiles)*	16 (13-20)
Female sex, n (%)	17 (59)
Diagnosis, n (%)*	
Sepsis	9 (30)
Coma	6 (20)
Oncological	6 (20)
Hypovolemic shock	4 (13.3)
Respiratory	3 (10)
Transplant	1 (3.3)
Trauma	1 (3.3)
ICU admission to awakening (d), median (25th-75th percentiles)	2.2 (1-4.2)
ICU LOS (d), median (25th-75th percentiles)	5.7 (3.6-8.5)
Duration of mechanical ventilation (d), median (25th-75th percentiles)	2.6 (1.6-5.2)
ICU-AW on awakening, n (%)	11 (37)
ICU-AW at ICU discharge, n (%)	6 (20)

NOTE. Body mass index calculated as weight in kilograms divided by height in meters squared.

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU-AW, intensive care unit-acquired weakness.

\* At ICU admission.

The construct validity of the Chilean-Spanish FSS-ICU version was assessed through hypotheses testing, presenting a moderate to strong correlation with inactivity time, MRC-SS, ICU LOS, and duration of mechanical ventilation. There was no floor or ceiling effect for the FSS-ICU on awakening, and similarly at ICU discharge there was no floor effect, while a ceiling effect was

interpreted to be adequately acceptable. The findings of this study enhance the clinimetric properties already assessed of the FSS-ICU, such as reliability, validity, responsiveness, and interpretability (see [supplemental table S1](#)) and are similar to those reported for the versions in English,<sup>10</sup> Portuguese,<sup>11</sup> and Turkish.<sup>12</sup>

The FSS-ICU, like other instruments measuring mobility such as PFIT-s, CPAX, and IMS, is an ordinal scale that allows classifying a patient's functional performance through a face-to-face assessment.<sup>5</sup> These assessments depend on the subjective perception of the assessor, which means there are only imperfect reference standards for measuring mobility. As a consequence, actigraphy was chosen as an objective method to assess the construct validity of the FSS-ICU. Previous studies have shown the feasibility and safety of using actigraphy for measuring movement in critically ill patients,<sup>20,21,36,37</sup> while others have reported the correlation between actigraphy with the gross motor activity: Comfort Scale ( $\rho=0.48-0.62$ ,  $P<.001$ ),<sup>47</sup> Richmond Agitation Sedation Scale ( $\rho=0.58-0.98$ ,  $P<.001$ ),<sup>47,48</sup> and direct observation of activities (lying, rolling, sitting, standing, and walking) ( $\rho=0.36-0.98$ ,  $P<.001$ ).<sup>26,49</sup>

Schweickert et al<sup>50</sup> and Schaller et al<sup>51</sup> have shown that critically ill patients participating in early mobilization programs that provide more activity time than usual care have lower mortality rates, fewer days with delirium, shorter duration of mechanical ventilation, and better functional performance. Additionally, actigraphy studies have shown that patients tend to increase their activity from their hospital stay up to the post-ICU follow-up.<sup>23,52,53</sup> Consequently, the main hypothesis for this study was that greater time or amount of movement during the ICU stay (actigraphy) would relate to better mobility (FSS-ICU) and also that greater inactivity time would relate to worse scores in the FSS-ICU. However, only inactivity time measured with actigraphy was correlated with the FSS-ICU. As in our findings, Estrup et al<sup>23</sup> found little correlation ( $r^2=0.14-0.25$ ,  $P<.017$ ) between the activity counts and the CPAX among ICU survivors who had low activity time. Our study found that activity time was equivalent to 2.5% of the whole ICU stay, which is similar to what Hussey et al found (4%) in patients after surgery.<sup>53</sup> Possibly, the low

**Table 2** Descriptive results of the FSS-ICU and Actigraphy measures

Variables	Awakening (n=30)	ICU Discharge (n=30)
FSS-ICU		
Rolling	5 (2-7)	7 (6-7)
Supine to sit transfer	3 (2-4)	6 (3-7)
Sitting at the edge of the bed	5 (4-7)	7 (7-7)
Sit to stand transfer	4 (1-5)	5 (3-6)
Walking	1 (0-5)	4 (2-5)
FSS-ICU total score	19 (10-26)	28.5 (22-32)
Actigraphy*		
Activity counts (counts)	99,396 (31,707-193,692)	309,104 (133,737-557,149)
Activity counts (counts/d)	31,590 (21,275-52,219)	50,483 (38,073-88,649)
Activity time (min)	42.7 (19.5-97.1)	217.8 (92.6-356.3)
Activity time (min/d)	17.8 (11.5-26.9)	35.5 (25.5-57.1)
Inactivity time (min)	3621 (2062-5953)	7669 (4754.3-11,769.1)
Inactivity time (min/d)	1422 (1413-1429)	1405 (1382.9-1414.5)
MRC-SS	50 (37-54)	56 (53-59)

NOTE. Data are presented as median (25th-75th percentiles).

\* For actigraphy variables, the column "Awakening" corresponds to the cumulative values from ICU admission to awakening, and the column "ICU Discharge" corresponds to the cumulative value from ICU admission to ICU discharge.



**Table 3** Hypotheses and found correlations between the FSS-ICU and study variables

Variables	No.	Hypotheses		Hypotheses Confirmed
		Expected Correlation	Found Correlation*	
Actigraphy: activity counts	1	>0.70 on awakening	-0.54 ( $P=.002$ )	No
	2	>0.70 at ICU discharge	-0.05 ( $P=.79$ )	No
Actigraphy: activity time	3	>0.70 on awakening	-0.49 ( $P=.006$ )	No
	4	>0.70 at ICU discharge	-0.51 ( $P=.004$ )	No
Actigraphy: inactivity time	5	>-0.70 on awakening	-0.62 ( $P<.001$ )	No
	6	>-0.70 at ICU discharge	-0.79 ( $P<.001$ )	Yes
MRC-SS	7	>0.44 on awakening <sup>†</sup>	0.67 ( $P<.001$ )	Yes
	8	>0.60 at ICU discharge <sup>†</sup>	0.72 ( $P<.001$ )	Yes
ICU LOS	9	>-0.25 on awakening <sup>†</sup>	-0.70 ( $P<.001$ )	Yes
	10	>-0.25 at ICU discharge <sup>†</sup>	-0.77 ( $P<.001$ )	Yes
Duration of mechanical ventilation	11	>-0.25 on awakening <sup>†</sup>	-0.60 ( $P<.001$ )	Yes
	12	>-0.25 at ICU discharge <sup>†</sup>	-0.62 ( $P<.001$ )	Yes

\* Correlation was calculated with Spearman  $\rho$ .

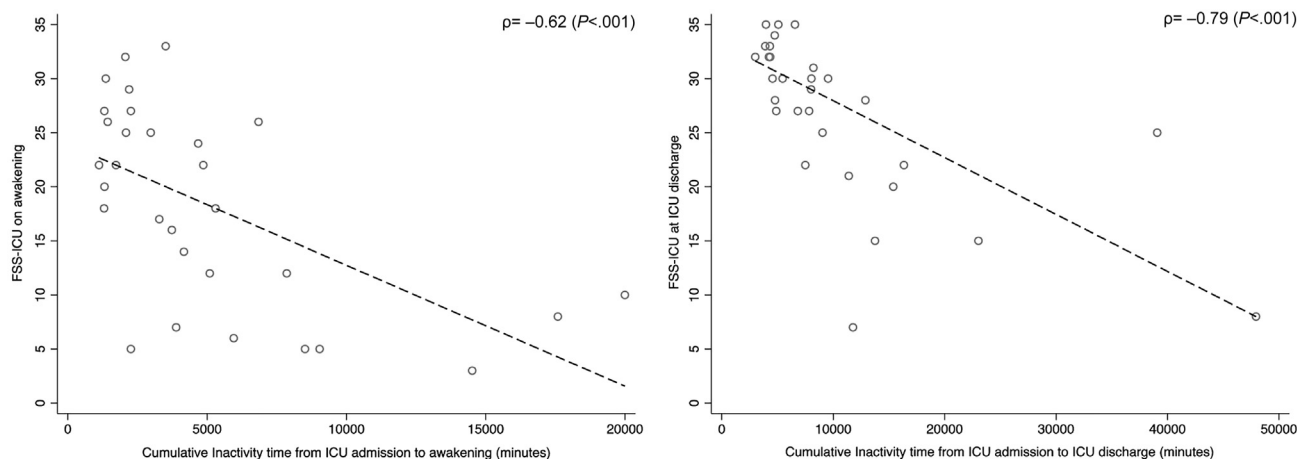
<sup>†</sup> Based on the combined results of previous data.<sup>10</sup>

correlation between the FSS-ICU and activity counts and activity time could be explained by how little activity time is experienced by patients during the ICU stay.

Additionally, a longer inactivity time during a hospital stay is associated with worse mobility.<sup>33,38</sup> In this study, patients were inactive 98.8% of the time between ICU admission and awakening and 97.5% between ICU admission and discharge. A recent randomized controlled trial reported high proportions of inactivity time during the ICU stay, with 95.7% for the control group and 92.3% for the group receiving early and progressive mobilization.<sup>33</sup> Moreover, Baldwin et al identified high levels of sedentary behavior (defined as time spent lying/sitting) before awakening (98.1%) and at ICU discharge (95.7%), which were correlated with mobility assessed with the PFIT-s and the Morton Mobility Index ( $\rho=-0.73, P<.001$ ).<sup>52</sup> The present study also found a moderate to strong correlation between inactivity time (defined as low intensity movement) and mobility measured with the FSS-ICU on awakening ( $\rho=-0.62, P<.001$ ) and at ICU discharge ( $\rho=-0.79, P<.001$ ). These findings are consistent with population-based data, where it has been found that low-intensity movement and long periods of sitting/lying are risk factors for negative health outcomes.<sup>54-56</sup>

Regarding the correlation between the FSS-ICU and other clinical variables, this study had different results from other studies assessing clinimetric properties in which the FSS-ICU had a weak correlation with the MRC-SS on awakening ( $r^2=0.44, P<.05$ ), moderate correlation at ICU discharge ( $r^2=0.60, P<.05$ ), and little correlation with FSS-ICU at ICU discharge with the ICU LOS ( $r^2=-0.25, P<.05$ ).<sup>10</sup> Conversely, in this study the correlation between the FSS-ICU and the MRC-SS was moderate on awakening ( $\rho=0.67, P<.001$ ) and strong at ICU discharge ( $\rho=0.72, P<.001$ ), while the correlation of FSS-ICU with ICU LOS was strong on awakening ( $\rho=-0.70, P<.001$ ) and at ICU discharge ( $\rho=-0.77, P<.001$ ). These differences could be explained because Huang et al<sup>10</sup> combined results of 5 data sets, where the data sets with larger sample sizes had weaker correlations than studies with smaller sample sizes. It would be plausible that studies with large sample sizes have greater variability, and therefore, the correlations are not as strong as the ones we found.

Future research should study and report on the lack of movement of critically ill patients because, according to the current literature, patients are inactive for extended periods, which is



**Fig 2** Relationship between the Functional Status Score for the Intensive Care Unit and inactivity time on awakening and at ICU discharge.

associated with worse mobility.<sup>33,52</sup> There is still the challenge to measure movement in real time to guide and inform decision making regarding dosage and strategies for preventing immobility of critically ill patients.

## Study limitations

This study has some potential weaknesses worth mentioning. The findings of this work came from clinical measurements of patients receiving few days of mechanical ventilation (median, 2.6d) and were performed in a single center, which could limit the external validity of the results. A high number of patients (n=23) were screened but were not included in the analysis because the patient awoke before completing 24 hours of actigraphy recordings. This high rate of ineligible patients should be considered for the recruitment of participants in future actigraphy studies with sedated individuals. Another important weakness was that differentiating voluntary from involuntary movement was not possible, which could have modified the correlations found between the activity counts and the FSS-ICU scores. This is particularly relevant for sedated critically ill patients who receive passive mobilization daily (eg, passive range of motion, cycling, positioning).

## Conclusions

In conclusion, the Chilean-Spanish version of the FSS-ICU has a strong correlation with inactivity time during the ICU stay in mechanically ventilated patients. These findings enhance the available clinimetric properties of the FSS-ICU, which is a useful tool for clinical practice and research.

## Suppliers

- a. ActiGraph.
- b. Stata/IC 15.0; StataCorp.

## Keywords

Actigraphy; Intensive care units; Outcome assessment (health care); Rehabilitation; Validation study

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