# Correlation of falls in patients with Amyotrophic Lateral Sclerosis with objective measures of balance, strength, and spasticity

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#### Abstract.

**BACKGROUND:** Persons diagnosed with Amyotrophic Lateral Sclerosis (ALS) often demonstrate neurological deficits that predispose them to repeated falls and associated adverse consequences. Determining contributing factors to falls in this population is critical to improve safety and patient outcomes.

**OBJECTIVE:** The purpose of this study was to correlate clinical measures of gait speed, balance, strength, spasticity, and a self-reported rating scale of function with fall incidence in individuals with ALS.

**METHODS:** Thirty-one participants with a confirmed ALS diagnosis were recruited from an outpatient clinic. Each participant performed the following tests: timed gait speed, Berg Balance Scale (BBS), manual muscle testing (MMT) for lower extremity (LE) strength, Modified Ashworth Scale (MAS) for LE spasticity, and the ALS Functional Rating Scale-Revised (ALSFRS-R). Each participant reported number of falls that occurred in the past three months. Pearson correlation coefficients were calculated to determine correlations between variables.

**RESULTS:** Significant correlation was found between fall incidence and composite LE strength score ( $r_p = 0.385$ , p = 0.032). **CONCLUSIONS:** There is a relationship between LE weakness and number of falls in the ALS population. Preventing disuse-related LE muscle weakness and education of need for external support may decrease the number of falls experienced by individuals with ALS.

Keywords: Amyotrophic Lateral Sclerosis, falls, gait speed, strength, spasticity, Berg Balance Scale, Amyotrophic Lateral Sclerosis Functional Rating Scale - Revised

# 1. Introduction

Amyotrophic lateral sclerosis (ALS) is the most common occurring motor neuron disease and is characterized by the deterioration of upper and lower motor neurons, resulting in loss of voluntary muscle function (Ashworth, Satkunam, & Deforge, 2006). Due to the complexity of the central and peripheral nervous systems, the wide variety of symptoms associated with ALS include muscle atrophy, weakness, spasticity, fatigue, difficulty speaking, difficulty swallowing, and shortness of breath (Bromberg, Anderson, Davidson, & Miller, 2001; Annegers, Appel, Lee, & Perkins, 1991). These neurologic and systemic deficits can contribute to postural instability

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and a predisposition for falling due to changes in strength, balance, endurance, and muscle tone (Tinetti, 1989; Cattaneo et al., 2002).

Falls can lead to negative health outcomes and increased health care costs for any individual; however, the effects can be more devastating for someone diagnosed with ALS. Adverse outcomes associated with falls include injury, hospital admission, loss of functional independence, inactivity, premature admission to nursing homes, morbidity, and mortality (Tinetti, Speechley, & Ginter, 1988; Shumway-Cook, Baldwin, Polissary, & Gruber, 1997; Rubenstein, 2006). Falls in the ALS population may be linked to lower extremity (LE) weakness, spasticity, inability to respond to postural changes, decreased coordination, and changes in balance (Kloos et al., 2004). Assessment of neurological impairments and identification of contributing factors to falls are imperative for fall prevention in this population (Cattaneo et al., 2002). Individual outcome measures and tests have been developed to assess various aspects of motor control and to distinguish fallers from nonfallers; however, these measures have not been used collectively to predict falls in the ALS population (Bohannon & Smith, 1987; Berg, Wood-Dauphinee, & Williams, 1995; Chiu, Au-Yeung, & Lo, 2003).

The Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) is a self-report instrument used to quantify function of an individual with ALS as the disease progresses. It consists of questions covering gross motor, fine motor, oral motor, and respiratory function and has been shown to have good reliability and construct validity (Cedarbaum & Stambler, 1997; Cedarbaum et al., 1999; Kauffmann, et al., 2005). Multiple studies have shown the Berg Balance Scale (BBS) to have good reliability and validity and the ability to predict falls in both the elderly and stroke populations (Shumway-Cook et al., 1997; Berg et al., 1995; Berg, Wood-Dauphinee, Williams, & Maki, 1989; Chiu et al., 2003). However, its use in people with ALS has not been reported in the literature. Spasticity can contribute to functional impairment by slowing voluntary movements, causing abnormal synergistic movement patterns, and limiting agonist muscle force, all of which can lead to gait deviations and increase risk of falling (Gregson et al., 1999; Nuygens et al., 1994; Sloan, Sinclair, Thompson, Taylor, & Pentland, 1992). The Modified Ashworth Scale (MAS) is the most frequently cited clinical rating scale for spasticity, although it has been shown to have inconsistent reliability for different muscle groups (Sloan

et al., 1992; Gregson et al., 2000; Allison, Abraham, & Petersen, 1996; Haas, Bergstrom, Jamous, & Bennie; 1996; Pandyan et al., 1999). Its use in measuring spasticity in people with ALS has also not been documented in the literature.

Studies on gait characteristics of the ALS population have concluded that decreased LE extremity strength is the primary component responsible for the highly variable gait deviations, including increased stride time and variability between steps (Goldfarb & Simon, 1984; Slavin, Jette, Andres, & Munsat, 1998; Jette, Slavin, Andres, & Munsat, 1999; Hausdorff et al., 2000). Gait speed is a well-established outcome measure and has been shown to be a good predictor of falls in the older population (Butler, Menant, Tiedemann, & Lord, 2009; Van Kan et al., 2009; Moyer, Gale, Severe, Braden, & Hasson; 2017). Manual muscle testing (MMT) by the Medical Research Council (MRC) scale has been shown to have good reliability and a strong correlation to ALSFRS-R scores in the ALS population (Sorenson, 2004). In addition, it has been shown to be a sensitive measure when tracking the progression of the disease (Great Lakes ALS Study Group, 2003).

Other investigators have studied the likely causes of falls and have provided insight into the risks and predictability of falling among other patient populations; however, limited research has been conducted to investigate the causes or predictability of falls in the ALS population (Cattaneo et al., 2002; Tinetti et al., 1988; Shumway-Cook et al., 1997; Rubenstein, 2006). One prospective study by Montes et al. (2007) found that performance of the Timed Up and Go test was predictive of falls, while MMT and ALSFRS-R scores were not.

The purpose of this study was to determine if falls within the ALS population were correlated with clinical measures of walking speed, balance, strength, and spasticity that have been well-established in other populations. We hypothesized that there would be a relationship between the clinical measures of gait speed, balance, strength, spasticity, ALSFRS-R, and number of falls occurring in the previous three months in people with ALS.

## 2. Methods

#### 2.1. Participants

Thirty-one male and female participants with a confirmed diagnosis of ALS were recruited from

patients attending the Houston Methodist Hospital Neurological Institute ALS clinic. Inclusion criteria included the following: 1) ability to ambulate 20 feet with or without an assistive device and with or without the assistance of one person and 2) age 18 to 80. Exclusion criteria included the following: 1) unconfirmed ALS diagnosis, 2) non-healed fracture or weight bearing limitation of either LE, 3) concurrent active medical condition, such as cancer or cardiopulmonary disease, that would limit performance on tests for reasons other than ALS, 4) past neurological medical history, such as stroke, acquired brain injury, or spinal cord injury, and 5) past medical history of orthopedic limitations, such as joint fusions or contractures, that would predispose the participant to falling.

This study protocol was approved by the Committees for the Protection of Human Subjects of the Houston Methodist Hospital Research Institute and Texas Woman's University Institutional Review Board. Written informed consent was obtained from each person. They participated in research testing procedures during his or her routine visit to the ALS clinic.

#### 2.2. Instrumentation

The BBS requires a step stool, two chairs (one with armrests and one without armrests), and a tape measure. A handheld stopwatch was necessary for several aspects of the BBS and to measure the time required to walk 20 feet. A gait belt was used to assist for safety for mobility tasks. The participants were positioned on a padded examination table during strength and spasticity testing.

# 2.3. Measurements

All tests were conducted by a physical therapist (PT) with five years of experience working with the ALS population. All procedures were conducted in the same order: gait speed, self-report of fall history, ALSFRS-R, BBS, LE strength assessment with MMT, and LE spasticity assessment using the MAS.

# 2.3.1. Gait speed

Overground gait speed was determined as the participant walked 20 feet. The participant was instructed to walk at his or her own self-selected pace using any required assistive device or orthosis. For safety precautions, the PT applied a gait belt and guarded the participant during the test in case of any loss of balance. Using a stopwatch, the evaluator measured the number of seconds required for the participant to walk the required distance on a level surface. A start and finish line were marked with tape 20 feet apart. The participant started three feet behind the starting line, and timing began when the participant crossed the starting line with his or her first foot. Participants continued walking at their self-selected pace three feet past the finish line, and timing stopped when the participant's first foot crossed the finish line. The participants were required to walk 20 feet without stopping to rest. Any participants unable to complete the distance were given a score of zero.

## 2.3.2. Fall history

A fall was defined as any change of balance that occurred during normal activities that resulted in the participant's body unintentionally coming in contact with furniture, the ground, a wall, or any other surface (Boulgarides, McGinty, Willett, & Barnes, 2003). Participants were asked to report how many falls they experienced in the previous three months. Episodes of tripping or loss of balance with safe recovery without making contact with another object or person were excluded. Three months was selected due to timing of previous clinic visit, potential for recall bias with longer time periods, and more recent fall occurrences being more indicative of current functional status due to progressive nature of ALS.

#### 2.3.3. ALSFRS-R

The ALSFRS-R, a 12-item questionnaire, was administered by the PT, who simplified medical terminology used in the questions, as needed. Dyspnea was described as shortness of breath, orthopnea was described as breathing difficulties, and respiratory insufficiency was described as a need to use equipment to assist with breathing (Miano, Stoddard, Davis, & Bromber, 2004).

#### 2.3.4. Berg Balance Scale

The BBS, a 14-item balance measure, was administered in the order of the items as written in the scale. Participants wore gait belts around their waists, and the PT administering the test guarded the patient in the event of a loss of balance.

#### 2.3.5. Lower extremity strength

LE strength was measured with MMT on a scale from zero to five with + and – values according to the MRC scale. Each muscle was examined in the gravity resisted position first, followed by the gravity eliminated position if the participant was unable to perform the test against gravity. These positions were taken from standard MMT textbooks (Kendall, McCreary, & Provance, 1993; Hislop & Montgomery, 1995). Hip flexor, hip extensor, hip abductor, knee extensor, knee flexor, ankle dorsiflexor, and ankle plantarflexor muscles were measured bilaterally. As described by Florence et al. (1992), the score for each muscle group was transformed to a value on a zero to ten-point scale. All scores were summed and averaged to determine an overall LE composite strength score (Florence et al., 1992; Great Lakes ALS Study Group, 2003).

Plantarflexors were tested in two positions, prone at the beginning of the testing and weight bearing in standing at the end of testing. If a participant was unable to assume the prone position for testing due to difficulty breathing or other medical conditions, hip extensors, knee flexors, and plantarflexors were assessed in the sidelying position.

## 2.3.6. Muscle spasticity

Muscle spasticity was assessed in the LE using the Modified Ashworth Scale (MAS) in supine on a padded table. To avoid participant discomfort, the pain-free range of motion of the LE was determined prior to assessing muscle tone (Nuyens et al., 1994). Participants were instructed to relax during testing. The muscles were assessed on each LE individually in the following order: knee flexors, knee extensors, and plantarflexors in two positions, with the knee flexed and knee extended. Each movement was assessed through the available range of motion four times, each over the duration of one second as recommended by Bohannon and Smith (1987). The MAS score was recorded as the smallest, or optimal score (Bohannon and Smith, 1987; Gregson et al., 2000).

# 2.4. Statistical analysis

All statistics were calculated using IBM SPSS 11.0 (SPSS Inc. Chicago, IL). Descriptive statistics and histograms were calculated for each dependent variable to determine distributions. Recurrent falls were considered  $\geq$  two falls in the past three months (Shumway-Cook, 1997). Pearson's correlations were calculated to determine relationships between variables (Portney & Watkins, 2009). A *p* value <0.05 was used to determine significance.

## 3. Results

Descriptive statistics of the 31 subjects are shown in Table 1. When spasticity of the ankle muscles was low, spasticity in the more proximal LE mus-

Subject characteristics $(n = 31)$					
	n (%)	Mean ± SD (Range)			
Age (years)	_	55.0 ± 14.1 (33-76)			
Time since initial ALS symptoms (months)	_	$36.0 \pm 33.9 (6 - 131)$			
Gender					
Female	14 (45)	_			
Male	17 (55)	-			
Participant's initial symptoms					
Bulbar	12 (39)	-			
UE	12 (39)	-			
LE	7 (23)	-			
Extremity symptoms distribution					
Right side	8 (26)	-			
Left side	10 (32)	-			
Right and left sides	1 (3)	-			
Proximal involvement	0 (0)	-			
Distal involvement	19 (61)	-			
Assistive device required					
None	16 (52)	-			
1 AFO	2 (7)	-			
SPC	3 (10)	-			
RW	6 (19)	-			
RW and 1 AFO	1 (3)	-			
RW and 2 AFOs	3 (10)	-			

Table 1 Subject characteristics (n = 31)

Abbreviations: SD = standard deviation, UE = upper extremity, LE = lower extremity, AFO = ankle foot orthosis, SPC = single point cane, RW = rolling walker.

cles was also noted to be low. As spasticity in ankle muscles increased and clonus appeared, the spasticity in the quadriceps and hamstrings increased. Descriptive statistics of the research variables are shown in Table 2. The average number of falls reported in the preceding three months was  $5.45 \pm 8.56$ .

Pearson's correlations between all variables are shown in Table 3. LE strength composite score showed a significant positive correlation to number of reported falls (p = 0.032). LE strength composite score also showed a significant negative correlation to gait speed (p = 0.002) and a significant positive correlation to BBS score (p < 0.0001). Gait speed and BBS showed a significant negative correlation (p < 0.0001), and gait speed had a significant positive correlation to the MAS score of the left quadriceps (p = 0.025) and left hamstrings (p = 0.039). The need to use an assistive device for ambulation had a significant positive correlation to gait speed (p =0.006), a significant negative correlation to BBS score  $(p \le 0.0001)$ , and a significant negative correlation to LE strength composite score ( $p \le 0.0001$ ). The need to use an assistive device was significantly correlated with spasticity of the right quadriceps (p = 0.037) and left quadriceps (p = 0.019). The need to use an assistive device was also significantly correlated with spasticity of the right hamstrings (p = 0.025) and left hamstrings (p = 0.006).

# 4. Discussion

Among Americans aged 65 and older, falls are the leading cause of fatal and nonfatal injuries (Bergen, Stevens, & Burns, 2014). One out of five falls in the older adult population causes a serious injury such as a broken hip or head injury, and falls are the leading cause of traumatic brain injuries among all Americans (Sterling, O'Connor, & Bonadies, 2001; Taylor, Bell, Breiding, & Xu, 2017). According to the Centers for Disease Control and Prevention, 2.8 million older adults are treated in emergency departments for fall injuries, and over 800,000 people are hospitalized due to a fall injury each year (Centers for Disease Control and Prevention, 2016). Complications due to falls can lead to decreased functional

Table 2 Descriptive Statistics for Research Variables

	Mean	Standard Deviation	Range
Number of Falls in Past 3 Months	5.45	8.56	0-36.00
Gait Speed (seconds)	10.12	8.68	3.50-41.72
ALSFRS-R Score	34.23	6.68	21.00 - 44.00
BBS	40.45	14.20	10.00 - 56.00
LE strength summation score	101.45	25.43	45.00-137.00

Abbreviations: ALSFRS-R = Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised, BBS = Berg Balance Scale, LE = lower extremity. Gait speed recorded as number of seconds needed to walk 20 feet.

Table 3   Pearson Correlations									
	Falls	Speed			Composite	Needs			
Reported Falls									
Gait Speed	-0.106								
BBS	0.305	-0.686*							
ALSFRS-R	0.215	-0.236	-0.481*						
LE Strength Composite	-0.385*	-0.530*	-0.818*	-0.309					
Assistive Device Needs	-0.238	-0.485*	-0.682*	-0.219	-0.735*				
MAS R Quadriceps	0.111	-0.351	-0.173	-0.013	0.011	-0.376*			
MAS R Hamstrings	0.192	-0.316	-0.147	-0.033	-0.005	-0.401*			
MAS R Gastrocnemius	0.174	-0.151	0.115	-0.033	-0.271	0.114			
MAS R Soleus	0.207	-0.184	0.069	-0.036	-0.247	0.171			
MAS L Quadriceps	0.092	-0.403*	-0.227	-0.035	-0.044	-0.419*			
MAS L Hamstrings	0.110	-0.373*	-0.242	-0.085	-0.062	-0.483*			
MAS L Gastrocnemius	0.182	-0.171	-0.094	-0.066	-0.274	0.100			
MAS L Soleus	0.160	-0.352	0.112	-0.044	-0.282	0.091			

Abbreviations: BBS = Berg balance scale, ALSFRS-R = Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised, LE = lower extremity, MAS = Modified Ashworth Scale. n = 31, \*p < 0.05.

mobility, decreased independence, and ultimately, early morbidity. Physical therapy interventions such as LE strengthening, functional training, balance retraining, and education about fall prevention and appropriate assistive devices have been shown to decrease risk factors related to falls in the older population (Tricco, Thomas, & Veroniki, 2017).

Individuals with ALS face many functional mobility challenges and are very vulnerable to falling. However, there is very limited literature available evaluating fall risk in this population. The goal of this study was to examine the relationship between commonly used clinical outcome measures and examination techniques with reported number of falls in people with ALS in order to gain a better understanding of the risk factors contributing to falls in this population. The results of this study support the relationship between LE strength deficits and falls in the ALS population. Many other studies have supported the relationship between strength and falls in the geriatric population, but we believe this is the first study to show the relationship in the ALS population (Tinetti, 1989; Rubenstein, 2006; Wolfson, Judge, Whipple, & King, 1995). Rubenstein (2006) concluded that 10 to 25% of falls are caused by muscle weakness and gait limitations, which was the second most common predisposing factor of falling after accidental and environmental incidents. Wolfson et al. (1995) proposed that LE strength measures below a significant threshold value for ambulation may be related to declining functional mobility levels and an increase in fall episodes. They found that ankle dorsiflexor weakness was a key impairment among repeated fallers due to the decreased ability to use the ankle balance strategy to prevent posterior losses of balance, in addition to increased difficulty clearing the foot during swing phase advancement during gait (Wolfson et al., 1995; Kemoun, Thoumie, Boisson, & Guieu, 2002). Taking into account these studies and the results of the present study, strength measures below certain requirements for functional mobility can compromise gait and balance in many populations, including ALS. Although ALS is a progressive disease and development of muscle weakness is inevitable, it may be important to prevent additional disuse muscle atrophy of the LE with appropriate activity levels and fatigue management. In addition, education regarding fall prevention, including environmental modification, and recommendations for assistive devices may improve safety while ambulation is still possible for people with ALS.

This is the first study to investigate the relationship between BBS and fall incidence in the ALS population Although the average BBS score was 40.45, which is well below the standard score indicative of elevated fall risk, there was no significant correlation between number of reported falls and BBS score (Berg et al., 1992). However, a positive trend was noted. Other researchers have found a significant relationship between the BBS and fall incidence in the geriatric population with a longer fall incidence reporting period (Shumway-Cook et al., 1997; Berg et al., 1995; Berg et al., 1992). A larger participant pool may have demonstrated a larger stronger relationship between the BBS and fall incidence in the ALS population.

The average gait speed for all participants was 0.604 meters per second (m/s). According to Fritz and Lusardi (2009), 0.604 m/s corresponds to ability to perform limited community ambulation. This gait speed is also linked to needing assistance to perform activities of daily living, an increased risk of being hospitalized, and the need for interventions to reduce fall risk (Fritz & Lusardi, 2009). In addition, gait speed and spasticity did not correlate with number of falls reported. This finding may be related to the levels of functional mobility of the participants with more severe spasticity and decreased gait speed. The ambulation ability of the participants varied from being able to walk for long community distances to only ambulating short household distances. The participants with a lower level of ambulation possibly limited their walking at home for safety concerns, thus lowering their chance of falling (Delbaere, Crombez, Vanderstraeten, Willems, & Cambier, 2004; Denkinger, Luka, Nikolaus, & Hauer, 2015). Concern or fear of falling could have limited the number of reported falls in participants who were more impaired and would be expected to have more falls. The ALSFRS-R was not correlated with any of the main variables of the study except the BBS. This finding may be explained by the ALSFRS-R including impairments of ALS other than LE strength and function that may still be intact in individuals who are able to ambulate.

Additional significant correlations were observed between variables in this study that did not specifically relate to the hypothesis. LE impairments, such as muscle weakness and spasticity, were related to the need to use an assistive device for ambulation, decreased gait speed, and lower BBS score. While not directly related to number of reported falls, these variables show a relationship with functional mobility in individuals with ALS.

One possible limitation of this study was the method used to collect fall information. It may be beneficial to increase the period of time from the previous three months to previous six or 12 months to gather more information about fall history, examining if or when fall incidence changes as the disease progresses. In addition, the participants may not be able to report an accurate number of falls, so including information from the caregiver or family members may improve the accuracy of the fall history. Also, the strict inclusion and exclusion criteria limited the number of participants, thus decreasing the power of the study and limiting the chance of finding significant relationships between reported number of falls and other variables. Future studies could strive to increase sample size and extend the length of the study to follow the participants longitudinally to examine fall incidence and monitor functional measures as the disease progresses. However, the rapid disease progression and mortality will make these efforts particularly challenging.

In conclusion, LE strength was determined to have a significant positive relationship with number of recent falls within the past three months reported by people with ALS. We believe this study contributes to the body of literature that exists to inform clinicians and the community about functional limitations and safety considerations for individuals with ALS. We hope this study serves as a foundation for future investigations to continue improving outcomes for this vulnerable population.

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#### **Conflict of interest**

The authors have declared that no competing interests exist.

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