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Effect of Botulinum Toxin –A on Upper and Lower Limb Spasticity Assessed by FIM and Motricity Index

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Abstract
Objectives: *To find the effect of botulinum toxin A on upper and lower limb spasticity and compare functional scale with a global scale of spasticity.*
Methods: *This is an open level prospective study, involving patients with upper and lower limb spasticity. Assessment were done at 3 weeks, 12 weeks, and at 24 weeks post injections. The Modified Ashworth and Modified Tardieu scale of spasticity, Percentage of passive range motion, Motricity Index was used. A total of 34 patients were enrolled 25 male, 9 female. There were 51 upper limb and 49 lower limb muscle groups. Three patients were lost during follows up.*
Results: *There was significant improvement in all the parametric variables after injections. Aggregate outcome scores comparing groups post base line showed significant difference in Modified Tardieu (MTS), Motricity Index (MI), Interventional goal assessment (IGA) scales muscle groups other than FIM. Lower limb faring better then upper limb spasticity.*
Conclusion: *Botulinum toxin A is an effective modality of treatment in appropriate clinical cases.*
Keywords: *Spasticity, Botulinum toxin A, upper limb, lower limb, Motricity Index, FIM.*

Introduction

Spasticity is loosely defined as velocity dependent increase in tonic stretch reflex as defined by Lance in 1980 and again redefined in 2003 by Decq. It is considered primarily as an upper motor neuron phenomenon which is again a blanket term. So even at clinical level it is very complex. It is now accepted that the exaggerated stretch of the muscle is only partly responsible for hypertonia .Other positive features of the upper motor

syndrome such as co-contraction, athetosis, hyper-reflexia, release of primitive reflexes, dystonia also contribute significantly to the resistance to this clinical condition and hence spasticity was again redefined in 2003 by Decq accommodating this observations.

Botulinum toxin-A has several unique advantages in of treatment in spasticity .It is reversible, relatively painless, achieves selective dose related weakness and overall very safe. For these advantages botulinum toxin-A is finding increasing acceptance for treatment of spasticity.

If used appropriately it has shown satisfactory results in treatment of spastic conditions[1, 2, 3, 4, 5, 6]. Local anaesthetic or phenol blocks are difficult to perform, toxicity of systemic therapy also limit their use. Moreover function of the affected limb is not predictably achieved by these interventions.

Botulinum Toxin –A is a costly treatment and requires a well co-ordinated team effort of physiatrists, neurologist and orthopaedicians. Most critical part is patient selection and assessment which is not very standardized to instill maximum clinical confidence. Hence there are needs to establish common assessment protocols that help the cross-talk between the above specialists to determine the course of action.

Aims and Objective of Study

- To compared the effects of botulinum toxin A in upper and lower limb spasticity**.**
- To compare a global scale with a function specific scale for assessment of function.

Research Methodology

Type of study: Open level prospective

Location: Dept of PM&R at the IPGME&R Kolkata in collaboration with Movement Disorder Clinic in the Dept of Neuro-medicine, Bangur Institute of Neuroscience, Kolkata.

Duration January: 2005 –March 2007.

Inclusion criteria: (1) spasticity ≥ 3 months (2) focal (3) poor response to other treatment. (4) Ability to give informed consent (5) complies with instructions on scales. (6) Spasticity ≥ 2 and ≤ 3 in Computed Modified Ashworth and Tardieu Scale (6) functional difficulties (7) Age ≥ 7 years.

Exclusion criteria: (1) fixed contracture (2) previous botulinum toxin-A therapy. (3) Previous chemoneurolysis. (4) Aminoglycosides, any muscle relaxants (7) Previous serial casting or surgical corrective procedures. (8) Others like pregnancy, neuromuscular disease hypersensitivity to botulinum toxin.

Sample Size

The sample size: 29 patient were required aiming to detect difference of 6 in Motricity between muscle groups and with a .5 % probability of Type ⊃ error (⟨ - 0.05) and 80% power (1 - ® = 0.8).

The data was entered into a Microsoft spread sheet and analysed by STATISTICA version 6 (STASTSOFT Incorporation; Tulsa, Oklahoma, 2001)

Assessment

We assessed disability, impairment and finally intervention goal was evaluated.

Disability measure

(1) Subjective rating of problem severity - The patient and care giver for its severity on the scale of one to seven, where one identified an extreme problem and seven identified no problem at all.

(2) Motricity Index - This is a weighted score derived from the Medical Research Council (MRC) grades. Six-limb movement was tested & scored for arm and leg. Six movements are pinch grip, elbow flexion, shoulder abduction, ankle dorsiflexion, knee extension, hip flexion.

(3) FIM (Functional Independence Measure) - a global scale.

Impairment having

A: The Non Dynamic Component

(1) **Spasticity (passive component)- MAS** (Modified Ashworth scale).

(2) **The Passive ROM at the target joint - % NROM** (Percentage of Normal Passive Range movement) with goniometry.

B: The Dynamic Componenet

(1) **Dynamic Length – MT (**Modified. Tardieu scale)

(2) **Clonus - MT**.

The intervention goal evaluation

A treatment goal was set e.g. To be able to grasp and release an object, to be keep both feet on the floor when standing from sitting.

The intervention goal was evaluated on a simple 3-point scale (0= not achieved; 1=partially achieved; and 2=achieved and maintained) at 12 weeks follow up.

Analysis of the Data

To facilitate computation of data, categorical variables of the Modified Ashworth Scale were assigned numerical values, designated as "computed MAS score" in this study. (MAS value 0=1,MAS value 1 =2, MAS value 1+=3, MAS value 2=4, MAS value 3=5, MAS value 4=6) similarly we had a "computed Modified Tardieu Scale"(cMT) here we took only the measure of quality of muscle reaction (X)[MT (X) value 0 =1, MT (X) value 1=2, MT (X) value 2= 3, MT (X) value 3= 4, MT (X) value 4=5, MT (X) value 5=6.]

Changes over time of clinical futures were analysed by using the Friedman test. Analysis of variance for the parametric ones (age, weight, duration of spasticity, units, number of sites).

Procedure

Written, informed consent was obtained before participation. Each patient received 1 set of injections after baseline assessment and reevaluated at 3 weeks, 12weeks and 24 weeks after discussion with the patient, care giver and the treating therapist.

Anatomical landmarks for motor point localisation and injection of were used. Injections of botulinum toxin–A, (Botox, Allergen) 21-30-gauge needle used. Large muscle dilution up to 1:4 and for smaller muscles dilution up to 1:2 was used. The doses and distribution of the injections were guided by the clinical and subjective rating of the problem. Active rehabilitation management program given for 6 months.

Results & Discussion

A total of 34 patients were enrolled in the study 25 were male 9 patients were female. 11 patients were ≤ 15 years of age of them 3 patients had 9 upper limb joint muscle group involvements. 8 patients had 25 lower limb joint muscle group involvements. 23 patients were ≥ 15 years of age, of them 14 had 42 upper limb joint muscle group involvements. 10 patients had 24 lower limb joint muscle group involvements. Of the total number of patients enrolled 3 patients were lost after the 3 weeks post base line follow up. All those lost at 3 week post baseline follow up belong to greater than 15 year age group, 2 of them had upper limb joint muscle group involvement and one had lower limb joint muscle group involvement. The mean age of the patients was 36.19 the mean duration of spasticity was 6.68 years of them 7 patients had duration of spasticity for less than 1 year and 27 patients had spasticity for more than 1 year.

Mean of the sites injected 2.85 (SD 1.27) units; mean dilution used was 3.08 with (SD 1.00) units.

In the lower limb group the mean size of the of the dose was 40.41(SD 12.49) units. Mean duration of spasticity 3.64(SD 3.01) years and mean dilution used was 4 .0 (SD 0.0) units *For parametric tests* on the aggregate outcome scores were compared groups post baseline.

Figure 1: Secondary Measure of Impairment

Graphs depicting decrease in Modified Ashworth and Tardieu scores with corresponding increase in percentage increase in range of motion at around 3 weeks time period

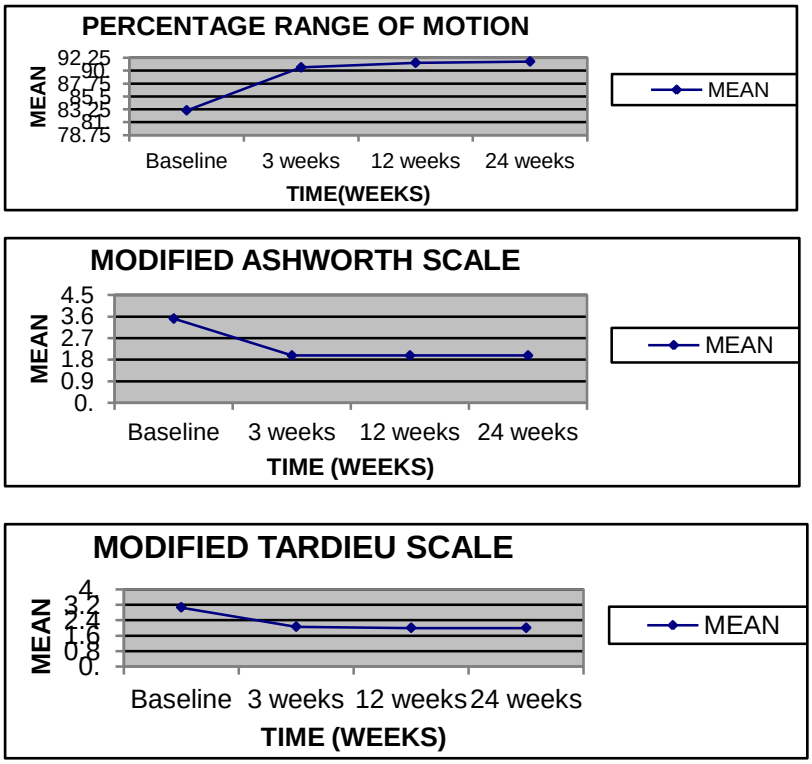

Figure 2: Primary Measure of Focal Disability

Graphs depicting increase in Motricity Index with corresponding increase in subjective ratings by patient at around 3 weeks time period

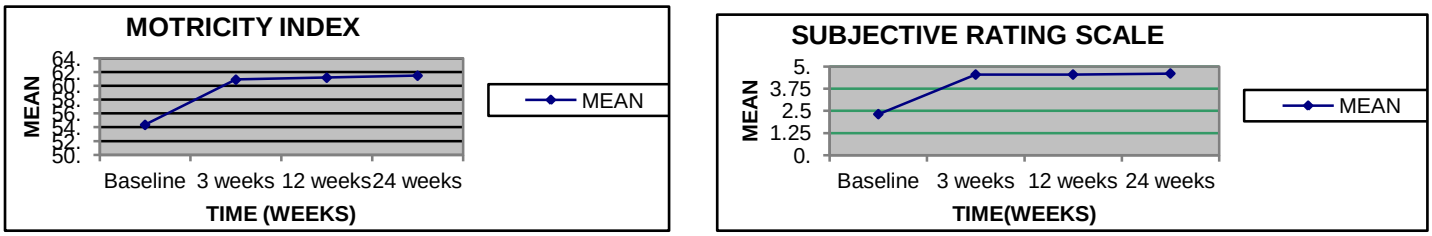

Table 1 p values of non parametric variables determined by Friedmans Test

	SRS	PRM	MAS	MTS	MI	FIM
LL	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.112**
UL	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.112**

(LL =Lower Limb, UL =Upper Limb, p = p value)

The above table showed that there were very significant improvement in all the non parametric variables measured post botulinum toxin-A intervention across the time period of the study except FIM.

(SRS =Subjective Rating Scale, PRM= Percentage Range of Motion, MAS=Modified Ashworth Scale, MTS=Modified Tardieu Scale, MI=Motricity Index, FIM=Functional Independence Measure)

Comparison of significant change (either increase or decrease in numerical values) across time period for each group were analysed with Friedman's Test for non-parametric variables. There was significant improvement of all the parameters used.

Functional Independence Measure (FIM) didn't show significant changes across time of the study .All spasticity measures showed significant reduction in muscle tone in both upper and lower limbs irrespective of aetiology. This has been substantiated in a recent systemic analysis[13]. This same analysis concluded combining results of variety of disorder to improve clarity is seldom possible .This might be primarily due non-uniformity of assessment scales used in different studies analysed in this systemic analysis. Our study included spasticity of various aetiology assessed with same outcome measure.

Mann-Whitney U test was used to compare results across groups.

Modified Ashworth Scale

1. The comparison of the effect of BTX-A between *lower and upper limb muscle groups* at 3 weeks (p=0.84), at 12 weeks (p=0.83) at 24 weeks (p=0.83) Comparison showed no significant better scores between the groups.

Modified Tardieu Scale

1. Comparison between *lower limb and upper limb muscle groups,* post baseline at 3 weeks (p=0.003), 12 weeks (p=0.019), 24 weeks (p=0.027). The results showed significant improvement of scores of spastic lower limb muscle group's dynamic length X at 3 weeks, 12 weeks and 24 weeks in comparison to upper limb muscle group.

Percentage Range Of Motion

1. Comparison between *lower limb and upper limb muscle groups,* at 3 weeks (p = 0.06), at 12 weeks (p = 0.16), at 24 weeks (p = 0.15). No significant difference was noted between the groups.

Motoricity Index

1. Comparison between *lower limb and upper limb muscle,* at 3 weeks (p=0.02), at 12 weeks (p=0.02), at 24 weeks (p=0.0266), post base line showed significant difference of scores between the groups with significant increase in motor ability in the lower limbs as detected by the Motricity Index at 3 weeks, 12 weeks and at 24 weeks. Post base line

For lower limb significant improvement was detected in Modified Tardue score but not in Modified Ashworth scale. Thus in our study Modified Tardue more effectively detected changes in lower limb spasticity[7, 8]. Interestingly lower limb spasticity cases showed a significant success in goal attainment set prior to injection as compared to upper limb. This finding substantiated a recent similar report[9]. Above results also showed significant improvement in Motricity index as compared to more generalised Functional Independence Measure[10,11]. Focal improvement of function were significantly detected by Motricity Index .Which tested key functional aspect of a particular joint muscle group. This finding is very similar to recommended spasticity measurement in a reputed literature for clinicians[12].

Conclusion

It was concluded that BTX – A has a definite favourable effect on impairment and focal disability due to spasticity. Global scales are of limited use for functional assessment and planning. Function specific scales are useful to guide treatment protocol with more accuracy. Studies to standardise such scales are imperative to guide treatment for better outcome.

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