Results of Ponseti Method in the Management of the Congenital Clubfoot

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Abstract

Background: Clubfoot is a debilitating pathology and a source of abnormal gait in children. Treatment with the Ponseti method is the treatment used in the management of congenital clubfoot in children under 9 years old. This study aims to identify the proportion of children with clubfoot supported by the Ponseti method and to evaluate their effectiveness. Materials and Method: A multicenter retrospective descriptive study for six (06) months from June 1st to November 30th, 2019 concerning the evaluation of the Ponseti method in the management of clubfoot in Madagascar was conducted. Results: One hundred ninety-one (191) children with club feet were screened during the study period. One hundred and fifty children, or 226 congenital equine varus clubfoot were treated with the Ponseti method during the study period. The male gender was the most affected compared to the female gender with a sex ratio of 1.75. The clubfoot was bilateral in 50.66% of cases and idiopathic in 92.66%. The initial Pirani score was on average (±SD) 5.04/4.98 (±1.22/1.20). A proportion of 23.33% of cases of recurrence was recorded at 3 months of use of brace abduction splint. Conclusion: In Madagascar, the incidence of congenital clubfoot remains relatively low but clubfoot is still the main limitation of walking and a lack of footwear in children. Ponseti method is the gold standard in the management of this pathology. However, it requires a long-term follow-up.

Keywords

Clubfoot, Outcomes, Ponseti, Tenotomy
1. Introduction

Clubfoot affects approximately 1 in 1000 live births [1]. It is the main cause of physical disability due to congenital malformation of the lower limbs. The three-dimensional orthopedic deformity of the foot is the characteristic of this pathology. It can be idiopathic but also part of a neuromuscular disease or a complex malformation syndrome. The management of clubfoot can be based on physiotherapy, orthopedic, or surgical treatment. The main goal is to provide plantigrade painless and functional foot. Early extensive and iterative surgical treatment, has proven to produce stiff and painful feet in adulthood [2]. An orthopedic treatment was discovered by Ignatio Ponseti [3] in 1963 for the treatment of clubfoot. It is based on a serial manipulation and casting method to correct the different deformities of clubfoot (cavus/supinatus, then adductus and varus and lastly the equinus) completed by an Achilles tenotomy and followed by wearing Braces to maintain the correction. Before this period, physiatrists, physiotherapists, nurses, orthopedists, and pediatric orthopedists, encounter difficulties in managing this pathology. Many disastrous therapeutic failures have also been reported, with an increased percentage of recurrence. The method described by Ponseti is however today a revolutionary technic and is widely used around the world. Forty-seven years after Ponseti’s first article on his method [3] an analysis of data from the Centers for Disease Control and Prevention and the Nationwide Inpatient Sample in the USA revealed that the estimated number of surgical releases performed in patients less than 12 months of age decreased from 1641 releases in 1996 to 230 releases in 2006 with the percentage of club feet treated with surgical release dropping from 72% in 1996 to 12% in 2006 [4]. But not only in the USA has the Ponseti method become established but also in Europe and other parts of the world with early reports on superior initial results from many different centers [5]. A review performed in 2011 showed there is clear evidence that the Ponseti method is the most successful treatment regime for congenital club foot available and reported an initial correction rate of around 90 % in most studies [6]. This study aims to determine the incidence of clubfoot in Madagascar and to evaluate the effectiveness of the Ponseti regime in the management of clubfoot.

2. Materials and Methods

2.1. Protocol and Analytical System Used

A multicenter retrospective, descriptive and analytical study was conducted on 6 rehabilitation centers for a period of 9 months from March 1 to November 30, 2018. These centers include the Equipment teaching Hospital of Madagascar, Equipment and rehabilitation service of Itaosy, Majunga, Tamatave, Fianarantsoa, and the rehabilitation unit of Tsiroanomandidy. The variables studied were socio-demographic variables such as age, gender, whether previous treatment was available or not. Then, there are also the clinical variables: the idiopathic or secondary nature of the score before tenotomy and at the end the follow, the
proportion of recurrence, success and tenotomy. The data clubfoot, the laterality of the involvement, the number of manipulation and cast series, the initial Pirani score, the Pirani from each center was collected and sent as a table for analysis, respectively. Microsoft Excel 2016 and Epi Info 7.2.2.6 were used for data analysis.

2.2. Patients
All the children with club feet who followed a treatment by the Ponseti method were screened. Children with club feet under 9 years old on the first consultation, of both genders, with idiopathic or secondary clubfoot, were included in the study; already treated or not, in recurrence or not. However, children lost to follow-up and incomplete records, i.e., without follow-up for 3 months or more, were excluded from the study.

2.3. Treatment Protocol Used
The same therapeutic protocol was used in the different centers for the management of clubfoot. After a primary medical consultation to confirm the diagnosis, classing the etiological type, and severity assessment of the foot, the children were followed up weekly for sessions of cast. In the different centers, the medical and paramedical professionals involved in the management of this pathology are physiatrist, residents in PMR and DU physicians in PMR, physiotherapists, and pedorthists. All these professionals have received identical, regular, certified training in clubfoot management using the Ponseti method. The correction of foot deformities is done progressively in two (02) phases according to Ponseti [3]. First, start with the correction of the cavus of the medio foot, in order to open the plantar fold, followed by the correction of the adductus of the forefoot by the progressive abduction of the forefoot. Then comes the reduction of the varus of the rear foot by fixing the foot in a slight eversion. Finally, reduction of equinus by placing the foot in dorsal flexion, possibly with an outpatient percutaneous tenotomy of the calcaneal tendon. Tenotomy is not routinely performed if the dorsal flexion of the foot is greater than or equal to 10˚ [7]. At each weekly appointment, the three-dimensional deformity of the foot is evaluated according to the Pirani score. This score determines the progression of the correction to the next stage of Ponseti management. Pirani et al. devised a simple scoring system based on six clinical signs of contracture. Each sign is scored according to the following principle: 0, no abnormality; 0.5, moderate abnormality; 1, severe abnormality. The six signs are separated into three related to the hindfoot (severity of the posterior crease, emptiness of the heel and rigidity of the equinus), and three related to the midfoot (curvature of the lateral border of the foot, severity of the medial crease and position of the lateral part of the head of the talus). Thus, each foot can receive a hindfoot score between 0 and 3, a midfoot score between 0 and 3 and a total score between 0 and 6 [8]. In this study, Ponseti method is considered effective if the Pirani score is zero. The second
phase consists of immobilizing the foot in perfect abduction and dorsal flexion maintained day and night until the age of 2 years old, and then only at night until the age of 5 years. The Steenbeck type abduction brace used [9] is regularly checked by the doctor and the orthesist at each follow-up to detect wear and tear of the material or possible deformation of the brace.

3. Results

One hundred ninety-one (191) children with club feet were screened during the study period. Among them, there were 26 lost to follow-up and 15 incomplete records. So, the study has been carried out on 150 children with 226 club feet. The age of the study population ranged from 17 days to 8 years old. The most represented age group was 1-12 months (43.33%) (Figure 1).

Clubfoot affected significantly more boys than girls with a sex ratio of 1.75. The foot deformity was bilateral in 50.66% of cases. From an etiological point of view, the initial assessments performed at the beginning of the treatment protocol revealed a major predominance of the idiopathic form of clubfoot (92.66%). Secondary clubfoot was found in 11 (7.34%) children. Among these 11 children out of 150 who presented with secondary clubfoot, associated malformations were found in more than half of the cases, such as a cardiac malformation in a trisomic 21 child, a contralateral metatarsus adductus, and especially a malformation of the amniotic flange type (Table 1).

In this study, 3 children had received previous treatment for their deformity. One third of the children who received previous treatment were treated with traditional massage. The number of manipulation and plastering sessions was on average (±ET) 5.95 (±3.06) sessions per week during the study period (Figure 2).

![Figure 1. Distribution of children by age group.](image_url)

Table 1. Distribution according to the etiological form.

<table>
<thead>
<tr>
<th>Etiologic form</th>
<th>Number</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idiopathic form</td>
<td>n = 139</td>
<td>92.66%</td>
</tr>
<tr>
<td>Secondary form</td>
<td>n = 11</td>
<td>7.34%</td>
</tr>
</tbody>
</table>
According to the clinical foot deformity assessed by the Pirani score, in this study 127 of the 150 children studied had a severe foot deformity before the cast sessions (Table 2).

According to the correction obtained in the first phase and according to the Pirani score at each appointment, tenotomy was performed in 117 (78%) club-feet during the study period (Table 3).

This tenotomy is therefore not systematic. A proportion of 23.33% of cases of early recurrence was recorded after 3 months of use of a Steenbeck-type abduction brace. These cases of recurrence require the restart of the correction of the deformities by weekly cast sessions, thus prolonging the follow-up. The number of people kept out is proportional to the number of recurrences. In this study, Ponseti method is considered effective if the Pirani score is zero. Of the 57 female children who were managed, 41 of them had successful treatment. In other words, girls are 0.87 times more likely to have successful Ponseti clubfoot treatment, but the association is not significant (CI 95%: 0.73 - 1.03). Children with clubfoot(s) under 2 years of age had a 0.85 greater chance of successful Ponseti treatment, but the association between age under 2 years and successful treatment was not significant (CI 95%: 0.69 - 1.04). Children with bilateral clubfoot were more likely to be successful in treatment than children with unilateral clubfoot, but the association was not significant (CI 95%: 0.72 - 1.0). Idiopathic clubfoot responds better to treatment than secondary clubfoot. They are 0.84 times more likely to succeed with treatment than secondary clubfoot. Children presenting a severe clubfoot were 0.88 times more likely to successfully complete Ponseti treatment than children with moderate deformity and this association is significant (Table 4).

Nevertheless, in this study, a success rate of 74.66% was found during the study period. In fact, 112 out of 150 children had corrected and shoe-able feet.

4. Discussion

In the management of clubfoot, the Ponseti method remains a revolutionary
Table 2. Distribution according to baseline Pirani score.

<table>
<thead>
<tr>
<th>Clubfoot</th>
<th>Number</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>moderate (score &lt; 3.5)</td>
<td>23</td>
<td>15.34%</td>
</tr>
<tr>
<td>severe (score ≥ 3.5)</td>
<td>127</td>
<td>84.66%</td>
</tr>
</tbody>
</table>

Table 3. Pirani score on each step of the treatment.

<table>
<thead>
<tr>
<th>Pirani Score</th>
<th>Initial score n (%)</th>
<th>Before tenotomy n (%)</th>
<th>Final score n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>zero</td>
<td>0 (0%)</td>
<td>33 (22%)</td>
<td>112 (74.66%)</td>
</tr>
<tr>
<td>moderate 0.5 - 3</td>
<td>23 (15.34%)</td>
<td>116 (77.33%)</td>
<td>37 (24.67%)</td>
</tr>
<tr>
<td>severe ≥ 3.5</td>
<td>127 (84.66%)</td>
<td>1 (0.67%)</td>
<td>1 (0.67%)</td>
</tr>
</tbody>
</table>

Table 4. Distribution by treatment results.

<table>
<thead>
<tr>
<th></th>
<th>Effective</th>
<th>Non effective</th>
<th>Relative risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>41</td>
<td>16</td>
<td>0.87 [0.73 - 1.03]</td>
</tr>
<tr>
<td>Male</td>
<td>77</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Age:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2 years old</td>
<td>92</td>
<td>29</td>
<td>0.85 [0.69 - 1.04]</td>
</tr>
<tr>
<td>&gt;2 years old</td>
<td>26</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Laterality:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral</td>
<td>55</td>
<td>21</td>
<td>0.85 [0.72 - 1.0]</td>
</tr>
<tr>
<td>Unilateral</td>
<td>63</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Type:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idiopathic</td>
<td>106</td>
<td>31</td>
<td>0.84 [0.64 - 1.10]</td>
</tr>
<tr>
<td>Secondary</td>
<td>12</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Pirani score at the beginning:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Severe ≥ 3.5</td>
<td>103</td>
<td>30</td>
<td>0.88 [0.72 - 0.85]</td>
</tr>
<tr>
<td>- Moderate &lt; 3.5</td>
<td>15</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Clubfoot is still common, especially in developing countries like Madagascar. Under-detected due to lack of antenatal ultrasound or inadequate screening at birth, this foot deformity is often diagnosed at the walking age and sometimes after the failure of previous treatment. In this study, 150 children with 221 equine varus club feet were identified. The most common age range was 1 - 12 months. This predominance has also been found in Nigeria [10]. In their series, 67.33% of the patients followed up were less than 11 months old, i.e. 237 out of 352 children. However, this differs from the proportion found by Hosea and his team [11]. This result may be related to a lack of information among parents about the existence of clubfoot treatment. Clubfoot is most often seen after an attempt at traditional treatment. For developing countries like Madagascar, access to health care is precarious and mainly focused on the manage-
ment of tropical infectious diseases. Health programs rarely target congenital malformations of the locomotor system. This leaves many cases in children.

In this study, it was found that clubfoot affects boys more preferentially than girls. In other series such as the one by Azarpira and colleagues [12], a 72.2% predominance of clubfoot in boys was found. In a study conducted in India in 2018, a percentage of 78.8% of boys with club feet was found [13]. All these findings point to the existence of a male predominance of this foot deformity. For this reason, the chromosomal origin of the anomalies has been suggested [14]. Nevertheless, this remains an incrimination without real confirmation. The involvement of several aetiological factors on the one hand and on the other hand the occurrence of clubfoot as part of a complex malformation syndrome increases the incidence of severe forms. As in the present study, 86.44% of the children presented with severe deformities. This has also been found in Senegal [15].

A predominance of severe club feet at 79.4% of cases in 2017 was observed. The existence of a large proportion of severe deformity would predict an increased incidence of tenotomy during management [15]. In this study, a low number of cast sessions was found. According to a French study conducted in 2012 [16], an average of 9.2 sessions are required to correct a varus equinus clubfoot during the first phase. According to Kampa et al. [17] the average is 6 casts. These weekly cast sessions are conditioned by the gain in the correction of the deformity. The transition to another stage of correction is assessed by the Pirani severity score. The number of cast sessions depends on the severity of the deformity (Figure 2). A significant rate of tenotomy of 78% was found in our study. This surgical procedure, performed percutaneously under local anesthesia, is often necessary for the absence of correct ankle flexion following plastering sessions. The tenotomy is not systematic but is also a major condition for the success of the treatment and considerably reduces recurrence of the treatment. This percutaneous tenotomy is a major component of the Ponseti method for the management of equine varus clubfoot. A higher rate of tenotomy than ours has been found by some authors including Bronfen and al [18] tenotomy in 87.6% of cases, Faldini and al [19] in 98.03% of cases, Abbas and al [20] in 96%. The tenotomy determines the therapeutic efficacy, but not performing a tenotomy demonstrates a good correction of dorsiflexion following plastering sessions. A study of 221 clubfeet performed in France by Marleix et al. suggests that tenotomy should be performed routinely for all types of clubfoot after the series of casts to avoid early recurrence and additional surgery [16]. Concerning the success of the treatment, all researchers [12] have shown a success rate of almost 100%, in our study, this success rate was 74.66% in the 6 centers studied. Studies done by Batti et al., [21] [22] affirm that they didn’t obtain any proof that Ponseti method was superior over French method. The treatment of clubfoot remains controversial. Two methods exist : the functional method (or French method) and the Ponseti method. Ponseti and French functional method are equally ef-
effective. This French method need daily visits, specialized training of the physical therapist and committed, educated parents [23]. The success of the treatment would be conditioned by several factors. These factors include the existence of previous treatment prior to Ponseti treatment, the age of onset of treatment, the severity of the deformity, and parental compliance with treatment. Children presenting with severe clubfeet were 0.88 times more likely to successfully complete Ponseti treatment than children with moderate deformity and this association is significant (Table 3). The study we have carried out show that the more severe the deformity (Pirani score > 3.5/6) the worse the outcome [24] [25]. On the other hand, the more severe the deformity is, the greater the probability of a tenotomy is. Thus, a more severe foot deformity requires a much longer series of manipulation and casts. This results in a longer follow-up and an increased risk of loss of sight. Of the children followed and treated with the Ponseti method, a significant percentage of recurrences were reported. Niyondiko and his team reported a recurrence rate of 4.71% [15]. A rate of up to 33.91% recurrence was reported by Azarpira et al. [12]. The recurrence rates are thought to be mainly related to the lack of compliance of the parents with the use of Steenbeck splints during the immobilization phase. The marital status of the parents, especially the mother’s education level, has been incriminated [26]. However, this study was carried out in rehabilitation centers in the major cities of Madagascar and would not reflect the general population. It was limited in the children who came to the different rehabilitation centers. In Madagascar, access to care is precarious, so a significant number of children with clubfeet would not have been seen. This would require a mobile consultation with villagers in remote areas in order to cover a larger population and have representative data. The existence of many patients seen in consultation and then lost of follow-up has a great influence on the sample size and the data analyzed. In order to obtain a success ratio close to 100%, tenotomy should be achieved without hesitation in front of any suspicion of limitation of dorsiflexion, while establishing a management involving the parents. A much longer follow-up of the cohort would better record the evolution of the deformity at each step and could better highlight cases of recurrence.

5. Conclusion

The incidences of clubfoot in Madagascar were relatively low, with 191 children screened. The Ponseti method remains the gold standard in the management of congenital clubfoot. It is easily accessible and inexpensive. However, it requires a long-term follow-up of the child’s foot, hence the need to involve the parents in the management. The percentage of recurrences remains significant, leaving room for retreatment or the introduction of surgical treatment.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.
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