Post-ponseti bracing compliance in Egyptian population during treatment of idiopathic talipes equinovarus

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Background
Several factors may play a role in influencing family acceptance of brace protocol after successful initial correction of talipes equinovarus by Ponseti method.
Patients and methods
A total of 40 children presented with relapsed sixty idiopathic talipes equinovarus were included. Their age ranged from 8 to 24 months, with a mean of 16 months. Twenty patients (40 clubfeet) (66.6%) were bilaterally affected, and 20 patients (20 club feet) (33.3%) were unilaterally affected. The patients comprised 25 (60%) boys and 15 (40%) girls. Pirani score was used to assess the relapse and severity. Several factors affecting bracing compliance in Egyptian population were studied and analyzed.
Results
The number of children per family, the ability of one parent alone to apply the brace, residence of parents, the baby's compliance, bracing hour compliance, and parents get fed up early from using the brace had statistically significant relation with brace noncompliance.
Conclusion
Proper instructions, education, and encouragement to the parents in the proper use of the postcorrective brace are crucial factors for success of clubfoot treatment by Ponseti method.

Keywords:
clubfoot, foot abduction brace, Ponseti

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Introduction

Congenital talipes equinovarus (TEV), or clubfoot, is a common deformity where the affected foot is turned inward. It occurs in every 1.2/1000 live births [1].

Nowadays, conservative treatment is generally accepted as the first choice for correction of clubfoot, and the most popular approach is the Ponseti method, which consists of serial manipulations and specific casting along with or without an Achilles tenotomy [2–5].

The foot correction achieved by Ponseti's method should be maintained using a well-designed foot abduction brace to prevent relapses [6].

Although success has been achieved in obtaining the initial correction in clubfeet, maintaining the correction is more challenging. The most common problem is the poor compliance with brace wear [6]. Bracing is a very important component of the treatment for clubfoot. Adherence to proper bracing protocol is crucial factor for the long-term success of the treatment [1].

The aim of this study was to evaluate bracing compliance in Egyptian population during treatment of idiopathic TEV by Ponseti technique.

Patients and methods

A total of 40 children who presented with relapsed 60 TEV were recruited in this work. The age ranged from 8 to 24 months, with a mean of 16 months. Twenty patients (40 clubfeet) (66.6%) were bilaterally affected, and 20 patients (20 club feet) (33.3%) were unilaterally affected. Twenty-five (60%) patients were boys and 15 (40%) girls. There were no associated anomalies.

All feet were treated by Ponseti technique [7], followed by locally fabricated foot abduction brace foot abduction brace (FAB). The foot piece was adjusted at 15° dorsiflexion and 60°–70° of external rotation. In unilateral cases, the normal one was adjusted at 45° external rotation. The parents were told that the brace should be applied for 23 h/day, during the first 3 months. After that, they were instructed to apply the brace for 12 h at night for 3–4 years. Tendo-Achilles tenotomies were performed for 45 (75%). All parents reported successful initial correction. The age at the start of

treatment was ranged from 2 weeks to 3 months. The initial treatments were performed at our institute by different orthopedic surgeons. The data of initial treatments were collected from the hospital records of 300 club feet. The relapse was defined as a return of one or more of the components of the clubfoot deformity that required recasting or surgery.

Each clubfoot was assessed by the Pirani system [8]. The relapse patterns were assessed according to the classification pattern of Bhaskr and Patni [9].

Direct questionnaires were obtained from the parents during interview in the clinic: the sex and age of the patient, educational level of parents, income, the number of children per family, the side involvement (unilateral/bilateral), the ability of the parents to contact the treating team, the ability of one parent alone to apply the brace, residence of parents, social relation (separation, divorce, . . .), and body weight of patients.

An approval was given by the institutional review board, and informed consent was obtained from each parent.

Method of statistical analysis

Statistical analysis was performed using the statistical program for the social sciences (SPSS, IBM, New York, United States), version 20. *t*-Test was used to analyze the relations between the obtained results and the different variables. The results were considered to be significant at *P* value less than 0.05.

Results

Between 2012 and 2017, 40 patients with 60 relapsed club feet were studied. All were treated by Ponseti technique, and the parents reported successful correction after the last cast removal. The age at the time of relapse ranged from 8 to 24 months, with a mean 16 months. The Pirani score ranged from 2.5 to 4 points, with a mean three points. Family demographic data with respect to the brace compliance were analyzed (Table 1).

Forty (67%) feet presented with relapsed dynamic forefoot adduction, 10 (17%) with fixed adduction of forefoot and midfoot, five (8%) with decrease in ankle dorsiflexion from 15° to neutral, and five (8%) with two or more fixed deformities (Fig. 1).

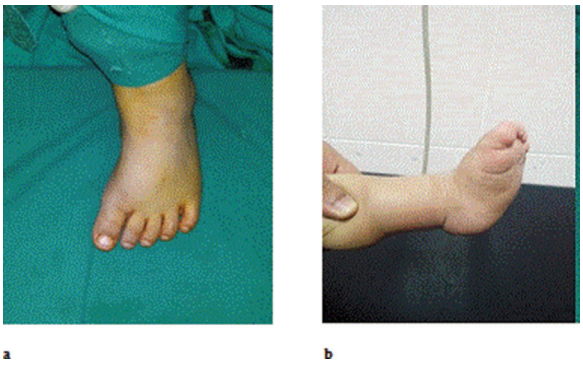
There were 30 (75%) of patients of less than 2 months and 10 (25%) were of 2 months and older. The age of the patients had no statistically significant correlation with brace noncompliance (*P*=0.23). There was no

Table 1 Family demographics and brace factors

Variables	*N* (%)	*P* value
Age at start of Ponseti (months)		
<2	30 (75)	0.23
≥2	10 (25)	
Sex		
Males	25 (60)	0.43
Females	15 (40)	
Education level of parents		
High	18 (45)	0.10
Low	22 (55)	
Income		
Reasonable	16 (40)	0.30
Low	24 (60)	
The number of children per family		
≤2	5 (12.5)	0.001*
≥3	35 (87.5)	
Side		
Bilateral	20 (50)	0.56
Unilateral	20 (50)	
The ability of the parents to contact		
Able	15 (40)	0.43
Difficult	25 (60)	
The ability of one parent alone to apply the brace		
Able	10 (25)	0.003*
Unable	30 (75)	
Residence of parents		
Rural	35 (87.5)	0.001*
Urban	5 (12.5)	
Social relation		
Good	16 (40)	0.30
Bad	24 (60)	
Body weight of patients		
Overweight	17 (42.5)	0.07
Normal	23 (57.5)	
Bracing instruction clarification		
Yes	40 (100)	0.876
No	0	
Brace is expensive		
Yes	10 (25)	0.30
No	30 (75)	
The baby compliance		
Calm	15 (40)	0.003*
Irritable	25 (60)	
Bracing hour compliance		
Yes	10 (25)	0.003*
No	30 (75)	
Parents got fed up early from using the brace		
Yes	35 (87.5)	0.001*
No	5 (12.5)	
Times of brace change		
1	5 (12.5)	0.12
2	5(12.5)	
3	20 (50)	
4	10 (25)	

*significant= <0.05.

Figure 1



(a) Relapsed dynamic forefoot adduction. (b) Relapsed dynamic equinus.

Figure 2

A 2-year-old child after initial successful correction by Ponseti method. The clubfoot relapsed. The parents did not change the brace. The foot was bigger than the brace and did not fit. The parents got fed up early of bracing. They did not contact the treating doctor for a long period. There were social troubles.

statistically significant effect of the sex and the side affected on brace noncompliance (P=0.43 and 0.56, respectively). The education level of parents was low in 22 (55%) and high in 18 (45%). Overall, 24 (60%) patients were from low-income and 16 (40%) were reasonable-income family. Both the education level and income had no statistically significant correlation with brace noncompliance (P=0.10 and 0.30, respectively). Although 25 (60%) parents had difficulty in contacting the treating team, it had no statistically significant effect on brace noncompliance (P=0.43). Moreover, parents of 35 (87.5%) patients had three or more children, which had a statistically significant effect on brace noncompliance (P=0.001). In 30 (75%) families, one parent alone could not apply the brace, and this had statistically significant correlation with brace noncompliance (P=0.003). There was a significant effect of parent's residence on brace noncompliance (P=0.001) where 35 (87.5%) families were living in rural and five (12.5%) in urban areas. Troubles in social relation (divorce and separation) were found in 24 (60%) families, but they had no statistically significant effect on brace noncompliance (P=0.30). There were 17 (42.5%) overweight (BMI at or above the 85th percentile and below the 95th percentile for children and teens of the same age and sex) [10] and 23 (57.5%) normal babies. The body weight of babies had no statistically significant effect on brace noncompliance (P=0.07). Overall, 25 (60%) babies were crying and irritable during bracing period with disturbed sleep, and this had statistically significant effect on brace noncompliance (P=0.003). A total of 35 (87.5%) parents got fed up early from using the brace, and this had a statistically significant effect on brace noncompliance (P=0.001). The bracing hour compliance was present in 30 (75%) families, and it had a statistically significant effect on brace noncompliance (P=0.003). The brace was changed only once in five (12.5%) patients, changed two times in five (12.5%), three times in 20 (50%) patients, and four times in 10 (25%) patients. The times of brace changes had no statistically significant relation with brace noncompliance (P=0.12; Fig. 2).

Discussion

Recently the Ponseti technique of clubfoot has gained considerable popularity, with a success rate of more than 90% for initial correction. However, relapses are not uncommon, and the rate varies from 10 to 30% depending on the amount of follow-up [11–13].

Several factors have been associated with relapse following initial correction of clubfoot deformity using the Ponseti method. Bracing is a very important component of the Ponset's technique for treatment of clubfoot. Adherence to the bracing protocol is a crucial factor associated with the long-term success of the treatment [1]. Noncompliance with brace use was found to be the most critical factor leading to clubfoot relapse after a successful initial correction with the use of the Ponseti technique [14–16]. Clinical research on the use of the Ponseti method for idiopathic clubfoot has shown rates of noncompliance with the use of a postcorrective FAB ranging from 32 to 61% [16].

Goriainov *et al*. [17] defined relapse as any deformity occurring after the start of the FAB that required further treatment. In their study, 17 feet of 80 relapsed after a mean period of 23 months after the initiation of the FAB. They excluded children who had had primary treatment elsewhere. In this study; dynamic forefoot adduction was the common type of relapse (40 of 60 feet). Bhaskr and Patni [9] reported

that dynamic forefoot adduction or supination that manifests as intoeing was the most common type of relapse pattern seen with the Ponseti technique and was seen in 24 of 91 children. They also found splint compliance was compromised in both their groups of patients (bilateral and unilateral groups). Only 10 (10.98%) children wore the FAB for the recommended 12 h at bedtime. These 10 children had mild flexible relapses. A total of 81 children had poor compliance (89%); 39 of these were flexible relapses, 25 progressed to rigid equinus or adduction deformity, and eight progressed to full relapse of their clubfoot deformity requiring a complete subtalar release. Thus, they found noncompliance with FAB was associated with worse outcome.

Porecha *et al*. [18] studied 49 children with clubfeet treated with the Ponseti technique after a mean follow-up of 5 years. They used the functional Ponseti scoring system to analyze their results. Fourteen (28%) children presented with relapse at varying age groups and poor compliance with the orthosis was identified as the main cause.

Several factors may play a role in influencing family acceptance of brace treatment. Dobbs *et al*. [4] showed that low levels of education (high-school education or less) were more frequent among noncompliance parents and were considered to be a significant risk factor for the recurrence of clubfoot deformity after correction with the Ponseti method. In this study, the education level of parents was low in 22 (55%) and high in 18 (45%) children. but it had no statistically significant relation with brace noncompliance. Jawadi *et al*. [19] found no statistically significant relation between the education levels of parents and brace compliance. Parents frequently report that bracing makes their child fussy and limits movement [20]. This was agreed with the findings in this study, where 60% of babies were irritable and crying during brace application with difficult sleep; often when the bay cries, the parents remove the brace, and this had a statistically significant effect on brace noncompliance (P=0.003). Frequent removal of the brace can lead to relapse of the deformity.

Although instructions were given to all parents in this study, some failed to understand the importance of bracing to the success of the treatment, whereas others forget or were confused regarding the instructions, or were unplanned, decreasing bracing hours. This problem was reported by others in other countries [20,21], and also, it is not related to the educational or financial level, but was mainly emotional.

Dobbs *et al*. [4] reported that psychosocial factors, such as the stigma associated with prolonged use of an orthosis, may affect compliance. This was agreed with this study, where 35 (87.5%) parents got fed up early from using the brace and that had a statistically significant effect on brace noncompliance (P=0.001).

In this study, 35 (87.5%) parents had three children or more, and it was found to be a significant risk factor for brace noncompliance (P=0.001) .This factor is important in Egypt, because most Egyptian families have three or more children, which might explain the decrease of parental care and compliance with brace use.

There were 35 (87.5%) parents from rural areas, and this might explain the difficulty in contacting the treating team among 25 (60%) cases owing to difficult transportation methods as well as the low income. The residence of parents was a significant risk factor of brace noncompliance (P=0.001). In 30 (75%) families, one parent alone could not apply the brace, which had significant effect on brace noncompliance (P=0.003). In addition, 24 (60%) families had bad social relations (divorce and separations), and the care decreased with poor brace compliance.

In this study, a locally fabricated static FAB was used. It was relatively cheap and affordable by 30 (75%) of patients (average of 350 Egyptian pounds). The static nature of the brace might explain the discomfort of some infants, but it is widely used in our country with high success rate. Others believed that using a dynamic foot abduction orthosis resulted in improved compliance compared with a standard straight abduction brace denis brown bar (DBB) [22]. On the contrary, others concluded that the new and more expensive brace design did not provide better compliance results compared with the DBB. They found that a strong family-treatment team partnership is crucial to adherence with the brace protocol [23,24].

Conclusion

Although initial correction of the clubfoot deformity can be easily achieved by Ponseti method, the challenge lies in preventing relapse. The key to maintaining initial correction of the foot lies in proper instructions, education, and encouragement of parents in the proper use of the postcorrective brace, especially among parents at risk of noncompliance.

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Conflicts of interest
There are no conflicts of interest.

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