MAGNETIC RESONANCE IMAGING AND RADIOGRAPHIC FINDINGS IN CHRONIC LOW BACK PAIN.A CLINICORADIOLOGICAL CORRELATIONAL STUDY.

A dissertation submitted as partial fulfilment of the requirements of the University of Nairobi, for the Award of the Degree of Master's in Medicine in Diagnostic Radiology.

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DECLARATION

I, **Dr. Laura N. Watiti** declare that the work contained herein is my original idea and has not been presented at any other place in Kenya to the best of my knowledge.

Signature ……...Date……..

Approval by Supervisor

This dissertation has been submitted with my approval as a University supervisor

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Signature……. Date…….

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DEDICATION

I dedicate this work to my daughter Timina Natalie Namaemba and my parents Daniel and Janet for their undying support and encouragement during my entire study period.

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ACRONYMS AND ABBREVIATIONS

LIST OF ABBREVIATIONS

KNH - Kenyatta National Hospital

UON - University of Nairobi

LBP- Low Back Pain

MRI- Magnetic Resonance Imaging

L/S - Lumbo sacral

AP- AnteroPosterior

CT- Computed Tomography

ACP- American College of Physicians

APS- American Pain Society

DEFINITION OF TERMS:

Disc Herniation- Displacement of intervertebral disc material beyond the normal confines of the disc but involves <25% of the circumference. Can either be focal or broad based.

Disc bulge- Displaced intervertebral disc material beyond the normal confines but involves >25% of the circumference of the disc circumference.

Hypolordosis- Reduced normal curvature of the lumbar spine. This is evaluated as being significant on imaging when the Cobb angle is <20degrees. This has been associated with para-spinal muscle spasm.[(1)].

ABSTRACT

Background: Chronic Low Back Pain (LBP) commonly referred to as Lumbago is one of the most common causes for consultations in outpatient clinics and specialized orthopaedic departments. Although the differential diagnosis of LBP is broad, the majority of patients seen in primary care will have nonspecific LBP. In most cases, radiology plays a key role in identifying the cause and thereby assisting in clinical decision making. Plain radiography and MRI are the main imaging modalities used in LBP. MRI is expensive and not readily affordable to most of the Kenyan public. The purpose of this study was to develop an imaging protocol that categorized which patients were most likely to benefit from MRI imaging to enable judicious utilization of imaging in a resource poor setting.

Aim: The aim of the study was to evaluate the findings of Plain radiography and MRI in relation to the clinical presentation of patients presenting with Chronic Low Back Pain so as to ascertain which category of patients are most likely to benefit from imaging.

Methodology: A cross sectional study was carried out at two diagnostic imaging centres in Nairobi: Kenyatta National Hospital (KNH) and Plaza Imaging Solutions.

Study population: Patients referred for Lumbosacral radiographs and Spine MRI examination were consecutively recruited into the study following informed consent over a period of 4months between September and December 2014. Patients' clinical presentation and imaging findings were documented in a data collection sheet, correlated and analysed using STATA.

Results:A total of 180 patients comprising of 53(29.4%) males and 127(70.6%) females were enrolled into the study. The mean age was 47.3years (SD=14.5 Years).The mean BMI among the patients was 26.3 (SD=26.3). Majority of the patients worked in an office setting (48%), 38.5% worked as domestic workers (housewives/unemployed), 10% had manual jobs and the rest (3.4%) were students.

Only 57(31.7%) patients presented with only chronic low back pain. The rest had additional complaints which included radicular lower limb pain and numbness.

The most common imaging findings were hypolordosis (muscular spasm), disc disease and osteophytes on both imaging modalities. Osteophytes (anterior and posterior) were seen in 60% of the patients on plain radiographs and 47.7% on MRI. Disc lesions were more

prevalent on MRI at 83% compared to 43% for plain radiography.MRI was found to be able to further characterize the disc lesions.The commonest disc diseases on MRI were disc desiccation(71.1%) and disc herniation (72.2%). Only 10(6%) patients had disc bulges (protrusion).

Statistically significant differences in occurrence of positive imaging findings were observed between the different age groups, occupations and BMI categories ($p<0.05$). Osteophytes and disc disease were more common in the older age groups. Osteophytes alone were mainly seen in manual workers and domestic workers. Most office workers had muscle spasm. There was significant association between disc disease, osteophytosis, spinal canal stenosis and narrowing of exit foramen with lower limb numbness and radicular pain ($p<0.05$)

Conclusion: Findings in this study showed that clinical findings correlated well with imaging findings. The commonest imaging findings were osteophytes and degenerative disc desiccation which were depicted on both plain radiographs and MRI respectively.Increasing age, manual labour and high BMI were important risk factors to disc disease.

No malignancy or life threatening condition was picked on all the images reviewed inferring that most patients with chronic LBP are more likely to have a benign aetiology.

Recommendations: Chronic low back pain in association with radiculopathy and constitutional symptoms warrants radiological imaging and especially MRI.

Good history taking and examination is therefore an important step in determining which patients with chronic low back pain would benefit from further imaging by MRI.

1.0 INTRODUCTION

Chronic Low Back Pain (Lumbago) is a common musculoskeletal complain that can originate from many spinal structures including: ligaments, facet joints, vertebrae, paravertebral musculature, blood vessels and spinal nerve roots [2].The main causes being muscular and ligamentous injuries, age related degenerative processes in the intervertebral disks and the facet joints. Others include spinal stenosis and disc herniation [2].

It is the second most common cause for patients' visits to the Accident and Emergency units, clinics and hospitals according to several studies [3, 4]including the 2010Global burden of diseases[5].It is estimated that 50%-80% of all adults will develop Low Back Pain (LBP) sometime in their lifetime [5] and frequently females with peak age of 40-80years[6]

An updated systemic review of global prevalence of LBP in the adult population published in the year 2000 showed a point prevalence of between 12%-33% and a one year prevalence of 22%-65 %[7].

It has been found that in Africa, the average lifetime prevalence of LBP among adults is 62% while the mean LBP point prevalence is 4 %[8].

A local study on LBP in Africa by Mulimba found that within a study period of 2years, patients presenting with LBP constituted 10% of the total number of patients and that most of the complainers were in their third to fifth decade[9].

LBP is common in children and adolescents as is in adults. Some studies have shown lifetime prevalence as high as 70%-80% by 20 years of age. For a majority of children, the back pain is self-limiting and studies have shown that imaging techniques are poorly able to discriminate between children with and without back pain [10].Furthermore, the symptoms in childhood rarely result in consultation hence imaging is rarely done.

However new epidemiologic evidence has indicated paediatric LBP may be much more prevalent than previously perceived [11-14].

The diagnosis and treatment of LBP is complicated by difficulty in precisely identifying the exact cause and by the non-specificity and vagueness of the pain in many cases [15]. This has led to a varied way of patient care by the clinicians suggesting there is professional

uncertainty about the optimal approach [16, 17]. Thorough history taking and physical examination are therefore essential in reaching a diagnosis in patients with Chronic LBP [18].

MRI of the lumbosacral spine gives a better yield in evaluation of patients with LBP compared to conventional radiography, but it has been seen to be costly [18, 35]. A cost effective diagnostic plan is therefore necessary in these patients especially in resource poor settings like our set up.

This study aimed to evaluate the imaging findings of MRI and Plain radiography in relation to the clinical presentation in patients presenting with Chronic Low Back Pain so as to ascertain the role of imaging in these patients and to be able to develop imaging guidelines in these group of patients.

1.1 LITERATURE REVIEW

1.1.1 Role of imaging in Low Back Pain

Radiological imaging is found to be the most important investigation and it is most importantly required in the diagnosis, planning surgical management and follow-up in patients with Low Back Pain (LBP)[18].

This is however controversial in non- specific acute LBP. A review paper by Lateef. H, Patel. D et al in 2009 recommended a conservative approach in patients with back pain of less than six weeks (acute LBP) with reassessment only after 4-6weeks [19]. This was because it was found that acute LBP was self-limiting and benign with no cause identified in up to 95% of patients and that the findings on imaging correlated poorly with the symptoms [19].

In view of this, the American College of Physicians (ACP) and the American Pain Society (APS) have developed guidelines that emphasize on focused history and physical examination and initial pain management without imaging in non-specific Acute LBP. Imaging is then considered in those without improvement after a period of six weeks [20].

A meta-analysis by Chou and Deyo et al on imaging strategies for LBP recommended that clinicians should refrain from routine immediate lumbar imaging in patients with acute or sub-acute LBP and without features suggesting a severe underlying pathology [21].

Some authors advocate that conservative management is effective and radiological investigation is unnecessary [20]. On the other hand, some studies have shown that conservative management may be disastrous in cases of spinal stenos is from disc prolapse

and herniated nucleus pulposus. In such cases, radiology then plays a critical role in evaluation [2].

The radiological management of Chronic Low back pain ranges from radiography, Computed Tomography(CT), Magnetic Resonance Imaging(MRI), myelography and Radionuclide Imaging(RNI)[2]. Modern imaging techniques like MRI are commonly recommended and have improved the diagnosis and detection of the likely causes of LBP. MRI has been known to be quite expensive and therefore a cost effective plan is necessary for the management LBP [18]. The correlation between clinical presentation, plain radiography and MRI is important so that maximum benefit can be achieved from MRI in the evaluation of LBP [18].

It is therefore crucial to properly examine patients with LBP and assess the possible relationship between radiological characteristics and the clinical presentation [2].

The use of plain radiography in evaluation of nonspecific LBP is quite high. Unfortunately the yield is low as for example disk herniation (seen as the most common surgical amenable cause of Chronic LBP) cannot be diagnosed on plain radiography [22]. Due to this, spine radiographs have been labelled as having very low diagnostic yield [23]. Thus the use of MRI instead of radiographs as the initial imaging modality has become common, especially considering that several randomized controlled trials have suggested that substituting MRI for radiography is not only safe but essential since MRI scans detect a greater number of abnormalities including neoplasms in a primary care population [24]. It is for these reasons that McNally E.G, Wilson D.J and Ostlere S.J have decided to substitute radiographs with limited MRI in patients with LBP of at least six weeks as a routine practice [24].

Contrary to this, Jarvik J.G, HollingworthW.et al conducted a similar controlled randomized trial of replacing lumbar spine radiographs with MRI in primary care of patients and found that there was no difference in disability, pain or general health status in either of the imaging modalities but still there was a huge preference among both patients and physicians for MRI because of reassurance and patient satisfaction [25]. Replacing plain radiographs with Rapid MRI did not provide any incremental value [25]. They observed that the mean health service costs in the routine use of rapid MRI increased significantly but the patients with LBP did not have a measurable benefit in pain or functional status [25]. They therefore discouraged the use of MRI as the initial imaging test for primary care of patients with back pain.

While most studies rate highly the diagnostic imaging power of MRI, plain radiographs still play a major role in the provision of certain additional information which can be limited in MRI. Standing and dynamic radiographs can reveal misalignment and instability (iatrogenic and degenerative) as well aspseudoarthroses, endplate sclerosis, erosions and additional calcific densities. These bony changes are difficult to see on MRI due to their inherent properties [(26)].

The main drawback of lumbar radiography is radiation exposure to the patient. It contributes to cumulative low levels of radiation exposure which could promote carcinogenesis. The average radiation exposure of lumbar radiography has been estimated to be seventy five times higher than for chest radiography [(27)]. Plain radiographs are also poor in soft tissue assessment and evaluation of disk disease and nerve impingement [(12)].

Despite its draw backs, Yong PY, NAA Alias et al in 2003 still maintain that plain radiographs are important in the assessment of LBP. They found that the radiographs were sensitive though nonspecific, and that some specific findings were best picked on plain radiographs when compared to MRI, for example defects in the pars interarticularis[(18)].

MRI is considered to be the best imaging modality for chronic back pain evaluation due to its high contrast and spatial resolution and lack of ionizing radiation [(20)]. It's recognized as being accurate for detecting intervertebral disk diseases and in differentiating the subtypes of disk pathologies [(27)]. Using rapid MRI early clinical management might benefit patients by providing a swifter definitive diagnosis, obviating further imaging or referral, and reassuring both patient and physician that there is no serious disease.

A local study by Dr. Ally Pilly on the role of MRI in management of LBP in 2003 at the University of Nairobi concluded that there was no need for further radiological evaluation following MRI examination. This made MRI of the lumbar spine the best imaging modality for evaluation of patients with LBP [(28)].

The sensitivity of MRI to evaluate the spine is further undermined in a study by Jensen M.C and Brant Zawadski who found a high prevalence of abnormal findings in lumbar MRIs of ninety eight asymptomatic persons .Only 36% of the studied asymptomatic patients had normal MRI findings, of the remaining 64%, 52% had disc bulges and 28% had disc herniation[(29)]. They concluded that the high prevalence of disc lesions on MRI in patients with LBP may actually be coincidental.

Plain radiographs have also been found to have incidental findings unrelated to back symptoms, like facet joint abnormalities, mild sclerosis: commonly seen in persons with no back pain [30]. As a result, questions have arisen as to which patients should be imaged since early and advanced imaging has been associated with increased rates of interventional procedures and surgeries[31].

This was confirmed in a study by Deyo and J.A Turner which showed a higher rate of spinal surgeries for LBP in the states which had higher utilization rates of advanced imaging techniques [32].

These findings basically suggest that although advanced imaging can detect more and even the mildest of abnormalities, the abnormalities are most of the time not necessarily clinically significant [33]. The study by Ally P. et al [28] supports this since one of her recommendations advised that any study done on imaging of the back to evaluate the cause of back pain should include clinical correlation so as to assess the accuracy of the MRI findings.

Locally, the use of MRI in evaluation of chronic LBP has been encouraged. The main drawback for MRI is the costs and availability as opposed to plain radiographs which are cheap and readily available. This has been reaffirmed in a local study done to examine the relationship between socio-demographic and clinical characteristics of patients with LBP[34].

The study found that lumbar disc disease was the commonest cause of LBP which is obviously better picked on MRI and therefore recommended that public hospitals should be adequately equipped with radiological equipment especially MRI which was found lacking in most hospitals.

In addition, subsidizing of MRI costs was recommended which would help in improvement of diagnosis and management of the patients with chronic LBP [34].In view of the foregoing, this study aimed at determining which group of patients would best benefit from additional imaging in our set-up.

1.2 STUDY RATIONALE AND JUSTIFICATION

Kenyatta National Hospital receives many patients with complaints of chronic LBP known in the accident and emergency unit as well as in its outpatient clinics.

Most of the patients will almost always be sent for radiological imaging besides other tests. The aim of this study was to define the role of imaging in patients with chronic LBP and to categorize which patients would benefit most from a specific type of imaging modality. This would enable more evidence based decision making to the clinical management of low back pain locally as well as form a basis on which other researchers could easily design and conduct comparative effective studies of diagnostic imaging in patients with Low Back Pain.

Since no guidelines are available locally for imaging patients with chronic low back pain, the findings from this study would help in the development of clinical imaging guidelines to reduce the rates of unnecessary imaging in this group of patients.

1.3 RESEARCH QUESTIONS.

1. What are the plain lumbar radiographic findings in patients with Chronic Low Back Pain?
2. What are the MRI findings in the same pool of patients with Chronic Low Back Pain?
3. How do the imaging findings of conventional plain radiographs and MRI compare with the clinical presentation?

1.4 OBJECTIVES

1.4.1 Broad Objectives

To correlate clinical presentation with imaging findings with MRI as the gold standard in diagnosis of chronic Low Back Pain.

1.4.2 Specific Objectives

1. To establish the lumbar radiographic findings in patients with chronic LBP.
2. To establish MRI findings in patients with chronic LBP.
3. To assess the agreements in diagnosis of LBP between Conventional plain radiographs and MRI.
4. To help develop local imaging guidelines in patients with Chronic LBP.

2.0 STUDY DESIGN AND METHODOLOGY

2.1 Study site:

The study was conducted at the Radiology department of Kenyatta National Hospital (KNH) and at Plaza imaging Solutions. Both Imaging centres are located in Nairobi County and are approximately 1km apart from each other. The centres share an almost similar category of patients for imaging services. Both centres use similar radiological equipment and have digital radiography (Shimadzu flexa-vision system) and MRI machines of similar magnetic strengths of 1.5T and model; Philips Intera model with a 1year difference in the year of manufacture; (KNH 2005 and Plaza, 2006).

2.2 Study design:

This was a cross sectional study. The study was conducted over a period of 4months (September 2014 and December 2014). Convenience sampling was used.

2.3 Study population:

The study population were patients seeking radiological diagnosis of LBP in the Radiology Department of Kenyatta National Hospital (KNH) and Plaza imaging solutions. Both centres attend to approximately 40 patients per day with radiological requests for the evaluation of Low Back Pain. This is because there are no imaging guidelines locally as to which patients would benefit from imaging. Consecutive convenience sampling of patients was done in both centres until the minimum sample size was reached. Since both centres cater for the same type of patients, no specific number was assigned to any of the centres.

2.4 Sample size estimation:

A minimum sample size of 174 participants was sufficient to demonstrates an agreement of k=0.7 between conventional radiography and MRI in diagnosis of chronic lower back pain. The study was powered at 80% with 95% level of confidence. The hypothesized agreement between conventional radiography and MRI was based on a study conducted by P.Y Yong, NAA Alias, ILShuaib that demonstrated an agreement of 0.7. The sample size calculation assumed a lower limit of the kappa co-efficient of k=0.6 and a 50% occurrence of chronic

lower back pain among clients who are served in the study sites. The table below indicates derived sample sizes based on the following[1]:

K_0 = Hypothesized kappa co-efficient (0.7)

k_L = Lower confidence limit of the hypothesized kappa co-efficient (0.6)

π = prevalence of chronic lower back pain (50%)

n = number of raters. In this case it will be 2; conventional radiography and MRI

			Number of Raters (n)			
κ_0	κ_L	π	2	3	4	5
		0.10	559	373	301	255
0.50	0.40	0.30	264	146	112	95
		0.50	228	120	89	76
		0.10	140	94	76	64
0.60	0.40	0.30	66	37	28	24
		0.50	57	30	23	19
		0.10	463	311	247	207
0.70	0.60	0.30	205	124	99	87
		0.50	174	102	81	73
		0.10	116	78	62	52
0.80	0.60	0.30	52	31	25	22
		0.50	44	26	21	19

The sample size is based on the formula[2]:

$$n = \frac{(z_\alpha + z_\beta)^2 \cdot (E + F - G)}{[(1 - p_e)^2 \cdot \Delta\kappa]^2},$$ ……………………………………… (1)

Where;

[1]Donner, Allan and Rotondi, Michael A. (2010) "Sample Size Requirements for Interval Estimation of the Kappa Statistic for Interobserver Agreement Studies with a Binary Outcome and Multiple Raters," *The International Journal of Biostatistics*: Vol. 6: Iss. 1, Article 31.**DOI:** 10.2202/1557-4679.1275

[2]Lee Tzeh San and CDC.On determination of sample size for the positive kappa Lee Tzeh San and CDC. On determination of sample size for the positive kappa Coefficient .Joint Statistical meetings.

E = $E = \sum_{i=1}^{2} p_{ii} \cdot [(1-p_e) - (p_{i.} + p_{i.})(1-p_o)]^2$, ……. (2)

F = $F = (1-p_o)^2 \cdot \sum_{i=1}^{2} \sum_{j \neq i} p_{ij} \cdot (p_{.i} + p_{j.})^2$, ……. (3)

G = $G = [p_o \cdot (1+p_e) - 2p_e]^2$. …….. (4)

n = sample size

Zα= the derivative that represents the 95% level of confidence (1.96)

Z_β =value of the standard normal distribution corresponding to the desired level ofpower of the study (0.84 for power of 80%)

P_e= is the hypothetical probability of chance agreement *(applied in calculating the Cohen's kappa co-efficient)*

P α = relative observed agreement among raters*(applied in calculating the Cohen's kappa co-efficient)*

2.5 Sampling:

Eligible and consenting participants were recruited into this study conveniently at the study sites until the minimum sample size was attained. Patients were recruited when they came in for an MRI since most of the patients already had a plain radiograph prior to the MRI.All patients recruited had a previous plain radiograph. History taking and clinical evaluation was done prior to the MRI.

2.6 Eligibility criteria:

2.6.1 Inclusion criteria:

1. Consenting adults attending the KNH and Plaza imaging solutions radiology clinics.
2. Patients with a history of chronic LBP not less than 6weeks duration who have both a plain radiograph and an MRI.
3. Patient with no lumbar surgery prior to the investigation.

2.6.2Exclusion criteria:

1. Patients with acute Low back pain <6weeks duration.
2. Patients with history of acute trauma to the back.
3. Patients with only plain radiography with no MRI (incomplete investigation).
4. Patients who do not provide consent to be enrolled into the study.
5. Patients with contraindications to MRI such as metallic implants.
6. Patients who have undergone any form of lumbar surgery.
7. Patients with known primary malignancy.(spine/other sites)

2.7 ETHICAL CONSIDERATIONS

All measures were taken to safeguard the ethical rights of the study patients.

2.7.1Confidentiality:

In order to safeguard the confidentiality of the study patients, the principal investigator ensured that there was no identifier that may link the research data to study patients. Each study patient was allocated a unique numeric identifier that was used in the data abstraction tool and database. Access to the participant data was restricted. No unauthorized persons were allowed any access to participant records. These records were stored in a locked in cabinet. All electronic databases were password protected to control access.

2.7.2 Protection from harm:

All participants were protected from any health, physical, social or economic harm. The principal investigator ensured that no information that is abstracted from the participant records exposed the study patients to any form of harm.

2.7.3 Ethical clearance:

The research team obtained ethical clearance to conduct this study from the KNH/UoN Ethics and Scientific Review Committee.

3.0 STUDY AND DATA COLLECTION PROCEDURES.

The patients with chronic back pain were sent by their clinicians initially for a plain radiograph and the main reason was due to the persistent low back pain despite medication, and subsequently an MRI based on the plain radiographic findings, the progression of symptoms or as a recommendation from a radiologist. In this study, most of the patients who were send for MRI were seen to have associated lower limb radicular pains or numbness. There is no clinical or radiological guideline in our setup as to which patients with chronic LBP would benefit from imaging.

The patients who come for MRI due to back pain almost always had previous plain radiographs. The patients were recruited into the study conveniently the moment they came in for MRI, and patients with no plain radiograph prior to the MRI study, were excluded from the study. A detailed history was taken from the patient before the MRI was done. This was done by the researcher and the technician who was conducting the MRI using the standard data collection form. The additional details not written on the request form by the referring clinician were therefore added to ensure all required information for data collection was captured.

The main clinical features that we looked for were:

- The patients' demographic data, the BMI and occupation.
- Duration of pain.
- Additional clinical features like- radicular pain, lower limb numbness, sensory deficit, paraplegia, neurogenic claudication and back tenderness.

BMI was derived by dividing the patients' weight in kilograms by the square of the body height in meters (kg/m^2). A standard calculator was used to get the accurate values.

The observer error in this study was minimized by ensuring that there was an agreement between the two radiologists reporting the images before a final report was given. The radiologists on duty (general radiologists) and the principal researcher gave the final report.

The plain radiographs accepted for the study included the standard Antero posterior (AP) and lateral views while the MRIs included the following sequences: Sagittal T1 and T2FSE, Axial T2FSE and axial Proton Density (PD).

Loss of the normal lumbar curvature (lordosis) was reported as muscle spasm since hypolordosis in symptomatic patients has been associated with para-spinal muscle spasm.

The imaging findings of each of the modalities were entered into an MS excel table and comparison was made based on the level of pathology example: whether both modalities picked an abnormality at the same vertebral level or whether a certain modality missed the pathology, and whether the findings correlated with the clinical findings etc.

3.1 Data collection procedures

3.1.1 Piloting of study tools

The data collection tools were piloted before the study began by collecting data from 3 patients in each of the study sites. The piloting tested the comprehensibility of the questions in the questionnaire, the flow of questions and the time taken to collect data on each participant. The final data collection tools were printed after all revisions were made.

3.1.2 Data collection

After receiving Ethical clearance to conduct this study, administrative authority was sought from the management of KNH and Plaza Imaging Solutions. Demographic and participant data such as age, type of occupation, gender, weight, height and clinical findings were collected from the eligible and consenting participants. A structured questionnaire and abstraction from patient records was applied to collect these data.

Clinical data such as history of lumbar surgery and the final radiological diagnoses of the conventional radiology and MRI scans were abstracted from the participants' medical records. The Principal Investigator collected the data, which was then keyed into an MS Excel database. Data quality checks were conducted by running consistency, range and correctness checks on the data.

3.2 DATA MANAGEMENT AND ANALYSIS

3.2.1 Data management.

All data abstraction tools and electronic databases (MS Excel) utilized in this study were protected by procedures which was consistent with applicable laws, policies, regulations and standards in Kenya. Computers used to enter data were password protected at the operating system level using software that is commercially available. Electronic data bases were password protected.

3.2.2 Data analysis
Data was analysed using Stata version 10 (Stata Corp; Texas).

3.2.3 Descriptive statistics
Categorical variables were presented as proportions in tables and graphs (bar or pie charts). Continuous variable were summarized as means or medians and presented in table form. The demographic data (age, BMI, gender, nature of occupations etc.); clinical diagnosis; prevalence of chronic lower back pain were analysed descriptively and presented in tables and graphs.

3.2.4 Inferential statistics
The extent of final agreement in the final diagnosis based on the conventional radiology and MRI readings was calculated using the Cohen's Kappa analysis and the strength of agreement was demonstrated by the kappa co-efficient. The kappa co-efficient (k) was translated as follows:

≤0=poor agreement, 0.01–0.20=slight agreement, 0.21–0.40=fair agreement, 0.41–0.60=moderate agreement, 0.61–0.80 =substantial agreement, and 0.81–1=almost perfect.

Clinicians differential diagnosis	Radiographic diagnosis	MRI diagnosis	Kappa-coefficient
Muscular spasm(hypolordosis)			
Disc disease/Prolapsed disc			
Lumbar spondylosis			
Potts disease			
Nerve root compression			
Cord compression			

This study also assessed whether different participant characteristics influenced the agreement in the diagnosis of LBP by radiography and MRI.

4.0 RESULTS

A total of 180 patients were enrolled into this study. The mean age was 47.3 Years (SD=14.5years). Fifty three (29.4%) were male and 127(70.6%) were female. Majority of patients worked in office settings (48%), 38.5% worked in domestic setting(house wives/farmers/unemployed) and 10% worked manual jobs. The rest 3.4% were college students. 164 out of the 180 patients had their BMI calculated. 72% were found to be overweight while 64% had a normal BMI. The mean BMI among the patients was 26.3 (SD=26.3). The mean interval between plain radiograph and MRI was 28.3 days.

4.1 DEMOGRAPHIC CHARACTERISTICS

Figure 1: Age distribution

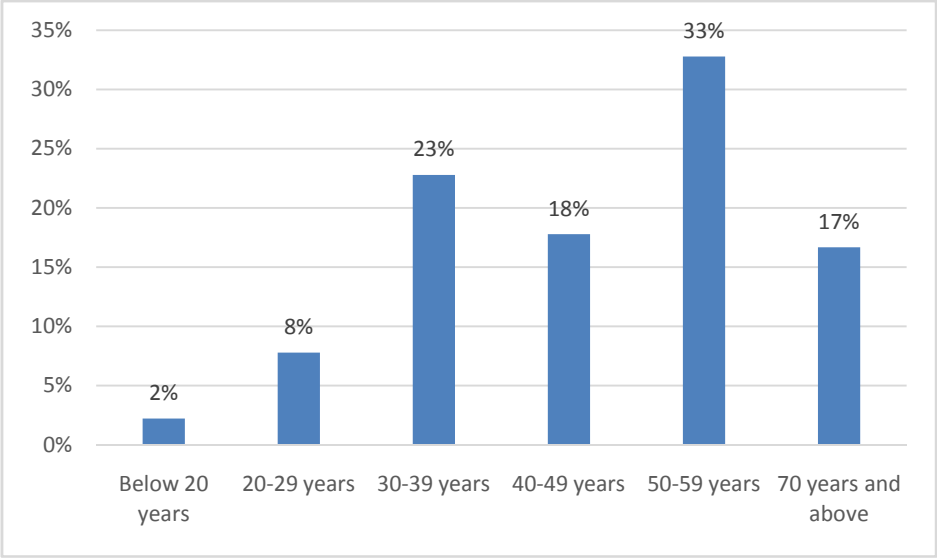
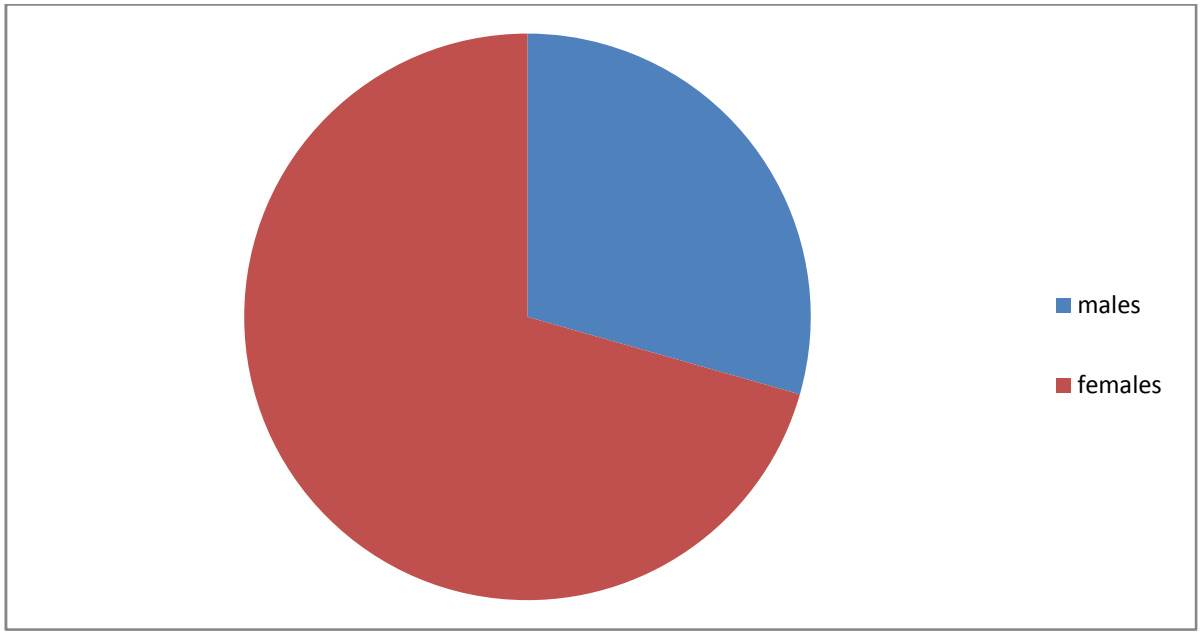


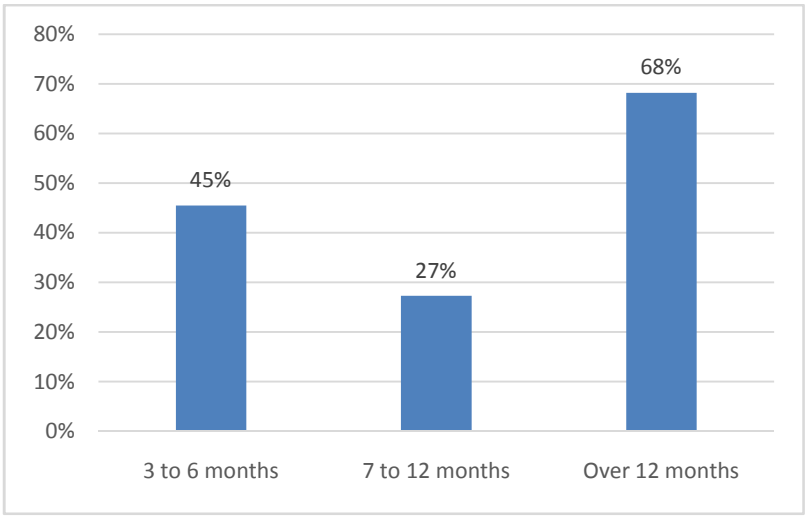
Figure 2: Gender distribution



4.2 Duration of back pain

All the patients reported experiencing back pain for more than 3 months. Out of the 180 patients who reported their duration of back pain, 59 (32.8%) had experienced it for less than one year and 121 (67.2%) had experienced back pain for more than one year as summarized in figure 3. The median duration of back pain was 24 months (min=3 months; max=156 months).

Figure 3:Duration of back pains among study participants



4.3Additional patient characteristics (BMI and Occupation)

Table 1: BMI distribution

	No. Of Patients (%)
Underweight	4 (2.4%)
Normal	64 (39%)
Overweight	72 (43.9%)
Obese	24(14.6%)
Total	164

Table 2: Occupation of participants

Occupation	No. Of Patients	Percent
Manual	19	10.6%
Office	86	47.8%
Domestic(house wives/farmers/unemployed)	69	38.3%
Student	6	3.3%
Total	180	100%

4.4CLINICAL CHARACTERISTICS OF STUDY PARTICIPANTS

A total of 180 patients were recruited into the study. All the patients had the primary complaint of chronic low back pain. 57(31.7%) had no additional clinical complaint or examination findings. Out of the 180, 123(68.3%) patients had additional clinical complaints of either unilateral or bilateral radicular pain or lower limb numbness as summarized in the tables below.

4.4.1Additional clinical characteristics

Table 3: Radiating lower limb pain

		Frequency	Percent
	Left	8	4.5%
	Right	19	10.6%
	Both	92	51.4%
	None	60	33.5%
	Total	180	100.0%

Table 4: Lower limb numbness

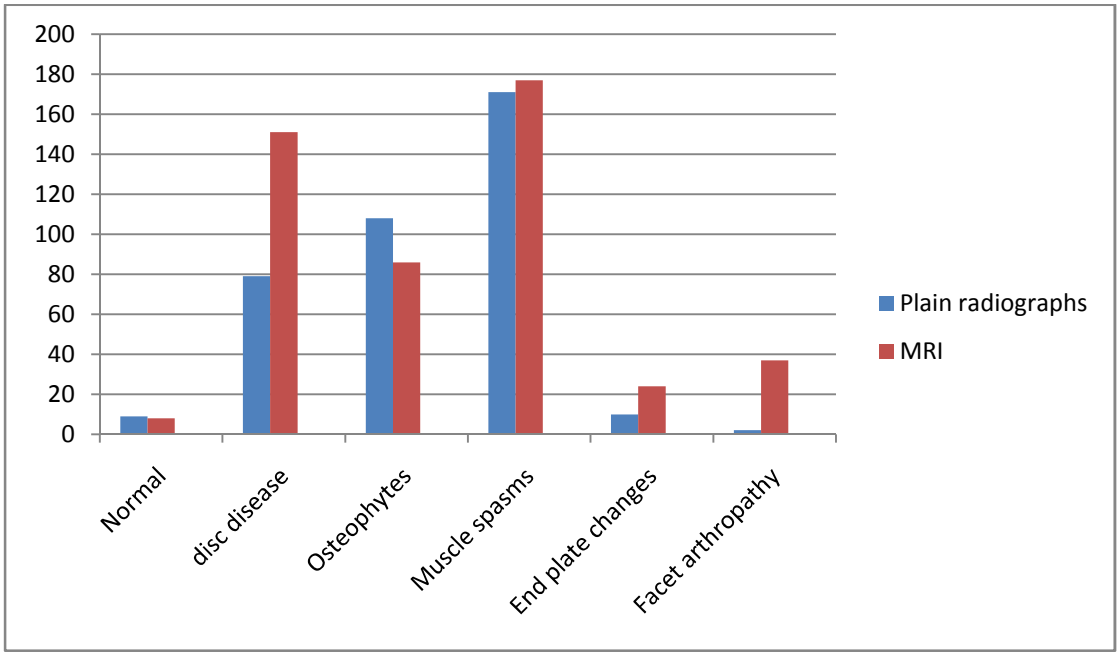
		Frequency	Valid Percent
	Left	5	2.8%
	Right	4	2.2%
	Both	42	23.5%
	None	128	71.5%
	Total	180	100.0%

4.5 IMAGING FINDINGS

4.5.1 Frequencies of diagnoses on radiographs and MRI

As illustrated in figure 4, muscle spasms, osteophytes and disc disease were the most common findings in conventional radiography and MRI

Figure 4:Bar chart showing frequency of various findings on plain radiographs and MRI



4.6 CORRELATIONS OF PATIENT CHARACTERISTICS (AGE, BMI AND OCCUPATION) WITH SPECIFIC IMAGING FINDINGS.

Most of the patients recruited were found to have disc disease, anterior osteophytes or muscular spasm (hypolordosis) on both MRI and plain radiography. On MRI disc disease was either disc desiccation seen as change in T2 signal, reduced disc height or disc herniation. Disc bulges were very few accounting for only 6%. On plain radiography disc disease was seen as reduced intervertebral disc height. These findings affected either a single vertebral level or multiple sites. The findings are summarized in the tables below.

NB: The Fishers Exact test was applied to test the association between radiological findings and the exposure variables (Age, occupation and BMI category). Associations with a p value of less than 0.05 were considered statistically significant.

4.7 PLAIN RADIOGRAPHIC AND MRI FINDINGS WITH AGE CORRELATION.

i) **Reduced disc height**

Table 5: Age vs reduced disc height-radiograph.

		Reduced disc height		Total
		Positive	Negative	
Age Category	Below 20 years	0	4	4
	20-29 years	2(2.5%)	12	14
	30-39 years	11(14%)	30	41
	40-49 years	17(21.5%)	15	32
	50-59 years	26(32.9%)	33	59
	60 years and above	23(29.1%)	7	30
Total		**n= 79(100%)**	**101**	180
Fishers Exact test p value:<0.001				

Analysis of association showed a significant difference in findings across different age groups. This table shows patients above 50 years of age had higher occurrences of reduced disc heights. (p=<0.001)

ii) Osteophytes

Table 5: Age Vs osteophytes- radiograph

		radio_osteophytes		Total
		Positive	Negative	
Age Category	Below 20 years	1(1%)	3	4
	20-29 years	0	14	14
	30-39 years	15(13.9%)	26	41
	40-49 years	20(18.5%)	12	32
	50-59 years	48(44.4%)	11	59
	70 years and above	24(22.2%)	6	30
Total		**n=108(100 %)**	72	180
Fishers Exact test p value:<0.001				

Analysis of association showed a significant difference in findings across different age groups. This table shows patients between 50-59 years of age had higher occurrences of osteophytes. (p=<0.001)

Disc desiccation

Table 6: Age Vs degenerative disc dessication-MRI

		MRI disc desiccation		Total
		Positive	Negative	
Age Category	Below 20 years	0	4	4
	20-29 years	2(1.5%)	12	14
	30-39 years	20(15.6%)	21	41
	40-49 years	29(22.7%)	3	32
	50-59 years	48(37.5%)	11	59
	60 years and above	29(22.7%)	1	30
Total		**n=128(100 %)**	**n=52**	180
Fishers Exact test p value: <0.001				

Analysis of association showed a significant difference in findings across different age groups. This table shows patients above 40 years had higher occurrences of degenerative desiccation with the majority being between 50-59years. (p=<0.001)

Disc herniation.

Table 7:AgeVs disc herniation-MRI

		MRI disc herniations		Total
		Positive	Negative	
Age Category	Below 20 years	0	4	4
	20-29 years	7(5.3%)	7	14
	30-39 years	24(18.5%)	17	41
	40-49 years	26(20%)	6	32
	50-59 years	47(36.2%)	12	59
	60 years and above	26(20%)	4	30
Total		**n=130(100 %)**	**50**	180
Fishers Exact test p value:**<0.001**				

Analysis of association showed a significant difference in findings across different age groups. This table shows patients between 50-59 years of age had higher occurrences of disc herniations. (p=<0.001

Reduced disc height

Table 8:Age Vs reduced disc height-MRI

		Reduced disc height		Total
		Positive	Negative	
Age Category	Below 20 years	0	4	4
	20-29 years	2(2.5%)	12	14
	30-39 years	11(14%)	30	41
	40-49 years	17(21.5%)	15	32
	50-59 years	26(32.9%)	33	59
	60 years and above	23(29.1%)	7	30
Total		**n= 79(100%)**	**101**	180
Fishers Exact test p value:<0.001				

Analysis of association showed a significant difference in findings across different age groups. This table shows patients above 50 years of age had higher occurrences of reduced disc heights. (p=<0.001)

Osteophytes

Table 9: Age Vs Osteophytes- MRI

Count		mri_osteophytes		Total
		Positive	Negative	
Age Category	Below 20 years	0	4	4
	20-29 years	0	14	14
	30-39 years	11(13%)	30	41
	40-49 years	15(17.4%)	17	32
	50-59 years	39(45.3%)	20	59
	60 years and above	21(24.3%)	9	30
Total		**n=86(100%)**	94	180
Fishers Exact test p value:<0.001				

Analysis of association showed a significant difference in findings across different age groups. This table shows patients between 50-59 years of age had higher occurrences of osteophytes. (p=<0.001)

4.8 RADIOLOGICAL FINDINGS AND BMI CORRELATION.

Table 10: BMI and Hypolordosis (Muscle spasm)

		Radiography muscle spasm			P value
		Positive	Negative		
BMI category	Underweight	1 25.0%	3 75.0%	4	0.002
	Normal	57 89.1%	7 10.9%	64	
	Overweight	69 95.8%	3 4.2%	72	
	Obese	23 95.8%	1 4.2%	24	
Total		150 91.5%	14 8.5%	164	

The difference in frequencies of positive findings was significant across different BMI categories. This table shows that overweight and obese patients had a significantly high occurrence of muscle spasm. (p=0.002)

Table 11: BMI and osteophytes.

		Radiography osteophytes		Total	P value
		Positive	Negative		
BMI category	Underweight	0 0.0%	4 100.0%	4 100.0%	<0.0001
	Normal	33 51.6%	31 48.4%	64 100.0%	
	Overweight	43 59.7%	29 40.3%	72 100.0%	
	Obese	22 91.7%	2 8.3%	24 100.0%	
Total		98 59.8%	66 40.2%	164 100.0%	

The difference in frequencies of positive findings was significant across different BMI categories. This table shows that overweight and obese patients had a significantly high occurrence of osteophytes. (p<0.0001)

Table 12: BMI and disc disease(reduced height).

		Radiography disc disease		Total	P value
		Positive	Negative		
BMI category	Underweight	0 0.0%	4 100.0%	4	0.076
	Normal	29 45.3%	35 54.7%	64	
	Overweight	29 40.3%	43 59.7%	72	
	Obese	15 62.5%	9 37.5%	24	
Total		73 44.5%	91 55.5%	164	

The difference in frequencies of positive disc disease findings was not statistically significant across different BMI categories. This table shows that no significant difference in frequencies of occurrence of disc disease was seen across the different BMI categories. (p=0.076)

4.9 MRI FINDINGS AND BMI CORRELATION.

Table 13:BMIand osteophytes.

		MRI_osteophytes		Total	P value
		Positive	Negative		
BMI category	Underweight	0 0.0%	4 100.0%	4	0.015
	Normal	26 40.6%	38 59.4%	64	
	Overweight	34 47.2%	38 52.8%	72	
	Obese	17 70.8%	7 29.2%	24	
Total		77 47.0%	87 53.0%	164	

The difference in frequencies of positive osteophyte findings was significant across different BMI categories. This table shows that obese patients had a high occurrence of osteophytes. . (p<0.015)

Table 14:BMIand disc herniation

		MRI-disc herniation		Total	P value
		Positive	Negative		
BMI category	Underweight	2 50.0%	2 50.0%	4	0.071
	Normal	54 84.4%	10 15.6%	64	
	Overweight	57 79.2%	15 20.8%	72	
	Obese	23 95.8%	1 4.2%	24	
Total		136 82.9%	28 17.1%	164	

The difference in frequencies of positive disc herniation findings was not statistically significant across different BMI categories. ($p<0.071$). This table shows that no significant difference in frequencies of occurrence of dischernia tion was seen across the different BMI categories.

Table 15:BMI and Hypolordosis (muscular spasm)

		MRI_muscle_spasm		Total	P value
		Positive	Negative		
BMI category	Underweight	2 50.0%	2 50.0%	4	0.0161
	Normal	59 92.2%	5 7.8%	64	
	Overweight	68 94.4%	4 5.6%	72	
	Obese	23 95.8%	1 4.2%	24	
Total		152 92.7%	12 7.3%	164	

The difference in frequencies of positive muscle spasm findings was significant across different BMI categories. This table shows that overweight and obese patients had a significantly high occurrence of muscle spasm. ($p=0.016$)

4.10 PLAIN RADIOGRAPHIC FINDINGS AND OCCUPATION CORRELATION.

Table 16: Occupationand Hypolordosis (muscle spasm)

		Radiography _muscle_spasm		Total	P value
		Positive	Negative		
Occupation	Manual	18 100.0%	0 0.0%	18	0.001
	Office	78 90.7%	8 9.3%	86	
	Domestic	59 85.5%	10 14.5%	69	
	Student	2 33.3%	4 66.7%	6	
Total		157 87.7%	22 12.3%	179	

The difference in frequencies of positive findings was significant across different occupations. This table shows that all manual workers were reported to have muscle spasm followed by office workers who equally had a significantly high occurrence of muscle spasm. (p=0.001)

Table 17: Occupation and osteophytes

		Radiography _osteophytes		Total	P-value
		Positive	Negative		
Occupation	Manual	12 67%	6 33%	18	0.005
	Office	50 58.1%	36 41.9%	86	
	Domestic	48 69.6%	21 30.4%	69	
	Student	0 0.0%	6 100.0%	6	
Total		110 61.4%	69 38.6%	179	

The difference in frequencies of positive findings was significant across different occupations. This table shows manual and domestic workers had a significantly high occurrence of osteophytes. (p=0.005)

Table 18: Occupation and disc disease(reduced disc height)

		Radiography _disc_disease		Total	P value
		Positive	Negative		
Occupation	Manual	8 44.4%	10 55.6%	18 100.0%	0.079
	Office	32 37.2%	54 62.8%	86 100.0%	
	Domestic	38 55.1%	31 44.9%	69 100.0%	
	Student	1 16.7%	5 83.3%	6 100.0%	
Total		79	100	179	
		44.1%	55.9%	100.0%	

The difference in frequencies of positive disc disease findings was not statistically significant across the different occupations. ($p<0.079$). This table shows that no significant difference in frequencies of occurrence of disc disease on plain radiography was seen across the different occupations.

4.11 MRI FINDINGS AND OCCUPATION CORRELATION

Table 19:Occupationand disc herniations

		MRI disc_herniation		Total	P value
		Positive	Negative		
Occupation	Manual	17 94.4%	1 5.6%	18	0.002
	Office	68 79.1%	18 20.9%	86	
	Domestic	63 91.3%	6 8.7%	69	
	Student	2 33.3%	4 66.7%	6	
Total		150 83.8%	29 16.2%	179	

The difference in frequencies of positive findings was significant across different occupations. This table shows manual and domestic workers had a significantly high occurrence disc herniation on MRI. ($p=0.002$)

Table 20:Occupation and osteophytes

		MRI_osteophytes		Total	P value
		Positive	Negative		
Occupation	Manual	14 77.8%	4 22.2%	18	0.002
	Office	35 40.67%	51 59.3%	86	
	Domestic	43 62.3%	26 37.7%	69	
	Student	0 0.0%	6 100.0%	6	
Total		92 51.4%	87 48.6%	179	

The difference in frequencies of positive findings was significant across different occupations. This table shows manual and domestic workers had a significantly high occurrence of osteophytes. (p=0.002)

Table 21:Occupation and hypolordosis (muscle spasm)

		MRI_muscle_spasm		Total	P value
		Positive	Negative		
occupation	Manual	18 100.0%	0 0.0%	18	<0.0001
	Office	80 93.0%	6 7.0%	86	
	Domestic	60 87%	9 13%	69	
	Student	1 16.7%	5 83.3%	6	
Total		159 88.8%	20 11.2%	179	

The difference in frequencies of positive imaging findings was significant across different occupations. This table shows that all manual workers were reported to have muscle spasm followed by office workers who equally had a significantly high occurrence of muscle spasm. (p<0.0001)

4.12 CORRELATION OF MRI FINDINGS AND CLINICAL FEATURES.

A total of 123 patients had additional clinical findings. The findings were either lower limb numbness or lower limb radicular pain. This was either unilateral or bilateral (Refer to tables 3 and 4)

The clinical features were correlated with MRI findings based on findings on status of the neural exit foramina or the spinal canal, presence of osteophytes and disc disease.

Plain radiographs were not able to evaluate the spinal canal or the neural exit foramina due to the limited views of AP and Lateral that were evaluated.

NB: Fishers Exact test was applied to test the association between radiological findings and the presence or absence of lowerlimb numbness or radicular pains. Associations with a p value of less than 0.05 were considered statistically significant.

Table 22: Lower limb numbness and narrowed exit foramen

		MRI-narrowed foramen		Total	P value
		Positive	Negative		
Lower limb numbness	Left	4 80.0%	1 20.0%	5 100.0%	<0.001
	Right	4 100%	0 0%	4 100.0%	
	Both	33 78.5%	9 28.5%	42 100.0%	
	None	53 41%	75 59%	128 100.0%	
Total		94 52.5%	85 47.5%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of narrowed exit foramen between patients with lower limb numbness (left/right/both) and those without(none).($P<0.001$). Patients with numbness showed significantly high occurrences of narrowed exit foramina therefore showing narrowing of exit foramen is highly associated with lower limb numbness.

Table 23:Lower limb numbness and osteophytes

		MRI_osteophytes		Total	P value
		Positive	Negative		
Lower limb numbness	Left	3 60.0%	2 40.0%	5 100.0%	0.002
	Right	3 75.0%	1 25.0%	4 100.0%	
	Both	29 69.0%	13 31.0%	42 100.0%	
	None	51 39.8%	77 60.2%	128 100.0%	
Total		86 48.0%	93 52.0%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of osteophytes between patients with lower limb numbness (left/right/both) and those without (none). (P=0.002). The patients with numbness showed significant higher occurrences of osteophytes on MRI.

Table 24: Lower limb numbness and disc herniation.

		MRI_disc_disease		Total	P value
		Positive	Negative		
Lower limb numbness	Left	5 100.0%	0 0.0%	5 100.0%	0.047
	Right	4 100.0%	0 0.0%	4 100.0%	
	Both	40 95.2%	2 4.8%	42 100.0%	
	None	101 78.9%	27 21.1%	128 100.0%	
Total		150 83.8%	29 16.2%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of disc disease between patients with lower limb numbness (left/right/both) and those without (none). P=0.047). The patients with numbness showed significant high occurrences of disc herniation on MRI.

Table 25:Lower limb numbness and canal stenosis

		MRI_canal stenosis		Total	P value
		Positive	Negative		
Lower limb numbness	Left	0 0%	5 100%	5 100.0%	<0.001
	Right	1 25%	3 75%	4 100.0%	
	Both	14 33.3%	28 66.7%	42 100.0%	
	None	12 9%	116 91%	128 100.0%	
Total		27 15%	152 85%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of spinal canal stenosis between patients with lower limb numbness (left/right/both) and those without (none). (P<0.001). The patients with numbness showed significant high occurrences of spinal canal stenosis on MRI.

Table 26: Radicular pain and narrowed exit foramen

		MRI_narrowed foramen		Total	P value
		Positive	Negative		
Lowerlimb radicular pain	Left	6 75%	2 25%	8 100.0%	<0.001
	Right	16 84.2%	3 15.8%	19 100.0%	
	Both	63 68.5	29 31.5%	92 100.0%	
	None	9 15%	51 85%	60 100.0%	
Total		94 52.5%	85 47.5%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of narrowed exit foramen between patients with lower limb radicular pain (left/right/both) and those without (none). (P<0.001). Patients with radicular pains showed significantly higher occurrences of narrowed exit foramina.

Table 27:Radicular pain and osteophytes

		MRI_osteophytes		Total	P value
		Positive	Negative		
Radicular Lower Pain	Left	3 37.5%	5 62.5%	8 100.0%	<0.001
	Right	10 52.6%	9 47.4%	19 100.0%	
	Both	57 62.0%	35 38.0%	92 100.0%	
	None	16 26.7%	44 73.3%	60 100.0%	
Total		86 48.0%	93 52.0%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of osteophytes between patients with lower limb radicular pains (left/right/both) and those without (none). ($p<0.001$). The patients with numbness showed significant high occurrences of osteophytes on MRI.

Table 28:Radicular pain and disc herniation.

		MRI_disc_disease		Total	
		Positive	Negative		P value
Radicular Lower Pain	Left	7 87.5%	1 12.5%	8 100.0%	0.001
	Right	19 100.0%	0 0.0%	19 100.0%	
	Both	85 92.4%	7 7.6%	92 100.0%	
	None	39 65.0%	21 35.0%	60 100.0%	
Total		150 83.8%	29 16.2%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of disc herniation between patients with lower limb radicular pains (left/right/both) and those without (none). ($P=0.001$). The patients with radicular pains showed significant high occurrences of disc disease on MRI.

Table 29:Radicular pain and canal stenosis

		MRI_canal stenosis		Total	P value
		Positive	Negative		
Lower limb numbness	Left	1 12.5%	7 87.5%	8 100.0%	<0.001
	Right	2 10.5%	17 89.5%	19 100.0%	
	Both	24 26%	68 74%	92 100.0%	
	None	0 0%	60 100%	60 100.0%	
Total		27 15%	152 85%	179 100.0%	

This table shows a significant difference in frequency of occurrence/observation of spinal canal stenosis between patients with lower limb radicular pains (left/right/both) and those without (none). (P=0.047). All patients with no radicular pain showed a normal spinal canal(100%).

4.13 AGREEMENT BETWEEN PLAIN RADIOGRAPHS AND MRI

FINDINGS

The extent of final agreement in the final diagnosis based on the conventional radiography and MRI readings was determined using the Cohen's Kappa analysis and the strength of agreement was demonstrated by the kappa co-efficient. The kappa co-efficient (k) was translated as shown in box 1:

Box 1: Interpretation of kappa co-efficient (k)

≤0=poor agreement
0.01–0.20=slight agreement
0.21–0.40=fair agreement
0.41–0.60=moderate agreement
0.61–0.80 =substantial agreement
0.81–1=almost perfect agreement.

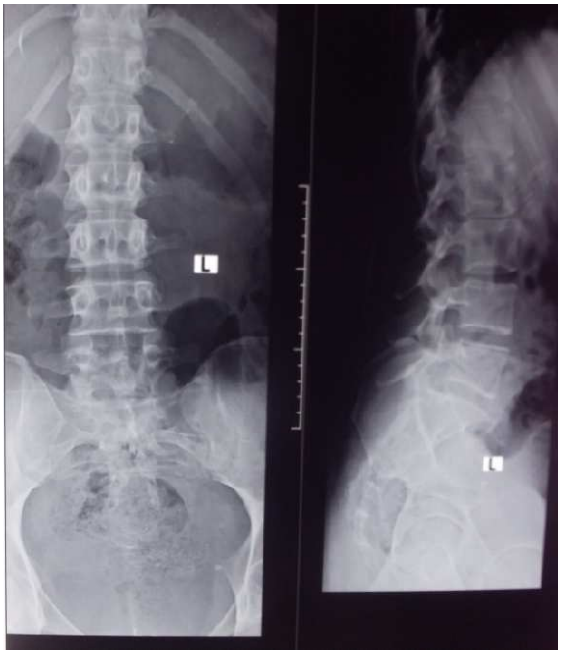
The agreement between the plain radiographs and MRI tests for normal, muscle spasm, osteophytes had an almost perfect agreement as illustrated in table 1 below. The agreement between radiography and MRI was for disc disease was rated as moderate.

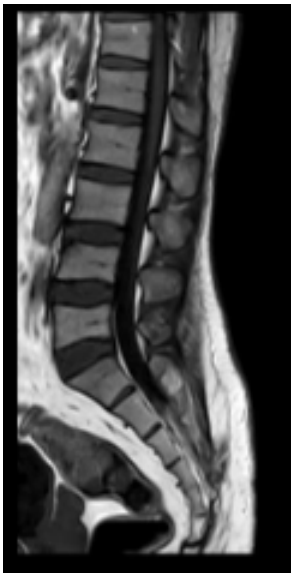
Table 30:AGREEMENT BETWEEN PLAIN RADIOGRAPHS AND MRI

	Agreement	Kappa co-efficient (standard error)	p-value	Rating
Normal	98.3%	0.8148 (0.0744)	<0.0001	Almost perfect agreement
Hypolordosis	97.2%	0.8127 (0.0741)	<0.0001	Almost perfect agreement
Osteophytes	86.7%	0.7357 (0.0723)	<0.0001	Almost perfect agreement
Disc disease	55.6%	0.1791(0.0502)	0.0002	Moderate agreement

4.14 IMAGE ILLUSTRATIONS

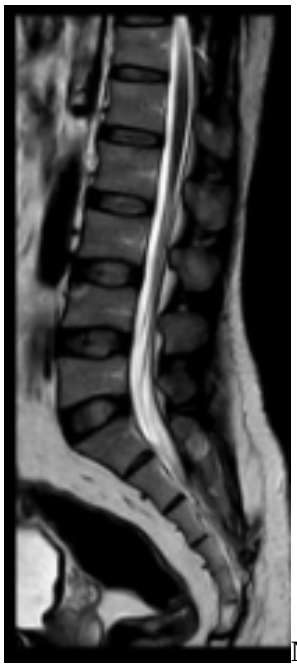
1. 27 year old female with Low back pain for 4months. Both plain radiograph and MRI were reported as normal. The intervertebral discs show normal bright nucleus pulposus on T2W images with a dark peripheral annulus fibrosus. The normal discs are kidney shaped as seen on axial T2W images.

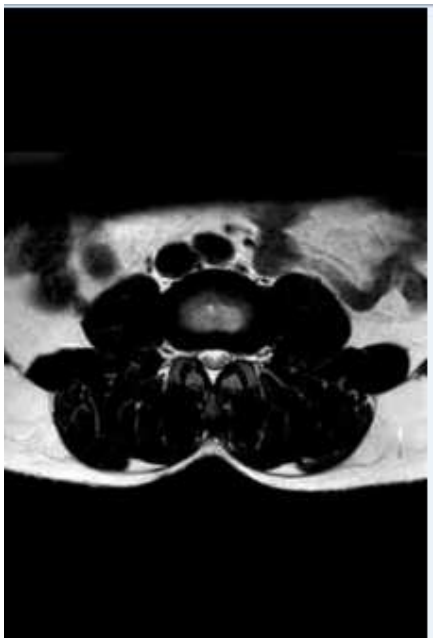




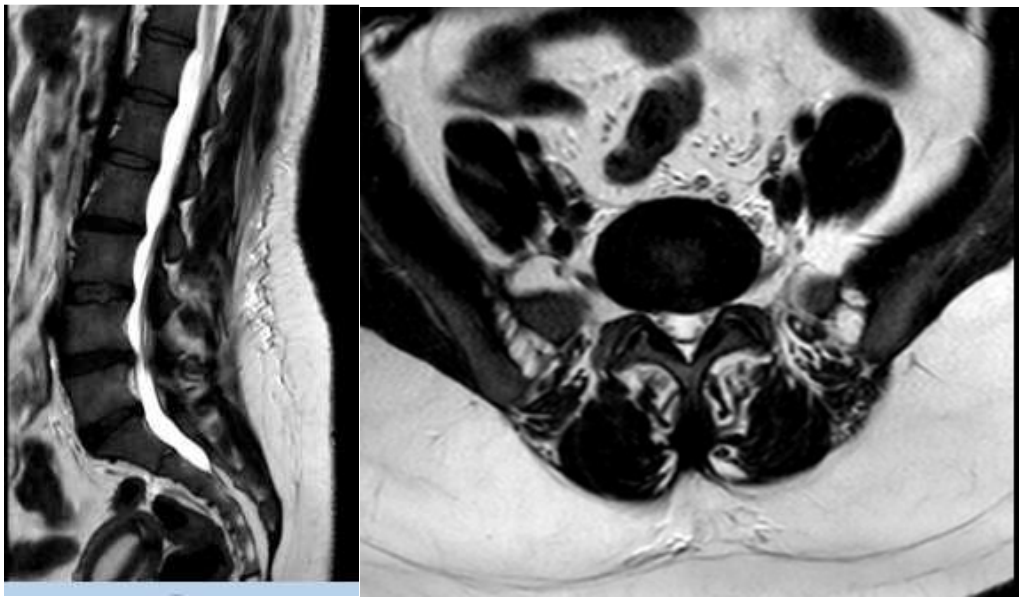
T1W SAG

Normal plain radiograph

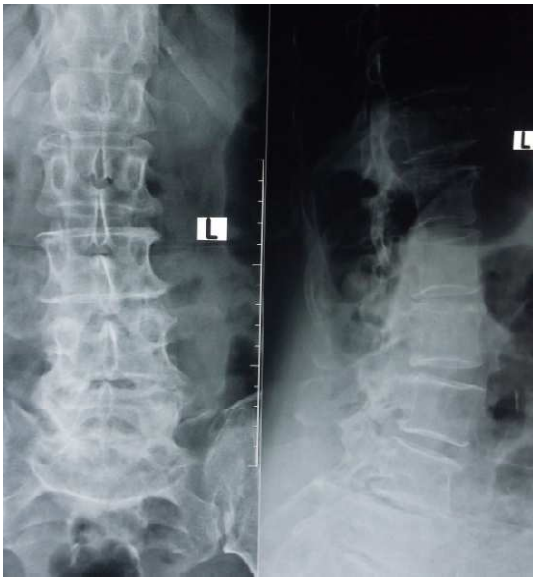


Normal T2W SAG /AXIAL 

2. 44yr old female Patient with chronic LBP and radicular pain. Plain radiographs show anterior osteophytes and reduced L4/L5 andL5/S1 intervertebral disc spaces. MRI shows L2/L3, L4/L5 , L5/S1 disc desiccation, reduced disc heights and a diffuse disc bulge at L5/S1 level(loss of the normal kidney shape) with bilateral narrowed exit foramen.

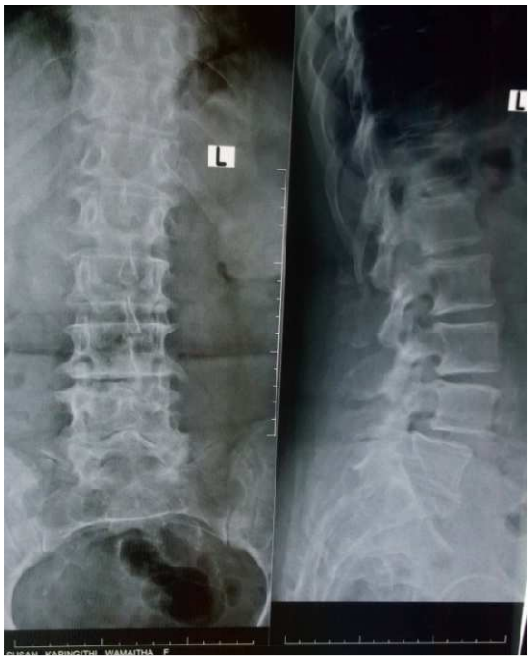


T2W SAG/AXIAL MRI

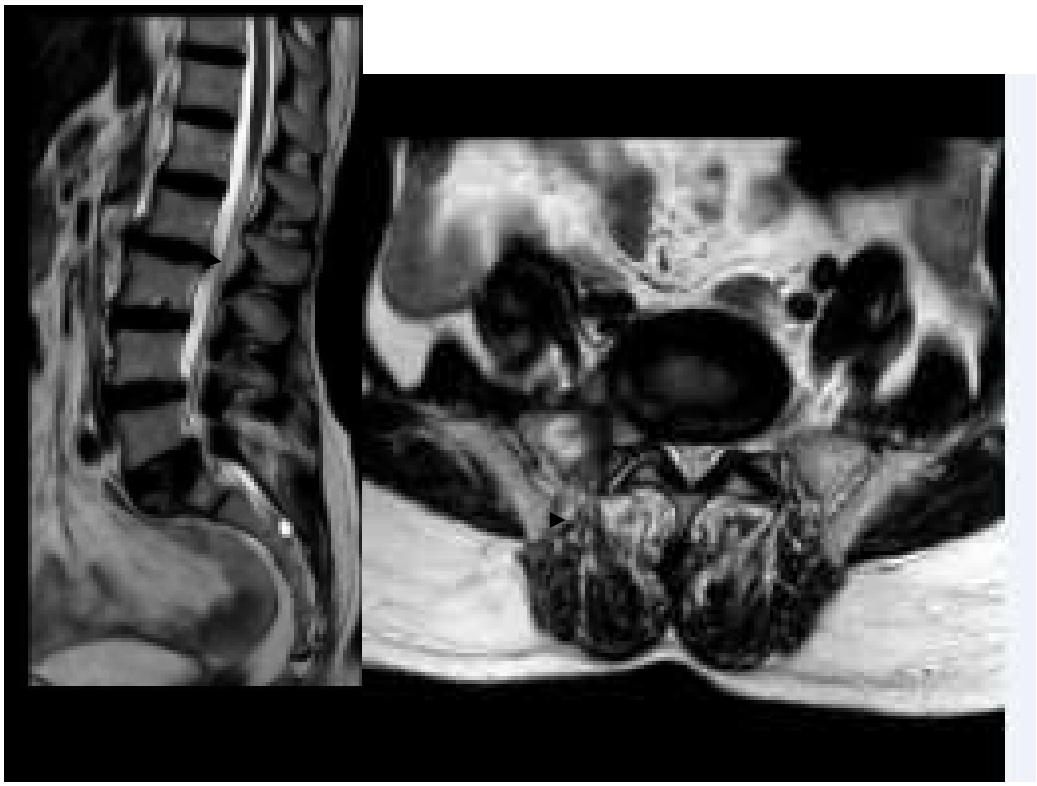


PLAIN AP/LATERAL RADIOGRAPHS

3. Patient with LBP and bilateral radicular pain and numbness. Plain radiographs showed large anterior, lateral and posterior osteophytes, and L5/S1 grade 1 spondylolisthesis. MRI showed multilevel disc dessication, with L5/S1 broad bases protrusion and reduced intervertebral disc height. A small left L5/S1facetjoint effusion is noted. The spondylolisthesis and the osteophytes are not obvious on the MRI.



PLAIN AP/LATERAL RADIOGRAPHS



T2W SAG/AXIAL MRI

5.0 DISCUSSION:

The main objective of this study was to correlate clinical presentation and the findings on imaging using MRI as the gold standard in order to develop image guidelines for use in evaluation of patients with chronic low back pain. No guidelines are available in our setup to direct clinicians on which patients would benefit from what imaging study in this group of patients.

5.1 DEMOGRAPHIC CHARACTERISTICS:

The mean age for presentation of Low Back Pain (LBP) was 47.3years (+/-14.5yrs). This is similar to several studies [6, 9, 34]. Damian Hoy, Christopher Ban et al in their study found the peak age was between 40-80years. Mulimba [9] in his study on LBP in Africa found that most of the complainers were in their third to fifth decade which our study group falls in the same category.

Similar findings are also seen in the study by N.K Irurhe et al [35] titled MRI findings in adult Nigerians with LBP. The study showed the mean age of LBP was 54.5+/-12.5.

Probable explanation to the age group in this study is that likely most individuals in this group might be undergoing age related degenerative changes hence the occurrence of back pain.

This can be supported by the findings by Cassar- Pallucino V.N in his study titled MRI of the ageing herniating intervertebral disc which showed that by the age of fifty, 97% of individuals have a degenerated disc [36].

Low back pain was seen to be more common in females in this study. The females accounted for 70.6% as compared to the males who accounted for 29.4%. The study by Damian Hoy et al [6] and Mulimba [9] observed similar findings of female preponderance. Mulimba related the female preponderance to the kind of daily chores women do at home in comparison to men as being a risk factor to low back pain.

Contrary results were seen in study by N.K Irurhe et al [35] which showed LBP to be more common in males (65.5%) as opposed to females (34.5%).

The gender preponderance in this study confirms what was reported by Mulimba. Most of the women were house wives and likely the daily house chores contributed to their back pain.

A total of 72 patients (43.9%) were observed to be overweight while 24(14.6%) were obese. The differences in frequencies of observations of positive findings on both imaging modalities were found to be significant across the different BMI categories. Osteophytes and muscle spasm (hypolordosis) were some of the common findings observed in obese and overweight patients. (Tables 11 and 12). Similar findings have been seen in a study by Igbinedion B. et al[(2)] where the authors concluded that; obesity is known to result in increased stress in the weight bearing spine with resultant osteophyte formation [(2)]. Obesity and/or increase in weight are risk factors to development of low back pain.

There were significant differences in frequencies of occurrence of positive imaging findings across different occupations. Manual workers showed highest frequencies of muscle spasms, osteophytes and disc disease. This is similar to a study by Massimo et al which showed that heavy physical work load had severe detrimental effects to the back with worsening of degenerative changes if any[(41)].Heavy physical activity has been known to result in increase in osteophyte formation[(2)]. Manual workers tend to be exposed to strenuous jobs hence the observations in this study.

Most of the patients in this study were office workers (48%). Most of them were seen to have muscle spasm (hypolordosis). This is comparable to a local study by Juliette Orege et al [(34)] which observed majority of the patients in the study were employed and that most of them had a sedentary lifestyle.

The findings of high occurrences of muscle spasm (hypolordosis) in this study among office workers could be attributed to the poor postures/positions at work places and also likely prolonged sitting positions in office setups.

5.2 IMAGING FINDINGS:

5.2.1 Plain radiography Versus MRI.

The Kappa statistic was used to evaluate the agreement between MRI and the plain radiographs. There was moderate agreement between findings of disc disease on both modalities (k=0.1791, p=0.002). This shows that MRI picked more disc lesions as compared to plain radiographs which could only show reduced disc heights. The findings confirm that plain radiographs may be sensitive in detection of disc disease but are very non- specific with regards to the type of disease and the severity. A study by P.Y Yong et al[18] also observed no significant relationship between reduced disc heights on radiographs and disc disease (herniation) on MRI. This therefore means that when reduced intervertebral height was observed on a plain radiograph in a symptomatic patient, then MRI was recommended to evaluate the state of the spinal canal and the neural exit foramen.

Both MRI and plain radiography reported muscular spasm (hypolordosis) in 92.7% and 91.1% of the patients respectively with an almost perfect agreement (p=<0.0001). Reduction of lumbar lordosis which is thought to be caused by muscular spasm has been thought to be a major cause of LBP [2].

Presence of osteophytes had an almost perfect agreement in both modalities (Table 31). Despite this, plain radiographs still picked a higher number of osteophytes (108(60%) patients) compared to MRI (86(47%) patients). Refer to figure 4. This could be attributed to the limited ability of MRI to properly evaluate bony structures [26] as opposed to plain radiography.

No malignancy/tumour was reported in all the images evaluated.

5.2.3 Clinical features versus imaging:

The most observed findings on both plain radiographs and MRI were disc disease and osteophytes (Figure 4). The commonest specific disc abnormalities were disc desiccations and disc herniation which accounted for 71.1% and 72.2% respectively.

This is comparable to several studies [5, 18] that demonstrated disc desiccation being the commonest radiological abnormality on MRI. Disc herniation was also a common finding in our study. Seventy two per cent of the studied patients had disc herniation. This was similar to a number of studies [35, 36, and 37]. The studies confirmed that disc disease including disc herniation is commonly associated with LBP. It has been shown that MRI is recognized as

being accurate for detecting disc herniation with high accuracy and is able to differentiate the various subtypes [36].

Most of the findings affected multiple discs and the findings were seen to have a significant difference in occurrence amongst the different age groups. Most of the patients with disc disease were seen to be above fifty years old. This finding compares with a number of studies [18, 35] which showed disc disease having a significant association with increasing age.

In this study, the analysis of association performed using Fischer's exact test showed significant differences in frequencies of observed imaging findings in patients with additional symptoms (lower limb numbness/radicular pains) in comparison to patients who presented with back pain alone.

The patients with additional clinical symptoms showed significantly higher occurrences of narrowing of exit foramina, disc disease, osteophytosis and spinal canal stenosis as opposed to the patients with no additional symptoms (tables 23-30). Similar findings were observed in a study by Shobeiri et al [42] which showed that patients with low back pain and sciatica were more likely to have canal stenosis, disc herniation and narrowing of exit foramen compared to those patients presenting with back pain alone. This has been attributed to the fact that nerve root compression by a herniated disc was the major causative factor of sciatica.

Staiger [38] et al in their study found that sciatica was 95% sensitive in predicting disc herniation. In their conclusion therefore they said that in the absence of sciatica, a clinically meaningful disc herniation was very unlikely.

Both plain radiographs and MRI showed presence of osteophytes as being common in patients with additional clinical characteristics with a significant difference with the findings in patients without the symptoms. Large osteophytes have been associated with nerve impingement at the exit foramen and most studies on back pain have related osteophytes to disc disease and sciatica.Bulging degenerated intervertebral discs as well as large posterior and lateral osteophytes may impinge on the exit foramen or cause spinal canal stenosis resulting to radicular pain or neurological deficit [2, 35].

This confirms that clinical symptoms had a good correlation with imaging findings, especially on MRI.

Despite the above observations, a number of patients without additional symptoms were reported to have narrowed exit foramen (Tables 23 and 27). This can only be attributed to the fact that not all positive MRI findings have a clinical significance[29].

The extent of foraminal narrowing was equally important in the eventual development of sciatica. A mildly narrowed foramen may not cause symptoms of sciatica. Patients with positive findings on MRI which had no clinical significance should be managed conservatively.

6.0 CONCLUSIONS:

1. Lumbar osteophytosis and degenerative disc desiccation are the commonest imaging findings in patients with Chronic Low Back Pain and are best evaluated by both radiography and MRI.
2. Increasing Age, high BMI, and Manual work are important risk factors to chronic low back pain.
3. There is significant correlation between clinical features and clinically significant imaging findings in patients with chronic low back pain.
4. No malignancy or life threatening condition was picked on all the images reviewed. This infers that most patients with chronic LBP will have a benign etiology. Most of the patients with high risk conditions almost always have a risk factor and signs and were therefore excluded in this study population.

7.0 RECOMMENDATIONS AND IMAGING GUIDELINES.

This study has shown that significant imaging findings were found in patients who were above 40 years of age, were overweight, had a history of manual labour and had additional complains of lower limb radiculopathy or numbness. The findings were statistically significant and are supported in several studies [2, 9, 35, 36, and 41].

It is therefore recommended that:

- Low back pain of <6weeks duration does not require imaging unless the following **red flags** are present;
    - Progressive neurological deficits or disabling symptoms, caudaequina syndrome.
    - Sudden back pain with associated tenderness.
    - Unexplained weight loss.
    - Trauma, cumulative trauma.
    - Unexplained fever.
    - History of malignancy
    - Age>50years, especially with osteoporosis or compression fracture.
    - Drug abusers/ immunosuppression or suspected osteomyelitis.

- Non-specific low back pain of >6weeks in the absence of worsening neurologic deficits or other red flags requires no imaging [19,20].
- Low back pain of >6weeks in the presence of progressive neurologic deficits requires advanced (MRI) imaging [20].

The proposed **imaging guidelines** adapted from the ACRappropriateness criteria® low back pain can be used to justify requests to imaging in patients with low back pain, thereby reducing the prevalence of inappropriate or unnecessary imaging which is imperative in resource-poor regions. It therefore means:

1. Clinicians should conduct a thorough history and physical examination on patients with low backpain so as to identify the patients who definitely require imaging.
2. Imaging should be performed on patients with LBP when worsening neurological deficits are present or in presence of red flags(listed above).
3. Patients with long standing low back pain with radiculopathy or signs of spinal stenosis should be evaluated with MRI soas to decide on surgical management or epidural spinal injection.
4. Clinicians should avoid routine imaging of patients with non- specific LBP.
5. Patient counseling including information on patient self- care, reassurance and physiotherapy should be part of the main management strategies in patients with chronic- nonspecific LBP.
6. Pharmacologic and non- pharmacologic (physiotherapy) therapies should be considered as the initialoptions in management of LBP.

REFERENCES:

1. J.W Gilbert, Greg. R et al. Lumbar MRI hypolordosis in symptomatic patients: association with paraspinal muscle spasm. J Chiropr. Med 2009 Sep 8(3) 95-100

2. Igbinedion B, Achigbe A. Correlations of radiographic findings in patients with low back pain. Niger. Med journal. 2011; 52(1):28-34.

3. Gaskill M.F, Lukin R, Wiot JG. Lumbar disk disease and stenosis. ClinRadiol North Am 1991; 29: 735-764.

4. Rubin D.I. Epidemiology and risk factors of spine pain. Neurol. Clin. 2007; 25 (2): 353-371.

5. 1990-2010 a systematic analysis for global burden of disease study 2010. Lancet: 2012: 380(9859): 2163-96.

6. Damian Hoy, Christopher Bain, Gail Williams et al. Systematic review of the global prevalence of Low Back Pain. Arthritis and rheumatism 2012; 64 (6):2028-2037.

7. Walker B.F. The prevalence of Low Back Pain. A systematic review of literature from 1966-1998. J. Spinal disord. 2000; 13:205-217.

8. Louw Q.A, Morris L.D., Grimmer-somers K. The prevalence of Low Back Pain in Africa ; a systematic review. BMC musculoskeletal disorders 2007; 8:105.

9. Mulimba J.O. Problems of Low Back Pain in Africa. East African Medical Journal 1990; 67 (4):250-253.

10. Epidemiology of Low Back Pain in children and adolescents. Arch. Dis Child 2005; 90: 312-316.

11. Balague F, Dutoit G, Waldburger M. Low Back Pain in school children: An epidemiological study. Scand J Rehabil Med. 1988;20:175-179.

12. Duggleby T, Kumar S. Epidemiology of juvenile Low Back Pain: a review. DisabilRehabil. 1997;19:505-512

13. Olsen TL, Anderson RL, Dearwater SR, Kriska AM, Cauley JA, Aaron DJ, LaPorte RE. The epidemiology of Low Back Pain in an adolescent population. Am J Public Health. 1992;82:606-608

14. Salminen JJ, Pentti J, Terho P. Low Back Pain and disability in 14year old schoolchildren. ActaPaediatr. 1992;81:1035-1039

15. Scientific approach to the assessment and management of activity related spinal disorders. A monograph for clinicians. Report of the Quebec task force of spinal disorders. Spine 1987;12(1):S1-S59

16. Hart LG, Deyo RA, Cherkin DC. Physician office visits for Low Back Pain ; Frequency, Clinical evaluation and treatment patterns from a US national survey. Spine 1995;20:11-19

17. Anderson GBJ. Epidemiologic factors of Chronic Low Back Pain. Lancet 1999;354;581-585

18. P.Y Yong, NAA Alias, I.L Shuaib. Correlations of clinical presentation, radiography, and Magnetic Resonance Imaging for Low Back Pain. J. HK CollRadiol 2003; 6:144-151.

19. Lateef H. Patel D. What is the role of imaging in acute Low Back Pain? Curr Rev Musculoskeletal Med 2009; 2 (2); 69-73.

20. ACR appropriateness criteria® Low Back Pain national guidelines 2011. www.guideline.gov/content.aspx?id=35145.

21. Chou R, Carrino J.A., Deyo R.A., Imaging strategies for Low Back Pain, Systematic review and meta-analysis. Lancet 2009. 373(9662) 463-472.

22. Petz D.M, Hadeland R.G. Radiological investigations of Low Back Pain. CMA J 1989; 140:289-295.

23. Selim A.J, Finke G, Ren X.S et al. Patient characteristics and patterns of use of lumbar spine radiographs: Results from the Veterans Health Study. Spine (Phila Pa 1976) 2000; 25(19):2440-2444.

24. McNally E.G, Wilson D.J, Ostlere S.J. Limited Magnetic Resonance Imaging of Low Back Pain instead of Plain radiography. ClinRadiol. 2001; 56(11): 922-925.

25. Jarvik J.G, Hollingworth W, Martin B.S., Rapid Magnetic Resonance Imaging Vs. radiographs for patients with Low Back Pain: A Randomized Controlled Trial. JAMA.2003;289(21):2810-2818

26. Kuzma B.B, Goodman J.M. Paradoxic appearance of calcification on Magnetic Resonance Imaging. Surg. Neurol. 1996; 46 (5):513-514.

27. Fazel. R, Krumholz H.M, Wang Y. et al. Exposure of low dose ionizing radiation from medical imaging procedures. N. Engl. J. Med 2009; 361:849-857.

28. Ally Pilly et al. Role of Magnetic Resonance Imaging in management of patients with Low Back Pain. University of Nairobi, 2003(NOT PUBLISHED)

29. Jensen M.C, Brant Zawadzki M.N. Magnetic Resonance Imaging of the lumbar spine in people without Low Back Pain. N. Engl. J Med 1994; 331:69-73.

30. Van Tulder M.W, Assendelf W.J, Koes B.W, Bounte L.M. Spinal radiographic findings and non-specific Low Back Pain. A systematic review of observational studies. Spine 1997; 22:427-434.

31. Verruli. D, Welch H.G. Impact of disc testing on therapeutic interventions. JAMA 1996; 275:1189-1191.

32. Deyo. R.A, Mirza. S.K, Turner J.A et al. Over treating Chronic Low Back Pain? Time to back off. J. Am Board Fam. Med 2009; 22: 62-68.

33. Chou. R, Qaseem A, Owen D.K. Diagnostic imaging for Low Back Pain. Advice for high value health care from American College of Physicians. Ann Intern Med 2011; 154(3) 181-189

34. Julliette A. Orege, Joseph Abuya. Association of lumbar disc degeneration with sociodemographics of Low Back Pain patients in Eldoret. International Journal Of Advanced Research 2013; 1(4):115-123.

35. N.K Irurhe, O.O. Adekola. MRI Scan findings in adult Nigerians with Low Back pain. World Journal of Medical Sciences 7(4):204-209. 2012.

36. Cassar-pallucino V.N. Magnetic Resonance Imaging of the ageing and herniating intervertebral disc. Eur J. Radiol 1998;27:214-228.

37. Rehman L, S Khaleeq, A Hussein, G.E Mushtaq and K Zaman. Correlation between clinical features of MRI findings in patients with Lumbar disc herniation. Journal of Post graduate Medical institution 2007;21(1):65-70

38. Staiger T.O, Paauw D.S, Deyo R.A, Jarvikjg. Imaging studies for acute Low Back Pain, when and when not to order them. Postgrad Med. 1999;105:161-172.

39. Lamer T.J. Lumbar spine pain originating from vertebral osteophytes. Reganaesth. Pain Med. 1999;24(4):347-351.

40. Jandic S, Antic B. Low back pain and degenerative disease. Med Pregl. 2006; 59(9-10):456-461.

41. Massimo mariconda, OlimpioGallasso, Luigi I, Giovanni Lotti and Carlo Milano. Relationship between alterations of the lumbar spine visualized with Magnetic Resonance Imaging and occupational variables. Eur Spine J 2007; 16(2):255-266

42. Shobeiri E, Khalatbari M. R, Taheri M.S. Magnetic Resonance Imaging in patients with Low Back Pain and those with sciatica. Singapore Med J. 2009;50(1):87-93.

APPENDICES

APPENDIX A: PARTICIPANT CONSENT FORM

Name of Principal Investigator: DR. LAURA. N. WATITI

Name of the Institution: KENYATTA NATIONAL AND REFERRAL HOSPITAL/ PLAZA IMAGING SOLUTIONS

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

My name is Dr. Watiti Laura a postgraduate student in the department of Diagnostic Imaging and Radiation Medicine at the University of Nairobi. I am carrying out a study on the imaging findings on Plain radiographs and MRI Scans in adult patients referred with chronic back pain and correlating with the clinical findings. This study will help to ascertain the role of imaging in the evaluation of these patients. I would like to recruit you in this study. Information obtained from you will be treated with confidentiality. Only your hospital number will be used.

I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain them. If you have any questions in the course of our interview later, feel free to either ask me or the radiology technician who is attending to you. Any information you provide during the study will be kept strictly confidential.

Your participation in this study is fully voluntary and you are free to withdraw from the study at any stage during the study. I am available at the contacts given below for any further clarification about the study.

Who to Contact

If you have any questions you may ask now or later during the study. If you wish to ask questions later, you may contact the department of Radiology 020-726300-9) or the KNH/UON Research Ethics Committee uonknh_erc@uonbi.ac.ke

This proposal has been reviewed and approved by the KNH/UON Ethics Review Committee, which is a committee whose task it is to make sure that research participants are protected from harm.

You can ask me any more questions or clarification about any part of the research study, if you wish to.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I…….....……...have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands all the details of this study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

APPENDIX B: KIBALI CHA KUSHIRIKI KATIKA UTAFITI

Jina langu ni Daktari Laura Watiti, mwanafunzi katika chuo cha udaktari, Chuo Kikuu cha Nairobi. Ninafanya utafiti unaohusu wagonjwa wenye maumivu ya muda mrefu kwenye mgongo na matokeo ya picha ambazo huagizwa ili kuweza kubaini sababu ya maumivu hayo haswa xray na Magnetic Resonance Imaging. Utafiti huu utasaidia kuweza kutambua umuhimu wa picha hizi katika kubainisha sababu ya maumivu ya mgongo.

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

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

Asante sana kwa ushirikiano wako.

Nimekubali kwamba nimeelezewa kikamilifu kuhusu utafiti huu na nakubali kushiriki.

Sahihi ya mgonjwa: _____

Tarehe: _____

APPENDIX C: QUESTIONNAIRE: DATA COLLECTION FORM

Form No: _____

Patient X-ray N^{o}: _____

Age: _____

Gender: M_____ F_____

Height: _____cm Weight: _____kg

Nature of Occupation:

Manual:_____

Office:_____

Domestic:_____

Presenting complaints: _____

Duration: _____

Clinical findings(tick where appropriate)

Clinical finding	**Yes**	**No**
Radicular lower limb pain	Lt….. Rt……	
Lower limb numbness	Lt…… Rt…….	
Sensory deficit	Level_____	
Paraplegia		
Neurogenic claudication		
Back Tenderness	Level_____	

Imaging findings. Tick where appropriate (Please indicate vertebral level .eg disc disease at L2)

Imaging findings	**Plain radiograph(date of examination :…./……/20…….)**	**MRI(date of examination:…/…./20……..)**
Normal		
Muscle spasms		
Osteophytes		
Disc disease		
End plate changes		
Facet joint arthropathy		
Spondylolysthesis		
Spondylolysis		
Schmorls node		
Vacuum phenomenon		
Spinal stenosis		
Narrowed exit foramina		
Paravertebral mass		
Vertebral body collapse		
Others		

KEY: Codes for findings with more than one characteristic

Disc disease: Reduced disc height- D01
Abnormal signal intensity-D02
High Intensity Zone-D03
Disc bulge-D04
Disc herniation-D05
Disc prolapse-D06
End plate changes: End plate sclerosis- E1
Modic changes (M1/M2/M3)

APPENDIX D: BUDGET

ITEM	QUANTITY	UNIT PRICE (Ksh)	TOTAL (Ksh)
WRITING PENS	1 BOX	200	200
NOTEBOOKS	5 PIECES	60	300
FILES	8 PIECES	50	400
PRINTING PAPER	5 RIMS	400	2000
CARTRIDGE	1 PC	6000	6000
INTERNET SURFING	200 HRS	60	12000
FLASH DISCS	2 PCS	2000	4000
PRINTING DRAFTS AND FINAL PROPOSAL	10 COPIES	500	5000
PHOTOCOPIES OF QUESTIONNAIRES	300 COPIES	10	3000
PHOTOCOPIES OF FINAL PROPOSAL	6 COPIES	100	600
BINDING COPIES OF PROPOSAL	6 COPIES	60	360
ETHICAL REVIEW FEE	1	2000	2000
SUBTOTAL			**35860**
PERSONNEL			
RESEARCH ASSISTANT	1	15000	15000
BIOSTATISTICIAN	1	15000	15000
SUBTOTAL			**30000**
DATA COLLECTION, DATA ANALYSIS AND THESIS DEVELOPMENT			
PRINTING OF THESIS DRAFTS	10 COPIES	1000	10000
PRINTING FINAL THESIS	6 COPIES	1000	6000
BINDING OF THESIS	6 COPIES	300	1800
DISSEMINATION COST			10000
SUBTOTAL			**27800**
CONTINGENCY (10% OF TOTAL BUDGET)			9266
GRAND TOTAL			**102926**

APPENDIX E: STUDY WORK PLAN

Activity	Action by	May 2014	Jun 2014	Jul 2014	Aug 2014	Sep 2014	Oct 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	Mar 2015	Apr 2015	May 2015
Writing Research Proposal	Student	■	■											
Revising and Finalizing Proposal	Student & Supervisor			■	■									
Ethical Approval	KNH-ERC					■	■	■	■	■	■			
Data collection and cleaning	Student R. Assistant								■	■	■	■		
Data Analysis and Interpretation n	Student Biostatisticia n												■	
Writing up	Student Supervisor													■
Dissertation submission	Student													■

APPENDIX F: KNH/UON-ERC LETTER OF APPROVAL

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

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

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

Ref: KNH-ERC/A/367 Link:www.uonbi.ac.ke/activities/KNHUoN 13th November 2014

Dr.Laura Naliaka Watitti
Dept.of Diagnostic Imaging and Radiation Medicine
School of Medicine
University of Nairobi

Dear Dr. Watiti

Research proposal – Magnetic Resonance Imaging and Radiographic findings in chronic low backpain. A clinicoradiological correlational study (P427/07/2014)

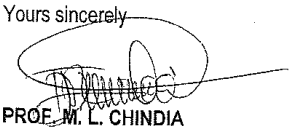
This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 13th November 2014 to 12th November 2015.

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.**

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH/UON-ERC
The Dean, School of Medicine, UoN
The Chairman, Dept.of Diagnostic Imaging and Rad. Medicine,UoN
Supervisors: Dr. A. Aywak, Dr. Gladys Mwango