

## Comparison of Standard versus Accelerated Ponseti Protocol for Club Foot

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**Abstract:** Clubfoot (congenital talipes equinovarus) is a common congenital musculoskeletal deformity, and the Ponseti method is the current gold standard for its management. While the standard Ponseti protocol is well-established, accelerated protocols have been introduced to potentially reduce treatment time without compromising outcomes. **Objective:** To compare the effectiveness of the standard Ponseti protocol versus the accelerated Ponseti protocol in the management of clubfoot. **Methods:** This quasi-experimental study was conducted at the Pak-Emirates Military Hospital, Combined Military Hospital, Rawalpindi, from April 2024 to February 2025. A total of 144 patients with clubfoot were enrolled and randomly allocated into Group A (standard Ponseti protocol) and Group B (accelerated Ponseti protocol). The Ponseti method was applied as per group allocation, and treatment effectiveness was evaluated using the Pirani scoring system at baseline and at six months follow-up. Data were analyzed using SPSS version 22, with a p-value <0.05 considered statistically significant. **Results:** Among the 144 patients, the median age was 4.00 (IQR: 1.00–8.00) months, with 92 (63.89%) males and 52 (36.11%) females. The median pre-treatment Pirani score was 5.00 (IQR: 4.00–6.00). At six months, the median post-treatment Pirani score was 1.00 (IQR: 0.00–4.00) in both groups; however, the difference between groups was statistically significant (p=0.005). Treatment effectiveness at six months was higher in the accelerated protocol group (83.33%) compared to the standard protocol group (56.94%) (p=0.001). **Conclusion:** The accelerated Ponseti protocol demonstrated superior effectiveness compared to the standard protocol for the management of clubfoot, potentially offering faster correction without compromising treatment outcomes.

**Keywords:** Casting, Clubfoot Deformity, Foot Deformity, Outcome, Talipes Equinovarus

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### Introduction

Talipes equinovarus, commonly known as the club foot deformity is a debilitating and painful foot deformity that negatively effects the lives of newborns by making their ability to move around difficult if not treated appropriately and timely (1, 2). Anatomically club foot deformity can be classified as typical and complex types. Typical anatomy includes presence of cavus, adducts, equines and varus of midfoot, hind foot and ankle, respectively while complex club foot deformity has additional features of shortened first metatarsal, planter flexed metatarsals, big toe being hyperextended and presence of deep folds in the sole. (3, 4).

When it comes to the magnitude of this congenital anatomical anomaly, it has been reported that its global prevalence is 1.18/1000 live births with much higher prevalence in underdeveloped nations having a prevalence reaching up to 2/1000 live births (5). In Pakistan, according to an estimate around 7500 children are born with this foot deformity each year which is a large number (6). Such high prevalence warrants to hold a large-scale awareness drive so that all the parents with children suffering from this foot deformity may seek medical help. The reason behind this is that in cases of non-provision of timely and appropriate treatment, children with this deformity may end up living with lifelong disability which not only lowers their life quality but also result in socioeconomic burden on the sufferer for life (7).

One method that is widely accepted throughout the world for correcting this foot deformity is the Ponseti method which involves serial casting and manipulations which help in rendering the foot position into its normal orientation. (8). This method can be performed in standard as well as accelerated fashion but which amongst the two techniques is better and provides superior outcomes is yet to be determined. Therefore, present

study was conducted with the aim of comparing the outcomes of standard versus accelerated Ponseti protocol for management of club foot. Results from this study may help determining the better technique of performing this life improving procedure that can provide best outcomes in children with talipes equinovarus.

### Methodology

These two phases quasi-experimental study was conducted at Pak-Emirates Military Hospital (PEMH), Combined Military Hospital, Rawalpindi from April-2024 to February-2025 after getting approval from institutional ethical committee (Ref No: ERC 47/2025 and ERC 804 respectively). Sample size was calculated through World Health Organization (WHO) calculator and sample size was obtained through following formula:

Sample size calculation was performed by using level of significance 5%,

$$n = \frac{\left\{ z_{1-\alpha/2} \sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

power of 80% and anticipated effectiveness of standard and accelerated Ponseti protocol of 80.8% and 59.6%, respectively. <sup>9</sup> This gave a sample size of 144 (72 in each group). Study sample was selected by using non-probability consecutive sampling technique.

**Inclusion criteria:** Male and female patients, aged 12 month or less who presented with bilateral club foot deformity were included.



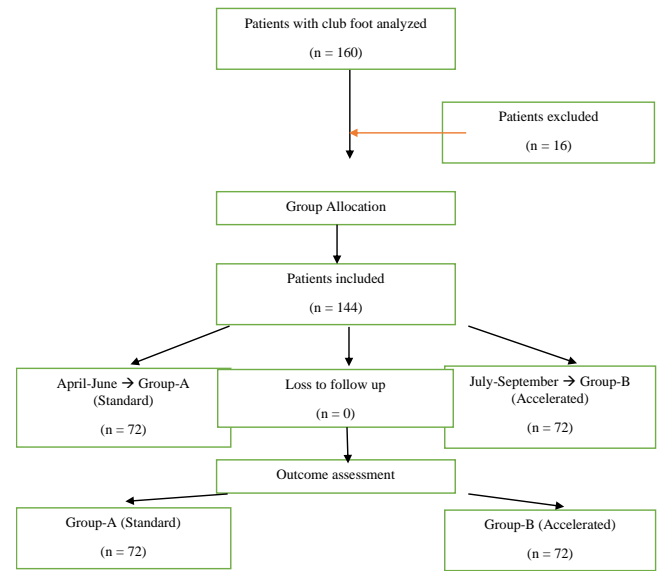
**Exclusion criteria:** Patients with unilateral deformity, congenital structural anomaly of the spine or brain, syndromic talipes equinovarus, congenital neurological anomalies and previously operated club foot deformity were excluded.

Before being included in the current research, a written consent form was signed by the parent of every patient and they were educated about the Ponseti procedure. After that baseline characteristics including age, gender and pretreatment Pirani score were documented. Pirani score is a clinical score that assess six different signs contracture with minimum score to be given being 0 indicating absence of any deformity and maximum score to be given being 1 indicating presence of severe deformity.<sup>10</sup> Pirani score was determined by the consultant surgeon who did not perform the Ponseti procedure on the same patients to minimize operator bias. Group allocation was performed based on the phase of study. During the first phase extending from April to June 2023, patients were managed through standard Ponseti protocol and were allocated in Group-A and the casting & manipulation was performed one time per week. During the second phase from July to September 2023, patients were managed through accelerated Ponseti protocol and were allocated in Group-B and the casting & manipulation was performed two times per week. Ponseti method was performed by consultant orthopedic surgeon with minimum experience of three years as per the standardized protocols. Except from the length of cast immobilization, the steps for the Ponseti procedure were the same in both groups. Manipulation and casting were carried out at times according to group allocation throughout the treatment term. One minute was spent in manipulation. Following removal of the last cast, bracing using a foot abduction orthosis was done during the maintenance period. Except for the equinus deformity, which was rectified in the final cast, all the clubfoot defects were addressed concurrently. If tendoachilles tenotomy was needed, or for two weeks otherwise, the final cast was placed for three weeks with the foot in more than 15° of dorsiflexion and 70° of abduction. After the last cast was taken off, talocalcaneal angle, talus-first metatarsal angle and tibiocalcaneal angle were computed from the foot radiographs. After that, the foot abduction brace was worn 23 hours a day for three months and subsequently throughout nap time and sleep (9)

The follow-up visits took place once a month until six months when the final Pirani score and procedure effectiveness were evaluated. Effectiveness was labeled in case of achievement of Pirani score ≤ 2.

To statistically analyze the collected data, Statistical Package for Social Sciences (SPSS) software version 22 was used. Quantitative variables (age and Pirani score) was presented as median interquartile range (IQR) after checking normality of data by Shapiro-Wilk test which showed that these were not distributed normally. Qualitative variables (gender and effectiveness) was presented as frequency and percentages. To compare median pre-treatment and post-treatment Pirani score in within groups, Wilcoxin matched pain signed rank test was used. Post-treatment Pirani

score was compared between groups using Mann Whittney U-test. Effectiveness of procedure was compared between group using Chi-square test. A p-value of ≤ 0.05 was considered as statistically significant.



**Figure-1: CONSORT patient flow diagram**

## Results

In this study, 144 patients were included. Median age was 4.00 (8.00 – 1.00) months. There were 92 (63.89%) male and 52 (36.11%) female children. Median Pirani score at presentation prior to any intervention was 5.00 (6.00 – 4.00). These baseline characteristics of study groups are compared below in Table-1

Median post-treatment Pirani score at six months follow up in Group-A was 1.00 (4.00 – 0.00) and in Group-B it was 1.00 (4.00 – 0.00). Comparison of pre-treatment and post-treatment Pirani score in both the groups is given below in Table-2

Median post-treatment Pirani score at six months follow up in Group-A was 1.00 (4.00 – 0.00) and in Group-B it was 1.00 (4.00 – 0.00), (p = 0.005). Effectiveness of Ponseti procedure, defined as achievement of Pirani score ≤ 2, assessed at six months follow up in Group-A (n = 72) was 60 (83.33%) while in Group-B (n = 72) it was 41 (56.94%), (p = 0.001). This comparison of post-treatment Pirani score and effectiveness between study groups is given in Table-3.

**Table-1: Comparison of baseline characteristics between study groups (n = 144)**

Parameter	Group-A (n = 72)	Group-B (n = 72)	p-value
Median age	4.00 (7.00 – 1.00) months	3.50 (8.00 – 1.00) months	0.865
Gender			
Male	47 (65.28%)	45 (62.50%)	0.729
Female	25 (34.72%)	27 (37.50%)	
Median pre-treatment Pirani score	5.00 (6.00 – 4.00)	5.00 (6.00 – 4.00)	0.709

**Table-2: Comparison of pre-treatment and post-treatment Pirani score in both the groups (n = 144)**

Groups	Pre-treatment Pirani score	Post-treatment Pirani score	p-value
A	5.00 (6.00 – 4.00)	1.00 (4.00 – 0.00)	< 0.001
B	5.00 (6.00 – 4.00)	1.00 (4.00 – 0.00)	< 0.001

**Table-3: Comparison of post-treatment Pirani score and effectiveness at six months follow up between study groups (n = 144)**

	Group-A (n = 72)	Group-B (n = 72)	p-value
Median post-treatment Pirani score at 6 months follow up	1.00 (4.00 – 0.00)	1.00 (4.00 – 0.00)	0.005
Effectiveness	60 (83.33%)	41 (56.94%)	0.001

## Discussion

In this study, most of the children suffering from this foot deformity were males constituting 63.89% of total population. Similar to present study, a study was conducted in Pakistan by Ul-Ain et al. (11). In which they reported that among all patients found to have this deformity, more than 58% were males showing a clear male predominance. In another study, conducted by Abdu et al. (12). Similar male predominance was observed with males constituting 77.3% of talipes equinovarus cases. The reason behind this higher chances of male to have this condition is not clear till date, however, researchers have predicted that this occurs due to an interaction between genetic and environmental factors through a polygenic threshold model (13). To assess the severity of club foot and the effectiveness of the procedure, Pirani score was utilized which has been reported to be a validated tool to be used in this regard (14).

Talipes equinovarus is a structural deformity in the alignment of the foot architecture that leads to the anatomically distorted foot shape resulting in poor life quality and disability (15). Prompt and appropriate correction of club foot deformity is vital for preserving the ability of the patient to walk properly and improve the quality of their lives (16, 17). Current study aimed at comparing two different technique of performing the Ponseti procedure which is considered as most useful intervention to effectively manage this structural deformity of the foot (18, 19).

Upon comparative analysis of the effectiveness of the two different approaches to perform Ponseti procedure, it was observed that accelerated procedure was significantly more effective compared to the standard procedure among patients treated for talipes equinovarus ( $p = 0.001$ ). In addition, Upon analyzing the Pirani score at six months follow up after treatment, it was observed that there was a statistically significantly difference based on post-treatment Pirani score at six months follow up between the accelerated as compared to the standard approach of the Ponseti procedure ( $p = 0.005$ ). Similar to this finding, a study was conducted by Hussain et al (9). Who found significantly better outcomes among club foot deformity sufferers who were managed through accelerated procedure rather than the standard one ( $p = 0.018$ ). In one study conducted by Imran et al (20). It was observed that accelerated Ponseti procedure effectiveness was observed in 80.8% of the patients which was comparable the effectiveness of accelerated approach being observed in present study.

Contrary to the results of present study, a study was conducted at national level by Alam et al (21). In which it was reported that there was no difference in the effectiveness between these two approaches of performing Ponseti procedure among patients with this deformity of the foot ( $p = 0.396$ ). Similarly, there are international studies conducted with the similar aim by Singh et al (22). And Islam et al (23). In India in which they also found both the approaches to be equally effective in managing patients with talipes equinovarus without any significant difference with the respective p-values of 0.630 and 0.24, respectively.

In addition to this benefit of greater effectiveness, accelerated approach may also be a better approach since it allows more frequent visits of the patients to the treating doctor and at each visit they have the option to talk to the treating physician about the physical condition of their patient. This helps them not only to keep track of the treatment progress of the patient but also aids in building a good rapport with the treating physician that is an important component of modern healthcare. One aspect that may be considered a bit impractical, given the overall socioeconomic conditions and patient-to-doctor ratio in Pakistan, accelerated approach may be difficult to adopt as a general practice. At the same time given its high level of effectiveness being clearly demonstrated in the study, there is a clear cut advantage of using accelerated approach of Ponseti procedure for superior effectiveness in patients with talipes equinovarus as compared to the standard protocol. Therefore, patients who present with club foot deformity should be treated with accelerated Ponseti procedure for better outcomes.

In this study, only those cases of talipes equinovarus were included who had typical anatomical features including cavus, adductus, equinus and

varus of midfoot, hind foot and ankle, respectively while complex cases were not included?

## Conclusion

In conclusion, accelerated Ponseti procedure is more effective as compared to standard procedure for managing patients with club foot.

## Declarations

### Data Availability statement

All data generated or analysed during the study are included in the manuscript.

### Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-24)

### Consent for publication

Approved

### Funding

Not applicable

## Conflict of interest

The authors declared the absence of a conflict of interest.

## Author Contribution

### NM (PGR)

Manuscript drafting, Study Design,

### SA (Professor)

Review of Literature, Data entry, Data analysis, and drafting article.

### IA (Professor)

Conception of Study, Development of Research Methodology Design,

### KAN (PGR)

Study Design, manuscript review, critical input.

### QA (PGR)

Manuscript drafting, Study Design,

### HM (Medical Officer)

Review of Literature, Data entry, Data analysis, and drafting article.

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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