

**A SURVEY OF FACTORS ASSOCIATED WITH
IDIOPATHIC CLUBFOOT RELAPSE AFTER PONSETI
TREATMENT**

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**A Thesis submitted in partial fulfillment of the requirements for the Award of
the Degree of Master of Medicine in Orthopedic Surgery of the University of
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DECLARATION

STUDENT'S DECLARATION

I hereby declare that this thesis is my original work and has not been presented for a degree at any other university.

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DEDICATION

I dedicate this study to my loving parents Stephen Kinyanjui and Olive Kinyanjui for their continued support throughout my education to my beautiful triplets Keira, Kqurtney and Kylie.

ACKNOWLEDGEMENT

I would like to acknowledge the following people:

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LIST OF ABBREVIATIONS

KNH	Kenyatta National Hospital
UON	University of Nairobi
FAB	Foot abduction brace
POP	Plaster of Paris
CTEV	Congenital talipes equinovarus
AIC	African Inland Church
FHL	Flexor Hallucis Longus
FDL	Flexor Digitorum Longus
AFO	Ankle Foot Orthosis

DEFINITIONS

ADHERENCE: Brace worn 23hours/day in the 1st 3months followed by 12hours night time wear for 3-4years

NON-ADHERENCE: Failure of following bracing protocol

CORRECTION: Pirani score 0

RELAPSE: Pirani score 1 or more

ABSTRACT

Worldwide, Congenital Talipes Equinovarus (CTEV) is a common foot deformity encountered in the pediatric population with an incidence of 1 in every 1000 births. This problem is more common in low-middle income countries. In Africa, the prevalence of CTEV is 2/1000live births (Uganda).At the Kenyatta National Hospital (KNH) in Kenya, an average of 260 children are diagnosed with CTEV annually.

While a lot of effort has been made to treat CTEV, success rates are not always 100% and about 25% of operated clubfeet will develop recurrence or show a marked residual deformity. Between 3% - 5% rates of recurrence of clubfoot after Ponseti treatment have been reported across the world. Studies have attributed CTEV relapse after Ponseti manipulation to poor adherence to treatment regime and improper use of foot braces.

At KNH Treatment for CTEV is both operative and non-operative. The gold standard for non-operative treatment is Ponseti manipulation.

There is need to study relapse after Ponseti manipulation to determine risk factors and identify corrective measures especially in low resource settings like Kenya.

Objective: To determine the factors associated with clubfoot recurrence after Ponseti treatment.

Design: Case-Control study.

Setting: Foot clinic at KNH and the outpatient clinic at Kijabe AIC Cure Hospital.

Patient and methods: Patients diagnosed with idiopathic CTEV and had used the Foot Abduction Brace (FAB) for at least one year were recruited. Sample size was 24 cases and 70 controls. Data on socio-demographic characteristics, duration of treatment, compliance in use of brace, presence of CTEV relapse, type of CTEV relapse and mitigating efforts employed by care providers to contain the relapse. The following parameters were used to determine the presence of CTEV relapse; Pirani score, foot bisector, thigh foot angle and foot progression angle.

Absence of relapse was defined as having a Pirani score of 0 and foot bisector passing through second toe.

The frequency of flexibility/stiffness of ankle joint, presence of callosities, gait characteristics (toe walking, side stepping), and parental/guardian satisfaction, was tabulated.

The study was carried out over a six week period through the months of December 2016 and April 2017.

Relapse factors were compared and analyzed in terms of socio-demographic characteristics, history of treatment for clubfoot, duration of treatment for clubfoot and the outcome measures.

Data collection through structured questionnaires was analyzed using IBM statistics (SPSS) version 21. Results are presented using tables, textual write up, charts and graphs.

1. CHAPTER ONE

1.2 INTRODUCTION

Clubfoot, also referred to as talipes equinovarus, is a complex foot and ankle deformity involving forefoot adduction and supination, midfoot cavus, hindfoot varus and equinus, inversion at the subtalar joint, adduction at midtarsal joint and internal tibial torsion (1)



Figure 1.2-1: Talipes Equinovarus

Forefoot adductus is attributed to tight tibialis posterior, midfoot cavus is due to tight FHL, FDL & intrinsic muscles. Hindfoot varus due to tight tibialis posterior, tendoachilles & hindfoot equinus due to tight tendoachilles (5). Treatment of clubfoot has evolved over the years. Non operative management includes Ponseti technique, Kite technique and French technique, the more popularized Ponseti technique is what is used at our local facilities (7).

Ponseti involves two phases, phase one involves manipulation of deformed foot through a weekly series of movements at the subtalar joint, supination of forefoot and dorsiflexion of 1st ray corrects the cavus, abduction with gentle pressure under 1st ray and fulcrum at the head of talus corrects adduction and varus, dorsiflexion plus or minus tenotomy corrects equinus, manipulation takes approximately 5-6 wks, after every manipulation a long leg cast is applied to maintain the position (2).



Figure 1.2-2: Casting in the Ponseti Method

After full correction is achieved, the second phase of treatment includes the use of foot abduction braces (FAB), worn to maintain correction achieved post manipulation and prevent relapse (4)



Figure 1.2-3: Dennis Brown Brace

Annually, 150,000 children are born with clubfoot representing 1.2/1000 live births worldwide. Eighty (80%) of these cases are in developing nations (1,3,4). In Africa and specifically in Uganda 1-2 cases of clubfoot were reported in every 1000 live births (24).

Ponseti technique has a success rate of 90-98%(1,2,11).A recurrence rate reported by Ponseti 1-2/10 cases with the gap occurring during the foot abduction brace phase due to noncompliance to protocol. Incidence of recurrence reduced significantly when foot abduction bracing was emphasized (1, 2, 10, 16).

Clubfoot is a condition that can be disabling to the affected individual. It causes pain, abnormal foot position and if not corrected gait is altered (4,34). Callosities form on the lateral aspect of the foot which leads to difficulty in shoe wear (22).

The family and community are affected psychosocially (9,13) . Treatment can be expensive, time consuming and emotionally draining (16).

Recurrence rates and the factors contributing to relapse are unknown in our population; this information will help close the gap in the treatment of the deformity.

2 CHAPTER TWO

2.1 LITERATURE REVIEW

2.1.1 INFLUENCE OF BRACING IN RELAPSE RATES

Bracing is an integral part of Ponseti treatment. This phase starts after full correction of the deformity has been achieved. It involves wearing a FAB, which comprises of well fitted, open toed, high- top straight-lace shoes. These are mounted onto a bar that corresponds to the child's shoulder width. Full time wear for 23hours/day in the first 3months followed by part time wear for 12-14 hours/day for 3-4 years (1, 9, 10, 11, 12).

If this is not adhered to, then recurrences are observed. Ponseti et al described relapse as the reappearance of any of the components of the initial deformity, which include forefoot adduction, hindfoot varus or equinus. This definition is similar to the IOWA group. Haft et al studied 51 children and found a recurrence rate of 41%; Ponseti et al established a recurrence rate of 1-2/10 case. Studies have attributed recurrence to low educational level of parents, Native American ethnicity, and annual family income of < US\$20,000. The most common factor however was non-compliance of brace wear in the reviewed papers. Non-compliance rate varies from 36%-60%(1,3,5,10,11,13,16,25).

A difference in the definitions of compliance and non-compliance was observed in many studies. Morcuende et al defined non compliance as not using the FAB for 10hours/day, Dobbs et al defined non compliance as complete discontinuation of brace wear, this was similar to Abdelgawad et al, Avilucea et al described it as premature discontinuation of bracing, while Panjavi et al defined it as lack of full time bracing in the 1st 3months or night time bracing for 9 months thereafter. Differences in definitions could contribute to difference in results (3, 5, 7, 25, 26).

Treatment centers have adopted different protocols of bracing. Laaveg et al and Ponseti et al advised on 22-23hours/day for the 1st 2-3 months followed by night time 10-12hours/day for 2-4years, Morcuende et al agreed with the 23hours/day but night time preferred 12-14hours/day for 3-4years. Some authors suggested wearing the brace full time for 2-4years then night time thereafter. These differences may contribute to significant differences in the results, the less the hours spent in the brace the higher the recurrence noted (1, 4, 7, 11, 13, 27, 28).

2.1.2 AGE AT PRESENTATION

Early presentation has several benefits, soft tissues are more supple therefore easier to manipulate, bones have not ossified making it easier to manipulate and the stretch period is reduced due to viscoelastic properties and collagen organization (16,18,29).

Ponseti treatment showed a success rate of 80% as per Smoley et al in the initial stage, later in the 1990's after revisions and more understanding of CTEV the rate improved to 90-98%.

Smoley et al selected children between 1wk-6mnths and had 56% recurrence, Patil et al compared two groups, 1st group <6mnths had relapse of 7.14%, 2nd group >6mnths had a relapse rate of 15.5%. Verma et al selected 1-3yr olds and had a success rate of 89%. Most studies targeted children who were below 1 year and they reported a success rate of 90-98%. Morcuende et al had full correction in older children (5, 6, 7, 13, 29, 30, 31). Differences in ages of children in studies can contribute to significant difference in results, having more relapses in children above 2 years.

2.1.3 INITIAL SEVERITY OF DEFORMITY

Numerous systems have been proposed to classify severity of deformity. This allows planning of treatment and predicting out. Catterall/Pirani and Dimeglio/Bensahel are systems where components of the deformity are assigned numerical scores; higher scores indicate a more severe deformity. Both systems are reported to have a high interobserver reliability after a short course of learning (17, 18, 19, 20, 21, 23, 22).

Dyer et al used the Catterall/Pirani system to estimate the number of weekly casts required, they also used the hindfoot score to predict the need for tenotomy. There was a significant association between the initial Pirani score and the number of cast changes required to correct the deformity (21).

Some authors like Morcuende et al, Dobbs et al, Wainwright et al and others showed that there is no correlation between initial severity and treatment outcomes or risk of relapse. Out of these studies Wainwright proposed that Dimeglio system was more reliable in categorization of deformity (3, 7, 23). Comparing children with varying severity of deformity can lead to a difference in treatment success and the risk of recurrence results. Most studies showed Pirani scoring being easier to use, it's reliability has been proved (17,18).

2.1.4 RELATIONSHIP OF GENDER AND RELAPSE

Idiopathic clubfoot affects males more often than females with ratios of 2.5:1 and 6:1.1. clubfoot deformity occurs bilaterally in 50% of the cases. Zions et al had 240 patients with idiopathic clubfoot, their Dimeglio scores were 13 for the males and 13.6 for females. There was no significant difference in severity of deformity due to sex, the p value=0.61. Bilateral cases showed no increase in severity but had a large range of severity when compared to unilateral cases. Willis et al and Dobbs et al showed no significant relationship between gender and risk of recurrence (2, 3, 15, 31, 32, 33).

Kruse et al had results that suggested that female patients are 5.5 times more likely than male patients to transmit idiopathic clubfoot to their children. A study on need of surgery depending on genetics was done by Goldstein et al; they stated that female patients were 5.3 times more likely to need surgery (15, 34).

In these studies the incidence is higher in boys due to an inherent difference in susceptibility to the deformity. Girls have a higher chance of transmitting the deformity to their children.

2.1.5 ATYPICAL DEFORMITY

Results of treatment depend on the type of clubfoot. Morcuende et al described an atypical deformity which comprised of small, bean shaped, stiff feet with short big toe and volar crease. These feet were resistant to manipulation and kept having recurrences. Bensahel et al reviewed children with idiopathic, neurogenic and malformative clubfoot. Malformative were associated with other congenital deformities. One surgeon using the same method treated all cases. They reported 88% success rate in idiopathic feet and 25% success rate in malformative feet (7, 19).

Wudbhav et al suggested using gait analysis preoperatively to pick the subtle deformities not evident on visual observation. Patients with recurrence were referred to them from different centers. Gait analysis which was clinical and computerized revealed that 30 out of 35 patients had additional deformities. Surgical plans of 19 patients had to be changed (63%) of cases.

In clubfoot deformity thorough evaluation is a must; this involves a detailed family history, careful visual observation and gait analysis. Pretreatment classification helps with planning for the appropriate management depending on the type of clubfoot (35).

2.1.6 RACE/ETHNICITY

Lochmiller et al carried out a study on epidemiology in the USA. Whites 1.2/1000, Hispanics 1.3/1000, African American 1.14/1000. Mkandawire et al showed an incidence of 2/1000 live births in Malawi. In Uganda, Mathias et al had an incidence of 1.2/1000 births.

Dobbs et al compared whites and nonwhites and the rate of recurrence. Results showed no significant relationship between race and risk of recurrence. In Newzealand Haft et al showed a high recurrence (41%) but could not attribute results to high proportion of deformity in the Polynesian children. The Polynesian patients had a less severe deformity and were less likely to require surgery than the white patients. Although they did not score the feet of those patients who chose operative treatment, they had an equal number of Polynesian patients in each group. Avilucea et al showed an increase in recurrence in Native Americans living in rural areas than those in urban centers and other ethnicities. They suggested that the rate could be attributed to problems in communication (3, 16, 24, 25, 33, 36).

2.1.7 PARENTAL FACTORS

Parents play a major role in success of Ponseti treatment. The education level, income and general attitude to the treatment can contribute to recurrence. Dobbs et al found a significant relationship between parental education and recurrence rates. Parents with high school level or below carried a 10 fold increased risk of relapse post Ponseti treatment. Fact. Haft in 2007 also found no association between any parental factors and recurrence rate (3, 16).

Avilucea had a significant relationship between relapse and 1) unmarried parents 2) parental education especially high school level or less 3) family income of less than \$20,000. All these factors like parental marital status and parental income, led to parents not embracing the treatment fully (25).

2.1.8 PREVIOUS TREATMENT

Multiple studies have reported that idiopathic clubfoot deformities, previously treated with non operative interventions respond well to Ponseti manipulation and casting. Alves et al manipulated and casted children of 2yrs and below. They reported 93% success rate. Bor et al re-manipulated infants referred to them, one patient (2.8%) required surgery at the end of

treatment. A previous study done at the same institution at a previous date included older children and reported similar results (7, 37, 38).

No association has been found between previous non-operative treatment and risk of recurrence after Ponseti treatment for children up to 4 years (25, 36, 47).

2.1.9 NUMBER OF CASTS

Several authors have attempted to link the number of casts required for correction with the risk of recurrence. Dobbs et al found that the more severe the initial deformity the greater the number of cast changes. Morcuende et al reported that the number of casts required was not a long-term prognostic factor for recurrence after treatment.

Others have found a significant difference in the number of casts required for those with recurrence compared with those who did not (3, 7, 20, 25, 37, 42, 47, 54).

Number of casts depends on technique of casting, stretch period needed and discomfort on the child.

2.2 CONCLUSION

In the studies reviewed, the main factor associated with clubfoot relapse is non-adherence to bracing. Low parental education and poor attitude to bracing contributed to non-adherence. Children selected in the studies were of different ages and included both sexes that could influence results. Locally no studies are available that evaluate factors associated with idiopathic clubfoot relapse after Ponseti treatment. Settings in these regions differ from our setting, which makes it difficult to compare results

3 CHAPTER THREE

3.1 STUDY QUESTION

What factors contribute to clubfoot recurrence after Ponseti treatment?

3.2 STUDY JUSTIFICATION

Clubfoot is the commonest deformity affecting the pediatric population. Treatment of choice in our facilities locally is the Ponseti manipulation for idiopathic type.

Relapsed deformities are either manipulated and casted again or treated surgically. Burden of retreatment can be reduced if the condition and factors affecting recurrence are better understood.

A gap exists locally in knowledge and awareness of the condition and the factors that contribute to recurrence.

This study surveyed the factors that contribute to relapse and permitted development of strategies in prevention.

3.3 STUDY OBJECTIVES

3.3.1 MAIN OBJECTIVE

To survey factors that contribute to clubfoot relapse after Ponseti treatment

3.3.2 SPECIFIC OBJECTIVES

To determine the influence of brace adherence in recurrence of clubfoot deformity.

To determine parental factors that may contribute to relapse of deformity.

To determine the relationship between gender and the rate of recurrence of clubfoot

3.4 METHODOLOGY

3.4.1 STUDY DESIGN

Case control Study.

3.4.2 STUDY SETTING

AIC Cure Kijabe Hospital wards and outpatient clinics, this is a pediatric orthopedic hospital that deals with childhood deformities both congenital and acquired, KNH pediatric foot clinic.

These two centers have personnel that are trained in the Ponseti manipulation; training begins with the curriculum including this manipulation, constant workshop training, training in FAB manufacture and utilization through apprenticeship.

3.4.3 STUDY POPULATION

Children with idiopathic clubfoot deformity who have successfully completed first phase of treatment (serial casting) and are in the second phase (bracing) for at least 1 year.

CASE DEFINITION

For the purpose of this study, a case is defined as a recurrence of deformity, occurring after successful correction (Pirani 0).

SELECTION OF CONTROLS

Control group comprised the clubfoot clients who had maintained correction (Pirani 0).

3.4.4 SAMPLE SIZE

The sample size is calculated using OPENEPI based on Kelsey et al. (1996) with the following specifications:

SPECIFICATION	VALUE
Two sided confidence interval	95%
Power (CI)	80
Ratio- controls: cases	3:1
Proportion of controls with exposure	0.02
Proportion of cases with exposure	0.05
Least extreme odds ratio to be detected	4

The sample size is calculated according to Kelsey et. al. (1996):

$$n_1 = \frac{\left(Z_{\alpha/2} + Z_{1-\beta} \right)^2 p' q' (r + 1)}{r(p_1 - q_1)^2}$$

and $n_2 = rn_1$

where n_1 = number of cases n_2 = number of controls

$Z_{\alpha/2}$ = standard normal deviate for two-tailed test for a 95% confidence interval

$Z_{1-\beta}$ = standard normal deviate for one-tailed test for a power of 80%

r = ratio of controls to cases

p_1 = proportion of cases with exposure and $q_1 = 1-p_1$

p_2 = proportion of controls with exposure and $q_2 = 1-p_2$

and

$$p' = \frac{p_1 + rp_2}{r + 1}$$

and $q' = 1 - p'$

This worked out to **24 cases** and **70 controls**.

3.4.5 INCLUSION CRITERIA

1. Children (5years and below) diagnosed with idiopathic clubfoot deformity and have completed first phase of treatment.
2. Children (5 years and below) already on foot abduction braces for at least one year
3. Willing and consenting parents to clubfoot clients

3.4.6 EXCLUSION CRITERIA

1. Children (5years and below) with neurogenic or syndromic CTEV
2. Children (5years and below) with Pirani score >0 at the end of manipulation
3. Unwilling and non-consenting parents of clubfoot clients

3.4.7 OUTCOME MONITORING

Assessment of correction maintenance or relapse was undertaken using the Pirani scoring system, foot bisector and foot progression angle. The Pirani score obtained at the interview was compared to that documented at the completion of treatment.

Questionnaires provided a subjective assessment of the parent/guardian/caretaker of state of the patient's feet, their feelings on the Ponseti method.

Brace wear was evaluated by the state of the laces, leather, sole, callosities and the number of times the brace had been changed.

3.4.8 DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data was collected using structured questionnaires and entered into a password protected Microsoft Access Database. The hard copy data forms were stored in a lockable cabinet either in the statistician's office or the Principal Investigator's office. Upon completion of Data entry, hard copy forms were compared with the entered data to identify errors and corrections made appropriately.

Descriptive statistics of variables included; frequencies and percentages while continuous variables were summarized using measures of central tendency such as mean, median, mode and standard deviation.

Associations between two variables were determined using Chi-squared tests and Fisher's exact tests for categorical variables and t-tests for continuous variables. Multivariate analyses, independent factors associated with clubfoot recurrence were identified using binary stepwise backward logistic regression.

Data was analyzed using IBM Statistics (SPSS) Version 21. Results have been presented using tables, textual write up, charts and graphs.

3.5 STUDY LIMITATIONS

1. Proof of brace compliance; relied on truthfulness of the parents.
2. Guardians opting out of study; education on purpose of study was done at enrollment.
3. Loss to follow up; some patients receiving treatment were already lost to follow up.
4. Lack of the initial Pirani score.

3.6 DISSEMINATION OF FINDINGS

Copies of the study will be availed to the following places:

- The University of Nairobi College of Health Sciences Library.
- Library of the Department of Orthopedics, University of Nairobi.
- Library of AIC Cure Kijabe Hospital.
- Kenyatta National Hospital Research Department.
- Published in peer-reviewed journal.
- Conference presentation.

3.7 ETHICAL CONSIDERATIONS

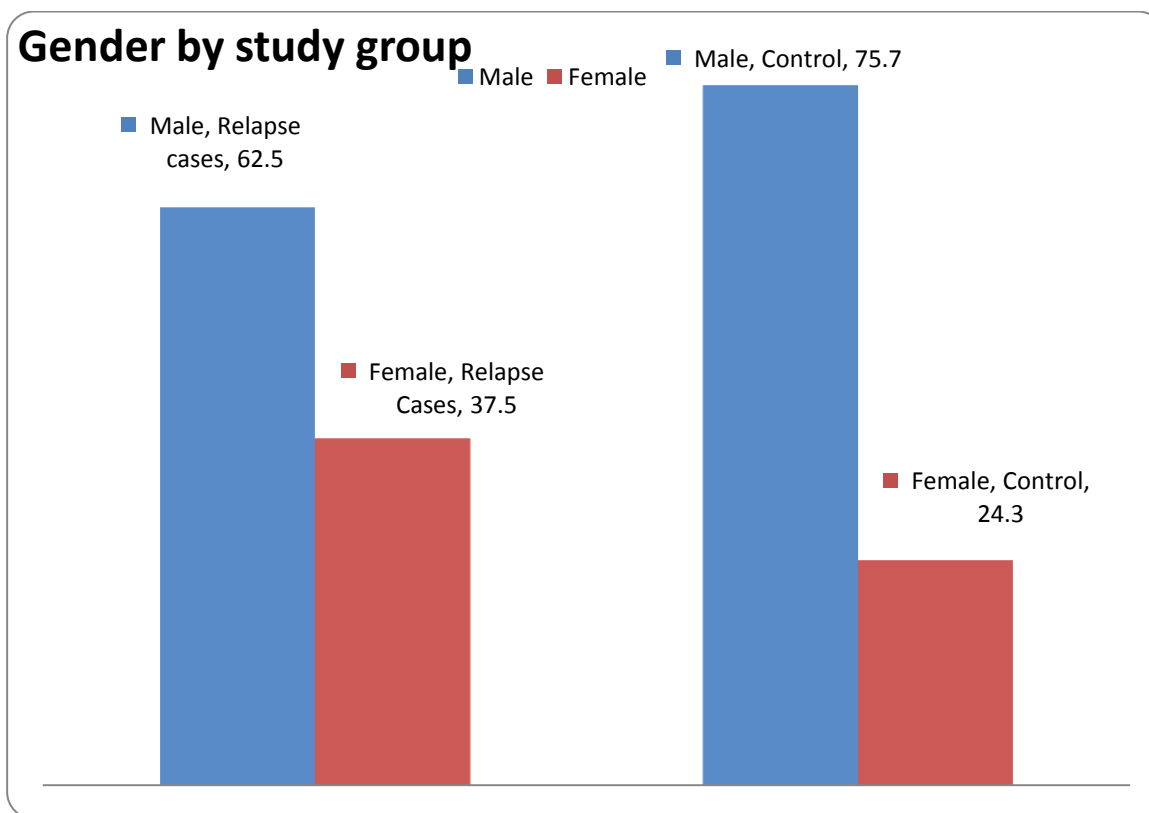
Approval for the study was obtained from department of orthopedic surgery, University of Nairobi, AIC Cure hospital and the KNH ethics and research committee (KNH/ERC) before commencement.

Informed consent was obtained from the patients parents/guardians who had accepted to participate in the study. For those who did not consent and had relapsed, they were managed as per the Ponseti relapse protocol but were not included in the study. Their treatment was not affected by refusal to give consent.

4 CHAPTER FOUR

4.1 RESULTS

4.1.1 DISTRIBUTION BY GENDER



Graph 4.1-1: Distribution by Gender within the Study Groups

PV=0.2

A total of ninety four (94) respondents were interviewed at the beginning of our study. The males with clubfoot deformity formed a majority at 72.3% giving a male: female ratio of clubfoot occurrence of 2.3:1. Of the patients who relapsed the males had the highest number at 62.5% giving us a male: female ratio of clubfoot recurrence of 1.7:1

4.1.2 AGE AT INTERVIEW BY STUDY GROUP

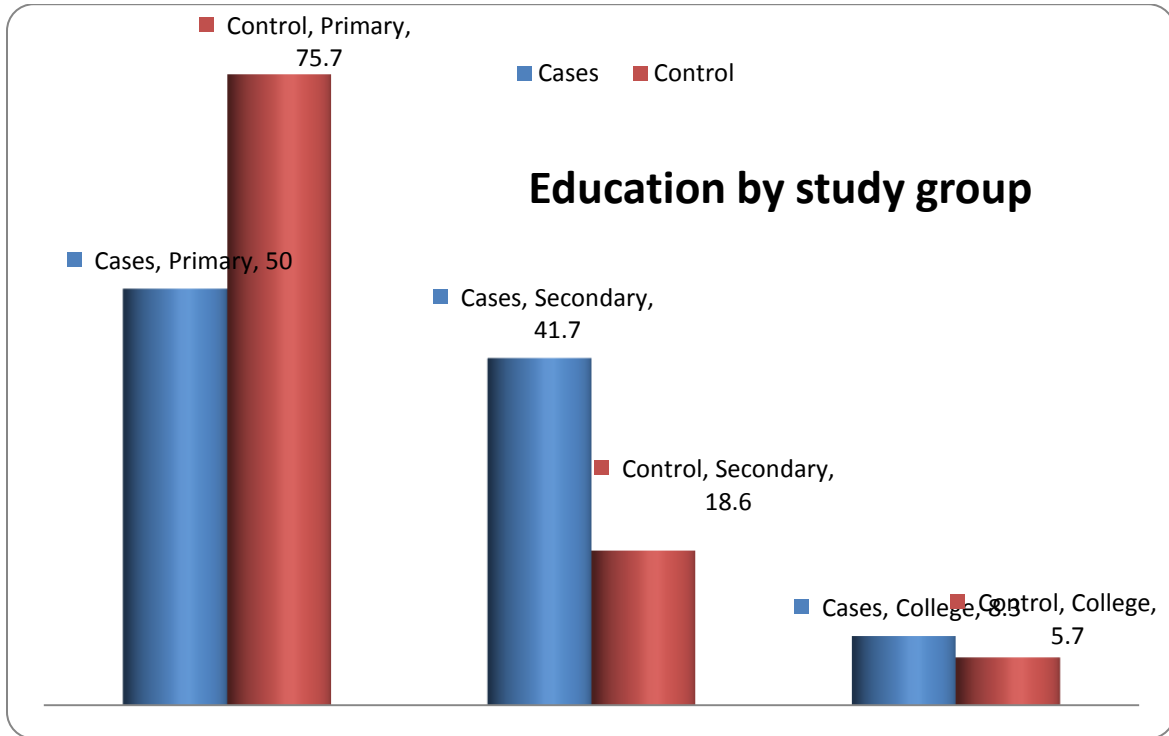
Age at interview	Study group				Totals	
	Case		Control			
	No.	(%)	No.	(%)	No.	(%)
1 year	2	8.3	5	7.1	7	7.4
2 years	8	33.3	1	1.4	9	9.6
3 year	5	20.8	5	7.1	10	10.6
4 years	3	12.5	11	15.7	14	14.9
5 years	6	25.0	48	68.6	54	57.4
Totals	24	100.0	70	100.0	94	100.0

Table 4.1-1: Distribution by Age within the Study Groups at time of Interview

PV=0.000

In the study, we selected children aged between 1 year to 5 years. This allowed us to pick early relapses which are usually noted by one year of age, it also enabled us to review patients at 5 years after completion of bracing. Earliest recurrences were picked at 1 year (8.3%), most relapses were seen at 2 years of age (33.3%).

4.1.3 PARENTAL EDUCATION

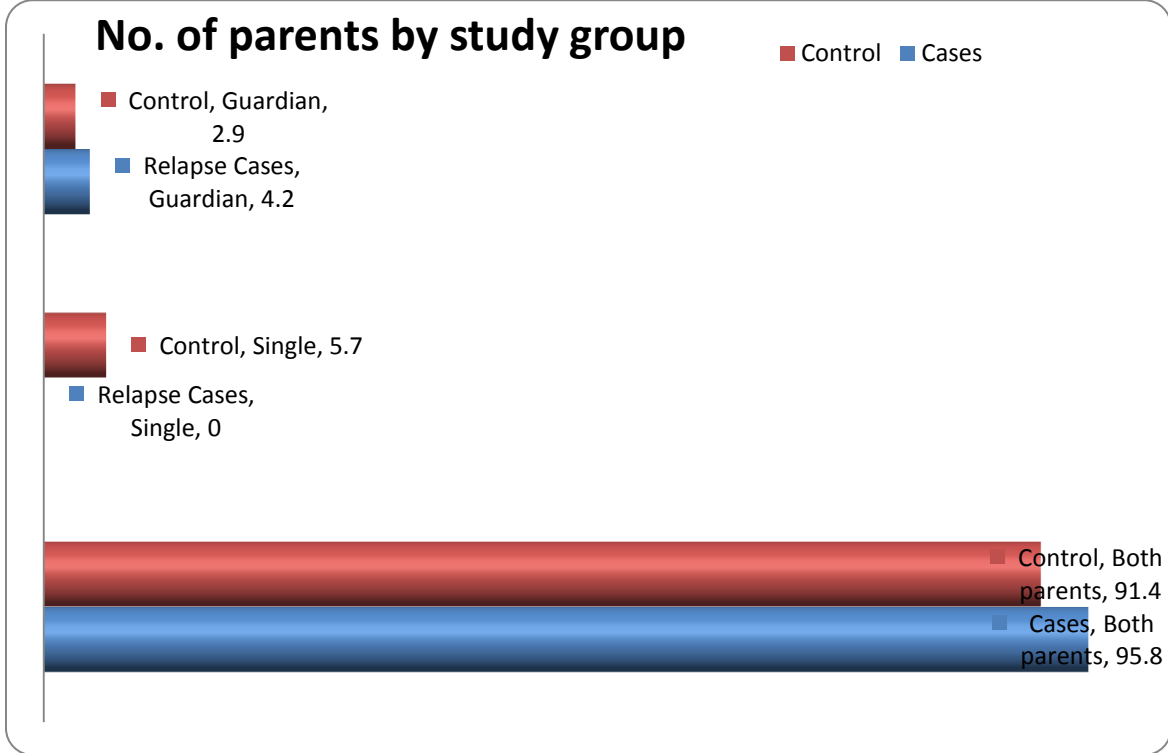


Graph 4.1-2: Parental Education Level within the Study Groups

Pv=0.05

Most of the parents interviewed during our study reported having attained a primary school level of education, with a total of 69.1%. The highest number of children found with relapse of clubfoot deformity came from families whose parents had a primary school level of education. When we compared the education level between the participating spouses we noted that the mother had a lower education level in most families. There was correlation significance between the education of the parents in comparison to the cases and controls with a *P*-value of 0.05

4.1.4 NUMBER OF PARENTS

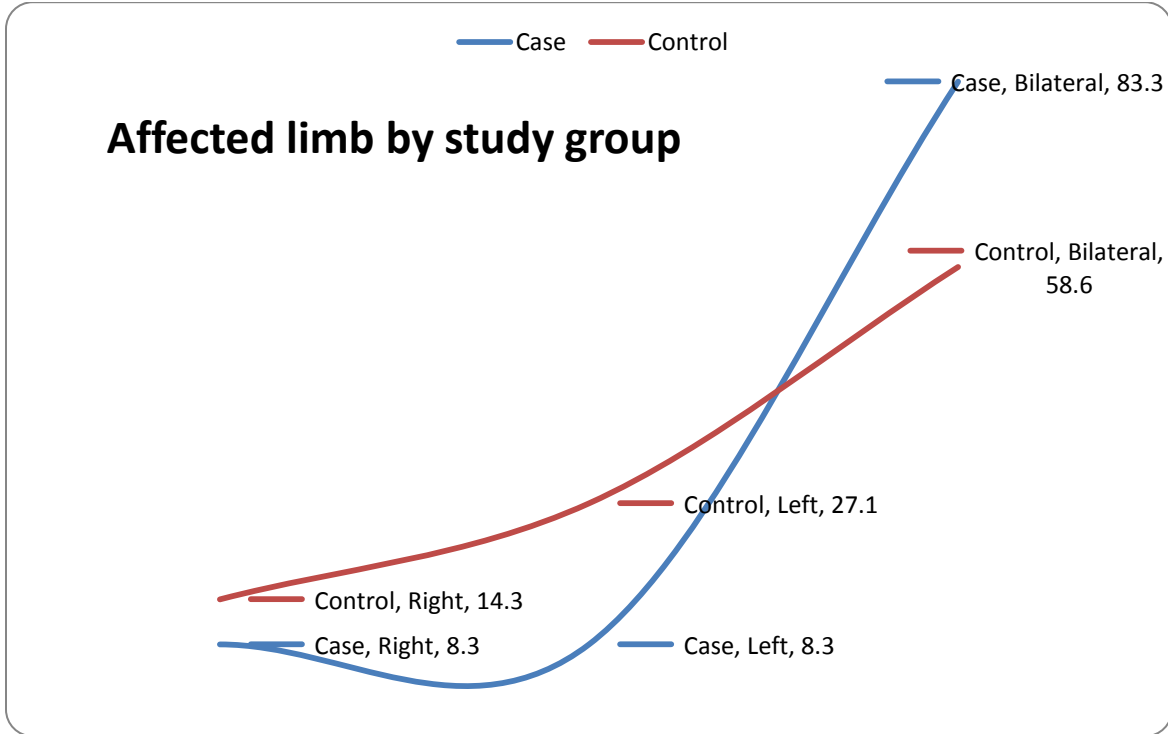


Graph 4.1-3: Number of Parents by Study Group

Pv=0.4

Majority of the children participating in our study came from two parent families. This differed from clinic attendance as the mother alone was the parent accompanying the child to the clinic in most cases. This was reflected in our relapse group who attended the clinic in the presence of the mother only. Information about clubfoot deformity and the protocol of treatment was discussed by the doctor to the mother in most of our participants. The parent attending the clinic was the one delegated with application and removal of the foot abduction brace.

4.1.5 AFFECTED LIMB



Graph 4.1-4: Distribution of Affected Limb by Study Group

Pv=0.08

In our study bilateral cases were the majority at 64.9%. The severity of clubfoot deformity was worse when both limbs were involved. The unilateral cases observed in our study, left sided involvement was higher at 37.7% with a ratio of left: right at 1.6:1. Recurrence of clubfoot deformity was noted more in the bilateral group of patients.

4.1.6 INITIAL PIRANI SCORE- (RIGHT SIDE)

Pirani Score	Case		Control		Totals	
	No.	(%)	No.	(%)	No.	(%)
0.5	0	0.0	2	2.9	2	2.1
1.0	0	0.0	1	1.4	1	1.1
1.5	3	12.5	8	11.4	11	11.7
2.0	2	8.3	7	10.0	9	9.6
2.5	2	8.3	3	4.3	5	5.3
3.0	2	8.3	3	4.3	5	5.3
3.5	2	8.3	3	4.3	5	5.3
4.0	3	12.5	6	8.6	9	9.6
4.5	4	16.7	6	8.6	10	10.6
5.0	1	4.2	3	4.3	4	4.3
5.5	2	8.3	3	4.3	6	6.4
6.0	0	0.0	6	8.6	6	6.4
Totals	24	100.0	70	100.0	94	100.0

Table 4.1-2: Initial Pirani score for the Right Limb

PV=0.5

Pirani scores were taken before treatment of every patient and documented. From our evaluation most children had a Pirani score of 1.5. The worst Pirani score recorded was 6.0. In the group of participants who had recurrence of clubfoot deformity they started out with a Pirani score of 5.5

4.1.7 INITIAL PIRANI SCORE-(LEFT)

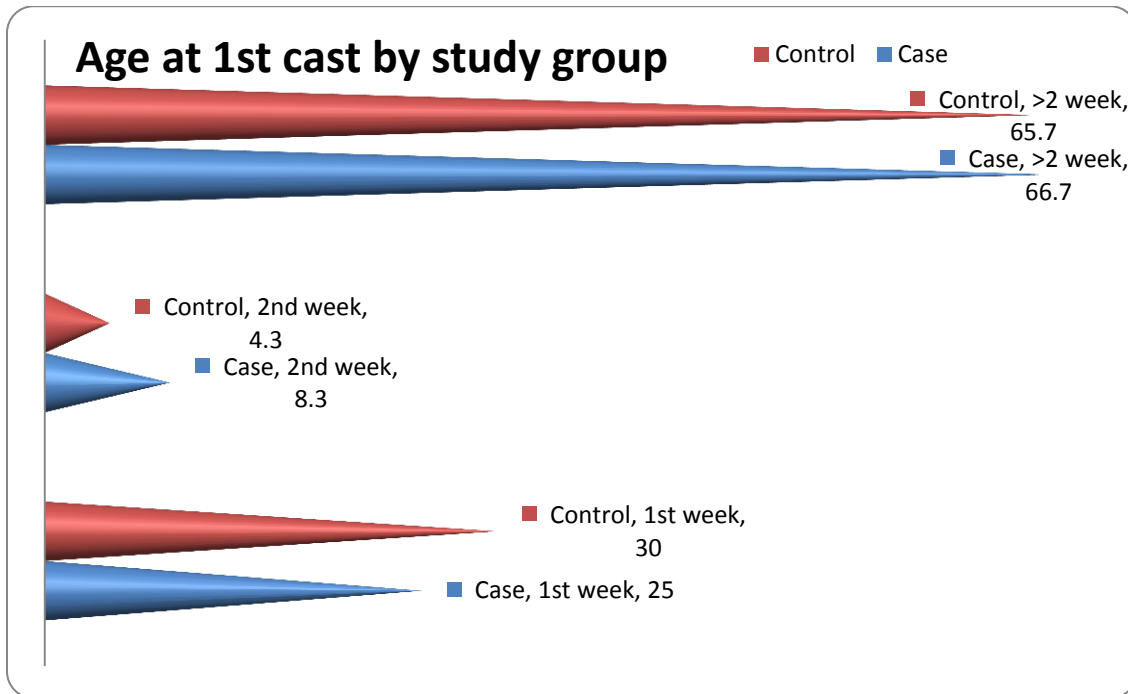
Pirani Score	Case		Control		Totals	
	No.	(%)	No.	(%)	No.	(%)
0.5	0	0.0	2	2.9	2	2.1
1.0	0	0.0	1	1.4	1	1.1
1.5	1	4.2	8	11.4	9	9.6
2.0	2	8.3	9	12.9	11	11.7
2.5	2	8.3	2	2.9	4	4.3
3.0	2	8.3	4	5.7	6	6.4
3.5	3	12.5	6	8.6	9	9.6
4.0	7	29.2	10	14.3	17	18.1
4.5	2	8.3	3	4.3	5	5.3
5.0	1	4.2	5	7.1	6	6.4
5.5	2	8.3	3	4.3	5	5.3
6.0	0	0.0	7	10.0	7	7.4
Totals	24	100.0	70	100.0	94	100.0

Table 4.1-3: Initial Pirani score for the Left Limb

PV=0.5

Pirani scores of the left limb were taken before manipulation was started and documentation was done for reference. Most of the participants had a score of 4.0, the worst Pirani score was 6.0. Our patients with recurrences that occurred involving the left foot had an initial Pirani score of 4.0

4.1.8 AGE AT FIRST CAST



Graph 4.1-5: Age at First Cast

Pv=0.7

Most patients who presented early to the clinic led to the early diagnosis and early initiation of manipulation and casting. The physiotherapists, who casted the patients found it easier to manipulate and achieve correction. The highest number of our participants presented at more than 2 weeks of age, this was due to the fact that they had been seen at other facilities and were referred for further management in our facility. Recurrence of clubfoot deformity was higher in the group that presented after 2 weeks.

4.1.9 NUMBER OF CAST CHANGES

Number of Cast Changes	Case		Control		Totals	
	No.	(%)	No.	(%)	No.	(%)
4	4	16.7	13	18.6	17	18.1
5	4	16.7	18	25.7	22	23.4
6	7	29.2	15	21.4	22	23.4
7	1	4.2	11	15.7	12	12.8
8	6	25.0	7	10.0	13	13.8
9	1	4.2	3	4.3	4	4.3
10	0	0.0	1	1.4	1	1.1
12	1	4.2	0	0.0	1	1.1
13	0	0.0	2	2.9	2	2.1
Totals	24	100.0	70	100.0	94	100.0

Table 4.1-4: Number of Cast Changes

PV=0.2

The numbers of cast changes were documented from the very first casting done. For the patients that had been referred it was assumed that they were starting treatment therefore previous casts done elsewhere were disregarded. Children who had relapse of clubfoot deformity had a total of 6 cast changes. The children who maintained correction had fewer cast changes.

4.1.10 PIRANI SCORE AT INTERVIEW-(RIGHT)

Pirani Score	Case		Control		Totals	
	No.	(%)	No.	(%)	No.	(%)
0	2	8.3	45	64.3	47	50
0.5	1	4.2	23	32.9	24	25.5
1.0	3	12.5	2	2.9	5	5.3
1.5	6	25.0	0	0.0	6	6.4
2.0	4	16.7	0	0.0	4	4.3
2.5	6	25.0	0	0.0	6	6.4
3.0	1	4.2	0	0.0	1	1.1
3.5	1	4.2	0	0.0	1	1.1
Totals	24	100.0	70	100.0	94	100.0

Table 4.1-5: Pirani Score at Time of Interview for the Right Side

PV=0.000

The right foot Pirani score of patients attended to at the interview showed an improvement from the initial scores. The most common score was at 0 meaning correction had been maintained in most patients. In the group of patients who had recurred clubfoot deformity, the highest score was 3.5

4.1.11 PIRANI SCORE AT INTERVIEW-(LEFT)

Pirani Score	Case		Control		Totals	
	No.	(%)	No.	(%)	No.	(%)
0	3	12.5	49	70	52	55.3
0.5	0	0.0	20	28.6	20	21.3
1.0	2	8.3	1	1.4	3	3.2
1.5	7	29.2	0	0.0	7	7.4
2.0	7	29.2	0	0.0	7	7.4
2.5	3	12.5	0	0.0	3	3.2
3.0	2	8.3	0	0.0	2	2.1
Totals	24	100.0	70	100.0	94	100.0

Table 4.1-6: Pirani Score at Time of Interview for the Left Side

PV=0.000

The left foot Pirani score of patients reviewed after completion of treatment showed that the commonest score was 1.5. In the group of patients that recurred the new Pirani score was at 3.0. From these scores we find that the left foot corrected at a slower rate than the right foot

5 CHAPTER FIVE

5.1 DISCUSSION

In this study, we set out to find the factors that are associated with idiopathic clubfoot relapse after Ponseti treatment.

We had a total of 94 children with idiopathic clubfoot deformity, 24 patients had a relapse of the deformity while 70 maintained the correction (figure 1).

Out of our participants, males had the greatest numbers (figure 2). We had more male patients showing recurrence. Most studies report a higher prevalence of idiopathic clubfoot deformity in male patients (1,11,15,32). Our higher number in male recurrence could be attributed to a higher number of males in the total group, or the lower number of cases compared to controls (15,32). The study by Goldstein et al showed a higher incidence in boys due to an inherent difference in susceptibility to clubfoot.

Children who participated in our study were aged between 1 year-5 years (figure 4). Out of 94 children 54 (57.4%) were aged 5 yrs. This ensured that there was adequate follow up post manipulation before the interview. Most relapses were seen at 2 years of age, followed by 5 years of age. Earliest recurrences that were visible to the caretakers/parents occurred after one year. Our research team picked subtle recurrences during the interview using the Pirani score. The commonest relapse seen in our study was dynamic forefoot adduction. The relapses were treated by full time splint application, re-casting. Splint compliance was compromised in both groups.

Overall, bilateral cases were highest at 64.9%, followed by unilateral left foot. The least group was that of unilateral right foot (figure 6). This shows that the left foot is more affected at 1.74 times more than the right foot. Bilateral cases were 1.85 times more than unilateral cases. Most cases are bilateral in 50% of the studies (2, 13, 24). Bilateral cases showed no increase in severity but had a large range of severity when compared to unilateral cases.

In our study both parents accompanied the children to the clinic only during the first clinic, thereafter the mother was the parent available (figure 5). This was noticed in both the cases and the controls. In the control group discussing the clubfoot protocol at the beginning of treatment with both parents made it easier. In consequent visits, only one parent was involved as this

reduced the transport fee used. The fathers were rarely available due to their jobs. This could have affected the relapse rates.

Most parents reported to have a primary school education level (figure 3). The mother had a lower education level compared to the father in most of our participating families; this could have contributed to our recurrence rates as the mothers were the primary caretakers of the children. Only two participants attended college in the cases group. From our study low education level was associated with recurrence. There was correlation significance between the education of the parents in comparison to the cases and controls with a p value of 0.05. Interviewed parents stated that they had been educated by the doctors and physiotherapists on clubfoot protocol but only a few could recall it step by step. The results may have been affected by lack of understanding or a fear of asking the care givers for clarification. Dobbs et al found that parental education at high school level or below carried a tenfold increased risk of clubfoot recurrence after Ponseti treatment (3).

Initial Ponseti score of the right foot, the commonest score was 1.5. The highest score of the group that had recurrence was 5.5, while the highest score of the control group was 6.0 (figure 7). This proved that having a severe initial Ponseti score did not mean that relapse would occur. In the initial Ponseti score of the left foot, the commonest score was 4.0 in the total group. The highest Pirani score of the control group was 5.5, while the highest score of the relapse group was 6.0 (figure 8). This shows that in most cases, the left foot is usually more severe compared to the right foot.

Some of the parents presented their children as early as a few hours post delivery, for initiation of treatment (figure 9). We also had children coming for treatment months down the line, but most of these cases were referrals from other centers. In the cases the highest number of patients presented more than two weeks of age, this could have contributed to relapse due to the difficulty in manipulation. From other studies early presentation has several advantages, soft tissues are suppler therefore making it easier to manipulate, bones have not ossified also contributing to ease of manipulation. The stretch period is reduced due to viscoelastic properties and collagen organization (5, 6, 13, 30, 3).

Several authors attempted to link the number of cast changes to risk of recurrence. In the cases group most children had 6 cast changes, while in the control group most children had 5 cast changes (figure 10). More cast changes were needed in the group that had recurrences; this

reflects studies that found a significant difference in the number of casts required for correction with risk of recurrence (3, 7, 20, 37, 42, 54).

Final Ponseti score was done at the interview. Right foot had commonest final case scores as 1.5 and 2.5 and highest final score at 3.5. Control group had commonest final score of 0.0 and highest final score of 1.0. Left foot had commonest final case scores of 1.5 and 2.0 and highest final score of 3.0. Right foot highest case score initially was at 5.5 and final case score was at 3.5. Right foot highest control score was initially at 6.0 and final control score was at 1.0. Left foot highest case score was at 5.5 initially and the final highest case score was 3.0. Left foot highest control score was at 6.0 and the final highest control score was at 1.0.

5.2 LIMITATIONS

The study had some limitations. We relied on the information provided by guardians or parents and this could have affected our results as we depended on their recall capacity. The duration of the study was not long enough for long term follow up .Most participants refused to fill in the income per month question. In the future, a study can be designed to overcome these limitations.

5.3 CONCLUSIONS

Clubfoot relapse rate (25.5%)

Males with idiopathic clubfoot had a higher rate (72.3%) while females had (27.7%)

Males recurred at a higher rate (62.5%)

Most recurrences occurred at 2 years of age (33.3%)

Bilateral clubfoot involvement (64.9%)

Recurrence highest in bilateral cases (83.3%)

Commonest unilateral clubfoot involvement left sided (27.3%)

Right side recurred more out of the unilateral cases (14.3%)

Recurrence higher in patients who started Ponseti later than 2wks (66.7%)

Recurrence was associated with a higher number of cast changes (23.4%)

Parents with primary school educational level had children with a higher relapse rate (50%)

95.8% had recurrence despite having both parents

5.4 RECOMMENDATIONS

Early diagnosis which would lead to early commencement of treatment.

Teaching more personnel on Ponseti treatment to avoid referrals and overloading of patients in some specific centers.

Detailed parent education on clubfoot deformity, diagnosis of condition, and necessity of early treatment and parent compliance.

Application of brace should be taught to more than one caretaker, incase one does not understand the process.

Materials used in clubfoot treatment e.g. casts and braces should be provided free of charge to all patients thus increasing the number of parents seeking intervention for their children.

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7 APPENDICIES

7.1 DATA COLLECTION SHEET

PATIENT BIODATA

STUDY NUMBER.....

AGE (YRS)..... (MNTHS).....DOB.....

3. SEX MALE

(a) FEMALE.....

CHILD NUMBER IN FAMILY.....

AGE AT FIRST CASTING.....

DATE TREATMENT COMMENCED.....

SCHEDULED REVIEW ATTENDANCE (1).....

1. (2).....

2. (3).....

3. (4).....

INTERVAL OF CASTING; 1) 1ST CHANGE.....

(a) 2) 2ND CHANGE.....

(b) 3) 3RD CHANGE.....

(c) 4) 4TH CHANGE.....

(d) 5) OTHERS

9. LATERALISATION 1) UNILATERAL RT..... LT

(i) 2) BILATERAL.....

10 PIRANI SCORE BEFORE TREATMENT.....

11. NUMBER OF CAST CHANGES.....

12. PIRANI SCORE AT INTERVIEW.....

13. BRACE FITTING 1) YESDATE.....

(a) 2) NO.....

COST OF BRACE (Ksh.)

NUMBER OF BRACE CHANGES.....

ACTIVITY OF CHILD; 1) CRAWLING.....

- (a) 2) SITTING.....
- (b) 3) WALKING.....

ADHERENCE/NON-ADHERENCE

- 1 NO APPLICATION.....
- 2 SUB-OPTIMAL FREQUENCY OF APPLICATION.....
- 3 DURATION AND TIMING OF APPLICATION.....
- 4 TO THE LETTER ADHERENCE AS INSTRUCTED BY CARETAKER.....

- 18. RELATIONSHIP TO CHILD 1) PARENT
- (i) 2) GURDIAN
- (ii) 3) CARETAKER.....

- PARENT EDUCATION LEVEL 1) PRIMARY (YRS).....
- (i) 2) SECONDARY (YRS).....
- (ii) 3) TERTIARY (YRS).....

- 20. CLINIC ATTENDANCE 1) SINGLE PARENT.....
- (i) 2) BOTH PARENTS.....
- (ii) 3) GUARDIAN.....

- 21. BRACE APPLICATION/REMOVAL TEACHING 1) YES
- a. 2) NO.....

- 22. PERSONELL DOING THE TEACHING 1) PHYSIO
- 1. 2) NURSE.....
- 2. 3) DOCTOR.....

- 23. EASE OF APPLICATION/REMOVAL OF BRACE.....

- 24. OCCUPATION 1) FORMAL EMPLOYMENT.....
- .1 2) INFORMAL EMPLOYMENT.....
- .2 3) FARMER.....
- .3 4) PESANT.....

- 25. YEARLY INCOME 1) <50,000KSHS.....
- (a) 2)50-100,000KSHS.....
- (b) 3) >100,000KSHS.....

- 26. INTERRUPTION OF CASTING 1) SWOLLEN FEET.....
- (i) 2) SKIN ULCERATION.....

(ii) 3).OTHERS.....

27. INTERRUPTION OF BRACE APPLICATION 1) YES.....

a. 2) NO.....

2 IF YES; REASON.....

28. FALL OUT/LOOSENING OF CAST.....

29. PERCEIVED CHILD DISCOMFORT

A) CAST 1) YES.....2) NO.....

B) BRACE 1) YES.....2) NO.....

C) INTERVENTION 1) MEDICATION.....

.1 2) SPLINT REMOVAL.....

30. TENOTOMY 1) YES.....DATES.....2) NO.....

31. POST TENOTOMY CASTING DURATION.....

32. DISTANCE FROM HOSPITAL OF CARE 1) <50KM.....

1. 2)50-100KMS.....

2. 3)100-200KMS.....

3. 4)>200KMS.....

33. OTHER FACTORS.....

.....

.....

7.2 CONSENT INFORMATION

7.2.1 ENGLISH VERSION

This is an informed consent form for persons in the study whose title is factors contributing to clubfoot relapse post Ponseti treatment.

Principal investigator: Dr Kinyanjui .M. Grace

Institution: School of Medicine, Department of orthopedic surgery, University of Nairobi

Supervisors: Dr Edward Gakuya, Dr Vincent Mutiso.

PART 1: Information sheet

Study title

A survey of factors associated with clubfoot relapse after Ponseti treatment

Investigators statement

My name is Dr Kinyanjui Grace, a post graduate student at the school of medicine, University of Nairobi. I am conducting a research study titled ‘**Factors Contributing to Clubfoot Relapse Post Ponseti Treatment**’.

Study background

Clubfoot deformity is a common problem encountered at KNH & Kijabe, treatment of choice is the Ponseti method, a few relapses are seen, and no study has been done locally to evaluate the factors that contribute to relapse.

Study objective

This study aims to find out the factors that contribute to recurrence rates.

Using the information derived from this study, conclusions will be drawn which may influence treatment practices locally.

What is expected of you and the patient

Once you accept your child to participate in this study, you will be expected to fill a questionnaire with the help of the principle investigator or with one of the research assistants. Your child will also be examined to further evaluate recurrence.

You are not expected to pay anything to participate in this study. In the unlikely event that your child will be required to be seen again by the investigator, then your transport expenses will be refunded.

Voluntariness of participation

I would like to invite you to take part in this study. Participation is purely voluntary and you are allowed to consent either immediately after getting this information or after a period of consultation. You are free to ask any questions at any time regarding this study, or to seek any clarification from either myself or my research assistant. If you consent to participate in the study, some personal details as well as information concerning your baby's condition will be sought.

Confidentiality

I guarantee that all the information taken from you will be kept strictly confidential and will not be accessed by anyone other than the researchers and personnel authorized by the University of Nairobi/Kenyatta National Hospital Ethics and research committee. This information will be coded with numbers to maintain privacy.

Benefits of participation

Your participation in this study will be through a clinical interview and a clinical examination. In case of unacceptable outcome the patients will be sent for review by the orthopedic surgeon for appropriate management.

Risks of participation

You will not be exposed to any risks as you participate in this study.

Duration of study

The duration of study is 9 weeks.

Right of withdrawal

Withdrawal from this study can be done at any stage and will not affect your treatment at these hospitals.

Compensation

You will receive no compensation for participating in this study.

CONSENT FORM

This proposal has been reviewed and approved by the UON/KNH-ERC which is a body that ensures the protection of persons like you that take part in research studies. This approval has been granted after submission of the study proposal to the committee by the Chairman of the Department of Orthopedic Surgery, School of Medicine, and University of Nairobi with the approval of a University supervisor.

If you require any additional information one can contact the following:

The Secretary, UON/KNH-ERC

P.O.BOX 20723-00202

KNH, NAIROBI.

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Tel: 0721932799

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Dr Vincent Mutiso

Supervisor, Lecturer University of Nairobi

Tel: 0723289922

Email:mutisovm@yahoo.com

To indicate that you understand the conditions of this study and that you agree to take part in it, please sign or put your thumbprint in the space provided below.

I confirm that the study has been fully explained to me and I give full consent to participate in it.

Signature/thumbprint:.....

Investigator's signature:.....

Date:.....

7.2.2 KISWAHILI VERSION

B) FOMU YA MAELEZO

Kichwa: MAMBO YANAYOCHANGIA RELAPSE YA KIGUU BAADA YA MATIBABU YA PONSETI

Mpelelezi: Dr Grace.M.Kinyanjui

Wasimamizi: Dr.E.Gakuya, Dr.V.Mutiso

Maono ya mpelelezi: Nataka kuchukua nafasi hii kukushukuru Kwa kuchukua muda Na kusoma fomu hii. Hii fomu itakufahamisha zaidi juu ya utafiti ambao unaendelea ndivyo upate nafasi ya kuamua Kama utahusika na huu utafiti.

Utangulizi: Unaombwa kushiriki Kwa utafiti kuhusu mambo yanayochangia relapse ya kiguu baada ya matibabu ya Ponseti. Utafiti huu Ni ajili ya kutaka kujua yanayo changia relapse ya kiguu Ili tuweze kuyazingatia Na kuepusha watoto wasipate relapse.

Utaratibu: Ukikubali kuhusika Na huu utafiti, nitakuuliza maswali mengine ambayo yaeza kuwa nyeti, kuhusu kiwango cha elimu, mshahara wako. Baadaye nitaichunguza miguu ya mtoto wako kudhibitisha kama imenyooka, ama bado iko na kasoro.

Matokeo ya faida: Matokeo ya utafiti huu yata tufaidi Kwa njia tofauti, nitapata nafasi ya kuhitimu katika chuo cha upasuaji, nitaweza kuchapisha matokeo Kwa jarida tofauti Na yanaeza kutumika kubadilisha namna matibabu yanavyo fikia wananchi Kwa jumla.

Usiri: Habari utakayo peana Kwa utafiti, Usiri utazingatiwa kutoka mwanzo mpaka mwisho, majina hayatumika Kwa fomu ya taarifa, watafiti pekee ndio wataeza kuona majina yako.

Umepewa uhuru wa kuamua kutoka kwa utafiti wakati wowote na bado utapata matibabu ya mtoto wako inavyostahili bila gharama yoyote.

Nimepewa kibali kutoka Kamati ya Utafiti na Maadili ya Kituo Kikuu cha Nairobi na Hospitali Kuu ya Kenyatta. Ufafanuzi zaidi waweza kupatikana kutoka wafuatao.

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Kuonyesha umesoma na kuelewa jinsi ya utafiti huu na umepeana ridhaa ya kushiriki, tafadhali weka sahihi au weka kidole katika nafasi ilitengwa hapo chini:

Sahihi yangu/kidole:.....

Sahihi ya mpelelezi:.....

Tarehe:.....