Assesment of Post-stroke Elbow Flexor Spasticity in Response to Passive Stretch in Different Forearm Positions

Brief Title: Assesment of post-stroke elbow flexor spasticity in different forearm positions

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Background

Determination of which muscle is more spastic before injection of the botulinum toxin, and subsequently the application of the targeted treatment to that muscle is expected to result in more improvement in stroke patients with spasticity. From the view of point of post-stroke elbow flexor spasticity, there are three main muscles that contribute to spasticity; musculus biceps brachii, musculus brachialis and musculus brachioradialis (1). However, there are conflicting results regarding which muscle or muscles should be selected as treatment target in post-stroke elbow spasticity (2,3). Here the question is how to select the right muscle.The superficiality of the biceps brachii muscle makes it an easy target for botulinum toxin injection (2). In dynamic electromyography studies, it has been reported that brachioradialis muscle is the most common contributor one to elbow flexion spasticity, followed by biceps brachii muscle (3). In the diagnostic selective nerve blocks, the brachialis muscle has been reported to be foreground (2).

It is known that the muscles that flex elbow in healthy individuals change according to forearm position (4). While the biceps brachii flexes the forearm in supination, the brachioradialis flexes the forearm in the neutral position. The brachialis muscle acts as a primary flexor muscle when the forearm is in pronation, but it flexes the elbow in all forearm positions (4). In the light of this anatomical and biomechanical knowledge, can the target muscle be selected by examination instead of other methods such as electromyography where equipment is required and the evaluation period is relatively long? Can semi-quantitative methods such as Modified Ashwort Scale (MAS) (5) and Modified Tardieu Scale (MTS) (6) be used to assess the severity of spasticity provide reliable information regarding the muscle or muscles that contribute to elbow flexor spasticity? In this study, hypothesis is that the severity of the post-stroke elbow spasticity

differs depending on the forearm position that is one of the determinants which elbow flexor muscle to be more active in healthy subjects.

Aim

The aim of this study is to investigate whether the severity of spasticity differs depending on the forearm position.

Methods

Study design

This study is a single group, observational and cross-sectional study. Participants who meet the inclusion criteria and give written informed consent will be included in the study. This study was approved by the non-interventional Ethics Committee of Faculty of Medicine of İzmir Katip Çelebi University with approval number of 21.02.2018-84.

Setting

Subjects will be recruited based on identification of stroke patients with elbow flexor spasticity who present to outpatient or inpatient clinics of Physical Medicine and Rehabilitation (PMR) Department of İzmir Katip Çelibi University Atatürk Training and Research Hospital. All assessments will also be performed at the department of PMR of İzmir Katip Çelibi University Atatürk Training and Research Hospital.

Selection criteria

First the physician will ask potential participants (patients affected by stroke whose elbow is in flexion position) if they are interested in including the study. If they are, physician will assess them in terms of following inclusion and exclusion criteria:

- Elbow flexor spasticity
- Grade 1 to 3 spasticity measured with MAS (5)
- To agree to participate in the study

Exclusion Criteria

- <18 years old
- Pregnancy
- Botulinum toxin injection within the last three months
- Presence of elbow contracture
- History of operation to spastic upper extremity
- Spasticity due to other causes other than stroke
- Do not agree to participate in the study

In case of voluntary participation, patients will be asked to sign written informed consent. Immediately after, another study physican will perform the assessments.

Randomization and blinding

This study is a non-randomized and unblinded study.

Outcome assessment and data collection

After recording general demographic information (age, gender) and clinical patient characteristics (stroke type and side, disease duration, spontaneous elbow angle in upright position and Brunnstrom stage of motor recovery (7), participants will be assessed in terms of elbow flexor spasticity with MTS (6).

Primary outcome: Dynamic component of spasticity measured with MTS

The MTS is a spasticity scale that evaluates the velocity-dependent muscle reaction (6). Slow passive stretching (V1) evaluates passive range of motion (R2). To grade the quality of muscle reaction, passive stretch is performed by taking into account the falling speed of the limb segment under gravity (V2). The quality of muscle reaction ranges from 0 to 4. Grade 0 represents no spasticity and grade 4 represents severe spasticity. The angle of muscle reaction (R1) [the point of catch in response to spasticity in case of quality of muscle reaction to be score of 2 or higher] is evaluated by stretching the limb segment as fast as possible (V3). The difference between the R2 and R1 (R2-R1) represents the dynamic component of spasticity (spasticity angle). A big difference suggests spasticity while the low difference suggests muscular contracture.

Procedure

In this study, slow controlled motion, muscle reaction to fast stretching, quality of muscle reaction and dynamic component of spasticity will be assessed separately in the pronation, neutral and supination positions of forearm unlike the classical MTS assessment. Dynamic component of spasticity is selected as the primary outcome measure which best represents the spastic component of hypertonia. The MTS measurement will be performed while the patient is in sitting position on an examination bed, and his/her shoulder is adducted as described elsewhere (8), but differently, in three different forearm positions . Patients were asked to relax as much as possible. First, R2 will be measured with slow controlled maneouvre at the speed of V1, and than muscle reaction angle and quality of muscle reaction will be measured at the speed of V2 which will be extrapolated from healthy side of the patient. R2 and R1 will be measured with a standard goniometer (Baseline®, Fabrication Enterprises Inc, Newyork, USA) by two physician. One of them (A) will first position the limb, and than A will ask other one (B) to hold the positioned limb. Immediately after, while the B is holding the positioned limb, A will measure the elbow

angle. To measure the R1 and R2 in supination position of forearm; axis of goniometer will be placed in the lateral epicondyle of humerus, stationary arm will be aligned towars the center of acromion process and moving arm will be aligned towards the styloid process of radius (9). To measure the R1 and R2 in neutral position of forearm; axis and stationary arm placement will not change, but moving arm will be aligned towards the long finger by positioning the wrist in a neutral position. To measure the R1 and R2 in pronation position of forearm; axis and stationary arm placement will also not change, but moving arm will be aligned towards the styloid process of ulna. The end position is 180 degrees of full elbow extension. Because the R1 and quality of muscle reaction are evaluated at the same stretching speed (V2), these two measurements will be performed at the same time. In case of quality of muscle reaction to be score of 0 or 1, R1 and R2 will be accepted equal.

Sample size and power

The primary outcome of this study is to detect the differences in dynamic component of poststroke elbow flexor spasticity in different forearm positions. As far as we know, no such study has been conducted to date. Therefore, a priori sample size calculation for this study was based on some arbitrary assumptions including a moderate effect size (0.25) with correlation among repeated measures of 0.5 and epsilon of 1 for one way repeated measure ANOVA . Based on these assumptions with a Tip I error rate of 5.0 and 90% power, to reject the null hypothesis of no difference between dynamic components of elbow flexor spasticity in three different forearm positions, at least 36 patients were required. Sample size calculation was performed with G*Power software (G*Power, version 3.1.9.2, Germany).

Statistical analyses

Firstly a descriptive analyses of demographic and clinical characteristics of patients will be performed. For the primary hypothesis, a one way repeated measure analysis of variance will be

performed to compare differences in dynamic component of elbow flexor spasticity within three forearm positions. However, if the assumptions for one way repeated measure ANOVA are not met, Friedman's two way analysis of varience with Bonferroni correction will be performed. A level of 0.05 for statistical significance will be fixed.

Reporting of results

The results of this study will be presented at national and/or international meetings and will be pulished in journals.

Keywords: Stroke, elbow, muscle spasticity

Funding: No

Ethics approval: This study was approved by the non-interventional Ethics Committee of Faculty of Medicine of İzmir Katip Çelebi University with approval number of 21.02.2018-84.

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