

Ponseti method of treating clubfoot - Is there difference if treatment is started before or after one month of age?

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ABSTRACT

Introduction: Most of the authors currently agree that congenital talipes equinovarus (CTEV) or idiopathic clubfoot can be effectively treated with the Ponseti method instead of extensive soft tissue surgery. This study was conducted to investigate whether there is a difference in the outcome between starting treatment before one month of age or after that age.

Methods: This is a retrospective study on babies with CTEV treated in University Malaya Medical Centre from 2013 to 2017. The 54 babies (35 boys and 19 girls) were divided into two cohorts, Group 1 that had treatment before the age of one month, and Group 2 that had treatment after one month old. The number of cast changes, rate of full correction, and rate of relapse after treatment were compared between the two groups.

Results: Of the 54 babies, with 77 CTEV treated during the period, our outcome showed that the mean number of cast change was 5.9 for Group 1 and 5.7 for Group 2. The difference was not statistically significant. All the affected feet (100%) achieved full correction. One foot in the Group 1 relapsed, while three feet in Group 2 relapsed, but the difference was also not statistically significant. All of the relapsed feet were successfully treated with repeated Ponseti method.

Conclusions: Treating CTEV using Ponseti method starting after one month was not associated with more casting change of higher rate of relapse.

KEYWORDS:

Clubfoot, serial casting, Ponseti, relapse, starting treatment

INTRODUCTION

Clubfoot is a general term for foot deformities characterized by forefoot adductus, midfoot varus and hindfoot equinus. This deformity can be associated with various conditions such as myelodysplasia, arthrogryposis and other congenital or acquired pathologies. Congenital talipes equinovarus (CTEV), also known as idiopathic clubfoot is a common congenital foot deformity with a global incidence of about 1 per 1000 live births.^{1,2} A recent systematic review based on 48 studies from 20 low and middle income countries reported birth prevalence of CTEV of between 0.51 to 2.03/1000 live births.³

Serial manipulation and casting, as described by Ponseti IV has become the mainstay of treatment for CTEV worldwide over the last two decades.^{4,5} Ponseti's method describes weekly serial manipulation and casting following a prescribed protocol. The final cast is applied after a percutaneous tenotomy in a majority of cases. This is then followed by bracing in a foot-abduction-orthosis. This method has demonstrated good short-term⁶ and long-term outcomes.^{7,8} Evidence of undesirable outcomes following extensive open surgery⁹ has also resulted in the decline in the use of this method of treatment for CTEV, in favour of the Ponseti method.

It is generally recommended that treatment of CTEV should be initiated as soon as possible after birth.^{4,8,10} In the first European consensus meeting on Ponseti clubfoot treatment, Stephanie Bohm stated that treatment for clubfoot should start not later than within the first months of life, without giving any evidence to support this consensus.¹¹

With the increasing usage of the Ponseti treatment, successful treatments have also been reported in older children. In 2009, Alves et al., compared treatment outcome between clubfoot children treated before and after six months of age, and reported mean relapsed rates of 8% in both groups, suggesting no difference in the treatment outcome.¹² However, in the following year, Iltar et al., reported that children treated within the first month of life had poorer outcome compared to those who began treatment later than the first month of life¹³ postulating that bones in new born babies may be too soft to produce effective stretching of the soft tissue. This finding apparently does not support the recommendation for starting treatment as soon as possible. However, most centres still strongly recommend treatment as early as possible.

In many developing countries, babies with CTEV were usually referred to centres where the Ponseti method of treatment is available, and it is not uncommon for treatment to be started more than one month after birth. In addition, some traditional practices forbid mothers to leave their homes during the "confinement" period, resulting in delay in starting treatment. Most hospitals try to initiate treatment as early as possible based on the protocol adapted by many established centres in the Western world. Thus, it is important to compare the treatment outcome between the two practices and the aim to conduct this study to provide evidence to support the practice that treating CTEV after one month of age can still have a favourable outcome was initiated.

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Table I: Demographics information and outcome between the two groups of children with CTEV

Variable	Total number	Group 1 (<30 days old)	Group 2 (>30 days old)	p-value
Number of patients	54	21	33	
Number of clubfeet	77	31	46	
Mean age (weeks / SD)	54	1.8 (0.8)	26.2 (24.6)	
Male : Female	54	13:8	22:11	>0.05
Unilateral : Bilateral	54	11:10	20:13	>0.05
Number of casts	na	5.9 ± 1.5 SD	5.7 ± 2.2 SD	0.576
Tenotomies	51	17 (54.8%)	34 (73.9%)	0.083
Relapses	4	1 (3.2%)	3 (6.5%)	0.644

Na : not applicable
SD : Standard Deviation

MATERIALS AND METHODS

This was a retrospective comparative study at the University Malaya Medical Centre (UMMC). After obtaining approval from the ethical committee of UMMC we traced the folders of all babies treated in our hospital for CTEV between January 2013 and June 2017. Babies with CTEV that had started treatment before being referred to UMMC, and those with clubfoot deformities secondary to neuromuscular, or syndromic conditions were excluded. The babies were then separated into two groups; Group 1 was babies who were treated before 30 days of life, and Group 2 were babies for whom treatment was started at or after 30 days of life.

All our babies were treated with the standard Ponseti method of serial manipulation and casting. The procedure was performed by a paediatric orthopaedic specialist and a plaster technician, with more than 10-year experience, using Plaster of Paris. Serial manipulation and change of casts were performed on weekly intervals at the CTEV clinic. Percutaneous heel cord tenotomy was performed on babies who had a resistant equinus component. If the ankle could not be dorsiflexed more than 15 degrees by passive manipulation during the 5th cast change, a tenotomy was performed by paediatric orthopaedic specialists. All babies who achieved full correction (70° abduction of the forefoot, and 20° valgus and dorsiflexion for the midfoot and hindfoot) would then start to wear a foot abduction brace with a cross bar. The affected side is splinted in 70° abduction, while the not affected side will be at 45°. The babies are then required to wear this orthosis for 23 hours a day for the first 3 months, after completion of casting. After three months, they were allowed to wear the foot abduction orthosis only at night, supplemented with foot stretching exercises 3 to 4 times a day. This protocol is done until the fifth birthday of the child.

A CTEV deformity that could not be corrected to neutral position by stretching alone was considered a resistant CTEV, while those that achieved full correction but subsequently recurred were considered relapsed CTEV. In relapsed CTEV, the deformity recurs and is not passively correctable. This would require another course of treatment with the Ponseti method, starting from the first cast to the repeated tenotomy if required.

The main outcome variables include number of cast changes, rate of resistant CTEV (failure of full correction), and rate of

relapsed CTEV. This study also looked at the rate of heel cord tenotomies, complication of cast application, and problems with foot abduction orthosis encountered by parents.

All collected data was tabulated using Microsoft Access software, and analysed using SPSS version 18. We first checked the distribution pattern using a normality test, and then proceeded to compare the difference between individual parameters using corresponding statistical tests. Statistical significance was set at p-value <0.05.

RESULTS

In all 54 babies identified with 77 feet treated for CTEV during this study period that fulfilled the selection criteria. There were 35 boys and 19 girls (male female ratio of 1.8:1), and 23 of them (42.6%) had bilateral deformities. The mean length of follow-up for the whole of two cohorts was 22.39 months following completion of casting (range, 12-51 months). In Group 1 there were 13 boys and eight girls with 31 clubfeet, with a mean age of 1.8 weeks, while in Group 2 there were 22 boys and 11 girls with 46 clubfeet, with a mean age of 6 months (between one to 23 months of age). Differences in gender distribution and rate of bilateral involvement between the two groups were not statistically significant (Table I). None of the patients dropped out of the study cohort.

The mean number of cast changes for all babies was 5.83. Group 1 required 5.9 cast changes, while Group 2 required 5.7 cast changes. The difference between the two groups was not statistically significant (p=0.576). Percutaneous Achilles tenotomy was performed in 17 out of 31 (54.8%) feet in Group 1, and 34 out of 46 (73.9%) in Group 2. Although the rate of tenotomy was higher in Group 2, the difference was not statistically significant (p=0.083). Full correction was achieved in all our clubfeet patients (100%), with no case of resistant CTEV or treatment failure. During the follow up period, four of the 77 clubfeet (5.2%) developed relapsed deformity. One of them was in Group 1 (3.2%), while the other three were in Group 2 (6.5%). This difference was however not statistically significant (p=0.644). There were no major complications documented during the period of treatment in all patients. None required early return for treatment or change in casting protocol. No cast slippage was reported. The four babies with relapsed CTEV were subsequently treated with a repeat of the Ponseti protocol. All of them were eventually able to achieve full correction with a

mean of 4 cast changes, and only one foot requiring percutaneous heel cord tenotomy. All the children were prescribed foot abduction orthosis following removal of cast.

DISCUSSIONS

Our study cohort showed male to female ratio of 1.8:1, and male predominance was also observed by most other studies.¹²⁻¹⁷ We noted slightly less than half of the babies had bilateral CTEV (42.6%). Although this was consistent with most other studies,^{13-15,17,18} a few studies reported more bilateral involvements.^{19,20} We have slightly more babies who started treatment more than one month after birth (Group 2) compared to those who were treated early (Group 1). In the series reported by et al. Iltar,¹³ more babies were treated before one month of age.

In this study the mean number of cast changes for all babies was 5.83, and this was consistent with many other studies that reported between 5 to 6 cast changes.^{10,12,13,21-24} There was no significant difference in the rate of cast changes between those started on treatment before or after one month of age. Slightly more than half (66.2%) of the clubfeet had percutaneous heel cord tenotomies. This is in contrast with other studies where the indication for tenotomy was more liberal.^{11,25} Even with the lower rate of tenotomy, we were able to achieve full correction for all the CTEV patients in both the groups.

The rate of relapse CTEV in our short term follow up was 3.2% in Group 1 compared to 6.5% in Group 2, but the difference was not statistically significant. Our overall rate of relapse was 5.4%, and this was relatively low compared to other studies that reported relapsed rate of between 10 to 33%.^{21,26-30} Rate of relapse has been associated with non-compliance to application of the foot-abduction-orthosis and has been supported by various studies.^{6,27,28,30-32} These studies did not take into account the age at which treatment was initiated.

We are aware that our mean follow-up period of 22.39 months was relatively shorter compared to other studies. A longer follow-up period might introduce risk factors that are not related to time of initiating treatment. Similar studies on the timing of starting treatment by Iltar et al.,¹³ and Zionts et al.,²⁵ only considered relapsed rate up to 12 months of age.

A study by Alves et al showed that outcomes in CTEV patients treated after 6 months of age was similar with those treated earlier.¹² Zionts et al., reported similar findings and concluded that there is no need for CTEV to be treated urgently.²⁵ Our study supported their findings, showing no difference in the number of casts required for full correction, and no significant difference in rate of relapsed cases between those treated before and after one month of age. However, we did not detect any findings to suggest poorer outcome in babies treated before one month of age as reported by Iltar et al.¹³ The study by Iltar et al. was based on foot morphology (using the Dimeglio score) whereas other studies, including ours were based on number of cast changes, rate of full correction and rate of relapse. Our results also support favourable reports by Morcuende et al., for using the Ponseti method for correction of the deformity in older children, although the

positive outcome was based on avoidance of open surgical procedure.²⁷ We noted slightly higher rate of heel cord tenotomy in babies treated after one month of age, but the difference was not statistically significant. Indications for tenotomy is relatively variable and subjective as it is based on clinical judgement. Most authors do not report that as part of the treatment outcome.

The postpartum period is an important time for a mother. This is especially so for those who were delivered by Caesarean section, where there is a higher reported risk of infection, haemorrhage,³³ and pain.^{25,34} In Malaysia, postpartum "confinement" is practiced among mothers of various ethnicities, to help the new mothers recover from childbirth. While specific details may vary according to cultural beliefs, mothers are generally expected to remain at home during this confinement period, which can last from 30 days to 45 days after childbirth.³⁵⁻³⁷ Thus, it is difficult for mothers to accompany their babies to the hospital for the weekly cast changes. Based on our findings, we would like to recommend parents to take their child for treatment whenever they feel that the mother and baby are both ready. This period may vary, but in general one month is acceptable to most parents, based on the major Asian cultures and traditions. This period may be longer in premature babies who spend substantial time in the neonatal intensive care unit, or mothers who developed postpartum complications.

The main limitation of this study is the small sample size, of 54 children with 77 clubfeet. The two groups may not be totally comparable, in addition to date of starting treatment since the case enrolment were conducted in a retrospective manner. We did not consider the short follow up period as a limitation because relapsed rate following longer follow up periods would not reflect the influence of starting treatment.

CONCLUSION

This study showed good outcomes in CTEV patients treated using the Ponseti method, even though the treatment was initiated after one month of age. This is based on the average number of casts required and the rates of relapse. Babies with neonatal conditions, mothers with post-partum morbidities, and families who decided to observe confinement practices will be able to delay treatment safely knowing that they can expect similar favourable outcomes compared to those treated earlier than their babies.

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