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Original Research Article

Can we treat idiopathic CTEV without tenotomy? A prospective study

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ABSTRACT

Tendoachillis tenotomy is the procedure of choice to correct equinus deformity in Ponseti technique. Though Tenotomy is the most frequently done procedure, is associated with complications in 11% to 50% of cases. So, we were in search of an alternative which would have less complication and will give similar results to a standard tenotomy. One such method is Botulinum toxin type A injection into the gastronemius-soleus muscle which causes reversible paralysis of the muscle leading to lengthening of muscle unit, easy manipulation and casting. In our study, we compared the outcomes of Botulinum toxin with tenotomy in the correction of hindfoot equinus in children (<2>0.05) between the two groups in the post-intervention Pirani score and ankle dorsiflexion was seen at 3&6 weeks and 3,6,12 month post intervention. Average dorsiflexion was around 11±1° in both groups upto 1 year post intervention.
Early results shows that Botulinum toxin type A is a good alternative to a routine tendoachillis tenotomy to correct hindfoot equinus in the management of clubfoot by the Ponseti method.

1. Introduction

Ponseti method is the gold standard in management of CTEV[1] with success rate of more than 90% in children below 2 years.[2] Sequence of deformity correction - cavus, adductus, varus followed by hindfoot equinus. Tenotomy is procedure of choice for hindfoot equinus correction in Ponseti method. Surgical intervention have reported complications in 11% to 50% of cases.[3] Complications seen are calcaneal deformity from over-lengthening of the tendon or equinus from inadequate release or presence of accessory tendon. Gait analysis has shown decrease in power generation in triceps surae muscle by 27%. Avoiding a tenotomy preserves the viscoelastic properties of the tendon and may avoid potential complications of surgery.

Alternative methods available are Botulinum toxin type A injection into gastronemius-soleus muscle or a dynamic dorsiflexion splint.[1] Botulinum toxin A (BTX-A) causes reversible paralysis of Gastrosoleus muscle unit, there by permitting lengthening of muscle unit and easier manipulation. Studies on Botox have shown, can be effectively used for equinus correction.[3–5] Hence we opted to compare the outcomes between tenotomy and Botox.

We hypothesized that medical tenotomy using Botulinum toxin type A versus tendoachillis surgical tenotomy in infants with idiopathic clubfoot under 2years treated by Ponseti method has similar outcomes. Our aim was to compare the clinical and functional outcomes of Botulinum toxin type A versus tendoachillis tenotomy in hindfoot equinus correction in children with idiopathic clubfoot treated by Ponseti method.

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2. Materials and Methods

It was a randomized Prospective interventional Study and included Infants with idiopathic clubfoot treated by Ponseti method less than 2yrs of age. Infants with congenital anomalies (Syndromic clubfoot), recurrent clubfoot or previously operated for clubfoot and neurogenic clubfoot were excluded.

All Children included in the study were initially started on serial casting as per Ponseti technique, at the time of equinus correction after obtaining adequate abduction children were divided into two groups by Simple random sampling method. Group-01 treated with Botulinum toxin type A while Group-02 underwent percutaneous tendoachillis tenotomy to correct hindfoot equinus.

2.1. Botulinum toxin injection technique[1]

BTX-A at 10 IU/kg injected into the gastronemius-soleus muscle complex, dose was recommended by the Spasticity Study group.[6] BTX-A was diluted to 10 IU/1 mL of unpreserved normal saline. Immediately following BTX-A injection, above knee casts were applied. Then weekly cast were changed until we get full dorsiflexion, following full correction cast given for 3 weeks. Never try to dorsiflex ankle forcefully post injection, can lead to rocker bottom deformity.

Figure 1: BOTOX injected into all 4 quadrants in a stellate pattern, followed by cast in maximum possible dorsiflexion without force

2.2. Percutaneous tenotomy

Children were placed in prone position, local anesthesia block using 2% Lignocaine. Foot held in dorsiflexion and tendon is felt, Blade of 11 size used to cut tendoachillis 1cm above insertion at calcaneum. Tendon is cut from medial to lateral direction. "Pop" is felt when tendon is cut and cast is applied in maximal dorsiflexion and 70 degree abduction for 3 weeks.

2.3. Bracing and follow up:[7]

After full correction of deformity, children of both groups were given foot abduction brace (Steinbeck). Bracing was done according to Ponseti protocol. Children were followed up weekly for first 3 weeks after bracing, then monthly follow up done for 3 months after which 3 monthly follow up upto 2 years of age. During follow up serial Pirani score, ankle dorsiflexion, relapse rate and complications were noted.

Study was started after getting approval from CTRI (CLINICAL TRIAL REGISTRY OF INDIA) and institute ethics committee(AIIMS RAIPUR). The study was done on 31children (51 feet) of idiopathic clubfoot deformity. Though sample size calculated was 34 based on number of clubfoot patients coming to Orthopaedics OPD in a year and the prevalence of clubfoot in India, sample size could not be achieved due to COVID-19 pandemic.

3. Observation and Results

A total of 31 (51 feet) children included in study with Group A (BOTOX) 14 children and Group B (TENOTOMY) 17 children.

In group A majority of children were female (71.4%) while in group B majority of children were male (70.6%). But when both groups were combined, sex distribution (Male 51.6%, Female 48.4%) was almost equal in our study. In clubfoot, children who present early (age at presentation) have more favorable outcome when compared to those who present late. In our study majority of children presented early (less than 1 month) accounting for 58.1% of study population, which is also an important factor for favorable outcome in both groups. Total number of cast required to correct deformity was higher in group A when compared to group B by an average of 2 casts in 50% and 1 cast in 28.7% of children in BOTOX group. Similarly, total number of visit was also higher in group A than group B.

In our study there is no significant difference between two groups in pre and post intervention Pirani score. If we follow the graph we can see there is a gradual decrease in pre intervention score with every cast showing that there is a gradual correction in deformity with each cast. Post intervention score was almost zero in both groups upto 1 year post deformity correction.

Ankle dorsiflexion was measured with help of goniometer with knee in extension. No significant difference(p-value $>$ 0.05)between two groups in post intervention. With BTX A we can also notice that there is gradual increase in dorsiflexion over a period of 1 year where as we get maximum dorsiflexion post intervention in tenotomy group and it continues to be the same. If we compare the scores from 3 weeks there is no difference between the groups and both groups have similar outcomes. Average dorsiflexion was around $11 \pm 1^{\circ}$ in both groups upto 1 year post intervention.

3.1. Complications

1. Pressure sores in the proximal thigh due to the proximal end of the cast. Can be avoided by adequate padding. Deep sore require a cast holiday of one week.

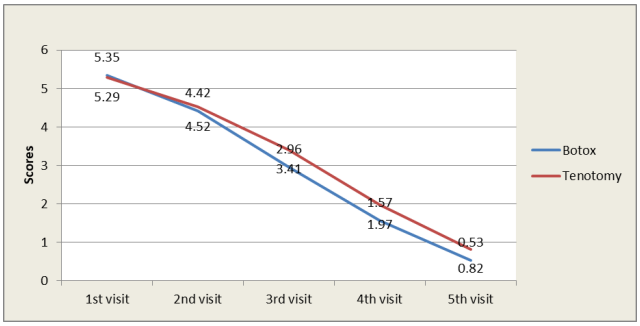

Figure 2: Comparison of pre-intervention modified pirani score

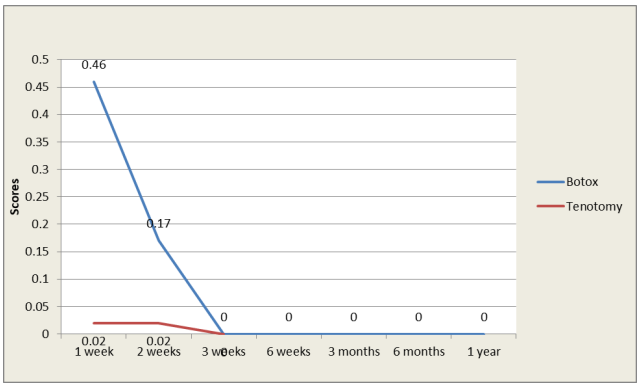

Figure 3: Comparison of post intervention modified pirani score

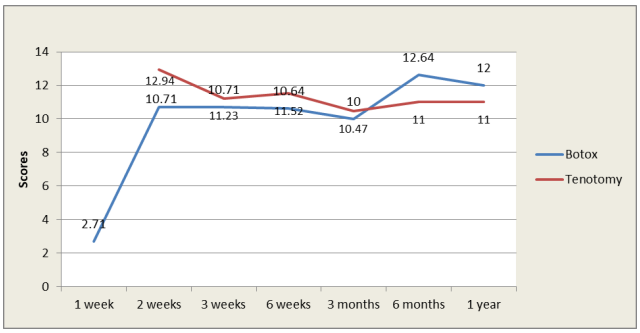

Figure 4: Comparison of ankle dorsiflexion between two groups

2. Pustules and blisters due to bad hygiene (soiling and soakage due to urine.
3. Slipping of the cast due to improper molding of the cast is commonly seen.

4. Discussion

Tendoachillis tenotomy is a pivotal point in the management of clubfoot according to the Ponseti technique and is the procedure of choice in correction of hindfoot equinus. Tenotomy involves complete transaction of tendon few centimeters above its insertion into the calcaneum followed by cast in maximum dorsiflexion. Healing

Figure 5: Pressure sore on thigh

Figure 6: Pustules on the thigh

Figure 7: Slippage of cast due to improper moulding

leads to lengthening of tendon and thereby helping in correction of hindfoot equinus, which is maintained by bracing the foot in abduction and dorsiflexion. Tendon regeneration is seen after 3 to 6 weeks by ultrasound[8,9] or magnetic resonance imaging.[10] Tenotomy is not without its drawbacks and complications like calcaneal deformity from over-lengthening of the tendon or recurrence from inadequate release or presence of accessory tendon. Gait analysis has shown decrease in power generation in triceps surae muscle by 27%. Recurrent tenotomy is associated with scarring of tendon. So we searched for alternatives to tenotomy which could give similar results.

One such method is Botulinum toxin injection into gastro-soleus muscle complex. It causes relaxation of muscle and helps in lengthening of muscle by decreasing the myofibril overlap, results have also shown that Botulinum toxin can be used in equinus correction and for a long time it has been used in cerebral palsy children to prevent and

correct deformities. Advantage of using toxin instead of tenotomy includes preserving the viscoelastic properties of tendon, multiple injections can be given without interrupting muscle tendon unit because its action is temporary on muscle and avoiding complications of surgery. Some of the known side effects of Botox includes fever, extremity weakness, constipation, and adjoining muscle weakness, these are rare and transient.

Our experience with Botox from this study is that, it is a good alternative to tendoachillis tenotomy and is safe to use in children less than 2 years of age. When we compare our studies with similar studies that were done in the past, we can observe that the results are similar and comparable. Good results in this study can be attributed to the compliance of educated parents. Strict adherence to the follow-up protocol and their direct involvement are important factors in treating clubfoot. Clubfoot treatment aims to achieve a plantigrade, functional, painless, and pliable foot. Our modification of the Ponseti method has shown similar results to that of the original method described and is a simple procedure when compared to routine tenotomy, with no complication being noted in both groups due to intervention. The limitation of our study was the small sample size and follow-up due to the COVID-19 pandemic.

5. Conclusion

In this prospective study, we primarily compared the clinical and functional outcome of Percutaneous tendoachillis surgical tenotomy (group B) versus Botulinum toxin type A (group A) in correcting hindfoot equinus in the management of idiopathic clubfoot by the Ponseti method. Clinical outcome was monitored by serial Pirani score and functional outcome by ankle dorsiflexion. We found that both groups had similar outcomes till 1 year follow up. So we conclude that Botulinum toxin type A is a good alternative to a routine tendoachillis tenotomy to correct hindfoot equinus in the management of clubfoot by the Ponseti method.

6. Source of Funding

None.

7. Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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