

**EFFECT OF AGE AT PRESENTATION ON SHORT TERM  
OUTCOME OF THE PONSETI METHOD IN THE MANAGEMENT  
OF CONGENITAL TALIPES EQUINOVARUS.**

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**MMed (Orthopaedics and Traumatology) Dissertation  
Muhimbili University of Health and Allied Sciences  
October, 2014**

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**By**

**Jokha Yusuf Aliy, MD**

**A Dissertation Submitted in Partial Fulfillment of the Requirement for the Degree  
of Master of Medicine in (Orthopaedics and Traumatology) of the  
Muhimbili University of Health and Allied Sciences**

**Muhimbili University of Health and Allied Sciences  
October, 2014**

**CERTIFICATION**

The undersigned certifies that, he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: “*Effect of age at presentation on short term outcome of the Ponseti method in the management of Congenital Talipes Equinovarus*” in partial fulfilment of requirement for degree of Master of medicine in Orthopaedics and Trauma Surgery of Muhimbili University of Health and Allied Sciences.

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**Dr. Robert I. Mhina**

(Supervisor)

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Date

**DECLARATION**

**AND**

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I, **Jokha Yusuf Aliy** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award

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Date.....

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All this would not have been possible without the will and might of God for keeping me in good health throughout my study period.

## **DEDICATION**

This dissertation is dedicated to my dad Captain Yusuf Amir who passed away on February 26<sup>th</sup> 2014, for his love, support and providing me with a good education to where I am to date.

**ABSTRACT**

Congenital talipes equinovarus (CTEV) also known as clubfoot is one of the most common congenital conditions presenting at the paediatric orthopaedic clinics at MOI and CCBRT. **Historically the treatment of clubfoot evolved from gentle manipulation to aggressive forced manipulation and finally radical surgeries with evidence of unfavourable outcome. Currently non-operative management with the Ponseti method is advocated and has shown high success rates.** The age factor has been shown by most authors to have no significant effect on treatment but some still think otherwise.

**Objective:** The main aim of this study was to look into the effect of the initial age of presentation at the clinic on short term treatment outcome of the Ponseti method among patients with CTEV.

**Methodology:** A prospective, descriptive cross sectional study, was conducted at MOI-paediatric orthopaedic clinic and CCBRT hospital in April 2013-March 2014. 170 children met the inclusion criteria and were enrolled. Children were studied from the beginning of treatment to when they had achieved correction by manipulation and casting sufficiently to require Steenbeek foot abduction brace or tenotomy and a final cast. Data was collected using a structured questionnaire and a validated assessment tool then coded, entered and analysed using SPSS version 16 program.

**Results:** **75.9% of children seen were 0-6 months of age, their ages ranged from 1 week to 48months old.** The male to female patients ratio was 1.6:1. The distribution of bilateral and unilateral cases was 47.1% by 52.9% respectively. Overall success rate with the Ponseti treatment in manipulation and casting was 99.4%, 42.9% required tenotomy and one patient needed extensive soft tissue release. Majority of patients (79.2%), below 25 months of age achieved correction faster, 1-5 castings, compared to children 25months and above.

**Conclusion:** The success rate with Ponseti treatment among all age groups was high The age at initial treatment favours good short term outcome with the Ponseti method of treatment of clubfoot with fewer sessions of manipulation and castings.

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**LIST OF ABBREVIATIONS**

ASEA	Association of Surgeons of East Africa
CCBRT	Comprehensive Community Based Rehabilitation in Tanzania
COSECSA	College of Surgeons of East Central and Southern Africa
CTEV	Congenital Talipes Equinovarus
MOI	Muhimbili Orthopaedic Institute
MUHAS	Muhimbili University of Health and Allied Sciences
SPSS	Statistical Package for Social Science

## **DEFINITION OF KEY TERMS**

Talipes Equinovarus in this context will be used interchangeably with the terminology clubfoot referring to the same anomaly.

## CHAPTER ONE

### 1.1. INTRODUCTION

The most frequent causes of paediatric orthopaedic visits, aside from trauma, are foot and ankle problems (1). Such defects usually have their origin during a very early period of intra uterine life, but lack of proper access to the involved structures at the beginning of the mal development poses a big hindrance into discussing and explaining the aetiology behind it (2).

#### **Aetiology**

Though treatment has evolved successfully, securing good correction and restoration of function, a thorough knowledge of the pathology underlying this anomaly is essential. Clubfoot is a common congenital deformity but its aetiology and pathogenesis remain unknown despite numerous hypotheses (3). It may be associated with myelodysplasia, arthrogryposis, or multiple congenital abnormalities, but is most commonly an isolated birth defect and considered idiopathic (4).

#### **Genetic Factors**

The incidence of club foot shows a wide variation with respect to race and gender and increases with the number of affected relatives suggesting the aetiology is at least partly influenced by genetic factors (4). Evidence shows variation in incidence among different races; ranging from 0.39 per 1000 among the Chinese Population to 1.2 per 1000 among Caucasians to 6.8 per 1000 among Polynesians (5,6). Males are twice more affected than females; a ratio of 2.5:1 was reported by Lochmiller and his colleagues (7).

Siblings of affected individuals have a thirty times higher risk of having the deformity. It affects both siblings in 32.5% of monozygotic twins but in only 2.9% in dizygotic twins (8).

### **Intrauterine Factors**

Aschner and Engelmann listed the following factors as having an influence;

- Pressure of the wall of the uterus
- Active contraction of the uterus
- General narrowness of the amnion
- Amniotic constriction
- Constriction by umbilicus
- Compress between the umbilicus and the amnion
- Extra uterine pregnancy
- Uterine tumours
- Multiple pregnancy
- Narrowing due to pelvic tumours
- Infectious diseases of the mother

These authors pointed out that, the relationship of these causes and effect were inconsistent given the fact that the mal development occurs early in intrauterine life whereas such mechanical agents are more active in the late periods of pregnancy (9).

Hippocrates suggested that the foot is held in equinovarus by external uterine compression and oligohydramnios (6), but this was refuted by Turco suggesting it's unlikely that such increased pressure would repeatedly produce the same deformity, and especially in the first trimester-the time a clubfoot forms-when there is enough room. Turco also observed that there were as many right clubfeet as left despite the asymmetrical position of the foetus in the uterus, concluding that position couldn't possibly be a factor (6).

### **Histological Anomalies**

Almost every tissue in clubfoot has been described as abnormal (10). Histological and immunohistochemical findings from Fukuhara et al showed the cells and collagen fibers of the medial ankle ligaments of club feet appeared to be the site of earliest changes in that they had lost their spatial orientation and had contracted (3).

**Vascular Abnormalities**

Observations from Hootnick et al, as well as Sodre et al **noted** that the majority of clubfoot deformities were associated with hypoplasia or absence of the anterior tibial artery (11,12).

**Muscular Anomalies**

Anomalous muscles were identified in about 15% of patients with clubfoot (6). Anomalies in the flexor calf muscles of five children with clubfeet have also been identified and that patients with this anomalous muscle were noted to have a greater frequency of first degree relatives with clubfeet (13).

**Classification and Evaluation**

In the evaluation of a patient with clubfoot physical examination of the entire body cannot be over emphasised. Associated anomalies involving the upper extremities, back and legs as well as abnormal reflexes can provide important information on the aetiology of the deformity (14). The foot is examined with the knee flexed at 90° and assessed for torsional alignment, varus, valgus, size and shape of the leg, foot and ankle.

Equinus should be assessed with the knee flexed and extended as well. With the knee in extended position assessment will reflect on the true contracture of gastrocnemius-soleus muscle complex. The difference noted in equinus between flexion and extension indicates the amount of stiffness in the ankle joint (14).

Simon differentiated classification from evaluation (15,16). Classification focusing on typing the foot by aetiology such as neurogenic, teratologic or idiopathic whereas evaluation involves measuring the foot size, shape, range of motion of the joint and radiographic angles.

The initial evaluation of club foot at presentation is guided by two classification systems widely used, developed by Dimeglio et al(17) and Pirani (18). They are both applied based on different physical findings added up to a point score which correlates with the clubfoot

severity. Furthermore these two classification systems have been reported to have very good interobserver reliability (19).

## **Treatment**

### **Non operative treatment**

The first historically recorded treatment of clubfoot dates back as far as 400BC in the works of Hippocrates, he recommended gentle manipulation of foot followed by splinting (20). Non-operative treatment continued evolving with introduction of Plaster of Paris (PoP) cast by Guerin (21), and devices such as the Thomas wrench, which allowed the foot to be corrected more rapidly by forceful manipulation (22). Dr Hiram Kite recognised the adverse effect of this forced manipulation and recommended to revert back to gentle manipulation and casting for non-operative treatment (23).

Non-operative technique is based on correcting deformity through the production of plastic deformation of shortened ligaments and tendons of the affected foot. These techniques are numerous and many authors have reported success rates of less than 50% for non-operative treatment (14).

The two most reported techniques with highest long term success rates are the Kite and Lovell technique (24) and Ponseti technique (25). Other methods involving dynamic mechanism by application of corrective shoes that were attached to a bar, were introduced in 1937 by Denis Browne (26), and modified by Thompson(27), in 1942. Other non-operative treatment modalities used include; manipulation by a physical therapist developed by Bensahel et al (28,29), the French technique reported by Johnston and Richard(30), where a regimen of stretching exercises was used and that introduced by Delgado et al(31), where injection of botulinum toxin in the soleus-gastrocnemius complex and posterior tibial muscle was employed.

**At Muhimbili Orthopaedic Institute, until May 2008 the Ponseti method for treatment of congenital clubfoot had not been introduced.** The Ponseti International, in collaboration with, Christian Blind Mission (CBM) and International Society for

Prosthetics and Orthotics (ISPO) conducted a training workshop on the Ponseti method of conservative treatment of clubfoot. By June 2008 this method of treatment was adopted and its preliminary results presented in the ASEA/COSECSA regional meeting in Zanzibar 2009 in terms of trend of the outcome with the Ponseti treatment using the Pirani score. It was concluded from the one year observations of treating 109 clubfeet that the Ponseti method offered good results to warrant continued use of the technique for treatment of clubfoot (32).

### **Operative treatment**

In some patients non-operative treatment alone is not enough to attain correction, hence an indication for soft tissue release. Perioperative assessment of which anatomical components of the deformity remains to be corrected is essential, to ensure surgery addresses only those structures. For instance a foot in which all components of the deformity are still present likely requires full posteromedial and plantar lateral release but in persistent equinus a posterior release suffices (14).

Revision surgeries are meant to address residual deformity, for instance in patients under two years with residual forefoot adduction can be treated with repeated soft tissue releases (33). Radical procedures in older children more than four years of age have been described including excision of distal part of calcaneus (34), fusion of calcaneocuboid joint (35), opening wedge osteotomy of first cuneiform, metatarsal osteotomies, and tarsal metatarsal capsulotomies (36). Salvage procedures like triple arthrodesis have been known to be used in children older than 10years (37).



## **1.2. LITERATURE REVIEW**

### **Demographics**

Globally approximately 150-200,000 babies are born with clubfeet annually(38), and it's estimated that 80% of these will be in middle and low income countries (39). Congenital clubfoot is known to be the most common cause of ambulatory disability in the developing world, with a worldwide incidence of approximately 1 in 1000 live births (40).

In a door to door survey for congenital orthopaedic anomalies in the rural Indian population an incidence of 2.25 cases per 1000 population was found. Clubfoot was the most common with an incidence of 0.9 per 1000 (41). Omolulu et al in his prospective study documented the most common congenital orthopaedic malformation was clubfoot (50%) among all congenital musculoskeletal malformations(42). The Uganda Sustainable Clubfoot Care Project determined the incidence of the disease as 1.2 per 1000 live births(43).

Parker et al (44), in a multistate surveillance pooled data from several birth defects surveillance programs, and estimated, the overall prevalence of clubfoot was 1.29 per 1000 live births; 1.38 among non-Hispanic whites, 1.30 among Hispanics, and 1.14 among non-Hispanic blacks or African Americans. Factors like maternal age, parity, education, and marital status were significantly associated with clubfoot. In addition to this maternal smoking and diabetes also showed significant associations. Several of the noted associations were consistent between the different states surveillance programs.

Carey et al observed a prevalence of associated talipes equinovarus at birth in Western Australia of 0.90 per 1000 births and isolated talipes equinovarus of 1.25 per 1000 births. The isolated deformities were seen to be higher in Aboriginal infants than Caucasians, with the rate of Aboriginal males being four times than females (45).

In a clinical genetic and epidemiologic study Yamamoto observed an incidence of 0.87 per 1000 live births the male to female ratio 2:1 with equal numbers of unilateral and bilateral

deformities. A fall in incidence among relatives with remote blood relations suggested compatibility with model of multifactorial inheritance (46).

A study conducted at Queen Elizabeth Central Hospital in Malawi by Mkandawire and Kaunda(47), revealed an incidence of 2 per 1000 live births with a male to female ratio of 1.3:1, 73% had bilateral deformities and within the unilateral the right foot was more affected (71%). Syndromic talipes was observed in 34.4% of children and neurotube defect was the commonest associated anomaly. Lavy et al in their study observed a similar male preponderance and 50% of cases had bilateral clubfeet (40).

### **Pirani evaluation system**

The use of the Pirani score for evaluation has been described as a simple, easy to use tool for severity assessment of clubfoot at presentation and progress monitoring (38). It has been found to be both valid and reliable (48). Dyer and David showed in the study its predictive ability for treatment outcomes with the Ponseti method, observing that a higher Pirani score indicated that a higher number of cast will be required (49).

### **The Ponseti Method and idiopathic talipes equinovarus**

The treatment of clubfoot has been observed to evolve from radical surgical procedures with less long term success rates to the less traumatic closed treatment with good outcomes. **Specifically the Ponseti method has been practiced by orthopaedic surgeons in the United Kingdom for seven years now as reported in 2010** (50). So far since its development by Dr Ignacio Ponseti over fifty years ago, it has been the most cost effective treatment of clubfoot with no significant side effects. Besides this various health care providers can perform the treatment making it a practical option for eradicating clubfoot around the world (39).

Currently the Ponseti method of correction is the most popular closed technique in the treatment of clubfoot(51,52), which incorporates gentle sequential manipulation of the foot to achieve a plantigrade, functional foot (53). The technique has been used in Malawi to

good effect, and could be learned and practised effectively by clinical officers in remote and rural areas (54).

Lehman and others reported a high success rate with the treatment, lower complication rates, less pain and higher function as compared to operative treatment. Patients treated early before seven months of age as well as those who were compliant had a 92% success rate at an early follow up after casting was completed (55).

In their systematic review Jowett et al found most studies showed excellent results with the Ponseti method giving initial correction rate of around 90% in idiopathic club feet. Their conclusion was that the current best practice for treatment of CTEV is the original Ponseti method, with minimal adjustment being hyper-abduction of the foot in the final cast and bracing for a long term of up to 4 years (56).

### **Early treatment Versus Delayed Treatment**

Ponseti advocates that treatment should start early after birth giving reasons that neglected clubfoot limits the child prospects of leading a normal life which is pain free, job opportunities and functional ability to carry out tasks (25). The Ponseti method has been reported to be successful in children presenting after neonatal period. Despite this, the results from different studies conducted are variable and thus it is still not clear whether age at initial treatment has an effect on the clinical outcome.

Arkan et al in their study showed a success rate of 85.7% with the Ponseti method and revealed that the earlier the treatment started the better the outcome. The group of children who started treatment before two months of age had 100% success rate compared to the other group which started after four months of age showing a success rate in 50% of cases (57).

On the other hand Bor, Herzenberg and Frick (58), reviewed a number of children who were first seen after the age of three months in whom conservative treatment had failed. After a period of 24 months, only one of 36 feet (2.8%) required extensive surgery. The conclusion was unlike what most paediatric orthopaedist thought, that successful casting

depends on treatment started early, their data suggested otherwise and that older infants can be treated successfully without extensive surgery. Their results were similar to a study they conducted with younger infants, where only one (2.9%) of 34 feet treated required posteromedial release.

Lourenco et al also concluded that the Ponseti method is a safe, effective and cost effective treatment for neglected idiopathic clubfoot presenting after walking age. In this study of 17 children (24 feet) plantigrade foot was obtained in 16 feet without a need for extensive soft tissue release (59).

Alves et al retrospectively studied two groups of children undergoing treatment one presented below six months of age and the other after six months. They concluded that given the results observed age at the beginning of treatment did not seem to influence the final outcome. The cut off age for successful Ponseti treatment has yet to be defined and late presenting cases should still start with Ponseti treatment (60).

To support this, Dobbs et al found severity of the deformity age at initiation of treatment and previous treatment did not have significant effect on recurrence but rather non-compliance and parents' educational level were significant risk factors (61).

Spiegel et al retrospectively reviewed records of 171 patients (260 feet) to determine whether initial correction could be achieved using the Ponseti method in untreated idiopathic clubfeet of patients presenting between the ages of 1 and 6 years. Of these 205 feet (79%) required tendon Achilles tenotomy, all patients achieved plantigrade feet and extensive soft tissue release was avoided in 94% of patients (62).

In Malawi, Tindall et al found 98% of 100 feet treated with the Ponseti technique achieved plantigrade position out of which 25% were after the walking age of 18-48 months. The treatment was offered by mainly Orthopaedic clinical officers. An average, five casts were applied, 59% required no surgical intervention while 41% underwent percutaneous tenotomy (54).

Kessi (63) retrospectively studied various parameters pertaining to management of clubfoot at Sint Radboudziekehuis Nijmegen and Muhimbili Medical Centre, Dar Es Salaam between 1976-1981. Conservative treatment during those times included; stretching and strapping, forceful manipulations, serial plaster casting, cast and splints corrective surgical boots and splints alone.

Fifty children with a total of 84 clubfeet were treated. The **treatment methods included conservative, soft tissue operations and bone operations. 26 patients ( 39 feet) underwent radical (Tachdjian) posteromedial release while 24 patients(45 feet) were treated by the other methods.** Overall 78% of the patients had excellent or good clinical results while 22% unsatisfactory. Of those treated by conservative method 55.2% had either excellent or good clinical outcome. Out of the total number of patients treated with the radical posteromedial release 92.3% had excellent and good clinical results , 92.3% . **One of the factors attributed to failure with the posteromedial release was age and delayed treatment whereas negligence of patients parents to adhere to treatment accounted for failure with the conservative method.** Of those treated with soft tissue operation 65.5% obtained satisfactory results with majority requiring repeat surgeries. The author concluded the Tachdjian posteromedial release offered the best clinical outcome.(63)

### **1.3. PROBLEM STATEMENT**

Clubfoot is one of the commonest congenital malformations seen at the Muhimbili Orthopaedic Institute, paediatric orthopaedic unit. Treatment as seen from various studies has evolved from aggressive and invasive methods to the current non-operative management which has proven successful.

Cultural beliefs include misinformation that suggests that Ponseti management is ineffective given the misconception the deformity is due to evil spirits, witchcrafts or mothers' misdeeds hence one of the barriers to Ponseti treatment(64). Stigma also leads to delays on onset of treatment since the child is hidden by the family as a source of shame.

Neglected clubfoot hinders the child from leading a normal life due to the disability associated with the deformity. The prospects of having a normal productive life with good education are limited by this disability. Furthermore families of infants born in villages may lack awareness of the diagnosis or the need of early treatment.

### **1.4. RATIONALE**

This study aims at proving the importance of early treatment in achieving best results in shorter duration in a resource limited setting. Furthermore our limitation to accessible extensive soft tissue release surgeries necessitates on working on improving the success rates with the Ponseti technique which have shown excellent results with earlier treatment post natal. The results of this study can be used to provide the basis in the development of a national campaign for the eradication of neglected clubfoot especially in remote rural areas

### **1.5. RESEARCH QUESTIONS**

1. At what age do children with CTEV present at MOI and CCBRT?
2. What is the short term treatment outcome with the Ponseti method?
3. Does the age of the child at start of Ponseti treatment influence the treatment outcome?

## **1.6. OBJECTIVES**

### **1.6.1. Broad Objective**

To assess the influence of age, beginning the Ponseti treatment on short term outcome among paediatric patients with CTEV attended at MOI and CCBRT April 2013-March 2014.

### **1.6.2. Specific Objectives**

1. To determine the age of patients at onset of Ponseti treatment for congenital clubfoot at the two clubfoot centres (MOI and CCBRT).
2. To evaluate the progress of the Pirani score during follow up for the different age groups.
3. To determine the number of casts used to achieve correction with the Ponseti method for the different age groups.
4. To determine treatment failure rates in different age groups with the Ponseti method.

## **CHAPTER TWO**

### **2.0. METHODOLOGY**

#### **2.1. Study design**

This was a prospective, hospital based cross-sectional study.

#### **2.2. Study area**

The study was conducted at two major hospitals dealing with management of patients with CTEV in Dar es Salaam. These hospitals are Muhimbili Orthopaedic Institute (MOI) and Comprehensive Community Based Rehabilitation in Tanzania (CCBRT) hospital. MOI and CCBRT are currently the major clubfoot centres in Dar es salaam.

MOI is a national referral hospital for orthopaedic, trauma and neuro-surgical conditions. It has a bed capacity of 181 patients with one main theatre accommodating five operating tables and one emergency theatre. Patients were drawn from the Paediatric Orthopaedic Department clinic of the institute.

CCBRT hospital which is a registered non-governmental organisation was established in 1994. It is currently the largest provider of disability and rehabilitation services in the country. Patients were enrolled from clubfoot clinics which are conducted from Mondays to Thursdays.

#### **2.3. Study period**

The study was conducted from April 2013 to March 2014.

#### **2.4. Study population**

All patients with congenital talipes equinovarus attending the clinics for the first time for treatment.



## 2.5. Inclusion criteria

Patients with congenital talipes equinovarus attending clinic for the first time.

## 2.6. Exclusion criteria

Patients with atypical talipes equinovarus. Children with syndromic clubfoot.

Parents who do not consent to being part of the study.

## 2.7. Variables

1. Outcome/ dependent variables measured-Pirani scores

Number of casts to achieve correction

Treatment success/failure

2. Independent/explanatory variables- Age at presentation

Sex

Area of residence

Severity of deformity

Side of deformity

## 2.8. Sample size

Sample size had been estimated by using the following formula.

P = 12.6% obtained from a pilot survey of new cases at paediatric clinic with CTEV among all the new cases seen during the year 2011.

95% confidence interval (Z) =1.96      Error rate=d =5%

$$N = Z^2/d^2 (p (100-p))$$

$$n = (1.96/5)^2 \times (12.6(100-12.6)) \text{ Hence minimum sample size} = 169$$

A 10% over estimation accounting for loss to follow up.

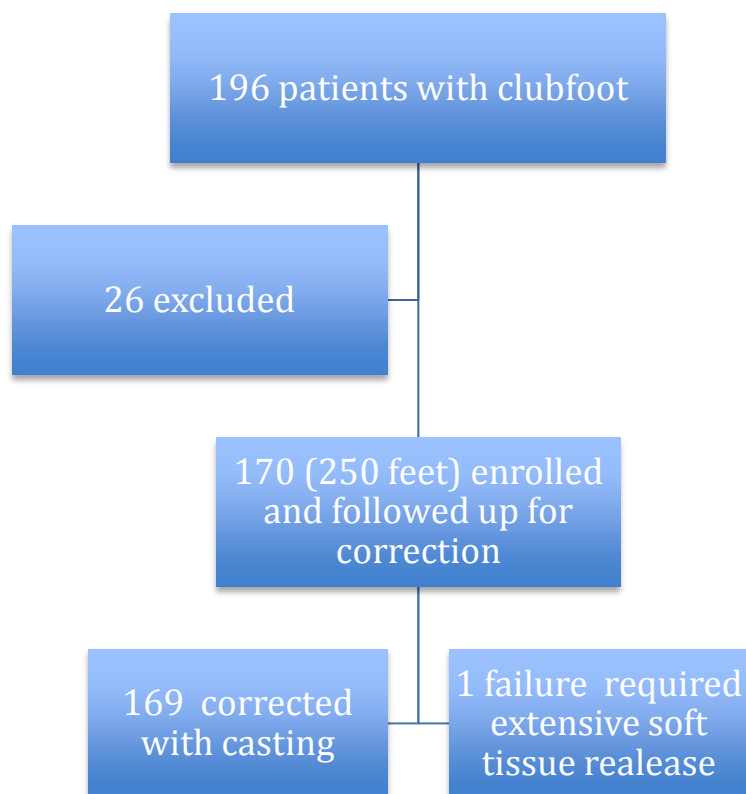
Hence n=186

## 2.9. Patient enrollement and data collection method

Patients with CTEV attending clinic at either one of these institutions as new cases were recruited as per inclusion criteria.

Data was obtained by interviewing parents and examining patients, using a structured questionnaire. Patients were evaluated at initial visit using the Pirani scoring system and commenced to treatment with the Ponseti technique. They were evaluated with the Pirani score followed with manipulation and casting according to the Ponseti treatment protocol.

Treatment and assessment was done by the Prinicpal investigator or Orthopaedic specialist assisted by a team of nurses and technician who had been formally trained in the Ponseti treatment of clubfoot.



**Figure 1. Summary of patients recruitment and follow up**

Follow up in this study stopped after achieving correction with manipulation and casting as guided by the Pirani scoring tool to foot abduction bracing or deemed failure by just casting and planned for a more extensive soft tissue release. The number of manipulation and casting needed was recorded to later represent the rate at which correction was achieved with regards to age at beginning of treatment.

In this study failure was considered when correction is not achieved after ten sessions of manipulation and casting.

### **2.10. The Treatment Process**

The Ponseti treatment method involved manipulation and casting to correct deformity in stages on weekly basis. The first cast aims at correcting the cavus. The forefoot is positioned in proper alignment with the hindfoot, then supinated till a normal medial arch is achieved.

The manipulation that follows allows correction of all the components of the clubfoot deformity except equines. To achieve this, the head of the talus, which is the fulcrum of the correction must be located and stabilised. By doing so it provides a pivot point around which the foot is abducted, hence gradually by this manipulation and maintaining with the casts, adductus and varus are corrected.

The ankle equines gradually improves with manipulation. Direct attempt to correct it at the beginning is avoided. Once heel varus is corrected the remaining equines is corrected with casting by dorsiflexion, and when necessary Achilles tendon tenotomy is done before final cast is applied.

The patients were seen on weekly basis where the cast would be removed and foot assessed using the Pirani scoring tool. Treatment would then continue guided by the progress depicted from the Pirani scores. As the scores dropped showed progress towards achieving correction of the deformity.

DATE						
Side	R	L	R	L	R	L
Curve of lateral border						
Medial crease						
Talar head						
<b>Midfoot contracture score</b>						
D.posterior crease						
E.equinous rigidity						
F.empty heel						
<b>Hindfoot contracture score</b>						
Total						
Complications Y/N						
Treatment						

**Figure 2. The Pirani scoring tool (38)**

Treatment code: **M** manipulate **C** cast **T** tenotomy **B** brace **O** others (describe)

For each component a value of 0, 0.5 or 1 was given depending on the degree of deformity.

0 meant normal and 1 severe for that particular component of the deformity.

The definition of clubfoot severity in this particular study was based on the Pirani scores; scores 1-3 representing mild deformity, 3.5-4.5 moderate and 5-6 as the severe form of the clubfoot deformity.

### **2.11. Data analysis**

The data recorded from the questionnaires was coded, entered, cleaned and analysed using the Stastical Package for Social Sciences version 16 computer. Frequency distribution tables were used to describe categorical variables; age group, sex, side of deformity and severity while means and standard deviation were used to describe/summarise continuous variables; number of casts and median for age distribution. Chi-square or Fisher's exact

test was used to compare the difference in proportions of serial casting needed to achieve correction in different age groups and age distribution by sex.

The mean differences in Pirani scores during evaluation at week one, three and five were compared using T test. P-value less than or equal to 0.05 was considered to be statistically significant.

### **2.12. Ethical Consideration**

Ethical clearance was sought from Muhimbili University of Health and Allied Sciences senate, Research and Publication Committee and the study began when the permission to conduct the study was granted by the Executive Director of Muhimbili Orthopaedic Institute and authorities of CCBRT.

Both verbal and written consent were obtained from the respondents. Explanation was given to the respondents on the aim of the study and that all the data obtained will be used for research purpose only.

To ensure confidentiality, Respondent's names were not written rather initials used in the questionnaire. Freedom to participate, or refuse to participate or withdrawal from the study without prior information was clearly explained to all participants, that it will not affect patient treatment quality and would still continue even when out of the study.

## CHAPTER THREE

### 3.0. RESULTS

#### Demographics

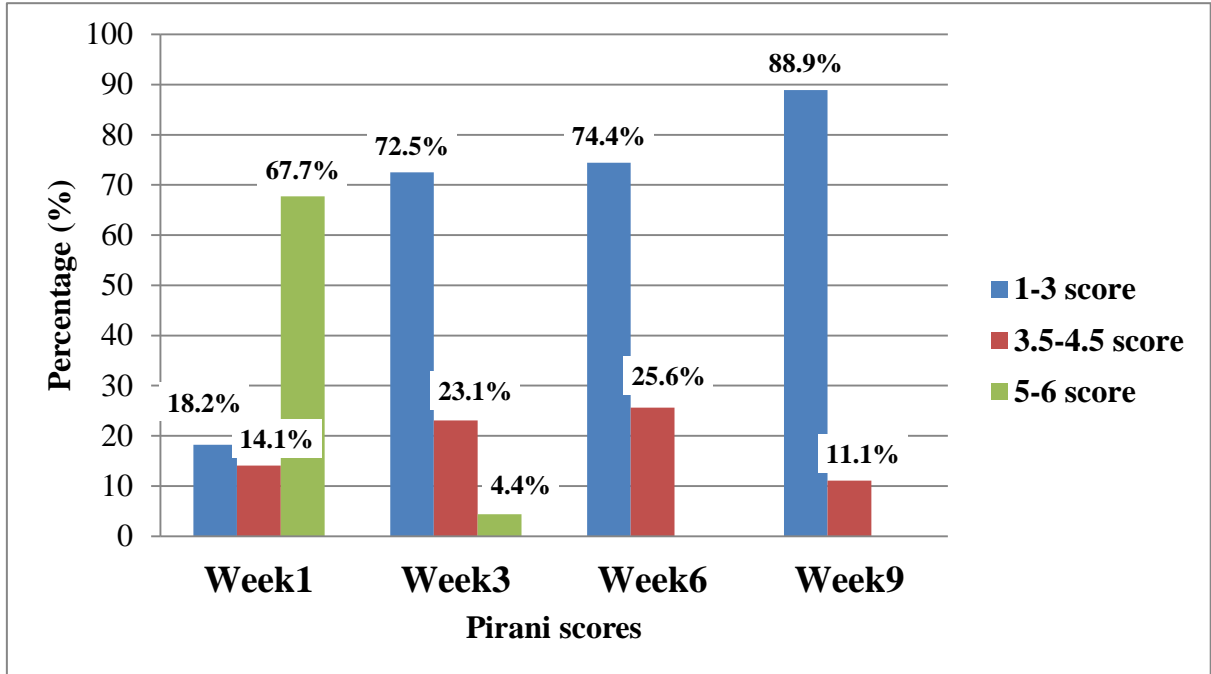
A total number of 170 patients who had met the inclusion criteria were enrolled during the study period and followed up for a minimum of three weeks. The majority of the patients (75.9%) fell within age group of 0-6 months, with a median age was 2.125months. The youngest child enrolled into the study was 1 week old and the oldest 48months. Male patients dominated the study group, 105(61.8%). Most patients came from the coastal zone, within which were the majority of the youngest age group as well as the oldest age group (Table 1).

Severe clubfoot dominated (67.6%), with almost overall equal distribution of unilateral and bilateral deformity (52.9%, 47.1%). There was no noted preference of side between left, 44 (25.8%) and right 46 (27.1%) among the patients who had unilateral clubfoot (Table 1).

**Table 1: Social Demographic**

<b>Variable</b>	<b>Frequency</b>	<b>Percentage</b>
<b>Age group (Months)</b>		
0 – 6	129	75.9
7 – 12	26	15.3
13 - 18	7	4.1
19 – 24	2	1.2
25 and above	6	3.5
<b>Sex</b>		
Female	65	38.2
Male	105	61.8
<b>Residence</b>		
Northern	9	5.3
Southern Highlands	23	13.5
Central	6	3.5
Coastal	125	73.5
Lake	4	2.4
Zanzibar	3	1.8
<b>Severity</b>		
Mild	31	18.2
Moderate	24	14.2
Severe	115	67.6
<b>Side of deformity</b>		
Right	46	27.1
Left	44	25.8
Bilateral	80	47.1

### Ponseti Treatment Progress



**Figure 3: Trend of scores during treatment follow-up**

The Pirani scores at week 1(baseline), week 3, 6 and week 9 of treatment were used to evaluate progress during Ponseti treatment. Majority of patients at baseline, 115 (67.7%) had severe deformity that is scores 5-6 by week six none of them had scores range of 5-6 (Fig 3). The differences in mean scores were found to be statistically significant when compared at week 1, week 3, week 6 and week 9 showing generally significant improvement during treatment with Ponseti method (table 2).



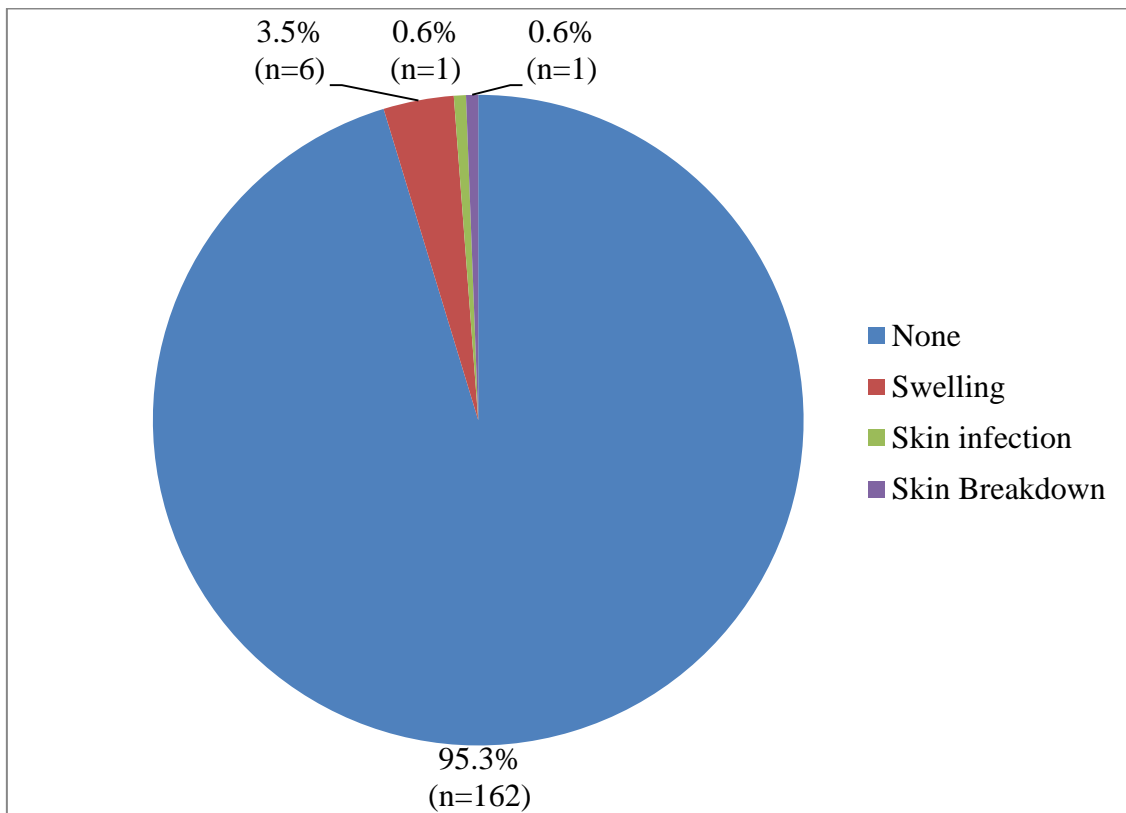
**Table 2: Differences in mean Pirani scores from week1 (baseline) as taken in week 3, week 6 and week 9**

	<b>At week 1</b>	<b>Week 3</b>	<b>Week6</b>	<b>Week9</b>	<b><i>p</i>-value</b>
<b>Independent sample (n=170)</b>	5.05	4.28	1.33	1.85	< 0.001
<b>Paired sample (n=111)</b>	5.77	3.18	1.22	1.29	< 0.001

**Table 3: Progress of Ponseti treatment per age group**

Variable	1-3 score N (%)	3.5-4.5 score N (%)	5-6 Score N (%)	p-value
<b>Week 1</b>				
<b>Age group (Months)</b>				
0 – 6	23(17.8)	19(14.7)	87(67.4)	
7 – 12	4(15.4)	3(11.5)	19(73.1)	
13 - 18	2(28.6)	2(28.6)	3(42.8)	
19 – 24	0(0)	0(0)	2(100)	
25 and above	2(33.3)	0(0)	4(66.7)	0.746
<b>Total</b>	31(18.2)	24(14.1)	115(67.7)	
<b>Week 3 assessment</b>				
<b>Age group (Months)</b>				
0 – 6	94(77.0)	25(20.5)	3(2.5)	
7 – 12	16(64.0)	7(28.0)	2(8.0)	
13 - 18	4(66.7)	2(33.3)	0(0)	
19-24	1(50.0)	1(50.0)	0(0)	
25 and above	1(20.0)	2(40.0)	2(40.0)	0.021
<b>Total</b>	116(72.5)	37(23.1)	7(4.4)	
<b>Week 6 assessment</b>				
<b>Age group (Months)</b>				
0 – 6	20(80.0)	5(20.0)	0(0)	
7 – 12	5(71.4)	2(28.6)	0(0)	
13 - 18	1(50.0)	1(50.0)	0(0)	
25 and above	3(60.0)	2(40.0)	0(0)	
<b>Total</b>	29(74.4)	10(25.6)	0(0)	0.515
<b>Week 9 assessment</b>				
<b>Age group (Months)</b>				
0 – 6	4(100.0)	0(0.0)	0(0)	
7 – 12	2(100.0)	0(0.0)	0(0)	
13 - 18	1(100.0)	0(0.0)	0(0)	
25 and above	1(50.0)	1(50.0)	0(0)	
<b>Total</b>	8(88.9)	1(11.1)	0(0)	0.556

The progress of the Ponseti treatment as per different age groups showed that among the youngest age group, at week three 84 patients with highest scores had a drop in their scores. Two patients in the oldest age group with highest Pirani scores persistently had high scores this comparison was statistically significant. At week six of evaluation all patients who had scores 5-6 had a reduction in the Pirani scores. (Table 3).



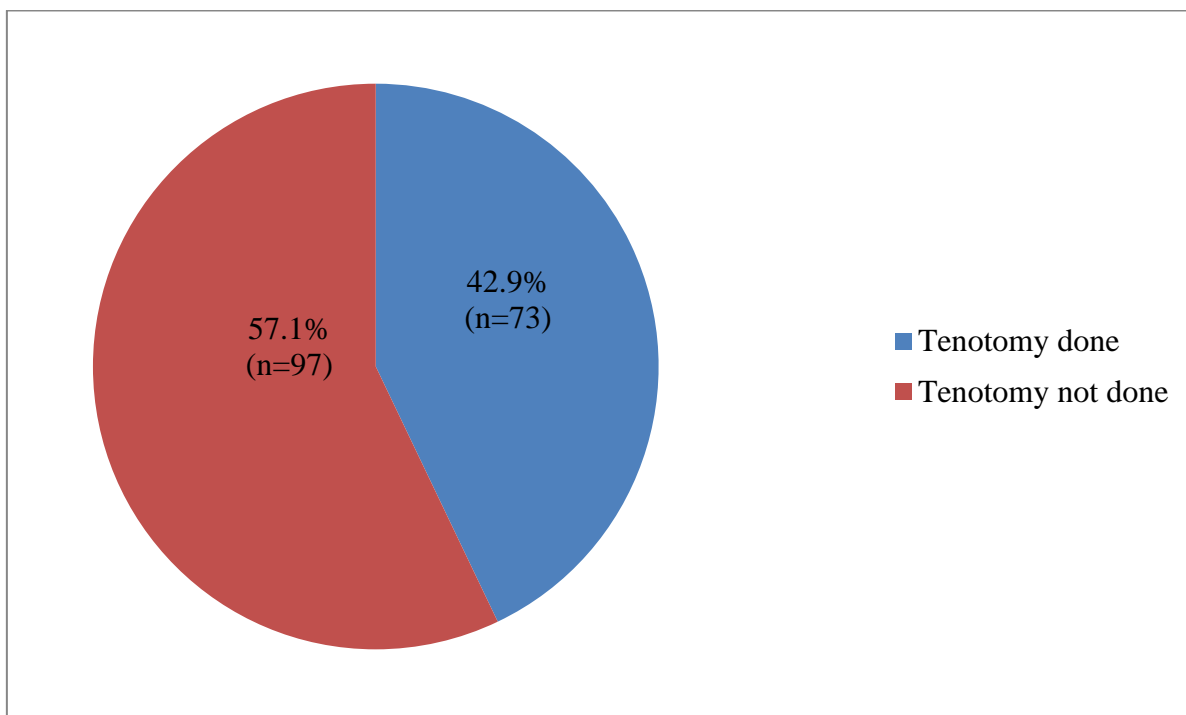
**Figure 4: Distribution of sample by Complications**

During manipulation and casting 162 (95.3%) had no complications, while 8( 4.7%) did, distributed as follows 6 (3.5%) swelling, 1 (0.6%) skin breakdown and 1 (0.6%) as well with skin infection as in the form of pustules (Fig 4).

### **Treatment outcome**

All patients except one attained correction by manipulation and casting of which 57.1% required percutaneous Achilles tendon tenotomy, before the final cast to correct residual

equinous, ready for the next stage of treatment, fitting of the Steenbeek foot abduction brace. One child did not get adequate correction of the deformity with manipulation and casting hence required further extensive soft tissue release beyond Achilles tendon lengthening (Fig 5).



**Figure 5: Distribution of Tenotomies done**

Overall 99.4% had successful treatment with the Ponseti method with 0.6% failure rate. The association among different age categories and outcome was statistically significant favouring the younger age groups (table 4).

**Table 4. Association between the age of onset of treatment and the success of the Ponseti treatment.**

	Success (%)	Failure (%)	Total
Age (months)			
0-6	129 (100)	0 (0)	123
7-12	26 (100)	0 (0)	26
13-18	7 (100)	0 (0)	7
19-24	2 (100)	0 (0)	2
25 and above	5 (83.3)	1(16.7)	6
<b>Total</b>	<b>169(99.4)</b>	<b>1(0.6)</b>	<b>170</b>

**P value 0.047**

**Table 5: Number of casts to correction**

Variable	1-5 Casts N (%)	6-10 Casts N (%)	>10 Casts N (%)	P-Value
<b>Age group (Months)</b>				
0 – 6	104(80.6)	25(19.4)	0(0)	
7 – 12	19(73.1)	7(26.9)	0(0)	
13 - 18	5(71.4)	2(26.9)	0(0)	
19 – 24	2(100)	0(0)	0(0)	
25 and above	1(16.7)	4(66.6)	1(16.7)	0.006
<b>MILD</b>				
<b>Age group (Months)</b>				
0 – 6	23(100)	0(0)	0(0)	
7 – 12	4(100)	0(0)	0(0)	
13 - 18	2(100)	0(0)	0(0)	
25 and above	1(50)	1(50)	0(0)	0.129
<b>MODERATE</b>				
<b>Age group (Months)</b>				
0 – 6	17(89.5)	2(10.5)	0(0)	
7 – 12	3(100)	0(0)	0(0)	
13 - 18	1(50)	1(50)	0(0)	0.268
<b>SEVERE</b>				
<b>Age group (Months)</b>				
0 – 6	64(73.6)	23(26.4)	0(0)	
7 – 12	12(63.2)	3(36.8)	0(0)	
13 - 18	2(66.7)	1(33.3)	0(0)	
19 – 24	2(100)	0(0)	0(0)	
25 and above	0(0)	3(75.0)	1(25.0)	0.010

On average 5 (SD2) series of manipulation and casting were done during Ponseti treatment, ranging from two casts to eleven cast. The majority of patients who attained correction with the least number of manipulation and casting fell in the youngest age group, 80.6%. Patients of, 25 months old and above required more than five manipulations and casting 66.6%. There was a statistically significant association between the age at initial treatment and the number of manipulations and casting required to attain correction before proceeding to foot abduction bracing (Table 5).

With respect to severity of the deformities there was no significant association in number of castings among different age groups in patients who had mild or moderate number of manipulation and casting but the difference noted was significant in patients with severe clubfoot P value 0.010 (Table 5).

## CHAPTER FOUR

### 4.0. DISCUSSION

In this study 170 patients with CTEV attending clinic at MOI, paediatric orthopaedic unit and CCBRT, clubfoot clinic were observed. In total 250 feet were treated. The male to female ratio was 1.6:1. Patients with bilateral clubfeet were 47.1%, 27.1% right and 25.8% had left clubfeet.

Lavy et al found similar results, male patients were more than female patients, in his study males were twice more susceptible than female patient and 50% of cases were bilateral (40). Yamamoto observed a male to female ratio of 2:1 with equal numbers of unilateral and bilateral deformities (46). Mkandawire and Kaunda revealed a male to female ratio of 1.3:1, on the contrary 73% had bilateral deformities and among the unilateral right foot was more affected 71%. All these authors found a male preponderance to clubfeet.

The age of patients seen in this study ranged from 1 week to 48 months. 75.9% of the children presented at the age of six months or less, 24.1% were above six months. The oldest child was 48 months old. Tindal and others in their study in Malawi had an age distribution of 25% ranging from 18-48 months old, similar to this study the oldest child seen was 48 months old (54). The study Arkan and his colleagues conducted in Tikrit, Iraq, had 35 cases distributed in the range of less than 2 months, to 4-6 months (57). Alves et al had retrospectively, studied two groups one presented below six months and the other above six months the youngest was one day old and oldest 31 months old, total of 68 children (60). The variability in age group distribution in all these studies supports the fact that a specific age cut off point for optimal results is still not clear (60).

In this study the Pirani score, evaluation system was used to monitor progress of the Ponseti treatment. The majority of children 67.7% had severe clubfoot at presentation. It was found that there was good progress, depicted by changes in the Pirani score to lower values as they continued with weekly manipulation and casting. The Pirani score is a reliable and validated evaluation system (48), and has been described as a simple, easy to



use tool for severity assessment of clubfoot at presentation and progress monitoring (38). Dyer and David showed in the study its predictive ability for treatment outcomes with the Ponseti method, observing that a higher Pirani score indicated that a higher number of cast will be required (49). Although the predictive ability of the Pirani scores in Ponseti treatment outcome was not the primary focus of the current study it was found that the trend in scores in evaluating progress during treatment by third week correlated with age of the patient. The children above 25months progress were slower compared to the children below that age.

Ponseti treatment has been documented to be an effective treatment modality in clubfoot. The overall treatment success rate observed in this study was 99.4%. 57.1% required Achilles tendon tenotomy and one patient in which the Ponseti method failed went on to requiring extensive soft tissue release. Similarly higher success rates with this mode of treatment have been documented by several authors (51–55).

Despite the success rate reported with Ponseti technique the question of influence of age at initial treatment on the success is still debateable among different authors. It has been documented that treatment should start immediately after birth for optimal results (27).

The treatment success rate in children below 25months was 100% these were 164 children with clubfeet and 83.3% of six children aged 25 months and above. Arkan et al(57) had 100% success rate in children less than two months in keeping in with the current study, proving the earlier the treatment the higher the success rate. On the other hand had a higher failure rate 50% in children 4-6months of age in contrast with the current study where success rate was still 100%. The failure rate in the study by Arkan and colleagues was attributed to experience factor and these were patients reported to have been seen early at the beginning of the study (57).

To further support the current study, Lehman et al observed patients treated early before seven months of age had a 92% success rate on early follow up after casting (55). It was

consistent with the current study that high success rate was eminent with treatment initiated at age seven months and below.

On the other hand the effect of age has been proved not to have any influence on treatment outcome by other authors hence contradicting the findings of this study, Bor et al, had two different studies in younger infants and older infants above 3months, which showed similar rates of the need for extensive soft tissue release 2.9%, 2.8% respectively.(58) Lourenco et al found successful treatment in children 1.2-9 years old with no extensive soft tissue release needed (59). This could be attributed to the modifications done with the traditional Ponseti treatment in the latter cited study. Similarly Alves et al observed that age at the beginning of treatment did not seem to influence the final outcome and cut off age for successful treatment not yet defined (60).

Despite that overall success rate was still higher, the number of manipulations and casts varied in children presenting younger and those older. Given that the manipulations are done weekly this meant to reflect longer duration in different age groups. This study observed a mean number of 5 casts ranging from 2-11 casts. Out of the six children 25 months and above five (83.3%) required more than five manipulations and casts while (20.8%) of children who were below that age. Tindall et al had a mean number of 5.3 manipulations though his study does not show the number variations in older children after walking age (54).

Arkan et al reported a frequency of 5-6 castings with two patients requiring more than seven casts the age group of his study population was limited to six months compared this study and didn't show the frequency in different age groups (57).

Alves et al reported different findings from the current study children less than six months mean casts of 5.3 ranging from 4-8 casts whereas above six months had a mean cast of 4.3 with a range of 3-7 casts. Hence the conclusion derived from that study, age did not influence treatment outcome(60).

## CHAPTER FIVE

### 5.0. CONCLUSION

**This study observed most children with clubfoot starting treatment at younger age, as young as one week old with a few patients with neglected clubfoot. Majority resided in the coastal zone of Tanzania, the significance of this is yet to be determined, could be because the zone has most regions or rather the close vicinity to major clubfoot treatment centers which are within the coastal zone.**

This study showed high success rate with the Ponseti treatment method. This method of treatment was successful even in children above two years (88.3%) of age.

Good progress was achieved with fewer manipulations and cast in majority (79.2%) of children below 25 months compared to children above 25months. One child out of six children who were above 25months of age needed extensive soft tissue release to correct the deformity and this child was 48months old.

Older children above 25 months can be treated with Ponseti method and attain correction but at a rate slower than the younger children. However there is a chance of failure to correction.

## **5.1. RECOMMENDATIONS**

- **Children below 48months presenting with clubfoot should commence with Ponseti method of treatment.**
- **A campaign creating awareness encouraging parents to bring in children for treatment early be devised with the benefit of achieving early correction.**
- **The Pirani score continue to be used as an assessment tool for monitoring progress, for its simplicity.**
- **Further studies are warranted to look into treatment outcome in the children above 48months on a long-term basis.**

## **5.2. LIMITATIONS**

There are few studies looking into the influence of age at presentation on the treatment outcome with the Ponseti treatment. Some look into the treatment outcome with neglected clubfoot others the age distributions are vastly variable from one study to another to be able to compare with this study.

Due to the available time given to conduct this study, long-term treatment follow up was not feasible given treatment of clubfoot goes upto four years and even beyond. Most studies cited were on long-term basis and took into account other factors affecting treatment such as compliance to treatment and rate of recurrence.

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## APPENDICES

### Appendix I: Consent Form (English Version)

My name is **Dr. Jokha Yusuf Aliy** from Muhimbili University of Health and Allied Sciences. I am conducting a research study on congenital talipes equinovarus. This study has been approved by the MUHAS Ethics and Research Committee and MOI.

**Purpose of the Study:** is to assess the effect of age at initial management with the Ponseti method on short term outcome among patients with CTEV.

**What participation involves:** If you agree to participate in this study, you will be asked a series of questions your child will then be examined then proceed to treatment using Ponseti technique then evaluated weekly using the Pirani score. This is not a new treatment method but the standard treatment for the management of congenital clubfoot. If you do not agree your child will receive equal treatment.

**Confidentiality:** All information collected will be entered into computer with only an identification number; no names included.

**Risk:** We expect no harm to happen to you during the course of this study.

**Rights to withdraw:** Taking part in this study is completely voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated and followed up as per the usual treatment protocol of the Institute for all patients with congenital clubfoot.

**Benefits:** If you agree to participate in this study, you will be followed-up closely and be assessed on the progress of your condition by the investigating doctor. We hope that the obtained information from this study will benefit others.

**Who to contact:** If you have any other questions regarding this study, feel free to contact me, the investigator, Dr. Jokha Yusuf Aliy, Muhimbili Orthopaedic Institute, P.O. Box 65474, Mobile number 0713722012, Dar es Salaam.

If you have any questions concerning your rights as a participant, you may contact Prof. M. Moshi, Chairman of the Research and Publication Committee, P.O. Box 65001, Dar es salaam. Telephone: 2150302/6.

**Signature**

Do you agree to participate? .....

Participant does not agree.....

I, .....have read the consent form and my questions have been answered and I agree to participate in this study.

Signature of Participant.....

Signature of Investigator.....

Date of signed consent.....

**Appendix II: Consent form (Swahili Version)**

Jina langu ni Dr. Jokha Yusuf Aliy. Nimepata ruhusa ya kufanya utafiti huu kutoka, Kamati ya Utafiti na Maadili ya Chuo Kikuu cha Tiba Muhimbili na pia kutoka kwa uongozi wa Taasisi ya Tiba ya Mifupa Muhimbili.

**Dhumuni la utafiti huu:** Kuangalia uhusiano wa umri mtoto anapoanza matibabu juu ya matokeo ya matibabu ya watoto wanaozaliwa na ulemavu wa clubfoot kwa njia ya Ponseti katika Taasisi ya Tiba Mifupa Muhimbili.

**Ushiriki:** Kama unakubali kushiriki kwenye utafiti huu, utaulizwa maswali, mtoto atachunguzwa kwa kina na kuanza matibabu kwa njia ya Ponseti kama ilivo protokali ya tiba ya viguu virungu na atafuatiliwa ipasavyo kutumia Pirani score. Nakuhakishia hii njia ya Ponseti sio tiba ngeni na ndio inayotumika kwa matibabu ya ulemavu huu. Iwapo hutakubali kushiriki mtoto atapata tiba vilevile inavyopaswa.

**Usiri:** Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya utambulisho; jina halitanukuliwa.

**Madhara:** Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu

**Haki ya kujitoa kwenye utafiti:** Kushiriki katika utafiti huu ni hiari, na kutokubali kushiriki au kujitoa hautaadhibiwa au kupoteza haki yako ya matibabu. Utatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza kwa mtoto mwenye ulemavu wa viguu virungu.

**Faida ya kushiriki kwenye utafiti:** Kama utakubali kushiriki kwenye utafiti huu, Faida utakazopata ni pamoja na kuonwa na kufuatiliwa kwa ukaribu na daktari anayefanya utafiti. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wengine pia.

**Kwa mawasiliano zaidi:** Kama una maswali or maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, Dr. Jokha Yusuf Aliy, Muhimbili Orthopaedic Institute, P.O. Box 65474, simu: 0713722012 DSM. Kama una maswali kuhusu haki yako kama mshiriki

wasiliana na Prof. M. Moshi, Mwenyekiti wa kamati ya utafiti, P.O. Box 65001, DSM.  
Simu 2150302/6.

**Saini:**

Je, umekubali kushiriki? .....

Mshiriki hajakubali kushiriki .....

Mimi.....nimesoma maelezo na  
kuyaelewa vizuri, na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki.....

Sahihi ya Mtafiti.....

Tarehe .....

**Appendix III: Questionnaire**

**Title: Effect of age at presentation on short term outcome of the Ponseti method in the management of Congenital Talipes Equinovarus.**

**Demographics**

Date.....

1. IP number.....
2. Date of birth.....
3. Place of birth
  - a) Hospital
  - b) Health centre
  - c) Home
4. Sex      a) F       b) M
5. Physical address .....
6. Mothers initials.....
7. Telephone number.....
8. Tribe
9. Occupation
  - a) Peasant
  - b) Business
  - c) Formal employment
  - d) Casual labourer
  - e) Unemployed
  - f) Unknown
10. Level of education
  - a) Primary
  - b) Secondary
  - c) Higher education
  - d) None
  - e) Unknown
11. Fathers initials.....



12. Telephone number.....

13. Tribe.....

14. Level of education

- a) Primary
- b) Secondary
- c) Higher education
- d) None
- e) Unknown

15. Occupation

- a) Peasant
- b) Business
- c) Formal employment
- d) Casual labourer
- e) Unemployed
- f) Unknown

**PIRANI SCORING SHEET**

DATE																				
Side	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L
A.curve of lateral border																				
B.medial crease																				
C. talar head																				
<b>Midfoot score</b>																				
D.posterior crease																				
E.equinus rigidity																				
F.empty heel																				
<b>Hindfoot score</b>																				
<b>Total</b>																				
<b>Complications</b> Y/N																				
<b>Treatment</b>																				

Treatment code: **M** manipulate **C** cast **T** tenotomy **B** brace **O** others (describe)

Complications:

Clinical examination (check if normal describe if abnormal)

Head and neck    Upper limbs    Spine    Lower limbs

Describe.....

Consent given Yes    No

Diagnosis    CTEV    , Syndromic Talipes , Positional Talipes , Normal , O

