UTILITY OF PLAIN RADIOGRAPH IN LOW BACK PAIN OF NON-TRAUMATIC ORIGIN AS SEEN AT KENYATTA NATIONAL HOSPITAL

A dissertation submitted in part fulfilment of the requirements of the University of Nairobi for award of the Degree of Master of Medicine in Orthopaedic Surgery (M.Med. Orthopaedic Surgery).

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DECLARATION

I hereby declare that this study is my original work and has not been presented as a dissertation at any other university.

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DEDICATION

I dedicate this work to my lovely wife, Lily Lemayian, our two wonderful children, Nemayian and Lekishon for their unequivocal support during this arduous journey.

I also dedicate it to my parents, Mr. and Mrs. Lemoko for encouraging me relentlessly through these many years spent in pursuit of higher academic honour.

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Mr.Phillip Ayieko for his professional input in data analysis.

All the patients who accepted to participate in this study.

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LIST OF ABBREVIATIONS

AP - Anteroposterior

CT - Computed Tomography

CXR-Chest Radiograph

CBC-Complete Blood Count

DEXA-Dual-Energy X-Ray Absorptiometry

ERC-Ethics and Research Committee

ESR-Erythrocyte Sedimentation Rate

KNH-Kenyatta National Hospital

LS -Lumbosacral

L5-S1-space between 5^{th} lumbar and 1^{st} sacral vertebral bodies

MRI-Magnetic Resonance Imaging

PID-Prolapsed Intervertebral Disc

T12-L1-space between 12^{th} thoracic and 1^{st} Lumbar vertebral bones

TB-Tuberculosis

UON-University of Nairobi

UA-Urinalysis

USA-United States of America

WORKING DEFINITIONS

Positive Radiological findings: This refers to reported findings on plain radiographs, limited to the lumbosacral spine, and directly attributed to the causation of the low back pain.

Mechanical low back pain: Refers to simple low back pain with no definable causative factor.

Chiropractors: These are health practitioners who provide natural, drugless and non-surgical treatment to patients with neurological and musculoskeletal health problems.

Primary care: This is a term for health services by providers who act as the principal point of consultation for patients within a healthcare system.

Transitional vertebrae: They are abnormally-formed vertebral bones that have characteristics of two types of vertebrae.

Vacuum phenomenon: This is a linear or oval radiolucency in the intervertebral disc space that corresponds to gas, a typical finding of osteonecrosis. It is specific for local bone ischemia associated with a non-healing vertebral collapse.

Scoliosis: This is a complex spine deformity clinically evident as a side-to-side (coronal) curvature.

Lordosis: This is an inward curvature of a portion of the lumbar and cervical vertebral columns

Osteopaenia: Refers to reduced bone density

Endplate sclerosis: This refers to increased density of the caudal and cranial margins of the vertebral bodies.

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ABSTRACT

BACKGROUND

Low back pain is a commonly recognized problem worldwide and is a major cause of debilitation to many patients. Plain radiography is used in many of these patients as an initial investigative and evaluative tool, as was evidenced by data from the Department of Radiology, University of Nairobi. However, it was not known how truly useful this investigation was in making definitive diagnosis for many of the causes of low back pain seen at KNH. This study sought to establish the utility of plain radiographs in arriving at diagnostic conclusions for patients presenting with low back pain of non-traumatic origin.

OBJECTIVE: To determine diagnostic utility of plain radiographs in patients presenting with low back pain that is of non-trauma origin.

MATERIALS AND METHODS: This was a prospective study conducted at the orthopaedic clinics and wards at the Kenyatta National Hospital from 1st February 2013 to 30th May 2013.One hundred and two (102) consecutive patients who presented to the orthopaedic clinics or admitted to the wards with low back pain of non-traumatic origin were recruited into the study after meeting the selection criteria. Data was collected by the principle investigator with the help of a research assistant using a structured questionnaire. Plain radiograph films ordered by the clinicians were reviewed for diagnostic yield by two qualified radiologists.The data was analyzed using Stata/1C computer program version 11.0 and presented using tables, charts and graphs.

MAIN OUTCOME MEASURE: Determination of frequency of occurrence of radiographic findings in patients reporting low back pain not caused by trauma.

RESULTS: In this study, the average age of patients presenting with low back pain was 50.9years, with a male to female ratio of 1:2.4. Majority of these patients (96%) presented with chronic low back pain. Most of the patients presented with sensorimotor deficit. There was a high rate of positive radiological findings (98%), possibly attributed to the chronicity of the presenting symptoms. The most common occurring findings included muscle spasm, osteoporosis, reduced lumbar lordosis, spondylosis, disc degenerative disease and osteophytes.

There was poor ability to diagnose infectious causes, inflammatory conditions, transitional vertebrae and tumor metastasis.

Assessment of inter-rater variability showed good level of agreement on presence of spondylolisthesis and vacuum phenomenon (k=0.71), moderate agreement on reduced disc space, reduced lumbar lordosis, spondylosis (k=0.42-0.56) and poor agreement on film quality, infections, tumor metastasis, osteophytes, prolapsed intervertebral disease (PID), osteoporosis, scoliosis, muscle spasm and sacroilitis (k=0.13-0.21)

Follow-up of these patients showed that 33% underwent further investigations to enhance diagnostic yield.

CONCLUSION: This study showed that most of the patients present to KNH with chronic low back pain and have increased probability of having positive radiological findings.

However, usefulness of plain radiography is limited by factors such as inter-rater variability, film quality, the underlying pathology, views taken, among others.

As such, it is the recommendation of this study that clinicians should be encouraged to adhere to already established international protocols on referral of patients for radiography.

CHAPTER 1: INTRODUCTION

Low back pain as defined by Andersson, is pain limited to the region between the lower margins of the 12th rib and the gluteal folds[1]. This is a global and increasing problem[2]. It is the most prevalent musculoskeletal condition and most common cause of disability in developed nations[3,4] .

It is the second most common reason for patients to seek medical treatment in the United States[5] and a common condition for people seeking care in emergency departments[6]. In Australia, it is estimated that four out of every five adults will have an episode of low back pain at some point in their lives, and each year, about one in twelve people will experience low back pain for the first time[7]. It is reported to be the second most common clinical complaint leading Australians to seek care in general practice [8].

The lifetime risk of low back pain in the United States is estimated to be 84%[9], with estimates of point prevalence ranging between 12% and 35% and lifetime prevalence between 49% and 80%[10].

In Africa, the average lifetime prevalence of low back pain among adolescents is 36% and among adults 62%. Mean low back pain point prevalence among adolescents is 12% and among adults 32%. The average one year prevalence among adolescents is 33% and 50% among adults. These findings indicate that prevalence of low back pain among Africans maybe comparable to that reported elsewhere globally[11].

In a retrospective study carried out by Mulimba (1982-1987) in a private orthopaedic clinic in Nairobi , it was found out that 10% of the patients seen suffered from low back pain, with a male to female ratio of 1:1.7. It was also found out that the incidence was uncommon under the age of 10 years, rising steeply from 20-50 years of age, and then decreasing thereafter. It was postulated that the decline in incidence after 60 years of age at the time was because ours was a young society with the most affected being the reproductive age group[12].

Data from medical records at KNH indicates that between 2008 and 2011, 53 patients were admitted suffering from severe non-traumatic low back pain.

A study carried out in Uganda by Galukande et al.(2005) in Mulago Hospital, concluded that the point prevalence of low back pain in that country was 20% with a mean age of occurrence of 47years 10months.The male to female ratio was 1:2. 62.3% of the affected patients had mechanical pains, 19.1% had nerve root compression due to prolapsed intervertebral discs, 17.2% had serious spinal pathology due to TB, Brucellosis, fractures and degenerative changes while 1.5% had no determinable cause. However, there were no statistically significant age and gender differences among the diagnoses[13].

A recent retrospective study by Gakuu et al.(2012) to ascertain the characteristics of prolapsed intervertebral discs in an African population concluded that this condition, which causes 20-35% of low back pains, occurred most frequently between 21-60 years(87.8% incidence) and was commonest at the lumbar region(L4,5 and L5,S1). The likely explanation given was that individuals are most active during this period and were more involved in outdoor activities, exposing them to continuous trivial trauma to the spine[14].

Global research has shown that the cost of low back pain is high. A study carried out by Maniadakis and Gray (2000) found that in the United Kingdom in 1998, the direct healthcare cost of back pain was approximately 1.632 billion pounds, 5% of which was directly attributable to radiology and imaging[15]. The socioeconomic impact of low back pain maybe difficult to assess, but a recent study in the US showed that the total cost of low back pain exceeds 100 billion dollars per annum[16].

CLASSIFICATION OF LOW BACK PAIN

It is widely varied among various authors. The commonest classification is that of:

- Acute if the pain is of less than six weeks duration
- Sub acute if it lasts between six and twelve weeks
- Chronic if it persists for more than twelve weeks[16-20]

ACUTE LOW BACK PAIN

Most of the causes of acute low back pain are benign and non-specific, and serious pathologies are rare. Hence, the term **mechanical-causes** of low back pain. Most of these are myofascial strains. Acute mechanical pain accounts for more than 90% of causes of low back pain[21].

Some of the more specific causes include acute intervertebral disc herniation, osteoarthritis, spinal stenosis, spondylolisthesis, ankylosing spondylitis, infections and malignancies. Therefore, it is imperative that a good history is taken and a proper physical examination be carried out to help in differentiating potentially serious conditions from the less serious ones.

Overall, 60-70% of patients with low back pain recover by six weeks and 80-90% by twelve weeks[22].

As shown in figure 1, the smooth curve indicates a progressive recovery from low back pain as time goes by.

Time Course of Acute Low Back Pain

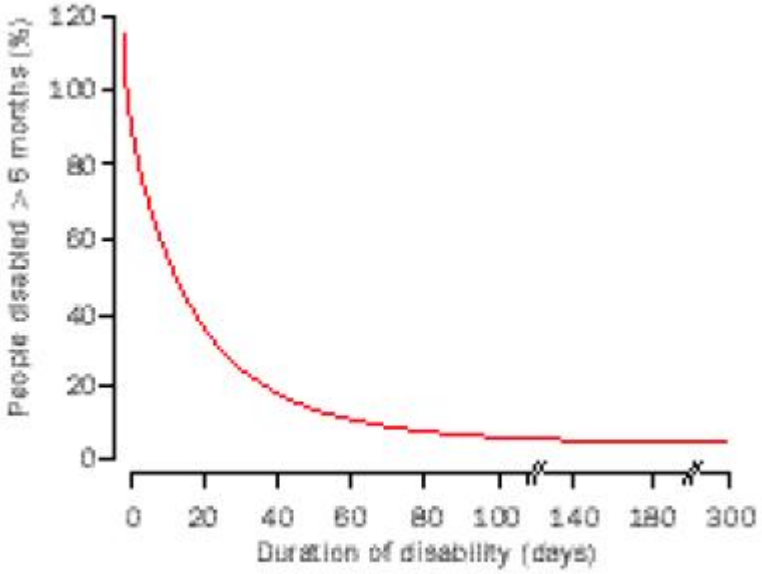


Figure 1: **Time course of acute low-back pain**

Recovery after twelve weeks is slow and uncertain. Fewer than half of the individuals disabled for more than six months return to work and after two years of absence from work, return-to-work rate is nearly zero[23].

CHRONIC LOW BACK PAIN

This is a condition commonly seen in people aged above 40-50 years, in occupations that require frequent bending or lifting, exposure to repetitive vibrations e.g. truck drivers, obese patients and those who are physically unfit. Association with smoking has largely remained inconclusive.

Most studies done to ascertain effect of weight on low back pain have concluded that overweight and obesity have the strongest association with chronic low back pain and the propensity to seek medical care for low back pain. This association seems stronger for women than men. However, body weight per se is recognized as a weak risk factor for low back pain[24-26].

Most of these studies hypothesize that increased body weight modifies spinal posture and function favoring onset of chronic low back pain. Obesity is thought to enhance increase in anterior pelvic tilt, inducing greater flexion of sacroiliac joints resulting in higher torque on L5-S1 joints and discs. This possibly increases the shear forces at this level and overloads the disc, thereby increasing risk of disc degeneration.

Causes of low back pain can be classified into:

a) **INTRASPINAL CAUSES:**
   -degenerative disc changes
   -disc herniation
   -lumbar stenosis
   -cauda equina syndrome
   -Intermittent neurogenic claudication
   -infections e.g. Osteomyelitis, Discitis, TB, Epidural Abscess
   -Neoplasms, whether primary or metastatic (especially from breast, lungs, prostate and multiple myeloma)
   -Inflammatory conditions

-Osteoporotic compression fractures
-musculotendinous insufficiency

Infections account for 0.01% of these causes, neoplasms account for 0.7% and osteoporotic fractures account for about 4 %[27].

b) EXTRASPINAL CAUSES (REFFERED PAIN)

These include:
-abdominal aortic aneurysm
-benign gynaecological conditions such as ovarian cysts, endometriosis etc
-pelvic/ abdominal malignancies
-sacroiliac arthritis
-arthritides of the hip joint such as osteoarthritis, inflammatory arthritis, osteonecrosis etc.
-trochanteric bursitis
-abductor tendinitis
-physical deformities e.g. kyphosis, scoliosis, exaggerated lumbar lordosis
-ñBack Mouseò (fibro-fatty nodule)-this is fat herniation through fascia just above the iliac crest in patients, mostly young athletic women[28].
-others e.g. pancreatitis, diabetes mellitus, fibromyalgia, osteomalacia, pregnancy. About 50% of pregnant women experience low back pain due to exaggerated abdominal sagittal and transverse diameter and depth of lumbar lordosis[29].

Some of these causes are summarized in Table 1 page 8 in relation to anatomical site and pathology.

Some authors arbitrarily classify adult low back pain into five categories:

i. Referred back pain (mostly caused by extraspinal sources)
ii. Low back pain with radiculopathy or myelopathy
iii. Low back pain with deformity (scoliosis, kyphosis etc)
iv. Low back pain secondary to fractures, tumors and infections
v. Mechanical low back pain caused by ligamentous or muscular strains, poor posturing, facet joint irritation etc.

Some of the potential pain generators in the lumbar spine include facet joints, muscular insertions, vertebral endplates, intervertebral discs, spinal nerves with branches of sinuvertebral nerve, posterior longitudinal ligament and interspinous ligament.

Figure 2 is a pictorial representation of the functional spinal unit with anatomical detail of the potential pain generators in the lumbar spine.

NORMAL ANATOMY OF THE FUNCTIONAL SPINAL UNIT(L4-5) AND ASSOCIATED NEURAL STRUCTURES

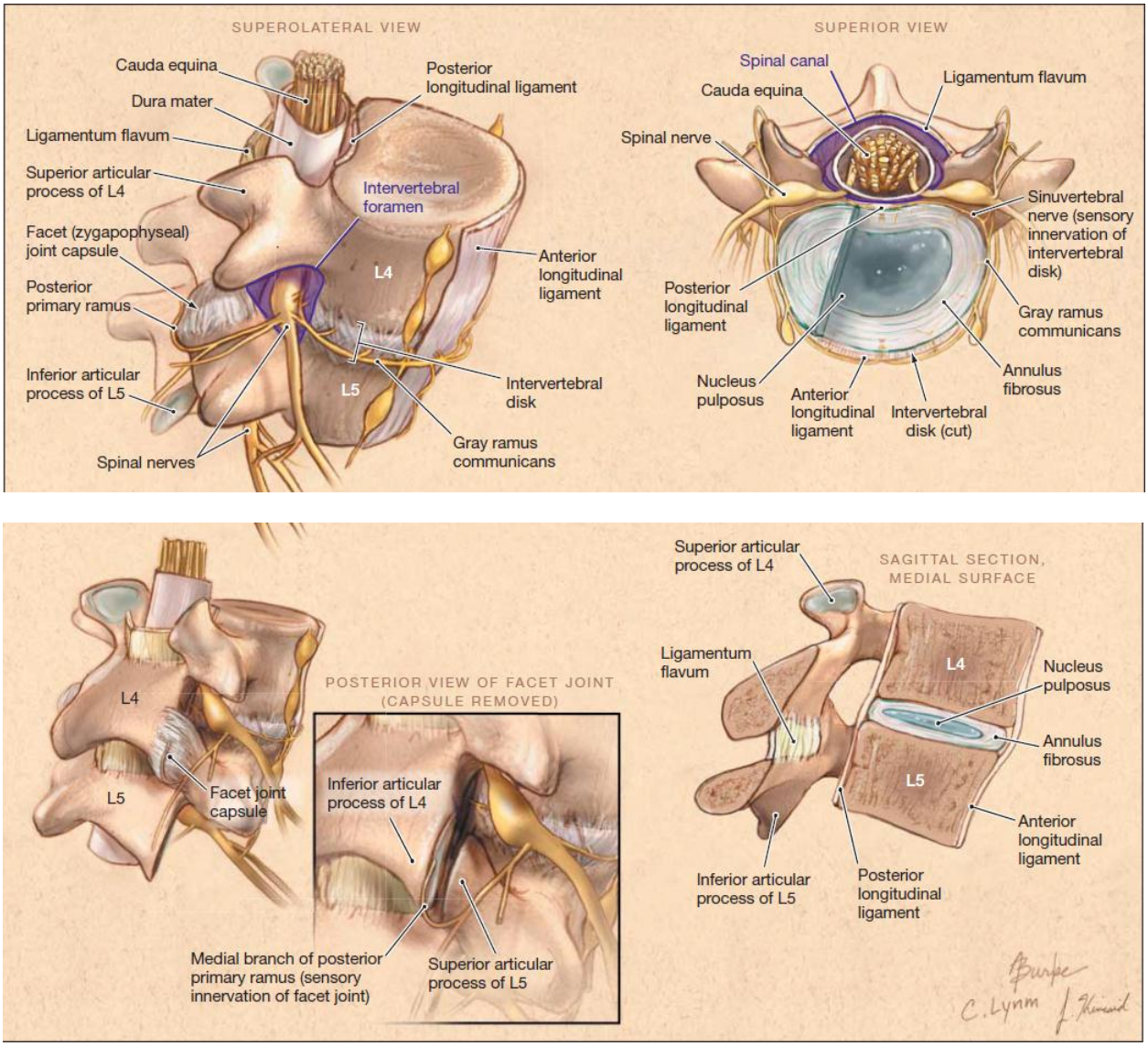


*Figure 2: The basic unit of the spine known as the **functional spinal unit**, is composed of 2 adjacent vertebral bodies with two posterior facet joints, an intervertebral disc and surrounding ligamentous structures*

Source: Rathmell JP.JAMA.2008; 299:2066-2077

Table 1: Systematic summary of causes of low back pain in terms of anatomical site and pathology;

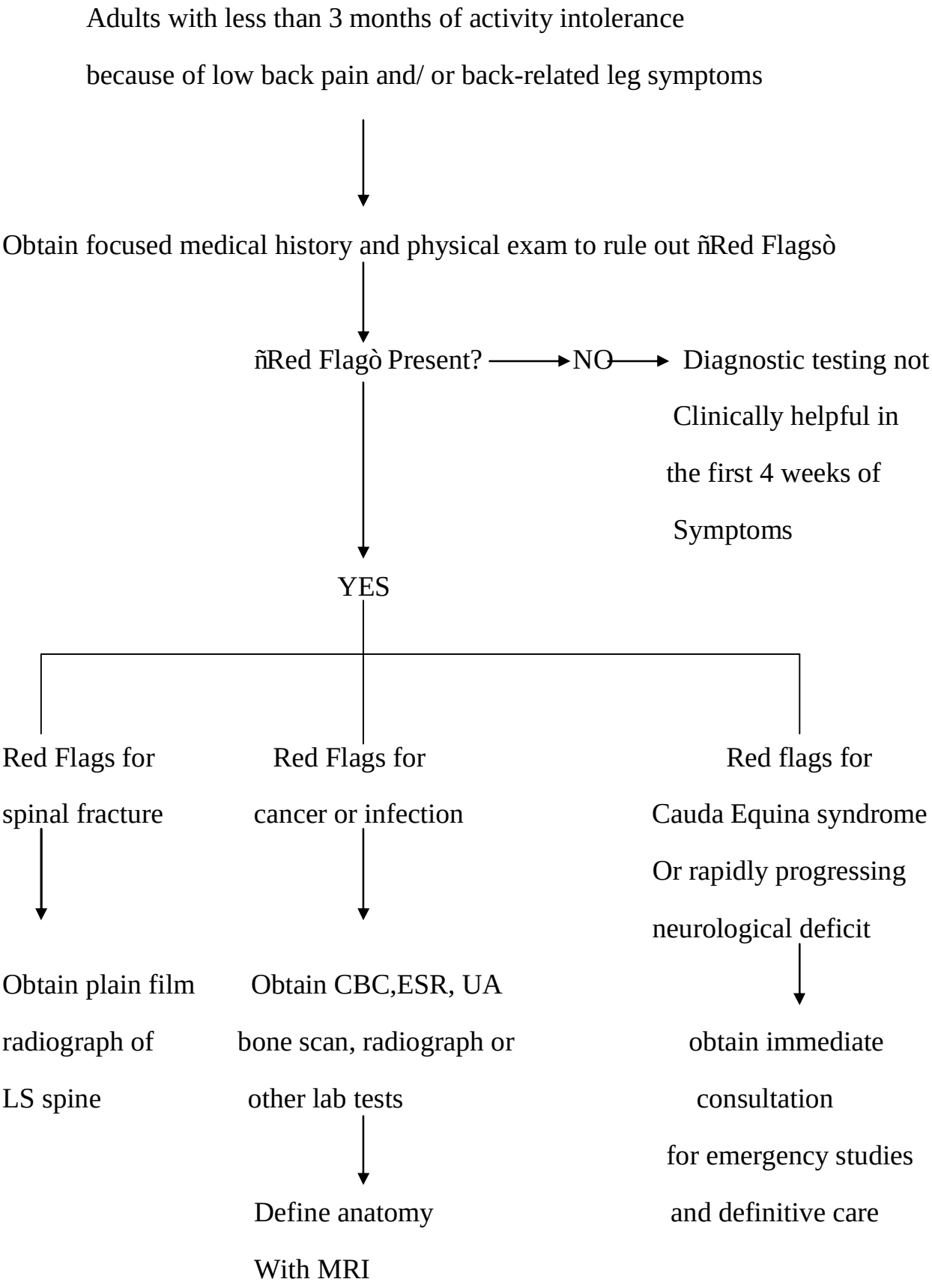
PATHOLOGY	ANATOMICAL SITE					
	MUSCLE	FASCIA	LIGAMENT	BONE	JOINT	DISC
TRAUMA	sprain	tear	sprain	fracture	sprain	sprain
FATIGUE FAILURE				fracture		internal disc disruption
INFECTION	abscess			osteomyelitis	arthritis	discitis
INFLAMMATION	myositis		enthesopathy		arthritis	
TUMOUR	sarcoma			primary metastatic	primary	
MECHANICAL / PHYSIOLOGICAL	spasm trigger points	compartment syndrome			"dysfunction"	

CHAPTER 2: LITERATURE REVIEW

Plain radiographs are utilized by many clinicians in the initial evaluation of patients presenting either as outpatients or inpatients with low back pain.

Data from the Radiology Department of the University of Nairobi at KNH indicates that from January 2010 to December 2011, there were 1,220 plain lumbosacral radiographs done for various low back problems, giving an average of 610 radiographs per annum. There were 8 oblique lumbar views done during the same period, 17 sacro-coccygeal and 63 thoracolumbar x-rays done.

Fig. 3: The following diagram illustrates commonly used steps in initial assessment of patients presenting with low back pain.


Adults with less than 3 months of activity intolerance
because of low back pain and/ or back-related leg symptoms
Obtain focused medical history and physical exam to rule out ñRed Flagsò
ñRed Flagò Present?
NO
Diagnostic testing not
Clinically helpful in
the first 4 weeks of
Symptoms
YES
Red Flags for
spinal fracture
Red Flags for
cancer or infection
Red flags for
Cauda Equina syndrome
Or rapidly progressing
neurological deficit
Obtain plain film
radiograph of
LS spine
Obtain CBC,ESR, UA
bone scan, radiograph or
other lab tests
Define anatomy
With MRI
obtain immediate
consultation
for emergency studies
and definitive care

Several guidelines have been formulated in many countries to guide clinicians on the utilization of imaging modalities for diagnosis of low back pain.

The Australian Guideline ñEvidence-based management of acute musculoskeletal painò recommended against use of plain radiography, MRI or CT Scanning in absence of **"Red Flags"** in non-specific low back pain of less than twelve weeks duration[30]. ñRed Flagsò are physical risk factors which suggest the presence of serious underlying pathological causes of low back pain[30-32](see Table 2). These guidelines state that plain radiographs are not helpful in identifying the cause of pain and do not contribute to greater improvement in a patientôs physical function, pain or disability.

Numerous other studies support this recommendation[19,33-36].

Condition	Alerting features associated with condition
Infection	• Symptoms of infection (e.g. fever) • Risk factors for spinal infection (e.g. underlying disease, immunosuppression, penetrating wound, intravenous drug use)
Fracture	• Major trauma • Minor trauma, if >50 years old, with a history of osteoporosis, and/or taking corticosteroids
Malignancy	• History of malignancy • >50 years old • Unexplained weight loss (e.g. >4.5kg in <6 months) • Pain at multiple sites • Pain at rest
Aortic aneurysm, leak or rupture	• Sudden onset • Associated collapse/hypotension • Pain not aggravated by spinal movement • Abdominal pain radiating to back
Cauda Equina Syndrome	• Saddle anaesthesia • Urinary and/or faecal incontinence or retention, of recent onset • Widespread motor and/or sensory weakness

Table 2: Table of Red Flags.Adapted from Evidence-based management of acute musculoskeletal pain: therapeutic guidelines: rheumatology[31] and Refshauge[32].

Jarvik and Deyo (2002) in a retrospective study carried out over a period of five years also concluded that for adults less than 50 years of age presenting with no signs or symptoms of systemic disease, symptomatic therapy without imaging was appropriate. For patients older than 50 years or those whose findings suggest systemic disease, plain radiography and simple laboratory tests could almost completely rule out underlying systemic disease. They also recommended that advanced imaging should be reserved for patients who were considering surgery or those in whom systemic disease was strongly suspected[37].

In the UK, the first set of national guidelines specifying referral criteria for radiography of the lumbar spine were published by the Royal College of Radiologists in 1989[38].These guidelines which have been refined over time aim at reducing the number of unnecessary radiographs by limiting referrals only for the patients with red flags.The United States Agency for Health Care Policy and Research (AHCPR) also released similar guidelines in 1994 concerning investigation and management of low back pain[39]. Despite longstanding recommendations against use of plain radiographs in acute low back pain with no red flags, overuse of imaging has been documented in a number of settings[40-46].Carey et al. in Northern Carolina found that radiography was commonly used as a diagnostic test for patients with acute back pain[42]. Harger et al.[47], Ammedolia et al.[48] also found out that 74% and 63% of chiropractors respectively used radiography on patients with uncomplicated low back pain lasting less than one week despite their actions not being supported by existing evidence.Kendrick et al.[49,50] found out that lumbosacral x-rays in primary care patients with low back pain of at least six weeks duration was not associated with improved functioning, severity of pain or overall health status and was instead directly related to increased clinician workload.

Studies in USA have found utilization rates of plain radiographs of between 16-18% in patients presenting with low back pain despite the absence of red flags[6,51]. Some of the main reasons given by the practicing clinicians were:

i. patient reassurance
ii. desire for an explanation of symptoms
iii. overestimation of patientôs expectations of imaging
iv. fear by clinicians of being prosecuted[53]

v. pressure created by waiting times for secondary care or MRI[41]
vi. fear of strain in the patient-doctor relationship[41]

A similar study in Australia in 2000 showed that 29% of all first-time presentations for back pain led to lumbar or lumbosacral imaging of which 54% were x-rays and 15% CT Scans[54].

A retrospective study carried out by Ogengô and Ongeti in 2011 of patients diagnosed with PID at KNH between January 1997 and December 2007 found that among the six hundred and three patients seen, 38.5% had plain radiographs done, 44.1% had MRIs and 9.1% had CT Scans[55].In the UK, 1.5million patients undergo plain radiography for low back pain each year[56].Evidence suggests that findings from both plain radiographs and advanced imaging studies does not strongly correlate with acute low back pain symptoms[57]. Other studies where plain radiographs were used for non-specific low back pain showed that there were no demonstrable abnormalities or demonstrated only minor degeneration for 95% of primary care and 86% of emergency care presentations[40,52]. Hence, they are neither sensitive nor specific in the detection of many serious conditions. Some studies show a similar prevalence of degenerative changes on radiographs in patients without low back pain and in those with low back pain[37,57,58]. Other studies do not find any clear relationship between x-ray findings and non-specific low back pain[57,59].

Several trials and programs have tried to focus on improving the appropriateness of ordering imaging tests for low back pain[40,60-62]. However, several authors have questioned whether the introduction of radiography guidelines would reduce the utilization of lumbosacral radiographs[63,64]. They argue that where current utilization of radiography is low, then strict adherence to guideline criteria may increase the number of requests for lumbosacral radiographs, hence this might only alter the nature and not necessarily the rate of referrals.

The National Physiciansô Alliance (NPA) developed a list of top five activities in primary care for which changes in practice could lead to higher quality care and better use of limited clinical resources[65]. One of these top five recommendations was for clinicians to avoid imaging for low back pain within the first six weeks

unless red flags are present. This is considered to be responsible physician stewardship which can help improve quality and reduce potential harms of care.

Overuse or inappropriate use of radiographs have several recognized disadvantages:

- waste of limited resources.
- irrelevant findings resulting in inappropriate diagnoses and hence ñpatient labelingò and treatment.
- unnecessary exposure to gonads and bowel. Lumbosacral x-ray (AP View) is associated with a dose of ionizing radiation equivalent to approximately 65 CXRs[38,66]. The oblique views are said to cause double the exposure of standard views[67,68].
- According to the International Commission on Radiology Protection, five malignancies are induced per one million persons exposed to lumbar spine radiographs[69]. In Britain, the National Radiation Protection Board estimates that 19 lives are lost each year because of unnecessary lumbar spine radiographs[70].

Two other major drawbacks to radiography are difficulty in interpretation and unacceptably high rate of false positive findings[71].

It has also been noted that inter- and intra-observer variation among radiologists in interpretation of plain radiographs of the lumbosacral spine may actually mislead clinicians and reduce the usefulness of the investigation[72]. This particular study concluded that inter-observer agreement was best for vertebral fractures(though this is outside the scope of this study), osteopaenia, spondylolisthesis at L5-S1, reduced disc height at L4-L5, L5-S1 and osteophytes at L2-S1. The interobserver agreement was poorest for spina bifida at S1, degenerative spondylolisthesis, facet joint arthrosis at T12-L4, narrowed spinal canal and film quality.

Several studies related to the utility of plain radiographs in low back pain have been done in other countries, particularly in the west, very few have been done in Africa, and even fewer in the East African regional block. Most of the studies done in Africa are in Nigeria and South Africa.One of such studies was undertaken by two radiologists in Nigeria in 2011, involving 337 patients to determine the

frequency of occurrence of radiographic findings in patients reporting low back pain[73].

This study found out that osteophytes were demonstrable in 73.6% of the patients (with the anterior margin of L4 having been commonly involved);spondylolisthesis in 13.4% (mostly anteriorly located and at L4/L5 and L5/S1) with disc degeneration having been demonstrated in 28.2% (Vacuum phenomenon was evident in 15.1%, endplate sclerosis in 18.4% and reduced disc space in 8.6%); scoliosis in 10.7%; transitional vertebrae in 32.3% (lumbarization in 5.9%, sacralization in 26.4%); reduced lumbar lordosis in 41.2% while 4.5% had normal radiographic findings.Mulimba[12] in his study found that some commonest radiological features (on AP and lateral views) included loss of lumbar lordosis in 15%, scoliosis in 8%, loss of disc height in 1.8% and osteophytes in 27%.

Ansary and colleagues[74] in a study conducted in a Bangladeshi Hospital (Neurosurgical Unit) between 2005 and 2006 to assess plain x-ray findings of lumbosacral spine in prolapsed lumbar intervertebral disc (PLID), found out that there were significant changes in the plain x-ray in most cases of PLID.These changes included scoliosis, loss of lumbar lordosis (76%), sacralization (10%), reduced intervertebral space (76%), spondylolisthesis (6%), osteophytes (52%) and narrowing of intervertebral foramina (46%).

STUDY QUESTION

Are plain radiographs useful in diagnosis of low back pain of non-traumatic origin?

NULL HYPOTHESIS

There is no statistically significant occurrence of abnormalities in plain radiographs of patients presenting with non-traumatic low back pain.

STUDY JUSTIFICATION

Low back pain is a very common problem with various causes. It causes significant morbidity and has a great socioeconomic impact. Plain radiographs are heavily utilized as a preliminary investigative modality for patients presenting with low back pain despite numerous recommendations advocating for the contrary.This is supported by data from the Radiology department of the University of Nairobi at the KNH as discussed earlier.

Many of the investigated patients end up undergoing more advanced imaging tests such as MRI, CT SCAN and CT MYELOGRAM after initial plain radiographs and, therefore, this begs the question: Are plain radiographs really useful in detecting causes of low back pain?

Lumbosacral x-rays carry inherent radiation risks (delivers a radiation dose of about 1.30mSV equivalent to 65 CXRs) and, therefore, exposes sensitive reproductive organs and bowel to radiation. It,therefore, calls for avoidance of unnecessary radiological investigations. Unnecessary exposure to radiation predisposes patients to malignancies.

During the literature review, it was noted that most of the studies had been done in developed countries and only a few African countries, notably South Africa and Nigeria. Whereas most of these studies are in agreement that there is no role for plain radiographs in acute low back pain with no red flags, it was important to have a local study to provide local data on this important subject. It was also important for us to know how frequently plain radiographs were ordered in patients presenting with low back pain and ascertain how frequently abnormalities were detected on this investigative tool. The cost of doing these investigations is high, both in the form of primary cost of the x-rays and secondary costs in the form of follow-up investigations such as the CT Scans and MRI.

It is hoped that results from this study can be utilized in the formulation of local guidelines for clinicians to use in investigating patients presenting with low back pain as well as reduce costs involved in the management of low back pain, reduce unnecessary radiation exposure to patients and subsequently reduce the possibility of radiation-induced malignancies and deaths in such patients.

STUDY OBJECTIVES

MAIN OBJECTIVE

To establish the diagnostic utility of plain radiographs in patients presenting with low back pain of non-traumatic origin as seen at Kenyatta National Hospital.

SPECIFIC OBJECTIVES

1. To determine the rate of positive radiological findings on plain x-rays.

2. To determine how many of the patients with initial plain lumbosacral radiographs end up having secondary investigations such as MRI, CT SCAN and DEXA.

3. To ascertain factors that determine diagnostic utility of the plain radiographs.

CHAPTER 3: MATERIALS AND METHODS

STUDY DESIGN

Prospective study, with convenient sampling of consecutive patients.

STUDY SETTING

The study was conducted at the Orthopaedic clinics and wards at Kenyatta National Hospital. KNH is a metropolitan, tertiary, referral and teaching hospital situated at Upper Hill area along Hospital Road about 5km from Nairobi city centre. It has a 2000 bed capacity and is one of the two main referral hospitals in Kenya, also serving the greater East and Central African region.

STUDY POPULATION

Patients above 18yrs of age presenting to Orthopaedic clinics and wards at Kenyatta National Hospital with non-traumatic low back pain limited to the lumbar region.

INCLUSION CRITERIA

1. Patients above 18years of age presenting with either acute, subacute or chronic low back pain limited to the lumbar region with or without radiculopathy
2. Those who gave consent
3. Patients with available lumbosacral radiographs

EXCLUSION CRITERIA

1. Patients below18 years of age
2. Those who were unable or unwilling to give consent
3. Those with low back pain of traumatic origin
4. Those presenting with low back pain but without accompanying plain radiographs

SAMPLING

All eligible patients were enrolled into the study until the required sample size was obtained.

SAMPLE SIZE

The sample size was calculated using Fischerôs formula because this was a cross-sectional study with the main objective aimed at getting proportions

$$n = \frac{Z^2_{(1-Đ/2)} \times P(1-P)}{d^2}$$

where ;

n = sample size to be determined

$\mathbf{Z^2}_{(1-\infty/2)}$ =is the standard error of the mean corresponding to a 95% confidence interval and the corresponding value from a t-table is 1.96.

P =is the expected prevalence of the event to occur. Value of P was 0.955.

d = is the target margin of error which will be 4 %(0.04) to increase precision.

$$n = \frac{1.96^2 \times 0.955 \, (1 \text{ï } 0.955)}{0.04^2}$$

Hence n = 102 patients

DATA COLLECTION

(a) Patient Recruitment

The principle investigator with the help of a research assistant contacted the already informed and sensitized Surgical Senior House Officers (SHOs)/Registrars (both Orthopaedic and General Surgery residents).The registrars contacted were attending to patients at the orthopaedic clinics during clinic days or in orthopaedic wards.The information gathered was on patients presenting with non-traumatic low back pain, having fulfilled the inclusion criteria and having been referred for plain lumbosacral radiographs.

The research assistant is an orthopaedic technologist working at the KNH. The clinicians were not guided as to whether or not to refer the patients for plain radiography. This was entirely upon their own discretion. Patientsô consent was sort before recruiting them into the study.

(b) Data Collection and analysis

Patientôs biodata was taken and duly filled in the questionnaire. Names were not recorded and instead they were assigned serial numbers.

Lumbosacral radiographs taken were submitted for reporting by two independent qualified radiologists. Patients were followed up for a period of two months to ascertain whether they underwent any further tests to establish a diagnosis.This was done by recording down their mobile phone numbers which were then used to contact them after two months to enquire whether any further tests had been done on them. Results were then entered into a structured questionnaire for analysis.

The study was limited to use of only anteroposterior (AP) and lateral views.

Analysis of the radiographs by two different qualified radiologists was aimed at quality control (to reduce bias) as well as assessing inter-rater variation.This was to ascertain whether there was significant variability in the reporting of the x-ray films by different radiologists.

DATA PRESENTATION

Data was collected using a structured questionnaire. It was then entered and analyzed using Stata/1C program Version 11.0.

Continuous variables such as age were summarized using mean, while patientsô weights were summarized using median to minimize the effect of outlier values. A P-value of <0.05 was considered significant. The inter-rater strength of agreement was analyzed using kappa. Values <0.20 indicated poor strength of agreement, 0.21-0.40 indicated fair level of agreement, 0.41-0.60 indicated moderate agreement, 0.61-0.80 indicated good agreement, whereas values between 0.81-1.00 indicated very good agreement.

Results were presented in form of tables, pie-charts or graphs.

STUDY LIMITATIONS

a. Some patients already recruited, opted out of the study.
b. Co-ordination between getting the radiograph from the patient and having it interpreted on time by the radiologists proved challenging.
c. Patientôs serostatus was reported by the patient themselves and there was no attempt made to clarify that report.

ETHICAL CONSIDERATIONS

Approval to conduct the study was sought from the Department of Orthopaedic Surgery, University of Nairobi as well as Kenyatta National Hospital, Ethics and Research Committee (KNH/UoN-ERC). Data collection commenced once this approval was granted.

Participants in this study or their next of kin were required to give a written informed consent. The consent sought was to enable the principle investigator and his assistant to take the patientôs bio-data details, mobile phone number as well as history related to the presenting illness. The participants were also consenting to their radiographs being interpreted by the radiologists. The mobile number provided was used to trace the participant after two months of follow-up to ascertain whether further tests had been done.

The investigator clarified to the participants that the objective of this study was to determine the usefulness of plain radiographs in low back pain that is non-trauma related and that there were no risks nor any invasive procedures involved.

Participants were also informed that they would not benefit directly in this research but that the results obtained may help improve on the appropriateness of referral for the investigations for patients presenting with low back pain. There were also no financial costs to the patients involved in this study except for the few minutes they spent answering to the questions in the questionnaire.

Participation in this study was purely voluntary in nature and as such, it was clarified to the participants that they would be free to participate or even withdraw their participation at any point during the study without any explanation. Withdrawal of participation would not have affected the participantôs treatment or management in any way whatsoever.

Some questions such as patientôs immune status would have been considered invasive by some participants. As such, participants were free to answer or to decline to answer such questions without any prejudice or any consequences whatsoever.

All information obtained was treated with utmost confidentiality. All participants were allocated a study serial number linking them to their bio-database accessible only to the principle investigator. Patientsô names were not used.

CHAPTER 4: RESULTS

This study recruited a total of 102 patients with low back pain of non-traumatic origin investigated using plain radiography at KNH. There were no patients lost to follow up. The analysis of the characteristics of the patients and the utility of plain radiographs in the management of non-traumatic low back pain showed the following:

Baseline Characteristics

Patients' age

The ages of patients ranged from 19 to 88 years and the average age of patients with low back pain was 50.9 years (SD ± 13.9).

As shown in table 3 below, most patients were aged between 40-49 years (26.5%) and 50-59 years (25.5%). The youngest (19-29 years) and oldest (Ó 70 years) age groups accounted for 6.9% and 8.8% of the participants, respectively.

Table 3: Percent distribution of patient's ages

	Frequency (n)	**Percent**
Age in years		
19-29 years	7	6.9
30-39 years	14	13.7
40-49 years	27	26.5
50-59 years	26	25.5
60-69 years	19	18.6
70 years and above	9	8.8
Total	**102**	**100**

Sex Distribution

Figure 4 represents the gender distribution of patients who presented with low back pain. There were 72 (70.6%) females and 30 (29.4%) males investigated for low back pain using plain radiography with a male to female ratio of 1:2.4.

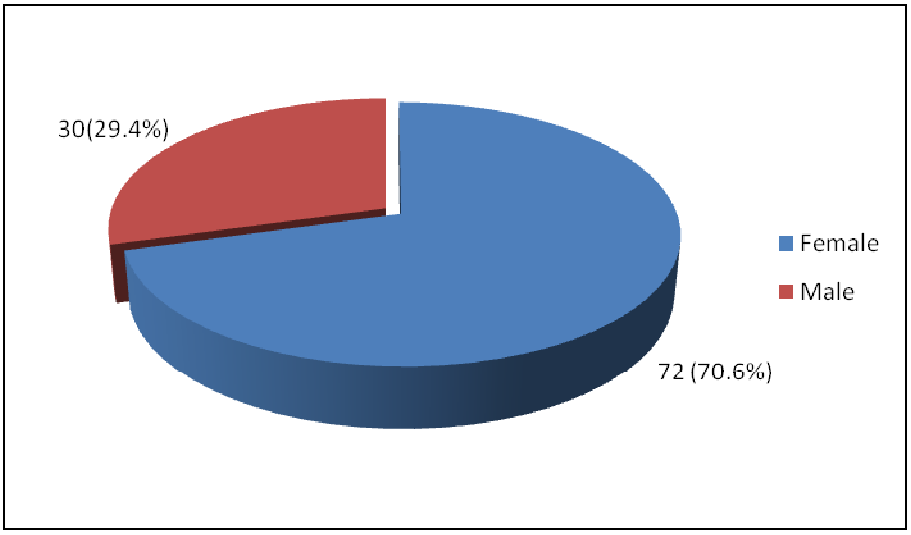


Figure 4: Gender Distribution

Body weight

As shown in table 4, the body weights of patients with low back pain ranged from 46 to 125 kgs. The average body weight of the participating patients was 73.9 kg (SD± 14.2). One patient was not weighed because he was stretcher-bound.

Table 4: Descriptive statistics of patient's body weights

Variable	N	Mean	Std. Dev.	Min	Max
Body weight (in kgs)	101	73.9	14.2	46	125

As shown in figure 5, the median body weights of female patients with back pain was 75.5 kgs compared to a median body weight of 70 kgs among males. There was however, no statistically significant difference in body weight of males compared to females (Kruskal Wallis p = 0.55).

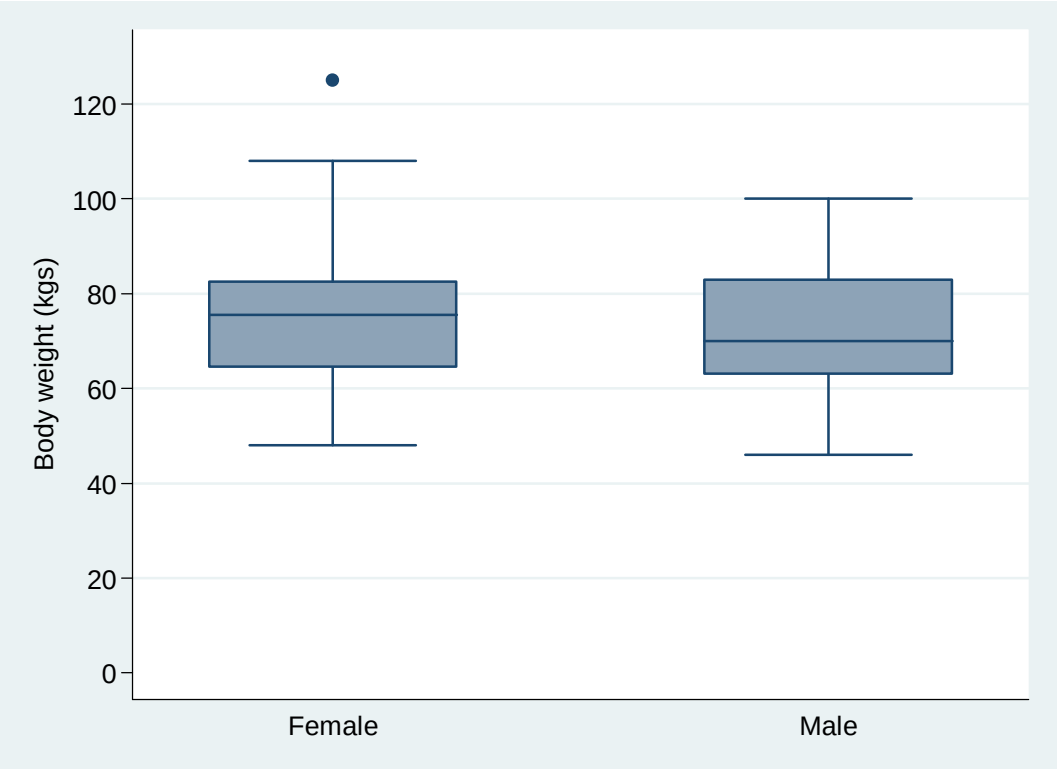


Figure 5: Comparison of median body weights of patients according to gender

Occupation

The occupation of patients with low back pain is presented in figure 6. The two most common occupations were farming (21.6%) and casual/manual labourers (20.6%). Approximately 11% of patients were formally employed and 15.7% were engaged in small scale businesses and other forms of self employment. Formal employment included those who were teachers, nurses and police officers. Support staff included clerks, drivers,receptionists, secretaries and sales agents. Casual/manual labourers included masons, plumbers, waitresses, artisans, security

guards, saloonists, storekeepers and shop-attendants. Prisoners and those who do not undertake any work were grouped as ñothers.ò

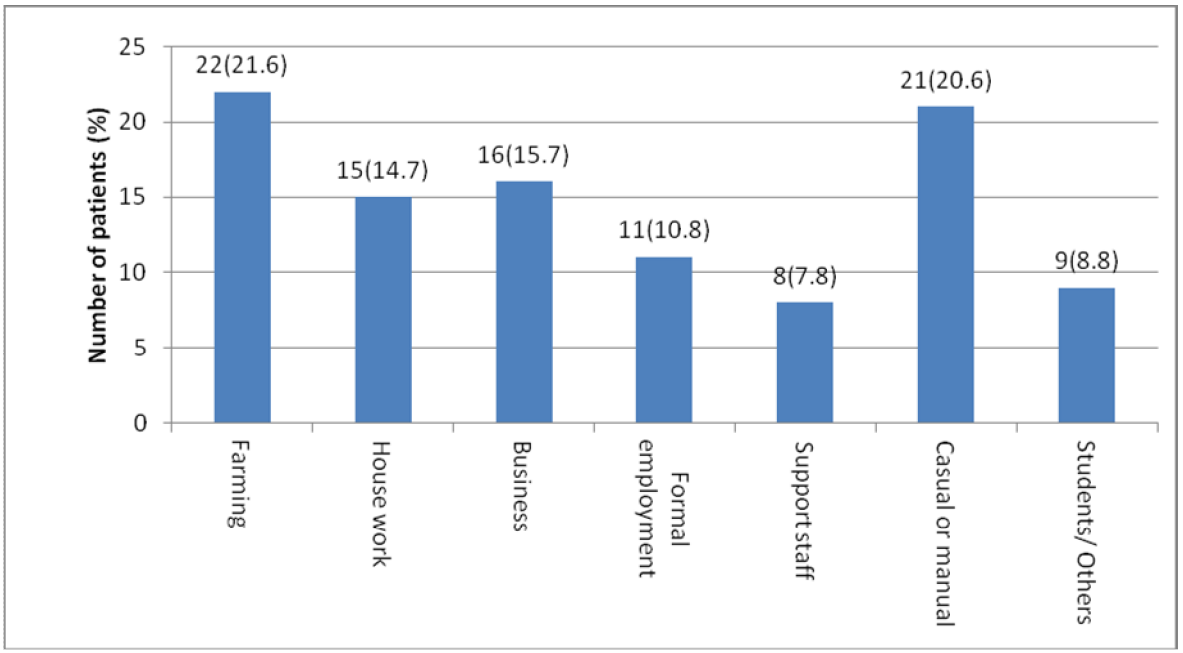


Figure 6: Occupation of patients presenting to KNH with low back pain

Low back pain presentation

Duration of time during which patients had experienced low back pain ranged from less than 6 weeks to duration longer than 3 months. Table 5 below shows that six patients experienced low back pain for less than 12 weeks with 4 (3.92%) reporting pain for 6-12 weeks and 2 (1.96%) reporting pain lasting less than 6 weeks. Most (94.12%) patients presented with low back pain that had lasted for more than 3 months.

	Frequency	Percent
Duration of pain		
More than 3 months	96	94.12
6-12 weeks	4	3.92
Less than 6 weeks	2	1.96
Total	**102**	**100**

Table 5: Duration of presenting symptoms

On evaluation of the red flags, the most common presentation was motor and or sensory weakness of the lower limbs as reported in 65 (63.7%) patients. Other presentations were seen less frequently and constituted approximately 25%. There were no patients presenting with either immunosuppression or history of intravenous drug abuse (See Table 6).

Red Flags	Number (n)	Percent
Motor/ sensory weakness	65	63.7
Weight loss in the last 6 months	6	5.9
Urinary/ fecal incontinence or retention	4	3.9
Fever	4	3.9
History of recent lumbar puncture or spinal anaesthesia	3	2.9
Pain at multiple sites	3	2.9
Saddle anaesthesia	3	2.9
History of malignancy	2	2.0
Abdominal pain radiating to the back with associated collapse or hypotension	1	1.0

Table 6: Presenting symptoms (red flags)

PLAIN X-RAY INVESTIGATIONS

The same x-ray films were submitted for reporting by the two independent radiologists, but in 9 cases, radiologist B intimated that more views (largely cone view) were required to arrive at a better diagnosis (see table 7).

	Radiologist A	**Radiologist B**	**Extra view required (Radiologist B)**
X-ray film view			
Both AP and lateral view	97(95.1%)	97(95.1%)	None
AP view only	2(2.0%)	2(2.0%)	1(0.98%)
Lateral view only	3(2.9%)	3(2.9%)	None
Cone view	-	-	8(7.8%)
Total	**102(100%)**	**102(100%)**	**9(8.78%)**

Table 7: X-ray film views requested

Overall, the two radiologists were in agreement that majority of the radiographs (91 out of the 102) were of good-to-excellent reportable quality, with only 4 radiographs being considered to be of poor quality by radiologist B (see table 8). Statistically, this translates to 89.2% agreement with a k-value of 0.12 (see table 9 below).

	Radiologist B			
	Poor	Good	Excellent	Total
Radiologist A				
Poor	0	2	0	2
Good	4	90	5	99
Excellent	0	0	1	1
Total	**4**	**92**	**6**	**102**

Table 8: Film quality

Agreement	Expected Agreement	Kappa (κ)	Std. Err.	Z	P value
89.2%	87.7%	0.12	0.063	1.98	0.024

Table 9: Level of inter-rater agreement on film quality

X-RAY FINDINGS

It is evident that both radiologists are in agreement that the radiographs largely indicated more abnormal findings (positive findings). On average, 98% had positive radiological findings and only 1.96% were normal radiographs (see Table 10 below).

	Radiologist A	Radiologist B	Both Radiologists
Abnormal Film Findings			
YES	97(95.1%)	83(81.4%)	100(98.04%)
NO	5(4.9%)	19(18.6%)	2(1.96%)
TOTAL	**102(100%)**	**102(100%)**	**102(100%)**

Table 10: Rates of positive and negative radiological findings

Spondylolisthesis

All cases of spondylolisthesis were anteriorly located, majority being at L4/L5 (10 according to radiologist A, 12 according to radiologist B). The other common location was L5/S1 (3 according to radiologist A and 6 according to radiologist B). Each of the two radiologists made one diagnosis of multilevel spondylolisthesis (see figure 7).

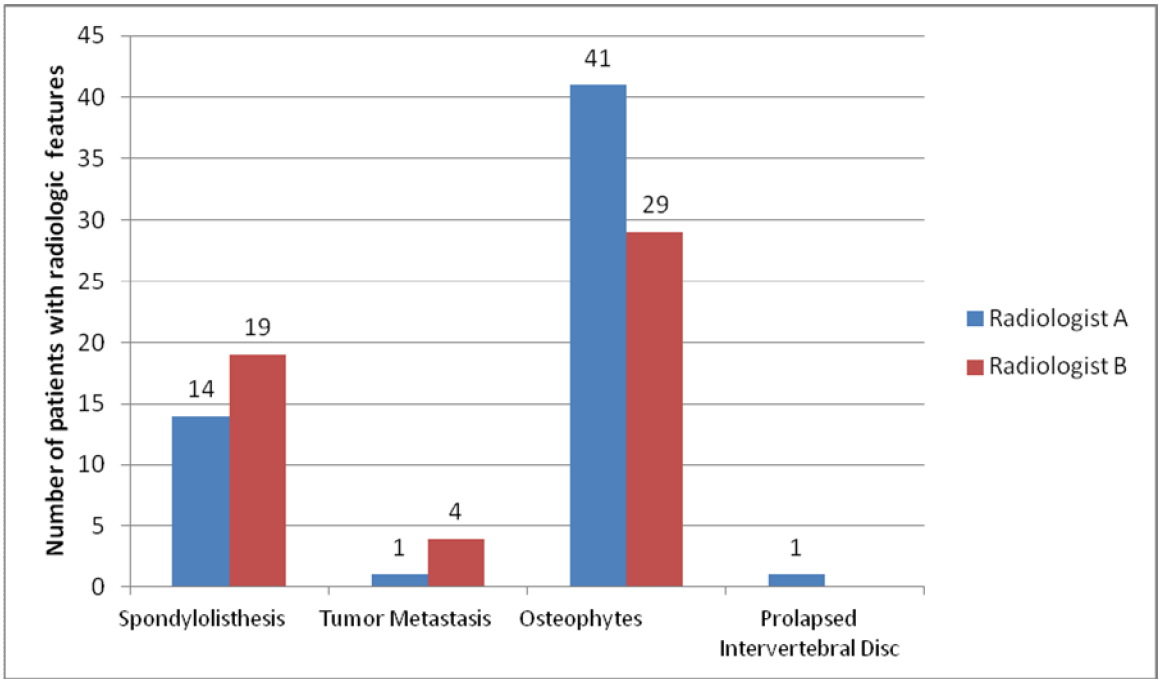


Figure 7: Plain x-ray findings among patients at KNH

There was a strong degree of agreement on both the presence and absence of spondylolisthesis between the two radiologists, with a poor level of agreement on presence of tumor metastasis, osteophytosis and PID (see Table 11).

Radiologic feature and κ (Kappa) statistic	**Radiologist**		**Agreement**		
	A	**B**	**Yes**	**No**	**Total**
	n/ N (%)	n/ N (%)	N	N	%
Spondylolisthesis ə = 0.71	14/102 (13.7%)	19/102 (18.6%)	12	82	92%
Tumor metastasis ə = NA	1/102 (0.98%)	4/102(3.9%)	0	97	95%
Osteophytes ə = 0.19	29/102 (28.4%)	41/102 (40.2%)	16	48	63%
Prolapsed intervertebral disc ə = NA	1/102 (0.98%)	0/102(0%)	0	101	99%

Table 11: Level of inter-rater agreement on spondylolisthesis, tumor metastasis, osteophytes and PID

Infections

There was no evidence of osteomyelitis in the reported films. Radiologist B made a diagnosis of Tuberculosis of the lumbar spine in 6 cases and only one case of discitis, while radiologist A diagnosed two cases of discitis and no cases of TB (See Figure 8).

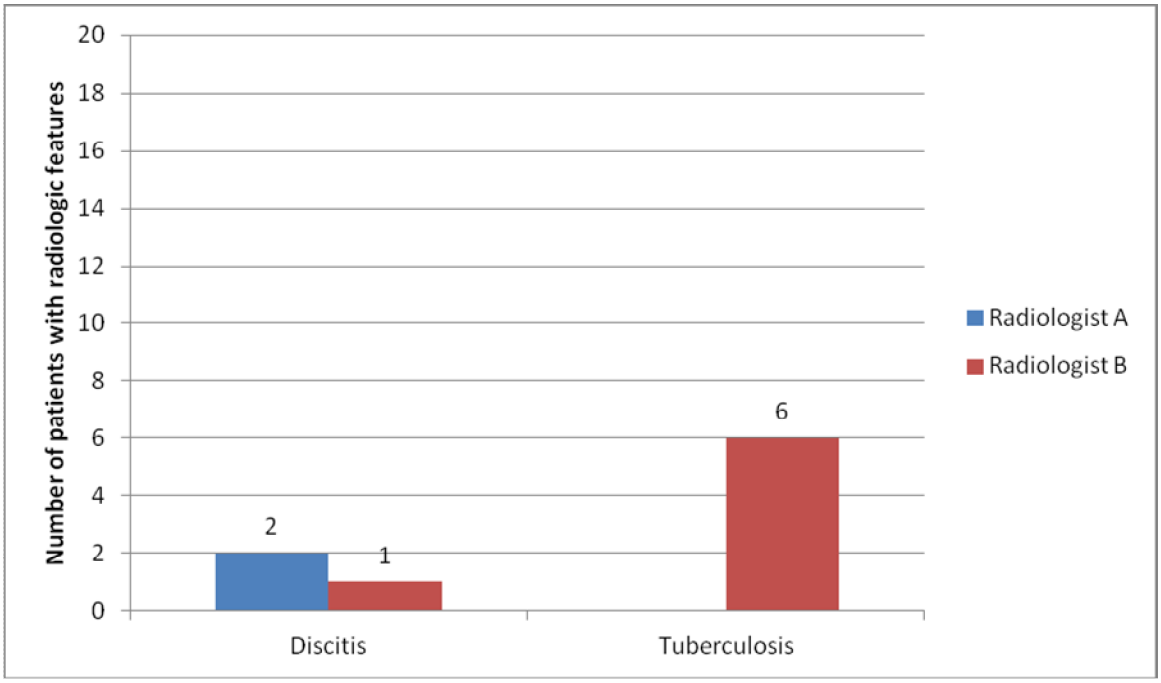


Figure 8: Plain X-ray findings related to infections

There was a 97% agreement among the two radiologists that there was no discitis and a 94% agreement that there was no tuberculosis of the lumbosacral spine, but very poor agreement on presence of either (see Table 12).

Radiologic feature and ə (Kappa) statistic	**Radiologist**		**Agreement**		
	A	**B**	**Yes**	**No**	**Total**
	n/ N (%)	n/ N (%)	N	N	%
Discitis ə = NA	2/102(1.96%)	1/102(0.98%)	0	99	97%
TB ə = NA	0/102(0%)	6/102(5.8%)	0	96	94%

Table 12: Level of inter-rater agreement on infections

Disc degenerative disease

As shown in Figure 9, it is easier to diagnose reduced disc space on a plain radiograph, followed by endplate sclerosis and finally vacuum phenomenon in diagnosis of disc degenerative disease. This trend is similar among the two independent radiologists. However, as shown in table 13, there is a higher degree of agreement among the two radiologists on diagnosis of vacuum phenomenon followed by reduced disc space and a very poor agreement on diagnosis of end-plate sclerosis as evidenced by kappa values.

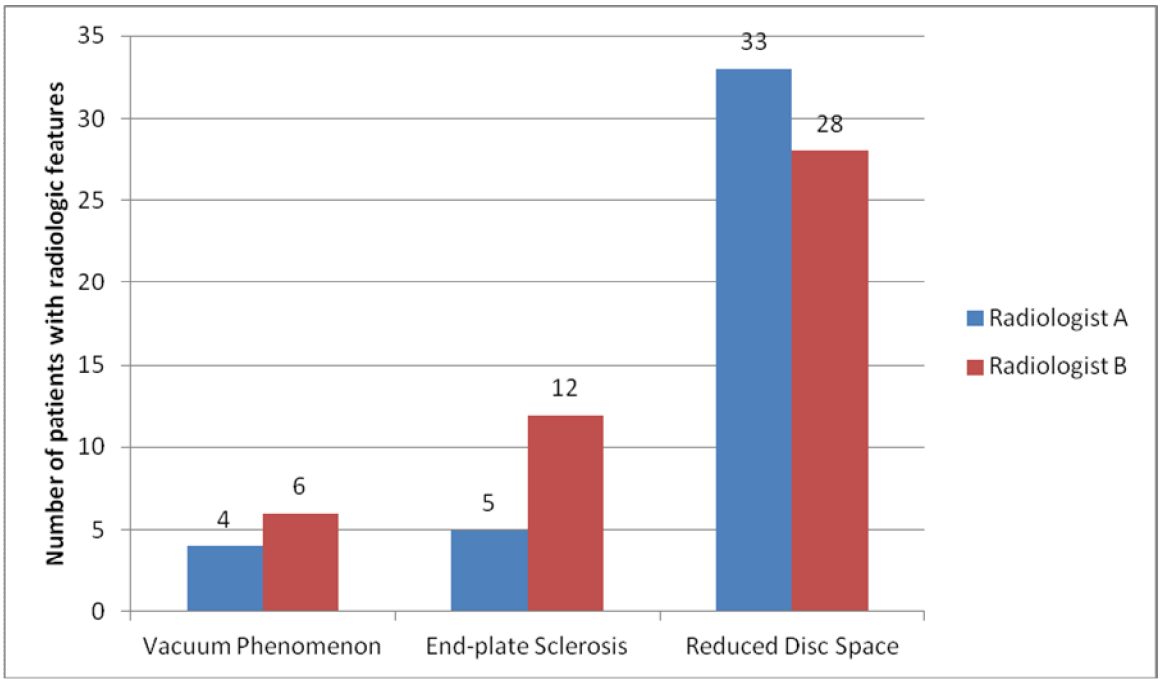


Figure 9: Disc degenerative disease findings on plain X-ray films

Table 13 below shows that the strongest inter-rater agreement among the two radiologists was on the diagnosis of vacuum phenomenon with a kappa value of 0.71 and a total agreement of 92%. There was only moderate degree of agreement on the presence of reduced disc space and a poor agreement on end-plate sclerosis.

Radiologic feature and ə (Kappa) statistic	**Radiologist**		**Agreement**		
	A	**B**	**Yes**	**No**	**Total**
	n/ N (%)	n/ N (%)	N	N	%
Vacuum phenomenon ə = 0.71	4/102 (3.9%)	6/102 (5.8%)	1	93	92%
End-plate sclerosis ə = 0.17	5/102 (4.9%)	12/102 (11.8%)	2	87	87%
Reduced disc space ə = 0.56	33/102 (32.4%)	28/102 (27.5%)	21	62	81%

Table 13: Level of inter-rater agreement on disc degenerative disease

According to the plain radiograph findings, muscle spasm was the commonest occurring finding according to radiologist A(69.6%), followed by osteoporosis and reduced lumbar lordosis (both at 58.8%), spondylosis (55.9%), disc degenerative disease (41.2%)[reduced disc space 32.4%, end-plate sclerosis 4.9%, vacuum phenomenon 3.9%], multilevel osteophytes (28.4%), spondylolisthesis and increased lumbar lordosis (both at 13.7%).

The least occurring findings include osteomyelitis (0%),tuberculosis (0-5.8%), tumor metastasis (0.98%), prolapsed intervertebral disc (0.98%),discitis (1.96%), scoliosis (1.96%), ankylosing spondylitis (1.96%), transitional vertebrae (7.8%)[lumbarisation 2.9%, sacralisation 4.9%],sacroilitis (8.8%) and normal lumbar lordosis (12.75%).

There was a slight difference in order of occurrence of findings according to radiologist B.The commonest finding was spondylosis (51%), disc degenerative disease (45.1%)[reduced disc space 27.5%, endplate sclerosis 11.8%, vacuum phenomenon 5.8%], osteophytes 40.2%, reduced lumbar lordosis (36.3%), muscle spasm (26.5%), spondylolisthesis (18.6%), scoliosis (15.7%) and osteoporosis (13.7%) (see Figures 10 and 11 below).

Infections, tumor metastasis and transitional vertebrae still were the least occurring findings according to radiologist B.

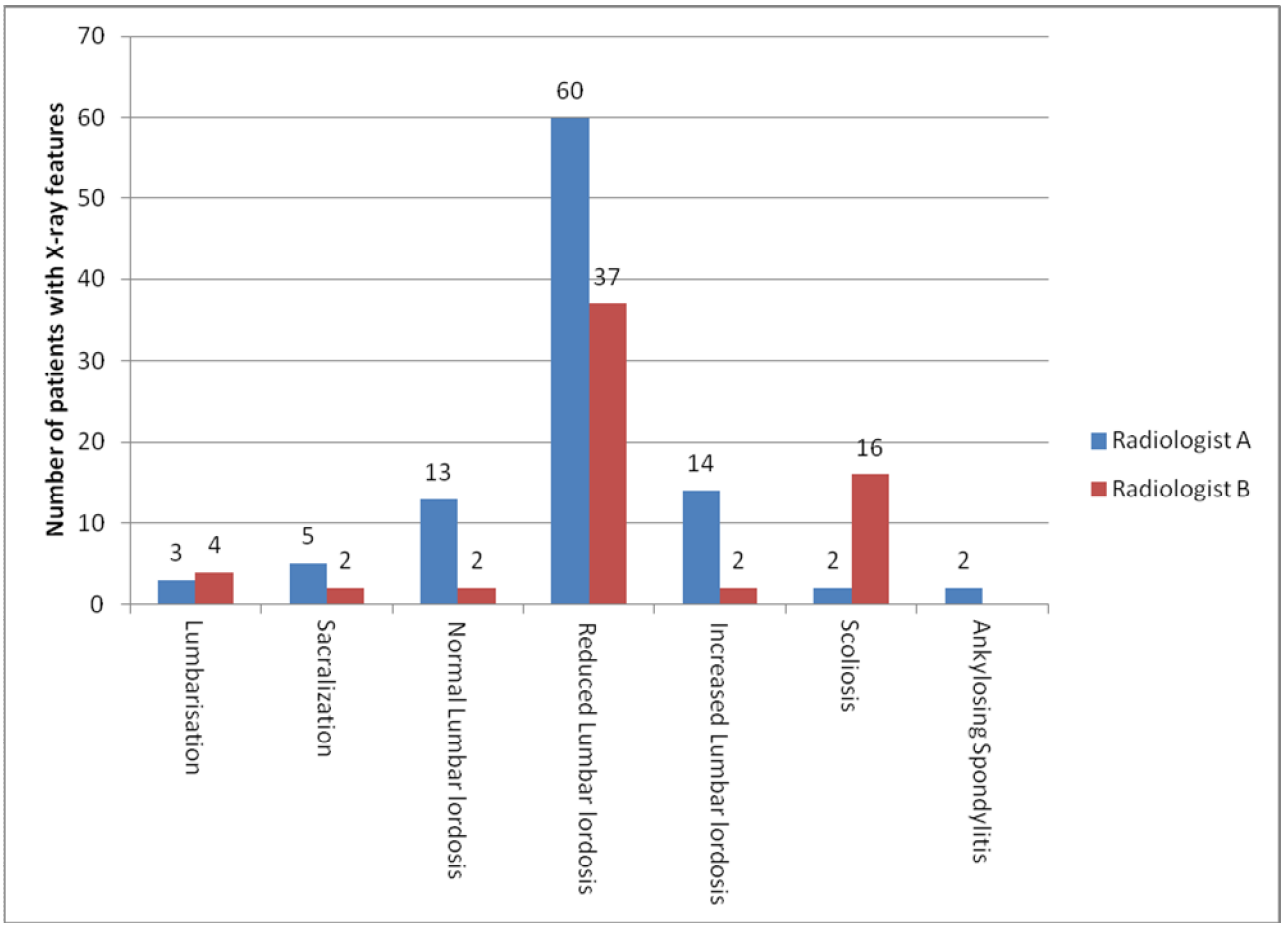


Figure 10: Further findings on plain radiographs among patients with low back pain

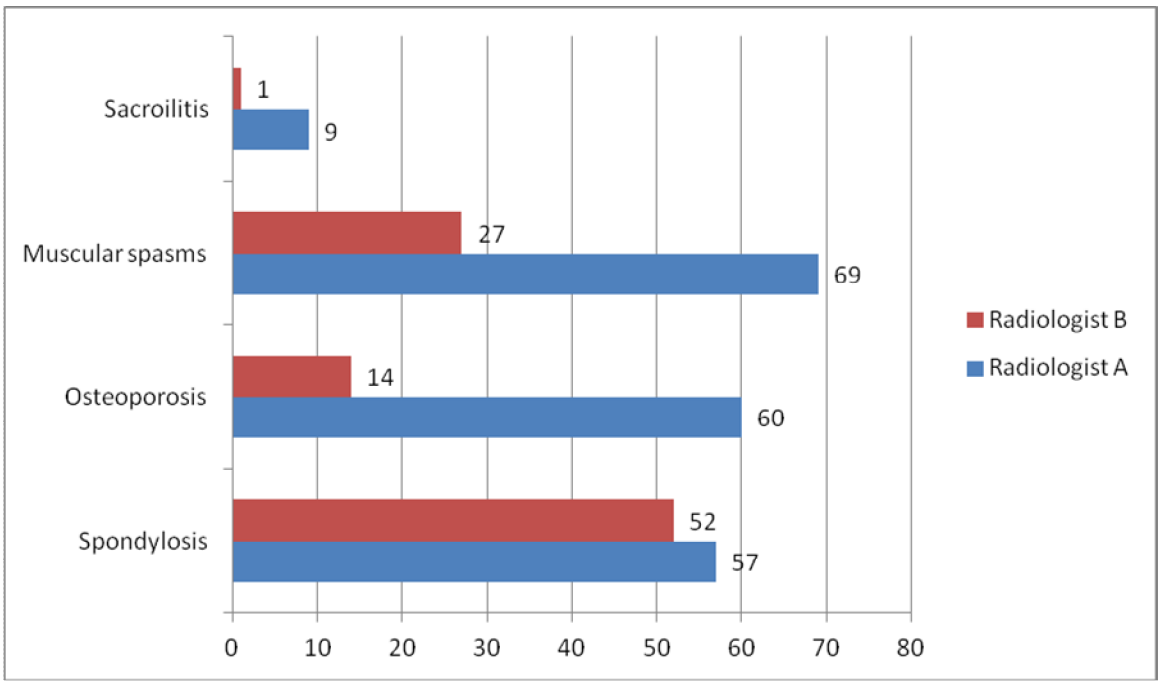


Figure 11: other findings

There was poor agreement among the two radiologists on the presence of normal, reduced or increased lumbar lordosis as well as scoliosis. It was difficult to ascertain inter-rater agreement on presence of transitional vertebrae and ankylosing spondylitis though there was a 93% and 98% agreement on the absence of either, respectively (see Table 14 below).

Radiologic feature and ə (Kappa) statistic	Radiologist		Agreement		
	A	B	Yes	No	Total
	n/ N (%)	n/ N (%)	N	N	%
Lumbarization ə = NA	3/102 (2.9%)	4/102 (3.9%)	0	95	93%
Sacralization ə = NA	5/102 (4.9%)	2/102 (1.96%)	0	95	93%
Lumbar lordosis					
Normal ə = 0.1	13/102 (12.75%)	2/102 (1.96%)	1	88	87%
Reduced ə = 0.42	60/102 (58.8%)	37/102 (36.3%)	33	38	70%
Increased ə = 0.22	14/102 (13.7%)	2/102 (1.96%)	2	88	88%
Scoliosis ə = 0.21	2/102 (1.96%)	16/102 (15.7%)	2	87	87%
Ankylosing spondylitis ə = NA	2/102 (1.96%)	0/102 (0%)	0	100	98%

Table 14: Level of inter-rater agreement on transitional vertebrae, lumbar lordosis, scoliosis and ankylosing spondylitis

As illustrated below, a moderately strong inter-rater agreement exists on occurrence of spondylosis on the plain radiographs, but a very poor level of agreement on occurrence of osteoporosis, muscle spasm and sacroilitis. There was a high level of agreement (90%) on the absence of sacroilitis, but a poor agreement on its presence (kappa=0.13) (see Table 15).

Radiologic feature and ə (Kappa) statistic	**Radiologist**		**Agreement**		
	A	**B**	**Yes**	**No**	**Total**
	n/ N (%)	n/ N (%)	N	N	%
Spondylosis ə = 0.55	57/102 (55.9%)	52/102 (51%)	43	36	77%
Osteoporosis ə = 0.13	60/102 (58.8%)	14/102 (13.7%)	12	40	51%
Muscle spasm ə = 0.13	69/ 102 (67.6%)	27/ 102 (26.5%)	22	28	49%
Sacroilitis ə = 0.13	9/102 (8.8%)	3/102 (2.9%)	1	91	90%

Table 15: Level of inter-rater agreement on spondylosis, osteoporosis, muscle spasm, sacroilitis

Slightly more than half the studied population had spondylosis with most cases being epicentered around L3 to S1 with L5 being the commonest location, atleast according to radiologist A (See Table 16).

	Radiologist A	Radiologist B
Spondylosis	57 (55.9%)	52 (51%)
Location		
L1	4	-
L2	4	2
L3	5	1
L4	7	1
L5	10	4
S1	5	4

Table 16: Spondylosis location

After a two month follow-up, among the 102 patients recruited, 29.4% further underwent MRI Scan to establish a diagnosis, 2% underwent CT Scanning and 1.6% underwent DEXA.There were no patients who underwent CT Myelogram or Bone Scanning (See Table 17 below).

Investigation	Number	Percent
MRI	30	29.4
CT scan	2	2.0
DEXA	1	1.6
Total	33	33.0

Table 17: Follow-up investigations

The following was the distribution pattern of findings among those patients who underwent secondary investigations:

INVESTIGATION	NO. OF PATIENTS	FINDING
MRI	2	Tumor metastasis
	9	PID
	1	Discitis
	2	Tuberculosis of spine
	11	Nerve root compression
	3	Facet joint degenerative disease
	1	Hypertrophy of ligamentous flavum and interspinous ligament
	1	Osteomyelitis
CT SCAN	1	Tumor metastasis
	1	Intra-osseous lipoma
DEXA	1	Osteoporosis

Table 18: Findings of secondary investigations

CHAPTER 5: DISCUSSION

The use of plain radiography in investigating patients presenting with low back pain is well documented in the literature. Whereas in most developed countries clear guidelines have been formulated on use of plain radiography for patients with low back pain[19,30,33-39], such guidelines are non-existent locally, contributing largely to the overuse of this investigative modality on patients presenting with low back pain, irrespective of duration of symptom presentation.The overuse of this investigative modality is well documented by statistics from Department of Radiology, University of Nairobi at the Kenyatta National Hospital as indicated on page 9.

As is evident from the results, the middle-aged group suffers more from low back pain (52% of all patients recruited were in the 40-59year age bracket).This could be attributed to the fact that this is an active age bracket. Other comparable studies were those by Mulimba[12] who reported an average age of presentation of between 20-50yrs with a decline in incidence after 60yrs, Galukande et al.[13] with a mean age of 47yrs and Gakuu et al.[14] who reported an age range of 21-60yrs.

Male to female ratio of 1:2.4 in this study is comparable to that by Mulimba[12] and Galukande et al[13].The higher ratio of females could be attributed to the kinds of activities they engage in that probably involve bending a lot or standing for long periods of time.These include farming (21.6%), household chores (15%), different forms of businesses (16%), casual labourers e.g. waitresses, saloonists and storekeepers. Receptionists and secretaries are also affected, probably because of poor ergonomics in their work places.

Several university students also suffered from low back pain and this could be related to probably poor sitting postures during studies.

Body weights of the patients recruited ranged from 46-125kg with an average weight of 73.9kg. However, there was no statistically significant difference in the body weights of males and females, despite the fact that almost twice as many females suffered from low back pain compared to males. This could therefore infer that weight has little bearing on presence or absence of low back pain in the cohort of patients recruited in this study. This is in keeping with other studies that only found a strong association between overweight and obesity with chronic low back

pain. Body weight, per se, was recognized as a weak risk factor for low back pain[24-26].

From this study, 94.12% of the patients were those who presented with chronic low back pain (more than 3 months of symptoms) and 5.88% presented with more acute symptoms. This, again, is in keeping with most literature reports that chronic low back pain is a condition commonly seen in people aged above 40-50yrs, in occupations that require frequent bending, lifting or outdoor activities predisposing to continuous trivial trauma to the spine[12-14].

This pattern may also be explained by health-seeking behaviours, in which most patients do not seek immediate medical attention unless the problem has persisted for long or is considered ñserious.ò

In terms of analysis of presenting symptoms to ascertain presence of red flags, majority of the patients reported sensorimotor deficit (63.7%). This correlated poorly with the study by Galukande[13] that found that 19.1% presented with features of nerve root compression as a result of PID. Serostatus was reported by the patients and not investigated.However,no patient reported being HIV positive or gave history of intravenous drug abuse.This, however, was a limitation as there was no objective way of assessing these parameters.

From this study, radiologist A was satisfied with all the provided AP and lateral radiograph views, but for radiologist B, in 9 cases, he required more views to make better diagnosis.

By and large, the AP and lateral views were sufficient in making a diagnosis in majority of the patients (93-100%). The view taken did not seem to significantly affect diagnostic yield.

It is worth noting that assessment of film quality is difficult and subjective. However, both radiologists were in agreement that majority of the films were of good reportable quality.

From the study, the most common occurring findings include muscle spasm (67.6%), osteoporosis (58.8%), reduced lumbar lordosis(58.8%), spondylosis(51-56%), disc degenerative disease(41.2-45.1%) and osteophytes(40.2%).

In comparison, the study by Mulimba[12] found loss of lumbar lordosis in 15%, scoliosis in 8%, reduced disc space in 1.8% and osteophytes in 27%. On the other hand, the study done in Uganda by Galukande[13] found that 19.1% had PID with resultant nerve root compression, 17.2% had a mixture of findings (TB, Brucellosis and degenerative changes) and 1.5% had indeterminate cause.

This study demonstrated that plain radiography was poor in diagnosing infectious causes (Osteomyelitis (0%), discitis (0.98-1.96%), tuberculosis (0-5.8%)), tumor metastasis (0.98-3.9%), transitional vertebrae (1.96-4.9%) and inflammatory conditions such as sacroilitis and ankylosing spondylitis.

These findings also seem to correlate poorly with the study done in Nigeria[73], but comparable to the one done in Bangladesh[74]. This could be explained by different patient characteristics and dynamics as well as the fact that majority of the patients presented late with more than 3 months history of low back symptoms (some had symptoms dating back several years).

This study also had high rate of positive radiological findings (98.04% for both radiologists), with only 1.96% normal findings. The Nigeria study[73], even though correlated poorly with this study in terms of the exact radiological findings, also found only 4.5% normal findings. As alluded to earlier, this finding could be related to the fact that majority of the patients seen presented with chronic symptoms, thereby increasing chances of positive radiological findings.

On assessment of inter-rater agreement among the two radiologists who independently reported the films, the study revealed that there was good inter-rater agreement on presence of spondylolisthesis and vacuum phenomenon (k=0.71). There was only moderate degree of agreement on presence of reduced disc space (k=0.56), reduced lumbar lordosis (k=0.42) and spondylosis (k=0.55). However, there was only fair-to-poor agreement on film quality (k=0.12), presence of infections, tumor metastasis (k=NA),osteophytes (k=0.19), prolapsed intervertebral disc, endplate sclerosis (k=0.17), transitional vertebrae, scoliosis (k=0.21), osteoporosis, muscle spasm and sacroilitis (k=0.13).

In cases where Kappa could not be calculated, there was a strong negative agreement among the interpreters i.e. on the absence of the condition, but a poor agreement on its presence.

According to the study by Espeland and his colleagues[72], there was best inter-rater agreement on osteopaenia, spondylolisthesis at L5-S1, reduced disc space and osteophytes. This same study found poor agreement among the raters on spina bifida, facet joint arthrosis, narrowed spinal canal and film quality.

After a two month follow-up, 29.4% of the patients had MRI Scan done as a follow-up investigation to try and determine the diagnosis, 2% had CT SCANS and 1.6% had DEXA. This, therefore, means that about a third of the patients recruited for the study underwent further tests to determine the cause of their low back pain or to evaluate some of their pathologies further. This is comparable to the study carried out by Ogengô and Ongeti[55] in which case 44.1% had MRIs and 9.1% had CT Scans. Evaluation of the findings from these secondary investigations reveals that MRI and CT SCAN are better than plain radiographs in diagnosis of tumor metastasis, compression of nerves at the exit foramina as well as infectious and inflammatory conditions.

Therefore, from these findings, it is strongly evident that there are many factors that determine the diagnostic yield of plain radiographs in respect to low back pain. These include, but not limited to:

1. Duration of symptom presentation: The more chronic the duration, the higher the likelihood of positive radiological findings.
2. Inter-rater variability
3. Presence of red flags
4. Quality of the film
5. Radiograph views: from this study, the utilization of only AP and lateral views seemed adequate in the diagnosis in majority of cases.
6. The underlying pathology: whereas plain radiography seemed useful in cases of mechanical low back pain, its usefulness is greatly limited in infectious and inflammatory conditions, tumor metastasis and nerve root compressions.

CHAPTER 6: CONCLUSION

The use of plain radiography as an investigative tool for patients presenting with low back pain is carried out by clinicians worlwide. However, in developed countries, clear guidelines and policies exist on its utilization. This is in an attempt to standardize medical practice related to management of low back pain and minimize untoward effects associated with exposure to radiation.

This study indicated that most of the patients seen at KNH presented with chronic low back pain and this increased the probability of having positive radiological findings on plain radiographs. However, the usefulness of this investigative tool is limited by factors such as inter-rater variability in terms of film interpretation, film quality, underlying pathology and views taken, among others. This limitation in the usefulness of the plain radiographs accounted for close to a third of the recruited patients undergoing further tests to enhance ability to make a diagnosis.

As such, plain radiographs should not be over-relied on by clinicians despite the fact that they still remain a very important screening tool for patients presenting with low back pain.

RECOMMENDATIONS

Following the study just concluded, the following recommendations are made to the University of Nairobi and the Kenyatta National Hospital:

1. That despite the fact that this study revealed high rates of positive radiological findings, clinicians ought to be encouraged to adhere to the already established international protocols on when to refer patients for radiography.

2. That patients with low back pain be encouraged and advised to seek early medical care to minimize on the need for plain radiography and hence reduce their untoward effects. This can be carried out by means of sensitization through:
    - The media (print media, television, radio etc).
    - Posters in the clinics, wards, Accident and Emergency Department.
    - Talks during clinic visits etc.

3. That in cases of suspected infectious and inflammatory conditions of the lumbosacral spine, clinicians should be encouraged to undertake other investigative modalities such as blood workup (CBC, ESR,CRP) and other forms of imaging modalities such as CT SCANS, MRI and BONE SCAN since plain radiographs seem to have very limited role in their diagnosis.

DISSEMINATION

This dissertation and the recommendations emanating from it will be made available for dissemination to the community as follows:

1. Placement of copies of the dissertation in the Department of Orthopaedic Surgery library.
2. Placement of copies in the University of Nairobi College of Health Sciences library.
3. Publication of the results in journals

DISCLAIMER

I,Dr.Peter Lemayian Ole-Moko, do hereby declare that I have received no financial or other assistance from any party that might benefit commercially towards the dissertation outlined above.

CHAPTER 7

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CHAPTER 8: APPENDICES

APPENDIX 1: DATA COLLECTION SHEET

Study serial Numberé é é é é é é Hospital Numberé é é é é é é é ..

Date of recruitmenté é é é é é Mobile Numberé é é é é é é é ..

A.Patientôs Bio-data details

a. Ageé é é é é ..
b. Sex
   Ǐ female
   Ǐ male

c. Weight (kg)é é é é é

d. Occupationé é é é

B. Presenting Features

a. Duration suffered low back pain

   Ǐ less than 6 weeks (1½mths)

   Ǐ 6 to 12 weeks (1½-to-3mths)

   Ǐ more than 12 weeks (3mths)

b. Presence of any of the following:

   Ǐ fever

   Ǐ history of I.V. drug abuse

   Ǐ history of recent lumbar puncture or spinal anaesthesia

   Ǐ Immunosuppression

   Ǐ weight loss in the last 6 months

   Ǐ history of malignancy

   Ǐ pain at multiple sites

Ĭ saddle anaesthesia

Ĭ urinary/ fecal incontinence or retention

Ĭ motor/ sensory weakness

Ĭ abdominal pain radiating to the back with associated collapse or hypotension

C (a).Plain X-ray View

Ĭ AP

Ĭ Lateral

C (b). Any Extra views required?

Ĭ YES

Ĭ NO

D. Consultant Radiologist interpreting the X-ray film

Ĭ Consultant A

Ĭ Consultant B

E. Quality of film according to the radiologist

Ĭ poor

Ĭ good

Ĭ excellent

F. X-Ray Findings

Ĭ spondylolisthesis locationé é é é é .

Ĭ Anterior

Ĭ posterior

y⁄Grade: Ĭ 1 Ĭ 2 Ĭ 3 Ĭ 4

Ĭ Tumor Metastasis Locationé é é é é .

Ĭ Osteophytes Locationé é é é é

Ĭ Prolapsed Intervertebral Disc Locationé é é é é

Ĭ Features suggestive of bone infection

- Ĭ Discitis Specify Locationé é é é é .
- Ĭ Tuberculosis Specify Locationé é é é é .
- Ĭ Osteomyelitis Specify Locationé é é é é .

Ĭ Disc Degenerative Disease features

- Ĭ Vacuum Phenomenon
- Ĭ End-plate Sclerosis
- Ĭ Reduced Disc Space

Ĭ Transitional Vertebrae:

- Ĭ Lumbarization
- Ĭ Sacralization

Ĭ Lumbar Lordosis

- Ĭ Normal
- Ĭ Reduced
- Ĭ Increased

Ĭ Scoliosis

- Ĭ Concavity to the Right
- Ĭ Concavity to the Left

Ĭ Ankylosing Spondylitis

Ĭ Others (Specify)é é é é é

G. Follow-up Investigation done:

Ĭ MRI

Ĭ CT SCAN

Ĭ CT MYELOGRAM

Ĭ BONE SCAN

Ĭ OTHER (Specify)é é é é

APPENDIX II (a): CONSENT FORM

Study numberé é é é é .. Hospital Numberé é é é é .

I am Dr. Peter Lemayian Ole-Moko, a postgraduate student at the University of Nairobi currently pursuing masters degree in orthopaedic and trauma surgery. As part of my coursework I shall be carrying out a research entitled ñUtility of plain radiograph in low back pain of non-traumatic origin as seen at Kenyatta National Hospital.ò

I wish to request you to participate in this study whose objective is to determine the usefulness of plain radiographs in diagnosing causes of non-traumatic low back pains.

The study has been approved by the Department of Orthopaedic Surgery, University of Nairobi and The Kenyatta National Hospital Ethics and Research Committee (KNH/UON-ERC) vide approval number é é é é é .

In this study you will be asked to provide personal information after undergoing plain x-ray for your low back pain and consenting to the study. This information shall be treated with utmost confidentiality. Your involvement in this study is purely voluntary and you can opt out at any stage without any consequences. There are no risks involved and the study does not involve any invasive procedures.

I é é é é é é é é é é é .. do hereby consent to participate in this study as explained to me by Dr. é é é é é é é é é .. I have been informed of the nature of the study being undertaken and that there are no risks or invasive procedures involved. I also understand that my participation in the study is voluntary and the decision to participate or not to participate will not affect my treatment in any way whatsoever. I may also choose to discontinue my involvement in the study at any stage without any explanation or consequences. I have also been reassured that my personal details and the information I will relay will be kept confidential. I confirm that all my concerns about my participation in the study have been adequately addressed by the investigator.

Participantôs Signature (or thumbprint)é é é é é é é é é é é é

Dateé é é é é é é

I confirm that I have clearly explained to the participant the nature of the study and the contents of this consent form in detail and the participant has decided to participate voluntarily without any coercion or undue pressure.

Investigatorôs Signatureé é é é é é é é é é é . Date é é é é é é é

Witnessôs signature é é é é é é é é é é é é .( )

Dateé é é é é é

For Any Enquiries, please contact:

1. Dr.Peter Lemayian ole-moko
   Principle investigator
   Mobile Number: 0729 699788
   E-Mail: olemokopeter@yahoo.com

2. Mr. Emmanuel mayakah onduso
   Research Assistant
   Mobile No: 0725 416795

3. The Chairman,
   Kenyatta National Hospital Ethics and Research Committee
   Tel: 020-2726300 Ext 44355

APPENDIX II (b): FOMU YA IDHINI

Nambari Ya Utafitié é é é é é é é .. Nambari Ya Hospitali é é é é é é ...

Mimi ni Dkt. Peter Lemayian Ole-Moko, mwanafunzi katika kitivo cha upasuaji wa mifupa katika Chuo kikuu cha Nairobi. Kama masharti mojawapo wa kuhitimu kwangu, ninafanya utafiti unaoitwa ñUtumizi wa picha za X-ray kwa wagonjwa walio na shida za mgongo isiyosababishwa na ajali au kuvunjika, kama tunavyoona katika hospitali kuu ya Kenyatta.ò

Ningependa kukurai ushiriki katika utafiti huu ambao kiini chake ni kungôamua umuhimu wa picha za x-ray katika kuelewa chanzo cha maumivu ya mgongo isiyosababishwa na ajali au kuumia.

Utafiti huu umeidhinishwa na chuo kikuu cha Nairobi pamoja na kitengo cha utafiti katika hospitali kuu ya Kenyatta kulingana na nambari ya idhinié é é ...

Katika utafiti huu, utaulizwa maswali kadhaa za kibinafsi baada ya kupigwa picha ya x-ray ya mgongo unaokuuma na baada ya kupeana idhini.Maswala hayo yote utakayopeana yatawekwa kisiri.

Kuhusika kwako katika utafiti huu ni kwa hiari yako na unaweza kuamua kutoendelea kushiriki bila kugandamizwa au kushurutishwa kwa njia yeyote. Hakuna madhara yeyote inayokadiriwa katika utafiti huu.

Mimi é é é é é é é é é é é é é najitolea kushiriki kwenye utafiti huu baada ya kuelezwa na Dkt. é é é é é é é é é é é ... Nimejulishwa kuhusu pana ya utafiti unaoendelea na kwamba hakuna madhara yeyote inayokadiriwa kwenye utafiti huu. Pia nimeelezwa ya kwamba kushiriki kwangu ni kwa hiari yangu na uamuzi wa kushiriki au kutoshiriki kwangu hakutaweza kuadhiri matibabu yangu kwa njia yeyote. Ninaweza kufanya uamuzi wa kusitisha kushiriki kwangu kwenye utafiti huu wakati wowote bila kutoa sababu yeyote na bila kuathirika kwa njia yeyote.

Nimedhibitishiwa ya kwamba habari yeyote kunihusu itawekwa kwa njia ya siri.

Ninathibitisha ya kwamba maneno yeyote kuhusu kushiriki kwangu kwenye utafiti huu yameelezwa kinaganaga na mchunguzi.

Sahihi(ama alama ya kidole cha gumba) ya Mhusikaé é é é é é é é é é .

Tareheé é é é é é é é é

Ninathibitsha ya kwamba nimetoa maelezo sahihi kwa mhusika kuhusu pana ya utafiti na yale yote yaliyomo kwa ustadi, naye mhusika ametoa uamuzi wa kushiriki bila ya kushurutishwa.

Sahihi ya mchunguzié é é é é é é é é é é . Tareheé é é é é é é é

Sahihi ya anayeshuhudiaé é é é é é é é é é Tareheé é é é é é é é

Ukiwa na maswali yeyote kuhusu utafiti huu, wasiliana na:

1. Dkt. Peter Lemayian Ole-Moko

   Mchunguzi mkuu

   Nambari ya rununu: 0729 699788

   Tovuti; olemokopeter@yahoo.com

2. Mr. Emmanuel mayakah onduso

   Mchunguzi msaidizi

   Nambari ya rununu: 0725 416795

3. Mwenyekiti, kitengo cha utafiti katika hospitali kuu ya Kenyatta

   nambari ya simu: 020- 2726300 Ext 44355.

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1st February 2013

Dr. Peter Lemayian Ole-Moko
Dept.of Orthopaedic Surgery
School of Medicine
University of Nairobi

Dear Dr. Ole Moko

RESEARCH PROPOSAL: UTILITY OF PLAIN RADIOGRAPHIC IN LOW BACK PAIN OF NON-TRAUMATIC ORIGIN AS SEENAT KENYATTA NATIONAL HOSPITAL (P458/08/2012)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above revised proposal. The approval periods are 1st February 2013 to 31st January 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect 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.
e) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN**

"Protect to Discover"

Yours sincerely

PROF. A.N. GUANTAI
SECRETARY, KNH/UON-ERC

c.c. The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine, UoN
The Chairman, Dept. of Orthopaedic Surgery, UoN
The HOD, Records, KNH
Supervisors: Prof. L.N. Gakuu, Dept.of Orthopaedic Surgery, UoN
Dr. Sitati F.C. Dept.of Orthopaedic Surgery, UoN

APPENDIX III: APPROVAL FROM KNH/UON-ERC