

**THE TREATMENT OUTCOMES OF NEUROGENIC AND
IDIOPATHIC CLUBFOOT AFTER USING PONSETI
TECHNIQUE AMONGST CLIENTS ENROLLED IN AIC
CURE HOSPITAL, KIAMBU, KENYA FROM 2005 WHEN
THE CLINIC BEGAN AND 2014 AFTER COMPLETION
OF FIRST TREATMENT CYCLE**

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**The Treatment Outcomes of Neurogenic and Idiopathic Clubfoot
after using Ponseti Technique amongst Clients Enrolled In AIC
Cure Hospital, Kiambu, Kenya from 2005 when the clinic began and
2014 after completion of first treatment cycle**

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**A Thesis Submitted in Partial Fulfillment of the Requirements for
the Degree of Master of Science in Physiotherapy of the Jomo
Kenyatta University of Agriculture and Technology**

2023

DECLARATION

This thesis is my original work and has not been presented for a degree in any other University

Signature.....Date.....

.....

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This thesis has been submitted for examination with our approval as University Supervisors

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DEDICATION

For my unborn child

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ABBREVIATIONS AND ACRONYMS

AIC	Africa Inland Church
CCK	Clubfoot Care for Kenya
CF	Clubfoot
CTEV	Congenital talipes equinovarus
LMIC	Low and middle-income countries
SFAB	Steenbeek foot abduction brace
SPSS	Statistical Package for Social Scientists
UK	United Kingdom
USA	United States of America

DEFINITION OF TERMS

Clubfoot	Congenital deformity of the foot characterized by foot facing downwards and inwards.
Ponseti technique	A conservative method of clubfoot treatment that involves specific techniques in casting and manipulation, followed by tenotomy and finally bracing to 5 years of age.
Outcome	Changes in health that result from measures or specific health care interventions
Neurogenic clubfoot	Clubfoot associated with nervous system defect or condition

ABSTRACT

Treatment of neurogenic clubfoot is challenging due to the high risk of complications such as pressure sores, high cast rate, increased chance of relapse and failure to correct. The Ponseti method, was initially devised for idiopathic clubfoot, but it is increasingly being used for neurogenic clubfoot. The basis of this study was to do a comparative analysis on the treatment outcomes for patients with neurogenic and idiopathic clubfoot using Ponseti technique in order to determine the applicability of this technique in managing the two types of congenital clubfoot in children. In carrying out this study a retrospective study design was adopted. The study site was the clubfoot clinic at AIC Cure International hospital situated in Kiambu County, Kenya. The study examined 218 respondents out of the target population of 740 patients. A systematic random sampling technique was applied where every second file was selected. Data was extracted using a desk review tool and the variables included sociodemographic data and clinical outcomes including Pirani scores, number of casts applied, tenotomy, complications, relapse, need for surgical correction and failure to correct. In addition to the desk review, researcher telephoned the study participants' parents/guardians to get information on whether participant is pain free, able to wear shoes and whether parent is satisfied with treatment outcomes. The study findings showed that 93% (n=203) of patients had idiopathic whilst 4.8% (n=15) had neurogenic clubfoot. The mean age at 1st assessment was 5 months while most patients were 109 – 120 months (10 years) at time of study. Idiopathic clubfoot participants were casted fewer times than neurogenic. Relapse rate and need for surgery respectively were statistically significant ($P=.000$ & $P=.017$) among neurogenic clubfoot participants. Failure of Ponseti occurred in 3 out of 203 idiopathic and 2 out of 15 neurogenic patients. Pain in affected feet/foot was reported in 3 and 51 neurogenic and idiopathic clubfoot participants respectively. Care givers of neurogenic participants expressed less satisfaction with 16.7% being "very dissatisfied". There is implication that Ponseti has acceptable outcomes in managing idiopathic as well as neurogenic clients although neurogenic clients are at risk of relapse and additional surgery.

CHAPTER ONE

INTRODUCTION

1.1 Background information

The Ponseti method, which was initially meant for correcting idiopathic clubfoot (CF), is increasingly being used for neurogenic CF worldwide (Dobbs & Gurnett, 2009; Ganesan et al., 2017; Zhao et al., 2014). Idiopathic type of clubfoot accounts for the majority of all clubfoot whereas, neurogenic CF makes up to 20% (Balasankar et al., 2016). Other types of clubfoot include idiopathic, syndromic and postural. The most common etiologies of non-idiopathic clubfoot include arthrogryposis and spina bifida (Dobbs & Gurnett, 2009; Mulder et al., 2018).

The Ponseti method involves specific manipulations and serial casting, followed by tenotomy of the achilles tendon and later bracing to maintain correction for up to 5 years of age (Ganesan et al., 2017). Apart from Ponseti, other methods of treatment of CF include Kite, surgery, French method and specific splinting and taping (He et al., 2017). A recent study showed a 96% success rate in treatment of idiopathic CF using the Ponseti method (Ganesan et al., 2017). Invasive methods such as surgery have been linked to painful feet, high recurrence and failure rates including poor quality of life (Balasankar et al., 2016; Ganesan et al., 2017). Proponents of Ponseti as the conservative treatment method of choice for neurogenic clubfoot argue that it decreases the number of surgical interventions needed (He et al., 2017).



Pic 1 Before and after
Ponseti treatment for
clubfoot

Despite the risks, the Ponseti method is of late being used for neurogenic patients partly due to its favourable functional outcomes in idiopathic CF and its conservative nature (Matar et al., 2016)

Limited studies have been done in the Western world to find out the correlation between outcomes of the Ponseti method for neurogenic and idiopathic CF. In a Canadian hospital study on 40 non-idiopathic CF clients 1 year after undergoing the Ponseti method, Janicki et al.(2009) found that 28% of the patients required more procedures, casts, and had a higher rate of failure and recurrence as compared to idiopathic participants. Even with these findings, Janicki et al (2009) concluded that the Ponseti method should be used in non-idiopathic cases since it only failed completely in 4 patients. Mulder, Prinsen and Campenhout (2018) also argue that the Ponseti method is valuable in treatment of non-idiopathic CF because of it's non-invasive nature.

In a longitudinal study conducted in USA that grouped 36 patients into CF associated with myelomeningocele and those with idiopathic CF, Gerlach et al (2009) found that 96% of the myelomeningocele patients achieved full correction, although they had more severe forms of CF at initial assessment and higher rates of relapse that required surgery. These findings were also demonstrated in a retrospective study that followed 18 clubfeet with myelomeningocele for 9 years in UK in which Matar, Beirne and Garg (2016) found a success rate of 83% using the Ponseti method, with 3 clubfeet failing the Ponseti treatment. In a separate study conducted in the USA, Trevor, Alexander, Nancy, and Gaia, (2017) found that out of a total of 24 patients, 42% of patients with tethered cord syndrome experienced a clubfoot relapse as compared to 8% in idiopathic.

Essentially, the skeletal malalignment for both neurogenic and idiopathic are similar though of different causes (Balasankar et al., 2016). This informs the motivation for the use of Ponseti technique in treatment of both neurogenic and idiopathic CF. However, there is lack of literature on the outcomes of the Ponseti technique in neurogenic CF as similarly reported by Ganesan et al., (2017). This study will fill this gap. Therefore, the purpose of this study is to determine correlation between Ponseti technique outcomes and types of clubfoot amongst clients enrolled in AIC Cure hospital clubfoot clinic from 2005 to 2014. Research reported effectiveness of the Ponsetti method in treatment of idiopathic CF resulted in its adoption as an approach of choice among rehabilitation professionals worldwide (Ganesan et al., 2017). Similarly, this research findings on the correlation of outcomes of the Ponsetti method in the treatment of neurogenic and idiopathic CF has the potential to change rehabilitation professionals' practice.

1.2 Statement of the Problem

There is lack of information on the outcomes of the Ponseti method to correct neurogenic clubfoot in Kenya and Africa at large. However, research has been done to prove the efficacy of the Ponseti technique in the management of idiopathic CF in Africa (Adewole *et al.*, 2014; Ganesan *et al.*, 2017). Lack of information on the outcomes of the Ponseti technique in treatment of neurogenic CF raises concern as to whether its outcomes are good. Moreover, clinicians at AIC Cure Kijabe hospital have had this concern because a significant amount of complications is noted from neurogenic CF patients. Therefore, establishing whether there is an association between neurogenic and idiopathic types clubfoot and outcomes of Ponseti technique amongst patients enrolled in the AIC Cure hospital clubfoot clinic from 2005 to 2014, is worthwhile.

1.3 Justification of the study

Mobility in the community setting is an important human achievement that increases the likelihood of developing human and social capital. For example, when clubfoot goes untreated it causes callus formation, pressure sores, infection of sores and much difficulty in mobility which eventually lead to lack of participation in age appropriate activities including schooling (Balasankar *et al.*, 2016). As a consequence, causes illiteracy, isolation and poverty. Neurogenic CF is such form of clubfoot that is difficult to manage and is responsible for a significant fraction of clubfoot related disability. Neurogenic clubfoot is particularly difficult to treat because the feet are more rigid and have higher risk of complications and tendency to relapse (Janicki *et al.*, 2009; Matar, Beirne, & Garg, 2017). Improvement of approaches to management of neurogenic CF has the likelihood of ameliorating its consequences and promote inclusion in important areas of human development. It is envisaged that the findings of this study will provide baseline information on whether there is an association between outcomes of the Ponseti method of clubfoot treatment and neurogenic and idiopathic types of clubfoot. This will increase the knowledge of rehabilitation and other health care professionals who will in turn use the new knowledge in designing appropriate protocols for the management of CF. This will result in better clients' functional outcomes. In addition, it has potential to help rationalize resources distribution into the other methods if proved necessary.

1.4 Objectives

1.4.1 General objective

To assess the treatment outcomes of neurogenic and idiopathic clubfoot after using Ponseti technique amongst clients enrolled in AIC Cure hospital, Kiambu, Kenya from 2005 when the clinic began and 2014 after completion of first treatment cycle.

1.4.2 Specific Objectives

1. To establish the proportions of patients who were treated with neurogenic and idiopathic clubfoot using ponseti technique at AIC Cure hospital the clubfoot clinic from 2005 – 2014.
2. To establish the treatment outcomes among patients with neurogenic clubfoot after using Ponseti technique amongst clients enrolled in AIC Cure hospital, Kiambu, Kenya from 2005
3. To establish the treatment outcomes among patients with idiopathic clubfoot after using Ponseti technique amongst clients enrolled in AIC Cure hospital, Kiambu, Kenya from 2005
4. To establish how the treatment outcomes compared between patients treated with neurogenic and idiopathic clubfoot after using Ponseti technique amongst clients enrolled in AIC Cure hospital, Kiambu, Kenya

1.5 Research questions

1. What are the proportions of neurogenic and idiopathic clubfoot cases among patients enrolled in the AIC Cure hospital clubfoot clinic from 2005 – 2014?
2. What are the treatment outcomes among patients with neurogenic clubfoot after using Ponseti technique amongst clients enrolled in AIC Cure hospital, Kiambu, Kenya from 2005 - 2014?
3. What are the treatment outcomes among patients with idiopathic clubfoot after using Ponseti technique amongst clients enrolled in AIC Cure hospital, Kiambu, Kenya from 2005 - 2014?

4. What is the comparison between Ponseti technique outcomes of neurogenic and idiopathic clubfoot amongst clients enrolled in AIC Cure hospital clubfoot clinic from 2005 to 2014?

CHAPTER TWO

LITERATURE REVIEW

2.1 Clubfoot anatomy and epidemiology

Clubfoot, also known as Congenital talipes equino varus (CTEV), is one of the most common pediatric orthopedic conditions with a global incidence of 1 in 1000 live births (Dobbs & Gurnett, 2009; Zhao et al., 2014). Up to 80% of children born with clubfoot are in low and middle-income countries (LMIC) such as most Sub-Saharan countries, including Kenya (Balasankar et al., 2016; Drew et al., 2016). Preliminary results of an on-going Kenyan study in 3 major hospitals involving 13,209 babies, has shown that clubfoot contributes to 57% of all birth defects (Field epidemiology and laboratory training program, Unpublished).

Clubfoot is best diagnosed clinically as opposed to radiographically, therefore, outcomes are measured clinically (Baghdadi et al., 2017). There are 4 main types of CF namely; idiopathic, neurogenic, postural and syndromic (Balasankar et al., 2016; Dobbs & Gurnett, 2009). Idiopathic CF is an isolated foot condition that can be seen in utero and consists of four main components; mid-foot cavus, fore-foot adduction, heel varus and ankle equinus (Ganesan et al., 2017). Neurogenic CF is CF associated with neuromuscular conditions such as spina bifida, cerebral palsy, hydrocephalus, arthrogryposis, among others. Syndromic clubfeet are more rigid and are associated with syndromes such as Down's syndrome. Essentially, the skeletal malalignment for both neurogenic, syndromic and idiopathic are similar though of different causes (Dobbs & Gurnett, 2009). Babies with postural CF can actively move out of the clubfoot like position in their feet, there is no rigidity or tightness (Balasankar et al., 2016).

The cause of clubfoot is yet to be established albeit some unproven opinions exist (Balasankar et al., 2016). One of the opinions includes crowded in utero positioning. Some researchers have shown that there exists a strong association between CF and maternal obesity (Dobbs & Gurnett, 2009; Werler et al., 2014). In clients with neuromuscular conditions, the imbalance in the tone of foot muscles feet is theorized to be the cause of neurogenic CF (Univeristy of Oxford, 2017). In a retrospective study Werler et al. (2014) found that there was an association between environmental factors such as prenatal smoking

and CF. Genetic factors have also been shown to play a role in causing clubfoot (Dobbs & Gurnett, 2012).

2.2 Ponseti method

The Ponseti method is currently the treatment of choice for idiopathic clubfoot (Adegbehingbe et al., 2010; Ganesan et al., 2017; He et al., 2017; Švehlík et al., 2017; Zhao et al., 2014). However, surgery on clubfoot still continues (Dobbs & Gurnett, 2009). Other conservative methods, such as Kite, have been shown to have poor outcomes (Balasankar et al., 2016; Ganesan et al., 2017). The Ponseti method has shown best functional outcomes, lowest rates of relapse and pain free feet as opposed to all other methods including surgery (Adegbehingbe et al., 2010; Ganesan et al., 2017; Švehlík et al., 2017).

The Ponseti method involves specific manipulation and casting of the affected foot, tenotomy of the achilles tendon and foot abduction bracing till 5 years of age. The main difference between it and other conservative methods is that manipulations target the talus bone and long leg casts are applied as opposed to short leg casts. The other main difference is that Ponseti realized that the deformities are interrelated where as others such as Kite attempted correcting the deformities separately (Ganesan et al., 2017). Treatment commences by manipulation and casting to first correct cavus then adduction, parallelly, varus corrects automatically as abduction occurs. Upon achieving at least 50° of abduction, the tenotomy procedure is done which is a percutaneous complete cut of the achilles tendon (Ganesan et al., 2017). Bracing is then applied to maintain correction (after casting and tenotomy) since clubfoot can recur. In Kenya, the most commonly used brace is the Steenbeek foot abduction brace (SFAB) due to its durability and affordability. The bracing period has increased along the years with the current being up to 5 years of age. In Kenya, challenges such as caregivers incurring high transport costs, treatment being delayed because parents want to have more children, lack of support to mothers, among others, are experienced during clubfoot treatment (Drew et al., 2016; Kinyanjui, 2017). The most utilized tools of assessing clubfoot treatment progress are the Pirani and Dimeglio forms (Ganesan et al., 2017). These tools are used on every clinic visit to assess progress of a patient so as to determine the next treatment phase, identify complex and relapse cases. In Kenya the Pirani tool is most widely used.

The Ponseti method was only meant for idiopathic CF children below the age of 2 years but research is showing that its effective for even older children (Ganesan et al., 2017). A typical

idiopathic clubfoot case usually involves 8 – 12 weekly casts, if casting starts before 2 months of age. After casting the child undergoes a tenotomy after which a 3-week cast is applied with the foot in dorsiflexion. The tenotomy casts stays longer because the tendon has been shown to heal well in 3 weeks (Dobbs & Gurnett, 2009). The child should be around 5 months of age when bracing begins. In the first 3 months, the child wears the SFAB for 23 hours a day, only allowing removal for nappy changes and bathing. After 3 months of full-time bracing, the child commences day and nap time bracing up to the age of 5 years. Regular follow up appointments are made to ensure relapse does not occur and brace size changes are done as the child grows. Complete discharge from treatment occurs at 5 years of age if the clinician approves.

2.3 Outcomes of the Ponseti method for neurogenic and idiopathic clubfoot

Generally, Ponseti has been shown to have good outcomes for idiopathic CF patients (Ganesan *et al.*, 2017). A retrospective study aimed at evaluating mid-term results of the Ponseti method with a minimum of 5 years follow up found that the method was successful in 89% of the 74 idiopathic participants (Bor *et al.*, 2009). However, 32% of the babies required additional surgery excluding tenotomy, brace intolerance rate was as high as 44% but parents showed major satisfaction at 6 years of child's age. An RCT study based in India by Rijal *et al.*, (2011), prospectively followed 38 idiopathic patients under Kite and Ponseti methods for their casting period. Rijal *et al.*, (2011) found that Pirani scores significantly reduced faster in patients under Ponseti than Kite. A study that analyzed patients after an average of 3 years on the Ponseti technique using the Quantitative Assessment of Deformity protocol found that calf atrophy was not significant as compared to a group that underwent surgery (Rasit *et al.*, 2017).

The outcomes of a study that assessed 26 idiopathic patients at an average age of 4.6 years after the Ponseti method included; mean number of eight casts, one recurrence, 42% of patients had pain on exertion and 73% of parents were very satisfied with the treatment (Chueire *et al.*, 2016). It is important to note that records were analyzed then patients were called in for administering the questionnaire that assessed satisfaction and pain.

In a UK based retrospective research on effectiveness of the Ponseti method for clubfoot associated with arthrogryposis amongst 10 children (17 clubfeet), Matar *et al.*, (2016) found satisfactory outcomes in 64.7% of the participants followed up for 8 years. However, Matar

et al., (2016), noted high cast and recurrence rates. A retrospective study done in Iran demonstrated 45.8% relapses in non-idiopathic cases as compared to 16.3 % of idiopathic clubfoot cases following Ponseti method (Azarpira *et al.*, 2016). In another study on neurogenic clubfoot associated with amniotic band, (Carpiaux *et al.*, 2016) showed that under the Ponseti method, 95% of 12 cases had successful initial corrections although 33% of the clients later developed a recurrence. A study by Arkin, Ihnow, Dias, & Swaroop, (2018) concluded that clients with spina bifida and clubfoot require an open tenotomy as opposed to closed that is familiar in Ponseti. This was after they noted 100% of 17 spina bifida and CF patients studied who had received a percutaneous tenotomy experienced a recurrence where as only 18% of those who had an open surgery had a recurrence.

In their study, Gerlach *et al.*(2009), reported 100% on initial correction with the Ponseti method in idiopathic cases and 96% in cases with myelomeningocele. According to Gerlach *et al.*(2009), the Ponseti method is effective for treatment of neurogenic clubfoot although some later need surgical correction due to relapse. Moreover, Janicki *et al.*, (2009), and Matar, Beirne, and Garg (2017) argue that neurogenic CF is particularly difficult to treat because the feet are more rigid and have higher risk of complications and tendency to relapse.

The most agreed on criteria for assessing success of treatment after Ponseti treatment was established through a Delphi-based consensus by African clubfoot trainers (Smythe *et al.*, 2017). It includes 4 main components, which are pain free feet, parental satisfaction, ability to wear normal shoes and plantigrade feet. Most researches done in developed countries have compared neurogenic and idiopathic clubfoot outcomes after Ponseti method as opposed to gathering data only on neurogenic clubfoot, in efforts to understand how successful it's treatment is (D.J. Gerlach *et al.*, 2009; Trevor *et al.*, 2017). A literature gap exists on whether Ponseti technique outcomes are influenced by type of clubfoot. This study will attempt to fill this gap by revealing whether there is a statistical association between Ponseti technique outcomes and the two main types of clubfoot i.e., neurogenic and idiopathic.

CHAPTER THREE

METHODOLOGY

3.1 Study site

AIC Cure International hospital is a non-profit making faith-based organization that is based in Kijabe, Kiambu county, Kenya. It was founded in 1998 by an American based organization named Cure International, in conjunction with the Africa Inland Church. AIC Cure was the first pediatric orthopedic hospital in Africa and the first that Cure International established. The hospital also conducts mobile clinics in 16 counties that reach children in somewhat interior parts of Kenya. The 32-bed capacity facility also trains orthopedic surgeons among other health care professionals.

Clubfoot Care for Kenya (CCK) was founded by AIC Cure Hospital and CURE Clubfoot. Cure clubfoot in 2019 changed its name to Hope Walks and has been supporting CCK since inception. Currently CCK has 23 partner clinics that are based mostly in government hospitals. CCK supports the clinics with supplies needed for CF treatment, trains clinicians on the Ponseti method and conducts activities to raise the awareness of clubfoot in Kenya.

3.2 Study design

This study was retrospective in design utilizing a quantitative approach. The design was selected because children undergoing the Ponseti technique are discharged after 5 years of age, hence an equivalent amount of time would be needed to follow clients prospectively. Retrospective designs have been proven to be effective in studies of this nature, as accounted for by (Mann, 2003). Treatment outcome related information was extracted from files of clients who commenced treatment between 2005 to 2014. To obtain answers to 3 questions on the data collection tool, telephone interviews were conducted. Therefore, some data was obtained in a cross-sectional manner.

3.3 Study Population

This study population was all clients diagnosed with clubfoot and managed in AIC Cure hospital clubfoot clinic from 2005 to 2014.

3.4 Sample size determination

The sample size was determined using Yamane (1967:886) formula as the population size is known (Israel, 2013). The population size (N) for all clubfoot cases enrolled in the AIC Cure hospital from 2005 to 2014 were 740 cases. Therefore, the sample size calculated using Yamane (1967:886) formula is as follows:

$$n = \frac{N}{1+N(e)^2} = \frac{740}{1+740(.05)^2} = 260$$

Key: N – Population

n- sample

e – Precision level

However, after examining the 740 files of all patients treated with the Ponseti technique between 2005 and 2014, only 218 files had complete data hence the sample size reduced to 218.

3.5 Sampling method

Systematic random sampling was used to obtain the sample. The files at the health records department were serialized. Since 2005 AIC Cure hospital had an accumulated repository of 740 files for clients seen over the period of 9 years from when the clubfoot clinic started. The researcher therefore picked every 2nd file from the 740 files of 2005 to 2014 until 338 had been picked.

3.5.1 Inclusion Criteria

- All files for clients diagnosed with idiopathic and neurogenic clubfoot and enrolled in the Clubfoot Care for Kenya program at AIC Cure hospital, between 2005 and 2014. Neurogenic CF was diagnosed in clients who in addition to clubfoot had cerebral palsy, spina bifida, hydrocephalus and tethering of spinal cord.
- Only patients who would have finished 5 years in treatment to from enrollment to current study time were included.
- Only files that were complete and had no missing data were included

3.5.2 Exclusion criteria

- Clients who had any other serious condition/s apart from one of neurogenic origin were not be included in the study.
- Files of clients who had not completed the 5-year treatment period of Ponseti technique.
- Data for caregivers/parents who could not communicate to the researcher during the telephone interview due to a language barrier or mental handicap was not included in the research

3.6 Instrumentation and Outcome Measures

The criteria to determine a successful outcome of clubfoot treatment after Ponseti method use includes clinical and patient reported outcomes (Arkin *et al.*, 2018; Azarpira *et al.*, 2016; Chueire *et al.*, 2016; Ganesan *et al.*, 2017; Gerlach *et al.*, 2009; Janicki *et al.*, 2009; Matar *et al.*, 2016; Smythe *et al.*, 2017; Trevor *et al.*, 2017). Being a retrospective study, a data extraction tool was used. The tool comprised of three sections. Section one had five questions on demographic characteristics and social history. Section two investigated eight clinical outcomes namely, number of casts applied, tenotomies done, brace compliance, relapse, surgical correction, failure to correct, age at last assessment and Pirani scores. The Pirani classification scale, developed by Shafique Pirani, is a tool that is used worldwide to assess the severity of clubfoot, determine next stage of treatment and identify relapse (Aggarwal & Gupta, 2016; Fan *et al.*, 2017; Khan *et al.*, 2017; Samir *et al.*, 2012). Section three of the tool, which investigated patient reported outcomes, had three indicators that included, ability to wear shoes, pain free and parental satisfaction. (Smythe *et al.*, 2017).

3.6.1 Validity and reliability of the Pirani scale

In order to ascertain the validity of the data extraction tool, the tool was subjected to an internal validity establishment process. Eleven experts were selected based on their vast experience in clubfoot treatment and as trained medical doctors and rehabilitation professionals within and out of Kenya. They are also part of various organizations that work in clubfoot treatment and development of curriculums for Ponseti training. Experts in the field of clubfoot were blinded and requested to give feedback on the instrument for 2 rounds after which 70% consensus was achieved.

The Pirani scale, which evaluated whether plantigrade, is one of the most widely used tools for assessing clubfoot (Aggarwal & Gupta, 2016; He *et al.*, 2017). The Pirani scale has been shown to have excellent inter-rater agreement of 83% (Flynn *et al.*, 1998; Samir *et al.*, 2012). It has been shown to be a good tool for assessing the severity of clubfoot, and a good predictor of need for tenotomy and relapse (Aggarwal & Gupta, 2016). It is also quick to use, cost effective and simple such that parents can also easily understand (Khan *et al.*, 2017).

3.7 Data Collection Procedure

Upon attaining ethical clearance to access the clubfoot clinic AIC Cure hospital files, the researcher produced the permission to the medical records department. The researcher with assistance of the medical records personnel then identified the files for the research. All files for clubfoot clients at AIC Cure hospital were serialized from 2005 to date. The researcher and research assistants then selected every 2nd file until 312 files were randomly selected. The researcher then conducted a desk review of the selected files using the data collection tool. After data collection, the files were returned to the medical records department. As supported with a Delphi study by Smythe, Wainwright, Foster, and Lavy, (2017) Delphi study concerning determination of successful clubfoot treatment, the researcher contacted the clients through telephone to establish the outcomes following Ponseti technique, that is, whether their feet are pain free, are able to wear shoes and level of parental satisfaction.

3.8 Data analysis

After data collection, the data was entered into the Statistical Package for Social Sciences (SPSS) version 26. Thereafter, descriptive statistics was calculated and presented in summary tables and charts. Analysis of treatment outcomes following Ponseti technique was based on Smythe, *et al.* (2017) criteria and comparison made between neurogenic and idiopathic clients. The normality of data was tested using the Shapiro–Wilk test of SPSS and this determined whether to use parametric or non-parametric comparison tests. Since the data was not normally distributed the Chi-square was used to determine the association between variables. A 95% confidence interval i.e., level of significance set at $p \leq 0.05$.

3.9 Ethical consideration

Authority to carry out the study was sought and obtained from National Commission for Science, Technology and Innovation and approval from Jomo Kenyatta University of Agriculture and Technology Ethical Review Committee. Permission to collect data was also sought from AIC Cure International hospital research board. Consent from parents/caregivers of children included in the study was sought through the telephone conversation. The study information and consent form were read to them before acquiring verbal consent and continuing with the interview. The researcher observed anonymity by not assigning any names on the responses. The researcher ensured that the information attained was kept confidential by locking the filled data collection tools in lockers only accessible to the researcher. The results of the study were shared with AIC Kijabe hospital for the administration and practitioners to remain advised on the recommendations of the study. Any recommendations understandable to parents and caregivers will be summarized and published into brochures and shared in accessible places for them.

3.10 Limitations

The study had some limitations. The researcher could not invite clients to the clinic for assessment as previously planned, due to Covi19 restrictions. This meant that caregivers were contacted via telephone of which was challenging for the both researcher and caregivers to communicate through. Some caregivers were hesitant to open up to the researcher while some were not sure of the answers and had to give phone numbers of other caregivers.

CHAPTER FOUR

RESULTS

4.1 Response rate

Out of the 740 files of the clients treated between 2005 to 2014 only 218 had complete files while the others had missing data hence necessitating examination of only 218 files(respondents).

4.2 Sociodemographic characteristics

Most participants were 109 – 120 months (10 years) of age at time of study. The mean age of the clients at 1st assessment was 5 months. Males accounted for the majority at 164 (71.9%). Only 37 (16.2%) of the participants reported that there was a history of clubfoot in their immediate and extended family. Most participants, 199 (87.3%), were recorded to have been born in a medical facility while 20 (8.8%), were born at home and 8 (3.5%) files were not documented. The majority of participants 116, 53%) had bilateral clubfoot. Refer to table 4.2.

Table 4.1: Demographic characteristics of clients with neurogenic and idiopathic clubfoot included in data collection

Age (at time of research)									
Age (years)	6	7	8	9	10	11	12	13	14
Frequency	18	24	35	34	38	41	25	10	3
Percentage	7.9	10.5	15.4	14.9	16.7	18	11	4.4	1.3
Mean									9.50
Gender									
	Frequency				Percentage				
Male	164				71.9				
Female	64				28.1				
P value									1.28
Presence of clubfoot in family history									
	Frequency				Percentage				
Yes	37				16.2				
No	191				83.8				
P value									1.84
Where was child born									
	Frequency				Percentage				
Medical facility	199				87.3				
Home	20				8.8				
Other	1				.4				
Not documented					8				
P value									1.20
Laterality									
	Frequency				Percent				
Unilateral Right	59				27.1				
Unilateral Left	43				19.7				
Bilateral	116				53.2				
Total	218				100.0				

4.3 Number of casts applied during correction phase of Ponseti treatment

Idiopathic participants were casted less since the most, 68.5%, had 1–6 casts. Neurogenic ones on the contrary had more casts since more than half of them, 53.4%, had more than 6 casts. The Chi square test yielded a p value of 0.071 which is > 0.05 implying that there is no statistically significant difference in the distribution of number of casts by type of clubfoot.

Table 4.2: shows the comparative number of casts applied when managing both neurogenic and idiopathic CF using the Ponseti technique

		Number of casts				Total	
		1 - 6	7 - 12	13 - 20	21 - 30		
Type of clubfoot	Neurogenic	Count	7	4	4	0	15
		%	46.7%	26.7%	26.7%	0.0%	100.0%
	Idiopathic	Count	139	42	16	6	203
		%	68.5%	20.7%	7.9%	3.0%	100.0%
Total		Count	146	46	20	6	218
		%	67.0%	21.1%	9.2%	2.8%	100.0%
Chi-Square test		df	3			p value =	.071

4.4 Tenotomy rate

Neurogenic participants, 60%, had more tenotomies done than idiopathic 56.2%. 15 (7.5%) idiopathic participants had more than one tenotomy done while no neurogenic did. In total, only 56.2% of the 216 total participants had a tenotomy. The Chi square test yielded a p value of 0.776 which is > 0.05 implying that there is no statistically significant comparison in tenotomies and type of clubfoot.

Table 4.3: Number of idiopathic and neurogenic participants who did and did not receive a tenotomy during correction phase of Ponseti treatment

	Tenotomy done	Tenotomy not done	Totals
Neurogenic	9 (60%)	6 (40%)	15 (100%)
Idiopathic	113(56.2%)	88 (43.8%)	201(100%)
Totals	122 (56.5%)	94(43.5%)	216 (100%)
Chi-square test	df 0.81	P value	0.776

4.5 Brace compliance

Good bracing compliance was noted in 53.2% of the clients while 15.6% had poor brace compliance. Most of the neurogenic participants had fair brace compliance as opposed to idiopathic who had mostly good. 3 idiopathic clients didn't reach bracing stage. The Chi square test yielded a p value of 0.207 which is > 0.05 implying that there is no statistically significant difference in the distribution of brace compliance by type of clubfoot.

Table 4.4: Level of brace compliance in neurogenic and idiopathic CF participants during bracing phase of treatment

			Brace compliance				Total
			Poor	Fair	Good	Not reached bracing	
Type of clubfoot	Neurogenic	Count	1	8	6	0	15
		%	6.7%	53.3%	40.0%	0.0%	100.0%
Idiopathic		Count	33	57	110	3	203
		%	16.3%	28.1%	54.2%	1.5%	100.0%
Total		Count	34	65	116	3	218
		%	15.6%	29.8%	53.2%	1.4%	100.0%
Chi-square test			df	3	P value		0.207

4.6 Treatment complications

Among 218 total participants, 94% did not have any recorded complications. 1 neurogenic had experienced knocked knees during bracing and another pressure sores. Among idiopathic participants 4 experienced pressure sores during casting, 3 rash/redness, 1 tibial bowing and 3 knocked knees during casting. There was no statistically significant association between complications and type of clubfoot ($X^2 = 3.781$ (4); $p = .436$).

Table 4.5: Complications during casting, tenotomy and bracing of idiopathic and neurogenic CF participants

		Complications during treatment					Total	
		None	Pressure sores	Rash or redness	Tibial bowing	Knocked knees		
Type of clubfoot	Neurogenic	Count	13	1	0	0	1	15
		%	86.7%	6.7%	0.0%	0.0%	6.7%	100.0%
	Idiopathic	Count	192	4	3	1	3	203
		%	94.6%	2.0%	1.5%	.5%	1.5%	100.0%
Total		Count	205	5	3	1	4	218
		%	94.0%	2.3%	1.4%	.5%	1.8%	100.0%
Chi square test			df 4		P value 0.436			

4.7 Relapse

The relapse rate among all 218 participants was 21.6%. Table 4.8 shows the relapse was significantly higher in neurogenic participants at 60% while in idiopathic only 18.7% ($P = .000$). The mean age of relapse for all clients was 28.3 with a range of 6 to 96 months. The mean age of relapse for neurogenic clients was 41.6 while for idiopathic was 25.2 months demonstrating that relapse in neurogenic clients was noted later than in idiopathic.

Table 4.6: Relapse experienced by neurogenic and idiopathic participants during bracing period of treatment

	Relapse during bracing		Total	Mean age at relapse (months)
	Yes	No		
Neurogenic	9 (60%)	6 (40%)	15 (100%)	41.6
Idiopathic	38 (18.7%)	165(81.3%)	203 (100%)	25.2
Totals	47 (21.6%)	171(78.4%)	218 (100%)	28.3
Chi square test	df	1	P value	0.000

4.8 Surgical correction

Surgery such as tibialis anterior transfers, posterior-medio release (PMR) and others were indicated in 17.4% of all 218 participants. Neurogenic participants demonstrated a higher need for surgery at 40% while idiopathic was 15.8%. The Chi square test yielded a p value of 0.017 which is < 0.05 implying that there is statistically significant difference in the distribution of need for surgical correction by type of clubfoot. Refer to table 4.9

Table 4.7: Number of neurogenic and idiopathic participants who required additional surgery to tenotomy after initial successful Ponseti treatment

	No surgery after Ponseti	Surgery after Ponseti	Totals
Neurogenic	9(60%)	6(40%)	15(100%)
Idiopathic	171(84.2%)	32(15.8%)	203(100%)
Total	180(82.6%)	38(17.4%)	218(100%)
Chi square test		1	P value 0.017

4.9 Failure of Ponseti method

Only 3 out of 203 idiopathic participants were documented as having poor outcomes after casting using the Ponseti method. In contrast, only 2 (13.3%) of neurogenic participants were documented as having poor outcome after Ponseti casting. Overall Ponseti casting failed in 5 participants. There was no statistically significant association between type of clubfoot and outcome of Ponseti casting, although Chi square test yielded a *p* value of 0.003.

Table 4.8: Failure of Ponseti casting and tenotomy in treatment of idiopathic and neurogenic participants

	Failure of Ponseti casting	Yes	No	Totals
Type of Clubfoot	Neurogenic	2(13.3%)	13(86.7%)	15(100%)
	Idiopathic	3(1.5%)	200(98.5%)	203(100%)
	Totals	5(2.3%)	213(97.7%)	218(100%)
Chi square test		df 1		P value 0.003

4.10 Pirani scores

The Pirani scores were used to evaluate the severity of clubfoot at different phases of treatment. The study further sort to establish whether there were statistically significant differences between types of clubfoot and Pirani scores. The Pirani score ranges between 0 – 6 with the higher score representing a poor outcome. The differences in mean Pirani score for neurogenic and idiopathic clients at the various phases of treatment were not statistically significant with all *p* values > 0.05. Neurogenic clients had a mean Pirani score of 4.3 and 4.0 respectively for right and left feet at first assessment. Scores before tenotomy were 5.4 for right foot and 4.6 for left, at first brace application 2.9 for right and 1.7 for left and at last visit 2.6 for right and 1.8 for left. Idiopathic clients did not score differently from neurogenic as the scores were 4.9 and 5.2 for first assessment on right and left feet respectively. Before

tenotomy idiopathic clients scored 5.2 for right and 5.6 for left, at first brace application scored 2.2 for right and 2.9 for left and at last visit 1.9 for right and 2.6 for left.

The mean Pirani score at first assessment was 4.9 for right and 5.1 for left. Before tenotomy the mean score was 5.3 for right and 5.5 for left, first brace was 2.3 right and 2.8 left, finally, last visit was 2.0 right and 2.6 left. The scores before tenotomy were slightly higher than those at first assessment.

Table 4.9: Pirani scores during casting, tenotomy and bracing stages of treatment for idiopathic and neurogenic participants

Type of clubfoot	Neurogenic		Idiopathic		Total	
	Mean	N	Mean	N	Mean	N
1st assessment right foot	4.333	15	4.933	203	4.892	218
1st assessment left foot	4.033	15	5.185	203	5.106	218
Before 1st tenotomy on right foot	5.367	15	5.261	203	5.268	218
Before 1st tenotomy on left foot	4.600	15	5.611	203	5.541	218
1st brace application for right foot	2.867	15	2.234	203	2.278	218
1st brace application for left foot	1.700	15	2.926	203	2.842	218
On last visit for right foot	2.633	15	1.941	203	1.989	218
On last visit for left foot	1.767	15	2.616	203	2.557	218

4.11 Age at last assessment

The study utilized age at last assessment as part of the outcome indicators of treatment. Majority of clients, 24.3%, last appeared at the clinic at 0 – 12 months of age. The overall mean age at which all the clients were last seen at the clinic was 32 months. The mean age at last assessment for neurogenic clubfoot was 40.9 while that for idiopathic clubfoot was 31.3 months. Neurogenic clients had a longer follow up period with most of them last appearing at 37 - 48 months of age. While most idiopathic clients last appeared at the clinic at 0 – 12 months of age, the difference between both types of clubfoot was not statistically significant ($p=0.659 < 0.05$). Only 13.8% (30) of the total number of clients reached the current recommended age of discharge which is 5 years.

Table 4.10: Age at last documented assessment for neurogenic and idiopathic CF participants during course of treatment

Plea	Neurogenic		Idiopathic		Totals	
	Count	%	Count	%	Count	%
0 - 12	1	6.7	52	25.6	53	24.3
13 - 24	3	20	43	21.2	46	21.1
25 - 36	2	13.3	37	18.2	39	17.9
37 - 48	4	26.7	28	13.8	32	14.7
49 - 60	3	20.0	27	13.3	30	13.8
61 - 72	1	6.7	9	4.4	10	4.6
73 - 84	0	0.0	2	1.0	2	0.9
85 - 96	0	0.0	1	0.5	1	0.5
97 - 108	1	6.7	3	1.5	4	1.8
109 - 120	0	0.0	1	0.5	1	0.5
Totals	15	100	203	100	218	100
Mean age	40.87		31.32		31.97	
Chi square test			df	9	P value	0.659

4.12 Telephone interview - Pain

Pain in affected feet, ability to wear parent/guardian choice of shoes and parent/guardian satisfaction were used as an outcome indicator. In all 218 clients, 63.8% reported “no” to whether the child currently has pain in the affected feet/foot. Out of the 12 neurogenic clients, 9 reported “no” to pain while 4 reported “yes, but it doesn’t limit their activity” and 1 reported “yes, it often limits their activity”. 54 out of the 203 idiopathic clients reported that pain was present but did not limit activity while 16 it sometimes did and 3 that it often did. There was no statistically significant relationship between type of clubfoot and pain.

Table 4.11: Current level of pain in idiopathic and neurogenic CF participants after treatment

		Does your child complain of pain in the affected foot or feet?				Total	
		Yes it often limits their activity	Yes, it sometimes limits their activity	Yes but it doesn't limit their activity	No		
Type of clubfoot	Neurogenic	Count	1	1	4	9	15
		%	6.7%	6.7%	26.7%	60.0%	100%
	Idiopathic	Count	3	16	54	130	203
		%	1.5%	7.9%	26.6%	64.0%	100%
Total		Count	4	17	58	139	218
		%	1.8%	7.8%	26.6%	63.8%	100%
Chi-square tests			df	3	P value	0.550	

4.13 Telephone interview – Ability to wear normal shoes

Among all clients, 70.2% reported that they were “always” able to wear shoes of their choice while 19.7% “usually” did, 7.8% “sometimes” did and 2.3% “never”. A higher percentage, 13.3% of neurogenic clients reported that they could “sometimes” wear shoes of their choice as opposed to idiopathic who were 7.4%. The difference between types of clubfoot and ability to wear shoes of parents/guardians choice had a *P* value of .505 which is >0.05 and is not statistically significant.

Table 4.12: Ability of neurogenic and idiopathic participants to wear shoes of care giver/participant’s choice

		Can your child wear shoes of your/their choice?				Total
		Never	Sometimes	Usually	Always	
Type of clubfoot	Neurogenic	Count 1	2	2	10	15
		% 6.7%	13.3%	13.3%	66.7%	100%
	Idiopathic	Count 4	15	41	143	203
		% 2.0%	7.4%	20.2%	70.4%	100%
Total		Count 5	17	43	153	218
		% 2.3%	7.8%	19.7%	70.2%	100%
Chi-square tests		df	3	P value	0.505	

4.14 Telephone interview – Parent/guardian satisfaction with treatment outcomes

Parents of neurogenic clients were less satisfied with the outcomes of treatment since 26.6% were “somewhat and very dissatisfied” as compared to only 7.9% of idiopathic clients. In general, 19.7% of clients were “somewhat satisfied”, 6.4% “somewhat dissatisfied” and 2.8% “very dissatisfied”. Only 46.7% of neurogenic patient parents/guardians were very satisfied with treatment while 72.9% of idiopathic were. There was statistically significant association between type of clubfoot and parent/guardian satisfaction outcome, with Chi square test *p* value of 0.023.

Table 4.13: Parent/guardian satisfaction with treatment outcomes of idiopathic and neurogenic CF participants

		Are you as the child's parent or guardian satisfied with the outcomes of the treatment?				Total
		Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied	
Type of clubfoot	Neurogenic	Count 2	2	4	7	15
		% 13.3%	13.3%	26.7%	46.7%	100%
	Idiopathic	Count 4	12	39	148	203
		% 2.0%	5.9%	19.2%	72.9%	100%
Total		Count 6	14	43	155	218
		% 2.8%	6.4%	19.7%	71.1%	100%
Chi-square tests		df	3	P value	0.023	

Table 4.14: Summary of all clinical and parent/guardian reported outcomes of idiopathic and neurogenic clubfoot participants

	Idiopathic	Neurogenic	P value
% Clients with 1 – 6 casts	68.5	46.7	0.071

% Tenotomy rate	60	48.8	0.776
% with good brace compliance	54.2	40	0.207
% with no complications	94.6	86.7	0.436
% with relapse	18.7	60	0.000
% who required surgery after Ponseti	84.2	60	0.017
% failed at Ponseti casting	1.5	13.3	0.003
% age at last assessment 0 – 12 months	25.6	6.7	0.659
% pain often limits activity	1.5	6.7	0.550
% never able to wear shoes of choice	2.0	6.7	0.505
% caregivers very dissatisfied with treatment outcomes	2.0	13.3	0.023

CHAPTER FIVE

DISCUSSION

In this study, the researcher set to determine the comparison between Ponseti technique outcomes of neurogenic and idiopathic clubfoot amongst clients enrolled in AIC Cure hospital clubfoot clinic between 2005 and 2014. In total 218 clients' files were analyzed from which 15 were neurogenic and 203 idiopathic. Most clients, 53%, had bilateral clubfoot as opposed to unilateral. Males made up the majority of clients at 72% which has been replicated in many studies on clubfoot showing that it is twice as common in males compared to females (Adewole *et al.*, 2014; Chen *et al.*, 2018; Dobbs & Gurnett, 2009, 2012). Out of 218 files, 16.2% confirmed a positive presence of clubfoot in their families. Previous research has proven that clubfoot demonstrates hereditary links in as much as 25% of idiopathic clubfoot clients (Dobbs & Gurnett, 2012; Ganesan *et al.*, 2017). The average age of the clients was 20 weeks in idiopathic and 23 weeks in neurogenic. Older studies have shown the same results of neurogenic clients starting treatment later than idiopathic (Gerlach *et al.*, 2009; Janicki *et al.*, 2009) while recent research has shown treatment started earlier (Gelfer *et al.*, 2014; Jackson *et al.*, 2019; Moroney *et al.*, 2012). This can be attributed to increased awareness amongst care givers and health workers regarding clubfoot treatment.

Neurogenic clubfoot clients were casted more as compared to those with idiopathic type since 53.4% of them had more than 6 casts while 68.5% of idiopathic had 1 – 6 casts. This finding correlates to that of a systematic review of the effectiveness of Ponseti technique in non-idiopathic clubfoot treatment that most studies reported an average of 7.2 casts in all non-idiopathic cases (Mulder *et al.*, 2018). Neurogenic clubfoot clients have been shown to be more resistant to casting as opposed to idiopathic (Janicki *et al.*, 2009). In a prospective 5 year study, an average of 6.4 casts were required for non-idiopathic correction as opposed to 5.1 for idiopathic while in another retrospective study the average for non-idiopathic was 6.5 casts (Arkin *et al.*, 2018; Mulder *et al.*, 2018).

Percutaneous tenotomy refers to the complete cut made to the Achilles tendon to allow dorsiflexion. The percutaneous tenotomy rate in this study was low at 60% for neurogenic and 48.8% in idiopathic. One retrospective study of patients in Canada who were treated between 2001 and 2005 had a similar tenotomy rate to the current study at 68% (Janicki *et*

al., 2009). However, the low rate of tenotomy in both studies might be because only until recently most clinicians perceived that a tenotomy is not compulsory in clubfoot treatment. Many studies of neurogenic clubfoot demonstrate a tenotomy rate of as high as 93% (Arkin *et al.*, 2018; Bor *et al.*, 2009; Janicki *et al.*, 2009; Mulder *et al.*, 2018) which demonstrates that even for neurogenic clubfoot, a tenotomy rate of above 90% can be achieved. Some clinicians tend to erroneously believe that tenotomy should not be done for neurogenic clubfoot due to the lack of muscle strength in some patients.

It is important to note that in many clubfoot clinics outside Africa open tenotomies are done for neurogenic clients and have shown to have less relapse as compared to percutaneous tenotomy (Arkin *et al.*, 2018). None of the neurogenic clients in this study were reported to have a tenotomy more than once while 7.5% of idiopathic did. This finding is different from others which have shown that after relapse it is not uncommon for tenotomy to be done after re-casting (Gerlach *et al.*, 2009; Moroney *et al.*, 2012; Mulder *et al.*, 2018). Furthermore, some studies have established an association between a higher number of casts and stronger need for tenotomy in idiopathic patients (Bor *et al.*, 2009).

Brace compliance has been identified as the most important factor in clubfoot relapse (Goriainov *et al.*, 2010; Moroney *et al.*, 2012; Zhao *et al.*, 2014). Maintenance of the corrected foot through bracing recommended until the child is 5 years of age to prevent relapse. In this study, a higher percentage of neurogenic clients, 53.3%, were rated to have “fair” brace compliance while 54.2% of idiopathic had “good” compliance. A retrospective study showed similar results with 55.7% of idiopathic clients having “good” brace compliance (Bor *et al.*, 2009). Neurogenic clubfoot is considered typically harder to brace since the correction achieved is not always optimal (Janicki *et al.*, 2009; Mulder *et al.*, 2018). Regardless, many studies have shown high brace non-compliance rates in idiopathic clubfoot patients (Zhao *et al.*, 2014). In Kenya, the Steenbeek foot abduction braces (SFAB) is the most commonly used brace for clubfoot since it is inexpensive. The SFAB is fixed in 70° abduction and 15° dorsiflexion with a bar between the shoes making it hard for the child to move feet independently (Desai *et al.*, 2010). Parents often find this difficult since the child takes time to adjusting to both feet being held. It is important to note that non-compliance is not clearly stated in the clinic that was understudy.

Complications are usually found in the casting phase of treatment and do not necessitate a major change in the course of treatment (Khan *et al.*, 2017; Mulder *et al.*, 2018). Redness,

blistering and swelling are the most common complications. In addition to these complications, cast slippage, developmental dysplasia of the hip (DDH) and knocked knees can also occur in neurogenic patients (Gerlach *et al.*, 2009; Matar *et al.*, 2017). Complications such as DDH and knocked knees occur due to muscle tone changes that are caused by neurogenic system damage (Matar *et al.*, 2017). Most idiopathic and neurogenic clients, 94.6% and 86.7% respectively, in this study did not experience any complications during their treatment. In contrast to the current study finding, previous studies show a higher percentage of neurogenic clients had complications (Arkin *et al.*, 2018; Gerlach *et al.*, 2009; Mulder *et al.*, 2018). In this research, as with other similar ones, there was no statistically significant association between complications and type of clubfoot (Mulder *et al.*, 2018).

Relapse was higher in neurogenic clients in this study at 60% while idiopathic only 18.7%. A systematic review by Mulder *et al.*, (2018), replicated the current finding since they found 43.3% versus 11.5% relapse rates in neurogenic and idiopathic clients respectively. Other studies found relapse rates of approximately 55% - 60% and some replicated the (Arkin *et al.*, 2018; David J. Gerlach *et al.*, 2009; Janicki *et al.*, 2009). These results are not surprising since neurogenic clubfoot is considered as more rigid and expected to relapse more than idiopathic (Mulder *et al.*, 2018). The current study has slightly higher relapses for both idiopathic and neurogenic. This may be explained by the fact that majority of clients, 24.3%, last appeared at the clinic at 0 – 12 months of age meaning that that is when they had stopped bracing. In the early 2000s bracing was being done until the affected children are aged 3 – 4 years as opposed to the current gold standard of 5 years. Brace wear of less than 5 years has been statistically linked to relapse (Mulder *et al.*, 2018; Zhao *et al.*, 2014).

Furthermore, it is important to realize that the definition of relapse is not universal. Some studies define it as a return in any of the clubfoot signs (Park *et al.*, 2012) while others, as in this research, define it as a need for recasting or surgery following relapse (Janicki *et al.*, 2009). Relapse in neurogenic clubfoot is often treated with recasting and tenotomy but some clinicians prefer surgery since they claim not to have good results with recasting (Arkin *et al.*, 2018). This clinical standpoint might be valid since a high percentage of neurogenic clients in the current study, 40%, also required surgery after initial treatment. Whereas, only 15.8% idiopathic clients required surgery in the current study, there was as statistically significant ($P = .017$) association between type of clubfoot and need for surgery. Similar previous studies results show slightly higher surgery rates of 33% and 37% (Bor *et al.*, 2009; Janicki *et al.*,

2009; Moroney *et al.*, 2012). This might be because surgery in more developed countries is more readily accessible than in Kenya.

Though rare, the Ponseti method has been shown to fail to achieve correction in some clients with clubfoot (Ganesan *et al.*, 2017; Mulder *et al.*, 2018; Zhao *et al.*, 2014). Failure of Ponseti is difficult to define since only recently has a universally accepted definition for success been established (Smythe *et al.*, 2019). In this study the Ponseti method failed to achieve initial correction in 3 neurogenic (13.3%) and 2 idiopathic (1.5%) demonstrating failure of Ponseti technique in more neurogenic clients. These findings are similar to those of a research conducted by Janicki *et al.* (2009) that showed a higher rate of failure to achieve initial correction in neurogenic versus idiopathic clients (10% versus 2%). Gerlach *et al.* (2009), in a prospective study, noted that only in 1 out of 28 spina bifida clients there was failure to achieve initial correction while no idiopathic patient did. Treatment of neurogenic clients is challenging, and this might be the cause of increased rate of failure.

The Pirani score is an outcome measure for clubfoot used in assessment and treatment. It comprises of 2 sections, the midfoot and hindfoot. The total score that can be achieved is 6, the higher the score the more severe the clubfoot (Aggarwal & Gupta, 2016). The mean initial Pirani score of the clients in the current study was 4.89 and 5.11 for the right and left respectively. This was slightly higher than the scores of Smythe *et al.*, (2019) who had 3.8 in the left and 3.7 in the right foot. Other studies demonstrated generally higher scores and neurogenic having a higher score than idiopathic (Bor *et al.*, 2009; Moroney *et al.*, 2012).

The Assessing Clubfoot Treatment (ACT) tool was used in this study to assess outcomes including pain in affected feet/foot, whether feet are in plantigrade, if shoes of parent's/clients choice can be worn and caregiver satisfaction. In the current study, 63.8% (n=109) caregivers reported "no" to whether the child currently has pain in the affected feet/foot. A significant number of caregivers, 73 for idiopathic and 6 for neurogenic, reported that pain was present with 3 and 1 respectively reporting that the pain limited activity. These findings correlate with one study that used the ACT tool which found 32% of their idiopathic clients experience pain (Smythe *et al.*, 2019). Another study found that 16.7% of their spina bifida clients had an unsatisfactory outcome including pain at 3 – 9 years after initial correction (Matar *et al.*, 2017). Bor *et al.*, (2009) asked parents a yes/no question regarding pain during a 5 year follow up assessment and found 88.2% of 68 idiopathic patient caregivers reported that pain was provoked with moderate exercise. Other studies on clubfoot

amongst neurogenic clients do not include assessment of pain probably because it is assumed that since there is neurological impairment, pain sensation is not present. Regardless, the current and other previous studies have shown that pain is experienced even in neurogenic clients. This implies that neurogenic clubfoot clients should be assessed just as those with idiopathic.

The ability to wear shoes of the caregivers choice was reported as “always” in 66.7% and 70.4% in neurogenic and idiopathic clients respectively. There was no statistically significant association between type of clubfoot and the ability to wear shoes. These findings suggest that the feet were not in plantigrade and that further assessment is needed to confirm relapse. In a study by Smythe *et al.* (2019) in Zimbabwe, 71% of the caregivers reported that clients who had idiopathic clubfeet wore shoes of their choice “always”. It is important to note that the clients in this study had idiopathic clubfoot only and 3.5 to 5 years of age while the ones in the current study were 10 years. Other similar studies on neurogenic clients showed similar results, in that, 64.7% to 83.3% of the clients had a satisfactory outcome including “braceable and functional feet” (Matar *et al.*, 2017). Idiopathic clients have also been reported to have 73.5% and 82.4% shoes liked and shoes fit scores respectively denoting good outcomes on satisfaction even in other settings (Bor *et al.*, 2009).

In the current study, caregivers of neurogenic clubfeet clients were less satisfied than those with idiopathic type. Other similar studies have not found this relationship but found between 70% - 90% parental satisfaction with idiopathic clubfoot (Bor *et al.*, 2009; Chueire *et al.*, 2016; Švehlík *et al.*, 2017). Some studies on outcomes of Ponseti method in neurogenic clubfoot have not looked at parental/caregiver satisfaction (Matar *et al.*, 2017). Using the ACT tool, (Smythe *et al.*, 2019) found 65% of caregivers of clients who had completed casting were very satisfied with the outcome. The question on parental satisfaction is a unique aspect of the ACT tool since it encourages a more holistic look at healing as opposed to only medical.

5.1 Conclusions

In conclusion, Ponseti appears to have acceptable outcomes in managing idiopathic as well as neurogenic clients. It is apparent that neurogenic clients contributed one out of twenty cases seen at AIC Cure International hospital between 2005-2014 that is comparable to reports from studies in other countries. On average over two thirds of the clients with idiopathic

clubfeet had 6 casts or less while a half of neurogenic clubfeet clients had more than 6 casts. Further slightly under 2 out of 3 neurogenic clubfeet clients had tenotomy compared to those of idiopathic type who had 1 out of 2 that underwent the procedure. Rate of relapse was marked in neurogenic clubfeet clients as opposed to those with idiopathic form. It was apparent that neurogenic clubfeet clients are more likely to require additional surgery compared to those with idiopathic form. This could imply that there is a possibility of failure of the Ponseti method to yield expected results in neurogenic clubfoot. Furthermore, there was a statistically significant relationship between: type of clubfoot and relapse, need for surgical correction, failure of the Ponseti method and caregiver satisfaction.

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APPENDICES

Appendix I: Timelines

	Nov 2018 - Apr 2019	May 2019- Dec 2019	Dec 2019- June 2020	July 2020- Aug 2020	Sept 2020- Nov 2020	Dec 2020- Jan 2021	Feb 2020- Mar 2020
Proposal development							
Presentation to BPS							
Ethics application							
Data collection							
Data analysis							
Presentation of results							
Write up							
Submission							
Publication							

Appendix II: Budget

Item	No of units	Each cost	Total cost
Research assistant fees	2	3000	6000
Transport fees	8	500	4000
Stationary and photocopying	300	10	3000
Telephone charges	-	-	2000
Internet services	-	-	5000
Total			20,000Ksh

Contacts: Sign:

Person Obtaining Consent:

Name of Person Obtaining Consent: Title.....

Contacts: Sign:

Date:

Appendix IV: Data Collection Tool

Data collection tool

Serial No; _____

- Clubfoot diagnosis – Neurogenic
- Idiopathic
- Laterality – Bilateral
- Unilateral

Section 1 Participant demographic details

- Age - _____
- Sex- _____
- County of residence - _____
- Clubfoot presence in family history – Present
- Absent
- Place of birth – Medical facility
- Home
- Other

Section 2 Outcome indicators

- Number of casts applied - _____
- Tenotomy done – Yes
- No
- More than once
- 1st brace compliance – Poor
- Fair
- Good
- Complications during treatment if any – None
- Pressure sores
- Rash or redness
- Tibial bowing

A = Allergic Reaction; **B** = Broken / Damaged Cast; **C** = Compression; **CO** = Cast Came Off; **CS** = Cast Slipped / Shifted; **O** = Other Problem; **P** = Pressure Sore; **R** = Relapse; **S** – Skin Rash

Brace Compliance Key: Good, Fair, Poor

Treatment Key:

C - Manipulation & Casting; **T** - Tenotomy; **B** - Brace Application, **R** - Refer; **S** - surgery, **O** - Other Treatment (please give details); **TS:** Treatment Suspended, **FTA** Failure to Attend.

Brace wearing schedule:

First 3 months: fulltime (except bathing)


Until Child is 5 years: nights only

Section 3 Telephone interview

Introduction about the researcher and study. Verbal consent taken.

- Does the child experience any pain? Yes No
- Is the child able to wear the normal shoes? Yes No
- Are you as the parent/guardian of the child satisfied with the outcomes of the treatment? Yes No

Appendix V: NACOSTI approval



The image shows a research license document from the National Commission for Science, Technology & Innovation (NACOSTI). It includes the Kenyan coat of arms, the NACOSTI logo, and the text: 'RESEARCH LICENSE', 'Date of Issue: 15-May-2021', 'License No: NACOSTI/P/20/4920', and 'Applicant Identification Number: 485811'. A photograph of Victoria Kimathi is included. The license certifies her for research on 'Correlation between Ponseti technique outcomes of neurogenic and idiopathic clubfoot amongst clients enrolled in AIC Cure hospital clubfoot clinic from 2005 to 2014 for the period ending : 15/May/2021'. It also features a signature of the Director General and a QR code for verification.

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Appendix VI: JKUAT ERC approval



**JOMO KENYATTA UNIVERSITY
OF
AGRICULTURE AND TECHNOLOGY**
P. O. Box 62000-00200 Nairobi, Kenya Tel 0675870225 OR Extn 3209
Institutional Ethics Review Committee

September 20th, 2019

REF: JKU/2/4/896B

Victoria Naitore Kimathi,
Department of Physiotherapy.

Dear Ms. Kimathi,

RE: CORRELATION BETWEEN PONSETI TECHNIQUE OUTCOMES OF NEUROGENIC AND IDIOPATHIC CLUBFOOT AMONGST CLIENTS ENROLLED IN AIC CURE HOSPITAL CLUBFOOT CLINIC FROM 2005 TO 2014


The JKUAT Institutional Ethics Review Committee has reviewed your responses to issues raised regarding your application to conduct the above mentioned study with you as the Principal Investigator.

The is to inform you that the IERC has approved your protocol. The approval period is from September 20th 2019 to September 20th 2020 and is subject to compliance with the following requirements:

- a) Only approved documents (informed consent, study instruments, study protocol, etc.) will be used.
- b) All changes (amendments, deviations, violations, etc.) must be submitted for review and approval by the JKUAT IERC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the IERC immediately.
- d) Any changes, anticipated or otherwise that may increase the risks to or affect the welfare of study participants and others or affect the integrity of the study must be reported immediately.
- e) Should you require an extension of the approval period, kindly submit a request for extension 60 days prior to the expiry of the current approval period and attach supporting documentation.
- f) Clearance for export of data or specimens must be obtained from the JKUAT IERC as well as the relevant government agencies for each consignment for export.
- g) The IERC requires a copy of the final report for record to reduce chances for duplication of similar studies.

Should you require clarification, kindly contact the JKUAT IERC Secretariat.

Yours Sincerely,


DR. PATRICK MBINDYO
SECRETARY, IERC



JKUAT is ISO 9001:2015 and ISO 14001:2015 Certified
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Appendix VII: Publication

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CORRELATION BETWEEN PONSETI TECHNIQUE OUTCOMES OF NEUROGENIC AND IDIOPATHIC CLUBFOOT AMONGST PATIENTS ENROLLED AT AIC CURE HOSPITAL CLUBFOOT CLINIC FROM 2005 TO 2014

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**CORRELATION BETWEEN PONSETI TECHNIQUE OUTCOMES OF
NEUROGENIC AND IDIOPATHIC CLUBFOOT AMONGST PATIENTS
ENROLLED AT AIC CURE HOSPITAL CLUBFOOT CLINIC FROM 2005 TO 2014**

V. N. Kimathi, J. M. Matheri, W. K. Mugambi and T. B. Kagoda

ABSTRACT

***Objective:* To determine the correlation between Ponseti technique outcomes of neurogenic and idiopathic CF amongst patients enrolled at AIC Cure hospital clubfoot clinic from 2005 to 2014**

***Design:* A retrospective study in which files were randomly sampled**

***Setting:* AIC Cure International hospital clubfoot clinic situated in Kiambu County, Kenya.**

***Study participants:* Neurogenic and idiopathic clubfoot patients registered at clinic between 2005 and 2014**

Main outcome measures: Standard tools were used to measure number of casts applied, tenotomies done, brace compliance, relapse, surgical correction, failure to correct, age at last assessment, plantigrade, pain, ability to wear shoes of choice and parental satisfaction.

Results: Among all files reviewed, 64% (n=203) of patients had idiopathic whilst 4.8% (n=15) had neurogenic clubfoot. The mean age at 1st assessment was 5 months while most patients were 109 – 120 months (10 years) at time of study. Idiopathic CF patients were casted less than neurogenic. Neurogenic CF patients had a statistically significant higher relapse rate at 60% ($P= .000$) and higher need for surgery ($P=.017$). Failure of Ponseti occurred in 3 out of 203 idiopathic and 2 out of 15 neurogenic patients. Care givers of neurogenic patients expressed less satisfaction with 16.7% being “very dissatisfied”.

Conclusion: Clinicians attending to patients with CF should consider modifying the Ponseti method to improve neurogenic patients outcomes and care giver satisfaction.

INTRODUCTION

The Ponseti method, which was initially meant for correcting idiopathic clubfoot (CF), is increasingly being used for neurogenic CF worldwide^{1,2}. Idiopathic type of CF accounts for the majority of all CF whereas those associated with other conditions such as spina bifida makes up to 20%³. Other proportions include syndromic and postural CF. The commonest etiologies of nonidiopathic CF include arthrogryposis and spina bifida^{2,4}.

The Ponseti method involves specific manipulations and serial casting, followed by tenotomy of the achilles tendon and later bracing to maintain correction for up to 5 years of age¹. Apart from Ponseti, Kite, surgery, French method and specific splinting and taping are used in treatment for CF⁽⁵⁾. A recent study showed a 96% success rate in treatment of idiopathic CF using the Ponseti method¹. Invasive methods such as surgery have been linked to pain, high relapse and failure rates including poor quality of life¹. Proponents of Ponseti as the conservative treatment method of choice for neurogenic CF argue that it decreases the

number of surgical interventions needed⁵. Neurogenic CF is difficult to treat because of a myriad of risks including swelling and pressure sores when casted, relapse, deformity after bracing and failure to correct⁶. Despite the risks, the Ponseti method is of late being used for neurogenic patients due to the favourable functional outcomes seen in idiopathic CF and the conservative nature⁶.

Limited studies have been done to find out the correlation between outcomes of the Ponseti method for neurogenic and idiopathic CF. In a Canadian hospital study of 23 non-idiopathic CF patients and 171 idiopathic CF patients, 1 year after undergoing the Ponseti method, Janicki et al.(2009) found that 28% of non-idiopathic CF patients required more procedures, and had a higher rate of failure and relapse. Janicki et al (2009) also observed that the Ponseti method only failed completely in 4 nonidiopathic CF patients indicating suitability of its use. This concurs with Mulder, Prinsen and Campenhout (2018) proposition that the Ponseti method is valuable in treatment of non-idiopathic CF because of its noninvasive nature.

Essentially, the skeletal malalignment for both neurogenic and idiopathic CF are

similar³. The similarity in the malalignment informs the motivation for the use of Ponseti technique in treatment of both neurogenic and idiopathic CF. However, there is lack of literature on the outcomes of the Ponseti technique in neurogenic CF as also reported by Ganesan et al., (2017). The purpose of this study was to fill the gap by establishing the correlation between types of CF and the Ponseti technique outcomes amongst patients enrolled in AIC Cure International hospital CF clinic from 2005 to 2014. Empirical data on the effectiveness of the Ponseti method in treatment of idiopathic CF informed its adoption as an approach of choice for clubfoot treatment¹. It is therefore envisaged that findings from studies such as the current one may inform future clinician decisions to improve outcomes of patients with neurogenic CF.

METHODOLOGY

The study was conducted at AIC Cure International hospital in Kiambu, Kenya which has a CF clinic supported by Hope Walks through Clubfoot Care for Kenya (CCK). Ethical approval was obtained from Jomo Kenyatta University of Agriculture and Technology Ethical Review committee and AIC Cure International research board. Patient files were sampled from those who had Ponseti treatment between 2005 and 2015 excluding those who had not completed the 5-year treatment period at the time of the study. Simple random sampling was employed where every 5th file from a

population of 1800 files was picked. A total sample of 327 patient files were selected. Of the 327 patients, 10 declined to participate when contacted by telephone and 4 were deceased. The distribution by diagnosis of the 313 patients included 38 syndromic, 57 postural, 203 idiopathic and 15 neurogenic. Data from the files was extracted using a structured tool that had three sections. Section one had five questions on demographic characteristics and social history. Section two investigated eight clinical outcomes namely, number of casts applied, Pirani score, tenotomies done, brace compliance, relapse, surgical correction, failure to correct and age at last assessment. Section three was a modified "Assessing Clubfoot Treatment" (ACT) measure for, ability to wear shoes, pain free and parental satisfaction. Data for the third section of the tool was gathered through telephone interview. The Pirani score and ACT measure have been validated in various contexts. The Pirani scale has been shown to have excellent inter-rater agreement of 83%^{8,9}. Complete questionnaires were serialised for confidentiality. SPSS version 26.0 was used to analyze the data.

RESULTS

Out of a sample of 313 files, 203 (64.9%) were idiopathic whilst 15 (4.8%) were neurogenic. The rest of the files were for postural and syndromic patients. Only the files for idiopathic and neurogenic CF patients (218) were included for further analysis (see table

Table 1
Proportions of types of clubfoot

Type of CF	Number of files	Percentage
Idiopathic	203	64.9
Neurogenic	15	4.8
Postural	57	18.2
Syndromic	38	12.1
Total	313	100

1). Most patients were 109 – 120 months (9-10 years) of age at time of study. The mean age of the patients at 1st assessment was 5 months. Males were (n=164, 71.9%) more than females (n=64, 28.1%). Only 37 (16.2%) of the patients reported that there was a history of CF in their immediate and extended family. Total number of files that had data on number of casts was 214, 199 idiopathic and 15 neurogenic. Idiopathic patients had less number of cast applications with 68.8% having 1–6 casts while, 53.4% of neurogenic patients had more than 6 casts. There was no statistically significant correlation between number of casts and the type of CF ($P=0.078$). Concerning percutaneous tenotomies, more neurogenic participants, 60%, had tenotomy done compared to only 48.8% of those with idiopathic CF. Overall, only 56.2% of the 216 patients who completed Ponseti method regime received tenotomy. There was no statistically significant correlation between tenotomies and type of CF ($P=0.776$). After casting, 3 idiopathic clients did not reach bracing stage. Brace compliance data was only found for 188 patients out of which 54.3% had good brace compliance while 14.4% had poor. Most of the neurogenic patients 53.8% (7) had fair level of brace compliance while 54.9% of those with idiopathic had good. There was no statistically significant significance in the distribution of brace compliance by type of CF ($P=0.164$). A 21.6% relapse rate was recorded among the 218 patients which was significantly associated with type of CF ($P = 0.000$). A higher proportion of patients (60%) with neurogenic compared to only 18.7% among those with idiopathic CF had relapse. Generally, the mean age of relapse was 28.3 months with a range of 6 to 96 months. However, the mean age of relapse for those with neurogenic was 41.6 months while for

extended family. Most participants, 199 (87.3%), were recorded to have been born in a medical facility while 20 (8.8%), were born at home and 8 (3.5%) participants' files lacked that information. The majority of patients, 116 (53%) had bilateral clubfoot.

idiopathic was 25.2 months. Of all 218 participants, 17.4% were indicated for tibialis anterior transfers, posterior-medio release (PMR) and other forms of surgery. Neurogenic patients demonstrated a statistically higher need for surgery ($P=0.017$). Only 3 out of 203 idiopathic patients were documented as having unsatisfactory outcomes after Ponseti casting. In contrast, 2 (13.3%) of neurogenic patients were documented as having failed Ponseti casting. In total 5 patients failed Ponseti casting. Only 30 (13.8%) of the total number of patients reached the recommended age of discharge which is 5 years. Majority of patients, 24.3%, last appeared at the clinic at 0 – 12 months of age. The mean age at last assessment for neurogenic CF was 40.9 months while that for idiopathic CF was 31.3 months. Neurogenic patients had a longer follow up period with most of them last appearing at 37 - 48 months of age. The correlation between both types of CF and age at last assessment was not statistically significant ($p=0.659 < 0.05$).

From ACT tool questions on “pain in affected feet, ability to wear parent/guardian choice of shoes and parent/guardian satisfaction” were used as outcome indicators. While conducting the telephone interviews, 53 parents/guardians did not pick the researchers' call and 2 reported that their children were deceased. In all 163 patients that responded, 66.9% reported “no” to whether the child currently has pain in the affected feet/foot. Out of the 12 neurogenic patients, 9 reported “no” to pain while two reported “yes, but it doesn't limit their

activity” and one reported “yes, it often limits their activity”. A significant number of idiopathic patients, 23.8%, reported that pain was present but did not limit activity while 7.9% reported that it sometimes did limit activity and 2% that it often did. There was no statistical correlation between type of CF and pain ($P = 0.369$).

Among all patients, 76.1% reported that they were “always” able to wear shoes of their choice while 14.1% “usually” did, 7.4% “sometimes” did and 2.5% “never”. A higher percentage, 16.7% of neurogenic patients reported that they could “sometimes” wear shoes of their choice as opposed to idiopathic who were only 6.6%. There was no

correlation between types of CF and ability to wear shoes of parents/guardians choice ($P = 0.283$).

Parents of neurogenic patients were less satisfied with the outcomes of treatment as compared to those of idiopathic CF. This was also found to be statistically significant ($P=0.009$) indicating an association between type of CF and parent/guardian satisfaction. In general, 18.4% of patients were “somewhat satisfied”, 6.7% “somewhat dissatisfied” and 3.1% “very dissatisfied”. Only 41.7% of neurogenic patient parents/guardians were very satisfied with treatment while 74.2% of idiopathic were.

Table 2 Summary of outcomes according to type of clubfoot

	Idiopathic	Neurogenic	P value
% Patients with 1 – 6 casts	68.8	46.7	0.078
% Tenotomy rate	60	48.8	0.776
% with good brace compliance	54.9	46.2	0.164
% with no complications	94.5	86.7	0.448
% with relapse	18.7	60	0.000
% who required surgery after Ponseti	84.2	60	0.017
% failed at Ponseti casting	1.5	13.3	0.003
% age at last assessment 0 – 12 months	25.6	6.7	0.659
% pain often limits activity	2	8.3	0.369
% never able to wear shoes of choice	2	8.3	0.283
% caregivers very dissatisfied with treatment outcomes	2	16.7	0.009

DISCUSSION

In this study, the researcher set to determine the correlation between Ponseti technique outcomes of neurogenic and idiopathic CF amongst clients enrolled in AIC Cure hospital CF clinic between 2005 to 2015. Most patients, 53%, had bilateral CF as opposed to unilateral. Males made up the majority of clients at 72% which is similar to reports of previous studies that show male female ratio of 2:1^{2,10}. In the current study, 16.2% of patients' files had proof of family history of clubfoot. Previous studies show disparate proportions of patients with family history of CF ranging from 3% to 25%². In our study, 20 weeks was the average age at which treatment commenced for idiopathic and 23 weeks for neurogenic CF patients. Late start of treatment for neurogenic patients in our study setting might have been occasioned by longer Neonatal Born Unit (NBU) stay due to medical instability and spina bifida correction.

Concerning casting, over half of neurogenic CF patients (53.4%) had more than 6 casts applied compared to less than a third (31.1%) of those with idiopathic clubfoot. This study finding is similar to previous studies that showed an average of 6.4 casts for nonidiopathic CF correction as opposed to only

5.1 for idiopathic ones⁴. According to Janicki et al. (2009) neurogenic patients are more resistant to casting as opposed to idiopathic because of increased rigidity that limit kinematic coupling movements during correction.

Further, in this study, percutaneous tenotomy rate was at 60% for neurogenic and 56.2% in idiopathic which is low compared to over 90% rate which is recommended in the Ponseti method and reported in high income countries^{4,7,11}. The rate is however lower in Haiti where 34% was reported¹². The difference in tenotomy rates might be because most clinicians in Kenya perceive that tenotomy as not priority in CF treatment. However, through introduction of the standardized Africa Clubfoot Training, Kenyan clinicians have began to appreciate the importance of tenotomy¹³.

Brace compliance has been identified as the most important factor in CF relapse prevention^{14,15}. In this study, a higher percentage of neurogenic patients (53%) were rated to have "fair" brace compliance while (54%) of idiopathic had "good" compliance. A retrospective study showed similar results with 55.7% of idiopathic patients having "good" brace compliance¹⁶. Neurogenic CF is typically harder to brace since correction achieved is not always optimal^{4,7}.

In the current study, relapse is defined as a need for recasting and tenotomy or surgery after successful initial treatment⁷. Relapse was statistically significantly associated with type of CF (60% relapse rate for neurogenic and 18.7% for idiopathic clubfeet ($P = .000$)). Our study finding is similar to a systematic review by Mulder et al., (2018), that established there was an association between relapse as an outcome and type of CF (43.3% versus 11.5% relapse rates for neurogenic and idiopathic patients respectively).

Other previous studies reported relapse rates of approximately 55% - 60% for neurogenic and some replicated the association (Arkin et al., 2018; Gerlach et al., 2009; Janicki et al., 2009). The results are not unexpected since neurogenic CF is more rigid and is reported to require repeat treatment^{4,7,11}. Majority of patients, 24.3%, last appeared at the clinic at 0 – 12 months of age which may imply they had stopped bracing due to care givers doubt of recurrence. In the early 2000s bracing was being done until 3 – 4 years of age as opposed to the current gold standard of 5 years. Application of braces for less than 5 years has been linked to relapse^{4,15}. It is important to note that in some countries, open tenotomies are done for neurogenic patients and have shown to have less relapse as compared to the less costly percutaneous tenotomy performed in our context¹¹.

Though rare, the Ponseti method has been shown to fail in some patients^{1,4,15}. In this study the Ponseti method failed in 13.3% of neurogenic and 1.5% of idiopathic patients. However, there was no correlation between failure of Ponseti and type of CF. These findings were similar to those found by Janicki et al., (2009) that showed higher rate of failure to achieve initial correction in neurogenic compared to idiopathic clufoot patients (that is, 10% and 2% respectively). In the current study, surgery was indicated in 40% and 15.8% of neurogenic and idiopathic CF patients respectively. The correlation between type of CF and need for surgery was statistically significant ($P= 0.017$). Similar studies reproduced these results with surgery indicated in 33% to 37% of neurogenic CF patients^{7,14,16}.

In the current study, 23.8% idiopathic and 16% neurogenic reported that pain was present in the affected feet/foot but did not limit activity while 2% and 8.3% respectively reported that pain limited them in physical activities. These findings correlate with one study that used the ACT tool which found 32% of their idiopathic patients experienced pain¹⁸. Another study found that 16.7% of their spinal bifida patients had an unsatisfactory outcome including pain at 3 – 9 years after initial correction⁶.

The ability to wear shoes of the caregivers choice was reported as “never” in 8.3% of neurogenic and 2% of idiopathic patients. There was no statistically significant association between type of CF and the ability to wear shoes. These findings suggest that for caregivers who reported “usually”, “sometimes” and “never”, the affected feet may not be in plantigrade hence further assessment is needed to confirm relapse. It is important to note that for neurogenic the choice of shoe also depends on muscle strength and function not only structural integrity. Other similar studies on neurogenic patients showed similar results in which 35.3% to 16.7% of the patients had a unsatisfactory outcome regarding “braceable and functional feet”^{6,18}. In the current study, caregivers of neurogenic CF patients were less satisfied than those of idiopathic. In one other similar study major satisfaction of parents of idiopathic CF patients was shown at an average followup of 6.3 years¹⁶. Similar to the current study, Smythe et al. (2019) found that 65% of caregivers of idiopathic CF patients who had completed casting were very satisfied with the outcome.

ONCLUSION

There was a statistically significant correlation between type of CF and relapse and need for surgical correction. Less parent/guardian satisfaction with the treatment outcomes and failure of Ponseti casting in neurogenic CF patients, were also noted although not statistically significant. Some neurogenic patients were reported to have pain by their parents/guardians. Therefore, clinicians should consider that pain is a possible outcome in neurogenic CF patients as well. In general, the traditional Ponseti method proved to have acceptable outcomes in idiopathic CF in this study. On the contrary, neurogenic patients had mixed outcomes and it is necessary for clinicians to consider modifying the Ponseti method for this group of patients.

RECOMMENDATIONS

Patients adhere to the full 5 years Ponseti treatment protocol for better outcomes
Review of the Ponseti method for neurogenic CF to include some steps cited in current study to have generated better outcomes
Experimental studies with similar objectives to the current study should be done on randomly controlled groups of patients in order to verify these outcomes

LIMITATION

Poor recording of information on patient files contributed to shedding of several potential patients.

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