Clinical, Radiological, Pedobarographic, and Quality of Life Outcomes of the Ponseti Treatment for Clubfoot: A Prospective Study from Iran

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Abstract

Background: Talipes equinovarus, also known as clubfoot, is a congenital anomaly that affects one newborn per 1000 live births. Its standard treatment strategy is the Ponseti casting management. This study aims to report the long-term outcomes of the Ponseti treatment in Iran.

Methods: A prospective cohort study was enrolled to evaluate clinical outcomes, radiological results, pedobarographic measurements, and quality of life after the Ponseti treatment in patients with clubfoot who were followed for at least five years.

Results: In this study, 25 clubfeet of 18 patients were included. Significant reductions in Pirani, Dimeglio, and CAP scores, improved ankle dorsiflexion, and acceptable pedobarographic indices were observed in this study. From the radiological evaluation indices, the calcaneal pitch and lateral talus-first metatarsal angles were significantly reduced. The quality of life of patients after five years of treatment was favorable, which was better in females. This study showed that the results of the Ponseti treatment remained acceptable after five years.

Conclusions: The Ponseti management for clubfoot in the long term appears to maintain significant improvements. However, the rate of recurrence – albeit without disruption to daily activities - cannot be ignored.

Background

Talipes equinovarus, also known as clubfoot, is a congenital anomaly in the lower extremities that may be part of a syndrome [1]. The disorder, which is one of the most common problems in pediatric orthopedics, affects one newborn per 1000 live births with varying degrees of severity [2, 3]. The prevalence of clubfoot in male infants is almost twice that of female ones [2]. It has a wide range of problems, depending on its severity, the treatment, and the success of that treatment [4, 5].

Achieving plantigrade locomotion with normal and painless function is the goal of clubfoot treatment [6]. Varieties of treatments are suggested for patients [7]. The standard and benchmark treatment strategy is the Ponseti method of management, which involves manipulation and weekly casting, percutaneous Achilles tenotomy in most patients, and maintenance of correction with braces for several years [4, 8]. The rationale for using braces is that recurrence of clubfoot is common even after successful correction [9].

There are various methods for patients' follow-up, including scoring severity of deformities, scoring clinical examination with the proposed protocols, radiological evaluations and measuring radiographic angles, measuring the pressure exerts by the sole on the ground using a pedobarograph, and assessing the patient’s quality of life [5, 10].

Although about 80% of patients with clubfoot are from developing countries, a significant number of patients are missed in these countries, and genetics and race play a role in this disorder, to the best of our knowledge, there was no study to evaluate the long-term results of Ponseti treatment in Iran and the Eastern Mediterranean region [5, 11, 12]. One of the goals of this study is to evaluate the durability of the results because a number of previous studies have reported remarkable results in the short term using this treatment [11, 13]. This prospective cohort study aims to report the long-term clinical outcomes, radiological results, pedobarographic measurements, and quality of life of patients with clubfoot who were treated with the Ponseti method.

Methods

Study design and setting

A prospective cohort study was designed to evaluate the long-term results and outcomes of the Ponseti method in patients with clubfoot from August 2013 until September 2015. After each visit, the patient's information was transferred from the medical records to our hospital information system, and finally, the information required for the study was collected from the hospital information system.

This study is in accordance with the Declaration of Helsinki and its subsequent revisions [14]. Our institutional review board approved this study. Written informed consent was obtained from each patient at the beginning of the study.

Participants

Through the records sampling, all patients with clubfoot who were treated with the Ponseti method to correct the deformity and were followed for at least five years were included in the study. All patients were visited and treated by two pediatric orthopedists (BP and MHN).

Assessments

a. Demographic information was collected, including age at the time of data analysis and gender.

b. Pirani and Dimeglio scoring systems were used to assess the deformity severity in the first and last follow-up visits. The Pirani score has six parameters and evaluates midfoot and hindfoot. This scoring system is given a score of 0 to 6 for each patient, and the higher the score, the more severe the deformity [15]. The Dimeglio scoring system has eight parameters, and the closer the final score is to 20, the more severe the anomaly. The parameters of this scoring system for severity evaluation include equinus, varus, supination, and adductus (each from 0 to 4) and posterior crease, medial crease, cavus, and deviant muscle function (each from 0 to 1) [16].

c. At each visit, patients underwent physical examinations to assess functional and structural status, and a standard instrument was used for more precise assessments. The clubfoot assessment protocol (CAP) consists of twenty parameters in four subsets, including passive mobility, muscle function, morphology,

and motion quality, and have sufficient reliability [17]. Evaluation of the foot structure and function during clubfoot treatment was also performed by the method introduced by Bensahel *et al.* and the International Clubfoot Study Group (ICSG). In this system, scores of 0 and 60 indicate the best and worst results, respectively [18].

d. Radiological examinations were performed by radiographs in anteroposterior (AP) and lateral views of the foot in stress dorsiflexion position and measuring calcaneal pitch angle, lateral talocalcaneal angle, kite angle, lateral talus-first metatarsal angle, and AP talus-first metatarsal angle [19].

e. Pedobarography was another method of evaluating the treatment results, which is measuring the pressure on the sole. The device pedobarograph has a pressure-sensitive plastic plate that converts the foot image into visible pressure patterns [20].

f. The PedsQL that is a standard quality of life questionnaire was used, too. This questionnaire has 23 questions in four areas including health and physical function (8 questions), emotional function (5 questions), social function (5 questions), and academic function (5 questions). Parents scored each question from 1 to 5. Finally, the scores of the areas were added, and the lower the final score, the better the quality of life [21].

g. Recurrence was defined as the reappearance of one to all previous deformities after successful initial treatment [4].

Statistical analysis

IBM SPSS statistics 25 (IBM corporation, Armonk, NY, USA) was used to perform all statistical analyzes. Descriptive statistics such as mean, standard deviation, and percentage were used to describe the data, Independent samples t-test was used to compare means, and Chi-square test was used to examine the relationship between qualitative variables. The One-sample Wilcoxon signed-rank test was used for variables that did not have a normal distribution. The Mann – Whitney U test was used to compare the quality of life of males and females. A *p*-value of less than 0.05 was considered significant.

Results

Participants

In this study, 25 clubfeet of 18 patients with mean age ± standard deviation (SD) of 6.88 ± 1.68 years at the time of data analysis were included. 13 and 5 of the patients were male and female, respectively, and their ages did not differ [*p*-value = 0.104 using the independent t-test].

Outcomes

Table 1 has detailed the measurements of the scoring systems, clinical examinations, and radiological evaluations variables. The mean ± SD reductions in the Pirani and Demeglio scoring systems from the first visit to the last follow-up visit was 3.05 ± 1.95 and 6.55 ± 3.22, respectively, which were significant

using the one-sample t-test and the Wilcoxon test, respectively. Also, the mean CAP score of patients during the follow-up period had a significant decrease of 10.38 ± 10.34 using the one-sample t-test. In addition, the Wilcoxon test showed that the dorsiflexion angle of the patients' feet was significantly improved. The mean ± SD of ICSG at the last follow-up visit was 9.38 ± 10.86 - this variable was not calculated at the first visits. All radiologically evaluated angles were significantly reduced after five years of treatment using the one-sample t-test, except for the AP talus-first metatarsal angle, which decreased by an average of 0.30 ± 0.73 - it was not significant using the Wilcoxon test.

Table 1
Mean ± standard deviation (SD) of measured variables in the first and last visits. CAP clubfoot assessment protocol. AP anteroposterior. * significant.

Variables	**Mean ± SD at the first visit**	**Mean ± SD at least after five years**	***p*-value**
Pirani	8.29 ± 2.28	5.24 ± 1.86	0.000*
Dimeglio	15.76 ± 2.50	9.21 ± 2.37	0.000*
CAP	60.15 ± 13.66	70.53 ± 7.89	0.004*
Foot dorsiflexion	41.86 ± 13.70	9.40 ± 13.00	0.000*
Calcaneal pitch angle	24.65 ± 16.20	11.75 ± 4.38	0.001*
Lateral talocalcaneal angle	38.65 ± 12.51	28.35 ± 9.34	0.006*
Kite angle	38.21 ± 9.82	31.50 ± 7.07	0.002*
Lateral talus-first metatarsal angle	17.25 ± 7.95	8.80 ± 6.81	0.000*
AP talus-first metatarsal angle	0.80 ± 0.41	0.42 ± 0.50	0.083

Table 2 reports the results of the pedobarographic evaluations of patients. These assessments were performed only at the time of the last follow-up visit.

Table 2
Mean ± standard deviation (SD) of pedobarographic variables.

Variables	**Mean ± SD**
Initial foot contact	Not measured
Initial metatarsal contact	46.65 ± 11.16 kPa
Initial fore-foot contact	108.67 ± 15.71 kPa
Heel off	178.00 ± 38.06 kPa
Final foot contact	593.19 ± 32.70 kPa

The mean PedsQL of all patients, males, and females were 8.69 ± 8.70, 10.73 ± 9.40, and 3.14 ± 1.21, respectively. The observed difference between males and females was statistically significant, indicating that in long-term follow-up, the quality of life in females was significantly higher than in males [*p*-value = 0.003 using the Mann–Whitney U test]. Clubfoot recurrence was observed in 3 feet of 3 patients.

Discussion

In the current study, with a five-year follow-up of patients with clubfoot who were treated with Ponseti method, Pirani scores decreased, Dimeglio decreased, scores CAP scores decreased, ankle dorsiflexion improved, several radiological indicators improved, patients' foot condition was acceptable determined by the pedobarographic device, and patients' quality of life was favorable. The only adverse outcomes were lateral talocalcaneal angle and kite angle. This study showed that the results of the Ponseti treatment remained acceptable after five years. The results of this study are weaker than the short-term studies that have reported remarkable outcomes, and this difference may indicate a recurrence - albeit without functional problems - in patients [11, 13].

In this study, the mean Pirani score of patients remained significantly reduced and acceptable after five years of follow-up. In Azimi and Narouie's study of 32 clubfeet, the mean Pirani score dropped from 5.53 to 0.09 after 4 to 14 months of treatment, which was to be expected, given the scoring shortly after treatment [13]. Kumar *et al.* have also reported a decrease in mean Pirani score from 5.3 to 0.8 following six to twenty months of Ponseti management [22].

Also, the patients' Demeglio score decreased significantly and remained acceptable after five years in this study, which indicates continuation of good function in the long run. Hallaj-Moghaddam *et al.* by designing a prospective study in patients with severe clubfoot reported a significant reduction in the mean Demeglio score from 16 to 1.6 [23]. In another prospective study on 110 idiopathic clubfeet, Bouchoucha *et al.* reported a reduction in a mean of this score from 12.9 to 1.3 [24].

Improvement of ankle dorsiflexion following treatment and remaining this outcome for five years was one of the findings of this study. Spiegel *et al.* and Sanghvi and Mittal reported an average dorsiflexion angle of 12.5 and a maximum dorsiflexion angle of 12, respectively [25, 26].

In this study, children's quality of life was assessed five years after the start of treatment. The mean score of the standard questionnaire of PedsQL indicates the high quality of life in children - especially in female ones - following clubfoot treatment with the Ponseti method. A study by Smith *et al.* found that children who underwent surgery to treat clubfoot reported more pain than children who underwent Ponseti treatment; however, both groups were functional and had a high quality of life [27]. Causes of decreased quality of life in these patients include prolonged use of braces and consequent inability to play and anxiety and discomfort caused by thinking of others about how they walk [5, 28].

Recurrence was observed in 12% of feet in this study. Porecha *et al.* observed recurrence of clubfoot in 19 feet (28.35%) of 14 patients subsequent to initial Ponseti treatment of 67 clubfeet of 49 patients [29].

Hallaj-Moghaddam *et al.* also reported a recurrence rate of 27.1% after three years [23]. The recurrence rate following Ponseti treatment varies considerably from study to study, with Gupta *et al.* reporting recurrence in 9 feet out of 154 clubfeet and Sud *et al.* reporting recurrence in 7 feet out of 33 clubfeet [30, 31]. Gelfer *et al.* by conducting a systematic review of 10535 clubfeet found that the relapse rate reported in various studies was between 1.9% and 45%, which increased over follow-up time [32]. A study by Qudsi *et al.*, which examined clinical outcomes and risk factors for the Ponseti method in 168 children with clubfoot, found that female gender and a higher Pirani score increased the risk of recurrence [33].

Although this study has significant advantages such as long-term follow-up, evaluation by various assessments, and prospective design, it also has disadvantages that should be noted. First, the number of patients in this study is small. Second, the assessments performed at follow-up visits did not include evaluations through the assessments mentioned in the materials and methods section, so they were not reported. Third, the ICSG assessment was not performed at the first visit.

Conclusion

Given the decline in Pirani, Dimeglio, and CAP scores, low ICSG scores, improved ankle dorsiflexion function, improved several radiological indices, and acceptable quality of life, the Ponseti's approach to treating clubfoot in the medium term appears to maintain significant improvements. However, the rate of recurrence using this method and the worsening of clubfoot improvement indices compared to short-term results can not be ignored. Therefore, preventive tools such as using braces should be used for preventing recurrence of deformity.

Declarations

- **Ethics approval**: The Tehran University of Medical Sciences (TUMS) Review Board confirmed the current study. [Reference Number: IR.TUMS.CHMC.REC.1398.021].
- **Consent to participate**: Not Applicable.
- **Consent to publish**: Written informed consent was obtained from the patient’s parents to published any and all published material in this study.
- **Availability of data and materials**: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.
- **Competing interests**: All authors declare that there were no competing interests for this study.

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and preparing the manuscript and its submission. RZ helped in data gathering and manuscript preparation.

References

1. Miedzybrodzka Z. Congenital talipes equinovarus (clubfoot): a disorder of the foot but not the hand. Journal of anatomy. 2003;202(1):37–42.
2. Parker SE, et al. Multistate study of the epidemiology of clubfoot. Birth Defects Research Part A: Clinical Molecular Teratology. 2009;85(11):897–904.
3. Werler MM, et al. Descriptive epidemiology of idiopathic clubfoot. American journal of medical genetics Part A. 2013;161(7):1569–78.
4. Stouten JH, Besselaar AT, Van Der Steen MCM. Identification and treatment of residual and relapsed idiopathic clubfoot in 88 children. Acta Orthop. 2018;89(4):448–53.
5. Stevanović VB, et al. Clubfoot in children. Acta Chir Iugosl. 2011;58(3):97–101.
6. Clegg J, Gaffey A, Patankar. J *A PRELIMINARY REPORT OF THE COVENTRY EXPERIENCE IN THE USE OF THE UMEX SYSTEM OF EXTERNAL SKELETAL FIXATION, IN THE MANAGEMENT OF CLUB FOOT AND OTHER PAEDIATRIC FOOT DISORDERS*. in *Orthopaedic Proceedings*. 2006. The British Editorial Society of Bone & Joint Surgery.
7. Dobbs MB, et al. Treatment of idiopathic clubfoot: an historical review. Iowa Orthop J. 2000;20:59.
8. Ponseti I, et al., *Clubfoot: ponseti management.* Global-HELP Organisation, 2005. **8**.
9. Zionts LE, Dietz FR. Bracing following correction of idiopathic clubfoot using the Ponseti method. JAAOS-Journal of the American Academy of Orthopaedic Surgeons. 2010;18(8):486–93.
10. McKay DW. New concept of and approach to clubfoot treatment: section III—evaluation and results. Journal of Pediatric Orthopaedics. 1983;3(2):141–8.
11. Owen RM, Kembhavi G. A critical review of interventions for clubfoot in low and middle-income countries: effectiveness and contextual influences. Journal of Pediatric Orthopaedics B. 2012;21(1):59–67.
12. Keret D, et al. Efficacy of prenatal ultrasonography in confirmed club foot. J Bone Joint Surg Br. 2002;84(7):1015–9.
13. Azimi HH, Narouie B. *Ponseti Method in Correction of Clubfoot Deformity*.
14. Cantín M. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human subjects. Reviewing the Latest Version. International Journal of Medical Surgical Sciences. 2014;1(4):339–46.
15. Pirani S, et al. *A reliable method of clinically evaluating a virgin clubfoot evaluation*. in *21st SICOT congress*. 1999.
16. Dimeglio A, et al. Classification of clubfoot. Journal of Pediatric Orthopaedics B. 1995;4(2):129–36.

17. Andriesse H, Hägglund G, Jarnlo G-B. The clubfoot assessment protocol (CAP); description and reliability of a structured multi-level instrument for follow-up. BMC Musculoskelet Disord. 2005;6:40–0.
18. Celebi L, et al. *Bensahel et al. and* International Clubfoot Study Group evaluation of treated clubfoot: assessment of interobserver and intraobserver reliability. Journal of Pediatric Orthopaedics B. 2006;15(1):34–6.
19. Besselaar AT, et al. Guideline on the diagnosis and treatment of primary idiopathic clubfoot. Acta Orthop. 2017;88(3):305–9.
20. Sinclair MF, et al. Pedobarographic Analysis Following Ponseti Treatment for Congenital Clubfoot. Clin Orthop Relat Res. 2009;467(5):1223–30.
21. Varni JW, Seid M, Rode CA. *The PedsQL™: measurement model for the pediatric quality of life inventory.* Medical care, 1999: p. 126–139.
22. Kumar R, Suman SK, Manjhi L. *Evaluation of outcome of treatment of idiopathic clubfoot by ponseti technique of manipulation and serial plaster casting*. International Journal of Orthopaedics Sciences, 2017: p. 23–27.
23. Hallaj-Moghaddam M, et al., *Ponseti Casting for Severe Club Foot Deformity: Are Clinical Outcomes Promising?* Advances in Orthopedics, 2015. 2015: p. 821690.
24. Bouchoucha S, et al. Early results of the Ponseti method using the Steenbek foot abduction brace: a prospective study of 95 feet. J Pediatr Orthop B. 2008;17(3):134–8.
25. Spiegel DA, et al. Ponseti method for untreated idiopathic clubfeet in Nepalese patients from 1 to 6 years of age. Clin Orthop Relat Res. 2009;467(5):1164–70.
26. Sanghvi AV, Mittal VK. Conservative management of idiopathic clubfoot: Kite versus Ponseti method. J Orthop Surg (Hong Kong). 2009;17(1):67–71.
27. Smith PA, et al. Long-term results of comprehensive clubfoot release versus the Ponseti method: which is better? Clin Orthop Relat Res. 2014;472(4):1281–90.
28. Lööf E, et al. Neurodevelopmental difficulties negatively affect health-related quality of life in children with idiopathic clubfoot. Acta Paediatr. 2019;108(8):1492–8.
29. Porecha MM, Parmar DS, Chavda HR. Mid-term results of ponseti method for the treatment of congenital idiopathic clubfoot - (A study of 67 clubfeet with mean five year follow-up). Journal of Orthopaedic Surgery Research. 2011;6(1):3.
30. Gupta A, et al. Evaluation of the utility of the Ponseti method of correction of clubfoot deformity in a developing nation. International orthopaedics. 2008;32(1):75–9.
31. Sud A, et al. Ponseti's vs. Kite's method in the treatment of clubfoot–a prospective randomised study. International orthopaedics. 2008;32(3):409–13.
32. Gelfer Y, et al. Congenital talipes equinovarus. The Bone Joint Journal. 2019;101-B(6):639–45.
33. Qudsi RA, et al. Clinical outcomes and risk-factor analysis of the Ponseti Method in a low-resource setting: Clubfoot care in Haiti. PloS one. 2019;14(3):e0213382.