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Abstract

Introduction: Reliable and valid tools must be used to assess spasticity in clinical practice and research settings. There is a paucity of literature regarding the validity of the Modified Modified Ashworth Scale (MMAS) and the Modified Tardieu Scale (MTS). No study, to date, has been performed to compare the validity of the MMAS and the MTS. This neurophysiological study protocol will compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods and Analysis: First, wrist flexor spasticity will be assessed clinically using the MMAS and MTS. The tests will be applied randomly. For the MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. Second, neurophysiological measures of H-reflex latency, H_{\max}/M_{\max} ratio, H_{slp} , and $H_{\text{slp}}/M_{\text{slp}}$ ratio will be collected randomly from both affected and unaffected sides. The results will be analyzed using Spearman's rho test or Pearson correlation test to determine the validity of the MMAS and the MTS as well as to compare the validity between the MMAS and the MTS.

Ethics and dissemination: The Research Council, School of Rehabilitation, and the Ethics Committee of Tehran University of Medical Sciences approved the study protocol. The study results will be disseminated in peer-reviewed publications and presented at international congresses.

Key words: Stroke; Spasticity; Modified Modified Ashworth Scale; Modified Tardieu Scale; Validity

INTRODUCTION

Spasticity is a common symptom observed following upper motor neuron syndrome. Diseases such as stroke, traumatic brain injury, spinal cord injury, cerebral palsy, and multiple sclerosis are associated with significant spasticity. Spasticity has been defined classically by Lance as a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes.¹ There are several studies addressing the prevalence of spasticity after stroke.² The prevalence of spasticity after a first stroke has been inconsistent, ranging between 18% - 38%.³⁻⁸ In addition a recent study indicated that the prevalence of spasticity in patients with stroke referred to a Department of Rehabilitation Medicine was 42.4%.⁹ Excessive spasticity needs to be controlled, because it can interfere with functional recovery, and may lead to secondary complications such as contractures and pain.^{10,11} Reflex hyperexcitability and soft tissue stiffness both have been reported to contribute to increased resistance to passive stretch.¹²

To assess spasticity accurately in clinical practice and for research purposes, reliable and valid tools must be used. The Ashworth and Tardieu scales are common clinical measures of spasticity. The Ashworth scale was originally developed in 1964, and modified by Bohannon and Smith in 1987.^{13,14} The Bohannon-Smith Modified Ashworth Scale (MAS) has been recently modified by Ansari et al. in 2006 as the Modified Modified Ashworth Scale (MMAS) (table 1).¹⁵ The MMAS is an ordinal level measure of spasticity, which grades the intensity of spasticity from 0-4. The results of several studies have demonstrated that the MMAS is a reliable measure for assessing spasticity in either upper or lower limbs of patients with spasticity.¹⁶⁻²²

The Tardieu scale was developed by Tardieu et al in 1954.²³ Held and Pierrot-Deseilligny modified it in 1969, and it was further modified in 1999 by Boyd

and Graham.²⁴ This latest version of Tardieu scale is called the Modified Tardieu Scale (MTS).^{25,26} The MTS considers R2, R1, and R2-R1 to measure spasticity. The R2 is the passive range of motion measured during slow passive stretch. The R1 is the angle of muscle reaction measured during fast passive stretch, and occurs in a particular angle of “catch” from hyperactive stretch reflex. Large and small differences between R2 and R1 indicate spasticity and muscle contracture, respectively.^{25,27} Quality of muscle reaction during fast passive stretch is also graded based on 0-4 scores and is defined as the MTS scores (table 1).^{28,29}

Table 1 about here

Studies regarding the reliability of the MTS have been mostly performed in children.³⁰⁻³³ The reliability of the MTS has been questioned for various patients groups.^{32,34,35} Paulis et al. compared the test-retest and inter-rater reliability of Tardieu Scale scores measured with inertial sensors (IS) and goniometry and found excellent reliability for IS.³⁶ Ansari et al. showed insufficient inter-rater reliability for MTS when measuring elbow flexor spasticity in adult patients with hemiplegia using goniometry.³⁴ In a study by Singh et al. it has been shown that the intra-rater reliability of MTS is very good for R1, R2, R2-R1, and MTS scores across two sessions in elbow flexors and ankle plantar flexors using goniometry.³⁷ A study comparing the reliability of the MTS with the Bohannon-Smith MAS in adult patients with severe brain injury found significantly higher test-retest and inter-rater reliability for MTS, however poor to moderate inter-rater reliability for both scales.³⁸

There is a paucity of literature exploring the validity of MMAS and MTS. The validity of MMAS has been evaluated neurophysiologically with the measurement of wrist flexor spasticity in patients with stroke.³⁹ Naghdi et al. found a significant

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positive correlation between the MMAS scores and H_{slp}/M_{slp} ratio ($r = 0.39$, $p = 0.04$), traditional index of H_{max}/M_{max} ratio ($r = 0.39$, $p = 0.04$), and H_{slp} ($r = 0.45$, $p = 0.02$) indicating the validity of the MMAS.³⁹ In another study, the authors showed that the MMAS and the Brunnstrom recovery stages were highly correlated in the evaluation of motor recovery in patients with stroke.⁴⁰ Recently, the content validity of the Tardieu Scale and the Ashworth Scale was assessed in independently ambulating children with cerebral palsy.⁴¹ The authors demonstrated that the Tardieu Scale was more effective than the Original Ashworth Scale in identifying the presence of spasticity, the presence of contracture and the severity of contracture. Neither scale was able to identify the severity of spasticity.⁴¹

AIMS AND OBJECTIVES

No study has compared the validity of MMAS and MTS. The present neurophysiological study protocol is designed to compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods

Study Design

This study is designed for comparing the criterion validity between the MMAS and the MTS in the assessment of wrist flexor spasticity in patients poststroke. The clinical measures of MMAS and MTS will be obtained, and will be correlated with neurophysiological measures of H-reflex latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio.

Setting

The measurements will be taken at the Department of Electrophysiology,

University Hospital of Shafa in Tehran, Iran.

Approval of Study Protocol

The study protocol has been approved by the Research Council, School of Rehabilitation, Tehran University of Medical Sciences (TUMS). Ethical approval has been granted by TUM Ethics Committee.

Informed Consent

Written informed consent from the eligible subjects will be obtained before tests are performed. We will instruct patients that they are free to obtain any information about the detail of the study from the investigator, and they are free to discontinue their participation in the study at any time.

Participants

The study is designed to include 32 subjects with the following criteria. Inclusion criteria will be: 1) first stroke; 2) history of stroke between 1-24 months; 3) age between 40 to 65 years; and 4) ability to understand and follow instructions.

Exclusion criteria will be: 1) fixed contracture at wrist joint; 2) wrist pain due to degenerative changes; 3) taking antispastic drugs; 4) contraindication of passive movement at wrist joint; 5) cervical discopathy; 6) diabetes; and 7) nonconsent.

Procedures

The patients will be interviewed to collect demographic characteristics including: age; etiology (i.e. ischemic or vascular stroke); time elapsed from onset of stroke; and affected side. Wrist flexor spasticity will be assessed clinically on the affected side using MMAS and MTS. For MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. The sequence of tests will be

randomized. The neurophysiological data will also be collected from the affected side. One trained physiotherapist will perform both clinical and neurophysiological tests. The clinical tests will be applied first.

Outcome Measures

Muscle spasticity is primarily due to an exaggerated stretch reflex and alpha motor neuron excitability.¹ The MMAS and MTS will be used for the assessment of muscle spasticity. The H-reflex is an objective method for the measurement of spasticity.⁴² The H- reflex parameters of latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio will be applied to examine alpha motor neuron excitability.

The H_{max}/M_{max} ratio indicates the level of motoneuron excitability. The H_{slp} is a measure of the relationship between the number of motoneurons activated and a given incremental rise in stimulation intensity.^{43,44} The H_{slp}/M_{slp} ratio is a new method of spasticity measurement, and presumes that the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp}) is a better parameter for evaluating the motoneuron excitability.

The Modified Modified Ashworth Scale

Wrist flexor spasticity will be quantified using the clinical scale MMAS, which has been shown to be reliable at the wrist joint.^{17,18} The procedure used and described in previous studies will be followed to measure wrist flexor spasticity. Briefly, the patient will be in supine position, head in midline, and arms alongside the trunk. The rater will hold the forearm in mid-position just proximal to the wrist joint with one hand, and will grasp the patients hand with the other hand. The rater will move the wrist from maximum possible flexion to maximal possible extension counting one thousand and one.^{17,18} The rater will score muscle spasticity from 0-4.

Only one passive stretch will be applied to rate spasticity.¹⁵

The Modified Tardieu Scale

A standard goniometer will be utilized to measure R2 and R1. The patient will be in sitting position with elbow joint flexed at 90°. The stretching velocity of V1 and V3 will be applied to measure R2 and R1, respectively. The quality of muscle reaction will be graded at the stretching velocity of V3, as well.^{16,17} The difference between R2 and R1 will be the measure of the dynamic component of spasticity.

Measurement of H-reflex

The H-reflex and the M-wave will be obtained using an EMG machine (Myto II, Italy). The H-reflex will be elicited in the flexor carpi radialis (FCR) muscle of the affected side of the participants. A digital thermometer will be used to measure the skin temperature. The bandpass filter will be set at 5Hz to 3KHz, sweep speed at 5 ms/div, and sensitivity at 200- 500 μ v. The stimulator will apply rectangular electric pulses with 1 ms duration, every 5 seconds.^{39,40} Paired surface electrodes (Ag/AgCl) will be attached to the skin on the muscle belly. The median nerve will be stimulated at the elbow crease using a bipolar stimulating electrode. The recording electrodes will be placed over the muscle belly of the FCR. The active electrode will be placed on the belly of the FCR at one third of the proximal distance between the medial epicondyle of humerus and the radial styloid. The electric resistance between the two electrodes will be less than 10 K Ω . The ground will be attached to the skin between stimulating and recording electrodes. Stepwise increase in stimulus intensity will be used to record the H-reflex and M-wave. The stimulus intensity will start at 0.5 mA and will be increased in steps of 0.5 mA to record H_{max} and M_{max} .^{39,40}

Recruitment Curves

To build the recruitment curves of H-reflex and M-waves, we will follow the methods described elsewhere.^{39,40,43-45} Five pulses will be delivered sequentially at each stimulus intensity and the mean amplitude of evoked H-reflexes and the M-responses will be calculated. The amplitudes will be measured peak to peak. Mean amplitudes will be normalized according to the following formula:

$$\text{Normalized amplitude (H or M)} = [\text{Mean amplitude of five wave} / M_{\max}] \times 100$$

Stimulus intensities will be presented as the ratio of the threshold intensity of the M-wave (M_{th}). All data measured at stimulus intensities less than the threshold of the M-wave will be used to determine the H_{slp} . Data from M_{th} up to maximum amplitude of M-wave will determine the M_{slp} . Equation of simple linear regression will be determined, and the slope of this line will be considered as H_{slp} or M_{slp} . Maximum mean amplitude of the H-reflex and maximum mean amplitude of the M-wave will be regarded as H_{\max} and M_{\max} , respectively. The H_{\max} relative to M_{\max} is H_{\max}/M_{\max} ratio. The H-reflex latency will be calculated from stimulus wave to the onset of first deflection of H-wave, and the amplitude of recorded reflexes and waves will be measured.

Sample Size Calculation

In the study by Naghdi et al., correlation of the MMAS with the H_{\max}/M_{\max} ratio or the $H_{\text{slp}}/M_{\text{slp}}$ ratio was $r = 0.39$.³⁸ Assuming the correlation is 0.4, and to show a similar validity with 0.95 % power at 5% significance level, it will require that data is taken on 32 participants.

Statistical Analysis

To determine the validity of the clinical tests, the relationships between the

clinical tests and the H-reflex indices will be assessed by calculating Spearman's rho test (i.e. MMAS and the ordinal component of the MTS) or Pearson correlation test (i.e. ratio components of the MTS). Comparing correlations test will be used to compare the validity of the MMAS and the MTS.⁴⁶

Results

Demographic Characteristics

Demographic characteristics of participants will be illustrated as shown in table 2.

Table 2 about here

Clinical Characteristics

Clinical spasticity grades with MMAS, MTS measures and quality of muscle reaction will be illustrated in table 3.

Table 3 about here

Neurophysiological Data

Objective neurophysiological assessment results using the H-reflex will be illustrated as shown in Table 4.

Table 4 about here

DISCUSSION

This article describes a neurophysiological study protocol for comparative evaluation of the validity of two important clinical measures in the field of neurological rehabilitation. To our knowledge, this investigation will be the first to compare the criterion validity of the MMAS and the MTS. This protocol utilizes conventional and new indicators of motoneuron excitability in spasticity for comparative validity evaluation. Further, the protocol utilizes standard methodology for spasticity assessment to indicate the excitability of the alpha motoneuron pool.⁴²

The results of the present protocol will be important. Due to the limitations of the Ashworth scales and questioned reliability and validity,⁴⁷ the new MMAS has emerged to improve the metric characteristics of the scales. The results of the metrics for the MMAS have been encouraging up to this point. The MMAS needs to be further examined for additional psychometric properties and be utilized during intervention based studies.⁴⁸ Since the original and Modified Ashworth Scale have been reported to have poor reliability and validity the MTS has been suggested as an alternative and suitable measure for use in assessment of spasticity.^{29,49} However, the results of reliability for the MTS have been mixed, with a dearth of studies exploring the validity of the MTS. This study will be the first report investigating the validity of the MTS through establishing correlation between the MTS and the alpha motor neuron excitability indicators. While the MTS has been explained theoretically as a suitable spasticity measure, there is no evidence to compare this scale with existing clinical measures such as the MMAS. The results of this protocol will provide neurophysiological evidence for the validity of the MMAS and the MTS as clinical scales for the measurement of muscle spasticity.

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Contributors NNA and SN contributed to the conception of the study. NNA and SN contributed to the study design. HA contributed to drafting the protocol. All authors read and revised the manuscript for important intellectual content. All authors reviewed the final manuscript and gave approval of the version to be published.

Ethics approval The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol.

Funding Support for this study was provided by the Research Deputy of TUMS.

Competing interests None.

ARTICLE SUMMARY

Article focus

▪ A neurophysiological study protocol to compare the validity of the Modified Modified Ashworth Scale (MMAS) and the Modified Tardieu Scale (MTS) in the assessment of wrist flexor spasticity after stroke.

Key messages

- Reliable and valid tools must be used to assess spasticity accurately in clinical and research settings.
- The results of this protocol will provide evidence for the validity of the MMAS and the MTS for the measurement of muscle spasticity.

Strengths and limitations of this study

- This study will use conventional and new measures of motoneuron excitability for the objective evaluation of spasticity.
- This study will be the first to compare the criterion validity of the MMAS and the MTS.
- This study will provide neurophysiological evidence for the validity of the MMAS and the MTS, and will help us determine the place of the new MMAS and MTS in assessing muscle spasticity.

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Table1: Definitions of the Modified Tardieu Scale and the Modified Modified Ashworth Scale.

Grade	Modified Tardieu Scale (Boyd and Graham, 1999)	Modified Modified Ashworth Scale (Ansari et al, 2006)
0	no resistance throughout the course of the passive movement	No increase in muscle tone
1	slight resistance throughout the course of the passive movement, with no clear catch at precise angle	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
2	Clear catch at precise angle, interrupting the passive movement, followed by release	Marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part (s) easily moved
3	Fatigable clonus (<10 seconds when maintaining pressure) occurring at precise angle	Considerable increase in muscle tone, passive movement difficult
4	Infatigable clonus (>10 seconds when maintaining pressure) occurring at precise angle	Affected part(s) rigid in flexion or extension.

Table 2: Demographic and clinical characteristics

	Number	Mean (SD)	Minimum	Maximum
Gender (M/F)				
Age				
Weight				
Height				
BMI				
Time since stroke				
Affected side(R/L)				

Table 3: The results for spasticity grades and measurements of R1, R2, and R2-R1

MTS measures	Median (IQR)	Mean (SD)	Min-Max	95% CI
R1				
R2				
R2-R1				
MMAS grades				
MTS grades				

R1: Angle of muscle reaction; R2: passive range of motion; R2-R1: dynamic component or spasticity

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Table 4: The results for H-reflex indices

	Mean (SD)	Min-Max	95% CI
H_{\max}/M_{\max}			
Latency			
$H_{\text{slp}}/M_{\text{slp}}$			
H_{slp}			

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Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

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Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

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Abstract

Introduction: Reliable and valid tools must be used to assess spasticity in clinical practice and research settings. There is a paucity of literature regarding the validity of the Modified Modified Ashworth Scale (MMAS) and the Modified Tardieu Scale (MTS). No study, to date, has been performed to compare the validity of the MMAS and the MTS. This neurophysiological study protocol will compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods and Analysis: Thirty-two patients with stroke from the University Rehabilitation clinics will be recruited to participate in this cross-sectional, non-interventional study. All measurements will be taken in the Physical Medicine and Rehabilitation Department of Shafa University Hospital in Tehran, Iran. First, wrist flexor spasticity will be assessed clinically using the MMAS and MTS. The tests will be applied randomly. For the MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. Second, neurophysiological measures of H-reflex latency, H_{\max}/M_{\max} ratio, H_{slp} , and H_{slp}/M_{slp} ratio will be collected from affected side. The results will be analyzed using Spearman's rho test or Pearson correlation test to determine the validity of the MMAS and the MTS as well as to compare the validity between the MMAS and the MTS.

Ethics and dissemination: The Research Council, School of Rehabilitation, and The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol. The study results will be disseminated in peer-reviewed publications and presented at international congresses.

Key words: Stroke; Spasticity; Modified Modified Ashworth Scale; Modified Tardieu Scale; Validity

INTRODUCTION

Spasticity is a common symptom observed following upper motor neuron syndrome. Diseases such as stroke, traumatic brain injury, spinal cord injury, cerebral palsy, and multiple sclerosis are associated with significant spasticity. Spasticity has been defined classically by Lance as a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes.¹ There are several studies addressing the prevalence of spasticity after stroke.² The prevalence of spasticity after a first stroke has been inconsistent, ranging between 18% - 38%.³⁻⁸ In addition a recent study indicated that the prevalence of spasticity in patients with stroke referred to a Department of Rehabilitation Medicine was 42.4%.⁹ Excessive spasticity needs to be controlled, because it can interfere with functional recovery, and may lead to secondary complications such as contractures and pain.^{10,11} Reflex hyperexcitability and soft tissue stiffness both have been reported to contribute to increased resistance to passive stretch.¹²

To assess spasticity accurately in clinical practice and for research purposes, reliable and valid tools must be used. The Ashworth and Tardieu scales are common clinical measures of spasticity. The Ashworth scale was originally developed in 1964, and modified by Bohannon and Smith in 1987.^{13,14} The Bohannon-Smith Modified Ashworth Scale (MAS) has been recently modified by Ansari et al. in 2006 as the Modified Modified Ashworth Scale (MMAS) (table 1).¹⁵ The MMAS is an ordinal level measure of spasticity, which grades the intensity of spasticity from 0-4. The results of several studies have demonstrated that the MMAS is a reliable measure for assessing spasticity in either upper or lower limbs of patients with spasticity.¹⁶⁻²²

The Tardieu scale was developed by Tardieu et al in 1954.²³ Held and Pierrot-Deseilligny modified it in 1969, and it was further modified in 1999 by Boyd

and Graham.²⁴ This latest version of Tardieu scale is called the Modified Tardieu Scale (MTS).^{25,26} The MTS considers R2, R1, and R2-R1 to measure spasticity. The R2 is the passive range of motion measured during slow passive stretch. The R1 is the angle of muscle reaction measured during fast passive stretch, and occurs in a particular angle of “catch” from hyperactive stretch reflex. Large and small differences between R2 and R1 indicate spasticity and muscle contracture, respectively.^{25,27} Quality of muscle reaction during fast passive stretch is also graded based on 0-4 scores and is defined as the MTS scores (table 1).^{28,29}

Table 1 about here

Studies regarding the reliability of the MTS have been mostly performed in children.³⁰⁻³³ The reliability of the MTS has been questioned for various patients groups.^{32,34,35} Paulis et al. compared the test-retest and inter-rater reliability of Tardieu Scale scores measured with inertial sensors (IS) and goniometry and found excellent reliability for IS.³⁶ Ansari et al. showed insufficient inter-rater reliability for MTS when measuring elbow flexor spasticity in adult patients with hemiplegia using goniometry.³⁴ In a study by Singh et al. it has been shown that the intra-rater reliability of MTS is very good for R1, R2, R2-R1, and MTS scores across two sessions in elbow flexors and ankle plantar flexors using goniometry.³⁷ A study comparing the reliability of the MTS with the Bohannon-Smith MAS in adult patients with severe brain injury found significantly higher test-retest and inter-rater reliability for MTS, however poor to moderate inter-rater reliability for both scales.³⁸

There is a paucity of literature exploring the validity of MMAS and MTS. The validity of MMAS has been evaluated neurophysiologically with the measurement of wrist flexor spasticity in patients with stroke.³⁹ Naghdi et al. found a significant

positive correlation between the MMAS scores and H_{slp}/M_{slp} ratio ($r = 0.39$, $p = 0.04$), traditional index of H_{max}/M_{max} ratio ($r = 0.39$, $p = 0.04$), and H_{slp} ($r = 0.45$, $p = 0.02$) indicating the validity of the MMAS.³⁹ In another study, the authors showed that the MMAS and the Brunnstrom recovery stages were highly correlated in the evaluation of motor recovery in patients with stroke.⁴⁰ Recently, the content validity of the Tardieu Scale and the Ashworth Scale was assessed in independently ambulating children with cerebral palsy.⁴¹ The authors demonstrated that the Tardieu Scale was more effective than the Original Ashworth Scale in identifying the presence of spasticity, the presence of contracture and the severity of contracture. Neither scale was able to identify the severity of spasticity.⁴¹

The basic neural circuit in spasticity is the monosynaptic stretch reflex arc characterized by the sensory Ia afferent and alpha motor neuron.⁴² Various neurophysiological changes have been shown to occur in muscle spasticity, including alpha motor neuron hyperexcitability.^{12, 43} The H-reflex is a simple, noninvasive method which can be used to study reflex pathway reliably.⁴⁴⁻⁴⁸ The H-reflex parameters of H_{max}/M_{max} ratio and latency are reliable measures of alpha motor neuron hyperexcitability, and have been suggested for objective quantifying of muscle spasticity.^{49, 50} In patients with spasticity, H-reflex latency is usually decreased and H_{max}/M_{max} ratio is increased.⁴⁹

The H_{slp}/M_{slp} ratio [the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp})] has been proposed as a better indicator for evaluating the excitability of a motor neuron pool in spasticity.^{51, 52} The slope of the H-reflex recruitment curve (H_{slp}) representing the relationship between stimulation intensity and reflex recruitment of motor neurons is free from the H-reflex discharge collision and shows the intrinsic excitability of the

motor neurons and the reflex arc (Higashi et al, 2001).^{52, 53} The H_{slp} is more sensitive than H_{max}/M_{max} , provides more information about the recruitment threshold and can estimate spinal excitability.^{52, 54} It has been demonstrated that flexor carpi radialis (FCR) H-reflexes can be reliably evoked in post-stroke paretic and non-paretic arms, and the FCR recruitment slope is a sensitive measure of spinal excitability after stroke.⁵⁵ The H-reflex tests will be used for validation of the MMAS and the MTS.

AIMS AND OBJECTIVES

No study has compared the validity of MMAS and MTS. The present neurophysiological study protocol is designed to compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods

Study Design

This cross-sectional, non-interventional study is designed for comparing the criterion validity between the MMAS and the MTS in the assessment of wrist flexor spasticity in patients poststroke. The clinical measures of MMAS and MTS will be obtained, and will be correlated with neurophysiological measures of H-reflex latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio.

Setting

The measurements will be taken at the Department of Electrophysiology, University Hospital of Shafa in Tehran, Iran.

Approval of Study Protocol

The study protocol has been approved by the Research Council, School

of Rehabilitation, Tehran University of Medical Sciences (TUMS), and Ethical approval has been granted by TUMS Ethics Committee (Reference number 1322).

Informed Consent

Written informed consent from the eligible subjects will be obtained before tests are performed. We will instruct patients that they are free to obtain any information about the detail of the study from the investigator, and they are free to discontinue their participation in the study at any time.

Participants

Patients with stroke who attend the Rehabilitation clinics of TUMS will be screened for eligibility. Eligible patients will be invited to participate in the study. The study is designed to include 32 subjects with the following criteria. Inclusion criteria will be: 1) first stroke; 2) history of stroke between 1-24 months; 3) age between 40 to 65 years; and 4) ability to understand and follow instructions. Exclusion criteria will be: 1) fixed contracture at wrist and elbow joints; 2) wrist pain due to degenerative changes; 3) taking antispastic drugs; 4) contraindication of passive movement at wrist joint; 5) cervical discopathy; 6) diabetes; and 7) nonconsent.

Procedures

The patients will be interviewed to collect demographic characteristics including: age; etiology (i.e. ischemic or vascular stroke); time elapsed from onset of stroke; and affected side. Effort will be made to provide a similar testing condition. All measurements will be taken in the morning hours of 9.00-12.00. Before testing commencement, all patients will be asked to rest on the bed with shoes removed for 5 minutes and remain comfortable and relaxed. To provide a quiet testing environment, all tests will be performed in a closed quiet room with natural light from windows.

The temperature of the testing room will be set at approximately 25°. We will also ask the patients to empty their bladder prior to testing. The room is electrically shielded and earth-grounded for H-reflex measurements.

The wrist flexors will be tested in this study, because they are usually spastic in patients poststroke, and spasticity can be reliably measured in wrist flexors.^{17, 18, 56} Clinical and neurophysiological tests will be performed in a single session. Wrist flexor spasticity will be assessed clinically on the affected side using MMAS and MTS. For MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. The sequence of tests will be randomized by tossing a coin. The neurophysiological data will also be collected from the affected side. One trained physiotherapist will perform both clinical and neurophysiological tests. The clinical tests will be applied first. The tester will be blinded to the neurophysiological data analyses.

Outcome Measures

Muscle spasticity is primarily due to an exaggerated stretch reflex and alpha motor neuron excitability.¹ The MMAS and MTS will be used for the assessment of muscle spasticity. The H-reflex is an objective method for the measurement of spasticity.⁴⁹ The H-reflex parameters of latency; H_{\max}/M_{\max} ratio; H_{slp} ; and $H_{\text{slp}}/M_{\text{slp}}$ ratio will be applied to examine alpha motor neuron excitability.

The H_{\max}/M_{\max} ratio indicates the level of motoneuron excitability. The H_{slp} is a measure of the relationship between the number of motoneurons activated and a given incremental rise in stimulation intensity.^{51,52} The $H_{\text{slp}}/M_{\text{slp}}$ ratio is a new method of spasticity measurement, and presumes that the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp}) is a better parameter for evaluating the motoneuron excitability.

The Modified Modified Ashworth Scale

Wrist flexor spasticity will be quantified using the clinical scale MMAS, which has been shown to be reliable at the wrist joint.^{17,18} The procedure used and described in previous studies will be followed to measure wrist flexor spasticity. Briefly, the patient will be in supine position, head in midline, and arms alongside the trunk with shoulder in slight abduction. The rater will hold the forearm in mid-position just proximal to the wrist joint with one hand, and will grasp the patients hand with the other hand. The rater will move the wrist from maximum possible flexion to maximal possible extension counting one thousand and one.^{17,18} The rater will score muscle spasticity from 0-4. Only one passive stretch will be applied to rate spasticity.¹⁵

The Modified Tardieu Scale

A standard goniometer will be utilized to measure R2 and R1. The patient will be in sitting position with elbow joint flexed at 90°. The stretching velocity of V1 and V3 will be applied to measure R2 and R1, respectively. The quality of muscle reaction will be graded at the stretching velocity of V3, as well.^{16,17} The difference between R2 and R1 will be the measure of the dynamic component of spasticity.

Measurement of H-reflex

As with the clinical test, the patient will be positioned in supine, head in midline, and arms alongside the trunk. Patients will be asked to remain calm, and relax completely during testing.

The H-reflex and the M-wave will be obtained using an EMG machine (Myto II, Italy). The H-reflex will be elicited in the flexor carpi radialis (FCR) muscle of the affected side of the participants with the arm in supination. The H-reflex in FCR

muscle has been commonly employed in studies of H-reflex in the upper limb, and can be reliably evoked and measured.^{46, 49, 57, 58} A digital thermometer will be used to measure the skin temperature. The bandpass filter will be set at 5Hz to 3KHz, sweep speed at 5 ms/div, and sensitivity at 200- 500 μ v.

The stimulator will apply rectangular electric pulses with 1 ms duration, every 5 seconds.^{39,40} Paired surface electrodes (Ag/AgCl) will be attached to the skin on the muscle belly. The median nerve will be stimulated at the elbow crease using a bipolar stimulating electrode. The stimulating electrodes will be positioned in line with the median nerve in the cubital fossa just medial to the biceps brachii tendon with the cathode proximal to the anode to prevent anodal block.⁵⁹

The recording electrodes will be placed over the muscle belly of the FCR. The active electrode will be placed on the belly of the FCR at one third of the proximal distance between the medial epicondyle of humerus and the radial styloid. The reference electrode will be positioned 4 cm distal and lateral to the active one. The electric resistance between the two electrodes will be less than 10 K Ω . The ground electrode will be attached to the skin between stimulating and recording electrodes. Stepwise increase in stimulus intensity will be used to record the H-reflex and M-wave. The stimulus intensity will start at 0.5 mA and will be increased in steps of 0.5 mA to record H_{max} and M_{max} .^{39,40} H-reflex conditioning will not be used in this protocol, as FCR H-reflex can be easily evoked without facilitation in most cases.⁴⁷

Recruitment Curves

To build the recruitment curves of H-reflex and M-waves, we will follow the methods described elsewhere.^{39,40,51, 52, 60} Five pulses will be delivered sequentially at each stimulus intensity and the mean amplitude of evoked H-reflexes and the M-responses will be calculated. The amplitudes will be measured peak to peak. Mean

amplitudes will be normalized according to the following formula:

$$\text{Normalized amplitude (H or M)} = [\text{Mean amplitude of five wave} / M_{\max}] \times 100$$

Stimulus intensities will be presented as the ratio of the threshold intensity of the M-wave (M_{th}). All data measured at stimulus intensities less than the threshold of the M-wave will be used to determine the H_{slp} . Data from M_{th} up to maximum amplitude of M-wave will determine the M_{slp} . Equation of simple linear regression will be determined, and the slope of this line will be considered as H_{slp} or M_{slp} . Maximum mean amplitude of the H-reflex and maximum mean amplitude of the M-wave will be regarded as H_{\max} and M_{\max} , respectively. The H_{\max} relative to M_{\max} is H_{\max}/M_{\max} ratio. The H-reflex latency will be calculated from stimulus wave to the onset of first deflection of H-wave, and the amplitude of recorded reflexes and waves will be measured.

Sample Size Calculation

In the study by Naghdi et al., correlation of the MMAS with the H_{\max}/M_{\max} ratio or the $H_{\text{slp}}/M_{\text{slp}}$ ratio was $r = 0.39$.³⁹ Assuming the correlation is 0.4, and to show a similar validity with 0.95 % power at 5% significance level, it will require that data is taken on 32 participants.

Statistical Analysis

To determine the validity of the clinical tests, the relationships between the clinical tests and the H-reflex indices will be assessed by calculating Spearman's rho test (i.e. MMAS and the ordinal component of the MTS) or Pearson correlation test (i.e. ratio components of the MTS). Comparing correlations test will be used to compare the validity of the MMAS and the MTS.⁶¹

RESULTS

Demographic Characteristics

Demographic characteristics of participants will be illustrated as shown in table 2.

Table 2 about here

Clinical Characteristics

Clinical spasticity grades with MMAS, MTS measures and quality of muscle reaction will be illustrated in table 3.

Table 3 about here

Neurophysiological Data

Objective neurophysiological assessment results using the H-reflex will be illustrated as shown in Table 4.

Criterion Validity

The criterion validity will be analyzed by correlations between the clinical measures and neurophysiological tests. Criterion validity will be established when significant moderate correlations between the MMAS/the MTS and the neuropsychological measures are found. The results of correlation analyses will be presented in Table 5.

Table 4 about here

Table 5 about here

DISCUSSION

This article describes a neurophysiological study protocol for comparative evaluation of the validity of two important clinical measures in the field of neurological rehabilitation. To our knowledge, this investigation will be the first to

compare the criterion validity of the MMAS and the MTS. This protocol utilizes conventional and new indicators of motoneuron excitability in spasticity for comparative validity evaluation. Further, the protocol utilizes standard methodology for spasticity assessment to indicate the excitability of the alpha motoneuron pool.⁴⁹

The results of the present protocol will be important. Due to the limitations of the Ashworth scales and questioned reliability and validity,⁶² the new MMAS has emerged to improve the metric characteristics of the scales. The results of the metrics for the MMAS have been encouraging up to this point. The MMAS needs to be further examined for additional psychometric properties and be utilized during intervention based studies.⁶³ Since the original and Modified Ashworth Scale have been reported to have poor reliability and validity the MTS has been suggested as an alternative and suitable measure for use in assessment of spasticity.^{29,64} However, the results of reliability for the MTS have been mixed, with a dearth of studies exploring the validity of the MTS. This study will be the first report investigating the validity of the MTS through establishing correlation between the MTS and the alpha motor neuron excitability indicators. While the MTS has been explained theoretically as a suitable spasticity measure, there is no evidence to compare this scale with existing clinical measures such as the MMAS. The results of this protocol will provide neurophysiological evidence for the validity of the MMAS and the MTS as clinical scales for the measurement of muscle spasticity.

LIMITATIONS

A limitation of the study is that the tests will be performed by only one person. This will be the most significant limitation of the study.

Contributors HA, NNA, SN, KM, NG, and SH contributed to the conception of the study. All authors contributed to the study design. HA contributed to drafting the protocol. All authors read and revised the manuscript for important intellectual content. All authors reviewed the final manuscript and gave approval of the version to be published.

Ethics approval The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol.

Funding Support for this study was provided by the Research Deputy of TUMS.

Competing interests None.

ARTICLE SUMMARY

Article focus

- Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

Key messages

- Reliable and valid tools must be used to assess spasticity accurately in clinical and research settings.
- The results of this protocol will provide evidence for the validity of the MMAS and the MTS for the measurement of muscle spasticity.

Strengths and limitations of this study

- This study will use conventional and new measures of motoneuron excitability for the objective evaluation of spasticity.
- This study will be the first to compare the criterion validity of the MMAS and the MTS.
- A weakness of the study is that the tests will be carried out by one person.

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Table1: Definitions of the Modified Tardieu Scale and the Modified Modified Ashworth Scale.

Grade	Modified Tardieu Scale (Boyd and Graham, 1999)	Modified Modified Ashworth Scale (Ansari et al, 2006)
0	no resistance throughout the course of the passive movement	No increase in muscle tone
1	slight resistance throughout the course of the passive movement, with no clear catch at precise angle	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
2	Clear catch at precise angle, interrupting the passive movement, followed by release	Marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part (s) easily moved
3	Fatigable clonus (<10 seconds when maintaining pressure) occurring at precise angle	Considerable increase in muscle tone, passive movement difficult
4	Infatigable clonus (>10 seconds when maintaining pressure) occurring at precise angle	Affected part(s) rigid in flexion or extension.

Table 2: Demographic and clinical characteristics

	Number	Mean (SD)	Minimum	Maximum
Gender (M/F)				
Age				
Weight				
Height				
BMI				
Time since stroke				
Affected side(R/L)				

Table 3: The results for spasticity grades and measurements of R1, R2, and R2-R1

MTS measures	Median (IQR)	Mean (SD)	Min-Max	95% CI
R1				
R2				
R2-R1				
MMAS grades				
MTS grades				

R1: Angle of muscle reaction; R2: passive range of motion; R2-R1: dynamic component or spasticity
MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale

Table 4: The results for H-reflex indices

	Mean (SD)	Min-Max	95% CI
H_{\max}/M_{\max}			
Latency			
$H_{\text{slp}}/M_{\text{slp}}$			
H_{slp}			

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Table 5: Correlation coefficients between spasticity clinical measures and neurophysiological tests

		H _{max} /M _{max}	Latency	H _{slp} /M _{slp}	H _{slp}
MMAS	Spearman's rho				
	Sig.				
MTS	Spearman's rho				
	sig				
R2-R1	Pearson correlation				
	sig				

MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale

Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

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Abstract

Introduction: Reliable and valid tools must be used to assess spasticity in clinical practice and research settings. There is a paucity of literature regarding the validity of the Modified Modified Ashworth Scale (MMAS) and the Modified Tardieu Scale (MTS). No study, to date, has been performed to compare the validity of the MMAS and the MTS. This neurophysiological study protocol will compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods and Analysis: Thirty-two patients with stroke from the University Rehabilitation clinics will be recruited to participate in this cross-sectional, non-interventional study. All measurements will be taken in the Physical Medicine and Rehabilitation Department of Shafa University Hospital in Tehran, Iran. First, wrist flexor spasticity will be assessed clinically using the MMAS and MTS. The tests will be applied randomly. For the MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. Second, neurophysiological measures of H-reflex latency, H_{max}/M_{max} ratio, H_{slp} , and H_{slp}/M_{slp} ratio will be collected from affected side. The results will be analyzed using Spearman's rho test or Pearson correlation test to determine the validity of the MMAS and the MTS as well as to compare the validity between the MMAS and the MTS.

Ethics and dissemination: The Research Council, School of Rehabilitation, and The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol. The study results will be disseminated in peer-reviewed publications and presented at international congresses.

Key words: Stroke; Spasticity; Modified Modified Ashworth Scale; Modified Tardieu Scale; Validity

INTRODUCTION

Spasticity is a common symptom observed following upper motor neuron syndrome. Diseases such as stroke, traumatic brain injury, spinal cord injury, cerebral palsy, and multiple sclerosis are associated with significant spasticity. Spasticity has been defined classically by Lance as a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes.¹ There are several studies addressing the prevalence of spasticity after stroke.² The prevalence of spasticity after a first stroke has been inconsistent, ranging between 18% - 38%.³⁻⁸ In addition a recent study indicated that the prevalence of spasticity in patients with stroke referred to a Department of Rehabilitation Medicine was 42.4%.⁹ Excessive spasticity needs to be controlled, because it can interfere with functional recovery, and may lead to secondary complications such as contractures and pain.^{10,11} Reflex hyperexcitability and soft tissue stiffness both have been reported to contribute to increased resistance to passive stretch.¹²

To assess spasticity accurately in clinical practice and for research purposes, reliable and valid tools must be used. The Ashworth and Tardieu scales are common clinical measures of spasticity. The Ashworth scale was originally developed in 1964, and modified by Bohannon and Smith in 1987.^{13,14} The Bohannon-Smith Modified Ashworth Scale (MAS) has been recently modified by Ansari et al. in 2006 as the Modified Modified Ashworth Scale (MMAS) (table 1).¹⁵ The MMAS is an ordinal level measure of spasticity, which grades the intensity of spasticity from 0-4. The results of several studies have demonstrated that the MMAS is a reliable measure for assessing spasticity in either upper or lower limbs of patients with spasticity.¹⁶⁻²²

The Tardieu scale was developed by Tardieu et al in 1954.²³ Held and Pierrot-Deseilligny modified it in 1969, and it was further modified in 1999 by Boyd

and Graham.²⁴ This latest version of Tardieu scale is called the Modified Tardieu Scale (MTS).^{25,26} The MTS considers R2, R1, and R2-R1 to measure spasticity. The R2 is the passive range of motion measured during slow passive stretch. The R1 is the angle of muscle reaction measured during fast passive stretch, and occurs in a particular angle of “catch” from hyperactive stretch reflex. Large and small differences between R2 and R1 indicate spasticity and muscle contracture, respectively.^{25,27} Quality of muscle reaction during fast passive stretch is also graded based on 0-4 scores and is defined as the MTS scores (table 1).^{28,29}

Table 1 about here

Studies regarding the reliability of the MTS have been mostly performed in children.³⁰⁻³³ The reliability of the MTS has been questioned for various patients groups.^{32,34,35} Paulis et al. compared the test-retest and inter-rater reliability of Tardieu Scale scores measured with inertial sensors (IS) and goniometry and found excellent reliability for IS.³⁶ Ansari et al. showed insufficient inter-rater reliability for MTS when measuring elbow flexor spasticity in adult patients with hemiplegia using goniometry.³⁴ In a study by Singh et al. it has been shown that the intra-rater reliability of MTS is very good for R1, R2, R2-R1, and MTS scores across two sessions in elbow flexors and ankle plantar flexors using goniometry.³⁷ A study comparing the reliability of the MTS with the Bohannon-Smith MAS in adult patients with severe brain injury found significantly higher test-retest and inter-rater reliability for MTS, however poor to moderate inter-rater reliability for both scales.³⁸

There is a paucity of literature exploring the validity of MMAS and MTS. The validity of MMAS has been evaluated neurophysiologically with the measurement of wrist flexor spasticity in patients with stroke.³⁹ Naghdi et al. found a significant

positive correlation between the MMAS scores and H_{slp}/M_{slp} ratio ($r = 0.39$, $p = 0.04$), traditional index of H_{max}/M_{max} ratio ($r = 0.39$, $p = 0.04$), and H_{slp} ($r = 0.45$, $p = 0.02$) indicating the validity of the MMAS.³⁹ In another study, the authors showed that the MMAS and the Brunnstrom recovery stages were highly correlated in the evaluation of motor recovery in patients with stroke.⁴⁰ Recently, the content validity of the Tardieu Scale and the Ashworth Scale was assessed in independently ambulating children with cerebral palsy.⁴¹ The authors demonstrated that the Tardieu Scale was more effective than the Original Ashworth Scale in identifying the presence of spasticity, the presence of contracture and the severity of contracture. Neither scale was able to identify the severity of spasticity.⁴¹

The basic neural circuit in spasticity is the monosynaptic stretch reflex arc characterized by the sensory Ia afferent and alpha motor neuron.⁴² Various neurophysiological changes have been shown to occur in muscle spasticity, including alpha motor neuron hyperexcitability.^{12, 43} The H-reflex is a simple, noninvasive method which can be used to study reflex pathway reliably.⁴⁴⁻⁴⁸ The H-reflex parameters of H_{max}/M_{max} ratio and latency are reliable measures of alpha motor neuron hyperexcitability, and have been suggested for objective quantifying of muscle spasticity.^{49, 50} In patients with spasticity, H-reflex latency is usually decreased and H_{max}/M_{max} ratio is increased.⁴⁹

The H_{slp}/M_{slp} ratio [the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp})] has been proposed as a better indicator for evaluating the excitability of a motor neuron pool in spasticity.^{51, 52} The slope of the H-reflex recruitment curve (H_{slp}) representing the relationship between stimulation intensity and reflex recruitment of motor neurons is free from the H-reflex discharge collision and shows the intrinsic excitability of the

motor neurons and the reflex arc (Higashi et al, 2001).^{52, 53} The H_{slp} is more sensitive than H_{max}/M_{max} , provides more information about the recruitment threshold and can estimate spinal excitability.^{52, 54} It has been demonstrated that flexor carpi radialis (FCR) H-reflexes can be reliably evoked in post-stroke paretic and non-paretic arms, and the FCR recruitment slope is a sensitive measure of spinal excitability after stroke.⁵⁵ The H-reflex tests will be used for validation of the MMAS and the MTS.

AIMS AND OBJECTIVES

No study has compared the validity of MMAS and MTS. The present neurophysiological study protocol is designed to compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods

Study Design

This cross-sectional, non-interventional study is designed for comparing the criterion validity between the MMAS and the MTS in the assessment of wrist flexor spasticity in patients poststroke. The clinical measures of MMAS and MTS will be obtained, and will be correlated with neurophysiological measures of H-reflex latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio.

Setting

The measurements will be taken at the Department of Electrophysiology, University Hospital of Shafa in Tehran, Iran.

Approval of Study Protocol

The study protocol has been approved by the Research Council, School

of Rehabilitation, Tehran University of Medical Sciences (TUMS), and Ethical approval has been granted by TUMS Ethics Committee (Reference number 1322).

Informed Consent

Written informed consent from the eligible subjects will be obtained before tests are performed. We will instruct patients that they are free to obtain any information about the detail of the study from the investigator, and they are free to discontinue their participation in the study at any time.

Participants

Patients with stroke who attend the Rehabilitation clinics of TUMS will be screened for eligibility. Eligible patients will be invited to participate in the study. The study is designed to include 32 subjects with the following criteria. Inclusion criteria will be: 1) first stroke; 2) history of stroke between 1-24 months; 3) age between 40 to 65 years; and 4) ability to understand and follow instructions. Exclusion criteria will be: 1) fixed contracture at wrist and elbow joints; 2) wrist pain due to degenerative changes; 3) taking antispastic drugs; 4) contraindication of passive movement at wrist joint; 5) cervical discopathy; 6) diabetes; and 7) nonconsent.

Procedures

The patients will be interviewed to collect demographic characteristics including: age; etiology (i.e. ischemic or vascular stroke); time elapsed from onset of stroke; and affected side. Effort will be made to provide a similar testing condition. All measurements will be taken in the morning hours of 9.00-12.00. Before testing commencement, all patients will be asked to rest on the bed with shoes removed for 5 minutes and remain comfortable and relaxed. To provide a quiet testing environment, all tests will be performed in a closed quiet room with natural light from windows.

The temperature of the testing room will be set at approximately 25°. We will also ask the patients to empty their bladder prior to testing. The room is electrically shielded and earth-grounded for H-reflex measurements.

The wrist flexors will be tested in this study, because they are usually spastic in patients poststroke, and spasticity can be reliably measured in wrist flexors.^{17, 18, 56}

Clinical and neurophysiological tests will be performed in a single session. Wrist flexor spasticity will be assessed clinically on the affected side using MMAS and MTS. For MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. The sequence of tests will be randomized by tossing a coin. The neurophysiological data will also be collected from the affected side. One trained physiotherapist will perform both clinical and neurophysiological tests. The clinical tests will be applied first. The tester will be blinded to the neurophysiological data analyses.

Outcome Measures

Muscle spasticity is primarily due to an exaggerated stretch reflex and alpha motor neuron excitability.¹ The MMAS and MTS will be used for the assessment of muscle spasticity. The H-reflex is an objective method for the measurement of spasticity.⁴⁹ The H-reflex parameters of latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio will be applied to examine alpha motor neuron excitability.

The H_{max}/M_{max} ratio indicates the level of motoneuron excitability. The H_{slp} is a measure of the relationship between the number of motoneurons activated and a given incremental rise in stimulation intensity.^{51,52} The H_{slp}/M_{slp} ratio is a new method of spasticity measurement, and presumes that the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp}) is a better parameter for evaluating the motoneuron excitability.

The Modified Modified Ashworth Scale

Wrist flexor spasticity will be quantified using the clinical scale MMAS, which has been shown to be reliable at the wrist joint.^{17,18} The procedure used and described in previous studies will be followed to measure wrist flexor spasticity. Briefly, the patient will be in supine position, head in midline, and arms alongside the trunk with shoulder in slight abduction. The rater will hold the forearm in mid-position just proximal to the wrist joint with one hand, and will grasp the patients hand with the other hand. The rater will move the wrist from maximum possible flexion to maximal possible extension counting one thousand and one.^{17,18} The rater will score muscle spasticity from 0-4. Only one passive stretch will be applied to rate spasticity.¹⁵

The Modified Tardieu Scale

A standard goniometer will be utilized to measure R2 and R1. The patient will be in sitting position with elbow joint flexed at 90°. The stretching velocity of V1 and V3 will be applied to measure R2 and R1, respectively. The quality of muscle reaction will be graded at the stretching velocity of V3, as well.^{16,17} The difference between R2 and R1 will be the measure of the dynamic component of spasticity.

Measurement of H-reflex

As with the clinical test, the patient will be positioned in supine, head in midline, and arms alongside the trunk. Patients will be asked to remain calm, and relax completely during testing.

The H-reflex and the M-wave will be obtained using an EMG machine (Myto II, Italy). The H-reflex will be elicited in the flexor carpi radialis (FCR) muscle of the affected side of the participants with the arm in supination. The H-reflex in FCR

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muscle has been commonly employed in studies of H-reflex in the upper limb, and can be reliably evoked and measured.^{46, 49, 57, 58} A digital thermometer will be used to measure the skin temperature. The bandpass filter will be set at 5Hz to 3KHz, sweep speed at 5 ms/div, and sensitivity at 200- 500 μ v.

The stimulator will apply rectangular electric pulses with 1 ms duration, every 5 seconds.^{39,40} Paired surface electrodes (Ag/AgCl) will be attached to the skin on the muscle belly. The median nerve will be stimulated at the elbow crease using a bipolar stimulating electrode. The stimulating electrodes will be positioned in line with the median nerve in the cubital fossa just medial to the biceps brachii tendon with the cathode proximal to the anode to prevent anodal block.⁵⁹

The recording electrodes will be placed over the muscle belly of the FCR. The active electrode will be placed on the belly of the FCR at one third of the proximal distance between the medial epicondyle of humerus and the radial styloid. The reference electrode will be positioned 4 cm distal and lateral to the active one. The electric resistance between the two electrodes will be less than 10 K Ω . The ground electrode will be attached to the skin between stimulating and recording electrodes. Stepwise increase in stimulus intensity will be used to record the H-reflex and M-wave. The stimulus intensity will start at 0.5 mA and will be increased in steps of 0.5 mA to record H_{max} and M_{max}.^{39,40} H-reflex conditioning will not be used in this protocol, as FCR H-reflex can be easily evoked without facilitation in most cases.⁴⁷

Recruitment Curves

To build the recruitment curves of H-reflex and M-waves, we will follow the methods described elsewhere.^{39,40,51, 52, 60} Five pulses will be delivered sequentially at each stimulus intensity and the mean amplitude of evoked H-reflexes and the M-responses will be calculated. The amplitudes will be measured peak to peak. Mean

amplitudes will be normalized according to the following formula:

$$\text{Normalized amplitude (H or M)} = [\text{Mean amplitude of five wave} / M_{\max}] \times 100$$

Stimulus intensities will be presented as the ratio of the threshold intensity of the M-wave (M_{th}). All data measured at stimulus intensities less than the threshold of the M-wave will be used to determine the H_{slp} . Data from M_{th} up to maximum amplitude of M-wave will determine the M_{slp} . Equation of simple linear regression will be determined, and the slope of this line will be considered as H_{slp} or M_{slp} . Maximum mean amplitude of the H-reflex and maximum mean amplitude of the M-wave will be regarded as H_{\max} and M_{\max} , respectively. The H_{\max} relative to M_{\max} is H_{\max}/M_{\max} ratio. The H-reflex latency will be calculated from stimulus wave to the onset of first deflection of H-wave, and the amplitude of recorded reflexes and waves will be measured.

Sample Size Calculation

In the study by Naghdi et al., correlation of the MMAS with the H_{\max}/M_{\max} ratio or the $H_{\text{slp}}/M_{\text{slp}}$ ratio was $r = 0.39$.³⁹ Assuming the correlation is 0.4, and to show a similar validity with 0.95 % power at 5% significance level, it will require that data is taken on 32 participants.

Statistical Analysis

To determine the validity of the clinical tests, the relationships between the clinical tests and the H-reflex indices will be assessed by calculating Spearman's rho test (i.e. MMAS and the ordinal component of the MTS) or Pearson correlation test (i.e. ratio components of the MTS). Comparing correlations test will be used to compare the validity of the MMAS and the MTS.⁶¹

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RESULTS

Demographic Characteristics

Demographic characteristics of participants will be illustrated as shown in table 2.

Table 2 about here

Clinical Characteristics

Clinical spasticity grades with MMAS, MTS measures and quality of muscle reaction will be illustrated in table 3.

Table 3 about here

Neurophysiological Data

Objective neurophysiological assessment results using the H-reflex will be illustrated as shown in Table 4.

Criterion Validity

The criterion validity will be analyzed by correlations between the clinical measures and neurophysiological tests. Criterion validity will be established when significant moderate correlations between the MMAS/the MTS and the neuropsychological measures are found. The results of correlation analyses will be presented in Table 5.

Table 4 about here

Table 5 about here

DISCUSSION

This article describes a neurophysiological study protocol for comparative evaluation of the validity of two important clinical measures in the field of neurological rehabilitation. To our knowledge, this investigation will be the first to

compare the criterion validity of the MMAS and the MTS. This protocol utilizes conventional and new indicators of motoneuron excitability in spasticity for comparative validity evaluation. Further, the protocol utilizes standard methodology for spasticity assessment to indicate the excitability of the alpha motoneuron pool.⁴⁹

The results of the present protocol will be important. Due to the limitations of the Ashworth scales and questioned reliability and validity,⁶² the new MMAS has emerged to improve the metric characteristics of the scales. The results of the metrics for the MMAS have been encouraging up to this point. The MMAS needs to be further examined for additional psychometric properties and be utilized during intervention based studies.⁶³ Since the original and Modified Ashworth Scale have been reported to have poor reliability and validity the MTS has been suggested as an alternative and suitable measure for use in assessment of spasticity.^{29,64} However, the results of reliability for the MTS have been mixed, with a dearth of studies exploring the validity of the MTS. This study will be the first report investigating the validity of the MTS through establishing correlation between the MTS and the alpha motor neuron excitability indicators. While the MTS has been explained theoretically as a suitable spasticity measure, there is no evidence to compare this scale with existing clinical measures such as the MMAS. The results of this protocol will provide neurophysiological evidence for the validity of the MMAS and the MTS as clinical scales for the measurement of muscle spasticity.

LIMITATIONS

A limitation of the study is that the tests will be performed by only one person.

This will be the most significant limitation of the study.

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Contributors HA, NNA, SN, KM, NG, and SH contributed to the conception of the study. All authors contributed to the study design. HA contributed to drafting the protocol. All authors read and revised the manuscript for important intellectual content. All authors reviewed the final manuscript and gave approval of the version to be published.

Ethics approval The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol.

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Competing interests None.

ARTICLE SUMMARY

Article focus

- Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

Key messages

- Reliable and valid tools must be used to assess spasticity accurately in clinical and research settings.
- The results of this protocol will provide evidence for the validity of the MMAS and the MTS for the measurement of muscle spasticity.

Strengths and limitations of this study

- This study will use conventional and new measures of motoneuron excitability for the objective evaluation of spasticity.
- This study will be the first to compare the criterion validity of the MMAS and the MTS.
- A weakness of the study is that the tests will be carried out by one person.

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Table1: Definitions of the Modified Tardieu Scale and the Modified Modified Ashworth Scale.

Grade	Modified Tardieu Scale (Boyd and Graham, 1999)	Modified Modified Ashworth Scale (Ansari et al, 2006)
0	no resistance throughout the course of the passive movement	No increase in muscle tone
1	slight resistance throughout the course of the passive movement, with no clear catch at precise angle	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
2	Clear catch at precise angle, interrupting the passive movement, followed by release	Marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part (s) easily moved
3	Fatigable clonus (<10 seconds when maintaining pressure) occurring at precise angle	Considerable increase in muscle tone, passive movement difficult
4	Infatigable clonus (>10 seconds when maintaining pressure) occurring at precise angle	Affected part(s) rigid in flexion or extension.

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Table 2: Demographic and clinical characteristics

	Number	Mean (SD)	Minimum	Maximum
Gender (M/F)				
Age				
Weight				
Height				
BMI				
Time since stroke				
Affected side(R/L)				

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Table 3: The results for spasticity grades and measurements of R1, R2, and R2-R1

MTS measures	Median (IQR)	Mean (SD)	Min-Max	95% CI
R1				
R2				
R2-R1				
MMAS grades				
MTS grades				

R1: Angle of muscle reaction; R2: passive range of motion; R2-R1: dynamic component or spasticity
 MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale

Table 4: The results for H-reflex indices

	Mean (SD)	Min-Max	95% CI
H_{max}/M_{max}			
Latency			
H_{slp}/M_{slp}			
H_{slp}			

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Table 5: Correlation coefficients between spasticity clinical measures and neurophysiological tests

		H_{\max}/M_{\max}	Latency	$H_{\text{slp}}/M_{\text{slp}}$	H_{slp}
MMAS	Spearman's rho				
	Sig.				
MTS	Spearman's rho				
	sig				
R2-R1	Pearson correlation				
	sig				

MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale



Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

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Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

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Abstract

Introduction: Reliable and valid tools must be used to assess spasticity in clinical practice and research settings. There is a paucity of literature regarding the validity of the Modified Modified Ashworth Scale (MMAS) and the Modified Tardieu Scale (MTS). No study, to date, has been performed to compare the validity of the MMAS and the MTS. This neurophysiological study protocol will compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods and Analysis: Thirty-two patients with stroke from the University Rehabilitation clinics will be recruited to participate in this cross-sectional, non-interventional study. All measurements will be taken in the Physical Medicine and Rehabilitation Department of Shafa University Hospital in Tehran, Iran. First, wrist flexor spasticity will be assessed clinically using the MMAS and MTS. The tests will be applied randomly. For the MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. Second, neurophysiological measures of H-reflex latency, H_{\max}/M_{\max} ratio, H_{slp} , and H_{slp}/M_{slp} ratio will be collected from affected side. The results will be analyzed using Spearman's rho test or Pearson correlation test to determine the validity of the MMAS and the MTS as well as to compare the validity between the MMAS and the MTS.

Ethics and dissemination: The Research Council, School of Rehabilitation, and The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol. The study results will be disseminated in peer-reviewed publications and presented at international congresses.

Key words: Stroke; Spasticity; Modified Modified Ashworth Scale; Modified Tardieu Scale; Validity

INTRODUCTION

Spasticity is a common symptom observed following upper motor neuron syndrome. Diseases such as stroke, traumatic brain injury, spinal cord injury, cerebral palsy, and multiple sclerosis are associated with significant spasticity. Spasticity has been defined classically by Lance as a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes.¹ There are several studies addressing the prevalence of spasticity after stroke.² The prevalence of spasticity after a first stroke has been inconsistent, ranging between 18% - 38%.³⁻⁸ In addition a recent study indicated that the prevalence of spasticity in patients with stroke referred to a Department of Rehabilitation Medicine was 42.4%.⁹ Excessive spasticity needs to be controlled, because it can interfere with functional recovery, and may lead to secondary complications such as contractures and pain.^{10,11} Reflex hyperexcitability and soft tissue stiffness both have been reported to contribute to increased resistance to passive stretch.¹²

To assess spasticity accurately in clinical practice and for research purposes, reliable and valid tools must be used. The Ashworth and Tardieu scales are common clinical measures of spasticity. The Ashworth scale was originally developed in 1964, and modified by Bohannon and Smith in 1987.^{13,14} The Bohannon-Smith Modified Ashworth Scale (MAS) has been recently modified by Ansari et al. in 2006 as the Modified Modified Ashworth Scale (MMAS) (table 1).¹⁵ The MMAS is an ordinal level measure of spasticity, which grades the intensity of spasticity from 0-4. The results of several studies have demonstrated that the MMAS is a reliable measure for assessing spasticity in either upper or lower limbs of patients with spasticity.¹⁶⁻²²

The Tardieu scale was developed by Tardieu et al in 1954.²³ Held and Pierrot-Deseilligny modified it in 1969, and it was further modified in 1999 by Boyd

and Graham.²⁴ This latest version of Tardieu scale is called the Modified Tardieu Scale (MTS).^{25,26} The MTS considers R2, R1, and R2-R1 to measure spasticity. The R2 is the passive range of motion measured during slow passive stretch. The R1 is the angle of muscle reaction measured during fast passive stretch, and occurs in a particular angle of “catch” from hyperactive stretch reflex. Large and small differences between R2 and R1 indicate spasticity and muscle contracture, respectively.^{25,27} Quality of muscle reaction during fast passive stretch is also graded based on 0-4 scores and is defined as the MTS scores (table 1).^{28,29}

Table 1 about here

Studies regarding the reliability of the MTS have been mostly performed in children.³⁰⁻³³ The reliability of the MTS has been questioned for various patients groups.^{32,34,35} Paulis et al. compared the test-retest and inter-rater reliability of Tardieu Scale scores measured with inertial sensors (IS) and goniometry and found excellent reliability for IS.³⁶ Ansari et al. showed insufficient inter-rater reliability for MTS when measuring elbow flexor spasticity in adult patients with hemiplegia using goniometry.³⁴ In a study by Singh et al. it has been shown that the intra-rater reliability of MTS is very good for R1, R2, R2-R1, and MTS scores across two sessions in elbow flexors and ankle plantar flexors using goniometry.³⁷ A study comparing the reliability of the MTS with the Bohannon-Smith MAS in adult patients with severe brain injury found significantly higher test-retest and inter-rater reliability for MTS, however poor to moderate inter-rater reliability for both scales.³⁸

There is a paucity of literature exploring the validity of MMAS and MTS. The validity of MMAS has been evaluated neurophysiologically with the measurement of wrist flexor spasticity in patients with stroke.³⁹ Naghdi et al. found a significant

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positive correlation between the MMAS scores and H_{slp}/M_{slp} ratio ($r = 0.39$, $p = 0.04$), traditional index of H_{max}/M_{max} ratio ($r = 0.39$, $p = 0.04$), and H_{slp} ($r = 0.45$, $p = 0.02$) indicating the validity of the MMAS.³⁹ In another study, the authors showed that the MMAS and the Brunnstrom recovery stages were highly correlated in the evaluation of motor recovery in patients with stroke.⁴⁰ Recently, the content validity of the Tardieu Scale and the Ashworth Scale was assessed in independently ambulating children with cerebral palsy.⁴¹ The authors demonstrated that the Tardieu Scale was more effective than the Original Ashworth Scale in identifying the presence of spasticity, the presence of contracture and the severity of contracture. Neither scale was able to identify the severity of spasticity.⁴¹

The basic neural circuit in spasticity is the monosynaptic stretch reflex arc characterized by the sensory Ia afferent and alpha motor neuron.⁴² Various neurophysiological changes have been shown to occur in muscle spasticity, including alpha motor neuron hyperexcitability.^{12, 43} The H-reflex is a simple, noninvasive method which can be used to study reflex pathway reliably.⁴⁴⁻⁴⁸ The H-reflex parameters of H_{max}/M_{max} ratio and latency are reliable measures of alpha motor neuron hyperexcitability, and have been suggested for objective quantifying of muscle spasticity.^{49, 50} In patients with spasticity, H-reflex latency is usually decreased and H_{max}/M_{max} ratio is increased.⁴⁹

The H_{slp}/M_{slp} ratio [the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp})] has been proposed as a better indicator for evaluating the excitability of a motor neuron pool in spasticity.^{51, 52} The slope of the H-reflex recruitment curve (H_{slp}) representing the relationship between stimulation intensity and reflex recruitment of motor neurons is free from the H-reflex discharge collision and shows the intrinsic excitability of the

motor neurons and the reflex arc (Higashi et al, 2001).^{52, 53} The H_{slp} is more sensitive than H_{max}/M_{max} , provides more information about the recruitment threshold and can estimate spinal excitability.^{52, 54} It has been demonstrated that flexor carpi radialis (FCR) H-reflexes can be reliably evoked in post-stroke paretic and non-paretic arms, and the FCR recruitment slope is a sensitive measure of spinal excitability after stroke.⁵⁵ The H-reflex tests will be used for validation of the MMAS and the MTS.

AIMS AND OBJECTIVES

No study has compared the validity of MMAS and MTS. The present neurophysiological study protocol is designed to compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods

Study Design

This cross-sectional, non-interventional study is designed for comparing the criterion validity between the MMAS and the MTS in the assessment of wrist flexor spasticity in patients poststroke. The clinical measures of MMAS and MTS will be obtained, and will be correlated with neurophysiological measures of H-reflex latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio.

Setting

The measurements will be taken at the Department of Electrophysiology, University Hospital of Shafa in Tehran, Iran.

Approval of Study Protocol

The study protocol has been approved by the Research Council, School

of Rehabilitation, Tehran University of Medical Sciences (TUMS), and Ethical approval has been granted by TUMS Ethics Committee (Reference number 1322).

Informed Consent

Written informed consent from the eligible subjects will be obtained before tests are performed. We will instruct patients that they are free to obtain any information about the detail of the study from the investigator, and they are free to discontinue their participation in the study at any time.

Participants

Patients with stroke who attend the Rehabilitation clinics of TUMS will be screened for eligibility. Eligible patients will be invited to participate in the study. The study is designed to include 32 subjects with the following criteria. Inclusion criteria will be: 1) first stroke; 2) history of stroke between 1-24 months; 3) age between 40 to 65 years; and 4) ability to understand and follow instructions. Exclusion criteria will be: 1) fixed contracture at wrist and elbow joints; 2) wrist pain due to degenerative changes; 3) taking antispastic drugs; 4) contraindication of passive movement at wrist joint; 5) cervical discopathy; 6) diabetes; and 7) nonconsent.

Procedures

The patients will be interviewed to collect demographic characteristics including: age; etiology (i.e. ischemic or vascular stroke); time elapsed from onset of stroke; and affected side. Effort will be made to provide a similar testing condition. All measurements will be taken in the morning hours of 9.00-12.00. Before testing commencement, all patients will be asked to rest on the bed with shoes removed for 5 minutes and remain comfortable and relaxed. To provide a quiet testing environment, all tests will be performed in a closed quiet room with natural light from windows.

The temperature of the testing room will be set at approximately 25°. We will also ask the patients to empty their bladder prior to testing. The room is electrically shielded and earth-grounded for H-reflex measurements.

The wrist flexors will be tested in this study, because they are usually spastic in patients poststroke, and spasticity can be reliably measured in wrist flexors.^{17, 18, 56} Clinical and neurophysiological tests will be performed in a single session. Wrist flexor spasticity will be assessed clinically on the affected side using MMAS and MTS. For MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. The sequence of tests will be randomized by tossing a coin. The tester will be tossing the coin to randomize the procedure and will be observed by an impartial colleague. The neurophysiological data will also be collected from the affected side. One trained physiotherapist will perform both clinical and neurophysiological tests. The clinical tests will be applied first. The tester will be blinded to the neurophysiological data analyses. The analyst of neurophysiological data will be blinded to the clinical testing results.

Outcome Measures

Muscle spasticity is primarily due to an exaggerated stretch reflex and alpha motor neuron excitability.¹ The MMAS and MTS will be used for the assessment of muscle spasticity. The H-reflex is an objective method for the measurement of spasticity.⁴⁹ The H-reflex parameters of latency; H_{\max}/M_{\max} ratio; H_{slp} ; and $H_{\text{slp}}/M_{\text{slp}}$ ratio will be applied to examine alpha motor neuron excitability.

The H_{\max}/M_{\max} ratio indicates the level of motoneuron excitability. The H_{slp} is a measure of the relationship between the number of motoneurons activated and a given incremental rise in stimulation intensity.^{51,52} The $H_{\text{slp}}/M_{\text{slp}}$ ratio is a new method of spasticity measurement, and presumes that the developmental slope of the

H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp}) is a better parameter for evaluating the motoneuron excitability.

The Modified Modified Ashworth Scale

Wrist flexor spasticity will be quantified using the clinical scale MMAS, which has been shown to be reliable at the wrist joint.^{17,18} The procedure used and described in previous studies will be followed to measure wrist flexor spasticity. Briefly, the patient will be in supine position, head in midline, and arms alongside the trunk with shoulder in slight abduction. The rater will hold the forearm in mid-position just proximal to the wrist joint with one hand, and will grasp the patients hand with the other hand. The rater will move the wrist from maximum possible flexion to maximal possible extension counting one thousand and one.^{17,18} The rater will score muscle spasticity from 0-4. Only one passive stretch will be applied to rate spasticity.¹⁵

The Modified Tardieu Scale

A standard goniometer will be utilized to measure R2 and R1. The patient will be in sitting position with elbow joint flexed at 90°. The stretching velocity of V1 and V3 will be applied to measure R2 and R1, respectively. The quality of muscle reaction will be graded at the stretching velocity of V3, as well.^{16,17} The difference between R2 and R1 will be the measure of the dynamic component of spasticity.

Measurement of H-reflex

As with the clinical test, the patient will be positioned in supine, head in midline, and arms alongside the trunk. Patients will be asked to remain calm, and relax completely during testing.

The H-reflex and the M-wave will be obtained using an EMG machine (Myto

1
2
3 II, Italy). The H-reflex will be elicited in the flexor carpi radialis (FCR) muscle of the
4
5 affected side of the participants with the arm in supination. The H-reflex in FCR
6
7 muscle has been commonly employed in studies of H-reflex in the upper limb, and
8
9 can be reliably evoked and measured.^{46, 49, 57, 58} A digital thermometer will be used to
10
11 measure the skin temperature. The bandpass filter will be set at 5Hz to 3KHz, sweep
12
13 speed at 5 ms/div, and sensitivity at 200- 500 μ v.
14

15
16 The stimulator will apply rectangular electric pulses with 1 ms duration, every
17
18 5 seconds.^{39,40} Paired surface electrodes (Ag/AgCl) will be attached to the skin on the
19
20 muscle belly. The median nerve will be stimulated at the elbow crease using a bipolar
21
22 stimulating electrode. The stimulating electrodes will be positioned in line with the
23
24 median nerve in the cubital fossa just medial to the biceps brachii tendon with the
25
26 cathode proximal to the anode to prevent anodal block.⁵⁹
27

28
29 The recording electrodes will be placed over the muscle belly of the FCR. The
30
31 active electrode will be placed on the belly of the FCR at one third of the proximal
32
33 distance between the medial epicondyle of humerus and the radial styloid. The
34
35 reference electrode will be positioned 4 cm distal and lateral to the active one. The
36
37 electric resistance between the two electrodes will be less than 10 K Ω . The ground
38
39 electrode will be attached to the skin between stimulating and recording electrodes.
40
41 Stepwise increase in stimulus intensity will be used to record the H-reflex and M-
42
43 wave. The stimulus intensity will start at 0.5 mA and will be increased in steps of 0.5
44
45 mA to record H_{max} and M_{max}.^{39,40} H-reflex conditioning will not be used in this
46
47 protocol, as FCR H-reflex can be easily evoked without facilitation in most cases.⁴⁷
48
49
50
51
52

53 Recruitment Curves

54
55 To build the recruitment curves of H-reflex and M-waves, we will follow the
56
57 methods described elsewhere.^{39,40,51, 52, 60} Five pulses will be delivered sequentially at
58
59
60

each stimulus intensity and the mean amplitude of evoked H-reflexes and the M-responses will be calculated. The amplitudes will be measured peak to peak. Mean amplitudes will be normalized according to the following formula:

$$\text{Normalized amplitude (H or M)} = [\text{Mean amplitude of five wave} / M_{\max}] \times 100$$

Stimulus intensities will be presented as the ratio of the threshold intensity of the M-wave (M_{th}). All data measured at stimulus intensities less than the threshold of the M-wave will be used to determine the H_{slp} . Data from M_{th} up to maximum amplitude of M-wave will determine the M_{slp} . Equation of simple linear regression will be determined, and the slope of this line will be considered as H_{slp} or M_{slp} . Maximum mean amplitude of the H-reflex and maximum mean amplitude of the M-wave will be regarded as H_{\max} and M_{\max} , respectively. The H_{\max} relative to M_{\max} is H_{\max}/M_{\max} ratio. The H-reflex latency will be calculated from stimulus wave to the onset of first deflection of H-wave, and the amplitude of recorded reflexes and waves will be measured.

Sample Size Calculation

In the study by Naghdi et al., correlation of the MMAS with the H_{\max}/M_{\max} ratio or the $H_{\text{slp}}/M_{\text{slp}}$ ratio was $r = 0.39$.³⁹ Assuming the correlation is 0.4, and to show a similar validity with 0.95 % power at 5% significance level, it will require that data is taken on 32 participants.

Statistical Analysis

To determine the validity of the clinical tests, the relationships between the clinical tests and the H-reflex indices will be assessed by calculating Spearman’s rho test (i.e. MMAS and the ordinal component of the MTS) or Pearson correlation test (i.e. ratio components of the MTS). Comparing correlations test will be used to

compare the validity of the MMAS and the MTS.⁶¹

RESULTS

Demographic Characteristics

Demographic characteristics of participants will be illustrated as shown in table 2.

Table 2 about here

Clinical Characteristics

Clinical spasticity grades with MMAS, MTS measures and quality of muscle reaction will be illustrated in table 3.

Table 3 about here

Neurophysiological Data

Objective neurophysiological assessment results using the H-reflex will be illustrated as shown in Table 4.

Criterion Validity

The criterion validity will be analyzed by correlations between the clinical measures and neurophysiological tests. Criterion validity will be established when significant moderate correlations between the MMAS/the MTS and the neuropsychological measures are found. The results of correlation analyses will be presented in Table 5.

Table 4 about here

Table 5 about here

DISCUSSION

This article describes a neurophysiological study protocol for comparative evaluation of the validity of two important clinical measures in the field of

neurological rehabilitation. To our knowledge, this investigation will be the first to compare the criterion validity of the MMAS and the MTS. This protocol utilizes conventional and new indicators of motoneuron excitability in spasticity for comparative validity evaluation. Further, the protocol utilizes standard methodology for spasticity assessment to indicate the excitability of the alpha motoneuron pool.⁴⁹

The results of the present protocol will be important. Due to the limitations of the Ashworth scales and questioned reliability and validity,⁶² the new MMAS has emerged to improve the metric characteristics of the scales. The results of the metrics for the MMAS have been encouraging up to this point. The MMAS needs to be further examined for additional psychometric properties and be utilized during intervention based studies.⁶³ Since the original and Modified Ashworth Scale have been reported to have poor reliability and validity the MTS has been suggested as an alternative and suitable measure for use in assessment of spasticity.^{29,64} However, the results of reliability for the MTS have been mixed, with a dearth of studies exploring the validity of the MTS. This study will be the first report investigating the validity of the MTS through establishing correlation between the MTS and the alpha motor neuron excitability indicators. While the MTS has been explained theoretically as a suitable spasticity measure, there is no evidence to compare this scale with existing clinical measures such as the MMAS. The results of this protocol will provide neurophysiological evidence for the validity of the MMAS and the MTS as clinical scales for the measurement of muscle spasticity.

LIMITATIONS

A limitation of the study is that the tests will be performed by only one person. This will be the most significant limitation of the study.

Contributors HA, NNA, SN, KM, NG, and SH contributed to the conception of the study. All authors contributed to the study design. HA contributed to drafting the protocol. All authors read and revised the manuscript for important intellectual content. All authors reviewed the final manuscript and gave approval of the version to be published.

Ethics approval The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol.

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Competing interests None.

ARTICLE SUMMARY

Article focus

- Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

Key messages

- Reliable and valid tools must be used to assess spasticity accurately in clinical and research settings.
- The results of this protocol will provide evidence for the validity of the MMAS and the MTS for the measurement of muscle spasticity.

Strengths and limitations of this study

- This study will use conventional and new measures of motoneuron excitability for the objective evaluation of spasticity.
- This study will be the first to compare the criterion validity of the MMAS and the MTS.
- A weakness of the study is that the tests will be carried out by one person.

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Table1: Definitions of the Modified Tardieu Scale and the Modified Modified Ashworth Scale.

Grade	Modified Tardieu Scale (Boyd and Graham, 1999)	Modified Modified Ashworth Scale (Ansari et al, 2006)
0	no resistance throughout the course of the passive movement	No increase in muscle tone
1	slight resistance throughout the course of the passive movement, with no clear catch at precise angle	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
2	Clear catch at precise angle, interrupting the passive movement, followed by release	Marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part (s) easily moved
3	Fatigable clonus (<10 seconds when maintaining pressure) occurring at precise angle	Considerable increase in muscle tone, passive movement difficult
4	Infatigable clonus (>10 seconds when maintaining pressure) occurring at precise angle	Affected part(s) rigid in flexion or extension.

Table 2: Demographic and clinical characteristics

	Number	Mean (SD)	Minimum	Maximum
Gender (M/F)				
Age				
Weight				
Height				
BMI				
Time since stroke				
Affected side(R/L)				

Table 3: The results for spasticity grades and measurements of R1, R2, and R2-R1

MTS measures	Median (IQR)	Mean (SD)	Min-Max	95% CI
R1				
R2				
R2-R1				
MMAS grades				
MTS grades				

R1: Angle of muscle reaction; R2: passive range of motion; R2-R1: dynamic component or spasticity
MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale

Table 4: The results for H-reflex indices

	Mean (SD)	Min-Max	95% CI
H_{\max}/M_{\max}			
Latency			
$H_{\text{slp}}/M_{\text{slp}}$			
H_{slp}			

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Table 5: Correlation coefficients between spasticity clinical measures and neurophysiological tests

		H_{max}/M_{max}	Latency	H_{slp}/M_{slp}	H_{slp}
MMAS	Spearman's rho				
	Sig.				
MTS	Spearman's rho				
	sig				
R2-R1	Pearson correlation				
	sig				

MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale

Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

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Abstract

Introduction: Reliable and valid tools must be used to assess spasticity in clinical practice and research settings. There is a paucity of literature regarding the validity of the Modified Modified Ashworth Scale (MMAS) and the Modified Tardieu Scale (MTS). No study, to date, has been performed to compare the validity of the MMAS and the MTS. This neurophysiological study protocol will compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods and Analysis: Thirty-two patients with stroke from the University Rehabilitation clinics will be recruited to participate in this cross-sectional, non-interventional study. All measurements will be taken in the Physical Medicine and Rehabilitation Department of Shafa University Hospital in Tehran, Iran. First, wrist flexor spasticity will be assessed clinically using the MMAS and MTS. The tests will be applied randomly. For the MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. Second, neurophysiological measures of H-reflex latency, H_{max}/M_{max} ratio, H_{slp} , and H_{slp}/M_{slp} ratio will be collected from affected side. The results will be analyzed using Spearman's rho test or Pearson correlation test to determine the validity of the MMAS and the MTS as well as to compare the validity between the MMAS and the MTS.

Ethics and dissemination: The Research Council, School of Rehabilitation, and The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol. The study results will be disseminated in peer-reviewed publications and presented at international congresses.

Key words: Stroke; Spasticity; Modified Modified Ashworth Scale; Modified Tardieu Scale; Validity

INTRODUCTION

Spasticity is a common symptom observed following upper motor neuron syndrome. Diseases such as stroke, traumatic brain injury, spinal cord injury, cerebral palsy, and multiple sclerosis are associated with significant spasticity. Spasticity has been defined classically by Lance as a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes.¹ There are several studies addressing the prevalence of spasticity after stroke.² The prevalence of spasticity after a first stroke has been inconsistent, ranging between 18% - 38%.³⁻⁸ In addition a recent study indicated that the prevalence of spasticity in patients with stroke referred to a Department of Rehabilitation Medicine was 42.4%.⁹ Excessive spasticity needs to be controlled, because it can interfere with functional recovery, and may lead to secondary complications such as contractures and pain.^{10,11} Reflex hyperexcitability and soft tissue stiffness both have been reported to contribute to increased resistance to passive stretch.¹²

To assess spasticity accurately in clinical practice and for research purposes, reliable and valid tools must be used. The Ashworth and Tardieu scales are common clinical measures of spasticity. The Ashworth scale was originally developed in 1964, and modified by Bohannon and Smith in 1987.^{13,14} The Bohannon-Smith Modified Ashworth Scale (MAS) has been recently modified by Ansari et al. in 2006 as the Modified Modified Ashworth Scale (MMAS) (table 1).¹⁵ The MMAS is an ordinal level measure of spasticity, which grades the intensity of spasticity from 0-4. The results of several studies have demonstrated that the MMAS is a reliable measure for assessing spasticity in either upper or lower limbs of patients with spasticity.¹⁶⁻²²

The Tardieu scale was developed by Tardieu et al in 1954.²³ Held and Pierrot-Deseilligny modified it in 1969, and it was further modified in 1999 by Boyd

and Graham.²⁴ This latest version of Tardieu scale is called the Modified Tardieu Scale (MTS).^{25,26} The MTS considers R2, R1, and R2-R1 to measure spasticity. The R2 is the passive range of motion measured during slow passive stretch. The R1 is the angle of muscle reaction measured during fast passive stretch, and occurs in a particular angle of “catch” from hyperactive stretch reflex. Large and small differences between R2 and R1 indicate spasticity and muscle contracture, respectively.^{25,27} Quality of muscle reaction during fast passive stretch is also graded based on 0-4 scores and is defined as the MTS scores (table 1).^{28,29}

Table 1 about here

Studies regarding the reliability of the MTS have been mostly performed in children.³⁰⁻³³ The reliability of the MTS has been questioned for various patients groups.^{32,34,35} Paulis et al. compared the test-retest and inter-rater reliability of Tardieu Scale scores measured with inertial sensors (IS) and goniometry and found excellent reliability for IS.³⁶ Ansari et al. showed insufficient inter-rater reliability for MTS when measuring elbow flexor spasticity in adult patients with hemiplegia using goniometry.³⁴ In a study by Singh et al. it has been shown that the intra-rater reliability of MTS is very good for R1, R2, R2-R1, and MTS scores across two sessions in elbow flexors and ankle plantar flexors using goniometry.³⁷ A study comparing the reliability of the MTS with the Bohannon-Smith MAS in adult patients with severe brain injury found significantly higher test-retest and inter-rater reliability for MTS, however poor to moderate inter-rater reliability for both scales.³⁸

There is a paucity of literature exploring the validity of MMAS and MTS. The validity of MMAS has been evaluated neurophysiologically with the measurement of wrist flexor spasticity in patients with stroke.³⁹ Naghdi et al. found a significant

positive correlation between the MMAS scores and H_{slp}/M_{slp} ratio ($r = 0.39$, $p = 0.04$), traditional index of H_{max}/M_{max} ratio ($r = 0.39$, $p = 0.04$), and H_{slp} ($r = 0.45$, $p = 0.02$) indicating the validity of the MMAS.³⁹ In another study, the authors showed that the MMAS and the Brunnstrom recovery stages were highly correlated in the evaluation of motor recovery in patients with stroke.⁴⁰ Recently, the content validity of the Tardieu Scale and the Ashworth Scale was assessed in independently ambulating children with cerebral palsy.⁴¹ The authors demonstrated that the Tardieu Scale was more effective than the Original Ashworth Scale in identifying the presence of spasticity, the presence of contracture and the severity of contracture. Neither scale was able to identify the severity of spasticity.⁴¹

The basic neural circuit in spasticity is the monosynaptic stretch reflex arc characterized by the sensory Ia afferent and alpha motor neuron.⁴² Various neurophysiological changes have been shown to occur in muscle spasticity, including alpha motor neuron hyperexcitability.^{12, 43} The H-reflex is a simple, noninvasive method which can be used to study reflex pathway reliably.⁴⁴⁻⁴⁸ The H-reflex parameters of H_{max}/M_{max} ratio and latency are reliable measures of alpha motor neuron hyperexcitability, and have been suggested for objective quantifying of muscle spasticity.^{49, 50} In patients with spasticity, H-reflex latency is usually decreased and H_{max}/M_{max} ratio is increased.⁴⁹

The H_{slp}/M_{slp} ratio [the developmental slope of the H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp})] has been proposed as a better indicator for evaluating the excitability of a motor neuron pool in spasticity.^{51, 52} The slope of the H-reflex recruitment curve (H_{slp}) representing the relationship between stimulation intensity and reflex recruitment of motor neurons is free from the H-reflex discharge collision and shows the intrinsic excitability of the

motor neurons and the reflex arc (Higashi et al, 2001).^{52, 53} The H_{slp} is more sensitive than H_{max}/M_{max} , provides more information about the recruitment threshold and can estimate spinal excitability.^{52, 54} It has been demonstrated that flexor carpi radialis (FCR) H-reflexes can be reliably evoked in post-stroke paretic and non-paretic arms, and the FCR recruitment slope is a sensitive measure of spinal excitability after stroke.⁵⁵ The H-reflex tests will be used for validation of the MMAS and the MTS.

AIMS AND OBJECTIVES

No study has compared the validity of MMAS and MTS. The present neurophysiological study protocol is designed to compare the validity of the MMAS and the MTS in the assessment of poststroke wrist flexor spasticity.

Methods

Study Design

This cross-sectional, non-interventional study is designed for comparing the criterion validity between the MMAS and the MTS in the assessment of wrist flexor spasticity in patients poststroke. The clinical measures of MMAS and MTS will be obtained, and will be correlated with neurophysiological measures of H-reflex latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio.

Setting

The measurements will be taken at the Department of Electrophysiology, University Hospital of Shafa in Tehran, Iran.

Approval of Study Protocol

The study protocol has been approved by the Research Council, School

of Rehabilitation, Tehran University of Medical Sciences (TUMS), and Ethical approval has been granted by TUMS Ethics Committee (Reference number 1322).

Informed Consent

Written informed consent from the eligible subjects will be obtained before tests are performed. We will instruct patients that they are free to obtain any information about the detail of the study from the investigator, and they are free to discontinue their participation in the study at any time.

Participants

Patients with stroke who attend the Rehabilitation clinics of TUMS will be screened for eligibility. Eligible patients will be invited to participate in the study. The study is designed to include 32 subjects with the following criteria. Inclusion criteria will be: 1) first stroke; 2) history of stroke between 1-24 months; 3) age between 40 to 65 years; and 4) ability to understand and follow instructions. Exclusion criteria will be: 1) fixed contracture at wrist and elbow joints; 2) wrist pain due to degenerative changes; 3) taking antispastic drugs; 4) contraindication of passive movement at wrist joint; 5) cervical discopathy; 6) diabetes; and 7) nonconsent.

Procedures

The patients will be interviewed to collect demographic characteristics including: age; etiology (i.e. ischemic or vascular stroke); time elapsed from onset of stroke; and affected side. Effort will be made to provide a similar testing condition. All measurements will be taken in the morning hours of 9.00-12.00. Before testing commencement, all patients will be asked to rest on the bed with shoes removed for 5 minutes and remain comfortable and relaxed. To provide a quiet testing environment, all tests will be performed in a closed quiet room with natural light from windows.

The temperature of the testing room will be set at approximately 25°. We will also ask the patients to empty their bladder prior to testing. The room is electrically shielded and earth-grounded for H-reflex measurements.

The wrist flexors will be tested in this study, because they are usually spastic in patients poststroke, and spasticity can be reliably measured in wrist flexors.^{17, 18, 56}

Clinical and neurophysiological tests will be performed in a single session. Wrist flexor spasticity will be assessed clinically on the affected side using MMAS and MTS. For MTS, the components of R1, R2, R2-R1, and quality of muscle reaction will be measured. The sequence of tests will be randomized by tossing a coin. The tester will be tossing the coin to randomize the procedure and will be observed by an impartial colleague. The neurophysiological data will also be collected from the affected side. One trained physiotherapist will perform both clinical and neurophysiological tests. The clinical tests will be applied first. The tester will be blinded to the neurophysiological data analyses. The analyst of neurophysiological data will be blinded to the clinical testing results.

Outcome Measures

Muscle spasticity is primarily due to an exaggerated stretch reflex and alpha motor neuron excitability.¹ The MMAS and MTS will be used for the assessment of muscle spasticity. The H-reflex is an objective method for the measurement of spasticity.⁴⁹ The H-reflex parameters of latency; H_{max}/M_{max} ratio; H_{slp} ; and H_{slp}/M_{slp} ratio will be applied to examine alpha motor neuron excitability.

The H_{max}/M_{max} ratio indicates the level of motoneuron excitability. The H_{slp} is a measure of the relationship between the number of motoneurons activated and a given incremental rise in stimulation intensity.^{51,52} The H_{slp}/M_{slp} ratio is a new method of spasticity measurement, and presumes that the developmental slope of the

H-reflex (H_{slp}) recruitment curve as a ratio of the developmental slope of the M-response (M_{slp}) is a better parameter for evaluating the motoneuron excitability.

The Modified Modified Ashworth Scale

Wrist flexor spasticity will be quantified using the clinical scale MMAS, which has been shown to be reliable at the wrist joint.^{17,18} The procedure used and described in previous studies will be followed to measure wrist flexor spasticity. Briefly, the patient will be in supine position, head in midline, and arms alongside the trunk with shoulder in slight abduction. The rater will hold the forearm in mid-position just proximal to the wrist joint with one hand, and will grasp the patients hand with the other hand. The rater will move the wrist from maximum possible flexion to maximal possible extension counting one thousand and one.^{17,18} The rater will score muscle spasticity from 0-4. Only one passive stretch will be applied to rate spasticity.¹⁵

The Modified Tardieu Scale

A standard goniometer will be utilized to measure R2 and R1. The patient will be in sitting position with elbow joint flexed at 90°. The stretching velocity of V1 and V3 will be applied to measure R2 and R1, respectively. The quality of muscle reaction will be graded at the stretching velocity of V3, as well.^{16,17} The difference between R2 and R1 will be the measure of the dynamic component of spasticity.

Measurement of H-reflex

As with the clinical test, the patient will be positioned in supine, head in midline, and arms alongside the trunk. Patients will be asked to remain calm, and relax completely during testing.

The H-reflex and the M-wave will be obtained using an EMG machine (Myto

II, Italy). The H-reflex will be elicited in the flexor carpi radialis (FCR) muscle of the affected side of the participants with the arm in supination. The H-reflex in FCR muscle has been commonly employed in studies of H-reflex in the upper limb, and can be reliably evoked and measured.^{46, 49, 57, 58} A digital thermometer will be used to measure the skin temperature. The bandpass filter will be set at 5Hz to 3KHz, sweep speed at 5 ms/div, and sensitivity at 200- 500 μ v.

The stimulator will apply rectangular electric pulses with 1 ms duration, every 5 seconds.^{39,40} Paired surface electrodes (Ag/AgCl) will be attached to the skin on the muscle belly. The median nerve will be stimulated at the elbow crease using a bipolar stimulating electrode. The stimulating electrodes will be positioned in line with the median nerve in the cubital fossa just medial to the biceps brachii tendon with the cathode proximal to the anode to prevent anodal block.⁵⁹

The recording electrodes will be placed over the muscle belly of the FCR. The active electrode will be placed on the belly of the FCR at one third of the proximal distance between the medial epicondyle of humerus and the radial styloid. The reference electrode will be positioned 4 cm distal and lateral to the active one. The electric resistance between the two electrodes will be less than 10 K Ω . The ground electrode will be attached to the skin between stimulating and recording electrodes. Stepwise increase in stimulus intensity will be used to record the H-reflex and M-wave. The stimulus intensity will start at 0.5 mA and will be increased in steps of 0.5 mA to record H_{max} and M_{max}.^{39,40} H-reflex conditioning will not be used in this protocol, as FCR H-reflex can be easily evoked without facilitation in most cases.⁴⁷

Recruitment Curves

To build the recruitment curves of H-reflex and M-waves, we will follow the methods described elsewhere.^{39,40,51, 52, 60} Five pulses will be delivered sequentially at

each stimulus intensity and the mean amplitude of evoked H-reflexes and the M-responses will be calculated. The amplitudes will be measured peak to peak. Mean amplitudes will be normalized according to the following formula:

$$\text{Normalized amplitude (H or M)} = [\text{Mean amplitude of five wave} / M_{\max}] \times 100$$

Stimulus intensities will be presented as the ratio of the threshold intensity of the M-wave (M_{th}). All data measured at stimulus intensities less than the threshold of the M-wave will be used to determine the H_{slp} . Data from M_{th} up to maximum amplitude of M-wave will determine the M_{slp} . Equation of simple linear regression will be determined, and the slope of this line will be considered as H_{slp} or M_{slp} . Maximum mean amplitude of the H-reflex and maximum mean amplitude of the M-wave will be regarded as H_{\max} and M_{\max} , respectively. The H_{\max} relative to M_{\max} is H_{\max}/M_{\max} ratio. The H-reflex latency will be calculated from stimulus wave to the onset of first deflection of H-wave, and the amplitude of recorded reflexes and waves will be measured.

Sample Size Calculation

In the study by Naghdi et al., correlation of the MMAS with the H_{\max}/M_{\max} ratio or the $H_{\text{slp}}/M_{\text{slp}}$ ratio was $r = 0.39$.³⁹ Assuming the correlation is 0.4, and to show a similar validity with 0.95 % power at 5% significance level, it will require that data is taken on 32 participants.

Statistical Analysis

To determine the validity of the clinical tests, the relationships between the clinical tests and the H-reflex indices will be assessed by calculating Spearman's rho test (i.e. MMAS and the ordinal component of the MTS) or Pearson correlation test (i.e. ratio components of the MTS). Comparing correlations test will be used to

compare the validity of the MMAS and the MTS.⁶¹

RESULTS

Demographic Characteristics

Demographic characteristics of participants will be illustrated as shown in table 2.

Table 2 about here

Clinical Characteristics

Clinical spasticity grades with MMAS, MTS measures and quality of muscle reaction will be illustrated in table 3.

Table 3 about here

Neurophysiological Data

Objective neurophysiological assessment results using the H-reflex will be illustrated as shown in Table 4.

Criterion Validity

The criterion validity will be analyzed by correlations between the clinical measures and neurophysiological tests. Criterion validity will be established when significant moderate correlations between the MMAS/the MTS and the neuropsychological measures are found. The results of correlation analyses will be presented in Table 5.

Table 4 about here

Table 5 about here

DISCUSSION

This article describes a neurophysiological study protocol for comparative evaluation of the validity of two important clinical measures in the field of

neurological rehabilitation. To our knowledge, this investigation will be the first to compare the criterion validity of the MMAS and the MTS. This protocol utilizes conventional and new indicators of motoneuron excitability in spasticity for comparative validity evaluation. Further, the protocol utilizes standard methodology for spasticity assessment to indicate the excitability of the alpha motoneuron pool.⁴⁹

The results of the present protocol will be important. Due to the limitations of the Ashworth scales and questioned reliability and validity,⁶² the new MMAS has emerged to improve the metric characteristics of the scales. The results of the metrics for the MMAS have been encouraging up to this point. The MMAS needs to be further examined for additional psychometric properties and be utilized during intervention based studies.⁶³ Since the original and Modified Ashworth Scale have been reported to have poor reliability and validity the MTS has been suggested as an alternative and suitable measure for use in assessment of spasticity.^{29,64} However, the results of reliability for the MTS have been mixed, with a dearth of studies exploring the validity of the MTS. This study will be the first report investigating the validity of the MTS through establishing correlation between the MTS and the alpha motor neuron excitability indicators. While the MTS has been explained theoretically as a suitable spasticity measure, there is no evidence to compare this scale with existing clinical measures such as the MMAS. The results of this protocol will provide neurophysiological evidence for the validity of the MMAS and the MTS as clinical scales for the measurement of muscle spasticity.

LIMITATIONS

A limitation of the study is that the tests will be performed by only one person. This will be the most significant limitation of the study.

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Contributors HA, NNA, SN, KM, NG, and SH contributed to the conception of the study. All authors contributed to the study design. HA contributed to drafting the protocol. All authors read and revised the manuscript for important intellectual content. All authors reviewed the final manuscript and gave approval of the version to be published.

Ethics approval The Ethics Committee of Tehran University of Medical Sciences (TUMS) approved the study protocol.

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Competing interests None.

ARTICLE SUMMARY

Article focus

- Comparing the validity of the Modified Modified Ashworth scale (MMAS) and the Modified Tardieu scale (MTS) in the assessment of wrist flexor spasticity in patients with stroke- protocol for a neurophysiological study

Key messages

- Reliable and valid tools must be used to assess spasticity accurately in clinical and research settings.
- The results of this protocol will provide evidence for the validity of the MMAS and the MTS for the measurement of muscle spasticity.

Strengths and limitations of this study

- This study will use conventional and new measures of motoneuron excitability for the objective evaluation of spasticity.
- This study will be the first to compare the criterion validity of the MMAS and the MTS.
- A weakness of the study is that the tests will be carried out by one person.

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Table1: Definitions of the Modified Tardieu Scale and the Modified Modified Ashworth Scale.

Grade	Modified Tardieu Scale (Boyd and Graham, 1999)	Modified Modified Ashworth Scale (Ansari et al, 2006)
0	no resistance throughout the course of the passive movement	No increase in muscle tone
1	slight resistance throughout the course of the passive movement, with no clear catch at precise angle	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
2	Clear catch at precise angle, interrupting the passive movement, followed by release	Marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part (s) easily moved
3	Fatigable clonus (<10 seconds when maintaining pressure) occurring at precise angle	Considerable increase in muscle tone, passive movement difficult
4	Infatigable clonus (>10 seconds when maintaining pressure) occurring at precise angle	Affected part(s) rigid in flexion or extension.

Table 2: Demographic and clinical characteristics

	Number	Mean (SD)	Minimum	Maximum
Gender (M/F)				
Age				
Weight				
Height				
BMI				
Time since stroke				
Affected side(R/L)				

Table 3: The results for spasticity grades and measurements of R1, R2, and R2-R1

MTS measures	Median (IQR)	Mean (SD)	Min-Max	95% CI
R1				
R2				
R2-R1				
MMAS grades				
MTS grades				

R1: Angle of muscle reaction; R2: passive range of motion; R2-R1: dynamic component or spasticity
 MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale

Table 4: The results for H-reflex indices

	Mean (SD)	Min-Max	95% CI
H_{max}/M_{max}			
Latency			
H_{slp}/M_{slp}			
H_{slp}			

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Table 5: Correlation coefficients between spasticity clinical measures and neurophysiological tests

		H_{\max}/M_{\max}	Latency	$H_{\text{slp}}/M_{\text{slp}}$	H_{slp}
MMAS	Spearman's rho				
	Sig.				
MTS	Spearman's rho				
	sig				
R2-R1	Pearson correlation				
	sig				

MMAS, Modified Modified Ashworth Scale; MTS, Modified Tardieu Scale