

Causes of Non-compliance of Foot Abduction Orthosis amongst Local Patients of Relapse Idiopathic Club Foot

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ABSTRACT

Background: Clubfoot is the most common lower extremity birth defect. It causes the feet of affected individuals to point inward and downward thus preventing them from walking normally. Its treatment ranges from gentle manipulation to less invasive surgery. Foot abduction orthosis is the major method of manipulating the clubfoot, which consists of taping the foot onto a bar to maintain the position obtained by manipulation. **Objective:** The purpose of present study was to determine the causes of non-compliance of foot abduction orthosis amongst relapsed idiopathic clubfoot patients. **Study Design:** Retrospective cohort study. **Sampling Technique:** Non-probability, purposive sampling technique. **Period:** **Setting:** Study was conducted in Outdoor Patient Department (OPD), Paediatric Orthopaedics Department, The Children Hospital and Institute of Child Health, Lahore after ethical approval from committee on research ethics of relevant institute. **Sample Size:** A Sample size of 67 patients was estimated by using 90% confidence level, 1% margin of error with expected %age of compliance (CTEV) as 6 %. **Methods:** Total 67 patients (45 males and 22 females) of age between 1-5 years were selected by non-probability, purposive sampling technique. Dimeglio scoring system was used for evaluation of relapsed deformity. Goniometer was used to check ROM of foot. An approved questionnaire based on the causes for non-compliance of foot abduction orthosis was used for data collection. Data was obtained and percentage of different factors causing non-compliance of foot abduction orthosis amongst relapse idiopathic clubfoot patients was calculated. **Results:** The main causes of non-compliance were financial problems 24(35.82%)M and 10(14.92%)F; emotional reasons of parents 25(37.31%) M(male) and 11(16.41%)F (female); ignorance 12(17.91%)M and 08(11.94%)F; skin problems 15(22.38%)M and 05(7.26%)F; swelling & redness 12(17.91%)M and 10(14.92%)F; infection 05(7.26%)M and 05 (7.26%)F and lack of cosmesis 13(19.40%)M and 05(7.26%)F. Patients (62 out of 67) with multiple reasons were also found. **Conclusions:** It was concluded that major causes of non-compliance in both males and females were financial problems and emotional reasons of parents during manipulation, whereas, the least cause of non-compliance in both males and females was infection.

Keywords: Clubfoot, Ponseti, Males, Females, Multiple reasons.

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INTRODUCTION

Clubfoot, also called congenital talipes equinovarus, can easily be recognized because the cosmetic appearance resembles a club on the end of the leg. This disorder is highly variable with regard to rigidity, severity, and response to treatment¹. When they grew up with deformed feet, the feet become painful, deformed, restrict their social, economic wellbeing, and cause much frustration to the family.² Incidence of clubfoot differs between ethnic groups. In Western countries incidence ranges from 1-1.50 per 1000 live births and in some developing countries goes up to

3 per 1000 live births.³⁻⁵ Male-to-female ratio of deformity was 3 to 1^{3,6}. Most cases were idiopathic but may be associated with other conditions such as spina bifida, cerebral palsy and arthrogryposis. The etiology of idiopathic still remains debated but facts suggests genetic etiology, although inheritance pattern is unclear.⁷ Most of the agreements concerning the treatment of clubfoot are in support of conservative treatment by Ponseti method in its early stage; however, the treatment ranges from gentle manipulations to less invasive surgical treatment. Surgical procedures are predominated by

Ponseti because it is considered as a method that could obtain full and long-lasting correction⁸. Widespread soft-tissue release can result in scarring which may lead to pain, stiffness and recurrent deformity.⁹

Denis Browne described his special foot abduction orthosis for treatment of clubfoot in 1934. Treatment consisted of taping the feet onto a bar to sustain the position obtained by manipulation. Modern commercial foot abduction orthosis consists of adjustable footplates that keep the feet externally rotated, provide the forefoot abduction forces by the shoes and add an external rotation stretching force at the ankles. The bar can often bend, center downward and away from the patient to include a valgus moment at the hind foot. The length should be equal to the width of child's pelvic. Maintenance of correction requires strict devotion to a bracing program. This appliance is worn on a full-time basis for 3 months, or until the child is learning to crawl. Night bracing is continued to age 3 or 4 years.¹

Clubfoot is an avoidable deformity that just needs early non-operative intervention, which occur at any age in childhood before it becomes a fixed bony deformity. The Ponseti management combined with percutaneous tenotomy achieves excellent results but without proper follow-up of bracing program, relapse occurs in more than 80% of non-compliant families while relapse occur only 6% in compliant families.¹⁰ Lack of compliance results mostly in relapse as children have problem in sleeping or wearing foot abduction orthosis, that is why parent counseling is very important in this regard. Bracing play important role in maintenance of corrected clubfoot and allows foot to achieve normal position after tenotomy followed by serial casting. Bracing holds foot not in corrected but over corrected position, so that the normal position of foot could be achieved after correction. Without bracing, it is almost impossible for physician or surgeon to maintain correction.¹¹

There may be different reasons for non-compliance of foot abduction orthosis amongst relapsed idiopathic clubfoot patients. Clubfoot patients can be treated in better way after ruling out the factors involved. Thus, this study was planned to determine the causes of non-compliance of foot abduction orthosis amongst relapsed idiopathic Club Foot Patients.

Research objectives

The purpose of present study was to determine the causes of non-compliance of foot abduction orthosis amongst relapsed idiopathic clubfoot patients.

METHODOLOGY

Retrospective cohort study

Sampling Technique

Non-probability, purposive sampling technique

Period:

Setting

Study was conducted in Outdoor Patient Department (OPD), Paediatric Orthopaedics Department, The Children Hospital and Institute of Child Health, Lahore after ethical approval from committee on research ethics of relevant institute.

Sample Size (Raosoft Software)

A Sample size of 67 patients was estimated by using 90% confidence level, 1% margin of error with expected %age of compliance (CTEV) as 6 %.

$$n = z^2 \cdot p \cdot q / d^2$$

Z=confidence level 90 %

p=compliance rate

q=1-p

d=margin of error

n= number of patients

Selection Criteria

Inclusion criteria

- Patients in the age range from 1 year to 5 years were selected.
- Both male and female patients were selected.
- Patients were prescribed foot abduction orthosis.
- Patients were well informed about objective of the study.
- Written consent was taken from parents of each club foot patient
- Patients having unilateral or bilateral relapse idiopathic congenital talipesequino-varus (CTEV) / clubfoot were included in the study.

Exclusion criteria

- Patients (both male and female) above 5 years of age.
- Patients with any other disease or disorder i.e. hematological, cardiac, hepatic, renal, respiratory, gastrointestinal disorders.
- Patients with secondary congenital talipesequino-varus (CTEV) / clubfoot due to diseases (spina bifida, polio etc.) or postural.
- Uncooperative patients.

Methodology

For evaluation of relapsed deformity, we used Dimeglio scoring system.¹² It was derived from detail scoring system based on following four parameters;

- Equinus in sagittal plane
- Varus in frontal plane
- Derotation of talus calcaneo-forefoot
- Adduction of forefoot on hind foot in horizontal plane.

This system also includes four additional points for presence of medial crease, posterior crease, cavus and poor musculature. This system has maximum 20 points and deformity can be graded as benign, moderate, severe or very severe. It is shown in Table 1 and Figure 1.

Data Collection and Data Analysis

A questionnaire-based data was collected and the measurements were taken by Goniometer. Collected data was analyzed after calculating the percentage of each observation (parameter). Qualitative variables like gender were also presented as frequency & percentages. Data was presented in the form of Tables and Figures using Microsoft excel version 2007.

RESULTS

There were 67 patients from Outdoor Patients Department (OPD) of Pediatric Orthopedic Surgery, The Children Hospital and Institute of Child Health, Lahore. Out of 67 patients 45 (67.16 %) were males and 22 (32.83 %) were females. Ratio between males and females was 2:1 respectively. Their age ranged from 1-5 years with average of 2.04 years. About 30 (44.77 %) patients were bilateral while 37 (55.22 %) patients were unilateral. In unilateral cases right side is mostly affected, about 27 (72.97 %) patients. Out of 67 patients, 62 patients with multiple causes were found.

Table 1: Dimeglio scoring system for congenital talipesquinovarus (CTEV)

C-Grade	Type	Score	Reducibility
I	Benign	< 5	> 90% soft-soft, resolving
II	Moderate	5 to < 10	> 50% soft-stiff, reducible, partly resistant
III	Severe	10 to < 15	< 50% stiff-soft, resistant, partly reducible
IV	Very severe	15 to < 20	< 10% stiff-stiff, resistant

The main causes of non-compliance of foot abduction orthosis amongst relapse idiopathic club foot patients have been presented in Table 2 and Figure 2 and Figure 3 which shows that the biggest reason of non-compliance of foot abduction orthosis amongst relapse idiopathic club foot male patients was emotional factor (25 out of 67; 37.31%) preceding with financial problem (24 out of 67; 35.82%), skin problems (15 out of 67; 22.38%), lack of cosmesis (13 out of 67; 19.40%), ignorance (12 out of 67; 17.91%), swelling and redness (12 out of

67; 17.91%) and infections (5 out of 67; 7.26%). Similarly, the largest reason of non-compliance of foot abduction orthosis amongst relapse idiopathic club foot female patients was emotional reason (11 out of 67; 16.41%) followed by financial issues (10 out of 67; 14.92%), swelling (10 out of 67; 14.92%), ignorance (8 out of 67; 11.94%) and 5 out of 67 (7.26%) each for skin problem, infection and lack of cosmesis.

Table 2: The causes of non-compliance of foot abduction orthosis amongst relapse idiopathic club foot patients

Causes	Males Patients (%)	Females Patients (%)
Financial Problems	24 (35.82%)	10 (14.92%)
Emotional reasons of parents (irritation, crying of baby etc.)	25 (37.31%)	11 (16.41%)
Ignorance	12 (17.91%)	08 (11.94%)
Skin Problems	15 (22.38%)	05 (7.26%)
Swelling & Redness	12 (17.91%)	10 (14.92%)
Infection	05 (7.26%)	05 (7.26%)
Lack of Cosmesis	13 (19.40%)	05 (7.26%)

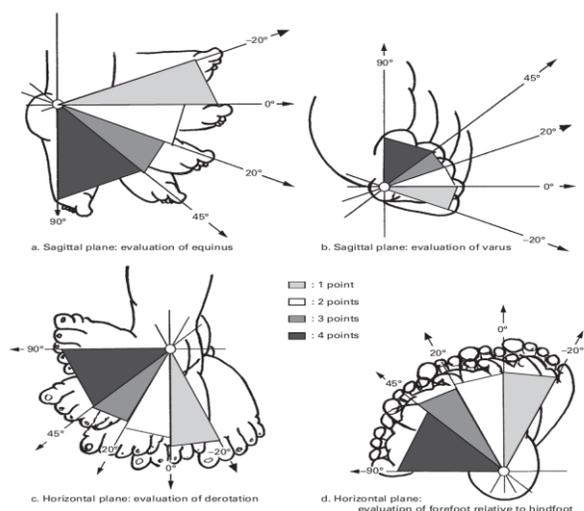


Figure 1: Diagrammatic presentation of Dimeglio scoring system for congenital talipesquinovarus (CTEV)

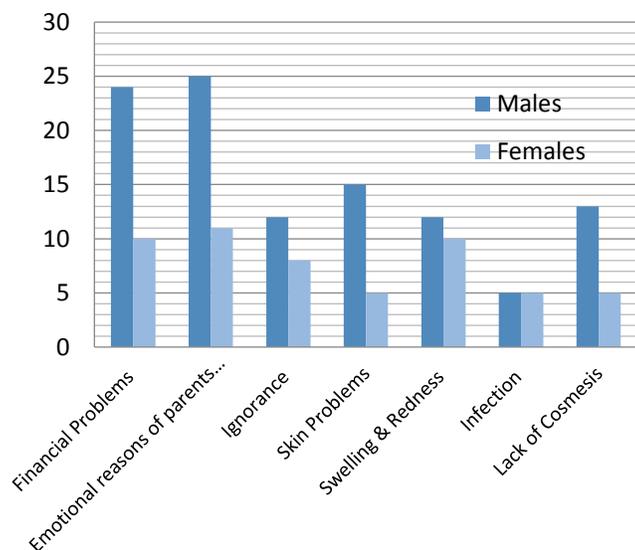


Figure 2: Causes of non-compliance of foot abduction orthosis amongst relapsed idiopathic club foot (No. of Patients)

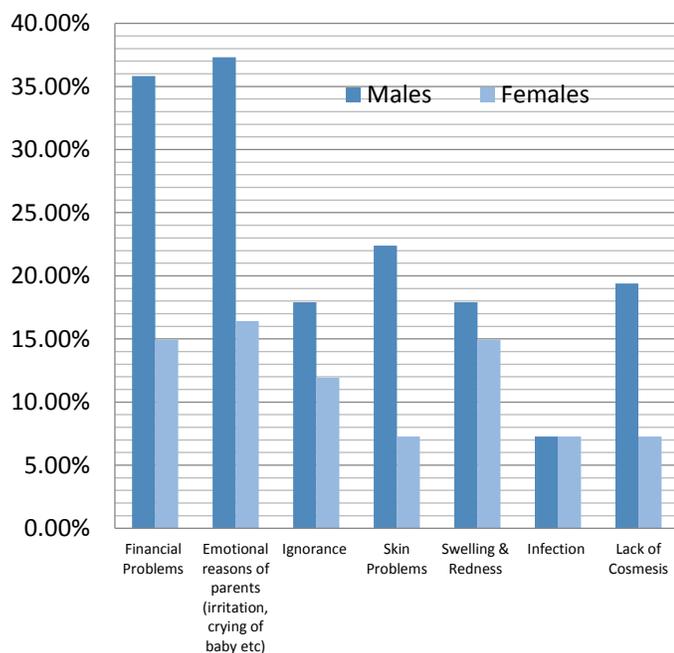


Figure 3: Causes of non-compliance of foot abduction orthosis amongst relapsed idiopathic club foot (Percentage)

DISCUSSION

The congenital talipes equinovarus distortion (CTEV) is a standout amongst the most well-known foot distortion that may obstruct kid's physical, emotional, financial and social improvement when not treated effectively or left untreated. Clubfoot is a

preventable distortion that simply needs early non-invasive intervention, which can begins at any age in childhood before it turns into a settled hard deformation. The Ponseti system of serial control followed by utilization of foot abduction orthosis (FAO), has been demonstrated better than other non-invasive techniques. This study was led to demonstrate the fundamental reason of resistance of FAO in Lahore, Pakistan. Various reasons were discovered and patients with different reasons were likewise found.

The period of support treatment requires devotion, thorough care with respect to both the treating doctor and the parents.¹³ Practically every Ponseti expert has reported the bracing stage as an important part of management for the success of treatment.¹³⁻¹⁷ Moreover, Morcuende¹⁸ have called orthotic treatment "a critical part to avoid relapse", and its successful use declines the requirement for broad surgical release up to 58%-95%. Avilucea¹³, Ramirez¹⁷, Haft¹⁶, Dobbs¹⁴ and Morcuende¹⁸ recommended solid relationship of non-compliance with brace wear to increase the danger of relapse. According to the observations made by Avilucea¹³ the Native American ethnicity, unmarried parents, open or no protection, less parental education and a family salary of under \$20,000 were reasons for recurrence in patients living in a rural area. The non-compliance rate was 36% and kids who suspended wearing the brace were 120 times more prone to have recurrence of clubfeet. While in investigation of Dobbs¹⁴ the non-compliance rate was 41% and youngsters who ceased wearing the brace were 183 times more inclined to have recurrence of clubfeet. Haft¹⁶ considered bracing as a vital part of the treatment, reporting five times more chance of having relapse in non-compliant than compliant families. Morcuende¹⁸ proposed that non-compliance was linked with 17 times more chances of relapse compared with compliance. In another study by Morcuende¹⁹, the relapse rate was 80% in non-compliant and 6% in compliant families. Abdelgawad¹⁵ observed a relapse in 60% of clubfeet in kids who were not ready to utilize the FAO as recommended contrasted with a relapse in 16% of clubfeet in patients who were consistent with the FAO protocol follow up for 3 years or more. In the investigation of Jawadi²⁰, more children per family, unilateral clubfoot and the failure of a single parent alone to apply the brace were observed to be significant factor for non-compliance of brace. In another study, the non-compliance of new dynamic and conventional FAO was compared. It was found that non-compliance was accounted for in just 2

(7.1%) of the 28 patients in the new dynamic FAO contrasted to authors' already reported 21 (41%) of 51 patient's non-compliance rate in patients treated with the utilization of the conventional FAO. There were 2 patients (7%) who experienced skin irritation in the new orthosis compared with 12 (23.5%) of 51 patients who experienced irritation with the utilization of traditional orthosis.²¹ In a study conducted by Zhao²², the most widely recognized explanation behind non-compliance with the brace treatment is distress. Numerous authors reported that orthosis intolerance ranges from 0% to 51%. In another investigation, real purpose behind poor compliance was lack of time and cost for regular follow-up in 15 (12.5%) cases. Additionally, 20 (16.67%) had inconsistent use because of postponement in re-obtainment of FAO once the kid had outgrown the shoe. Just 4 (3.33%) discussed social obstructions and conflicting situation between the parents.²³ Porecha²⁴ reported poor compliance with the FAO which was thought to be the primary reason of disappointment in these patients. In 9 patients out of 14 relapse clubfoot cases the FAO was utilized rarely and it was never utilized in 5 patients.

Studies conducted by researchers in Pakistan^{8, 25}, India²⁶ and Africa²⁷ have reported effective results (98%-100%) with Ponseti treatment. They have related their results of relapse with seriousness, age, ethnicity, social boundaries and travelling distance to treatment destinations. In contrast to it the investigations of Ramirez¹⁷, revealed the utilization of the FAO is to a great degree important with the Ponseti procedure result (relapse) in the treatment of idiopathic talipes equinovarus. However, non-compliance was not related with family education, society or income.

Reports presented by Haft¹⁶, Morcuende¹⁸ and Morcuende¹⁹ found no critical relationship of relapse with age at presentation, past unsuccessful treatment, complicated nature or characteristic seriousness of the deformation, number of cast required for correction, ethnicity or family history of clubfoot. Haft¹⁶ and Aviluceia¹³, however, have reported some relationship of social components combined with the distance from the site of care and caregivers' resistance to increased frequency of relapse, partial or complete non-compliance.

In our meetings with parents, money related issue and emotional state of parents were two primary explanations behind conflicting utilization of FAO and non-compliance. A large portion of patients in our organization came from distant areas and there were not monetarily strong, that is the cause behind why they cannot manage the cost of regular follow-

ups, travelling and FAO itself. Subsequently, shoes were given partially or completely free of cost. Besides, when child began crying and kicking on bed, the kindhearted parents evacuated the brace to lighten the discomfort. Without brace, the deformation recurs and slowly become more serious. Monetary non-compliance was less seen in patients from urban population than rural. Though the conflicting use and untimely stopping of the brace was more in rural than urban area patients. Skin irritation because of erosion at heel in wide shoes, at dorsum by rubbing with tongue of the shoe that were utilized without socks because of hot climate was another variable for children's resistance. The articulated dynamic FAO has been presented recently with essentially low rate of non-compliance, as low as 7%²¹. Least non-compliance is accounted due to good response by the kids and comfort with dynamic orthosis. In any case, we have no involvement with dynamic orthosis to talk about.²⁸

CONCLUSION

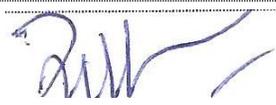
It was concluded that major causes of non-compliance in both male and female children were financial problems and emotional reasons of parents during manipulation, whereas, the least cause of non-compliance in both male and female children was infection. Skin problem and lack of cosmesis were also observed as less common cause of non-compliance in female patients. Training and educating the parents of child patients may improve the compliance of foot abduction orthosis and hence outcome of the therapy too.

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