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Short Term Functional outcome of Ponseti's Method in Infants with Congenital Talipes Equinovarus

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Introduction

Clubfoot or congenital talipes equinovarus is a congenital birth abnormality affecting feet which causes cosmetic abnormality and progressive difficulty in walking. In most cases etiology is unknown even though there are many theories regarding the same. It is said to be seen in 1 out of 1000 live births.

It is managed now with Ponseti technique developed by Ignacio V. Ponseti in the 1940s. One of the major principles of this technique is the concept that the tissues of a new-born's foot, including tendons, ligaments, joint capsules, and certain bones, will yield to gentle manipulation and casting of the feet at weekly intervals. This has brought a drastic change in the treatment and hence has improved the results of clubfoot treatment without resorting to major surgeries.

This treatment is economical and when implemented correctly, will significantly result in deformity correction in children with clubfoot. Major manipulation and surgical procedures are avoided. The feet gets improved in appearance and function. Also the long term complications of uncorrected feet like osteoarthritis and painful bursitis don't happen with this treatment.

Aim of the Study

The aim of our study is to explore the functional outcome of Ponseti method for the management of congenital talipes equinovarus in children less than 12 months who attended at club foot clinic of orthopaedic outpatient department, medical college Thiruvananthapuram.

Primary Objective

The objective of the study is to evaluate the functional outcome of Ponseti method for the management of congenital talipes equino varus in patients less than 12 months, who attended the clubfoot clinic of orthopaedic outpatient department of medical college Thiruvananthapuram using Catteral/Pirani scoring system and Dimeglio/Bensahel scoring system.

Secondary Objective

The socio-demographic information of the study patients are also tabulated and evaluated.

Review of Literature

Congenital talipes equinovarus or clubfoot is one of the most common birth defects involving the musculoskeletal system. Idiopathic clubfoot is an isolated deformity of the foot and leg that is identifiable in utero and consists of four components: equines, hind foot varus, forefoot adductus, and cavus.

Etiology

Clubfoot deformity may be idiopathic (no known cause) or associated with myelodysplasia, arthrogryposis, poliomyelitis sequalae or even part of other congenital abnormalities. The most common presentation is an isolated birth defect and so considered idiopathic. The secondary clubfeet (clubfoot due to other known causes behave in a different way than the idiopathic ones and are usually resistant to treatment.

Using a candidate gene approach, common genetic variants have been associated with clubfoot including variants in homeodomain transcription factors HOXD12 and HOXD13, and several apoptotic genes including the caspase genes.

The identification of the exact aetiology of clubfoot may eventually be helpful in determining both prognosis and the selection of appropriate treatment methods in an individual patient.

Treatment of Clubfoot

Kite in 1939 introduced a method of manipulation that primarily involved serial manipulations and casting. Correction of the heel varus was attempted by abducting the foot at the midtarsal joints and by applying direct pressure on the calcaneocuboid joint. However, by abducting the forefoot in this manner, the calcaneus was actually blocked from adducting under the talus and the heel varus persisted. Therefore, because of this fundamental flaw in technique, this method of correction was often quite lengthy with children being casted for up to 2 years. In addition, 50% to 75% of patients still required soft tissue release surgery because of incomplete corrections. Also patients finally ended up with stiff painful feet due to the scaring of the surgeries.

Ponseti Method

The Ponseti method is a method of serial manipulation, casting, and tenotomy of the Achilles tendon to achieve correction of the clubfoot. This method included weekly serial manipulation of all deformities except equinus followed by abduction bracing to retain correction as well as strategies to treat relapses once they occur based on age of the child. The parents are clearly explained about the procedure along with the duration, the need for regular visits, plaster and tenotomy care protocols and use of brace. Even though there are a few dropouts (due to various personal reasons) most of them comply and achieve excellent results due to its child friendly approach as against older painful manipulation techniques.

The treatment is ideally started as early as possible within the first few weeks of life and consists of gentle manipulation of the foot in an office setting followed by serial application of a long leg cast as described by Ponseti. Though Ponseti advocates the use of plaster for the cast material as it is easier to mould, the fiberglass materials can also be used for achieving clubfoot correction. Regardless of the casting material used, the casts are changed every 5 to 7 days.

Children over 3 year of age present with hindfoot varus in combination with a dynamic supination of the forefoot observed while walking require a different approach. The varus of the heel and adduction of the foot are first corrected with serial casting. Once these deformities are corrected a full tibialis anterior tendon transfer to the third cuneiform is performed. The child is casted for6 weeks postoperatively, but there is no need for use of the foot abduction brace after this procedure. The physical therapy can be incorporated into the post casting regime for these patients to help with gait training and muscle strengthening.

French Method

Another popular method of clubfoot treatment that also avoids extensive surgical treatment is the French or functional method. This method requires daily manipulations of the new-born clubfoot by a skilled physiotherapist followed by immobilization with adhesive taping to maintain the correction achieved with stretching.

Role of Surgery in Clubfoot Correction

The use of surgery for primary clubfoot correction today has been limited to an "a la carte" approach, where structures are released only as and when needed to obtain correction as an adjunct to a more conservative manipulative approach. The vast majority of idiopathic clubfeet should be treated with casting and a percutaneous Achilles tendon Tenotomyalone.

Club Foot Scoring Systems

There is no agreed method of grading the severity of deformity or monitoring the natural history, but there is a reported need for such a classification .which should be reliable, reproducible, feasible in a clinical setting, and predict appropriate treatment.

Pirani et aldevised a simple scoring system based on six clinical signs of contracture. Each is scored according to the following principle: 0, no abnormality; 0.5, moderate abnormality; 1, severe abnormality. The six signs are separated into three related to the hindfoot (severity of the posterior crease, emptiness of the heel and rigidity of the equinus), and three related to the midfoot (curvature of the lateral border of the foot, severity of the medial crease and position of the lateral part of the head of the talus). Thus, each foot can receive a hindfoot score between 0 and 3, a midfoot score between O and 3 and a total score between 0 and 6. Score are interpretation when assessed for inter-observer reliability, the kappa score showed this to be almost perfect and much better than any of previous scoring system

Dimeglio and his colleagues divided clubfoot deformity into four measurable anatomical features, or subgroups, which are scored on a scale of 20 points. These subgroups are equinus in the sagittal plane, varus deviation in the frontal plane, derotation around the talus of the calcaneus causing-forefoot block, and adduction of the forefoot on the hindfoot in the horizontal plane. Each subgroup is assessed in severity from 1 to 4 points. In the presence of a posterior or medial fold, extreme cavus and/or muscle weakness, another point is added to each category for a possible total of 5 points.

The Dimeglio and Pirani scoring systems are useful in evaluating the degree of correction of the foot as well as the potential for the prognosis of the disease.

The superiority of any one scoring system over another has not been validated yet.

Materials and Methods

Study Design: Hospital level prospective, descriptive study.

Study Setting: Clubfoot clinic in Orthopaedic Out Patient Department, Govt. Medical College Hospital Thiruvananthapuram, a tertiary care referral and teaching hospital.

Study Period - 1 year (Jan 2015 to Dec 2015)

Study Population- Infants having Idiopathic Congenital Talipes Equinovarus, both unilateral and bilateral foot.

Inclusion Criteria- Patients both male and female with club foot for whom casting method was employed by Ponseti technique for at least three consecutive treatment session.

Exclusion Criteria

1. Children with clubfeet above the age of 12 months. 2 Children with teratologic clubfoot. 3 Children with syndromic associations. 4 Recurrent and relapsed clubfeet consequent to failed surgical treatment. 5 Patients who discontinued their treatment from Outpatient Unit. 6 Patients who did not receive casting for minimum three sessions in outpatient unit.

Sample Size- All patients satisfying the inclusion criteria of congenital talipes equino varus who were attended the clubfoot clinic in the first six months of the study and followed up for a period of three to six months. And so the sample size is 40.

Data Collection Tool- clinical examination, clinical records. Patients are assessed by semistructured questionnaire, Catteral/ Pirani scoring system and Dimeglio/ Bensahel scoring system.

Informed Consent- Informed consent was obtained from the parents of the patient after

counselling them regarding the benefits of the treatment and their active role in the treatment protocol as emphasized by Ponseti himself.

Study Procedure- The socio-demographic details of the patients were assessed in the first sitting itself using the questionnaire and the clubfeet are initially assessed with Pirani scoring system and Dimeglio/Bensahel scoring system. After counselling the parents, and with their full active involvement to direct away the child's attention, and with the help of an assistant, the clubfeet were manipulated strictly in accordance to the scheme described by Ponseti.

First Cast: Prior to casting, the position of the forefoot in relation to the heel is assessed for any abnormally high arch (cavus) of the foot. The first cast application addresses this foot deformity, aligning the forefoot with the hindfoot. By doing this, the cavus is corrected typically after one cast. First a short-leg cast was applied to just below the knee, which was then extended above the knee. Ponseti emphasizes the importance of long-leg casts, which are essential to maintain adequate stretching of tendons and ligaments.

Second Cast: After one week the first cast is removed and after a short period of manipulation the next long leg (toe to groin) plaster cast is applied. This manipulation and casting is focused on straightening the foot, aligning the forefoot with the heel. Further Casting: Manipulation and casting was continued on a weekly basis for the next two to six weeks in order to gradually straighten the forefoot, allowing the forefoot to move in line with the heel.

Every foot was scored each week for HS, MS, and total score. Pirani score was the road to treatment. Tendoachilles Tenotomy is indicated when HS>l, MS<1, and the head of talus is covered, that is score '0'. The Dimeglio score was also assessed at each visit. The Achilles tendon percutaneous release is a quick procedure that is typically done through a small puncture, under local anesthesia.

The final cast: After the tenotomy the foot and ankle are then casted in the final corrected position with Achilles tendon stretched further and

the forefeet pointed upward. After removal of the final cast, the infant is placed into a brace, which maintains the foot in its corrected position. Brace was prescribed by usual bracing protocol as described by Ponseti: and was applied immediately after the last cast was removed, 3 weeks after tenotomy. The brace should be worn full time (day and night) for the first 3 months after the last cast was removed. After that, the child 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 during each 24 hour period. Children were assessed after the end of casting treatment, at 3 months in the bracing period and at 6 months of follow up using Catteral/Pirani scoring system and Dimeglio/Bensahel scoring system. The treatment was considered as success if pirani score was ≤ 0.5 at the end of treatment.

Data Management and Analysis- Data was entered into Microsoft excel sheet and appropriate statistical test were applied based on the variables using SPSS software.

Ethical Issue-Approval obtained from the Superintendent Govt. Medical College Thiruvananthapuram, The Head of the Department of Orthopaedics, Govt. Medical College Thiruvananthapuram .a research committee and the institutional ethical committee of Medical College Thiruvananthapuram. The investigator strictly followed the guidelines given by local ethical review committee according to rules and guidelines of WHO and local research committee. The questionnaire was developed and approved by supervisor of the researcher. All the data was reviewed in strict secure and maintained.

Results and Analysis

Quantitative variables are presented as mean \pm SD or median (range).

In the group, comparison of qualitative variables were analysed with Wilcoxon rank test, chi-square test with Friedman test where ever necessary.

Between Qualitative variables are described by frequency distribution.

Groups, comparison of qualitative variables were analysed by chi-square test with Fischer's Exact test. Correlation is assessed by spearman's rho test.

Between groups, comparison of quantitative variables were analysed by t-test

A p-value of 0.05 was taken as the level of significance.

Data were statistically analyzed with the use of the Statistical Package for Social

Science Program (SPSS version 22.0.0 for Windows)

A total of 40 patients contributing a total 59 foot were studied. 26 (65%) were males and 14(35%) were females.

SEX	Number of patients	Percentage
Male	26	65
Female	14	35
Total	40	100

Mean age in weeks at the start of the treatment was 7.15(SE-1.08) (Range 1-30 weeks) with median age of 4 weeks. 14 patients were only 1 week of age, four patients each were 4 weeks and 2 weeks of age. Three patients each were 9 and 7 weeks of age. Two were 10 weeks old. One patients each with 3,5,6,8,18,21,25,26,28,and 30 weeks of age. From this it is clear that most of the patients are younger than two months of age.

Involvement	Female	Male	Total
Unilateral	9	12	21
Bilateral	5	14	19
Total	14	26	40

23 (57.5%) were first born, 14(35%) were second born and 2(5%) third born. Only one patient (2.5%) was first child of the twins and the second child was normal. 19 patients (47.5%) were bilaterally affected and 21(52.5%) has unilateral disease.

Only 4(10%) are from urban area and rest 36(90%) are from rural area

16 patients (40%) are from nuclear family and 24(60%) patients are from extended type of family.

6(10%) patients are preterm babies and rest of them are full term delivery with no post term babies.

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None of the patients had other comorbidities also none of them has post natal complications.

Dimeglio score at initial presentation was Type III for 48 feet (81.4%) and Type IIb for rest of the 11 feet. At the completion of casting treatment all of them are Type I, and at 6 months 57 feet (96.6%) had typel score and 2 feet (3.4%) had Type Ha score.

Median intial pirani score was (range 3 to 6) after the casting the median score was 0.5 (range 0-1) and the dimeglio score at the same time was 19 (range 14-19) and 4 (range 4-5) respectively.

Out of the 23 tenotomy feet, 10 foot was of female children and 13 were of male. Of the nontenotomy group 9 foot was of female and 27 of male children. Also there was no complication related to tenotomy neither on performing nor on follow up.

There was no statistically significant difference in the incidence of tenotomy in female and male children as determined by Fisher's Exact test (chi square value 2.195, P=0.138). Out of 23 tenotomy foot 12 were left and 11 right and in nontenotomypatients, out of 36, 18 each were left and right. And also there is no statistically significant difference between left and right foot in the incidence of tenotomy as by Fisher's Exact test (chi square value 0.027, P=0.871).

The median Pirani score at start of the treatment was 6 (range 3-6) and at completion of casting treatment was 0.5(range 0-1). There is significant difference in the Pirani score at the start of the treatment and completion of casting treatment as by Wilcoxon signed rank test (P=0.0001). Also

there is statistically significant difference in the Pirani score after treatment completion and follow up at 3 months on foot abduction brace (P=0.0001) and at 6 months (P=0.0001). The difference in Pirani score at 3 months of follow up and at 6 months of follow up are also statistically significant. (P=0.025, Wilcoxon signed rank test, after excluding the relapsed and residual deformity cases).

	Median pirani score	range	P Value (Wilcoxon signed rank test
At the start of treatment	6	3-6	
At completion of casting treatment	0.5	0-1	0.0001
At 3 months of FAB	0	0-1	0.0001
At 6 months	0	0-3	0.0001

The median Dimeglio score at the start of treatment was 19(range 14-19) and at completion of casting treatment was 4(range 4-5) at 3 months of foot abduction brace 1(range 0-2) and at 6 months of follow up 0(range 0-2). There also statistically significant difference in the Dimeglio score at start of treatment to completion of casting treatment (P=0.0001, Wilcoxon signed rank test), at 3 months of follow up (P=0.0001) and at 6 months of follow up (P=0.0001). The difference is also significant between ends of casting treatment to 3 months on FAB and at 6 months of follow up (p=0001 each) the same is true between 3 months and 6 months score.

	Median dimeglio score	Range	P Value (Wilcoxon signed rank test
At the start of treatment	19	14-19	
At completion of casting treatment	4	4-5	0.0001
At 3 months of FAB	1	0-2	0.0001
At 6 months	0	0-2	0.0001

Table (5.4): Test result of Dimeglio score at different point of time with initial score by Wilcoxon signed rank test.

There is positive correlation between the initial Pirani score and number of cast required for correction assessed by spearman's rank correlation test (correlation coefficient= 0.493, P=0.0001).

A positive correlation also between initial Dimeglio score and number of cast has required for correction (spearmans rank correlation test, coefficient 0.454, P=0.0001).

From above it is clear that initial Pirani score is more predictive (correlated) to number of cast than initial Dimeglio score. The mean number of cast for patients not requiring tenotomy was 4.58 (SE-0.2710 with minimum number of cast 3 and maximum 8. For tenotomy patients it is 6.48(SE-0.453) with minimum 3 and maximum 10 cast.

The mean initial Pirani score for tenotomy group was 5.457(SD-0.782, SE-0.1631) and for nontenotomy group was 5.181(SD -1.063, SE-0.1772). And there is no statistically significant difference between initial Pirani score of patient requiring tenotomy and those not requiring tenotomy (P=0.288).

The mean initial Dimeglio score for tenotomy group was 18.26(SD-1.251, SE-0.261) and for nontenotomy patients 17.83(SD-1.828, SE-0.305). Also there is no statistically significant difference in initial Dimeglio scores between patients requiring tenotomy and those requiring no tenotomy (P=0.330).

Mean n	o of	Mean intial Pirani	Mean intial Dimeglio
Cast (SE, r	ange)	Score (SD, SE)	Score (SD, SE)
Tenotom	4.58	5.46(0.782,0.163	18.26(1.251,0.26
у	(0.271,	1)	1)
patients	3-8		
Patients	6.48	5.18(1.063,0.177	17.83(1.828,
with no	(0.453,3)	0.305)
tenotom	-10)		
У			
P value		0.288	0.330

Table (5.5) Initial Pirani and Dimeglio score with Tenotomy- test result

The treatment was success in 36 patients, that is 52 foot (88.1%), and not successful in According to Friedman Test the mean rank at start of treatment for Pirani score was 4, and at

completion of casting treatment 2.7, at 3 months on FAB 1.71, at 6 months of follow up 1.59. There was statistically significant difference in Pirani score in these periods (P=0.0001, chi square value of Friedman test is 142.03)

Time period	Rank (pirani)
At start of treatment	4
At completion of casting	2.7
technique	
At 3 months	1.71
At 6 months	1.59
P.value	0.0001
Chi square	142.03

Table (5.6) Friedman test results for Pirani score

The mean rank at the start of treatment for Dimeglio score was 4,at the end of casting treatment 3,at 3months on FAB 1.79 and at 6 months 1.21. This indicates that there is statistically significant difference in Dimeglio score at these periods (P=0.0001, chi square value of Friedman test is 152.024. From the chi square value it can be also conclude that Dimeglio score is more significant in determining the functional outcome than Pirani score.

Time period	Rank (dimeglio)
At start of treatment	4
At completion of casting technique	3
At 3 months	1.79
At 6 months	1.21
P.value	0.0001
Chi square	152.024

There is also positive correlation between initial Pirani and Dimeglio score (spearman's rho test, correlation coefficient 0.825). The same correlation continued throughout the casting and towards the end of casting treatment the Pirani score plateaus sothat the correlation decreases (at the end of casting treatment correlation coefficient is 0.533). This correlation become less significant on further follow up in FAB and at 3 months, as Pirani score is same 0 value and Dimeglio score is serially decreasing, the correlation coefficient was only 0.192). Again at the end of 6 months there is positive correlation between Pirani and Dimeglio score because both are touches or around 0 value (correlation coefficient 0.589, excluding the relapsed cases). This indicates that both Pirani and

Dimeglio scores can be used for assessing the progress at the time of casting treatment but Dimeglio is more useful in follow up periods as Pirani score plateau towards the end of treatment.

Time period	Spearman's correlation coefficient
At start of treatment	0.825
At the end of casting	0.533
treatment	
At 3 months on FAB	0.192
At 6 months of follow up	0.589

Table (5.8)Correlation between Pirani andDimeglio score by spearman's test

Discussion

The ponseti technique has been effective at both short and long term follow up. This technique involves two phases, the correction phase where the deformity is corrected by serial manipulation and casting, and the maintenance phase were the correction achieved is maintained in the growing foot. The use of foot abduction brace after casting treatment and tenotomy is an important part of ponseti technique and in this second phase is where chance of recurrence usually occurs and to prevent this it is advised that to use foot abduction braces once the foot deformity correction was obtained.

This study shows that initial Pirani and Dimeglio scores can be used to roughly estimate the number of weekly cast required for correction. That is higher the initial score the higher the number of cast required. Among them Pirani score is more predictive of the number of cast than Dimeglio score. With each cast the Pirani and Dimeglio scores are gradually decreasing, which means that there was increase in functional outcome of foot. But there was no correlation between initial Pirani and Dimeglio score to the need of Tenotomy in the later stage of the treatment, and this finding was against the previously demonstrated association in many studies. Also it is possible to explain the disease prognosis based on the severity of deformity at initial time, using these scoring system

Tenotomy is the only area of Ponseti casting method that involve surgical intervention. All deformities except equinus must be corrected before this procedure.

If the deformity recurs the casting technique should be restarted as early as possible even though a number of studies support the finding that surgical methods have good results after recurrences .Ponseti method to be tried before surgery to avoid fibrosis, scar tissue and to prevent anaesthetic complications. The success rate of the Ponseti technique is good in patients with recurrence of the deformity also. If the first treatment was not Ponseti then also this technique is effective in recurrence. Nogueira et al reports that in patients who had unsuccessful surgical treatment, 86% were corrected by Ponseti method. In this study it is observed that Pirani score plateaus just prior to completion of casting treatment unlike Dimeglio score, there is still a gradual fall at the same time. So it is better to use both scores at the casting treatment time but once that time is over, the Dimeglio score is more useful for follow up, in assessing the functional outcome. From this it is concluded that both scores can be used for clubfoot evaluation at the time of casting treatment depending on surgeon's choice as they do not show any superiority over the other at that time and it is better to use Dimeglio score at follow up after casting treatment.

By analysing the socio-demographic data the positive finding in the literature that is in consistence with my study group was the more prevalence of clubfoot in male children.

Based on the current data of this study the Ponseti casting technique has excellent early results and decreases the necessity of extensive surgical procedures at early stages. And now a days, in consistence with this study findings, Ponseti technique is accepted as the gold standard for idiopathic congenital talipes equinovarus. Short term outcome from this study has shown that Ponseti technique can be applied as the primary treatment of idiopathic congenital talipes equinovarus and also anticipate that the long term results to be similar and to correspond to short term outcome as depicted here. Long term follow up needed for actual determination of recurrence/relapse and residual deformity assessment.

Also from the study it is found that Pirani and Dimeglio scoring system to be practicable, reproducible and helpful in the management of idiopathic congenital talipes equinovarus by the Ponseti method.

Summary and Conclusion

In infants with idiopathic CTEV, a proper correction, thereby the functional outcome can be obtained by using the Ponseti method and can be used as the primary treatment modality. Both Pirani and Dimeglio scores can be successfully used for the evaluation especially during casting treatment and do not show any superiority over another. They are practical, reproducible and helpful in the management of the disease. But once the patient is put in the brace, it is the Dimeglio score which is more useful. Hence both can be used effectively used in daily practice depending on surgeon's choice.

There is a definitive correlation between Pirani and Dimeglio scores in the first phase of the treatment that is the casting time. But the same decreases during follow up, when patient is on follow up or the bracing period, as Pirani score plateaus meantime. By Ponseti technique with each cast the Pirani and Dimeglio scores decreases and thereby the functional outcome of the foot improves.

There was no correlation between initial Pirani and Dimeglio scores to Tenotomy. The Ponseti method should be the first choice in the treatment of both primary cases and relapse/recurrences. The literature until now also points that the Ponseti method as the gold standard in clubfoot treatment and so the new methodologies should be compared with Ponseti method to evaluate their benefit.

The results or functional outcome of the clubfoot treatment by Ponseti method in this study is good and this method is very safe, efficient treatment for the correction of clubfoot and decreases need for extensive corrective surgical procedures

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