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COMPARATIVE STUDY OF FUNCTIONAL OUTCOME OF IDIOPATHIC CTEV TREATED BETWEEN PONSETI TECHNIQUE AND ACCELERATED PONSETI TECHNIQUE USING PIRANI SCORE.

Orthopaedics

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ABSTRACT

Background & Objectives: Congenital talipes equinovarus, also referred to as clubfoot, occurs in one in 1000 live births and is one of the most common birth defects involving the musculoskeletal system. Ponseti method involves weekly manipulation of the deformity followed by a long-leg cast is the time proven method of management. Modified accelerated treatment protocols were designed to reduce the total duration of treatment. This study was conducted to compare the efficacy of accelerated Ponseti method versus standard Ponseti method. **Methods:** A randomized controlled study was conducted with participants randomized to two groups- Study group and Control groups. All feet were scored using Pirani score, recorded by an independent assessor at each visit. Plaster treatment was continued until clinical correction achieved. **Results:** The current study had comparable demographic distribution between the groups. Accelerated Ponseti technique has relatively shorter duration of manipulation compared to the standard Ponseti technique. Total number of casts used is not significantly different for accelerated Ponseti technique compared to the standard Ponseti technique. Accelerated Ponseti technique for club foot management was found to be equally effective compared to the standard Ponseti technique in managing idiopathic congenital talipes equinovarus assessed by Pirani scoring. **Interpretation & Conclusion:** No evidence exists to support the use of a cast change interval of one week. It can be concluded that the accelerated versions of the Ponseti method can safely be used in the treatment of clubfoot without risking any significant increase in the required number of casts.

KEYWORDS

Congenital talipes equinovarus; Ponseti method; Accelerated Ponseti method.

INTRODUCTION

Idiopathic congenital talipes equinovarus (CTEV), also known as clubfoot, has been a recognized deformity since the time of the ancient Egyptians and was independently described by both Hippocrates and the Aztecs. It is the most common congenital foot disorder. [1]

Initial treatment options all were variations on manipulation and splinting. Surgical intervention began in the late 1700s with Lorenz's Achilles tenotomy, but effective soft- tissue releases, osteotomies, and tendon releases were not developed until the late 1800s. In 1930, Kite popularized gentle manipulation and serial casting, which remains the initial treatment of choice. [2]

The incidence of CTEV is 5–6 per 1000 live births. The goal of any type of CTEV management is to reduce, if not to eliminate all elements of the clubfoot deformity, hence achieving a functional, pain free, normal looking plantigrade, mobile, callous free, and normally shoeable foot. The various factors that have been associated with the poor prognosis in CTEV management are female child, hereditary, late age of presentation, severity of deformity, rigidity of foot, associated cavus, associated clawing of toes, and small heel. [3]

Kite rationalized the whole treatment of clubfoot by conservative means. Recently, various workers have shown satisfactory results by Ponseti method of manipulation and serial casting. [4] The first description of the Ponseti technique was published in 1963; 15 years after, Ponseti had actually begun using this method. Popularity of the technique spread by time resulted in a great decrease in the rate of extensive clubfoot surgery. Ponseti method involves weekly manipulation of the deformity followed by a long-leg cast. It takes about 4–5 weeks to correct all components of the deformity with the exception of the equinus. [5,6]

Shortening the correction time is required for patients travelling long distances seeking for treatment; decreased correction time offers a financial gain for the parents. Modified accelerated treatment protocols were designed by developed by Morcuende et al, Xu and few others with equivalent outcomes. [6,7]

There is only limited evidence available regarding the comparison of Ponseti technique with accelerated Ponseti technique especially among the Indian population. Hence, a randomized controlled study was conducted to determine effectiveness of a shorter duration of treatment so that most effective and economical strategies may be adopted in management of these patients.

AIMS AND OBJECTIVES

1. To compare the efficacy of accelerated Ponseti with standard Ponseti method for treatment of idiopathic clubfoot as assessed by Pirani scoring system.
2. To determine effectiveness of a shorter duration of treatment in the management of CTEV

METHODOLOGY

After obtaining the clearance from institutional ethical committee, subjects were enrolled who were born out of elective Caesarian section and were found to have CTEV. Informed written consent was taken from the parents of the subjects.

Inclusion Criteria

1. Subjects willing to give informed consent
2. Subjects with idiopathic ctev
3. Subjects with age less than 2 years.

Exclusion Criteria

1. Subjects with Syndromic club foot
2. Subjects with secondary club foot
3. Subjects with previously operated club foot
4. Clubfoot previously treated with a casting technique
5. Neglected or relapsed clubfoot
6. Subjects who are unfit or non-complaint to the prescribed technique
7. Subjects with age more than 2 years.

Random allocation sequence was generated using www.randomizer.com. Generation of the random allocation sequence, enrolling and assigning participants to interventions were carried out by people who have no clinical involvement in the trial. Hence the investigators were blinded.

Participants randomised to two groups- Study group – accelerated

Ponseti method and Control group – standard Ponseti method. All feet were scored using pirani method at each visit. Plaster treatment was continued until clinical correction achieved.

A percutaneous tendo achillis tenotomy was performed if dorsiflexion is <10° at the end of manipulation and plastering. Both groups were put into plaster, following tenotomy, for three weeks. The defined endpoint of treatment for both groups, labeled 'treatment time in plaster' refers to the number of days in plaster prior to a tenotomy.

Within the accelerated group we defined failure as a pirani score of >1.0 at 21 days of plaster treatment. Both groups were given abduction braces to wear for three years following their plaster treatment, 23 hours per day for the first three months followed by night time bracing until the child's third birthday, in accordance with the standard local ponseti programme. All patients were treated as out patients, thereby reducing any bias from altered compliance and enabling us to directly compare the efficacy of the two methods in terms of correction of the deformity.

Corrective Phase

During the corrective phase the position of the foot was gradually corrected using a series of manipulations and plaster of Paris casts, then finally a small outpatient procedure was performed to cut the Achilles Tendon (Tenotomy). On an average took 4–8 weeks and the babies were seen weekly and another twice weekly for the treatment.

We began treatment in the first weeks or two of life in order to take advantage of the favorable elasticity of the tissues forming the ligaments joint capsules and tendons. A plaster cast was applied after each session to retain the degree of correction obtained and to soften the ligaments. Thereby, the displaced bones were gradually brought into the correct alignment.

5 - 7 plaster casts extending from the toes to the upper thigh with the knees at right angle should be sufficient to correct the clubfoot deformity. Before applying the last plaster, cast which was to be worn for three weeks tenotomy was done to complete the correction of the foot. By the time the cast was removed the tendon would be regenerated to a proper length.

Step 1. Find the Lateral Head of Talus

The lateral head of talus is the central point or fulcrum around which the foot moves after its corrected, and it's the point where the manipulator's thumb needs to apply gentle pressure.

It is usually about 1cm anterior to the lateral malleolus. In some children the anterior process of the calcaneum (red) can also be felt, just below the lateral head of talus (black).

Figure 6: Anterior process of the calcaneum (red) felt just below the lateral head of talus (black).

Step 2. How to Hold the Foot

For right foot as in the picture below, we use the left thumb on the lateral head of talus with the left index and middle fingers holding the medial malleolus but not touching the heel. The right hand's fingers can then manipulate the forefoot as needed. For a left foot we used the right thumb on the head of talus and the fingers of the right hand going round the ankle, with the left hand free to manipulate the forefoot. Remember: The calcaneum must not be touched during manipulation as its position corrects naturally as the forefoot is brought into abduction. This picture shows a right foot. The manipulator's left thumb is on the talar head and the right hand is free to manipulate the forefoot.

Figure 7: Right Foot Holding Position

Step 3. Correction of Cavus

The cavus was corrected by supinating the forefoot, thereby placing the forefoot in proper alignment with the hindfoot. The sole of the foot should be examined whilst doing this, with the aim being to position the forefoot to create a normal looking arch of the foot. Since the cavus usually was not a fixed deformity at birth, correction often occurs with the first cast. Correction of severe cavus in a stiff foot needed 2 or 3 cast changes with the forefoot in supination.

It should be noted that often a Clubfoot can look worse after correction of the cavus. Parents should be reassured that this is temporary. It was seen that if the arch was high and that to correct it the first metatarsal needs to be elevated (in the direction of the black arrow). Cavus Deformity These two pictures show the first metatarsal (first ray) being elevated to correct the cavus. (Elevating the first ray was supinating the forefoot) First cast after correction of cavus. Remember that parents can worry at this stage as the foot can look a little worse.

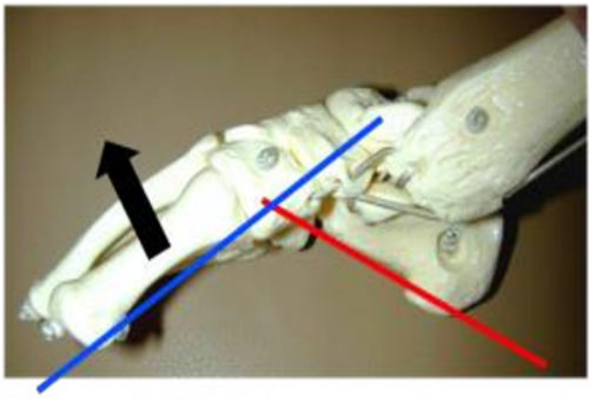

Figure 8: Correction of cavus

Figure 9: Cavus deformity

Figure 10: After correction of cavus

Step 4. Correction of Adductus

Once the cavus was corrected then manipulations to correct the adduction of the forefoot can be started.

Figure 11: Abduction, counter pressure on head of talus, ligaments stretched on medial side.

The plantar flexed foot was slowly abducted while counter-pressure was used on the head of the talus. Ligaments on the medial side of the foot are stretched. The distal end of the calcaneum disengages from its position under the head of the talus and allows the calcaneum to abduct.

Figure 12: Method of Correction of Adductus

Plastic model showing method of correction of adductus. While the midfoot was kept in supination and plantarflexion, it was gently abducted under the talus. The thumb applies pressure to the lateral side of the head of the talus, NOT the calcaneum.

Used gentle continuous pressure for a few seconds and repeated once or twice more when the baby was relaxed, and aim for a total of 60 seconds of stretching. Do not struggle with the baby. The aim was to achieve 50-70 degrees of abduction. This usually occurs in about 4 weeks of manipulation. As the abduction increases, we felt that the lateral head of talus was started to be covered by the navicular as it moves laterally. Once 50–70 degrees of abduction were achieved the talus was usually fully covered.

Step 5. Automatic Correction of Varus

The varus of the heel and the whole foot does not need to be actively corrected because it corrects automatically as the forefoot adduction was corrected. While the forefoot was abducted the navicular, the cuboid, and the entire foot are displaced laterally in relation to the head of the talus. The anterior portion of the calcaneum follows, and automatically the heel varus deformity was corrected. This was better seen from behind as in the pictures below.

Figure 13: Posterior View of Calcaneus and everting.

If you look at a model of the clubfoot from behind you will see that as the forefoot is abducted so the heel varus corrects automatically. The heel on the left is in varus (tilted towards the midline) but as the forefoot is abducted it tilts in the direction of the white arrow until it reaches a neutral or slightly valgus (tilted away from the midline) position. The heel do not need to be touched.

This automatic correction of the varus heel was due to the shape of the joint between the talus and the calcaneum and was known as "Kinematic coupling". The improvements obtained by each manipulation are maintained by immobilizing the foot in a well-molded plaster cast for 7 days, before removing it for the next cast.

After 4 or 5 casts, the entire foot should be abducted between 50 and 70 degrees under the talus and be no longer supinated. The navicular moves laterally away from the medial malleolus. The lateral aspect of the head of the talus cannot now be palpated since it was covered by the navicular. The heel was in some valgus. The calcaneum was in the right position relative to the talus and the foot was ready for correction of equinus.

Step 6. Correction of Equinus

This was the last stage in the correction of the clubfoot deformity. A little correction of equinus occurs naturally as the foot was abducted but no attempt made to actively dorsiflex until:

- The talar head was covered, usually the midfoot contracture score is 0
- The foot is abducted to 50 - 70 degrees
- The heel is in valgus or at least neutral

These 3 points was achieved at this stage and gentle dorsiflexion done.

Figure 14: Picture showing the stages of correction of clubfoot: Cast 1 was put on after correction of the cavus. Casts 2, 3, and 4 show progressive abduction of the midfoot Cast 5 shows the position after tenotomy with good dorsiflexion

Step 7. Casting

The application of casts was a crucial part of the correction of clubfoot deformity. The cast was needed to maintain the correction that has been achieved by manipulation. If the cast is badly put on it can slip and lose correction, it can also cause rubbing and skin breakdown.

Step 8. Tenotomy

The tenotomy corrects the rigid equinus. It was a complete cut through of the Achilles Tendon, not a Tendon Lengthening. It creates a very small incision - it was known as a percutaneous ("through the skin") tenotomy or Achilles Tenotomy.

Maintenance Phase

Following Correction Phase, the clubfoot deformity tends to relapse without adequate management. To prevent relapses, when the last plaster cast was removed brace must be worn full-time for 2 -3 months and thereafter at night for 3- 4 years. The brace, known as a Foot Abduction Brace, consists of a bar (the length of which is the distance between the baby's shoulders) with open-toed shoes attached at the ends of the bar in about 70 degrees of External Rotation. The baby may feel uncomfortable at first when trying to alternatively kick the legs. However, the baby soon learns to kick both legs simultaneously and feels comfortable. In children with only one clubfoot, the shoe for the normal foot was fixed on the bar in 40 degrees of external rotation. During the daytime the children wear regular shoes. Child was followed up for any relapses. Referral to a center with expertise in the non- surgical correction of Clubfoot should be sought before considering surgery.

Statistical Analysis

Data collected was entered in a MS Excel sheet. The descriptive and analytical statistics were performed using with the Statistical Package of Social Sciences (SPSS) version 22 software.

Percentages, means and standard deviations (SD) were computed for descriptive purposes. Student t test was used to compare the mean of age, number of casts and Pirani Score between study group and comparison group. Chi Square test was used to compare frequency distributions between the two groups. A *p* value of less than 0.05 was considered as statistically significant.

Sample Size Estimation

Based on previous study conducted by Sharma P, et al., by considering the absolute precision of 10% sample size can be calculated as follows. Sample size was estimated by using the formula:

$$N = \frac{(Z_a + Z_{1-b})^2 (P_1Q_2 + P_2Q_2)}{d^2}$$

$$= \frac{(1.96 + 0.84)^2 (97.1*2.9 + 95.7*6.3)}{10^2}$$

$$= \frac{(7.84)(281.59 + 411.51)}{100}$$

$$= 54.33$$

By considering 10% of drop rate final sample size was calculated as follows

= 54.3 + (10% of 54.3)

=59.76

The final total sample size was rounded of to 60. Hence 30 subjects were allocated in each group.

RESULTS

Table 1: Distribution of study samples according to age

Age (weeks)	Control group	Study group	P Value
1-12	21 (52.5%)	24 (60%)	
13-24	19 (47.5%)	16 (40%)	
Total	40 (100%)	40 (100%)	
Mean ± SD (years)	12.5±5.35	10.86±6.21	0.21

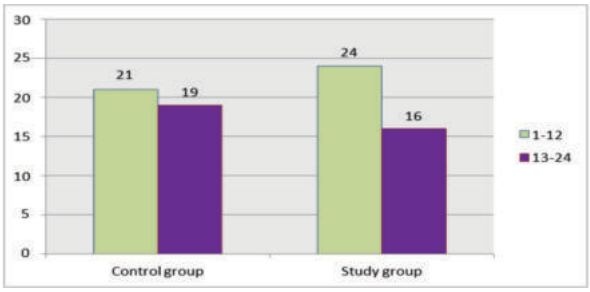

Chart 1: Distribution of study samples according to age

There was no statistically significant difference (p=0.21) between the groups regarding age

Table 2: Distribution of study samples according to sex

Sex	Control group	Study group	P Value
Male	26 (65%)	24(60%)	1
Female	14 (35%)	16 (40%)	
Total	40 (100%)	40 (100%)	

There were 65% males among the samples in study group and 60% males in control group. There was no significant statistical difference among the groups with respect to sex(P=1).

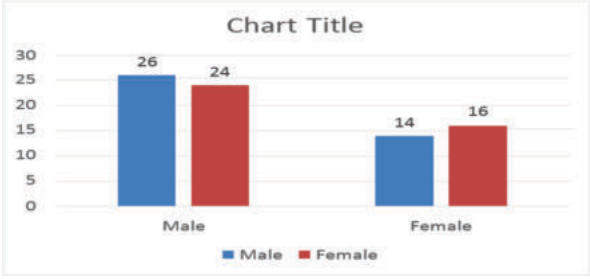

Chart 2: Distribution of study samples according to sex

Table 3: Distribution of study samples according to manifestation of anomaly

	Control group	Study group	P Value
Bilateral	10 (50%)	10 (50%)	1
Unilateral	30 (50%)	30 (50%)	
Total	40 (100%)	40 (100%)	

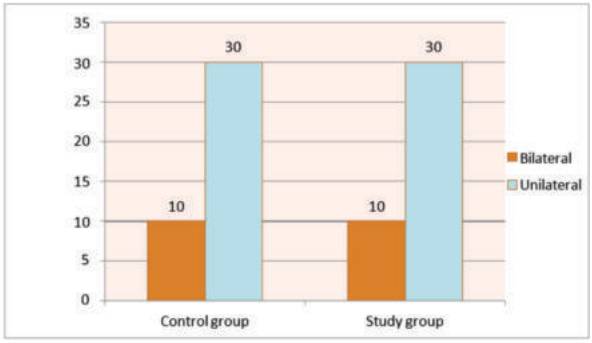

Chart 3: Distribution of study samples according to manifestation of anomaly

There was no significant statically difference between between the groups with respect to unilateral and bilateral ratio.

Table 4: Distribution of study samples according to duration from start of correction till tenotomy

Duration (days)	Control group	Study group	P Value
<28	3 (7.5%)	38 (95%)	
≥28	37 (92.5%)	2 (5%)	
Total	40 (100%)	40 (100%)	
Mean ± SD (years)	35.68±5.44	19.30±3.91	0.001

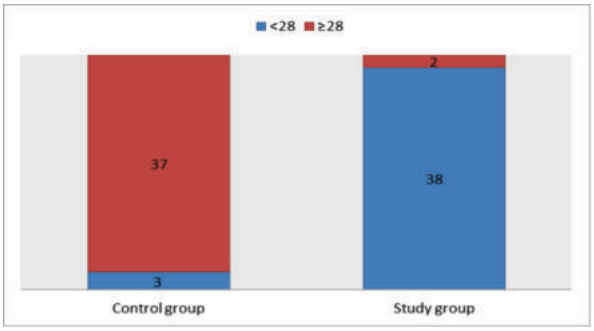

Chart 4: Distribution of study samples according to duration from start of correction till tenotomy.

Among 40 samples of control group, 7.5% took less than 28 days for correction till tenotomy while 92.5% took more than or equal to 28 days.

Among 40 samples of study group, 95% took less than 28 days for correction till tenotomy while 5% took more than or equal to 28 days. There were 10 Bilateral and 20 Unilateral in both study and control group.

Among control group, mean duration was 35.68±5.44 days while it was 19.30±3.91 days, in study group. There was statistically significant difference (p=0.001) between the groups regarding duration of correction.

Table 5: Distribution of study samples according to Number of casts used.

Number of casts	Control group	Study group	P Value
3	3 (7.5%)	0	
4	11 (27.5%)	6 (15%)	
5	22 (55%)	11 (27.5%)	
6	4 (10%)	17 (42.5%)	
7	0	5 (12.5%)	
8	0	1 (2.5%)	
Total	40 (100%)	40 (100%)	
Mean ± SD (years)	4.91±0.74	5.2±0.94	0.076

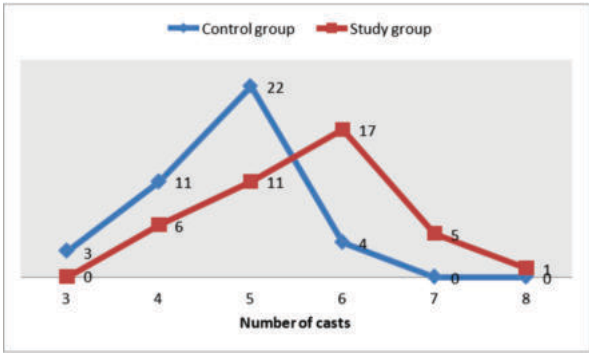

Chart 5: Distribution of study samples according to Number of casts used.

Among control group, mean casts used was 4.91±0.74 while it was 5.2±0.94 in study group. There was no statistically significant difference (p=0.076) between the groups regarding number of cast used. On an average 5 cast were used in control group and 5.5 cast were used in study group.

Table 6: Distribution of study samples according to Initial Pirani Score

Initial Pirani Score	Control group	Study group	P Value
4	5 (12.5%)	5 (12.5%)	
5	28 (70%)	22 (55%)	
6	7 (17.5%)	13 (32.5%)	
Total	40 (100%)	40 (100%)	
Mean ± SD (years)	5.06±0.52	5.19±0.67	0.317

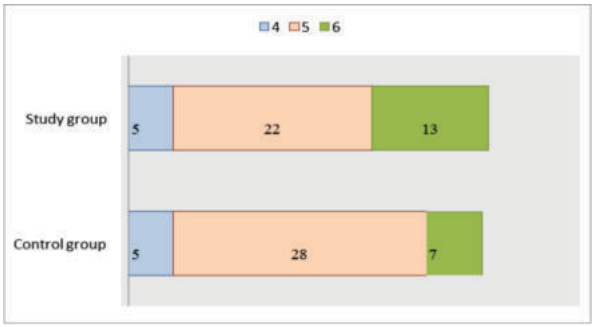

Chart 6: Distribution of study samples according to Initial Pirani Score

Among control group, mean initial Pirani score was 5.06±0.52 while it was 5.19±0.67 in study group. There was no statistically significant difference (p=0.317) between the groups regarding initial pirani score.

Table 7: Distribution of study samples according to Final Pirani Score

Final Pirani Score	Control group	Study group	P Value
0	21 (52.5%)	23 (57.5%)	
1	19 (47.5%)	17 (42.5%)	
Total	40 (100%)	40 (100%)	
Mean ± SD (years)	0.48±0.506	0.43±0.501	0.658

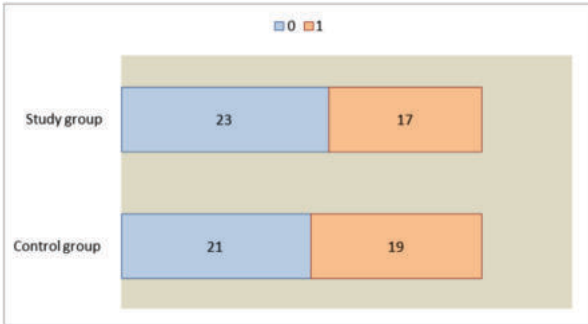

Chart 7: Distribution of study samples according to Final Pirani Score

Among control group, mean final Pirani score was 0.48±0.506 while it was 0.43±0.501 in study group. There was no statistically significant difference (p=0.658) between the groups regarding final pirani score.

Table 8: Distribution of study samples according to Tenotomy

Tenotomy	Control group	Study group	P Value
Performed	13 (32.5%)	14 (35%)	0.9
Not Performed	27 (67.5%)	26 (65%)	
Total	40 (100%)	40 (100%)	

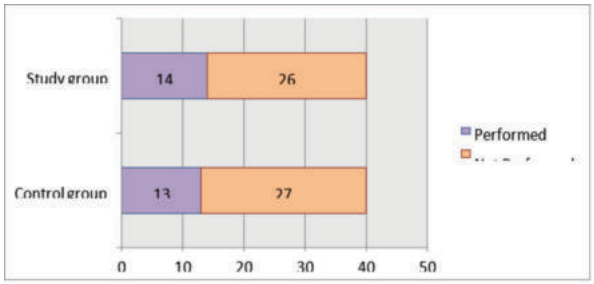

Chart 8: Distribution of study samples according to Tenotomy

Majority of the samples in control group (67.5%) and study group (65%) were undergone tenotomy and the difference between the groups was not statistically significant (p=0.9). We had not lost follow up of any patients.

DISCUSSION

Traditionally, idiopathic unilateral and bilateral clubfoot are considered to have similar characteristics and have been classified within the same group for scientific research.[8] As per the epidemiological evidence, 50% of all the cases are bilateral in manifestation.[9] According to Sharma et al, out of total 40 patients they had 13 bilateral cases (35%). According to Harnett p et al, 21 cases were bilateral out of 40 cases (52.5%). Our study also demonstrated similar prevalence ratio of 50% among both groups which is in line with the previous studies.[10,11,12]

Shortening the interval time could be advantageous for several reasons like reduced number of visits to the hospital, compliance of treatment, financial advantages.[13] According to Harnett p et al, the median number of treatment days in in plaster was 16 in the accelerated group and 42 days in the control group which was statistically significant. According to Sharma P et al, the average duration of treatment in the accelerated was 15 days whereas in the conventional method was 35 days which was statistically significant. In our study, most of the subjects in the Ponseti technique group had a longer duration (35.68±5.44) of treatment compared to the accelerated Ponseti technique group (19.30±3.91) and the difference is statistically significant. This proves the advantage of accelerated Ponseti technique over the traditional Ponseti technique with respect to the convenience of the subjects in terms of shorter duration.

The current study doesn't show a significant difference in number of casts used between the groups. The study group (accelerated Ponseti technique) had used (5.2±0.94) a greater number of casts compared to the other group (4.91±0.74) which is in line with some of the previous studies. [14,12] and in contrast with the other studies. [15,16] However the difference between the groups regarding mean number of casts used was not significant in our study.

Since the outcome of the Ponseti method is affected by factors such as experience or the strictness of the adherence to the Ponseti method, treatment outcomes such as the required number of casts vary among health care institutions.[17] This explains the disparity among the mean total casts used among the studies.

There was no significant difference between the groups regarding Pirani Score in baseline and final score which proves that both the techniques are equally effective. According to the studies done by Harnett P et al and Biswajit Sahu et al there was no statistical difference in initial as well as final pirani scores among both the groups.

A percutaneous tendo achillis tenotomy was performed if dorsiflexion is <10 at the end of manipulation and plastering. Both groups were put into plaster, following tenotomy, for three weeks. There was no difference between the groups regarding the number of subject under gone tenotomy. This is supported by study done by Mahendra Solanki

et al. It can be concluded that the accelerated versions of the Ponseti method can safely be used in the treatment of clubfoot without risking any significant increase in the required number of casts.

Further Reccomendations

This study provides insight into the efficacy of accelerated Ponseti technique.

1. Longitudinal long term follows up studies are required to establish a better evidence and influence of relapse.
2. Accelerated Ponseti technique is effective in treating idiopathic ctev. Hence, it should be used as part of routine practice.
3. The medical associations and authorities should come up with evidence-based guidelines regarding accelerated Ponseti technique.

CONCLUSION

Accelerated Ponseti technique for club foot management was equally effective compared to the standard Ponseti technique in managing idiopathic congenital talipes equinovarus. Accelerated Ponseti technique has relatively shorter duration of manipulation compared to the standard Ponseti technique. Total number of casts used is not significantly different for accelerated Ponseti technique effective compared to the standard Ponseti technique. However, further studies with large sample size and more duration of follow up is necessary to conclude the findings of this study.

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