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Research Article

Causes of Non-Compliance and Abandonment of the Ponseti Method Related to the Abduction Splint: A Case Series Analysis

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Abstract

Background: The Ponseti method is widely recognized as the gold standard for congenital clubfoot correction. However, treatment protocol disruption during the abduction splint phase remains the primary risk factor for deformity relapse.

Objective: To determine the causes of abandonment of the treatment of clubfoot with the Ponseti method during the use of the abductor splint.

Material and Methods: A retrospective case series study (Level of Evidence IV) was conducted. Medical records from a total pool of 71 patients treated with the Ponseti method were screened. After applying strict exclusion criteria (incomplete records, non-Ponseti protocols, or abandonment prior to the splint phase), 7 referred/external patients with secondary congenital clubfoot recurrence due to treatment non-compliance were selected and analyzed.

Results: Bilateral involvement was present in 72% of the sample, with a marked male predominance (86%). The age of recurrence peaked between 1 and 3 years (43% each). Two primary categories for treatment abandonment were identified according to the original protocol: (a) Non-compliance with the abduction splint (71.4%), driven by parental non-compliance (42.9%; protocol misunderstanding, lack of perceived importance, and child splint intolerance) and poor medical orientation (28.6%). (b) Abduction splint structural deficiencies (28.6%), driven by technical errors in design and improper orthotic sizing. Overall, parental factors accounted for 42.9% and medical/technical management errors accounted for 57.1% of the relapses.

Discussion: Relapse in a previously well-corrected foot is strongly tied to poor brace compliance. While parental compliance is deeply influenced by socioeconomic and cultural factors, a significant portion of treatment failures stems from inadequate medical communication and technical follow-up. Comprehensive pre-brace family education and professional orthotic surveillance are vital to prevent recurrence.

Keywords: *Clubfoot; Recurrence; Abduction splint; Ponseti method; Treatment refusal; Evidence Level IV.*

Introduction

The Ponseti method is recognized as the best treatment for congenital idiopathic clubfoot in newborns, and its principles have also been adopted for the treatment of older children with neglected deformity. Clubfoot is a complex, three-dimensional congenital musculoskeletal deformity that can be easily managed after birth through correct manipulation and serial casting [1].

Despite the excellent results widely documented worldwide, the problem of relapses remains highly problematic. A relapse or recurrence can be defined as the reappearance of the deformity in a previously well-corrected foot. This must be clearly distinguished from a residual clubfoot, in which the foot was never fully corrected but rather partially corrected due to an incorrect or incomplete treatment protocol [2]. Crucially, historical and physiological observations highlight that the period of abandonment frequently presents itself during the utilization of the abduction splint, a critical phase originally meticulously systematized by Ponseti to prevent musculotendinous and ligamentous adaptive relapse [3,4].

Clubfoot is the most common congenital musculoskeletal deformity, with an incidence of approximately 1 in 1,000 live births, increasing to 1 in 20 if there is a genetic predisposition [5]. Initially, this deformity is managed conservatively through serial circular casting. In cases of failure or severe neglect, surgical correction or complex reconstructive salvage procedures of the deformity are required [5].

The Ponseti treatment is simple, cost-effective, and widely utilized. Numerous studies conducted by researchers across different countries during the last two decades have demonstrated that more than 90% of newborn cases with idiopathic clubfoot can be successfully treated using the Ponseti method [6]. However, a successful outcome requires constant patient follow-up and consistency from the parents or caregivers. Therefore, understanding the causes by which patients abandon the treatment scheme is highly beneficial from a medical perspective [6].

By identifying and listing the causes of non-continuity, healthcare providers can anticipate these challenges and prevent their occurrence, thereby increasing the treatment success rate and minimizing relapses [7]. Clinical trials and cross-sectional studies on structural adherence emphasize that barriers to bracing compliance are multifaceted, shifting across socioeconomic limitations, parental psychological fatigue, and orthotic fit tolerances [8,9]. Given that this is the most common congenital musculoskeletal condition and the Ponseti method is the most efficient and widely used alternative, it is the responsibility of the medical staff not only to thoroughly understand its theoretical and practical application but also to recognize the threats and factors that could cause the method to fail, which are directly attributable to the patient or those responsible for them [7].

In this context, treatment abandonment is one of the primary factors negatively influencing patient rehabilitation and predisposing them to deformity recurrence, a challenge that requires specialized center experience in secondary clinical management [10]. Consequently, preparing the patient and family, and foreseeing potential problematic situations, becomes of paramount importance [5]. Therein lies the significance of this study, aimed at evaluating the reality of the patient and the specific variables that result in treatment discontinuation during the abduction splint phase.

Materials and Methods

Study Design and Population

A retrospective, descriptive case series study was conducted (Evidence Level IV) to analyze the factors influencing treatment abandonment during the abduction brace maintenance phase of the Ponseti protocol. The research complied with standard ethical tenets, institutional guidelines, and the Declaration of Helsinki. Explicit verbal and written informed consent was obtained from the parents or legal guardians of all included pediatric patients prior to data collection. Due to the retrospective, non-interventional nature of the medical record review, formal approval was reviewed and an Institutional Review Board (IRB) waiver status was recognized.

The structural reporting of this case series analysis was aligned with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines for reporting observational research.

The screening pool originally consisted of the medical records of 71 patients diagnosed with clubfoot who had initiated treatment under the Ponseti method. After a thorough review and longitudinal follow-up attempts via direct contact, 39 patients were unreachable (non-responsive). Of the remaining 32 active records, 25 patients were excluded based on predefined criteria, leaving a final sample of 7 patients for in-depth analysis.

Selection Criteria

Inclusion Criteria: Patients with a definitive diagnosis of congenital clubfoot; history of complete initial management through the corrective phase of the Ponseti method (serial circular casting and percutaneous Achilles tenotomy); documented diagnosis of recurrent clubfoot deformity secondary to premature abandonment or incorrect application of the abduction splint protocol; complete and auditable medical charts detailing clinical course and parent interviews.

Exclusion Criteria: Incomplete, ambiguous, or unverified medical records; deformities managed through alternative conservative or initial open-surgical protocols differing from the Ponseti method; treatment abandonment occurring during the active serial casting or immediate post-surgical phases, prior to the official prescription and fitting of the abduction splint; clubfoot of syndromic, neurogenic, or secondary etiologies.

Data Collection and Variables Analysis

Data were systematically gathered from medical charts using a structured clinical survey addressed to the patients' parents or primary caregivers. The analyzed variables were structured into four primary dimensions:

- **Demographic and Clinical Data:** Name, age, sex, locality, etiology (congenital vs. neurogenic), and laterality (unilateral vs. bilateral);
- **Treatment Continuum:** Success of the initial corrective phase and subsequent documentation of anatomical relapse;
- **Timeline of Desertion:** Definition of the exact treatment phase where compliance failed (specifically isolated to the abduction splint stage);
- **Categorization of Non-Compliance:** Specific qualitative triggers behind abandonment, sub-divided into parental/caregiver factors and physician/technical factors.

Results

A total of 71 medical records were scrutinized; 55% (n = 39) of the population could not be reached, leaving 45% (n = 32) available for active screening. Upon applying the exclusion criteria to these 32 patients, 78% (n = 25) were excluded, and 22% (n = 7) met all criteria, constituting the final study sample.

Notable demographic traits revealed that 100% (n = 7) of these cases were 'referred/external' patients, meaning their initial casting or orthotic prescription was initiated at outside institutions before transferring to our specialized unit due to the relapse. Regarding baseline clinical characteristics, 100% of the sample presented strictly with congenital clubfoot, with zero neurogenic or syndromic cases included. A major male predominance was observed, accounting for 86% (n = 6) of the cases, while females represented 14% (n = 1). Bilateral clubfoot deformity was highly prevalent, affecting 72% (n = 5) of the patients, whereas unilateral presentation was found in 28% (n = 2). The age at clinical presentation for deformity recurrence peaked in early childhood: 43% (n = 3) were 1 year old, 43% (n = 3) were 3 years old, and 14% (n = 1) was 4 years old (Table 1).

Table 1. Demographics and Clinical Baseline of the Sample (n = 7)

Variable	Sub-category	Frequency (n)	Percentage (%)
Origin	Referred / External	7	100%
	Native Center	0	0%
Etiology	Congenital	7	100%
	Neurogenic / Syndromic	0	0%
Gender	Male	6	86%
	Female	1	14%
Laterality	Bilateral	5	72%
	Unilateral	2	28%
Age at Relapse	1 Year Old	3	43%
	3 Years Old	3	43%
	4 Years Old	1	14%

All 7 cases evaluated in the sample experienced a documented clinical relapse caused by treatment abandonment. Based on the original document protocol, the explicit causes of abandonment were successfully detailed into two primary categories and specific sub-motives (Table 2):

a) Non-compliance with the abduction splint – 71.4% (n = 5): This primary category accounted for the highest number of relapses and was further segmented into specific sub-motives:

• Parental Non-compliance: Representing 42.9% (n = 3) of the total sample. This was driven by explicit factors inherent to the parents, such as the child's severe discomfort with the splint, overlapping acute childhood conditions, a complete lack of perceived importance regarding long-term bracing, or profound protocol misunderstanding by the parents.

• Poor Medical Orientation: Representing 28.6% (n = 2) of the total sample. This was directly caused by inadequate explanations or insufficient guidance provided by the initial treating physician.

b) Abduction splint does not fulfill structural characteristics – 28.6% (n = 2): This category represented direct technical or clinical failures in orthotic management and accounted for two specific sub-motives: Technical errors in orthotic design and inappropriate orthotic sizing (incorrect splint size or inadequate materials). In these cases, the responsibility is directly attributable to the managing medical personnel.

When analyzing overall accountability across all categories, 42.9% (n = 3) of the reasons for abandonment were directly related to parental/caregiver choices, whereas 57.1% (n = 4) were directly related to medical management—either through poor patient orientation or orthotic design and sizing failures.

Table 2. Original Categorization of Triggers for Ponseti Method Abandonment

Primary Category (Original)	Specific Sub-motive Triggers	Case Count (n)	Relative %	Total Category %
a) Non-compliance with abduction splint	Parental factors (Discomfort, protocol misunderstanding, lack of perceived importance)	3	42.9%	71.4%
	Poor orientation by the treating physician	2	28.6%	
b) Splint does not fulfill characteristics	Orthotic structural design errors / Improper sizing or materials	2	28.6%	28.6%
Total Sample	All abandonment factors combined	7	100%	100%

Discussion

The Ponseti method for treating idiopathic clubfoot has demonstrated high efficacy and has witnessed a significant growth in popularity, with various specialized centers reporting outstanding clinical results [6,9]. According to clinical studies conducted in the region, post-treatment evaluations using the Ponseti method yielded excellent or good results in 96.5% of cases; only a minor fraction (3.5%) persisted with severe deformity and required formal open surgical interventions, with varus and forefoot adduction being the predominant residual patterns [2]. Crucially, those studies only accounted for patients who completely fulfilled the method. Therefore, it can be affirmed that the Ponseti method, when correctly applied, possesses a success rate approaching 100% [2].

However, the primary success of this procedure is centered not merely on rectifying the initial deformity, but on avoiding long-term relapse. The most frequent cause of recurrence is non-compliance with the preestablished post-corrective orthotic protocol [1,3,9]. Consequently, identifying and isolating the specific factors that provoke treatment abandonment is of paramount importance, as pinpointing these causes allows medical staff to take preemptive action before parental or technical errors are committed [1,3,9].

As previously stated, treatment abandonment is one of the primary factors negatively influencing patient outcomes and predisposing them to relapses; hence, thoroughly preparing the patient's family and anticipating potential problematic situations is essential [5]. Socioeconomic status, cultural elements, and the complex interaction between the physician and the parents heavily influence adherence and represent the thin margin between therapeutic success and failure [8]. Implementing targeted strategies to foster adherence includes instructing the family from the very inception regarding the strict biological relevance of reinforcement, incentive tracking via calls or follow-up visits, providing clear written directives, preventing or rapidly treating skin lesions, and avoiding criticism of the caregivers [9]. This aligns perfectly with the cumulative regional data compiled by specialized Ponseti units, confirming that focused physical follow-up dramatically reduces recurrence curves [10].

Furthermore, it is fundamental that the medical personnel in charge of these cases thoroughly master the technical application of the method. Beyond technical excellence, clinicians must possess the communication skills required to correctly transmit information so that parents fully comprehend the vital importance of strictly complying with medical indications [7]. This must be coupled with rigorous longitudinal clinical surveillance and parent awareness campaigns to ensure every step of the process and its long-term purpose are understood [7].

In our series, 100% of the cases presenting with recurrence secondary to abandonment were referred/external patients. The primary causes behind their relapses highlight a combination of poor technical application of the abduction splint and deficient follow-up by the initial healthcare provider. This underscores the clinical necessity that trained specialists with extensive experience handle these cases from their very inception [7,10].

It is noteworthy that despite its clinical relevance in preventing method failure, current literature rarely provides a detailed, structured categorization of the specific causes behind Ponseti protocol abandonment. While existing studies broadly discuss failure percentages and generic technical aspects, they seldom isolate or punctuate the direct technical and parental triggers of treatment desertion. Our study addresses this gap by utilizing the original protocol classifications—(a) non-compliance with the abduction splint and (b) structural deficiencies of the splint—to highlight that medical management and orthotic surveillance represent 57.1% of protocol failures, shifting the classical blame away from parental compliance alone.

Data Availability Statement

The clinical, demographic, and statistical datasets generated or analyzed during the current study are not publicly deposited due to patient privacy laws but are completely available from the corresponding author, upon reasonable academic request.

Authors' Contributions

All authors met the international standards for authorship established by the ICMJE:

JP: Conceived the study, designed the initial research protocol, and performed primary data collection.

RM: Contributed to data collection, technical validation of orthotic variables, and literature review.

JL: Performed data analysis, structured the statistical distribution, translated/drafted the manuscript, and managed corresponding editorial communication.

AS: Critically reviewed the manuscript for intellectual content, updated surgical/clinical terminology, and gave final approval for submission.

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Conflict of Interest

The authors declare that they have no competing interests.

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