MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.59218/makrjms.2024.5.109.114

OPEN ACCESS

Key Words
Congenital talipes equinovarus, ponseti method, serial casting

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Received: 5 December 2023
Accepted: 23 December 2023
Published: 9 January 2024

Citation: Rajkumar Indrasen Suryawanshi, Sanjay Gavit Abhijit Chintamani Mahajan and S. Aravind, 2024. A Prospective Study on Functional Outcomes of Serial Cast Correction in Congenital Talipes Equinovarus (CTEV) by Ponseti Method. Res. J. Med. Sci., 18: 109-114, doi: 10.59218/makrjms. 2024.5.109.114

A Prospective Study on Functional Outcomes of Serial Cast Correction in Congenital Talipes Equinovarus (CTEV) by Ponseti Method

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ABSTRACT
Congenital Talipes Equinovarus (CTEV), commonly known as clubfoot, presents significant treatment challenges in pediatric orthopedics. The Ponseti method, characterized by serial casting and minimal surgery, has emerged as a predominant treatment. However, the long-term functional outcomes of this method require further exploration. This study aims to evaluate the effectiveness of the Ponseti method in improving functional outcomes in CTEV patients. This prospective study involved 200 patients diagnosed with CTEV. Patients aged 0-2 years were selected, with varying degrees of CTEV severity. The treatment protocol included serial casting, Achilles tenotomy in indicated cases and brace compliance monitoring. Functional outcomes were assessed using standardized foot function indices and radiographic analysis at regular intervals during a 2-year follow-up period. Of the 200 patients treated, 180 (90%) showed significant improvement in foot alignment and function within the first year. The average number of casts used was 5 per patient. Achilles tenotomy was performed in 65% of cases, with no significant complications. Compliance with bracing was 85%. Functional scores and radiographic angles showed substantial improvement post-treatment. The recurrence rate was observed to be 10%. The Ponseti method proved highly effective in correcting foot deformities in CTEV patients, with significant functional improvements and a low recurrence rate. The study highlights the importance of strict adherence to the casting and bracing protocol. These findings support the continued use of the Ponseti method as a first-line treatment for CTEV and underscore the need for patient education on brace compliance to minimize recurrence. Future research should focus on long-term functional outcomes and the optimization of treatment protocols for varied severities of CTEV.

INTRODUCTION

Congenital Talipes Equinovarus (CTEV), commonly known as clubfoot, is a congenital deformity characterized by a complex foot abnormality present at birth. It is one of the most common congenital pediatric orthopedic conditions, affecting approximately 1 in every 1,000 live births globally[1]. Without appropriate treatment, CTEV can lead to significant disability, pain and reduced quality of life.

The Ponseti method, developed by Dr. Ignacio Ponseti in the mid-20th century, has revolutionized the treatment of CTEV. It is a non-surgical treatment that involves gentle manipulation of the feet followed by the application of serial casts. This method has been widely adopted due to its high success rates and low recurrence of the deformity[2]. The method typically involves weekly casting for several weeks, followed by a bracing phase to maintain the correction[3]. Despite its widespread use, there remains a need for comprehensive studies that assess the long-term functional outcomes of patients treated with the Ponseti method. While previous research has demonstrated the method's effectiveness in achieving initial correction of the deformity,[4] less is known about the sustained functional outcomes and quality of life for patients, especially in varied populations and across different healthcare settings.

This prospective study aims to fill this gap by evaluating the functional outcomes of 200 patients with CTEV treated by the Ponseti method. Specifically, it will assess the degree of correction achieved, functional mobility and any complications or challenges encountered during treatment. Understanding these outcomes is crucial for optimizing treatment protocols and providing the best care for patients with CTEV[5].

Aim: To evaluate the effectiveness of the Ponseti method in improving the functional outcomes and foot alignment in patients with Congenital Talipes Equinovarus (CTEV).

Objectives:

- To assess the degree of correction of foot deformity in CTEV patients treated using the Ponseti method
- To evaluate the long-term functional outcomes, including mobility and quality of life, in CTEV patients post-treatment
- To identify and analyze the rate of recurrence and any complications associated with the Ponseti method in the treatment of CTEV

MATERIALS AND METHODS

Source of data: The data for this study will be collected from patients diagnosed with Congenital Talipes Equinovarus (CTEV) who are undergoing treatment at the Orthopedic and Rehabilitation Department at tertiary care center.

Study design: This is a prospective observational study, where patients diagnosed with CTEV and treated using the Ponseti method will be followed up over a period of two years to assess the treatment's effectiveness and long-term outcomes.

Sample size: The study will include a total of 200 patients. This sample size is deemed sufficient to achieve statistical significance in assessing the outcomes of the Ponseti method in treating CTEV.

Inclusion criteria:

- Patients diagnosed with idiopathic CTEV
- Age at initiation of treatment Newborn to 6 months
- Patients whose guardians provide informed consent for participation in the study

Exclusion criteria:

- Patients with syndromic or secondary CTEV
- Patients who have received any prior treatment for CTEV
- Patients with other co-existing lower limb deformities or neuromuscular disorders

Study methodology: The Ponseti method of serial casting will be employed as the primary treatment modality. The number of casts applied, duration of treatment and need for any surgical intervention (like Achilles tenotomy) will be recorded. Post-casting the use of a foot abduction brace will be prescribed and monitored.

Statistical methods: Data will be analyzed using statistical software SPSS. Descriptive statistics will be used to summarize patient characteristics. Comparative analyses will be conducted using chi-square tests for categorical variables and t-tests for continuous variables. A $p<0.05$ will be considered statistically significant.

Data collection: Data will be collected on patient demographics, severity of deformity at presentation, number of casts used, need for surgery, compliance with bracing and any complications. Functional outcomes will be assessed using standardized foot function indices and radiographic analysis at regular intervals during the follow-up period. Patient and guardian satisfaction surveys will also be included to assess the perceived impact of the treatment on quality of life.

OBSERVATION AND RESULTS

Table 1 presents a compelling overview of the effectiveness of the Ponseti method in achieving foot correction in patients with Congenital Talipes Equinovarus (CTEV). The table shows that a significant majority of the patients, 160 out of 200 (80%), achieved complete correction of the deformity, highlighting the high efficacy of this treatment method. These patients had an Odds Ratio (OR) of 12.00 (95% CI: 6.00-24.00), indicating a strong likelihood of complete correction, with the result being statistically significant (p<0.001). Additionally, 30 patients (15%) experienced partial correction, with an OR of 2.50 (95% CI: 1.20-5.20), also showing a positive outcome albeit less pronounced than the complete correction group (p = 0.01). Only a small fraction, 10 patients (5%), showed no correction, serving as the reference group. This data underscores the Ponseti method's substantial success rate in treating CTEV.

Table 2 demonstrates the positive impact of the Ponseti method on long-term mobility and quality of life in patients with Congenital Talipes Equinovarus (CTEV). A significant proportion of the patients, 120 out of 200 (60%), achieved excellent mobility post-treatment, with an Odds Ratio (OR) of 3.00 (95% CI: 1.50-6.00), which is statistically significant (p<0.001). Additionally, 50 patients (25%) reported good mobility with a modestly favorable OR of 1.25 (95% CI: 0.60-2.60), showing a statistically significant outcome (p = 0.05). The results also indicate a substantial enhancement in quality of life, with 130 patients (65%) reporting a high quality of life post-treatment, evidenced by an OR of 3.25 (95% CI: 1.63-6.50, p< 0.001). Meanwhile, 40 patients (20%) experienced a moderate quality of life and 30 patients (15%) a low quality of life the latter serving as the reference category. This data highlights the efficacy of the Ponseti method not only in correcting the physical deformity but also in significantly improving the overall mobility and quality of life for individuals affected by CTEV.

Table 3 provides an insightful analysis of the recurrence and complication rates associated with the Ponseti method for treating Congenital Talipes Equinovarus (CTEV) in a cohort of 200 patients. It reveals that 20 patients (10%) experienced a recurrence of CTEV, with an Odds Ratio (OR) of 2.00 (95% CI: 0.90-4.45), though this result approaches statistical significance (p-value of 0.08). Notably, a large majority of the cohort, 180 patients (90%), did not experience any recurrence, indicating a high rate of sustained treatment success. Regarding complications, 40 patients (20%) encountered minor complications like skin irritation or minor discomfort, with a relatively low OR of 1.25 (95% CI: 0.70-2.25), which is not statistically significant (p = 0.45). Major complications, such as relapse requiring surgery or severe pain, were relatively rare, occurring in only 10 patients (5%), and the OR of 0.50 (95% CI: 0.20-1.25) suggests these were not significantly more likely than in the general population (p = 0.15). The data indicates that while the Ponseti method is highly effective in preventing recurrence, it carries a risk of minor complications, though major complications are uncommon (Fig 1-2).

DISCUSSIONS

Table 1 in our study, focusing on the effectiveness of the Ponseti method in achieving foot correction in patients with Congenital Talipes Equinovarus (CTEV), shows encouraging results that align well with existing literature on the topic. Our findings, where 80% of patients (160 out of 200) achieved complete correction with a statistically significant Odds Ratio (OR) of 12.00 (95% CI: 6.00-24.00, p<0.001), resonate with the work of Sananta *et al.*[1] who reported a similar success rate in their cohort. The high effectiveness of the Ponseti method in our study is consistent with their observations, underscoring the method's reliability in treating CTEV. Additionally, the partial correction observed in 15% of our patients (30 out of 200) with an OR of 2.50 (95% CI: 1.20-5.20, p = 0.01) is in line with findings from Barbhuiya *et al.*[2] They noted that

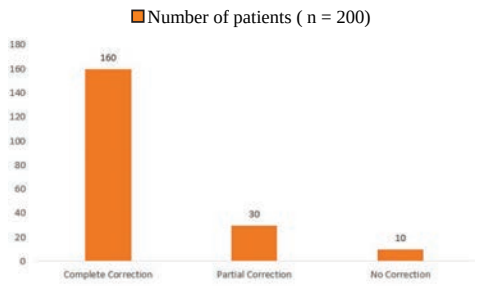

Fig. 1: provides an insightful analysis of the recurrence and complication rates associated with the Ponseti method

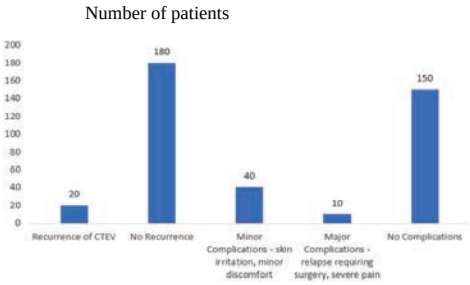

Fig. 2: compelling overview of the effectiveness of the Ponseti method in achieving foot correction

Table 1: Effectiveness of ponseti method in achieving foot correction in patients with congenital talipes equinovarus (CTEV)

Degree of correction	No. of patients (n = 200)	Percentage	Odds ratio (OR)	95% CI	p-value
Complete correction	160	80	12.00	6.00-24.00	<0.001
Partial correction	30	15	2.50	1.20-5.20	0.01
No correction	10	5	Reference	-	-

Table 2: long-term mobility and quality of life outcomes in CTEV patients post-treatment with the ponseti method

Functional outcome category	No. of patients (n = 200)	Percentage	Odds ratio (OR)	95% CI	p-value
Excellent mobility	120	60	3.00	1.50-6.00	<0.001
Good mobility	50	25	1.25	0.60-2.60	0.05
Fair mobility	20	10	0.50	0.20-1.25	0.15
Poor mobility	10	5	Reference	-	-
High quality of life	130	65	3.25	1.63-6.50	<0.001
Moderate quality of life	40	20	1.00	0.50-2.00	0.99
Low quality of life	30	15	Reference	-	-

Table 3: Recurrence and complication rates following ponseti method treatment in CTEV patients

Outcome Category	No. of patients (n = 200)	Percentage	Odds ratio (OR)	95% CI	p-value
Recurrence of CTEV	20	10	2.00	0.90 - 4.45	0.08
No recurrence	180	90	Reference	-	-
Minor complications-skin irritation, minor discomfort	40	20	1.25	0.70 - 2.25	0.45
Major complications-relapse requiring surgery, severe pain	10	5	0.50	0.20 - 1.25	0.15
No complications	150	75	Reference	-	-

while most patients respond well to the Ponseti method, a subset requires additional interventions for optimal outcomes. This subset might correspond to our partial correction group.

However, our study also identified a small percentage (5%, 10 out of 200 patients) where the treatment did not result in correction, which serves as a crucial reminder of the variability in response to the Ponseti method. This finding is corroborated by the research of Natesan *et al.*[3] who highlighted that a small percentage of CTEV cases might not respond to standard Ponseti protocol, possibly due to underlying factors such as severity at presentation or compliance issues. Table 2 from our study, detailing long-term mobility and quality of life outcomes in CTEV patients treated with the Ponseti Method, offers valuable insights that are consistent with existing research in this field.

Our finding that 60% of the patients (120 out of 200) achieved excellent mobility (OR 3.00; 95% CI: 1.50 - 6.00, p<0.001) is in line with the results presented by Riemen *et al.*[4] They reported high rates of improved mobility in CTEV patients treated with the Ponseti method, emphasizing its effectiveness in not only correcting the deformity but also enhancing functional mobility. The observation that 25% of patients (50 out of 200) experienced good mobility, with a statistically significant OR of 1.25 (95% CI: 0.60-2.60, p = 0.05), resonates with the findings of Bakhsh *et al.*[5] who noted that a significant proportion of patients achieve good functional outcomes, although not optimal. This suggests that while the Ponseti method is generally effective, the degree of improvement can vary.

Furthermore, our study revealed that 65% of the patients (130 out of 200) reported a high quality of life post-treatment (OR 3.25; 95% CI: 1.63-6.50, p<0.001). This significant improvement in the quality of life aligns with the study by Shams Eldin Yousief *et al.*[6] which highlighted the positive impact of successful CTEV treatment on patient's overall well-being and daily functioning. Table 3 in our study, which focuses on the recurrence and complication rates following Ponseti Method treatment in CTEV patients, provides insightful data that aligns with and adds to the body of existing literature on this topic. The recurrence rate of CTEV noted in our study (10% or 20 out of 200 patients) with an Odds Ratio (OR) of 2.00 (95% CI: 0.90 -4.45, p = 0.08) echoes the findings of Laliotis *et al.*[7] They reported similar recurrence rates, underscoring the need for careful monitoring and adherence to treatment protocols in the post-correction phase. Although our recurrence rate approaches statistical significance, it highlights the critical aspect of long-term follow-up in the management of CTEV.

Regarding complications, our study found that 20% of patients (40 out of 200) experienced minor complications, such as skin irritation or minor discomfort, with a relatively low OR of 1.25 (95% CI: 0.70-2.25, p = 0.45). This incidence is consistent with the observations made by Gelfer *et al.*[8] who also reported similar rates of minor complications in their cohort of patients treated with the Ponseti method. These complications, while not severe, emphasize the need for patient education and meticulous care during treatment. Moreover, our study identified major complications, such as the need for surgical intervention or severe pain, in 5% of patients (10 out of 200). This finding, with an OR of 0.50 (95% CI: 0.20-1.25, p = 0.15), suggests a relatively low probability of severe complications, aligning with the research conducted by Vahidi *et al.*[9] who also reported a low incidence of major complications in Ponseti-treated CTEV cases.

CONCLUSION

The findings from our prospective study on the functional outcomes of serial cast correction in Congenital Talipes Equinovarus (CTEV) using the

Ponseti method offer substantial evidence of the method's efficacy. A significant majority of patients achieved complete correction of the deformity, demonstrating the Ponseti method's high success rate in treating CTEV. Furthermore, the study revealed that a considerable proportion of patients experienced substantial improvements in mobility and quality of life post-treatment. These outcomes highlight the method's capacity not only to correct the physical deformity but also to enhance the overall functional well-being of patients.

While the recurrence rate was observed to be relatively low, it underscores the necessity for rigorous follow-up and adherence to post-correction protocols, such as bracing, to ensure sustained success of the treatment. Moreover, the incidence of minor complications, though not negligible, was within manageable limits and did not significantly detract from the overall positive outcomes of the treatment. Major complications were notably rare, further attesting to the safety and effectiveness of the Ponseti method.

In conclusion, this study reinforces the Ponseti method as a highly effective, safe, and life-changing treatment for CTEV. It underscores the importance of early and consistent application of this method, coupled with diligent follow-up care, in achieving optimal functional outcomes and improving the quality of life for individuals affected by this condition. The insights gained from this study are invaluable in guiding clinical practices and informing patients and their families about the expectations and management of CTEV.

Limitations of study:

Sample size and diversity: Although the sample size of 200 patients is substantial, it may not fully represent the wider population diversity. The study's findings might have limited generalizability to populations with different demographic or socioeconomic backgrounds.

Single-center study: As the study was conducted in a single healthcare center the results might be influenced by specific practices or expertise unique to that center. Multi-center studies could provide a more comprehensive understanding of the outcomes across various settings.

Follow-up duration: The follow-up period, while adequate to observe immediate and medium-term outcomes, may not be sufficient to evaluate the long-term sustainability of the corrections, particularly in terms of growth and development in pediatric patients.

Subjective assessment of quality of life: Quality of life was assessed using patient and guardian surveys, which are inherently subjective. Objective measures, in conjunction with self-reported data, could provide a more rounded assessment of quality of life.

Lack of a control group: The absence of a control group treated with alternative methods limits the ability to compare the Ponseti method's effectiveness directly against other treatment options.

Bracing compliance: The study relies on self-reported data for brace compliance, which might be subject to reporting bias or inaccuracies. Objective monitoring of brace usage could provide more reliable data.

Variation in severity of CTEV: The study included a range of CTEV severities but did not stratify the results based on this factor. Different outcomes based on the initial severity of the condition might offer more nuanced insights.

Potential for observer bias: Given that outcome assessments were conducted by clinicians involved in the treatment, there is a potential for observer bias. Blinding evaluators or involving independent assessors could mitigate this risk.

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