Original Article

Assessment of Treatment Outcomes in the Management of Club foot using the Ponseti Technique: A cross-sectional study

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Abstract

Background: The Ponseti technique remains the preferred method for club foot treatment. Although measures of treatment outcomes have been well documented, there is no consensus on the determinants of those outcomes. This study aims to assess treatment outcomes and the factors which can influence treatment outcomes. **Materials and Methods:** This is a cross-sectional study. A total of 472 children representing 748 feet in total were recruited. Patient characteristics such as age at presentation, gender, tenotomy, walking with or without deformity, parental educational status and occupation were documented. Outcomes of care were assessed using indictors such as parents' satisfaction with the outcome of treatment and the patients' ambulation without deformity. The relationships between the determinant factors and these outcomes were explored using multivariable binary logistic regression. **Results:** Most of the children (69.1%) were aged below 2 years. Brace compliance was very high (89.9%). The pre-treatment average Pirani scores were 3.9 ± 1.8 and 4.3 ± 1.8 for the right and left feet, respectively. Majority (88.3%) of the children achieved ambulation without deformity, whereas most (87%) of the parents were satisfied with the treatment outcomes. In total, parental satisfaction with child's treatment outcomes was lower in parents who were not formally educated odds ratio (OR) = 0.19 (95% confidence interval [CI] 0.08–0.43), but parental satisfaction was lower if the child had higher Pirani score OR = 0.77 (95% CI 0.62–0.96). Children who had more casts applied to the affected foot were more likely to walk without deformity OR = 1.24 (95% CI 1.01–1.52). **Conclusions:** This study revealed that treatment outcomes in children with club foot can be determined by some sociodemographic and treatment-related factors.

Keywords: Ambulation without deformity, clinic visits determinant of outcomes, club foot, parental satisfaction

Introduction

The idiopathic talipes equinovarus (club foot) is the most common foot deformity. The most popular conservative treatment method is the Ponseti technique. This method of treatment has better outcome when applied early or immediately after birth. It is primarily a non-operative technique which is valuable in both developed and developing countries. It requires less resource but more commitment from the physician and the parents or guardians. The goals of club foot treatment are a pain free, supple and plantigrade feet suitable for walking and parental satisfaction. The Ponseti technique is basically divided into two phases; the correction/manipulation with casts phase and the maintenance/bracing phase.[1]

Several authors have used different indices to measure treatment outcomes and proposed different determinants of outcome but there is yet no consensus on the determinants of treatment outcomes. There is consensus on the goal of treatment which is anatomically and functionally corrected painless supple foot for walking. In his article, Dobbs *et al*.[2] proposed that compliance rate and parental education are major factors which determine recurrences which could affect outcome, whereas Cooper and Dietz[3] found out that pain and limitation of function were

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good outcome criteria. Roye *et al*.[4] designed a disease-specific instrument for the evaluation of outcome in surgically treated club foot, which was evaluated by Dietz *et al*.[5] in another study. An African study by Malinga *et al*.[6] applied this instrument and reported good results. Smythe *et al*.[7] employing the Delphi method deduced that no pain, parental satisfaction, ability to wear normal shoes and plantigrade foot are good outcome measures.

These authors published a systematic review which concluded that there are no standardised outcome reporting measures despite numerous articles on outcome.[1] The aim of this study is to determine simple outcome measures which can be easily used and their determinants.

Materials And Methods

This was a cross-sectional, hospital-based study which was conducted in the outpatients clinic of the paediatric unit of both the University of Calabar Teaching Hospital, Calabar and National Orthopaedic Hospital, Enugu. The data were collected for 10 years, from 1st February, 2012 to 31st January, 2022. It focused on children who were below 5 years of age and had presented with idiopathic talipes equinovarus (club foot). Those with syndromic, complex, secondary and previously treated clubfeet were excluded from the study. They were consecutively recruited into the study for the first 5 years, whereas each patient was followed up over the next 5 years. This was to allow for brace use for 4 years and a year to observe feet for any deformity post-bracing. Informed consent was obtained from the parents or guardians of the patient and documented in their medical records. Efforts were made to encourage follow-up clinic visits by obtaining the patient's, parent's or guardian's personal phone number and residential address. They were put on a list for reminders using short messaging service and calls if warranted.

The authors and trained research assistants attended to the participants on each visit. The foot was assessed for full correction following bracing. During follow-up visits, the child's foot was assessed for deformity during walking (maintaining a plantigrade foot), absence of pain and the parent's/guardian's satisfaction with the treatment outcomes. Brace compliance and recurrence or relapse were also assessed. The participants' sociodemographic and clinical data were collected using a structured questionnaire at the presentation. Data of clinical interest included the nature of club foot and its severity, the care given to the child and the outcome of care.

The relationships between the key determinant variables and indicators of treatment outcomes (which were parental satisfaction and ambulation without deformity in this study) were explored using binary logistic regression. Parental satisfaction was dichotomised to place parents who were satisfied in one category and these were tagged 'satisfied', whereas those who were either not satisfied or unsure were placed in the second category which was tagged 'others'. In the statistical models, the determinants of outcome were the child's age in months, sex, parental or caregivers educational (refers to formal education) status, the number of casts applied in the course of treatment, and the total number of visits the child made to the clinic. These determinants were selected based on the authors' appraisal of existing literature. The Pirani scores for children with bilateral lesion were entered separately for each foot as a different entry in a second spreadsheet which was created for the statistical modelling. Thus, each child with bilateral lesions had two separate entries in the spreadsheet, and each entry was supported with the Pirani score for the index foot. We did not see any need to do a cluster analysis as any child who had more than one entry had only a maximum of two entries. It was therefore unlikely to have a clustering effect in children who had bilateral lesions. All the analyses were conducted using SPSS version 20 (IBM Corp., Armonk, NY, USA) at a 95% confidence level (CI). Cases with missing data were excluded from analyses involving the affected variable.

Ethical clearance was given by the Institutional Ethics Review Board of Both Hospitals (NHREC 01 January, 2012).

Results

There were 472 children in this study aged between 0 and

Table 1: Sociodemographic data

Variable	Categories	Frequency (%)
Sex	Male	275 (58.5)
	Female	195 (41.5)
Age group (years)	<2	326 (69.1)
	≥2	146 (30.9)
Educational status of parents or guardians	Educated	310 (90.1)
	Uneducated	34 (9.9)
Employment status of parents or guardians	Employed	123 (37.1)
	Unemployed	224 (62.9)

Table 2: Clinical features, severity and treatment-related factors

Variable	Categories	Frequency (%)
Laterality	Right foot	81 (17.3)
	Left foot	109 (23.2)
	Bilateral	279 (59.5)
Corrective surgery	Yes	18 (3.8)
	No	374 (96.2)
Tenotomy	Yes	196 (52.1)
	No	180 (47.9)
Number of times tenotomy was done	None	255 (47.7)
	One	179 (37.9)
	Two	32 (6.8)
	Three	3 (0.6)
Brace compliance	Yes	328 (89.9)
	No	22 (6.0)
	Not sure	15 (4.1)
Number of casts till bracing	0-19‡	4.6±3.5*
Number of clinic visits	0-42‡	5.1±5.7*
Right-foot Pirani score	0-6‡	3.9±1.8*
Left-foot Pirani score	0-5.5‡	4.3±4.8*

*Mean±SD, ‡Minimum-maximum. SD: Standard deviation

60 months. The mean age was 10.4 ± 11.9 months and most of the children (n = 326, 69.1%) were aged below 2 years. About 59% (n = 275) of the study participants were male. The majority of the parents had formal education, but a higher proportion of these parents were unemployed [Table 1].

Most of the children (59.5%, n = 109) had a bilateral deformity, whereas the lowest occurring pattern involved the right foot (n = 81, 17.3%). The vast majority of the children (96.2%) did not require further surgical intervention, but higher proportions had tenotomy. Brace compliance was very high in these participants. On average, the study participants visited the clinic five times. The pre-treatment average Pirani scores were 3.9 ± 1.8 and 4.3 ± 1.8 for the right and left feet, respectively [Table 2].

The majority of the children (n = 287, 88.1%) achieved ambulation without deformity. Approximately 87% (n = 268) of the parents/guardians were satisfied with the outcome of the treatment, whereas 27% (8.8%) were uncertain about how satisfied they were with the child's progress following clinical care [Table 3].

Table 3: Outcome indicators

Variable	Categories	Frequency (%)
Ambulation	With deformity	38 (11.7)
	Without deformity	287 (88.3)
Patent/guardian satisfaction	Yes	268 (87.0)
	No	13 (4.2)
	Not sure	27 (8.8)

Modelling parental satisfaction for all the children regardless of which foot was involved revealed higher odds of satisfaction with the child's treatment outcome among parents who had formal education and the difference was statistically significant, odds ratio (OR) = 0.19 (95% CI 0.08–0.43). In addition, the level of parental satisfaction was lower with higher Pirani scores for the affected foot. A one-unit increase in the Pirani score was associated with a 23% reduction (95% CI 0.62–0.96) in the odds of parental/guardian satisfaction [Table 4]. Stratifying the model by the foot involved showed that parents/guardians of older children had lower odds of being satisfied with the child's treatment outcome, OR = 0.96 (95% CI 0.90–0.99), and this association was statistically significant. Parental satisfaction was also lower among uneducated parents, OR = 0.11 (95% CI 0.03–0.36). No determinant variable was significantly associated with parental satisfaction with the treatment outcome in the left foot [Table 4].

Overall, the odds of the child's ambulation without deformity showed a statistically significant association with feet which required higher frequency of cast application to achieve correction, OR = 1.24 (95% CI 1.01–1.52). In contrast, the higher the number of times the child was brought to the clinic for care, the lower the odds of ambulation without defect, OR = 0.89 (95% CI 0.81–0.98). Stratifying the model by the

Table 4: Odds ratios for determinants of parental satisfaction

Determinants	Categories	OR (95% CI)		
		All feet	Left foot	Right foot
Age (months)		0.98 (0.95-1.00)	1.00 (0.96-1.05)	0.96 (0.90-0.99)
Sex	Male Female	0.89 (0.48-1.64)	0.91 (0.38-2.18)	0.89 (0.36-2.19)
Parents educational status	Educated Uneducated	0.19 (0.08-0.43)	0.32 (0.09-1.12)	0.11 (0.03-0.36)
Number of casts		1.09 (0.93-1.27)	1.04 (0.83-1.30)	1.14 (0.90-1.43)
Number of clinic visits		1.00 (0.91-1.09)	1.01 (0.89-1.14)	0.99 (0.88-1.13)
Pirani score		0.77 (0.62-0.96)	0.81 (0.60-1.08)	0.73 (0.52-1.02)

OR: Odds ratio, CI: Confidence interval

Table 5: Odds ratios for determinants of ambulation with deformity

Determinants	Categories	OR (95% CI)		
		All feet	Left foot	Right foot
Age (months)		1.01 (0.97-1.04)	1.01 (0.96-1.07)	1.00 (0.96-1.06)
Sex	Male Female	0.98 (0.47-2.02)	1.24 (0.45-3.46)	0.77 (0.27-2.19)
Parents educational status	Uneducated Educated	1.57 (0.31-7.85)	1.54 (0.16-14.85)	1.66 (0.17-16.05)
Number of casts		1.24 (1.01-1.52)	1.32 (0.98-1.78)	1.66 (0.17-16.05)
Number of clinic visits		0.89 (0.81-0.98)	0.88 (0.77-1.00)	0.90 (0.79-1.02)
Pirani score		1.16 (0.91-1.48)	1.20 (0.87-1.67)	1.10 (0.77-1.58)

OR: Odds ratio, CI: Confidence interval

foot affected showed some suggestive association between the age in months and ambulation without defect, in which case older children tended to ambulate without defects in the right or left foot. In addition, the application of more casts to the child was suggestively associated with an increased odd of ambulation without defect in the left foot. The statistical associations in these stratified models were not statistically significant [Table 5].

Discussion

Our study showed very high brace compliance among study participants. Parents who had formal education were more likely to be satisfied with the outcome of Ponseti treatment on the child. In addition, a lower Pirani score was associated with higher odds of parental satisfaction with treatment outcome. A lower age in months was also associated with higher parental satisfaction. The child's ability to walk without a physical deformity was positively associated with the application of more casts during the Ponseti technique management but was paradoxically lower in children who visited the clinic more often.

Our study reveals a very high brace compliance rate; therefore, we did not include this factor as a determinant of treatment outcome in the statistical model. This deviated from previous reports which showed relatively low compliance. These reports also suggested that brace compliance is a determinant of treatment outcome.[2,8] Although brace compliance is subjective, over time people have come to understand through frequent medical outreaches the importance of bracing post-correction. Brace compliance is a modifiable factor in that doctors or caregivers must start early to educate guardians/parents on its importance before this phase of treatment arrives.[9]

In our study, parental satisfaction was an outcome. This is the proverbial '*mother's intuition'*, which is sometimes needed regarding the state of illness or well-being of her child. Parental satisfaction is a highly subjective but very reliable measure of treatment outcome. This has been reported by some authors and it has been included in their assessment tool for the outcome as the only parental response.[4,7] In this study, higher parental satisfaction was significantly determined by a lower Pirani score and parental formal education. Parental literacy is a crucial component of child care. This implies that educated parents have better understanding of the clinical condition and tend to comply better with instructions. These parents are more fulfilled and better satisfied as one author has noted.[2]

In our study, a lower initial Pirani score was a determinant of higher likelihood of parental satisfaction, because existing literature reports higher Pirani scores are associated with an increased number of casts required for correction of deformity, increased relapse rate and poor parental satisfaction. Our finding is similar to that reported by a Haitian study[10] and Chinese study.[8]

Our study reveals that increasing age at presentation was associated with lower parental satisfaction in the right foot. This finding has been corroborated by some Asian studies.[8,11,12] However, some authors have argued that the Pirani score, previous treatment received, compliance with both treatments, and bracing could modify the effects of age on parental satisfaction. A study in a low-income setting puts age as a contextual issue, whereas a Portuguese study concludes that age has no effect but all their study participants were within 1–31 months age bracket.[10,13] We have observed a changing trend in access to healthcare in African, from late presentation to early presentation due to increased awareness and establishment of health insurance. Overall, parents tend to bring the children to the hospital at an earlier age. We argue that there is no doubt that age has a role to play due to the changing intrinsic characteristics of the foot with increasing age.

We explored another indicator of post-treatment outcome, namely, the ability of the child to walk without any physical deformity. This implies the ability to run, wear any type of shoes, especially for the female gender, and the absence of pain. In an article by Symthe *et al*.,[7] the ability to wear shoes was assessed as a treatment outcome, whereas Roye *et al*.[4] assessed walking and running among other indicators. We decided to keep our assessment approach simple so that the observation of ambulation without defect can be done by any category of health worker.

In our study, gender was not a significant determinant of either parental satisfaction or ambulation without defect, contrary to a report by Qudsi *et al*.[10] Furthermore, previous treatment received is worth mentioning but this will depend on whether this treatment was non-operative or operative. Several authors have reported good success with referred previously non-operative treated club foot.[13,14]

The strengths of this study include a high sample size and the two-centre recruitment of patients which would likely blunt performance bias in the management of the patient. This study would have benefited a great deal if the time to recovery had been used to affect a longitudinal analysis of treatment outcome. This was not possible as the follow-up times were scantly reported. This is an obvious weakness. However, since we did not set out to compare the outcomes of different treatment techniques, this omission is much less of a setback.

Conclusions

This study shows that parental formal education and a lower initial Pirani scores were associated with a higher likelihood of the child's parent or guardian being satisfied with the outcome of Ponseti treatment. Ambulation without deformity was higher with the application of more casts, but lower with frequent clinic visits. These treatment outcome measures can be explored in further studies to ascertain if they complement each other and if they are good indicators of longer-term prognosis in the treated foot.

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Conflicts of interest

There are no conflicts of interest.

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