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A Retrospective Review Assessing the Impact of Socioeconomic Factors on Brace Adherence in Clubfoot Patients Treated with the Ponseti Method

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Abstract

Introduction: The Ponseti method is a widely adopted nonsurgical approach for correcting clubfoot deformities, but its success relies heavily on consistent brace usage during the maintenance phase. The present study seeks to analyze whether socioeconomic factors affect brace adherence in clubfoot patients.

Study Design: The present study was reviewed and approved by the Institutional Review Board. The charts of 83 patients treated for clubfoot by two providers at a single institution between 2013 and 2022 were reviewed to investigate the impact of various socioeconomic variables on brace adherence and its association with treatment outcomes. Brace adherence was determined based on provider documentation noting self-reported parental accounts of adherence. Annual family income was derived from North Carolina census data based on zip code. Chi-squared tests and two sample t t-tests analyses were performed, controlling for clinical factors such as treatment strategy, comorbidities, laterality, and prenatal diagnosis.

Results: Patients from families with higher annual income based on zip codes demonstrated higher brace adherence rates. Patients from racial minority backgrounds exhibited reduced adherence with brace usage, likely in the context of greater obstacles to care. No significant correlations were found between brace adherence and distance to the hospital, gender, or language.

Conclusion: The findings highlight the multifaceted nature of brace adherence in clubfoot patients undergoing Ponseti treatment, suggesting the importance of addressing specific patient demographics, socioeconomic contexts, and caregiver support structures to optimize treatment outcomes. Further research involving a larger and more diverse cohort is necessary to validate these findings.

Keywords: Clubfoot, social determinants of health, clinical outcomes, brace compliance.

Introduction

Talipes equinovarus, otherwise known as clubfoot, is a common anatomical deformity found in orthopedic pediatric patients. Although its incidence is as high as 1-2 per /1,000 births, its underlying etiology remains unknown, and it does not correct with age if left untreated [1, 2]. It is believed to be mediated by a multifactorial genetic process [3]. While most cases are idiopathic, clubfoot can be seen in the setting of other conditions, including spina bifida, arthrogryposis, hemimelia, and amniotic band syndrome, among others [4-6]. Clubfoot is typically defined by a high, high-arched midfoot, an inward inward-pointed forefoot, an inverted heel, and a plantarflexed ankle [7]. The Pirani score is used to classify the severity of clubfoot deformities based on the presence and degree of these specific anatomical anomalies [2,8]. The gold standard treatment for clubfoot is the Ponseti method, which involves serial casting and percutaneous tenotomy to correct the deformity, followed by bracing to maintain the correction. The Ponseti method was developed

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Table 1: A stepwise clinical approach to clubfoot treatment with the Ponseti method

The ponseti method	
1	Weekly gentle manipulations: The foot is gently manipulated into a more corrected position, with gentle stretching and casting to maintain the correction achieved
2	Serial casting: After each weekly manipulation, a long-leg cast is applied from the toes to the upper thigh to hold the foot in the corrected position
3	Percutaneous Achilles tenotomy: If a residual equinus deformity (downward pointing of the foot) persists after the serial casting phase, a minor percutaneous procedure is performed to lengthen the Achilles tendon, allowing for further dorsiflexion of the foot
4	Final cast: After the Achilles tenotomy (if required), a final long-leg cast is applied for 3 weeks to allow for tendon healing
5	Bracing: Following cast removal, patients were fitted with a foot abduction brace or Dennis-Browne bar to maintain the correction and prevent relapse. Patients are instructed to wear the brace full-time for the first 3 months and then during the night-time and at naptimes for several years.

in 1948 using Denis Brown splints with custom-molded heels worn full time for several months after surgical correction. This original brace was intended to evert the corrected foot without abducting the calcaneus, thereby reducing the risk of ligamental retracting fibrosis and progressive recurrence of the deformity [9]. The use of a post post-corrective brace is still implemented today and is known as the foot abduction orthosis (FOA), which is typically worn for 3 months 23 hours a day, and then up to 4 years of age at night and during naps.

The Ponseti method has been almost universally adopted over surgically invasive alternatives [10, 11]. While most infants with clubfoot have successful initial correction using this method, the challenge is maintaining correction to prevent relapse [12, 13]. The relapse rates are reported to be between 26%- and 48%. Relapses may be addressed with an additional series of manipulations, casting, and bracing, or in more severe cases, with anterior tibial tendon transfer to the third cuneiform [12, 13]. The literature shows a positive relationship between brace adherence and successful maintenance of correction with a decreased need for additional casting and unplanned surgery. The most consistent factor leading to relapse is parental adherence to postoperative protocols and bracing practices. This paper will explore the variables that affect brace adherence for patients treated with the Ponseti method for clubfoot at a single academic pediatric orthopedic practice. These variables may include patient factors (comorbidities, age at onset of treatment, bilateral vs. unilateral) and external or family-related factors (distance from home to our practice, median family income, race, language spoken at home).

Materials and Methods

Study group

The present study was reviewed and approved by the Institutional Review Board. This study is a single-center retrospective chart review of patients treated with the Ponseti method for clubfoot between 2013 and 2022 by two orthopaedic providers. One patient was excluded based on South Carolina residency, since census data out of state was not included in the database utilized to generate income data.

Treatment technique

All patients in this study received the Ponseti method as the initial treatment for clubfoot deformity. The Ponseti method is a widely accepted, minimally invasive approach that involves a series of gentle manipulations and castings to gradually correct clubfoot deformity (Table 1).

In cases where the clubfoot deformity did not fully correct with the Ponseti method alone or if relapse occurred, additional interventions were considered. In some cases, an additional round of serial casting was sufficient. In more severe cases additional surgical interventions, such as a tendon transfer, were needed. Patients who exhibited persistent dynamic supination deformity or forefoot adduction after the Ponseti method underwent a tibialis anterior tendon transfer (TATT) procedure. The TATT involves detaching the tibialis anterior tendon from its insertion on the medial cuneiform and rerouting it laterally to insert into the lateral cuneiform or cuboid bone. This transfer is aimed at augmenting the poor or absent function of the evertor muscles, ultimately improving the dynamic alignment and stability of the foot [11].

Clinical evaluation

Patients in this study were seen every two 2 or three 3 months in the first 1st year, then every 6 months until age 4. Progress notes and operative notes were used to measure clinical progress and brace adherence. Providers noted in their progress notes whether patients had difficulty wearing the brace as instructed. Providers also indicated the severity and progression of the clubfoot deformity in their notes. Pirani scores were not included in this study because providers recorded these scores inconsistently.

Data extraction

A single medical student conducted the chart review to collect independent variables such as average annual income, distance to clinic, race, and language spoken in the home. The patients' zip code was recorded, and North Carolina Department of Commerce data was used to extrapolate county-based average annual income and an economic distress index [14]. An

economic distress score of 1-–3, with 1 representing the greatest economic distress, was based on the unemployment rate, median household income, percentage growth in population, and adjusted property tax per capita. Distance to clinic was calculated using an online map; mileage between clinic and chart zip code was recorded. Race and language spoken in the home were directly extrapolated from the chart. Other clinical data -such as sex, comorbidities, laterality of clubfoot, and presence of prenatal ultrasound diagnosis was also extrapolated from the chart. The dependent variables studied were brace adherence and clubfoot recurrence. Brace adherence was assessed through the provider notes. If at least one provider noted the patient had not been adherent with their brace wearing protocol, the patient was characterized as brace non-adherent. To assess clubfoot recurrence, a score of 0-–2 was ascribed to each patient: ""0" indicated that none of the notes mentioned signs of worsening or recurrent clubfoot deformity, "1" indicated that a provider noted at least once a worsening or recurring clubfoot deformity after prior correction, and "2" indicated the need for an additional surgical intervention or another round of serial casting after prior correction of the original deformity. For the first 10 patients included in the study chronologically, a second medical student completed an independent chart review recording brace adherence and clubfoot recurrence. The interrater reliability between the two medical students was 1.00 for brace adherence and 0.9 for clubfoot recurrence, validating this methodology.

Statistical analysis

Statistical analysis was performed using STATA/SE software (version: 18.0 StataCorp, College Station, Texas). Descriptive analyses of clubfoot patients are listed in Table 2. Using adherence as

Table 2: Demographic and environmental characteristics of clubfoot patients treated with the Ponseti method at a single center between 2013 and 2022 (*n*=83)

Variable	Value (%)
Sex- no. (%)	
Male	57 (68.67)
Female	26 (31.33)
Race -no. (%)	
Non-hispanic caucasian	51 (61.45)
Hispanic caucasian	15 (18.07)
Black/African American	9 (10.84)
Other	8 (9.64)
Average annual income ($)	
Mean, (standard deviation)	$63,916.78, ($14,901.05)
Socioeconomic factor (income stratification)-no. (%)	
Low ($35,000-$50,000)	15 (18.07)
Middle ($50,001- $75,000)	52 (62.65)
High (>$75,001)	16 (19.28)
Average distance from clinic (Mi.)	
Mean, (standard deviation)	55.87, (33.95)
County distribution -no. (%)	
Wake	11 (13.25)
Harnett	7 (8.43)
Onslow	6 (7.23)
Brunswick	5 (6.02)
Other Counties (×<4)	54 (65.07)
Economic distress rank -no. (%)	
1. High economic distress	26 (31.33)
2. Medium economic distress	19 (22.89)
3. Low economic distress	38 (45.78)
Language-no. (%)	
English	79 (95.18)
Spanish	4 (4.82)
Comorbidities -no. (%)	
None	67 (80.72)
Presence of comorbidities	16 (19.28)
Prenatal ultrasound -no. (%)	
No ultrasound	20 (24.10)
Ultrasound	42 (50.60)
Ultrasound status unknown	21 (25.30)
Laterality -no. (%)	
Left	22 (26.51)
Right	17 (20.48)
Both	44 (53.01)
Adherence	
Non-adherence	19 (22.89)
Adherence	64 (77.11)
Treatment	
Serial casting	77 (92.77)
No TAL shoe brace	4 (4.82)
Tendon transfer	2 (2.41)
Recurrence	
No signs	64 (77.11)
Some signs	11 (13.25)
Additional surgical intervention or recasting required	8 (9.64)

the dependent variable, we conducted two two-sample t-tests with patient's annual median income and average distance from the clinic. In addition, we calculated Chi-squared and Fisher's exact tests for economic distress ranking and race. Lastly, to investigate the association between adherence and recurrence, we calculated odd ratios with 95% confidence intervals. Values of P lower than or equal to 0.05 were considered significant.

Table 3. : The effect of income, economic distress, race, and average distance from the clinic on brace adherence in clubfoot patients at a single center treated with the PonsetMethod method between 2013- and 2022 (n=83)

Variable	Adherence	Non-adherence	T-score	Chi-squared	*P*-value
Income ($)	Mean= $65,904.61	Mean= $57,220.95	−2.66		0.011*
Economic distress					0.345
High economic distress	18 (28.12)	8 (44.44)		2.13	
Intermediate economic distress	14 (21.88)	5 (26.31)			
Low economic distress	32 (50.00)	6 (31.57)			
Race				13.06	0.007*
Non-hispanic caucasian	42 (65.62)	9 (47.4)			
Hispanic caucasian	11 (17.19)	4 (21)			
Black	3 (4.69)	6 (31.6)			
Other	8 (12.50)	0 (0.00)			
Avg distance to clinic (miles)	Mean= 55.80 miles	Mean= 56.11 miles	0.04		0.971

*Denotes statistical significance indicating aP<0.05

Results

A total of 83 patients were included in the study. Demographic data was collected through chart review. (Table 2).

Socioeconomic variables

Median annual income was calculated based on North Carolina Bureau of commerce Commerce census Census data [14]. Patients in the nonadherent group had a significantly lower median annual income ($57,220.95, n = 19) compared to the adherent group ($65,904.61, n = 64), with a mean difference of $8,683.66 (P = 0.011) (Table 3). Economic distress by county, however, was found to have no effect on adherence (P = 0.345) (Table 3).

Race was also a factor contributing to brace adherence. The non-adherent group was more racially diverse than the adherent group which was largely composed of Nonnon-Hispanic Caucasian patients (P = 0.005) (Table 3). Black/African American patients had the highest prevalence of nonadherence (66.67%), followed by hispanic caucasian patients (26.67%), non-hispanic caucasian patients (17.65%), and patients identified as "other' other" (0%).

Distance to the clinic was not a significant variable in patient adherence. The average distance to the clinic in the adherent group (mean = 55.8 miles, n = 64) was not significantly different than in the non-adherent group (mean = 56.11 miles, n = 19) (P = 0.97) (Table 3).

The data indicated a greater prevalence of nonadherence in Spanish Spanish-speaking patients (52%) than English English-speaking patients (21.52%). But However, no further statistical analysis was conducted on this variable, given the small sample size of non-English speakers (n = 4) included in the study.

Clinical variables

Of the 83 patients, 92.77% received serial casting and Achilles tenotomy, 4.82% received serial casting but did not require tenotomy, and 2.41% required tendon transfer (P = 0.319). Comorbidities were absent in 80.72% of patients (P = 0.661), and 53.01% had bilateral clubfoot (P = 0.878). Prenatal ultrasound diagnoses were recorded in 50.60% of cases (P = 0.102). None of these variables were found to be statistically significant in contributing to brace adherence.

Adherence and recurrence

Overall, 77.11% of patients were adherent with brace usage, while 22.89% were non-adherent. Patients in the adherent group showed significantly lower rates of recurrence overall. Only 4.69% of adherent patients exhibited any clinical sign of recurrence compared to 84.21% of nonadherent patients. Furthermore, 26.32% of non-adherent patients required additional surgical intervention or recasting, indicating more severe recurrence of deformity, while only 4.69% of adherent patients needed further intervention. The odds ratio for all clinical signs of recurrence (with or without further intervention) in the non-adherent group was 108.44 (P <

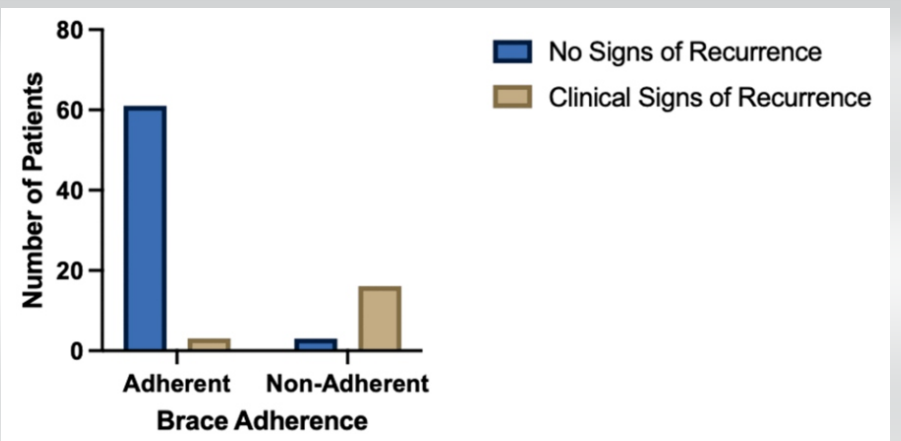

Figure 1: Incidence of deformity recurrence by brace adherence (n=83).

0.0005), indicating a strong association between adherence and recurrence rates (Fig. 1).

Discussion

Many studies have established the effectiveness of the Ponseti method and favored its application over more invasive and cost-prohibitive surgical interventions [15-18]. Nevertheless, the success of this method is limited by adherence to its bracing protocols, which have been criticized for their heterogeneity [13, 19-21]. There is a consensus that a lack of adherence with brace brace-wearing procedures is the single largest cause of deformity recurrence after correction via the Ponseti method. According to the literature, there are 30-–60% rates of non-adherence in brace (FOA) wearing [9, 22]. The present study found a prevalence of 22.89% of non-adherence. In this study, only 4.69% of patients in the brace-adherent group showed clinical signs of recurrence or recurrence requiring additional intervention, while more than 80% of patients in the non-adherent group experienced recurrence. These findings support what is documented in the literature and underscore the importance of brace wearing in the success of Ponseti treatment.

Since clubfoot patients are infants, parents bear the burden of ensuring their child's adherence with brace brace-wearing regimens and there are numerous factors determining their ability to comply with stringent brace brace-wearing protocols [23]. A recent study analyzed Facebook posts in a clubfoot Clubfoot support group and revealed that more than 23% of the posts were about parental concerns regarding brace brace-wearing [24]. An alternative study in the Netherlands revealed that compared to healthy peers, clubfoot patients reported greater rates of sleeping, motor functioning, and skin complications as a result of their brace brace-wearing protocols [25]. While parental distress and quality of life may affect brace brace-wearing practices, it is not clear how much larger socioeconomic factors contribute to this problem. The costs associated with transportation to the hospital, the visits themselves, and the braces prescribed all contribute to mounting costs of treatment that some families may not be able to accommodate. Although the Ponseti method is more cost cost-effective than surgical intervention, it can remain a burden on low- and middle-income families [20,26,27]. Systemic problems such as level of education, cultural or linguistic differences, and relationships with healthcare can also present barriers to patient care in this context [10, 28, 29].

This chart review revealed that socioeconomic factors, particularly annual family income, race, and language spoken, were significant determinants of brace adherence. Patients from lower lower-income areas demonstrated markedly reduced adherence rates. The median annual income of the non-adherent group was significantly lower than that of the adherent group, indicating that the potential financial impact of clubfoot treatment for low-income families may impede brace adherence. Interestingly, although transportation could be a further limitation for these patients, no effect was found on the distance between a patient's primary residence and our clinic site. The influence of race and language on adherence rates represents a novel finding that warrants further investigation. Hispanic Caucasian and African American patients exhibited markedly greater rates of non-adherence than did their Nonnon-Hispanic Caucasian counterparts. Similarly, Spanish-speaking families demonstrated poorer adherence. These disparities may reflect underlying cultural factors, communication barriers, or socioeconomic dimensions not fully captured by income level alone.

Limitations

However, most of the patients in this study were Nonnon-Hispanic Caucasian, and larger sample sizes of patients from minority backgrounds are required to better capture this relationship in the future. Moreover, this study was conducted at a single academic institution, which may limit the generalizability of these findings. The use of chart review presents further limitations as our data relies upon the accuracy and completeness of the medical record. This is further complicated by subjective variables such as brace compliance and recurrence of clubfoot deformity which were based upon clinician reporting in the electronic medical record. Nevertheless, our results highlight the need for culturally sensitive approaches and enhanced efforts to bridge language gaps when counseling families on the importance of bracing.

Conclusions

Although the Ponseti method has proven to be highly effective in correcting clubfoot deformities, our study demonstrated that the full benefits of this intervention may not be equitably realized across all patient populations. Socioeconomic disadvantages and cultural barriers can undermine treatment adherence, leading to higher rates of recurrence and the need for additional interventions. These findings highlight the importance of implementing targeted strategies to enhance brace adherence, particularly among socioeconomically disadvantaged and minority communities. More research, with larger and more diverse cohorts, is needed to find target areas for improvement in increasing the access and quality of care provided to all clubfoot Clubfoot patients. In addition to considering the clinical variables their patients present with, health care providers should be encouraged to provide patient-specific education and counseling, with materials tailored to address cultural and linguistic barriers. Other systematic interventions to help address these discrepancies may include financial assistance programs to alleviate the economic burden

of brace acquisition and maintenance, community outreach and support networks to foster treatment adherence, and innovative technological solutions such as brace sensors or gamification strategies to promote engagement with bracing regimens. By addressing the underlying determinants of nonadherence, healthcare providers can work toward ensuring that all patients have equitable access to the full benefits of the Ponseti method regardless of their socioeconomic or cultural background.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.
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