ORIGINAL ARTICLE

Difficulties in maintenance of clubfoot abduction brace and solutions — maintenance of clubfoot abduction brace, locks and keys

Iftikhar Memon,[1] Anisuddin Bhatti,[2] Parvez Ali,[3] Kashif Mahmood,[4] M. Saeed Minhas[5]

Abstract

Objective: To determine the frequency of early relapse after achieving good initial correction in children who were on clubfoot abduction brace.

Methods: The cross-sectional study was conducted at the Jinnah Postgraduate Medical Centre, Karachi, and included parents of children of either gender in the age range of 6 months to 3years with idiopathic clubfoot deformities who had undergone Ponseti treatment between September 2012 and June 2013, and who were on maintenance brace when the data was collected from December 2013 to March 2014. Parents of patients with follow-up duration in brace less than six months and those with syndromic clubfoot deformity were excluded. The interviews were taken through a purposive designed questionnaire. SPSS 16 was used for data analysis.

Results: The study included parents of 120 patients. Of them, 95(79.2%) behaved with good compliance on Denis Browne Splint, 10(8.3%) were fair and 15(12.5%)showed poor compliance. Major reason for poor and non-compliance was unaffordability of time and cost for regular follow-up. Besides, 20(16.67%) had inconsistent use due to delay inre-procurement of Foot Abduction Braceonce the child had outgrown the shoe. Only 4(3.33%) talked of cultural barriers and conflict of interest between the parents. Early relapse was observed in 23(19.16%) patients and 6(5%) of them responded to additional treatment and were put back on brace treatment; 13(10.83%) had minor relapse with forefoot varus, without functional disability, and the remaining 4(3.33%) had major relapse requiring extensive surgery. Overall success was recorded in 116(96.67%) cases.

Conclusion: The positioning of shoes on abduction brace bar, comfort in shoes, affordability, initial and subsequent delay in procurement of new shoes once the child's feet overgrew the shoe, were the four containable factors on the part of Ponseti practitioner.

Keywords: Abduction brace, Clubfoot, Congenital, Idiopathic, Relapse, Talipes Equino Varus. (JPMA 64: S-70 (Suppl. 2); 2014)

Introduction

All non-operative treatments, including Ponseti management, correct idiopathic clubfoot deformity, but do not remove the cause of clubfoot, which has a stubborn tendency to recur when the correction achieved is not maintained properly for due time. Parents' frustration with relapse of deformity is exhibited with loss of confidence in treatment, discontinuation of treatment (maybe for some time) and recourse to poor compliance for brace. Impatient parents thenopt for other treatments, including extensive surgical correction, which entails significant time, cost and more compromised results. The gene responsible for clubfoot deformity remain active with excessive collagen synthesis in ligaments, tendons and muscles until age 3-4 years.[1,2] This tendency to recur lessens considerably by the age of 4-5 years, and hence 91% relapses occur before 5 years and almost rarely after age 7.[2,3] Early relapse occurs with the loss of dorsiflexion, subsequently heel varus, and later adductus develops and sometime cavus reappears. The intervention to correct early relapse is easier than to correct late relapse. Hence, continued care with Foot Abduction Brace (FAB) and regular follow-up after achieving initial correction becomes mandatory. This is, however, a bit difficult for the parents to comply strictly with Ponseti's protocol for FAB to be used for 3-4 years of age[4,5] on account of expenses and time that is required as well as the psychosocial impact, such as the stigma of prolonged use of orthosis, which have an impact on compliance.[6] The inconsistent use of brace and non-compliance have been attributed as major risk factors for the relapse of clubfoot deformity, which occurs in 41% feet.[6-11] Local studies12-14 published so far have reported early successful results approaching 96%and persistent deformities corrected with extensive surgery in 4%-10% cases. They have not addressed the issue of relapse and non-compliance. Therefore, the current study was designed to recognise factors related to poor compliance, including psychosocial factors. The recognition of non-compliance factors shall help us develop future strategy to contain these risk factors with early intervention to improve compliance and outcome.

Department of Orthopaedic Surgery, Jinnah Postgraduate Medical Centre (JPMC), Karachi, Pakistan.

Correspondence: Anisuddin Bhatti. Email: dranisbhatti@gmail.com

Subjects and Methods

The cross-sectional study was conducted at the Jinnah Postgraduate Medical Centre, Karachi, and included parents of children of either gender in the age range of 6 months to 3years with idiopathic clubfoot deformities who had undergone Ponsetiserial manipulation and castings on a weekly basis between September 2012 and June 2013, and who were on maintenance brace when the data was collected from December 2013 to March 2014. Parents of patients with follow-up duration in brace less than six months and those with syndromic clubfoot deformity were excluded. The interviews were taken through a purposive designed questionnaire.

After achieving initial correction with Pirani score 0-0.5, with or without Per-Cutaneous Tendo Achilles Tenotomy (PCTAT), FAB (Denis Browne Splint) was applied on the day when the last cast was removed. The parents were trained for applying the FAB for 23 hours a day, off for an hour and its re-fixing. Continued in this way for three months and thereafter, applying brace at night and nap till the child was over three years of age, or for one year in children who started the brace after two-and-a-half years of age. Parents were also taught about positioning of both shoes rotated externally on the abduction bar for 70 degrees in bilateral deformity; whereas, in unilateral cases, the affected foot was held at 70-degree external rotation and the normal foot at 30-40 degrees and the bar was curved with convexity away from the child for 10-15 degrees to hold the feet in dorsiflexion of feet.[2,15] They were trained to ensure that the heel was seated in the bottom of the shoe, confirmed through rear bottom inspection hole. Parents were also taught to exercise the child's knee together as a unit (flex and extend) in the brace, to customise the baby to move legs simultaneously. Otherwise child may frustrate with interference of the bar when singles move alone.[2] They were briefed to check for skin red spot or blister when the child cries excessively. The education brochures in local language were given to parents on each visit and they also got knowledge about how to apply, remove and re-apply FAB through wall-mounted posters in the local language while they were waiting at the Clubfoot Clinic. In the later phase of study, to overcome the vendors' supply delay and varied fabrication of shoes, the FAB stock of 22 pair of 8cm to 13cm shoe sizes and three sizes of bars were made readily available in each clinic. However, before June 2013, this problem was covered by taking measurement of one affected feet in bilateral and of the normal foot in unilateral deformities on the day before the last cast was applied for 3 weeks. We made an indigenous "template" for shoe sizes with marking made for 8cm to 13cm shoe sizes (Figure 1-A). The measurement was made by placing patient's foot on matching shoe size template (Figure 1-B). This would indicate the inside size for the shoe required. By the time the cast was removed after 3 weeks, the vendor would have supplied the FAB with matching size.

Patients with follow-up duration in braceless than six months were excluded and so were those having clubfoot associated with teratogenic/spastic/paralytic/syndromic and/or other musculoskeletal disorders.

The study was conducted with the approval of the institutional review board, and with prior informed written consent from parents taken during briefing when the first cast was applied, and again during the interview for this study. All parents signed a written consent for publication and display of photographs.

The parents were interviewed through a purposive designed questionnaire related to brace compliance/problems. The assessment of non-compliance factors for FAB and relapse was made through the questionnaire and the purposive predesigned proforma. The factors included fabrication of shoes, ill-fitting, bar length, parents' affordability in terms of cost, time and travel, parents education level and psychsocial factors. Compliance was defined as 'strict adherence to brace wear protocol in accordance with Ponseti'steaching'.[1,2] Early relapse was defined as loss of correction achieved with Ponseti treatment that required additional casts with or without minor surgery. Signs of early relapse were defined with reference to Ponseti.[1,2] Demographic data, findings of clinical examination, Pirani scoring and FAB status made on each visit and on the last visitwas retrieved from the soft and hard files maintained for each patient.

The collected data was analysed using SPSS 16 software. Mean and standard deviation (SD) were calculated for age. Frequency and percentages were calculated for gender, foot affected and outcome variables like early relapse and compliance (yes/no). Effect modifier was controlled through stratification of data with age, gender and foot affected to see the impact of these on outcome variables. Post-stratification, chi square test was applied and $p<0.05$ was considered significant.

Results

The study included parents of 120 patients whose age range at last follow-up was between 3 months and 3 years with a mean of 2.57±1.18 (p=0.001). The most common age group was12-18 months in 47(39%). The female-to-male ratio was 1:1.3. Unilateral versus bilateral clubfoot deformity ratio was 1:1.4 (Table-1).

Table-1: Patients age at the time of interview from parent, last visit.

◆ 9-12 Months, Non walker	23 (19.17%)
◆ 12-18 Months, Non walker	23 (19.17%)
◆ 12-18 Months, Walker	24 (20%)
◆ 18-24 Months, Walker	34 (28.34%)
◆ 2-3 Years, walker*	5 (4.16%)
◆ 3 + years, walker‼	11 (9.16%)
◆ Total	120 children

*80% of them continued Foot Abduction Brace, 2(1.67%) have minor relapse, ‼: all discontinued Foot Abduction Brace, 3 (2.5%) have minor relapse.

Table-2: Compliance and relapse rate.

Compliance; Good: 79.17% (95). Fair: 8.33% (10).	Poor: 12.5% (15)
Typical Responsive Feet Patients, no relapse	80.83% (97)
EARLY Relapse:	19.17% (23)
Atypical feet Patients, responded after additional treatment	5% (6)
Residual, minor, acceptable forefoot Varus deformity	10.83% (13)
Resistant feet Patients needed extensive surgery, failure	3.33% (4)
Overall Success Rate (116)	96.67%

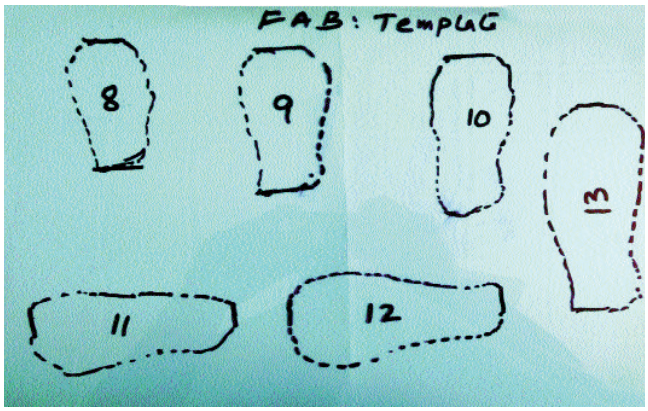

Figure-1-A: The template for measurement, of inside shoe sizes range from 8cm (size 0) to 13cm (size 5). The size 8cm (size 0) often suits to infant of the age of 2months.

In 95(79.2%) cases, the compliance was good, 10(8.3%) were fair and 15(12.5%) showed poor compliance.

Early relapse was observed in 23(19.16%) patients and 6(5%) of them responded to additional treatment and were put back on brace treatment; 13(10.83%) had minor relapse with forefoot varus, without functional disability, and the remaining 4(3.33%) had major relapse requiring extensive surgery. Overall success was recorded in 116(96.66%) cases (Table-2).

Major reason for poor and non-compliance was unaffordability of time and cost for regular follow-up in 15(12.5%) cases. Besides, 20(16.67%) had inconsistent use due to delay in re-procurement of FAB once the child had outgrown the shoe. Only 4(3.33%) talked of cultural barriers and conflict of interest between the parents (Table-3).

Table-3: Problems notified by parents in FAB wear and compliance.

1: Poor and FairCompliancedue to unaffordability of time and Cost:	n=15
◆ Difficult to reach CFC, long distance	n=8
◆ Cannot afford time to reach CFC	n=7
2: Inconsistent Use due to uncomfortable Shoes:	n=17
◆ Hard leather, cutting margins, not using shoe tongue	n=1
◆ Pressure sore	n=7
◆ Abduction bar wider than Shoulder breadth causing knee valgus deformity	n=9
3: Inconsistent use due to Psycho-Social Issues	n=4
◆ Parents & Guardians conflict of interest and lack of cooperation in completion of treatment with FAB	
4: Problem Fabrication of Shoes:	n=51
◆ Looseness of bolt	n=8
◆ Frequent slippage of foot from shoe, Posterior High top, Vertical slope	n=13
◆ Heel not touching Platform	n=8
◆ Placing Cotton/Foam / cloth pad under heel	n=2
◆ No inspection hole in Shoes:	n=20
5: Vendors Factors:	n=20
◆ Delayed supply: (in early 8 months) they were given another cast for 1-2 weeks till availability of FAB, this include 09 case with small size shoes	
6: Physician Factors: incomplete, inconsistent counselling and behaviour. Number could not be evaluated particularly at Public hospital care. And it was a limitation of study that multiple personnel'swere involved in counselling and parents' education. However, deficiencies were there.	

All these issues occurred at various times in different patients, but the relapse occurred only in 23 patients.
FAB: Foot Abduction Brace.

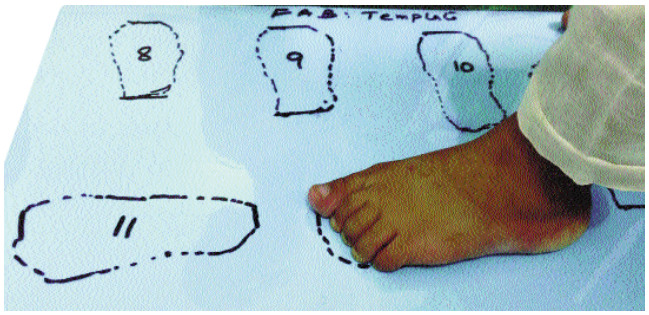

Figure-1-B: Method of measuring inside shoe size for a child needing FAB.

Discussion

The congenital clubfoot deformity (CCFD) is one of the most common foot deformities that may impede child's physical, emotional, economic and social development when not treated successfully or left untreated. When they grew up with deformed feet, the feet become painful, deformed, restrict their social life, economic wellbeing, and cause much frustration to the family.[16]

Clubfoot is a preventable deformity that just needs early non-operative intervention, which can be started at any age in childhood before it becomes a fixed bony deformity. Morcuende[10] reported no increased difficulty in correcting the deformity in children up to the age of 2 years or in patients who previously had a non-surgical correction attempt. The Ponseti technique of serial manipulation, specific technique of cast application with a possible PCTAT, has been proved superior to other non-operative techniques. "The method has been reported to have short-term success rates approaching 90%, and equally impressive long-term results.[6,17] Morcuende10 reported that >95% of idiopathic clubfoot can be corrected without the need for extensive corrective surgery. Ponseti management is based on two phases. Phase one includes three steps: screening for foot deformity, confirmation of clubfoot deformity, correction of deformity by 4-6 weekly serial manipulations and casts, with or without PCTAT. More than 80% of the deformities get completely corrected within 2 months of the initiation of treatment.[10] The second phase is the longest one spanning over 3-4 years, where relapse of deformity is prevented by FAB. This phase of brace treatment requires dedication, meticulous care on the part of both the treating physician and the parents.[9] Almost every Ponseti practitioner has reported the bracing phase as an essential part of management for the success of treatment.[6-9,11,18] Further to that, Herzenberg[18] and Morcuende[10] have called orthotic treatment "a critical part to avoid recurrence", and its successful use reduces the need for extensive surgical release upto 58%-95%.[10,18] Dobbs,[6] Ramirez,[7] Haft,[8] Avilucia,[9] Morcuende[10] and Thacker[19] suggest strong association of non-compliance with brace-wear to increase the risk of relapse. Haft[8] considered bracing as a crucial part of the treatment, reporting five times greater chance of having a recurrence in non-compliant than compliant families. Morcuende[10] observed that non-compliance was associated with 17 times greater odds of relapse (15 of 17) compared with compliance (6 of 14). He further reported second relapse in 2.5% cases that were non-compliant and required tibialis anterior tendon transfer (TATT). In another study by Morcuende,[20] the relapse rate was reported as 80% in non-compliant and 6% in compliant families. Abdelgawad et al[11] reported significantly high (16%) rate of relapse in compliant families compared to 6% reported by Morcuende[10] and others.[8,9,10] It was also higher than most other studies.[8-10,20] However, Abdelgawad[11] reported this high rate with Ankle Foot Orthoses (AFO) instead of FAB. The AFO is not recommended by Ponseti's teaching, as the abduction of foot is difficult to be maintained with AFO and it reproduces high rate of relapse. Out of 23 relapsed patients in our study, 6 were among compliant families. One of them was using pad under the heel to accommodate heel-raise within the shoes. The other one developed second and third relapse after additional treatments despite good brace compliance. He was lately diagnosed to have neurological involvement of S1, L5 nerve root agenesis. The other 4 patients relapsed because of inconsistent use due to delayed procurement of the brace. The remaining patients with relapse were among the non-compliant families or those who discontinued FAB. The underlying muscle imbalance and ligament stiffness of the foot[15,20] has been cited as the cause for relapse in the compliant group, and it is further reported to have less severe relapse, minor forefoot varus in compliant families compared to the non-compliant ones.[19] This was also seen in our study that minor residual deformities, like forefoot varus without functional disability,[19,21] were more in the compliant group compared to the noncompliant.

Literature from Pakistan,[12,14] India[15] and Africa[21] has reported successful results with Ponseti treatment ranging from 98%-100%, but have not thoroughly assessed the issues of relapse and compliance. They have generally associated relapse with initial severity, age at presentation, ethnicity, cultural barriers and travel distance to treatment sites. The present study and reports by Haft[8] and Morcuende[10,20] find no significant relationship of relapse with age at presentation, previous unsuccessful treatment, complexity or intrinsic severity of the deformity, number of casts required for correction, ethnicity or family history of clubfoot. Haft,[8] Aviluceia,[9] however, have reported some relationship of cultural factors coupled with the distance from the site of care and caregivers' tolerance to increased incidence of relapse, recurrence, partial compliance and non-compliance. In our interviews with parents, the cultural factors and the distance to travel was the second highest reason for inconsistent use of FAB and non-compliance. The cultural factors were more apparent among parents from higher societies. They discontinued FAB while attending festivals and parties, often did not re-apply FAB on that night, some discontinued on religious holidays and with this relaxation, the child avoided to wear FAB again. When child started crying and kicking on bed, the compassionate parents removed the brace to alleviate the discomfort. Without brace, the deformity recurs and gradually becomes more severe.

Cultural non-compliance was less often obvious in patients from rural population than urban. Whereas the inconsistent use and premature discontinuation of the brace was more in rural than urban area patients, majority

of these parents related discontinuation with low income, affordability of time and travel due to work engagements. Avilucea[9] referred to this issue as: "cultural factors coupled with the distance from site of care results in difference in clinical outcome"; he considered FAB after cast treatment as key factor in success or failure of the Ponseti method. We were able to contain these issues in later half of the study by making repeated calls to parents, counselling and arranging good inventory of FAB. About a couple of dozen pairs of all shoe sizes were arranged and provided free/partially free of cost, as charity or donations. This significantly improved compliance and encouraged parents to continue the treatment. Procurement from single vendor also helped to contain shoe fabrication factors leading to children intolerance to FAB. Skin blister formation due to friction at heel in wide shoes, at dorsum by rubbing with tongue of the shoe that were used without socks due to hot weather was another factor for kids' intolerance. The kids' non-acceptability with continuous crying and kickingled to intolerance in four parents, leading to inconsistence use and frequent discontinuation of FAB. This raised significant conflict of interest in two families, but one of the grandparents continued to bring the child repeatedly for treatment of the relapse that was again resolved after repeated counselling. Regarding acceptability of FAB, Avilucia[9] observed that the distinction between when the infant is merely annoyed by the brace and when he or she is expressing pain is difficult to ascertain. However, to contain these issues excellent communication between the physician and the family is really required.[9,11,15] We could overcome the issue of cultural, social and financial barriers with frequent telephone calls and counselling, to partial/poor compliant parents, especially those who had not attended clinics in the preceding three months. The significant change in mindset was also observed in parents when the number of parents interact with each other while waiting in clinics and reading education material, wall-mounted and clubfoot fliers. Haft,[8] Dobbs,[6] Avilucia[9] and Gupta[15] also emphasised on this issue and observed that integrated approach, proper motivation and persuading the parents to accept long-term brace treatment that helps to maintain correction over a longer period of time and prevents relapse.[15] However, 'no level of motivation can compensate for an imperfect brace'.[22] The articulated foot abduction dynamic brace has been introduced recently with significantly low rate of non-compliance; as low as 7%.[22] Minimum non-compliance is reported due to maximum acceptance by the children and comfort with dynamic orthosis. However, we have no experience with dynamic brace to comment on.

Conclusion

The positioning of shoes on the abduction bar, comfort in shoes, affordability, initial and subsequent delay in procurement of new shoes are the four containable factors on the part of Ponseti practitioners. The continuation of brace treatment over three years of age and psycho-social factors are also easy to contain with timely counselling during parents' visits or with frequent telephone calls to poor-compliant parents. Measuring shoe size on the day of the last cast can also easily contain the delay on the part of vendors. The other way is to make available the stock of braces required for at least two months. Here comes the two real challenges for Ponseti practitioner to overcome; one to get persistence and long-term adherence to FAB, which is the key factor. Second one is the success of educating the parents and family regarding their role in the maintenance of correction.

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