

RESEARCH ARTICLE

Epidemiological Profile and Treatment Results of Ponseti

Sandy Lizeth Guerrero Sorto¹, Gustavo A. Vasquez Garcia^{1,2},
Nolvia Sarahi Diaz Cruz^{1,2*}, Paola Estela Figueroa Avilez¹, Gabriela
Alejandra Contreras Aleman¹

¹Universidad Catolica de Honduras, San Pedro Sula, Honduras

²Fundacion Ruth Paz, San Pedro Sula, Honduras

*Corresponding author: Nolvia Sarahi Diaz Cruz: saradz-cr@hotmail.com



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Abstract:

Background: Congenital clubfoot is a common deformity characterized by an abnormal development of the foot. The etiology is multifactorial and genetic causes have been related. The Ponseti method is a conservative treatment for the clubfoot, mostly used in idiopathic cases. This method involves serial plaster cast changes, tenotomy of the Achilles tendon and use of braces to prevent relapses. This study was designed to identify the characteristics of the patients diagnosed with congenital clubfoot who were treated with the Ponseti method and the main outcomes of this treatment in children under five years.

Method: A retrospective study was conducted in Fundación Ruth Paz in San Pedro Sula, Honduras, since June 1st 2015 to May 31st 2017. This study included patients under five years who were diagnosed with congenital clubfoot and treated with Ponseti method. The data were collected from the clinical files of the identified cases. *Results:* Congenital clubfoot was more common among males (66.3%) and the localization of the deformity was more commonly bilateral (51.8%). The cases of idiopathic clubfoot represent 91.6% of all the cases. The tenotomy of the Achilles tendon was performed in 51.8% of the patients. Complete treatment was identified in 90.4% of the cases and relapses were reported in 12% of the children who completed treatment.

Conclusions: Ponseti method was effective for treat children under five years diagnosed with clubfoot (idiopathic and non-idiopathic) and a significant decrease of the Pirani scoring after treatment was identified in all the cases. A correct use of braces is necessary to avoid relapses.

Keywords: Congenital clubfoot, Ponseti method

Introduction

This study was designed to identify the characteristics of the patients diagnosed with congenital clubfoot who were treated with the Ponseti method and the main outcomes of this treatment in children under five years at Fundación Ruth Paz in San Pedro Sula, Honduras.

Ignacio Ponseti developed a method for the treatment of clubfoot that has been widely spread; it is effective, simple and low cost, with great long-term outcomes in most of the patients, reasons that made this method very popular. (1) The Ponseti method involves serial plaster cast changes after performing manipulations of the foot aiming to correct the deformities except the equinus. After the last plaster cast change, a percutaneous tenotomy of the Achilles tendon can be performed to correct the equinus and three weeks later when continuity of the tendon is restored, use of braces are necessary to prevent relapses. During the first three months, the patient must wear the braces the entire day, followed by the use during sleeping time or 12 to 16 hours per day. The use of braces can be extended until three or four years of age. (2,3)

The Ponseti method is expected to allow the patients to evolve satisfactorily, without limitations, avoiding long hospitalizations, high expenses and further disability when the treatment is performed early to achieve functional results and painless.(4)

During 2009, according to Global Clubfoot Initiative, it is estimated that 203 children received treatment for congenital clubfoot in Honduras; during 2011, a smaller group was reported with 109 cases; in 2013 a group of 165 children received treatment.(5) However, this data was provided by a non-governmental organization and it is possible to underestimate the overall incidence of clubfoot in this population. The Ponseti method is often used in the health center of this study (Fundación Ruth Paz) because it is affordable for our population due to the socioeconomic background.(5)

Materials and method

A cross sectional retrospective study performed in Fundación Ruth Paz in San Pedro Sula, Honduras, since June 1st 2015 to May 31th 2017. This study included patients under five years who were diagnosed with congenital clubfoot and treated with Ponseti method. The inclusion criteria were: patients aged less than five years diagnosed with congenital clubfoot, complete clinical files, patients treated in Fundación Ruth Paz. Exclusion criteria were: patients aged five years or older, acquired clubfoot, patients treated with surgery or physiotherapy and incomplete clinical files. A total of 279 cases of congenital clubfoot were diagnosed during the period of this study, 196 files were excluded due to the following causes: misdiagnosis (13 cases), children older than five years (45 cases), incomplete data in clinical files (39 cases) and children who received surgical

treatment instead of Ponseti's method (99 cases). A total of 83 cases of congenital clubfoot in children under five years were evaluated during this study through the information in the clinical file. Patient data were collected from the database of the Fundación Ruth Paz. The access to the clinical files was obtained through a solicitude to the general manager of the foundation who gave permission to obtain the data from the statistics department. The data was obtained from the registers of daily attentions during the period of June 2015 to May 2017, the files were reviewed according to the number of file of patients diagnosed with clubfoot, this data were not identified with named to maintain confidentiality. A total of 83 clinical files were reviewed, the data were obtained through a questionnaire that included demographic data (department of provenance, gender, age and age range), characteristics of the pathology (classification of the illness as idiopathic and non-idiopathic, localization of the deformity as bilateral, right or left foot), characteristics of the treatment (Pirani scoring before treatment, number of plaster cast changes, range of plaster cast changes, Pirani scoring after treatment, tenotomy of the Achilles tendon, use of braces, Pirani scoring after treatment and relapses).

This study did not involve risks for the patients because it is a retrospective study and the data were obtained through the clinical files, confidentiality was kept by no recording other data than the necessary and no names were included according to the Declaration of Helsinki. This research did not need written informed consent and the study was approved by the ethical committee of the Fundación Ruth Paz.

After data recollection, the outcomes were introduced in the computer in the Statistical Package for the Social Sciences software (SPSS, version 22) for Windows. The qualitative variables were analyzed with Chi square test and the quantitative variables were analyzed with t-student test, statistically significant difference was set at p value ≤ 0.05 and confidence interval of 95%.

Results

A total of 279 cases of clubfoot were attended in Fundación Ruth Paz since June 2015 to May 2017; 196 files were not included in this study due to misdiagnosis (13 cases), children older than five years (45 cases), incomplete data (39 cases) and children who received surgical treatment instead of Ponseti's method (99 cases). A total of 83 cases of congenital clubfoot in children under five years were evaluated during this study. The majority of cases were in males (66.3%). The most frequent Department of origin was Cortés (74.7%), followed by Yoro (9.6%) and Santa Bárbara (8.4%). Most of patients started treatment between one month and one year of age (65.1%). The mean age was 6.611 ± 3.823 months at the moment of treatment. The cases of idiopathic congenital clubfoot represented 91.6% of all the cases and 51.8% of the cases presented bilateral deformity. The general characteristics are summarized in Table 1.

Table 1. General characteristics of the congenital clubfoot cases.

Characteristic	N	%
Gender		
Male	55	66.3%
Female	28	33.7%
Department of provenance		
Cortés	62	74.7%
Yoro	8	9.6%
Santa Bárbara	7	8.4%
Atlántida	3	3.6%
Comayagua	1	1.2%
Francisco Morazán	1	1.2%
La Paz	1	1.2%
Age (start of treatment)		
Less than 1 month	25	30.1%
1 to 12 months	54	65.1%
More than 12 months	4	4.8%
Congenital clubfoot classification		
Idiopathic	76	91.6%
Non idiopathic	7	8.4%
Localization of the deformity		
Right	21	25.3%
Left	19	22.9%
Bilateral	43	51.8%

The mean of Pirani's classification before treatment was 5.307 ± 1.2042 points. According to Pirani's classification, all the cases scored 1 point or higher and 67.5% scored six points. The cases treated with the Ponseti's method included plaster cast changes; the mean number of changes was 3.94 ± 1.493 . In 51.8% of the cases, the tenotomy of the Achilles tendon was performed. In 7.2% of the cases, this procedure was not performed yet due to incomplete serial plaster change. To prevent relapse, children have to wear the brace in 91.6% of the cases, the rest have not completed the treatment yet (serial plaster cast). The treatment received is summarized in Table 2.

Table 2. Characteristics of treatment with Ponseti's method in children diagnosed with congenital clubfoot.

Characteristics	n	%
Piraniscoring before treatment		
1.5	3	3.6%
2.0	1	1.2%
3.0	4	4.8%
4.0	9	10.8%
5.0	10	12.0%
6.0	56	67.5%
Plaster cast changes		
1	3	3.6%
2	13	15.7%

3	16	19.3%
4	20	24.1%
5	21	25.3%
6	6	7.2%
7	3	3.6%
8	1	1.2%
Tenotomy of Achilles tendon		
Yes	43	51.8%
No	34	41.0%
Not apply*	6	7.2%
Use of braces		
Yes	76	91.6%
Not apply*	7	8.4%

*Not apply in cases where patient was still in a previous stage of treatment

The number of plaster cast changes was associated with range of age and classification of clubfoot; children aged between one month and twelve months required similar plaster cast changes than children aged under one month (mean of 4.04 and 4.02 changes) but the mean of cast changes was higher than children aged more than twelve months (mean of 2.25 changes); also, children with non-idiopathic clubfoot required more plaster cast changes than children with idiopathic clubfoot (mean of 4.43 vs 3.89 changes). Gender and localization of the deformity were not associated with the number of plaster cast changes. The association between this variables is shown in Table 3.

Table 3. Association of variables and number of plaster cast changes.

Variables	Chi square test	p value
Range of age	31.605	0.005*
Gender	7.755	0.355
Localization of the deformity	16.003	0.313
Classification of clubfoot	15.095	0.035*

*statistically significant difference

Children who required tenotomy of Achilles tendon also needed more plaster cast changes than children who did not required this procedure (mean of 4.30 vs 3.74 changes), the association between these variables was statistically significant ($p=0.007$). The treatment with Ponseti's method was completed by 90.4% of the patients. The majority of the cases scored 0 points in the Pirani's classification after completing the treatment. The mean of Pirani scoring after completing the treatment was 0.167 ± 352 points. The mean of reduction of Pirani scoring after treatment was 5.093 ± 1.3015 points, which shows a considerable improvement in this scoring and better outcomes. Relapse of clubfoot deformities after completing the treatment with Ponseti's method were registered in 10.8% of the cases. The main outcomes of the treatment with Ponseti's method are summarized in Table 4.

Table 4. Outcomes of the treatment of congenital clubfoot with Ponseti's method

Outcome	n	%
Complete treatment		
Yes	75	90.4%
No	8	9.6%
Pirani scoring after completing treatment		
0	59	78.7%
0.5	8	10.7%
1.0	7	9.3%
1.5	1	1.3%
Relapse		
Yes	9	10.8%
No	66	79.5%
Not apply*	8	9.6%

*Not apply in cases where patient has incomplete treatment

In cases where the treatment was completed, the relapse of the deformity occurred in 12% of the cases while no relapse was detected in 88% of the cases. In 9.6% of the cases, the relapse can not be evaluated due to incomplete treatment during the period of this study.

We found no statistical differences in relapse of the deformity regarding of age, gender, classification of congenital clubfoot, localization of the deformity, Pirani scoring before treatment and plaster cast changes. The association between this variables is summarized in Table 5.

Table 5. Association of variables with relapse of deformity of clubfoot

Variables	Chi square test	p value
Age	28.199	0.877
Gender	2.315	0.314
Localization of the deformity	4.566	0.335
Classification of clubfoot	0.857	0.651
Plaster cast changes	12.348	0.578
Range of plaster cast changes	6.656	0.155
Pirani scoring before treatment	11.687	0.307

The Pirani scoring after treatment was associated with the classification of congenital clubfoot; the idiopathic congenital clubfoot had lower Pirani scoring after treatment than the non-idiopathic cases, this is show in Table 6.

Table 6. Classification of congenital clubfoot and the Pirani scoring after treatment

Classification of congenital clubfoot	Pirani scoring after treatment			
	0 n (%)	0.5 n (%)	1.0 n (%)	1.5 n (%)
Idiopathic congenital clubfoot	53 (77.9%)	8 (11.8%)	7 (10.3%)	0 (0%)
Non-idiopathic congenital clubfoot	6 (85.7%)	0 (0%)	0 (0%)	1 (14.3%)

Other variables such as range of age, gender, localization of the deformity and range plaster cast changes did not show statistically significant difference in the Pirani scoring after completing the treatment. The association between these variables is shown in Table 7.

Table 7. Association between variables and Pirani scoring after treatment

Variables	Chi square test	p value
Range of age	53.629	0.602
Gender	2.271	0.518
Localization of the deformity	8.087	0.232
Classification of clubfoot	11.307	0.010*
Range of plaster cast changes	7.774	0.255

Quantitative variables were analyzed with t- student test: Pirani scoring before treatment and its outcome in Pirani scoring after treatment showed that all the patients had a lower Pirani scoring when the treatment was completed and patients with higher Pirani scoring before treatment showed greater improvement in Pirani scoring after treatment ($p=0.742$). In patients aged one year or older, the number of plaster cast changes was lower than in younger patients ($p=0.027$). Patients with higher Pirani scoring before treatment needed more plaster cast changes than Patients with lower Pirani scoring ($p=0.298$). Patients aged one year or older had a higher Pirani scoring before treatment than younger patients did ($p=0.686$). Patients aged one year or older had a lower Pirani scoring after treatment ($p=0.175$). The results of the t-student test are showed in Table 8.

Table 8. Results of t-student test for quantitative variables

Variables	Mean	Standard deviation	Mean of standard error	95% confidence interval		t	lg	Sig.
				Inferior	Superior			
Pirani scoring before treatment- Pirani scoring after treatment	5,0933	1,3015	,1503	4,7939	5,3928	33,892	74	,000
Age- number of plaster cast changes	-1,3289	4,4289	,4861	-2,2960	-,3618	-2,734	82	,008
Pirani scoring before treatment- number of plaster cast changes	1,3675	1,8063	,1983	,9731	1,7619	6,897	82	,000
Age- Pirani scoring before	-2,6964	3,9562	,4342	-3,5602	-1,8325	-6,209	82	,000

treatment								
Age- Pirani scoring after treatment	2,3573	3,6465	,4211	1,5183	3,1963	5,599	74	,000

Discussion

The treatment of congenital clubfoot with Ponseti method is less invasive than traditional surgery repair, therefore it is a viable option for the management of children with this pathology. According to literature review, the outcomes of this methods are acceptable, that is the reason to consider this method as the preferred technique for congenital clubfoot in many countries.(6)

Congenital clubfoot was more common among males (66.3%), in a proportion of twice males than females (2:1), this finding is consistent with prior results that show higher frequency of this pathology in males; Allende (2008) reported 68% of congenital clubfoot in males. (7) Most of the congenital clubfoot cases treated in Fundación Ruth Paz come from the department of Cortés (74.7%), which is the department where the foundation is located, the second most common department was Yoro (9.6%) which is next to Cortés.

The mean age where the treatment started was 6.611 ± 3.823 months, the treatment began before one month of age in 30.1% of the cases of congenital clubfoot, this is lower than previously reported by Robles (2015) in Guatemala, who found that the treatment was started before two weeks of age in 39.39% of the cases. This difference could be due to the system of the foundation, where most of the treated cases are sent by another hospital or health center to this establishment. (8) The congenital clubfoot cases treated with Ponseti method were idiopathic in 91.6% and only 8.4% were non-idiopathic, this difference is because this cases are often treated with surgery or physiotherapy instead of Ponseti method but this was an exclusion criteria. This finding is similar to data reported by Rivera (1968), who explained that congenital clubfoot was associated with another deformities in 4 to 12% of the cases (non-idiopathic cases of clubfoot).(9) The congenital clubfoot was bilateral in 51.8% of the cases, this finding is consistent with literature review, Perez et al. (2003) found 60% of bilateral clubfoot, Luque et al. (2015) described bilateral clubfoot in 87% of the cases and Allende (2008) described bilateral deformity in 52.6% of the cases of clubfoot. (2,7,10)

Most of the patients had a severe deformity. Lampasi et al. (2017) reported mean of 4.8 point in Pirani scoring, but despite the slight difference, both results showed severe deformity. (11)

The first stage of the Ponseti method involves serial plaster cast changes, the mean of casts used by the children during this treatment was 3.94 ± 1.493 and according to literature review in young children like the population in this study, the Ponseti method requires 4 to 6 cast changes. (12)

The tenotomy of the Achilles tendon is a common procedure during this technique, it was practiced in 51.8% of the patients in our study without considering children that were still using cast as part of this treatment. Similar findings are widely reported in other researches, Allende (2008) described this

procedure in 58.6% of the patients treated with Ponseti method; Román (2010) reported tenotomy of the Achilles tendon in 58.33% of the children diagnosed with clubfoot and treated with Ponseti method; Robles (2015) found that the tenotomy of the Achilles tendon was performed in 54% of the patients with clubfoot during the treatment with Ponseti method. (7,8,13)

Only 9.6% of the patients did not complete the treatment, an overall relapse was identified in 10.8% of the cases. Overall, satisfactory outcomes were identified in 79.5% of the cases; while in the group that completed treatment 88% of the patients had satisfactory outcomes. According to literature review, good correction rates are close to 90% with the Ponseti method. Relapses may occur often due to failure to use the brace, therefore, proper instructions to the parents or caregivers must be taught to ensure proper use of the brace. Allende (2008) found 93% of satisfactory outcomes in a smaller group of patients while other study conducted by Di Meglio (2014) reported 75.4% of satisfactory outcomes in a group of 10 patients and this approach was based on parents perception. Other researches showed that relapse rates are lower when the use of braces is correct than those with incomplete treatment or abandon of the braces. (6,7,14,15)

Previous researches suggested that relapses of clubfoot could be related with the severity of the deformity or higher Pirani scoring before treatment, however, we found no association between this variables and others like gender, localization, age, classification of the illness and plaster cast changes (no statistically significant difference was found).(2)

Patients diagnosed with non-idiopathic clubfoot had a higher Pirani scoring after treatment than the idiopathic cases, this could be due to proper etiologic causes and larger comparison studies are required to establish the causes, also this could be related with the preferred treatment options for these cases, non-idiopathic clubfoot is often treated with surgery while idiopathic clubfoot is more often treated with Ponseti method; despite this finding, both groups had a satisfactory outcome after treatment and relapses were as frequent in both groups.

Patients diagnosed with clubfoot who completed treatment with Ponseti method had a satisfactory outcome and few relapses were identified during this study, 88% of the patients who completed treatment had no relapses and all the treated patients showed a significant reduction in the Pirani scoring when treatment was completed. It is important that caregivers or parents follow the instructions for the use of braces in order to prevent relapses and further research is needed in this population to find if the uses of braces is correct and if it is related with relapse rates.

Conclusions

Congenital clubfoot was more frequent in males. Most of the patients began treatment before 12 months of age; also, most of the patients were classified as idiopathic congenital clubfoot and the most common deformity was bilateral.

Ponseti method was effective for treat children under five years diagnosed with clubfoot (idiopathic and non-idiopathic) and a significant decrease of the Pirani scoring after treatment was identified in all the cases.

Recommendations

Follow up studies are necessary to identify long-term outcomes and complications in children treated with Ponseti method. As literature suggests, the correct use of braces is needed to prevent relapses and this has to be one of the main goals of the treatment; studies to identify the cause of relapses are required in this population.

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