COMPARISON OF EFFICACY OF BOTULINUM INJECTION WITH SURGICAL RELEASE IN CEREBRAL PALSY CHILDREN WITH FOOT EQUINUS

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Date Received:
March, 24th 2021
Date Revised:
December, 29th 2021
Date Accepted:
January, 03rd 2022

ABSTRACT

Objective: To compare the efficacy of surgical release and Botulinum Toxin injections for treating foot equinus in Cerebral Palsy (CP) patients.

Methodology: This Quasi-experimental study was conducted in the Orthopedic Department, Khyber Teaching Hospital (KTH) Peshawar-Pakistan. The study enrolled 60 patients from 1st March 2018 to 1st June 2019 via non-probability consecutive sampling. All diagnosed cases of CP with equinus foot of either gender and age between 4-18 years with no previous surgery or botulinum injections and no joint deformity were included; while all patients with myasthenia gravis, neuromuscular junction disease, use of aminoglycoside, and those with discontinued physiotherapy were excluded. The patients were distributed into two equal groups, group A (botulinum group) and group B (surgery group). The outcome of the interventions in each group was measured based on improvement in Gross Motor Function Measure-66 (GMFM-66). Data was analysed using SPSS v.21.0, descriptive and analytical analysis was conducted where needed.

Results: The mean age of patients was 11.47±4.01 years with male to female ratio of 1.22:1. The right and left foot distribution among the patients was 31 (52%) and 29 (48%) respectively. Botulinum type A (BTX-A) injection resulted in improvement of GMFM-66 score in 27 (90%) patients in group A while the surgical release was effective in 20 (66.7%) patients in group B in terms of improvement in GMFM-66 score.

Conclusion: The study concluded that Botulinum Toxin has much better effectiveness as compared to surgical release in treatment of foot equinus among CP patients.

Key Words: Efficacy; Botulinum Toxin; Surgical Release; Equinus; Cerebral Palsy.

INTRODUCTION

Cerebral Palsy (CP) has an incidence of 1.5-3 cases per 1000 live births and is one of the most common causes of physical disability in humans.[1] CP is defined as a disorder of posture and movement that appears at an early age. It is not caused by degenerative or progressive disease of the brain and is secondary to dysfunction or lesion of the central nervous system. CP is most prevalent in premature children and represents around 65% of all cases.[2] Equinus is a common deformity in cerebral palsy patients and is defined as the inability to dorsiflex the foot above the plantigrade, with the knee extended and the hindfoot in a neutral position.[3] Equinus is caused by triceps surae contracture. It has a direct impact on the gait and standing ability of the patient.[4] Its treatment options consist of non-operative modalities like physical therapy, stretching the contracted tissue with serial casting, botulinum toxin injection, brace management, and finally, and triceps surae lengthening.[5]

Equinus surgery is aimed to produce a plantigrade foot and improve standing function and gait but there is a danger of overcorrection to hyper dorsiflexion causing progressive crouch. Recurrence is very common after surgical treatment and the outcomes of the surgical intervention have been extensively reported.[5] On the other hand, Botulinum toxin is a neurotoxin protein produced by the bacterium Clostridium botulinum.[6, 7] Botulinum toxin A (BTX-A) is considered an effective and safe therapy for children with cerebral palsy (CP).[8] BTX-A injections were found effective for spastic equinus in cerebral palsy in 64% of cases and the remaining cases were reported as poor responders.[9] Equinus is the most common ambulatory problem in CP and produces an inefficient and unstable gait pattern. It can progress to permanent deformities of the foot requiring surgical intervention if not managed at an early stage. Early intervention can allow children to maximize func-

This article may be cited as
Iqbal K, Khan M, Usama M, Ali I. Comparison of efficacy of botulinum injection with surgical release in cerebral palsy children with foot equinus. J Postgrad Med Inst 2021;35(4):220-4. https://doi.org/10.54079/jpmi.35.4.2875.

tional mobility and regain or maintain a full range of motion (ROM). In addition, these interventions help prevent contracture and delay surgical intervention.[10]

Several studies demonstrate the effectiveness of BTX-A injections and surgical treatment in achieving these goals.[11] However, no particular local data in the subject area is available from a tertiary care hospital of the Peshawar. So, this is designed to compare the efficacy of surgical release and Botulinum Toxin for the treatment of foot equinus in cerebral palsy patients.

METHODOLOGY

This quasi-experimental study was conducted in the Orthopedic Department, Khyber Teaching Hospital Peshawar-Pakistan from 1st March 2018 to 1st June 2019. Patients of both gender and aged between 4-18 years with diagnosed Cerebral Palsy (CP) and equinus foot irrespective of the degree of equinus, with no previous surgery or botulinum injection, and no joint deformity were included in the study. All those Patients with myasthenia gravis, neuromuscular junction disease, use of aminoglycoside, and those who discontinued physiotherapy were excluded from the study. Total of 60 patients were included in the study and were distributed equally into 2 groups. Group A consisted of patients that received Botulinum Toxin injections while patients treated surgically were included in group B.

This study was conducted after approval from the ethical committee of the hospital. All patients presented to the emergency department or were admitted through Out Patient Department, meeting the inclusion criteria were included in the study and were followed by informed consent. All the patients underwent a detailed history and clinical examination including the Silfverskiold test followed by routine lab investigations. The patients were treated under the supervision of seniors who were fellows of CPSP and have more than 5 years of experience as consultant Orthopedics. Patients were assessed in terms of GMFM-66 score at baseline i.e., before either intervention and at 1.5, 3, and 6 months intervals.

For group A, 100U of botox toxin type A were diluted in 1 ml normal saline achieving a concentration of 10U/0.1ml. Under sterile conditions, patients were injected with 4U/kg BTX-A (with a maximum dosage of 200U) with half of the dose injected on the medial side of gastrocnemius while the other half on the lateral side. For group B we did percutaneous Achilles tendon lengthening using Hoke's three incision techniques in which after identifying the Achilles, it is cut part way through using a small incision. The first incision is made near the insertion of the tendon and it cuts through the skin and half of the tendon usually the medial half. The second incision is made 1-2 cm above the first in the same way as the first but on the lateral half. A third incision is made 1-2 cm from the second incision and is used for releasing the inner half of the tendon followed by gentle pressure applied to the foot to allow the sliding of the fibers over each other in the cut areas and the Achilles tendon is lengthened gently. Finally, the incisions are stitched. The patient is immobilized with the ankle joint in a neutral position.

Data were analyzed using SPSS v.21.0. Mean and standard deviation was used for quantitative data. Frequency and percentages were used for qualitative data. Shapiro Wilk's test was done to find the normality of the data. T-test was applied to measure the difference in efficacy between the two groups keeping P-Value < 0.05 as significant.

RESULTS

This study included a total of 60 patients with a mean age of 11.47 years ± 4.01 SD. The basic demographics of the study are mentioned in (Table No 1).

Postintervention effectiveness in group A showed an improvement of GMFM-66 score in 27(90%) patients while 3(10%) patients have no improvement. Group B showed an improved score in 20 (66%) patients while no improvement in 10(34%). The details of improvement in GMFM-66 score at the baseline and a follow up of 1.5, 3, and 6 months is shown in (Table No 2)

DISCUSSION

Cerebral palsy (CP) is the most common cause of physical disability in children, affecting 1 of 400 children.[10] It has a multitude of motor disorders like paresis, spasticity, in-

Table 1: Basic Demographics of the Study

Mean Age of Patients			
	Group A	Group B	Overall mean age
Male	11.03 ± 4.02 years	11.63 ± 4.06 years	11.47 ± 4.01 years
Distribution of patients based on gender			
	Group A	Group B	Total
Male	17 (56%)	16 (53%)	33 (55%)
Female	13 (44%)	14 (47%)	27 (45%)
Male to female ration	1.3:1	1.1:1	1.22:1
Distribution of patients based on side involvement			
	Group A	Group B	Total
Right	20 (66%)	11 (63%)	31 (52%)
Left	10 (34%)	19 (37%)	29 (48%)

Table 2: Stratification of in Terms of Gmfm-66 Score

Distribution based on GMFM-66 score			
	Improvement in GMFM score	No Improvement in GMFM score	p-value
Group A Botulinum Toxin group	27 (90%)	3 (10%)	0.029
Group B Surgery Group	20 (66%)	10 (34%)	
Details of improvement in GMFM- 66 Score			
	Group A	Group B	
	Mean±SD	Mean±SD	
Pre-injection (Baseline)	71.51±13.44	68.54±10.88	
Post-injection 1.5 month	72.53±13.54	69.03±11.06	
Post-injection 3 months	74.44±13.31	70.14±11.98	
Post-injection 6 months	77.45±13.53	70.93±12.09	
Change (1.5 month)	1.02±2.99	0.49±2.45	
Change (3 month)	1.91±3.27	1.11±3.26	
Change (6 month)	3.01±3.49	0.79±3.10	

coordination, and dystonia. Lower limb spasticity causes a problem in walking in 80% of these children.[11] Clostridium botulinum produces a potent neurotoxin called Botulinum toxin.[12]

This quasi-experimental study demonstrated the efficacy of botulinum toxin for the treatment of CP-related equinus gait in terms of improvement in GMFM-66 score. The parameters of gait that are related to spasticities of the gastrocnemius and soleus muscle complex, like ankle position and gait pattern, showed significant improvement with botulinum toxin (BTX-A). the pattern of improvement of gait from baseline was followed for 6 months and found was statistically significant. As demonstrated by a previous double-blinded trial, this study also confirms the improvement in ambulation in patients with the BTX-A injections when compared with a placebo.[13]

In addition to improvement in ankle position and gait pattern, botox toxin also caused improvement in knee position thus improving knee recurvatum during gait. Even though upper leg muscles are more important for the position of the knee during gait, spasticity of gastrocnemius can contribute to knee recurvation as well.[14, 15] In fact, we can achieve a normal foot contact by knee recurvatum when we have a persistent equinus of the ankle. Thus if we decrease the position of the equinus foot, knee recurvatum can be made less evident with the passage of time.

A slight improvement in the position of the hindfoot was also noted during foot strike. Improvement in the position of the foot is a significant finding because due to BTX-A administration the muscles controlling the ankle and foot may become more balanced. A single BTX-A injection had a lasting effect of an average of 3 to 6 months, which was in accordance with other studies of focal dystonia.[16, 17]

The GMFM-66 is an adequate scale for assessing function in children of cerebral palsy.[18] Compared to the patients treated surgically, we noted a clinically significant improvement in patients after BTX-A injection in terms of GMFM-66. In the BTX-A group, the GMFM-66 score improved from 71.51 to 77.45 with a total change of 5.94 at the 6 month follow up while in the surgery group it improved from 68.54 to 70.93 with a total change of 2.39 at 6 months follow up.

After the administration of BTX-A injection, we did not notice any differences in improvement in GMFM-66 in hemiplegic versus diplegic children. GMFM score has rarely been used as an outcome measure in studies even though it is a recommended tool for assessing motor performance in cerebral palsy patients.[19, 20]

Boyd and Graham reported a significant functional improvement in a subset of 2-4-year-old CP patients that lasted for more than 18 months after the administration of BTX-A.[21] The dose of BTX-A be tailored according to the need of the patient because the duration of the therapy and its effect depends on the factors like the physiology of the muscle before injection including endurance, spasticity, and power, delivering the toxin into the target muscle(s); extensibility of connective tissue and joint range of motion.

Due to developmental changes in the pattern of gait and maturational changes of the musculature it is difficult to predict the long-term success of surgical intervention to improve ambulation. If performed in early childhood the recurrence rate of equinus in children is very high.[22] The necessity for surgery can be delayed by decreasing muscle spasticity with BTX-A injections thus providing time for gait patterns muscles to mature.

Richardson states that BTX-A injection provides a favorable opportunity for making changes in muscle function, length, pattern of movement, and also in antagonist motor control.[23] BTX-A provides the necessary active and passive stretch for longitudinal muscle growth. Although the literature is deficient concerning muscle growth in CP children, Eames et al noted an increase in length of gastrocnemius after BTX-A injection.[24] BTX-A causes a decrease in focal muscle spasticity which provides an opportunity for children to strengthen and learn the use of opposing muscles via occupational and physical rehabilitation.

In this trial, BTX-A injection caused an improvement in the gait of children having equinus deformity and this improvement was maintained over 6 months period of follow-up. The outcome of our trial suggests and also supports the idea that reduction of excessive foot and ankle tone with BTX-A may improve gait and can be a first-line therapeutic option in the treatment of equinus foot deformity due to cerebral palsy.

A key limitation of this study is that the data was collected from a single institution, even though we included the data from different surgical teams, the generalizability of our results becomes limited.

CONCLUSION

The study shows that Botulinum toxin is more efficacious, can be easily administered as an outpatient procedure and causes more improvement in walking among patients with equinus foot due to cerebral palsy.

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Author's Contribution

KI designed, analyzed the data, and drafted the study. MK designed, analyzed the data, and drafted the study. MU collected & analyzed the data with drafted the study. IA collected the data with drafted the study. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

Grant Support and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.