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Research Article

Outcomes Of the Ponseti Method in Treating Clubfoot and Predictors of Relapse: A Retrospective Study

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Abstract:
Background: Clubfoot is the most common congenital deformity affecting the foot. Limited data are available in the literature regarding the management of this condition in the Middle East, including Yemen. This study aims to identify the outcomes and predictors of relapse in patients with congenital clubfoot treated with the Ponseti method.
Patients and Methods: A retrospective study was conducted on 102 pediatric patients with congenital clubfoot treated with the Ponseti method at Modern Hospital in Sana'a, Yemen, between 2010 and 2020. Patient demographics, treatment details, and outcomes were collected and analyzed. Univariate and multivariate analyses were used to investigate factors associated with relapse.
Results: The median age was 6.5 months (IQR: 4.0, 9.0), with 83.3% of the patients being under 10 months, and 63 (61.8%) being male. Bilateral clubfoot was found in 55 (53.9%), and 69 (67.6%) of the patients resided in rural areas. Achilles tenotomy was performed in 96 (94.1%) of the cases. With a mean follow-up of 36.0 ± 6.7 months, an average of 9.5 ± 1.6 corrective casts were used. Significant improvements in treatment efficacy were observed, with the initial Pirani score of 4.0 ± 0.6 improving to 1.5 ± 0.2 ($P < .001$) and the initial Dimeglio score of 12.1 ± 1.7 improving to 4.5 ± 0.7 ($P < .001$). A total of 15 children (14.7%) experienced a relapse; ten responded to recasting and tenotomy, while three required further treatment, and two underwent additional surgery. In multivariable analysis, the factors significantly associated with relapse were the initial Pirani score (OR: 2.40; 95% CI: 1.43-4.25; $p = 0.001$) and an increased number of casts (OR: 8.37; 95% CI: 2.89-115.92; $p = 0.009$).
Conclusion: In this study, the Ponseti method has proven to be an effective intervention for congenital clubfoot in a pediatric population in Yemen, as demonstrated by significant improvements in both the Pirani and Dimeglio scores. Despite these favorable outcomes, the documented relapse rate of 14.7% underscores the necessity for ongoing monitoring and reevaluation of treatment strategies. Notably, factors such as the initial Pirani score and the number of corrective casts were identified as significant predictors of relapse, warranting further investigation in future research.

Keywords: Clubfoot, Foot Deformities, Ponseti Method, Relapse, Treatment Efficacy, Treatment Outcomes.

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Introduction:

Congenital clubfoot is a prevalent and complex deformity observed in children, typically characterized by a combination of the following anatomical deviations: equinus of the calcaneus, hindfoot varus, forefoot adductus, and cavus foot deformity [1, 2]. Despite advances in our understanding of the condition, the exact etiology of congenital clubfoot remains shrouded in uncertainty [3]. The overwhelming consensus among healthcare professionals is that non-surgical management should be the initial treatment approach for this condition [4].

The Ponseti method is widely recognized as the most effective and economical approach for correcting congenital clubfoot, even in severe cases [5-7]. Despite its widespread endorsement, the method is not without limitations; specifically, relapses are frequently observed in severe clubfoot presentations, potentially attributable to the inherent complexities of the underlying pathology that precipitates the deformity [8]. Research indicates that the recurrence rate following the application of the Ponseti technique can be as high as 40% [9]. The multifactorial nature of these recurrences continues to spark scholarly debate, with various contributing factors yet to be conclusively identified [1, 2]. This study aims to identify the outcomes and predictors of relapse in patients with congenital clubfoot treated with the Ponseti method.

Material and Methods

Study design

A retrospective study was conducted involving 102 pediatric patients diagnosed with congenital clubfoot, all of whom received treatment using the Ponseti method at the Orthopedic Department of Modern Hospital in Sana'a, Yemen, between January 2010 and October 2020.

Inclusion Criteria

Patients newly diagnosed with idiopathic clubfoot, who underwent treatment via the Ponseti method and were monitored for a minimum duration of three years, were eligible for inclusion, provided they had untreated typical clubfoot cases.

Exclusion Criteria

Patients with clubfoot associated with conditions such as arthrogryposis multiplex congenita or cerebral palsy, diagnoses of clubfoot not of congenital origin, and cases that had previously undergone surgical intervention or been treated with non-Ponseti casting techniques were excluded from the study.

Ponseti Procedure for the Treatment of Clubfoot Deformity

The treatment followed the standardized Ponseti protocol, with caregivers provided a detailed manual for reference [10]. A certified therapist began by performing manual manipulations and training caregivers on proper foot manipulation and brace application. Regular outpatient visits were arranged to track progress, manage any complications, and adjust the treatment plan as necessary. The Ponseti method, a non-surgical approach, was employed to correct clubfoot deformity (congenital talipes equinovarus). This technique involves a sequence of manipulations and casting procedures designed to gradually realign the foot.

1. Patient Assessment: The process began with a comprehensive evaluation of the infant's foot and leg to determine the severity of the clubfoot deformity. Clinical measurements and physical exams were conducted to establish a treatment baseline.
2. Initial Manipulation: The foot was gently manipulated to initiate correction. The therapist dorsiflexed, abducted, and externally rotated the foot to encourage proper alignment of soft tissues and bones.
3. Casting Protocol: After each manipulation, a plaster or fiberglass cast was applied to hold the foot in the corrected position. The cast extended from the toes to just above the knee, with the first cast applied immediately after the initial manipulation.
4. Weekly Follow-Up: Casts were replaced weekly over 4 to 6 weeks. During each visit, further manipulations were performed, and a new cast was applied to ensure progressive correction. Adjustments were made based on the clinical response and alignment achieved.
5. Tenotomy Indication: In cases where equinus (ankle stiffness) persisted despite correction of forefoot adductus, hindfoot varus, and cavus, a percutaneous Achilles tendon tenotomy was performed. This minor procedure, done under local anesthesia, was followed by immediate recasting to maintain the corrected position.
6. Bracing Protocol: Once the desired correction was achieved, the infant was fitted with a Denis Browne splint or Ponseti brace. The brace was worn 23 hours a day for the first 3 months, then only at night for an additional 1 to 3 years. Caregivers were trained on proper brace use and maintenance to prevent deformity recurrence.
7. Follow-Up and Monitoring: Regular follow-up appointments were scheduled to monitor progress, ensure compliance with the bracing protocol, and address any complications. Clinical evaluations included checks for foot alignment, mobility, and skin integrity.

Data Collection and outcome

Data were systematically documented by a experienced orthopedic specialist with extensive expertise in the Ponseti method and casting techniques, prior to treatment and throughout the duration of follow-up. The data collected encompassed the following variables: age at initiation of treatment, gender, residency, severity assessments as determined by initial and final follow-up Pirani scores and Dimeglio scores, number of casts applied, laterality of clubfoot (unilateral or bilateral), occurrence of tenotomy, family history of congenital clubfoot, presence of associated congenital anomalies, adherence to the brace protocol, treatment outcomes, relapse, and factors contributing to relapse.

Statistical Analysis

Descriptive statistics, including mean ± SD and median (IQR), were employed to analyze quantitative variables, while qualitative variables were assessed using frequency distributions. To evaluate the normal distribution of the variables, the Kolmogorov-Smirnov test was conducted. Pearson Chi-square tests and unpaired Student's t-tests were utilized to investigate the relationships between various factors and the occurrence of relapse. Additionally, binary logistic regression analysis was performed to identify and evaluate potential risk factors associated with relapse.

Ethics Approval

The present study received ethical approval from the Ethics Committee of 21 September University, in accordance with the principles established in the Helsinki Declaration. Given the retrospective nature of the research, the ethics committee waived the necessity for individual consent or parental consent for chart reviews. All data were securely encrypted and stored in a confidential manner to ensure the protection of participants' privacy.

Results:

The study comprised 102 participants, with a mean age of 7.8 months (± 5.0 SD) and a median age of 6.5 months (IQR: 4.0, 9.0). The majority of children (83.3%) were under 10 months of age, while 14 children (13.7%) were aged 11-18 months, and 3 participants (2.9%) were aged 19-24 months. Males constituted 61.8% of the population (N = 63). Most participants were born full-term, accounting for 89.2% (N = 91), while 8 participants (7.8%) were preterm, and 3 participants (2.9%) were post-term. Bilateral clubfoot was identified in 53.9% of the cases (N = 55), and a majority of the participants (67.6%) resided in rural areas. Extended family arrangements were predominant among the participants (66.7%), with only 5 participants (4.9%) reporting a family history of clubfoot. Congenital anomalies were observed in 10 participants (9.8%) (Table 1).

Achilles tenotomy (AT) was performed in 94.1% of the participants (N = 96). The initial Pirani score was 4.0 (±0.6; median 4; IQR: 3.0, 5.5), while the final score demonstrated a statistically significant improvement to 1.5 (±0.2; median 1.5; IQR: 1.0, 2.0; $P < 0.001$). Additionally, the initial Dimeglio score averaged 12.1 (±1.7; median 12; IQR: 9.0, 16.5) and improved significantly to 4.5 (±0.7; median 4.5; IQR: 3.0, 6.0; $P < 0.001$). The average follow-up duration was 36.0 months (±6.7), with participants receiving an average of 9.5 casts (±1.6). The overall relapse rate was 14.7% (N = 15) (Table 2).

Fifteen participants (14.7%) experienced a relapse, with 10 individuals responding positively to re-casting and tenotomy, 3 requiring further treatment, and 2 undergoing additional surgical interventions (including the Joint External Stabilization System (JESS) and plantar fascia release) to address complications.

Analysis of Factors Associated with Relapse:

Although the univariate analysis indicated a significant association between age and relapse risk (OR = 1.18, p = 0.001), this relationship weakened in the multivariable context (OR = 1.25, p = 0.140). Gender differences in relapse rates were observed in the univariate analysis (female OR = 5.25, p = 0.006); however, these differences did not reach statistical significance in the multivariable analysis (OR = 4.19, p = 0.474). Additionally, while the need for Achilles tenotomy demonstrated a notable decrease in relapse rates in the univariate analysis (OR = 0.15, p = 0.006), this finding did not maintain statistical significance in the multivariable analysis (OR = 0.00, p = 0.069) (Table 3). However, the multivariable analysis revealed that the initial Pirani score served as a significant predictor of relapse, with an odds ratio (OR) of 2.4 (95% CI: 1.43-4.25; p = 0.001), indicating a strong correlation between higher initial severity and an increased risk of relapse. Furthermore, the number of casts applied was also identified as a significant contributing factor, with an OR of 8.37 (95% CI: 2.89-115.92; p = 0.009) (Table 3).

Discussion:

This study aimed to evaluate the midterm clinical and functional outcomes of patients treated for clubfoot using the Ponseti technique. Our findings demonstrate that the Ponseti method is an effective intervention for congenital clubfoot in Yemen's pediatric population, as indicated by significant improvements in both the Pirani and Dimeglio assessment scores. Despite these favorable outcomes, we recorded a relapse rate of 14.7%. Significant predictors of relapse include the initial Pirani score and the number of corrective casts, warranting further investigation in future research.

The Ponseti method, which involves weekly manipulations, casting, and sometimes percutaneous Achilles tenotomy, is widely regarded as the most effective treatment for idiopathic clubfoot [11]. This technique has been widely adopted since the 1950s, achieving efficacy rates of 92% to 100% [12]. In total, 102 feet were analyzed; 87 (85.3%) demonstrated favorable clinical outcomes, while 15 (14.7%) showed suboptimal results with moderate to severe deformities. These outcomes align with other reports of treatment success rates ranging from 82.2% to 98% % [3, 12, 13]. However, a contrasting study in Uganda indicated a lower success rate of 68% in a low-income context [14]. The mean follow-up duration was 36.0 ± 6.7 months (range, 9.0 - 31.0), comparable to the 1.83 years reported by Alam et al. [15]. However, our duration was shorter than that in studies by Morcuende (4.6 years) [16], Hu et al. (≥ 5 years) [3], Matar et al. (5.8 years) [17], and Avi Shah et al. (5.8 years) [8]. This may result from our retrospective design. A shorter follow-up may not sufficiently capture the frequency and patterns of relapses in arthrogrypotic clubfeet, which develop over time.

Our participants had an average age of 6.5 months, predominantly under ten months. Older patients exhibited poorer clinical outcomes and increased relapse risk, though this association was not statistically

significant in multivariate analysis. Existing literature recommends initiating treatment within the first three weeks of life for optimal results [18, 19]. In contrast, some studies argue that the age of treatment onset has minimal impact on the Ponseti method's success [20]. Notably, Liu et al. found that starting treatment between one and three months improved outcomes, whereas treating at a very young age was linked to higher relapse rates [21]. Anatomical factors, such as smaller foot size and increased partial Achilles tenotomies, may hinder outcomes in newborns, while older patients often present with reduced tissue elasticity, complicating corrections [5].

The Dimeglio and Pirani classifications are established tools for reliably assessing the severity of clubfoot, demonstrating considerable interobserver and intra-observer consistency [22-24]. In our study, the initial median Dimeglio score of 12 indicated a severe form of clubfoot. Notably, the Pirani score showed a significant improvement, decreasing from 4.0 pre-treatment to 1.5 post-treatment ($P < 0.001$). Similarly, the Dimeglio score decreased significantly from 12.1 to 4.5 following treatment ($P < 0.001$). Furthermore, we observed that elevated initial Pirani scores were substantial predictors of relapse, aligning with findings from the existing literature [3, 25, 26]. Conversely, the Dimeglio score did not emerge as a statistically significant predictor of relapse in the multivariate analysis. It can be inferred that the standard practices in treating clubfoot offer a more impartial evaluation compared to the basic training sessions. These classification systems play a crucial role in monitoring therapeutic progress, as they evaluate clinical indicators derived from midfoot and hindfoot variables [22].

Noncompliance with the foot abduction brace (FAB) poses challenges. Key factors include the absence of standardized criteria for assessing compliance, decreased adherence in children after 1.5 years of age, and parents' limited understanding of the brace's importance. Premature cast removal at home can also lead to significant correction loss [27]. Ideally, casts should be removed no more than one hour prior to a new cast application [3, 27]. Our investigation revealed that a higher number of casts required during treatment emerged as a statistically significant predictor of relapse, underscoring the critical role of patient and parental compliance in achieving successful outcomes. This finding aligns with existing knowledge, which suggests that inadequate adherence to treatment protocols can compromise long-term results [3, 28]. In this context, noncompliance, manifested by an increased number of casts required, highlights the need for more effective strategies to enhance treatment fidelity and promote adherence among patients and parents [2]. In our clinical experience, postoperative compliance with FABs is low in arthrogryposis multiplex congenita (AMC) clubfeet, often due to inadequate fibrotic muscle development. This noncompliance can impede correction, primarily occurring within the first nine months post-correction. To maintain correction, we recommend a minimum of four years of bracing, supplemented by stretching exercises and a multidisciplinary approach to address the children's complex needs, as supported by Alam et al. [15].

Our investigation into the predictors of clubfoot relapse failed to identify significant correlations between relapse rates and factors such as gender, side of involvement, family history of clubfoot, and tenotomy. This finding concurs with the existing body of literature. Specifically, Hu et al. conducted a comprehensive analysis, which revealed high Pirani scores, inadequate adherence to follow-up appointments and brace wear (noncompliance with FABs), and an early initiation of casting treatment as significant risk factors for relapse [3]. Conversely, no associations were observed between relapse rates and gender, number of casts administered, side of involvement, or maternal age [3].

The failure rate of the Ponseti method is approximately 3% to 5%, while recurrence occurs in 20% to 49% of patients [2, 29, 30]. Most recurrences arise from insufficient corrections rather than true recurrence; however, late recurrences can happen even after complete correction. Notably, recurrence rates drop significantly by eight years post-correction, potentially indicating non-idiopathic clubfoot [2]. Our study observed a 15% recurrence rate, consistent with previous research on clubfoot cases treated with the Ponseti method.

Among our participants, 15 relapses (14.7%) were documented, with ten responding positively to re-casting and tenotomy. Three required further treatment, and two underwent additional surgical procedures, including the Joint External Stabilization System (JESS) and plantar fascia release. Notably, no major bony surgeries were performed, which we attribute to effective initial Ponseti management that facilitated soft tissue stretching around the rigid ankle-foot complex. The success of the Ponseti method relies heavily on the appropriate use of the FAB. Our findings align with prior studies reporting eight relapses, five of which responded to re-casting ± tenotomy, while three patients required surgical intervention for persistent deformities [15].

Study Strengths:

This investigation represents the first systematic evaluation of outcomes and relapse rates among Yemeni children with clubfoot treated using the Ponseti technique. Our study adhered to rigorous inclusion criteria and maintained a standardized treatment protocol, differentiating our approach from previous studies that have employed variations of the classical Ponseti technique. Furthermore, our medium-duration follow-up period was notably longer than that of many extant studies in this field, providing a more comprehensive view of treatment effectiveness and outcomes.

Study Limitations:

Despite its strengths, our study has several significant limitations that warrant attention. Firstly, the small sample size and retrospective design may undermine the robustness of our findings. The dependence on

secondary data introduces variability in data quality, potentially arising from inconsistent documentation practices. Additionally, the exclusive participation of experienced orthopedists may introduce bias, leading to more favorable outcome measures than might be observed in a more diverse clinical setting. The limited follow-up duration and the absence of a comparator group further restrict our capacity to evaluate long-term relapse patterns and functional outcomes as patients transition into adulthood. These limitations highlight the need for future research employing larger sample sizes and multicenter designs to deepen our understanding of the treatment challenges and opportunities in resource-limited contexts.

Conclusion:

This study underscores the effectiveness of the Ponseti method for managing congenital clubfoot in Yemen's pediatric population, evidenced by significant improvements in Pirani and Dimeglio scores. However, the observed relapse rate of 14.7% highlights the necessity for ongoing assessment of treatment sustainability. Notably, the initial Pirani score and the number of corrective casts were identified as predictors of relapse, emphasizing the need for tailored treatment protocols and diligent follow-up. These findings reveal a critical knowledge gap in clubfoot management within the Middle East, warranting further research. Future investigations should focus on additional relapse determinants, the psychosocial aspects of treatment adherence, and the long-term quality of life for affected individuals, ultimately contributing to evidence-based clinical practices on a global scale.

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Ethics approval: This study was approved by the 21 September University Institutional Ethics Committee and followed the Helsinki Declaration.

Availability of data and material: All the data was included in this study.

Competing interests: The author declares no potential conflict of interest.

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Authors' contributions: All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Patient consent for publication: Written informed consent was obtained for anonymized patient information to be published in this article.

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Table 1: Demographic and Clubfoot Deformity Characteristics of the Study Population (N = 102)

Characteristic	**N (%)**
Age (month)	
Mean ±SD	7.8 ±5.0 (Range 2.0 - 23.0)
Median (IQR)	6.5 (4.0, 9.0)
Age group	
Birth-10 month	85 (83.3%)
11-18 month	14 (13.7%)
19-24 month	3 (2.9%)
Gender	
Male	63 (61.8%)
Female	39 (38.2%)
Gestational age	
Full term	91 (89.2%)
Preterm	8 (7.8%)
Post-term	3 (2.9%)
Site involvement	
Unilateral	47 (46.1%)
Bilateral	55 (53.9%)
Residency	
Urban	33 (32.4%)
Rural	69 (67.6%)
Family type	
Extended family	68 (66.7%)
Nuclear family	34 (33.3%)
Family history	5 (4.9%)
Associated congenital anomaly	10 (9.8%)
Club foot type	
Rigid	38 (37.3%)
Non rigid	61 (59.8%)
Resistance rigid	3 (2.9%)

Abbreviations: SD: Standard Deviation, IQR: Interquartile Range.

Table 2: Treatment Characteristics of Clubfoot Deformity in the Study Population (N = 102).

Characteristic	**N (%)**
Achille tenotomy	96 (94.1%)
Initial Pirani score	
Mean ±SD	4.0 ±0.6 (Range 3.0 - 5.5)
Median (IQR)	4 (3.0, 5.5)
Final Pirani score	
Mean ±SD	1.5 ±0.2 (Range 1.0 - 2.0)
Median (IQR)	1.5 (1 ,2)
Initial Dimeglio score	
Mean ±SD	12.1 ±1.7 (Range9.0 - 16.5)
Median (IQR)	12 (9 ,16.5)
Final Dimeglio score	
Mean ±SD	4.5 ±0.7 (Range 3.0 - 6.0)
Median (IQR)	4.5 (3 ,6)
Follow-up (month), Mean ±SD	36.0 ±6.7 (Range 9.0 - 31.0)
Cast number, Mean ±SD	9.5 ±1.6 (Range 7.0 - 12.0)
Median (IQR)	9 (7 ,15)
Relapse	15 (14.7%)

Abbreviations: SD: Standard Deviation, IQR: Interquartile Range.

Table 3: Factors Associated with Relapse in univariate and multivariate analysis.

Characteristic	**Subgroups**	**No (87)**	**Yes (15)**	**Univariate; OR (95% CI)**	**p-value**	**Multivariate; OR (95% CI)**	**p-value**
Age (year)	Mean ±SD	7.0 (4.8)	12.0 (3.7)	1.18 (1.07-1.32)	**0.001**	1.25 (0.94-1.78)	0.140
Gender	Male	63 (92.6)	5 (7.4)	Ref	**0.006**	Ref	
	Female	24 (70.6)	10 (29.4)	5.25 (1.69-18.36)		4.19 (0.07-446.73)	0.474
Cast number	Mean ±SD	9.3 (1.6)	12.3 (1.5)	3.33 (2.01-6.80)	**<0.001**	8.37 (2.89-115.92)	**0.009**
Initial Pirani score	Mean ±SD	4.1 (0.6)	4.7 (0.5)	2.51 (1.66-4.25)	**<0.001**	2.40 (1.43-4.25)	**0.001**
Achille tenotomy	No	6 (54.5)	5 (45.5)	Ref	**0.006**	Ref	
	Yes	81 (89.0)	10 (11.0)	0.15 (0.04-0.59)		0.00 (0.00-0.52)	0.069
Residency	Urban	33 (86.8)	5 (13.2)	Ref			
	Rural	54 (84.4)	10 (15.6)	1.22 (0.40-4.21)	0.734		
Involved site	Unilateral	42 (89.4)	5 (10.6)	Ref	0.289		
	Bilateral	45 (81.8)	10 (18.2)	1.87 (0.61-6.41)			
Initial Dimeglio score	Mean ±SD	4.1 (0.6)	4.7 (0.5)	7.49 (2.52-28.06)	**0.001**	1.28 (0.32-5.69)	0.727

Abbreviations: SD: Standard Deviation, IQR: Interquartile Range, OR: Odds Ratio, CI: Confidence Interval