

## Evaluation of Ponseti technique for the management of congenital talipes equinovarus

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### Abstract

**Background:** Congenital talipes equinovarus (CTEV), also known as Clubfoot, is a complicated congenital malformation of the foot that, if left untreated, can limit a person's mobility by making walking difficult and painful. Low- and middle-income nations account for 80% of children born with clubfoot. **Objectives:** Present study was planned with objective to evaluate the functional outcomes of congenital talipes equinovarus management by the Ponseti technique. **Materials and Methods:** All clubfoot patients above the age of 12 months who had normal hips and spines and gave their consent to participate were included in the study. The study excluded patients over the age of 12 months who had previously undergone other surgeries and had linked neurological problems, spine, or hip concerns. The conventional approach described by Ponseti was followed, with the exception that percutaneous tenotomy of the tendo Achilles was performed when necessary. The Pirani score was employed in the evaluation. **Results:** 17 individuals with 28 feet of congenital idiopathic clubfoot were treated using the Ponseti technique. In our study, the mean initial Pirani score at the time of case presentation was 6.29 and was 0.66 at the final follow-up. The difference between starting treatment within two weeks versus starting treatment after two weeks was shown to be statistically insignificant. Relapse of the deformity occurred in 4 foot (14.29%). **Conclusion:** The Ponseti technique is a very safe, efficient, and cost-effective way to treat clubfoot in a developing country like India, where resources are scarce and the referral system is inadequate.

**Key-words:** Congenital Talipes Equinovarus; Clubfoot; Ponseti Technique; Pirani Score

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### Introduction

Congenital talipes equinovarus (CTEV), also known as 'club-foot,' is a common but understudied lower-limb developmental condition[1]. Fixation of the foot in adduction, supination, and varus, i.e. inwards, axially rotated outwards, and pointing downwards, is specified. The calcaneus, navicular, and cuboid bones are medially rotated in reference to the talus, and ligaments and tendons hold them in adduction and inversion. Despite the fact that the foot is supinated, the front of the foot is pronated in comparison to the back, resulting in cavus. The first metatarsal is also more plantar flexed[2]. Congenital talipes equinovarus is classified as 'syndromic' when it occurs in conjunction with other symptoms as part of a hereditary condition, or as 'idiopathic' when it occurs on its own. Many neurological and neuromuscular conditions, such as spina bifida or spinal muscular atrophy, cause syndromic talipes equinovarus[3].

The Pirani method, which has been found to have strong interobserver reliability and reproducibility[4], is the most commonly used classification system based on clinical examination[5]. CTEV affects children for the rest of their lives, causing discomfort in the feet and the inability to wear normal shoes, as well as the social shame that comes with living with the deformity. The goal of clubfoot treatment is to develop a functional, pain-free, plantigrade foot with high mobility that does not necessitate the use of customised shoes[6]. Over a period of time, CTEV treatment has progressed from solely non-operative management to primarily surgical correction of the deformity, and then back to solely non-operative management. Over the many years that clubfoot therapy has been documented, different methods of splinting, binding, and casting have been investigated[7].

In the early twentieth century, surgical correction of the deformity by several techniques, the most common of which was the posteromedial release, essentially replaced these efforts[8-10]. Prior to 1948, substantial posteromedial soft tissue releases were customary, although they frequently caused stiffness and recurrence. With his approach of serial manipulation and casting, Joseph Hiram Kite established the foundations of non-operative clubfoot care. Kite reported a 90 percent success rate in patients who began therapy before the age of one year, with a cast duration of 26-49 weeks[11]. Other surgeons, on the other hand, were unable to achieve similar results with Kite's approach, with just a 20-50 percent success rate[12].

Ignacio V Ponseti of the University of Iowa in the United States of America first presented his clubfoot treatment method in 1948. Between 1948 and 1956, he published the first results from patients he managed for, revealing that 71% of them had satisfactory outcomes[13]. Acceptance of the approach was gradual in the mainstream orthopaedic community until long-term follow-up for his patients over a period of 10 to 27 years revealed that 90% of them were happy with their treatment outcomes[14]. Cooper and Dietz found that following a 30-year follow-up, 78 percent of the participants had excellent or good outcomes[15]. Ponseti's procedure was widely adopted as a result of its positive long-term results, and several other surgeons were able to demonstrate high success rates employing the Ponseti technique[15,16]. Series of interventions and casting utilising the Ponseti approach has been proven as the most acceptable treatment for CTEV worldwide in the last decade, out of the several surgical and non-operative treatment modalities available[17,18].

The classic Ponseti clubfoot regimen entails weekly manipulation and casting in a certain order in repairing the deformity. The feet are immediately placed in an abduction brace, which the youngster wears during the day for the first three months after the final cast is removed. The duration of the bracing is gradually reduced until the

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child is about 4 years old, at which point the youngster is only braced at night. To avoid relapse or recurrence, strict adherence to the bracing strategy is required[19]. Because the casting operation is relatively inexpensive, it is especially pertinent to low-income regions, where the majority of CTEV sufferers reside. Some parents are obliged to migrate to these towns or cities for the duration of the manipulation and casting procedure because many patients with the disease reside far away from centres with the expertise for treatment. Other parents and caregivers have expressed a wish for a shorter casting duration in order to alleviate the challenges in handling the casts. Due to these challenges, researchers are considering a variety of expedited casting techniques in order to achieve a faster repair of the deformity. It was first discovered that changing castings every five days instead of seven days produced the same results, potentially saving ten to twelve days during the first casting phase[20]. Other studies have found evidence that more frequent castings can produce similar results to weekly castings utilising the Ponseti approach[21,22].

With this background, present study was planned with objective to evaluate the functional outcomes of congenital talipes equinovarus management by the Ponseti technique.

### Materials and methods

Between 2006 and 2009, a prospective clinical study was conducted at the orthopaedic department of SCL hospital Ahmedabad, India. Prior to the start of the study, the ethical approval was obtained from Institutional Ethics Committee. Before enrolling the participant into the study, written informed consent was obtained from each participant's parents by filling out a consent form.

The study included all clubfoot patients above the age of 12 months who had normal hips and spines and gave their consent to participate. Patients over the age of 12 months who had previously been treated with other procedures and had related neurological abnormalities, spine and hip issues were excluded from the study. Children under the age of two are classified as having untreated clubfoot, according to the Ponseti classification[23,24]. A careful study of the literature indicated that there have been numerous published studies on children up to the age of two, but few studies on children up to the age of one year[25-27]. As a result, we chose to focus our research on children aged 12 months.

The parents were asked to provide a detailed history of the patient's illness, including any additional associated anomalies, any family history of the same ailment or a history of consanguineous marriage among the parents, and maternal obstetric history. All of the patients were assessed in terms of laterality, sex distribution, and deformity severity. To rule out any other congenital defects, a general examination was performed. The Ponseti technique was used to treat all of the study's participants. Parents were given information on the condition, management techniques, and, most crucially, the Ponseti technique's course.

We followed Ponseti's technique[28], which was initiated as soon as feasible after birth. Ponseti's approach was used to address cavus, forefoot adduction, and heel varus (excluding equinus) at the same time, with initial manipulation and immobilisation in an above knee plaster cast at weekly intervals for four to twelve weeks. Tenotomy of the tendo Achillis was performed under general anaesthetic in the operating room if necessary, rather than under local anaesthesia as an outpatient surgery, as reported by Ponseti. After that, a foot abduction orthosis (Denis Browne splint) with 70 degrees of external rotation on the affected side and 40 degrees on the normal side was used. The brace was worn full-time for three months before being used at night and during naps for up to four years. Both at the start and at the

completion of the treatment, the severity of the deformity and the functional outcome were rated using the Pirani scoring system. Each patient was followed-up until the age of 3 years.

Using Microsoft Office Excel, the acquired data was statistically analysed. Data was presented in the form of absolute numbers with or without percentages, means with standard deviations, or medians with ranges. As the level of statistical significance, a probability value of 0.05 was accepted.

### Results

In this study, 17 individuals with 28 feet of congenital idiopathic clubfoot were treated using the Ponseti technique. The average age at the time of presentation was 1.34 months, with a range of 3 days to 12 months. The most prevalent age group at presentation was less than 4 months, which accounted for 14 patients (82.35%); 2 patients (11.76%) were between the ages of >4–8 months; and 1 patient was between the ages of 8 months and less than 12 months. A male: female ratio of 3.25:1 has been discovered, with male predominance. Eleven individuals (64.71%) had bilateral deformity. Left-sided deformity was more common than right-sided deformity, with a Left-to-Right ratio of 2:1 and a bilateral-to-unilateral ratio of 1.84:1. 5 (29.41%) patients had a positive CTEV family history. A prenatal ultrasound was used to diagnose 2 (11.76%) of the CTEV patients. In our research, 41.18% of CTEV patients were firstborn, whereas 35.29% were second-born. The relationship between CTEV and birth order was not statistically significant. (P value >0.05). (Table 1)

In our study, the mean initial Pirani score at the time of case presentation was 6.29 (range 3.5 to 7) and was 0.66 at the final follow-up (range 0 to 2.9) (Table 2). In the age group of 4 months, the mean standard deviation (SD) at the initial and final Pirani scores were  $6.10 \pm 0.67$  and  $0.40 \pm 0.21$ , respectively. In the age range of >4–8 months, the mean SD at initial and final Pirani scores were  $6.60 \pm 1.23$  and  $0.90 \pm 0.55$ , respectively. In the age range of >8–12 months, the mean SD at initial and final Pirani scores were  $6.50 \pm 0.89$  and  $1.40 \pm 1.23$  respectively.

In 41.18% (11 feet) patients started treatment in first week of the life and 64.71% patients presented within first two weeks of life. The difference between starting treatment within two weeks versus starting treatment after two weeks was shown to be statistically insignificant (P value > 0.05). In our study, 68.86% of feet required five or fewer plasters, with no patient requiring more than six, a statistically significant difference with a p-value of 0.05. In our investigation, tenotomy was necessary in 82.14% of the feet, which was statistically insignificant (p>0.05). In 89.29% of feet, treatment lasted less than two months, with an average of 1.8 months for plaster treatment. It was found to be statistically significant when comparing treatment durations of less than two months to treatment durations of more than two months. (p-value <0.05). (Table 3)

According to table 4, the most common residual deformity was forefoot adduction (FFA), followed by heel varus (HV), which indicated average or poor compliance with foot abduction orthoses (FAO). No heel Varus was found in 82.14 percent of feet, whereas fair findings were seen in 18 percent of feet (0-10°). In our study, 82.14 percent (23) of the feet had >10° of Dorsiflexion and 13.5% (05) of the feet had 0-100 degrees of Dorsiflexion, indicating good and fair performance, respectively. Good correction was discovered in 82.14 percent of feet in our investigation, which was statistically insignificant (p value 0.15). The findings for 5 feet (17.86 percent) were acceptable. In our study, relapse of the deformity occurred in 04 foot (14.29%), which was statistically insignificant (p-value > 0.05) (figure 1).

**Table 1: Distribution of cases according to different characteristics (n=17)**

Variables		Number of Patients	Percentage
Age (Months)	≤4	14	82.35
	4–8	2	11.76
	8–12	1	5.88
Gender	Male	13	76.47
	Female	4	23.53

Laterality	Right	2	11.76
	Left	4	23.53
	Bilateral	11	64.71
Consanguinity		4	23.53
Family history of clubfoot		5	29.41
Diagnosed by antenatal ultrasound		2	11.76
Birth Order	1st	7	41.18
	2nd	6	35.29
	3rd	3	17.65
	4th	1	5.88

Table 2: Pirani score: pre- and post-treatment

Age (Months)	Pirani Score				p Value
	Pre-treatment		At last follow-up		
	Mean	SD	Mean	SD	
≤4	6.10	0.67	0.40	0.21	<0.001
4–8	6.60	1.23	0.90	0.55	<0.01
8–12	6.50	0.89	1.40	1.23	<0.05

Table 3: Distribution of cases according to management characteristics

Variables		Number of Patients/Feet	Percentage	p- value
Age at Treatment Started (n=17)	0-1 weeks	7	41.18	>0.05
	>1-2 weeks	4	23.53	
	>2-3 weeks	0	0.00	
	>3-4 weeks	3	17.65	
	>4 weeks	3	17.65	
No. of cast required for correction (n=28)	3	1	3.57	<0.05
	4	5	17.86	
	5	13	46.43	
	6	9	32.14	
Feet required tenotomy (n=28)	Yes	23	82.14	>0.05
	No	5	17.86	
Duration of treatment by cast + tenotomy (n=28)	1-2 Months	25	89.29	<0.05
	>2-3 months	3	10.71	

Table 4: Final outcome (n=28)

Residual deformities/Result	Number of Patients/Feet	Percentage
Forefoot adduction	Good (0°-10°)	21
	Fair (10°-20°)	7
Heel varus	Good (0°-10°)	23
	Fair (10°-20°)	5
Ankle dorsiflexion	Good (0°-10°)	23
	Fair (10°-20°)	5
Overall clinical results	Good	23
	Fair	5

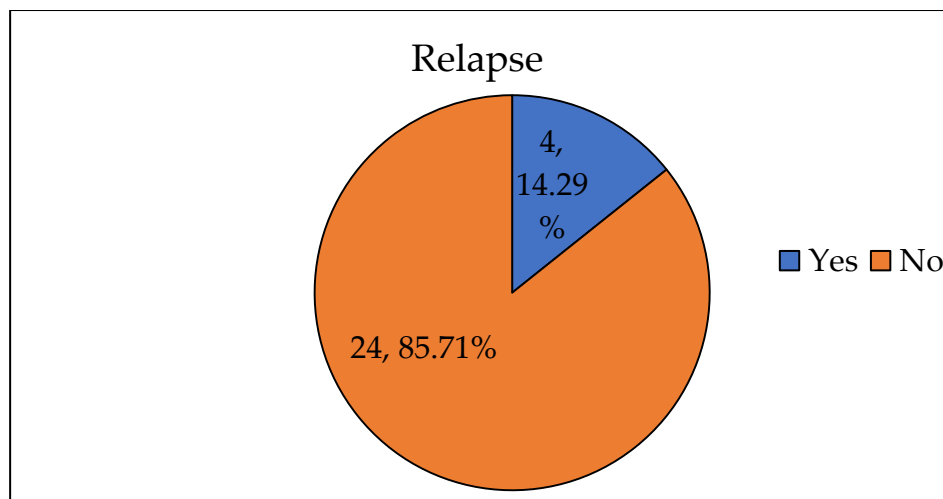


Fig 1: Relapse (n=28)

## Discussion

One of the most frequent congenital malformations is CTEV. It is a difficult to fix deformity that includes equinus, varus, adductus, and cavus. The treatment of the deformity necessitates a diligent and dedicated effort on the side of the treating surgeon and parents. The goal of treatment is to minimise or eradicate these abnormalities such that the patient has a functional, pain-free plantigrade foot with good mobility and no calluses that does not require the use of special shoes[26]. Every year, approximately 25,000 children in India are born with idiopathic clubfoot. With such a huge population living in poverty, the Ponseti approach of non-invasive clubfoot therapy has the potential to have a significant impact on health outcomes for children who would otherwise be handicapped by it[29]. The goal of the present study was to assess the Ponseti method by using the Pirani score as a functional tool to assess its efficacy.

In the present study, patients with only idiopathic clubfoot treated by Ponseti technique were included. Bilateral deformity was more common than unilateral deformity, among which left side was more common than right. Male patient was more affected in comparison to female. Despite the fact that many studies have identified a male majority among patients with clubfoot deformity, there is no evidence in the literature to suggest a link between the patient's sex and the severity of the deformity[30-32]. The ratio of bilateral to unilateral clubfoot varies from 1:1 to 2:1 in terms of laterality[30-32]. Patients with bilateral clubfoot required tenotomy and brace application in both feet at the same time. When one of the feet in a bilateral case was ready for tenotomy before the other, tenotomy was postponed until the second foot was ready, as per the Ponseti protocol.

A positive CTEV family history was found in 5 (29.41%) of the participants in this study. In the study, 4 (23.53%) patients had a history of consanguineous marriages of their parents, which is comparable to the study by T. Sreenivas and A.R. Nataraj, which found 54 (31%) of the 174 patients were born of a consanguineous marriage[33]. Prenatal ultrasonography was used to diagnose two (11.76 percent) of the CTEV patients, which is a relatively low rate when compared to Biruk WL's study[34]. This underlines the importance of specialised training in order to do proper prenatal screening. CTEV prenatal diagnosis has psychosocial ramifications for the mother and her family, and in certain situations, it might alter the pregnancy's path. Even if the deformity's progression cannot be altered in pregnancy, most women consider knowing about it before their child's birth to be beneficial. Although a prenatal diagnosis leaves some things unanswered (such as rigidity) and the chance of a false positive remains, it does allow the mother to begin therapy as soon as the baby is born and seek genetic counselling[35].

In our study, the mean initial Pirani score at the time of case presentation was 6.29 (range 3.5 to 7) and was 0.66 at the final follow-up (range 0 to 2.9). In the age group of 4 months; >4–8 months; >8–12 months, at the initial and final Pirani scores were  $6.10 \pm 0.67$  and  $0.40 \pm 0.21$ ;  $6.60 \pm 1.23$  and  $0.90 \pm 0.55$ ;  $6.50 \pm 0.89$  and  $1.40 \pm 1.23$  respectively. Similar type of results also has been found in study carried out by Malhotra R, et al[36]. According to these findings, the severity of the deformity grows as the age of presentation increases. The Ponseti method was effective in treating the deformity in all age groups of our study, as the p-value remained statistically significant in all age groups, although highly significant in the lower age group of 4 months ( $p < 0.0001$ ) when compared to the higher age groups >4–8 months ( $p < 0.005$ ) and >8–12 months ( $p < 0.05$ ). This suggests that the earlier therapy begins, the better the outcomes will be. According to the available literature, the effects were better if this medication was started as soon as possible after birth[15,37].

In our study patients came early and treatment was started in 1st week of life in majority of the cases, indicating awareness of parents and referring physicians. In our study average plasters required for correction of deformity was 5 plasters/patient. In study carried out by Malhotra R, et al., the mean total number of casts used to rectify the deformity up to the final follow-up was 6.9 (ranged from 5 to 10) which was comparable to other studies[36,38,39]. Percutaneous tendoachilles tenotomy was required in majority of the cases which is

comparable to other studies as well[36,38,39]. In the current study, residual deformity was observed to be linked to poor FAO compliance. The parent's cooperation in the usage of FAO is critical in preventing deformity recurrence. After Heel Varus, the most common residual deformity in our study was Forefoot Adduction. The use of an FAO is critical, and non-compliance with the orthosis is linked to the recurrence of deformity. As a result, parents should be adequately informed about the significance of wearing the brace and receiving regular follow-up. The abnormality relapsed in four feet (14.29%), which was statistically insignificant ( $p\text{-value} > 0.05$ ).

Because of its high first correction rate, Ponseti clubfoot treatment has grown in popularity over the last decade. However, the most common issue influencing the long-term success of the procedure is deformity relapse. Non-compliance with the Ponseti brace treatment is a significant factor in relapse. Although it has been observed that more comfortable braces improve compliance, they all have the same design and no significant adjustments to the protocols have been made. The relapse rate has been significantly reduced after the Ponseti method was refined and parents were made aware of the need of wearing a brace. However, some patients do not have a recurrence while not being entirely consistent with the brace treatment, while others do have a recurrence despite being completely cooperative with the brace treatment[40]. In a low-income country like India, the Ponseti approach for the treatment of club foot is cost-effective and practical, making it likely the best method for combating the scourge of clubfoot.

## Conclusion

The Ponseti approach can effectively treat CTEV, which is the most prevalent musculoskeletal congenital disease. The earlier the management started, the better the outcome. Prenatal screening, postnatal neonatal assessment, and public education will reduce the chances of the condition being missed at an early age. When the Ponseti procedure is used to treat CTEV, it produces good functional and cosmetic results when the patient follows the Ponseti protocols, which include serial casting, bracing maintenance, and parental education, which can begin as soon as the child is born. The Ponseti approach is a very safe, efficient, and cost-effective way to treat clubfoot in a developing country like India, where resources are scarce and the referral system is inadequate.

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