Original versus Accelerated Ponseti Techniques in Treatment of Congenital Talipes Equinovarus

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ABSTRACT
Background: Clubfoot, a prevalent congenital orthopedic anomaly, demands extensive treatment. Ignacio Ponseti introduced a non-invasive approach for its management.

Objective: This study aimed to compare the accelerated and traditional Ponseti therapy methods for congenital talipes equinovarus (clubfoot). Patients and Methods: Sixty infants diagnosed with idiopathic congenital talipes equinovarus were enrolled in an RCT. Patients were divided into two groups, each comprising thirty individuals. One group underwent modified accelerated Ponseti therapy with casts applied every three days, while the other followed the traditional Ponseti method with casts applied weekly. The severity of clubfoot was assessed using the Pirani grading system, and the Ponseti procedure was employed for casting. Tendo-Achilles tendonitis and tenotomy (TAT) were monitored, with a six-month follow-up period.

Results: The duration of treatment was significantly shorter in the modified accelerated group (Group II) compared to the traditional group (Group I) (P<0.001). Group II exhibited greater improvement at six months and one-year post-tenotomy compared to Group I. Complication and recurrence rates were similar between the groups. The modified accelerated Ponseti method not only reduced treatment duration but also facilitated in-hospital supervision, alleviating parental burden. Early identification of issues is possible with this approach. Conclusions: Besides expediting treatment, the modified method offers the advantage of hospital supervision, reducing parental stress associated with frequent travel for plaster changes. Complication rates and recurrence were comparable between the two methods.

Keywords: Original Ponseti Techniques, Accelerated Ponseti Techniques, Congenital Talipes Equinovarus, Pirani scoring system.

INTRODUCTION

There are few congenital orthopaedic disorders as common as clubfoot, a deformity that affects 1-2 percent of live babies and requires substantial therapy. French lexicographer Nicolas Andry defined "Pedis Equinai" as "foot of the horse" in his "Orthopaedica" (1743). Ankle, pes, equinus, and varus are the Latin roots of the English term "talips equinovarus," which means horselike, plantarflexed, adducted, or inverted [1].

Ancient Egyptian tomb paintings were the first to depict clubfoot, and by 1000 B.C., the condition had made its way to India, where it was treated. The earliest known written account of the disease dates back to Hippocrates, who lived approximately 400 B.C. He went on to say that strapping and repeated manipulation are effective therapies, adding that it's important to address the disease early on before the deformities become permanent [2].

This disease, clubfoot, "the source of which is not known, the pathological anatomy of which is equivocal, the behaviour of which is uncertain and the therapy of which remains controversial," as Gartland famously stated in 1964. It holds current relevance [3].

Clubfoot is an umbrella term for a group of related congenital foot deformities. Idiopathic, atypical, syndromal, and postural clubfoot abnormalities are all included under this umbrella category. The degree, kind, presence of co-morbidities, and laterality of a clubfoot are all affected by many factors [4].

The term "clubfoot" describes the four different foot positions: equinus, adductus, varus, and cavus. It manifests as a bilateral issue approximately 50% of the time. The right foot is somewhat more likely to get clubfoot than the left [5].

The exact cause of clubfoot, which can be either unilateral or bilateral, remains a mystery. Incorporating data from both unilateral and bilateral clubfoot patients is common in trials, although it is unclear if these examples represent a new condition or two separate unilateral cases on the same individual [6].

Postural clubfoot is not considered a "real" clubfoot deformity because it just impacts the range of motion of the foot and does not hinder normal foot movement [6]. The difference between idiopathic clubfoot and syndromal clubfoot is that the latter usually occurs in conjunction with other abnormalities rather than alone. Atypical clubfoot, a more severe type of the deformity, can occur independently or as a sign of another, more systemic disorder [7].

The degree of clubfoot might vary. To evaluate the seriousness of clubfoot, researchers employ a variety of instruments, including the Pirani and Dimeglio Scales [8].

In the early 1940s, Ignacio Ponseti developed a non-operative approach of treating clubfeet [9].

The current research set out to evaluate the effectiveness of both the accelerated and traditional Ponseti procedures—one that had been tweaked and one that had been originally developed—in the treatment of congenital talipes equinovarus (club foot).

PATIENTS AND METHODS

This randomised controlled clinical trial took place at Benha University Hospital outpatient clinic
from October 2022 to October 2023 and involved sixty neonates who were diagnosed with idiopathic congenital talipes equinovarus. This study did not include individuals who had meningomyelecele, talipes equinovarus recurrent or relapsing, cerebral palsy, spina bifida, or talipes equinovarus older than 12 months.

Sixty patients were a part of the research. Using serial casts spaced one week apart, the standard Ponseti method was given to half of the patients. Half of the subjects were given the modified accelerated Ponseti method, which entailed three-day intervals between each cast. Following a thorough history taking that included the patient's age, sex, medical history, and current symptoms, a clinical examination of the foot was performed to confirm the diagnosis of congenital club foot. The severity of the condition was then determined using the Pirani rating method.

During the evaluation process, patients underwent a battery of tests. These included a routine physical examination to rule out conditions such as spina bifida, arthrogryposis, sacral agenesis, myelodysplasia, and arthrogryposis multiplex congenita; a neurological evaluation to rule out conditions like cerebral palsy and meningomyelecele; an evaluation of the patient's limbs to rule out conditions such as arthrogryposis multiplex congenita, diastrophic dwarfism, and related hip dysplasia; and a study of their foot (on the right, left, or both sides).

Management:

The methodologies were based on the concepts of the Ponseti approach. Treatment for the deformity began with a light lifting and abduction of the first metatarsal in conjunction with counter pressure on the talus head. The simultaneous correction of the cavus deformity and the other components were made possible by this. The initial casting above the knee can be applied after the back foot is correctly aligned. After it is completed, serial casts are employed.

The "accelerated" group changed their casts every three or four days, whereas the "standard" group changed theirs weekly [10]. The necessity of a Tendo-Achilles Tenotomy (TAT) was ascertained by the outcome of the previous cast removal. Until the patient was three or four years old, a locally made foot abduction brace was used to keep the corrected foot in place and prevent relapses. It is critical to keep the corrected foot in a dorsiflexed and abducted position. The final cast was removed three weeks after the tenotomy, and the brace was immediately fastened. The brace, which resembles open-toed, high-top shoes with a straight sole, was attached to a bar. Adjusting the brace to rotate the clubfoot side 60–70 degrees outward and the normal side 30–40 degrees outward helped the patient with unilateral foot difficulties. When employed, it was turned such that it could rotate externally by 70 degrees on both sides [11].

Method of assessment: Throughout the trial, the outcomes of babies were examined using the Pirani scoring system. The study recorded the Pirani scores of each foot at the following intervals for comparison: initial presentation before casting, last cast, after the required feet' tenotomy, six months after tenotomy, and one year after tenotomy.

Follow up: The infants were closely watched for six months to assess the maintenance of the correction and the likelihood of relapse. For the same reason, we employed the Pirani scoring system.

Calculation of Sample Size:

The sample size was computed, utilising G*Power 3.1.9.2. Hussain et al. [12] contrasted the standard Ponseti technique and the accelerated Ponseti Technique in their investigation of children with congenital talipes equinovarus. This research was utilised as the foundation for the present inquiry. A statistically significant difference (p=0.042) was identified in the mean Ponseti scores of the two groups by the researchers. The mean Pirani score for the conventional group was 1.9231 ±1.6898, but the accelerated group had a significantly lower average score of 1.4808 ±1.01923. The study employed the subsequent parameters: power (1-α) = 0.80, effect size d = 0.391, error = 0.5, test family: t tests, statistical test: mean: Wilcoxon-Mann-Whitney test (two groups), and kind of power analysis: (A priori: Compute required sample size - given, power and effect size). As a result of the exclusion of 30 patients from the criterion, the ultimate output parameter was reduced to 60 patients.

Ethical considerations: The study was done after being accepted by the Research Ethics Committee, Benha University (MS 8-6-2023). Parents of the patients provided written informed consents prior to their enrolment. The consent form explicitly outlined their agreement of participation of their children in the study and for the publication of data, ensuring protection of their confidentiality and privacy. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis: The data analysis was conducted utilising version 20.0 of the IBM SPSS software (IBM Corp, New York). Qualitative data were presented as frequency and percentage and were compared by Chi-square test, Fisher's exact, and Monte Carlo correction. The Shapiro-Wilk test was employed to confirm the normality of the distribution of quantitative data, which were presented as mean ± standard deviation (SD) and were compared by the following: Student t-test, Mann Whitney test, and Friedman test. The post hoc test (Dunn's) was used to facilitate pairwise comparisons. In order to evaluate the results, a significance level of 5 percent was applied.
RESULTS
In relation to age, affectional orientation, and gender, no observable distinctions existed between the two cohorts (Table 1).

Table 1: Gender, age and side of affection in the studied patients

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>50.0</td>
<td>15</td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>50.0</td>
<td>15</td>
</tr>
<tr>
<td>Age (Days)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>10</td>
<td>33.3</td>
<td>7</td>
</tr>
<tr>
<td>Left</td>
<td>6</td>
<td>20.0</td>
<td>7</td>
</tr>
<tr>
<td>Bilateral</td>
<td>14</td>
<td>46.7</td>
<td>16</td>
</tr>
</tbody>
</table>

Regarding tenotomy and the overall count of casts, no statistically significant distinction was seen between the two cohorts. In comparison to group I, group II had a much shorter duration (Table).

Table 2: The number, duration, and tenotomy of casts in the groups under study

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenotomy</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Duration (days)</td>
<td>20</td>
<td>66.7</td>
<td>24</td>
</tr>
<tr>
<td>Number of casts</td>
<td>4.80 ± 1.24</td>
<td>5.0 ± 1.49</td>
<td>Mann-Whitney test =8.486</td>
</tr>
</tbody>
</table>

*: Significant

No statistically significant distinction was observed between the pre-cast and post-cast groups one year or six months after the tenotomy (Table 3).

Table 3: Analysis of the two groups being examined in relation to the Pirani score

<table>
<thead>
<tr>
<th>Pirani score</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>U</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-cast</td>
<td>4.37 ± 1.45</td>
<td>4.15 ± 1.61</td>
<td>419.50</td>
<td>0.636</td>
</tr>
<tr>
<td>After cast</td>
<td>0.43 ± 0.37</td>
<td>0.48 ± 0.31</td>
<td>412.0</td>
<td>0.532</td>
</tr>
<tr>
<td>Post tenotomy</td>
<td>0.03 ± 0.13</td>
<td>0.03 ± 0.13</td>
<td>450.0</td>
<td>1.000</td>
</tr>
<tr>
<td>After 6 months</td>
<td>0.08 ± 0.23</td>
<td>0.07 ± 0.17</td>
<td>448.0</td>
<td>0.960</td>
</tr>
<tr>
<td>After 1 year</td>
<td>0.15 ± 0.30</td>
<td>0.10 ± 0.24</td>
<td>418.50</td>
<td>0.504</td>
</tr>
</tbody>
</table>

Analysis of the two groups being examined in relation to the Pirani score is shown in Table 4.

Table 4: Analysis of the two groups being examined in relation to the Pirani score

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>Fr</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-cast</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p0</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p1</td>
<td>0.001*</td>
<td>0.006*</td>
<td>0.027*</td>
<td></td>
</tr>
<tr>
<td>Significance between periods</td>
<td>p2=0.627, p3=0.307, p4=0.596</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p0</td>
<td>0.001*</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>p1</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td>0.001*</td>
<td></td>
</tr>
<tr>
<td>Significance between periods</td>
<td>p2=0.775, p3=0.568, p4=0.775</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*: Significant

Relapse and complications (including skin lesions, edema, and slippage) were insignificantly different between the two groups (Table 5).
Table 5: Analysis of the two groups being examined in relation to complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>$\chi^2$</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Skin lesions</td>
<td>1</td>
<td>3.3</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Edema</td>
<td>1</td>
<td>3.3</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Slippage</td>
<td>1</td>
<td>3.3</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Relapse</td>
<td>6</td>
<td>20.0</td>
<td>3</td>
<td>10.0</td>
</tr>
</tbody>
</table>

CASES

**Case 1:** A 39-day-old male newborn with right talipes equinovarus (TEV). He was assigned to Group 1. (performed weekly). Following the application of seven casts over a period of fifty days, and subsequent to tenotomy treatment for residual equinus, his diagnostic Pirani score diminished to 0.5, ultimately culminating in a score of 0. Following the tenotomy, the patient was immobilised with a locally fabricated brace designed to maintain the correction for a minimum duration of three weeks. Follow-up Pirani scores revealed no recurrence; these scores were similar to those obtained following the tenotomy (Figure 1).

**Case 2:** 33-day-old boy infant diagnosed with right CTEV. The family expressed a need for a more streamlined timetable due to an upcoming international trip in two months. Thus, he was placed to Group 2 (cast every 3 days). His initial Pirani score was three. His Pirani score fell to 0.5 following four casts over a period of fourteen days. He subsequently underwent Achilles tendonolysis. The results were deemed satisfactory upon comparing the pre-cast score of 3 to the final Pirani score of 0. Following this, a custom-made ankle-foot brace was affixed to the patient, who was also directed to maintain a Pirani score of zero throughout the six-month follow-up period (Figure 2, 3).
DISCUSSION

In recent studies on the Ponseti method for correcting clubfoot, various research groups have reported on the effectiveness and efficiency of standard versus accelerated treatment protocols. While no significant difference was found in the number of casts required for correction between treatment groups across several studies, there was a notable variance in the duration of treatment. For instance, the accelerated Ponseti group consistently required a shorter period for treatment compared to the standard Ponseti group, with significant differences in treatment duration reported (P<0.001). This pattern suggests that while both treatment approaches are effective in correcting deformities, the accelerated approach may offer a faster route to correction without increasing the risk of complications such as pressure ulcers or the need for percutaneous tenotomy.\textsuperscript{[13, 14]}

Moreover, the studies highlighted the variability in treatment specifics, such as the mean number of casts required, the mean duration of cast application, and the tenotomy rates among different groups.\textsuperscript{[15]} Despite these variations, the statistical analysis did not reveal a significant difference in the outcome measures like the Pirani scores post-treatment. However, a significant correlation was observed between the duration of treatment and the successful correction of the foot, underscoring the potential benefits of the accelerated treatment protocol in reducing the overall treatment time. These findings point to the accelerated Ponseti method as a potentially more efficient option for patients, without compromising the treatment outcomes, echoing the need for further research to optimize clubfoot treatment protocols.\textsuperscript{[16, 17]}

The comparative study between traditional and accelerated Ponseti methods for clubfoot correction by Elgohary and Abulsaad\textsuperscript{[18]} highlighted that initial Pirani scores were similar between both groups, with no significant difference in scores post-treatment. Both approaches were effective, reducing Pirani scores to near zero, and required a similar number of casts for correction, though the accelerated group achieved correction in significantly fewer days (P = 0.001). The high rate of tenotomy requirement in both groups aligns with findings from other studies, indicating a consistent need for this procedure in the majority of cases. The results underscore the efficacy of both Ponseti methods in achieving initial correction, with the accelerated approach offering a faster route to correction without compromising outcomes.

Further comparison with other studies reveals a broad consensus on the effectiveness of the Ponseti method. Radler et al.\textsuperscript{[19]}, Porecha et al.\textsuperscript{[20]}, and others\textsuperscript{[21, 22]} reported similar tenotomy rates, emphasizing the method's widespread applicability. Hussain's et al.\textsuperscript{[12]} study noted a statistically significant faster improvement in Pirani scores in the accelerated group, particularly among certain age groups and genders, suggesting potential areas for tailored approaches.

Overall, these findings collectively affirm the Ponseti method's success in clubfoot treatment, with the accelerated version promising a quicker, yet equally effective, correction pathway. Research by Islam et al.\textsuperscript{[23]} and Doski and Jamal\textsuperscript{[24]} highlights the nuanced outcomes of clubfoot treatment using the Ponseti method, emphasizing the effectiveness of the accelerated protocol alongside traditional approaches. These studies documented significant changes in Pirani and Dimeglio scores across different stages of treatment, including initial assessment, post-treatment, and follow-up periods, showcasing the method's ability to improve foot deformities effectively. Despite occasional increases in Pirani scores due to recurrence, the overall findings suggested no significant difference in recurrence rates, quality of life, or treatment-related complications such as skin lesions or edema between the two groups. This suggests that both the accelerated and traditional Ponseti methods are equally effective in managing clubfoot, with recurrence being managed successfully through recasting or additional interventions like tendo Achillis tenotomy.

Furthermore, the benefits of reducing plaster application time were underscored, with implications for improved patient and caregiver experience, reduced risk of complications associated with prolonged immobilization, and earlier initiation of the bracing phase, which could potentially lower relapse frequencies. The accelerated Ponseti method also offers practical advantages, especially in resource-limited settings, by decreasing the need for frequent travel to treatment facilities, thereby saving costs and time for families. Kumar and Singh's\textsuperscript{[15]} findings on the occurrence of recurrences and the effective management through recasting further affirm the method's efficacy. The studies collectively support the accelerated Ponseti method not only as a cost-effective treatment strategy but also as a means to enhance compliance and treatment outcomes, indicating a promising direction for future clubfoot management protocols.

Doski and Jamal\textsuperscript{[24]} along with Singh et al.\textsuperscript{[14]} reported on the challenges and outcomes associated with the Ponseti method for treating clubfoot, highlighting the occurrence of complications such as skin sores and recurrence of deformity. The studies indicate that such complications are present across both traditional and accelerated Ponseti treatment groups, with no significant differences in the rates of these issues between the groups. Specifically, a small percentage of patients experienced skin sores, while a higher proportion saw a recurrence of their deformities, necessitating further interventions like posteromedial release surgery or tenotomy to achieve correction. Despite these challenges, the majority of patients in both the accelerated and traditional treatment groups achieved favorable outcomes, suggesting the efficacy of...
the Ponseti method in managing clubfoot, albeit with a recognized risk of recurrence and related complications.

Further insights from Ahmad et al. [19] and Radler et al. [19] Mageshwaran et al. [21] shed light on the nuances of clubfoot treatment, including the relapse rates, the importance of brace compliance, and the effectiveness of different Ponseti method adaptations. The recurrence of specific deformities such as forefoot adduction, heel varus, and equinus was noted, with both the conventional and accelerated approaches effectively addressing these relapses. However, the studies also underscored the significant impact of brace noncompliance and other factors like casting mistakes and lack of parental awareness on treatment outcomes. Despite these challenges, the accelerated Ponseti technique was noted for its safety and efficacy, offering a promising modification to the standard method. Collectively, these findings highlight the complexity of clubfoot treatment and the critical role of comprehensive care strategies, including patient and caregiver education on brace use, to enhance the success rates of the Ponseti method.

Limitations: The number of patients and the length of the follow-up period were both limited in this single-center trial.

CONCLUSIONS
In the context of correcting clubfoot, the expedited or standard Ponseti technique are both as effective. The expedited protocol diminishes the overall duration of treatment and offers evident advantages, including the elimination of the need for parents to travel considerable distances to transport their children to the hospital for frequent plaster changes, as the entire process can be monitored in one location. Due to the patient’s hospitalisation during treatment, any complications can be promptly detected.

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Conflict of Interest: Nil.

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