CORRELATION OF HIGH-RESOLUTION ULTRASONOGRAPHY AND CONVENTIONAL RADIOGRAPHY IN THE EVALUATION OF HEEL PAIN AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

I, **Dr. SUHAILA SALIM ABEID SAID**, declare that the work contained herein is my original idea and has not been presented at any other place to the best of my knowledge.

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SUPERVISORS' APPROVAL

This research proposal has been submitted with our approval as University supervisors

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DEDICATION

I dedicate this thesis to the memory of my late father, my mother, husband and sisters for their faith, love, affection and constant support.

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First and foremost, I must acknowledge my limitless thanks to Allah, the Ever-Magnificent, for His help and bless and for letting me through all the difficulties.

I wish to acknowledge and give my warmest thanks to my supervisors Dr. Gladys Mwango and Dr. Callen Onyambu who offered their supervision and support during the study.

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To the radiographers, receptionists and colleagues whom I interacted with and learnt from, I was humbled working with you.

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ABBREVIATIONS

µm	-	Micrometers
ADM	-	Abductor digiti minimi
AH	-	Abductor hallucis
cm	-	Centimetre
BMI	-	Body mass index
CSA	-	Cross-sectional Area
CT	-	Computed Tomography
ESSR	-	European Society of Skeletal Radiology
GRF	-	Ground reaction force
FDB	-	Flexor digitorum brevis
FB	-	Foreign body
LALSS	-	Longitudinal arch load sharing system
mm	-	Millimetres
MR	-	Magnetic resonance
MRI	-	Magnetic resonance imaging
MSK	-	Musculoskeletal
US	-	Ultrasound
PA	-	Plantar Aponeurosis
PF	-	Plantar Fascia
PFD	-	Plantar Fascia Disorder
PHP	-	Plantar heel pain
STJ	-	Subtalar Joint

ABSTRACT

Background: The recent improvements in ultrasound technology coupled with wide availability, safety, portability, cost-effectiveness, non-ionizing with high spatial resolution renders it the initial choice of imaging for the evaluation of most musculoskeletal diseases. Ultrasound is a particularly useful tool to quickly and accurately localize and characterize pathologies of the sole.

Heel pain is a common presenting complaint and affects a wide range of the adult population. Plantar fasciitis is the commonest cause in primary care settings. It presents with heel pain, discomfort, and disability limiting day-to-day weight-bearing activities. Although clinical history and examination give useful information, imaging allows further assessment of the plantar fascia and helps to determine the differentials. In our setup, the first imaging modality requested is a plain radiograph which is a limited modality when it comes to depicting soft tissue pathology.

With the above-mentioned, ultrasound could be used as the diagnostic imaging modality for evaluating the heel as well as allow for follow up of patients with known plantar fascia disorders.

Objective: To quantify, characterize and correlate the ultrasonographic and radiographic findings in the diagnosis of plantar fascia disorders in patients presenting with heel pain at Kenyatta National Hospital

Sample size: Fifty nine (59) patients with heel pain were included in the study.

Sampling Design: This was a prospective descriptive study.

Study setting: Radiology Departments of the University of Nairobi and Kenyatta National Hospital

Study duration: The study was carried out between May 2021 and November 2021

Study Methodology: Following ethical approval, 59 consecutive patients referred for either a heel ultrasound or radiograph to the Department of Radiology, University of Nairobi or Department of Radiology, Kenyatta National Hospital because of heel pain were included in the study. The ultrasound examination was conducted as per the ESSR guidelines 2010 using General Electric Logic 7 or Phillips HD 11 at UoN and Toshiba- Aplio 400 or Philip 70G at

KNH for the performance of a heel ultrasound. Lateral heel radiographs done were reviewed thereafter. Findings were captured in a data collection form. The data was analyzed using SPSS Version 22.

Study results

Normal findings were recorded in 8 patients (13.6%) with abnormal findings seen in 51 patients accounting for 86.4%. The abnormal findings were twice more common in females (40) than in men (19) with a mean age of 42.3(SD 12.4) years. Heel pain was the only presenting complaint in the examined patients, majority 48(81.3%) presenting within a duration of 1 month and 1 year with a mean duration of 6 months (IQR 3.0-12.0). The mean weight was 79.7kg (SD 10.6) with only 9 (15.3%) patients categorized as having healthy weight, while the rest of the patients ranged from overweight 21 (35.6%) to obese 29 (49.2%). The most prevalent pathology was plantar fasciitis in 45 (76.3%) followed by plantar fascia tears 6 (10.2%). There was a statistical significant association between plantar fasciitis with age and BMI as assessed by the independent sample t-test (p value = <0.001 and 0.010 respectively). Abnormal plantar fascia thickness (67%) and echogenicity (71.6%) were the most sonographic findings encountered. An associated common finding of calcaneal spur (60.2% and 69.3%) was seen in both ultrasound and X-ray respectively. The sensitivity, specificity, PPV, NPV and diagnostic accuracy of heel ultrasound compared to plain radiography was 97.5%, 60.2%, 69.5%, 97.2% and 78.6% for abnormal plantar fascia thickness, 87.6%, 100%, 100%, 75.5% and 85.9% for calcaneal spurs and 100%, 64.4%, 80.2%, 100% and 85.4% for cortical irregularities, respectively.

Conclusion

Heel sonography achieved acceptable diagnostic accuracy of 78.6% when compared to plain radiography in the diagnosis of plantar fascia disorders. It may be considered an initial imaging modality to confirm clinically suspected plantar fasciitis in point-of-care settings

CHAPTER ONE: INTRODUCTION

Ultrasound is a real-time, non-ionizing modality that is readily available, portable, rapid, and less expensive to conduct (1) Its application to musculoskeletal(MSK) conditions continues to expand and has become the basic initial methodology of imaging for the greater part of MSK conditions (2)

With innovative advances such as greater spatial resolution and dynamic imaging abilities, ultrasound can be considered a vital diagnostic alternative to MRI. Other advantages from a clinicians perspective include; assessment of a region situated on the opposite side for comparison as well as direct interaction with the patient allowing for immediate correlation with the patients' symptomatology (3)

Ultrasound (US) is an excellent imaging modality to determine the nature of a lesion or mass differentiating solid from cystic structures within soft tissues. The flexibility of probe placement permits multiple view analysis of a structure (2)
Contrary to other superior modalities, US does not present constraints as a result of metal artifacts. Colour and power Doppler also provide physiologic information on a particular structure (3) However its greatest disadvantage is the inability to evaluate the internal structure of tissue types with high acoustic impedance (4)

A high-resolution linear transducer is judged proportionate to MRI for a range of soft tissue abnormalities including muscles, tendons, ligaments, fascia, and bursae (3) Reportedly, a 200µm resolution is provided by the use of a 15MHz probe, exceeding that of routine MRI. The technology advances have positively impacted the utilization of MSK-US thus improving the degree of objectivity behind soft tissue clinical diagnoses (5)

Plantar fasciitis is inflammation of the plantar fascia. It is considered the commonest cause of plantar heel pain (PHP) (6). It occurs as a result of repetitive use or excessive load on the fascia, typically seen in active or sedentary adults. Although considered the most common diagnosis in patients with PHP, in the long run affecting 1 in 10 persons, a range of disorders can as well affect the plantar fascia. If the cause of heel pain is misdiagnosed or not diagnosed early

enough, it may lead to long-term pain and discomfort for the patient, significantly hindering routine activities.

Although proper history taking and physical examination can give important information to capably diagnose plantar fascia disorders, diagnostic imaging plays a vital role in achieving the correct diagnosis, prompting appropriate treatment, and determining the prognosis (7).
The primary line of imaging for patients in our set up presenting with heel pain more often involves plain radiographs which have been recognized to not have a direct relationship to a diagnosis of plantar fascia disorder being a soft tissue pathology (8)

Ultrasonography is presently being progressively utilized in assessing the PF, more so in patients with a clinical diagnosis of plantar fasciitis. Owing to its higher spatial resolution, it has the ability to appreciate minor anatomical details better than MRI, however, MRI remains superior in contrast resolution (9) It provides information such as the thickness, echogenicity, presence of ruptures, calcifications, fluid collections, and bony spurs. A properly conducted MSK-US works as a definitive imaging modality and dismisses the necessity for a further MRI examination. Contrary to MRI, no contraindications are reported to sonography (7)

In addition, colour Doppler ultrasound can identify hyperaemia in the plantar fascia, near its proximal insertion and in the perifascial soft tissue. Hyperaemia is a well-known feature in plantar fasciitis due to neurovascular growth and may contribute to pain. Similarly, in the case of infectious fasciitis, the PF is hyperaemic on Doppler evaluation. Colour Doppler therefore aids in ruling out the rest of the plantar fascia disorders as fibromas, xanthomas and tears show no vascular flow. Ultrasound and colour Doppler option can also be used for serial follow-ups as well as for treatment guidance (4)

Limitations of Ultrasound

US is considered to be an operator-dependent technology with poor repeatability. Acquisition of US skills takes time depending on the trainee's hand-eye coordination skills
Even with advances in the resolution of the transducers, deeper structures are difficult to visualize as the higher-frequency transducers have lower tissue penetration.
Furthermore, ultrasound is also not capable of evaluating the internal structure of tissue types with high acoustical impedance such as bone and air (4)

This study proposes to determine the imaging findings and frequency of plantar fascia disorders in patients presenting with heel pain at KNH using radiography and ultrasonography. It will further determine the level of agreement between the two imaging modalities.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Plantar fasciitis is the commonest cause of heel pain, however, several other pathologic plantar fascia disorders can mimic its presentation, frequently causing discomfort and disability among the general population. Imaging is often required to give an accurate diagnosis and rule out other differentials. Ultrasound, with growing evidence, is increasingly being used as a first-line modality of imaging for most musculoskeletal conditions. Since its first application in 1974, a tremendous increase in the use of MSK ultrasound has been reported in the developed world. Sharpe et al reported a +316% rise in the diagnostic MSK ultrasounds done between 2000 and 2009 in the United States of America (10)

An article by Ahmed R. et al, 2016 on the effectiveness of US as an effective tool in PF concluded that the several advantages of US i.e. non-ionizing, non-invasive, portable, and a dynamic imaging technique with fewer contraindications, ranks it superior as a diagnostic modality in the diagnosis of PF (7)

A study by Draghi. et al, 2017 on imaging findings of plantar fascia disorders concluded that ultrasound be deemed the first imaging modality to evaluate plantar fascia disorders on account of being cheap, quick, dynamic with a greater spatial resolution (11)

In 2018, Lulu He. Et al, in the comparison study on MRI findings after MSK-US to reduce redundant imaging, concluded that ultrasound examinations seldom missed major key imaging findings and suggested that a well-performed MSK-US examination can serve as a conclusive modality lessening the need for another examination such as an MRI (4)

In an article on the diagnostic accuracy of US for MSK soft tissue pathologies, MSK-US is recommended as an affordable, accurate, and easily accessible imaging examination with high diagnostic accuracy for soft tissue pathologies of the extremities (1)

N. Anwar et al in their study on the correlation of ultrasound and MRI in the diagnosis of PF summarized a diagnostic US accuracy of 73.9% in diagnosing a thickened plantar fascia, 69.5% and 78.2% for fascia rupture and fluid collection, respectively. Conclusion on the accuracy of US was comparable to that of MRI (12)

Wu et al, 2019 established that the ultrasound measurements of plantar fascial thickness have a high degree of confidence comparable to cross-sectional modalities such as CT and MRI proving its accuracy (13)

Chen et al. conducted a study to investigate the effectiveness of device-assisted US-guided steroid injection for treating plantar fasciitis and revealed that patients who received US-guided injection had better therapeutic outcomes than palpation-guided injection. The injection done is site-specific and done in real-time therefore inadvertent soft tissue and intravascular injection can be avoided leading to a more reliable and successful treatment. Usually, non-fluorinated, long-acting corticosteroids are used. They reduce the edema and inflammation of the fascia and is usually sufficient when combined with physiotherapy for most of the patients (4)

Other common plantar fascia lesions to be considered as differentials include; plantar fibromatosis, plantar fascia tears, xanthomas, plantar infections, and foreign body reactions (11)

2.2 Normal Plantar Fascia Anatomy

The plantar fascia, also known as plantar aponeurosis is located on the bottom part of the foot. It is a massive sheet of a thick band of fibrous connective tissue that runs the whole length superficially connecting the forefoot to the hindfoot.

It is triangular in shape with its apex located posteriorly, emerging from the plantar surface of the calcaneum at the medial calcaneal tubercle and fans out running forward. As it approaches the metatarsophalangeal joints (MTP), it splits into 5 divisions that attach to the five metatarsal heads, on the plantar aspect and proximal phalanges of the toes. The origin of the calcaneum encounters most of the weight-bearing stress.

It is made up of predominantly longitudinal oriented collagen fibers with 3 structural components i.e. central, medial, and lateral bands. The largest and most prominent part is the central band. It is thickest proximally and distally thin, adhering to the underlying flexor digito-rum brevis muscle (FDB). The medial part attaches to the abductor halluces (AH) while the lateral part attaches to the abductor digiti minimi (ADM) muscle. Distally, the medial and lateral parts run to attach to the first metatarsal joint and fifth metatarsal joint capsule, respectively.

Often PF is used to refer to the large central band and is considered most important in the setting of plantar fasciitis, however, all the bundles contribute to maintaining the height of the longitudinal arch of the foot, providing a strong mechanical linkage between the toes and the calcaneus (14).

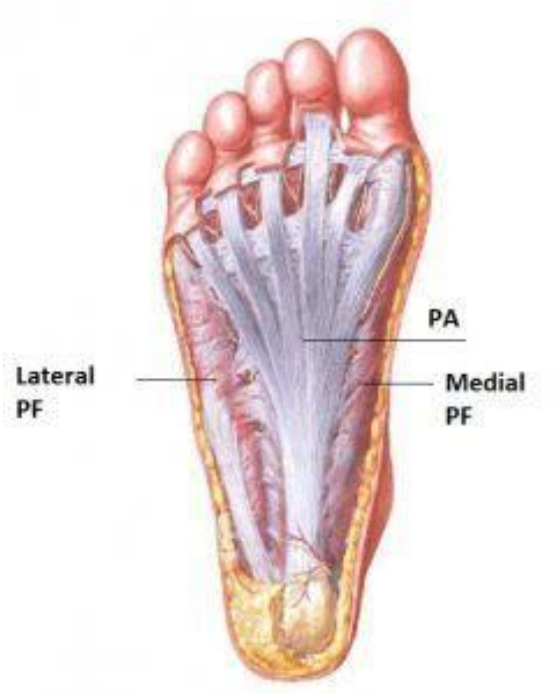


Figure 1: Anatomy of the plantar fascia. Image courtesy of Atlas of Human Anatomy by Frank H. Netter, 7th Edition

2.3 Biomechanical Function of Plantar Fascia

The plantar fascia is a vital and essential structure that involves all foot joints except for distal interphalangeal joints (DIP). Its several biomechanical functions are vital in a normal foot as it allows normal lower extremity operations in an individual's daily weight-bearing activities. It carries about 14% of the total load of the foot.

The plantar fascia (PF) stiffens and stabilizes mainly the longitudinal foot arch. It serves as a tension-bearing tie rod between the bones of the rearfoot and forefoot preventing stretching and leveling down of the arches when weight is borne.

Due to its distal insertion onto all the five digits, the PF plantarflex the digits onto the ground, and the rest of the forefoot dorsiflexed relative to the rear foot, increasing the PF tension force during weight-bearing activities

It is considered part of the longitudinal arch load sharing system (LALSS). It acts in mechanical synergy along with the plantar intrinsic muscles and ligaments distributing the tension load-bearing forces to prevent longitudinal arch lengthening and flattening, and while doing so, reduces the tension strain within plantar ligaments. The opposite is seen in patients with plantar fascia lesions or in those who underwent fasciotomy (15)

Furthermore, it plays an important role in an individual's gait. During propulsion, the fascia assists in resupination of the subtalar joint by preventing unrestrained medial foot column dorsiflexion. A heel lift off dorsiflexes the first MTP joint resulting in longitudinal arch raising of the foot as well as supination of the subtalar joint (STJ)
The later mechanism therefore also assists the deep compartment muscles posteriorly i.e. flexor halluces longus (FHL), flexor digitorum longus (FDL), and posterior tibial in STJ supination in the stance phase of walking (16)

Wright and Rennels revealed the elasticity property of the PF as it elongates under tension loading and with decreased tension returns to its original length, therefore stores and releases sufficient strain energy making activities such as running more energy efficient (17)

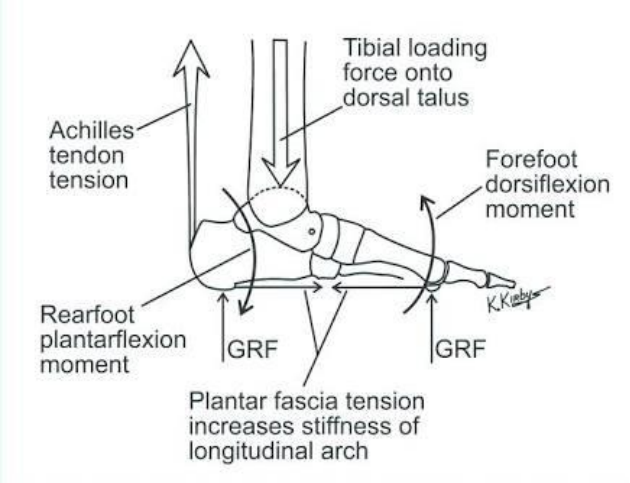


Figure 2: Longitudinal arch load sharing system. Image courtesy of The American Podiatric Medical Association (17)

2.4 Normal Sonographic Appearance

The normal plantar fascia is made up of longitudinally oriented type 1 collagen fibers. Similar to tendons and ligaments, it shows a fibrillar pattern consisting of multiple parallel lines in the long axis due to the echogenic appearance of the collagen fibers embedded within a hypoechoic matrix (21).

The PF is reported to be 2 to 4 mm in thickness and a thickness greater than 4 is considered diagnostic for plantar fasciitis (22)

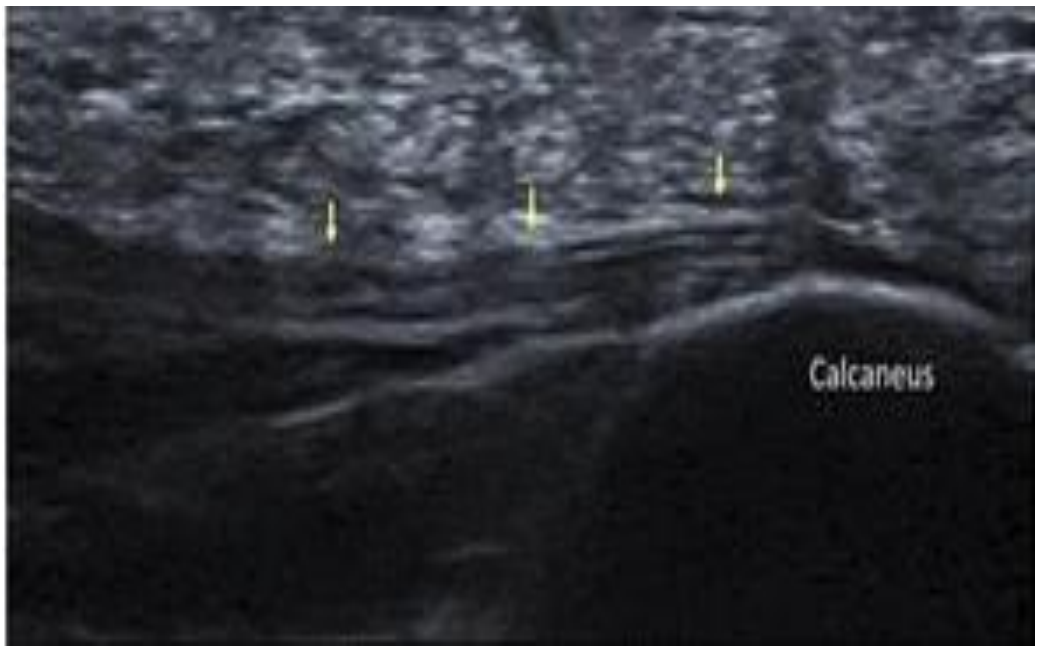


Figure 3: Normal plantar fascia on a sagittal ultrasound scan. Image adapted from a study by Draghi et al, 2017 on Imaging of plantar fascia disorders (11)

2.5 Plantar Fascia Disorders

2.5.1 Plantar Fasciitis

Plantar fasciitis is the most common cause of plantar heel pain affecting 1 in 10 persons at some point in their life. Cutts et al. reported that 4% to 7% of people have heel pain at any given time and about 80% of the cases are due to plantar fasciitis (6). Previously considered an inflammatory syndrome, recent studies describe plantar fasciitis as a non-inflammatory degenerative process hence preferably termed as plantar fasciosis. It occurs as a result of repetitive use or excessive load on the fascia, made note of in active or inactive adults over a range of ages, more commonly in individuals between the ages of 40-70 years (23)

Common predisposing factors include; excessive weight, occupations involving prolonged standing or walking, overtraining, foot deformities such pes planus and pes cavus, reduced ankle dorsiflexion or over-pronation, and unsuitable footwear (24,25)

Typically, involves the central component of the plantar fascia at its proximal attachment. The principal complaint is characterized by stabbing pain at the heel region when weight is borne, worse in the early morning or after a rest period, and is relieved by usual walking. Tenderness is palpated at the medial calcaneal tubercle (14)

Although proper history taking and physical examination can give important information to capably diagnose plantar fasciitis, diagnostic imaging plays a vital role in its definitive diagnosis.
Typical grey scale sonographic characteristics include thickening of the plantar fascia over 4mm, hypoechoic changes with loss of the fibrillary pattern, edema within or around the fascia, intrafascial calcifications, presence or absence of bony spurs, and sometimes hyperemia on Doppler ultrasound in an acute setting (26)

Association with plantar calcaneal spur has been reported, seen in approximately 50% of patients with plantar fasciitis with some investigators describing them as the primary contributory cause, but this remains controversial (27,28,29)

M. Akfirat et al established that calcaneal spurs are visible and commonly encountered sonographically. They have been concluded to exist side by side with plantar fascial thickening in patients with plantar heel pain (30)

Gibbon, in his study on ultrasound of the plantar aponeurosis, concluded that ultrasound being quick, safe, and affordable with a greater spatial resolution for superficial structures is better than MRI in the assessment of plantar fasciitis (31,32)

Sabir et al, on the study of the usefulness of ultrasound in diagnosing plantar fasciitis clinically, showed a sensitivity and specificity of 80% and 88.5% respectively in the assessment of plantar fasciitis compared with MRI (33)

A study by Walther et al described marked or moderate hyperemia as a power Doppler feature in acute plantar fasciitis and can therefore be used with routine B mode ultrasound to differentiate acute from chronic plantar fasciitis (14)

Furthermore, Chen et al, 2014 and others concluded that MSK-US allows real-time visualization and can be used as guidance to accurately inject treatment into and around the PF in patients with plantar fasciitis as well as evaluate treatment response, increasing the success rates (34,35)

Plain radiographic findings of plantar fasciitis include increased thickness of the PF measuring more than 4–5 mm off its calcaneal attachment and changes in the cortex of the calcaneus at the attachment of the PF (lucency or sclerosis) with or without spur formation and calcification (11)

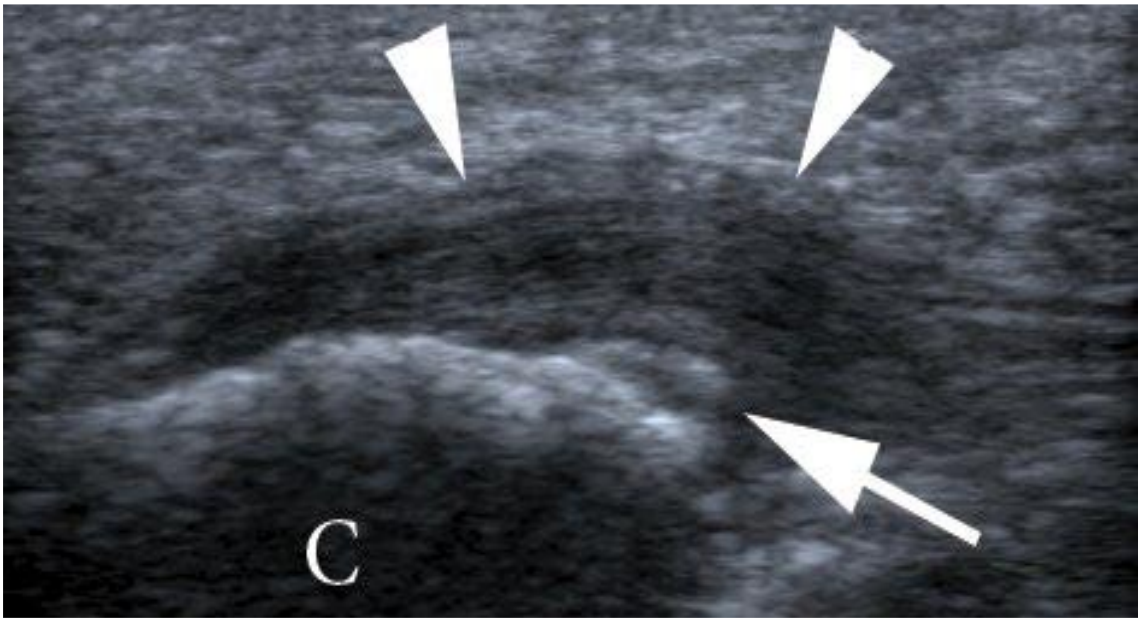


Figure 4: Plantar fasciitis on US with a bony spur at the insertion. Image adapted from a study by Claire Filippini, 2019 on Ultrasound features of the sole of foot pathology (14)

2.5.2 Plantar Fibromatosis

Also known as Ledderhose disease, plantar fibromatosis is a rare benign fibroblastic proliferation of the PF resulting in nodule formation usually along the medial and central components of the fascia, and may extend to deeper structures or the skin superficially. George Ledderhose, a German physician, initially described the disease in 1897 following his observation of fifty cases. Typically occurs between the ages of 30 and 50 years, however, the exact etiology is not known. Presentation ranges from a slow-growing lump that is tender affecting the patient's ability to walk, to local discomfort, and swelling to being asymptomatic. Multiple fibromas may come about over time and worsen the patient's symptoms (36)

Plantar fibromatosis is typically an isolated disease, however, association with Dupuytren's disease has been recognized. The pathological phases include; the proliferative phase characterized by a rise in fibroblastic activity and cellular proliferation, followed by an active phase with the formation of a nodule, and lastly residual phase with scar formation and tissue contracture (37)

Young et al, 2019 study states that ultrasound permits differentiation of smaller lesions from PF better than MRI with a pathognomonic pattern of a single, rarely multiple hypoechoic nodules measuring about 1cm with clear cut margins and absence of fluid collection, calcifications, and internal vascularity on color Doppler (38)

Given the superficial nature of the nodules, US is summarized as the most ideal, useful, and inexpensive modality for the accurate evaluation and characterization of plantar fibromas (39) Owing to its greater spatial resolution, MSK-US allow for better characterization of plantar fibromas. Cohen et al, 2018 reports a new plantar fibroma morphologic appearance of alternating isoechoic - hypoechogenic linear bands termed "Comb Sign" seen in 51% of his study cases (40)

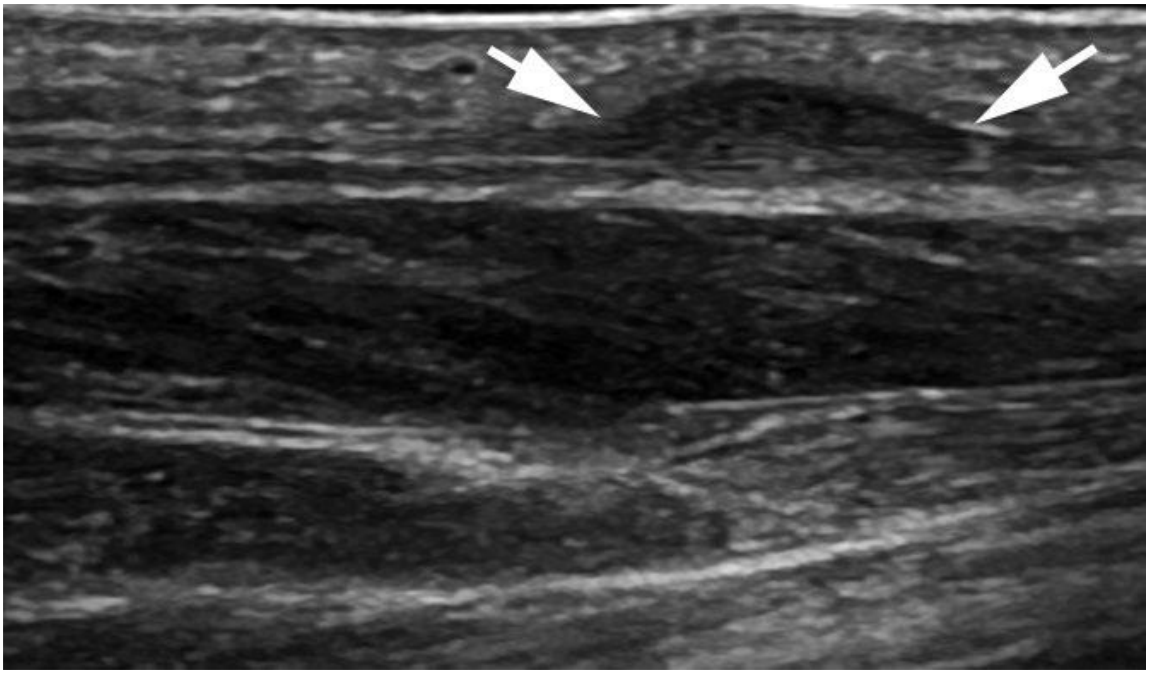


Figure 5: Plantar fibroma seen as a fusiform hypoechoic mass arising from the plantar fascia. Image adapted from a study by Claire Filippini, 2019 on Ultrasound features of the sole of foot pathology (14)

2.5.3 Plantar Fascia Tear

Tears of the PF are rare and have been reported in cases of longstanding plantar fasciitis or patients following treatment with steroid injections. They can be partial or complete i.e. rupture. Spontaneous tears are usually traumatic and are seen in athletic individuals following a sudden unexpected vigorous activity resulting in forced plantar flexion of the foot commonly distal to the calcaneal insertion of the PF. Reported biomechanical predisposing factors match those of plantar fasciitis and include weight changes, shoe wear, activity level, pes planus and cavus, hyperpronation, leg length discrepancy, and reduced dorsiflexion

Clinical presentation includes a 'snap' sound along with acute pain, local swelling, and on examination tenderness to palpation and ecchymosis on the medial plantar surface of the foot (14)

Sonographic features include; abnormal thickening, partial or complete disruption of the plantar fascia fibers with hypoechoic changes relating to inflammation and hematoma at the site of injury (11)

Louwers et al, 2010 in their study on sonographic assessment of spontaneous plantar fascia rupture concluded that Ultrasound, because of its around the clock availability can quickly, accurately, and affordably be used to diagnose a plantar fascia tear when compared with MRI, thus ultimately leading to earlier and faster treatment and improved outcomes.
Sabir et al successfully identified 1.3% of fascial ruptures in their study on the clinical utility of sonography in diagnosing plantar fasciitis (33)

The severity of a tear determines the type of treatment but usually involves bed rest and immobilization, administration of nonsteroidal anti-inflammatory drugs, physiotherapy, and gradual return to weight-bearing (41)

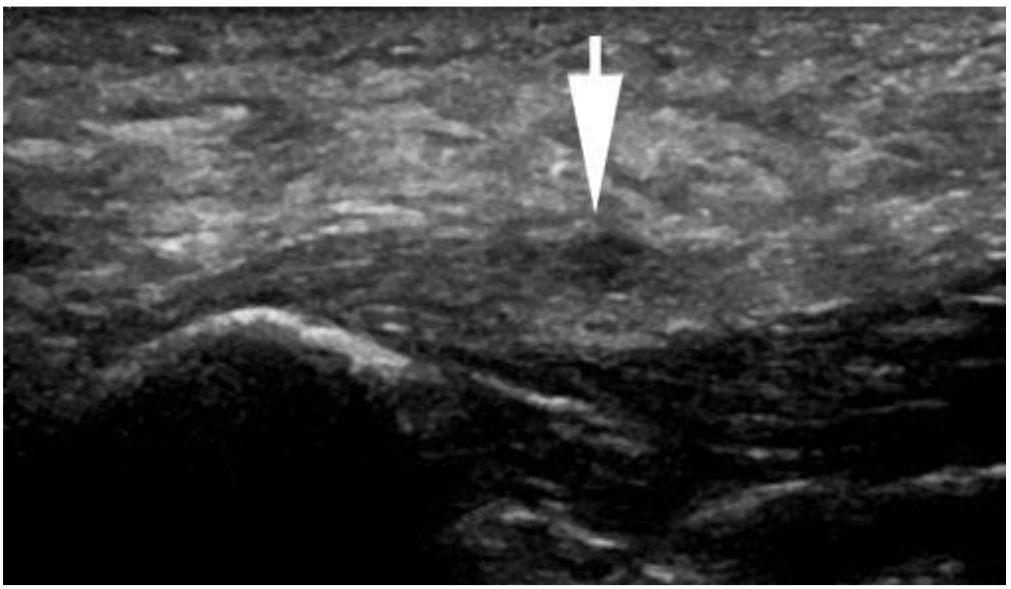


Figure 6: Partial plantar fascia tear seen as a small hypoechoic focus. Image adapted from a study by Claire Filippini, 2019 on Ultrasound features of the sole of foot pathology (14)

2.5.4 Plantar Xanthoma

Xanthomas occasionally occur in the plantar fascia but are frequently seen in the skin, subcutaneous tissues, and tendons as well. They are non-neoplastic localized collections, composed primarily of collagen and lipid-laden macrophages usually associated with hyperlipidaemias.
Symptoms include vague pain with or without a palpable mass on the sole of the foot but are usually asymptomatic. Sonographically, xanthomas are not specific and therefore should be

considered in the differentials of plantar fascia masses. The appearance simulates that of plantar fibromatosis.

A study by Yura Kim, et al showed that they appear as a nodular or fusiform thickening in the medial component of PF with no internal vascularity. Coexisting skin or subcutaneous nodular masses, as well as xanthomatous involvement of the Achilles tendon, is more diagnostic especially in patients with a history of hyperlipidemia (42)

2.5.5 Foreign Bodies

The most common foreign bodies include wood, glass, needles, thorns, metal, and stone, sometimes seen within or adjacent to the Plantar fascia. Occur following a penetrating injury even though the history of trauma or cut is rarely reported. Clinical presentation is similar to that of plantar fasciitis. Complications of retained foreign bodies include pain, discharging wound, abscess or granuloma formation, and migration of the FB resulting in neurovascular damage that renders its removal necessary.

Typical features include a small echogenic material surrounded by hypoechoic tissue within or adjacent to the PF. Acoustic shadowing posteriorly and ring down artifacts may also be seen especially in cases of metal objects (43)

Plain radiographs are usually ordered to check for the presence of a radio-opaque foreign body, however, they are negative for wooden FB in 86% of cases. However, radiopaque foreign material, such as metals, may be easily revealed. Ultrasound is not only considered best for the detection but in the removal of radiolucent FB as well. Sonography features a reported sensitivity of 95% for the detection of foreign bodies. It provides three-dimensional information on the size, depth, and anatomical relationship with adjacent structures (44)

Mohammadi et al in their study on sonographic findings of non-opaque soft tissue foreign body reported a 100% sensitivity and specificity of sonography diagnosis of soft tissue foreign bodies in correlation with surgery (45)

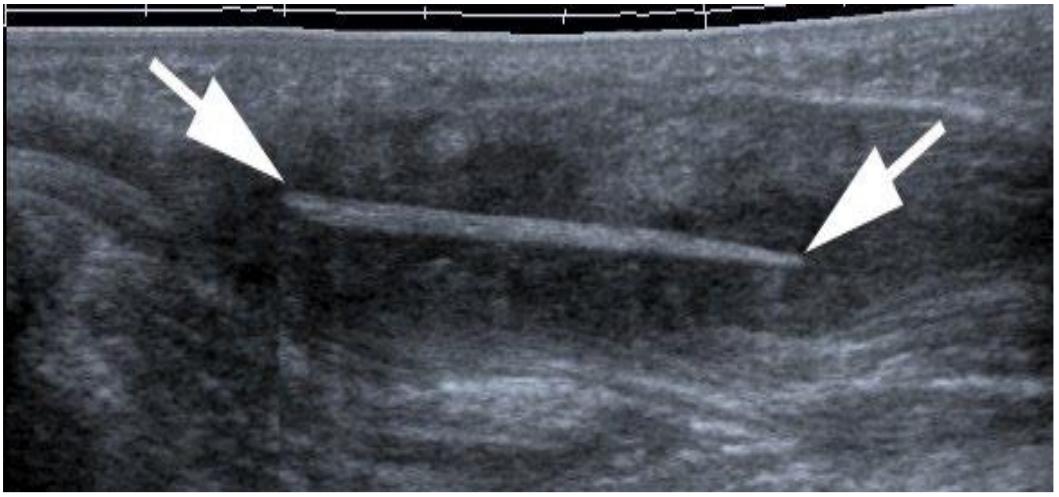


Figure 7: Echogenic FB within the plantar fascia. Image adapted from a study by Claire Filippini, 2019 on Ultrasound features of the sole of foot pathology (14)

2.5.6 Plantar Infections

Also referred to as infectious fasciitis, seen to occur following a neighboring infection source, wounds from penetrating injuries or post-procedure, in diabetics' feet and the immunocompromised patients as well. Its major complication is the spread and involvement of adjacent structures to the fascia such as soft tissues, muscles, and bones.

The utility of ultrasound is reported in the evaluation of musculoskeletal infections especially when it comes to differentiating acute from chronic infections as well as non-infective diseases and malignancy.

The sonographic characteristics include increased size of the plantar fascia, loss of fibrillary appearance, perifascial edema, and increased vascularity on Doppler assessment while radiographic characteristics include soft-tissue swelling and blurring of soft-tissue planes. Concomitant osteomyelitic changes in bone morphology can also be detected and mainly include lytic lesions, osteopenia, loss of trabecular architecture, new bone apposition, and periosteal thickening (11)

CHAPTER THREE

3.1 Study Justification

Heel pain is a frequent disabling symptom. It can cause torment and incapacity and may abridge the performance of routine and other work-related obligations. With the large range of possible diagnoses, plantar fascia disorders form an important group with plantar fasciitis being the most common diagnosis. In our setup, initial evaluation consists of clinical history and examination, followed by a plain radiograph where indicated, which gives limited data in terms of the delicate soft tissue involvement.

Ultrasound is a non-invasive, radiation-free, and cost-effective approach that is also well tolerated by patients and has been shown to be effective in demonstrating plantar fascia disorders. The findings of this study will help create an awareness to the referring clinicians on the benefits of heel sonography within the conclusion of plantar fascia disorders. It will also add to the local scientific knowledge by helping identify the sonographic patterns of plantar fascial disorders in our setup.

The American Podiatric Medical Association demonstrated the significance of ultrasound in diagnosing and managing patients with plantar heel pain by identifying several aetiologies and proved that most of the disorders such as fibromas and tears are unattainable from clinical judgement alone. To the best of my knowledge, no study has been carried out locally to assess and correlate the ultrasound and radiographic findings in patients presenting with heel pain.

3.2 Research Question

What is the pattern of ultrasound and radiographic findings of plantar fascia disorders in patients presenting with plantar heel pain at Kenyatta National Hospital?

3.3 Study Objectives

3.3.1 Broad Objective

To quantify, characterize and correlate the ultrasonographic and radiographic findings in the diagnosis of plantar fascia disorders in patients presenting with heel pain at Kenyatta National Hospital

3.3.2 Specific Objectives

a) To characterize the ultrasound and radiographic findings of patients presenting with heel pain.

b) To determine the prevalence of the imaging findings.

c) To correlate the radiographic and sonographic findings.

CHAPTER FOUR: STUDY METHODOLOGY

4.1 Introduction

Study design, method of data collection, analysis, and presentation utilized in this study will be addressed. The chapter centers on the steps and strategies that will be taken to improve the legitimacy, reliability, and quality of information collected from the study.

4.2 Study Design

The study will be a descriptive cross-sectional study.

4.3 Study Area

The study will be conducted at Kenyatta National Hospital (KNH) which is the largest national teaching and referral hospital in Kenya and East Africa at large, which serves as a principal healthcare facility for the Nairobi county residents.

The hospital consists of a 6000 staff capacity, 1800 bed capacity with an approximated 600,000 and 90,000 yearly out-patient and in-patient attendance respectively. It comprises 50 wards, 22 outpatient clinics, 24 theatres, and an Accident & Emergency department.

KNH receives referrals from other hospitals and institutions countrywide for specialized healthcare services. It also provides teaching and research facilities for the University of Nairobi and the Kenya Medical Training College trainees

The study will be conducted at the Radiology department (Ultrasound room 4) Kenyatta National Hospital and at the Department of Imaging and Radiation Medicine, University of Nairobi. Approximately 9 patients with heel pain get a calcaneal radiograph done at KNH

4.4 Study Population

Patients attending KNH and the Department of Imaging and Radiation Medicine, the University of Nairobi with a referral for a heel radiograph or heel ultrasound and fit the inclusion criteria will be included in the study following informed consent

Age bracket: Adults commonly people between 30 and 60 years.

4.4.1 Inclusion Criteria

Inclusion criteria include:

Patients presenting with heel pain referred for a heel/calcaneal radiograph and are 18 years and above who consent to heel ultrasound as an additional imaging modality.

4.4.2 Exclusion Criteria

Exclusion criteria include:

- Patients with previous local surgery
- Patients with history of acute trauma

- Patients who decline consent to the heel ultrasound examination

4.5 Sample Size

Fisher's formula is the recommended formula for descriptive studies and is used to determine the sample size. The assumption is that the sample will be representative, the sampling error will be small and the results will be generalizable.

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

Daniel WW (1999). Biostatistics

Where,

n = Desired sample size

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

P = expected true proportion (the estimated prevalence of patients presenting with proximal plantar heel pain at the radiology department)

d = desired precision (0.05)

This study will desire a 95% confidence level (z=1.96) and ±5% precision. We will assume p=0.5 since there is no similar study conducted in regions similar to our settings

$$n_0 = \frac{1.96^2 x\ 0.5(1-0.5)}{0.05^2} = 384$$

70 active patients visited Kenyatta national hospital seeking treatment in the last 6 months and fit the inclusion criteria. The patient's register was used as a source document. Gearing the sample size for finite populations less than 10,000

$$nf = \frac{n_0}{1 + \frac{n_0 - 1}{N}} = \frac{384}{1 + \frac{384 - 1}{70}} = 59$$

A sample size of 59 patients will be needed for the study.

4.6 Materials and Methodology

A pilot study will be done to familiarize with the imaging technique, study protocol and assess the adequacy of the data collection tool. Patients who are referred for a heel radiograph and fit the inclusion criteria will sequentially be included in the study.

Informed consent will be acquired, the biodata and clinical history taken, a physical examination done and filled using a structured questionnaire by the principal investigator.

General Electric Logic 7 or Phillips HD 11 at the University of Nairobi and Toshiba-Aplio 400 or Philips Affiniti 70G ultrasound machines at Kenyatta National hospital and a linear transducer with a frequency of 9-15MHz will be used. The European Society of Skeletal Radiology (ESSR 2010) guidelines, which provide standardized protocols for examining the plantar fascia will be used. The principal investigator will carry out the examination with the help of study supervisors. Standardization will be attained by constancy and strict adherence to the examination protocol, and by having any pathology noted confirmed by either of the supervisors. The real-time images acquired will be stored, along with representative images of any pathology noted printed. Data collection tool will be used to take down the examination findings and the information will be analyzed to meet the objectives of the study.

Data collected will include:

a) Patient demographic details (age, gender) which will help in achieving one of the objectives of the study.

b) Ultrasound and radiographic appearance of the plantar fascia and the abnormality characterized further and classified.

Sonographic data to be collected and that will help in the analysis will include:

The size, echogenicity, and vascularity of the plantar fascia. Auxiliary findings such as masses, calcifications, perifascial edema, and bony spurs. A correlation with a lateral plain radiograph performed before or after will be done and the results reviewed only after the heel ultrasound examination is performed.

During this Covid-19 period, safety measures include; Proper use of personal protective equipment and disposal. Researchers will be in face masks and gloves and perform hand hygiene at all times. They will also be mindful of social distancing for patient safety by scheduling appointments at infrequent intervals and spacing seats in waiting rooms. Ultrasound transducers and cables will be cleaned and disinfected in between patients. All patients are to wear a facial mask and wash their hands or sanitize before and after the procedure. Patients coming for a scan will be advised not to bring anyone with them unless they need assistance. To reduce the risk of exposure, scans will be limited to 10 minutes per evaluation

4.7 Plantar fascia Ultrasound Examination Technique (ESSR 2010 Guidelines)

The patient will be made to lie in a prone position. The symptomatic foot dorsiflexed to form 90 degrees with the distal leg and placed to hang over the edge of the table. The transducer will be placed over the plantar aspect of the foot. Long-axis ultrasound scans for the symptomatic heel will be performed with medial inclination to target the attachment of the plantar fascia to the calcaneal tubercle, to better appreciate the longitudinally placed fibrillar structure, sweeping across the entire width of the origin. The standard measuring point will be where the fascia crosses the anterior-most aspect of the inferior border of the calcaneus, the point where it leaves the calcaneal tuberosity. Coupling gel will be applied with the pre-sets and focus adjusted appropriately for superficial MSK examination. The gains will be adjusted for good penetration of the thick skin of the heel (19). No advantage is seen with transverse scanning in the evaluation of PF (20)

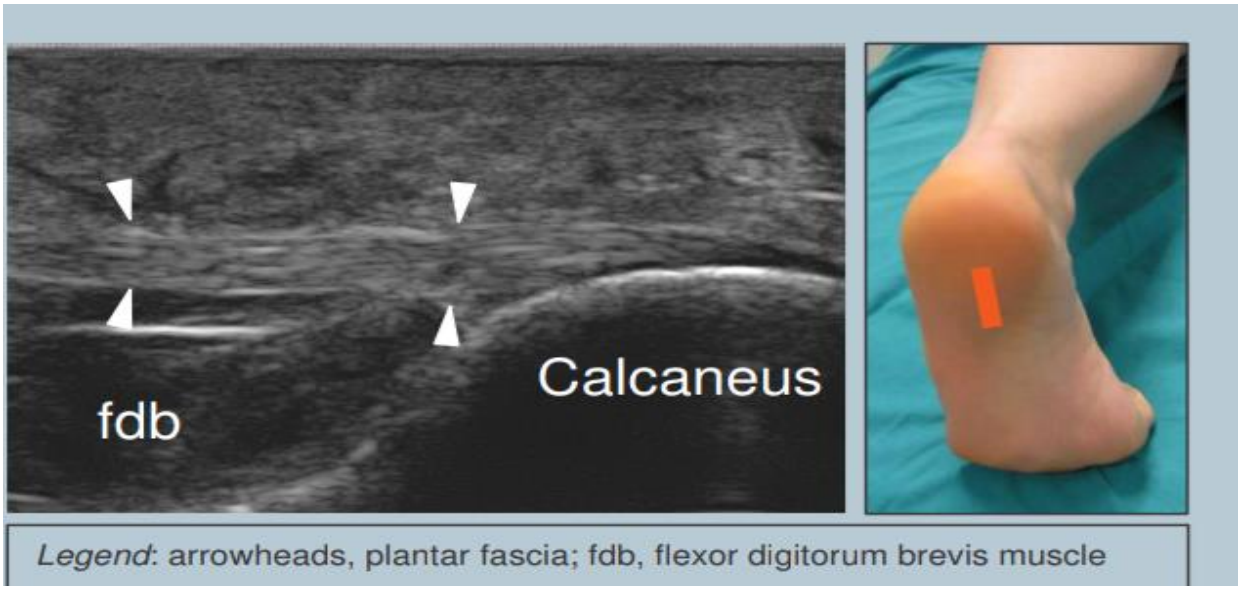


Figure 8: Transducer Position and Representative Image of the plantar fascia. Image adapted from European Society of Skeletal Radiology (ESSR) guidelines 2010 (19)

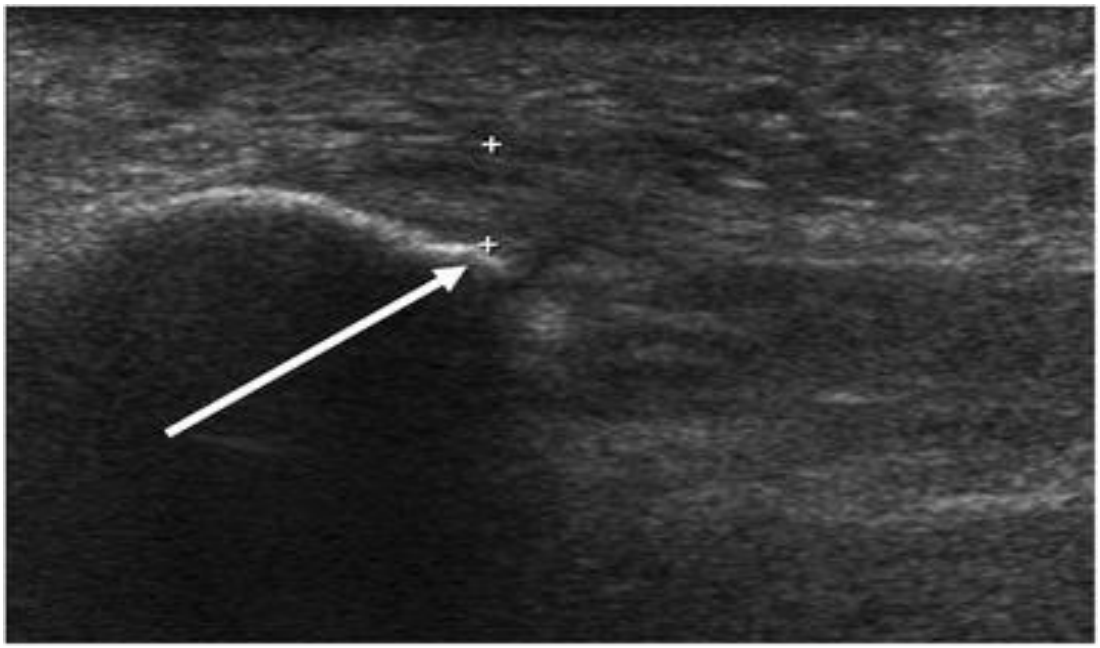


Figure 9: Standard reference point for PF measurement. Image adapted from European Society of Skeletal Radiology (ESSR) guidelines 2010 (19)

4.8 Conventional Calcaneum Radiography Technique

The patient is placed in a supine position and rotated onto the affected side such that the plantar surface of the foot lies perpendicular to the image receptor. The foot is dorsiflexed to form 90 degrees with the distal leg. The Centre point is 2.5cm distal to the medial malleolus with the vertical beam ray perpendicular to the image receptor (mediolateral projection). Collimation covers skin margins of distal phalanges anteriorly, calcaneus posteriorly to essentially include the adjacent tarsal bones, and superiorly the ankle joint (46).

Figure 10: Positioning for lateral projection of calcaneum. Image adapted from Clark's Positioning in Radiography, 12th Edition (46)

Figure 11: Normal lateral Calcaneal radiograph. Image adapted from Clark's Positioning in Radiography, 12th Edition (46)

5.0 ETHICAL CONSIDERATION

Ethical approval will be attained from the KNH/UON-ERC. Permission for performing heel ultrasound will be obtained from both, the head of the department at the department of diagnostic imaging, KNH, and the UON. Informed consent from study participants who meet

the inclusion criteria will be looked for. Each participant will be requested to sign a consent form before inclusion in the study. This shall be after an explanation of the risks involved in the study, the benefits and ethical considerations are fully understood by the participant. The study participation will be entirely voluntary and the participants allowed to dismiss the study at any time.

There will be no risks involved to the participants as ultrasound uses sound waves to interrogate the inner structures of the body part being examined. It is a safe modality of imaging that is not harmful to the body. It also does not cause any pain and will be done in private. Justification for the conventional radiography examinations done will be sorted by determining the appropriateness of the indications on the requests. Radiation doses to the patients and the environment will be minimized to a level as low as reasonably achievable (ALARA principle) The information regarding the study participant's identity will be kept confidential. Identification information such as participant's names will not be included in the data collection forms. Serial numbers will be assigned to each participant. New, unexpected, or incidental findings will be informed to the study subject as a responsibility and obligation even though it's not part of the research. The study data will be highly protected and only accessible to the principal investigator. Contacts of the investigators will be provided to the participants in case of any questions or concerns that may arise about participating in the study and the study staff will payback for the charges to these numbers if the call is for study-related communication.

6.0 DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data will be entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 24. Demographic and clinical characteristics that are categorical will be analyzed and presented as frequencies and proportions and continuous data will be presented as means with standard deviations or as median with interquartile range. A descriptive analysis of each demographic variable in the data will be conducted. The main outcome will be abnormal findings on heel US and the characteristics described. Characteristics and classification of the sonographic spectrum of findings as well as the demographic characteristics will be analyzed and presented as frequencies and proportions.

The correlation between the sonographic findings and the symptomatology will be analyzed and presented. Data will be summarized as mean ± SD and simple linear correlation (Pearson's correlation) will also be done.

7.0 STUDY LIMITATIONS

One of the disadvantages of ultrasound is that it is operator-dependent which will be reduced during the pilot study and further countered by following the ESSR 2010 guidelines on the methodology of performing a heel ultrasound and with help from my supervisors. Correlation with MRI would have been useful, but due to its cost implications and not being commonly done, including it in the study would not be feasible.

8.0 DATA DISSEMINATION PLAN

Once the research is complete, the study findings will be disseminated to the KNH administration and head of the radiology department as well as to the study participants and other stakeholders through a Continuous Professional Development (CPD) meeting. Publication of the research findings will also be done in a local peer-reviewed journal.

9.0 RESULTS

Fifty nine patients who met the inclusion criteria were scanned at the Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi. Eighty eight heel ultrasounds were performed with heel radiographs of the same reviewed thereafter. Data collection was done between May 2021 and November 2021.

9.1 Demographics and Patient Characteristics

The minimum and maximum age was 19 years and 74 years. The mean age of patients examined was 42.3 (SD 12.4) years and the median age was 42.0 (IQR 32.5 – 52.5) years. Two patients (3.4%) were under 20 years, 25 (42.4%) were between 21-40 years, 29 (49.2%) were between 41-60 years and 3 patients (5.9%) were above 60 years as illustrated in figure 1 below.

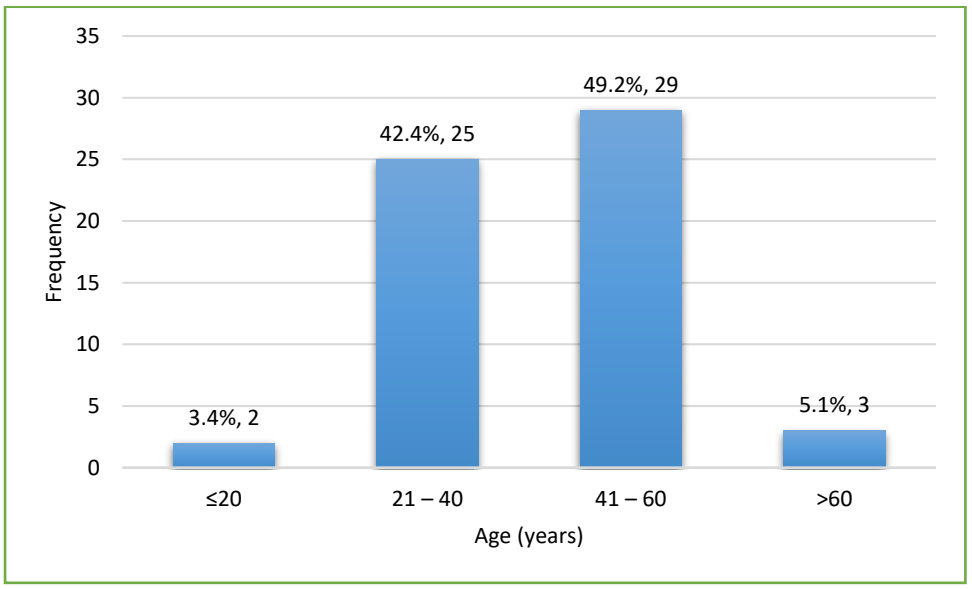


Figure 1: Age distribution of the patients

There were more female patients, 40 accounting for 67.8% than male patients, 19 representing 32.2% of all patients, where the ratio for male to female was 1:2.1

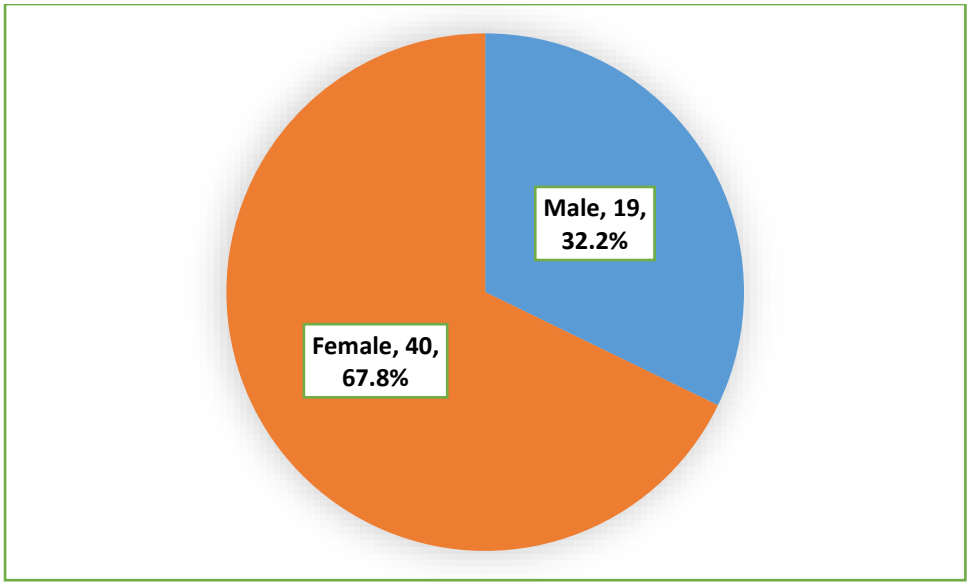


Figure 2: Gender distribution of the patients

The mean weight was 79.7kg (SD 10.6). Only 9 (15.3%) patients were categorized as having healthy weight, while the rest of the patients ranged from overweight 21 (35.6%) to obese 24 (40.7%) and the remaining 5 (8.5%) patients being severely obese

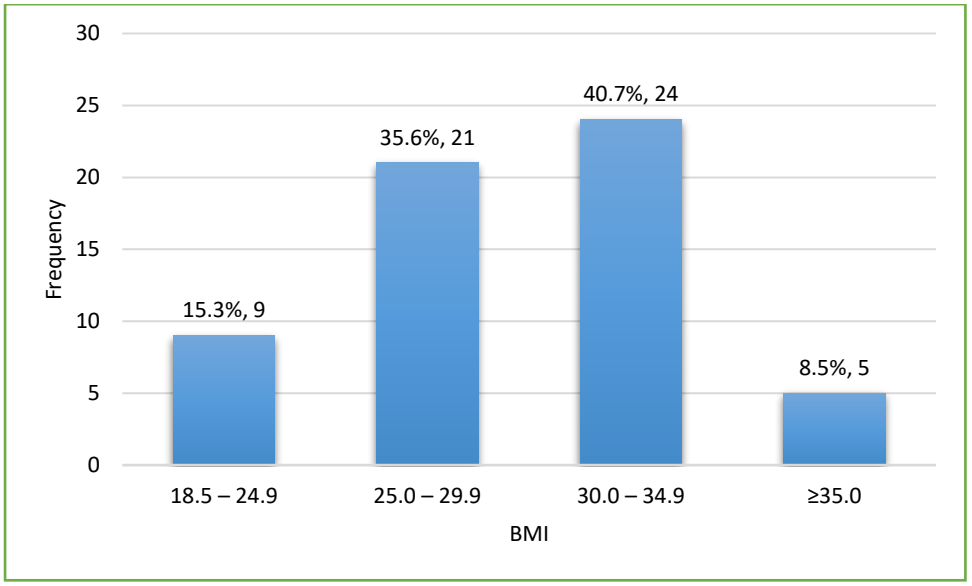


Figure 3: BMI distribution of the patients

The most common clinical presentation was heel pain in all 59 patients (100%). Twenty nine (49.2%) were bilateral and 30 (50.8%) unilateral. Of the unilateral 17(56.7%) were on the right and 13(43.3%) on the left resulting in the total number of symptomatic heels to 88. The average duration of symptoms was 1-10months in 34 patients, 1 year in 14 patients, 2years in 8 patients and 3 years in 3 patients. The median duration was 6.0 months (IQR 3.0-12.0)

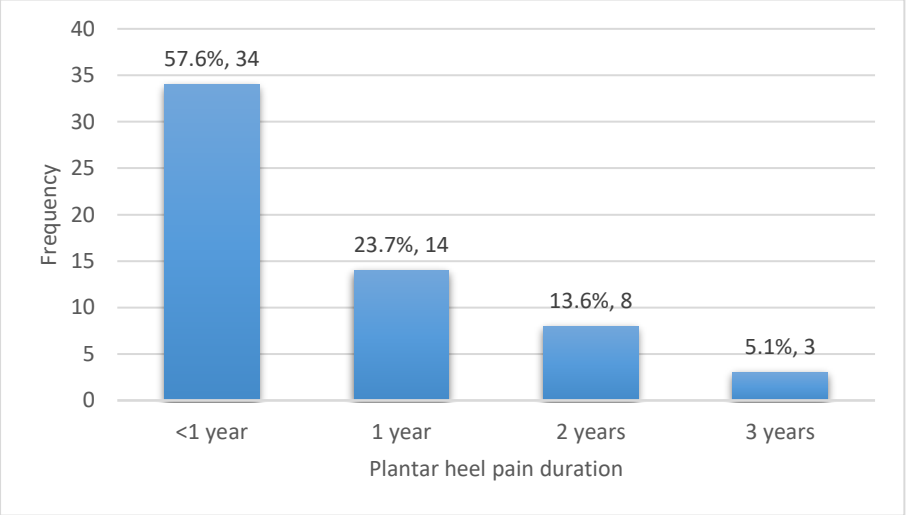


Figure 4: Plantar heel pain duration

Out of the 59 patients, no patient had a positive previous history of trauma but on history of co-morbid conditions, only 13 (22.0%) had history. The most common comorbid condition was hypertension found in 8 (13.6%) patients. Of the 13 patients with comorbid conditions, 1 (1.7%) had diabetes mellitus and 4 (6.8%) had both hypertension and diabetes mellitus.

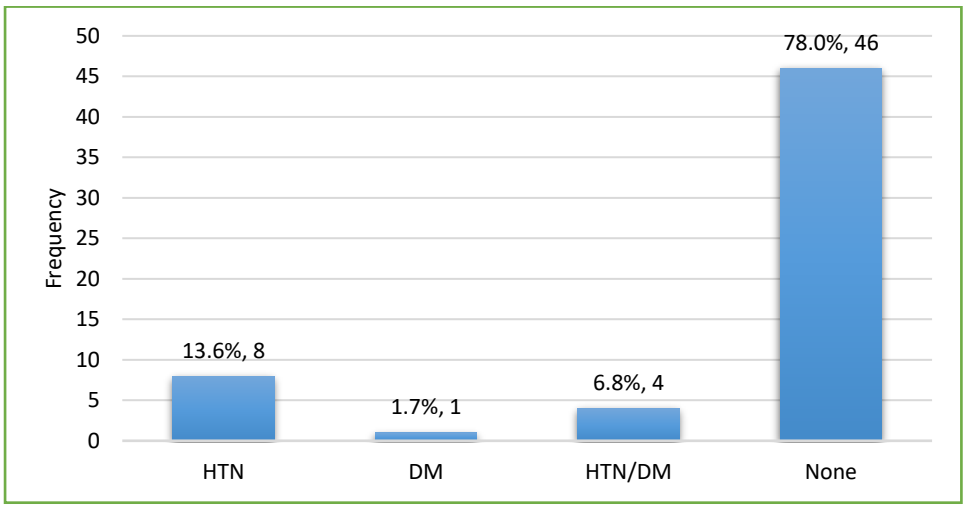


Figure 5: History of co-morbid condition

9.2 Ultrasound findings

Only 8 patients (13.6 %) of the study population did not have any plantar fascia pathology detected by ultrasound despite having a clinical complaint of plantar heel pain, with the remaining 51 (86.4%) being abnormal.

The most common pathology encountered was plantar fasciitis in 45 (76.3%) patients, of which 16 (27.1%) cases were bilateral and 29 (47.4%) cases unilateral, left 16 (27.1%) more affected than the right 13 (22.0%) followed by plantar fascia tears seen in 6 (10.1%)patients, 4(6.8%) cases on the right and 2(3.3%) on the left. There were no cases of plantar foreign body, plantar xanthomas or plantar fibromas seen in our period of study.

A total of 88 feet were examined by ultrasound for heel pathology and the findings are shown on table below

Table 1: Ultrasound findings

	Normal, *n (%)*	**Abnormal,** *n (%)*
PF thickness	29 (32.9)	59 (67.0)
PF echogenicity	25 (28.4)	63 (71.6)
PF vascularity	53 (60.2)	35 (39.7)
	Present, *n (%)*	**Absent,** *n (%)*
Calcaneal spur	53 (60.2)	35 (39.7)
Calcifications		88 (100.0)
Perifascial edema	58 (65.9)	30 (34.0)
Foreign body		88 (100.0)
Mass lesion		88 (100.0)
Cortical irregularities	65 (73.9)	23 (26.1)

9.2.1 Plantar fasciitis

Plantar fasciitis accounted for 76.3% of the pathologies seen in patients with a mean age of 45. The male to female ratio was 1:2. The most common sonographic finding in the diagnosis of plantar fasciitis was an abnormal plantar fascia thickness with a mean of 5.9mm in males and 5.6mm in females seen in 59 (67%) of the total scanned symptomatic heels. Right heels scanned accounting for 28 (31.8%) and the left 31 (35.2). Second, is the finding of diffuse plantar fascia hypo-echogenicity seen in 57 (64.7%) symptomatic heels, 26 (29.5%) on the right and 31 (35.2%) on the left.

Table 2: Association between Plantar fasciitis with Age, BMI and gender

		Plantar fasciitis		
		Yes, *(n=44)*	**No,** *(n=15)*	**p-value**
Age, *mean ± SD*		45.7±11.5	32.3±9.4	**<0.001**
BMI, *mean ± SD*		30.3±3.9	27.4±4.1	**0.010**
Gender, *n (%)*	Male	14 (31.8)	5 (33.3)	0.951
	Female	30 (68.2)	10 (66.7)	

There was a statistical significant association between plantar fasciitis with age and BMI as assessed by the independent sample t-test (p value = <0.001 and 0.018 respectively). However the association was not significant between gender and plantar fasciitis as assessed by Pearson chi-square test (p value =0.914)

9.2.2 Plantar fascia tear

It was the second commonest pathology seen in 6 patients accounting for 10.2% in a younger age group with a mean of 33. The male to female ratio was 1:5 characterized by abnormal thickening and partial disruption of the plantar fascia fibers with focal hypoechoic changes**.**

Table 3: Association between Plantar fascia tears with Age, BMI and gender

		Plantar fascia tear		
		Yes, *(n=7)*	**No,** *(n=52)*	**p-value**
Age, *mean ± SD*		33.2±7.4	43.3±12.5	0.058
BMI, *mean ± SD*		28.6±2.1	29.7±4.3	0.526
Gender, *n (%)*	Male	1 (16.7)	18 (34.0)	0.653
	Female	5 (83.3)	35 (66.0)	

No statistical significant association between plantar fascia tears with age and BMI (p value= 0.058 and 0.526 respectively) as assessed by the independent sample t-test, and the association was also not significant between gender and plantar fascia tears (p value= 0.653) as assessed by Pearson chi-square test.

9.3 Plain radiograph findings

The radiographs of the total 88 symptomatic feet examined by ultrasound were reviewed and the findings are shown on the table below

Table 4: Heel radiograph findings

		Normal, *n (%)*	**Abnormal,** *n (%)*
Plantar fascia thickness		46 (52.2)	42(47.7)
		Present, *n (%)*	**Absent,** *n (%)*
Bony spur		61 (69.3)	27 (30.7)
Soft tissue swelling		23 (26.1)	65 (73.9)
Calcifications			88 (100.0)
Foreign body			88(100.0)
Cortical irregularities		52 (59.0)	36 (40.9)
Others	Achilles enthesopathy	3 (5.1)	56 (94.9)

Only 42 (47.7%) of plantar fascia thickness were abnormal, contrary to heel ultrasound where a higher number of 59 (67%) of the symptomatic heels were abnormal. Similarly, cortical irregularities were seen in slightly fewer patients 52 (59%) compared to the 65 (73.9%) seen in ultrasound examination. Only 23 (26.1%) patients had soft tissue swelling. However 61 (69.3%) bony spurs were detected with a less number 53 (60.2%) seen with ultrasound and a total of 3 patients had other findings of achilles enthesopathy.

No findings of calcifications, mass/nodules or foreign body detected on both modalities.

9.4 Diagnostic accuracy of Ultrasound

The standard of practice imaging modality was plain radiography, of which the study was to determine the sensitivity, specificity and the diagnostic accuracy of ultrasound against the standard.

9.4.1 PF thickness

		Plain Radiograph						
		Abnormal	Normal	**Sen.**	**Spe.**	**DA**	**PPV**	**NPV**
	US							
PF thickness right	Abnormal	19	9	95.0%	65.4%	78.3%	67.9%	94.4%
	Normal	1	17					
PF thickness left	Abnormal	22	9	100.0%	55.0%	78.6%	71.0%	100.0%
	Normal	0	11					

For PF thickness, for the right foot, US was found to have sensitivity of 95.0% (95% CI, 75.1% - 99.9%), specificity of 65.4% (95% CI, 44.3% - 82.9%), PPV of 67.9% (95%CI, 55.2% - 78.3%), NPV of 94.4% (95% CI, 71.2% - 99.2%), and overall diagnostic accuracy of 78.3% (95% CI, 63.6% - 89.1%). For the left foot, the sensitivity was 100.0% (95% CI, 84.6% - 100.0%), specificity of 55.0% (95% CI, 31.5% - 76.9%), PPV of 71.0% (95% CI, 60.1% - 79.9%), NPV of 100.0% (95% CI, 84.6% - 100.0%), and overall diagnostic accuracy of 78.6% (95% CI, 63.2% - 89.7%)

9.4.2 Calcaneal spurs

		Plain Radiograph						
		Present	Absent	**Sen.**	**Spe.**	**DA**	**PPV**	**NPV**
	US							
Spurs right	Present	27	0	96.4%	100.0%	88.5%	100.0%	94.7%
	Absent	1	18					
Spurs left	Present	26	0	78.8%	100.0%	83.3%	100.0%	56.3%
	Absent	7	9					

For Calcaneal spurs, for the right foot, US was found to have sensitivity of 96.4% (95% CI, 81.7% - 99.9%), specificity of 100.0% (95% CI, 81.5% - 100.0%), PPV of 100.0% (95% CI, 84.6% - 100.0%), NPV of 94.7% (95% CI, 72.4% - 99.2%), and overall diagnostic accuracy of 97.3% (95% CI, 88.5% - 99.9%). For the left foot, the sensitivity was 78.8% (95% CI, 61.2% - 91.0%), specificity of 100.0% (95% CI, 66.4% - 100.0%), PPV of 100.0% (95% CI, 87.6% - 100.0%), NPV of 56.3% (95% CI, 40.0% - 71.3%), and overall diagnostic accuracy of 83.3% (95% CI, 68.6% - 93.0%)

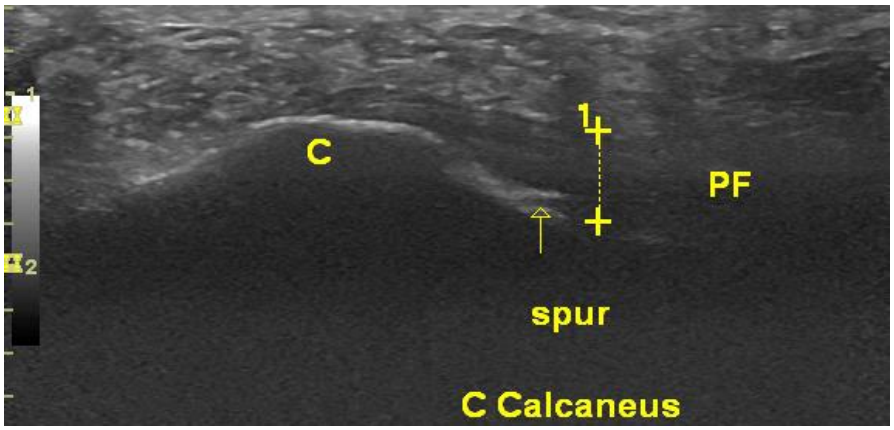
9.4.3 Cortical irregularities

		Plain Radiograph						
		Present	Absent	**Sen.**	**Spe.**	**DA**	**PPV**	**NPV**
	US							
CI right	Present	26	8	100.0%	60.0%	82.6%	76.5%	100.0%
	Absent	0	12					
CI left	Present	26	5	100.0%	68.8%	88.1%	83.8%	100.0%
	Absent	0	11					

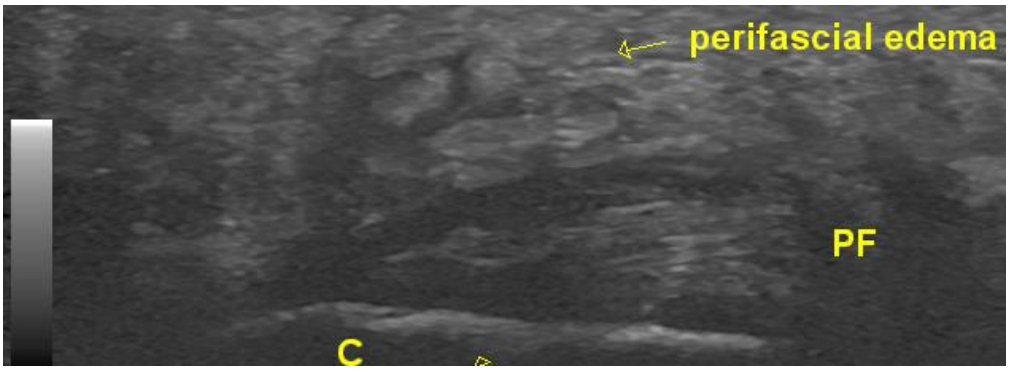
For Cortical irregularities, for the right foot, US was found to have sensitivity of 100.0% (95% CI, 86.8% - 100.0%), specificity of 60.0% (95% CI, 36.1% - 80.9%), PPV of 76.5% (95% CI, 65.5% - 84.8%), NPV of 100.0% (95% CI, 88.6% - 100.0%), and overall diagnostic accuracy

of 82.6% (95% CI, 68.6% - 92.2%). For the left foot, the sensitivity was 100.0% (95% CI, 86.8% - 100.0%), specificity of 68.8% (95% CI, 41.3% - 89.0%), PPV of 83.8% (95%CI, 71.5% - 91.5%), NPV of 100.0% (95% CI, 89.2% - 100.0%), and overall diagnostic accuracy of 88.1% (95% CI, 74.4% - 96.0%)

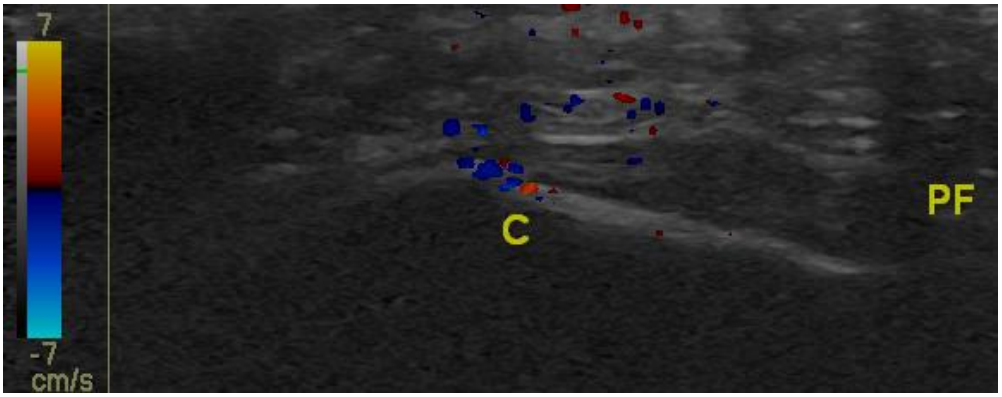
ILLUSTRATION OF SAMPLE CASES



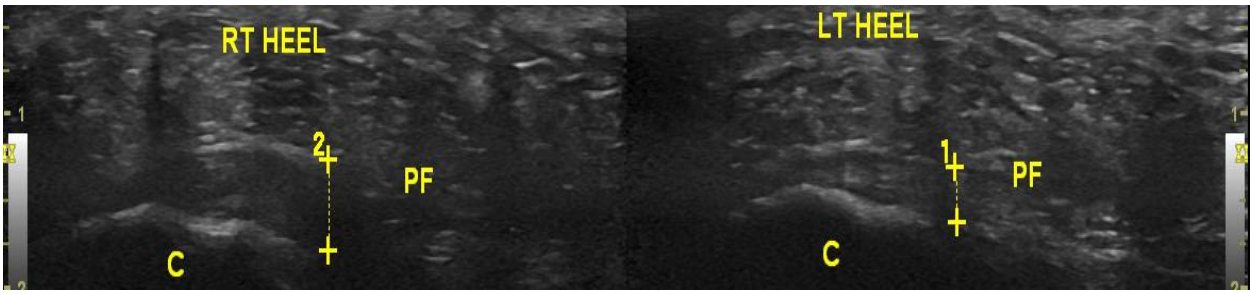
Case 1: Sample case from study showing abnormally thickened, diffusely hypoechoic plantar fascia that measured 4.9mm with presence of a calcaneal spur



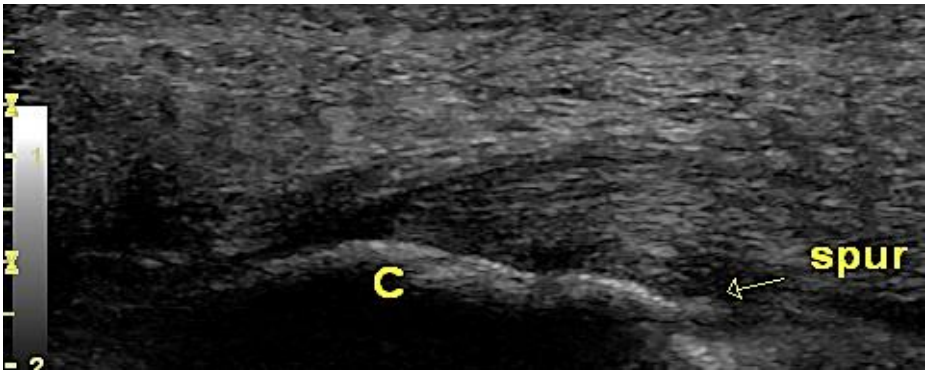
Case 2: Demonstration of perifascial edema. Note the thickened hypoechoic plantar fascia that measured 5.5mm



Case 3: Colour Doppler showing increased vascularity at the proximal end of an abnormally thickened hypoechoic plantar fascia



Case 4: A patient with bilateral heel pain. Right plantar fascia is abnormally thickened and diffusely low in echogenicity (5.7mm) .Left plantar fascia is normal in thickness and echogenicity (3.6mm). Presence of bilateral calcaneal cortical irregularities.



Case 5: Shows a thickened plantar fascia with normal echogenic fibrillary pattern but with a focal areas of hypoechogenicity, one subjacent to a calcaneal spur(arrow)

Case 6: Left heel pain showing a thickened plantar fascia measuring 4.8mm on lateral X-ray. Presence of calcaneal cortical irregularities

Case 7. Bilateral heel with right sided calcaneal spur. Normal plantar fascia thickness bilaterally.

CHAPTER TEN: DISCUSSION, CONCLUSION, LIMITATION & RECOMMENDATIONS

10.1 DISCUSSION

This study has shown that heel pain is more common in female patients than men with a male to female ratio of 1:2.1. Similar findings have been observed in studies in Egypt and Turkey by Ashraf et al and M. Afrikat et al (24,30).

The mean age of the study patients was 42.3 years (S.D 12.4) and did not differ markedly to studies from Italy and Turkey by Draghi F et al, 2017 and M. Afrikat et al in their studies who reported slightly older mean ages of 44 and 47(11,30). The authors postulated that this finding was related to the fact that the condition is primarily a degenerative process and was associated with standing upright and weight bearing. It was commonly seen in active working adults (22).

Fifty-nine patients (100%) presented with heel pain as their only primary complaint. This concurred with several articles stating that the commonest cause of heel pain is plantar fasciitis. Majority, 34 patients (57.6%) had symptoms between one month and one year followed by 25 patients (42.4%) with symptoms for more than a year. The mean duration was 6 months (IQR 3.0-12.0).

Only 9 (15.3%) patients were categorized as having healthy weight, while the rest of the patients 50 (84.8%) ranged from overweight to obese. There was a statistically significant association between a high BMI and Plantar fasciitis with a p-value of 0.010. Similar findings of a higher body mass index BMI >27 in patients with plantar fasciitis has been shown in a study from Australia by Van Leeuwen KDB et al (25).

Plantar fasciitis was seen in 61 (76.3%) of the 88 feet in our study. There was statistically significant difference in the average plantar fascia thickness in the 61 feet with plantar fasciitis compared to the 21 feet negative for plantar fasciitis (p-value of <0.001). However no statistical difference was seen with gender in both groups (p values of 0.951 and 0.116), respectively. Argekaris NG et al, 2015 in their study on Ultrasound diagnosis and evaluation of Plantar heel pain noted that the average plantar fascia thickness in patients with plantar fasciitis was larger at 6mm when compared to mean thickness of 3.5mm in patients without plantar fasciitis (36).

A study in Egypt by Ashraf et al showed a highly significant difference in plantar fascia thickness between patients with plantar fasciitis and the control group (p value <0.001) (24).

Our study only found diffuse hypoechogenicity in fifty seven of the 88 feet with plantar fasciitis (64.7%) which contrasted to a study by E Cardinal et al, 2012 who reported diffuse hypoechogenicity in 84% symptomatic heels in patients (n=15) with plantar fasciitis (20). The reason for the higher value was that the study population was less and included patients with already a clinical diagnosis of plantar fasciitis, who were then compared to 15 asymptomatic volunteers.

However, despite plantar fascia hyperemia being considered to be an important feature of acute plantar fasciitis, only 35 (39.7%) of symptomatic heels demonstrated hyper-vascularity in our study. Similar findings were reported in a study by McMillan AM et al, 2013 who found hyperemia of the plantar fascia present in only 8 of 30 participants with plantar fasciitis (47). They postulated that the lack of hyperaemia could be because of different heel thickness among patients and small vessels that could also potentially be compressed during scanning.

Plantar fascia tears were not common in our study (10.2%) with the main sonographic finding of partial disruption of the plantar fascia fibres and focal hypoechoic changes accounting for 4 (4.5%) on the right and 2 (2.3%) on the left of the total hypo-echogenicities seen in symptomatic heels. This is in contrast to the study in New York, 2015 who demonstrated a higher finding of 34% but seen in a larger study population where 175 feet were examined (36).

Plantar calcaneal spurs and plantar fasciitis and tears frequently co-existed in our study at Kenyatta National Hospital, Nairobi, Kenya (60.2%). Similar findings were seen in a study by Hylton B. Menz et al, 2018 where plantar calcaneal spurs and fascial thickening frequently coexisted (60%) with a conclusion that plantar calcaneal spurs in the absence of fascial thickening was uncommon (4%) (29). Johal et al study in the United Kingdom demonstrated a significant association between plantar fasciitis and calcaneal spur (p value 0.002)

Gibbon et al, however, detected a lower rate in bony spurs (24%) in a larger population than ours with plantar fasciitis (31). Further research is warranted to assess the association and whether it is causal.

Other prevalent features assessed by the ultrasound were presence of perifascial edema present in 58(65.9%) of 88 heels which was comparable in a previous study from Qatar that reported a sonographic diagnostic accuracy of 60.8% for edema around the plantar fascia in patients with plantar fasciitis (12).

Correlating with plain radiographic findings as a reference standard for plantar fasciitis, our study showed that heel sonography had relatively high sensitivity of 97.5% but lower specificity of 60.2%. The overall diagnostic accuracy was 78.6%. Our results were different from Sabir. et al who showed a higher specificity of 88.5% and a higher diagnostic accuracy of 83.3% was revealed by Elham S. et al (33,49). However these sonographic findings were in correlation with MRI as the standard reference.

Sonography revealed a slightly higher sensitivity and specificity, 87.6% and 100%, respectively in detecting calcaneal spurs in patients with an overall diagnostic accuracy of 85.9% which is contrary to a study by Abdel wahab et al, who reported that the lowest diagnostic accuracy of ultrasound in the detection of associated calcaneal spurs (56.5%) but in a lower study population with only 23 symptomatic heels examined (12).

These findings show that more plantar fascia abnormalities were detected by ultrasound when compared with radiography, into consideration that plain radiographs gives limited data in terms of the delicate soft tissue involvement and therefore does not have a direct relationship to a diagnosis of plantar fascia disorder being a soft tissue pathology. These findings were consistent with those seen in a study by Osborne et al, 2006 who reported a sensitivity of 85% and specificity of 95% for plantar fasciitis and concluded that the key radiological features were not spurs but rather changes in the soft tissues (48).

Despite ultrasound having a limitation of evaluating bony structures, this study found that 65(73.8%) of the symptomatic heels had cortical irregularities. This was a higher prevalence than those detected on plain radiography 52(59%) and could be explained by the ability to sweep the ultrasonic beam across the area of interest severally that enables the detection of subtle contour irregularities (11). The sensitivity of ultrasound when compared to radiography in the detection of cortical irregularities was 100% with a specificity of 64.4% and a diagnostic accuracy of 85.4%

No mass nodules, foreign body or calcifications were identified in both modalities, this may be due to low number of patient turn up attributed to the pandemic and a short duration of study.

10.2 CONCLUSION

The study concludes that ultrasound can detect plantar fascia pathologies in patients presenting with heel pain and therefore may be useful as a first line imaging modality in resource poor settings where sonography is readily available and cost effective. A high BMI was consistently associated with heel pain and plantar fascia disorders.

10.3 LIMITATION

A drawback of our study is that our sonographic examinations were focused and concentrated only on the diagnostic criteria of plantar fascia disorders by assessment of the sonographic signs with no attempt made to look for associated causes of hindfoot pain.

10.4 RECOMMENDATIONS

This study recommends that a larger number of patients to be expanded to further elaborate on the heel ultrasound findings and verify the results within the Kenyan population. A dedicated footprint ultrasound transducer for musculoskeletal ultrasound would be ideal for future examinations. Radiologists should also be encouraged to take up musculoskeletal sonography as a subspecialty. Clinicians should be empowered with knowledge on the usefulness of musculoskeletal ultrasound in assessing heel pathologies.

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12.0 APPENDICES

Appendix A: Data Collection Form

1. Patient ID:

2. Age…….years

3. Sex : Male ☐ Female ☐

4. Body mass(kg) …….. Height…… BMI…….

5. Presenting Symptoms

		Duration
Plantar heel pain	☐	……
Plantar heel swelling	☐	…….
Plantar heel nodule/mass	☐	……

6. Unilateral ☐ ☐ R L Bilateral ☐

	Yes	No
7. History of Trauma	☐	☐
8. History of Co-morbid condition (E.g Diabetes, Hypertension)	☐	☐

8. Ultrasound findings	Normal	Abnormal
PF thickness	☐	☐
PF echogenicity	☐	☐
PF vascularity	☐	☐

Other findings:	Present	Absent
Calcaneal spur	☐	☐

Calcifications	☐	☐
Perifascial Edema	☐	☐
Foreign body	☐	☐
Mass lesion	☐	☐

(If present specify diagnosis)……..

Others…….

9. Heel radiograph findings:

	Normal	Abnormal
Plantar fascia thickness	☐	☐

	Present	Absent
Bony spur	☐	☐
Soft tissue swelling	☐	☐
Calcifications	☐	☐
Calcaneal cortical irregularities	☐	☐

Others

Specify…….

Appendix B: Participant Information and Consent Form

Title of Study: Correlation of ultrasound and radiography in the diagnosis of heel pain, prevalence and spectrum of imaging findings

Principal investigator: Dr. Suhaila Salim Abeid Said, Postgraduate student, Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi.
Co-investigators: Dr. Gladys Mwango, Senior Lecturer, UON
Dr. Callen Onyambu, Senior Lecturer, UON

A study is being carried out by the above-listed researchers. The motive of this consent form is to provide you with the necessary information needed to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to proceed in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in medical research:

i) Your decision to participate is entirely voluntary

ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal

iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities.

We will give you a copy of this form for your records.

May I continue?

YES/NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT?

The researchers listed above are interviewing individuals who present to KNH/UON with proximal plantar heel pain requested for a heel radiograph or ultrasound. The purpose of the interview is to find out the prevalence and spectrum of ultrasound findings of plantar fascia disorders in KNH. Participants will be questioned about their chief complaints and will have the choice to undergo a heel ultrasound examination.
There will be approximately 59 participants in this study and we are asking for your consent to consider participating in this study

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?
If you agree to participate in this study, the following things will happen:
You will be interviewed by myself or my supervisors in a private area where you feel comfortable answering questions. The interview will last approximately five minutes. The interview will cover topics such as your symptoms, duration, and any other relevant history.

After the interview has finished, I will perform the heel ultrasound by positioning the foot appropriately and using the ultrasound probe, I will examine the inner structures that constitute your heel.

A telephone number will be requested for contact when necessary and will only be used by the researchers and never shared with anyone. The main reason why we may need to contact you is to share and advise with you on the appropriate course of action depending on the findings

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Ultrasound uses sound waves to interrogate the inner structures of the body part being examined. It is a safe modality of imaging that is not harmful to the body. It is also not painful and will be done in private. The objective of the study is to find abnormalities of the plantar fascia seen on heel ultrasound. This evaluation will provide more information to your referring doctor.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving a free ultrasound examination. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand the role of ultrasound in musculoskeletal imaging and the spectrum of findings in KNH. This information is a contribution to science and also aid in patient management

WILL BEING IN THIS STUDY COST YOU ANYTHING?

The ultrasound examination will be done for free and you are not entitled to pay for it.

ANY QUESTIONS IN THE FUTURE?

If there are any further questions or concerns about participation in the study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant, please contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 or email at uonknh_erc@uonbi.ac.

If any call is made related to the study, the study staff will repay the amount used to the numbers.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is optional. You are free to decline to participate in the study and withdraw at any time without injustice or loss of any benefits.

Appendix C: Consent Form

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: Dr. Suhaila Salim Abeid Said (0713037415)

Date: Signature _____

_____

Role in the study: Principal Investigator

Supervisor

Dr. Gladys Nthambi Mwango and Dr. Callen K. Onyambu

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Appendix D: Fomu Ya Idhini Ili Kushiriki Katika Utafiti

Kichwa cha Utafiti: UANGALIFU WA ULTRASOUND KATIKA UTAMBUZI WA MARADHI YA KISIGINO

Mpelelezi mkuu na ushirika wa kitaasisi: DR. SUHAILA SALIM ABEID SAID, MWANAFUNZI WA SHAHADA YA UZAMILI KATIKA RADIOLOGY. CHUO KIKUU CHA NAIROBI, IDARA YA RADIOLOGY

Ninafanya utafiti kuhusu matokeo ya picha ya ultrasound kwa maradhi yanayohusika na kisigino. Hii inafanywa kwa kutumia ultrasound kwa kuangalia madhara yanayoathiri kifundo cha kisigino. Ni kama vile mgonjwa anavyo pigwa 'scan ya tumbo', lakini sasa tutaitumia kwa kifundo cha kisigino. Ultrasound inatumia wimbi za sauti na haina madhara yoyote kwenye mwili. Utafiti kwa njia hii utaweza kumpatia daktari wako maelezo zaidi juu ya ugonjwa ulionao.

Ningependa ushiriki katika huu utafiti na haki zako zitalindwa, habari utakayotoa au ile itakayopatikana kukuhusu, itakuwa siri wakati wote na itatumika katika utafiti huu pekee yake.

Ni muhimu kuelewa ya kwamba ushiriki ni wa kujitolea, sio lazima kushiriki katika huu utafiti, na pia unaweza kubadili nia yako wakati wowote kuhusu kuenedelea kushiriki, bila ya kuathiri huduma zako za kiafya.

Nakushukuru sana kwa ushirikiano wako.

Nambar ya mgonjwa……

Sahihi…… Tarehe…….

Nimekubali kwamba nimeelezwa kikamilifu kuhusu utafiti huu na nakubali kushiriki.

Dkt. Suhaila Salim Abeid Said

Sahihi……Tarehe……

Wasimamizi

Dr. Gladys N. Mwango & Dr. Callen K. Onyambu

Appendix E: Study Protocol-European Guidelines

Musculoskeletal ultrasound: technical guidelines DOI 10.1007/s13244-010-0032-

Table 1: Prevalence and demographic characteristics of Plantar Fascia Disorders

FINDINGS	NO. OF PATIENTS	% OF PATIENTS	MEAN AGE	MEAN BMI	SEX	
					% MALE	% FEMALE
PLANTAR FASCIITIS						
PLANTAR FIBROMAS						
PF TEAR						
PLANTAR INFECTION						
XANTHOMAS						
FOREIGN BODY						

Table 2: Ultrasound versus Plain X-ray Plantar fascia findings

Appendix F: Budget and Budget Justification

Variables			Patients	P-Value
Plain X-ray	PF thickening			
	Bony spur			
	Soft tissue swelling			
	Calcifications			
	Radio-opaque material			
	Normal			
Ultrasound	PF thickening			
	Bony spur			
	Mass/nodule			
	Calcifications			
	Echoic material			
	Vascularity	Hyper		
		Hypo		
	Normal			

ITEM	**QUANTITY**	**COST PER UNIT**	**TOTAL COST**
Stationery			
Thermal paper	2	1000	2000
Printing cartridge(black)	2	1150	2300
Printing cartridge(colour)	2	2500	5000
Pens	1 box	1000	1000

Document folders	15	250	
Notebook	2	100	200
Printing and Binding fee	-	-	25000
Approval			
Ethics board fees	-	-	2000
Consultation			
Statistician fee	-	-	30000
TOTAL			67500

Source of Funding: Principal Investig

Appendix G: Time Line

	SEP 2020	OCT 2020	NOV 2020	DEC 2020	JAN 2021	MAR 2021	APR 2021	OCT 2021	NOV 2021	DEC 2021
Identification of topic	X									
Proposal writing		X	X							
Supervisors review				X						
Submission to Ethics					X					
Proposal corrections					X					
Ethics approval of the final proposal						X				
Data collection							X			
Data analysis								X		
Write up of study report									X	
Approval by Supervisors										X
Submission of the final study report										X