CLINICAL OUTCOMES OF CASTING PHASE OF PONSETI METHOD FOR CORRECTION OF IDIOPATHIC TALIPES EQUINOVARUS AT THE KENYATTA NATIONAL HOSPITAL

DR. OCHOLA JAMES ONDIEGE

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A Dissertation submitted in partial fulfilment of the requirements for the award of the Degree of Master of Medicine in Orthopedic Surgery at the University of Nairobi.

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DECLARATION

This dissertation is my original work and has not been presented for a degree at any other university.

Sign _____ Date 30TH NOVEMBER 2021

Dr. Ochola James Ondiege

Registration Number: H58/68967/2013

M. Med Registrar, Department of Orthopedic Surgery

University of Nairobi.

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CERTIFICATE OF SUPERVISION

This dissertation is being submitted with our approval as university supervisors:

1. J.A.O MULIMBA

   CONSULTANT ORTHOPEDIC AND TRAUMA SURGEON

   PROFESSOR, DEPARTMENT OF ORTHOPEDIC SURGERY

   UNIVERSITY OF NAIROBI

   prof-jao@uhmc.co.ke

Sign _____ Date 30.11.2021.

2. G.K. MUSEVE

   CONSULTANT ORTHOPEDIC AND TRAUMA SURGEON

   SENIOR LECTURER, DEPARTMENT OF ORTHOPEDIC SURGERY

   UNIVERSITY OF NAIROBI

   gkmuseve@gmail.com

Sign _____ Date 30/11/2021

iii

DEPARTMENT APPROVAL

This is to certify that this is the original work of Dr. Ochola James Ondiege, a Master of Medicine in Orthopedic Surgery student at the University of Nairobi. This research will be carried out at the Kenyatta National hospital.

This dissertation proposal is hereby submitted with approval of the chairman.

V.M. MUTISO

CONSULTANT ORTHOPEDIC AND TRAUMA SURGEON

SENIOR LECTURER AND CHAIRMAN, DEPARTMENT OF ORTHOPEDIC SURGERY,

UNIVERSITY OF NAIROBI,

mutisovm@yahoo.com

DEPT OF ORTHOPAEDIC SURGERY
COLLEGE OF HEALTH SCIENCES
P. O. BOX 19676 - 00200 KNH
NAIROBI
TEL: 2720940 / 2726300, Ext. 43590

Sign _____ Date 30th Nov 2024.

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DEDICATION

I dedicate this work to my late parents, Patrick Ochola and Jennifer Nyanjom, for nurturing me, to my brother Andrew Weda for his unwavering support, to my boys Patrick and AJ.

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LIST OF ABBREVIATIONS

CTEV- Congenital Talipes Equinovarus

CPU – Calcaneopedal unit

HOX – Homeobox Gene

KNH- Kenyatta National Hospital

LMICs- Low and Middle-Income Countries

PITX1- Paired Like homeodomain 1.

TBX4 – T Box Transcription factor 4

KNH/UoN-ERC – Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

OPERATIONAL DEFINITIONS

1. Dimeglio score - A classification system used to grade the severity of the initial deformity of clubfoot.
2. Pirani score - Refers to a scoring system used to determine severity and monitor progress in the assessment and treatment of clubfoot.
3. Short-term outcomes - Refers to measurable treatment results observed less than 30 days after the corrective procedure.
4. End of casting – maximum of 7 weeks.
5. Outcome – Pirani score at the end of casting.

ABSTRACT

Background: Congenital talipes equinovarus (CTEV) also known as clubfoot, is a common musculoskeletal deformity at birth, affecting about 1-2 babies per 1000 live births, most of whom are born in low and middle-income countries. Treatment modalities for clubfoot involve nonsurgical and/or surgical interventions. Ponseti technique is the preferred intervention for nonsurgical management of clubfoot at Kenyatta National Hospital. Despite the global preference for this treatment technique, there is general paucity of data on clinical outcomes of this procedure in LMIC countries, especially in Sub-Saharan Africa. This study seeks to evaluate the clinical outcomes of the casting phase of the Ponseti method in this setting.

Study objective: To evaluate the outcome of the casting phase of the Ponseti method for clubfoot correction at Kenyatta National Hospital (KNH).

Study design: A retrospective cross-sectional study.

Patients and methods: Records of patients aged 24 months and below diagnosed and treated for idiopathic clubfoot were retrieved. Data was extracted, coded, and entered into the Statistical Package for Social Sciences (SPSS) (IBM Statistics Software Version 26, Armonk, New York, USA) for analysis. Prism 8 (GraphPad Software, San Diego, CA, USA) was used to generate graphs. Categorical data (clubfoot laterality, family history of clubfoot, tenotomy rate and complication rate) were reported as frequencies (%) while continuous data were reported as mean and standard deviation if it was normally distributed (pre-casting Pirani score, post-casting Pirani score and duration of casting), or as median and interquartile range (IQR) for data that was not normally distributed (age). Comparison of continuous outcomes between males and females was performed using the Mann-Whitney U Test (for data that was not normally distributed e.g., age) and the Independent Student's t-test (for data that was normally distributed). Comparison of categorical variables was performed using the Chi-square

statistic. Pearson's test was used to for correlation of continuous variables. Throughout the analysis, a p-value of <0.05 was considered significant at a 95% confidence interval. The results are presented as tables and graphs.

Results: A total of 68 records were retrieved. Only 63 had complete data and were therefore included in the final analysis. The median age at time of diagnosis was 0.46 months (IQR 0.2-1.5), and majority of them were males (M:F ratio 1.74:1). Slightly more than half of the patients had bilateral CTEV (50.8%), and a quarter (25.4%) had a positive family history. The mean pre-casting Pirani score was 3.8±1.8. The mean duration of Ponseti casting was 4.5 weeks (SD=1.9), and it positively correlated with age (p=0.026) and pre-casting score (p<0.001). The mean Ponseti score significantly reduced following casting phase from 3.7±1.8 (pre-casting score) to 0.2±0.7 (post-casting score) (mean difference= 3.5, p<0.001). The post-casting Ponseti score positively correlated with age (p<0.001). Tenotomy was performed in 14 patients (22.2%) after casting. Patients requiring a tenotomy tended to be older (3.3±4.7 vs 0.7±0.9 weeks; p<0.001) and had a higher pre-casting Pirani score (4.8±1.7 vs 3.5±1.7, p=0.006). A total of 6 patients (9.5%) developed complications following Ponseti casting. These complications included limb swelling (4 cases) and cast sore (2 patients).

Conclusion: Ponseti casting is an effective treatment technique for congenital talipes equinovarus, with minimal complication rate.

CHAPTER 1: INTRODUCTION

1.1 Introduction

Talipes equinovarus, also termed clubfoot, is a common developmental disorder of the lower limb. This disorder occurs in varying severity. The idiopathic variant, which is congenital, is particularly more common and is present at birth (1). There is general paucity of data on its etiology with both genetic and environment factors postulated (2). Due to its complexity, its treatment is sometimes associated with a variety of problems, and despite novel advances in its management, disability is often inevitable. Most affected children in low and middle-income countries (LMICs) often experience 'neglected' clubfoot after lacking treatment. This may be due to poor socio-economic status and health seeking behavior from the parents. This often leads to long term complications such as pain, immobility, and implications such as societal stigma, making it almost impossible to live a normal life (3).

The Ponseti treatment method which involves conservative techniques for management of clubfoot has increasingly gained popularity over the last two decades. This is because the technique is relatively non-invasive and records great short-term and long-term outcomes as reported by most authors. As such, it is widely regarded as the 'gold-standard' technique of clubfoot management (4). It involves serial manipulations, placement of casts, percutaneous Achilles' tendon tenotomy and subsequently the patient placed into a foot abduction orthosis (1).

Despite the global acceptance of the Ponseti method as the preferred treatment technique of clubfoot, there is general paucity of data locally on its clinical outcomes. This data would inform orthopedic specialists to make informed management decisions.

1.2 PROBLEM STATEMENT

Clubfoot is a common medical condition which if untreated, results in significant morbidity. Ponseti method of correction for clubfoot has shown to be effective and thus early diagnosis and prompt management beneficial to affected individuals. There is general paucity of data in KNH on the clinical outcomes of Ponseti method and this study sets out to determine the efficacy and complications of this method.

1.3 STUDY QUESTION

What is the clinical outcome of the casting phase in Ponseti method for clubfoot correction at KNH?

1.4 OBJECTIVES

1.4.1 Broad objective

To evaluate the outcome of the casting phase of Ponseti method for clubfoot correction in KNH

1.4.2 Specific objectives

1. To determine the duration of casting, and its relationship with age, sex and pre-casting Pirani score
2. To determine the changes in the Pirani score following Ponseti casting and its relationship with age and sex
3. To determine the tenotomy rates following casting, and its relationship with age, sex and pre-casting Pirani score
4. To determine complications rate during casting

1.5 STUDY JUSTIFICATION

A gap exists in local setup - KNH - in the understanding of the outcomes of the casting phase of Ponseti method. The study will evaluate the outcome following the casting phase of the Ponseti method. This data will aid fill the knowledge gap existing in available literature. The study will also enable identification of areas that can be improved in initial management, and thereafter follow-up of the patients seen with clubfoot at KNH. Due to the ever-increasing bias by healthcare practitioners towards evidence-based medicine, this data will also be pivotal in helping orthopedic specialists have a wide knowledge base for informed decision-making.

CHAPTER 2: LITERATURE REVIEW

2.1 Congenital talipes equinovarus: Incidence, embryological basis, pathophysiology, and management

2.1.1 Embryological Basis

CTEV is widely considered the most common musculoskeletal congenital deformity in children. In this deformity, the foot is usually fixed in adduction, supination and in varus.

Most other authors describe 4 components of foot deformities: hind-foot equinus, hind-foot varus, mid-foot cavus, and adduction of the fore-foot (5,6). The hind-foot equinus and varus are due to tight tibialis posterior and tendoachilles. The mid-foot cavus is due to tight flexor hallucis longus, flexor digitorum longus and intrinsic muscles. Fore-foot adduction is caused by a tight tibialis posterior tendon (7).

Calcaneopedal coupling may explain the deformities around CTEV (8). The calcaneopedal unit (CPU) comprises of the calcaneus, mid-foot and fore foot which are bound by ligaments that articulate with the talus. It is deformable and able to physiologically adapt to many situations while standing, in order to achieve the foot in plantigrade position.

Adduction and equinus of the CPU results in hind-foot varus (9,10). Fore-foot adduction with equinus, produces fore-foot pronation in relation to the hind-foot (11,12,13). The triceps surae and tibialis posterior produce a coupling force which when unopposed by the weak peroneals, leads to inversion (downward and medial rotation of the CPU) and adduction-pronation of the forefoot. Retracted soft tissues maintain locking of the foot in adduction of the CPU and maintain the fore-foot adduction (9). This resultant deformity changes the action of the tibialis anterior from a dorsiflexor to a supinator-elevator of the first ray.

The tarsal bones: calcaneus, cuboid and navicular bones are rotated medially in relation to the talus, assuming a position of adduction and inversion (14). They are reinforced in this position by soft tissue

structures, ligaments, and tendons. The cavus position is due to the fore parts of the foot pronating in relation to the hind.

Figure 1: Talipes equinovarus

CTEV is defined as ‘syndromic’ when it occurs concurrently with other deformities, usually due to a genetic defect. Idiopathic, ‘non-syndromic' CTEV is usually when it occurs as a single deformity in the lower extremities only (1).

2.1.2 Incidence

The incidence of CTEV varies with geographical location. Studies from European and American populations estimate the incidence as 1-2 per 1000 live births (15). Similar studies in the Asian communities place the incidence at a lower estimate of 0.39 per 1000 live births (16). A study conducted in Uganda estimated the incidence at 1.2 per 1000 live births (17). The highest prevalence in current literature is among the Hawaiians and Maoris (Polynesian ethnicity) where the incidence is reported to be up to 7 per 1000 live births (18). Most studies show a gender distribution of 2:1 male-to-female distribution of the cases (19).

2.1.3 Pathophysiology

The etiology as well as pathophysiology of CTEV remains unclear. Syndromic clubfoot appears to be associated with either neuromuscular or purely neurological anomalies such as spina bifida or muscular atrophy (20). Generally, CTEV is considered a multifactorial disorder with both genetic and environmental factors implicated (21). A recent systematic review of clinical evidence of genetic, demographic, and environmental risk factors involvement in clubfoot concluded that family history was the biggest independent risk factor with first degree relatives more likely to be affected compared to second degree relatives (2). This is further supported by a twin study that showed a concordance rate higher for monozygotic twins when compared to dizygotic twins (33 to 3%) (22). According to a few genetic studies, this is probably attributable to defects in proteins and genes such as HOX (specifying characteristics of position), TBX4 (T-box; role in development of hind limb), and PITX1 (limb patterning) (23). From the systematic review, the other clinically relevant risk factors noted were amniocentesis (24), maternal smoking (20,25, 26), maternal diabetes as well as selective serotonin reuptake inhibitors (2). These findings are supported by a similar meta-analysis (27).

Histological theories authored include primary germ plasm defect, dysmorphic talar neck angle and navicular subluxation (6), cartilage defects (28), increased collagen synthesis (29) - retraction fibrosis of the distal muscles of the calf and supporting connective tissue. Increase in fibroblastic cells and collagen fibers in tendons and ligaments of clubfoot (30). Other anatomical theories in literature include anomalous muscles in 15% of patients (31,32) and hypoplasia of the anterior tibial artery (33).

2.1.4 Grading and scoring

It is worthwhile noting that clubfoot patients are often classified by grading systems that eventually determine the type and degree of intervention to be administered. A few other classification methods have been developed to evaluate the outcome of the interventions (34). While there is no universally accepted classification system, the Dimeglio (35) and Pirani (36) assessment scores are used by most investigators. The Pirani score is from 0 to 6, where zero is a normal foot, and six is the most severe

deformity while the Dimeglio score has a maximum of 20 points with the deformity being graded as benign, moderate, severe, or very severe (37).

2.1.5 Management

The clinical management of clubfoot is controversial and is a big challenge in pediatric orthopedics. This may be due in part to the difficulty in comparing how effective different treatment methods are. The ultimate goal is to maintain long-term correction of the deformity, with the individual having a pain-free, functional foot.

The treatment options can be either surgical or non-surgical. Surgical interventions involve reduction and division of structures that cause tightness or stiffness. Non-surgical or conservative management involves stretching of tight structures in the foot allowing time for remodeling of soft tissues and realignment of the bones. In LMICs, the 'Ponseti' technique is described as the 'gold standard' of treatment of this condition (5).

2.2 The Ponseti Method and Pirani Scoring System

2.2.1 The Ponseti Method

The Ponseti technique, which was practiced at the University of Iowa as early as 1948, was not widely employed until recent times. Dr. Ignacio Ponseti, who developed the technique, had found that many patients treated with extensive surgeries for this condition had weak, rigid, and painful feet at long-term follow-up.

There are two phases of treatment, manipulation and casting, and maintenance phases. The casting phase involves serial manipulation, and casting of the limb and in some cases, an Achilles' tendon tenotomy. The maintenance phase then involves bracing the foot to maintain correction (19).

The basis of the Ponseti technique is the material properties of the osteoligamentous structures in the foot. During the manipulation-casting series, the ankle ligaments and tendons undergo sequential stress relaxations. This stretch caused by manipulation aims to produce sufficient plastic deformation. In response to this stretching, the extracellular matrix is remodeled and tissue growth and or lengthening occur.

Sequential stress relaxation helps achieve a higher final strain and thus a corrected foot, which is otherwise not possible with a single stretch. This is due to tissues adapting to strain during immobilization when in the cast.

Owing to the viscoelastic properties of the tendons and ligaments, the initial strain size, loading, and strain rate affect the relaxation behavior and mechanical strength of the tissue. Manipulations should be performed as slow as possible by decreasing the size of the strain step and interval of casting and/or increasing the overall number of casts. This produces a lower overall strain rate profile providing more tensile stimuli, allowing more time for remodeling, and preserving the mechanical integrity of the soft tissues (38).

The first step involves cavus correction and is achieved by supinating the forefoot and dorsiflexion of the first metatarsal. The next step is usually correction of varus and adduction. The second cast is placed after gradually abducting the forefoot around the head of the talus. This also everts the talus, correcting the varus. After the fourth cast, the deformity left is usually equinus and this is corrected by casting the affected foot with concomitant and progressive dorsiflexion.

Depending on the rigidity of the equinus and ability to dorsiflex to about 10 degrees (needed for stance phase of the gait cycle), percutaneous Achilles' tendon tenotomy procedure under local anesthesia may be indicated. A hind-foot score of less than 3 may require the procedure as long as the mid-foot score is less than 0.5 (15).

Figure 2: Cast series and foot appearance.

2.2.2 Pirani Scoring system

The Pirani system is generally used to assess treatment response, based on the deformities of hind-foot and mid-foot. In each group, a total of three deformities are assessed. One point is scored if deformity is present and fixed, a half a point if present and mild, and zero if deformity is absent. A total score of six indicates severity while a score of zero represents a normal foot (39).

Deformity	Present and fixed (1)	Mild (0.5)	Absent (0)
Hind-foot deformities			
Posterior heel crease	1	0.5	0
Empty heel	1	0.5	0
Rigidity of equinus	1	0.5	0
Mid-foot deformities			
Curvature of lateral border of foot	1	0.5	0
Medial crease	1	0.5	0
Lateral head of talus	1	0.5	0
Total score			

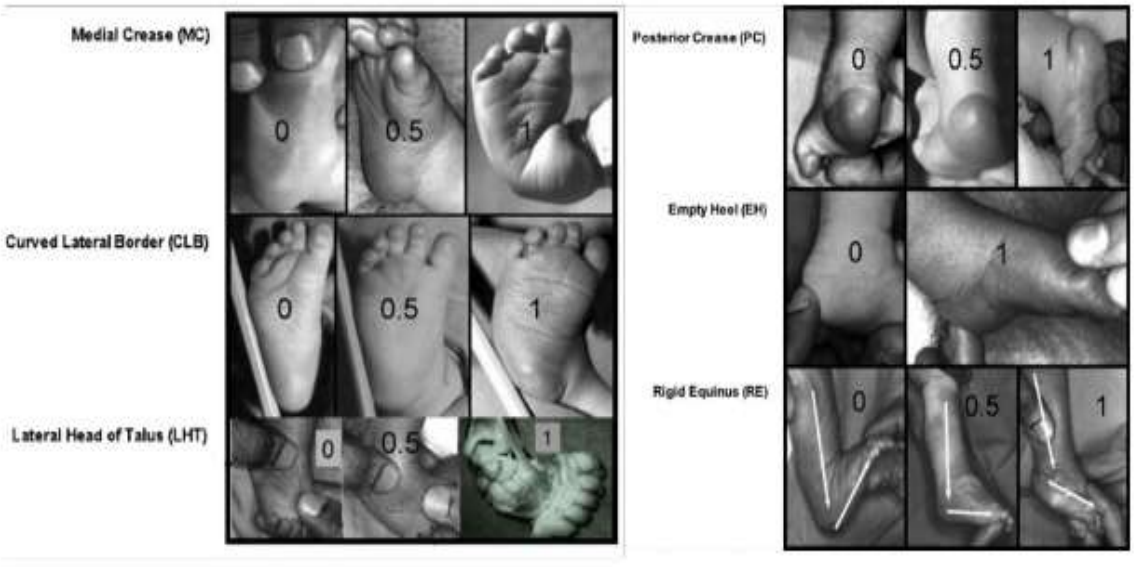

Figure 3: A chart and image showing the Pirani classification system. (48)

This study set out to evaluate the outcome of the casting phase of this method for clubfoot correction. The duration of casting, changes in Pirani score, tenotomy rates and complications during casting were determined. Studies have been carried out to correlate Dimeglio and Pirani scores with number of cast applications required (40) and comparing both scores in predicting number of applied casts and the need for tenotomy (41). Number of castings was determined by severity of clubfoot but not by weight and age of patients (42). However, some studies yielded significance in initial Pirani score and age (43), and recurrence higher in patients who started Ponseti later than 2 weeks (44).

A study conducted by Kinyanjui et al (44) sought to address the factors associated with relapse after Ponseti treatment. The study included children who had completed the casting phase of treatment and had been on a brace for at least one year (bracing phase). They did not however look at the procedure for casting phase and its outcomes. One of their limitations was a lack of initial Pirani score, which this study looks to address.

Ponseti technique has also been shown to be effective in correction of neglected clubfoot cases, reducing need for extensive surgery in correction of the deformities (45).

The procedure can be performed by trained orthopedic clinical officers and technologists with effective outcomes (46).

CHAPTER 3: METHODOLOGY

3.1 Study design

Retrospective cross-sectional study.

3.2 Study setting

Kenyatta National Hospital, the largest teaching and referral hospital in Kenya.

The study was conducted at the pediatric clubfoot clinic, one of the Orthopedic clinics run in the institution. The clinic sees approximately 100 children per year presenting with clubfoot.

3.3 Study population

Children 24 months of age and below who have undergone casting phase of Ponseti method formed the study population.

3.4 Source of data

Children who have undergone Ponseti method of management for clubfoot at KNH

3.5 Sample size estimation

Sample size calculation was done using the Charan and Biswas (2013) formula:

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = estimated proportion of an attribute present in the population (From a previous study, relapse was observed in 4.6% of subjects (47).

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.046(1-0.046)}{0.05^2} = 68$$

Therefore, the target sample size for this study was **68** patients.

3.6 Inclusion criteria

Children who were diagnosed with idiopathic clubfoot presenting to the clubfoot clinic.

Children aged 24 months and less with unilateral or bilateral clubfoot.

3.7 Exclusion criteria

Children with non-idiopathic (as seen in genetic syndromes, teratological anomalies and myopathies), and acquired established causes of clubfoot (neurogenic e.g., sciatic nerve damage, poliomyelitis, meningitis, and vascular e.g., Volkmann Ischemic Paralysis).

3.8 Study variables

The variables evaluated in this study include age, specific indication for Ponseti method procedure, tenotomy rates after casting, duration of casting, and complications resulting from the procedure (swelling, cast sores, crush heel, uncorrected foot and compartment syndrome).

3.9 Screening and recruitment

Data were collected by trained assistants on patients already screened for, and the Ponseti technique performed on for management of idiopathic clubfoot. Patients meeting the inclusion criteria were included. Consent was sought from the department records office to conduct the study.

3.10 Procedures

Data was obtained through scrutiny of records retrieved from the department records system upon approval and clearance from the department in-charge. The data included age, residence, gender, family history of disease or anomalies, pre-casting Pirani scores, duration of casting, tenotomy rates after casting, and complications following the procedure. The casting interval was one week, which was only altered in cases that had complications.

3.11 Ethical considerations

Approval to conduct the study was sought from the Department of Orthopedic Surgery, University of Nairobi as well as Kenyatta National Hospital, Ethics and Research Committee (KNH/UoN-ERC). Patients' names were not used to protect patients' privacy. All data obtained were always kept in the principal investigator's possession and subsequently entered into a password protected Microsoft Excel document after data coding.

3.12 Data analysis and presentation

Data was extracted, coded, and entered into the Statistical Package for Social Sciences (SPSS) (IBM Statistics Software Version 26, Armonk, New York, USA) for analysis. Prism 8 (GraphPad Software, San Diego, CA, USA) was used to generate graphs.

Categorical data (clubfoot laterality, family history of clubfoot, tenotomy rate and complication rate) were reported as frequencies (%) while continuous data were reported as mean and standard deviation if it was normally distributed (pre-casting Pirani score, post-casting Pirani score and duration of casting), or as median and interquartile range (IQR) for data that was not normally distributed (age).

Comparison of continuous outcomes between males and females was performed using the Mann-Whitney U Test (for data that was not normally distributed e.g., age) and the Independent Student's t-test (for data that was normally distributed).

Comparison of categorical variables was performed using the Chi-square statistic. Pearson's test was used to for correlation of continuous variables.

Throughout the analysis, a *p*-value of <0.05 was considered significant at a 95% confidence interval. The results are presented as tables and graphs.

4. CHAPTER FOUR

4.1 RESULTS

4.1.1 Patient characteristics

A total of 68 records were retrieved. Only 63 had complete data and were therefore included in the final analysis. The median age at time of diagnosis was 0.46 months (about 14 days) (IQR 0.2-1.5), and majority of them were males (M:F ratio 1.74:1). Slightly more than half of the patients had bilateral clubfoot (50.8%), while the rest had unilateral disease. Approximately a quarter (25.4%) of the patients had a family history of clubfoot. The mean pre-casting Pirani score was 3.7±1.8 (Table 4.1-1).

Variable		Male (n=40; 63.5%)	Female (n=23; 36.5%)	Total (n=63; 100%)	*p*-value*
Age (months) (Median, IQR)		0.4 (0.2-1.0)	1.0 (0.2-2.5)	0.5 (0.2-1.5)	0.315¶
Laterality	Unilateral	19 (47.5%)	12 (52.2%)	31 (49.2%)	0.797#
	Bilateral	21 (52.5%)	11 (47.8%)	32 (50.8%)	
Family history of club foot		12 (30%)	4 (17.4%)	16 (25.4%)	0.371#
Pre-casting Pirani score (Mean±SD)		3.9±1.8	3.5±1.8	3.7±1.8	0.633£
Duration of casting (Weeks)		4.5±1.9	4.5±2.0	4.5±1.9	0.463£
Tenotomy rate		8 (20%)	6 (26.1%)	14 (22.2%)	0.754#
Post-casting Pirani score (Mean±SD)		0.15±0.6	0.4±1.0	0.2±0.7	0.067£
Complication rate		4 (10%)	2 (8.7%)	6 (9.5%)	0.864#

*NB: *-the p-values are for male-female comparison. ¶- Mann-Whitney U Test, #- Chi-square test; £- Independent Student's t-test*

Table 4.1-1: Characteristics of the included patients

4.1.2 Duration of casting

The mean duration of Ponseti casting was 4.5 weeks (SD=1.9), with no significant differences between males and females (mean difference= 0 weeks, *p*=0.463) (Table 4.1-1). The duration of casting

positively correlated with age. (r=0.234 (95% CI 0.029-0.419); *p*=0.026) and pre-casting score (r=0.786 (95% CI 0.692-0.854); *p*<0.001) (Figure 4.1-2).

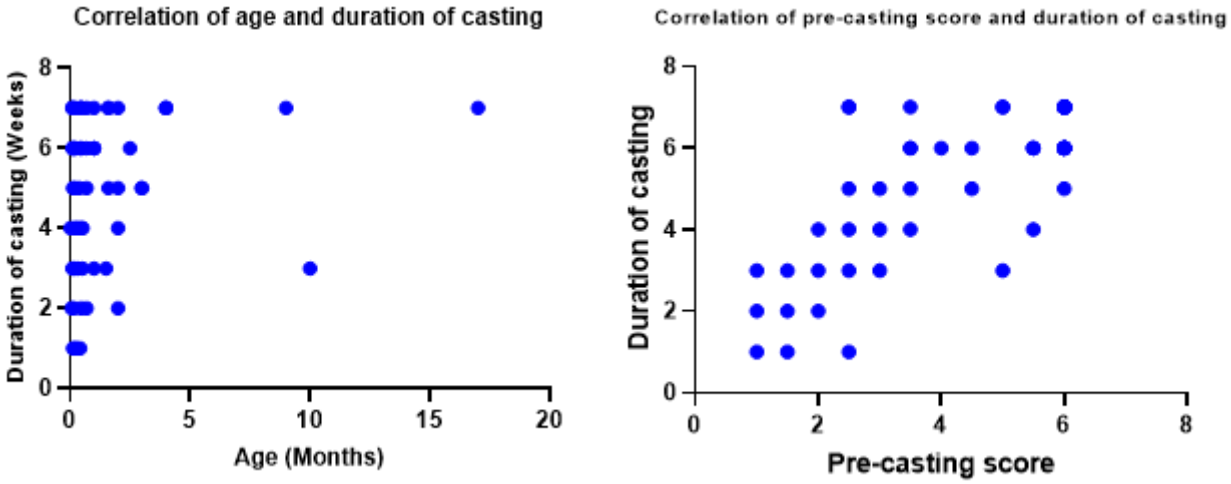

Figure 4: Correlation between age and duration of casting

4.1.3 Changes in the Pirani score following Ponseti casting and its correlation with age.

The mean Ponseti score significantly reduced following casting phase from 3.8±1.8 (pre-casting score) to 0.2±0.7 (post-casting score) (mean difference= 3.5, *p*<0.001). This reduction in the Ponseti score was observed in both males (3.9±1.9 vs 0.2±0.6, *p*<0.001*)* and females (3.5±1.8 vs 0.4±1.0, *p*<0.001). The post-casting Ponseti score positively correlated with age. (r=0.649 (95% CI 0.512-0.753) (Figure 4.1-3).

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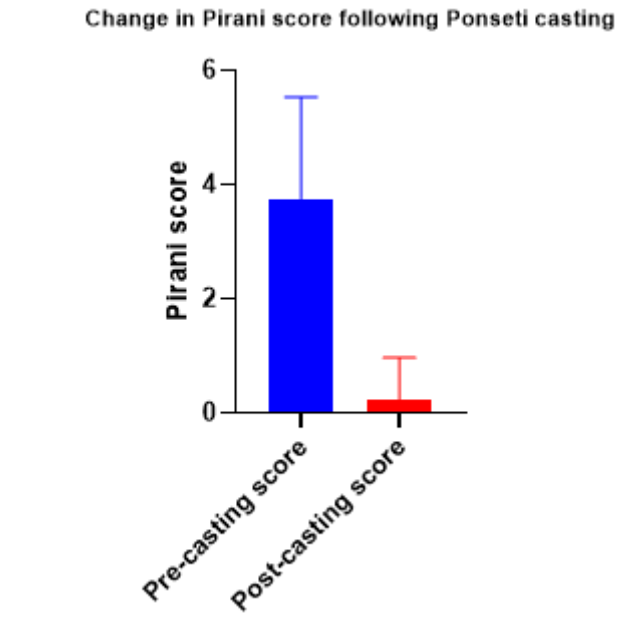

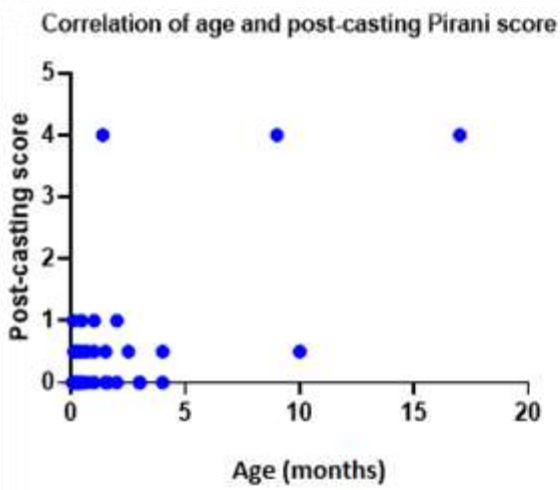

Figure 5: Changes in the Pirani score following Ponseti casting.

4.1.4 Tenotomy rates following casting.

Tenotomy was performed in 14 patients (22.2%) after casting. Patients requiring a tenotomy tended to be older (3.3±4.7 vs 0.7±0.9 weeks; $p<0.001$) and had a higher pre-casting Pirani score (4.8±1.7 vs 3.5±1.7, $p=0.006$). No significant sex differences were however noted ($p=0.754$).

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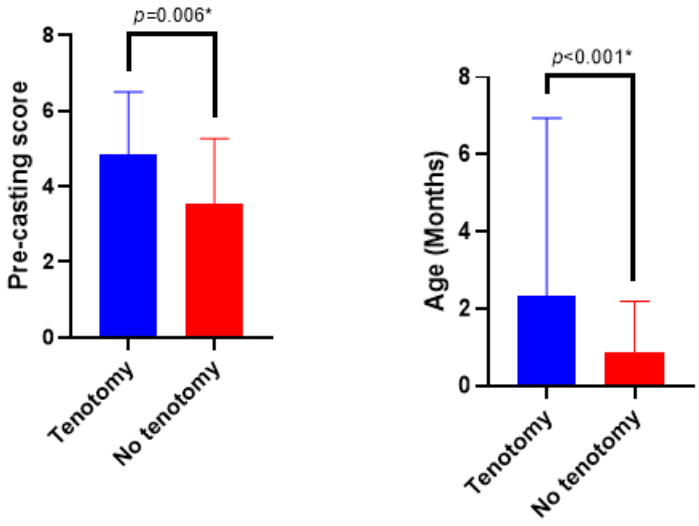

Figure 6: Relationship between age, pre-casting Pirani score and need for tenotomy.

4.1.5 Complications following casting.

A total of 6 patients (9.5%) developed complications following Ponseti casting. These complications included limb swelling (4 cases) and cast sore (2 patients). No age or sex differences significant differences were note in the complication rate. No relationship was noted between the Pre-casting Pirani score and the development of complications during the casting phase.

5. CHAPTER FIVE

5.1 DISCUSSION

This study was conducted to find out the outcomes of the casting phase of Ponseti technique for clubfoot correction. Data was collected from patient records, patients diagnosed with idiopathic clubfoot and were 24 months of age and below. The patients in the study presented with the condition and had not been managed in any other institution or priorly managed for the same.

63 patients were recruited in this study, 32 (50.8%) had presented with bilateral clubfoot. Siding, whether left or right, was, however not undertaken in this study. This is because we had not set out to compare affected limbs in this study. Males were more with a ratio of 1.74:1 to female (Table 4.1-1). Most studies have shown higher prevalence in males, 2:1 (19).

Presentation and diagnosis were noted, with the median age of presentation being 0.46 months, about 13 days. A study done previously (47) showed a significant number of patients presented at walking age, approximately 14%. Our study set to assess patients presenting at ages of 24 months and below and hence unable to assess management of the older populace. Post casting scores were shown to be higher in the patients presenting at older ages, and this also had an impact on them requiring tenotomies, a finding that concurs with Smythe et al (49).

The mean duration of casting was 4.5 weeks, which differs from a previous study (49) which had a longer duration. Children presenting at a younger age required fewer casts to attain a Pirani score of zero. A lower pre-casting Pirani score required fewer number of casts for correction. This finding concurs with a study by Agarwal et al (43) which found that fewer casts were required with younger age and a lower initial Pirani score. Casting was done weekly as compared to two weeklies as was done by Ayan et al (45).

Initial (pre-casting score) had an influence on number of casts applied, as also evidenced by studies by Awang et al (42) and Gao et al (40). There were, however, no changes in the score based on sex, no significant differences in pre-cast and post casting scores between male and female patients.

Twenty two percent of the patients required tenotomies performed after casting (figure 4.1-4), a finding within the range of previous authors' results (47). These rates are lower than those described by previous authors (15, 21, 49). Most were noted to have a higher pre-casting score (4.8±1.7). This is supported by a study done by Lampasi et al (41). It was found in this study that the patients requiring tenotomies had presented older (3.3±4.7 weeks) as compared to the younger ones. Tenotomy rates were also affected by number of casts applied, with those having fewer casts not requiring the procedure, a finding supported by previous studies (41).

Complications arising from casting were noted. Two patients developed cast sores while 4 patients had limb swelling. This represented 9.5% of the study sample, a higher rate than previous studies (50,51). This influenced duration of casting, for the patients who developed sores. The management for the cast sores was temporary cessation of casting, with wound care then re-application of casts upon healing. The average duration was 5 days for the sores to be managed then progression with casting.

For those that developed swelling, casts were removed for a day or two to allow for swelling to subside. They were then re-applied. There wasn't notable change in duration of casting for this group.

For the complications, there were no age or sex related differences, and no correlation to Pirani score.

6. CHAPTER SIX

6.1 CONCLUSION

From this study it can be concluded that the casting phase of Ponseti technique is effective in initial correction of idiopathic clubfoot. Casting phase had good outcomes, pre-casting scores averaging 3.8±1.8 and post casting scores reducing to 0.2±0.7 (figure 4.1-3).

Early diagnosis and commencement of management results in less casts applied and less need for tenotomy.

6.2 RECOMMENDATIONS

- Sensitization of parents, preferably in the ante-natal period about clubfoot deformity and need for early reporting to healthcare workers.
- Sensitization of health workers on importance of early detection of clubfoot, and role of early management.
- A follow up study on clinical outcomes of bracing phase of Ponseti technique would assist in further knowledge on effectiveness and success of this method in management of idiopathic clubfoot at KNH pediatric clubfoot clinic.
- A follow up study to analyze the staff expertise and skills, and analysis of documentation and records keeping as this was not part of this study. This will aid in standardization of procedures and documentation.

6.3 LIMITATIONS

The study encountered some limitations, including:

1. Incomplete data on 5 patients due to loss to follow up during the casting phase.

2. Inconsistent recording of data. Some of the patients' data was not entered in the score sheet showing scores of each assessed parameter. The final score was, however, indicated in the file notes.

3. Some files had missing sheets, loss of information.

4. Casting skill is different, may possibly result in longer correction time for some patients.

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8. APPENDICES

8.1 DATA COLLECTION SHEET

1. BIODATA

IP No (serial number)	
Age (months)	
Residence	
Gender	

2. RISK FACTORS (Tick where appropriate)

Familial history of clubfoot	Y ….... N ….....

3. PIRANI SCORE OF SEVERITY

Pre - cast	
End of casting	

4. CLINICAL OUTCOMES

TENOTOMY PERFORMED	Yes…….. No……
DURATION OF CASTING	
COMPLICATIONS	Yes……. (If yes, specify) ……. No……

CLINICAL OUTCOMES OF CASTING PHASE OF PONSETI METHOD FOR CORRECTION OF IDIOPATHIC TALIPES EQUINOVARUS

ORIGINALITY REPORT

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