

A 30-METER WALKING TEST AS A MEASURE OF CERVICAL SPONDYLOTIC
MYELOPATHY SEVERITY: TEST CHARACTERISTICS AND RESULTS FROM TWO
MULTICENTER COHORT STUDIES

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ABSTRACT

Background Context: Cervical Spondylotic Myelopathy (CSM) is a progressive, degenerative condition and the most common cause of spinal cord dysfunction worldwide. A timed 30-meter walking test (30MWT) has previously been recommended for testing disease severity in patients with CSM because of its objectivity, quantitative nature, and ease of administration. However, very little has been reported in the literature regarding its use.

Study Design/Setting: We utilized data from two prospective CSM cohort studies to analyze properties of the 30MWT test for patients with CSM. All patients had symptomatic CSM and subsequently underwent surgical decompression. Each patient completed 3 trials of the 30MWT at baseline as well as 6, 12, and 24 months following surgery.

Methods: Repeated measures analysis of variance (ANOVA) was used to examine test reproducibility, and Spearman's correlation coefficients were used to compare the results of the 30MWT to other validated scales used in the CSM population. Additionally, we used paired T-tests to assess the difference between baseline and 6-month post-operative 30MWT times. Standardized response mean was used to measure responsiveness.

Results: Moderate correlation (-0.551) was seen between the 30MWT and the modified Japanese Orthopedic Association (mJOA) scale as well as the Nurick score (0.468) at baseline. Low correlation was found between the 30MWT and the NDI (0.253) as well as the physical component of the Short-Form 36 Health Survey (-0.380). Walking time did not vary significantly between the three trials at baseline ($p = 0.66$). At 6 months post-op, patients completed the 30MWT 9.9 seconds faster compared to baseline ($p < 0.0001$).

Conclusions: The results from two prospective cohort studies demonstrate that the 30MWT is reproducible and moderately correlated with other validated scales used with CSM patients. Because the 30MWT is simple, quick, affordable, and assess gait parameters not accurately assessed by other standard metrics, it should be used as an ancillary test for CSM patients.

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TABLE OF CONTENTS

1. INTRODUCTION
2. METHODS
 - 2.1. Subjects
 - 2.2. Measures
 - 2.3. Statistical Analysis
3. RESULTS
 - 3.1. Reproducibility
 - 3.2. Correlation
 - 3.3. Differences in 30MWT Time Following Surgery
 - 3.4. Responsiveness
 - 3.5. Sensitivity Analysis
4. DISCUSSION AND CONCLUSION
5. BIBLIOGRAPHY

INTRODUCTION

Cervical Spondylotic Myelopathy (CSM) is a progressive, degenerative condition which causes chronic compression of the cervical spinal cord.¹ As the most common cause of spinal dysfunction worldwide, the incidence of CSM-related hospitalizations has been estimated to be 4.04/100,000 person-years.² However, estimations of the incidence of this disease have been difficult to ascertain due to ambiguous classification of CSM by diagnosis codes and a paucity of relevant literature.³ CSM may cause symptoms such as tingling, numbness and weakness of the upper and lower extremities, spasticity, difficulty walking, neck pain, and impotence.⁴ If left untreated, CSM may lead to quadriplegia. After the diagnosis of CSM has been made, surgery has been shown to be an effective modality for relieving the symptoms of CSM and halting the progression of disease.⁵⁻⁷ Several measures have been used to quantify the severity of disease among patients with CSM, with the Nurick Scale and Modified Japanese Orthopedic Association Scale (mJOA) being the most commonly used in the literature.^{8,9} Other common measures include the Visual Analog Scale (VAS) for pain, the Short-Form 36 (SF-36v2), the Neck Disability Index (NDI), and the Myelopathy Disability Index (MDI).¹⁰ Despite the frequent use of these measures, these assessments do not specifically address the gait dysfunction seen in CSM in an objective, quantifiable manner.^{8,9,11,12}

The 30-meter Walking Test (30MWT) was described in 1999 as a quantitative and objective test used for patients with Cervical Spondylotic Myelopathy.¹² The 30MWT is conducted by simply measuring the time taken by a patient to walk 30 meters. Taking a longer amount of time to walk 30 meters reflects greater disability. The 30MWT has been recommended for use in any clinical practice with patients with CSM, as well as for researchers studying CSM.⁸ In addition, the test has been used in the chronic obstructive pulmonary disease (COPD) population.¹³

Although the 30MWT is recommended for use in patients with CSM, very little has been reported in the literature regarding its use. In the original validation study, only 41 patients with CSM were evaluated. Additionally, the walking test results were only compared to the MDI and Nurick Scales. In order to provide more information on 30MWT reproducibility, validity, and responsiveness, we conducted a retrospective cohort analysis using data from two recent CSM prospective multicenter cohort studies.

METHODS

Subjects

We conducted a cohort analysis using data from two CSM studies: the AOSpine North America prospective multi-center study and the AOSpine International prospective multi-center study.^{6, 14} The AOSpine North America study was conducted between December 2005 and September 2007, enrolling a total of 278 patients. The AOSpine International study was conducted between October 2007 and January 2011, enrolling 479 patients. The key inclusion criteria were age of eighteen years or older, symptomatic CSM (secondary to either disc herniation, ossification of the posterior longitudinal ligament, ligamentum flavum hypertrophy, spondylosis, spondylolisthesis, or a combination of these changes), objective cervical cord compression as determined by magnetic resonance imaging (MRI), no prior surgical treatment for myelopathy, and the absence of symptomatic lumbar stenosis. A total of 757 patients were enrolled between the two studies. All participating patients provided informed consent. Investigators received approval to conduct the study from their Institutional Review Board.

Measures

For the 30MWT, each patient is asked to walk the 30-meter distance as quickly as he or she feels comfortable. Patients are allowed to use assistive devices that they would normally use (e.g. cane, walker). The 30MWT was repeated three times at each visit, and each iteration was timed by trained study coordinators. Several other validated measures were used to assess the severity of CSM. These

include the mJOA, Nurick scale, Neck Disability Index (NDI), and the Short-Form-36 (SF-36v2).

Information was obtained at baseline and post-operatively at 6, 12, and 24 months.

Statistical Analysis

To determine the reliability and reproducibility of the 30MWT, repeated measures analysis of variance (ANOVA) was used to determine possible differences between each trial given at baseline. In order to examine the validity of the walking test, we used correlation coefficients to compare the results of the 30MWT walking test to other validated scales including the Nurick, mJOA, NDI, and physical and mental component summary scores of the SF-36v2. We report the correlations compared to several other validated scales since currently no gold standard test exists in this field. Additionally, we assess the difference between baseline walking test times and walking test times six months post-operation. In order to incorporate patients who were unable to complete the walking test due to physical inability (e.g. wheelchair-bound) into some of the analyses (correlation and paired differences), we assigned those patients a time which corresponded with the highest recorded walking test time of any patient at baseline. By doing this, patients who may have lost or gained the ability to walk following surgery could be conservatively included in the statistical analysis. We conducted a sensitivity analysis to see the impact of this assumption by running an additional analysis with these patients excluded. Nonparametric Spearman correlation coefficients and the Wilcoxon signed rank test were used when patients who were unable to walk were included in the analysis, and parametric Pearson correlation coefficients and the paired t-test were used in the sensitivity analysis. To determine the responsiveness of the 30MWT, the effect size and standardized response mean were used to assess responsiveness at 6 months follow-up. Significance for all statistical tests used was set at an alpha level of .05. Statistical analysis was conducted using SAS version 9.4 for Windows (Cary, NC).

RESULTS

Table 1 shows the demographics of the study population. Of the 757 total patients enrolled between the two trials, data from at least one baseline walking test were available for 612

patients. The average time for the 30MWT was 33.8 seconds among these patients (standard deviation, 18.2 seconds; Median, 28.5; 25% Q1: 23 seconds; 75% Q3 37 seconds). These times ranged from a low of 13.33 seconds to a high of 146 seconds at baseline.

Table 1: Combined Cohort Demographics

General Characteristic	Means or Frequencies
Age (years)	56.4±11.8
Gender (male)	475 (62.75%)
Duration of Symptoms (months)	26.6±39.0
Weight (pounds)	171.2
Height (inches)	66.3
Body Mass Index	27.3
Race	
White or Caucasian	73.1%
Black or African-American	6.21%
East Asian	15.2%
Other	5.49%
Region	
North America	52.97%
Asia Pacific	19.82%
Europe	16.64%
Latin America	10.57%

Reproducibility

Between the two cohorts, 479 patients completed the walking test all three times at their baseline visit. ANOVA failed to show a statistically significant difference between these 30MWT trials ($p = 0.663$). Because no significant difference was seen between trials, each patient's average time over all three walking trials was used for further data analysis.

Correlation

Table 2 shows the Spearman correlation coefficients between the 30MWT and other validated scales at baseline and 6 months post-operation. These scales included the Nurick scale, mJOA, NDI, and physical and mental component summary scores of the SF-36v2. At baseline, the 30MWT demonstrated moderate correlation with the Nurick (-0.468) and the mJOA (-0.551). Moderately low correlation was seen between the 30MWT and the SF-36v2 physical component summary score (-0.380) while very low correlation was seen between the 30MWT and the Neck Disability Index (0.253) and mental component summary score of the SF36v2 (-0.274). The correlations between the 30MWT and other tests were comparable at 6 months following surgery. All 10 of the reported correlation coefficients were statistically significant ($p < 0.0001$).

Table 2: Correlations between 30MWT and Other Selected Measures at Baseline and 6 Months

Comparator with 30MWT	Number of patients for comparison at Baseline	Walking Test Correlation at Baseline	Number of Patients for Comparison at 6 Months	Walking Test Correlation at 6 Months, N
Nurick	680	0.468	573	-0.369
mJOA	680	-0.551	573	-0.520
NDI	593	0.253	513	0.304
SF-36v2 PCS	663	-0.380	563	-0.351
SF-36v2 MCS	663	-0.274	563	-0.286

All correlations were statistically significant at $p < 0.0001$. Nurick indicates Nurick scale; mJOA, modified Japanese Orthopedic Association; NDI, Neck Disability Index; SF-36v2, Short-form 36; PCS, physical component score; MCS, mental component score

Differences in 30MWT Time Following Surgery

Data for the 30MWT data were available at both baseline and 6 months following surgery for a total of 545 patients. The mean reduction in walking time at 6 months was found to be 9.93 seconds. This change was statistically significant ($p < 0.0001$) using the nonparametric Wilcoxon signed rank test.

Responsiveness

Effect size and standardized response mean were both calculated to examine the responsiveness of the 30MWT. Effect size is calculated by dividing the mean change between baseline and follow-up by the standard deviation of the baseline score. Similarly, standardized response mean is calculated by dividing the mean change between baseline and follow-up by the standard deviation of the individual changes in scores. Both effect size and standardized response mean can range from 0 to 1, with 1 representing perfect test responsiveness. Table 3 shows the results were 0.264 for the effect size and 0.327 for the standardized response mean. Because the 30MWT is expected to be more responsive for patients with CSM who have difficulty walking, effect size and standardized response mean were also calculated using samples of the overall study population. As expected, the responsiveness of the 30MWT increased when limiting the analysis to the top 50% and 25% of patients according to walking time (Table 3).

Table 3: 30MWT Responsiveness by Subpopulation

Sample	N	SRM	ES
All	545	0.327	0.264
Top 50% of cohort according to walking	293	0.461	0.420

time (30MWT > 28.5 seconds)			
Top 25% of cohort according to walking time (30MWT > 37 seconds)	169	0.600	0.638

Sensitivity Analysis

In the sensitivity analysis for correlation, 70 patients who were unable to walk at either the baseline or 6-month visit were removed from the analysis. Parametric tests were used for the sensitivity analysis because removing the 70 patients with a high walking time caused the data to be normally distributed. Regarding the relationship between the 30MWT and the other scales, the results demonstrated slightly different Pearson correlation coefficients compared to the corresponding Spearman correlation coefficients. The 30MWT showed low-moderate correlation with the Nurick (0.360) and mJOA (-0.403) and continued to show low correlation between the 30MWT and the NDI (0.187), physical component of the SF-36v2 (-0.288) and mental component of the SF-36v2 (-0.200). All p values remained less than 0.0001. When patients who were unable to walk were removed at baseline and six months, the mean reduction in walking time was 3.96 seconds among 488 patients compared to 9.93 seconds among 545 patients. This reduction in walking time was still statistically significant using paired a paired t-test ($p < 0.0001$). Table 3 shows the effect size and standardized response mean adjusted for the sensitivity analysis. Because the standard deviation was lower when removing these patients, the

responsiveness actually showed an increase in those with difficulty walking (top 50% and 25% of cohort according to walking time).

Table 4: 30MWT Responsiveness by Subpopulation in Sensitivity Analysis

Sample	N	SRM	ES
All	488	0.316	0.247
Top 50% of cohort according to walking time (30MWT > 28.5)	236	0.474	0.455
Top 25% of cohort according to walking time (30MWT > 37)	112	0.611	0.695

DISCUSSION AND CONCLUSION

Singh and Crockard developed the 30MWT and reported preliminary data on 41 patients with CSM in 1999.¹² Our study reexamines the test characteristics of the 30MWT using data from two recent prospective multicenter cohort studies. According to our results, the test was reproducible, as no significant difference was seen between each trial of the 30MWT given at baseline. Moreover, the 30MWT demonstrated moderate correlation with both the Nurick scale (0.468) and mJOA (-0.551), which are the most widely used measures in the CSM population⁸. Compared to the original 1999 validation study, our results demonstrated lower correlation between the 30MWT and the Nurick scale, as they reported a correlation of 0.61 and 0.69 at baseline and 2 months following surgery, respectively. A recent study examining the validity of the mJOA using patients from the CSM North America study, who were included in the current

study, reported a correlation between the mJOA and 30MWT of -0.382. This value is similar to the association that we report in our sensitivity analysis when patients who were unable to walk were excluded from the analysis. Finally, our results indicate that the responsiveness of the 30MWT, although low when calculated for all patients with CSM, increases to moderate when only patients with difficulty walking are included in the analysis. This makes sense, as we expect the 30MWT to only be helpful for assessing CSM severity in patients who have difficulty walking. Our sensitivity analysis showed that our assumption of imputing walking test times for patients unable to complete the walking test due to physical inability was valid. A significant change in walking time was still seen in the study population when patients unable to walk were excluded, and the test responsiveness was actually higher when removing those patients.

Several scales and scoring systems have been used to quantify the severity of CSM. These measures are vulnerable to several limitations, however. First of all, most of these measures rely on information reported by patients themselves, lacking the objectivity of a neurologic examination. Second, many measures are long questionnaires which may require a trained study coordinator or other aide to spend significant time with the patient in clinic. Third, currently used measures may not be available in resource-poor areas and often times have not been validated in other languages besides English. In contrast, the 30MWT objectively assesses gait parameters that are not accurately assessed by other metrics.

Our study has several limitations. First, reproducibility was assessed by timing the 30MWT for three trials on the same day at each visit. While this method provides a degree of information regarding reproducibility, it does not assess reproducibility from day to day and may fail to capture fluctuations in functional status. Additionally, only 545 of 757 patients had walking test data at both baseline and six months. This may introduce a selection bias via

selective follow-up. However, this study also has several strengths. First, our research utilized a multicenter international prospective study design with few inclusion criteria and many investigators. All of these characteristics increase the study's external validity and contribute to its real-world applicability. Furthermore, the severity of CSM was measured using several validated instruments, which allowed for proper comparison and correlation with the 30MWT.

Practically speaking, the 30MWT should not be considered a replacement for the mJOA or the Nurick scale, but it will act as a complementary test by providing an objective measure of gait not easily captured by other commonly used metrics. It is simple, objective, reproducible, and easy for patients and clinicians to perform. Language is not a barrier to its performance, and the continuous, objective measurement is useful in research settings. Additionally, it does not require sophisticated equipment to perform. Along with these unique advantages, the testing characteristics associated with the 30MWT, computed using data from two prospective multicenter cohort studies, suggest that the 30MWT is a useful ancillary test for measuring the severity of CSM.

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