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Assessment of pain control and function in patients with knee osteoarthritis attending the rheumatology and orthopedic clinics at the Kenyatta National Hospital.

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A STUDY DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE MASTER OF MEDICINE DEGREE IN INTERNAL MEDICINE

DECLARATION

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LIST OF ABBREVIATIONS AND ACRONYMS

Abbreviation	Definition
ACR	American College of Rheumatology
BMI	Body Mass Index
BPI	Brief Pain Inventory
BPI-SF	Brief Pain Inventory - Short Form
CDC	Centers for Disease Control and Prevention
DALY	Disability-adjusted life years
GABA	Gamma-aminobutyric acid
GBD	Global Burden of Disease
HIV	Human Immunodeficiency Virus
KHOA	Knee and Hip Osteoarthritis
KNH	Kenyatta National Hospital
KOA	Knee Osteoarthritis
MCP	Metacarpophalangeal
NHANES	National Health and Nutrition Examination Survey
NSAID	Nonsteroidal anti-inflammatory drug
OA	Osteoarthritis
SORT	Survey of Osteoarthritis Real World Therapies
SPSS	Statistical Package for the Social Sciences
TKA	Total knee arthroplasty
UON	University of Nairobi
WOMAC	The Western Ontario and McMaster Universities Osteoarthritis Index
YLD	Years Lived with Disability

DEFINITION OF KEY TERMS

Osteoarthritis: It is a disabling joint disorder characterized by degeneration of the joint complex including articular cartilage, subchondral bone, and synovium.

Pain: An unpleasant, subjective, emotional, and physical experience associated with actual or potential tissue damage.

Functional status: An individual's ability to perform normal daily activities required to meet basic needs and maintain health and well-being.

Adequacy: The fact of being enough or satisfactory for a particular purpose.

ABSTRACT

Background: Chronic pain in knee osteoarthritis influences the quality of life and functional status of these patients. Despite numerous treatment modalities, pain may be inadequately controlled and affect a patient's functional status. This may be more evident in our local setup as patients tend to present later in the disease. This study was designed to understand the burden of pain in knee osteoarthritis.

Objective: To assess pain control and the level of function in patients with knee osteoarthritis at the orthopedic and rheumatology clinics at the Kenyatta National Hospital.

Method: A cross-sectional descriptive study that assessed patients above the age of 18 with a diagnosis of knee osteoarthritis on follow-up who fit the inclusion criteria. The pain was assessed by the Brief Pain Inventory-Short Form (BPI-SF) and the functional status was assessed by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Any patient reporting a pain score >4 in question 5 of BPI-SF indicating moderate (4-7) or severe pain (>8) was classified as having inadequate pain control. Pain control was analyzed and presented as a proportion of patients achieving adequate pain control. Functional impairment was assessed using the WOMAC score (0-96). A higher score indicated poorer function. Pain severity was associated with functional status using the ANOVA test. The chi-squared test was used to associate patient-related factors with pain control. A 5% level of significance was used to interpret all the statistical tests (p-value less or equal to 0.05).

Results: A total of 270 patients were recruited into the study of whom 139 (51.5%) were females and 131 (48.5%) were males, The mean age of the study population was 55.1 years. The majority of the patients were overweight (n= 134, 49.6%) with a smaller number (n=27, 10%) being obese. The median duration of osteoarthritis diagnosis was 48 months. Bilateral knee osteoarthritis (n= 172, 63.7%) was more prevalent than unilateral disease (n= 98, 36.3%). Knee pain was inadequately controlled in 265 (98.1%) participants with these patients scoring >4 (moderate to severe pain) in Question no 5 (pain on average) of the BPI-SF. The majority of participants (n=259, 95.9%) also had functional impairment/disability. Participants with inadequate pain control (moderate pain or higher) had a worse functional status p-0.026 (<0.05).

Older patients had worse pain control p-0.029 (<0.05).

Conclusion: Pain control in knee osteoarthritis is mostly inadequate with most patients having a poor functional status Inadequate pain control is associated with older age and a poorer functional status. This limits their daily activities and enjoyment of life.

CHAPTER ONE: INTRODUCTION

1.1 Background to the study

Osteoarthritis is the most prevalent joint disorder and form of arthritis worldwide. It is an important cause of disability and is a source of significant health burdens having wide implications on patients' health, health systems, and socioeconomic cost. The burden has risen by almost 50% over the past three decades and is expected to rise higher owing to an aging population and increased rates of obesity (1)(2).

According to the Global Burden of Disease Study in 2019, 7% of the global population is affected by Osteoarthritis, with women accounting for 60% of cases. Osteoarthritis was the 15th highest cause of years lived with disability (YLDs) worldwide and was responsible for 2% of the total global YLDs (2).

In Africa, epidemiological data for rheumatic diseases is limited, despite the burden possibly being heavier due to later presentation by patients (3,4). Usenbo et al. in 2015 attempted to demystify this by conducting a systematic review and meta-analysis of the prevalence of arthritis in Africa. The review noted that prevalence data was lacking suggesting that more needs to be done to understand the true burden of rheumatic diseases and osteoarthritis in this part of the world (5).

The knee is the most affected joint in patients with osteoarthritis accounting for 60.9% of cases globally followed by hand and hip osteoarthritis accounting for a combined 29 % of cases (2). This is in keeping with the limited data from African studies which show that knee OA is the most prevalent arthritis in Africa (3,4).

Cui et al. in 2020 significantly added to this pool of data by conducting a meta-analysis of the estimated prevalence of knee OA in the global population. The sample size was the largest known to have been studied in the 21st century on knee OA prevalence with 9,440,250 participants from 34 countries. Knee OA was found to be prevalent in 16.0% of people aged 15 years and above and was 22.9% in individuals aged 40 and above; peaking at ages 70-79. Women were more affected (6).

In Kenya, Nour et al. (2014) noted that knee Osteoarthritis was the most common form of OA at the rheumatology and orthopedic clinics at The Kenyatta National Hospital, accounting for 77% of cases. This is comparable to global data despite it being based on a smaller population (7).

Pain is the characteristic symptom of Osteoarthritis (OA) that pushes patients to seek medical attention. Pain limits mobility and affects one's quality of life and functional status. The chief cause of disability in the elderly in the US is lower extremity OA (8). Such data is missing for the African population, although a systematic review done by Davies et al. in 2019 noted that knee OA was the commonest cause of total knee replacement in sub-Saharan Africa (9).

Pain control is therefore paramount as inadequate pain relief contributes further to the disease burden on an individual and society and has a significant economic cost.

1.2 Problem Statement

In patients with knee osteoarthritis, pain is a disabling symptom. Unlike acute conditions which may cause pain, OA is typically associated with chronic pain which leads to functional impairment that reduces the ability to participate in activities socially and recreationally, reduces the ability to perform daily activities and chores, and decreases the ability to work and enjoy life (8).

Pain severity has a well-known association with the degree of functional limitation. Creamer et al. noted that in patients with knee OA, the severity of pain has a bigger impact on functional status than the severity of radiographic changes (10). In 2016, Onsare found that among 177 patients at Moi Teaching and Referral Hospital with OA 93.84% presented with worsening pain, and 92.66% presented with functional limitation concluding that severe pain and functional limitation were among the most salient clinical characteristics seen in patients with OA (11).

In Kenya, the knowledge of pain control and functional status in knee OA is lacking despite studies being done on characterizing patients with osteoarthritis. Without such information, the burden of pain on patients with symptomatic knee OA cannot be fully appreciated.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Osteoarthritis (OA) is a disabling joint disease that involves structural changes to a joint. These changes occur in the articular cartilage, the bone, the ligaments, the synovial membrane, the joint capsule, and the periarticular muscles.

It is the most common degenerative joint disorder and is classified into either Primary (Idiopathic) or Secondary OA. Increasing age, obesity, and genetics are the most important risk factors in developing primary OA despite there being no identifiable cause. Secondary OA is attributed to recognized risk factors such as joint trauma, anatomic joint variants causing asymmetrical joint stress such as varus/valgus alignment & congenital acetabular dysplasia, & underlying conditions such as avascular necrosis, and Ehlers-Danlos syndrome to name a few. Secondary OA should be suspected in patients with atypical joint involvement (ankle joints, MCP joints) and early-onset OA (12).

Cartilage is the primary target in the pathophysiologic mechanisms of OA. Acute traumatic injury or chronic mechanical stress on the joints in addition to an age-related decrease in proteoglycans leads to cartilage loss and a decrease in its elasticity. This leads to degeneration and inflammation of cartilage mediated by pro-inflammatory cytokines and proteases including matrix metalloproteinases (MMPs). OA cartilage is characterized by the depletion of aggrecans, the unfurling of the tight woven collagen matrix, and the loss of type 2 collagen. This subsequently leads to joint space narrowing and subchondral sclerosis (13).

Knee OA contributes to 60.9 % of the total years lived with disability (YLD), compared to hand and hip OA which both contributed to 29% of the total YLD combined (14). A large meta-analysis of 9,440,250 participants from 34 countries noted that the global prevalence of knee OA in patients above the age of 15 years was estimated to be 16.0% and 22.9% in those aged above 40 years (6). The meta-analysis pooled data from 88 studies. Only one African study in the city of Douera in Algeria was included in this analysis due to the scarcity of African data. This study noted the incidence of knee OA to be at 21% among 400 participants (15).

Despite limited epidemiological data, knee OA is the commonest cause of arthritis in Africa. A large number of patients present later with rheumatic disease due to numerous factors including poor and limited resources, lack of education, religious and cultural beliefs, and the few numbers of rheumatology specialists which leads to delayed specialist care. Therefore the burden is probably greater in Africa (3,4).

Usenbo et al. echoed this in their systematic review and concluded that prevalence data of arthritis is lacking in Africa (5). 3 hospital-based African studies reported on the prevalence of knee osteoarthritis. In Burkina Faso, the prevalence among HIV-infected adult patients was 0.5% (16). A study in Tunisia reported a prevalence of 4.7% in 86 healthcare centers (17) and finally, in Cameroon, a descriptive study at two rheumatology centers noted that among 1,496 patients with musculoskeletal complaints, 9.9% were confirmed to have knee OA (18).

Locally, at The Kenyatta National Hospital, knee Osteoarthritis was the most common form of OA at the rheumatology and orthopedic clinics, accounting for 77% of cases among 201 patients with the knee (77%), hip (15%), hand (3%) and combined knee and hip (5%) osteoarthritis (7).

These studies show the huge global burden of disease in OA and knee OA. Few studies have been done regionally and locally to illustrate the rheumatologic spectrum of OA and this would include pain control and functional status of patients with knee osteoarthritis.

2.2 Pain experience in Knee Osteoarthritis

Pain is a debilitating symptom experienced by all patients with knee OA and is the main reason for hospital visits. Joint pain, stiffness, and movement limitation are the primary symptoms. Disease progression is slow and results in joint failure and disability (19).

OA is characterized by chronic pain. The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." (20). Biological, psychological, and social factors influence how one feels pain making it a subjective and complex feeling. (8).

Local inflammation is the main factor contributing to pain in OA. This pain is typically described as nociceptive, however, there is a suggestion that neuropathic pain also contributes to the pain experience (21). The mechanism is unknown but chronic stimulation of neurons transmitting pain may lead to a sensitization referred to as " central sensitization". (22). The quality and intensity of OA pain vary widely. Patients with knee OA use terms such as tingling, burning, and pins and needles to describe their pain. Although no specific nerve lesion has been identified in knee OA, these descriptors indicate that neuropathic mechanisms contribute to the pain experienced (23).

Qualitatively, there are two forms of pain – a dull pain that persists and a more sudden, intense, and short-lived pain that is intermittent. This was described by Hawker et al in 2008 where the pain experience of 143 participants (91 knee OA; 52 hip OA) aged 40 years and over was obtained using a patient-generated index. Intense intermittent pain had the biggest influence on their quality of life (24).

The etiology of pain is multifactorial, and the experience is multidimensional with a complex relationship between these factors and the subjective pain experience. Genetic predisposition (25), prior experience (26,27), analgesia used, societal and cultural beliefs and expectations, general mood, and, coping ability are some of the factors which contribute to an individual's pain experience and may be difficult to ascertain in a study. This is why assessing the adequacy of pain control and the functional status will help in understanding the overall experience of these patients (8).

2.3 Impact of OA-related pain and its burden on disease

OA-related pain plays a wide role in determining the functional status and disability of a person which has implications for their quality of life.

Osteoarthritis is the 15th highest cause of years lived with disability (YLDs) worldwide and 37th in disability-adjusted life-years (DALYs) according to the Global Burden of Disease study in 2019 (2).

In the United States, arthritis is among the top three causes of disability in adults. Difficulty in walking and climbing stairs are among the most common limitations. Adults with arthritis are up to 2.5 times more likely to have a fall and sustain an injury than adults without arthritis (28,29).

Pain and stiffness and their degree of severity have a well-documented association with the degree of functional limitation. Higher pain severity, older age, and obesity are associated with poorer functional outcomes. This association was stronger than radiographic severity (30). A similar study of 69 outpatients with symptomatic knee OA noted that pain and obesity are more associated with functional outcomes than radiographic changes (10). These studies illustrate that generic factors such as age, body mass index, and pain severity are better predictors of functional difficulties rather than radiographic disease severity.

Based on NHANES III data, about 80% of individuals with OA have some limitation in movement, 25% are unable to perform daily activities, and 25% require assistance with their care and needs (31).

Patients with symptomatic knee OA have a higher degree of movement limitation than those who are asymptomatic (32,33). Movement outside the house is significantly hindered by the severity of knee pain and is also associated with the ease of access to public transportation (34). Additionally, greater knee pain has been shown to reduce the amount of time spent performing a moderate-intensity physical activity such as brisk walking but less so on performing a light physical activity such as pushing a supermarket cart. The pain, therefore, dictates how fast or slow one performs an activity. Adequate pain control is fundamental in improving a patient's movement (35).

OA also affects the workforce of populations. There is an increased rate of absenteeism from work in patients with osteoarthritis at a significant economic cost (36). In Sweden, a study noted there is a higher rate of sick leave and a higher rate of disability pension in patients with osteoarthritis of the knee than in the general population (37). Additionally, a systematic literature review by Bieleman et al. noted reduced work participation by patients with OA. Despite experiencing difficulties with work many patients with OA cope with it (38).

There is also a significant economic impact with medical costs of osteoarthritis contributing up to 2.5% of the national gross domestic product in the US. This is because of the high cost of total knee joint replacement (1).

Treatment modalities are guided by the ACR. The 2019 guidelines have divided treatment recommendations into non-pharmacological methods such as physical, psychosocial, and, mind-body approaches and pharmacological methods which include the use of topical, oral, or intraarticular drugs (39).

In knee OA, exercise either land-based or aquatic, weight loss, and tai chi are recommended. Use of devices such as tibiofemoral knee braces and canes are also utilized for patients who have significantly impacted mobility and have reduced joint stability and increased pain. Pharmacologically, topical and oral NSAIDs are strongly recommended in the management of patients with KOA. Topical therapy should always be considered before oral therapy to reduce the systemic effects of oral therapy, however, oral NSAIDs remain the mainstay of treatment (39).

Intraarticular glucocorticoids are also strongly recommended in the treatment of KOA and are the only intraarticular drugs recommended as opposed to other therapies such as stem cell injections, intraarticular hyaluronic acid, and platelet-rich plasma. The use of intraarticular botulinum and tumor necrosis factor, interleukin-1 inhibitors are not recommended for the management of knee OA patients (39).

There are multiple published guidelines for the management of knee OA including the OARSI (Osteoarthritis Research Society International) 2019 and the AAOS (American Academy of Orthopedic Surgeons) 2021 guidelines. Generally, they agree but with a few key differences.

OARSI guidelines provide a framework for considering treatment options based on co-morbidity profiles while the AAOS guidelines provide recommendations for arthroscopic surgery (40,41).

Despite the numerous available treatment modalities, treatment should be tailored to an individual. In some cases, there may still be inadequate symptom control as there is no definitive disease-modifying therapy for OA. For this reason, total knee arthroplasty remains the only definitive therapy.

In 2008, OA was the 5th costliest condition to treat in the United States (US) due to hospitalization, accounting for close to $40 billion. Many of these hospitalizations were due to knee replacement surgeries. In the US, knee replacement surgeries are commonly performed, and the number of surgeries is expected to rise by more than 600% by 2030. This will only add to the current costs due to increased healthcare utilization (42).

In Africa, Davies et al. conducted a systematic review of total joint replacements, which was the first of its kind regionally, OA was noted to be the main indication for 763 total knee replacements from 12 papers (9).

A study by Onsare, J.N. to characterize OA patients at Moi Teaching and Referral Hospital in Eldoret, Kenya, noted that 92.66% of 177 participants reported functional limitation with 93.8% presenting because of worsening pain (11). Meanwhile, in Nairobi at the Kenyatta National Hospital, depression was prevalent in patients with knee and hip OA (KHOA). Among 164 patients, 17.1% were noted to have depression with a strong correlation to disease severity (43). This shows that despite little data there is a relatively high burden of OA in our society.

The societal and financial burden of OA is undeniable and adequate pain control should play a key role in reducing this burden, be it by reducing outpatient visits, reducing the number of knee replacement surgeries, reducing physical disability, or enabling patients with symptomatic knee OA to cope with symptoms such as pain and stiffness better.

2.4 Adequacy of pain control

Pain control can be adequate or inadequate while pain severity influences the functional status of patients with knee OA. A European study called a survey of osteoarthritis real-world therapies (SORT) enrolled 1,260 participants across 6 European countries and found that 54% of the cohort (558 of 1025) had inadequate pain relief (44).

In Spain, a retrospective study analyzed data of patients with OA from their electronic medical records database. More than half of patients with moderate-severe pain (56% or 16,748 out of 29,886) were reported to be inadequately treated (45).

In Africa, the importance of arthritis and rheumatic disease, in general, is lower than that of communicable diseases. Medical research is therefore minimal and the data available does not paint a true picture of the burden of these diseases (46).

Some studies have been done in Africa to characterize and assess pain in different patient populations and diseases. In Madagascar, a study on the epidemiology of joint pain noted that 32% of 400 patients had inflammatory-type pain caused mainly by Osteoarthritis (40.9%). The pain severity of these patients on average was moderate. They concluded that "It may be useful to do similar studies of joint pains in different situations in Africa to determine their causes and the frequency of various methods of pain management." (47). In Ghana, among 204 ambulatory oncology patients, pain management was adequate but there was a tendency towards opioid tolerance (48). Pain prevalence was also noted to be high among 100 HIV-infected patients in South Africa with only 34% having adequate pain control (49).

At Kenyatta National Hospital, a study by Mukopi, L (2018) evaluated pain control in 115 patients with rheumatoid arthritis concluding that pain was generally inadequately controlled (50) while an older study by Wanjuki J (2013) noted that among 520 ambulatory cancer patients, cancer pain was prevalent (38.5%) and its management was insufficient (51).

There is no objective way to measure pain the way we measure vital signs as the pain response of individuals is a conscious subjective experience that may be difficult to objectify. The best way to measure pain is by using tools that inquire about a patient's pain experience and how it affects their daily lives.

The pain experienced in knee OA is multidimensional and therefore should be assessed this way. Multidimensional scales are preferred over visual analog scales as they measure pain intensity, location and nature of pain, and its effect on patients' moods and activities. Among such available tools, the Brief Pain Inventory is the most reliable and commonly used (52).

The Brief Pain Inventory (BPI) was used in all the aforementioned studies to assess pain and its severity and how it affects daily activities. The important areas of assessment in this tool are the pain a patient felt over the last 24 hours and how much pain there is on average. It also questions how much pain impacts daily functions. The questionnaire is easy to use and takes 5 to 7 minutes to fill. The Cronbach alpha reliability coefficient ranges from 0.77 to 0.91 and a coefficient of more than 0.7 is considered reliable (53,54). A systematic review of the Brief Pain Inventory – Short Form (BPI-SF) by MacDermid et al. noted that the tool is valid and reliable, even more so than the Revised Short-Form McGill Pain Questionnaire (55).

In addition to assessing pain, the physical disability associated with symptoms of knee OA needs to be assessed. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a relevant tool used to measure function in symptomatic knee OA (56,57). McConnell et al. noted in their systematic review that "the reliability, validity, and responsiveness of the pain and physical function subscales of the WOMAC have been demonstrated in a range of patient groups and interventions." (56)

In 2014, a systematic review of the tool which included 76 studies from 22 countries was first published. It noted that the WOMAC is valid and reliable and the function scale has an excellent reliability coefficient of more than 0.9 (58). Locally, the WOMAC was used successfully in a study by Ochieng in the Department of Surgery to assess the functional outcome of patients who underwent surgical correction of femoral neck fractures (59).

2.5 Study Justification

Inadequate pain control and poor functional status of patients with knee OA increase the disease burden on this patient population. Therefore, there is a need to collect local data that will provide healthcare professionals with a better understanding of the burden of pain in knee OA (3). This burden may be more pronounced in our local hospitals where patients tend to present later in the disease stage (3).

Most of the African and local studies have focused on characterizing patterns of patients with Osteoarthritis and their associated sociodemographic factors and risk factors. This study, therefore, aimed to understand the pain control and functional status of patients with knee osteoarthritis. This may be used to aid the implementation of effective management plans for this patient population as better management begins with the assessment of pain and functional status.

2.6 Research Question

What is the burden of pain in patients with knee osteoarthritis?

2.7 Objectives

2.7.1 Broad Objective

To assess pain control and the level of function in patients with knee osteoarthritis attending the orthopedic and rheumatology clinics at the Kenyatta National Hospital.

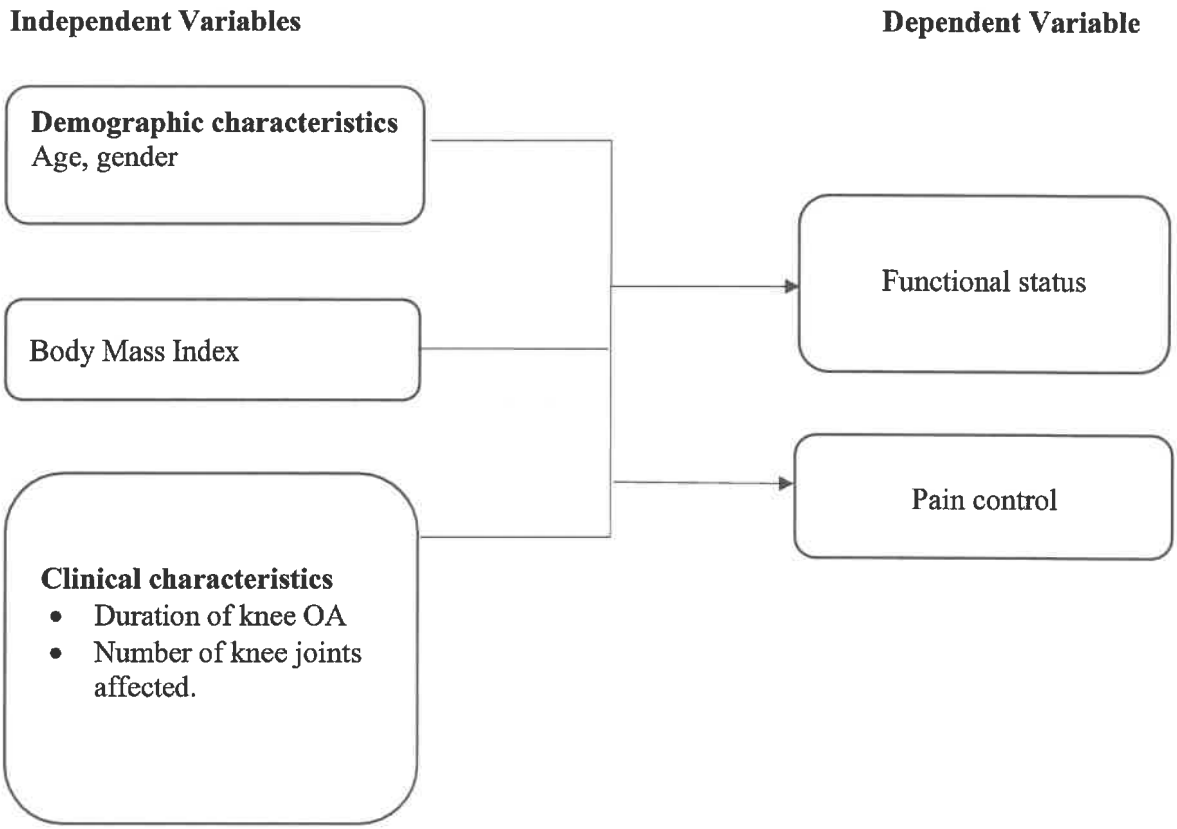
2.7.2 Specific Objectives

1. To determine the adequacy of pain control in patients with knee osteoarthritis.
2. To determine the functional status in patients with knee osteoarthritis.

2.7.3 Secondary Objectives

1. To determine the association between pain control and the functional status of patients with knee osteoarthritis.
2. To document patient-related factors that are associated with inadequate pain control in knee osteoarthritis patients.

2.8 Conceptual Framework



CHAPTER 3: METHODOLOGY

3.1 Study design

This was a cross-sectional descriptive study of pain control and level of function in patients with osteoarthritis of the knee attending the orthopedic and rheumatology clinics at Kenyatta National Hospital.

3.2 Study site

The location of the research was the Kenyatta National Hospital. It is a large referral hospital with 1800 beds located in Nairobi, Kenya. It has 22 specialist clinics. The study was carried out at the rheumatology and orthopedic clinics which offer outpatient services to osteoarthritis patients. The rheumatology clinic occurred twice weekly on Tuesday and Thursday at 14:00 hrs and approximately 20 patients with osteoarthritis were seen weekly. The orthopedic ran thrice weekly on Monday, Wednesday, and Friday mornings. Approximately 50 patients were seen weekly.

3.3 Study population

The study included adult patients with a documented diagnosis of knee osteoarthritis per the ACR criteria who are on treatment and follow-up at the orthopedic and rheumatology clinics at the Kenyatta National Hospital.

3.3.1 Inclusion criteria

The study included the following:

- Adults above the age of 18 with knee osteoarthritis (unilateral or bilateral) who are on treatment and follow-up and give informed consent.

3.3.2 Exclusion criteria

The study excluded the following:

- Patients with other forms of arthritis such as rheumatoid arthritis, septic arthritis, gouty arthritis, lupus arthritis, and, ankylosing spondylitis.
- Patients with knee osteoarthritis who are asymptomatic.
- Patients with hand or hip osteoarthritis.
- Patients with a history of total knee joint replacement.

3.4 Sampling

3.4.1 Sample size calculation

According to the medical records estimates at KNH, approximately 750 patients are on follow-up for knee osteoarthritis in the rheumatology and orthopedic clinics. A representative sample was drawn from this finite population and the sample size was determined as follows:

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

Where,

n = sample size

N = size of the target population = 750

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion achieving adequate control of pain = 50% (This is based on the SORT study in Europe which noted more than half of patients in their survey had inadequate pain control (44).)

d = margin of error = 5%

$$n = \frac{750 \times 1.96^2 \times 0.5 \times 0.5}{0.05^2 (750-1) + 1.96^2 \times 0.5 \times 0.5}$$

n = 270

Data from at least 270 participants were analyzed to determine the adequacy of pain control and functional status within a 5% level of precision.

3.4.2 Sampling technique

Participants for this study were recruited by using consecutive sampling. The principal investigator and two trained research assistants (two registered clinical officers) attended the rheumatology and orthopedic clinics on their respective clinic days and identified patients with knee osteoarthritis using the medical files. Patients that met the inclusion criteria were approached in order of time of arrival and were asked to take part in the study. Those who gave consent were recruited into the study. This process was repeated on each clinic day until the desired sample size was reached.

3.5 Participant recruitment

All patients with knee osteoarthritis attending the clinics who fit the inclusion criteria were offered participation in the study. The study purpose and process were explained to those who accepted to participate and were requested to sign an informed consent. Data were collected thereafter.

3.6 Data collection

Patient demographics were documented using a data collection sheet. Anthropometric measurements were then taken to determine the participants' BMI. A standard digital weighing scale was used to measure the patients' weights in kilograms to the nearest 0.1 kilograms. A stadiometer was used to measure the patients' heights in centimeters to the nearest 0.5 centimeters. This data was then recorded on the respective patients' collection sheets.

Data on pain control and functional status was collected using questionnaires. The Brief Pain Inventory – Short Form and the WOMAC Index were used to inquire about pain and functional status respectively. The questionnaires were interviewer administered. Tags were placed on the patients' files to indicate the date on which the patient was seen to avoid duplicate sampling.

3.7 Study Instruments

A data collection sheet was used to document patient details and characteristics including their age, sex, BMI, duration of illness, and the number of knee joints affected. Structured questionnaires including the BPI and WOMAC were then used to interview the patients.

3.7.1 Brief Pain Inventory

The BPI-SF (short form) (APPENDIX V: BRIEF PAIN INVENTORY-SHORT FORM (BPI-SF) is a popular tool to assess pain in diverse clinical conditions. It was initially created to assess pain in cancer patients but its use has extended to other conditions including musculoskeletal disorders such as osteoarthritis. It questions the degree of pain a patient feels by using a numeric pain rating scale and to what level this pain interferes with one's feelings and function. The level of pain in the last 24 hours, at the time of review, and on average is assessed. Additionally, seven interference items are used to enquire how the pain interferes with daily activities. Pain is scored from 0-10 with 0 meaning no pain, 1-3 indicating mild pain, 4-7 indicating moderate pain, and 8 and above indicating severe pain.

In this study, a score of 4 or more in question number 5 (pain on average) denoted inadequately controlled pain. This is extrapolated from the European SORT study (44). The pain control was

further classified into mild, moderate, or severe depending on the pain score. It took 5-7 minutes to fill and was interviewer-administered.

3.7.2 WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)

The WOMAC (APPENDIX VI: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)) is a tool used to measure physical function and disability in patients with knee osteoarthritis. It is an outcome measure of treatment intervention and may be self-administered or interviewer-administered.

The questionnaire is divided into three sections with a total of 24 questions assessing physical function, pain, and stiffness respectively. The Likert version rates each question from 0 to 4 with a score of 0 indicating no pain or no difficulty performing a function and a score of 4 indicating extreme pain or difficulty in performing a function. The scores of each of the three sections were added to produce a global score (WOMAC Index). The score range of the WOMAC Index is 0-96. A higher score indicated poorer physical function and increased disability and a lower score was vice-versa (60). For this study, the score was divided into three categories, 0-32 indicating mild physical impairment, 32-64 denoting moderate physical impairment, and 64-96 indicating severe physical impairment. This is because there is no fixed way to analyze the scores apart from a higher score indicating a worse function.

It took 10-15 minutes to fill in. It has been used in several clinical trials and more than 1000 peer-reviewed articles and is valid and reliable though has not been validated in an African population. The physical function scale has excellent reliability with a coefficient alpha of more than 0.9 (58). This is an open-source tool that was used with permission via email from womac.com.

3.7.3 Translated Study Instruments Measure of Reliability

The BPI-SF and WOMAC were translated into Kiswahili after obtaining consent from the copyright owners. Despite their validity and reliability in several different languages, no reliability testing and validation have been done in Kiswahili. Based on suggestions by Connelly et al., a pilot study consisting of 10% (27 patients) of the total sample size was conducted after

approval to conduct the research. This was to test the reliability of the translated tools. Reliability was defined as a Cronbach's alpha coefficient of >0.70 (54,61,62). The Cronbach alpha coefficient of the BPI-SF and WOMAC scored 0.71 and 0.75 respectively.

3.7.4 Translated Study Instruments Measure of Validity

The translated questionnaires were presented to the supervisors for expert opinion and review. Back translation was also done by the translator to ensure the validity of the translated study instruments.

3.8 Case definition

An adult patient with a known diagnosis of knee osteoarthritis as per the ACR criteria attended the orthopedic and rheumatology clinics during the study period.

3.9 Definition of study variables

3.9.1 Dependent variable

The main outcome measures of this study were pain control and functional status. Pain control was assessed using the BPI-SF. A score of >4 in item number 5 of BPI which asks "what is your pain on average?" defined inadequate pain control as this score is indicative of moderate-severe pain. This is adapted from the European SORT study (44). Functional status was assessed using the WOMAC index. A higher total score (WOMAC Index) defined poorer physical function and increased disability.

3.9.2 Independent variables

The sociodemographic variables included age in years and gender (male or female). The behavioral and anthropometric variables included smoking status (Yes/No) and the body mass index calculated by dividing weight in kilograms with height in meters squared. BMI was classified as below 18.5 as underweight, between 18.5 and 24 as normal, above 24 as overweight, and 30 as obese.

The clinical variables in this study were the duration of diagnosis of KOA and the number of knee joints affected (unilateral or bilateral).

3.10 Quality Assurance

The BPI questionnaire has been used worldwide and has also been used previously in a study evaluating pain at KNH. It is available in several different languages and has been linguistically validated and remained reliable. The WOMAC is a popular tool that has been used all over the world in several clinical trials and numerous peer-reviewed articles. It has been translated into more than 80 languages and has maintained reliability. These tools are user-friendly and took a relatively short time to fill and this minimized errors. The study assistants were taught how to approach participants, how to take informed consent, and how to store the data collected. The study assistants were also appropriately trained in how to administer the tools. No open-ended questions were used and the questions were asked exactly as they were stated in the questionnaires.

3.11 Data Management

A Microsoft Excel datasheet was used to code and enter data. Data were cleaned during data entry. SPSS 23.0 statistical software was used for data analysis. The study population was summarized into percentages and means or medians for categorical and continuous data respectively. Pain control was analyzed and presented as the percentage of patients achieving adequate pain control. The pain was divided into mild, moderate, and severe based on the pain score. Any patient reporting a pain score >4 indicating moderate (4-7) or severe pain (>8) was classified as having inadequate pain control.

Similarly, the functional status of the patients was analyzed and presented using percentages. Functional impairment was reported as mild (0-32), moderate (32-64), or severe (64-96) depending on the WOMAC score (0-96). Pain control was associated with functional status using the ANOVA (Analysis of Variance) test as more than 2 groups of means were being associated. The ANOVA test was also used to associate age with pain severity. The chi-squared test was used to associate the other patient-related factors (categorical variables) with pain severity. The median duration of knee OA was associated with pain severity using the Kruskal-Wallis test. A 5% level of significance was used to interpret all the statistical tests ($p<0.05$).

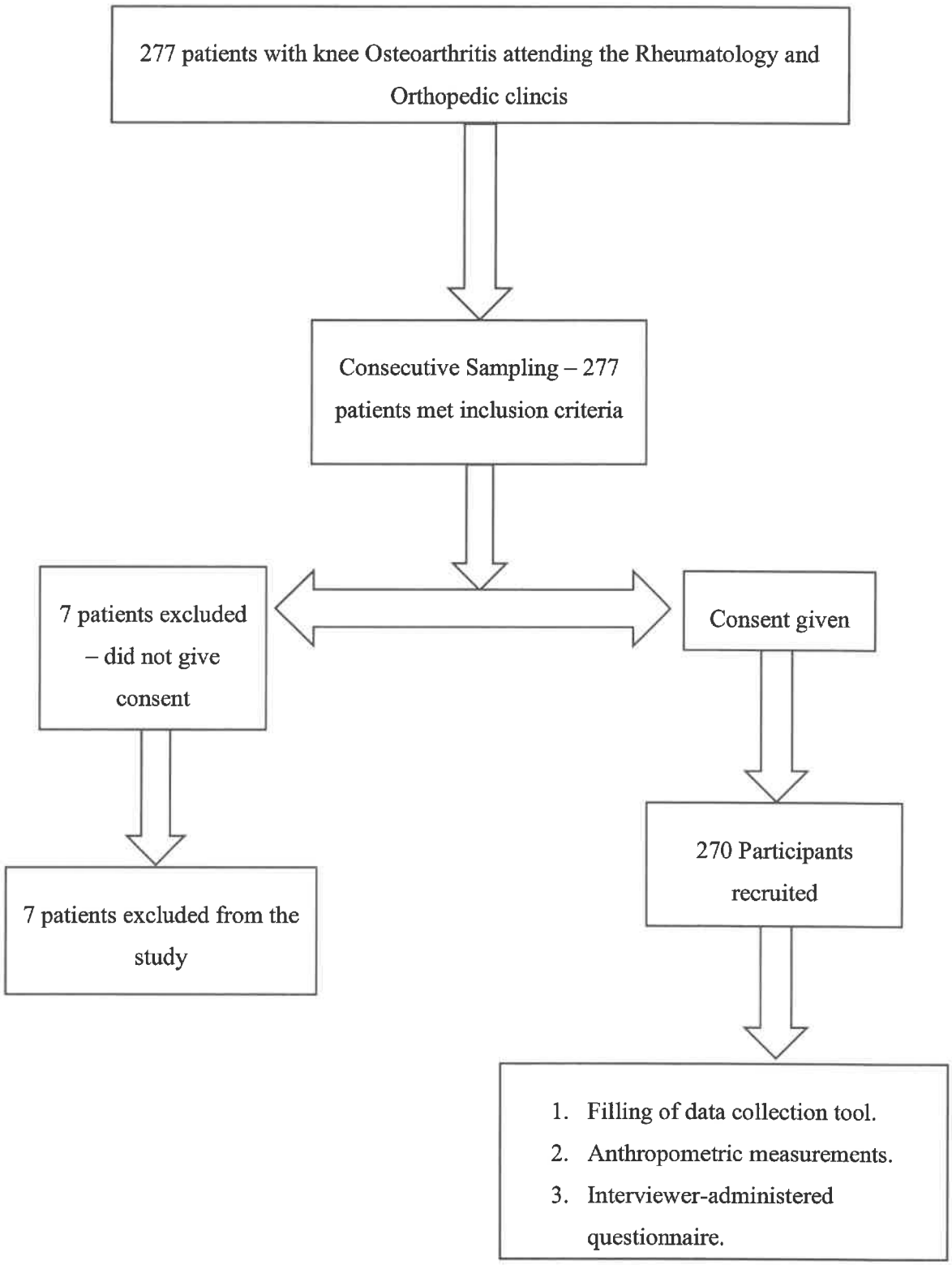
3.12 Ethical Considerations

Approval was granted from the KNH and UON Institutional Research Ethics Committee. The Declaration of Helsinki was followed to protect the rights of the participants.

The participants were given full information about the purpose of the study and the potential risks and benefits. All queries were welcomed and answered. This ensured that the participants had a detailed picture of the study before giving consent.

The study did not interfere with or delay patient care. Data collected were anonymized and stored in files that were only accessible by the research team using a password. There was no other use of the data collected except for the purposes set out in the protocol.

Figure 1 Flow chart of participant recruitment into the study



CHAPTER 4: RESULTS

The study was carried out at the Orthopedic and Rheumatology clinics at the Kenyatta National Hospital between May and June of 2022. A total of 277 patients were approached to participate in the study. 7 patients did not give consent and were excluded therefore 270 participants were recruited into the study.

4.1 Sociodemographic and Clinical Characteristics

Among the 270 patients recruited into the study, 139 (51.5%) were females and 131 (48.5%) were males, The mean age of the study population was 55.1 years with a standard deviation of 13.7. Sixty-five (24.1 %) participants are cigarette smokers - Table 1.

The majority of the patients were overweight (n= 134, 49.6%) with a smaller number (n=27, 10%) being obese. The median duration of osteoarthritis diagnosis was 48 months. Furthermore, a larger number of patients had osteoarthritis of both knees (n= 172, 63.7%) compared to those with one knee affected (n= 98, 36.3%) - Table 1.

Table 1 Sociodemographic and Clinical Characteristics

Variable	n=270
Age in years	
Mean (SD)	55.1 (13.7)
Min-max	18.0-83.0
Gender, n (%)	
Male	131 (48.5)
Female	139 (51.5)
Height (cm)	
Mean (SD)	162.5 (9.1)
Min-max	141-182
Weight (kg)	
Mean (SD)	67.9 (6.5)
Min-max	48.0-90.0
Body mass index (BMI), n (%)	
Underweight (<18)	2 (0.7)
Normal (18-24)	107 (39.6)
Overweight (>24)	134 (49.6)
Obese (>30)	27 (10.0)
Cigarette smoking, n (%)	
Yes	65 (24.1)
No	205 (75.9)
Duration of OA (in months)	
Median (IQR)	48.0 (12.0-72.0)
Min-max	1.0-360.0
Osteoarthritis of both knees, n (%)	
Yes	172 (63.7)
No	98 (36.3)

4.2 Adequacy of Pain Control

The majority of patients (n=173, 64.1%) experienced moderate pain on average (pain score 4-7) with a lesser number (n=92, 34.1%) experiencing severe pain (pain score >8). This meant that most of the patient population had inadequate pain control as their average pain score was >4 (n=265, 98.1%) - Table 2, Figure 2.

As depicted in Figure 3Figure 3, when exploring the patients' pain experience over the previous 24 hours before the interview, it was noted that most of the patients (n= 236, 87.4%) were experiencing severe pain (pain score >8) rather than moderate pain (pain score 4-7; n= 151, 55.9%) or mild pain (pain score 1-3; n=64, 23.7%). Meanwhile, at the time of the interview (pain right now), the majority of patients were experiencing moderate-severe pain with only 4 patients (1.5%) reporting mild pain. None of the participants reported no pain (pain score -0).

Table 2 Adequacy of Pain Control

Variable	**Frequency, n -270 (%)**
Rating of pain on the average (Average pain score)	
Adequate pain control (<4)	5 (1.9)
Inadequate pain control (>4)	265 (98.1)
Rating of pain on the average (Average pain score)	
No pain (0)	0
Mild pain (1-3)	5 (1.9)
Moderate pain (4-7)	173 (64.1)
Severe pain (>8)	92 (34.1)
Rating of pain at its worst in the last 24 hours (Pain score)	
No pain	0
Mild pain (1-3)	1 (0.4)
Moderate pain (4-7)	33 (12.2)
Severe pain (>8)	236 (87.4)
Rating of pain at its least in the last 24 hours (Pain score)	
No pain	0
Mild pain (1-3)	55 (20.4)
Moderate pain (4-7)	151 (55.9)
Severe pain (>8)	64 (23.7)
Rating of pain right now (Pain score)	
No pain	0
Mild pain (1-3)	4 (1.5)
Moderate pain (4-7)	140 (51.9)
Severe pain (>8)	126 (46.7)

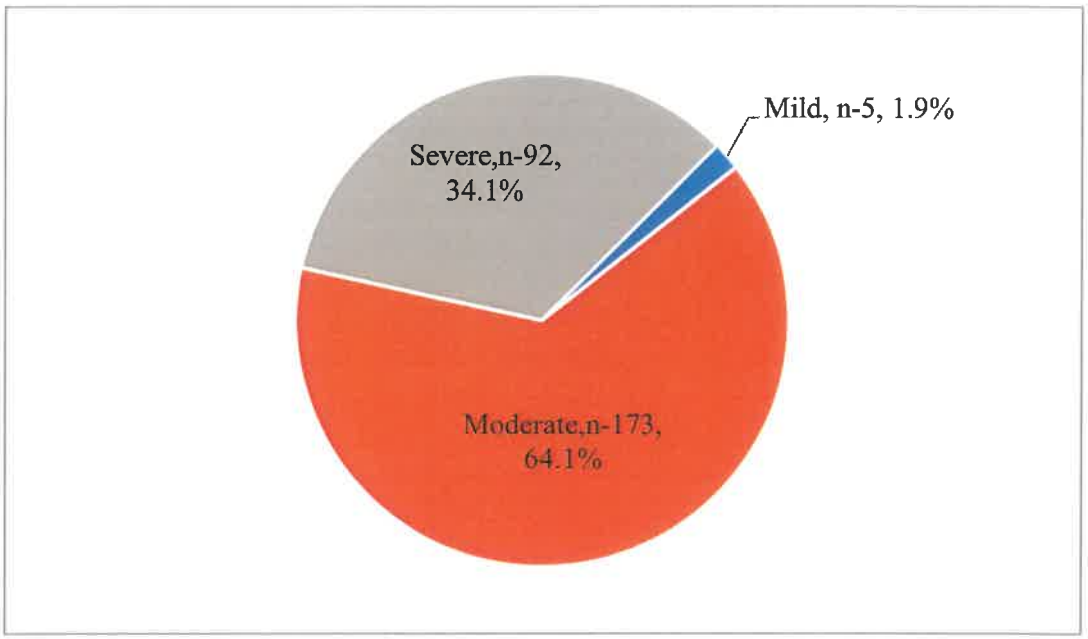


Figure 2 Pie Chart: Pain severity on average

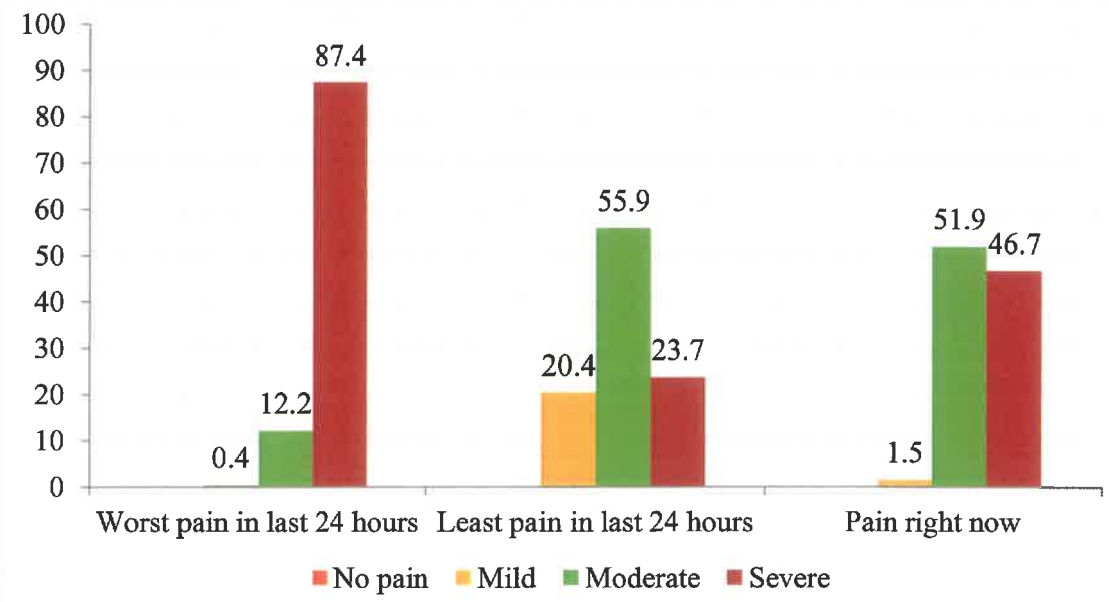


Figure 3 Pain in the last 24 hours

4.3 Pain interference in the past 24 hours

263 (97.4%) patients complained that pain interfered with general activity while 234 patients (86.7%) reported pain interfering with their walking ability. Normal work was affected in 232 patients (85.9%). This translated to a large number of patients (n=214, 79.3%) reporting that pain interfered with their general enjoyment of life - Table 3.

Fewer number of patients reported that pain interfered with relationships with other people (n=88, 32.6%), sleep (n=134, 49.6%), and mood (n=139, 51.5%).

Table 3 Pain Interference

Variable	**Number of patients (%) n-270**
General activity	
Interfered	263 (97.4)
Did not interfere	7 (2.6)
Mood	
Interfered	139 (51.5)
Did not interfere	131 (48.5)
Walking ability	
Interfered	234 (86.7)
Did not interfere	36 (13.3)
Normal work	
Interfered	232 (85.9)
Did not interfere	38 (14.1)
Relations with other people	
Interfered	88 (32.6)
Did not interfere	182 (67.4)
Sleep	
Interfered	134 (49.6)
Did not interfere	136 (50.4)
Enjoyment of life	
Interfered	214 (79.3)
Did not interfere	56 (20.7)

4.4 Functional Status

The mean WOMAC score was 46.8 with a standard deviation of 12.6 - Table 4.

Only 11 patients (4.1%) reported no to mild functional impairment (Womac score 0-32) while the remainder of the patients were classified as having either a moderate or severe functional impairment. 131 patients (48.5%) scored between 32-64 on the WOMAC score signifying moderate functional impairment and 128 patients (47.4%) scored between 64 and 96 on the WOMAC score indicating severe functional impairment - **Error! Reference source not found.**.

Table 4 Functional Status

Variable	**Frequency**
Functional status	
Mean (SD)	46.6 (12.6)
Category, (Womac Score)	**n-270 (%)**
No to mild functional impairment (0-32)	11 (4.1)
Moderate impairment (32-64)	131 (48.5)
Severe impairment (64-96)	128 (47.4)

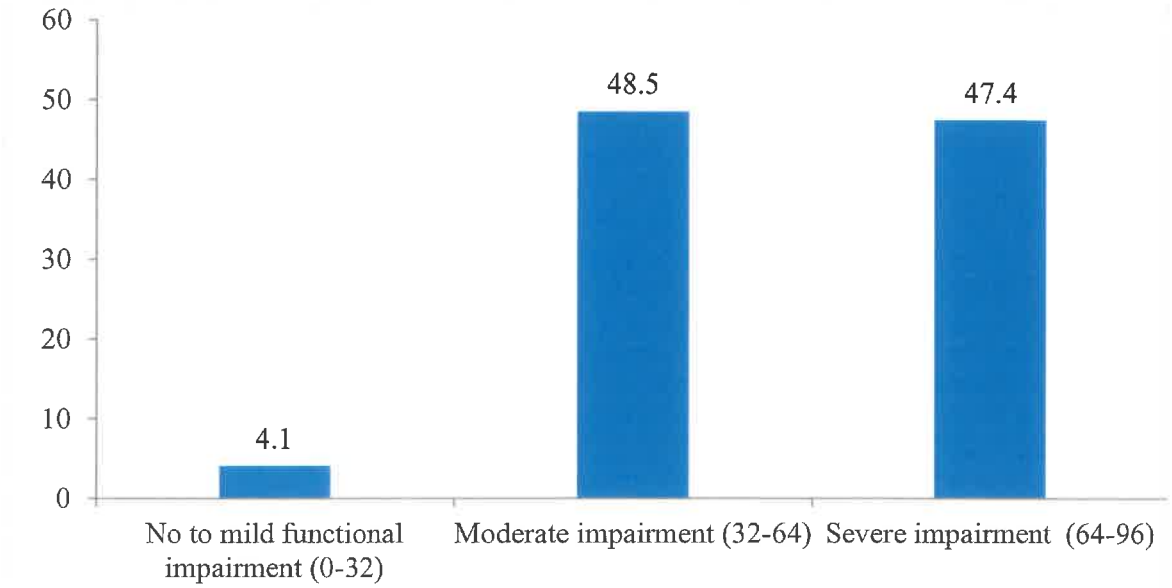


Figure 4 Functional Impairment

4.5 Association between pain control and functional status

Severe pain was associated with a higher WOMAC score indicating poorer functional status in these patients. The mean WOMAC score increased with increasing pain severity (mild – 38.6, moderate – 45.5, severe - 49.2). Therefore those with inadequate pain control (moderate pain or higher) had a worse functional status. This was statistically significant with a p-value of 0.026 (<0.05) - Table 5.Table 5 - Association of pain control and functional status

Additionally, the degree of functional impairment decreased with decreasing pain severity. The proportion of patients with severe functional impairment (63%) was much higher in those with severe pain compared to those with moderate pain (39.9%) (p-value – 0.003) - Table 5.

Table 5 - Association of pain control and functional status

Variable	**Pain severity**			**P value**
	Severe	**Moderate**	**Mild**	
Mean WOMAC score (SD)	49.2 (12.3)	45.5 (12.6)	38.6 (11.0)	**0.026**
Functional impairment (WOMAC score)	n (%)	n (%)	n (%)	
No to mild (0-32)	2 (2.2)	9 (5.2)	0	**0.003**
Moderate (32-64)	32 (34.8)	95 (54.9)	4 (80.0)	
Severe (64-96)	58 (63.0)	69 (39.9)	1 (20.0)	

4.6 Factors associated with pain control

Older patients had poorer pain control as noted in Table 6. The mean age increased with increasing pain severity with those with moderate pain having a mean age of 53.9 years while those with severe pain had a higher mean age of 57.9 years. A younger population (mean age - 46.8 years) experienced milder pain. This association was significant with a p-value of 0.029 ($p<0.05$).

A higher proportion of patients with severe pain were female (58.7%) and overweight (52.2%) compared to those with moderate pain though this association was insignificant. Patients with bilateral knee osteoarthritis had poorer pain control with 59.5% of these patients having moderate pain and 71.7% having severe pain. This association was also statistically insignificant - Table 6.

Table 6- Factors associated with inadequate pain control

Variable	**Pain severity**			**P value**
	Severe	**Moderate**	**Mild**	
Age - years				
Mean (SD)	57.9 (13.3)	53.9 (13.7)	46.8 (15.8)	**0.029**
Gender, n (%)				
Male	38 (41.3)	91 (52.6)	2 (40.0)	0.174
Female	54 (58.7)	82 (47.4)	3 (60.0)	
Body mass index (BMI)				
Underweight	1 (1.1)	1 (0.6)	0	0.722
Normal	37 (40.2)	68 (39.3)	2 (40.0)	
Overweight	48 (52.2)	83 (48.0)	3 (60.0)	
Obese	6 (6.5)	21 (12.1)	0	
Cigarette smoking, n (%)				
Yes	16 (17.4)	48 (27.7)	1 (20.0)	0.142
No	76 (82.6)	125 (72.3)	4 (80.0)	
Duration of OA in months				
Median (IQR)	48 (12-78)	48 (16-72)	24 (18-36)	0.582
OA of both knees, n (%)				
Yes	66 (71.7)	103 (59.5)	3 (60.0)	0.121
No	26 (28.3)	70 (40.5)	2 (40.0)	

CHAPTER 5: DISCUSSION

Pain is a disabling symptom and chronic pain affects the majority of patients with knee OA, affecting their ability to move, work and enjoy life. Pain control is an important factor in the level of functional limitation and this study assessed this in the patient population at Kenyatta National Hospital.

There was a slight female preponderance among participants at 51.5%. Onsare J (2016) noted a similar finding in gender distribution in his study in Eldoret at MTRH (11). Worldwide, the female sex is a strong risk factor for developing osteoarthritis (1). The mean age of the patient population was 55.1 years and the majority of the patients were overweight or obese making up 59.6% of the total study population. This is an expected finding as osteoarthritis is more common in patients who are older and overweight or obese (1).

Overweight or obese patients are more likely to develop bilateral knee osteoarthritis (7). Therefore, it is unsurprising that bilateral knee osteoarthritis (63.7%) was more common than unilateral disease (36.3%). The median duration of disease in our patient population was 48 months indicating that these patients had a longer duration of disease. This is expected as the Kenyatta National Hospital is the largest referral hospital in the country and the majority of patients who are seen at the clinics have been referred from lower-level hospitals or clinics.

The study revealed that the burden of pain in these patients is overwhelmingly high with 98.1% of patients reporting inadequate pain control rating their pain at 4 or more on average. A larger number of these patients reported moderate pain (64.1%) than severe pain (34.1%). It is difficult to ascertain why inadequate pain control was largely ubiquitous in the study population. Treatment in knee OA is multi-modal including non-pharmacological, pharmacological, and surgical approaches therefore it was beyond the scope of this study to evaluate the treatment of these patients given the descriptive nature of the study.

Having said this, the findings are comparable with previous studies done locally on pain control in ambulatory cancer patients and patients with rheumatoid arthritis where pain control was found to be largely inadequate (50,51). Notwithstanding the different cohorts of patients, Mukopi L (2018) also assessed the therapy of the patients with rheumatoid arthritis and their treatment

adherence. A low level of medication adherence was a significant contributor to inadequate pain control noted in this study (50).

In Europe, a large study on the survey of osteoarthritis real-world therapies (SORT) across 6 European countries also noted that more than half of their patients (54 %, n-1260) had inadequate pain control (44). The SORT study had a larger number of patients with different sociodemographic backgrounds, so the results of our studies might not be comparable.

General activity, work, and walking ability were all affected by pain. Ninety-seven percent of patients reported interference in their general activity with more than 85 % reporting pain interference in their work and walking ability. Expectedly this was reflected in the general enjoyment of life, with 79.3% of patients reporting that they do not enjoy life because of pain. Though remarkably high, these results are an expected finding based on NHANES III data, which noted that 80% of individuals with OA have some limitation in movement (31). Further scrutiny into why this is the case is required, to improve patients' quality of life. This can be done by conducting further studies into the treatment patterns of knee osteoarthritis and adherence to these treatments and also by enhancing and streamlining access to arthroplasty clinics.

Functional impairment was equally as high at 95.9%. The mean WOMAC score was 46.6 (SD-12.6) with the majority of patients being classified as having moderate (48.5%) or severe (47.4%) functional impairment. This high level of functional disability is not dissimilar to osteoarthritis patients at Moi Teaching and Referral Hospital in Eldoret, Kenya. A study including 177 patients conducted there in 2016 by Onsare J noted that most (92.66%) of the patients had a functional limitation with many patients presenting to the clinics because of worsening pain (93.84%). The patients' sociodemographics were similar to our study with females representing slightly more than half of the study population at 51.16%. However, their patient population was less overweight or obese (39.43%). Furthermore, their patients' main occupation was peasant farming or casual labor, a factor that wasn't assessed in our study (11).

The secondary objectives of this study were to associate functional status and pain control and to document factors that were associated with inadequate pain control.

Patients with inadequate pain control (moderate pain or higher) had a worse functional status. This association was significant with a p-value of 0.026 ($p<0.05$). This finding is expected as there is a known association between the level of pain and functional impairment. Creamer et al. noted that the main factors associated with functional impairment in patients with knee osteoarthritis are pain severity and obesity (10). Furthermore, in a large prospective multinational longitudinal study, Conaghan et al. noted that patients with inadequate pain relief were more likely to have worse quality of life, greater function loss, and greater pain interference (63).

Age was the most important factor associated with inadequate pain control in our study population. Older patients had a higher pain score and therefore had worse pain control (p-0.029). This was the only significant factor contributing to poorer pain control. Despite a higher proportion of patients with bilateral knee osteoarthritis having higher pain scores, this was not a significant factor in pain control. Body mass index, gender, and duration of disease were also not contributing factors to poorer pain control in our study population. This was entirely different from the SORT study which showed a significant association between BMI, duration of disease, and, the proportion of OA of both knees, with inadequate pain control (44).

Overall the burden of pain and disability in the study population was very high and steps need to be taken to improve the quality of lives of patients suffering from knee osteoarthritis. Both non-pharmacological and pharmacological approaches need to be optimized while considering early stratification of patients for surgical intervention as joint replacement is a clinically relevant and cost-effective treatment for end-stage osteoarthritis.

5.1 Conclusion

I. Pain in knee osteoarthritis is inadequately controlled and there is a high level of moderate and severe functional impairment in this patient population which limits their daily activities and affects their general enjoyment of life.
II. Functional impairment is associated with inadequate pain control and older age.

5.2 Recommendations

I. Patient education – to manage expectations, encourage weight management, and encourage activity.
II. Further studies to evaluate the management and assess the therapies of patients with knee osteoarthritis. This will aid in outlining the reasons for such poor pain control and high functional impairment and will help implement improved management.
III. Further studies to evaluate patient and health-care-associated factors that may lead to poor pain control and functional impairment in this patient population.
IV. A comparative study assessing pain in patients with total knee joint replacement and those without.

5.3 Study Limitations

I. This was a single-center, descriptive study which may not depict the true burden of pain in knee osteoarthritis in Kenya.
II. This study did not assess the therapies used for treating patients with knee osteoarthritis at KNH.
III. This study did not assess medication adherence.
IV. Recall bias in recalling their pain or functional experiences.
V. Response bias during interviews.

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APPENDICES

APPENDIX I: PATIENT INFORMATION AND CONSENT FORM

Title of Study: Assessment of pain control and function in patients with knee osteoarthritis attending the rheumatology and orthopedic clinics at the Kenyatta National Hospital.

Principal Investigator and Institutional Affiliation: Dr. Dino Suleiman Yakub / University of Nairobi

Introduction:

My name is Dr. Dino Suleiman. I am a postgraduate student in Internal Medicine at the University of Nairobi. I would like to inform you of a study I am undertaking assessing pain control and function in patients with knee osteoarthritis attending the rheumatology and orthopedic clinics at the Kenyatta National Hospital. The purpose of this study is to assess how well pain is controlled in patients with knee osteoarthritis.

Study procedure:

Participation in the study is of your free will and is voluntary. It will entail the following:

I. Obtaining personal and medical information with the help of questionnaires.
II. Measuring your height and weight to calculate your BMI.

This will take an estimated 25 minutes of your time.

Risks and costs incurred: There will be no delay or interference of care during your clinic visit. Covid-19 protection measures will be in place at all times as per hospital policy. No cost will be incurred by the participant.

Benefits: All the information gained from the above questionnaires and measurements will be put in your file. The results of the study will be shared with the primary care team and if pain control is found to be inadequate, changes in your treatment may be applied to optimize pain control.

Confidentiality: The information collected will be kept confidential. All the records are only accessible via password and only the research team will have access to this information. If this study is published your identity will be kept confidential.

Rights as a participant: Participation in the study is of your free will and is voluntary. Withdrawal from the study can occur at any point during the study. You may choose to terminate your session while answering the questionnaires at any time. There will be no victimization for withdrawal.

Compensation: There will be no monetary compensation for participation in this study.

Contacts:

You may contact the principal investigator for further information or queries:

Dr. Dino Suleiman

Principal Investigator

P.O.Box 34028-80118

Mombasa

Mobile no: 0723213433

Email: sullydino@gmail.com

INFORMED CONSENT

I have read and understood the above information/I am unable to read and have had the above information dictated for me in a language I understand.

I understand that participation in this study is of my free will and is voluntary and there will be no compensation for doing so. I also understand that I have a right to withdraw from the study at any point and refuse to answer questions I am uncomfortable with within the questionnaire.

I understand that my information and data will be kept confidential.

I freely agree to participate in this study and I have not given up any of the legal rights I have as a participant in a research study.

I agree to participate in this research study:

(Tick where appropriate)

YES **NO**

Participant's name: _____ **Signature/ Thumb stamp of participant:**

_____

Date: _____

Principal Investigator's / Research assistant's statement: I have explained all the above to the potential participant clearly and concisely in a language that he/she understands.

Principal Investigator: _____Signature:_____

Research Assistant's name: _____ Signature: _____

Contact us for further queries:

Principal Investigator: Suleiman Yakub Dino. Tel: 0723-213433, email: sullydino@gmail.com

Lead Supervisor: Prof. G.O. Oyoo. Tel: 0722-522359, email: george.oyoo@uonbi.ac.ke

KNH-UoN ERC: Tel: (254-020) 2726300-9 Ext 44355, email: uonknh_erc@uonbi.ac.ke

APPENDIX II: FOMU YA RIDHAA

Jina la Utafiti: Assessment of pain control and function in patients with knee osteoarthritis attending the rheumatology and orthopedic clinics at the Kenyatta National Hospital.

Mpelelezi Mkuu: Dk. Dino Suleiman Yakub wa Chuo Kikuu cha Nairobi

Utangulizi:

Jina langu ni Dk. Dino Suleiman. Mimi ni mwanafunzi aliyehitimu katika Tiba ya ndani katika Chuo Kikuu cha Nairobi. Napenda kukujulisha kuwa ninafanya utafiti juu ya utoshelevu wa udhibiti wa maumivu na athari zake kwa kiwango cha kazi kwa wagonjwa wenye ugonjwa wa goti wanaohudhuria rheumatology na kliniki cha mifupa katika Hospitali ya Kitaifa ya Kenyatta. Madhumuni ya utafiti huu ni kutathmini jinsi maumivu yanavyodhibitiwa kwa wagonjwa wenye ugonjwa wa goti.

Utaratibu wa kusoma:

Ushiriki wako katika utafiti huu ni wa hiari na utajumuisha yafuatayo:

I. Kupata habari yako ya kibinafsi na ya matibabu kwa msaada wa dodoso.

II. Kupima urefu na uzito wako kuhesabu BMI

Hii itachukua wastani wa dakika 25 za wakati wako.

Hatari na gharama: Hakutakuwa na kucheleweshe na kuingiliwa kwa utunzaji wakati wa ziara yako ya kliniki. Hatua za ulinzi wa Covid-19 zitakuwa mahali wakati wote kama sera ya hospitali. Hakuna gharama itakayopatikana na mshiriki.

Faida: Habari yote inayopatikana kutoka kwa dodoso na vipimo hapo juu vitawekwa kwenye faili yako. Matokeo ya utafiti yatashirikiwa na timu ya utunzaji wa msingi na ikiwa udhibiti wa maumivu unapatikana haitoshi, mabadiliko katika matibabu yako yanaweza kutumika kuongeza udhibiti wa maumivu.

Usiri: Habari zote zilizokusanywa kutoka kwako zitahifadhiwa siri. Rekodi zote zitahifadhiwa chini ya ulinzi wa nywila na kupatikana tu na mpelelezi mkuu na wasaidizi wa utafiti. Machapisho yoyote yanayotokana na utafiti huu hayatakujulisha wewe mwenyewe.

Haki kama mshiriki: Ushiriki wako katika utafiti huu ni wa hiari. Unaweza kuchagua kujiondoa kwenye utafiti wakati wowote na kukataa kujibu maswali fulani. Unaweza kuchagua kumaliza kikao chako wakati unajibu dodoso wakati wowote.

Fidia: Washiriki hawatapokea fidia yoyote ya pesa kwa kushiriki katika utafiti huu.

Mawasiliano:

Kwa habari yoyote zaidi au maswali unaweza kuwasiliana na mpelelezi mkuu:

Dk. Dino Suleiman

Mpelelezi Mkuu

P.O.Box 34028-80118

Mombasa

Nambari ya simu: 0723213433

Barua pepe: sullydino@gmail.com

FOMU YA IDHINI

Nimesoma habari hiyo hapo juu au habari hiyo ilinisomea kwa lugha ninayoelewa. Hatari na faida zimefafanuliwa kwangu wazi.

Ninaelewa kuwa kushiriki katika utafiti huu ni kwa hiari na hakutakuwa na fidia kwa kufanya hivyo. Ninaelewa pia kuwa naweza kukataa kujibu maswali kadhaa kwenye dodoso zilizopewa na naweza kuchagua kujiondoa kwenye masomo wakati wowote.

Ninaelewa kuwa juhudi zote zitafanywa kuweka habari yangu kuwa ya siri.

Nakubali kwa uhuru kushiriki katika utafiti huu na ninaelewa kuwa sijatoa haki yoyote ya kisheria ambayo mimi kama mshiriki wa utafiti.

Ninakubali kushiriki katika utafiti huu:

(Jibu inapofaa)

NDIYO **HAPANA**

Jina la mshiriki: _____ **Saini / muhuri wa kidole gumba ya mshiriki:**

_____

Tarehe: _____

Taarifa ya msaidizi wa Mpelelezi Mkuu/ Mpelelezi mkuu: Nimeelezea yote hapo juu kwa mshiriki anayeweza kueleweka wazi na kwa usawa katika lugha ambayo yeye anaelewa.

Mpelelezi Mkuu: _____ **Saini:** _____

Jina la Msaidizi wa Utafiti: _____ **Saini:** _____

Wasiliana nasi kwa maswali zaidi:

Mpelelezi mkuu: Suleiman Yakub Dino. Tel: 0723-213433, email: sullydino@gmail.com

Msimamizi mkuu: Prof. G.O. Oyoo. Tel: 0722-522359, email: george.oyoo@uonbi.ac.ke

KNH-UoN ERC: Tel: (254-020) 2726300-9 Ext 44355, email: uonknh_erc@uonbi.ac.ke

APPENDIX V: BRIEF PAIN INVENTORY-SHORT FORM (BPI-SF)

1903

Date: (month) / (day) / (year)

Subject's Initials: _____

Study Subject #:

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

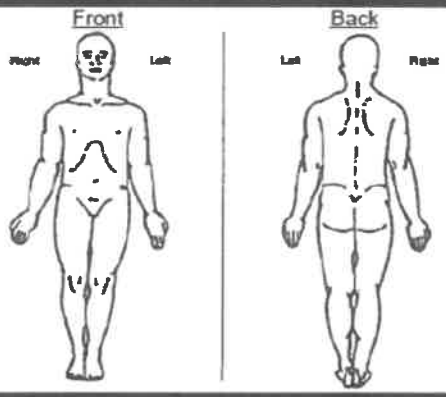
Revision: 07/01/05

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Pain As Bad As You Can Imagine

Page 1 of 2

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1903

Date: (month) / (day) / (year)

Subject's Initials : _____

Study Subject #:

Study Name: _____

Protocol #: _____

PI: _____

Revision: 07/01/05

PLEASE USE BLACK INK PEN

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐ No Relief	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

B. Mood

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

C. Walking ability

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

E. Relations with other people

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

F. Sleep

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

G. Enjoyment of life

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

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APPENDIX VI: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

WOMAC Survey Form Name: _____

Instructions: In Sections A, B, and C, questions will be asked about your hip or knee pain. Please mark each response with an X. If you are unsure about how to answer a question, please give the best answer you can.

A. Think about the pain you felt in your hip/knee during the last 48 hours.

Question: How much pain do you have?	None	Mild	Moderate	Severe	Extreme
1. Walking on a flat surface	☐	☐	☐	☐	☐
2. Going up and down stairs	☐	☐	☐	☐	☐
3. At night while in bed, pain disturbs your sleep	☐	☐	☐	☐	☐
4. Sitting or lying	☐	☐	☐	☐	☐
5. Standing upright	☐	☐	☐	☐	☐

B. Think about the stiffness (not pain) you have in your hip/knee during the last 48 hours. Stiffness is a sensation of decreased ease in moving your joint.

	None	Mild	Moderate	Severe	Extreme
6. How severe is your stiffness after first awakening in the morning?	☐	☐	☐	☐	☐
7. How severe is your stiffness after sitting, lying, or resting in the day?	☐	☐	☐	☐	☐

C. Think about the difficulty you had in doing the following daily physical activities due to your hip/knee during the last 48 hours. By this we mean your ability to move around and look after yourself.

Question: What degree of difficulty do you have?	None	Mild	Moderate	Severe	Extreme
8. Descending stairs	☐	☐	☐	☐	☐
9. Ascending stairs	☐	☐	☐	☐	☐
10. Rising from sitting	☐	☐	☐	☐	☐
11. Standing	☐	☐	☐	☐	☐
12. Bending to the floor	☐	☐	☐	☐	☐
13. Walking on flat surfaces	☐	☐	☐	☐	☐
14. Getting in and out of a car, or on or off a bus	☐	☐	☐	☐	☐
15. Going shopping	☐	☐	☐	☐	☐
16. Putting on your socks or stockings	☐	☐	☐	☐	☐
17. Rising from the bed	☐	☐	☐	☐	☐
18. Taking off your socks or stockings	☐	☐	☐	☐	☐
19. Lying in bed	☐	☐	☐	☐	☐
20. Getting in or out of the bath	☐	☐	☐	☐	☐
21. Sitting	☐	☐	☐	☐	☐
22. Getting on or off the toilet	☐	☐	☐	☐	☐
23. Performance heavy domestic duties	☐	☐	☐	☐	☐
24. Performing light domestic duties	☐	☐	☐	☐	☐

HSS ☐☐ - ☐☐ - ☐☐ 4 Draft

APPENDIX VII: BRIEF PAIN INVENTORY (SHORT FORM) – KISWAHILI

1903 Tarehe: ☐☐ / ☐☐ / ☐☐
(Mwaka) (Siku) (Mwaka)
Awali za Somo: _____

Jina la Utafiti: _____

Itifaki#: _____

PI: _____

TAFADHALI TUMIA KALAMU YA WINO MWEUSI

Somo#: ☐☐☐☐

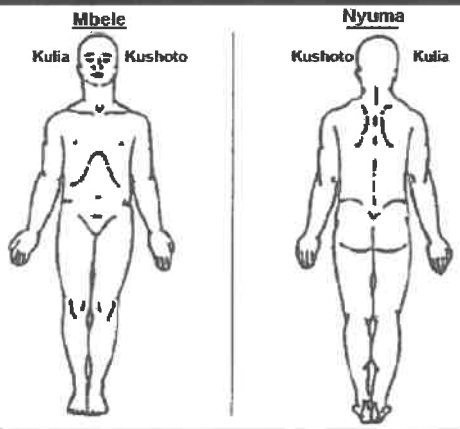
Rudio: 07/01/05

Orodha fupi ya Maumivu (Fomu fupi)

1. Katika maisha yetu yote, wengi wetu tumekuwa na maumivu mara kwa mara (kama vile kuumwa kichwa kidogo, kuteguka, na maumivu ya meno). Je, umekuwa na maumivu zaidi ya aina hizi za maumivu ya kila siku leo?

☐ Ndio ☐ Hapana

2. Kwenye mchoro, chora katika maeneo ambayo unahisi maumivu. Weka X kwenye eneo ambalo linaumiza zaidi.



3. Tafadhali onyesha kiwango cha maumivu yako kwa kuweka alama kwenye kisanduku kando ya nambari inayoelezea vizuri zaidi maumivu yako katika hali mbaya zaidi katika saa 24 zilizopita.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Hakuna maumivu — Maumivu mabaya

4. Tafadhali onyesha kiwango cha maumivu yako kwa kuweka alama kwenye kisanduku kando ya nambari inayoelezea vizuri zaidi maumivu yako angalau katika saa 24 zilizopita.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Hakuna maumivu — Maumivu mabaya

5. Tafadhali onyesha kiwango cha maumivu yako kwa kuweka alama kwenye kisanduku kando ya nambari inayoelezea vizuri zaidi maumivu yako kwa Wastani

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Hakuna maumivu — Maumivu mabaya

6. Tafadhali onyesha kiwango cha maumivu yako kwa kuweka alama kwenye kisanduku kando ya nambari inayoeleza ni maumivu kiasi gani uliyonayo sasa hivi

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Hakuna maumivu — Maumivu mabaya

Ukurasa wa 1 kati ya 2

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APPENDIX VIII: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) – KISWAHILI

WOMAC fomu ya uchunguzi. Jina: _____

Maagizo: Katika Sehemu A, B, na C, Maswali yataulizwa kuhusu maumivu kwa nyonga/kiuno au maumivu kwa goti. Tafadhali jibu kwa kutumia alama ya X kwa kila mmoja. Kama hauna hakika na jibu la swali, tafadhali jaribu kupeana jibu bora zaidi.

A. Fikiria kuhusu maumivu uliyosikia kwenye nyonga/kiuno au goti lako katika saa 48 zilizopita

Swali: Una maumivu kiasi gani?

	Hakuna	Kidogo	Wastani	Kali	Uliokithiri
1. Kutembea kwa ardhio nyororo	☐	☐	☐	☐	☐
2. Kutembea juu na chini ya ngazi	☐	☐	☐	☐	☐
3. Usiku ukiwa kitandani, maumivu yanasumbua usingizi wako	☐	☐	☐	☐	☐
4. Kukaa au kulala	☐	☐	☐	☐	☐
5. Kusimama wima	☐	☐	☐	☐	☐

B. Fikiria juu ya ugumu (sio maumivu) ulio nao kwenye nyonga/kiuno au goti lako katika saa 48 zilizopita. Ugumu ni hisia ya kupungua urahisi katika kusonga kiungo chako.

	Hakuna	Kidogo	Wastani	Kali	Uliokithiri
6. Je, ugumu wako ni mkubwa kiasi gani baada ya kuamka kwanza asubuhi?	☐	☐	☐	☐	☐
7. Je, ugumu wako ni mkubwa kiasi gani baada ya kukaa, kulala au kupumzika mchana?	☐	☐	☐	☐	☐

C. Fikiria kuhusu ugumu uliokuwa nao katika kufanya shughuli zifuatazo za kimwili za kila siku kutokana na nyonga/kiuno au goti lako katika saa 48 zilizopita. Kwa hili tunamaanisha uwezo wako wa kuzunguka na kujiangalia.

Swali: Je, una kiwango gani cha ugumu?

	Hakuna	Kidogo	Wastani	Kali	Uliokithiri
8. Kushuka ngazi	☐	☐	☐	☐	☐
9. Kupanda Ngazi	☐	☐	☐	☐	☐
10. Kuinuka baada ya kukaa	☐	☐	☐	☐	☐
11. Kusimama	☐	☐	☐	☐	☐
12. Kuinama	☐	☐	☐	☐	☐
13. Kutembea kwa ardhio nyororo	☐	☐	☐	☐	☐
14. Kuingia na kutoka kwa gari, au kwa basi	☐	☐	☐	☐	☐
15. Kwenda dukani	☐	☐	☐	☐	☐
16. Kuvaa soksi	☐	☐	☐	☐	☐
17. Kuinuka kutoka kitandani	☐	☐	☐	☐	☐
18. Kuvua soksi	☐	☐	☐	☐	☐
19. Kulala kitandani	☐	☐	☐	☐	☐
20. Kuingia au kutoka kwa bafu	☐	☐	☐	☐	☐
21. Kukaa	☐	☐	☐	☐	☐
22. Kuingia au kutoka kwenye choo	☐	☐	☐	☐	☐
23. Utendaji kazi nzito za nyumbani	☐	☐	☐	☐	☐
24. Kufanya kazi nyepesi za nyumbani	☐	☐	☐	☐	☐