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A Study on Effectiveness of FAB (Foot Abduction Brace) Using Bracing Protocol By Ponseti Technique in Idiopathic Clubfoot Management.

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Abstract:
Background: *clubfoot also known as Congenital talipes equinovarus (CTEV)is the most common congenital disorder of foot worldwide, with an incidence of 1-3 of every 1000 live births worldwide. It is characterized by easily seen foot deformities- forefoot adduction, midfoot cavus, hindfoot varus and equinus deformity. If left untreated, it is difficult for the child born with club foot to walk and run properly, and social stigma in neglected cases. Pirani scoring system formulated by DR. Shafique Pirani is a reliable method in assessing the severity of deformity in clubfoot and to diagnose recurrences during bracing protocol. Ponseti method of clubfoot management consists of weekly manipulation and above knee castings, percutaneous achilles tendon tenotomy for residual equinus correction and maintenance of that correction in foot abduction brace (Bracing protocol: FAB should we worn for 23 hours a day for1st 3months, later 14 to 16 hours a day upto 4years of age. The child should be reviewed for every 2weeks for the first two months and then 3 to 6 monthly for upto 4years of age). Ponseti technique is the gold standard method for clubfoot management worldwide and should be started immediately or as early as possible after birth.*
AIM: *To achieve painless, functional, normal plantigrade, flexible foot, shoe able with regular shoes, and cosmetically acceptable foot, from a stage of previously deformed foot at birth.*
Objectives: *To analyze the effectiveness of Bracing protocol of FAB after correction of deformities in clubfoot and identifying early recurrences and treating them. The posteriomedial retracting fibrosis resulting in tarsal bone deformations and misalignments is present upto 4years of age after birth in clubfoot. This is the reason for followup to 4years of age in bracing protocol.*
Materials and methods: *A Prospective study was carried out from June 2019 to June 2021 in children with previously untreated Idiopathic clubfoot attending orthopedics opd in government general hospital, Vijayawada.*
Results: *In this study 26 children (43clubfeet) were treated with Ponseti method of clubfoot management followed by FAB, and the results were analyzed during bracing protocol. The mean age at start of treatment for 26 children is 21.8 days and initial mean pirani score before treatment was 4.139. Three children (11.5%) with recurrence of varus deformity was observed in this study on followup in children who are on bracing protocol. The reason for recurrence was found to be noncompliance of children parent's to FAB bracing protocol.*
Conclusion: *Foot abduction brace makes an integral part of Ponseti method of treatment for CTEV, and strict adherence to bracing protocol is required to maintain the foot in normal position (painless, plantigrade, flexible and shoeable with regular shoes)and helps in recognizing the recurrences early during bracing protocol by pirani scoring of foot at each visit and managing them as early as possible in order to minimize the severity of recurrence.*

Keywords: *Congenital, Idiopathic, CTEV, Ponseti, Foot abduction brace, Bracing protocol.*

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I. Introduction

Clubfoot is the most common congenital anomaly affecting worldwide with an incidence of 1 to 3 per 1000 live births. The word Talipes is derived from talipes and pes and applied to those walking with their deformities neglected, so that talus rests on the ground as foot(pes). In Asia 75,000 children, in India, it is estimated that more than 53,000 children and in Andhra Pradesh on an average of 659 children are born

with Clubfoot every year[1]. CTEV may also present with conditions like neuromuscular disease, arthrogryposis (syndromic Clubfoot) Etc., among all, idiopathic Clubfoot is the most familiar presentation which occurs in normal infants. The female to male ratio is 1:2, and 40% of cases are bilateral. Many are having a positive family history. 1% chance in first degree relatives, 10% in siblings, 35% in monozygotic twins, 2% in dizygotic twins. Environmental risk factors include 0.16% chance in heavy maternal smoking, 1.3% in first trimester amniocentesis, 0.1% in mid trimester amniocentesis, 0.24% in maternal diabetes[2].

CTEV has been treated since ancient times, with conservative management techniques such as manipulating and strapping, casting, and so on. J.H. Kite[3], Ignacio V. Ponseti[4], and French[5] described conservative approaches. Among these, Ignacio V. Ponseti's technique, is most popular and acceptable worldwide which involves gradual and sequential correction of all abnormalities by manipulation and immobilisation with the above knee cast at weekly intervals, followed by TA tenotomy for residual equinus deformity and correction maintained by FAB upto 4years.

The basic pathology in CTEV is retracting contractile fibrosis on posteriomedial aspect (soft tissues like tendons, ligaments, capsules) of clubfoot which is present upto 4yearrs of age after birth. This is the basis for clubfoot correction by ponseti technique and maintaining in FAB upto 4years of age. Without diligent bracing the risk of recurrence is 90% in infancy, gradually reducing to about 10% at age of 4years.

The present study is taken up to know the importance of Bracing protocol of FAB in CTEV management , in maintaining correction achieved through castings and tenotomies and preventing recurrences.

II. Material And Methods

This prospective study is conducted on children with untreated idiopathic clubfoot attending orthopaedics OPD at Siddhartha medical college/ Government General hospital, Vijayawada, Andhra Pradesh, India, from June 2019 to June 2021 with a total of 43 clubfeet (26 children).

Study design: A Prospective study.

Study location: This is a tertiary care teaching hospital based on study done in Department of Orthopaedics, at Siddhartha medical college/ Government General hospital, Vijayawada, Andhra Pradesh, India.

Study period: June 2019 -June 2021-2years.

Sample size: 43 clubfeet (26 children).

Inclusion criteria:

1. Idiopathic clubfoot in new born upto 4years of age.
2. Idiopathic clubfoot that was previously untreated.

Exclusion criteria:

1. Postural clubfoot
2. Syndromic clubfoot
3. Neglected clubfoot
4. Relapsed clubfoot
5. Atypical clubfoot
6. Child more than 4years of age
7. Post surgical clubfoot

Procedure methodology: A total of 43 feet (26 patients) confirmed to have Untreated Idiopathic Clubfoot were enrolled in the study. The severity of each foot's deformity was graded using the Pirani scoring system formulated by Dr. Shafique Pirani [6]. The foot is graded using Pirani score during each visit and recorded on clubfoot management protocol sheet for every child.

PIRANI SCORING SYSTEM[6]:

This score clinically assesses the severity of deformity by measuring sic clinical signs that changes as the foot deformity improves. Each sign is scored 0(normal), 0.5(mild), 1(severe).

The Midfoot Score (MFS) is made up of three indicators that grade the degree of deformity from 0 to 3. Curved lateral border, Medial crease, and Talar head coverage are all part of the midfoot score.

The Hindfoot Score (HFS) is made up of three indications that grade the degree of deformity on a scale of 0 to 3. The posterior crease, rigid equinus, and empty heel are all parts of the hind foot score.

Total score (TS) is the sum of MFS and HFS. It assesses the severity of clubfoot as a whole with a score ranging from 0(normal) to 6(severe).

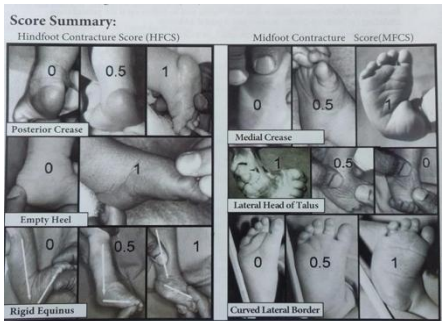


Fig 1: Pirani scoring system

Table 1: Pirani scoring

Parameters	Normal	Mild	Severe
MID FOOT			
Curved lateral border	0	0.5	1
Medial crease	0	0.5	1
Talar head coverage	0	0.5	1
HIND FOOT			
Posterior crease	0	0.5	1
Empty heel	0	0.5	1
Rigid equinus	0	0.5	1

Treatment Regimen – The Ponseti method of management. The treatment was in 2 stages:
Stage: 1: deformity correction by weekly serial manipulation and casting and percutaneous Achilles tendon tenotomy for residual equinus correction.
Stage: 2: maintenance of that correction using foot abduction braces upto 4years of age.

Statistical analysis:

Simple proportions and percentages for comparing different variables like age, sex, etc. were used. Comparison was tested for statistical significance using Chi-square test & t tests wherever applicable.

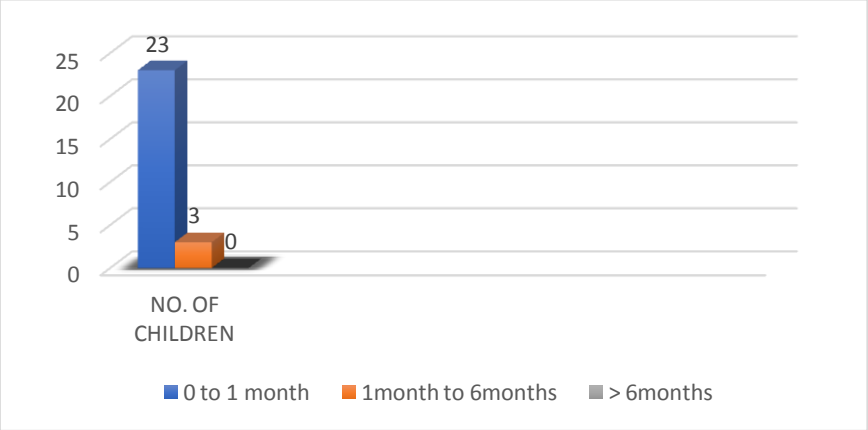
III. Results

In this prospective study total, 43 feet (26 patients) were treated by the Ponseti method and the endpoint of casting treatment is taken as ten casts. There are 9 unilateral and 17 bilateral cases among 26 children. After deformity correction (casting, heel cord tenotomy) and then started on the bracing protocol with foot abduction braces.

Table no 2: details of age of children in days

	AGE OF CHILDREN IN DAYS
MEAN	21.8
MEDIAN	10
MODE	7,30
MINIMUM	3
MAXIMUM	120

Table no 3: Age wise distribution



The mean age at start of treatment was 21.8days for 26children. The most common age group was 0 to 1 month with 23 (88.46%) children.

Table no 4: sex distribution

Sex	Frequency	Percentage
Female	5	19.23
Male	21	80.76
Total	26	100

There are 21 males (80.76%) and 5 females (19.23%), with male: female ratio of 4.2:1.

Table no 5: side of involvement

	Frequency	Percent
Bilateral	17	65.38
Unilateral	9	34.61
Total	26	100

There were 9 unilateral (34.61%) and 19 bilateral (65.38%) cases among 26 children, with bilateral: unilateral ratio of 1.8:1.

Table no 6: laterality in unilateral cases

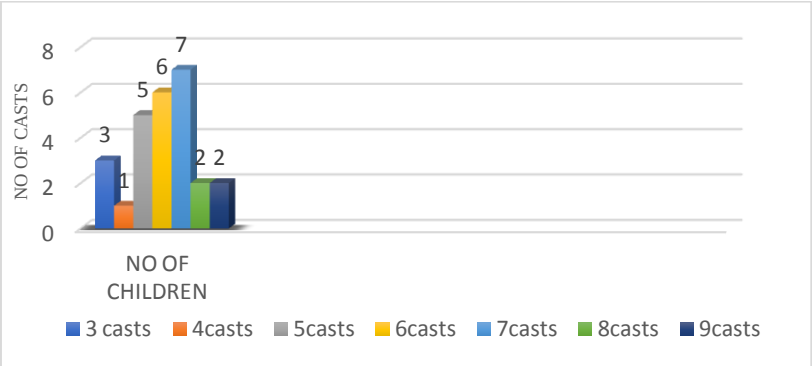
UNILATERAL	
RIGHT	6
LEFT	3
TOTAL CASES	9

Table no 7: feet based on pirani scoring system (initial scores before treatment)

PIRANI SCORE	NO OF CHILDREN
1.5 – 2.5	4
3 – 4.5	13
>= 5	9
Total no of children	26

Mean initial Pirani score for 43 clubfeet (26children) before treatment is 4.139.

Table no 8: no of castings required in this study.



Total number of casts required for this present study are 157 with a mean casting of 6.038.

Table no 9: tenotomy rates

Tenotomy	Frequency	Percent
Done	8	30.76
Not done	18	69.23

30.76 % of patients needed percutaneous Tenotomy of Achilles tendon at the end of casting.
No patient has undergone extensive surgery like posteromedial soft tissue release or bony procedures for correction of the deformity in present study.
Three cases of recurrence varus deformity were observed in present study with 26 children (11.5% recurrence rate), which was due to non-compliance towards the bracing protocol. They are treated with manipulation and casting till the deformity is corrected and again started on bracing protocol with FAB after counselling the parents and explaining them the importance of foot abduction braces in maintaining the feet in corrected posture.
Mean Pirani score before treatment for 43 clubfeet is 4.139 with a standard deviation of 1.31078, with 1.5 smallest and 6.0 largest data in our present study sample.
Mean Pirani score after treatment with weekly manipulation and casting for 43 clubfeet was 0.558 with a standard deviation of 0.71724 with smallest to largest ranging from 0 to 1.5.
Mean Pirani score at 6months follow-up for 43 clubfeet is 0.127 and standard deviation is 0.47675.
Mean change in Pirani score between initial scores and those after treatment is 3.581 with a standard error of 0.293 and 95% confidence interval ranging from -4.1696 to -2.9924 and with a significant P-Value less than 0.0001.
Mean change in Pirani score between initial scores and those after 6 months of follow up on bracing regime is 4.012 with a standard error of 0.274 and 95% confidence interval ranging from -4.5614 to -3.4626 and with a significant P-Value less than 0.0001.

IV. Discussion

With the advent of the Ponseti technique of clubfoot management around the world in recent decades, the treatment of congenital clubfoot has significantly transformed. In 1963, Ponseti published the first description of his treatment regimen, which included foot abduction bracing and tibialis anterior tendon transfer [4]. In 1973, he published a detailed account of his technique [7]. Ponseti and his colleagues have only made modest changes to their recommendations throughout the years. The Ponseti approach of clubfoot care is now widely accepted as the gold standard for treating the deformity and achieving a plantigrade, painless, and flexible foot.

Bracing is demanding for both parents and children and is the most problematic part of ponseti treatment. The most common cause of relapse is noncompliance to bracing protocol.[4] Three weeks after Tenotomy, the bracing is done immediately after the last cast is removed.
Foot abduction brace design:[1]
The shoes are leather, open-toed, and with lace-closures. Shoe has a deep heel cup which prevents the heel from riding up and promotes it to develop a normal shape. Medial peep hole allows one to see if the heel is riding up.
A 6 or 7mm malleable round iron bar connects the shoes, the bar can be bent to hold the shoes at different angles of abduction (shoe out angle) and extension (shoe up angle).
Shoe up angle: this is the angle between the sole of the shoe and the bar in the coronal plane. This angle should be 10 degrees for both the corrected clubfoot and the normal foot in unilateral cases.

Shoe out angle: this is the angle between the longitudinal axis of the shoe and the orthogonal to the bar in transverse plane. This angle should be 70 degrees for corrected clubfoot and 30 degrees for normal foot in unilateral cases and in bilateral cases 70 degrees for both of the corrected clubfeet.

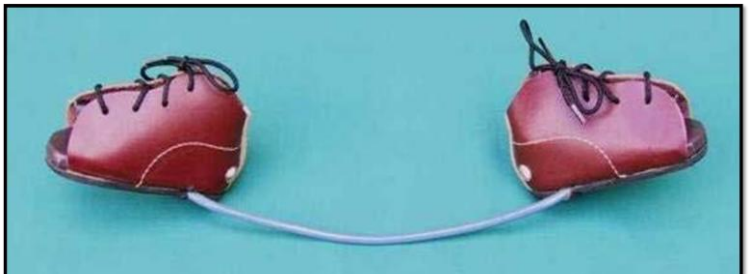


Fig 2: foot abduction brace

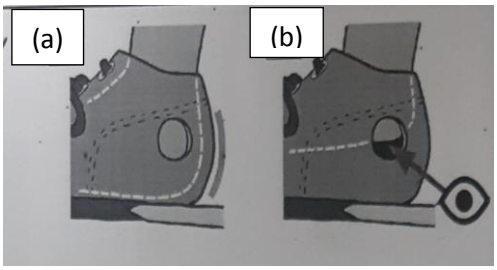


Fig 3: (a)deep heel cup; (b) medial peep hole

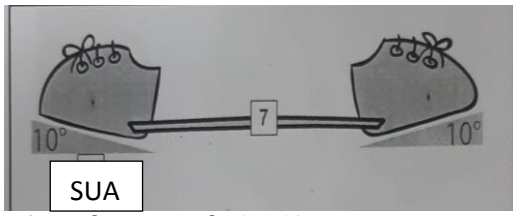


Fig 4: shoe up angle (SUA)

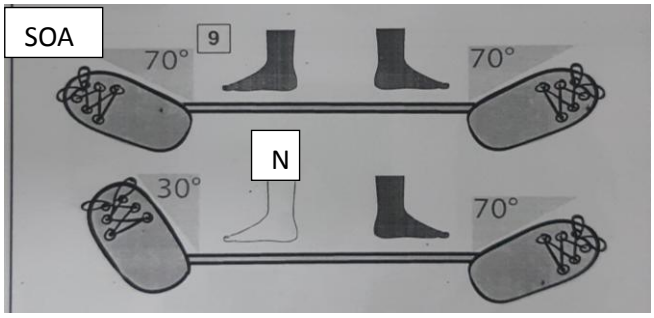


Fig 5: shoe out angle (SOA) ; N- Normal foot

FAB wearing protocol: [1]
For the first three months after the last cast is removed, the brace should be worn full-time (day and night) for 23 hours a day. After three months, the kid should wear the brace for 12 hours at night and 2 to 4 hours in the middle of the day, for a total of 14 to 16 hours every 24-hour period, and this protocol should be followed until the child is 3 to 4 years old.

Bracing followup schedule: [1]
Child should be reviewed 2 weeks after the start of FAB and again at 2months of bracing protocol and then the child should be reviewed every 3 to 6months until 4years of age to check for FAB fit, regular use and recurrence of deformity at each followup and recorded. At 4years of age stop FAB use and the child is discharged from the clinic if there is no relapse for 6months on further followup.
Common bracing problems encountered: [1]

1.Child is not used to brace and crying baby worries the house hold. Foot looks normal there are no sores, blisters and brace fits well. Child is crying probably because they are not used to wear the brace. This is the most common problem during first few nights following first brace application. Counselling is done and reassurance should be given to parents that within a few days the child gets used to the braces and stops crying and encourage the parents to continue bracing protocol.
2. Skin sores and swelling typically occur over the heel or on top of the foot, causing pain and discomfort to child on brace application.
3.Poor brace fitting, as the feet of the child grows faster and toes curl outside of the shoes. The feet of the child do not stay in brace and difficult to use, in such cases the child should be reviewed and a new brace should be applied.
4.Inconsistent brace use : daily brace application is demanding. As the feet looks corrected parents think that bracing is no longer required and become inconsistent in applying the brace
5.Premature stoppage of brace use: parents may stop using brace after 1 to 2 years rather than following the bracing protocol upto 4years of age.
How FAB prevents recurrence: [1]
The FAB prevents recurrence because it abducts and extend the feet without the need for knee flexion. It holds the foot corrected to maintain posteromedial soft tissues stretched, and tarsal bone deformations corrected. As the knees are free to move, when child kicks the gastrocnemius is stretched. Regular brace use according to bracing protocol reduces the recurrence rates to less than 10%.
In regard to brace non compliance rate or recurrence rate, many medical research centres and authors reported their findings on clubfoot treated by Ponseti technique followed by bracing protocol with FAB. In a study conducted by Dobbs et al.[8] non-compliance rate was 41% and children who did not follow the bracing protocol were 183 times more likely to have recurrence of deformity. Haft et al.[9] reported that noncompliance rate was 49% and children not adherent to bracing protocol were 5 times more likely to develop recurrence than children who were adherent to bracing protocol. Morcuende et al.[10] from university of IOWA hospital reported that noncompliance rate as 11% and children not compliant to FAB were associated with 17 times higher odds of relapse than those children compliant to bracing protocol. According to Morcuende et al. noncompliance is failure to use foot abduction brace for at least 10 hours a day. Dobbs et al. suggested noncompliance as complete discontinuation of FAB. In Ponseti[4] series the children who were compliant to foot abduction brace had a recurrence of 7% where as children noncompliant to FAB had a recurrence rate of 78%. In a study conducted by Thatikonda Sai Dinesh et al.[11] the recurrence rate was found to be 5.2% and the reason for recurrence was found to be noncompliance to bracing protocol. In a study conducted by Pavone et al.[12] recurrence rate was found to be 3.7%. In this present study with 26 children (43 clubfeet), on bracing protocol with FAB, noncompliance to bracing protocol was seen in 11.5 % of cases (3 children) with recurrence of varus deformity.

Table no 11: comparision of recurrence rates

STUDY	Relapse %
Dobbs et al.	41%
Haft et al.	49%
Morcuende et al.	11%
Thatikonda Sai Dinesh et al.	5.2%
Pavone et al.	3.7%
Present study	11.5%

Although success have been achieved in obtaining initial correction in clubfoot, maintaining that correction in FAB is more challenging. The most common problem encountered is noncompliance to the bracing protocol. Bracing protocol is similar to all children and should be followed till the child reaches 4years of age in order to prevent the recurrence of deformity. Retractile contractile soft tissue fibrosis on posteromedial aspect of the clubfoot plays an important role in the pathogenesis of clubfoot and relapse of clubfoot deformity. So, use of FAB is important because they help in stretching the posteromedial soft tissues of the clubfoot, thus preventing the recurrence of clubfoot deformity.[13,14]

Fig 6: feet of child on bracing protocol

Fig 7: feet of child on follow-up

V. Conclusion

Based on the results and observations obtained in our present study we conclude that Ponseti method of clubfoot management is effective in deformity correction without the need for major extensive surgical procedures. Non-compliance to bracing protocol is the most common cause of relapse of deformity. To attain the goal of a normal plantigrade, painless, flexible, and functioning foot from the stage of deformed clubfoot, strict adherence to the bracing protocol is required.

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