

The Efficacy of Intra-Muscular Botulinum Toxin A (Btx-A) Injections on Spasticity Reduction in Spastic Cerebral Palsy



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Abstract

Introduction: Cerebral palsy (CP) is known as a clinical syndrome that occurs following a breakdown to the motor areas of the immature brain. Therapeutic options include the injection of BTX-A.

Study Objectives: the main objective of the present study is to investigate the impact of BTX-A injection on the spasticity scores of children with CP.

Methods and Subjects: A prospective study design was conducted from January 2017 to June 2018 at Royal Rehabilitation Center. A total of 128 children with CP were included. Children with were treated with BTX-A and followed for 3 and 6 months. At basal level, demographical and clinical data were recorded. Data included age, gender, and spasticity scores. Spasticity scores were determined using Modified Ashworth Scale pre and post injections.

Study Results: The age mean was 8.73 ± 5.70 years. The score of spasticity at basal level was 3.34 ± 0.67 , and then it was decreased further after three months follow up and reached 1.27 ± 0.99 . The spasticity score was further increased to the level of 3.07 ± 0.86 after 6 months follow up. There was a significant impact of using single injection of BTX-A on lowering the spasticity score levels after 3 months and 6 months follow up ($p < 0.001$). There were also significant differences in the mean of scores at 3 and 6 months follow up ($p < 0.001$). At basal level, males have significantly increased levels spasticity scores compared with females ($p = 0.002$). At 3 and 6 months follow up, no significant differences were attributed to gender ($p > 0.05$).

Conclusion: The study findings showed that single doses of ABT-X has therapeutic effects in decreasing the levels of spasticity scores.

Keywords: Cerebral Palsy; Spasticity; Spasticity Scores; ABTX-A; Modified Ashworth Scale

Introduction

Cerebral palsy (CP) is known as a clinical syndrome which is not progressive from one side, and that occur following a breakdown to the motor areas of the immature brain [1-3]. CP is the most prevalent entity leading to physical disability in children with incidence of 2 to 2.5 per 1000 live births [4]. Most children with CP have clinical symptoms of spastic paresis, a muscle-tone and muscle control-regulation disorder [5]. Spasticity is regarded as the chief participating variable in the functional altering and lowering the growth of longitudinal muscle in spastic CP children [6]. Lowering spasticity can be achieved through several therapeutic options among which is the injection of botulinum toxin type A (BTX-A), that is considered as effective and safe [7].

The mechanism of action of BTX-A depends on a manner of dose-dependent and it is reversible chemodenervation of the injected muscle through the blocking of presynaptic release of acetylcholine [8]. Wang and Gao [9] conducted a study about the use of botulinum toxin A (BTX-A) that is used to treat children with spastic cerebral palsy. The duration of its injection is limited for short periods, which requires multiple injections. The authors aimed to assess the impacts and safety measures of multiple injections of BTX-A in children with spastic cerebral palsy. The results showed that the use of BTX-A was beneficial after one week of the injection, and side effects were noted within one week of injections. Taken together, BTX-A improved muscle tone significantly in 3 and 6 months after serial injections compared with baseline ($p < 0.05$).

Study Objectives: the main objective of the present study is to investigate the impact of BTX-A injection on the spasticity scores of children with CP.

Methods and Subjects

Study Design and Setting

A prospective study design was conducted from January 2017 to June 2018 at Royal Rehabilitation Center.

Study Sample

A total of 128 children with CP were included in the study.

Study Procedure

After the study had been approved by ethical committee of Royal Medical Services, researchers started the practical steps in conducting the study. Children with CP who were undergoing the treatment with BTX-A were followed for 3 and 6 months. At basal level, demographical and clinical data were recorded. Data included age, gender, and spasticity scores. Spasticity scores were determined using Modified Ashworth Scale pre and post injections. Dysport (AbobotulinumtoxinA, 500 IU per vial; Ipsen Ltd, Slough, UK) was used in this study. The dose range varied between 5-30 U/Kg/BW, with a maximum dose of 500 U Per patient. and was given according to the manufacturer's instructions.

Statistical Analysis

All data obtained were entered into excel sheet for each patient. After the data had been completely entered into excel sheet, the data were entered into SPSS version 21 for statistical analysis. Two modes of descriptive analysis, frequency and percentages for categorical variables such as gender, and means and standard deviations for continuous variables such as age, and spasticity scores were used to present data. The relationships between variables were computed based on paired sample T test, dependent and independent. The significance was considered at alpha <0.05.

Results

As shown in Table 1, the study included a total of 128 children with CP of whom, the most proportion (71.1%) was for males. The age mean was 8.73±5.70 years. The score of spasticity at basal level was 3.34±0.67, and then it was decreased further after three months follow up and reached 1.27±0.99. The spasticity score was further increased to the level of 3.07±0.86 after 6 months follow up.

Table 1: General characteristics of study participants.

Variable	Description
Gender: (N, %)	
Male	91 (71.1%)
Female	37 (28.9%)
Age (M±SD) years	8.73±5.70
Spasticity (M±SD):	
Basal level	3.34±0.67
3 months	1.27±0.99
6 months	3.07±0.86

The Impact of BTX-A on Spasticity Scores

As seen in Table 2, there was a significant impact of using single injection of BTX-A on lowering the spasticity score levels after 3 months, and 6 months follow up (p<0.001). There were also significant differences in the mean of scores at 3 and 6 months follow up (p<0.001).

Table 2: The impact of BTX-A on spasticity scores (using paired T test).

Spasticity levels	M±SD	Significance
Basal level	3.33±0.67	<0.001
3 months	1.27±0.99	
Basal level	3.33±0.67	<0.001
6 months	3.07±0.86	
3 months	1.27±0.99	<0.001
6 months	3.07±0.86	

The Impact of Gender on Spasticity Scores

We investigated if the gender may have impacts on the scores of spasticity following the injection of BTX-A. At basal level, males have significantly increased levels spasticity scores compared with females (p=0.002). At 3 and 6 months follow up, no significant differences were attributed to gender (p>0.05) (Table 3).

Table 3: The impact of gender on spasticity scores (using independent T-test).

Spasticity levels	M±SD	Significance
Basal level:		
Male	3.52±0.57	0.002
Female	2.93±0.79	
After 3 months:		
Male	1.27±0.99	0.576
Female	1.13±0.97	
After 6 months:		
Males	2.87±1.00	0.118
Females	3.08±0.60	

Discussion

The main objective of this study was to explore the effect of injections of BTX-A on lowering the spasticity scores among children with CP. The data of the present study showed that there was a significant impact of using single injection of BTX-A on lowering the spasticity score levels after 3 months, and 6 months follow up (p<0.001). This finding is consistent with other studies that indicated to improved spasticity scores as a result of treatment with BTX-A [10-12].

We investigated if the gender may have impacts on the scores of spasticity following the injection of BTX-A. At basal level, males have significantly increased levels spasticity scores compared with females (p=0.002). At 3 and 6 months follow up, no significant differences were attributed to gender (p>0.05). Our data agree with other studies in which gender has no effect on the following up of spasticity scores [13,14].

Conclusion

The study findings showed that single doses of ABT-X has therapeutic effects in decreasing the levels of spasticity scores.

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