UNIVERSITY OF NAIROBI

THE CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL SEVERITY OF PRIMARY KNEE OSTEOARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL

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2024

DECLARATION

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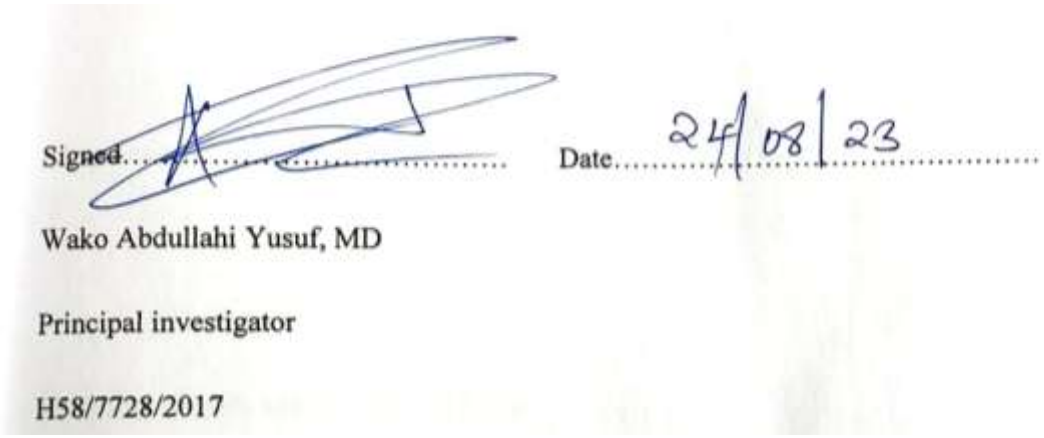

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ACRONYMS AND ABBREVIATIONS

ACR – American College of Rheumatology

ANA – Anti-Nuclear Antibodies

CMC – Carpometacarpal Joint

DIP – Distal Interphalangeal Joint

DMOAD – disease-modifying osteoarthritis drug

ESCEO – the European Society on Clinical and Economic aspects of Osteoporosis and Osteoarthritis

EULAR – European League Against Rheumatism

HCP – healthcare practitioners

KL – Kellgren and Lawrence

KNH – Kenyatta National Hospital

MCP – Metacarpophalangeal Joints

MTRH – Moi Teaching and Referral Hospital

NICE – National Institute for Health and Care Excellence

NSAIDs – Non- Steroidal Anti-inflammatory Drugs

OA – Osteoarthritis

PMN - Polymorphonuclear

RF – Rheumatoid Factor

THA – Total Hip Arthroplasty

TKA – Total Knee Arthroplasty

WBC – White Blood Cells

WOMAC - Western Ontario and Mcmaster Universities Osteoarthritis Index

WOMAC-pf – Western Ontario and McMaster universities osteoarthritis index- physical functioning

DEFINITION OF TERMS

Primary Knee Osteoarthritis – degenerative changes occurring in a knee characterized by pain and joint stiffness, as a result of articular cartilage degeneration without any known reason.

ABSTRACT

Background: Primary osteoarthritis is the main cause of knee pain in patients seen at the KNH arthroplasty outpatient clinic. Appropriate management of knee osteoarthritis is based on both clinical and radiological findings. However, there is discordance on how knee pain, deformity and functional impairment can be correlated. This would aid in informing management plans. Currently, there is no laid-out protocol on how to manage the different patients with primary knee OA at KNH. This study is aimed at establishing the correlation between the clinical and radiological severity of knee OA which would aid in developing a management protocol for such patients.

Broad objective: To correlate the radiological grading of primary knee OA with the severity of pain, stiffness, and degree of deformity of the knee

Study design: A prospective cross-sectional study

Study site: The Kenyatta national hospital arthroplasty outpatient clinic.

Methodology: Patients attending the arthroplasty outpatient clinic with a diagnosis of primary knee OA at Kenyatta National Hospital (KNH) will be included in this study. The American College of Rheumatology (ACR) clinical criteria will be used in the diagnosis of primary knee OA. Also recorded will be the patient demographic data including age, sex and body mass index. Only one knee will be considered for evaluation which will be the index knee and in instances of bilateral knee joint pains, the most painful joint will be recruited. Whereas if the magnitude of the knee pain is equal according to the patient, knee selection for the study will be done randomly and considered the index knee. The Kellgren and Lawrence scale will be used in grading the anteroposterior and lateral views radiographs of weight bearing knee. On the other hand, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) will be used in grading pain, stiffness, and degree of disability of the index knee. A sample size set at 70 will be determined using Fischer et al. formula. Data was analyzed using SPSS vs. 25.

Results: The study involved a sample of 70 patients with knee OA seen at KNH. The mean age was 61.49 ±11.09 years. A majority of the participants 35.7% (N = 25) were aged between 61 – 70 years, females patients 81.4% (N = 57), had the right knee affected 55.7% (N = 39), had mechanical knee pain 98.6% (N = 69), reported morning stiffness 65.7% (N = 46), had knee crepitus 82.9% (N = 58), had bonny tenderness 61.4% (N = 43), had bonny enlargement 51.4% (N = 36), and had palpable knee warmth 85.7% (N = 60). On WOMAC, the total score for the pain rating had a minimum of 2 while the highest score was 17 and a mean of 8.33± 3.62. The stiffness total score ranged from 0 - 7 with a mean of 3.19 (SD= 2.29). For the difficulty in completing activities of daily living, the score ranged from 6 to 63 with a mean of 30.39 (SD = 11.89). Overall, the minimum WOMAC score ranged from 11 through 86 with a mean of 41.91 (SD = 15.75). On KL classification, the three radiologist agreed that 35.7% (N = 25) participants had extreme OA, 30.0% (N = 21) had severe OA, 15.7% (N = 11) had moderate OA, 11.4% (N = 8) had mild OA while 7.1% (N = 5) had no OA. Cohen Kappa interrater reliability test indicated there was no agreement between the WOMAC and KL scale in grading the severity of knee OA ($k = -0.030$).

Conclusion: There was no agreement between the scoring of OA using the WOMAC in comparison to rating based on KL classification. Based on the primary findings, this study recommends the use of more than one scale in making the diagnosis for OA.

CHAPTER ONE: INTRODUCTION

1.1 Introduction

Osteoarthritis (OA) was considered one of the most common diseases of the musculoskeletal system occurring in adults. In individuals aged above 75 years, the disease was estimated to affect about 50% of the general population(1,2). The most common symptom occurring in individuals with osteoarthritis was the restriction of movement, joint stiffness, and pain. Also, OA presented with joint swelling and effusions. OA is a polymorphic disease that usually has a variety of presentations (3). Osteoarthritis was classified into primary and secondary diseases with each having different risk factors or etiologies. In secondary OA factors such as trauma, infections, dysplastic changes, inflammation, and biochemical changes were considered the common etiologies(4). In primary disease, the etiology of the disease was not clearly understood and was thought to include genetic factors, physiological changes related to age, ethnicity, and biochemical factors(5). There was no clear consensus on the definition of OA with existing definitions giving different parameters and diagnostic criteria. Therefore, often OA was usually classified as primary or idiopathic and secondary OA based on the underlying cause as gathered from the patient history or examination(6).

The OA of the patella femoral joint presented with pain while walking down stairs. Management of this form of OA included conservative management using interventions such as quadriceps strengthening exercises(6). Rarely, this OA is managed surgically using patella femoral arthroplasty. Several epidemiological studies had shown the concurrent occurrence of patella femoral OA with tibia femoral OA or in isolation with demographic differences in occurrence among the two conditions. Available evidence continued to suggest the independent impact on functions and symptoms by patella femoral OA. The diagnosis of knee OA was commonly diagnosed using The American College of Rheumatology (ACR) criteria(2). This criterion was used to assess the patient's symptoms and clinical findings. On the other hand, the Kellgren and Lawrence (K&L) criterion was used to assess radiographic structural changes in the knee joint(7).

There were studies done in the country and region on patterns of osteoarthritis. A study done in Jordan(8) reported the mean age for those with knee OA to be 55.3 years. The study further indicated there was a link between the age of the patient and radiographic severity or pain severity. In Nigeria, the prevalence of OA was reported as 16.3% for adults aged over 30 years in a rural community-based study(9). Females had a more serious knee OA than men while patients reported they believe the main causes were old age, evil spirits or hereditary. In Cameroon(10), the mean age for those with knee OA was 56.9 (SD = 10.7), with the majority being postmenopausal females reporting a mean pain duration of 1 year. Obesity was the main indicator associated with 52% of the cases followed by hypertension at 37.2%. By classification, 35.5% qualified as grade III and IV on Kellgren and Lawrence classification with bilateral knee OA reported in 52.7%. In a study conducted at Kenyatta National Hospital in 2013(11), the distribution of OA was 77% for the knee joint, 15% for the hip joint, and 3% for the hand joint. Most of the knee cases were unilateral (55.7%), with obese mainly linked to bilateral knee OA. These past studies indicated the burden of OA contributing to a disability, which necessitated this study.

Despite several studies covering a variety of scopes on the topic of OA, it was important to understand the relationship between clinical and radiological findings in OA and the relevant disease outcomes. Such understanding helps in predicting individuals that are at a greater risk of worsening disease and is vital in clinical research. The above criteria for clinical and radiological features help healthcare providers to have a better monitor of OA progression and determine intervention measures. The proposed study aimed at exploring associations and correlations between individual symptoms, clinical, and radiological findings of primary knee OA among patients diagnosed with primary knee OA attending the outpatient arthroplasty clinic at the Kenyatta National Hospital.

CHAPTER TWO: LITERATURE REVIEW

2.1 Background

In older adults, OA was the most common disease of the musculoskeletal system known to affect about 50% of individuals above 75 years of age. Patients suffering from this condition often reported problems such as the inability to engage the knee joint due to swelling, tenderness, rigidity, and effusion. The wide morphological characteristics of the condition complicated a one-fit-all definition for OA(1).

The interplay of mechanical, biochemical, genetic, cellular, and immunological factors were thought to contribute to the pathogenesis of the disease(5). Despite the hypothesis, the clear pathogenesis of the disease was poorly understood. These factors led to primary or idiopathic disease or secondary disease(12). Most of the definitions of OA usually incorporated the patient-reported clinical symptoms such as joint pains and the findings on radiologic examination(7). The two can be differentiated through the history of the patient by identifying when the OA was related to any underlying causes, hence secondary OA or not related to any know factors, hence primary OA(6). The proposed study only recruited those who have primary OA.

This proposed study incorporated the American College of Rheumatology (ACR) clinical criteria for the diagnosis of knee OA which incorporated symptoms and clinical findings. Other notable criteria for the diagnosis of knee OA that exist included European League against Rheumatism (EULAR) and National Institute for Health and Care Excellence (NICE)(13,14). The radiological findings on structural knee changes due OA were defined using the Kellgren and Lawrence (K&L) classification(15). Knee OA defined using the ACR score was consistent with tibia femoral OA defined using K&L core of greater than or equal to 2 [13]. There was a significant association between radiographic and clinical disease progression but had questionable clinical relevance.

In a study to assess the relationship between symptoms and radiologic findings on knee OA, Felson et al assessed the correlations between clinically and radiological defined knee OA. It was determined that clinical A correlated with the presence of large osteophytes on radiological

examination. Therefore, the study suggested that the definition of knee OA should include the presence of large osteophytes in the presence of advanced joint space narrowing coupled with one bony feature of OA(15).

Follow up of patients with OA over 3 years reveal that changes in symptoms and structure of the knee correlate to clinically relevant disease progression(16). Using the WOMAC-reported symptoms and pains, several studies have been done to evaluate the relationship between knee symptoms tibia femoral and patella femoral disease. However, the findings of physical knee examination were not included in reviewed studies. A meta-analysis of studies involving the investigation of the prevalence of tibia femoral and patella femoral OA in specific "knee pain" groups indicated that roughly 50% of those with painful knee or OA confirmed through radiology had patella femoral OA(14). Among the Kenyan population, there was insufficient data regarding the prevalence and the link between clinical findings and radiographic results among the unselected elderly population. Research to try to bridge this gap in available data would be very important in assisting physicians, especially in primary settings in predicting the effect of OA on the knee compartment in clinical assessment.

Areas of research interest would be the assessment of the relationship between clinical and radiologic findings in OA. Also, investigating disease outcomes, progression, intervention measures, monitoring, and devising a clinical and radiological approach to treatment and who was responsible for treatment would be ideal in adding to the current pool of recent papers and position statements(17). The absence of clear diagnosis and precise criteria and consensus on classifying structural changes especially in early disease were the major challenges noted in DMOAD development by the European Society on Clinical and Economic aspects of Osteoporosis and Osteo- arthritis (ESCEO)(18). Also, the ESCEO carried out further evaluation using a working group for the drugs for treatment OA, and in identification of high-risk patients who can respond to treatment could be done. Also, the "need for surgery" had been evaluated in recent research to investigate potential relevant outcomes and provide a clear definition for "need for surgery".

This study aimed to evaluate the relationship between symptoms, physical findings, and radiological features of primary knee OA among patients attending an arthroplasty clinic at Kenyatta National Hospital.

2.2 Epidemiology of Osteoarthritis

In North Eastern Nigeria a community study by Akinpelu et al. showed a 20.6% prevalence of knee OA among individuals over 40 years of age(9). The study also found that the prevalence was higher among women, advanced age, and obese individuals. Among the evaluation community, the health-seeking behavior were poor. In South Africa, Usenbo et al. found a 33.1% prevalence of knee OA in adults above 35 years of age in a rural setting population study(19). In a study done in Togo by Mijiyawa et al on knee OA in hospital outpatients, they concluded the high prevalence of knee OA in black Africans, female sex, obesity and varus or valgus deformities were the main risk factors for femorotibial OA(20).

While Nyakwara et al. in their thesis on the characterization of OA in patients in a hospital-based survey done at MTRH, Eldoret Kenya concluded that most patients with OA were above the age of 40 years, with knee OA having a prevalence of 24.29%, and females or those in with intense physical activities topping the list of patients(21). Issues of obesity, severe pain, knee joint impairment, and knee joint usage limitation were the frequent characteristics of the affected patients. Safiri et al further assessed the global burden of knee OA in 2017 from 195 countries(22). The systematic analysis used public health data reported from the countries between 1990 through 2017 noted that the problem was on a rising trend and further projected to worsen with the aging population increasing across the globe. In conclusion, knee OA was an under-reported disease among the low-income population in sub-Saharan Africa that mostly had incoherent management. With KNH arthroplasty outpatient clinic mostly serving this kind of population, the importance of optimizing patient care in an already overstretched public health care system in Kenya could not be emphasized enough.

2.3 Diagnosis of primary knee osteoarthritis

In modern orthopedic practice, primary knee osteoarthritis was diagnosed through the evaluation of both the radiological reports and a detailed patient assessment of the clinical manifestation of the problem. Runhaar et al, acknowledged the gap in having universally acceptable diagnostic criteria, especially for early knee OA, which the research recommended to have efforts directed in validating such a tool for ease of diagnosis and prompt intervention(23). Such a tool could be arrived at by collating the most predictive factors and clinical manifestations, which were scored to arrive at the diagnosis. The main presenting symptom of knee OA was reported to be mechanical knee pain. The pain in this condition could not be pinpointed to a single etiology with Polat et al noting that it was attributed to many factors such as nociceptive and neuropathic mechanisms(24). In their study, Polat et al reported that clients with neuropathic pain tended to have the pain last longer, often had severe knee OA, and had higher odds of disability(24). In their conclusion, radiological grading severity was more related to the patient's age as opposed to the pain scale score.

Szebenyi et al observed that higher levels of knee pain and loss of knee function were associated with the sclerosis of the subchondral bone causing significant structural compartmental changes(25). A study by Odole et al, from Nigeria assessing correlates and determinants of pain intensity and physical function in knee OA patients reported two significant findings(26). First, kinesiophobia correlated to pain, thereby giving a probable predictor of pain intensity. Secondly, kinesiophobia also correlated with self-efficacy, and thus a good predictor of physical functions. A study by Kocak et al.(27) concluded that more severe clinical features of primary knee OA correlate with KL grade III and IV, findings that correlated with findings in Kinshasa, Congo, by Lukusa et al.(28) However, no correlation was found between disease manifestation and radiological severity of knee OA by Talic-Tanovi et al.(29) and Steenkamp et al.(30)

Similarly, in Cameroon, Bija et al (10) found no correlation between pain severity and radiological features but found a correlation between pain and functional disability. The study found late presentation in patients with OA was attributed to limited health care access. Forestier et al noted that combining the Kellgren, ACR and Dougados criteria for diagnosis of knee OA selected a larger patients group than each criterion set used alone(31). Moreover, the combined

scale enabled filtering the role of family history of OA and/or symmetrical knee involvement, thereby improving sensitivity on uncategorized AO.

2.4 ACR Criteria for Early Diagnosis of Primary Knee Osteoarthritis

Evidence from multiple studies posits that even though primary knee OA could occur at any age, 40 years was the onset for the majority of the patients with equal occurrence across genders. However, some studies had shown greater prevalence among women(16). Mechanical knee pains was the common symptom of knee OA as was exacerbated by knee activities such as waking, standing, ascending or descending stairs or sitting with a flexed knee, and sometimes cold or dumpy environment. The symptoms were relieved by rest with no morning stiffness or less than 30min of morning stiffness. The symptomatology of knee OA varied from stage of disease with primary disease presenting with pain at the beginning of movement, later pain during knee movement, and in late disease persistent pain. The “gelling pain” or “gelling phenomena” occured when there was knee pain and/or stiffness occurring after coming out of a prolonged knee rest or sitting position(14). In knee OA patients presented with pains in other joints and muscles such as the hip joint, thigh, buttock, and calf muscle. In addition, crepitus or noisy knee, giving way, and locking knee were associated with chondromalacia patella, internal derangement of the knee, as well as synovial osteochondromatosis.

Findings on physical examination of patients with knee OA included crepitus on knee motion, body tenderness, and bony enlargement in the joint line(32). Also, joint swelling and effusion occured during a flare-up of primary disease. The analysis of synovial fluid drawn during joint effusion revealed clear fluid with normal viscosity, often cold but sometimes warm with associated synovitis and was referred to as “hydrarthrosis”. The effusion also had a white blood cell count of less than 2000/mm3 and less than 25% polymorphonuclear cells. Chronic knee OA presented with joint laxity, movement limitation, malalignment, and flexion contracture(31). Biochemistry evaluation did not provide significant positive findings including rheumatoid factor in primary disease. Autoantibodies such as rheumatoid factors and anti-nuclear antibodies were positive in approximately 20% of the population and low titers. These auto-antibodies thus could be used to rule out knee OA.

To date, ACR presented the most widely used criteria for categorizing knee OA(32). The study employed the use of these criteria in the diagnosis of knee OA cognizant that patients with chondromalacia patella were considered as having knee OA under this criterion. Knee OA was considered under this criteria in patients presenting with knee pain in any three of the following six symptoms; age >50 years, crepitus, morning stiffness <30min, enlarged bony structures, and knee tenderness, with or without the areas feeling warm on touch.

2.5 ACR criteria for knee Osteoarthritis Diagnosis

Knee OA was often non-specific with some patients being asymptomatic and it also lacked a diagnostic test. These challenges made developing diagnostic criteria. Biopsies for pathological examinations were ideal in supplementing diagnosis but were often impractical in most patients. The American rheumatism association made efforts in developing classification criteria with diagnostic and therapeutic criteria for OA in 1981 by a subcommittee to standardize the definition of OA which could be consistently used across research(32). Altman et al. in 1986 described that the definition of OA included whether it is primary or secondary and using a multicentre study group developed a clinical knee OA classification(33). The criteria compared knee OA with other pathologies affecting the knee such as rheumatoid arthritis and excluding any referred or periarticular pain. To serve the different investigative purposes and develop the set of criteria, variables such as medical history, clinical examination and laboratory findings, and radiological features were used which proposed new ACR criteria utilizing classification trees and algorithms.

The cartilage damage as assessed by arthroscopy was found to be accurately predicted by the ACR clinical and radiographic criteria as determined by a study in 2005 by Wu et al(34). Also, the criteria predicted cartilage damage before any radiographic changes. Furthermore, the ACR criteria was found to help assess severe cartilage damage while using the clinical and radiological criteria. Kawasaki et al reported good inter-observer reproducibility while validating the ACR criteria for knee OA but noted both sensitivity and specificity were slightly lower than the report by ACR(35). Nevertheless, they recommended the utilization of the ACR classification criteria for primary knee OA, but that imaging could be preferred in case it was possible. The ACR clinical criteria with or without laboratory findings were found to give

inconsistent results as compared to other ACR criteria in a 12-year general follow-up done by Schouten et al. On the other hand, based on other ACR criteria, the prediction of future OA could be done using Kellgren and Lawrence's criteria(36).

2.6 The Western Ontario and Mcmaster Universities Osteoarthritis Index (WOMAC)

This index was initially developed to assess OA of the hip and/or knee to measure symptoms and physical disability, especially as a result of medical intervention. Since the introduction of the WOMAC index in 1986, scholars and healthcare practitioners had widely explored the index validity as a measure of patient improvement. Ideally, the management of patients was best based on a tool that gave a reliable score of the impact of care. The WOMAC care had been evaluated for a wide variety of patients, such as those on total hip or total knee arthroplasty. Findings from such evaluations had corroborated the significant of the index in guiding patient prognosis and management approaches(37).

WOMAC was a disease-specific self-reporting multidimensional questionnaire assessing pain, stiffness and physical functional disability, with 5, 2 and 17 questions respectively. This proposed study employed the use of Likert Version 3.1 of the WOMAC index rating from 0 – 4. A score of 0 denoted the lowest levels of symptoms and physical disability. The respective maximum score of each subscale totalled 20, 8, and 68. A 5 – 10 minutes self – administered score was used with English and Swahili language variants. (38)

Leung et al, 2022, used the Rasch Model to assess the usability and validity of the WOMAC index. The evaluation was done in patients undergoing knee arthroplasty and the findings indicated that pain and functional scores from WOMAC were appropriate for the Rasch Model. This assessment provided a unidimensional measure of good reliability, responsiveness, and transformation to interval scale measurement of the WOMAC index that is applicable in research(37).

A study was carried out to assess the WOMAC index short version invariance and response stability on the physical function of the affected period over time. Ayala et al in 2018 concluded that the WOMAC-pf 7-item short version was invariant over time and joint when the item

“putting on socks” was removed(39). Thus, careful consideration should be done by researchers while using this item due to scale invariance and stability that may alter results during data comparison or computing of change scores.

The performance of the WOMAC index was noted to be good while exploring item functioning by Poland et al. assessment where only small differential item functioning was identified on physical function(40). Notably, an account must be taken to assess how differential item functioning influences weight, gender, and age. In another study by Bilbao et al, the assessment was achieved through a process that mapped WOMAC onto the EQ-5D-5L utility index among patients who had either hip or knee osteoarthritis, reporting high reliability and specificity(38). It was noted that the index could be very vital for healthcare providers and researchers in carrying out cost-effective studies and looking into the quality of life.

2.7 Kellgren and Lawrence Radiological Classification of Primary Knee Osteoarthritis

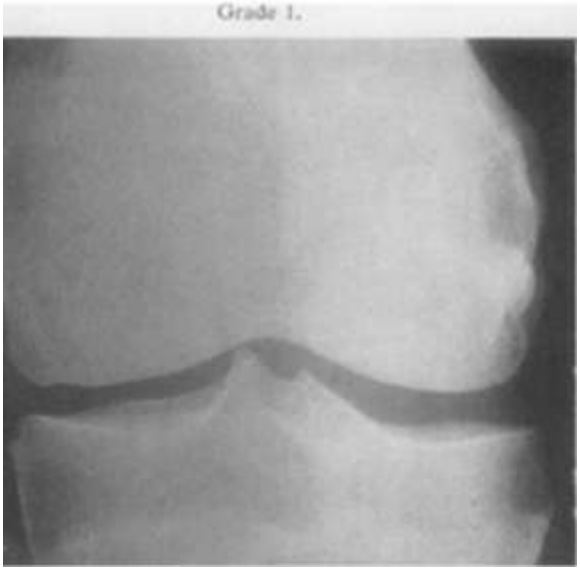
In 1957, the first formal attempt to establish a radiological classification of knee OA was made by Kellgren and Lawrence after a series of radiography analysis that proved the place of imaging in diagnosis(41). The radiographic changes that occurred among coal miners in Bedford Colliery in North West England with rheumatic arthritis were investigated by Kellgren by measuring the inter and intra-observer reliability. The investigations revealed wide discrepancies among observers thus Kellgren and Lawrence set out to establish a set of standardized radiographs for OA of diarthrodial joints. KL developed a five-grade classification method that they used to evaluate standardized radiographs from eight joints and thereafter calculated inter and intra-observer reliability. The joints included in the review include the first carpometacarpal, wrist, hips, and lumbar spine. Other joints include the distal interphalangeal joint, knees, and metacarpophalangeal joint. The study revealed that the knee joint, the tibiofemoral joint, showed the highest inter-observer correlation coefficient of $r = 0.83$. The range of all joints in the inter-observer of all the joints studied ranged from 0.10 – 0.83. On the other hand, the intra-observer correlation coefficient ranged from 0.42 – 0.88 with the knee joint rating second at 0.83. These results are beneficial in future applications relating to the knee joint. KL classification is the widely used radiological classification of knee OA. KL classification in research and radiological features atlas for OA had been employed in several epidemiological studies such as Scott et al.

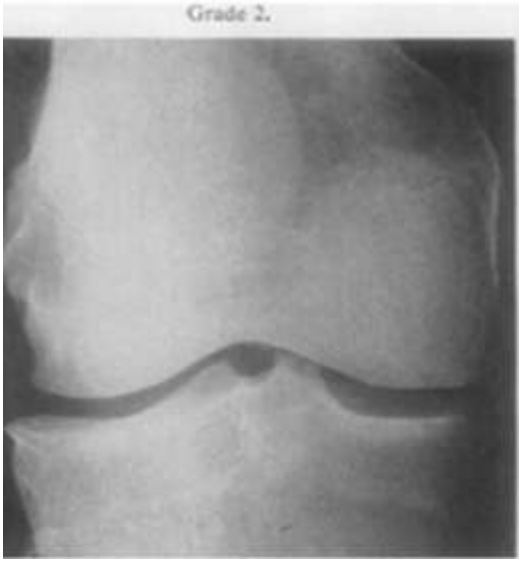
Health care providers providing treatment were able to use the KL algorithm in guiding in determining patients who benefitted from surgery.

However, the findings from clinical research employing the KL criteria require critical analysis and validation. Also, there was a continuous reevaluation of the schema to ascertain its relevance to patient-centered outcomes. The KL classification was applied in the diagnosis of knee OA using AP radiographs as described in their research with films rated from 0 – 4 based on severity. Grade 0 is when there was no evidence of OA on the radiograph and grade 5 represents severe OA.

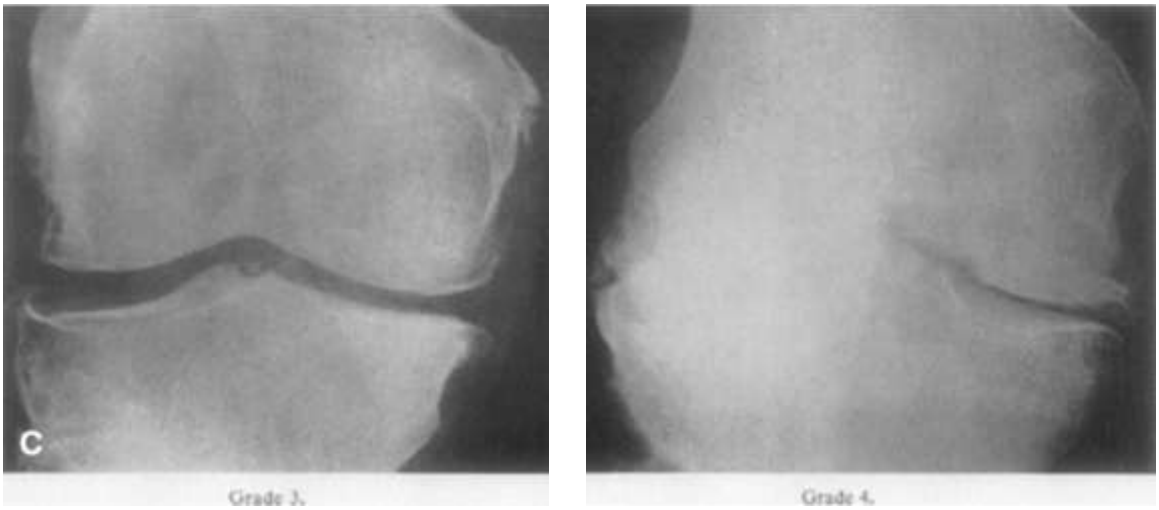
The sequence of OA development based on KL criteria started with osteophyte growth on joint martins or tibial spines. Subsequently, there was the development of periarticular ossicles, narrowing of joint cartilages with associated subchondral bone sclerosis, and finally altered the shape of bones due to small pseudo cystic areas with sclerotic changes. Critics of the KL classification base their argument on the assumption that the criteria seemed to portray that OA linear progression started with osteophytes development to the altered shape of bone ends. The figures below showed the grades of OA based on the KL classification

Figures 1 – 4: Grading of Knee OA





Grade: 1) radiograph showing borderline joint space narrowing and possible osteophyte formation and Grade 2) joint space narrowing with osteophyte formation



Grade: 3) joint space narrowing with moderate osteophyte formation. Also, visible are moderate osteophytes, subchondral bone sclerosis, and possible bone ends deformities. Grade 4) large osteophytes, severe narrowing of the joint space, marked sclerosis, and explicit bony ends deformity

This study sourced the services of three senior orthopedic surgeons to classify radiographs in randomized patients with knee OA to assess inter and inta-observer correlation as described in KL classification. The lateral and anteroposterior x-rays of the affected knees was taken in a weight-bearing position and was at least within 3 months from the time of enrolment into the study.

2.8 Statement of the Problem

Since the commencement of sub-specialized thematic units at the Department of orthopedic surgery at Kenyatta national hospital with a dedicated arthroplasty outpatient clinic, there had been an observed increase in patients attending the clinic diagnosed with primary knee osteoarthritis. The majority of these patients were usually elderly and came from low-income households, most of who by the time of presentation to the arthroplasty outpatient clinics either

presented with advanced disease or had been poorly managed at peripheral facilities that can't handle these cases.

Furthermore, even the few that presented to the specialized arthroplasty outpatient clinic at KNH early with primary knee OA, there was inconsistency in the relationship between clinical manifestations and the radiological grading. This led to unpredictable management of these patients among healthcare practitioners not only at KNH but also in secondary and primary health care facilities. Unfortunately, there were no current studies done at KNH to help in standardizing care for patients with knee OA.

2.9 Study Justification

These research findings helped in filling an existing knowledge gap that helped in standardizing patient care namely those that needed optimal drug therapy for primary knee OA and those that would greatly benefit from operative management in a setup of low financial capabilities.

2.10 Research questions

For patients presenting at Kenyatta National Hospital with primary knee osteoarthritis, do clinical presentations and radiographic features correlate?

2.11 Study Objectives

2.11. 1 Broad Objective

To correlate the radiological grading of knee OA with clinical symptoms of the severity of pain, stiffness and degree of deformity of the knee

2.11.2 Specific Objectives

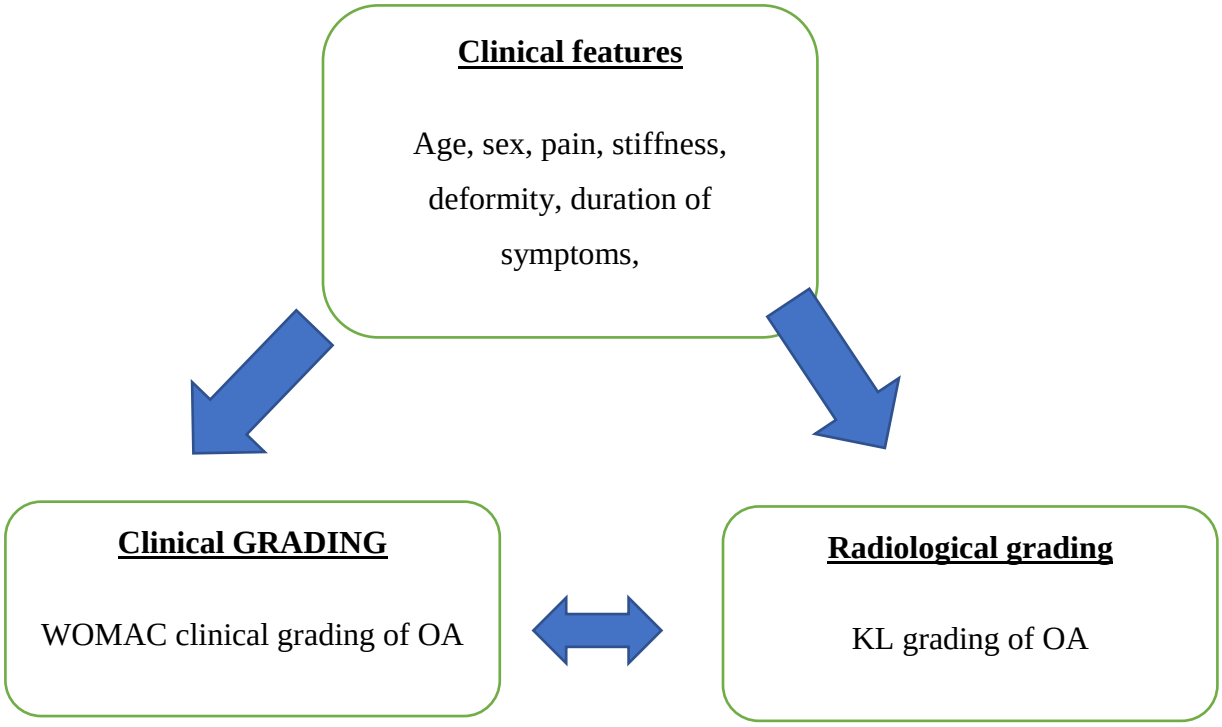
1. To determine the clinical grading of OA according to the WOMAC scale in patients presenting at the KNH arthroplasty clinic.
2. To determine the radiological grading of OA according to the Kellgren and Lawrence scale.

3. To assess the level of agreement between the WOMAC and the Kellgren and Lawrence scale in the assessment of OA.

2.12 The Conceptual Framework

The conceptual framework outlined the association between the clinical findings in osteoarthritis and the radiological findings (Figure 5). Exposures of arthritis such as age, sex, and duration of symptoms affected the clinical and radiological grading which the study sought to assess the correlation.

Figure 5: The Conceptual Framework



CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a facility-based cross-sectional study. The design was the best fit for this study due to several strengths. First, the research collected the data for the exposure such as sociodemographic and clinical features, and outcomes such as radiological grading and WOMAC categorization concurrently. Secondly, our study was not looking to assess how the time of care influenced the outcomes. Thirdly, cross-sectional studies were considered appropriate for estimating the occurrences of an event at a given moment in time, which was more or less what we set to establish before running the interrater reliability tests (Cohen Kappa test). However, the design was also prone to some weaknesses. One such weakness was the inability to establish cause-effect associations due to antecedence consequence bias. The second weakness was the limitation in the number of participants that were accessed compared to longitudinal studies. Despite these weaknesses, it was clear that they did not affect our study since we were not interested in a cause-effect relationship and the sample size calculated with the credible formula was adequate to respond to the study objectives (42).

3.2 Study Site

This study was conducted at Kenyatta National Hospital Arthroplasty Clinic. KNH is the national referral hospital in Kenya of all public hospitals in Kenya, with a significant number of patients managed for joint-related conditions.

KNH is a specialist hospital offering arthroplasty and sports-related outpatient clinics, joint arthroplasty and arthroscopy services and rehabilitation services. The arthroplasty clinic runs once every week all year round with approximately 25 to 30 patients with knee joint symptoms seen at the clinic every week.

3.3 Study Population

The population of interest comprised patients who presented at the arthroplasty clinic with symptoms of mechanical knee pain and those with a diagnosis of primary knee osteoarthritis.

3.4 Participants Eligibility

- Inclusion criteria: Those included in the study were patients presenting with primary knee OA at KNH, and willing to provide consent.
- Exclusion criteria: If they had secondary knee OA (based on etiology of osteoarthritis), patients who underwent previous knee surgery, pregnant women, and patients who do not consent

3.5 Sample Size Determination

The study sample was arrived at by using the Fisher et al formula

$$\mathrm{N} = \frac{Z^2 p(1-p)}{D^2}$$

- N = The desired sample size for the study
- Z = is 1.96, which is the standard error from the mean corresponding to 95% CI
- P = 24.29%, is the proportion of events, in this case, based on a study by Nyakwara et al (21).
- D = 5%, is the degree of error allowable

Substituting the values, $\mathrm{N} = \frac{1.96^2 0.243(1-0.243)}{0.05^2} = 283$

Due to the small target population, this study adjusted the sample size using a formula for finite population size as described by Thrusfield in 2005 as below;

$$\mathrm{n} = \frac{N(P)}{N+P}$$

Where *P* was the estimated population (sampling frame) while N was the pre-calculated sample. Every week roughly 10 patients on primary OA are seen at the KNH Arthroplasty Clinic. Thus in two months, an estimated 80 patients were seen with the condition.

Substituting the values, $n = \frac{N(P)}{N+P} = 63$

The sample was then adjusted upwards by 10% for attrition, meaning **70 participants were** recruited for this study.

3.6 Sampling Procedure

A total number of 283 patients were recruited by consecutive sampling technique. If the selected patient was not eligible or declined consent to participate in the study, the next most eligible patient was approached for possible enrollment. This was repeated until a small sample size of 63 was attained.

3.7 Variables

Table 3.7 Study Variables

Independent Variables	**Dependent Variables**
i. KL radiological grading of OA ii. WOMAC clinical grading of OA	Demographic Characteristics (age, sex, marital status, education level, occupation, residence, religion) Clinical symptoms (cause of knee injury, pain, stiffness, deformity, and duration of symptoms)

3.8 Data Collection

Data was collected using a structured, prepared questionnaire with the main sources of the data being the patient and their health records. The data of interest included sociodemographic particulars, medical history, and characteristics of knee symptoms. The eligible participants, were those diagnosed as having primary knee OA by ACR clinical criteria, were recruited. In

some cases, the patients had bilateral knee pain, but only one knee selected randomly by the researchers was assessed for this study. When both knees were equally symptomatic, the most painful knee was prioritized, otherwise selected at random. Data collection was done by research assistants, who were final-year medical school students. The research assistant was trained on the protocol, and supervised by the principle investigator throughout the data collection process to ensure they abided by the process. Each of the radiographs obtained by the researcher and research assistants were presented to three predetermined senior orthopedic surgeons at the Department of Orthopedic Surgery in Kenyatta National Hospital for classification of the radiographs. The three orthopedic surgeons were recruited by the researcher and allocated initials: Surgeons A, B, and C. Each surgeon was provided with the radiographs individually for classification according to K&L classification and recorded in the data collection tool.

3.8.1 Recruitment of research assistants

Medical students in their 6th year of studies were recruited and provided with a day of training on data collection in a standardized and uniform manner to work with the principal investigator as research assistants. The choice of the 6th-year medical students was logical and intentional since they were more conversant with radiology reporting and the shorthand used in the patient's files than the nurses.

3.8.2 Recruitment of study participants and study procedures

While attending the arthroplasty clinic for assessment and follow-up, patients who met the inclusion criteria were recruited. They were then required to sign an informed consent. Once a participant agreed to participate in the study and had signed the consent, they were asked questions following the study protocol. Clinical measurement of osteoarthritis was carried out in the clinic where a patient was also be asked to lie on the doctor's couch for examination. A weight-bearing anterolateral and lateral views radiographs of the knee were requested. For standardization purposes, all radiographs were taken at the radiological department at Kenyatta national hospital with a GEHealthcare x-ray machine model AL01C with a Wallstand model number 5181666 radiograph machine serial number 124449HLO. For the procedure of

performing a weight-bearing anteroposterior knee radiograph; the patient was asked to stand upright in front of an upright detector keeping the legs straight and knee not rotated.

3.9 Quality assurance measures

Pretesting of the data collection tool was done by interviewing 5% of desired sample size. This helped in estimating the total time it took to complete one form and the efficacy of the tool in capturing data according to the study protocol.

3.10 Ethical Considerations

In keeping with research ethics standards, approval to conduct the study was sought from the university department, and the University of Nairobi-Kenyatta National Hospital Ethics Research Committee (UoN-KNH ERC). In addition, permission was also sought from the Kenyatta National Hospital research department to access the clients and their records needed for the study data. During the data collection, all the participants signed an informed consent form. The consenting process was done without coercion or intimidation, and participants were explained they can request to not continue with the study at any point of the study process if they so wish without any repercussion on their quality of care. The proposed study possessed no additional risk beyond those of mundane life processes, but participants were informed of the possibility of a data leak, despite the researcher actively taking measure to seal all loopholes for privacy and confidentiality breach.

3.11 Data Management

Data was entered into a password-protected Microsoft Excel spreadsheet. Only the principal investigator and the authorized personnel were allowed to access the data. All hard copy data collection tools were placed under lock and key to avoid unauthorized access.

3.12 Data Analysis

Data was cleaned and entered into SPSS version 25.0 for data analysis. To describe the characteristics of the study participants, means, standard deviation, medians and ranges were

used for continuous variables while frequencies and proportions was used for categorical variables. The association was assessed by running the data for prevalence odds ratio, and statistical significance was considered for a p-value less than 0.05, considering the Fisher Exert test. The findings were then reported in the form of tables, charts, and bars.

3.13 Data dissemination

Once data was analyzed and the manuscript developed, study findings were disseminated with relevant stakeholders such as orthopedics units. The manuscript was also published in a peer-reviewed medical journal.

CHAPTER FOUR: FINDINGS

4.1 Overview

The data was collected from N = 70 patients with primary knee OA at Kenyatta National Hospital. They sample was involved in the analysis in full, with no cases of missing data from the participants. The results are reported following the study objectives' flow.

4.2 Baseline Characteristics

Based on the primary data we gathered, the baseline characteristics, presented in ***Table 4.2*** below, showed a majority of the participants were over 50 years old with mean age of 61.49 (Standard deviation 11.09) years. 35.7% (N = 25) were aged between 61 – 70 years, 27.1% (N = 19) aged between 51 – 60 years, 21.4% (N =15) aged above 70 years, with only 14.7% (N = 11) aged below 50 years. The females patients were the majority at 81.4% (N = 57) with males constituting of just 18.6% (N = 13). In a majority of the patients, the right knee was affected 55.7% (N = 39), had mechanical knee pain 98.6% (N = 69), reported morning stiffness 65.7% (N = 46), had knee crepitus 82.9% (N = 58), had bony tenderness 61.4% (N = 43), had bony enlargement 51.4% (N = 36), and had had palpable knee warmth 85.7% (N = 60).

Table 4.2 Baseline Characteristics

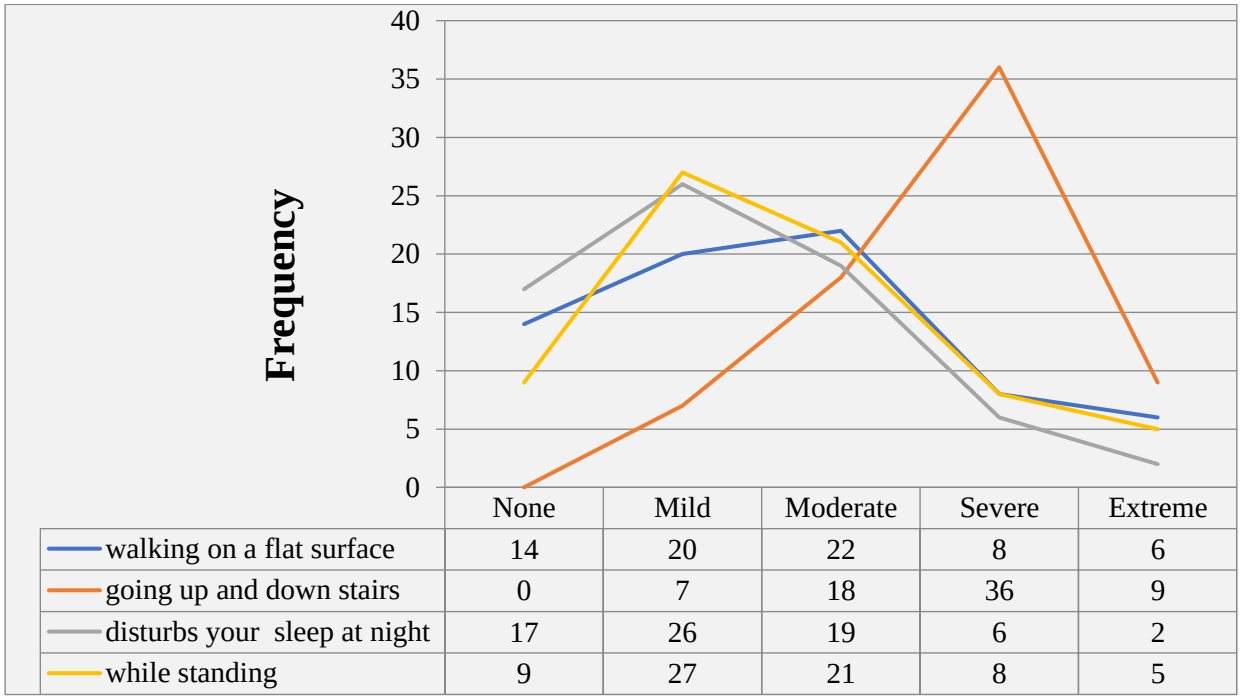
Variable	**Category**	**Frequency**	**Percentage**
Age	Below 40 Yrs.	4	4.7%
	41 – 50 Yrs.	7	10.0%
	51 – 60 Yrs.	19	27.1%
	61 – 70 Yrs.	25	35.7%
	> 70 Yrs.	15	21.4%
	Mean age = 61.49	*SD = 11.087*	
Sex	Male	13	18.6%
	Female	57	81.4%
Knee Affected	Right	39	55.7%
	Left	31	44.3%

Variable	Category	Frequency	Percentage
Mechanical knee pain	Present	69	98.6%
	Absent	01	1.4%
Morning Stiffness	Yes	46	65.7%
	No	24	34.3%
Knee Crepitus	Yes	58	82.9%
	No	12	17.1%
Bony tenderness	Yes	43	61.4%
	No	27	38.6%
Bony Enlargement	Yes	36	51.4%
	No	34	48.6%
Palpable knee Warmth	Yes	60	85.7%
	No	10	14.3%

4.3 Clinical Grading of OA According to the WOMAC Score

The first objective of the study was to determine the clinical grading of primary knee OA according to the WOMAC score. The first part of the WOMAC score assesses the severity of pain on a scale of 0 through 4, with 0 indicating none while 4 is extreme. The findings are as presented in ***Figure 4.3a*** below. Pain while going up or down the stairs was the worst of the four pain assessments with 51.4% (N = 36) indicating the pain was severe and 12.9% (N = 9) rating the pain as extreme. On the other hand, pain that disturbed patient's sleep was more tolerable where 24.3% (N = 17) reporting no pain, 37.1% (N = 26) rating it as mild, and 27.1% (N = 18) reported as moderate. Majority of the participants rated their pain while walking on flat surface as moderate 31.4% (N = 22) followed by those who felt it was mild 28.6% (N = 20) while 20.0% (N = 14) had no pain, 11.4% (N = 8) rated it as severe and 8.6% (N = 6 Indicating it as extreme.

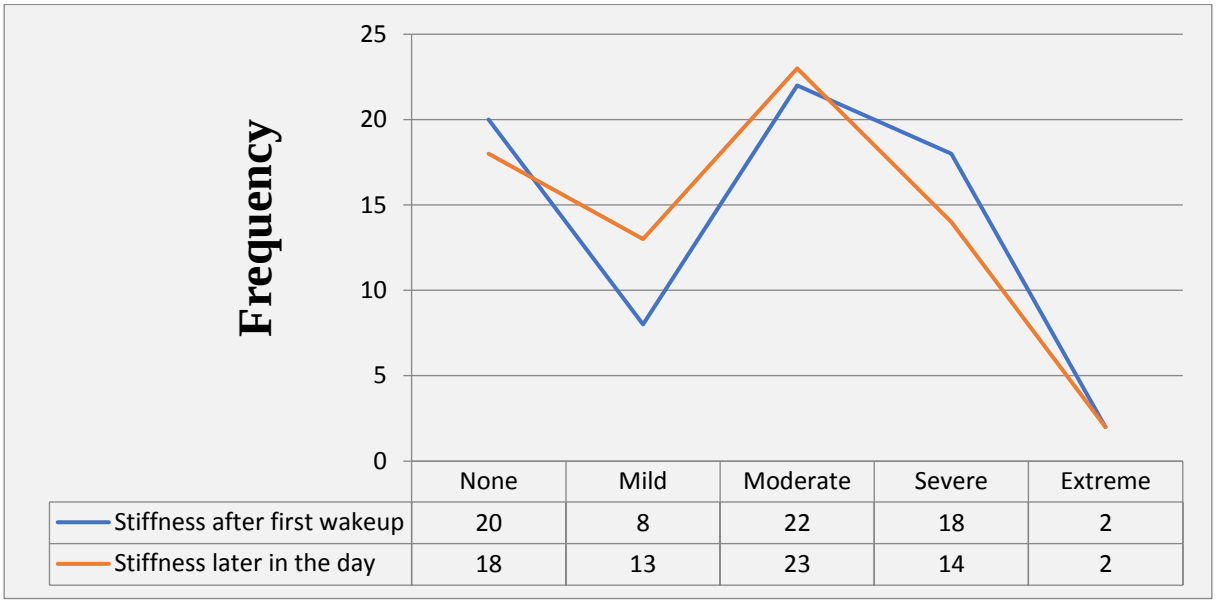
Figure 4.3a: Pain Assessment Segment of WOMAC Scale



	None	Mild	Moderate	Severe	Extreme
walking on a flat surface	14	20	22	8	6
going up and down stairs	0	7	18	36	9
disturbs your sleep at night	17	26	19	6	2
while standing	9	27	21	8	5

The second part of WOMAC score involves assessing the patient's level of stiffness early morning and later in the day. As presented in ***Figure 4.3b*** below, 2.9% (N = 2) indicated the stiffness was extreme at waking up and later in the day, 25.7% (N = 18) and 20.0% (N = 14) reported the stiffness was severe at waking up and later in the day respectively. Moderate stiffness was reported by 31.4% (N = 22) and 32.9% (N = 23) at waking up and later in the day respectively while 28.6% (N = 20) compared to 25.7% (N = 18) reported no stiffness at waking up and later in the day respectively.

Figure 4.3b: Knee Stiffness Assessment Part of the WOMAC Scale



The last part of the WOMAC Scale is on difficulty completing the activities of daily living, which are summarized in ***Table 4.3*** below. Notably, severe pain or extreme difficulties were highly reported for activities involving going up the stairs (50.0% severe and 18.6% extreme), going down the stairs (50.0% severe and 15.7% extreme), getting on and off the toilet (44.3% severe and 18.6% extreme), and getting on and off the car or bus (34.3% severe and 15.7% extreme). Difficulties in completing activities that were more tolerated involved those related to putting on socks (41.4% no difficulty while 32.9% had mild), taking off socks (42.9% had no difficulty and 32.9% had mild), lying in bed (32.9% had no difficulty while 52.9% had mild) and while sitting (21.4% had no difficulty while 42.9% had mild). In summary, most of the patients indicate a significant level of difficulties with the activities of daily living.

Table 4.3: Difficulties with ADL Assessment Segment of WOMAC Scale

Difficulty with Activities of Daily Living	**Participants Rating the Extent of Difficulty**				
	0	**1**	**2**	**3**	**4**
Difficulty going down the stairs	0	04 (5.7%)	18 (25.7%)	35 (50.0%)	13 (18.6%)
Difficulty going upstairs	0	03 (4.3%)	21 (30.0%)	35 (50.0%)	11 (15.7%)
Difficulty getting up from a sit	02	11	17	32	08

Difficulty with Activities of Daily Living	Participants Rating the Extent of Difficulty				
	0	1	2	3	4
	(02.9%)	(15.7%)	(24.3%)	(45.7%)	(11.4%)
Difficulty standing	14 (20.0%)	26 (37.1%)	15 (21.4%)	12 (17.1%)	03 (4.3%)
Difficulty bending to the floor	14 (20.0%)	26 (37.1%)	15 (21.4%)	12 (17.1%)	03 (04.3%)
Difficulty bending to the floor	14 (20.0%)	21 (30.0%)	21 (30.0%)	12 (17.1%)	02 (2.9%)
Difficulty walking on flat surface	13 (18.6%)	27 (38.6%)	23 (32.9%)	03 (4.3%)	04 (5.7%)
Difficulty getting on or off the car	02 (2.9%)	07 (10.0%)	26 (37.1%)	24 (34.3%)	11 (15.7%)
Difficulty going shopping	07 (10.0%)	41 (58.6%)	12 (17.1%)	08 (11.4%)	02 (2.9%)
Difficulty putting on socks	29 (41.4%)	23 (32.9%)	12 (17.1%)	03 (04.3%)	03 (04.3%)
Difficulty getting out of bed	09 (12.9%)	27 (38.6%)	19 (27.1%)	10 (14.3%)	05 (7.1%)
Difficulty taking off socks	30 (42.9%)	23 (32.9%)	12 (17.1%)	03 (04.3%)	02 (02.9%)
Difficulty lying in bed	23 (32.9%)	37 (52.9%)	04 (5.7%)	02 (2.9%)	04 (5.7%)
Difficulty getting out of the bathtub	09 (12.9%)	28 (40.0%)	22 (31.4%)	05 (7.1%)	06 (8.6%)
Difficulty while sitting	15 (21.4%)	30 (42.9%)	16 (22.9%)	07 (10.0%)	02 (02.9%0
Difficulty getting on or off the toilet	02 (02.9%)	05 (7.1%)	19 (27.1%)	31 (44.3%)	13 (18.6%)
Difficulty doing heavy household chores	02 (2.9%)	20 (28.6%)	27 (38.6%)	14 (20.0%)	07 (10.0%)
Difficulty finishing light household chores	02 (2.9%)	29 (41.4%)	23 (32.9%)	10 (14.3%)	06 (8.6%)

The total score for the pain rating had a minimum of 2 while the highest score was 17 and a mean of 8.33, Standard Deviation (SD) = 3.62). The stiffness total had least total of zero and maximum of 7 with a mean of 3.19 (SD= 2.29). For the difficulty in completing activities of daily living, the minimum total score was 6 and a highest being 63 with a mean of 30.39 (SD =

11.89). Overall, the minimum WOMAC score was 11 and the highest at 86 with a mean of 41.91 (SD = 15.75).

Table 4.3b: Summarized WOMAC Scale

	N	Min.	Max.	Mean	SD
Total Pain Score Per participant	70	2	17	8.33	3.618
Total Stiffness Score per Participant	70	0	7	3.19	2.286
Total ADL Difficulty Score per participant	70	6	63	30.39	11.806
Overall WOMAC Score	**70**	**11**	**86**	**41.91**	**15.755**

4.4 The Radiological Grading of primary knee OA According to the Kellgren and Lawrence scale.

Three orthopedic surgeons were involved in the KL scoring for the primary knee OA with the findings summarized in ***Table 4.4*** below. For the first surgeon, 34.3% (N = 24) of the patients had extreme OA, 31.4% (N = 22) had severe OA, 20.0% (N = 14) had moderate OA, 12.9% (N = 9) while 1.4% (N = 1). The second surgeon rated 31.4% (N = 22) as extreme, 28.6% (N = 20) as severe, 18.6% (N = 13) moderate, 12.9% (N = 9) as mild while 8.6% (N = 6) had no OA. The third surgeon followed the trend with majority of the patients being indicated as having extreme OA 42.9% (N = 30), followed by 27.1% (N = 19) severe OA, 20.0% (N = 14) as moderate, 10.0% (N = 7) mild and zero cases registered as having no OA.

At agreement level, the three surgeons failed to agree (at least two rating the OA similarly) on the grade of severity for four participants. Overall, the three surgeons agreed that 35.7% (N = 25) participants had extreme OA, 30.0% (N = 21) had severe OA, 15.7% (N = 11) had moderate OA, 11.4% (N = 8) had mild OA while 7.1% (N = 5) had no OA.

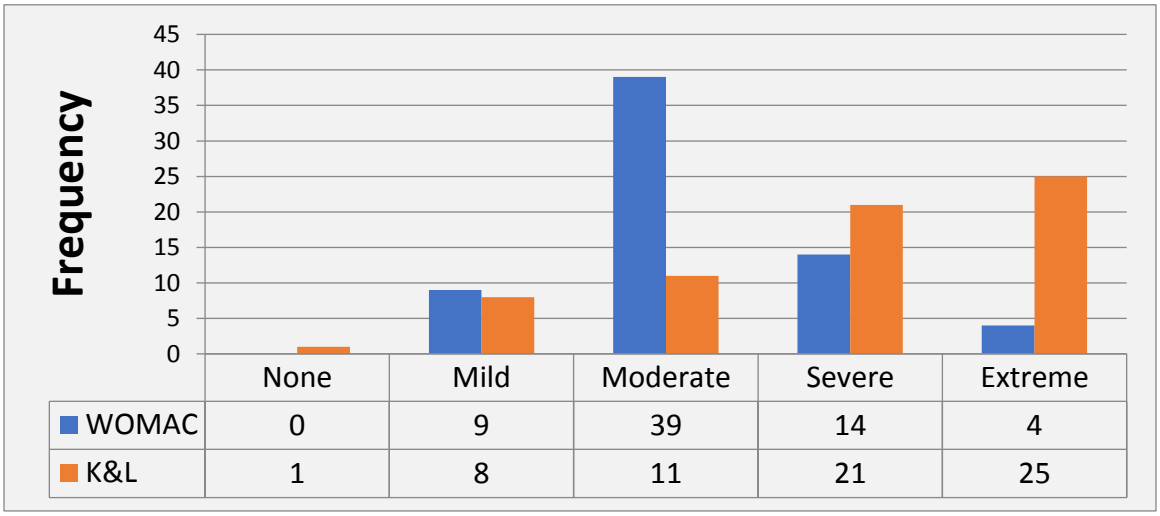
Table 4.4 Summary of KL Scoring by the Three Orthopedic surgeons

Orthopedic Surgeon Rating (K&L Scale)	Surgeon's Rating the OA				
	0	**1**	**2**	**3**	**4**
Surgeon A	1 (1.4%)	9 (12.9%)	14 (20.0%)	22 (31.4%)	24 (34.3%)
Surgeon B	6 (8.6%)	9 (12.9%)	13 (18.6%)	20 (28.6%)	22 (31.4%)
Surgeon C	0 (0.00%)	7 (10.0%)	14 (20.0%)	19 (27.1%)	30 (42.9%)
Agreed Radiological Scoring	5 (7.1%)	8 (11.4%)	11 (15.7%)	21 (30.0%)	25 (35.7%)
Overall mean					

4.5 The Level of Agreement between the WOMAC and the Kellgren and Lawrence Scale

In order to tests for interrater reliability between WOMAC and Kellgren & Lawrence Scale, we first classified the overall WOMAC scores into none OA (overall score = 0), Mild OA (overall score of 1 – 24), Moderate OA (overall score of 25 – 48), Severe OA (overall score of 49 – 72) and Extreme OA (overall score above 73). The distribution of the classified overall WOMAC compared to K&L scale is presented in ***Figure 4.5*** below.

Figure 4.5: Bar Graph on Comparison of WOMAC and KL Scores for Knee OA



The Cohen Kappa interrater reliability test indicated there was no agreement between the WOMAC and KL scale in grading the severity of knee OA (*k = - 0.030*). The findings depict the difference in the two scoring practices, which might indicate significant levels of subjective errors.

Table 4.5: Interrater Reliability Test

	WOMAC N (%)	**K&L N = (%)**	**Cohen Kappa (*k*)**
None	0	1 (1.5%)	
Mild	9 (13.6%)	8 (12.1%)	
Moderate	39 (59.1%)	11 (16.7%)	*k = - 0.030*
Severe	14 (21.2%)	21 (31.8%)	
Extreme	4 (6.1%)	25 (37.9%)	

CHAPTER FIVE: DISCUSSION

5.1 Overview

The primary data collected was adequate to respond to the study objectives. The distribution of the participants was majorly in agreement with the previous evidence published on primary knee osteoarthritis. In our study, most of those involved were females, and age over 50 years. The two socio-demographic characteristics are not coincidental given that most females tend to develop primary knee osteoarthritis post-menopausal age following the metabolic changes occasioned by the changes in the level estrogen hormone. In their studies, Akinpelu et al (9), Usenbo et al(19) and Mijiyawa et al(20) reported OA trend where women, especially those in their post-menopausal stage, were the most prevalent. Most of our cases had right knee affected, although that included random selection of the knee to assess for those with bilateral knee injuries.

5.2 Clinical Grading of OA According to WOMAC Scale

Collecting data using WOMAC tool demonstrated feasibility of the tool in our setting. The WOMAC scale allowed the patient to be assessed for the level of pain, stiffness, and how the two interact to affect the patient's ability to perform the activities of daily living. In our study, the patients' pain levels varied ranged from 2/20 through 17/20, stiffness scores ranged from 0/8 to 7/8. The impairment on the activities of daily living had a minimum score of 6/68 and a high of 63/68. A summation of all the three parameters gave a minimum score of 11/98 and a high score of 86/98. The mean score indicates that most of the patients were in the moderate OA scale category. A notable trend with our WOMAC score was that the data assumed the distribution of a normal curve with majority of the cases falling at the moderate category and reducing as they spread towards the mild or extreme ends.

The previous studies are replete with assertion that WOMAC scale is accepted and used globally for assessing the level of joint OA. The reliability for the scale is reputable but not without some criticism(37). Some of the criticisms are based on the subjectivity of the responses and the lack of direct association between pain/stiffness/difficulty in completing ADL with severity of OA based on an individual's tolerance/endurance level. In their study, Poland et al (40) indicated that

scoring the functioning of the patient using the tool should be further validate on how confounders such as patient BMI, sex, age, and occupation impact on the WOMAC scale.

5.3 Radiological Grading of Knee OA According to Kellgren and Lawarence Scale

In our study, the primary data indicated a significantly high level of agreeability with the three orthopedic surgeons failing to agree on just 5.71% of the cases. For the three surgeons involved, the proportions of the cases increased with increase in severity score. The agreed score for each of the patients indicated that 35.7% were grade IV, 30.0% grade III, 15.7% grade II, 11.4% scored as grade I, and 7.1% indicated as normal. The level of agreement among the surgeons using the KL classification is consistent with past evidence reported in the literature.

In the development of the scale, Kellgren and Lawrence reported an interrater reliability of 0.83. The KL classification is rigorous since it requires competency to interpret radiological reports, but often praised for using information that can be quantified rather than relying on subjectivity of the patients reporting as it is the case in WOMAC scale. Kocak et al.(27) noted that patients with severe clinical manifestation related to the knee OA were then likely to be graded either at grade III or IV using the KL classification. Lukusa et al.(28), which explored the OA condition in a central African country criticized KL classification for assuming the progression of OA as linear. Also, Talic-Tanovi et al.,(29) compared clinical and radiological characteristic for patient who presented with knee OA. Their overall conclusion showed that there lacked statistical significance between clinical parameters and radiological findings, but further cited that age was a critical confounder in radiological results among patient with knee OA. Steenkamp et al (30) studies reported lack of outright correlation between how the severity of their OA and the ultimate KL grading. In the two studies, they reported that some patient reported milder symptoms, yet the grades given were higher or the converse.

5.4 Level of Agreement between WOMAN and Kellegren & Lawrence Scale

In our study, there was no agreement between the severity of the OA symptoms assessed through the WOMAC scale and the radiological rates evaluated by three surgeons for the same sample of patients. Our Cohen kappa score ($k = -0.030$) showed that the two scales were different in the

way they graded the severity of the knee OA. However, our study findings are consistent with reports disputing a direct link between patient's symptoms and radiological evaluation results. Bija et al (10) study reported that patient's pain severity failed to correlate with radiological results. Bija et al reported that the level of pain was found to affect the score of functionality, especially the on ADL. They further showed that pain, thus was a significant influencer of the ultimate WOMAC score while radiological grading may overestimate the severity influenced by factors such as age, sex, body weight, and occupation. Also, Talic-Tanovi et al.,(29) compared clinical and radiological characteristic for patient who presented with knee OA. Their overall conclusion showed that there lacked statistical significance between clinical parameters and radiological findings, but further cited that age was a critical confounder in radiological results among patient with primary knee OA. In Steenkamp et al (30), there was no correlation between WOMAC scores and the radiological grades.

5.5 Study Limitations

Measurement errors – due to the cultural and lifestyle differences between the study group and those used to develop the WOMAC score some variables in the score question had to be explained for better patient understanding and this may impact the findings of the study.

5.6 Conclusion

In conclusion, there was no agreement between the scoring of OA using the WOMAC in comparison to rating based on KL classification. The WOMAC scale gave findings that assumed the normal distribution curve while the KL scale resulted in data that was incremental in frequency from mild towards severity. Our study shows the importance of using more than one scale in diagnosis of primary knee OA. The lack of interrater reliability between WOMAC and KL classification indicates the significance of further evaluation on the correlation between the two scales, which is emphasized in previous study findings. There lack direct transferability between patient clinical presentations to radiological scores. Based on the primary findings, this study recommends the use of more than one scale in making the diagnosis and management pathway for patient with primary knee OA.

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LIST OF APPENDICES

Appendix 1: Data collection tool

Title: THE CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL SEVERITY OF PRIMARY KNEE OSTEOARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL ARTHROPLASTY OUTPATIENT CLINIC

Investigator: Dr. Wako Abdullahi Yusuf, Resident Department of Orthopedics and Trauma Surgery, University of Nairobi

PATIENT BIODATA

Patient ID:……..

Age:……

Sex:…….

Knee affected: Right……. Left…….

ACR CLINICAL CRITERIA

Mechanical knee pain: Yes…….. No……

Age above 50yrs: Yes…….. No……..

Morning stiffness less than 30mins: Yes……..

No……...

Knee crepitus: Yes…… No…….

Bony tenderness: Yes…….. No……

Bony enlargement: Yes…….. No…….

No palpable knee warmth: Yes…… No…….

WOMAC Osteoarthritis Index (*LK3.1*) English version

Patient ID: .....

Date: .....

Section A: PAIN

Think about the pain you felt during the last 48 hours caused by the arthritis in your knee.

Select the number that best describes your pain

Question: How much pain have you had:	None	Mild	Moderate	Severe	Extreme
1. - when walking in a flat surface?	0	1	2	3	4
2. - when going up or down stairs?	0	1	2	3	4
3. - at night while in bed? (that is - pain that disturbs your sleep)	0	1	2	3	4
4. - while sitting or lying down?	0	1	2	3	4
5. - while standing?	0	1	2	3	4
				Total Pain Score (Max 20):	

Section B: STIFFNESS

Think about the stiffness (not pain) you felt during the last 48 hours caused by the arthritis in your knee.

Stiffness is a sensation of decreased ease in moving your joint.

Select the number that best describes your stiffness

None		Mild	Moderate	Severe	Extreme
6. - How severe has your stiffness been after you first woke up in the morning?	0	1	2	3	4
7. - How severe has your stiffness been after sitting or lying down or while resting later in the day?	0	1	2	3	4
				Total Stiffness Score (Max 8):	

Section C: DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities during the last 48 hours caused by the arthritis in your knee.

By this we mean your ability to move around and take care of yourself.

Select the number that best describes your difficulty

Question: How much difficulty have you had:	None	Mild	Moderate	Severe	Extreme
8. - when going down the stairs?	0	1	2	3	4
9. - when going up the stairs?	0	1	2	3	4
10. - when getting up from a sitting position?	0	1	2	3	4
11. - while standing?	0	1	2	3	4
12. - when bending to the floor?	0	1	2	3	4
13. - when walking on a flat surface?	0	1	2	3	4
14. - getting in or out of a car, or getting on or off a bus?	0	1	2	3	4
15. - while going shopping?	0	1	2	3	4
16. - when putting on your socks or panty hose or stockings?	0	1	2	3	4
17. - when getting out of bed?	0	1	2	3	4
18. - when taking off your socks or panty hose or stockings?	0	1	2	3	4
19. - when lying in bed?	0	1	2	3	4
20. - when getting in or out of the bathtub?	0	1	2	3	4
21. - while sitting?	0	1	2	3	4
22. - when getting on or off the toilet?	0	1	2	3	4
23. - while doing heavy household chores?	0	1	2	3	4
24. - while doing light household chores?	0	1	2	3	4
				Total Difficulty Score (Max 68):	

Total WOMAC Score (Max 96):	

WOMAC OSTEOARTHRITIS INDEX(LK 3.1) SWAHILI VERSION

Kitambulisho cha Mgonjwa:.....

Tarehe:.....

Sehemu A: MAUMIVU

Fikiria kuhusu maumivu uliyohisi wakati wa saa 48 zilizopita yaliyosababishwa na yabisi kwenye goti lako.

Chagua nambari inayoelezea vizuri zaidi maumivu yako.

Swali: Umekuwa na maumivu kiasi gani:	Hakuna	Mpole	Wastani	kali	Uliokithiri
1. - wakati wa kutembea kwenye uso wa gorofa?	0	1	2	3	4
2. - wakati wa kupanda au kushuka ngazi?	0	1	2	3	4
3. - usiku ukiwa kitandani? (Hiyo ni - maumivu ambayo yanasumbua yako kulala)	0	1	2	3	4
4. - ukiwa umekaa au umelala?	0	1	2	3	4
5. - ukiwa umesimama?	0	1	2	3	4
				Jumla ya Alama za Maumivu (Upeo 20):	

Sehemu B: UGUMU

Fikiria juu ya ugumu (sio maumivu) uliyohisi wakati wa saa 48 zilizopita uliosababishwa na yabisi katika goti lako.

Ugumu ni hisia ya kupungua kwa urahisi katika kusonga kiungo chako.

Chagua nambari inayoelezea vyema ugumu wako

	Hakuna.	Mpole.	Wastani.	Kali	Uliokithiri
6. - Ugumu wako umekuwa mkali kiasi gani baada ya kuamka kwanza asubuhi?	0	1	2	3	4
7. - Je, ugumu wako umekuwa mkali kiasi gani baada ya kukaa au kulala au wakati wa kupumzika baadaye mchana?	0	1	2	3	4
Alama ya Jumla ya Ugumu (Upeo 8):					

Sehemu C: UGUMU KUFANYA SHUGHULI ZA KILA SIKU

Fikiria kuhusu ugumu uliokuwa nao katika kufanya shughuli zifuatazo za kimwili za kila siku katika saa 48 zilizopita zilizosababishwa na ugonjwa wa yabisi katika goti lako.

Kwa hili tunamaanisha uwezo wako wa kuzunguka na kujitunza.

Chagua nambari inayoelezea ugumu wako vyema

Swali: Umekuwa na ugumu kiasi gani:

	Hakuna	Mpole.	Wastani.	Kali	Uliokithiri
8. - wakati wa kwenda chini ya ngazi?	0	1	2	3	4
9. - wakati wa kupanda ngazi?	0	1	2	3	4
10. - wakati wa kuinuka kutoka kwa nafasi ya kukaa?	0	1	2	3	4
11. - ukiwa umesimama?	0	1	2	3	4
12. - wakati wa kuinama kwa sakafu?	0	1	2	3	4
13. - wakati wa kutembea kwenye uso wa gorofa?	0	1	2	3	4
14. - kupanda au kutoka kwenye gari, au kupanda au kushuka basi?	0	1	2	3	4
15. - wakati wa kwenda kufanya manunuzi?	0	1	2	3	4
16. - wakati wa kuweka kwenye soksi zako au hose ya panty au soksi?	0	1	2	3	4
17. - wakati wa kutoka kitandani?	0	1	2	3	4
18. - unapovua soksi au hose ya panty au soksi?	0	1	2	3	4
19. - wakati umelala kitandani?	0	1	2	3	4
20. - wakati wa kuingia au kutoka kwenye bafu?	0	1	2	3	4
21. - ukiwa umekaa?	0	1	2	3	4
22. - wakati wa kuingia au kutoka kwenye choo?	0	1	2	3	4
23. - huku ukifanya kazi nzito za nyumbani?	0	1	2	3	4
24. - wakati wa kufanya kazi nyepesi za nyumbani?	0	1	2	3	4
				Jumla ya Alama za Ugumu (Upeo wa 68):	

Jumla ya alama ya WOMAC (isizidi 96):

K&L RADIOLOGICAL GRADING

Patient ID:……..

Date xray taken:…….

Orthopedic surgeon	Grade
Surgeon A	
Surgeon B	
Surgeon C	

Agreed grading of xray	

Appendix 2: Informed consent – English Version

PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY: ADULT PATIENT CONSENT FORM

Title of Study: THE CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL SEVERITY OF PRIMARY KNEE OSTEOARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL ARTHROPLASTY OUTPATIENT CLINIC

Principal Investigator: Dr. Wako Abdullahi Yusuf,

Institution: Resident at The University of Nairobi**,** Department of Orthopaedics Surgery.

Introduction:

I am Dr Wako Abdullahi Yusuf,. I am currently pursuing my postgraduate studies at the University of Nairobi. As part of my studies, I am required to undertake research. I am doing research to document the correlation between the clinical and radiographical changes in OA.

The purpose of this consent form is to provide you with adequate information in order to help you decide whether or not to be a participant in the study. You are free to ask any questions about the research, its purpose, implications of participating in the study, risks and benefits, volunteer rights, and any added information not included in this form that needs clarification. After your questions are satisfactorily answered, you can decide to take part in the study or not. This process is known as 'informed consent'. After you agree to take part in this study, I will request you to sign your name on this form.

You should understand the general principles which apply to all participants in a medical research:

i) Participation in the study is on voluntary basis.
ii) You have a right of withdrawal from the study at any time without necessarily giving a reason for your withdrawal.
iii) If you refuse to take part in the study, this does not in any way affect services provided to you in the facility or any other health facility.

A copy of this form will be provided to you 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 above researchers are interviewing individuals who have primary knee osteoarthritis.

All those who take part in this research study will be interrogated. You will also be required to undergo clinical examination and X ray testing of the affected knee(s) upon consenting. There will be approximately 289 participants in this study who are randomly chosen. We request for your consent to consider taking part in this study.

What Will Happen If You Decide To Be In This Research Study?

If you agree to take part in this research, the following will happen:

You will be interviewed in an area where your privacy guaranteed and you are comfortable to answer questions. The interview will take few minutes. If necessary, we will ask your phone number to contact you.

You will also be requested to undertake the X ray of the affected knee to assess the osteo-arthritis. This will be performed as part of the routine investigation for the condition.

Any contact information you provide will be used only by people conducting this study and will never be shared with others.

Are There Any Risks, Harms Discomforts Associated with This Study? Generally, medical research has the potential to introduce psychological, social, emotional and physical risks. One of the risks of being in the study is loss of privacy. Any information you give us is confidential and we will keep it private. We will identify you with a code-number in a password-protected computer database and all our paper records will be kept in a secure cabinet. You have the right to decline the interview or any questions asked in the process. This study includes getting a weight bearing radiograph done on your knee if you haven't done it yet or have a radiograph that is more than 3 months old. Radiographs involve use of ionizing radiation in the form of x-rays which may be harmful to your body. It's important to have a radiograph within 3 months of the recruitment into the study to quantify the accurate degree of joint degeneration. Also, all our staff conducting this study are professionals with training in these examinations/interviews.

Are There Any Benefits Being In This Study?

The study will help us understand better the correlation between clinical presentation and imaging findings in osteo-arthritis in patients seen at the Kenyatta National Hospital. This will further enable us to create feasible local guidelines guiding the same.

Will Being In This Study Cost You Anything?

No additional costs will be incurred.

Can I Withdraw From The Study Anytime?

Participation in the study is on voluntary basis and you have a right of withdrawal from the study and that at anytime you can decide to withdraw from the study without necessarily giving a reason for your withdrawal. This does not in any way affect services provided to you in the facility or in any other health facility.

For more information about your rights as a research participant you may contact the following persons:

Principal investigator:

Dr. Abdullahi Yusuf Wako

Telephone no: +254729940700

Department of Orthopedics and Trauma surgery

University of Nairobi,

Lead Supervisor:

DR. Mutiso M. Vincent

Department of Orthopedics and Trauma surgery,

University of Nairobi.

Tel no: +254723289922

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix 3- Consent Form (Statement of Consent)-ADULTS

Participant's statement

1. I have read this consent form or had the content read to me and I understood.
2. I have been given the chance to ask questions about this research study.
3. I have had my questions answered adequately in a language I understand.
4. The potential risks and benefits have been explained to me in a clear and precise manner.

I understand that I take part in this study voluntarily and that I can withdraw anytime.

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: _____

Contact (mobile number): _____

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. Wako Abdullahi Yusuf**

Date: _____ Signature _____

Role in the study: Principal investigator.

For more information, contact:

Principal investigator:

Dr. Abdullahi Yusuf Wako

Telephone no.: +254729940700

Department of Orthopedics and Trauma surgery

University of Nairobi,

Lead Supervisor:

DR. Mutiso M. Vincent
Department of Orthopedics and Trauma surgery,

University of Nairobi.

Tel no: +254723289922

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix 4 - Fomu ya Idhini Ili Kushiriki Katika Utafiti- (Watu Wazima)

Kichwa Cha Utafiti:. : THE CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL SEVERITY OF PRIMARY KNEE OSTEOARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL ARTHROPLASTY OUTPATIENT CLINIC

Mpelelezi Mkuu Na Ushirika Wa Kitaasisi: Dr. Abdullahi Yusuf Wako, Mwanafunzi wa Shahada ya Uzamili Katika Chuo Kikuu Cha Nairobi, Idara ya Magonjwa ya mifupa

Mimi ni Daktari; Hivi sasa ninaendelea na masomo yangu ya uzamili katika Chuo Kikuu cha Nairobi.

Katika masomo yangu, ninahitajika kufanya utafiti. Ninafanya utafiti kuchunguza magonjwa ya mfuko wa maji kwa wale walio umia uti wa mgongo.

Ningependa kukuambia juu ya utafiti unaofanywa. Madhumuni ya fomu hii ya idhini ni kukupa habari za kutosha ili kukusaidia kuamua iwapo utakuwa mshiriki wa utafiti au la. Uko huru kuuliza maswali yoyote juu ya utafiti, madhumuni yake, ni nini maana ya wewe kushiriki katika utafiti, ikiwa kuna hatari yoyote inayohusika na faida yoyote, haki za kujitolea, na habari yoyote iliyoongezwa isiyojumuishwa katika fomu hii na inahitaji ufafanuzi. Baada ya kujibu kwa kuridhisha maswali yako yote, unaweza kuamua kushiriki katika utafiti au la. Utaratibu huu unajulikana kama 'idhini ya habari'. Baada ya kukubali kushiriki katika utafiti huu, nitakuomba utie sahihi jina lako kwenye fomu hii.

Unapaswa kuelewa kanuni za jumla ambazo zinatumika kwa washiriki wote katika utafiti wa matibabu:

1. Kushiriki katika utafiti ni kwa hiari.
2. Wakati wowote unaweza kuamua kujiondoa kwenye utafiti.
3. Ukikataa kushiriki katika utafiti, hii haiathiri huduma unayopewa katika kituo hicho au kituo kingine chochote cha afya.

Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO AU LA

Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi Nambari_____

Utafiti Huu Unahusu Nini?

Watafiti hapo juu wanawahoji wagonjwa ambao wana shida ya uti wa mgongo na wale ambao wanatumia mpira katika shughuli ya haja ndogo. Sababu ya mahojiano ni kujua umri wako, aina ya mpira, na muda wa kutumia mpira wa mkojo. Kutakuwa na takriban washiriki 80 katika utafiti huu ambao wamechaguliwa bila mpangilio. Tunaomba idhini yako kufikiria kushiriki katika utafiti huu.

Je, Nini Kitatokea Ukiamua Kuwa Kwenye Utafiti Huu?

Ikiwa unakubali kushiriki katika utafiti huu, yafuatayo yatatokea:

Utahojiwa katika eneo ambalo faragha yako imehakikishiwa na unahisi vizuri kujibu maswali. Mahojiano yatachukua dakika chache. Baada ya mahojiano kumalizika, tutachukua mkojo kwa njia mpira ili kupima. Kisha, tutauliza nambari yako ya simu kuwasiliana nawe. Maelezo yoyote ya mawasiliano utakayotoa yatatumika tu na watu wanaofanya utafiti huu na hawatashirikiwa na wengine kamwe.

Je, Kuna Athari Zozote, Madhara, Usumbufu Zinazohusiana Na Utafiti Huu?

Kwa ujumla, utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemko na kiafya. Moja ya hatari ya kuwa katika utafiti huu ni kupoteza faragha. Habari yoyote unayotupatia ni ya siri na itachukuliwa kama siri.

Tutatumia nambari ya kukutambulisha kwenye hifadhidata ya kompyuta inayolindwa na nywila na rekodi zetu zote za karatasi zitahifadhiwa kwenye baraza la mawaziri iliyofungwa. Una haki ya kukataa mahojiano au maswali yoyote yanayoulizwa katika mahojiano. Utafiti huu unajumuisha kupata radiografu inayobeba uzito kufanywa kwenye goti lako ikiwa bado haujaifanya au una radiografu ambayo ina zaidi ya miezi 3. Radiografu inahusisha matumizi ya mionzi ya ioni kwa njia ya eksirei ambayo inaweza kuwa na madhara kwa mwili wako. Ni muhimu kuwa na radiografu ndani ya miezi 3 baada ya kuajiriwa katika utafiti ili kuhesabu kiwango sahihi cha kuzorota kwa viungo. Pia, wafanyikazi wetu wote wanaofanya utafiti huu ni wataalamu wenye mafunzo katika mitihani / mahojiano haya.

Je, Kuna Faida Zozote Ziko Katika Utafiti Huu?

Utafiti huo utatusaidia kuelewa vizuri jinsi …….. za kuchunguza ukuaji mzuri wa kijusi. Hii itapanua zaidi ufahamu wetu……..

Je, Kuna Gharama Kuwa Katika Utafiti Huu?

Hakuna gharama za ziada zitakazopatikana.

Je, Ninaweza Kuondoka Kwenye Utafiti Wakati Wowote?

Kushiriki katika utafiti ni kwa hiari na una haki ya kujiondoa kutoka kwa utafiti na kwamba wakati wowote unaweza kuamua kujiondoa kwenye utafiti bila lazima kutoa sababu ya kujitoa kwako. Hii haiathiri kwa vyovyote huduma unazopewa katika kituo hicho au katika kituo kingine chochote cha afya.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na watu wafuatao:

Mchunguzi Mkuu:

Dr. Abdullahi Yusuf Wako

Nambari ya Simu.: +254729940700

Department of Orthopedics and Trauma surgery

University of Nairobi,

Msimamizi Mkuu:

DR. Mutiso M. Vincent

Department of Orthopedics and Trauma surgery

University of Nairobi.

Nambari ya Simu: +254723289922

Ama,

Katibu,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Nambari ya simu :. 2726300 Ext. 44102

Email:uonknh_erc@uonbi.ac.ke.

Appendix 5 – Fomu Ya Idhini (Watu Wazima).

Kichwa Cha utafiti: THE CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL SEVERITY OF PRIMARY KNEE OSTEOARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL ARTHROPLASTY OUTPATIENT CLINIC

Jina la Mtafitu: Dr. Abdullahi Yusuf Wako, mwanafunzi wa Shahada ya Uzamili Katika Magonjwa ya mifupa **Chuo Kikuu cha Nairobi, Idara ya** Magonjwa ya mifupa

1. Nimesoma fomu hii ya idhini au nimesomewa yaliyomo na nilielewa.

2. Nimepewa nafasi ya kuuliza maswali juu ya utafiti huu.

3. Nimejibiwa maswali yangu vya kutosha katika lugha ninayoelewa.

4. Hatari na faida zinazowezekana nimeelezewa kwa njia wazi.

5. Ninaelewa kuwa mimi hushiriki katika utafiti huu kwa hiari na kwamba ninaweza kujiondoa wakati wowote.

Kwa kusaini fomu hii ya idhini, sijatoa haki yoyote ya kisheria ambayo ninayo kama mshiriki wa utafiti.

Ninakubali kushiriki katika utafiti huu: Ndio / Hapana

Ninakubali kutoa habari ya mawasiliano kwa ufuatiliaji: Ndio / Hapana

Jina la mshiriki aliyechapishwa:

_____

Mawasiliano (nambari ya rununu): _____

Saini ya mshiriki / Stempu ya kidole gumba _____ Tarehe _____

Kauli ya mtafiti

Mimi, aliyesainiwa chini, nimeelezea kabisa maelezo yanayofaa ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kwamba mshiriki ameelewa na kwa hiari ametoa idhini yake.

Jina la mtafiti: DR. Wako Abdullahi Yusuf

Saini _____

Wajibu katika utafiti: Mchunguzi mkuu.

Kwa habari zaidi, wasiliana na:

Mchunguzi Mkuu:
Dr. Abdullahi Yusuf Wako
Nambari ya Simu.: +254729940700
Department of Orthopedics and Trauma surgery
University of Nairobi,

Msimamizi Mkuu:
DR. Mutiso M. Vincent
Department of Orthopedics and Trauma surgery
University of Nairobi.
Nambari ya Simu: +254723289922

Ama,
Katibu,
Kenyatta National Hospital-University of Nairobi Ethics and Research Committee
Nambari ya simu :. 2726300 Ext. 44102
Email:uonknh_erc@uonbi.ac.ke.

Appendix 6: KNH Ethical Approval Form

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/261

22nd June, 2023

Dr. Abdullahi Yusuf Wako
Reg No. H58/7728/2017
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

Dear Dr. Wako,

ETHICAL APPROVAL-RESEARCH PROPOSAL: THE CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL SEVERITY OF PRIMARY KNEE OSTEOARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL (P247/03/2023)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P247/03/2023.** The approval period is 22nd June 2023 –21st June 2024.

This approval is subject to compliance with the following requirements;

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

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

Yours sincerely,

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

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept., KNH
The Chair, Dept. of Orthopaedic Surgery, UoN
Supervisors: Dr. Vincent S.M.Mutiso, Dept. of Orthopaedic Surgery, UoN
Dr. John K Kingori , Dept. of Orthopaedic Surgery, UoN