

Frequency of Satisfactory Outcome with Ponseti Treatment in Congenital Idiopathic Club Feet

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Abstract

Introduction: The Ponseti methodology of managing Congenital Idiopathic Clubfeet has been the gold standard, with a satisfactory proven long-term outcome at the adulthood. The pre-treatment scoring has not been found to accurately predict for need for number of casts, Achilles tenotomies to achieve a satisfactory outcome at a short- and long term follow-up. This study is designed to evaluate the frequency of outcome with reference to basic demographics and initial Pirani score.

Patients and Methods: This prospective observational study was carried out at the Paediatric Orthopaedic section of Department of Orthopedic Surgery, Jinnah Postgraduate Medical Centre, Karachi, Pakistan, from January 2015 to December 2019. The patients included were 103 children with 172 Idiopathic Congenital Club Feet, in age group 1 week to 2 years of either sex, laterality or having Pirani score 3 - 6 points. They were given treatment during 2015 to 2017 and followed up to the next 2 years. All the patient underwent Ponseti technique of weekly manipulation, serial casting and percutaneous Achilles tenotomy [as required]. All patients used a foot abduction brace for maintenance of correction as per Ponseti Protocols. The frequency of outcome was measured with reference to basic demographics and initial Pirani score, at minimum follow-up duration of 24 Months.

Results: Out of 103 patients, majority (76%) were male, 68% were infants below 6 months age, average age of 30.32 ± 36.08 weeks, with bilateral preponderance of 67%. At minimum 2 years follow-up, the mean number of casts required were 6.46 ± 1.28 and percutaneous tenotomy was performed 68.93%. The post-treatment Pirani mean score achieved was 0.58 ± 0.77 , ranging between 0 to 0.5/1. The stratification analysis revealed an insignificant satisfactory outcome among different age groups, gender, number of cast and laterality. While the satisfactory outcome was significantly high in children whose initial Pirani score was 3 to 4 ($p = 0.03$) and in those where Achilles tenotomy was performed (< 0.001).

Conclusion: This study concludes that despite being of lengthy duration of its maintenance phase bracing, the regular visits, reciprocal patience on the part of parents and physician and adherence to protocol advised, the Ponseti technique gives the best results to achieve pain free, supple, normal looking feet to wear normal shoes. Treatment has been statistically found significantly effective to achieve satisfactory results with Pirani score 3 - 4 and earlier the treatment started soon after birth.

Keywords: Idiopathic Congenital Talipes Equinovarus; Club Foot; Ponseti; Pirani Score

Introduction

The clubfoot deformity is easily explained to have four essential features of C.A.V.E (Cavus, Adductus, Varus and Equinus) [1] Lyn Ponseti. Because of this complexity of clubfoot deformity, it used to be a difficult problem to manage conservatively and achieve the successful results at adulthood with supple, pain free normal feet. Ignacio V Ponseti introduced modifications in routinely practiced sequential correction of clubfoot deformity Hiram Kite and others non-operative methodologies who failed to take advantage of the synchronous movements of the tarsal bones making up the subtalar joint, that take many months to correct deformity [1-8]. Ponseti advised simultaneous correction of Cavus, Adductus, and Varus followed by correction of Equinus, by taking advantage of the synchronous movements of tarsal bones at subtalar joint to unlock the deformity. Ponseti technique corrects the deformity by gradually rotating the foot around head of talus over a period of 5 - 6 weeks during cast correction [1,9]. His technique was based on a sound understanding of the functional anatomy of the foot, and on the biological response of young connective tissue and bone to changes in direction of mechanical stimuli, can gradually reduce or almost eliminate these deformities in most clubfeet [1,4,9-11]. Ponseti technique got worldwide recognition during early 1990's, after publication of very satisfactory long-term outcome by independent observers [8,12-14]. Today it is a gold standard and widely practiced method worldwide including Pakistan as well. The ultimate objective of Ponseti treatment has been targeted to a functional, supple, pain-free, foot with good mobility and with no callus development, so that the growth of limbs is normal, and patient is able to use a normal shoe without a frequent wear and tear [15,16].

To classify, evaluate, monitor the progress and outcome of clubfoot treatment, multiple scoring systems are used, the commonest being Pirani [9,17] and Dimeglio [18] but most of them cannot accurately satisfactory outcome, predict the need for Percutaneous Achilles tenotomy (PCAT) or the number of casts required before initiating the treatment [5,7]. However, Scher, *et al.* [19] in a comparative study on Pirani [17] and Dimeglio scores [18] and Dyer, *et al.* [19] found a significant relation between the high scoring foot deformity with number of casts needed and the Achilles tenotomy required.

In our community where we observed many non-compliant parents to continue maintenance phase treatment with FAB, the local literature has not yet been published enough to know the frequency of outcome with reference to basic demographics and initial Pirani score. The current study design thus provides a reasonable scientific data on frequency outcomes in relation to basic demographics and initial a Pirani score.

Patients and Methods

This prospective observational study was carried out at the Paediatric Orthopaedic section of Department of Orthopedic Surgery, Jinnah Postgraduate Medical Centre, Karachi, Pakistan, from January 2015 to December 2019. The patients included were having Idiopathic, congenital clubfeet, aged one week to two years of age of either sex, laterality and Pirani score of 3 - 6. Patients were managed during January 2015 - December 2017 and followed for the next 2 years. Patients with Club foot deformity associated with paralytic, teratogenic disorders, genetic or systemic syndrome and follow-up duration less than 2 years were excluded. The patients with foot deformity without having features of C.A.V.E (Cavus, Adductus, Varus and Equinus), specially not having Equinus component were excluded. The postsurgical residual clubfoot having had PMR (Posterior Medial Release) or open TAL (Tendo Achilles Lengthening) were also excluded. All the parents/guardians were counseled for duration of treatment, methodology, consequences, and written informed consent were taken for the treatment, research and photographs taken for publications. Study was dually approved by Institutional Review Board prior commencement.

The Patients were undergoing weekly Ponseti technique manipulation and casting for 6 - 7 cast and the last cast was applied for 3 weeks. Where needed, a Percutaneous Achilles Tenotomy (PCAT) was performed at the same setting of clubfoot clinic under local anaesthesia, after achieving a plantigrade foot followed by a last cast for three weeks [1,9,10]. All the patients were given (fixed with) Foot Abduction Brace (FAB) on the same day of plaster removal by achieving a Pirani Score of 0 - 0.5 points. The affected feet were maintained

on splint at external rotation of 700 and dorsiflexion of 300 by an inbuilt curvature in abduction bar directed away from the patient. FAB was used 23 hours a day for three months then at night and nab for the next 3 - 4 years [1,9,10]. Patients were advised regular follow-up weekly for a month, fortnightly for the next three months and every three months for 3 - 4 years. On each visit patients were evaluated for Pirani scoring, problems in FAB use, pressure sores and patient’s comfort. All above steps were strictly followed with a Ponseti protocol [1,9-11].

The patient’s data was entered in a predesigned demographic and follow-up forms of International Clubfoot Registry (ICR) of Ponseti International Association, record was maintained at the department and entered in ICR database as well. The basic demographic form was entered once at registration and signing written informed consent. Followup form filled on first and all subsequent visits, the form included: Pirani score points, degree of improvement in Cavus, Varus, Abductus and Equinus. Also, to note complication and compliance with use of FAB along with pre and post treatment photographs. The outcome was monitored every three months and evaluated for this study at the last followup not less than two years. The patients developing early relapse were given further treatment to achieve and maintain reduction as per Ponseti protocol [1,9-11].

The statistical analysis of patient’s data was analyzed by using SPSS 16. Mean and the standard deviation was calculated for age, Pirani score, and the number of casts. Frequency and percentage were calculated for gender, tenotomy, and the outcome variable (satisfactory and unsatisfactory). Effect modifier was controlled through stratification of age, gender, number of castings of CTEV foot (left or right) and Pirani score (3 - 4 and 5 - 6) to see the effect of this on outcome variable. Post-stratification, Chi-square test was applied and results with p-value < 0.05 were termed significant.

Results

The table 1 refers to basic demographics of 103 patients with 172 feet indicating preponderance of male gender (75.73%), bilateral clubfeet (67%) and age group below 6 months (67%). The mean age of the patients was 30.32 ± 36.08 weeks, with lowest percentage of 9.71% amongst 3 - 6 months and 13.59% in age range above 12 months. The mean number of casts was required was 6.46 ± 1.28, number of casts required were more in infants as shown in table 2. The table 1 also refers to number and ratio of PCAT, which were performed in 68.93% of children.

	Frequency	Percentage
Gender		
Male	78	75.73%
Female	25	24.27%
Age (Mean= 30.32 ± 36.08)		
Infant	69	66.99%
Toddler	20	19.42%
Walker	14	13.59%
Foot involved		
Unilateral	34	33.00%
Bilateral	69	66.99%
Percutaneous Achilles Tenotomy performed		
Yes	71	68.93%
No	32	31.07%

Table 1: Basic demographic characteristics (n = 103).

	Age			Total	p-Value
	Infant	Toddler	Walker		
Number of castings					
< 7	40 (67.79%)	11 (18.64%)	8 (13.55%)	59	0.277
≥ 7	29 (65.90%)	9 (20.45%)	6 (13.63%)	44	

Table 2: Number of castings in relation to age (n = 103).

The table 3 refers to frequencies of greater satisfaction achieved in male gender, age below 3 months, bilateral involvements, number of casts less than 6 and Pirani score above 5 points. The Pirani score revealed significant improvement from pre-treatment mean score mean of 4.86 ± 1.18, to post treatment mean score as 0.58 ± 0.77, with score range as ranged between 0 to 0.5/1. The frequency of satisfactory outcome in idiopathic CTEV patients is presented in figure 1. The stratification analysis revealed an insignificant satisfactory outcome among different age groups, gender, number of casts and laterality. While the satisfactory outcome was significantly high in children whose initial Pirani score was 3 to 4 (p = 0.03) as compared to those where tenotomy was performed (< 0.001).

	Outcome		Total	p-Value
	Satisfactory	Unsatisfactory		
Gender				
Male	73 (93.58%)	5 (6.4%)	78	0.36
Female	22 (88.00%)	3 (12.00%)	25	
Age				
Infant	65 (94.2%)	4 (5.79%)	69	0.59
Toddler	18 (90.00%)	2 (10.00%)	20	
Walker	12 (85.71%)	2 (14.28%)	14	
Foot involvement				
Unilateral	31 (91.17%)	3 (8.82%)	34	0.51
Bilateral	64 (92.75%)	5 (7.24%)	69	
Number of castings				
< 7	52 (88.13%)	7 (11.86%)	59	0.07
≥ 7	43 (97.72%)	1 (2.27%)	44	
Initial Pirani Score				
3 - 4	34 (100%)	0	34	0.03
5 - 6	61 (88.40%)	8 (11.59%)	69	
Percutaneous Achilles Tenotomy performed				
Yes	71 (100%)	0	71	<0.001
No	24 (75.00%)	8 (25.00%)	32	

Table 3: Frequency of satisfactory outcome in relation to other variables (n = 103).

Discussion

The clubfoot has been grouped in categories of typical and atypical based on presence of associated pathological problems, and the progress of treatment also varies with severity of pathology. The severity of deformity is subjectively graded from mild to moderate. However, to objectively determine its severity, monitor the progress and evaluate outcome multiple scoring systems are available, most

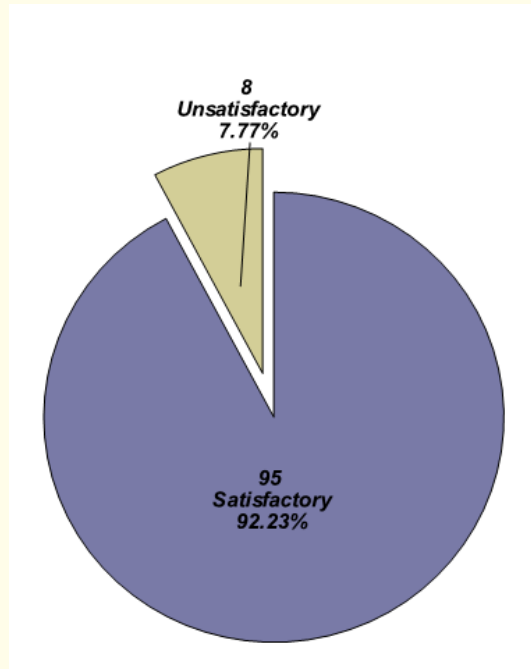


Figure 1: Frequency of satisfactory outcome in idiopathic congenital talipes equinovarus patients (n = 103).

frequently used being the Pirani’s [9,17] and Dimeglio’s scoring [18]. None of these scoring systems can accurately predict best required treatment, number of casts, need of Achilles Tendon Tenotomy and ultimate outcome. Pirani scoring has been widely practiced, easy to implement, reproduce, have a significant interobserver and intraobserver reliability and to some extent do predict the outcome and need for PCAT [19-22]. This system involve minimal mathematics and evaluates each component of this complex multicomponent deformity of C.A.V.E. based on severity of hindfoot contracture (HFC) and midfoot contracture (MFC). Each HFC and MFC contracture is given 3 points from 0 as normal and 1 as worse, highest worse being 6 and lowest normal as 0 [9,17,22]. Scher, *et al.* [20] compared Pirani’s and Dimeglio’s scores to find a relationship between referred score with a need for tenotomy. They report significant relation between the high scoring foot (Pirani score > 5) and the need for tenotomy. Dyer and Davis [19] reports 72% chances for need of tenotomy with clubfoot having Pirani’s hindfoot score 2.5 and 3 points. Dyer [19] and Saetersdal [21] further reports that with a Pirani score 4 or higher clubfoot requires at least four casts and require 3 or fewer cast when score is below 3 points.

The low severity score of deformity and earlier age soon after birth at initial cast has been widely considered as the major factors to achieve a high success rate of Ponseti treatment [12,16,23-26]. We too find, the frequency of 92.23% to 100% satisfactory outcome in age group less than 3 months and 3 - 6 months respectively (Table 2). This frequency is nearly comparable to 92% - 98% as reported by multiple investigators as Ponseti [10], Morcuende [15], Abbas [22], Saifullah [26], Lehman [27], Colburn [28]. But it is higher than Saetrasdal (78%) [21]. The pre-treatment Pirani score in current study was from 4 - 6 (mean=4.86 ± 1.18) while the post-treatment Pirani score ranged between 0 - 0.5/1 (mean=0.58 ± 0.77). This is nearly similar to what was reported earlier [10,13,15,18,20,26,29].

The Achilles tenotomies in current study were performed in 68.93% that was lower than earlier reports by Gupta, *et al.* (95%) [16], Saif Ullah, *et al.* (86.2%) [26] and Dobbs (91%) [30]. All these reports related higher percentage of Achilles tenotomy to initial sever de-

formity [13,23]. The lower frequency of PCAT in current study may attributed to higher number of cases (57.28%) being in age group < 3 months and 9.71% in age 3 - 6 months. The ponseti [11] and others [12] have cautioned for development Talar dome flatness at long term Follow-up with an over enthusiast application of pressure and increased number of casts to achieve remaining few degree of dorsiflexion. Hence, we are not sure that satisfactory success rate of 93.22% to 100% achieved in these two group shall sustain on long term follow-up, as 31% cases did not have Achilles tenotomy and had more than 7 number of casts.

The Ponseti with scientific evidences reports that the gene contributing to this deformity are active from the 12th - 20th week of fetal life up to 3 - 5 years of age [1,9,10]. Thus, after achieving satisfactory correction (Pirani score 0 - 0.5), the Ponseti treatment continued minimum 4 years to maintain that correction with regular use of FAB as per protocol advised [1,9]. The use of FAB should begin soon after removal of last cast on the same day to get a good compliance of patient. The ineffective adherence to Ponseti protocol for use of FAB for > 3 years, has been found to be the major factor in relapse. The relapse initially is indicated with development of Equinus, if not taken care of in due time, with 1 - 2 more casts, the further progress may lead to addition of heel varus and subsequent another components [1,31]. Thus, ratio of relapse has been lowest 6% in compliant families compared to a higher rate of relapse (80%) in non-compliant families [1,15,32]. Infact, it is the beauty of Ponseti treatment that despite being having relapsed, the feet remain less rigid, can effectively be treated by resuming to few more serial castings again, with or without PCAT. When patient grew over 30 months the relapses with dynamic supination may also require a transfer of tibialis anterior tendon to 3rd cuneiform that works as an internal splint and prevent further relapse [1,9,11].

Conclusion

This study concludes that Ponseti methodology is a very effective modality to achieve the best outcomes. Despite being of long duration of its maintenance phase, the regular visits, reciprocal patience on the part of parents and physician and adherence to advise, gives the best results to achieve pain free, supple feet to wear normal shoes. Treatment has been statistically found significantly effective to achieve satisfactory results with Pirani score 3 - 4 and earlier the treatment started soon after birth.

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