

# Ponseti Method versus Posteromedial Soft Tissue Release for the Management of Clubfoot: A Prospective Interventional Study

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## ABSTRACT

**Introduction:** Idiopathic clubfoot is a common complex deformity of newborns that can be managed either by manipulation, serial casting or by surgery with individualised success of treatment rated differently.

**Aim:** To determine functional outcome, health status of clubfoot patients and the percentage of recurrence that needs additional surgery at the end of three years of treatment by using both Ponseti method and posteromedial soft tissue release method.

**Materials and Methods:** A prospective interventional study was conducted in which two groups of idiopathic clubfoot patients were treated as per the two modalities of treatment (ponseti versus posteromedial release) at the Orthopaedic Department of Veer Surendra Sai Institute of Medical Science and Research, Odisha, India between March 2017 to February 2021, with regular follow-up for a period of three years. Forty patients with 63 feet were taken in the study. Out of which, 20 patients with 32 feet were managed by ponseti method in one group whereas another group containing 20 patients with 31 feet were treated by posteromedial soft tissue release. During follow-up foot function was assessed by Laaveg-Ponseti score, general well-being of the children was assessed by paediatric outcomes data

collection instrument and any complications were recorded in terms of recurrence.

**Results:** Mean age of presentation in Ponseti group is 4.73 month, whereas mean age of presentation in surgical group is 7.85 month. Though recurrence was the major complication in both the groups, significant difference was seen in severity of recurrence (p-value=0.049). More numbers of major recurrence were seen in posteromedial surgical group (5,16.13%) which subsequently required major surgical procedures for correction. Pretreatment pirani score of ponseti and surgical group (4.9±1.0, 5.1±0.90) was statistically improved (0.34±0.38, 0.20±0.33). Foot function was evaluated using Functional Rating System (FRS) total score showing higher in ponseti group 95.25±5.68 with good to excellent outcome. Health status of the patients was assessed by Paediatric Outcomes Data Collection Instrument (PODCI) score, showed no significant difference in result in both the groups (p-value=0.3562) in view of global function subscale.

**Conclusion:** This study have documented a favourable outcome towards ponseti group in terms of higher rate of excellent to good outcome, better parental satisfaction and better passive mobility of clubfeet with less number of revision surgery required for recurrence.

**Keywords:** Functional outcome, Health status, Idiopathic clubfoot, Laaveg-Ponseti score, Paediatric outcomes data collection instrument, Recurrence

## INTRODUCTION

Idiopathic congenital talipes equinovarus (clubfoot) is a common complex deformity that occurs in approximately one or two per 1000 newborn [1]. However, in India prevalence of clubfoot is 1.19 per 1,000 live births [2,3]. All population shows a consistency of 2:1 male predominance, with about 50% of cases being bilateral [4].

Treatment of clubfoot has been controversial as though initial correction of the deformity can be achieved with both primarily non surgical and surgical methods later in some cases, it leads to recurrence that needs additional surgery [5,6]. Similarly functional outcome and general well-being of these patients on subsequent follow-up presents differently [7,8]. The goal of treatment is to produce functional, pain free, plantigrade, cosmetically acceptable foot within short duration of time with least interruption of the socio-economical life of the parent and child [9].

Till now very few papers are there, which are directly comparing Ponseti technique with that of posteromedial soft tissue release for better outcome of foot in early aged clubfoot patients [7,8,10,11]. As because there are no data on worldwide use of different technique for clubfoot management one cannot predict which technique is better for treatment of idiopathic clubfoot. Success of treatment is rated differently in the literature with some authors claiming the success rate upto 80% in short to midterm outcomes for Ponseti management as well as surgical treatment [12,13]. The less invasive

character, well biomechanical concepts, favourable outcome and minimal complication in Ponseti technique motivated us to conduct a prospective cohort study to compare it with posteromedial soft tissue release which also is a common method practiced in our institution. The aim of the study was to determine functional outcome, health status of clubfoot patients and the percentage of recurrence that needs additional surgery at the end of three years of treatment by using both Ponseti method and posteromedial soft tissue release method.

## MATERIALS AND METHODS

A prospective interventional study was carried out in the Orthopaedic Department of Veer Surendra Sai Institute of Medical Science and Research, Odisha of Eastern India between March 2017 to February 2021. All clubfoot children presented during initial one and half year of study has been taken as sample and they were subsequently followed. Following approval was obtained from Institutional Ethical Board Committee (Regd. No. ECR/861/Inst/OR/2016 VIMSAR) prior to the study.

**Inclusion and Exclusion criteria:** Only patients with idiopathic clubfoot with a valid consent and a minimum period of three years of follow-up were included in the study. Age more than three years, syndromic clubfoot, neurogenic clubfoot and previously surgically treated clubfoot patients were excluded from the study.

At the time of presentation they were supposed to meet a dedicated nurse coordinator attached to the clubfoot clinic. This clinic constitutes of a staff nurse, two residents and two consultants under the supervision of professor. All parents were well counseled about the risks and benefits of both Ponseti method and initial below knee cast followed by surgical intervention. Informed consent was taken from the parents maintaining their choice of treatment. Those who were indecisive regarding plan of management, they were allotted to a group as per the convenience. Both the groups were treated as per the treatment protocol.

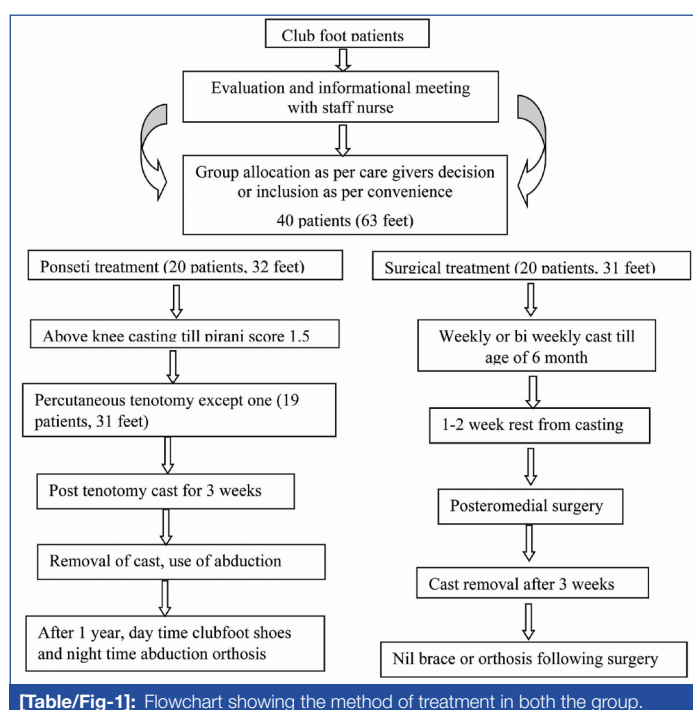
## Procedure

### A) Ponseti group

In Ponseti group, corrective above knee cast was made as described by Ponseti IV [9,14] at weekly interval till pirani score reaches upto 1.5. Any residual equinus deformity was corrected by percutaneous tenotomy and final cast was applied for three weeks. After removal of final cast Dennis Brown abduction orthosis was applied. Strict adherence to orthosis was ensured with the supervision of parents. When the child starts walking, clubfoot shoes were advised at day time. This protocol of management was continued for a period of two years. Any difficulty with orthosis, complications or non compliance was noted.

### B) Surgical group

In surgical group, patients with age more than six months were directly subjected to surgery. However, those presenting below the age of six months for them initial below knee cast was applied with upward directed pressure over cuboid to evert the foot simultaneously with correction of equinus deformity. Casts were changed biweekly till the child attends six months of age. Either posterior or posteromedial soft tissue release was planned according to the subjective finding observed by the senior consultant. Posterior release with achilles lengthening, release of tibio talar and subtalar joint was done for those presenting with significant hind foot deformities. However, child with both forefoot, hind foot deformity were undergone posteromedial soft tissue release. In all cases Cincinnati incision was used [15]. Following surgery cast was applied in maximum corrected posture for a period of three weeks. After cast removal patients were followed at serial intervals without addition of any brace or orthosis [Table/Fig-1].



[Table/Fig-1]: Flowchart showing the method of treatment in both the group.

Total 40 patients were enrolled in this study, out of which 20 patients with 32 feet were managed by Ponseti method in one group whereas rest 20 patients with 31 feet were treated by surgery. Meticulous clinical data were collected at each visit with pre decided data sheet. Initial pirani score was determined for

each foot with use of 6-point scale of Pirani, indicating severity of deformity and subsequently determined following six to eight plaster cast application or postsurgical correction [16]. In depth analysis of family data were made like consanguinity of marriage, family history, birth complication to rule out possibility of resistant clubfoot.

Data collection was made by residents under supervision of consultant in a predetermined clubfoot worksheet:

- Demographic profiles, pretreatment and post-treatment pirani scoring at each follow-up, number of casts, any complication associated with cast, surgery or orthosis were noted in details.
- The Functional Rating Score (FRS) of Laaveg SJ and Ponseti IV was considered as the primary outcome measure to assess foot function [17]. On interpreting FRS score, they have classified overall function as excellent (90-100 points), good (80-89 points), fair (70-79 points) and poor (<70 points).
- Additional Paediatric Outcomes Data Collection Instrument (PODCI, Paediatric Orthopaedic Society of North America) score used to assess the health status of the children was evaluated at the end of follow-up for each patient [18].

The Functional Rating System (FRS) and PODCI were evaluated at a mean of three years of age (range, 2.8-3.7 years). Final outcome measurement was done by a third consultant who was blinded to the study. Complication of each treatment method was closely monitored.

Most common among the complications was recurrence of deformity. Common clinical recurrence includes equinus, hindfoot varus, equinovarus, adduction and dynamic supination of forefoot, intoeing gait etc. Haft GF et al., classified surgical management of this recurrence as minor requiring extraarticular soft tissue procedures and major which requires intraarticular procedures [19]. Authors have followed the same protocol in the study. All these recurrences were treated at the time of presentation and analysed at the time of final follow-up.

## STATISTICAL ANALYSIS

Demographic characteristic between two groups were compared using Chi-square test. The groups were compared with regard to sex, side, consanguinity of marriage, family history, birth complication, initial pirani score etc. Clinical data like age at the time of presentation, total number of cast applied, pre and post cast as well as surgical complication and numbers of years of follow-up were also compared. A Student's unpaired t-test was used for continuous variables and Chi-square test was used for categorical variables. Similarly, the number of recurrences and the difference in the severity of the recurrence were compared with using Chi-square test. A p-value <0.05 was considered as significant. After matching all baseline characteristic, all data were analysed using Statistical Package for the Social Science) version 16.0.

## RESULTS

There was no significant difference between both the groups in terms of sex, family history, bilaterality, age at the time of first casting, average initial Pirani score or number of years of follow-up [Table/Fig-2,3]. Mean age of presentation in Ponseti group is 4.73 month, whereas mean age of presentation in surgical group is 7.85 month.

In the surgical group more pretenotomy/preoperative casts were applied compared to Ponseti group (12 compared to 5, p-value <0.001). Total 15 of 20 patients managed with below-the-knee cast in surgical group and three of the twenty patients managed with above-the-knee cast developed cast related complications like skin rash, ulcers etc. This difference in cast related complications was significant (p-value <0.001). Less number of patients (three of the twenty, p-value <0.001) in Ponseti group had surgery other than achilles tenotomy. One patient required posterior release and two patients had to undergo Achilles tendon lengthening [Table/Fig-3].

Variables	Ponseti method	PMSTR	p-value
No. of patients	20	20	
No. of clubfoot	32	31	
Bilateral involvement	12	11	0.94
Sex	Male	13	0.49
	Female	7	
Birth complication	Yes	4	0.68
	No	16	
Consanguineous marriage	Yes	7	0.74
	No	13	
Family history	Yes	3	0.59
	No	17	
Average pirani score per feet	4.9	5.1	0.21
Duration of follow-up	2.5	3	0.17

**[Table/Fig-2]:** Showing demographic profile of the patients included in the study. Chi-square test was used

Variables	Ponseti group	Surgical group	p-value	
Number of patients	20	20		
Age at first cast (months)	4.9	5.1	0.2	
Number of pretenotomy/presurgery cast	5	12	<0.001	
Casting complication	3	15	<0.001	
Surgery (other than percutaneous tenotomy)	3	20	<0.001	
Recurrence on follow-up	Total	9 (28.125%)	7 (22.58%)	0.613 $\chi^2=3.874$ $p=0.049$
	Minor	7 (21.875%)	2 (6.45%)	
	Major	2 (6.25%)	5 (16.13%)	
Abduction orthosis intolerance	6	NA	-	

**[Table/Fig-3]:** Comparison of observation between both the groups (Chi-square test was used). p-value <0.05 was considered as statistically significant

Recurrence of clubfoot developed in both the groups after an average follow-up period of 2.5 years in Ponseti group and 3 years in the surgical group. There was no significant difference between both the groups in terms of percentage of recurrence (p-value=0.613). However, in the view of severity of recurrence, ponseti group had more number of minor recurrences compared to surgical group which had more number of major recurrences. This difference was statistically significant with p-value=0.049 [Table/Fig-3].

Despite more minor recurrences like dynamic supination (3 feet), equinus deformity (3 feet), intoeing gait (1 foot) in Ponseti group only one foot required minor surgical procedures like anterior tibial tendon transfer. Two feet in Ponseti group required major surgical procedures like corrective osteotomy and posterior release with tendon transfer to correct the major recurrences like hindfoot varus and equinovarus respectively. In surgical group, seven feet developed recurrences of which two were minor treated by cast with percutaneous tenotomy. Five feet had major recurrences for which major surgical procedures were done [Table/Fig-4].

Pirani score statistically improved in both the groups following the procedure but the difference among the group at the end of the treatment hardly differs with p-value=0.14 [Table/Fig-5].

When foot function was evaluated after an average age of 3 years, patients in the Ponseti group scored higher (95.25 versus 84.38) in the FRS total score [Table/Fig-6]. None of the patients experienced foot pain and all feet had a plantigrade position while standing. The FRS category for gait, the passive motion category of the FRS like maximal dorsiflexion, varus-valgus were higher in the Ponseti group. Parental satisfaction following treatment modalities was significantly higher in Ponseti group (p-value <0.001). Excellent to good outcome was seen in all the patients of Ponseti group compared to similar result only in 75% patients of surgical group [Table/Fig-7].

Variables	Ponseti group	Surgical group	Management
Dynamic supination	3	1	Serial Casting
Equinus deformity	3	1	Serial Casting/ Percutaneous tenotomy
Intoeing gait	1		Anterior Tibial Tendon transfer
Hindfoot varus	1	1	Dwyer's Osteotomy
Equinovarus	1	1	Tendon transfer+Posterior release
Metatarsus adductus		1	Metatarsal osteotomy
Residual cavus		1	Posterior release +capsulotomy
Combined deformity		1	Osteotomy

**[Table/Fig-4]:** Late complications seen in both the groups as recurrence of deformity.

Pirani score	Ponseti group (Mean±SD)	Surgical group (Mean±SD)	t-value p-value
Initial	4.9±1.0	5.1±0.90	t=3.732 p=0.29
Final	0.34±0.38	0.20±0.33	t=1.216 p=0.14

**[Table/Fig-5]:** Pirani scores between the groups at the end of the treatment. Student's unpaired t-test was used; p-value <0.05 was considered as statistically significant

Variables	Ponseti group (mean score±SD)	Surgical group (mean score±SD)	p-value
<b>Patient/ parent reported outcome</b>			
Satisfaction (max.20 points)	19.15±1.04	17.05±1.73	<0.001
Function (max. 20 points)	18.90±1.12	17.05±1.64	0.0002
Pain (max. 30 points)	29.25±4.04	24.85±2.54	0.0002
<b>Physical examination/evaluation</b>			
Heel position (max. 10 points)	8.65±1.09	8.9±0.85	0.423
Dorsiflexion (max. 5 points)	4.715±0.45	3.795±0.72	<0.001
Varus-valgus ( max. 3 points)	2.83±0.22	2.62±0.37	0.0465
Inversion-eversion (max. 2 points)	1.95	1.82	0.1
Gait (max. 10 points)	9.8	8.3	0.001
Total score (max. 100 points)	95.25±5.68	84.38±7.34	<0.0001 (t-value 5.237)

**[Table/Fig-6]:** Functional Rating Scale (FRS) significant for Ponseti group. High score indicates good result; Student's unpaired t-test with significance level 0.05; SD: Standard deviation; max.: Maximum

FRS score	Ponseti group (n=20)	Surgical group (n=20)
Excellent (100-90)	16	03
Good (89-80)	04	12
Moderate (79-70)	00	04
Poor (<70)	00	01

**[Table/Fig-7]:** Categorised FRS total score as per classification by Laaveg SJ and Ponseti IV.

When the health status was assessed after the age of 3 years using PODCI, core scale for transfer and basic mobility was significantly limited in Ponseti group. However, other subscales like sports and physical functioning, pain and comfort, happiness, and the global function scale showed a score between 80 to 100, which were higher than surgical group, though statistically insignificant [Table/Fig-8].

## DISCUSSION

The management of idiopathic clubfoot has evolved over the last 3 decades from full surgical correction to less invasive procedure of correction, primarily developed by Ponseti IV [7,9]. Initial non operative management is the preferred method for the treatment of clubfoot in many institutions today [20], largely because of the promising short and long-term results reported by Ponseti and others [21,22]. For many decades extensive soft tissue release was the preferred

PODCI scale	Ponseti group		Surgical group		Two tailed p-value	95% confidence interval of this difference
	Mean±SD	Standard error of mean	Mean±SD	Standard error of mean		
Upper extremity function	97.3±1.922	0.43	97.4±2.257	0.505	0.8809	-1.442 to 1.242
Transfer and basic mobility	91.9±1.619	0.362	93.5±3.0175	0.675	0.0434	-3.15 to -0.0452
Sports and physical functioning	91.55±2.394	0.535	89.95±3.7059	0.829	0.1131	-0.397 to 3.6
Pain and comfort	91.3±2.597	0.581	89.5±4.673	1.045	0.1404	-0.62 to 4.222
Happiness	89.3±2.793	0.624	87.7±4.14	0.927	0.1601	-0.66 to 3.86
Global function	91.0125±1.98	0.44258	90.16±3.57	0.79829	0.3562	-0.9954 to 2.7

**[Table/Fig-8]:** Showing Paediatric Outcomes Data Collection Instrument (PODCI) scale of both the groups.

Two-tailed unpaired t test with significance level 0.05; SD: Standard deviation

method of treatment for clubfoot because it provides definitive correction of the deformity. Surgical approaches usually used can be classified into three main categories: the Turco's posteromedial incision [6], the Crawford's circumferential Cincinnati incision [15], and the two incisions Carroll approach [23]. Although most surgical series have shown satisfactory outcomes, a substantial number of feet require subsequent surgery and the potential for surgical complications exists at each intervention [5,24,25]. But there are few prospective studies comparing the short term results between Ponseti method and posteromedial release procedures [7,8].

Many parents of clubfoot child in the study population have a perception that surgery can make their foot absolutely correct in a quicker manner and hence gives a permanent cure. More over accessibility to a tertiary care hospital for repeated casting as well as lack of compliance by the caregivers regarding strict brace application postcorrection is the major concern among the parents which leads to inadequate treatment.

In the surgical group below-the-knee casts were applied to make feet more flexible. The aim was to reduce the extent of surgery by correcting the deformity partially. But all our patients in the surgical group subsequently required surgery for full correction of existing deformity. Herzenberg JE et al., in their study noticed 94% of their control group treated with traditional method of casting subsequently required surgery within first year of life, despite a longer period of casting [21]. Zwick EB et al., also have similar observation, where they had continued initial casting in their control group and finally all were undergone posteromedial release at the age of 6 to 8 month for correction of residual deformity [8]. It indicates below knee cast has got little role in correction of the deformity. The above knee casts in Ponseti method holds the limb better in corrected position with less cast related complications.

The relapse rate in clubfoot treated with Ponseti method varies from 10% to 30% depending on period of follow-up [26-28]. The relapse in clubfoot patients managed with Ponseti method is primarily due to non compliance in brace application [29]. Many parents have stopped brace application early after noticing complete correction of the foot. This recurrence is a major concern for clubfoot management.

Church C et al., in their study found a higher rate of surgical intervention and a higher percentage of major surgeries required for operative group compared to Ponseti group [30]. Around 33% cases in surgical group required repeat surgical intervention for relapse treatment, out of which 79% cases had undergone major surgery however in Ponseti group only 9% cases required surgical intervention which were minor in category. Another study by Halanski MA et al., have shown around 73% recurrence in Ponseti group and 14% recurrence in surgical group were minor [7], whereas 27% recurrence in Ponseti group and 86% recurrence in surgical group were major with a significant difference in severity of recurrence. In our study, majority of recurrence in Ponseti group were minor, treated either by cast or minor procedures. However, in surgical group these were major and treated by major surgical

procedures which have a negative effect on satisfaction of parents with the treatment.

Laaveg SJ and Ponseti IV score is a 100 point evaluation system most commonly used for functional outcome measurement following clubfoot treatment. It was initially predicted by Laaveg SJ and Ponseti IV in their study of seventy patients with 104 club feet, those were treated and followed for a period of ten to twenty-seven years [17]. It consists of six categories, out of which parental satisfaction has an important role in assessing long term outcome at the end of evaluation because unless the parents of the child are satisfied with the result, a physician based result is incomplete and erroneous. According to the rating, they have got satisfactory result in 88.5% of the feet and 90% of the patients were satisfied with both the appearance and function of the clubfoot. In our study, authors observed the parents of Ponseti group were very satisfied with the short-term outcome primarily due to less invasive procedure of correction, shorter hospital stay, easy accessible wound management and less number of major recurrences. Similarly, the brace compliance and recurrence of deformity did not have much effect on the satisfaction factor because most of the recurrences were being treated by manipulation and cast only.

Using the same rating system, few other studies have shown a significant better result for Ponseti group [8,10,11,22,31]. Zwick EB et al., in their study evaluated the foot function at the age of 3.5 years and noticed FRS total score was higher in Ponseti group (94.5 versus 84) [8]. Similar observation was also seen in Ippolito E et al., study [22]. In their study, total FRS score was better in Ponseti with limited posterior release group (85.4) compared to manipulative cast with posteromedial surgical group (74.7). They have opined that extensive posteromedial surgery neither prevents relapse nor completely corrects all the deformities like cavovarus, forefoot adduction etc.

In a multicentre comparative study by Saetersdal C et al., have shown that children treated with Ponseti method have a significantly better score compared to treatment by other method (84 versus 78) [31]. They have noted children with bilateral clubfeet in the pre Ponseti group had significantly poorer parent/patient reported outcome than children with unilateral clubfeet which was not seen in Ponseti group. In the present study, authors got an excellent scoring system for Ponseti group (95.25). Porecha M et al., in their study of 47 patients (67 club feet) followed the functional Ponseti scoring System and got good to excellent results in 44 patients (89.29%) at mean five year of follow-up [32]. Pavone V et al., found more than 95% good to excellent score whereas only 3.7% suffered with relapse [33]. Poor compliance with the Denis Browne splint was thought to be the main cause of failure. In a meta-analysis by Lykissas MG et al., they did not find any significant difference in terms of FRS score in both the groups (86.3 and 82.0, respectively) [10]. However, on comparing categorically, they found patients managed with Ponseti method had a higher rate of excellent or good outcome than patients treated with open surgery (0.76 and 0.62, respectively). All the patients had a worse functional outcome on long term follow-up. In our short term evaluation, the result has

revealed a good to excellent outcome more in favor of Ponseti group which ultimately gives rise better function of clubfoot, gait and better parental satisfaction.

General health status of the children was assessed by PODCI scale [18,34]. A normal score for PODCI ranges from 0 to 100 with higher score represents less disability and better functioning. It consists of five subscales which provide a broad view of physical, mental and psychosocial status of the child. On evaluation of health status of patients, authors have noticed both the groups had high scores in all dimensions of PODCI scale with statistically indifferent scores similar to Zwick EB et al., study except transfer and basic mobility subscale [8]. They have shown a score between 92 and 100 for all dimensions of PODCI scale and there was no significant difference between both Ponseti and surgical groups at the end of 3.5 years of evaluation. However, few long term studies have results more inclined towards Ponseti group.

Church C et al., in their study have opined a significantly higher score in Ponseti group in terms of pain and global functioning criteria where as happiness, upper extremity and basic mobility criteria showed a statistically indifferent result [30]. Overall, there were functional limitation and pain in operative group on compared to Ponseti group. Similarly a long term prospective study conducted by Svehlik M et al., have more favorable outcomes in terms of FRS (p-value=0.005) with better parent reported functional status (PODCI, p-value=0.018) in ponseti group compared to surgically treated group [11]. Surgically treated children had more difficulty in playing sports and experience more pain which has given inferior result to happiness domain of PODCI.

Corbu A et al., in their long term retrospective follow-up study have opined a superior result for Ponseti in terms of morphological, functional and radiological results as well as less severe residual deformity compared to surgical treatment [35]. Similar result was also seen even in non idiopathic clubfoot patients where author have claimed Ponseti method should be considered as a primary approach as it reduces need for complex intraarticular surgery and benefits patients by reducing complication rates, need for numerous surgeries etc., [36].

In a developing country like India lack of resources, inaccessibility, difficulties to bring child for regular follow up, unacceptability to surgery for the recurrences leads to parents preference towards traditional bone setters. As Ponseti method is a non operative modalities of treatment with less number of revision surgery is required, it is quite acceptable in our population which changed our method of treatment for clubfoot in our institute.

### Limitation(s)

First, the numbers of cases included in both groups were less. Hence, generalisation of this study result may differ from those which include a large cohort of population. Secondly, there was no randomisation and study samples were taken conveniently which creates selection bias in the study. Thirdly, idiopathic clubfoot is a complex deformity which may have recurrence later, for which long term follow-up is necessary for better predictability which lacks in this study. Finally, functional outcome was assessed taking only functional rating scale however no radiographic measurement has been taken through out.

### CONCLUSION(S)

The finding in this study population treated with Ponseti have higher rate of excellent to good outcome, better parental satisfaction, better passive mobility of clubfeet and finally less number of revision surgery is required for recurrence. However, still there is a room for improvement and a chance to enhance functional and morphological outcomes and quality of life of these patients by taking a large cohort of patients with long duration of follow-up.

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