



Ponseti's Method: Is It Effective in Conservative Management of Neglected Congenital Talipes Equino Varus

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ABSTRACT

Background: Clubfoot should be ideally corrected in infancy. Developing nations have inadequate medical and surgical resources. The cost of managing clubfoot surgically and the associated crippling deformities in later life makes conservative management a coveted means in developing. There are no guidelines in management of neglected clubfoot and the upper limit for age is yet to be determined.

Aim: To evaluate the effectiveness of Ponseti's method of conservative Management of Congenital Talipes Equino Varus in neglected clubfoot.

Settings and Design: This Prospective study was executed in the out-patient department & was conducted as a non-randomized prospective interventional analysis.

Methods and Material: All children in the weight bearing age group between 8 months to 16 years having Idiopathic Congenital Talipes Equino Varus, both unilateral and bilateral were included in the study. Altogether there were 37 patients amounting to a total of 61 clubfeet. They were all managed by Ponseti's method of casting. All the patients were compulsorily evaluated for 1.5 years and the evaluation was continued to the maximum possible until the tenure of the study. Children with clubfeet above the age of 16 years and below the age of weight bearing, those with teratologic clubfoot, those with syndromic associations and Recurrent or relapsed clubfeet consequent to failed surgical treatment were excluded from the study. Their pre-treatment Pirani score was noted and the scoring was done on every subsequent visits. The end point was a score ≤ 1.5 with the feet having 300-400 of external rotation and 150 of dorsiflexion.

Statistical analysis used: The means of Pre-treatment Pirani score was compared with the mean of Post-treatment Pirani score using paired t test. Linear Regression and correlation was used to analyse the number of casts required based on the age of the patient and Pre-treatment Pirani score

Results: 44 clubfeet were able to achieve the end point with Ponseti's protocol. There was a significant ($p < 0.001$) change in the mean pre-treatment and post treatment Pirani score. There was a strong correlation between the severity scoring and the number of casts needed and a weaker correlation between the age and the number of casts needed. The overall complications included equinus relapse, rigid equinus, skin erythema, knee rigidity and anaesthetic complication.

Conclusions: Ponseti's method is definitely an effective method in neglected clubfoot deformity. Even in stiff clubfeet it has its use as initial management. We were able to correct 72% of the clubfeet and in the rest, Ponseti's method helped in reducing the amount of deformity.

Keywords-Neglected, Resistant and complex clubfoot; plantigrade foot, prolonged casting, Pirani's score.

Introduction

Though Ponseti's method of management of congenital talipes equino varus (CTEV) has given reproducible results in both developed and developing nations [1,2,3,4,5-16,17], the upper age limit for application of the procedure remains to be determined. The Ponseti's method has been employed in older untreated cases with variable results [12,18,17,19,20]. In this study we wanted to test the effectiveness of Ponseti's method in management of neglected CTEV as a percentage of children in weight bearing age group before achievement of skeletal maturity who were able to achieve plantigrade foot with Ponseti's method with closed tenotomy and tibialis anterior transfers as supplementary methods. Thus additionally testing the correlation between the severity score, age and the number of casts during the treatment

Subjects and Methods

The study commenced from November 2011 and continued till September 2013. Consecutive patients who attended our outpatient department were treated. We were able to select 37 patients with a total of 61 clubfeet in our study. We excluded children who were less than 8 months of age or more than 16 years of age. Children with possibility of teratogenicity or syndromic associations were excluded from the study. Children who received prior surgical treatment coming back with residual correction or relapse were not included in this study. But we included patients who did receive some kind of non-surgical treatment in the past, though most of them couldn't recall the exact nature of the non-surgical treatment that they received in the past. The average age group of the study population was 5.8 years (Range 1 to 14 years). All the patients, from the beginning of the study were evaluated with Pirani's severity scoring system in a structured protocol, approved by the institution's research board and by the ethical committee, was used on their every subsequent visit. The casts were applied by trained junior residents and most of the children required tendo Achilles tenotomy to correct residual equinus. Surgeries were conducted by attending

consultant orthopaedic surgeons. When the treating surgeon felt that the treatment has reached a plateau phase and no further progress occurred, we mostly opted to treat using JESS distractor [21], and such cases were considered failures. Once the patients were evaluated with Pirani's score (hindfoot contracture score (HFCS) out of 3, includes three components of empty heel, posterior crease and rigid equinus each having a score between 0 and 1; midfoot contracture score (MFCS) out of 3, including 3 components of lateral border, medial crease and reducibility of the head of the Talus). Only above knee casts were used. The first cast was applied to correct the cavus by lifting and dorsiflexing the first metatarsal head. The cast was moulded all around the foot, heel, medial and lateral malleolus. Once the cavus was corrected the forefoot was slowly abducted in subsequent casts with a finger as fulcrum over the laterally placed talar head. Once the talar head got completely reduced, and an abduction of 40 degrees was achieved, equinus correction was assessed, and if MFCS was less than 1 and HFCS was greater than 1 with a fully reduced talar head (a score of 0) tenotomy was considered. Except the cast after tenotomy all other casts were changed every 1 week. The last cast that was applied after tenotomy were held in place for about 3 weeks. Casting was followed foot abduction brace. Since the children were in weight bearing age group and were comfortable and ambulant with their deformity. A complete 24 hr. application of the foot abduction brace (FAB) was not practical. Hence we chose bracing during night and nap time to improve adherence. Children between 1 to 2 years of age were treated with standard abduction bracing protocol with an abduction of 70 degrees. We used Steenbeek brace for FAB fig 1.



Figure 1: Steenbeek brace

As it was cheaper, more customizable, and was available in larger sizes. When we felt that the treatment has reached a plateau phase and no further casting is showing any improvement, or if the equinus could not be corrected by tendo Achilles tenotomy alone, we opted out of the protocol labelled the patients as failures and used JESS^[21] to treat the residual deformity.

Results

A total of 24 (65%) patients were male. 24 patients (65%) had bilateral club feet. Total number of right foot treated in this study was 32 and left foot was 29. 9(24%) patients had a positive family history of clubfoot deformity. 22 (59%) patients were first-born. A mean of 8 casts was required (1-20; 7.6 ± 2.72), and the number of casts required had a significant correlation with pre score (adjusted $R^2=0.54$; $P<0.01$) and age (adjusted $R^2=0.14$; $P<0.01$) (Fig 1 and Fig 2) of the child getting treated. The correlation of the latter was weaker when compared with the former.

Fig 2:

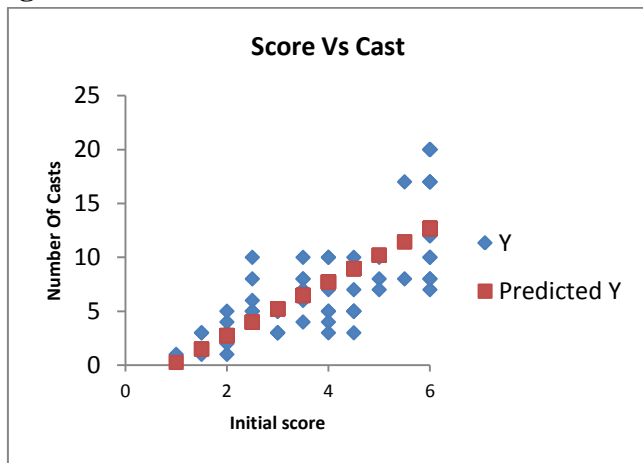
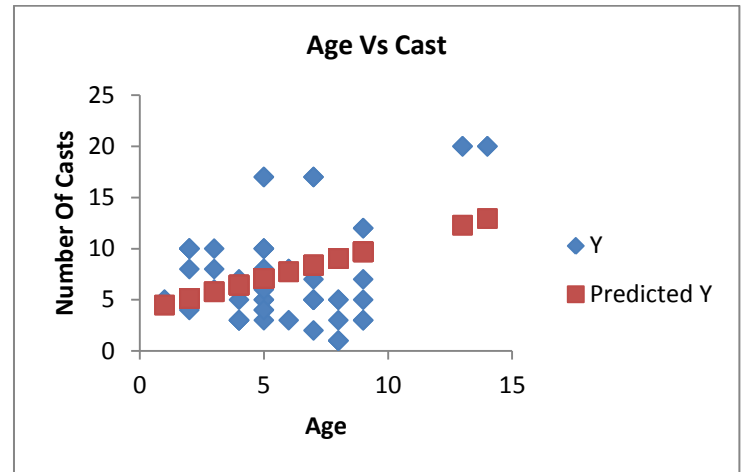


Fig 3:



The Pirani score for the entire group improved ($p<0.01$) after casting (mean of 3.96 ± 0.19 before casting and 1 ± 0.08 after casting). Age did not influence ($p = 0.67$) the post- Pirani scores. Eighty-seven percent of patients ($n=53$) were able to achieve plantigrade foot. The main surgeries that were performed were for correction of residual equinus. The procedures included percutaneous tendo-Achilles release in 43 (70.5%), a second tenotomy in 1 (1.6%), posterior release in 7 (13.1%), and tendon transfer in 8 (11.5%), JESS in 2 (3.3%) A plantigrade foot was achieved in 87% of cases without an extensive soft tissue release. Of which 72% ($n=44$) achieved plantigrade foot with casting & bracing supplemented with closed tenotomy or tibialis anterior transfer alone. Complications included Equinus relapse in 10 which was managed with either a Second percutaneous tenotomy (1), posterior release (3), JESS (1) or with continued casting(5); Skin erythema in 2 which was found to be due to application of cast on wet skin. The same improved on subsequent casts; Rigid equinus not corrected with percutaneous tenotomy was found in 4 was managed with posterior release in 3 patients and JESS in 1 patient; Knee rigidity due to casting in 3 we managed it by encouraging the children to have 15 to 30 minutes of active rom exercises of knee in between cast removal and application of fresh cast, same improved in subsequent casts; Anaesthetic complication in 1 while being posted for tendon transfer the child was resuscitated. All patients were maintained on a foot abduction brace.

Table 1: summary of results

Gender	
Male	65% (24)
Female	35% (13)
patient category	
Unilateral	35% (13)
Bilateral	65% (24)
Side	
Left	47% (29)
Right	53% (32)
No of casts (mean, SD)	
	7.6 (5.1)
Pre - Pirani score (mean, SD)	
	4 (1.5)
Post - Pirani score (mean, SD)	
	1 (0.7)
Surgeries	
Percutaneous tenotomy	70.5% (43)
Second percutaneous tenotomy	1.6% (1)
Posterior release	11.5% (7)
JESS	3.3% (2)
Tendon transfer	13.1% (8)
Treatment outcome	
Success	72% (44)
Failure	28% (17)

All of them complied with the protocol. Initial brace was changed in most of them as the brace was damaged or it was no longer fitting the size of feet. The parent compliance with the bracing protocol was remarkable. They were sounded as to their role in maintaining the correction with proper fitting shoes and changing the shoe size as the feet grew. A minimum follow-up of 6 months was possible with all the patients except one with a bilateral clubfoot, in whom, we lost the follow-up. Strict concordance to the protocol for follow-up outlined by Ponseti was maintained throughout the study. At each follow-up the feet were evaluated for any early sign of relapse if any. Patient who lost the follow-up (bilateral clubfoot) and six other clubfeet Pirani score of more 1.5 were considered as failures. Hence in this study we can conclude that 87% of the patients were cured using Ponseti technique of bracing supplemented by surgery. Of which 72% achieved success via Ponseti protocol the rest using other surgeries like soft JESS or Posterior release. While 13% of the neglected clubfeet remained

uncorrected. The entire result is summarized in table 1.

Fig 4:a, b, c, d, e



a) 14 year old boy presenting with bilateral CTEV



b) Before first cast



c) Application of first cast



d) After 8 Casts



c) After 12 casts



e) After 22 casts



d) foot after tenotomy

Fig 5: a, b, c, d, e
5 year old boy



a) Initial photo



e) On FAB



b) after 4 casts

Discussion

The management of CTEV has been constantly changing over the past few decades. As elaborated in a Historical review by Dobbs et al ^[8] it progressed from repeated manipulation at the time of Hippocrates to forceful manipulation, radical surgeries and now we are into the Ponseti's era. The method being lucrative as it is minimally invasive and thus has less degree of complication and can be applied with minimal cost. Dobbs et al. ^[8] reported poor results in nearly 50% of patients treated by an extensive soft tissue release at 25 years follow-up, mainly as a result of stiffness.

While the current Ponseti method has dramatically reduced the number of extensive soft tissue releases performed in various centres in both economically developed and underdeveloped nations of the world [1-17]

At the time of inception of this study, there was active debate going on about the application of this technique in elder children. There were published articles [20] which supported its effective use in elder children up to the age of 6 years. We therefore wanted to test whether the Ponseti method could achieve initial correction (a plantigrade foot) of untreated idiopathic clubfeet in skeletally immature patients presenting in weight bearing age group between 8 months and 16 years of age, and the results thus achieved suggest an initial correction of the deformity can be achieved without the need for an extensive soft tissue release (posteromedial release or other) in 87% of such cases. The upper age limit for this method remains to be determined, which gives us a scope for further studies in this area.

We agree that several limitations to this study are worth mentioning. Although the percentage of patients requiring surgical treatment for residual equinus after casting (87%) is comparable to published reports in patients, we were able to standardize the type of procedure used for correction of equinus. As there was lack of published guidelines on an upper age limit for a percutaneous tenotomy of the tendo-Achilles (standard component of Ponseti method), the decision had to be made by the attending surgeon based on his clinical experience. Percutaneous tenotomy (71%) was opted as the procedure of choice for correcting equinus, although a smaller number required either of second percutaneous tenotomy (2%), posterior release (12%), Tendon transfer (13%) or JESS (3%). We are still unable to conclude as to which would be the procedure of choice in correcting equinus in these older patients. There are studies which have used a percutaneous release up to age 9 years [12,17,18]. The employment of Posterior release or JESS [21] to achieve a plantigrade foot could be considered as treatment

failure, in which case the Ponseti protocol failed in an additional 15% of cases, and the majority of such patients were older than 3 years of age. Our threshold to opt out of the protocol seemed to have increased during the course of the study as we got acquainted with the results of prolonging the period of treatment. Though this study evaluates the efficiency of Ponseti's method in terms of achieving plantigrade foot, the study population needs to be followed up to determine how many of them are able to maintain the achieved correction. Pirani scoring system may be less reliable in the older age groups, as the medial and posterior creases become inconspicuous, and the "empty" heel pad may decrease with the normal loss of subcutaneous fat as a child grows. There is definitely a need for finding another scoring system which would include the degree of deformity, and the amount of suppleness which would be more useful in these older children. Patients from secluded region of our country have lesser awareness in terms of clubfoot treatment as a result most of them turn up late for their treatment. There are several current studies that have investigated the use of this method in patients of walking age [12,17,18] but none have tested its usefulness up to the age of skeletal maturity. Tindall et al. [17] reviewed 100 clubfeet treated by the orthopaedic clinical officers in Malawi (25% between 18 and 48 months of age) and reported only 2% required a posteromedial release. An average of five casts was required, and 59% of feet did not require any surgical intervention. Forty-one percent were treated by a percutaneous tenotomy after a plateau in casting. Success was defined as a plantigrade foot, and the final degree of dorsiflexion was not reported. Follow-up was impossible as a result of social and economic factors. Lourenco and Morcuende studied 24 feet in patients from 1 to 9 years of age [18]. The Ponseti protocol was modified for these older patients; each cast was left in place for 2 weeks, and an ankle-foot orthosis was worn full-time for 11 months after the initial correction was achieved (adherence to night-time abduction splinting could not be achieved). Additional surgery was required in nine of 17 feet to achieve a

plantigrade foot, including repeat percutaneous tenotomy (four) and posterior release (five). At a mean of more than 3 years follow-up, all patients had a successful outcome, defined as the absence of a limp, the ability to wear standard shoes, and the ability to participate in regular activities of daily living. D. A. Spiegel et al ^[20] did an extensive retrospective study in a population of 260 Nepalese children between age of 1 to 6 years; an accelerated protocol was followed changing the cast every five days. FAB was modified to night time use. 94% of the clubfeet were able to achieve correction; with an average dorsiflexion of 12.5 degrees 248 of the 260 required some sort of surgery for correction of residual equinus

We found that age combined with the severity score had a correlation with the number of casts required, an average of 7.6 casts per patient was required and was comparable with data from Malawi (five) ^[17], Brazil (nine) ^[18], India ^[19] & Nepal ^[20]. We changed our cast every week according to the standard ponseti protocol; in contrast, Lourenco and Morcuende recommend leaving each cast for 2 weeks in older patients to allow more time for relaxation of soft tissues and for chondro-osseous remodelling ^[18].

Abduction splinting is an essential component of the Ponseti method, and relapse rates of up to 70% may be expected when the abduction splint is not worn ^[9,13,14,22]. Adherence may become even more of a concern in a child who has been weight bearing. A variety of reasons may cause a lack of adherence to the splinting program, noncompliance as a result of social stigma and brace intolerance probably due to discomfort are some reasons worth mentioning. Whether comparable rates of recurrence, that may accompany non adherence with abduction bracing in the older patients remains to be determined. This requires long term follow up and determination of rate of recurrence of equinus varus and dynamic supination deformities. As of now, such long term studies are unavailable. Given that there are many socially and economically deprived section in India, such follow up studies are difficult to be obtained. Many such patients have more difficulty in reaching

a tertiary level hospital for obtaining treatment and come for follow up. In addition it is also necessary to assess the functional outcome of the treated patients in their domestic and work environment.

Conclusion

Thus though Ponseti's method have to be evaluated as an important tool in the arsenal to treat such cases, further studies must be directed in identifying these cases early so that such neglected cases are prevented from developing advanced deformities and associated morbidities. And effective planning must be done to take the treatment and screening to every remote villages where people will benefit from an early intervention. The utilization of resources like media and volunteers in spreading awareness for early case identification needs to be taken into consideration. The training of health professionals other than orthopaedic surgeons, & paraprofessionals may effectively administer the casting as shown in the United Kingdom (physiotherapists) ^[23] and Malawi (Orthopaedic clinical officers) ^[17]. Such nonconventional models must be explored if clubfoot care is to be delivered at the population level in low-income countries. The Ponseti method has been effective in achieving correction in patients with idiopathic clubfoot up to 2 years of age, and the upper age limit remains to be established. Our results suggest initial correction (a plantigrade foot) of an untreated idiopathic clubfoot may be achieved in the majority of patients up to 14 years of age. The results of several recent studies also suggest a role for this method in patients of walking age. Long-term follow-up will be required to assess adherence to abduction splinting, to define rates of recurrence, and to evaluate the functional outcome

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