

Outcome of management of congenital idiopathic clubfoot by ponseti technique

MM Newaz¹, AK Sikder²

Abstract

The congenital idiopathic clubfoot (CICF) is one of the most common serious birth defect of human bones and joints. Deformity leads to downward spiral of disability, dependency and demoralization. The Ponseti technique has become the standard for treatment of congenital clubfoot in the last 2 decades and a triumph in the very complex field of management of congenital idiopathic clubfoot. In this clinical study, our main aim is to evaluate necessity of the Ponseti treatment protocol in a timely, safe, effective & sustainable manner. In this clinical trial, 621 patients (with a total 1033 feet) of 00 (from birth) to 36 months of age were selected as the study population since October, 2009. Most of them were male children (71.3%) and majority were in >03-06 months of age group. In most of the patients (about 92%), only 05 serial plasters were found to be effective & quite sufficient, whereas, only in 5.3% patients, 06-07 plasters were required followed by 1.7% patients requiring more than 07 plasters. In this study, 06 resistant cases were found where correction was relatively slower than others, but no case of treatment failure was identified. The Mid foot score (MS) found to fall greatly in plaster phases and at the end of 5h plaster it was significantly lower (0.2), whereas, in case of the Hind foot score (HS), it declined rapidly following the percutaneous tenotomy (0.2) Then the total score (TS) trends to fall to near 0, at the end of 3rd post SFAB (Steenbeek Foot Abduction Brace) routine follow up and is maintained thereafter. Approximately 74. 1% patients ultimately required tenotomy of Tendo Achilles as a part of management and the rate was highest (83.6%) in >30-36 months age group, followed by 80.0% in >24-30 months age group. The relapse rate was estimated within post SFAB routine follow up, 1.9% was within 1st 6 months & 2-1% within 6 12 months after removal of bracing. All steps in all patients were done as day case procedures. No cases of posterior-medial release was required, as like the conventional or the original Ponseti treatment protocol, hence found cost effective to the patients with excellent patient's compliance (P<0.01)

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Introduction

The Ponseti method of treatment for congenital clubfoot has gained widespread clinical acceptance. In the last 2 decades, the Ponseti method of treatment for congenital clubfoot has gained widespread acceptance as a conservative way to address this complex deformity.¹ One report on the long term outcome of the Ponseti method particularly inspired pediatric orthopaedic surgeons to adopt this treatment.² The authors reported in detail on the simplicity of the method to achieve and maintain a flexible, plantigrade, and painless foot. However, because there are no data on the worldwide use of different methods for clubfoot management, one could assume numerous centers still treat congenital clubfoot by initial casting followed by surgical correction of

residual deformities. Outcome of treatment is rated differently in the literature with some authors presenting success rates of as much as 80% excellent or good short-to mid-term outcomes for Ponseti management and for surgical treatment.^{2,3} In light of seemingly comparable outcomes, the much less invasive treatment pioneered by Ignacio V. Ponseti is repeatedly cited as the preferred treatment.⁴⁻⁷ The evidence to support this estimation is based on retrospective trials and a few studies with historical control groups.^{7,8} Larger groups of patients with follow-up have been reported only by a couple centers worldwide.^{4,9}

For almost 3 decades, we treated congenital clubfoot with manipulation (following the guidelines of Johann Bosch from the 1950s,

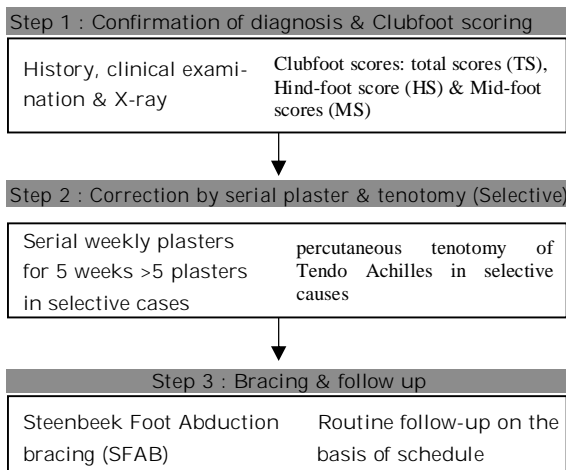
1. Md Mehedi Newaz, Assistant Professor, Dept. of Orthopaedics, Khulna Medical College & Hospital.

2. Avijit Kumar Sikder, Resident Surgeon (Orthopaedics), Khulna Medical College Hospital.

whose approach was remarkably similar to that of Ponseti) and casting up to the age of 6 months followed by posteromedial release.¹⁰ The less invasive character, the straight forward biomechanical concepts, and the favorable reports on the Ponseti method motivated us to organize a prospective, non randomized trial to evaluate the short term outcomes in our common orthopaedics practice before changing the treatment protocol at our institution fully & completely.

Methods and materials

This study was conducted in Orthopaedics outpatients department, Khulna Medical College Hospital, Bangladesh., as a non-randomized clinical trial with joined collaboration of GLENCOE Foundation- "Walk For Life" (a non-profitable international organization) among the patients of congenital idiopathic clubfoot from October, 2009 to August, 2015. Convenient type of purposive sampling was used as the method of sampling for selection of study population. In this study a total number of 679 patients were selected initially based on inclusion criteria among which 58 patients were discarded from study population based upon exclusion criteria. The total study population was 621 (with a total 1033 feet) & the age limit for the study population was 00 (from birth) to 36 months as one of the essential inclusion criteria. All selected patients underwent the following essential steps (On an average of a total 4-5 years). The follow up schedule is depicted in result section. All the patients were treated as day case basis.



Data were collected, processed, presented in tabulated form and discussed with compare & comparison on the basis of statistical analysis. In this research study, both manual and computer based statistical analysis of the data were done. Data were analyzed manually and then rechecked with SPSS (Statistic package for social science) computer package programmer. Data were analyzed using both analytic as well as descriptive

statistic, such as; mean, SD, percentage, coefficient of variation.

Results

In this clinical trial, the age and sex distribution of the 621 patients (with a total 1033 feet) is depicted in table I. All of them were between 00 to 36 months of age. Table I suggests that most of them (433 out of total 621 patients) were male children (approximately 71.3%) and majority (165 patients) were in >03-06 months of age group (approximately 26.6% of total study population) followed by about 17.1% in 00-03 months of age group.

Table I

Age & sex distribution of the study population

Age (Month)	Male %	Female %	Total %	Mean+SD			
00-03	77	12.4	29	04.7	106	17.1	
>03-06	112	18.0	53	08.5	165	26.6	
>06-12	51	08.2	21	03.9	72	11.6	
>12-18	70	11.3	32	05.2	102	16.4	8.8(+2.7)
>18-24	47	07.6	13	02.1	60	09.7	
>24-30	36	05.8	19	03.1	55	08.9	
>30-36	50	08.1	11	01.8	61	09.8	
Total	443	71.3	178	28.7	621	100	

Table II reveals that in case of most of the patients (approximately 92%), only 05 serial plasters were found to be sufficient, whereas, only in 5.3% patients 06-07 plasters were required followed by 1.7% patients requiring more than 07 plasters. In this study, 06 resistant cases were found where correction was relatively slower than others, but no case of treatment failure was identified (Table II)

Table II

Necessity of number of plasters in study population and resistant & failure cases

Indices	Total number of plasters				
	Upto 05	06-07	08-09	RC	TF
Number of patients	571	33	11	06	00
%	92.0	05.3	01.7	01.0	00

RC=Resistant cases after treatment, TF=Treatment failure cases

Evaluation of the average total score (TS), the hind foot score (HS) and the mid foot score (MS) in relation to different phases of management and follow up is tabulated in table III which suggests that the MS trends to fall greatly in plaster phases and at the end of 5h plaster it is significantly lower (0.2), whereas, in case of the HS, it declines rapidly following the percutaneous tenotomy (0.2).

he TS is found to fall to near 0 on an average, at the end of 3rd Post-SFAB (Steenbeek Foot Abduction Brace) routine Follow up and is maintained thereafter (Table III & Figure 1).

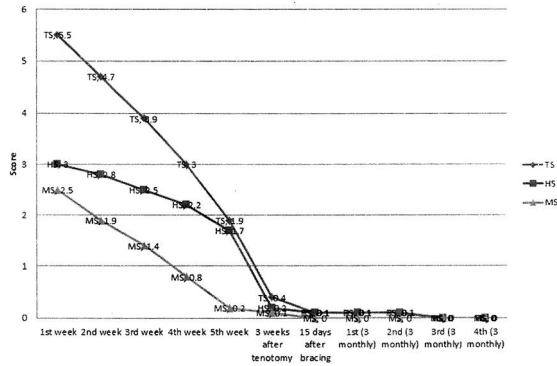


Fig.1 : The average (TS), the (HS) and the (MS) in relation to different phases of management and follow-up

Table III

Evaluation of the average (TS), the (HS) and the (MS) in relation to different phases of management and follow-up

Follow-up schedule	Average score (Except relapse cases)			p-value
	TS	HS	MS	
During plaster phase:				
Up to 5 plasters				
1st week	5.5	3.0	2.5	0.01
2nd week	4.7	2.8	1.9	
3rd week	3.9	2.5	1.4	
4th week	3.0	2.2	0.8	
5th week	1.9	1.7	0.2	
In case of >5 plasters:				
At last plaster	2.8	2.5	0.3	0.05
Before percutaneous tenotomy				
3 weeks after tenotomy	2.2	2.0	0.2	0.05
Before Bracing (SFAB)	0.4	0.2	0.1	0.05
15 days after bracing	0.3	0.2	0.1	0.01
Post-SFAB routine follow-up:	0.1	0.1	0.0	0.01
1st (3 monthly)	0.1	0.1	0.0	0.01
2nd (3 monthly)	0.1	0.1	0.0	
3rd to 11th (3 monthly)	0.0	0.0	0.0	

TS=The total score, HS=The hind-foot score, MS=The mid-foot score SFAB=Steenbeek foot abduction brace.

In table IV, it has been shown that approximately 74.1% (460 out of total 621) patients required tenotomy as a part of management and the rate was highest (83.6%) in >30-36 months age group, followed by 80.0% in >24-30 months age group. P value is highly significant here (Table IV).

Table IV

Patients required tenotomy as a part of treatment

Age (Month)	TP	TR	%	p-value
00-03	106	67	63.2	0.005
>03-06	165	113	68.5	
>06-12	72	57	79.2	
>12-18	102	81	79.4	
>18-24	60	47	78.3	
>24-30	55	44	80.0	
>30-36	61	51	83.6	
Total	621	460	74.1	

TP=Total patients, TR=Tenotomy required cases

In case of 96 (15.5%) patients out of total 621 study population, full 1 year follow up was done on a basis of every 6 months after the complete 4 years management. The relapse rate was estimated within this part of population during this period which is depicted in table V. P value 'is highly significant here.

Table V

Relapse rate in study population

Age (Month)	RP SFAB	%	R6M	%	R6-12M	%	p-value
00-03	00	00	00	00	00	00	0.001
>03-06	00	00	00	00	00	00	
>06-12	00	00	00	00	02	0.3	
>12-18	00	00	01	0.2	00	00	
>18-24	00	00	00	00	01	0.2	
>24-30	02	0.3	04	0.6	04	0.6	
>30-36	04	0.6	07	1.1	06	1.0	
Total	06	1.0	12	1.9	13	2.1	

RP SFAB= Relapse within Post SFAB routine follow up, R6M= Relapse within 1 st 6 after removal of bracing months, R6-12M= Relapse within 6-12 months

Discussion

The Ponseti technique has become the standard for treatment of congenital clubfoot in the last 2 decades.11 For almost 2 decades at our institution, the deformity was treated by initial casting and posteromedial release to correct residual deformities at the age of 6 to 8 months.

In this clinical trial, 621 patients (1033 feet) were included, most of them were male children (approximately 71.3%) and majority were in >03-06 months of age group. In most of the patients (approximately 92%), only 05 serial plasters were found to be effective & quite sufficient whereas, only in 5.3% patients 06-07 plasters were required followed by 1.7% patients required more than 07 plasters. In this study, 06 resistant cases were found where correction was relatively slower than others, but no case of treatment failure was

identified. P value is quite statistically significant here.

Changes in the average total score (TS), the hind foot score (HS) and the mid foot score (MS) in relation to different phases of management and follow up is tabulated in table III which suggests that the MS trends to fall greatly in plaster phases and at the end of 5th plaster it is significantly lower (0.2), whereas, in case of the HS, it declines rapidly following the percutaneous tenotomy (0.2). Analyzing the pattern of changes in scores, this result indicates that possibly cavus & some degree of adduction are corrected in Plaster 1. Adduction and in some cases equinus are gradually and fully corrected in the sequential Plasters 2, 3, 4 & 5. If equinus, is not corrected significantly after Plasters 4 or 5, percutaneous tenotomy of Tendo Achilles is required then holding of the foot in dorsi flexed & full abducted position with an addition subsequent plaster is needed. This supports previous reports regarding the importance of tenotomy of the tendoAchilles for short term success of the Ponseti method when a residual equinus is present after the first few weeks of Manipulation and Casting.^{12,13} After that to prevent the possible relapse, Steenbeek Foot Abduction Brace is required to be applied for the next 3-4 years. Then TS trends to fall to near 0, at the end of 3rd Post SFAB routine Follow up and is maintained thereafter P value is quite statistically significant here. Splinting in patients in the Ponseti group was terminated at 24 months, which is the shortest duration of splint application reported by 1 Ponseti similar to a report by Dobbs et al.¹¹

In our study, we found that approximately 74.1% patients ultimately required tenotomy of Tendo Achilles as a part of management and the rate was highest (83.6%) in >30-36 months age group, followed by 80.0% in >24-30 months age group. P value is highly significant here. On the contrary, the result of another study suggests that tenotomies, of the tendo Achilles were performed more frequently than reported so far (78% to 98%).^{7,14} Herzenberg et al. reported that 97% of the clubfeet could be managed with manipulation, casting, and tenotomy of the tendoAchilles.⁴ The wide range of surgery rates indicates modifications to the original technique and local factors might have a considerable impact on the success of the Ponseti method. The aim of the trial was to evaluate the Ponseti method when used in our specific local setting. All steps in all patients were done as day case procedures in this clinical trial. No cases of posterior-medial release was required (which usually required hospital stay), as like the conventional or the original Ponseti treatment protocol, hence found cost-effective to the patients with excellent patient's compliance.¹⁵

In case of 96 (15.5%) patients out of total 621 study population, full 1 year follow up was done

on a basis of every 6 months after the complete 4 years management. The relapse rate was estimated within post-SFAB routine follow up, 1.9% was within 1st 6 months & 2.1% within 6-12 months after removal of bracing. P value is highly significant here.

Data presented here evaluate the short term outcomes of the Ponseti method for congenital idiopathic clubfeet in our prospective clinical trial. The results reveal excellent outcomes. However, at our institute, we now follow up our participants in an open trial to evaluate midterm and long term outcomes.

Conclusion

The number of cases included in this trial is small and therefore its external validity must be interpreted with caution. Considering all aspects of the Ponseti method, particularly the more conservative approach and lower complication rate as reported in our study as well as in the other literatures, we suggest & recommend that this is the time to change the standard treatment protocol of idiopathic congenital clubfeet to the Ponseti method of treatment at our institution as well as other Orthopaedics & Medical institutes.

Acknowledgement

We are highly grateful to GLENCOE Foundation "Walk For Life" (a non profitable international organization) for the kind support, aids and valuable time to conduct us this research work and also for their noble approach to settle this unsettled issue to a final conclusive point, in a very large scale which will be able to save children of congenital idiopathic club foot from an inevitable catastrophic fate with burden of lifelong deformity & disability.

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