DIFFERENCES IN OUTCOMES OF TREATMENT OF IDIOPATHIC CLUBFOOT USING ACCELERATED VERSUS CONVENTIONAL PONSETTI TECHNIQUE IN CHILDREN UNDER TWO YEARS AT KIJABE CURE HOSPITAL AND KNH

A RESEARCH THESIS SUBMITTED AS PARTIAL FULFILLMENT FOR THE DEGREE OF MASTER OF MEDICINE IN ORTHOPEDIC SURGERY AT THE UNIVERSITY OF NAIROBI.

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STUDENT DECLARATION:

I declare that this study is my original work and has not been presented for the award of any degree at any other institution or university. Where I have used another person's work, I have acknowledged and referenced.

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LIST OF ABBREVIATIONS

CTEV	Congenital Talipes EquinoVarus
ICTEV	Idiopathic Congenital Talipes EquinoVarus
KNH	Kenyatta National Hospital
SPSS	Statistical Package for Social Sciences
PI	Principle Investigator
AVG	Average

DEFINITION OF TERMS

Efficacy of treatment method – defined as correction of deformity based on the number of casts placed during the entire treatment period and need for tendon Achilles tenotomy.

ABSTRACT

Background: Clubfoot is one of the most common congenital deformities, with an incidence of one in 1000 live births worldwide. Management of club foot can be conservative or surgical. Based on Hippocrates's principles of clubfoot management, there are several conventional methods (Kite method, French method, Ponseti method, which involves manipulation, casting, tenotomy, foot abduction brace, and other physical processes such as kinesiotherapy, thermo-therapy, electro-therapy, splinting, shoe modification and orthotic devices). The Ponseti method results in prolonged latent time to achieving optimal outcomes since the onset of the procedure. This can have increased cost, loss to follow-up and other unfavorable complications of casting.

Thus, adopting a method with shorter treatment time would be advantageous to both the hospital and the patient.

Broad Objective: To determine the efficacy of ICTEV treatment by comparing Conventional and Accelerated Ponseti technique.

Study design and site: Prospective cohort study design conducted in two hospital, KNH and Cure International Hospital.

Participants and Methods: Consecutive sampling of children below 24 months (2 years) and undergoing treatment for ICTEV was done. Exposure variable was the accelerated method with control of exposure/non-exposure being the conventional Ponseti method. Outcome variables was time to optimum Pirani score, number of casts changed and complication rates between the two methods.

Results: The number of patients enrolled in the study was 25, with a mean age of 5.2 months, male patients (64%) being more than the female patients (36%). Majority of the patients (56%) underwent the conventional ponseti method of treatment. The time taken for the patients treated

with accelerated method to achieve optimal Pirani score was significantly shorter ($p<0.001$) compared to the patients treated with conventional method. Accelerated method of treatment was also associated with fewer complications (25%) compared to the Conventional method (75%). The mean number of casts required in the accelerated method (6.1 ± 1.1) was higher than in the conventional method (5.8 ± 1.2). Lastly, majority of the patients who underwent tendon Achilles tenotomy (84.6%) had been treated with the accelerated method. This number was significantly higher than the patient who were treated with the conventional method ($p<0.001$).

Conclusion/ Recommendation: The accelerated method of treatment was associated with a shorter time to attaining the optimal Pirani score as well as fewer complications compared to the conventional ponseti method. Therefore, the accelerated method may be suitable alternative to the conventional method since it assures a quicker recovery with minimal complications.

The accelerated method is associated with higher incidences of Tendon Achilles tenotomy.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Clubfoot is one of the most common congenital deformities, with an incidence of one in 1000 live births worldwide. In Kenya, approximately 1200 infants are born with clubfoot every year, which, if left untreated, leads to painful, disabling deformity and social stigmatization (1). Globally, 150,000-200,000 babies with idiopathic congenital talipes equinovarus (ICTEV) are born each year, and approximately 80% of them are in the developing world with limited access to appropriate medical care. Untreated or incorrectly treated clubfoot leads complications as the child grows older and learns to walk. The affected children have abnormal foot anatomy and biomechanics, with the affected feet fixed in an extended, adducted position (2).

Characteristics of the club foot are four structural deformities in the foot and ankle: midfoot cavus, forefoot adductus, hindfoot varus, and ankle equinus. The structural deformities are caused by the subluxation of the talocalcaneonavicular joint, dislocation of the talus bone, abnormalities of peroneus and calf muscles, and contractures of soft tissues on the medial side of the foot. Children with untreated clubfoot suffer daily activities, such as difficulties in gait, mobility, daily living skills, and social activities. Children with untreated clubfoot walk on the dorsal side of the foot leading to complications such as callus formation, injuries, and infections on the dorsum of the foot (3).

Clubfoot mainly presents as a congenital disability (idiopathic congenital club foot). Around 20% of the clubfoot deformities are associated with other conditions such as arthrogryposis, myelodysplasia, Down syndrome, Larsen’s Syndrome, freeman-Sheldon syndrome, and multiple congenital abnormalities (4). Clubfoot are associated with risk factors such as male gender,

smoking during the antenatal period, gestational diabetes, maternal age, marital status, oligohydramnios, and parity (5).

Management of club foot can be conservative or surgical (6,7) . Based on Hippocrates's principles of clubfoot management, there are several conventional methods (Kite method, French method, Ponseti method, which involves manipulation, casting, tenotomy, foot abduction brace, and other physical processes such as kinesiotherapy, thermo-therapy, electro-therapy, splinting, shoe modification and orthotic devices) (4,8).

Ponseti method has been embraced as the gold standard due to excellent functional outcomes in the recent past (2). Its main drawback includes compliance and neglected follow-up with the Ponseti brace protocol and directly affect the success of treatment. Conversely, accelerated method has been shown to reduce the treatment period significantly, without changing the number of casts needed to optimal correction (9-12). This method also increases compliance, especially for parents with children who have to travel long distances for follow-up. Other potential advantages are reducing the likelihood of plasters slipping and the chance for more intensive education regarding the importance of boots and bars, with more visits over a shorter period (13).

Assessing the effectiveness of different methods in local environment would help establish the most effective method of care of patients with CTEV (14). Varied institutions perform different procedures with varied advantages and disadvantages to each method. This study aimed to assess the effectiveness of different methods (Ponseti vs Accelerated) in achieving the desired outcomes.

The main objective of this study was to investigate the effectiveness of the conventional Ponseti Technique compared to the Accelerated method.

1.2 Statement of the problem

Kenyatta National Hospital uses the traditional Ponseti Technique in management of patients with CTEV. Compared to Cure International Hospital which uses both conventional and accelerated Method. The conventional Ponseti method results in prolonged latent time to achieving optimal outcomes since the onset of the procedure. This can have increased cost, loss to follow-up and other unfavorable complications of casting.

1.3 Study Justification

Adopting a method with shorter treatment time would be advantageous to both the hospital and the patient since such a method would reduce cost of treatment, minimize complications such as cast slippage, loss of follow-up, inappropriate handling by caregivers, cellulitis, compartment syndrome, among others.

Thus, generating evidence supporting the use of accelerated method in favor of conventional ponseti technique is necessary in the local setting.

This would result to change in local hospital treatment guidelines for CTEV as well as inform clinicians on optimal methods of managing the condition.

1.4 Research question

1. Does the Accelerated method attain the desirable result in shorter treatment period compared to the conventional Technique?

2. Does the Accelerated method result in less complications compared to Conventional Ponseti Technique?

1.5 Hypothesis

I

Null: There is no difference in treatment time between Conventional and Accelerated Ponseti technique

Alternate: There is a difference in treatment time between Conventional and Accelerated Ponseti technique

II

Null: There is no difference in complications rate between Conventional and Accelerated Ponseti technique

Alternate: There is a difference in complications rate between conventional Ponseti and Accelerated technique

1.6 Objective

1.6.1 Main objective

To establish the differences in outcomes of ICTEV treatment comparing Conventional Ponseti and Accelerated technique

1.6.2 Specific Objective

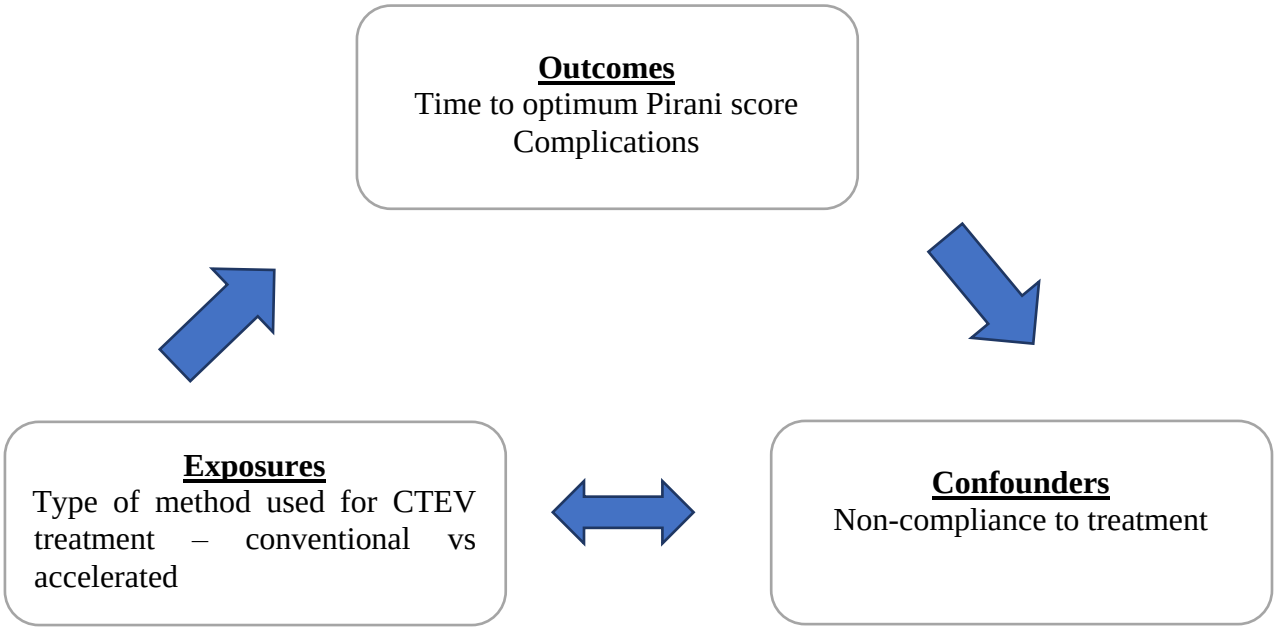
i. To assess the time to optimal Pirani scores (<=0.5) for patients undergoing ICTEV treatment comparing the Conventional and Accelerated Ponseti technique.

ii. To determine the complication rates in ICTEV treatment comparing the Conventional and Accelerated Ponseti technique.

The conceptual framework

The conceptual framework indicates the association between the outcomes (time to optimal Pirani score and complication rates) and the exposure variables (type of method used and age of patient)

Figure 1: The conceptual framework



CHAPTER TWO

2.0 Literature Review

2.1 Definition

Congenital talipes equinovarus (CTEV) represents congenital dysplasia of all musculoskeletal tissues (musculotendinous, ligamentous, osteoarticular, and neurovascular structures) distal to the knee. Congenital clubfoot is a deformity consisting of four components: cavus, adductus, varus, and equinus (CAVE) (15).

Clubfoot is classified into four types based on the causes and treatment responses: Postural, Idiopathic, Neurogenic, and Syndromic. Postural clubfoot is resolved by stretching and casting. Idiopathic clubfoot is 'true' clubfoot and is classified by various grades of severity. Neurogenic clubfoot is associated with neurological conditions such as spina bifida. Syndromic clubfoot is rigid and is associated with other anomalies. There are classifications available to measure the severity of the clubfoot based on the physical aspects of the clubfoot, such as the Pirani score and Dimeglio scale. Dimeglio et al. introduced clubfoot classification in 1995 into Grade I–Grade IV (4).

2.2 Epidemiology

Clubfoot is one of the most common congenital deformities, with an incidence of one in 1000 live births worldwide. In Kenya, approximately 1200 infants are born with clubfoot every year (1). The highest incidence of clubfoot occurs in the Polynesian population and the lowest incidence in the Chinese people (4). Most of the studies report that the incidence of clubfoot is higher in males than in females (2:1), and this ratio is consistent in all ethnic populations with an equal percentage for unilateral and bilateral club foot. Involvement of the right foot is higher in the unilateral clubfoot (4,16,17).

A study on Epidemiology, Pattern, and Prevalence of clubfoot at Enugu, South-east Nigeria, revealed: Idiopathic clubfoot had an occurrence rate of 92%, followed by secondary clubfoot at 6%. Positional clubfoot had 2%, which could be because the mothers did not go for a scan during pregnancy and were therefore not aware of the positioning of their babies before delivery. A study carried out by Moorthi RN et al. in 2005 reported idiopathic clubfoot as having the highest prevalence, with the male gender having 56% occurrences and females 44%. Many research studies on clubfoot prevalence reported male dominance. Bilateral clubfoot had 75% occurrences and unilateral 25% (15,18,19). Mkandawire also reported a high prevalence rate of bilateral clubfoot in Malawi, Africa, in 2004. The result also showed that most clubfoot patients present to the hospital between the ages of 1-and 2 months, with the peak at 1-1.5 months, which is the age when clubfoot becomes evident to the parents (20).

In a study on the Epidemiology of clubfoot in Sweden from 2016 to 2019, 612 children with clubfoot were selected. Of these, 564 were children with isolated clubfoot, generating a birth prevalence of 1.24/1000 live births out of which 8% were children with non-isolated clubfoot. This increased the birth prevalence to 1.35/1000 live births. Of the children with isolated clubfoot, 74% were boys, and 47% had bilateral involvement (19).

According to The Global Club Foot Initiative, Kenya has a population of 41.1 million, with 1653 children born with club foot every year, translating to 1.2/1000 live births. On the other hand, India has a population of 1.2 billion, with 30,000 babies born with club feet every year.

2.3 Complications of clubfoot

The affected children have abnormal foot anatomy and biomechanics, with the affected feet fixed in an extended, adducted position. The burden of untreated or incorrectly treated ICTEV negatively

impacts society. It should be viewed as a public health issue to reduce its prevalence through early diagnosis and the institution of appropriate treatment (2).

Children with untreated clubfoot have difficulties in gait pattern, mobility, daily living skills, and social activities (14,21). Moreover, children with untreated clubfoot walk on the dorsal side of the foot leading to complications such as callus formation, injuries, and infections on the dorsum of the foot (4).

Late sequelae of treated congenital clubfoot deformities include recurrent or residual deformity (cavus, heel varus, and forefoot adduction), pes planovalgus deformities, pain, limited ankle and subtalar range of motion, limitation of activities, abnormal gait, small foot, dorsal bunion, abnormal ankle architecture, navicular abnormalities, weakness, altered plantar pressures, degenerative joint changes, limitation of shoe wear, cock-up first toe pseudoaneurysm, and talar collapse (22).

Literature concerning patients in their second or third decades of life with clubfoot sequelae is scarce despite several showing up in medical institutions.

2.4 Management of Clubfoot

The goal of treatment of club foot is to achieve early and complete correction of all the four deformities of the foot (hind-foot varus, mid-foot cavus, fore-foot adductus, and ankle equinus), ensure that the patient has a functional (22), pain-free, plantigrade foot, with good mobility, without calluses (14), and does not need to wear modified shoes (18,19). The treatment modalities for ICTEV have evolved through trials since the 18th century.

2.4.1 The Ponseti Technique

In the 1950s, Ponseti developed a conservative method of club foot management. In the past 13 years, this method has been embraced as the gold standard due to excellent functional outcomes (2).

Ponseti method consists of weekly gentle manipulation, followed by application of serial long leg casting, which should change every 5 to 7 days. Before the final casting, if equinus deformity persists, Achilles tendon percutaneous tenotomy is done to correct the equinus deformity. The foot will then be immobilized for 21 days with 60◦ abduction and maximum dorsiflexion, and once the clubfoot is fixed, the child wears a full-time foot abduction brace for twelve weeks (23 hours per day) (3,15). After three months, foot abduction braces are used at night and nap time until the age of four to prevent the relapse of club foot. Foot abduction orthosis or brace is used after the foot achieves about 60◦–70◦ abduction and 20◦ dorsiflexion. In the initial application of the first casting, cavus is corrected by supination of the forefoot, providing pressure on the first metatarsal head of the forefoot (9,23). During the subsequent 3 or 4 casting applications, the clinician will correct forefoot adduction, hindfoot varus, and equinus deformity simultaneously by providing counter pressure on the talar head with positioning the foot in abduction and external rotation.

Non-compliance and neglected follow-up with the Ponseti brace protocol are significant problems and directly affect the success of treatment. Non-compliance could be caused by patients and families having difficulty bracing due to discomfort and more rigid feet. The incidence of non-compliance with bracing ranges from 0% to 51%, and Dobbs et al. reported that families who did not adhere to the bracing protocol were 183 times more likely to relapse (24). Avilucea et al. report sociodemographic factors related to relapse, including parental education limited to high-school level or below, Native American ethnicity, unmarried parents, absence of medical insurance, and a family income of less than $20, 000 per annum (2). The Kite method involved sequential correction of individual deformity taking the calcaneocuboid joint a fulcrum. This method took enormous amount of time for correction and produced excellent results only in the hands of Kite and no one else could reproduce the same results (6).

2.4.2 The accelerated technique

In a study by Giesberts et al. to establish the effectiveness of a twice-weekly accelerated protocol vis-à-vis the once-weekly standard protocol, a review article was published showing that accelerated protocols have a similar efficacy and safety profile as the traditional protocols (9,23,25). Accelerated method has been shown to reduce the treatment period, increasing compliance, especially for parents with children who must travel long distances for follow-up. Other potential advantages are reducing the likelihood of plasters slipping and the chance for more intensive education regarding the importance of boots and bars, with more visits over a shorter period (13).

Table 1: Summary of studies comparing Conventional and Accelerated method.

Author	Patient characteristics	Key differences in outcomes	Conclusion
P Harnett et al (2010) (9) - Malawi	Patients: 40, Feet: 61 Accelerated 19 pts, 21 feet. Conventional: 21 pts, 32 feet	Accelerated- shorter time to maximum correction -	No significance difference in final Pirani score
Hatem SA et al (2014) (10) - Egypt	41 patients, 66 feet Initial Pirani score >4 Conventional – 20 children, 34 feet, Accelerated – 21 children, 32 feet	Conventional casts – 4.8, Accelerated – 5.1. Time to optimal Pirani score: Accelerated - 11 – 22 days (Avg 18 days) Conventional – 21 – 42 days (Avg 33 days)	Accelerated had shorter time to treatment.
Sitanshu B et al (2018) (26) – India	30 patients – Conventional – 26 feet Accelerated – 25 feet.	Number of casts: Conventional – 5.2 Accelerated – 4.7 Time to optimal Pirani score: Conventional – 54 days Accelerated – 33 days.	Accelerated had shorter time to optimal Pirani Score.
Ibraheem GH et al (2017) (11) - Nigeria	RCT 28 patients, 45 feet Conventional – 23 feet, 14 patients	Time to optimal Pirani Score: Conventional – 52 days Accelerated – 39 days. Number of casts: no	Accelerated had shorter time to optimal Pirani Score.

	Accelerated – 22 feet, 14 patients.	statistical significance	
Mir Shahidul et al (2020) (12) - India	100 patients, 158 feet Conventional – 50 patients, Initial Pirani score – 4.67 Accelerated – 50 patients, Initial Pirani score – 4.35.	After casting Acc. Pirani score – 0.35, Conv. Pirani score – 0.34 Time to optimal Pirani Score: Conventional – 58.2 days Accelerated – 39.5 days. Number of casts: Conv – 6.3, Acc – 6.1	Accelerated had shorter time to optimal Pirani Score.

2.5 Assessing and Monitoring of treatment.

There are several methods of assessing and monitoring treatment outcomes for club foot: Pirani score and Dimeglio are the most used tools. The PBS (Shafique Pirani, Stephanie Boehm, and Marc Sinclair) score was used to assess the clinical outcome of each affected foot (27,28,29). The tool has seven assessed signs: hindfoot varus, standing foot supination, dynamic foot supination, early heel rise, active dorsiflexion, passive dorsiflexion, and passive subtalar abduction. During the assessment of the hindfoot varus, a patient in a weight-bearing position is examined from behind to assess heel alignment for varus/valgus and reported as having varus or neutral/valgus deformity (2). Roye et al. studied the measurement of patient functionality and parent satisfaction using a disease-specific instrument with two subscales: function and satisfaction (30).

Since the small bones of the newborn foot are essentially cartilaginous, ultrasonography to monitor treatment outcomes is also effective (13,31). Radiographs are used to assess correction before or

after tenotomy to confirm dorsiflexion obtained from the percutaneous tenotomy of tendon Achilles is at the ankle (3).

Pirani scoring system uses six clinical signs to measure the degree of abnormality of the CTEV. It has been noted to have a good intra-observer reliability. The scoring system is as follows: Each foot is scored for midfoot and hindfoot abnormality where the score ranges between zero to three and the total score for both feet is zero to six.

Specific score is 0 – normal; 0.5 – moderate abnormality; 1 – severe abnormality (32).

Dimeglio scoring involves visual estimation of the equines, hindfoot varus, midfoot rotation, and forefoot adduction without forcing the foot. Each feature is given 0 to 4 points according to reducibility (23,33).

CHAPTER THREE

3.0 Methodology

3.1 Study Design

This was a prospective cohort study of patients undergoing Accelerated vs Conventional Ponseti techniques for treatment of congenital club foot in two different facilities each routinely practicing its own method.

3.2 Study site

The study was carried out in different centers categorized under.

i. Public hospital- KNH, - **Practices the conventional method**

ii. Mission hospital-Cure International Hospital, Kijabe– **Practices the accelerated Ponseti method.**

3.3 Study population

The study target population included patients below the age of 2yrs undergoing Accelerated vs Conventional Ponseti treatment techniques for treatment of congenital club foot at two different institutions.

The Kenyatta National Hospital routinely uses the Conventional Ponseti Technique while the Kijabe Mission Hospital uses both the Conventional and Accelerated technique.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion criteria

1. Patients with idiopathic CTEV.

2. Age less than 24 months (2 years)

3.4.2 Exclusion Criteria

1. **Spine and pelvis pathology**
2. **Previous surgical interventions to the ICTEV**
3. **Absent of consent**

3.5 Study Variables.

3.5.1 Independent:

1. Type of method used – conventional vs accelerated methods.
2. Age **(**below 2yrs)
3. Sex (both Male and Female)

3.5.2 Dependent:

1. Time to resolution of the CTEV, measured by achievement of optimal Pirani Score (0-0.5)
2. Number of casts required to achieve optimal correction.
3. Number of cases that required Achilles tenotomy.

3.6 Sample size determination

Sample size was calculated using the formula for cohort studies.

$$N_1 = \left\{ z_{1-\alpha/2} * \sqrt{\bar{p} * \bar{q} * (1 + \frac{1}{k})} + z_{1-\beta} * \sqrt{p_1 * q_1 + (\frac{p_2 * q_2}{k})} \right\}^2 / \Delta^2$$

$$q_1 = 1 - p_1$$

$$q_2 = 1 - p_2$$

$$\bar{p} = \frac{p_1 + kp_2}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

$$N_1 = \left\{ 1.96 * \sqrt{0.5 * 0.5 * (1 + \frac{1}{1})} + 1.28 * \sqrt{0.75 * 0.25 + (\frac{0.25 * 0.75}{1})} \right\}^2 / 0.5^2$$

$$N_1 = 19$$

$$N_2 = K * N_1 = 19$$

p_1, p_2 = proportion (incidence) of groups #1 and #2
$\Delta = |p_2 - p_1|$ = absolute difference between two proportions
n_1 = sample size for group #1
n_2 = sample size for group #2
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α or β
K = ratio of sample size for group #2 to group #1

Thus, desired sample size was 19 feet per group i.e total sample size was 38 feet.

3.7 Sampling technique

Consecutive sampling technique was used for patients eligible to undergo treatment.

3.8 Data Collection Process

A structured data collection sheet in form of a structured data collection tool (Appendix 1) was used to collect data from the study participants in the different hospitals.

Primary participant is the patient undergoing treatment for CTEV. Due to patients being minors, the parent / guardian was required to respond to questions.

Data collected included the following variables.

Dependent variables: Initial and Optimal Pirani score (change in Pirani score), complications (Swelling, pain, cellulitis, compartment syndrome, cast pull off, pressure soars)

Independent variables: number of casts, time to optimal score, age, sex, method used (Ponseti vs Accelerated technique).

3.9 Data Management

During the data collection process, Principal Investigator (PI) ensured that no patient or surgeon identifying information was captured. This was done by de-identification of patients at all levels of data collection. No personal identifying information was collected. All patients were given codes. Confidentiality was maintained throughout the study process.

All hard copy forms were then locked in a safe to limit access to only the PI and to only authorized personnel.

3.10 Data Entry

Once data was collected, hard copy data in form of structured interview forms were converted to soft copy using Microsoft Excel 2019. On data entry, it was counter checked for errors and completeness. The information was kept in a password protected folder and only accessible to the Principal Investigator and Statistician.

3.11 Data Analysis

Statistical Package for Social Sciences (SPSS) Version 26 was used for data analysis.

For quantitative continuous data such **as age, and time to optimal Pirani score**, descriptive statistics such as means, modes, and medians were used to describe characteristics of the study participants. Proportions were used for categorical data such as sex, optimal Pirani score and occurrence of complications.

For hypothesis testing, student T test was used to assess mean differences in time to optimal Pirani score between the Conventional versus the Accelerated method. It was also be used to assess mean differences in the number of casts changed between the two methods. Difference in occurrence of complications between the two treatment methods was assessed using the Chi square test of independence.

The exposed group was the Ponsetti technique compared to control group, the conventional method. Thus, a relative risk was calculated by incidence in the exposed divided by incidence in non-exposed. Relative risk was reported with corresponding confidence intervals.

	No. Positive Events at 30 days months	**No. Negative events at 30 days**	
Ponsetti/accelerated			
Conventional			

NB: Events were defined as complications including swelling, pain, cellulitis, compartment syndrome, cast pull off, pressure soars at the specified period.

P values of <0.05 was considered statistically significant.

Data was presented in written reports, bar graphs, pie charts and frequency tables.

3.12 Data dissemination

A manuscript will be developed for submission in peer reviewed journal.

Information will be disseminated in conferences, professional meetings, and interest groups.

The study results were available at the UON orthopedic surgery research library and Cure International Hospital library.

3.13 Study limitations

This being a cohort study, there was a risk of losing patients to follow-up. However, we ensured that patients are followed up closely by taking their personal telephone contacts to ensure no loss to follow-up.

The fact that this study was conducted in two different centers, there was a slight difference in the technique and quality of care given to the patients.

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3.14 Ethical considerations

The approval of this study was sought from the Kenyatta National Hospital-University of Nairobi Research and Ethics Committee and Cure International Hospital Research committee. The study only commenced once approval was obtained. All patient data was kept confidential at all data abstraction, processing, and analysis stages. Patients participating in this study were informed of the study protocol and required to give an informed consent once they accepted to participate.

Administrative Consent (Appendix 2) to conduct the study was sought from respective hospital administrations. Data was stored in a password protected database.

CHAPTER FOUR:

RESULTS

Data analysis

The total number of patients enrolled in the study were 25. The mean age of the patients was 5.2 months, with a standard deviation of 5.4, median=2 and a range from 0.1 to 15 as shown in Figure 1below.

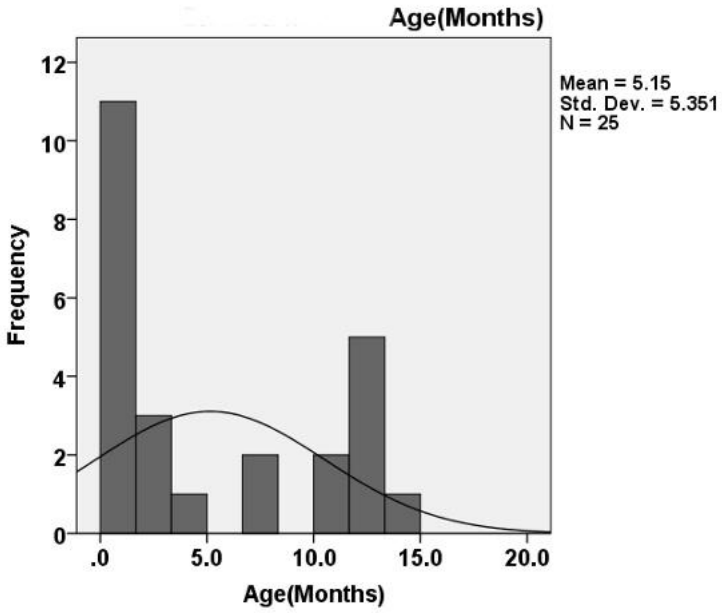

Figure 1: A histogram representing the distribution of Age in months.

There were more patients male 16(64%) than the female 9(36%) patients (Figure 2)

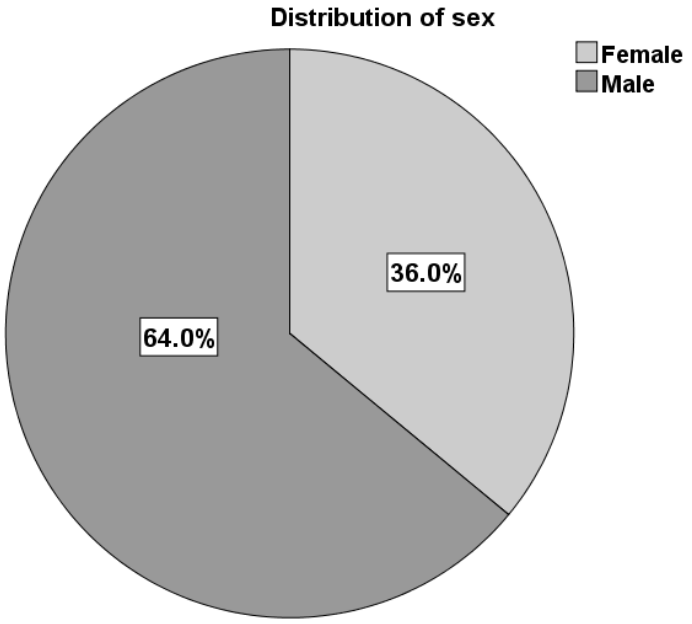

Figure 2: Distribution of Sex of the patients

Majority of the patients underwent conventional ponseti (56%) as a mode of treatment as compared to the accelerated ponseti (44%) ,(Figure 3).

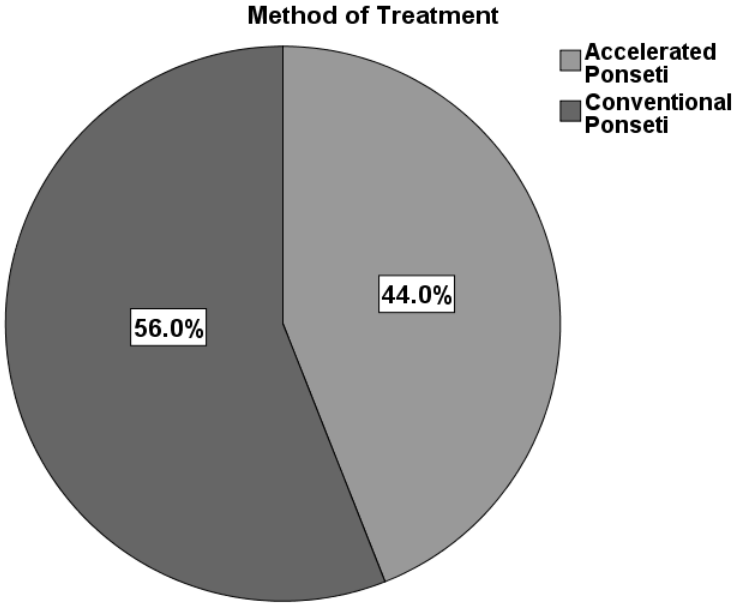

Figure 3: The distribution of method of treatment

The mean time taken for the entire study (including both methods) was 32.2 days with a standard deviation of 12.2 with a median of 35, within a range of 14 to 63 (Figure 4).

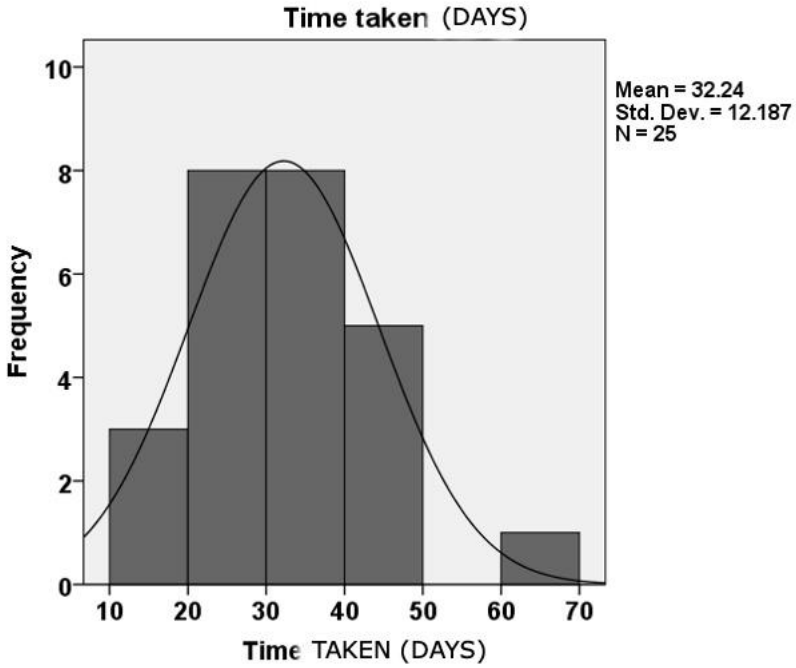

Figure 4: Distribution of time taken in days.

The mean number of casts was 5.9 with a standard deviation of 1.1 with median= 6 with a range of 4 to 9(Figure 5).

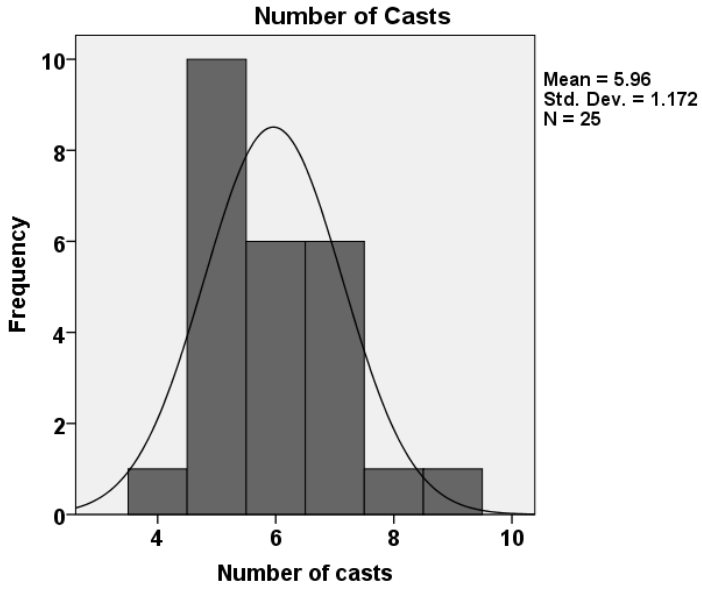

Figure 5: A histogram showing the distribution of the casts.

The number of cases that required tendon Achilles tenotomy were 13(52%) (Figure 6).

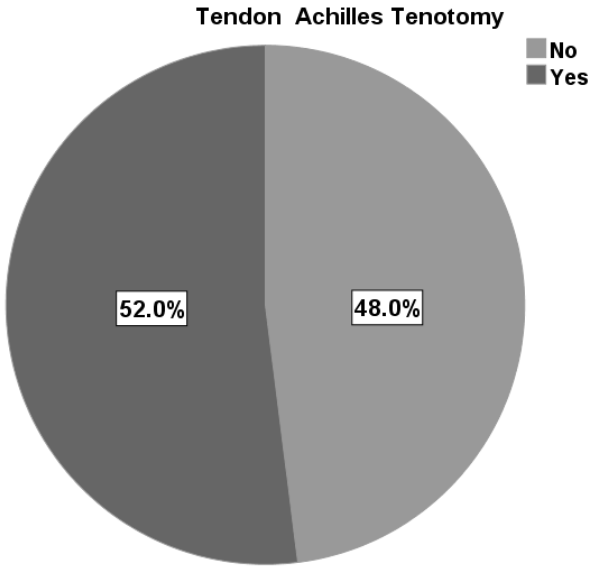

Figure 6: The distribution of the tendon Achilles tenotomy

The complications that were reported were 4(16%) (Figure 7).

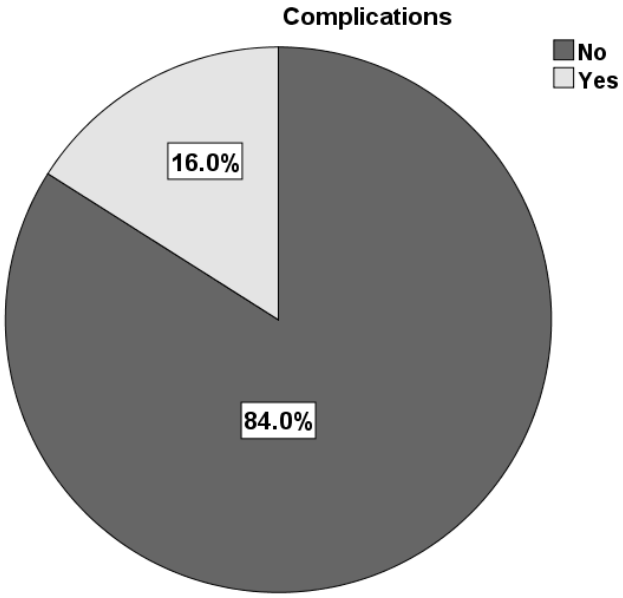

Figure 7: A pie chart representing the complications.

Objective 1

To assess the time in days to optimal Pirani scores (<=0.5) for patients undergoing ICTEV treatment comparing the Conventional and Accelerated Ponseti technique.

The table below shows the results of association between time to optimal Pirani scores and method of treatment (Table 1)

Table 1: Association between time taken and the method of treatment.

Group	Mean(±SD)	95% confidence interval		p-value
Acceleration	21.1(±3.9)	3.9	18.4	P<0.001
Conventional	41(±8.6)	36	45.9	

Objective 2

To determine the complication rates in ICTEV treatment comparing the Conventional and Accelerated Ponseti technique.

The table below shows the results of association between method of treatment and complications (Table 2)

Table 2: The table shows results of association between complications and method of treatment.

Complication	Acceleration	Conventional	p-value
Yes	1/4 (25%)	3/4 (75%)	0.604
No	10/21(47.6%)	11/21(52.4%)	

Table 3: A table to association between number of casts and mode of treatment

	Mean (SD)	**95% Confidence interval**		**P-Value**
Acceleration	6.1(±1.1)	5.3	6.8	0.6308
Conventional	5.8(±1.2)	5.1	6.5	

Table 4: A table showing the association between tendon Achilles tenotomy and mode of treatment.

	Acceleration	**Conventional**	**P-Value**
Yes	11/13(84.6%)	2/13(15.3%)	**P<0.001**
No	0	12/12(100%)	

CHAPTER FIVE

DISCUSSION

5.1. Patient demographics

In the current study, it was noted that the patients had a mean age of 5.2 months ranging from 0.1 to 15 months. Previous studies show that patients with club foot are likely to present to hospitals at the age of 1-2months which is the age at which the deformity becomes apparent to the parents (20). The mean age noted in the current study is slightly higher and this could probably be due to a delay in taking the patients to the hospital. In this setting, patients are likely to start by visiting a nearby health facility which may not be able to provide the definitive treatment for clubfoot. Since the data was collected in referral facilities, it is safe to say that the delay may have been necessitated by the time taken to refer the patients to these facilities.

Male patients were also found to be more than the female patients. This is similar to the findings from previous studies which reported a male preponderance (20,34). Moreover, the study included patients under 2 years of age, and this means that the patients who perchance their treatment went beyond 2 years were not accounted for.

In this study also, it was noted that majority of the patients underwent the conventional Ponseti method of treatment compared to the accelerated method. This is because the accelerated method was performed in only one facility while the conventional Ponseti method was carried out in both facilities. Secondly, patient preference may have played a role in deciding on the type of treatment with fewer patients preferring the accelerated method as it required frequent hospital visits.

5.2. Association between time taken and the method of treatment.

The current study reports a significantly shorter time to achieve optimal Pirani score with accelerated method compared to the conventional ponseti method. This finding is like those

reported by previous studies elsewhere (10,11,12,26). From the foregoing, the conventional ponseti method requires longer time between visits to the hospital compared to the accelerated method.

The time taken for the patients treated with accelerated method to achieve optimal Pirani score was shorter compared to the that reported by studies from India and Nigeria (11,12,26). This time was however comparable to the study conducted in Egypt (9). Sample size differences may have played a role in this case because the patients who underwent the accelerated method in the current study were fewer compared to the previous studies. Although previous studies fail to document the proportion of patients developing complications following the two treatment methods, it is evident from the current study that this proportion is smaller compared to that which develop complications. This factor could also play a role in the differences in time taken to reach optimal Pirani score as witnessed in the current study.

5.3. Association between complications and method of treatment

The current study generally reports fewer complications post clubfoot treatment. Most of the complications are seen in patients treated with the conventional ponseti method where two patients developed edema and one had plaster slippage. One patient from the accelerated group developed heat rash. For all the patients, casting was resumed after a week break. The proportion of patients who developed complications was like that obtained by Doski and Aqrawi (34). However, this proportion was relatively low compared the results of other studies (3,9, 26). The difference in the complications between the two treatment modalities was statistically not significant. Therefore, it can be concluded that the accelerated protocol was as safe as the conventional one.

5.4. Association between number of casts and mode of treatment

Generally, the accelerated method required a greater number of casts compared to the conventional method. This finding is like that already documented in literature (9,34, 35). The obvious reason for

this is that the accelerated method requires shorter time within which the casts must be changed (twice weekly compared to once a week in the conventional method). The difference in the mean number of casts between the two treatment methods was not statistically significant. Therefore, the accelerated method can be used without fear of cost implications.

5.5. Association between tendon Achilles tenotomy and mode of treatment

Tendon Achilles tenotomy was performed in a greater number of patients who underwent accelerated method compared to the conventional method. Previous studies have documented similar findings, where they attributed to a higher initial Pirani score among the patients treated with accelerated method compared to those treated with the conventional method. (34,35).

Limitations

The current study does not report whether the affected patients had bilateral or unilateral clubfoot and therefore no comparison between feet were made. Further, the current study does not document the type of complications that resulted from each of the treatment method used. Also, due to the shorter study period, the proportion of patients who developed relapse could not be followed up.

Conclusion

There is a significant reduction in the time taken for the patients treated with the accelerated method to reach optimal Pirani score. Moreover, the number of patients who develop complications following the accelerated method of treatment are fewer. Therefore, the accelerated method is a suitable alternative to the conventional method since it assures a quicker recovery with minimal complications. Also, this study reveals higher rates of tendon Achilles tenotomy in accelerated ponseti technique for than what is seen in conventional one.

Recommendations

Further studies with a larger sample size should aim at describing the individual complications that arise following clubfoot treatment and establish the differences in the types of complications between the two treatment methods. The outcomes after Tendon Achilles tenotomy should also be investigated.

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LIST OF APPENDICES

Appendix 1: Data collection tool

Form No.			
Institution of treatment:			
Age:			
Sex:			
Method of treatment:			
Pirani score	Initial Pirani score:		
	Final Pirani score:		
Time taken to optimal correction:			
Number of Casts:			
Tendon Achilles Tenotomy:		Yes	No
Complication:		Yes	No
If Yes, describe the complication			

NUMBER OF CAST	1	2	3	4	5	6	7
PIRANI SCORE							
TEMPERATURE							

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31st March, 2023

Dr. Nassor Mohamed Suleiman
Reg.No.H58/7629/2017
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

Dear Dr. Suleiman,

RESEARCH PROPOSAL: DIFFERENCES IN OUTCOMES OF TREATMENT OF IDIOPATHIC CLUBFOOT USING ACCELERATED VERSUS CONVENTIONAL PONSETTI TECHNIQUE IN CHILDREN UNDER TWO YEARS AT KIJABE CURE HOSPITAL AND KNH (P831/11/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P831/11/2022.** The approval period is 31st March 2023 – 30th th March 2024.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

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