Correlation of Pirani Scoring with the Outcome of Treatment in Idiopathic Congenital Talipes Equinovarus Treated with Ponseti Method: A Prospective Cohort Study

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Physical Medicine and Rehabilitation Section

# ABSTRACT

**Introduction:** Congenital Talipes Equino Varus (CTEV) is the most common congenital musculoskeletal malformation and Ponseti method of correction is most commonly used technique. Pirani score is the simplest, reliable and quick to use tool designed to assess the severity of deformity.

**Aim:** To evaluate the results of Ponseti method in children with idiopathic CTEV using modified Pirani score.

**Materials and Methods:** A prospective cohort study was conducted over a period of 18 months from September 2015 to February 2017 in the Departments of Physical Medicine and Rehabilitation (PMR) and Orthopaedics of Safdarjung hospital, New Delhi. Thirty cases representing 47 feet were recruited for the study. They were divided (15 in each) into 0-6 months (younger) and 6-12 months (older) group and were evaluated pre and post Ponseti correction using modified Pirani score in terms of number of casts required, necessity of Percutaneous Tendo-Achilles Tenotomy (PTAT) and the outcome after 12 months of follow-up. Spearman rank correlation coefficient was used for correlation.

**Results:** There was preponderance of bilateral CTEV, 17 (56.6%) and 38 severe cases (80.85%) had mean Pirani score higher (5.52) in older group than in younger group (5.38). Number of casts required to correct the deformity with Pirani score 0 at the end of the treatment was related to severity (p=0.001) and not age (p=0.591). Present study showed 43 feet (91.48%) required PTAT to correct the equinus deformity (p=0.041). Satisfactory outcome was noted in 41 feet (87.23%) of cases at 12 months of follow-up out of which more were in younger age group.

**Conclusion:** Requirement of number of casts and tenotomy was related with severity of CTEV.

Keywords: Malformation, Percutaneous tenotomy, Tendoachilles

# INTRODUCTION

The CTEV is the most common congenital musculoskeletal malformation. Its incidence in world varies from 0.39 per 1000 to 6.8 per 1000 depending on the race [1,2]. It is about three times more common among males [3]. The incidence in India being 0.9 per 1000 live births and the prevalence being 1.29 per 1000 with the sex ratio of 2-2.5 males per female [4]. Among various methods of managing CTEV, Kite's method and Ponseti method have been popular among orthopaedic surgeons [5,6]. Ponseti method of manipulation and serial casting has been shown to be very successful with studies reporting good results at short-term follow-up in infants, [7-9] but very few studies have compared early age groups i.e., 0-6 months vs 6-12 months in relation to severity and outcome [10-12]. Therefore, the present study was planned to evaluate the results of Ponseti method in children with idiopathic CTEV upto 1 year of age using modified Pirani score in terms of correlation between initial modified Pirani score and number of casts required for correction of CTEV, to predict the requirement of tenotomy after casting and also to determine whether the age at commencement of Ponseti treatment has an effect on clinical outcome.

# **MATERIALS AND METHODS**

The present study was a prospective cohort study done over a period of 18 months from September 2015 to February 2017 in the Departments of Physical Medicine and Rehabilitation and Orthopaedics, Safdarjung Hospital, New Delhi, India after obtaining ethical clearance (IEC/SJH/VMMC/Thesis/Oct-2015 dated 29/06/2017). Informed consent was obtained from parents/guardians of all children included in the study.

Inclusion and exclusion criteria: Thirty children with idiopathic CTEV under the age of one year were recruited, while children with CTEV as

part of a syndrome associated with any other lower limb deformities or previously treated for CTEV were excluded from the study.

**Sample size calculation:** Taking correlation coefficient, r=0.72 from similar earlier study [13] as reference, the minimum required sample size with 90% power of study and 5% level of significance was 16 patients. To reduce the margin of error, the sample size taken was 30.

The children were grouped into younger (0-6 months) and older (6-12 months) and feet were divided into mild (<2), moderate (2-4) and severe (>4) using modified Pirani score [14]. The evaluation and follow-up of patient has been depicted in the flowchart.

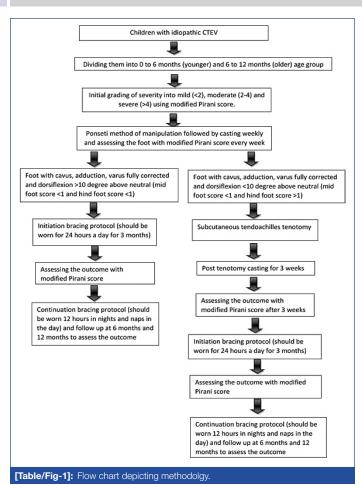
Outcome was assessed at the end of 12 months (as explained in the flowchart [Table/Fig-1]) as follows.

**Criteria for satisfactory outcome:** Pirani score of zero, normal position of the heel, normal/good range of motion of the foot joints, subjective assessment of parent's satisfaction.

Criteria for unsatisfactory outcome: All feet requiring further surgery for correction were considered as unsatisfactory outcome.

# STATISTICAL ANALYSIS

The data was entered in MS Excel spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Categorical variables were presented in number and percentage while continuous variables were presented as mean±SD and median. Normality of data was tested by Kolmogorov-Smirnov test. Quantitative variables were compared using unpaired t-test between the two groups while qualitative variables using Chi-square test. Spearman rank correlation coefficient was used to assess the association of Pirani score with age and number of cast. A p-value of <0.05 was considered statistically significant.



# RESULTS

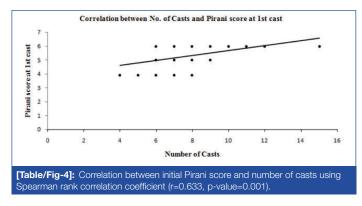
Out of thirty cases with 47 feet, 17 children (56.66%) had bilateral while 13 (43.33%) had unilateral club feet. No association was found between clubfeet laterality (unilateral vs bilateral) and severity of deformity (p=0.715). Males (23) predominated the female children (7) with 38 feet having severe clubfoot while rest nine were in moderate category. There were no cases with mild (<2) presentation. The number of feet in younger (0-6 months) and older group (6-12 months) were 24 and 23 respectively with 15 children in each group [Table/Fig-2].

Age group (Number of children)	Number of feet	Severity		Laterality	
		Moderate	Severe	Unilateral	Bilateral
0-6 months (15)	24	5	19	6	18
6-12 months (15)	23	4	19	7	16
Total (30)	47	9	38	13	34
[Table/Fig-2]: Characteristics of feet involved in two different age groups.					

The average modified Pirani score of younger group was  $5.27\pm0.88$  and of older group was  $5.47\pm0.83$ . The average number of casts required in younger group was  $7.73\pm2.71$  and in older group was  $9.60\pm2.32$ . The differences between average modified Pirani score (p-value=0.492) and number of casts required (p-value=0.591) in two groups were not statistically significant. The number of casts to correct the deformity in moderate group was  $6.22\pm1.64$  and for severe group was  $9.29\pm2.49$ , the difference was statistically significant with p-value=0.001 [Table/Fig-3].

Number of casts	Moderate (n=9)	Severe (n=38)	p-value		
Mean±SD	6.22±1.64	9.29±2.49			
Min-Max	4-8	6-15	0.001*		
Inter quartile range	4.7-8	8-11			
[Table/Fig-3]: Severity of CTEV and number of casts required. *unpaired t-test					

A moderately strong correlation was observed between initial severity and number of casts required with correlation coefficient r=0.633, p<0.001 [Table/Fig-4], but the correlation with age at presentation was weak with r=0.210. It was noticed that the average number of casts required in moderate grade of younger group was  $5.20\pm1.82$  whereas for older group, it was  $7\pm2.32$  with a p-value of 0.43. In the severe grade, the average number of casts required to correct the deformity was  $8.42\pm2.74$  in the younger group and  $10.15\pm2.68$  in the older group with a p-value of 0.45. Even though more number of casts were required in older group but it was not statistically significant.



Forty three feet required PTAT for equinus correction. Requirement of tenotomy was more (100%) in older group when compared to younger group (83.33%) but it was not statistically significant (p-value 0.47). However, there was statistically significant association between severity of CTEV and the need for PTAT (p-value 0.041) showing that all severe CTEV feet (38) underwent PTAT as compared to moderate feet (5 out of 9) [Table/Fig-5].

Tenotomy requirement	Age group		Severity		
	0-6 months	6-12 months	Moderate	Severe	
Yes	20 (83.33%)	23 (100%)	5 (55.56%)	38 (100%)	
No	4 (16.67%)	0	4 (44.44%)	0	
p-value	0.47		0.041		
[Table/Fig-5]: Tenotomy requirement as per age group and severity of Pirani score. *Chi-square test					

No association was found between the need for PTAT and the laterality (p-value=0.27) of the deformity. The results showed that 41 (87.23%) feet enrolled had satisfactory outcome at 12 months of follow-up. Even though moderate feet had better outcome (100%) compared to severe feet (84%), it was not statistically significant (p-value=0.579). When outcome was studied in relation to age group it was found that all moderate grade feet in both younger (0-6 months) and older group (6-12 months) had satisfactory outcome but in severe grade, younger group had 89.50% satisfactory result as compared to 78.90% of older group. This difference was not statistically significant (p-value=0.376).

Overall, 91.66% of younger group and 82.60% of older group had satisfactory outcome but it was statistically insignificant (p-value=0.66) [Table/Fig-6]. There was no association found between the clubfoot laterality and the outcome i.e., whether the involvement was unilateral or bilateral, the outcome was same. A total of 30 out of 34 bilateral feet (88.23%) and 11 out of 13 unilateral feet (84.61%) had satisfactory outcome but it was not significant statistically (p-value=0.713).

Age group	Final satisfactory outcome	p-value		
0-6 months	91.66% (22 out of 24)	0.00		
6-12 months	82.60% (19 out of 23)	0.66		
[Table/Fig-6]: Comparing outcome between younger and older groups.				

### DISCUSSION

Non surgical management of clubfoot is the preferred method of initial management of the deformity [15]. Ponseti's method of serial manipulation and casting has been shown to be an effective method for the treatment of CTEV [15-17]. The method and its results have

been extensively studied in children in their first few months of life [8,9,15-18].

Out of 30 cases recruited, 77% were male with male to female ratio of almost 3:1 and the male preponderance found in literature search was from 2-3:1 [14,17-19]. More than half (56.66%) of the cases had bilateral presentation. Among 47 feet, 80.85% were of severe grade and 19.14% were of moderate grade (no mild cases). The presentation of the feet under the study depicted the dominant presentation of severe grade CTEV in the community. The gender ratio, laterality and severity distribution were similar and comparable to the previous studies [8,13,17-19].

In the present study, estimated number of casts required to correct the deformity of the feet was different depending on the severity. Significant association (p-value=0.001) was observed between initial severity and the number of casts required. Average number of casts required to correct moderate grade feet with mean Pirani score of 4 was 6.22 (range=4-8) and for severe grade feet with mean Pirani score of 5.49 was 9.29 (range=6-15). In the literature search the average number of casts required for correction of deformity was also changing with the mean initial Pirani score with range of average number of casts required was 2-16 and mean Pirani score range was 2-6 in different studies [10,13,20-25]. They also observed a high degree of positive correlation between the initial Pirani score and the number of casts required similar to present study [13].

Though we found that older children (6-12 months) required more casts as compared to younger children (0-6 months) but the difference was statistically insignificant. Such correlation between age group and requirement of number of casts was not observed in any of the previous studies.

Correction of equinus deformity generally requires tenotomy. There were various studies indicating the need of tenotomy in the range of 61-94% for equinus correction [8,13,22,26]. Statistically significant association was found between the need for PTAT and severity of foot deformity (p- 0.041) in present study with 91.48% of the feet required tenotomy. All the feet with severe grade of deformity in both the younger and older age groups required tenotomy whereas only 55.56% of the moderate feet required tenotomy. When comparing the two groups, the requirement of tenotomy was increased as the child grows older. Twenty children (83.33%) of younger group and twenty three children (100%) of older group required tenotomy. In the moderate grade only 20% of younger group required tenotomy whereas all the feet in the older group required tenotomy. Such comparison about the need of requirement of PTAT in relation to the age of the child was not considered in any of the previous studies. Therefore, the result of this study indicated that the requirement of tenotomy would depend on the severity i.e., initial Pirani score of the feet and age of the child at the first presentation. In the literature review, the percentage of feet required tenotomy was from 72-90 % against the 100% of the present study in severe deformity [10,13,22,24].

Satisfactory outcome was obtained in 41 feet (87.23%) after 12 months of follow-up which was similar to the previous studies in which CTEV was treated with Ponseti method. The outcome percentage range in the literature lied between 62-94% [8,11,13]. Treated children achieved satisfactory outcome in 91.66% of younger group and 82.60% of older group in this study. Even though the outcome percentages were closer, the number of casts required was more in older group compared to the younger group to achieve the same outcome. While Alves C et al., who compared 0-6 months group and older than 6 months group in terms of outcome and found the outcome was similar in both the groups in terms of number of casts, requirement of tenotomy and need for posteromedial release [12]; the present study found the difference between two groups in terms of number of casts required to correct the deformity. In present study, 9 feet (100%) achieved satisfactory result in moderate grade feet of both younger and older group. In the severe grade feet, the satisfactory result was observed in 17 feet (89.47%) of the younger group and 15 feet (78.94%) of the older group. This type of comparison between age of presentation and satisfactory outcome was not considered in any of the previous studies.

Unilateral or bilateral deformity did not affect the outcome of the treatment. Eleven unilateral feet (84.61%) and thirty bilateral feet (88.23%) achieved satisfactory result similar with the results of Sonke whose results were 83% and 88%, respectively [11].

It was noticed that the clinical outcome in CTEV was dependent only on the severity of the feet and the age at which the manipulation started. Laterality of foot did not have significant effect on outcome of the treatment (p-value=0.742) as evident from previous studies also [13,23].

### Limitation(s)

Due to short duration of the study, the long-term outcome of Ponseti method in treating CTEV and the occurrence of relapse cannot be studied. Also, objective measure was not used to quantify parents/ guardians response.

# CONCLUSION(S)

Idiopathic CTEV can successfully be treated by Ponseti technique. Excellent results can be achieved when manipulations are started at an early age. Moderate CTEV has a better clinical outcome than severe CTEV. Severe CTEV is the most common form and most common presentation was bilateral involvement. The majority of clubfoot undergoing Ponseti treatment of clubfoot requires PTAT for the correction of equinus deformity. Treatment of idiopathic CTEV should be started as soon as possible after birth. Parents should be counselled properly regarding the importance of serial casting, abduction foot brace, effective usage and crucial role of it in preventing relapse of the deformity as most of the relapses are due to non compliance of brace usage.

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