UNIVERSITY OF NAIROBI

CORRELATION BETWEEN PATTERNS OF CLINICAL PRESENTATION AND MRI FINDINGS IN ADULT PATIENTS WITH LUMBOSACRAL SENSORY & MOTOR RADICULOPATHY SECONDARY TO DEGENERATIVE DISC DISEASE IN KENYATTA NATIONAL & COPTIC HOSPITALS

By

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H58/6799/2017

A dissertation to be submitted in partial fulfilment of the requirements for the award of the degree of Master of Medicine (M. Med) in Orthopaedic Surgery in the University of Nairobi.

@ Department of Surgery
July 2022

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DEDICATION

I dedicate this work to my loving mother Janet Mwongeli for her outstanding support and prayers, my dear wife Carolyne Moraa as well as my son Baraka Mwongela who kept telling neighbors children to talk in low tones, “dad is in class”. Am very grateful for the support.

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LIST OF ABBREVIATIONS & ACRONYMS

AF	Annulus Fibrosus
ALL	Anterior Longitudinal Ligament
CNE	Clinical neurologic examination
DDD	Degenerative Disc Disease
DEBIT	Disc Extension Beyond Interspace
ECM	Extracellular matrix
ERC	Ethics and Research Committee
HIZ	High Intensity Zone
IV	Intervertebral
KNH	Kenyatta National Hospital
LBP	Low Back Pain
LDH	Lumbar disc herniation
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
NHIF	National Hospital Insurance Fund
NP	Nucleus Pulposus
OR	Odds Ratio
PBSS	Post Back Surgery Syndrome
PLL	Posterior Longitudinal Ligament
S-LANSS	Self-reported leed assessment of neuropathic symptoms and sign score
SLR	Straight Leg Raise
SNRB	Selective Nerve Root Block
SPSS	Statistical Package of Social Sciences
UON	University Of Nairobi

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ABSTRACT

Background: Low back Pain (LBP) is a common complaint in patients with degenerative disc disease (DDD) with a global prevalence of 1.4-20%. Between 12-40% of patients with LBP have radiculopathy.

The biggest challenge in spine surgery is choosing the correct surgical procedure for alleviation of symptoms and signs that the patient has with minimal or absence of complications. This is achieved by correct clinical evaluation and relating findings to the MRI. While MRI is the gold standard of evaluation of lumbar DDD, there are inconsistencies that cloud decision making. These inconsistencies such as findings of MRI changes in disc anatomy for symptomatic and asymptomatic patients, whereby minimal changes have been observed in patients with severe radicular pain or patients presenting with less pain having advanced MRI changes.

Therefore, there is a need to examine how the patterns of presentation correlate to common reported disc changes in MRI scans.

Objective: To determine the correlation between clinical presentation and MRI findings in patients with lumbosacral radiculopathy secondary to degenerative disc disease (DDD) in Kenyatta National Hospital & Coptic Hospital.

Study Design: A Cross-sectional study undertaken at Kenyatta National Hospital (KNH) and Coptic Hospital (CH).

Patients and methods: Eighty nine adult patients of either sex who presented with low back pain associated with lumbosacral radiculopathy at the KNH and Coptic hospital during the study period were included. Clinical assessment of patients with LBP and lumbosacral radiculopathy was done at review in the hospital clinics. The presence and level of sensory radiculopathy including pain, paresthesia and numbness was recorded. Details of MRI findings was based on recently done scans in patients presenting with ready films or requested as per protocol of care by resident or specialist for subsequent review as part of routine patient care.

The degree of lumbar disc degeneration based of Pfirrmann grade, degree of vertebral end plate changes based on modic grades as well as anatomic and locational disc herniation were the MRI parameters that were studied.

Data was collected via a preformatted questionnaire administered to patients, and later keyed into the Statistical Package of Social Sciences (SPSS) version 23.0 for analysis. Descriptive statistics was applied to patient characteristics that included the demographic profile, clinical presentation and findings. Correlation between severity of lower back pain and radiculopathy with MRI findings was done using Analysis of Variance (ANOVA) test.

Significance and Relevance: In view of the high direct & indirect cost in management of patients with low back pain & radiculopathy, the findings of this study will hopefully be a guide of which pathological lesions in DDD are associated with certain symptoms, thus aid in decision making particularly on which patients that may require surgery versus those that could benefit from less invasive procedures like selective nerve root block, bearing in mind spine surgery can have debilitating repercussions thus reduce morbidity in patient care. This is in the background of limited local data correlating severity of sensory & motor radiculopathy with MRI findings.

Results: Out of the 89 patients who participated in the study 66 (76.4%) of them were females while 21 (23.6%) were males. The mean age of the patients was 51.5 (SD 12.7) years, where the minimum age was 24.0 years and the maximum age was 80.0 years. Majority of the patients were employed were 41 (46.1%). All of the 89 participants recruited in our study had low back pain and radicular pain to the lower limb with 78.7% reporting radiation to the feet whereby the left limb had majority at 44.9%. Paresthesia was reported by 95.5% of participants, 74.2% reported numbness while motor radiculopathy was reported in 9%.

Results of the disc pathology indicate that 64 (71.9%) of the patients had 1 level pathology (71.9%). The most involved disc was L5S1 with 56 (62.9%) of all the patients affected. Total number of levels were 119 in the 89 participants. The locational pattern was reported as either central, paracentral or far lateral, where Paracentral pattern was the highest at 75 (63.0%). Anatomical pattern of disc pathology was reported as bulge, protrusion, extrusion or sequestration, where the highest was bulge at 70 (58.8%).

Results of mean pain score was observed to be increasing with severity of the disk degeneration, and an Analysis of Variance (ANOVA) test was used to determine the association between the severity of lower back pain and radiculopathy with anatomical disc pathology, and the results indicate there was a statistical significant relation ($p=0.030$). Results of mean pain score was observed to be increasing as the grade was increasing, and an Analysis of Variance (ANOVA) test was used to determine the association between the severity of lower back pain and radiculopathy

with the Pfirrmann grade, but the results indicated there was no statistical significant relation (p=0.249).

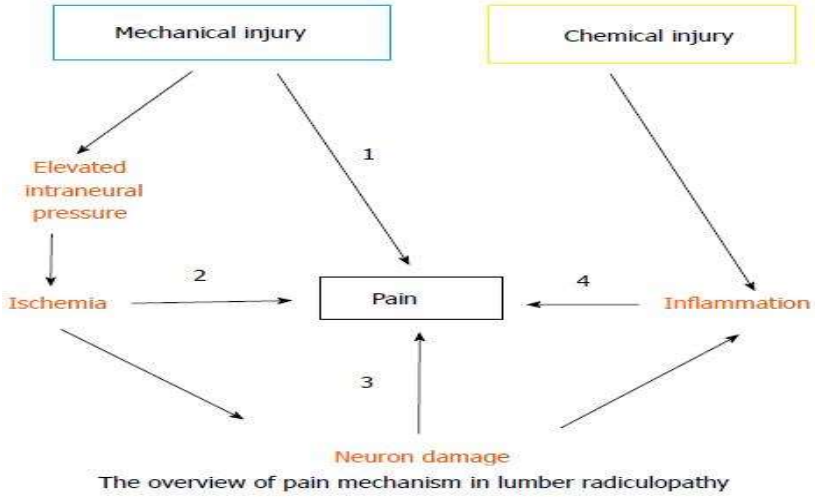
Conclusion: Our study has shown correlation between clinical severity of radiculopathy and pattern of MRI findings consistent with degenerative disc disease. This underscores the utility of thorough clinical assessments and judicious utilization of MRI as there were some instances where clinical picture was not in tandem with MRI findings.

1.0. INTRODUCTION

1.1. Background

Low back Pain (LBP) estimated to have a global prevalence of 1.4-20% is a common complaint reported by patients seeking healthcare services in health facilities (1, 2, 3, 4, 5, 6) Approximately 70-80% of adults report LBP at least once in their lifetime (1). LBP is attributed to many causes ranging from degenerative changes, neoplasms, spinal stenosis, infection, inflammatory conditions, trauma, and spine wear and tear processes. Degenerative disc disease which manifests through intervertebral disc herniation among other pathologies is a leading cause of low back pain and radiculopathy (1, 3, 8).

Figure 1: Mechanism of pain in radiculopathy



Adapted from; Lin J-H. Lumbar radiculopathy and its neurobiological basis. World J Anesthesiol. 2014;3(2):162.

Degenerative disc disease is a leading cause of LBP with radiculopathy. It involves L3-L4, L4-L5 and L5-S1 levels of the spine manifests commonly as disc desiccation, loss of disc height and disc herniation (1). This degenerative process subsequently leads to compression of lumbosacral nerves hence radiculopathy. Several risk factors are associated with this degenerative disc process namely advancing age, smoking, obesity, trauma, infections and occupations that involve heavy lifting and vibration (9, 10, 11)

The initial assessment of a patient is history and physical examination, including manual muscle, sensory & deep tendon reflexes testing, straight leg raise and Lasegue's test. Straight leg raise (SLR) test is performed on a patient lying supine, head and pelvis flat, knee extended as the limb is slowly raised to maximum elevation or when patient stops examiner due to pain. Patient reports shooting pain radiating to thigh leg or foot in a positive SLR test. Lasegue's test is assessed with the patient lying in the supine position, the knee is extended just like in SLR test, when radicular pain is experienced the examiner pauses and performs ankle dorsiflexion which in a positive Lasegue's exacerbates the radicular pain. Lasegue's and straight leg raise test stretch nerve roots L5 and S1 for about 2-6mm causing tension on the nerve roots. Femoral nerve stretch test elicits same tension to the roots L2, L3 and L4 (9, 12). When radiculopathy is caused by nerve root compression the sensory and motor symptoms are expected to follow a particular dermatomal and myotomal pattern respectively. The distribution of pain and motor findings on physical examination should guide the surgeon to the region of the spine to focus on, with further imaging examinations through modalities such as MRI (9, 11).

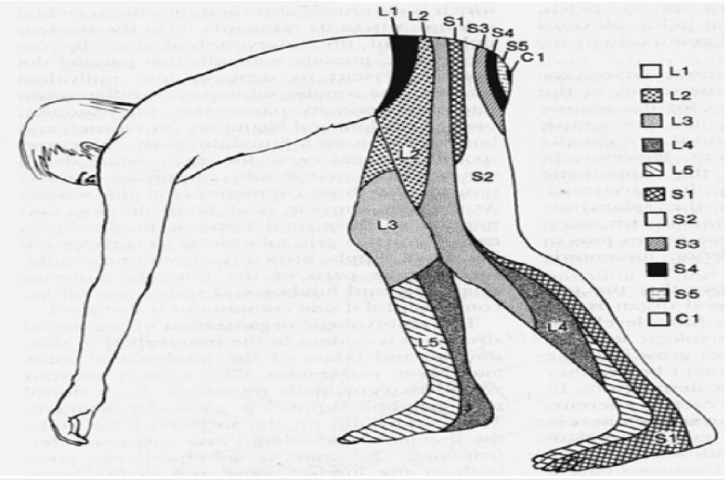
The key to good results in disc surgery is careful patient selection. Failed back surgery syndrome (FBSS) has been associated with inadequate correlation of history, physical and imaging results to arrive at accurate diagnosis pre operatively. The optimal surgical patient is one with predominant if not only unilateral leg pain extending below the knee. Physical examination should reveal signs of sciatic irritation and possibly objective evidence of localizing neurologic impairment. CT, lumbar MRI, should confirm the level of involvement consistent with the patient's examination (1, 2, 7, 13, 14).

Table 1: Physical findings in lumbosacral radiculopathy

Dermatome	Sensory Testing	Motor Testing	Reflex Testing
L1	Anterior proximal thigh near inguinal ligament	Iliopsoas (seated hip flexion)	
L2	Mid anteromedial thigh	Iliopsoas (seated hip flexion)	
L3	Just proximal or medial to patella	Quadriceps	Patellar tendon reflex (secondary)
L4	Medial lower leg and ankle	Tibialis anterior	Patellar tendon reflex
L5	Lateral and anterolateral leg and dorsal foot	Extensor hallucis longus Extensor digitorum brevis Gluteus medius	Tibialis posterior reflex Medial hamstring reflex
S1	Posterior calf, plantar foot, and lateral toes	Gastrocsoleus Peronei Gluteus maximus	Achilles' reflex
S2	Posterior thigh and proximal calf	Rectal examination	
S3, S4, S5	Perianal area	Rectal examination	

Adapted from The Orthopaedic Physical Examination by Bruce Reider Second Edition

Figure 2: Lumbosacral dermatomes

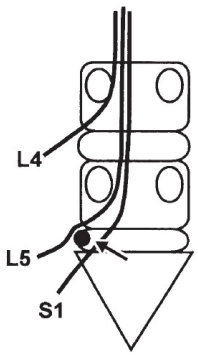


Adapted from James A. Berry, Christopher Elia, Harneel S. Saini, Dan E. Miulli. A Review of Lumbar Radiculopathy, Diagnosis, and Treatment

1.2. Anatomy of Lumbar Spine

Lumbosacral spine anatomy consists of spinal unit that houses spinal cord, conus medularis, cauda equina, meningeal sac, and exiting nerve roots. Spinal unit consists of vertebra, disc, ligaments and associated joints. Lumbosacral spine has five lumbar vertebra and five sacral vertebra except in the setting of lumbarization and sacralization. The functional segment of the spine is two vertebra, intervening Intervertebral disc, facet joints, alongside the associated ALL, PLL, ligamentum flavum, interspinous ligament, supraspinous ligament and muscles. (9,10,13)

Figure 3: Functional unit of lumbar Vertebra Coronal Section

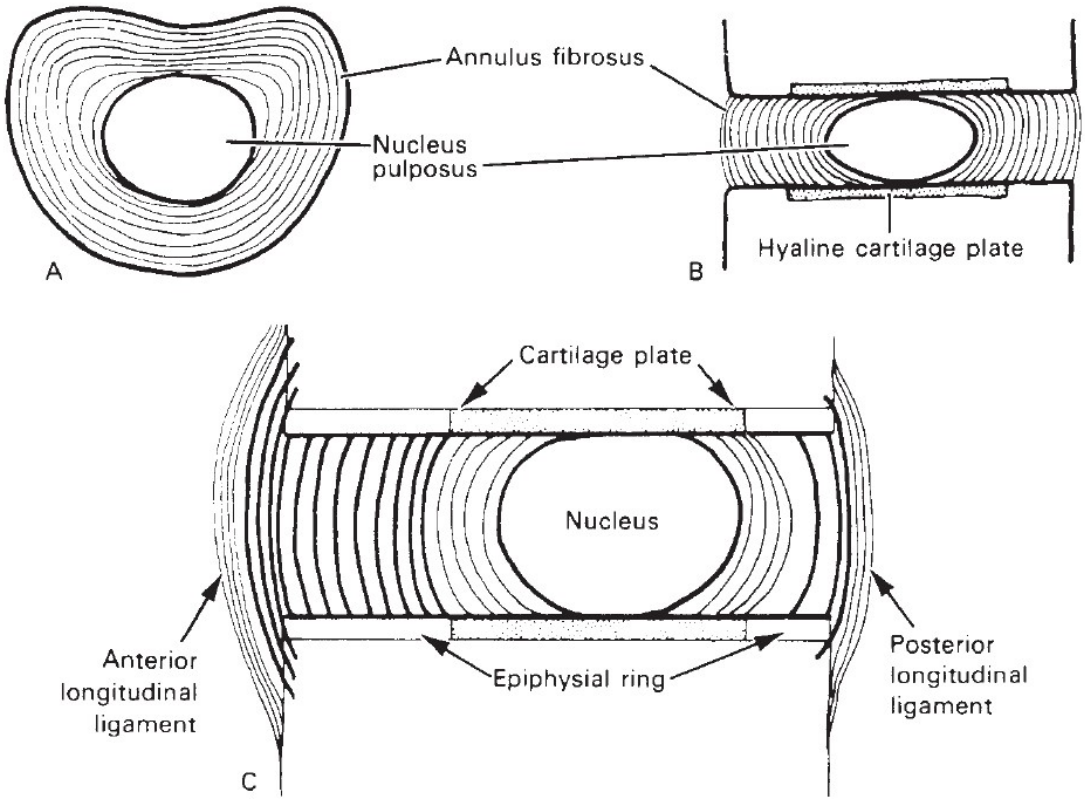


Adapted from Macnab's Backache fourth edition by David A. Wong MD MSc FRCS(C), Ensor Transfeldt MD Page11

There are terms with clinical utility in the lumbosacral segment; traversing nerve root, exiting nerve root and disc space level. Above drawing shows L4, L5 and S1 vertebra, the L4L5 disc is the disc between vertebra L4 and L5, L4 nerve root exits below L4 thus becoming exiting nerve root while L5 nerve root is passing through that disc level to exit below L5 foramen thus being traversing nerve root. The utility of the above anatomy is in anticipating the clinical presentation of radicular pain or radiculopathy in the setting of various patterns of disc herniation (9,10,13,15). Neural foramen anatomy is important in explaining the pathophysiology of radiculopathy as well as its management particularly in selective nerve root blocks (SNRB) administration. The superior and inferior borders are the pedicles of the vertebra above and inferior respectively. The posterior border is facet joint while anterior border is intervertebral disc and the vertebral bodies of the vertebra forming the functional vertebral segment. Understanding the transition from epidural sac to the epiradicular tissue is key in determining where to administer the block (16). Intervertebral disc is a very vital structure in spine function as it distributes load uniformly along the end plates when the spine undergoes compressive loading.

Intervertebral disc is composed of two main parts; Annulus fibrosus and nucleus pulposus. It is avascular structure with low cell density and a relatively large amount of extracellular matrix thus demonstrating limited self-repair capacity. Intervertebral disc undergoes degenerative process which involves diminished ability to secrete ECM as well as cellular dysfunction (3, 17, 18, 19). Annulus fibrosus (AF) which is the outer layer encases the inner nucleus pulposus as it links two adjacent vertebra. AF has outer and inner layers whose predominant cells are fibroblast-like cells and chondrocyte-like cells. The outer layer of AF is composed of mainly of tough type I collagen and type II collagen to some extent. The inner layer of AF is less organized, it has proteoglycan, water and type II collagen. It is organized into three layer of fibres namely outermost, middle and innermost. The outermost fibres linking vertebral body and epiphyseal ring as the middle fibres link two adjacent epiphyseal rings, the innermost fibres run from the endplates of adjacent vertebras. These fiber layers run in orthogonal pattern to enhance stability and ability to withstand tensile high tensile stress. The distribution of outermost and middle fibers is more prominent in the anterior and lateral aspect of the disc as opposed to posterior part. PLL is weaker and even narrower especially at the L4-L5 and L5-S1 levels thus being anatomical weak point (3, 13, 17 – 22).

Figure 4: Functional unit of lumbar Vertebra – Axial Sagital & Coronal



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Nucleus pulposus is gelatinous in architecture comprising cellular elements, water and extracellular matrix. In a healthy disc the water content can ranges between 80 and 88%, this percentage falls as the disk undergoes degeneration. Nucleus pulposus has chondrocyte like cells that secrete type II collagen and aggrecan whose sulfated glycosaminoglycans have a negative charge that facilitates the hydrated status of NP. Next to the disc are vertebral end plates superiorly and inferiorly composed of fibrocartilage and hyaline cartilage, the structure of an end plate is collagen, proteoglycan and water. Water functions as the conduit for solutes from the vertebra into and out of the disc for nutrition and to ensure standard intradiscal pressure as well as release of products of metabolism (3, 17, 18, 19).

Another key element of spinal segment is the synovial facet joints. These joints are supported mainly by AF outer fibers in addition to supraspinous ligament and ligamentum flavum thus explaining the concurrent changes experienced in the facet joints as disc degeneration takes place (17). The ligaments of the spine include ALL, PLL, ligamentum flavum, interspinous and

supraspinous ligaments. Posterior longitudinal ligament is quite flimsy and narrow at the lower lumbar region as opposed to the strong ALL (9, 10, 13, 17)

The intervertebral disc and facet joints play a very fundamental role in spine load bearing. The facet joints dissipates forces during axial torque and anterior shear as the IV disc bears the forces of axial compression, flexion, lateral and posterior shear. In degenerative disc disease the above functions are markedly impaired (9, 10). The spine ligaments stretch and resist tensile forces by utilizing their elastic properties while under compression they buckle with minimal role. At rest they maintain tension in a segment to minimize the strain on the muscles. The key ligament being the ALL and the facet capsule of the facet joint, PLL is the weakest while supraspinous and interspinous ligaments are intermediate in strength (9,10,13).

1.3. Disc Degenerative Process

Disc degeneration is a pathological process through which the functional architecture of the disc is distorted leading to replacement of the hydrated gelatinous ECM of the NP by fibrous tissue. There is distorted collagen crosslinking in annulus fibrosus causing the IV disc to lose its biomechanical properties thus leading to further degeneration as imbalance in anabolic and catabolic processes. This degeneration can manifest via herniation and subsequent canal or foraminal stenosis that can lead to low back pain and radiculopathy. (17, 23).

Degenerative disc disease occurs in three stages as described by Kirkaldy-Willis (10)

a) Dysfunction stage. This involves tear in the AF that can be either circumferential or radial alongside capsular synovitis.
b) Instability stage. This stage is associated by internal disc disruption with disc resorption with some significant facet joint pathologies including joint erosion, capsular laxity and occasional sublaxation.

   Dysfunction and instability stages are associated with disc herniation.
c) Stability (Final) stage. Hypertrophic bone changes occur around the disc and facet joint a process associated with canal stenosis.

A vicious cycle of mechanical overloading, catabolic cell response, and degeneration of the water-binding extracellular matrix are the cardinal events contributing to the above disc degeneration orchestrated by failure of fibroblasts to produce new collagen and drenched production of proteoglycans by chondrocytes. Diffusion of metabolic substrates to the disc namely sulfate, glucose and oxygen is affected that subsequently increases the intradiscal pH

which favors degradative activity by proteases. The disc smooth roller activity is lost thus unequal weight transmission as disc fails biomechanically since it cannot lose or gain water to adapt to various loads (3,10,18,19). This degenerative process might have the following outcomes (10); Asymptomatic degeneration, Painful IV disc process with localized back pain, Mechanical instability due to the accompanied ligamentous & facet joints degeneration and Nerve root compression and associated radicular pain.

Understanding anatomy of lumbosacral spine is crucial in managing patients with discogenic low back pain & radiculopathy as it forms the background in understanding the clinical presentation, interpretation of pathology as demonstrated in imaging, and subsequent decision making especially when surgical correction is indicated.

1.4. Problem Statement

Low back pain associated with radiculopathy is a debilitating condition, spine surgery too can lead to debilitating consequences.
Decision making in spine surgery is a challenging decision particularly in choosing the correct surgery for a certain pathology.
Decision to operate must be based on right procedure for the best outcome for the symptomatic pathology in the patient.

MRI has revolutionized decision making for patients needing spine surgery, while this imaging modality provides details of various spine pathologies some findings are not consistent with patients' symptoms, there are scenarios where patients have severe symptoms yet MRI findings are in tandem with mild symptomatology as well as significant MRI findings seen in symptomatic patients also being reported in asymptomatic patients.

The key to good results in management of low back pain with radiculopathy especially disc surgery is appropriate patient selection. Judicious use of radiological assessment alongside proper physical examination is very key in decision making.

1.5. Study Question

What is the correlation between patterns of clinical presentation and MRI findings in patients with lumbosacral sensory and or motor radiculopathy secondary to degenerative disc disease?

1.6. Justification and Significance

Low back pain & radiculopathy is a costly condition to manage ranging from the numbers involved, direct cost as well as indirect costs that include the labor market repercussions such as working hours lost & workman compensation associated with low back pain. Global prevalence of low back pain is reported about 9.4% as radiculopathy is reported in the range of 3-5% with the peak group being fourth and fifth decade which forms a big proportion of working population. William Thomas Crow and David R. Willis (24) reported that low back pain to have a major economic impact in United states with total cost incurred due to low back pain being in excess of United States 100 billion dollars per year, Geurts et al (25) reported that annual societal cost for a patient with chronic low back pain in Netherlands to be 7,911.95 euros per patient.

In view of the above global burden related to low back pain it is important to understand this disease well particularly in identifying the specific lesion causing patients' clinical presentation in order to intervene objectively and reduce the cost implication of this condition that range from the disease as well as repercussion of management like failed back surgery syndrome. In the global platform several studies have been carried out in attempt to evaluate correlation between clinical presentation and MRI findings in DDD demonstrating varying conclusions. MRI findings seen in symptomatic patients have also been reported in asymptomatic patients thus there exists a challenge in relating symptoms and MRI findings. There are clinical scenarios where patients have severe symptoms yet MRI findings are commensurate with mild disease.

In order to optimize care in patients with low back pain and radiculopathy as well as cut the morbidity burden and the direct & indirect costs incurred in care for these patients, it is important for the managing doctor to identify the particular lesions causing the symptoms. This will guide in making an informed decision towards management of these patients.

Currently there is limited locally published data in our population mapping the pattern and severity of low back pain and radiculopathy and correlating that with MRI findings in degenerative disc disease in this era of research & evidence based practice.

The direct and indirect cost to the patient and healthcare system at large as well as the labor market warrants research in low back pain and radiculopathy so as to be able to optimize management at a modest cost, decrease morbidity and maintain productivity of the working population.

The findings from this study will hopefully help show which pathological lesions in DDD are associated with symptoms thus guide in decision making particularly on which patients need surgery vs those that could benefit from less invasive procedures like selective nerve root block, bearing in mind spine surgery can have debilitating repercussions thus reduce morbidity in patient care.

1.7. Aim of study

To determine the correlation between patterns of clinical presentation and MRI findings in patients with lumbosacral sensory and or motor radiculopathy secondary to degenerative disc disease in Kenyatta National Hospital & Coptic Hospital.

1.8. Study Objectives

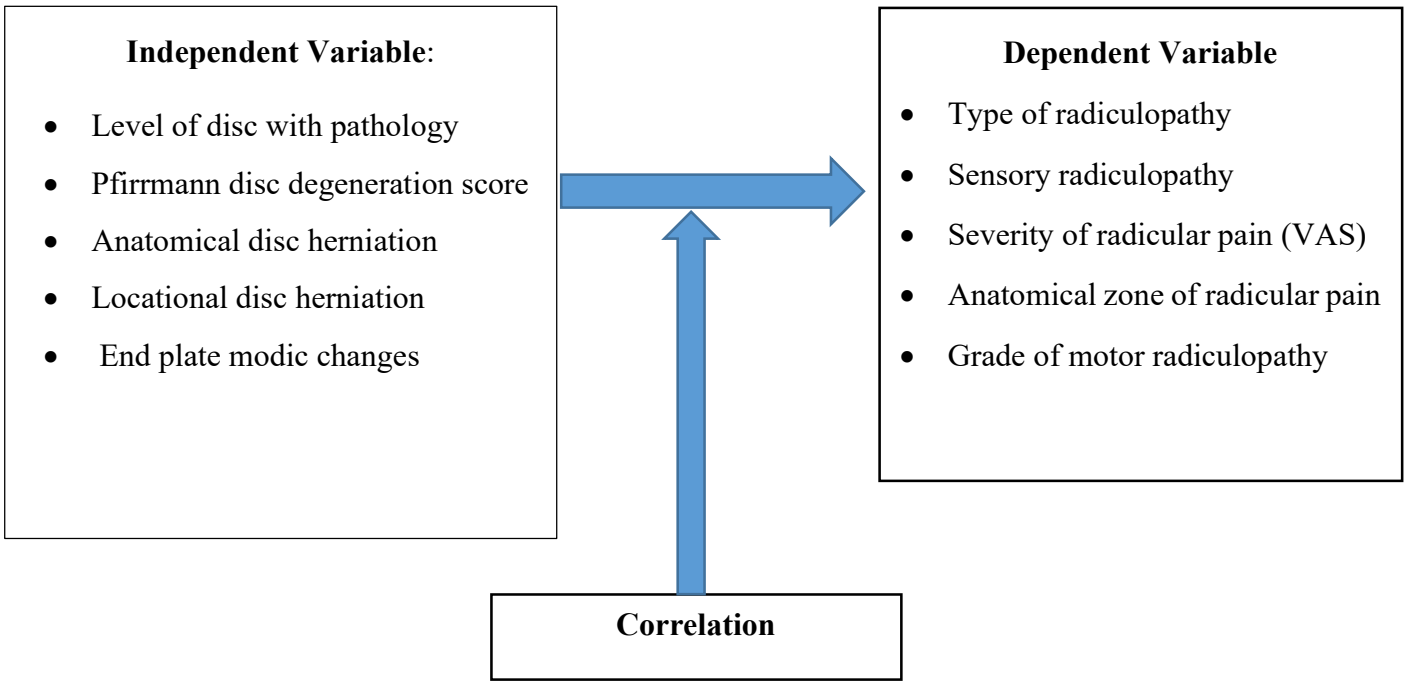
Broad Objective

To determine the correlation between patterns clinical presentation and MRI findings in patients with sensory and or motor lumbosacral radiculopathy secondary to degenerative disc disease in Kenyatta National Hospital & Coptic Hospital.

Specific Objectives

1. To determine the proportion of sensory and or motor lumbosacral radiculopathy in patients presenting with low back pain in Orthopaedic units in KNH & Coptic hospital.
2. To determine the severity of sensory and or motor lumbosacral radiculopathy in patients presenting with low back pain in Orthopaedic units in KNH & Coptic hospital.
3. To determine the pattern of MRI features consistent with lumbosacral degenerative disc disease in patients with sensory and or motor radiculopathy presenting with low back pain in Orthopaedic units in KNH & Coptic hospital.
4. To correlate patient clinical presentation with MRI findings consistent with lumbar degenerative disc disease in patients with sensory and or motor radiculopathy presenting with low back pain in Orthopaedic units in KNH & Coptic hospital.

1.9. Concept framework



2.0 LITERATURE REVIEW

2.1 Introduction

Discogenic low back pain plus or minus radiculopathy is a debilitating condition, operative management can lead to unfavorable outcomes thus increasing morbidity burden in dealing with a condition that has a high direct and indirect cost. MRI has become a very important tool in investigating discogenic low back pain and radiculopathy, however, there arises a challenge in utilizing this images in operative decision making since MRI findings seen in symptomatic patients have also been reported in asymptomatic patients. Brinjikji et al (26) in 2015 in a systematic review of 33 articles with a total 3100 asymptomatic patients done MRI demonstrated that prevalence of DDD features in 37% of persons 20 years of age and 96% in person aged 80 years. This features included loss of disc height, facet joint changes, disc bulges & protrusion as well as disc signal loss. This study concluded that spine degenerative changes should be interpreted in reference to patient symptoms and signs as this changes are part of aging process.

Jarvik et al (27) in a study involving asymptomatic patients followed up for three years with a baseline MRI and repeat MRI after 3 years on 131 patients did not find strong association between degenerative disc changes and patient symptoms. Incidence of pain was 67% with non-commensurate MRI degenerative changes which included 9% disc signal loss with four patients getting new nerve root impingement. Baber and Michael Ederk (8) while discussing current perspectives in failed back surgery syndrome demonstrated that there is increasing incidence of low back pain as high as by 64%, this was accompanied by increased surgical management for instance lumbar fusion by 170% and laminectomies by 11%, they reported incidence of Failed back surgery syndrome to be 5-36% with inaccurate diagnosis being implicated as a key cause, 58% of the cases of FBSS were noted to be secondary to undiagnosed lateral stenosis. Mohammed K Abubakar & Shamshudeen Mohammed (28) reported that poor patient selection to be a cause for failed back surgery syndrome, James R Danielle & Orso L. Osti (7) reaffirmed the importance of patient selection in operative spine management by showing patients who anticipated workman compensation and other forms of disability support pension to have poor surgical outcome. Kingori et al (29) in year 2005 to 2011 in Kikuyu orthopaedic & Rehabilitation Center Kenya did a study to evaluate effects of lumbar epidural injection for patients with radiculopathy and LBP. Study concluded that lumbar epidural injection had role in

well selected patients. Study had 121 patients of whom 58% had clinical improvement to the point of resuming work (29).

In view of above challenges there is need for the doctor managing patients with discogenic low back pain and radiculopathy to identify the particular MRI findings attributable to causing the symptoms before intervening to help address the morbidity burden of failed back surgery.

2.2 Type of radiculopathy

Radiculopathy which can be sensory and/or motor is reported in 12-40% of patients presenting with low back pain (30). Radiculopathy occurring as a consequence of pathological changes happening to a nerve is a constellation of symptoms ranging from radicular pain, numbness, paresthesia and muscle weakness. Radicular pain attributed to excitable nature of affected nerve is reported as sharp, burning or electric in nature and is reported to radiate down the lower limbs following a dermatomal pattern. Occasional it may be associated with numbness and paresthesia (15). Motor radiculopathy may be reported in such patients and it encompasses myotomal weakness and alteration in reflexes (30, 31). The prevalence of radiculopathy in patient population is reported to be 3-5% (15).

Radiculopathy occurs when a nerve root is compressed while in the dural sac, traversing through spinal canal or exiting via foraminal space thus undergoing both chemical and mechanical (compression and traction) injuries that lead to the symptoms. The nerve root undergoes ischemic changes, edema, fibrosis and demyelination whose end result is compromised function thus presenting as sensory and/or motor symptoms. A proinflammatory process attended by inflammatory cells and increased intraneural capillary permeability and subsequent nerve degeneration occurs when nucleus pulposus material gets into contact with neuronal tissue leading to neurological changes such as decreased nerve root conduction and increased nerve discharge. (1, 2, 10, 32).

Dydyk et al (33) reports the most common pattern of radiculopathy to be paresthesia at 63-72%, radicular pain in 35%, numbness at 27% and muscle weakness at 37%. Janardhana et al (34) demonstrated that L5 dermatome was the most affected followed by S1 dermatome. Gaffney et al (35) in their paper on painless weakness from lumbar disc herniation reported that the most common complaint to be radicular pain, they also reported that the incidence of motor radiculopathy to be variant in ranges of 30-50%. Ayse and Aaron (36) reported that 76.1% of

lumbar radiculopathies involve L5 & S1 nerve roots with sensory symptoms on the dorsum of the foot and lateral foot with or without ankle and toe extensors & flexors. Wang et al (37) reported that 94.6% of patients who had radiculopathy and gluteal pain had L4-L5 LDH, after L4-L5 microdiscectomy the pain disappeared returning with recurrence of the lumbar disc herniation. Akutotha et al (38) demonstrated that ankle dorsiflexors (L4) and hallux extensors (L5) were most affected myotomes. Yousif et al (39) reported that 40% had symptoms in L5 dermatome, 56.7% S1 dermatome with 3.3% being both dermatomes.

2.3 Severity of radiculopathy

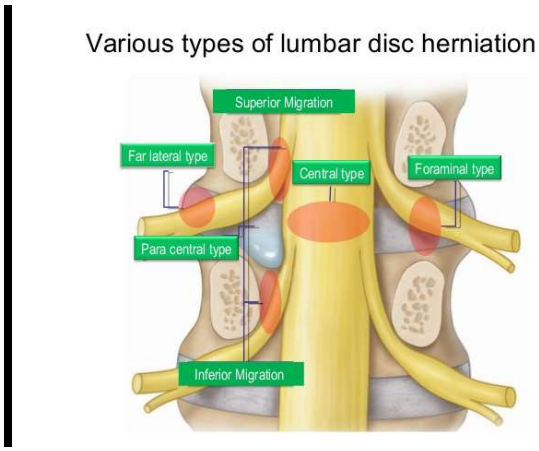
Gaffney et al (35) in their paper on painless weakness from lumbar disc herniation assessed motor radiculopathy using MRC scale. Danazumi et al (40) while assessing manual therapy techniques for management of radiculopathy used three scoring systems to assess patients' outcome (40) Visual analogue score, Roland Morris disability questionnaire, Sciatica bothersome index a score which evaluates paresthesia, weakness and leg pain &Modified Oswestry Disability Index which is good in assessing radicular pain and disability. Above scoring systems have significant clinical utility (38, 41, 42). Akuthota et al (38) in a study on clinical course of motor deficits from lumbosacral radiculopathy due to disc herniation used Manual muscle testing to assess the five lower limb myotomes and used MRC scale for grading power, L4 myotome scored 53%, L5 25% being the most affected myotomes, they used VAS to score radicular pain reporting average score of 4.7. Rainville et al (43) while assessing patients with lumbar radiculopathy used VAS to score pain and MRC scale to assess myotomal weakness.

2.4 MRI findings in radiculopathy consistent with Degenerative disc disease

Disc herniation of the same size may be asymptomatic in one patient and can lead to severe nerve root compromise in another patient. The diagnosis of the disc herniation many a times becomes complex because one not only has to correlate clinical symptoms and signs with imaging findings but also has to determine which of the anatomic abnormality is the cause of the patient's symptoms (32). Magnetic Resonance Imaging has emerged as an investigation of choice for herniated disc, however, despite the high sensitivity of MRI, there comes a challenge because some MRI findings seen in symptomatic patients have also been reported in asymptomatic patients as well as other scenarios where patients have severe symptoms yet MRI findings are in tandem with mild symptomatology (1, 9, 11, 31, 44). In order to utilize MRI in

diagnosing DDD and identifying the causative lesions it is important to understand the pathoanatomy of degenerative disc disease as discussed briefly below. Disc herniation is classified by both location, anatomically and disc level affected.

Figure 5: Location pattern of disc herniation

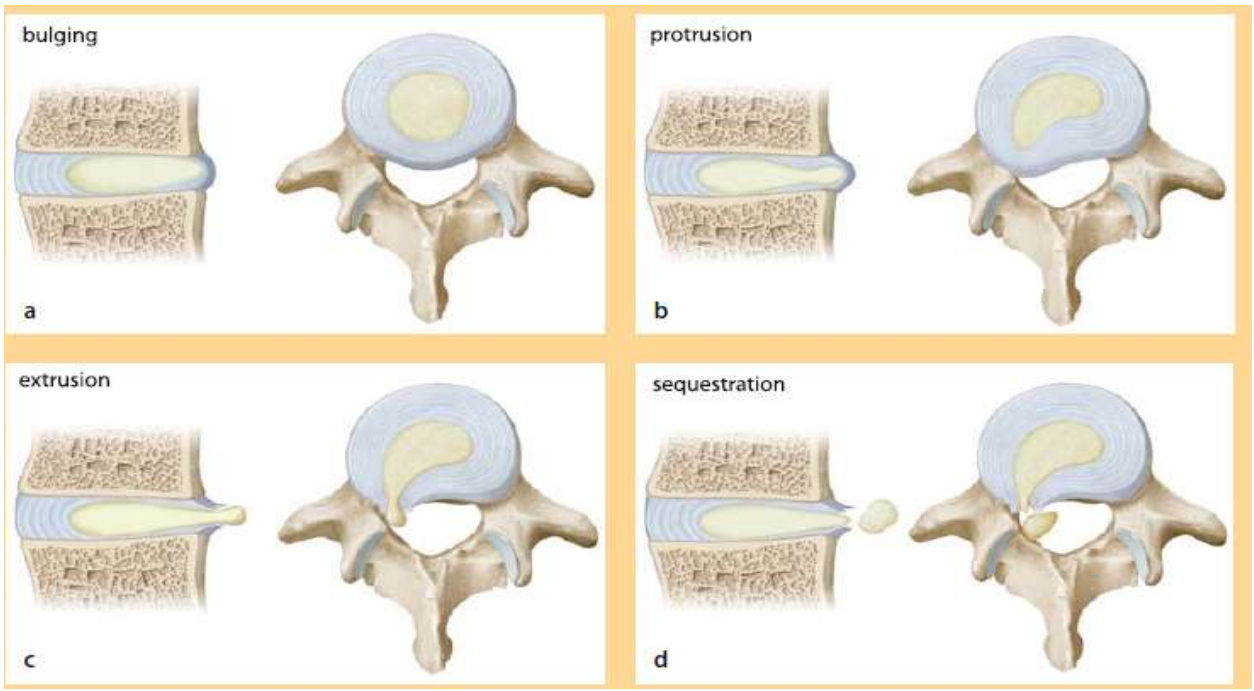


Adapted from Operative Neurosurgery

Location classification of disc herniation (35, 45, 46)

a) Central herniation; tends to be asymptomatic unless too large to compress thecal sac hence causing cauda equina syndrome or conus medularis if high lumbar spine, at times could compress traversing nerve root.
b) Posterolateral / paracentral; it is between dural sac and pedicle. This is the most common pattern, is associated with symptomatology of the traversing nerve root.
c) Foraminal /far lateral, extraforaminal) less common, affects exiting nerve root.
d) Axillary occurs if a paracentral herniation is sequestered superiorly hence causing double roots symptomatology by affecting both exiting and descending nerve roots.

Figure 6: Anatomic Classification of Lumbar Disc Herniation.



Adopted from Nobert Boss, Max Aebi. Spinal Disorders: Fundamentals of Diagnosis and Treatment Pages 491-494

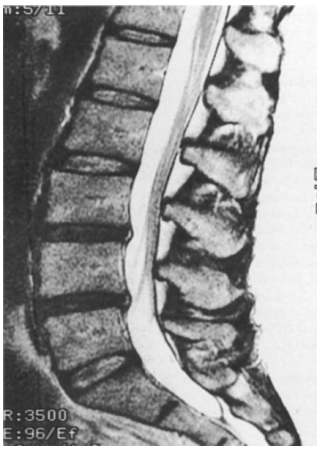
Anatomic disc herniation classification (9,47)

a) Disc Bulge: concentric disc bulging in the background of intact annulus.
b) Disc protrusion: eccentric disc bulging in the background of intact annulus which has wide based diameter in comparison to the diameter of the herniation in the canal.
c) Disc extrusion: breach in annulus with disc material herniating through annulus but remains continuous with disc cavity, remain in the axial plane as disc demonstrating a narrower base than the extruded portion.
d) Disc sequestration: free disc material herniates through annulus, can move superiorly or inferiorly in the canal, no continuity with disc space.

MRI is projected in T1 Weighted, T2 Weighted & grey scale, all in sagittal, coronal and axial views. In T1 weighted profile substances that have shortest T1 relaxation time appear bright; they include fat, fluids with high protein content and lipid-loaded molecules. Substances with long T1 time appear dark or grayer; they include cerebrospinal fluid, pure fluid, edema and tumors (10, 11).

In T2 weighted images pathological processes become more conspicuous in white signal.

Figure 7: T2 Weighted Sagital image of Lumbar region

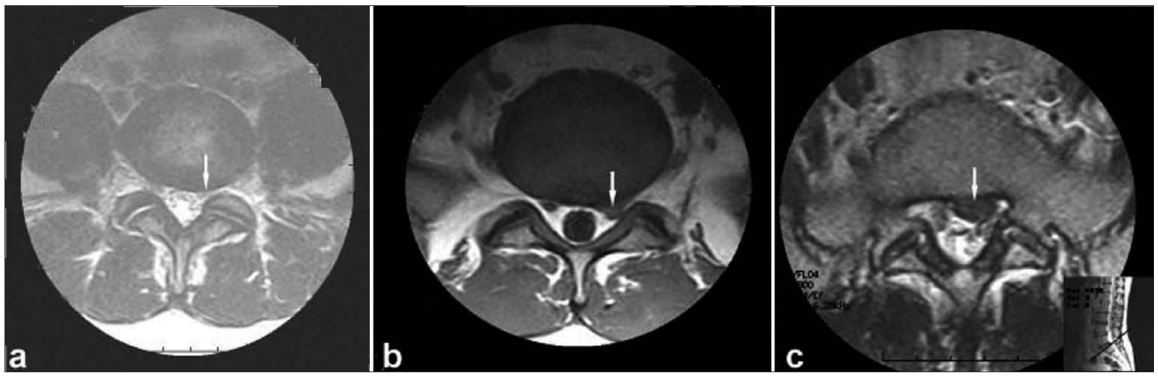


Adapted from Macnab's Backache fourth edition by David A. Wong MD MSc FRCS(C), Ensor Transfeldt MD Page 326

The above sagital image demonstrates decreased signal of L3-L4 and L4-L5 in keeping with DDD.

Other views are lateral sagittal profile to demonstrate foramina status; axial profile shows the spinal canal status as well as enabling reporting of location position of disc herniation (1, 34).

Figure 8: MRI axial slices demonstrating classification of disc herniation.



Adapted from Janardhana AP, Rajagopal, Rao S, Kamath A. Correlation between clinical features and magnetic resonance imaging findings in lumbar disc prolapse. Indian J Orthop. 2010;44(3):263–269.

Images a b & c demonstrates symmetric disc bulge, disc protrusion and disc extrusion respectively.

Degenerative disc disease is reported and scored via a number of categorizations namely endplate modic changes as well as Pfirrmann grading as demonstrated below (13, 34, 48).

Variables on magnetic resonance imaging finding used in severity scoring system

Table 2: Table demonstrating various elements in degenerative disc disease

Score	T2-signal intensity	DEBIT	Nucleus shape	Annular tears	Modic changes	Endplate integrity	Osteophytes
0	Normal	Intact	Round/oval	Intact	Normal	Intact	Absent
1	Intermediate loss	Bulge	Extension into inner annulus	Concentric tears	Type I	Isolated defects	Marginal
2	Marked loss	Protrusion	Extension into outer annulus	Radial tears	Type II	Schmorl's node <5 mm	Discontinuous
3	Absent signal	Extrusion/sequestration	Extension beyond outer annulus	Transversal tears	Type III	Schmorl's node >5 mm	Continuous, table osteophyte

Adapted from Rahyussalim AJ, Zufar MLL, Kurniawati T. Significance of the Association between Disc Degeneration Changes on Imaging and Low Back Pain: A Review Article. Asian Spine J [Internet]. 2020 Apr 30;14(2):245–57

Table 3: Endplate Modic changes Classification in degenerative disc disease

Type	T1-weighted images	T2-weighted images	Description
I	Low signal	High signal	Edema and inflammation of bone marrow
II	High signal	ISO to high signal	Marrow ischemia; yellow fatty marrow; transformation
III	Low signal	Low signal	Sclerosis over subchondral bony area

Adapted from Rahyussalim AJ, Zufar MLL, Kurniawati T. Significance of the Association between Disc Degeneration Changes on Imaging and Low Back Pain: A Review Article. Asian Spine J [Internet]. 2020 Apr 30;14(2):245–57

Table 4: Disc degeneration classification using Pfirrmann grading

Grade	Structure	Distinction nucleus and annulus	Signal intensity	Height of intervertebral disc
I	Homogenous, bright white	Clear	Hyperintense, isointense to cerebrospinal fluid	Normal
II	In homogenous with or without horizontal bands	Clear	Hyperintense, isointense to cerebrospinal fluid	Normal
III	Inhomogenous, gray	Unclear	Intermediate	Normal to slightly decreased
IV	Inhomogenous, gray to black	Lost	Intermediate to hypointense	Normal to moderately decreased
V	Inhomogenous, black	Lost	Hypointense	Collapsed disc space

Adapted from Rahyussalim AJ, Zufar MLL, Kurniawati T. Significance of the Association between Disc Degeneration Changes on Imaging and Low Back Pain: A Review Article. Asian Spine J [Internet]. 2020 Apr 30;14(2):245–257

Neural foramen compression is an essential component in Lumbar spine imaging. Lee et al came up with a neural foramen grading system which puts into consideration epidural fat, nerve root compression and change of morphology unlike other previous grading. This criteria has shown near perfect interobserver and intraobserver agreement, Grade 0 - Absence of foraminal stenosis, Grade 1- mild foraminal stenosis showing perineural obliteration of fat in two opposite directions, Grade 2 - moderate foraminal stenosis with perineural obliteration of fat in four direction not attended by morphologic nerve change , Grade 3 - severe foraminal stenosis attended by change in nerve morphology or nerve root collapse (49). Use of contrast can be used to distinguish disc rupture recurrence from scar tissue, infection and tumor because contrast is delivered to tissue with good blood supply (2,9,10,13).

Suthar et al (46) demonstrated that males were more affected than females at 55%, disc levels involved being multiple at average of 2.2 per patient, central and paracentral disc herniation were most common. They also noted that L4-L5 disc was most involved in terms of disc herniation, foraminal stenosis, central canal stenosis, facet hypertrophy. Abdalkader et al (50) reported two third of the patients had mild (Pfirrmann II & III) degenerative changes according to Pfirrmann score as one third had moderate (Pfirrmann IV) to severe (Pfirrmann V). L4-L5 & L5-S1 were the most affected levels by DDD. Yu et al (41) demonstrated that L4-L5 & L5-S1 was the commonest affected levels with Modic changes was noted to correlate well with disc

degeneration by Pfirrmann, commonest modic change was type II at 33%, Pfirrmann grade IV was the highest at 75%, type III at 12%, type V 12% , nil for type I and II. Ract et al. (51) showed Pfirrmann stage one and two had a high prevalence in the population followed by grade III and subsequently by grade IV & V. They also demonstrated that L4L5 & L5S1 as the most commonly affected levels. Ongeti et al (52) demonstrated L4-L5 being the commonest (42.3%) followed by L5-S1 (25.5%), multiple levels per patient was noted in 20.9%. Cervical spine was noted in 1.4%, thoracic just in a single patient. Male to female ratio was 1:1.26. The age bracket 31-50 years had the highest case load of disc prolapse. Janardhana et al (34) demonstrated that 90% of patients had disc degeneration of grade 4 and above involving more than one levels. 290 levels of disc herniation were noted, 71% being disc bulges, 19% protrusion and 8% extrusion. In the above 290 disc herniation levels foramen compromise was noted in 157, nerve compression in 66. Arslan et al (53) reports degenerative changes being in levels L4L5 & L5S1, disc bulge disc protrusion root compression was reported at 39%, 13% & 39% respectively. Yousif et al (39) demonstrated degenerative changes; 30% in L4-L5 level, 23.3% L5-S1 while both levels being 46%. Jacob et al (44) reported that among the Patients that had radiculopathy 84% had disc degeneration, 33% modic changes, 38% disc bulge, 76% disc herniation, 89% nerve root compression. As per spinal level L4-L5 was leading in all the above parameters followed by L5-S1 as L1-L2 had the least. Muthuuri et al (54) evaluated MRI and CT Scans from seven radiological centers in coastal region of Kenya where he assessed developmental lumbar canal stenosis and severity of radiculopathy, 19% of the enrolled patients had DLSS with radiculopathy being reported in 90% of them. In the patients without LCSS the prevalence of radiculopathy was 48%. This was attributed to the already compromised canal despite the fact that these individual can still develop spondyloarthropathy.

2.5 Correlation between patient clinical presentation with MRI findings

Bajpai et al (1) demonstrated that patients with foraminal stenosis in MRI were noted to have radiculopathy, in terms of anatomical LDH, 93% of disc extrusion, 69% of protrusion, 50% of sequestration and 21% of no disc herniation had radiculopathy thus correlating reasonably well with clinical pattern. Janardhana et al (34) reported that clinical findings correlate well with MRI finding however not all MRI abnormalities have clinical importance. Neural foramen compromise correlated better with clinical signs and symptoms. Milette et al (55) reported that loss of disc height and abnormal signal intensity highly predictive of symptomatic tears, disc bulges and protrusions had no additional significance. Beattie et al (56) reported that extrusions and severe nerve root compression were highly associated with radicular pain. Chou et al (57) in 2011 reviewed 5 studies on patients with LBP and degenerative changes reporting a OR of 1.8-2.8 in individual with low back pain and DDD. Visuri et al (58) in 2005 demonstrated LBP to be associated with degenerative disc disease with annular tear at OR of 2.0 decreased disc height 2.5, modic changes 4.2, posterior HIZ 2.5. Takatalo et al (59) in 2011 demonstrated association between IV disc degeneration and severity of LBP with severity of symptoms increasing with the higher Pfirrmann score. Nguyen et al (60) reported that the prevalence of disc bulge was higher by 48% in symptomatic patients, foraminal cross sectional area was smaller in symptomatic patients involving mainly L4-L5 & L5-S1.

Arslan et al (53) reports correlation between clinical symptoms in lumbar region as opposed to cervical region. Rahyussalim et al (48) found weak association between MRI changes in DDD and patients symptoms. Modic I, disc sequestration and protrusion showed some association with LBP. Yousif et al (39) demonstrated statistically significant correlation between physical findings and nerve root compression in MRI. Tawa et al (14) demonstrated significant positive correlation between S-LANSS, CNE & MRI findings among patients with LBP and radiculopathy.

Clear understanding of patterns of radiculopathy in discogenic low back pain and proper correlation with MRI findings, will hopefully help in proper diagnosis and appropriate decision making in choosing the right approach in management which is based on identifying the key cause of the radiculopathy. Such judiciously utilization of MRI will help reduce patient morbidity such as failed back surgery, reduce direct and indirect costs associated with low back pain & radiculopathy.

3.0. PATIENTS AND METHODS

3.1.1. Study Design

The study was a cross sectional study conducted in KNH and Coptic hospital. It involved reviewing adult patients presenting with sensory and or motor radiculopathy in low back pain secondary to degenerative disc disease. Sensory radiculopathy includes radicular pain, numbness & paresthesia and was mapped on the following lower limb anatomic zones: hip/ buttocks and or thigh and or leg and or foot. Severity of radicular pain was graded via Visual Analogue score. Motor radiculopathy regarded as loss of power was graded via MRC scale ranging from grade 0 to grade 5 and mapped via myotomes of the lower limb that include L2, L3, L4, L5 and S1. Lumbosacral MRI features of DDD were mapped per level of IV disc, anatomy & location of DDD, Pfirrmann classification of disc degeneration and modic end plate changes. Correlation between clinical pattern and MRI findings was done to assess if there is association between severity of clinical symptoms and reported MRI features.

3.1.2. Study Setting

The study was carried out in the Outpatient Orthopaedic Clinics, Orthopaedic Wards at KNH and Coptic Hospital. KNH is a level 6 teaching and referral hospital located in Nairobi city Upper hill handling patients from Nairobi and neighboring counties as well as referrals from far counties. The hospital runs vibrant Orthopaedic outpatient clinics on Tuesday, Wednesday and Friday where approximately 70 patients are attended to among them being patients with low back pain, on Tuesday and Friday specialized spine clinics run concurrently, each spine clinic has about 15 patients, majority of patients presenting with low back pain. KNH has three adult Orthopaedic wards that has an average of sixty patient admitted in each ward. Coptic Hospital is a level 6 mission hospital located in Nairobi along Ngong road one kilometer from city mortuary round about that runs daily Orthopaedic clinic with specialized spine clinics on Thursday and Friday. There is not precise documented number of the patients presenting in the two facilities that have radiculopathy secondary to degenerative disc disease at present.

3.1.3. Study Population

Eighty nine adult patients of either sex presenting at KNH and Coptic Hospital during the study period with sensory and or motor radiculopathy in low back pain secondary to degenerative disc disease as evidenced by clinical examination and lumbosacral MRI providing informed written consent personally/next of kin, were included in the study.

3.1.4. Inclusion Criteria

Adult patients of either sex presenting in KNH & Coptic hospital with sensory and or motor radiculopathy in low back pain secondary to degenerative disc disease as evidenced by clinical examination & lumbosacral MRI willing to provide written consent were included.

3.1.5. Exclusion Criteria

The following conditions and intervention could mimic or cloud the presentation of sensory and or motor radiculopathy in DDD thus the principal investigator to assessed, identified and excluded such patients so as to have results focused on primary disease which is DDD.

1. Non discogenic radiculopathy
2. Discogenic radiculopathy with comorbidity that might interfere with symptoms
3. Symptomatic hip osteoarthritis & Sacroiliitis
4. Spinal malignancy
5. History of spine trauma and or spine surgery
6. Underlying spine deformity not related to DDD
7. History of invasive spine procedure like SNRBs and epidural injections
8. Active spine infection

3.1.6. Ethical Approval And Consent

I certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers was followed during this research. In particular, ethical permissions was sought from the Department of Surgery, University of Nairobi as well as Kenyatta National Hospital, Ethics and Research Committee (KNH/UON-ERC).

All participants in this study were provided with written, informed consent documents in a language that they or their designated next of kin/guardian understood.
Approval to conduct the study was sought from the Department of Surgery,
University of Nairobi, as well as Kenyatta National Hospital, Ethics and Research Committee. Data collection commenced after the approval was granted. Participants in this study or their next of kin gave written informed consent.

The consent sought enabled the principal investigator to take the patient's bio-data details as well as history related to the presenting illness. The chief investigator clarified to the participants the objective of the study. Participation in the study was purely voluntary, and as such, it was made clear to the patients that they were free to participate or withdraw their participation at any point during the study without any explanation and consequences to their treatment.

The study participants were informed that withdrawal of participation will not jeopardize their treatment or management in any way.

Study was purely observational, no medical or surgical intervention.

Permission was sought from the administration of the two facilities before commencement of the study.

There was no financial benefit to the participating patients.

Patients did not incur any financial cost towards this study other than the basic standard of care in management of low back pain & radiculopathy.

All information obtained was treated with the utmost confidentiality. All participants were allocated a study serial number linking them to their bio database accessible only to the principal investigator. Patients' names were not used and data disposal will follow the laid down guidelines of KNH/UON-ER on data handling, retention and disposal.

3.1.7. Sample Size Calculation

Sample size was calculated using the formula illustrated below; (61)

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

Where,

n = Desired sample size

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

P = expected true proportion (estimated at 67.5%, from a study conducted by Dydyk et al (33) reports the most common pattern of radiculopathy to be paresthesia at 63-72%, of which the study will take the average of the two percentages i.e. (63 + 72)/2 = 67.5%

Sample Size Determination

Sample size will be calculated using the (1) formula;

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

$$n_0 = \frac{1.96^2 x\ 0.675(1-0.675)}{0.05^2} = 338$$

Records estimates at the two facilities indicated a figure of 30 patients per month presenting with sensory and or motor radiculopathy in low back pain. After clinical assessment and imaging evaluation approximately one third (10 patients) will be purely secondary to degenerative disc disease. This translates to annual estimate of 120 patient with sensory and or motor radiculopathy secondary to lumbosacral disc disease.

Adjusting the sample size for finite populations less than 10,000.

$$nf = \frac{n_0}{1 + \frac{n_0 - 1}{N}} = \frac{338}{1 + \frac{338 - 1}{120}} = 89$$

A Sample size of 89 patients was adopted for the study.

3.2.0. METHODS

3.3.0. Recruitment

Eligible participants were patients presenting with sensory and or motor radiculopathy in low back pain secondary to degenerative disc disease as evidenced by clinical assessment and MRI features. After fulfilling above criteria written consent was sought from the patient by principal investigator. Information was obtained through preformatted questionnaire for the clinical history, physical examination and reviewing the MRI images. This was done in the consultation room by the principal investigator. Eligible patients were recruited into the study by consecutive sampling. Only patients satisfying the inclusion criteria and giving informed written consent were included. All patients were assessed by the Principal Investigator plus or a specialist using a preformatted questionnaire to obtain the following information towards tackling study objectives.

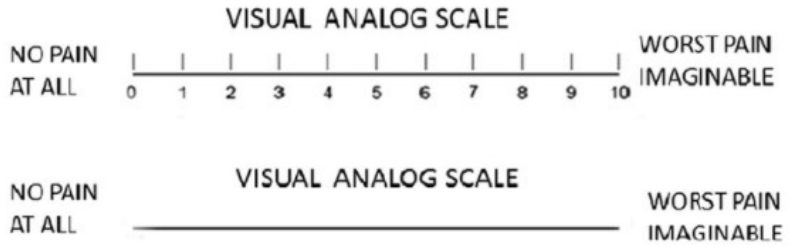
Covid 19 preventive measures & guidelines including and not limited to appropriately worn face mask, physical/ social distancing, and hand hygiene as stipulated by World Health Organization, Ministry of health and KNH-UON ERC were observed.

3.3.1. To determine type of radiculopathy

Whether patient has radicular pain and to which limb (right or left or both), what anatomical part of the lower limb it radiates to; hip/ gluteal region and or thigh and or leg and or foot. Patient then subsequently assessed for lower limb motor radiculopathy which is myotomal weakness mapped by myotomes of the lower limb involved.

3.3.2. To determine severity of radiculopathy

Severity of radicular pain was assessed using visual analogue scale as demonstrated below.



Motor weakness was assessed, graded and documented via MRC muscle power scale

Score	Description
Grade 0	No contraction
Grade 1	Presence of flicker or contraction
Grade 2	Active movement minus gravity
Grade 3	Active movement against gravity
Grade 4	Active movement against gravity plus some resistance
Grade 5	Active movement against gravity plus full resistance

3.3.3. To illustrate MRI features consistent with lumbar degenerative disc disease

After clinical assessment lumbosacral MRI which entails T11, T12, L1 through to L5 and sacral spine vertebra in T1 & T2 weighted in axial and Sagital views at least 1.5 tesla were ordered by the examining resident and or specialist. A report by a qualified radiologist was availed as well as a compact disc with images and printed films for the principal investigator and the specialist to review. Patients with recently performed MRIs were reviewed, key assessment parameters of the MRI were disc degeneration via Pfirrmann score, degree of disc herniation mapped by level, anatomic & location, and vertebral end plate status as per modic changes.

3.3.4. To correlate patient clinical presentation with MRI findings consistent with lumbar degenerative disc disease

After mapping of clinical presentation and MRI finding of interest in lumbar degenerative disc disease, correlation was undertaken to assess relation between severity of radiculopathy both motor and sensory vs anatomic, location and level of degenerative disc disease.

The degree of lumbar disc degeneration based of Pfirrmann grade, degree of vertebral end plate changes based on modic grades as well as anatomic and locational disc herniation were the MRI parameters that were studied.

Data was collected via a preformatted questionnaire administered to patients and entered into data editor of the Statistical Package of Social Sciences (SPSS) version 23.0.

Descriptive statistics was applied to patient age, sex, level and grade of both clinical and MRI findings. Correlation between severity of lower back pain and radiculopathy with MRI findings

was done using Analysis of Variance (ANOVA). All statistical tests were considered significant with a p-value ≤ 0.05.

3.3.5. Data Collection Tools And Management

Data was collected using a structured questionnaire (Patient Data Collection Form)
The collected data was reviewed for errors, double entered using Microsoft Excel for quality control, and analyzed using IBM SPSS version 23.0.
The case records was assessed for completeness and accuracy before data entry, then input into Microsoft Excel before being transferred to SPSS version 23.0 for analysis. Additionally, once data entry had been done, all cases were checked for double entry to ensure quality control and accuracy. The data set was also checked for any logical or typographical errors.
Categorical data was presented as frequencies and percentages. Continuous data was presented as means and standard deviations. These results were presented in tabular and/or graphical format by case demographic characteristics or variables.

The pattern of sensory and or motor lumbosacral radiculopathy in patients presenting with low back pain in Orthopaedic units in KNH & Coptic hospital was analyzed and presented as frequencies and percentages.

The severity of sensory and or motor lumbosacral radiculopathy in patients presenting with low back pain in Orthopaedic units in KNH & Coptic hospital was assessed using Visual analogue scale for radicular pain and MRC scale for muscle weakness then reported as frequency and percentages.

The pattern of MRI features consistent with lumbosacral degenerative disc disease in patients with sensory and or motor radiculopathy presenting with low back pain in Orthopaedic units in KNH & Coptic hospital was analyzed and presented as frequency and percentages.

Correlation between patients clinical presentation with MRI findings consistent with lumbar degenerative disc disease in patients with sensory and or motor radiculopathy presenting with low back pain in Orthopaedic units in KNH & Coptic hospital was done through frequency and percentages.

3.3.6. Validation and minimization of errors

1. The principal investigator personally evaluated the patients, administered the questionnaire to ensure there was commitment in the quality of research.

3.3.7. Quality assurance protocol

1. The case records were checked for completeness and accuracy before data entry.
2. Once data entry had been done, all the questionnaires were checked for double entry to ensure accuracy.
3. Additionally, the dataset was checked for any logical or typographical errors.

3.2.4. Study limitations

1. FINANCES; in scenario where a patient with signs and symptoms of radiculopathy but unable to afford lumbosacral MRI.

3.2.5. Study delimitations

1. Utilization of NHIF radiological package to lighten cost of MRI to the patient with active NHIF package.

3.2.6. Dissemination of the study findings and utility

The findings of the study will be disseminated in a three-tier fashion. One copy of the published dissertation will be kept at the Department of Surgery, University of Nairobi. A second copy will be placed at the University Library, while a copy shall also be shared with Coptic Hospital. The highest level of sharing of the findings will be through publication in a peer-reviewed journal. This information will hopefully help show which pathological lesions in DDD are associated with symptoms thus guide in decision making particularly on which patients need surgery vs those that could benefit from less invasive procedures like selective nerve root block, bearing in mind spine surgery can have debilitating repercussions thus reduce morbidity in patient care.

3.2.7. Conflict of interest

I have no conflict to declare.

CHAPTER 4: RESULTS

This study evaluated 89 patients presenting with sensory and or motor lumbosacral radiculopathy in degenerative disc disease to assess the pattern of radiculopathy, severity of radiculopathy as well as the MRI findings consistent with degenerative disc disease in these patients and also to assess the correlation between severity of radiculopathy and the MRI findings consistent with degenerative disc disease.

4.1 Age, Sex and Occupation distribution

Out of the 89 patients who participated in the study 66 (76.4%) of them were females while 21 (23.6%) were males. The mean age of the patients was 51.5 (SD 12.7) years, where the minimum age was 24.0 years and the maximum age was 80.0 years. The median age was 53.0 (IQR 43.0 – 60.0) years. The occupation status of the participants was as follows; those employed were 41 (46.1%), self-employed were 25 (28.1%), retired were 13 (14.6%) and unemployed were 10 (11.2%) as shown in table 4.

Table 4: Demographic characteristics

	Frequency (n=89)	Percent
Age		
≤40	21	23.6
41 – 50	16	18.0
51 – 60	30	33.7
>60	22	24.7
Gender		
Male	21	23.6
Female	68	76.4
Occupation		
Employed	41	46.1
Unemployed	10	11.2
Self-employed	25	28.1
Retired	13	14.6

4.2 Sensory Radiculopathy

4.2.1 Duration of presentation of Radiculopathy

Majority of the participants in this study had experienced low back pain and radicular pain for period of more than twelve weeks accounting for 78 (87.6%) in number as shown in table 5. One patient presented within two weeks of onset while three patients had had the complaint for over four years being the longest duration among the participants. Those presenting within 6 weeks were 6 (6.7%) while those between 7 and 12 weeks were 5 (5.6%).

Table 5: Duration of presentation of Radiculopathy

	Frequency (n=89)	Percent
Duration of pain		
0 to 6 weeks	6	6.7
7 to 12 weeks	5	5.6
>12 weeks	78	87.6

4.2.2 Severity of Low back pain and Sensory Radiculopathy

Severity of low back pain and radicular pain was assessed using visual analogue score. All participants reported pain score of six and above as shown in table 6; the highest reported pain score of 9 was reported by 42 (47.2%) participants, pain score 6 & 10 were the least reported by 1 (1.1%) & 2 (2.2%) respectively.

Table 6: Severity of Radicular pain

Severity of Radicular pain	Frequency (n=89)	Percent
6	1	1.1
7	19	21.3
8	25	28.1
9	42	47.2
10	2	2.2

4.2.3 Pattern of distribution of Radicular pain

Our study results show that 40 (44.9%) had symptoms to the left lower limb, 38 (42.7%) had symptoms to the right lower limb, while 11 (12.4%) had bilateral presentation. Distribution of pain to the zones of the lower limb was also assessed with 70 (78.7%) of the participants describing how the pain traversed from the low back through to the feet in a dermatomal pattern.

Table 7: Pattern of sensory Radiculopathy

Radiation of pain	Frequency (n=89)	Percent
Right	38	42.7
Left	40	44.9
Right and Left	11	12.4
Lower limb pain distribution by zones		
Buttocks		
Yes	88	98.9
No	1	1.1
Thigh		
Yes	88	98.9
No	1	1.1
Leg		
Yes	83	93.3
No	6	6.7
Foot		
Yes	70	78.7
No	19	21.3

4.2.4 Pattern of paraesthesia and numbness

Among our 89 participants 85 (95.5%) reported paraesthesia as 66 (74.2%) reported numbness.

Table 8: Numbness, paraesthesia and weakness of lower limbs

	Frequency (n=89)	Percent
Numbness		
Yes	66	74.2
No	23	25.8
Paraesthesia		
Yes	85	95.5
No	4	4.5

4.3 Motor Radiculopathy

Motor symptom was the least reported complaint, only 8 patients who account for 9% of the participants reported muscle weakness.

4.3.1 Pattern of motor radiculopathy and grading

Table 9: Motor Radiculopathy

Weakness	Frequency (n=89)	Percent
Yes	8	9.0
No	81	91.0

Among the 8 participants who reported muscle weakness one had L4, L5 and S1 myotomes with power grade zero being the most affected patient. L4 & L5 myotome were the most reported followed by S1.

Table 10: Myotomes affected and MRC grading of weakness

Grading	L4 (n=5)	L5 (n=6)	S1 (n=4)
0	1	1	1
3	0	1	1
4	4	4	2

4.4 MRI finding consistent with Degenerative Disc Disease

Lumbosacral MRI images of the 89 participants were subsequently reviewed to determine the pathology in keeping with degenerative disc disease including disc level, disc degeneration as per Pfirrmann classification, vertebral end plate changes as graded by modic changes and thereafter location & anatomical disc changes.

4.4.1 MRI finding by levels affected

Results of the disc pathology indicate that 64 (71.9%) of the patients had 1 level pathology, while 22 (24.7%) had two levels pathologies, 2 (2.2%) had three levels pathologies, and 1 (1.1%) had four levels pathology as demonstrated in the first part of table 11. The most involved disc was L5S1 with 56 (62.9%) of all the patients affected, followed by L4L5 with 54 (60.7%) of all the patients, while the least affected were L2L3 and L3L4 with 1 (1.1%) and 8 (9.0%) of all the patients affected. Total number of levels were 119 in the 89 participants.

Table 11: Levels of disc pathology

Number of pathologies by levels	Frequency	Percent
1	64	71.9
2	22	24.7
3	3	3.4
4	1	1.1

Level of disk	Frequency	Percent of patients (n=89)
L1L2	0	0%
L2L3	1	1.1%
L3L4	8	9.0%
L4L5	54	60.7%
L5S1	56	62.9%

4.4.2 MRI finding according to Anatomic and Location pattern

The locational pattern was reported as either central, paracentral or far lateral. Paracentral pattern was the highest proportion at 75 (63.0%), followed by far lateral at 43 (36.1%) and central at 1 (0.01%). Anatomical pattern of disc pathology was reported as bulge, protrusion, extrusion or sequestration. The highest proportion was bulge at 70 (58.8%), followed by protrusion at 39 (32.8%), extrusion at 8 (6.7%) and sequestration least proportion at 2 (1.7%).

Table 12: Anatomical and location patterns of Degenerative Disc disease

Anatomic	Location	L2L3	L3L4	L4L5	L5S1	Grand total
Bulge	Central	0	0	0	0	0
	Paracentral	1	5	18	20	44
	Far lateral	0	2	14	10	26
Sub total		**1**	**7**	**33**	**31**	**70 (58.8%)**
Protrusion	Central	0	0	1	0	1
	Paracentral	0	1	10	12	23
	Far lateral	0	0	6	9	15
Sub total		**0**	**1**	**16**	**20**	**39 (32.8%)**
Extrusion	Central	0	0	0	0	0
	Paracentral	0	0	4	3	7
	Far lateral	0	0	1	0	1
Sub total		**0**	**0**	**5**	**3**	**8 (6.7%)**
Sequestration	Central	0	0	0	0	0
	Paracentral	0	0	0	1	1
	Far lateral	0	0	0	1	1
Sub total		**0**	**0**	**0**	**2**	**2 (1.7%)**
Grand total		**1**	**8**	**54**	**56**	**119**

4.4.3 MRI findings on Disc degeneration

Disc degeneration status in the 119 levels noted to have pathology was assessed using Pfirrmann criteria. Majority of the disc degeneration was Pfirrmann III at 68%, Pfirrmann IV at 25%, Pfirrmann II at 5%. None of the pathological levels had Pfirrmann I or V according to our findings.

Table 13: Disc degeneration classification by Pfirrmann

Pfirrmann Grade	L2L3	L3L4	L4L5	L5S1	Total
II	0 (0.0)	1 (12.5)	2 (3.7)	4 (7.1)	7 (5.8)
III	1 (100.0)	6 (75.9)	42 (77.8)	33 (58.9)	82 (68.9)
IV	0 (0.0)	1 (12.5)	10 (18.5)	19 (33.9)	30 (25.2)
Total	**1**	**8**	**54**	**56**	**119**

4.4.4 MRI findings on Vertebral end plate modic changes

Vertebral end plates changes in the 119 levels noted to have pathology was assessed and reported as modic changes. Modic I changes reported in 45.4%, Modic II in 26.1%, Modic III in 10.9%. Twenty one levels accounting for 17.6% did not show any modic changes.

Table 14: Vertebral end plates modic changes

	L2L3	L3L4	L4L5	L5S1	Total
I	1 (100.0)	2 (25.0)	27 (50.0)	24 (42.9)	54 (45.4)
II	0 (0.0)	2 (25.0)	14 (25.9)	15 (26.8)	31 (26.1)
III	0 (0.0)	1 (12.5)	8 (14.8)	4 (7.1)	13 (10.9)
None	0 (0.0)	3 (37.5)	5 (9.3)	13 (23.2)	21 (17.6)
Total	**1**	**8**	**54**	**56**	**119**

4.4.5 Correlation Analysis between Severity of Radiculopathy MRI findings

Table 15: Severity of radicular pain vs Anatomical disc classification

	Bulge		Protrusion		Extrusion		Sequestration	
Severity	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
6	1	0	1	0	0	1	0	1
7	13	6	8	11	0	19	0	19
8	16	9	7	18	2	23	0	25
9	22	20	18	24	5	37	1	41
10	0	2	0	2	1	1	1	1

Results of mean pain score was observed to be increasing with severity of the disk degeneration, and an Analysis of Variance (ANOVA) test was used to determine the association between the severity of lower back pain and radiculopathy with anatomical disc pathology, and the results indicate there was a statistical significant relation (p=0.030).

Table 16: Correlation between VAS pain score and anatomical disc pathology

	N	Mean	SD	p-value
Bulge	45	8.16	0.796	**0.030**
Protrusion	34	8.24	0.923	
Extrusion	8	8.88	0.641	
Sequestration	2	9.50	0.707	

Results of mean pain score was observed to be increasing as the grade was increasing, and an Analysis of Variance (ANOVA) test was used to determine the association between the severity of lower back pain and radiculopathy with the Pfirrmann grade, and the results indicate there was no statistical significant relation (p=0.249).

Table 17: Correlation between VAS pain score and Pfirrmann Disc degeneration

	N	Mean	SD	p-value
Grade 2	4	8.00	1.155	0.249
Grade 3	57	8.19	0.915	
Grade 4	28	8.50	0.694	

Table 18: MRC grading of Motor Radiculopathy vs Anatomic disc pathology

	0	3	4
Bulge	0	1	0
Protrusion	1	0	3
Extrusion	0	0	2
Sequestration	0	0	1

Our study reported 8 patients with motor radiculopathy, severity of weakness reported via MRC scale. One patient was noted to have L4, L5 & S1 weakness MRC zero in the three myotomes, his anatomic lesion were protrusion, another patient had myotome weakness of MRC 4 having a sequestered disc. The lesions in the two patients were noted to be paracentral in location.

CHAPTER 5: DISCUSSION

5.1 Introduction

Low back Pain (LBP) estimated to have a global prevalence of 1.4-20% is a common complaint reported by patients seeking healthcare services in health facilities. Radiculopathy is reported in these patients in a significant percentage of 12-40% as it global prevalence is in the range of 3-5%. (1, 2, 3, 4, 5, 6) Approximately 70-80% of adults report LBP at least once in their lifetime (1). Degenerative disc disease manifests through intervertebral disc herniation among other pathologies is a leading cause of low back pain and radiculopathy (1, 3, 8). Low back pain associated with radiculopathy is a debilitating condition, spine surgery too can lead to debilitating consequences.

Decision making in spine surgery is a challenging decision particularly in choosing the correct surgery for a certain pathology. Decision to operate must be based on right procedure for the best outcome for the symptomatic pathology in the patient.

MRI has revolutionized decision making for patients needing spine surgery, while this imaging modality provides details of various spine pathologies some findings are not consistent with patients' symptoms, there are scenarios where patients have severe symptoms yet MRI findings are in tandem with mild symptomatology as well as significant MRI findings seen in symptomatic patients also being reported in asymptomatic patients.

The key to good results in management of low back pain with radiculopathy especially disc surgery is appropriate patient selection. Judicious use of radiological assessment alongside proper physical examination is very key in decision making.

Low back pain & radiculopathy is a costly condition to manage ranging from the numbers involved, direct cost as well as indirect costs that include the labor market repercussions such as working hours lost & workman compensation associated with low back pain. The peak group affected is fourth and fifth decade which forms a big proportion of working population. William Thomas Crow and David R. Willis (24) reported that low back pain to have a major economic impact in United states with total cost incurred due to low back pain being in excess of United States 100 billion dollars per year, Geurts et al (25) reported that annual societal cost for a patient with chronic low back pain in Netherlands to be 7,911.95 euros per patient.

In view of the above global burden related to low back pain it is important to understand this disease well particularly in identifying the specific lesion causing patients' clinical presentation

in order to intervene objectively and reduce the cost implication of this condition that range from the disease as well as repercussion of management like failed back surgery syndrome. In the global platform several studies have been carried out in attempt to evaluate correlation between clinical presentation and MRI findings in DDD demonstrating varying conclusions. MRI findings seen in symptomatic patients have also been reported in asymptomatic patients thus there exists a challenge in relating symptoms and MRI findings. There are clinical scenarios where patients have severe symptoms yet MRI findings are commensurate with mild disease.
In order to optimize care in patients with low back pain and radiculopathy as well as cut the morbidity burden and the direct & indirect costs incurred in care for these patients, it is important for the managing doctor to identify the particular lesions causing the symptoms. This will guide in making an informed decision in deciding the approach in management in these patients.
This study has delved in attempting to evaluate if there is correlation between presentation of sensory & or motor radiculopathy and MRI findings consistent with DDD in low back pain. The study evaluated 89 patients presenting with sensory and or motor radiculopathy in low back pain. Out of the 89 patients who participated in the study 66 of them accounting for 76.4% were females the other 23.6% were males. The mean age of the patients was 51.5 (SD 12.7), where the minimum age was 24.0 years and the maximum age was 80.0 years. The median age was 53.0 (IQR 43.0 – 60.0) years.

We had four set specific objectives as listed below.

5. To determine the proportion of sensory and or motor lumbosacral radiculopathy.
6. To determine the severity of sensory and or motor lumbosacral radiculopathy.
7. To determine the pattern of MRI features consistent with lumbosacral degenerative disc disease.
8. To correlate patient clinical presentation with MRI findings consistent with lumbar degenerative disc disease.

5.2 Pattern of Radiculopathy

In determining the pattern of radiculopathy several studies have reported varying results. Dydyk et al (33) reports the most common pattern of radiculopathy to be paraesthesia at 63-72%, radicular pain in 35%, numbness at 27% and muscle weakness at 37%. Gaffney et al (35) reported that the most common complaint to be radicular pain, they also reported that the incidence of motor radiculopathy to be variant in ranges of 30-50%. Ayse and Aaron (36) reported that 76.1% of lumbar radiculopathies involve L5 & S1 nerve roots with sensory symptoms on the dorsum of the foot and lateral foot with or without ankle and toe extensors & flexors. Akutotha et al (38) demonstrated that ankle dorsiflexors (L4) and hallux extensors (L5) were most affected myotomes. The 89 patients recruited in this study had low back pain and radicular pain to the lower limbs. The pattern of radiation was 42.7%, 44.9%, 12.4% to the right, left and bilateral lower limbs respectively. As the patients were assessed this pain was noted to follow dermatomal pattern as described by the patients. Radiation to the foot was reported in 78.7% of the patients which is consistent with L5 & S1 dermatomes, this prevalence is similar to findings in above mentioned studies. Paresthesia was the other reported sensory complaint at 95.5% followed by numbness at 74.2%. Motor symptoms were reported in only 8 (9%) of our 89 patients, L4, L5 & S1 were the myotomes of concern.

5.3 Severity of Radiculopathy

Previous studies have also assessed severity of radiculopathy by using some assessment tools. Gaffney et al (35) assessed motor radiculopathy using MRC scale. Danazumi et al (40) used visual analogue score reporting 8.75. Akuthota et al (38) used MRC scale for grading power, L4 myotome scored 53%, L5 25% being the most affected myotomes, they used VAS to score radicular pain reporting average score of 4.7. Rainville et al (43) used VAS to score pain and MRC scale to assess myotomal weakness. In this study we used Visual Analogue Score to assess radicular pain and MRC scale to assess motor weakness. Participants in this study reported pain score of 6 through to 10, score of 9 was the most reported at 47.2%. Pain score of 6 and 10 were the least reported at 1.1% and 2.2% respectively. Severity of motor radiculopathy was assessed in the 8 patients who had motor symptoms. One patient had complete motor weakness (MRC grade 0) in myotomes L4, L5 and S1. Myotomes L4 and L5 were the most reported as grade 4 weakness was the most reported weakness.

5.4 MRI findings consistent with Degenerative Disc Disease

Suthar et al (46) demonstrated disc levels involved being multiple at average of 2.2 per patient, in our study was at 1.3 per patient.This study demonstrated that levels L4L5 & L5S1 were the most affected levels at 60.7% and 62.9%. Abdalkader et al (50), Suthar et al (46), Yu et al (41), Ract et al. (51), Ongeti et al among other studies had similar findings.

Disc bulge was the most prevalent pathology at 60.5%, protrusion at 31.1%, extrusion at 6.7% and sequestration at 1.7%. Our finding are comparable to study by Janardhana et al (34) that demonstrated 71% being disc bulges, 19% protrusion and 8% extrusion.

Suthar et al (46) demonstrated the most common location pattern to be paracentral and central, our study demonstrated paracentral to be the highest at 63.0% followed by far lateral at 36.1%.

Disc degeneration was assessed through Pfirrmann classisfication. This study noted that Pfirrmann III at 68.9%, Pfirrmann IV at 25.2%, Pfirrmann II at 5.8% and 0% for Pfirrmann I & V. Other studies had similar as well as varying finding, Abdalkader et al (50) reported two third of the patients had mild (Pfirrmann II & III) degenerative changes according to Pfirrmann score as one third had moderate (Pfirrmann IV) to severe (Pfirrmann V). Yu et al (41) demonstrated that Pfirrmann grade IV was the highest at 75% type III at 12%, type V 12% , nil for type I and II.

Vertebral end plate changes were assessed and reported via modic changes classification. Modic I at 45.4%, modic II 26.1%, modic III 10.9%, no modic changes were observed 17.6%. Other studies have reported varying results, Teichtahl et al (62) showed that modic II to be most prevalent while Albert and Maniche (63) reported that modic I changes were the most prevalent in their studies.

5.5 Correlation between clinical presentation and MRI findings consistent with Degenerative Disc Disease

The pattern of sensory and motor radiculopathy in this study is comparable to other studies. The lower limb pain distribution is noted to be 78.7% to the feet a zone consistent with dermatomes L5 & S1 as demonstrated by studies such as Janardhana et al (34), Suthar et al (46). This study also demonstrated that levels L4L5 & L5S1 were the most affected levels at 60.7% and 62.9%. Abdalkader et al (50), Suthar et al (46), Yu et al (41), Ract et al. (51), Ongeti et al had similar

findings. The motor and sensory symptoms correlated well with the levels of degenerative disc pathology.

Results of mean radicular pain score was observed to be increasing with severity of the disk degeneration, and an Analysis of Variance (ANOVA) test was used to determine the association between the severity of lower back pain and radiculopathy with anatomical disc pathology, and the results indicate there was a statistical significant relation ($p=0.030$).

Results of mean pain score was observed to be increasing as the grade was increasing, and an Analysis of Variance (ANOVA) test was used to determine the association between the severity of lower back pain and radiculopathy with the Pfirrmann grade, and the results indicate there was no statistical significant relation ($p=0.249$).

Motor symptoms were reported in only 8 (9%) of our 89 patients, L4, L5 & S1 were the myotomes of concern. One patient was noted to have L4, L5 & S1 weakness MRC zero in the three myotomes, his anatomic lesion were protrusion, another patient had myotome weakness of MRC 4 having a sequestered disc. The lesions in the two patients were noted to be paracentral in location.

CHAPTER 6: CONCLUSION

Sensory and or motor radiculopathy secondary to degenerative disc disease in low back pain is a condition that requires thorough integrated treatment approach that involves history taking, physical examination and judicious use of MRI findings in order to identify the precise lesion that is causing symptomatology. This is founded on the finding that subtle imaging findings have been reported in patients with severe symptoms and the vice versa. Studies have also shown MRI images findings seen in symptomatic patients to be reported in asymptomatic patients. Treatment of this condition has high direct and indirect cost. Surgical management of these patients has been shown to have varying outcome including failed back surgery syndrome among other challenges thus decision to operate these patients should be arrived at after thorough assessment.

Our study has shown correlation between clinical severity of radiculopathy and pattern of MRI findings consistent with degenerative disc disease. This underscores the utility of thorough clinical assessments and judicious utilization of MRI as there were some instances where clinical picture was not in tandem with MRI findings.

6.1 Recommendation

In view of the burden of this disease in the global population more studies need to be done to find out the contribution of chemical element of radiculopathy if it might be the link in explaining some of the severe symptoms in the patients with subtle MRI findings.

There is need to increase the number of slices in our MRI images thus decreasing the distance between two slices to increase appreciation of disc pathology.

There is need to have studies conducted on motor radiculopathy separately for significant statistical analysis.

6.2 Study Limitations

1. Challenge of thoroughly assessing the pathology in MRI images due to being limited to the number of images printed.
2. Limitation in slicing dimensions thus challenge in delineation the anatomy of degenerative disc pathology.
3. Number of patients with motor radiculopathy was limited for thorough statistical analysis.

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8.0. APPENDICES

Appendix A. Patient Data Sheet

Questionnaire Identification Number: ._____.

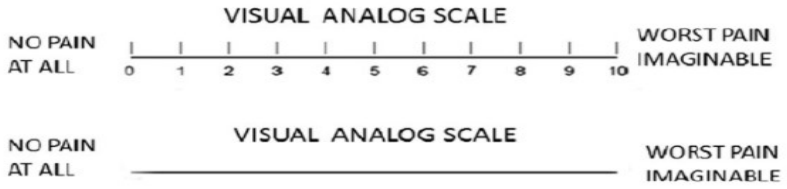
Demographic characteristics

1. Patient age in years:…….
2. Patients sex:
    a. Male b. Female
3. Patients employment status:
    a. Employed
    b. Self employed
    c. Unemployed
    d. Retired

Patient's symptoms

1. Do you experience low back pain?
    a. Yes
    b. No
2. Does this pain radiate (go to) to the lower limb?
    a. Yes
    b. No
3. Does it radiate to left or right lower limb?
    a. Right
    b. Left
4. If yes to above question does it move to the following zones?
    a. Hip/ Buttocks & or
    b. Thigh & or
    c. Legs & or
    d. Foot
5. What is the duration of low back pain in weeks? ……..

6. How severe is your pain in a scale of 0 – 10? ……



7. Do you experience numbness of the lower limbs?
    a. Yes
    b. No
8. Do you experience paresthesia of the lower limbs?
    a. Yes
    b. No
9. Do you experience weakness in the lower limbs?
    a. Yes
    b. No
10. If yes to lower limb weakness which muscle group(s) is involved?
    a. L2 – Hip flexion
    b. L3 – knee extension
    c. L4 – Ankle dorsiflexion
    d. L5 – Big toe extension
    e. S1 – Ankle planter flexion
11. MRC grading if myotomal weakness is weakness is reported above per myotome
    a. 0 – no muscle flicker
    b. 1 – Muscle flicker or trace of contraction
    c. 2 – Active movement (gravity eliminated)
    d. 3 – Active movement (against gravity)
    e. 4 – Active movement (against gravity and some resistance)
    f. 5 – Normal power

Table 4: MRI Findings

1. Level of Disc Pathology	L1L2 L2L3 L3L4 L4L5 L5S1
2. Anatomic DDD (bulge, protrusion, extrusion, sequestration)	L1L2 L2L3 L3L4 L4L5 L5S1
3. Location DDD (central, paracentral, far lateral)	L1L2 L2L3 L3L4 L4L5 L5S1
4. Disc degeneration classification by Pfirrmann	Grade I Grade II Grade III Grade IV Grade V
5. End plate modic changes	None I II III

Appendix B. Consent Form

Title of Study: Study on correlation between clinical presentation and MRI findings in patients with lumbosacral radiculopathy secondary to degenerative disc disease in two level 6 hospitals in Nairobi Kenya.

Principal Investigator\and institutional affiliation: Dr Mativo Boniface Mmed Orthopaedic surgery student H58/6799/2017 University of Nairobi.

Co-Investigators and institutional affiliation: No Co investigator.

Introduction:

I would like to tell you about a study being conducted by the above listed researcher. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records. May I continue? YES / NO This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. **P38-01-2022**

WHAT IS THIS STUDY ABOUT?

The researcher listed above is interviewing individuals who **present with low back pain and radiculopathy**. The purpose of the interview is to find out **your clinical signs, symptoms & MRI features of lumbosacral radiculopathy secondary to degenerative disc disease**. Participants in this research study will be asked questions about **if they have low back pain with radiculopathy, duration of symptoms, severity of the radicular pain, if they have numbness & paresthesia to the lower limb, lower limb myotomal weakness.** Participants will also have the choice to undergo **lumbosacral MRI which is part of management protocol in such clinical presentation**. There will be approximately **89** participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately **Twenty minutes**. The interview will cover topics such as **duration of low back pain & radiculopathy, severity of radiculopathy, presence of numbness, paresthesia, myotomal muscle weakness, reviewing lumbosacral MRI for features of DDD**. After the interview has finished, (explain in details any procedures that are necessary **No procedure.** We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: **to clarify information during proof reading of data incase need for clarification.**

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

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewer is professionals with special training in these examinations/interviews. You may feel some discomfort when **doing some spine examination maneuvers which are part of physical assessment in patients presenting with spine related symptoms such as straight leg raise.** In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free **health information on low back pain & radiculopathy**). Also, the information you provide will help us better understand **the clinical pattern and presentation of low back pain & Radiculopathy as well as MRI findings likely to cause above presentation**. This information is a contribution to science and **hopefully improve care delivery to patients presenting with sensory and or motor radiculopathy in low back pain secondary to degenerative disc disease.**

WILL BEING IN THIS STUDY COST YOU ANYTHING? (There will be no added cost to the patient)

_____

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY? (Patient money will not be used by the investigator)

_____

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

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

Appendix C. Consent Certificate

Participant's statement

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

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

I agree to participate in this research study: Yes No

I agree to have (define specimen) preserved for later study: Yes No

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

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

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

Researcher's Name: _____ Date: _____

Signature _____

Role in the study: _____ [Principal investigator & study staff who explained informed consent form.]

Witness Printed Name (If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date; _____

For Any Enquiries, please contact:

1. Dr. Boniface Mativo,
    a. Principle investigator
    b. Mobile number: 0728 203 387
    c. E-mail: sonmativo@gmail.com
2. Dr. Kirsteen Ondiko Awori,
    a. Senior lecturer, Department of Surgery, University of Nairobi.
    b. Mobile number: 0722 812 499
    c. Email: kawori@uonbi.ac.ke
3. Dr. John Kingori,
    a. Senior lecturer, Department of Surgery, University of Nairobi.
    b. Mobile number: 0725 979 524
    c. Email: john.kingori@gmail.com
4. Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
    Faculty of Health Sciences
    P.O. Box 19676-00202
    Nairobi
    Telephone: 020-2726300 Ext 44355/+254202726300-9
    Email: uonknh_erc@uonbi.ac.ke

Appendix D. Fomu ya Idhini

Msimamizi wa kanuni:

Dk Boniface Mativo

Idara ya Upasuaji wa Mifupa

Chuo Kikuu cha Nairobi

Maelezo ya utafiti

Huu ni utafiti unaoangalia jinsi picha za MRI ya uti wa mgongo kama zinalingana na msambao wa uchungu ama ulegevu wa misuli katika ugonjwa wa diski za uti wa mgongo katika wagonjwa wanaoonekana kwenye hospitali ya Rufaa ya Kenyatta na hospitali ya Coptic. Ushiriki wako utajumuisha kutoa maelezo yako ya kibinafsi kuhusu umri wako, kazi unayoifanya, na pia maendeleo yako wakati wa utafiti.

Faida za Utafiti

Matokeo ya utafiti huu hayawezi kuwa ya faida ya moja kwa moja / ya haraka kwako lakini inaweza kusaidia katika maamuzi ya matibabu kwa wagonjwa wa baadaye.

Maswali yote utakayoulizwa katika utafiti na uchunguzi wa mwili unaofuata ni sehemu ya mchakato wa matibabu yako. Kukataa kushiriki katika utafiti haitaathiri ubora wa matibabu yako kwa njia yoyote.

Hakutakuwa na faida za kifedha kwa kushiriki katika utafiti huu. Pia hautapa gharama zozote za kifedha kwa kushiriki katika utafiti huu.

Habari iliyopatikana itakuwa kutumika kwa utafiti tu.

Matokeo katika utafiti huu yatasaidia katika kuboresha mtazamo na jinsi ya kuhudumia wagonjwa walio na uchungu wa mgongo na msambao wa uchungu ama ulegevu wa misuli katika ugonjwa wa diski za uti wa mgongo

Usumbufu, hatari na haki ya kujiondoa kwenye utafiti

Unaweza kupata usumbufu kwa sababu ya maswali ya kibinafsi kwenye mahojiano.

Unaweza kuamua kutoka kwenye utafiti wakati wowote, kwa muda mfupi au kabisa.

Kushiriki katika utafiti ni kwa hiari tu. Hii haitaathiri ubora wa matibabu yako kwa njia yoyote.

Hakuna hatari au hatari zinazohusiana na kushiriki katika utafiti huu.

Ukikubali kushiriki, utaulizwa kutoa maelezo ya kibinafsi. Pia utahojiwa na mimi mwenyewe; Dkt. Mativo Boniface (Mchunguzi wa Msingi).

Usiri

Usiri mkali na faragha ya mgonjwa anayeshiriki katika utafiti huu utadumishwa.

Hojaji haitachukua jina lako na data zote zilizopatikana zitapatikana kuhifadhiwa salama. Habari juu yako itatambuliwa tu na nambari ya utafiti.

Tutanuia kushiriki matokeo yetu na watu wengine wanaofanya tafiti kama hizi.

Uchapishaji wa matokeo yetu katika majarida ya kisayansi au mawasilisho katika mikutano ya kisayansi haitakuwa na habari inayoweza kukutambulisha. Utambulisho wako hautafunuliwa katika chapisho lolote.

Maswali na uchaguzi

Maswali yoyote ambayo unaweza kuwa nayo yanaweza kushughulikiwa kwa mchunguzi mkuu kupitia njia ya mawasiliano iliyotolewa hapa chini. Ushiriki wako katika utafiti ni wa hiari. Wewe unaweza kuchagua kukataa kushiriki au kuondoa ushiriki wako kutoka kwa utafiti huuwakati wowote bila athari yoyote.

Appendix E. Cheti Cha Ruhusa ya kushiriki utafiti

Mimi, …… (Jina kamili kwa herufi kubwa)
nimepeana ridhaa ya mimi kushiriki katika utafiti uliofanywa na Dkt Mativo Boniface, asili ya ambayo nimeelezwa na yeye. Nimearifiwa na nimepata kuelewa ya kwamba kushiriki kwangu ni kwa hiari yangu na nikipenda naweza kujiondoa wakati wowote katika utafiti huu bila kuadhiri na hii haitabadilisha kwa njia yoyote matibabu ninayopewa..Matokeo ya utafiti huu huenda yasinifaidi kibinasi kwa sasa lakini Habari itakayopatikana itasaidia kupata njia nzuri ya kuhudumia wagonjwa wenye shida ya msambao wa uchungu ama ulegevu wa misuli katika ugonjwa wa diski za uti wa mgongo.

…… ..
Saini / Uchapaji wa kidole gumba wa (mshiriki)
Tarehe: …….

Sehemu III: Kauli ya shahidi ikiwa hiriki hajui kusoma na kuandika:

Nimeshuhudia usomaji sahihi wa fomu ya idhini kwa mshiriki, na binafsi.
Nimepata nafasi ya kuuliza maswali.
Ninathibitisha kwamba mgonjwa huyo ametoa idhini kwa hiari yake.
Jina la shahidi: …….
Saini ya shahidi: …… Tarehe: ……
Uchapishaji wa kidole gumba cha mshiriki.

Ukiwa na maswali yoyote kuhusu utafitihuu, wasiliana na:

1. Dkt. Boniface Mativo,
    a. Msimamizi wa Kanuni
    b. Simu ya rununu: 0728 20 3387
    c. Barua Pepe: sonmativo@gmail.com

2. Dkt. Kirsteen O. Awori,
    a. Mhariri Mkuu Orthopaedics, Chuo Kikuu cha Nairobi.
    b. Simu ya rununu: 0722 812 499
    c. Barua Pepe: kawori@uonbi.ac.ke

3. Dkt. John Kingori,
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    b. Simu ya rununu: 0725 979 524
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Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/179

12th May, 2022

Dr. Boniface Mativo
Reg. No.H58/6799/2017
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

Dear Dr. Mativo

RESEARCH PROPOSAL: CORRELATION BETWEEN PATTERNS OF CLINICAL PRESENTATION AND MRI FINDINGS IN ADULT PATIENTS WITH LUMBOSACRAL SENSORY AND MOTOR RADICULOPATHY SECONDARY TO DEGENERATIVE DISC DISEASE IN KENYATTA NATIONAL HOSPITAL AND COPTIC HOSPITALS (P38/01/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P38/01/2022.** The approval period is 12th May 2022– 11th May 2023.

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, KNH
The Chair, Dept. of Orthopaedic Surgery, UoN
Supervisors: Dr. Kristeen Ondiko Awori, Dept. of Human Anatomy and Physiology, UoN &
Consultant Orthopaedic Surgeon, KNH
Dr. John Kingori, Dept. of Orthopaedic Surgery, UoN

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR
SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **885918**

Date of Issue: **19/May/2022**

RESEARCH LICENSE

This is to Certify that Dr.. Mativo Boniface of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: CORRELATION BETWEEN PATTERNS OF CLINICAL PRESENTATION AND MRI FINDINGS IN ADULT PATIENTS WITH LUMBOSACRAL SENSORY for the period ending : 19/May/2023.

License No: **NACOSTI/P/22/17606**

885918

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Proposal

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