PONSETI METHOD IN IDIOPATHIC CLUBFOOT OF CHILDREN UPTO TWO YEARS OF AGE – A ONE YEAR FOLLOW UP STUDY

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INTRODUCTION

Clubfoot or Congenital Talipes Equino Varus (CTEV) is a fairly common complex congenital deformity of the foot. Its incidence varies from 0.39 per 1000 to 6.8 per 1000[1,2] depending on the race and is about 2.5 times more common among males[3].

This deformity may occur in isolation (idiopathic) or as a part of other congenital malformations like meningomyelocele, arthrogryposis etc (syndromic). The etiologic hypotheses of clubfoot are as varied as are the treatment methods used. The theories of causation vary from intra-uterine molding, germplasm defects, intra-uterine developmental arrest to neurogenic, myogenic and vascular explanations. Abnormalities have been found in almost all the tissues of affected feet including bones, muscles, ligaments, blood vessels etc[4].

Treatment of this deformity dates back to 5th century B.C by Hippocrates and has since undergone tremendous changes largely due to a better understanding of the deformity. Clubfoot has been treated by manipulations(forceful and gentle), plaster casts, strapping, splintage, passive motion, surgery(limited and extensive)[5]

Among these, Kite's method[6,7] of manipulation and casting has been popular among orthopedic surgeons. Recently, Ponseti's method of manipulation and serial casting[8-10] has been shown to be successful with a few studies[11-13] reporting good results at short-term follow-up in infants where treatment was started within first few months of life and no other treatment was initiated prior to the study. A retrospective study[14] has shown promising results with this method in children up to 2 years of age and when the child has already been treated by other non-operative methods.

In India, many children with clubfoot present to tertiary care centers after first few months of life and after having undergone traditional methods of treatment for variable periods and with variable results. In PGIMER, Chandigarh, fair amount of success have been obtained with casting methods in children who belong to this age group. The present study aims at evaluating the results with Ponseti method of serial manipulation and casting in children up to two years of age who have been treated unsuccessfully by other non-operative methods.

REVIEW OF LITERATURE

Incidence and patho-anatomy:

Incidence of clubfoot varies with race and gender. The incidence varies from 0.39 per 1000 among Chinese to 1.2 per 1000 among Caucasians to 6.8 per 1000 among the Polynesians[1-2]. No scientific data regarding the incidence of this deformity among Indian population. The male to female ratio[3] is 2.5: 1 Siblings of affected individuals have up to 30-fold increase in the risk of clubfoot deformity[4]. There is also increased incidence in both the twins in monozygotic twins compared to dizygotic twins[4].

Isaacs et al[15] demonstrated ultrastructural muscle abnormalities in the affected feet. Handelsman[16] showed an increase in the type I:II muscle fiber ratio suggesting a possible primary nerve abnormality. Irani and Sherman[17] suggested a primary germplasm abnormality. Ippolito[18] demonstrated the patho-anatomy of the bones wherein there is medial angulation of the neck of the talus and medial tilting and rotation of the body of the talus and medial rotation and tilting of the calcaneus. He also demonstrated increased fibrosis in the muscles of the affected feet.

Zimny et al[19] suggested that myofibroblasts on the medial side of the clubfoot may contribute to the

characteristic deformity.

Hootnick et al[20] and Sodre et al[21] reported vascular anomalies in clubfoot especially relating to absence of anterior tibial artery.

The deformity has four components[6] - equinus at the ankle, varus at the ankle and subtalar joint, adductus of the fore-foot and cavus. In addition, there is an element of tibial intorsion, which contributes to the deformity. The most severe deformities occur in the hind part of the foot. Talus and calcaneus is usually in severe equinus, the calcaneus is in varus angulation and medially rotated and the navicular is severely displaced medially. The posterior and plantar ligaments of the ankle and tendons of gastrocnemius, tibialis posterior and toe flexors are shortened.

Evaluation systems

There are numerous evaluation systems for grading the severity of clubfoot. All these systems use various parameters to assess the severity and correctability of clubfoot. Harrold and Walker[22] were among the first to describe a simple grading system. Although it allowed a basic assessment of the deformity , it was not sensitive enough to evaluate subtle improvements in outcome as a result of a particular intervention. Dimeglio- Bensahel[23] scoring system, Catterall-Pirani[24] system, the modified Hospital for Joint Diseases functional rating system[25] have all been used by workers in this field. Although a large number of evaluation systems have been proposed, there is little agreement on a standard reproducible method. Among these, the Dimeglio-Bensahel and the Catterall- Pirani scoring systems appear to have a number of clinical advantages[26]. Both score the dynamic correctability of the deformity, rely exclusively on clinical assessment and do not involve radiological assessment. This removes some of the inherent errors associated with radiographic interpretation in CTEV. The Dimeglio- Bensahel[23] scoring system incorporated eight components: equinus, varus, position of the talo-calcaneal-forefoot unit, forefoot adduction, and the presence of abnormal musculature, cavus, a medial crease and a posterior crease. Points are apportioned according to motion, with 4 points each for equinus, varus of the heel, internal torsion and adduction. One point each may be added for the presence of a posterior crease, a medial crease, cavus and a poor muscle condition. A total of 20 points is possible. The higher the number, the more rigid the clubfoot

In the most recent version of the Catterall-Pirani[24] method, six components are incorporated: these are the position of the lateral border of the foot, amount of posterior and medial creasing, the emptiness of the heel, the degree of palpation of the lateral part of the talar head, and the extent of ankle dorsiflexion passively. Points – 0, 0.5 or 1 are allotted for each parameter depending on the severity. A maximum of six points are possible. Here too the more the score more rigid the clubfoot

Flynn et al[27] studied inter-observer reliability in the evaluation of 55 feet with the use of the Dimeglio and Pirani systems and found very good reliability after an initial learning curve.

Management

The current opinion[8] regarding the treatment of idiopathic clubfoot is that the initial treatment should be non-operative. This includes stretching and adhesive strapping, physiotherapy, Denis Browne splint, manipulation and casting.

Shaw[28] in 1972 reported that gentle manipulation by repeated stretching followed by fixation in the corrected position by adhesive strapping is remarkably effective in the treatment of clubfoot.

Kite[6-7] in 1939 described a method of manipulation and casting of clubfoot. He advocated serial correction of the adduction, varus and equinus in that order. He used counter-pressure at the calcaneocuboid joint while correcting the inversion and adduction. One deformity was corrected at a time and a below- knee or above- knee plaster cast was applied depending on the age of the child. He found that an average of eight cast changes was needed to achieve full correction of the deformity. This method was widely practiced till recently.

Ponseti's method of serial manipulation and casting

Ponseti casting technique[8] involves weekly manipulation and casting as directed by knowledge of the precise patho-anatomy of clubfoot. In this method the first cast aims at correcting the cavus by supinating the first metatarsal bringing it in normal relation to the rest of the metatarsals and to bring the fore-part in alignment with the hind-part.

Further casts aim at correcting the inversion of the foot by rotating all of the foot distal to the talus while the talus is fixed in the ankle mortise. During this manipulation, a thumb is placed on the lateral aspect of the head of the talus using it as a fulcrum while outward pressure is exerted on the first metatarsal and first cuneiform. During this maneuver, an attempt is made to realign properly and simultaneously the calcaneocuboid, the talocalcaneonavicular and posterior talocalcaneal joints. This manipulation should be gentle and followed by the application of a well molded thinly padded light plaster cast. This correction may involve four to five plaster cast changes.

The equinus is corrected next by dorsiflexing the foot with the heel in a neutral or slight valgus position. Two to three casts may be needed in the attempt to correct equinus. If at this stage at least 15° of passive dorsiflexion could not be achieved with the examiner applying a single finger pressure, a simple percutaneous tenotomy of the tendoachilles may be performed with the patient under local anaesthesia. A toe-to-groin cast with the foot in maximum dorsiflexion and the knee at 90° angle is then applied for 3 weeks. Ponseti found that 85 to 90 percent of clubfoot could be successfully corrected by this method[12].

Ponseti's method, in which the counter pressure applied over the talar head laterally as the foot, held in supination, is abducted as a unit, differs from the Kite's method in which the pressure is applied on the calcaneocuboid joint. Ponseti termed this maneuver by Kite as "Kite's error", as it prevents the movement of calcaneum out from under the talus.

Herzenberg et al[13] evaluated Ponseti method of manipulation & casting in 27 patients of less than 3 months of age. They found that only 3% of this group required posteromedial release in the first year of life as compared to 94% of the control group where conventional casting method was used.

Colburn and Williams[29], in a prospective study of 57 clubfeet in children less than 3 months of age treated with Ponseti method, found that 54 of 57 clubfoot were successfully corrected without requiring posteromedial release. Only 3 feet required extensive surgical correction.

Ponseti reported that 89% of feet treated by this method had a good or excellent result at the time of thirty year follow up. In this series Achilles tenotomies were done in 70% of the patients.

Kite and Lovell[4] reported that upto 90% feet could be corrected without any surgery . However the average duration of cast treatment was 22 months as compared two to four months in the Ponseti method.

Lehman et al[30] in 2003 assessed the early results of Ponseti method of casting in 30 children (45 feet) with idiopathic clubfeet. The mean age of presentation for all patients was 10.8 weeks(range 0.5-40 weeks). 40 feet were corrected by mean 5.4 casts(range 4-9) and placed into abduction orthosis. 5 feet were not placed into foot abduction orthosis due to failure of castings. They found that these 5 feet had an age at presentation of >7 months and had undergone larger no. of casts(mean 6.4; range 4-9). 25 feet in this study were subjected to percutaneous tendoachilles tenotomy.

Morcuende et al[14] in a retrospective evaluation of the records of 157 children of up to 2 years of age (256 clubfeet) concluded that the Ponseti method is a safe and effective treatment for congenital idiopathic clubfoot and radically decreases the need for extensive corrective surgery even after previous unsuccessful non-surgical treatment. These children were treated by Ponseti's method of casting and a percutaneous tendoachilles tenotomy was done under local anaesthesia whenever equinus was not fully corrected with casts alone. Percutaneous tenotomy performed during the first few months of life has been shown by Cooper and Dietz[11] to be a benign procedure with no long term effect on the muscle strength.

There is no prospective study, in the available literature, which evaluates the efficacy of Ponseti's method in children up to two years of age and after unsuccessful treatment by non-operative methods. Moreover, there has been no study in Indian literature that evaluates Ponseti' s method of treatment.

AIMS AND OBJECTIVES

Evaluation of Ponseti method of serial manipulation and casting in uncorrected idiopathic congenital clubfoot in children up to 2 years of age previously treated by non-operative methods.

MATERIALS AND METHODS

Patients were selected from the Out Patient Section of the Department of Orthopedic surgery of the Post-Graduate Institute of Medical Education and Research, Chandigarh. Cases of idiopathic congenital clubfoot (CTEV) of age up to 2 years and were previously treated elsewhere with non-operative methods were selected. Only those patients with residual deformity of all the three components of clubfoot (forefoot adduction, hind foot varus and ankle equinus were included in the study. Those cases with associated congenital anomalies like meningomyelocele, spina bifida, and arthrogryposis were excluded.

Twenty three patients entered the study after explaining the study protocol and the possible necessity for Achilles tenotomy and foot abduction orthosis till the age of 4 years. Appropriate informed consent was obtained from the parents. 21 patients (13 unilateral and 8 bilateral CTEV) completed serial castings with or without Achilles tenotomy and were given foot abduction orthosis and were followed up for 12 months

Children who entered the study were assessed for the severity of the deformity using the scoring system of Dimeglio- Bensahel[23] and Catterall-Pirani[24] and clinical photographs obtained. Casting of the foot was started by the technique described by Ponseti IV (Pic 1-4). Initially a layer of cast padding was applied from groin to toe and the surgeon held the foot in corrected position. An assistant applied the cast using fast setting plaster in two sections. The first one comprised of a below knee plaster to hold the foot in the position. The next section consisted of extending the cast above knee to convert it into a groin to toe plaster cast. During this, the knee was held in 90degree flexion. After application of the cast the child was observed for about 30 minutes for any signs of limb ischemia. The parents were educated about possible complications like cyanosis, swelling, excess cry and the contact phone number in case of emergency were provided. They were then advised to report for the next cast after 7 days.

The first cast aimed at correcting the relative pronation of the first metatarsal and cavus by maximally supinating the foot and bringing the first metatarsal in line with the other metatarsals. At this stage, no attempt was made to correct varus or equinus.

The subsequent casts used progressively increasing amounts of abduction to achieve the maximal amounts of correction. In this the foot in supination was abducted while the surgeon applied counter-pressure on the head of the talus. The calcaneus abducts by rotating and sliding under the talus. Simultaneously it extends and everts and thus correcting the heel varus. To stretch the medial tarsal ligaments fully, the foot was severely abducted to an angle of about 60 degrees. After correction of cavus, hind foot varus and adductus, if there was easy passive dorsiflexion of the foot to 15 degree above neutral with the examiner applying a single finger pressure, a final cast was placed in the final corrected and fully

dorsiflexed position for three weeks. If dorsiflexion > 15 degrees was not possible with the examiner exerting pressure with a single finger, a percutaneous release of the Achilles tendon was done under l sedation using oral trichlorphos and local anaesthesia with 1% lignocaine in the minor operation theatre of the Out Patient Section. After this tenotomy, the foot was placed in the final cast in fully corrected and fully dorsiflexed position for 3 weeks.

Before cast placement every week , the foot deformity severity was assessed using the Dimeglio-Bensahel[23] and Catterall-Pirani[24] scores.

After achieving full correction with casts, a foot abduction orthosis with 70 degree external rotation of the affected foot and a 15 degree bend of the connecting bar is given for constant use (at least 23 ½ hrs per day) for the next 3 months or till the child is cruising. After this the abduction orthosis was used only for nightwear and CTEV shoes were given for daytime use to facilitate walking.

Follow-up till 12 months were available for all 29 feet of which 3 feet were treated by operative methods due to recurrence of deformity and another 8 feet were showing recurrent deformity warranting alternative treatment strategy.

There was a case of cast-saw injury over the anterior part of the leg. The wound was superficial and healed over a few days. Skin abrasions due to rubbing of the edge of the casts in three cases was managed by leaving the area hygienically open for a few days and application of neomycin powder locally. Skin blisters over the dorsum of the foot formed in two cases and was managed by leaving the area hygienically open for a few days and application of neomycin powder locally. In these cases the casting resumed once the skin lesions healed. Cast slippage down the foot occurred on three occasions when the foot was in severe equinus and when the flexion at the knee was suboptimal.

There were no cases of major complications like limb ischemia, skin ulceration due to casting. There was no vascular injury, wound gaping, scar dehiscence or wound infection due to percutaneous tenotomy. There were no complications related to sedation by oral trichlorphos or local anaesthesia due to lignocaine.

OUTCOMES

21 patients completed the study. There were 6 (28.6%) females and 15 (71.4%) males. Thus the male: female ratio was 2.5:1. This included 8 (38.1%) bilateral cases thus making the total no of affected feet 29. Among unilateral cases right side (9 feet) was found to be more affected than left (4) making the Right: Left ratio 2.25: 1.The patients of this study were of the age group 4 months to 15 months at the time of enrolment. Most patients were of 4 to 6 months age group -10 (47.6%) (Fig 1). Mean age – 7.6 months.

15 of these children (71.4%) were born by spontaneous vaginal delivery. Among maternal complications were Pregnancy Induced Hypertension(3), Fetal Distress(1). Oligohydramnios(2) and Breech(4).Breech presentation was found to be the most common antenatal complication.

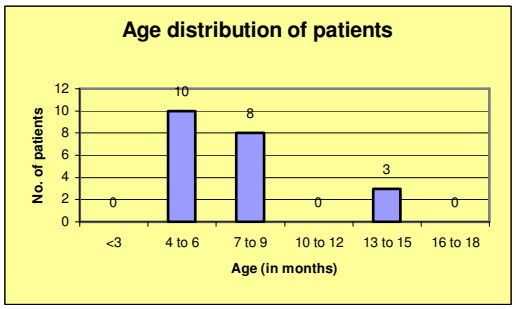

Fig.1 Age distribution of patients

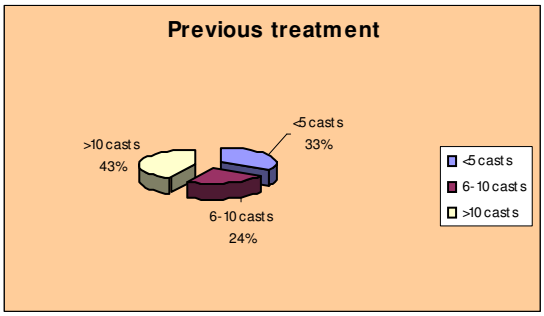

Fig 2.Pie chart showing previous treatment .

All the patients had previously been treated with casts in other centers. The most common group was the patients who underwent more than 10 casts elsewhere- 9 patients (42.9%) (Fig 2). Two patients had undergone manipulation in addition to castings.

Table 1 : Previous Treatment

Type of cast	No. of cases(total-21)	Percent
Below-the-knee	9	42.9%
Above-the-knee	12	57.1%

Table 2.Showing initial, final and follow–up Dimeglio Bensahel scores

Serial no.&Name	Age-(mon)	Sex	U/L or B/L	DB i	DB f	Change In DB	DB t	DB s	DB x	No. of casts
1. RT	4	M	R	14	0	14	2	4	6	10
2. AJ	13	M	R	10	0	10	0	0	1	5
			L	1	0	1	0	0	0	1
3. DS	6	F	R	12	1	11	1	1	2	10
			L	14	0	14	0	4	8	11
4. NH	15	F	L	6	0	6	0	0	0	3
5. SJ	5	M	R	15	0	15	2	7	op(7)	10
6. AK	14	M	L	19	0	19	1	4	8	11
7. SD	8	M	R	12	0	12	0	1	2	9
			L	10	0	10	0	0	1	7
8. ND	4	M	R	12	0	12	0	3	5	6
			L	13	1	12	0	2	4	8
9. AB	8	M	R	14	0	14	0	3	9	6
10. KK	6	M	L	9	0	9	0	0	0	10
11. SC	8	M	L	14	0	14	1	4	7	12
12. SS	6	M	R	10	1	9	0	1	2	8
			L	10	0	10	0	0	2	7
13. SU	9	M	R	8	0	8	0	0	0	5
14. RS	7	M	R	9	0	9	0	1	2	5
15. IR	6	M	R	11	0	11	1	1	1	7
			L	9	0	9	0	0	0	6
16. VI	9	M	R	9	1	8	1	0	0	8
17. SI	6	F	R	7	0	7	0	0	0	3
18. TK	4	F	R	8	1	7	1	1	1	6
19. LD	7	F	R	13	1	13	0	8	op(8)	8
			L	14	0	13	1	8	op(8)	10
20. AN	6	M	R	7	0	7	0	0	0	5
21. AR	8	F	R	15	1	14	0	3	7	6
			L	15	0	15	0	3	8	7
Mean	7.57			11.03	0.24	10.79	0.38	2.03	3.41	7.24

Db i - initial Dimeglio Bensahel score
DBn - Dimeglio –Bensahel score after nth cast
DBf - Dimeglio-Bensahel score after final cast
DBt - Dimeglio –Bensahel score at three month follow up
DBs - Dimeglio – Bensahel score at six month follow up
DBx - Dimeglio – Bensahel score at one year follow up
op - operated

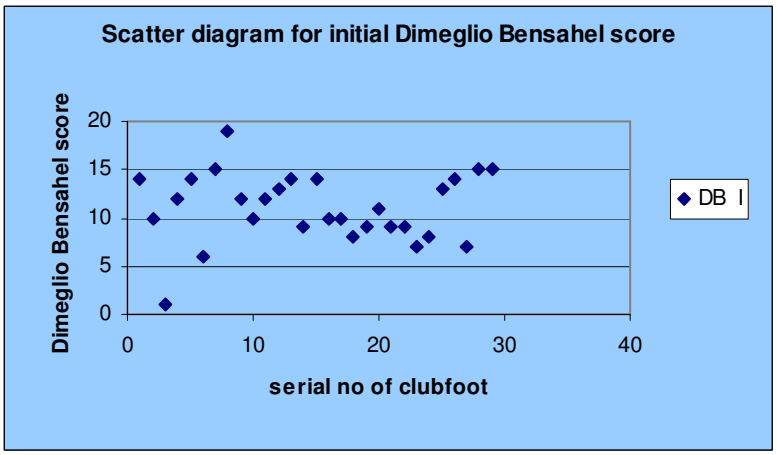

Fig 3.Initial Dimeglio Bensahel score of the 29 feet

Mean initial Dimeglio Bensahel score - 11.03 (Range- 1-19)

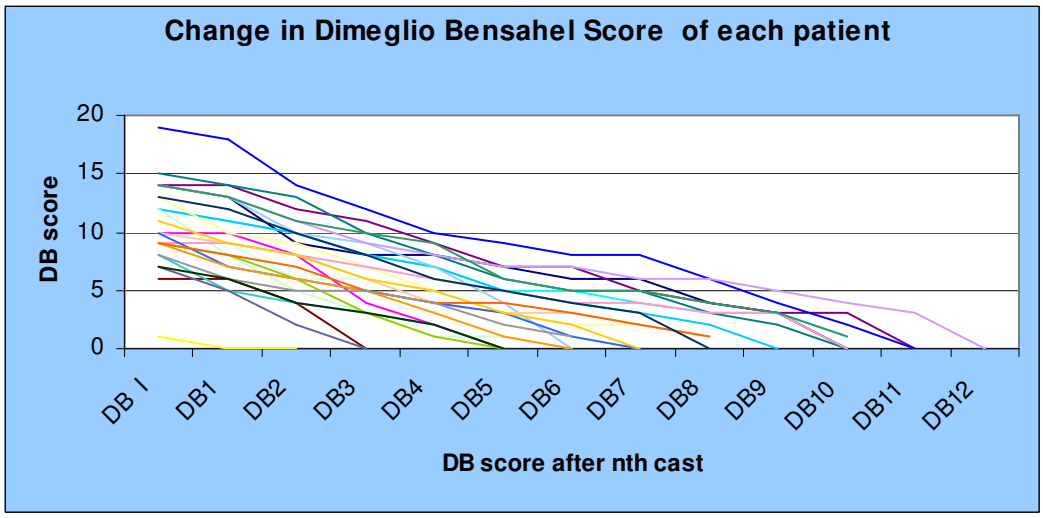

Fig 4.Change in Dimeglio Bensahel score of each patient with castings

Mean final Dimeglio-Bensahel score - 0.24

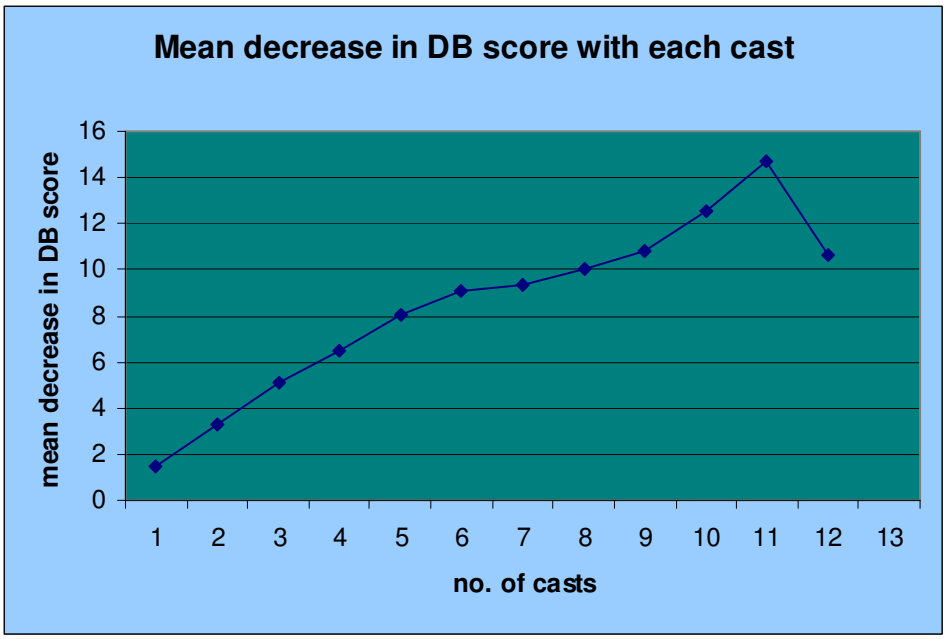

Fig 5. Mean decrease in DB score with each cast

The mean initial Dimeglio- Bensahel score for these 29 feet was 11.03 (range 1-19). After the application of a mean of 7.24 casts (range 1-12 casts) the score fell to 0.24. Mean change in Dimeglio Bensahel score at the end of casting was 10.79 (mean of difference between initial and final DB score) - 10.79 (Range 1-19). Subsequently the feet were put in abduction orthosis and follow up scoring done at 3, 6 and 12 months.

These follow up scoring revealed a tendency for recurrence as the scores rose to 0.38, 2.03 and 3.41 at three, six and twelve month follow up. However comparison to the initial scores by paired t test showed a p value of 0.000 which is significant By the end of one year three of these feet had already undergone operative procedures in the form of posteromedial release. Further, 8 feet had a score of more than 5 calling for alternative treatment.

Table 3:Table showing initial, final and three-month follow-up Catterall-Pirani scores

Serial no.&Name	Age-(mon)	Sex	U/L or B/L	CP i	CP f	Change In CP	CP t	CP s	CP x	No. of casts
1. RT	4	M	R	4.5	0	4.5	1	1.5	2	10
2. AJ	13	M	R	3.5	0	3.5	0	0	.5	5
			L	0.5	0	0.5	0	0	0	1
3. DS	6	F	R	4.5	0.5	4	0.5	0	.5	10
			L	5	0	5	0	1	2.5	11
4. NH	15	F	L	2	0	2	0	0	0	3
5. SJ	5	M	R	4.5	0.5	4	1	2.5	op(2.5	10
6. AK	14	M	L	5.5	0	5.5	0.5	1.5	2.5	11
7. SD	8	M	R	3.5	0	3.5	0	0	1	9
			L	3	0	3	0	0	0.5	7
8. ND	4	M	R	3.5	0	3.5	0	1	1.5	6
			L	3.5	0.5	3	0	0.5	1	8
9. AB	8	M	R	4	0	4	0	1	3	6
10. KK	6	M	L	3	0	3	0	0	0	10
11. SC	8	M	L	4.5	0	4.5	0.5	1	2.5	12
12. SS	6	M	R	3	0.5	2.5	0	0.5	1	8
			L	3.5	0	3.5	0	0	0.5	7
13. SU	9	M	R	2.5	0	2.5	0	0	0	5
14. RS	7	M	R	2.5	0.5	2	0	0.5	1	5
15. IR	6	M	R	3	0	3	0.5	0	0.5	7
			L	2.5	0	2.5	0	0	0	6
16. VI	9	M	R	3	0.5	2.5	0.5	0	0	8
17. SI	6	F	R	2	0	2	0	0	0	3
18. TK	4	F	R	2.5	0	2.5	0.5	0.5	0.5	6
19. LD	7	F	R	4	0	4	0	2	op(2)	8
			L	5	0.5	4.5	0.5	2	op(2)	10
20. AN	6	M	R	2.5	0	2.5	0	0	0	5
21. AR	8	F	R	3.5	0	3.5	0	1	2.5	6
			L	4	0.5	3.5	0	1	2.5	7
Mean	7.57			3.39	0.14	3.25	0.19	0.603	1.12	7.24

Cpi - Initial Catterall- Pirani Score
CPn - Catterall- Pirani Score after nth cast
CPt - Catterall- Pirani score at 3 months follow up
CPf - Catterall-Pirani score after final cast
CP s - Catterall- Pirani score at 6 months follow up
CP x - Catterall- Pirani score at one year follow up
op - Operated

Mean initial Catterall-Pirani score was 3.39 (Range 0.5 to 5.5). After a mean of 7..24 casts (range 1-12) Mean final Catterall- Pirani score was 0.14 (Range 0 to 0.5).Mean change in Catterall-Pirani score at the end of castings was 3.25 (Range 0.5 to 5.5).
At three, six and twelve month follow ups, the scores were 0.19, 0.603 and 1.12 respectively. These values , when compare to the initial CP scores by paired t test gave a p value of 0.000 which is significant.
Percutaneous tendoachilles tenotomy was done in 13 feet(44.8%) for correction of residual equinus deformity. Tenotomy was safely performed in children of age 6.5 to 11 months (mean 8.2 months)

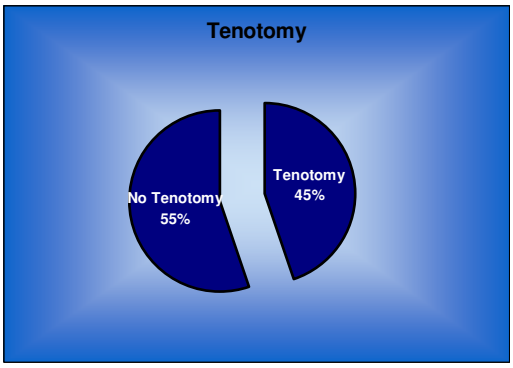

Fig 6. Percentage of cases in whom Achilles tenotomy was done

Table 4: Cast complications

There were complications in 9 cases

Complication	No. of cases
Cast saw injury	**1**
Skin abrasions	**3**
Skin blisters	**2**
Slippage of casts	**3**

The most common complications were skin abrasions and cast loosening and slippage

ANALYSIS

The data collected was analysed using students paired t test for comparison of scores before and after casting

DISCUSSION

Non-surgical management of clubfoot is the preferred method of initial management of the deformity[13,31] world over. Ponseti's method of serial manipulation and casting has been shown to be an effective method for the treatment[8-10]. The method and its results have been extensively studied in children in their first few months of life[8-14,30]. However few studies have evaluated this method in children of slightly older age group although clinical experience in our center has shown fair amount of success with traditional methods of casting in this age group. The present study evaluates the efficacy of Ponseti method in children up to 2 years of age after unsuccessful non-operative treatment elsewhere .

Patient profile

21 children with congenital clubfoot participated in the study, which lasted for 30 months (jan 2005-jul 2007). Total number of clubfeet was 29. All the patients were of age 0- 24 months (range 4-15 months) at initial casting (Fig.1). Mean age of the group was 7.6 months Morcuende et al[14] had retrospectively analyzed the records of 157 patients (256 clubfeet). These were from the period 1991-2001 (11 years). In this study also all the patients were of the age group 0-24 months. Although the mean age of the children in this study has not been mentioned, 81% of children were younger than 6 months and 29% were older than 6 months. No other study with mean age >6 months is available. Herzenberg et al[13] conducted a study with 27 patients , all under the age of 3 months, undergoing Ponseti method of casting. This was compared to a control group of 27 patients who underwent conventional method of casting. In the study conducted by Lehman et al[30], 30 children (45 feet) were treated by Ponseti method. The mean age at presentation was 8.2 weeks (range 0.5 to 40 weeks). This study divided the patients into two groups based on the success of treatment- group 1: who were given foot abduction orthoses after successful casting, and group 2: who had unsuccessful casting. The mean age of group 1 was 8.2 weeks and group 2 was 34 weeks. Although our study is comparable to these studies in terms of the age range, the mean age in these studies was <6months. The present study differs from the most published series in the higher mean age at initiation of Ponseti casting. Most orthopedists believe that as the age of the child increases, likelihood of failure of castings increase and the necessity for surgery increase.

There were 15 males and 6 females in the present study and the male: female ratio is 2.25:1. Morcuende[14] et al reported a male: female ratio of 2.13: 1 in their study. Ponseti found the incidence to be six times higher among males[32]. The United Kingdom talipes study[33] showed a male: female ratio of 2-3:1. The male preponderance found in this study is in agreement with other studies.

8 cases(38.1%) were bilateral clubfeet and 13(61.9%) had unilateral deformity. Among the unilateral cases, 9 (42.9%) had right-sided deformity while 4 (19%) had left-sided deformity. In Morcuende et al[14] study, 99 out of 157 (63.1%) were bilateral clubfeet and 58 (36.9%) were unilateral. In Lehman et al[30] series, the distribution of unilateral and bilateral cases was equal (15 each).

In the present study, only cases with idiopathic CTEV were included. Cases with associated meningomyelocele, arthrogryposis, spina bifida etc were excluded as, in these cases, the cause of the deformity is mainly neurogenic or teratologic. These syndromic cases of clubfoot are known to have poor results with non- operative management and high rates of recurrence.

Previous treatment

Among the patients of the present study all (100%) had undergone castings in other centers before entering the study. 7 (33.3%) had undergone <5 castings , 5 (23.8%) 6-10 castings and 9(42.9%) more than 10 casts. 66.7% patients had been treated with >5 casts (fig.2). The techniques employed in these centers are not known. In Morcuende et al[14] series, 113 patients (73%) had some form of previous treatment. 4.5% had physical therapy and 71% had serial manipulation and casting. The number of casts ranged from 1 to 20 with a median of 10. in Morcuende et al series, the severity of the deformity was graded by the no of casts needed by Ponseti's method for correction

In our study, as treatment before entering the study, 9 (42.9%) had received below-the-knee castings and 12(57.9%) had above-the-knee castings in other centers. In Morcuende series[14], 49 % had below-the-knee castings .In Ponseti method, groin-to-toe casts are applied in order to correct the tibial intorsion. For this, the leg is held in lateral rotation while the above –the-knee portion of the cast hardens. Below-the–knee casts cannot correct this component of the deformity and hence will not correct the deformity fully. Although this cannot fully explain the failure of the treatment taken from other centers this could have contributed significantly.

Antenatal history

6 patients (28.6%) were born by Caesarean section and 15 (71.4%) by vaginal delivery. The reason for caesarean section was maternal Pregnancy induced hypertension in 2 cases, fetal distress in 1 , oligohydramnios in 2 and breech presentation in 1. Among those who were born by vaginal delivery 3 were breech presentation , pregnancy induced hypertension was documented in 1 but no case of oligohydramnios was reported. No inference can be drawn from the data since, 5 cases delivered at home and hence no complete medical findings and documentation were available. Nevertheless, amongst those who had documented antenatal and intrapartum medical attention the rate of associated complicating factors appears to be more frequent than the normal incidence. Hippocrates had suggested that the foot is held in equinovarus position by the external uterine compression and oligohydramnios. However Turco[34] had refuted this view and suggested that it is unlikely that such increased pressure would repeatedly produce the same deformity, especially when there is plenty of room in the uterus at the time that a clubfoot develops(first trimester). Although the sample size is small for any definitive conclusion to be drawn , the presence of oligohydramnios in 2 out of 21 cases(9.5%) may suggest external compression as a contributory etiologic factor.

Scoring systems

In this study each foot was assessed at every visit and scoring was done by the Dimeglio-Bensahel[23] and Catterall-Pirani[24] schema. The severity of the foot was rated using a 1 to 20 point scale in Dimeglio Bensahel scheme. This took into consideration each component of the deformity – adduction, hindfoot varus, equinus,cavus, posterior and medial creases, atrophy of the muscles as well as the derotation of the calcaneo-forefoot complex in front of the talus. Catterall-Pirani scoring system uses a 0-6 point scale, which includes inspection, palpation and movement findings.

In the Morcuende et al[14] series no assessment regarding the severity of the deformity was available before the initiation of the castings as it was a retrospective analytical study. They used the number of casts needed for correction of CTEV as a marker of severity of the deformity. In the Lehman et al[30] series, three scoring systems were used – the Dimeglio Bensahel system[23], the Catterall-Pirani[24] system and the modified Hospital for Joint Diseases functional rating system[25`].

Both Dimeglio-Bensahel[23] and Catterall-Pirani[24] systems are easy to use and simple and fairly reproducible. In our study the scoring and casting was done by the same person throughout the period of 11 months and hence consistent readings have been obtained. The Dimeglio-Bensahel scoring system grades the foot on the basis of the passively corrected position and presence of posterior, medial creases and presence of atrophy of muscles. On the other hand, points in the Catterall- Pirani scores are allotted on the basis of inspection findings of the sole of the foot, lateral border, posterior and medial creases, palpability of the head of the talus and emptiness of heel as well as correctability of equinus.

Results

In this study full correction of the deformity was obtained in all the 29 feet (Pic 5-10, Pic11-16). In this study, the endpoint for castings was taken as the correction of all the components of the deformity irrespective of the number of casts taken to achieve this. This was augmented with percutaneous Achilles tenotomy under local anesthesia whenever needed. After the full correction of the deformity, the foot was placed in abduction orthosis to maintain the correction.

The mean age at initiation of treatment for the 21 patients(29 feet) was 7.57 months (range: 4-15 months) the mean Dimeglio Bensahel score at the beginning of the study was 11.03 (out of a maximum possible score of 20). Of these 1 was grade I foot, 13 were grade IIa, 14 were grade IIb and 1 was grade III foot .

The mean no. of casts taken for correction was 7.24 (range 1 to 12) and the mean final Dimeglio Bensahel score was found to be 0.24. The mean change in the Dimeglio Bensahel score was found to be 10.79. This change in score , when analyzed using paired t test gives a 'p' value of 0.000, which is significant (Table.10). In our study, percutaneous Tendoachilles tenotomy was done in 13 feet(44.8%) (Fig.13, Pic17-19).This was done when passive dorsiflexion of the ankle was $<15^0$ on applying one finger pressure after correction of all other components. Following this a final cast was placed in fully corrected position All the feet were placed in abduction orthosis after full correction and a scoring was done at 3 months. The mean value of Dimeglio Bensahel score at 3 months follow up was found to be 0.38. the mean change of the three-month follow-up score compared to initial score was10.66. This change in the score has a 'p' value of 0.000 which is significant (<0.05)..

The mean Dimeglio Bensahel score at six month and twelve month follow up were 2.03 and 3.41 respectively representing an increase in the deformity in spite of application of foot abduction orthosis. But comparison with the initial scores using paired t test show a p value 0.000 denoting a significant change in the scores

In Lehman[30] series, the Dimeglio score changed from a mean of 14.4 to 4.2 in an average of 5.3 castings with a p value of <0.001. This shows a mean change in Dimeglio score of 10.2 in mean 5.3 castings.

Similar results were obtained with the Catterall-Pirani score as well (Table. 11). The mean initial Catterall-Pirani score for the 29 feet were 3.39 (out of a maximum possible score of 6). After full correction by castings (mean 7.24 casts) the final score was found to be 0.14 and the mean change in the score was found to be 3.25. This was analyzed by the paired t test and the p value was 0.000, which is significant(<0.05). The mean value of Catterall-Pirani score at three months follow up was 0.19, which shows a change of 3.20 from the initial score. This change also has a p value of 0.000, which is

significant(<0.05). At the six and twelve month follow up, Catterall-Pirani scores were 0.603 ad 1.12 signifying an increase in the deformity. However these scores when analysed by the paired t test has a p value 0.000 and hence represent a significant change from the initial scores. In Lehman series[30], Catterall Pirani score changed from 4.6 to 0.6 in mean 5.3 casts. Although the final Dimeglio and Catterall scores obtained in our study are lower , the change in these scores obtained, as compared to the Lehman series, is similar. The mean no. of casts in our study is also higher possibly due to the use of full correction as the end point of castings

. In the retrospective study by Morcuende et al, correction was obtained in all but 3 patients (98%). These 3 patients were previously treated in other institutions and presented with severe deformities. Correction was obtained in 1 to 7 casts. 90% of the patients required 5 casts for correction Tendoachilles tenotomy was done in 86% of the cases. The average time from the first cast to the tenotomy was 20 days (range 14-24 days). The 100% correction obtained in our study may partially be due to the relatively smaller sample size (n=29) compared to Morcuende et al study(n=256) . Another factor that might have played a role is that the end point for castings in our study was correction of the deformity irrespective of the no of casts taken to achieve the same. The no. of casts required for correction ranged from 1 to 12 , the most patients requiring more than 6 casts. The mean no. of casts required was 7.24 casts which is higher as compared to Morcuende series. Another factor which might have contributed to the higher no. of casts is the higher mean age (7.57 months) as compared to Morcuende et al series in which 81%children were younger than 6 months.

From this study it appears that idiopathic congenital clubfoot in children of up to 15 months can be successfully corrected by Ponseti method of casting. This correction can be achieved with larger than usual no. of casts and with tendoachilles tenotomy in a significant number of these patients. Persisting with casting in spite of slow correction may be successful in up to 12 casts Higher age of the patient necessarily does not mean that the deformity is resistant to correction but may necessitate a more prolonged casting period. Tendoachilles tenotomy can be done safely up to 11 months of age without any adverse effect apparent at one year follow up . Attention to minor details in casting and allowing active feed back from the parents is essential.

A total of about 210 groin-to-toe casts were applied in the study There were three cases of abrasions over the thigh developing as a result of the casting(Fig.12). This was due to inadequate cast padding at the superior edge of the groin-to-toe cast and can easily be prevented by ensuring a layer of cast padding everted over the edge of the cast. Healing of these abrasions can be aided by leaving the area open clean and dry and application of neomycin powder considering the proximity to the genitals and perineum.

Cast slippage, which occurred in three cases, were in those with severe equinus deformity and when the cast was slightly loose or when the flexion at the knee was sub-optimal ($<90^0$). This can easily be prevented by meticulously adhering to the details of casting.

Blisters developed on the dorsum of the foot in two cases and were probably due to tight cast. These healed after the area was left open for a few days. There was one incident of cast saw injury while cutting the cast. The injury was superficial and on the anterior aspect of mid-leg and healed with antiseptic dressings.

An increase in the deformity noted at follow up visits up to one year is of concern. Increase in deformity (DB score >5)occurred in 11(37.9%) feet of which 3 were already operated at the time of 12 month follow up. Another eight showed DB score >5 thus warranting alternative treatment strategy. The Dimeglio Bensahel score increased to 2.03 at six months and 3.41 at one year follow up for the entire study group.

In the relapse group, the mean age was 7.14 months while the mean age for the entire study group was 7.6 months. Thus, in our study , age at initiation of treatment was not found to be a risk factor for relapse.

In this group, parents reported irregular use of the foot abduction orthosis in many cases.The real impact of this fact was not quantitatively assessed but might have contributed significantly to relapse of the deformity.

In the relapse group, the mean initial DB score was 14.45 compared to the mean DB score of 11.03 for the entire study group. Thus this group had more severe deformity to start with. Relapse appears related to non-compliance in wearing the orthosis, since all of these cases reported decreased duration of orthosis wear per day. In Lehman et al study, 27 out of the 38 feet were compliant with the orthosis and had good results at three months follow up. He found that the 11 feet of the non-compliant patients had good results as well at three months follow-up.

In the retrospective study of Morcuende et al, clubfoot correction was obtained in 253 out of 256 feet(98%). Of the patients who had initial successful correction, deformity relapsed in 10 %. He found that this relapse was not related significantly to age at presentation, previous unsuccessful treatment, or the number of casts required for correction. He found that relapses were associated with non-compliance with foot abduction brace. Non-compliance was associated with a 17 times greater odds of relapse compared with compliance.

Therefore, recurrence of the deformity may occur in a significant number of cases corrected by Ponseti method in children up to 15 months of age and is higher with more deformed feet. The more deformed feet may need more number of casts for full correction and have a higher tendency for recurrence. Although recurrence seems to be a significant problem in the more deformed feet, the severity of the recurrent deformity s less than the original one and hence the corrective operative procedures is expected to be less extensive. Moreover the casting allows for usefully spending the time in the infant till the anatomic structures become larger and the operative procedure easier while at the same time preventing the worsening of the deformity. Age at initiation of treatment appears not to affect the rate of recurrence of the deformity. Another factor contributing to the recurrence is the non-compliance with the use of foot abduction orthosis and parental knowledge regarding the importance of adherence to instructions. Longer-term studies are needed to follow the patients and to determine the incidence of recurrence

Three patients with unilateral clubfoot corrected by this method had a difference in the size of the foot compared to the normal side (Pic 20). The length of the foot was1.5- 3 cm short. This might have cosmetic implications if it fails to bridge the gap in the size of the feet. Long-term follow up is needed to assess the size and function of these feet.

Summary

The aim of this study was to evaluate Ponseti method of serial manipulation and castings in idiopathic clubfoot previously treated by other non- operative methods.

1. Twenty-one children (twenty-nine clubfeet) participated in the study of which 6 were females and 15 were males.
2. The age of the children varied from 4 months to 15 months, the mean age being 7.6 months. Maximum no. of children were of 4 to 6 months age.
3. There were 8 bilateral cases and 13 unilateral cases. The right to left ratio among the unilateral cases was 2.25:1.

4. Most of these children were born by spontaneous vaginal delivery (71%)
5. Most common antenatal significant history was Breech presentation in 4 and Pregnancy Induced Hypertension in 3 cases.
6. All the cases had undergone castings in other centers before enrolling in this study. About 43% of cases had received >10 casts in other centers.
7. All the cases were evaluated using the Dimeglio- Bensahel and Catterall-Pirani scoring schema initially and during each visit before casting.
8. These feet were treated with Ponseti's method of serial manipulation and castings employing groin-to-toe casts changed every week.
9. After correction, the feet were placed in foot abduction orthosis and a follow-up reading was obtained at three months in all cases and at six months in eight cases.
10. All the feet were corrected with casts and were placed in foot abduction orthosis. The mean no. of casts taken was 7.24
11. The mean Dimeglio Bensahel score changed from 11.03(initial) to 0.24(final) with mean 7.24 casts.
12. The Dimeglio score at six and twelve month follow up was 2.03 and 3.41 respectively indicating a tendency to relapse
13. Similar results were obtained with Catterall-Pirani score in which the mean score changed from 3.39(initial) to 0.14 (final) and then a slight increase to 0.603 and 1.12 at six and twelve months.
14. Percutaneous tendoachilles tenotomy was done in 45% of cases with a mean age of 8.2months at tenotomy.

CONCLUSIONS AND RECOMMENDATIONS

1. Ponseti method is effective in correction of idiopathic clubfoot in children up to 15 months of age.
2. The no. of casts needed for correction may be higher than what is conventionally needed in children of lower age group(up to 3 months of age)
3. Persisting with castings despite slow correction yielded correction in upto 12 casts.
4. Higher age of the patient may not necessarily mean that the deformity is resistant to correction but may necessitate a more prolonged casting period.
5. Tendoachilles tenotomy may be needed in a significant no. of these cases.
6. Tendoachilles tenotomy can be safely done up to 11 months of age with no apparent adverse effect apparent at three-month follow-up.
7. Recurrence of deformity may become apparent in a significant no. of these cases (37.9% in this study) at one year follow-up and may necessitate operative intervention.
8. Relapse of deformity was found to be more related to the non-compliance to foot abduction orthosis and severity of the deformity rather than the age of the patient.
9. Strict adherence to the casting technique helps in successful correction
10. Compliance on the parents' part in the use of foot abduction orthosis is essential to prevent the relapse of deformity
11. The most common cast-related complications were skin abrasions and cast slippage due to loosening and these respond well to simple treatment.
12. Although Ponseti method of casting in the more severe deformities has a significant rate of recurrence, it helps to decrease the severity of the deformity before an operative procedure is undertaken. This in turn can help to decrease the extent of surgical release and scarring.

13. Another advantage of this method in feet which may eventually require surgical release is that this helps to usefully spend time before the foot grows to a comfortable size from the surgeon's point of view.

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