



Prevalence and factors associated with relapse clubfoot treated by the Ponseti method in Peshawar, Pakistan: a retrospective study

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Background: Clubfoot or congenital talipes equino varus (CTEV) is a common orthopedic abnormality that is successfully treated by the Ponseti method all over the world. However, the foremost challenging problem to the Ponseti method is relapse. This study aimed to find out prevalence and factors associated with relapse clubfoot treated by the Ponseti technique in Peshawar.

Methods: We retrospectively studied all the children with idiopathic clubfoot which were treated with the Ponseti method in the Clubfoot Department, Lady Reading Hospital, Peshawar from December 2017 to October 2022. SPSS 25 was used for descriptive and statistical analysis. The Chi-square test was used to find the association between dependent variable (relapse) and independent variables (age, gender, Pirani score etc.). A P value less than 0.05 was taken as significant.

Results: The rate of relapse was 21.1%. The factors associated with relapse were age, non-compliance to foot abduction brace (FAB), stretching exercises, initial Pirani score, living area and low level of parents' education (P value <0.05). The rate of relapse was higher in bilateral foot as compared to unilateral. Tenotomy and gender had no significant association with relapse (P value >0.05).

Conclusions: This study found that non-compliance to FAB, low level of parents' education, stretching exercises, initial Pirani score, and high initial Pirani score were the main factors associated with relapse. The parents should be educated about compliance to brace protocol and routine follow-up to prevent relapse.

Keywords: Clubfoot; Ponseti method; relapse; Pirani score

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Introduction

Clubfoot is the seventh most common congenital birth defect and the most common musculoskeletal deformity (1). It is also known as congenital talipes equino varus (CTEV) and is composed of four components; fore-

foot adduction, cavus of mid-foot and equinus and varus of hind-foot (2). The worldwide incidence of clubfoot is 1.24 per 1,000 births, showing prevalence in all six continents of the world. Males are affected more than females at a 2:1 (3). Approximately, every year in Pakistan 7,500 children are born with clubfoot deformity (4).

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Regarding the treatment of clubfoot, the Ponseti method is considered as a gold-standard all over the world, which involves casting of the affected foot to manipulate, tenotomy and bracing (2). Although the Ponseti method has now been proven as a choice of treatment for clubfoot with significantly higher success rate; however, some children present with relapse of deformity after successful treatment. The Ponseti method retains a rate of relapse between 10% and 20% (5,6). Relapse clubfoot is the recurrence of any of its above-mentioned four components after complete correction by the Ponseti method (7). In most cases, relapse leads to equinus and varus deformities of hind foot (8). The relapse rates in different studies were 21.6%, 27%, 18.5%, and 8–28% (9-12).

The factors associated with relapse of clubfoot may be modifiable and non-modifiable. The modifiable factors were compliance with use of foot abduction brace (FAB) and stretching exercises. The non-modifiable factors were, initial Pirani score, number of casts, length of the stay, technical error in casting, and low level of education (9-11).

Clubfoot was successfully corrected by the Ponseti method in Clubfoot Department at Lady Reading Hospital, Peshawar but like in other countries a relapse is also common here. There is a lot of literature available on the effectiveness of the Ponseti method in managing clubfoot. However, a gap is present in the knowledge and awareness of the risk factors associated with relapse after the Ponseti method, more specifically in Pakistan. Therefore, we retrospectively investigated these factors to find their

association with relapse after the Ponseti method.

Methods

Data collection

We retrospectively studied all children with idiopathic clubfoot which were treated with the Ponseti Method in Clubfoot Department, Medical Teaching Institute, Lady Reading Hospital, Peshawar from December 2017 to October 2022. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was ethically approved by Physiotherapy Department Lady Reading Hospital-Medical Teaching Institute (LRH-MTI), Peshawar (Ref No. 028/PT&R/LRH-MTI-23) and Khyber Medical University, ASRB (Ref. No: 026/PT&R/LRH-MTI-23). Individual consent for this retrospective analysis was waived. The pre- and post- demographic and clinical data were recorded. The records included the following factors: age, gender, initial Pirani score, number of feet, parents' educational level, tenotomy, stretching exercises, living area and compliance to brace using.

Inclusion criteria

- (I) Children diagnosed with clubfoot and given the Ponseti treatment.
- (II) Children with unilateral or bilateral clubfoot deformities.
- (III) Children who had completed the first phase of treatment (casting phase).
- (IV) Children wearing FAB.

Exclusion criteria

- (I) Neurogenic clubfoot.
- (II) Syndromic clubfoot.
- (III) Atypical clubfoot.

Ponseti method and Pirani score

The Ponseti method is considered as a standard treatment technique for clubfoot which is composed of four steps: manipulation, serial casting, tenotomy and bracing. Following the initial correction with the Ponseti method, the frequency of follow-up visits (usually every 1–2 weeks initially) may decrease, occurring typically every 3–6 months during their growth and then annually. Pirani score is a reliable, simple and quick way to assess the severity of clubfoot deformity (2). The Pirani score measures six

Highlight box

Key findings

- Factors associated with relapse clubfoot are non-compliance to foot abduction brace (FAB), stretching exercises, living area, and initial Pirani score.

What is known and what is new?

- Age, Pirani score and non-compliance to brace are the known associated factors.
- Stretching exercises and rural/urban area are the factors that are not studied previously with the above factors.

What is the implication, and what should change now?

- It will help the health community and parents to focus on stretching exercises along with the compliance to FAB.
- This will provide a way for health administration to open clubfoot treatment department at a district level to reduce travel distance and help the children's parents to follow up the treatment.

clinical signs of contracture; 0 shows no abnormality, 0.5 is moderate abnormality and 1 is severe abnormality. Out of six clinical signs, three are related to mid foot (medial crease, curvature of the lateral border of the foot, and position of the lateral part of the head of the talus) and three are related to hind foot (posterior crease, emptiness of the heel, rigidity of equinus). So, each foot has a score of mid-foot between 0 and 3, a hind-foot score between 0 to 3, and a total score between 0 and 6. High scores indicate a more severe deformity.

Operational definitions

Relapse

Any foot that required further treatment after successful correction with the Ponseti method was taken as a relapse.

Compliance to brace using

After correction of deformity, the parents of the children were educated to wear full-time brace to the baby for 23 hours per day for 3 months, then only at night or during naps (14 hours) till 4 years old. The parents of walking age children were instructed to use bracing for 18 hours for 3 months and then during naps (14 hours) till 5 years old.

Data analysis

SPSS 25 was used for descriptive and statistical analysis. Chi-square test was used to find association between dependent variable (relapse) and independent variables (age, gender, tenotomy etc.). P value less than 0.05 was taken as significant.

Results

Between December 2017 to October 2022, 1,100 patients had taken the Ponseti treatment in Clubfoot Department, Lady Reading Hospital. Out of 1,100, 950 patients fulfilled our inclusion criteria. In 950 patients, 200 patients presented with relapse clubfoot with a prevalence of 21.1%. Out of 200 relapse, 136 (68.0%) were males and 64 (32.0%) were females. Bilateral CTEV relapse was more common as compared to unilateral CTEV. Relapse rate was 46%, 30% and 24% in bilateral, left and right foot respectively. In case of unilateral clubfoot; left side involvement was greater than right side. The mean age at the first casting of relapse clubfoot was 3.60 ± 3.3 months. The mean initial Pirani score was 5.57 ± 0.46 . Tenotomy, number of casts,

and gender showed no association with relapse while age, stretching exercises and parents' low level of education were statistically significant. The rate of relapse was high in those, who were not wearing the FAbB according to the standard requirement. In this study, those children who retained relapse had shown 30.5% compliance to brace use while 69.5% non-compliance (Table 1).

Discussion

The Ponseti method is considered as first choice of treatment for CTEV nowadays. This method has decreased extended surgery complications i.e., arthritis and stiffness of foot in later life. However, it retains relapse. Earlier research has indicated that the rates of relapse range from 8% to 28% (12). This study found that rate of relapse was 21.1% which showed similarity with Hu *et al.* 21.6% relapse rate (11). However common questions that usually arise are, "what are the factors associated with relapse clubfoot after the Ponseti method?" This study was done to find out these associated factors. This showed that age at first casting, high initial Pirani score, non-compliance to FAbB and low level of parents' education were the main factors for relapse CTEV after the Ponseti method. However, no association was found among relapse, gender and tenotomy.

As described by Ponseti, compliance to FAbB use is a vital part in maintains clubfoot correction. If a patient is not compliant to FAbB treatment, she/he would more likely to suffer a relapse (8). Compliance to FAbB protocol has variations from different studies. According to Morcuende *et al.*, the brace should be worn fulltime for the first 2–3 months and then during nap and night for 3–4 years (1). Bouchoucha *et al.* suggested that brace should be worn 23 hours per day for the first 3 months, followed by 12–14 hours per day (13). The relapse rate of non-compliance is 5.4 times greater than that of compliance. There is a positive relationship between relapse and non-compliance (11) which showed a similarity with our study. Non-compliance is not wearing the brace for at least 75% of the prescribed number of hours or discontinues or continues without proper recommendations (14,15). In our center, noncompliance with the brace was attributed to reduced FAbB usage and the premature removal of casts at home, aiming to minimize the time spent in the hospital before the scheduled cast change.

There is a consensus that the Ponseti method should be started as soon as possible. This method encourages starting the treatment soon after birth. The early starting time

Table 1 Factors associated with relapse clubfoot after Ponseti method

Variables	Relapse clubfoot	Non-relapsed clubfoot	P value
Gender			0.12
Male	136 (68.0)	465 (62.0)	
Female	64 (32.0)	285 (38.0)	
Age at first casting (months)	3.60±3.30	2.17±1.60	0.02
Parents' education			0.01
Non-educated	58 (29.0)	44 (5.9)	
Primary	99 (49.5)	41 (5.5)	
Matric	29 (14.5)	165 (22.0)	
Intermediate	11 (5.5)	299 (39.9)	
Graduation	3 (1.5)	201 (26.8)	
Initial Pirani score	5.57±0.46	4.80±1.46	0.10
Number of feet			<0.01
Left	56 (28.0)	330 (44.0)	
Right	40 (20.0)	255 (34.0)	
Bilateral	104 (52.0)	165 (22.0)	
Tenotomy			0.26
Yes	152 (76.0)	540 (72.0)	
No	48 (24.0)	210 (28.0)	
Number of casts	7.18±3.09	5.15±1.69	0.98
Compliance to brace using			<0.01
Yes	61 (30.5)	585 (78.0)	
No	139 (69.5)	165 (22.0)	
Perform stretching exercises			0.02
Yes	75 (37.5)	568 (75.7)	
No	125 (62.5)	182 (24.3)	
Living area			<0.01
Rural	123 (61.5)	249 (33.2)	
Urban	77 (38.5)	501 (66.8)	

Data are presented as n (%) or mean ± standard deviation.

instantly shape the treatment protocol (16). Ambia *et al.* and Hu *et al.* suggested that the best age to start the Ponseti method was less than 6 months. These studies showed that late casting increased the chances of relapse. The ligaments of newborn babies are composed of collagen bundles which allow the ligament to be stretched. As the child get older, then it became difficult to cope with casting and bracing

protocols due to strengthening of bone and ligament. As a result, the chance of relapse increases (11,17). According to literature, babies who were less than one year reported a success rate of 90–98% (18). Therefore, it is suggested to start treatment as soon as possible, if no skin issues are present (19-22). Our study also showed that rate of relapse decreased in those babies who started their treatment at an

early age.

Among the social factors, parents' low educational level (primary/uneducated) is considered as significant factor for relapse. The rate of relapse declines, if the parents' educational level is higher such as intermediate and graduation. The risk of relapse became 10-fold higher in those children whose parents had low level of education as compared to those who had high level of education (14,19,23). Our study also showed similarity with above factor. Non-educated parents are unable to fully understand treatment protocols, difficulties in follow-up, and communication barriers as compared to educated parents.

A few studies showed no association of relapse with bilateral or unilateral involvement (11,17). However, some studies showed support to our results that bilateral foot cases were 1.85 times greater than unilateral cases. The majority cases were bilateral in 50% of the studies (24). According to Gray *et al.*, the patients who experienced relapse, there would be high probability of involvement of both feet. According to them, 27% patients reported relapse having bilateral clubfoot (25). The involvement of both feet had inferior outcomes after the Ponseti as compared to unilateral (26,27). The above studies showed similarity to our results, which stated that rate of relapse become higher in those children who had bilateral clubfoot as compared to unilateral (left/right).

The rates of relapse lessen if the parents focused on routine exercises such as stretching and squatting when reached to walking age (28). A recent study showed that routine stretching exercises of the ankle and foot could be a vital part of keeping the range of subtalar and ankle movement after soft tissue release procedure for clubfoot (29). The addition of stretching exercises to bracing protocol significantly decrease relapse risk. Limpaphayom and Sailohit [2019] asked the babies' patients to perform stretching two times a day for about 20 minutes i.e., ankle-foot joint passive range of motion and squatting exercises for the walking age children (9). Panjavi *et al.* asked the babies' parents to perform abduction and dorsiflexion stretches three times a day for 10–15 minutes. Ninety-five feet completed this exercises program and only three retained a relapse. Thirty-four feet did not complete this exercises program, in which 21 feet showed relapse (30). The role of stretching exercises was also supported by Sheta *et al.*, who conducted a prospective study between August 2009 and November 2019. They divided the patients into two groups after The Ponseti casting phase completion. One group was assigned with brace use only

and the other was advised home based stretching exercises along with brace. They concluded that the rate of relapse was lessened in the second group (home based stretching exercises) as compared to first. The stretching exercises would reduce the dominant role of bracing (31). Our study also found that the rate of relapse become higher in those, who were not performing exercises. The above discussions suggest that addition of stretching exercises to the Ponseti method reduce the rate of relapse. However, there is still a limitation in evidence based study and more experimental studies are the need of the hour to provide recommendation in this regard.

Living areas may also be considered as risk factors for relapse. Living areas are two types; rural area and urban area. The rate of relapse becomes higher in those, who live in rural areas. The reasons of this are lack of awareness, no access to specialists, long travel distance to medical facilities and delayed diagnosis (17). Pigeolet *et al.* compared early relapse after the Ponseti method between rural and urban population. Their aim was to find whether distance had an impact on clubfoot treatment. They found that the rate of relapse were higher in pastoral areas as compared to city (32). The above two studies gave support to our study, which showed a positive relationship between relapse and rural areas. The reasons were limited access to healthcare, no awareness, low level of education, lower socio-economic status and cultural barriers in rural areas.

Limitations

The study was done in a single center. This might increase the chances of biasness. Non-compliance to brace using relied on truthfulness of the parents without any proof. This could affect our results.

Recommendations

A study of multi-center needed to be conducted in Khyber, Pakhtunkhwa. Awareness should be made regarding clubfoot diagnosis and early treatment in rural areas. Moreover, taking parents on-board to proper compliance to brace wearing and do routine exercises after correction of deformity could result to low relapse rate.

Conclusions

The Ponseti treatment is the first line of treatment for clubfoot. However, relapse is one of the risk factors of the

Ponseti method. In this study the main factors responsible for relapse were age, non-compliance to brace protocol, low level of parents' education and high initial Pirani score.

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Footnote

Data Sharing Statement: Available at <https://jxym.amegroups.com/article/view/10.21037/jxym-23-25/dss>

Peer Review File: Available at <https://jxym.amegroups.com/article/view/10.21037/jxym-23-25/prf>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://jxym.amegroups.com/article/view/10.21037/jxym-23-25/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was ethically approved by Physiotherapy Department Lady Reading Hospital-Medical Teaching Institute (LRH-MTI), Peshawar (Ref No. 028/PT&R/LRH-MTI-23) and Khyber Medical University, ASRB (Ref. No: 026/PT&R/LRH-MTI-23). Individual consent for this retrospective analysis was waived.

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