Original Article

Effectiveness of Home Stretching Exercise for the Treatment of Congenital Talipes Calcaneovalgus: A Randomized Controlled Trial

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Background: Congenital talipes calcaneovalgus (CTCV) is the deformities characterized by hyperdorsiflexion of the foot against the anterior surface of the tibia. The treatments proposed were gentle stretching exercises performed by the parents, corrective casting or splinting with or without stretching exercises. No information regarding effectiveness of the treatment or comparing the outcome between the treatments.

Objective: The purpose of this prospective randomized controlled study is to evaluate the effectiveness of stretching manipulation performed by the parents, in comparison with no treatment, in newborns with congenital talipes calcaneovalgus (CTCV).

Materials and Methods: The healthy babies aged ranging from 1 to 7 days, who were born with CTCV were included in the present study. Simple randomization was done to allocate the patients into 2 groups. In group A-the treated group, the parents were taught to perform stretching exercise consisting of passive plantar flexion of the deformed foot for at least 10 seconds each time and at least 10 times a day. Group B contained the newborns that did not receive any treatment other than explanation about diagnosis, prognosis and follow-up plan. The follow-up intervals for both groups were one, three, four, six and ten months after enrollment. The demographic data in sex, affected side, severity of the deformity, weight and height of the newborns were recorded. The outcome measured included rate and time to recovery for each group.

Results: There were 38 cases (16 boys, 22 girls) in group A and 36 cases (15 boys, 22 girls) in group B who had complete follow-up data for the final analysis. There were no statistically significant differences in sex, affected side, severity of the deformity, weight, height, recovery time, and success rate between the two groups.

Conclusion: The foot with uncomplicated CTCV have good prognosis and achieve full recovery within 300 days regardless of treatment.

Keywords: Effectiveness, Stretching exercise, Newborns, Congenital talipes calcaneovalgus, Randomized controlled trial

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Congenital talipes calcaneovalgus (CTCV) is one of the most common postural deformities of the newborns[1-3]. The deformity is characterized by hyperdorsi-flexion of the foot against the anterior surface of the tibia (Figure 1). Plantar flexion of the foot is limited as a result of contracture of the ante-rior ankle and foot structures. The treatments proposed in the literature were gentle stretching exercises performed by the parents, corrective casting or splinting with or without stretching exercises[4-7]. Our literature review did not find any documented information regarding effectiveness of the treatment, or previous study comparing the outcome between the treatments. The purpose

Figure 1. Newborn with bilateral congenital talipes calcaneovalgus (CTCV).

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of the present study is to find the effectiveness of the home stretching exercise program, as well as to compare the result with no treatment in newborns with CTCV using a prospective randomized controlled trial.

Materials and Methods

The present study was a prospective randomized controlled trial conducted from December 2016 to March 2018. The newborns ranging in age from 1-7 days old with CTCV were included in the study. All the babies were otherwise healthy. The diagnosis was made based on clinical examination done by fellowship-trained pediatric orthopedic surgeons. The deformity typically presented as shown in Figure 1. The newborns with arthrogryposis multiplex congenita, myelomeningocele, congenital spinal disorder, congenital anomalies of bone and joint, bone and joint infection, Larsen syndrome, skeletal dysplasia, or mental retardation were excluded from the study. The patients were also excluded if their parents refused to participate in the study.

After informed consent was obtained, simple randomization was done with Block stratified randomization window ver.6 and the participants were allocated into 2 groups. For group A, the treated group, the parents were instructed to perform stretching exercise by using their right hand to hold the right foot (and vice versa) and passively plantar flexing the deformed foot (Figure 2). The parents who could not pass with at least a performance score of 8 out of 10 were also excluded from the study. The stretching was performed for at least 10 seconds each time, and at least 10 times a day. The newborns in group B received no treatment. Nevertheless, a discussion about diagnosis, prognosis and follow-up plan were provided. The follow-up intervals for both groups were one, three, four, six and ten months after recruitment. The feet were re-evaluated at each visit by pediatric orthopedic surgeons. If the deformity persisted after ten months, the corrective casting or splinting was applied until the deformity resolved.

Figure 2. Newborn in group A, the treated group, the parents were instructed to perform stretching exercise by using their right hand to hold the right foot (and vice versa) and passively plantar flexing the deformed foot.

The sample size calculation was done using the formula for two independent proportions, where P1 is the success rate of Group A (98%) and P2 is the success rate of Group B (75%). The number of subjects for each group was calculated to be 34.

The demographic data in sex, side, weight, and height of the newborns were recorded. The initial severity of the CTCV foot was evaluated and scored according to the degree of reducibility from mild, moderate to severe depending on the resistance to plantar flexion of the foot. The outcome of recovery was determined by physical examination performed by a pediatric orthopedic surgeon. The recovery time, defined as the duration in days taken from foot with CTCV to full recovery, in both groups was documented. The success rate, which was the percentage of the patients achieved full recovery, in each group was recorded.

Statistical analysis was done using SPSS software (PASW Statistics for Windows, version 18.0. Chicago: SPSS Inc.). Chi-square test was used to compare categorical variables between groups. Unpaired student t-test was used to compare the difference between means of recovery time for both groups. A *p*-value of less than 0.05 indicated a statistically significant difference.

Results

There were 82 newborns with CTCV who met the eligibility criteria to be included into the study. Two patients were excluded because their parents refused to participate in the study. Eighty newborns were randomized into 2 groups, 40 in each group. Two cases in Group A and four cases in group B were lost to follow-up because their families relocated to another city. Therefore, 38 cases in group A and 36 cases in group B had complete follow-up data available for the final statistical analysis (Figure 3).

There were 16 boys, 22 girls in group A and 15 boys, 22 girls in group B. The demographic data including sex, side, and severity were summarized in Table 1. There was no statistically significant difference in sex, side, and severity between both groups (Table 1). Similarly, the weight and height of the patients in both groups were not significantly different (Table 2). No treatment-related complication was observed during the study period.

After the first month, the patients who received passive stretching exercise (group A) had a higher recovery rate (26.3 vs. 11.1%), although the difference was not statistically significant ($p = 0.095$) (Table 3). Furthermore, at the later follow-up intervals, there was no significant difference in the success rate when compared between both groups (Table 3). After 10 months (300 days), both groups of the patients had 100% success rate of recovery. The recovery time ranged from 20 to 300 days with an average (mean $\pm$ SD) of 97.1$\pm$60.1 days in group A, and 95.8$\pm$59.2

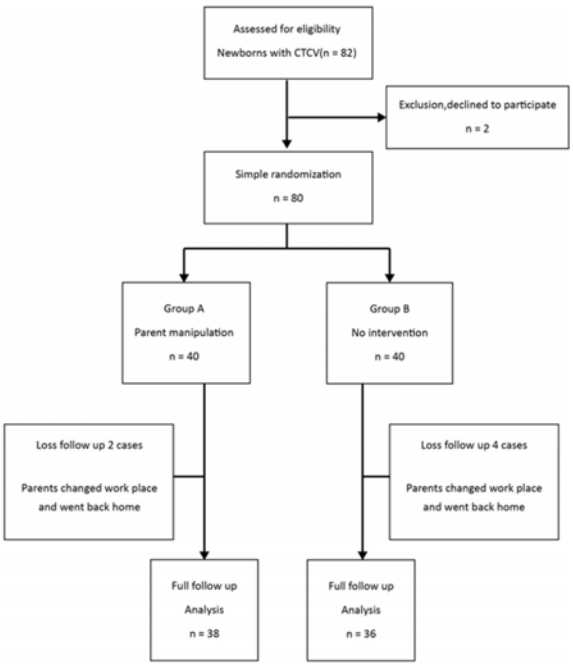

Figure 3. CONSORT diagram.

days in group B. This difference in recovery time between groups was not statistically significant ($p = 0.927$).

Discussion

CTCV is a common congenital foot deformity[1-3]. In most cases, clinical examination revealing the typical foot appearance is sufficient to make a diagnosis. Care needs to be taken to differentiate a simple CTCV from a more pathological condition, especially the congenital posteromedial bowing of the tibia caused by spina bifida which usually associates with gastrosoleus weakness[4]. Many standard textbooks have recommended stretching exercise program with or without cast or splint as the treatment of choice[4,6,7]. On the other hand, Staheli stated in his review that the treatment was not necessary[5]. A study by Widhe found that the deformity disappeared without treatment after 5 to 6 years of follow-up[8]. Wynne-Davies also found that the deformity in all patients with CTCV corrected spontaneously within a few months to one year[9].

The new information found in the present study contributes to the body of knowledge that uncomplicated CTCV has a powerful spontaneous recovery with 100% success rate. The authors recommend that the treatment is not necessary and the deformity can be observed for as long as 10 months for spontaneous resolution. In idiopathic CTCV, the high spontaneous recovery rate can be attributed to many reasons. First, the strong muscle power of gastrocnemius and soleus muscles act as plantar flexors of the foot to reduce the deformity. Second, there is no true rigid contracture of the anterior ankle and foot structures. Third, the muscles, tendons, and capsules of the anterior part of ankle do not have structural changes in cells or tissues. Fourth, the intrauterine deforming force, specifically dorsiflexion position of the foot causing CTCV, is temporary and only for a short period of time before birth[9,10].

Table 1. Demographic data of newborns in group A and group B

Variables	Group A number (%)	Group B number (%)	*p*-value
Sex			
Boys	16 (42.1)	15 (41.7)	0.58
Girls	22 (57.9)	21 (58.3)	
Total	38 (100)	36 (100)	
Side			
Unilateral			
Left	2 (5.2)	3 (8.3)	0.38
Right	18 (47.4)	11 (30.6)	
Bilateral	18 (47.4)	22 (61.1)	
Total	38 (100)	36 (100)	
Severity			
Unilateral			
Mild	8 (21.1)	9 (25)	0.12
Moderate	8 (21.1)	1 (2.8)	
Severe	4 (10.5)	4 (11.1)	
Bilateral left			
Mild	7 (18.4)	9 (25)	0.69
Moderate	9 (23.7)	11 (30.6)	
Severe	2 (5.3)	2 (5.6)	
Bilateral right			
Mild	6 (15.8)	8 (22.2)	0.59
Moderate	9 (23.7)	12 (33.3)	
Severe	3 (7.9)	2 (5.6)	
Total	38 (100)	36 (100)	

Table 2. Comparison weight and height of newborns between group A and group B

Variables	Group A mean ± SD	Group B mean ± SD	*p*-value
Weight (gram)	2,964.47±337.6	2,910.56±351.2	0.5
Height (cm)	49.13±2.2	43.19±1.7	0.8

Conclusion

There were no statistically significant difference in success rate and recovery time between the home stretching exercise group and spontaneous recovery group. The foot with uncomplicated CTCV had good prognosis for full spontaneous recovery without a need for treatment such as stretching exercise, cast or splint.

What is already known on this topic?

The CTCV is one of the common deformities in newborn which can be cured by itself or by manipulation or splint.

Table 3. The recovery time, number and percentage of success in group A and group B

Recovery time (day)	Group A (n = 38), success cases		Group B (n = 36), success cases		*p*-value
	Number	%	Number	%	
20	1	2.6	0	0	0.926
30	9	23.7	4	11.1	
60	5	13.2	14	38.9	
80	1	2.6	0	0	
90	4	10.5	6	16.7	
100	5	13.2	1	2.8	
120	5	13.2	4	11.1	
150	0	0	1	2.8	
160	0	0	1	2.8	
180	2	5.3	2	5.6	
200	6	15.8	2	5.6	
300	0	0	1	2.8	

What this study adds?

This study adds the percentage which was 100% and the time of spontaneous resolution which was within 300 days without any treatment in all cases.

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Potential conflicts of interest

The authors declare no conflict of interest.

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