



STUDY OF COMPARISON OF THE RECURRENCE PATTERNS IN CTEV PATIENTS WITH ADHERENCE TO BRACE PROTOCOL AND THOSE WITHOUT ADHERENCE TO BRACE PROTOCOL IN CHILDREN UP TO 5 YEARS.

Orthopedics

Dr Ravi Kumar*

Senior Resident, AIIMS Patna, Bihar. *Corresponding Author

Dr Shailendra Kumar Singh

Resident Orthopaedics, St. Stephens Hospital, New Delhi

ABSTRACT

BACKGROUND: The purpose of the study was to evaluate the comparative outcome of the recurrence pattern in congenital talipes equino varus (CTEV) patient's upto 5 years old following Ponseti correction and brace application. **METHODS:** A study of prospectively collected cohort data of 94 newly diagnosed idiopathic CTEV patients who were managed conservatively with Ponseti correction followed by tendoachilles (TA) tenotomy in 90 % of patients and brace application. Patients were evaluated with Pirani scoring prior to commencing Ponseti correction and during follow up and the parents were asked regarding the compliance and acceptance of the brace by the child and the difficulties faced while the child was on brace. **RESULT:** Out of 94 patients in our study, recurrence of deformity was noticed in 13 patients, while 81 patients had totally normal functional foot. **CONCLUSION:** We conclude that the Ponseti method enables us to correct most clubfeet with gentle manipulation, casting and foot abduction brace. Experience with the Ponseti method and great attention to the details of manipulation and moulding of the cast are necessary to achieve initial correction rate of over 98%.

KEYWORDS

Congenital Talipes Equino Varus, Foot Abduction Brace (FAB), Steenbeek Foot Abduction Brace (SFAB), Tendoachilles (TA)

Introduction:

Congenital Talipes Equino Varus (CTEV) or Clubfoot is one of the most common congenital deformities in paediatric orthopedics. Worldwide approximately one lakh new cases of clubfoot are added each year⁽¹⁾ The incidence is approximately 1 in 1,000 births.(2) Males are more commonly affected than females and up to 50% of cases are bilateral.(3) The aim of clubfoot treatment is to have a plantigrade, supple foot in minimum possible time. The Ponseti's method is most acceptable method of conservative treatment of clubfoot and presents several advantages with high quality reduction of the clubfoot with restoration of normal looking foot at low cost.(4) Correction achieved by Ponseti's method is maintained by using a post-corrective foot abduction orthosis brace.(5) Adherence to the protocol of brace wearing is as critical as Ponseti treatment itself. Lack of adherence to the protocol of brace wearing is probably the most common cause of relapse.(3) In most countries children with clubfoot get less access for attending school and often face stigma and social exclusion. Clubfoot makes the victim less sociable, feel ashamed of his/her disease, ignored by the community and family⁽⁶⁾

Noncompliance and the educational level of the parents (high-school education or less) are significant risk factors for the recurrence of clubfoot deformity after correction with the Ponseti method.

There are only few studies available in literature documenting adherence to brace wearing protocol post correction. Morgenstein and colleagues employed a pressure sensor to monitor initial brace use for 21 patients. The authors reported that patients wore the brace 91.7% of the physician recommended hours during the first month of use, whereas the rate declined to 77.1% at 3 months.(7)

Sophia N Sangiorgio et al. reported the objective measurement of brace-use adherence in the treatment of idiopathic clubfoot using temperature sensor.(8)

In the research by Haft, et al. the non-compliance rate was 49% and patients who did not adhere to the bracing protocol were 5 times more likely to have a relapse in comparison with children who wore the brace regularly.(9) Matthew B. Dobbs et al. did a study to assess the result of a newly designed dynamic foot abduction orthosis after correction with Ponseti method in terms of parental compliance and effectiveness in preventing recurrent clubfoot deformities. They came out with a conclusion that the most critical factor leading to clubfoot relapse remains non compliance with brace wear which includes difficulty in taking the brace on and off, irritability of the infant while using the brace, skin ulceration and blistering.(10)

The purpose of the study was to study the recurrence patterns in patients with adherence to brace protocol and those without adherence

to brace protocol in children up to 5 years.

Materials and methods

It was a prospective study conducted in department of Orthopedics of a teaching tertiary care hospital between January 2019 to June 2020. All newly diagnosed, treated and braced patients with clubfoot were studied prospectively. The sample size was of 94 patients. We included children affected with idiopathic clubfoot and treated with Ponseti method of correction from birth to 5 years in our hospital and all children coming for follow up after getting full correction of deformity and on brace protocol.

The exclusion criteria included: Non idiopathic clubfoot, cases treated with technique other than Ponseti method and refusal to participate in the study.

We studied the adherence to the protocol of brace wearing in idiopathic unilateral and idiopathic bilateral clubfoot prospectively from January 2019 to June 2020 in newly diagnosed, treated and subsequently braced patients.

All children were coming to hospital in the age group up to 5 years with idiopathic clubfoot were evaluated for severity of deformity and Pirani scoring for treatment. They were treated with Ponseti method of treatment. After completion of treatment they were put on Steenbeek brace protocol. Once they were on brace protocol, they were called for brace follow up initially at 2 weeks, followed by 6 weeks and then at 3 months.

At each visit Pirani scoring was done and the parents were asked regarding the compliance and acceptance of the brace by the child and the difficulties the parents face while the child was on brace.

Statistical analysis was done using SPSS software. Categorical variables were presented in number and percentage and continuous variables presented as mean $\pm$ SD. Normality of data was tested by Kolmogorov-Smirnov test. Qualitative variables were compared using Chi-Square test /Fisher's exact test. One way anova was used to compare mean between more than two groups. P-value less than 0.05 were considered as significant at 95% confidence level.

RESULTS: There were 94 patients in this cohort with 21 patients belonging to age group less than 6 months, 24 patients between 7 to 12 months, 33 patients were between 13 to 24 months and 16 patients belonging to more than 24 months. There were 67 males and 27 females with 40 patients with bilateral involvement and 54 patients with unilateral involvement.

The study group had 12 patients with right side, 13 with left side and 22

patients with bilateral involvement whose pirani score was equal to or less than 3, while 16 patients with right side, 13 patients left side and 18 with bilateral involvement had pirani score more than 3 at the onset of treatment.

In our study, there were 36 patients whose treatment started less than a month, 37 patients within 1 to 3 months and 21 patients are those whose treatment started more than 3 months.

We treated our patients after pirani scoring by Ponseti technique. In our study, all patients had gone through Ponseti corrective casting and 90.4% had percutaneous tenotomy. All patients were started with the bracing protocol. 81 (86.2%) patients strictly followed, while 13 patients had not followed the bracing protocol.

Leg hour glass sign and orthotic wear sign are the sign of adherence with the brace, which are present during infancy. In our study there were 42.6% patients had positive leg hour glass sign and 29.8% patients had orthotic wear sign.

Pirani score was done at last visit of child and it was found that 81 patients had a score of 0, two patients had score of 2, one patient had score of 2.5, six patients had score of 3 and four patients had score of 3.5.

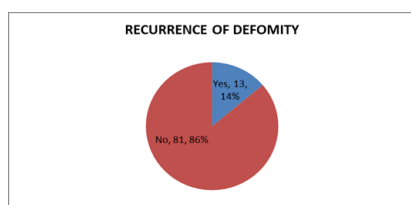


Figure 1

Out of 94 patients in our study, recurrence of deformity was noticed in 13 patients, while 81 patients had totally normal functional foot (Figure 1).

Signs of recurrence of deformities are cave sign, callosity formation and dynamic supinations.

Table 1

ADHERENT/N ON ADHERENT	REMARKS	RECURR ENCE		p-value	
		Yes	No		
ADHERENT	GOOD ADHERENT WITH BRACE	0	78	78	<0.001
	GOOD ADHERENT WITH BRACE,RECUR RENCE	3	0	3	
NON- ADHERENT	POOR ADHERENT WITH BRACE	0	3	3	0.003
	POOR ADHERENT WITH BRACE,RECUR RENCE	10	0	10	

In our study, recurrence was higher that is 10 in those patients, who had poor adherence with the brace while 3 patients with good adherence with the brace had recurrence of deformity. P value of adherent and non-adherent are <0.001 and 0.003 respectively which is statistically significant (Table 1).

DISCUSSION:

In our study for defining adherence to bracing protocol during the first 0 to 3 months of brace used, an arbitrary value of ≥ 18 hours of bracing is selected as cut off for adherence to bracing protocol and < 18 hours have been taken to be not adherent to bracing protocol. Similarly in 3 to

12 months of bracing protocol ≥ 12 hour of brace use is cut off for adherence to bracing protocol < 12 hours is considered non adherent. In 1 to 5 years of bracing protocol ≥ 8 hours of brace use is taken as cut off for adherent < 8 hours of brace use is considered non-adherent.

However there is no consensus on the definition of 'noncompliance' or 'compliance.' Morcuende et al. suggested non-compliance when the foot abduction brace was not used for at least 10 hours a day. Dobbs et al. suggested non-compliance on complete discontinuation of the use of the orthosis. Abdelgawad et al. defined non-compliance as complete discontinuation of the use of the FAO. Avilucea et al. defined non-compliance as premature discontinuation of the use of the brace during the maintenance phase. Panjavi et al. defined non-compliance as lack of full-time bracing in the first 3 months, or at night time 9 months thereafter. Different definitions may result in different findings.⁽¹¹⁾

Compliance with the orthosis was defined as fulltime brace use for 3 months and during sleep for 9 months or more, as suggested by Haft et al. Relapse was defined as a clubfoot requiring retreatment, as determined by the treating physician's clinical examination.⁽¹²⁾

Non-compliance is defined as failure to use the brace for 23 hour per day in first three month and for an average of 14 hours per day at night time and during naps.⁽¹³⁾

There were 50 % patients who had Pirani score less than three at the beginning of treatment and 50% had more than three. The treatment was initiated in 38% of patients before 1 month of age, 39% in the age group of 1-3 months and 22% in the age group of more than 3 months. This implies most of the children are brought to the hospital for treatment within first few months of life.

In our study, all patients had gone through Ponseti corrective casting and most of them (90%) had percutaneous tendoachilles (TA) tenotomy and all the children under study were followed for bracing protocol. 81 patients (86.2%) strictly followed, while 13 patients had not followed the bracing protocol. In African clubfoot training project chapter 8, they mentioned if bracing is stopped at any point during treatment, following relapse rates can be expected. Stopped during 1st year is 90 %, second year 70 to 80 %, third year 30 to 40 %.⁽¹⁴⁾

Leg hour glass sign is looked everytime the child comes after being put on bracing protocol in infancy. The clinical sign is appreciated better in infants than the older children using the brace. It was appreciated in just 43% of the patients as some patients were seen late hence the sign was not appreciated in them. Orthotic wear sign was appreciated in 30% of our patients.

We found that 88 patients brace was used more than 18 hours and in 6 patients it was less than 18 hours in 0 to 3 months of age group. In the age group between 3 to 12 months, out of 69 patients brace was used in more than or equal to 12 hours while 4 patients had used the brace less than 12 hours.

In age group between 1 to 5 years, 28 patients used brace more than or equal to 8 hours and 3 patients used less than 8 hours. On this basis we have calculated the total no of adherent and non-adherent children in various age groups.

After correction of the deformity by Ponseti method of casting and performing TA tenotomy, 90 % of the patients had Pirani score ≤ 1 . During the last evaluation the Pirani score was zero in 86.2 % of the patients and > 2 in 13.8 % who all presented with recurrence of deformity.

Cave sign was seen in 13 patients, Callosity was present in 4 patients under and dynamic supination was present in 3 out of 94 patients. Cave sign is statistically significant marker for recurrence in both adherent and non-adherent group.

In our study, there were 3 patients who had recurrence of deformity with presence of all the four of the cave signs (Cavus, Adductus, Varus and Equinus) in adherent and 10 patients with presence of cave sign had recurrence in non-adherent. This suggests that adherence to brace protocol children have less likely to develop recurrence. Appearance of cave signs after the initiation of brace protocol shows reappearance of one or other component of deformity thereby showing recurrence. It may appear at variable time interval depending upon Pirani

score/adherence to brace protocol. In our study we observed that appearance of cave sign is significantly correlated with adherence to brace protocol thereby recurrence. So those who had good adherence to brace protocol did not show any of the components of cave sign and did not have recurrence.

In our study, there were 2 patients had recurrence of deformity with presence of dynamic supination and 1 patient had recurrence without dynamic supination in adherent and 10 patients had recurrence in non-adherent. Out of these 10 patients only 1 patient had dynamic supination. We did not find any significance of correlation between dynamic supination and recurrence.

In our study, only 3 children with good adherence to protocol with the brace had recurrence of deformity, while recurrence was higher that is 10 in those patients, who had poor adherence to brace protocol. P value of differences in adherent and non-adherent are < 0.001 and 0.003 . This data is statistically significant. This clearly suggests that recurrence is more common in children non adherent to brace protocol. We compared our study with Runu, et al. who in their study found recurrence rate as 8.33%. Bouchoucha et al. reported a compliance rate of 94% with SFAB, with recurrence of 7.5%. (15)

Success of the Ponseti method is dependent on the parent's ability to consistently and properly apply the post-corrective brace. Thus it is important to develop strategies to ensure their cooperation. It is crucial to obtain full correction of the deformity before placing the infant in the FAB.

We conclude that the Ponseti method enables us to correct most clubfeet with gentle manipulation, casting and foot abduction brace. Experience with the Ponseti method and great attention to the details of manipulation and moulding of the cast are necessary to achieve initial correction rate of over 98%.

REFERENCES

- Colburn M, Williams M. Evaluation of the treatment of idiopathic clubfoot by using the Ponseti method. *J Foot Ankle Surg.* 2003;42(5):259-67.
- Werler MM, Yazdy MM, Mitchell AA, Meyer RE, Druschel CM, Anderka M, et al. Descriptive epidemiology of idiopathic clubfoot. *Am J Med Genet Part A.* 2013;161(7):1569-78.
- Desai L, Oprescu F, DiMeo A, Morcuende JA. Bracing in the treatment of children with clubfoot: past, present, and future. *Iowa Orthop J.* 2010;30(May):15-23.
- Jowett CR, Morcuende JA, Ramachandran M. Management of congenital talipes equinovarus using the Ponseti method: A systematic review. *J Bone Jt Surg - Ser B.* 2011;93 B(9):1160-4.
- Garg S, Porter K. Improved bracing compliance in children with clubfeet using a dynamic orthosis. *J Child Orthop.* 2009;3(4):271-6.
- Teklay H, Asmare Y, Kifle M, Abraha M, Baraki Z, Fissiha B, et al. Treatment of congenital clubfoot and its outcome in Study design. 2018;4:1-7.
- Morgenstein A, Davis R, Talwalkar V, Iwinski H, Walker J, Milbrandt TA. A randomized clinical trial comparing reported and measured wear rates in clubfoot bracing using a novel pressure sensor. *J Pediatr Orthop.* 2015;35(2):185-91.
- Sangiorgio SN, Ho NC, Morgan RD, Ebrahizadeh E, Zions LE. The objective measurement of brace-use adherence in the treatment of idiopathic clubfoot. *J Bone Jt Surg - Am Vol.* 2016;98(19):1598-605.
- Haft GF, Walker CG, Crawford HA. Early clubfoot recurrence after use of the Ponseti method in a New Zealand population. *J Bone Jt Surg - Ser A.* 2007;89(3):487-93.
- Chen RC, Gordon JE, Luhmann SJ, Schoenecker PL, Dobbs MB. A new dynamic foot abduction orthosis for clubfoot treatment. *J Pediatr Orthop.* 2007;27(5):522-8.
- Zhao D, Liu J, Zhao L, Wu Z. Relapse of Clubfoot after Treatment with the Ponseti Method and the Function of the Foot Abduction Orthosis. 2014;245-52.
- Goksan S. An Analysis of Factors Affecting Adherence with Foot Abduction Orthosis Following the Ponseti Method. *ACTA ORTHOPAEDICA et TRAUMATOLOGICA TURCICA.* 2015.)
- Jawadi AH, Al-Abbasi EM, Tamim HA. Factors predicting brace noncompliance among idiopathic clubfoot patients treated with the Ponseti method. *J Taibah Univ Med Sci [Internet].* 2015;10(4):444-8. Available from: <http://dx.doi.org/10.1016/j.jtumed.2015.06.003>
- Naomi O reilly .University of oxford:Africa clubfoot training team project.chapter 8,2017
- Bouchoucha S, Smida M, Saïed W, Safi H, Ammar C, Nessib MN, et al. Early results of the Ponseti method using the Steenbek foot abduction brace: A prospective study of 95 feet. *J Pediatr Orthop Part B.* 2008;17(3):134-8.