Relapse Pattern in Club Foot Treated with Ponseti Technique - A Prospective Observational Study from Kerala, India

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ABSTRACT

BACKGROUND

Though the Ponseti method has become the popular and standard of care for clubfoot correction, relapse of clubfoot deformity following correction is not uncommon. The relapsed feet can progress from flexible to rigid if left untreated and can become as severe as the initial deformity. The purpose of this study was to analyse the relapse pattern in clubfeet that have undergone treatment with the Ponseti method.

METHODS

Between 2015 and 2017, 78 children (134 feet), 58 boys and 20 girls were included in this study. It was a prospective observational study of relapse patterns in idiopathic clubfoot after one year of completion of the Ponseti method of treatment. Pirani scoring system was used to identify the relapse.

RESULTS

Dynamic, fixed, and complete relapse patterns were observed in this study. Patients were categorised into two groups - bilateral and unilateral. In the bilateral group, 18 children (36 feet i.e. 23 %) had decreased ankle dorsiflexion, 5 had (10 feet i.e. 6 %) rigid equinus, 22 had (44 feet i.e., 29 %) dynamic forefoot adduction or supination and 5 had (10 feet i.e. 6 %) fixed adduction in forefoot and mid-foot. Six children from the bilateral group showed complete relapse. Among the unilateral group, 8 children (8 feet i.e. 36 %) presented with decreased ankle dorsiflexion, 4 had (4 feet i.e. 18 %) rigid equinus relapse, 6 had (6 feet i.e. 27 %) dynamic forefoot adduction or supination and 4 had (4 feet i.e. 18 %) showed fixed forefoot adduction.

CONCLUSIONS

Dynamic forefoot adduction or supination pattern is common to relapse pattern in the bilateral group and dynamic hind-foot relapse was common in the unilateral group. Age at initial presentation, initial Pirani score, and the number of casts required were not significantly related to the incidence of relapse.

KEYWORDS

Club Foot, CTEV, Ponseti Method, Relapse Pattern

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DOI: 10.18410/jebmh/2021/206

How to Cite This Article:
Vishnu M, Mathew J, Karuppal R, et al. Relapse pattern in club foot treated with Ponseti technique - a prospective observational study from Kerala, India. J Evid Based Med Healthc 2021;8(16):1068-1073. DOI: 10.18410/jebmh/2021/206

Submission 19-11-2020,
Peer Review 29-11-2020,
Acceptance 26-02-2021,
Published 19-04-2021.

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BACKGROUND

Congenital talipes equinovarus or clubfoot is one of the most common and complex deformities of the foot.[1] Clubfoot is an unsolved clinical challenge for orthopaedic surgeons. A relapsed clubfoot is defined as the recurrence of one or more components of deformities after a successful correction.[2]

Most relapses develop gradually and may be difficult to recognise in the early stages. A relapse is detected when there is an appearance of a slight equinus and varus deformity of the heel. Forefoot adduction and cavus deformities are less frequent patterns.[1] The Ponseti method of manipulation and plaster casting is found to be very effective in the correction of clubfoot deformity.[3] The Ponseti technique is a low-cost method and has been adopted worldwide with good results. But the clubfoot has an inherent and stubborn tendency to relapse irrespective of the treatment modality we opt for.[1] Among the many manipulation treatment techniques, the Ponseti has attained great popularity due to the best results.[4] The Ponseti method has not solved the problem of relapse completely. Relapse following the Ponseti method of correction is not uncommon, and the rate of relapses varies from 10 % to 30 % depending on the duration of follow-up and brace compliance by various authors.[5,6,7]

In relapse, initial muscle imbalance causes dynamic deformities and if it were not addressed in time, can lead to static or rigid club foot deformity. Analysis of foot morphology, Pirani and / or Dimeglio score systems are used to detect and rate relapses. We have used the Pirani scoring system to identify the relapse. Early detection and interventions such as recasting to soft-tissue releases and bony osteotomies to external fixators have been described in isolation or combination for every relapse.

Relapse entails significant time and costs in additional treatment such as repeat manipulation and casting, repeat Achilles tenotomy, tibialis anterior transfer, and soft tissue releases. Each method has its own merits and demerits and none of it dealing with relapses are universally accepted as well. Regular follow-up for early identification of relapse patterns will help us to prevent the progression of deformity from mild dynamic to more severe rigid deformity.

Objectives

1. To analyse and describe the relapse pattern in both bilateral and unilateral clubfeet, the gender distribution of various relapse patterns that have undergone treatment with the Ponseti method.
2. To analyse the influence of age at initial presentation, initial Pirani score, and the number of casts required in relation to the incidence of relapse.

METHODS

This prospective observational study enrolled 78 children, with idiopathic clubfoot at the end of one year of treatment with the Ponseti technique, between May 2015 to May 2017.

Permission from the institutional ethics committee was obtained for our study. Informed consent was taken from the parents of the children after counseling them regarding detection of relapse, proper treatment for relapse, and the benefit of follow-up. Inclusion criteria for the study group was children with relapse of idiopathic clubfoot at the end of one year of treatment with the Ponseti technique (both unilateral and bilateral cases).

Exclusion criteria were those cases that failed to attend the regular follow-up and strict adherence to brace protocol as well. We also excluded children with syndromic clubfoot, neurogenic clubfoot, atypical club foot, and clubfoot treated with other methods. Altogether there were 78 children, (58 bilateral), amounting to a total of 134 feet. All fully corrected clubfoot deformity patients were followed up for a minimum of 1 year, after completion of one year of Ponseti treatment. Pirani scores of more than zero during follow up was taken as relapse. A detailed history was taken from parents regarding the onset of deformity and history of treatment. A detailed general examination was also done to rule out syndromic and neurogenic clubfoot. We relied on the parent's report concerning the use of a brace.

Initial treatment records for age at first presentation, initial Pirani score, number of corrective casts used for correction, and about tenotomy of these children were also analysed during the study period. We analysed both bilateral and unilateral groups separately. All patients were assessed for the deformities such as forefoot or hindfoot relapse, dynamic or fixed deformity, and the mobility of ankle and foot as well. All patients were assessed for the pattern of relapse of static deformities i.e. equinus, varus, adduction, cavus as well as for dynamic supination. We also quantified the deformity based on the Pirani score.[8]

Objective measures of brace compliance were not available, therefore verbal reports concerning the use of the brace were used by us as the primary means of assessment. Those cases of relapses were then treated by repeated Ponseti casting followed by foot abduction orthoses (FAO). Weekly cast application was performed in our clubfoot clinic using Ponseti classical two-hand technique. All casts were applied under strict supervision.

Percutaneous tenotomy of the tendo-Achilles, if required, was done mostly under local anaesthesia. Post-tenotomy casts were removed after two weeks. Tibialis anterior tendon transfer was done in children older than three years with dynamic supination. To maintain the achieved correction, a foot abduction orthosis was given to all, except patients who underwent tibialis anterior tendon transfer.

Statistical Analysis

This was done with a Statistical Package for Social Sciences (SPSS) version.2. Quantitative variables were analyzed with an unpaired t-test, nominal variables with the chi-square test, and a P-value of < 0.05 was considered statistically significant. The quantitative variables were expressed as mean and standard deviation. Pre-and post-treatment follow-ups were compared using the paired t-test.

RESULTS

Seventy-eight children fulfilled the eligibility criteria for our prospective observational study. Of them, 58 had bilateral and 20 had unilateral involvement. Among 78 children, 60 cases were initially treated from our institute and 18 cases were treated from elsewhere and further treatments were continued from our institute. The study group included 58 males (74 %) and 22 (26 %) female children with a mean age of 2.2 years (range, 2 - 3 years). Gender and side distribution data are shown in Table 1. The male-to-female ratio was 2.5:1. The gender distribution of various relapse patterns is shown in Figure 1.

We analysed the treatment records of the age at first presentation for initial Ponseti cast for deformity correction and found the mean age was 11.196 days in the bilateral group and 9.545 days in the unilateral group (range, 2 to 30 days). The mean initial Pirani score in the bilateral group was 5.563 (range, 3 - 6) and in the unilateral group was 5.568 (range, 4 - 6). The number of casts required before tenotomy in the bilateral group was 6.018 and in the unilateral group was 6.182 (range, 3 - 10 casts). There were no major complications associated with casting except loosening and breakage in a few cases. Percutaneous tenotomy was required in more than 95 % (73 / 78) of cases to correct equinus deformity. All children in this study group were on brace (foot ankle orthosis), but 54 children were not compliant, which is reported as one of the most common reasons for relapse in many studies.

In our interim observation in the Ponseti casing treatment for relapsed cases, we were able to achieve good correction in most of our patients without the need for any surgery except percutaneous tenotomy (95 %) and tibialis anterior tendon transfer (13.6 %). Results and its statistics concerning the age at initial presentation, initial Pirani score, and the number of the casts are summarised in Table 2.

Our study shows different relapse patterns during the follow-up, which is shown in Table 3. We found that the relapse of the forefoot was as common as relapse of hind foot deformities, and the relapse of deformities occurred either singularly or more commonly in various combinations.

The complications of Ponseti casting were seen in 8 patients (10.25), they had cast loosening and cast breakage which we managed by recasting. We had no cases with redness, swelling, or skin erosions.

Chi-square test was performed which did not show any statistical significance (P-value 0.25). The different relapse pattern distribution on a gender basis was also analysed as shown in Table 4. Although there was a male predominance in the distribution of various relapse patterns, this was not statistically significant (P-value = 0.29).

	Bilateral Group	Unilateral Group	Total
No. of males	42	16	58
No. of females	14	6	20
Total	**56**	**22**	**78**

Table 1. Gender and Side Distribution

	Side	N	Mean	Standard Deviation	Standard Error of Mean	P Value	T Value
Age at initial presentation (days)	B / L	56	11.196	6.7539	0.9025	0.34	0.96
	U / L	22	9.545	7.0355	1.5		
Initial Pirani score	B / L	56	5.563	0.7265	0.0971	0.973	0.034
	U / L	22	5.568	0.4704	0.1003		
No. of cast used for correction	B / L	56	6.018	0.9044	0.1208	0.494	0.69
	U / L	22	6.182	1.0527	0.2244		

Table 2. Age at Initial Presentation, Initial Pirani Score and Number of Cast with Its Statistics

Pattern of Relapse	B / L Group	U / L Group	Total
Decreased ankle dorsiflexion up to neutral	18	8	**26**
Rigid equinus	5	4	**9**
Dynamic forefoot adduction or supination	22	6	**28**
Fixed adduction of forefoot and midfoot	5	4	**9**
Complete relapse	6	0	**6**

Table 3. Rate of Occurrence of Various Relapse Pattern in Bilateral and Unilateral Group

Chi-square value = 5.42; P-value = 0.25

Pattern of Relapse	Males	Females
Decreased ankle dorsiflexion (less than 15 degrees / up to neutral)	21	5
Rigid equinus (less than neutral)	7	2
Dynamic forefoot adduction or supination	19	9
Fixed adduction of forefoot and midfoot	5	4
Complete relapse	6	0

Table 4. Gender Distribution of Various Relapse Patterns

Chi-square value = 4.97; P-value = 0.29

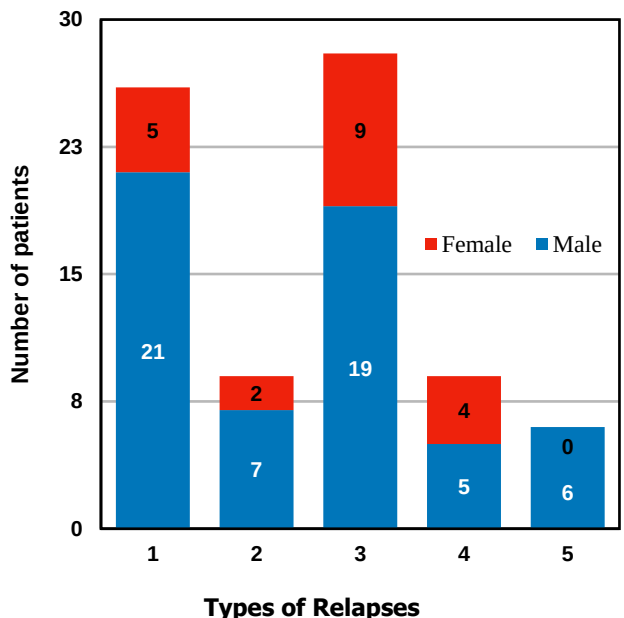

Figure 1. Gender Distribution of Various Relapse Patterns

1. Decreased ankle dorsiflexion (less than 15 degrees / up to neutral);
2. Rigid equinus (less than neutral);
3. Dynamic forefoot adduction or supination;
4. Fixed adduction of forefoot and midfoot;
5. Complete relapse.

DISCUSSION

The Ponseti method has become the popular and standard of care for idiopathic clubfoot correction during the last decade because of its high initial correction rate. The number of scientific studies has increased tremendously in the last two decades and all show consistent and

commendable success in the initial correction. Treatment for club foot has radically changed from surgical correction to the more conservative Ponseti method of correction. The most common problem affecting the long-term successful outcome is a relapse of the deformity. The relapsed deformity of the feet progresses from flexible to rigid type if left untreated and can become as severe as the initial deformity. Though relapse is not uncommon after the Ponseti method of correction, it is the most popular, efficient, and acceptable treatment which considerably decreases the need for radical surgery and its complication.[9] Relapse is the case where the deformity recurs after full correction.[2,10]

Relapse is also defined as any foot requiring further intervention following successful correction with the Ponseti technique by many.[11] Some authors use anatomical terms such as adductus, varus, equinus, or combination to describe the relapse. Others have used the Pirani or Dimeglio score to quantify the relapses.[7] Relapse can be classified as mild or severe depending on the extent of invasive surgery required on these feet.[12]

The Pirani score and Dimeglio classification are helpful to grade the initial status of the deformity and to assess the progress of foot correction during treatment.[8,13] Relapses following the Ponseti method of treatment are more subtle and the foot stays supple due to minimum surgical intervention, whereas it has often many issues like soft tissue scarring, skin problems, and foot stiffness following surgical treatment.[14,15] Typical deep medial and posterior creases are uncommon and the talar head is often reducible in mild forms.[11] If the initial relapses are not addressed in time, can lead to static or rigid deformities.[16] We have observed that the relapse pattern in clubfeet undergoing correction with the Ponseti regime follows a definite pattern. The initial relapses were supple, as the muscle imbalance causes dynamic deformities.

Most of the children with relapse of clubfoot included in our study were between 2 - 3 years of age i.e. during the maintenance phase of Ponseti correction. Relapse pattern may also be influenced by the foot abduction orthosis (FAO) which is an important component of the Ponseti regimen until 3 - 4 years of age. In many studies, it seems that relapses were rare after four years of age.[11]

We found dynamic forefoot adduction or supination relapse was the commonest type of relapse among the bilateral group in this study (37.93 %). And among the unilateral club foot group, decreased ankle dorsiflexion or dynamic hind-foot relapse pattern (30 %) was the most frequent relapsed deformity, which had no functional restrictions compared to the fixed forefoot and hind foot relapses. We found no child in the unilateral club foot group that presented with a complete relapse pattern compared to the bilateral group.

There are reports of the number of casts for correction in idiopathic clubfoot is influenced by both initial Pirani score and age of beginning of cast treatment.[16,17] We found age at first presentation for treatment, initial Pirani score, and the number of casts required before tenotomy showed no significant difference in the bilateral and unilateral group (P-values, 0.34, 0.973, 0.494 and T-values, 0.96, 0.034, 0.69 respectively). Our observations of male predominance in the club foot incidences were similar to many other studies.[12,18] The Pirani score and Dimeglio classification can predict the recurrences, the number of casts required, and need for tenotomy, but cannot predict compliance with the foot abduction orthosis which is mandatory for a successful outcome in the long term.[19]

Verbal reports concerning the use of the brace were used by us as the primary means of assessment. We have seen 53 children were not compliant with the brace and in many studies, poor compliance with a brace was the commonest cause of relapse. This non-compliance issues can be limited to a great-extent by the good communication between doctors and parents to convince them regarding the mandatory role of a brace in the final phase of treatment. Relapse is an important component associated with the Ponseti method of correction and early recognition with prompt treatment gives the best results.[16] Different authors have used varying terms to describe relapse.

During our assessment of clubfoot deformity at follow-up, we found dynamic forefoot adduction or supination pattern is common to relapse pattern in the bilateral group and dynamic hind foot relapse was common in the unilateral group. Initial muscle imbalance may cause dynamic deformities which if not addressed in time will lead to a fixed deformity that may require a surgical release. We found early relapse patterns are usually seen in the hind foot, i.e. a decrease in ankle dorsiflexion, with zero hind feet Pirani score. This loss in ankle dorsiflexion may be due to the growth of the foot as the child grows. Hence it is recommended to continue Ponseti cast even after dorsiflexion reaches neutral for a while to prevent fixed equinus deformity. Hence it is recommended that relaying on clinical examination is more desirable than depending on the Pirani score alone for early detection and timely intervention. Rigid deformity in the corrected club foot is always preceded by flexible muscle imbalance, and relapses are associated with discontinuation of foot abduction orthosis. Duration of splint less than 12 hours per day compromises the result after initial Ponseti correction. The foot abduction orthosis is an integral part of the Ponseti regime to prevent relapse. We believe the dynamic forefoot adduction or supination pattern of relapse with in-toeing, usually stays in the neutral position and this observation reinforces the need to maintain foot abduction orthosis for long period to prevent in-toeing.

Non-compliance with the foot abduction orthosis protocol was reported to be the major cause of relapse and has a direct effect on the success of treatment.[20] Nearly almost all recurrent cases of clubfoot deformity occurs during the brace protocol phase. The most common reason for non-compliance with the foot abduction orthosis treatment is discomfort. It is clear that foot abduction orthosis is important to the maintenance of correction of clubfoot after cast correction.[21]

Children with an idiopathic clubfoot who experienced relapse before two years of age are significantly more likely to be non-adherent with FAO than those who sustain recurrence after age two.[22]

We also believe that the recurrence of deformity due to

brace wear non-compliance is a preventable problem. There are many reports which show major complications such as cast loosening and cast-associated skin irritation, redness, swelling & skin erosions are common with Ponseti casting in relapsed clubfeet treatment.[23] We had no major complications associated with casting in the correction of relapse except loosening and cast breakage in a few cases.

Rigid deformities in an adequately corrected clubfoot are almost always preceded by flexible muscle imbalances. We have noted that relapses are usually preceded by discontinuation of night-time foot abduction orthosis or poor compliance in the majority of our patients. Duration of splint wear of less than 12 hrs / day compromises the result after the Ponseti technique and leads to a less satisfactory outcome.[24] In our series, we found percutaneous Achilles tendon tenotomy was required in more than 95 % (73 / 78) of cases to correct equinus deformity. Almost (13.6 %) children require transfer to support the evertor power of the forefoot tibialis anterior tendon. We believe to continue foot abduction orthosis for long term use to prevent intoeing secondary to foot invertor–evertor muscle imbalance. We prefer Achilles tendon tenotomy to obtain equinus correction which reduces the need for repeat casting and consequent stiffness of the foot. We followed a formal posterior capsular release rather than re-tenotomy alone for the rigid equinus deformity. This is to tackle the restriction of ankle dorsiflexion because of fibrosis due to the previous tenotomy.

CONCLUSIONS

Ponseti method should be the preferred initial treatment modality even for relapsed idiopathic clubfeet. The frequency of dynamic relapse patterns is more compared to fixed relapse patterns, probably due to initial muscle imbalance or poor compliance with the brace. Dynamic forefoot adduction or supination pattern is common to relapse pattern in the bilateral group and dynamic hind-foot relapse was common in the unilateral group.

Age at initial presentation, initial Pirani score, and the number of casts required were not significantly related to the incidence of relapse. Strict adherence to brace protocol and good communication between doctor and parents may reduce future incidences of relapse. Early identification of different relapse patterns helps us to provide appropriate interventions for the particular relapse pattern which will improve the outcome. Surgical intervention may be reserved for relapse cases if and only if a fair trial of Ponseti treatment fails.

Limitations

A larger study group and longer follow-up from multiple centres are desirable to validate our results. Also, we believe recorded recall-based data collection and chances of selection bias (since ours is a single-center study) are probably another limitation.

Bracing adherence (or not) was not based on the established clinical notes and therefore verbal reports concerning the use of the brace were used by us as the primary means of assessment. This is another limitation of our study.

Noncompliance with the Ponseti brace protocol is a major problem associated with relapse.[24] Without altering the basic principle and design of the brace, it is possible to improve compliance by making it more comfortable and affordable. After refinement in the Ponseti method and emphasizing the importance of brace to parents, the relapse rate can be markedly decreased. Nevertheless, some patients do not have any recurrence although they are not completely compliant with the brace treatment, whereas other patients have a recurrence even though they are strictly compliant with the brace treatment. Compared to a surgical correction, relapse following Ponseti treatment is subtle and easily correctable. So, it is important to identify the pattern of relapse at the earliest for providing proper treatment for relapse. It was interesting to observe in our study that age at first presentation, initial Pirani score, and the total number of casts required to correct deformity are insignificant factors to predict the relapse. Repeat tenotomy for relapse gives good correction without any complications, which we had practiced in a great majority of our patients. Further research in a large group may be required to identify high-risk feet and to develop individualised bracing protocols.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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