

Functional outcomes of Ponseti method among children with congenital clubfoot: a healthcare facility-based longitudinal study

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Background: The children with congenital clubfoot (CC) are being managed by the cost-effective Ponseti method (PM) for over a decade in Bangladesh, however, its functional outcomes in the dynamic foot tasks are little known here. Thus, this study aimed to evaluate the functional outcomes among children with CC who underwent PM in a selected healthcare center in Bangladesh.

Methods: It was a longitudinal study with repeated follow-up process conducted using secondary data from a total of 93 child patients with uni- and/or bi-lateral CC who attended the physiotherapy department of a selected hospital in Chattogram. Complying with the PM treatment protocol, those who completed a 3-month bracing period, continued regular follow-up visits and also maintained all the records properly, their data were used in this study. The functional outcomes were assessed through four basic physical functional parameters such as the tasks of standing on the ground, 10-repetition squatting, 12-feet walking, and 40-feet running that performed routinely during the total of 10 consecutive follow-up visits (once in every four months after the completion of bracing period).

Results: Majority of the patients were men (72.0%) and one month old during the 1st consultation (54.8%). Around, 16% of the patients were able to perform all the functional tasks at both 1st and 4th visits, independently, and 12–14% were able to do at the 5th–7th visits. Finally, all of them were able to perform all the functional tasks within their last visit, which reflected the 100% functional outcomes.

Conclusions: The functional outcomes of PM among children with CC in Bangladesh reflect a substantially significant positive effect. Further large-scale studies are recommended to explore the precise effectiveness of PM among the population in experimental approach.

Keywords: Congenital clubfoot (CC); functional outcomes; Ponseti method (PM); Bangladesh

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Introduction

Since the last century till today, poor prognosis as well as multiple complications have been observing in the surgical management of congenital clubfoot (CC) among children (1-3). While enhancing the interest in different conservative treatment procedures, among others in 1963, Ignacio V. Ponseti illustrated one of the key treatment methods that known as Ponseti method (PM) (4,5) approaching the routine physiotherapy management and splints (6).

In an earlier thorough literature review, the long-term follow-up study remains scarce to find (7) while short-term follow-up (8) study with positive results is available (9) with a special attention paid to the morphological changes and radiological improvements (10,11). At that time, the published articles were nothing less than assessed the subjective indices by developing tools such as the short form questionnaires for assessing the functional outcomes (7,12,13), while other examined pain, range of motion, manual muscle testing, and radiographic images of the lower extremity, static ankle and foot functions (7,14-16) in the absence of globally recognized outcome scoring system (17) to evaluate the dynamic functional skills corresponding to running, squatting, walking and jumping. There are still some disagreements about how to assess the success rate of clubfoot treatment (17,18). As a result, they adopted the most usual method of evaluating the success of PM: clinical examination (17). However, there is lack of long-term follow-up studies examining the dynamic foot functions among PM recipient children with CC (19). There is quite limited information in Bangladesh about the functional outcomes of PM treatment in the four fundamental foot functions such as standing, squatting, walking, and running that a child with CC needs to perform his/her daily activities. In this study, we aimed to assess the functional outcomes of PM treatment among children with CC those who attended a selected healthcare center in Bangladesh.

Methods

Ethical consideration

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The ethical review committee of the Department of Public Health, North South University, Dhaka, Bangladesh, approved the research protocol 2015/OR-NSU/IRB-No.0602. After that, permission was taken from the respective authority of Lion Mukhlesur Rahman Foundation (LMRF) Healthcare,

Chattogram Center, to use their patient's database. Assents from the parents were taken before the data collection.

Study design, setting, and population

A longitudinal study with repeated follow-up visits was conducted using secondary data from a total of 93 child patients with uni- and/or bi-lateral CC who attended the Zero Clubfoot Program of LMRF, Chattogram branch, between the years of 2015 and 2017. Since 2010, the leading LMRF has implemented the Zero Clubfoot Project by the trained PM practitioners. In 2016, LMRF Healthcare took over program and getaway activities in a social business model. This program sticks together with a total of eight district centers (dividing into three zones) of the south-eastern part of Bangladesh. Two PM practitioners are accountable for each zone. Tenotomy facility is available in four district centers, including our study center. Usually, the patients who require percutaneous Achilles tenotomy (pAT) are referred to the nearest centers. Chattogram branch has a dedicated and complete PM practitioner team, including two physical therapists and one orthopedic surgeon.

Participant selection procedure

The Chattogram branch was selected conveniently as the study center. The patients with a precise diagnosis of CC and who completed a 3-month bracing period protocol, continued regular follow-up visits and maintained all the records properly, were eligible for this study. However, the patients with neurological conditions such as cerebral palsy/90 degree knee bend spina bifida hinder and other foot conditions (e.g., clubfoot related to hip or knee deformities and arthrography) were excluded from the study. Finally, a total of 93 (out of 419) patients with 137 feet (out of 621) met the eligibility criteria after the exclusion, and all of them were recruited in this study. We used systematic random sampling technique where every third participant was counted in our study from the register book. A detail of participant selection procedure has been illustrated in the figure (*Figure 1*).

Ponseti treatment protocol (6)

This technique involved gentle manipulation with serial long leg plaster casts around the talar head (apart from the ankle joint). Casts changed once per week and pAT performed as per need to accurate remaining equinus deformity.

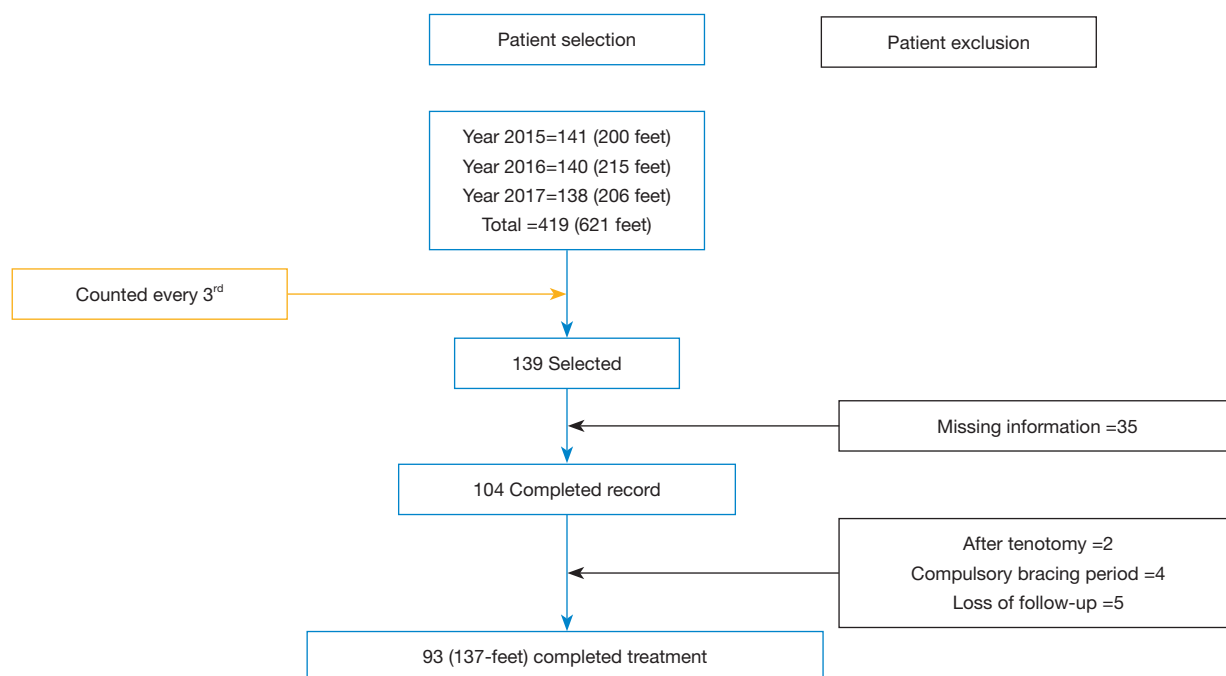


Figure 1 Sample selection procedure.

Afterwards, bracing was given for up to the age of five years in the maintenance phase. Instructed and emphasized in therapeutic exercise: stretching and mobilization of the affected foot or feet. The physiotherapist counseled for the parents' adherence with the instruction, exercise and physical activity throughout the treatment period.

Duration of casting

Casting begins at the second consultation day of the participants regardless of any age and sex. For gradual correction, the child underwent continuous casting in each week. Depending on severity, up to the 10 castings were considered, and severity was measured by the Pirani Scoring. Cavus, midfoot inversion, heel varus and the rigid equinus were needed to address for correction. The pAT was strongly suggested in most cases when equinus failed to meet the expected correction.

Bracing prescription

The average age of the child was 2.9 years and parents were instructed to change the bracing. Prescriptive hours and duration of bracing following casting:

- (I) Children start bracing less than 9 months of age.
 - (i) Fulltime =23 hours a day: 3 months;
 - (ii) Monthly reduced time =16–22 hours a day:

- 3 months;
- (iii) Night and nap time =14–16 hours a day: several months;
- (iv) Night time =12–14 hours a day: till age 4–5.
- (II) Children start bracing above 9 months of age.
 - (i) Most time =18–20 hours a day: 2 months;
 - (ii) Reduced time =16 hours a day: 3–4 months;
 - (iii) Night time =12–14 hours a day: till age 4–5.

Follow-up and measurement protocols of functional outcome parameters

At each follow-up visit, the designated physical therapist checked out the four fundamental daily living physical activities—standing, squatting, walking, running, and keeping the records in specific books in the assigned folders. The standard protocol was followed to conduct a comprehensive evaluation of the functional outcome parameter tasks based on the agreements of an expert panel of PM practitioners in Bangladesh, and evaluations were as following:

Standing

We observed the pelvic position; the child got the instruction, stood with the turnaround to identify unilateral or bilateral pelvic tilting caused by muscular weakness.

Simultaneously, we checked out the heel alignment, either its position normal, deviated, valgus or varus, or presence of arch.

Squatting

This indispensable active maneuver was used to sit on the floor, chair, or toilet, as a performance of a close kinetic chain. Each patient was instructed to do squats ten times. The sequences were: sitting posture aligned in parallel with dorsiflexed ankles, flexed knee and hip, without mediolateral movement, and the heels remain on the ground at all times.

Walking

All children completed this task on a 12-feet distance or a minimum of four full cycles of gait and were instructed to walk at a self-selected pace. At that point, we observed the heel strike on the ground, ankle and knee position, pelvis and hip tilting, and the foot progression angle. If a walking pattern was identified without any pathology, then participants were instructed for:

- (I) Heel walking: it was an imperative phase of gait, also known as heel strike. A child came by direction for Heel walking (feet position as dorsiflexion) for at least 10-feet. Responsible muscles for heel strike are quadriceps and ankle dorsiflexors. Further assessment was required to discover any abnormality arisen from muscle weakness or neurological pathology.
- (II) Toe walking: it was a combination of heel off (responsible muscles are ankle plantar flexor) and toe off phase (responsible muscles are hamstring and quadriceps), contributed to forwarding propulsion. The child got instructions for toe walking (feet position as plantar flexion and walking support by great toe) for at least 10-feet.

Running

Participants who completed a full cycle of gait and were able to stand on foot with full pressure, ran at least 40-feet distance in a total (field marked out up to 20-feet distance for forward and returned through the same distance). Participants were to set their own pace and allow them to take a rest if they desire.

Planter reflex

As per the need, as a part of the neurological investigation, this test was conducted for rehabilitative children to identify

any indication of abnormal reflex. The reflex was elicited when the sole stimulated with a blunt instrument. The reflex usually took one of two forms: in healthy adults, the plantar reflex caused a downward response of the hallux (flexion); and in a baby, an upward reaction (extension) of the hallux known as the Babinski sign.

Age consideration

When the age of children was not allowed to measure the parameters, we checked the ankle joint's range of motion, especially for the abduction (60–70°) and dorsiflexion (15–17°) whether stayed within the expected range, including the Babinski sign and around the calf muscles.

Data extraction

All the required data were extracted from the record book. Data were checked and rechecked for validity and reliability by the investigator. The developed structured questionnaire included essential demographic characteristics (such as sex and age of the participants, and completeness of mother's pregnancy term), clubfoot related necessary information (such as involved foot/feet, types of CC, PA tenotomy, and other health problems), functional outcomes related information assessed through squatting, standing, walking, and running.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) software for Windows, version 23 (IBM SPSS Statistic V23, Inc. USA) was used for data processing and statistical analysis. Descriptive statistics were performed for all of the variables, and the data were reported as a number, frequency, mean and standard deviation where appropriate.

Results

Essential demographic characteristics and clubfoot related information were presented in *Table 1*. Out of the 93 patients, majority were men (72.0%), one month old during the 1st consultation in LMRF Healthcare (54.8%), and was matured (full-term pregnancy) at birth (92.5%). Most of them had unilateral foot involvement (54.8%). The vast majority of the patient's clubfoot was typical (82.8%) and required pAT (94.6%). Moreover, only 2.2% of the patients had other health-related problems such as fever. Moreover,

Table 1 Demographic characteristics and clubfoot related information of the patients (n=93)

Characteristics	Number (%)
Sex	
Male	67 (72.0)
Female	26 (28.0)
Age at the first consultation	
1 month	51 (54.8)
>1 month	42 (45.2)
Term pregnancy at birth	
Mature (full-term)	86 (92.5)
Premature (pre-term)	7 (7.5)
Foot involvement	
Right	31 (33.3)
Left	20 (21.5)
Bilateral	42 (45.2)
Type of clubfoot	
Typical	77 (82.8)
Atypical	10 (10.8)
Syndromic	3 (3.2)
Complex	2 (2.2)
Neglected	1 (1.1)
pAT	
Yes	88 (94.6)
No	5 (5.4)
Other health problems	
Yes	2 (2.2)
No	91 (97.8)

pAT, percutaneous Achilles tenotomy.

the mean \pm SD of required number of castings was 5.2 ± 1.6 (interquartile range, 4–6), not shown in the table.

Table 2 shows the improvements in the PM's functional outcomes among the patients with CC according to the ten consecutive follow-up visits. The required follow-up visits were once in every 4 months after the completion of compulsory 3-month bracing period. The patients who were able to perform which functional parameter(s) in any of the visit, after that, they were not considered for further assessment for the same parameter(s) in the next

visit. However, the patients carried out follow-up visits up to the age of 5 years. We found that equally, a significant proportion (16.1%) of the patients were able to perform all the functional tasks in terms of standing, squatting, walking and running at the 1st visit. Near to similar proportion of them was able to perform all the functional tasks at the 4th visit. Around, 12–14% of them performed all the functional tasks at the 5th–7th visits, although the proportions were slightly varied within the individual functional parameters in the corresponding visits. Most importantly, all of them were able to perform all of the functional tasks within the last 10th visit, reflecting the PM's 100% functional outcome among children with CC in Bangladesh.

Discussion

Parents who have children with CC become worried about their future. Many of them are keen to know whether or not their child could execute daily life activities. Hence, the current study investigated four key functional states of CC child, which were entailed to take a step in everyday life.

We found that each child who continued the treatment had achieved outstanding (100.0%) performance in all four fundamental functional abilities. Our findings certainly were in line with other previous studies, which recommended that the athletic performance of a child with CC of the primary school in Japan was found excellent with 96.6% respectively accomplishment above 2nd of the average school child (20). The functional ability could be deteriorated over ageing as Aulie and colleagues (21) reported relatively lower functional presentation about three-quarters (60.67%) of children (out of 182) had normal motor abilities among the child at the age of nine years.

Findings in the present study regarding all phases of the gait cycle; stance and swing phases (walking) were excellent of each CC in their last visit as those who had in the walking age 2.9 (average), 16.1% participants usually walked in their initial consultancy day. Contrary to our results, a greater 52–91% had eccentricity in three parameters of functional abilities consisted mainly of standing, walking, and single foot hopping (22).

Each parent or attendance decreed to articulate their children in sporting activities inclusive of rope skipping, as it prevented ankle stiffness and maintained excellent ankle movement at the time of walking age, but unfortunately, we did not record it. Other authors reported that almost all the children participated in football, handball, skiing,

Table 2 Outcomes of the functional assessment parameters during the bracing period

Visits	Outcomes	Functional assessment parameters			
		Standing n (%)	Squatting n (%)	Walking n (%)	Running n (%)
01	Can do	15 (16.1)	15 (16.1)	15 (16.1)	15 (16.1)
	Can't do	78 (83.9)	78 (83.9)	78 (83.9)	78 (83.9)
	Total	93 (100.0)	93 (100.0)	93 (100.0)	93 (100.0)
02	Can do	3 (3.2)	3 (3.2)	3 (3.2)	3 (3.2)
	Can't do	75 (80.6)	75 (80.6)	75 (80.6)	75 (80.6)
	Total	78 (83.9)	78 (83.9)	78 (83.9)	78 (83.9)
03	Can do	6 (6.5)	7 (7.5)	6 (6.5)	6 (6.5)
	Can't do	69 (74.2)	68 (73.1)	69 (74.2)	69 (74.2)
	Total	75 (80.6)	75 (80.6)	75 (80.6)	75 (80.6)
04	Can do	14 (15.1)	14 (15.1)	13 (14.0)	13 (14.0)
	Can't do	55 (59.1)	54 (58.1)	56 (60.2)	56 (60.2)
	Total	69 (74.2)	68 (73.1)	69 (74.2)	69 (74.2)
05	Can do	11 (11.8)	16 (17.2)	12 (12.9)	12 (12.9)
	Can't do	44 (47.3)	38 (40.9)	44 (47.3)	44 (47.3)
	Total	55 (59.1)	54 (58.1)	56 (60.2)	56 (60.2)
06	Can do	12 (12.9)	10 (10.8)	13 (14.0)	12 (12.9)
	Can't do	32 (34.4)	28 (30.1)	31 (33.3)	32 (34.4)
	Total	44 (47.3)	38 (40.9)	44 (47.3)	44 (47.3)
07	Can do	15 (16.1)	12 (12.9)	14 (15.1)	15 (16.1)
	Can't do	17 (18.3)	16 (17.2)	17 (18.3)	17 (18.3)
	Total	32 (34.4)	28 (30.1)	31 (33.3)	32 (34.4)
08	Can do	10 (10.8)	10 (10.8)	10 (10.8)	10 (10.8)
	Can't do	7 (7.5)	6 (6.5)	7 (7.5)	7 (7.5)
	Total	17 (18.3)	16 (17.2)	17 (18.3)	17 (18.3)
09	Can do	4 (4.3)	3 (3.2)	4 (4.3)	4 (4.3)
	Can't do	3 (3.2)	3 (3.2)	3 (3.2)	3 (3.2)
	Total	7 (7.5)	6 (6.5)	7 (7.5)	7 (7.5)
10	Can do	3 (3.2)	3 (3.2)	3 (3.2)	3 (3.2)
	Can't do	–	–	–	–
	Total	3 (3.2)	3 (3.2)	3 (3.2)	3 (3.2)

and dancing. They also did not account for the frequency of the performance on the play (21). Sporting, therefore, ultimately resultant outstanding performance in standing parameters through our participants. To illustrate, studies

that adopted the MABC and MABC-2 instruments found the contrast in jumping, ball skills, and one leg stand analogous to normal values (21,23). The limitations of the present study included the retrospective, age of the ending treatment time

was not calculated, and higher loss of follow up.

The present study's strengths were that the mean (\pm SD) age of all the children at the initial consultancy, the appropriate treatment age, and treated by trained, experienced, and expert onsite partitioning physiotherapists—besides, therapeutic exercise education to their parents at the time of the regular visits to the physiotherapist. A recent study noted the significant positive outcomes reflected importance for the children and their parents, the physiotherapist and surgeon, respectively. Our statement supported by this study that frequent visits to the physical therapist in the newborn period, parental exercises, and close follow-up with the physiotherapist required for successful functional outcomes (24).

The present study did not find any difficulties that have hindered the running parameter of the clubfeet child. While in a similar study found 99% child completed the running test successfully in Bangladesh (25). However, the comparatively poor result was demonstrated by Kenmoku *et al.* (20) both at running and standing long jump. Even, so too, they claimed children with satisfactorily treated and did not have impaired functional activity. In our cohort, reviled the exceptional outcome of functional skills in both who required and did not require pAT. A non-randomized study included 81 children with CC at age 5, were analyzed gait found that the children treated non-operatively flaunted better function (23).

The not noted reappearance of any deformities and complicated cases acted as a defensive factor in achieving the vital functional skills of our participants. If we look at the previous study, there manifested complications, either excessive dorsiflexion or equinus in fewer children age by 5 aftermaths of delayed surgical correction between ages 2 and 5 (21). That was too suggested by few more studies the physical functioning in children was slightly fallen off (21,26). However, a systematic review pointed out that non-adherence to treatment was the cause of recurrence (23).

Conclusions

The functional outcomes of PM among children with CC in Bangladesh reflect a substantially significant positive effect. The guardians of the children with CC are encouraged to undergo through the PM to treat their child. However, further large-scale studies are recommended to explore the precise effectiveness of PM among the population in experimental approach.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://dx.doi.org/10.21037/jxym-21-15>). 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 ethical review committee of the Department of Public Health, North South University, Dhaka, Bangladesh, approved the research protocol 2015/OR-NSU/IRB-No.0602. After that, permission was taken from the respective authority of Lion Mukhlesur Rahman Foundation (LMRF) Healthcare, Chattogram center, to use their patient's database. Assents from the parents were taken before the data collection.

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