

**THE CORRELATION OF THE SELF-REPORTED LEEDS ASSESSMENT
OF NEUROPATHIC SYMPTOMS AND SIGNS SCORE, CLINICAL
NEUROLOGICAL EXAMINATION FINDINGS AND MAGNETIC
RESONANCE IMAGING FINDINGS IN PATIENTS WITH LUMBO-
SACRAL RADICULOPATHY.**

NASSIB TAWA



A thesis submitted to fulfil the requirements for the degree of
Doctor Philosophiae in Physiotherapy,
Department of Physiotherapy,
University of the Western Cape
Cape Town, South Africa

Supervisors

Professor Anthea Rhoda

Dr Ina Diener

(University of the Western Cape)

November 2014

KEY WORDS

Lumbar spine

Nerve root compromise

Radiculopathy

Diagnostic accuracy

Sensitivity

Specificity

S-LANSS

Neurological examination

Magnetic resonance imaging

Correlation



ABSTRACT

THE CORRELATION OF THE SELF-REPORTED LEEDS ASSESSMENT OF NEUROPATHIC SYMPTOMS AND SIGNS SCORE, CLINICAL NEUROLOGICAL EXAMINATION FINDINGS AND MAGNETIC RESONANCE IMAGING FINDINGS IN PATIENTS WITH LUMBO-SACRAL RADICULOPATHY.

N. T. Ndune

PhD Thesis (Musculo-Skeletal Physiotherapy), Department of Physiotherapy, University of the Western Cape, Republic of South Africa.

Lumbo-sacral radiculopathy (LSR) is clinically defined as low back and referred leg symptoms accompanied by an objective sensory and/or motor deficit due to nerve root compromise. LSR is a common condition encountered by physiotherapists in clinical practice and the assessment and diagnosis remains a challenge owing to the complex anatomy of the lumbo-sacral spine segment and the various differentials. Moreover, LSR imposes a significant impact on patients' health, functional ability, socio-economic status and quality of life. There are several diagnostic tools and procedures which are commonly utilised in practice, including diagnostic neuropathic pain screening questionnaires, clinical neurological tests, electro-diagnostics and imaging. However, the diagnostic utility and correlation of these tests have not been fully explored and remains debatable among clinicians and researchers in the fields of musculo-skeletal health and neurology. The aim of this study was to determine a correlation of the S-LANSS score, clinical neurological examination (CNE) findings and magnetic resonance imaging (MRI) reports in the diagnosis of LSR among patients who presented with low back and referred leg symptoms.

The study was conducted in three phases. In phase one, two systematic literature reviews were conducted; firstly, to establish the evidence-based accuracy of CNE in diagnosing LSR, and secondly, to establish the evidence-based accuracy of MRI in diagnosing LSR. In both systematic literature reviews, the diagnostic tests accuracy (DTA) protocol was used in planning, design and execution of literature search, selection of relevant studies, quality assessment, data analysis and presentation of the results. In phase two, clinical validation of an adopted S-LANSS scale and lumbar MRI reporting protocol were established, and a standardised evidence based lumbar CNE protocol developed.

The face and content validity of the original S-LANSS score was established among a sample of Kenyan physiotherapists and patients who presented with low back and referred leg symptoms, using both quantitative and qualitative research designs. This was followed by a test-re-test reliability study on the adapted version of the S-LANSS score. The face and content validity of the adopted lumbar MRI reporting protocol was established among a sample of Kenyan radiologists followed by an inter-rater reliability. An evidence-based lumbar CNE protocol was developed, standardised and inter-examiner reliability was also examined among a sample of Kenyan physiotherapists. Finally, in phase three, a cross-sectional blinded validity study was conducted in six different physiotherapy departments. Participants (patients, physiotherapists and radiologists) were recruited using strict in- and exclusion criteria and data was collected using a pain and demographic questionnaire, the S-LANSS scale, the CNE protocol, the Oswestry Disability Index (ODI) and the MRI lumbar spine reporting protocol. Data was captured, cleaned and analysed using SPSS version 21. Descriptive analysis was done using frequencies, means and percentages, while inferential analysis was conducted using Spearman's rank correlation coefficient test r to establish the correlation between the diagnostic tests.

Cross tabulations, receiver operating curves (ROC) and scatter plots were used to establish the sensitivity and/or specificity of S-LANSS scale and individual CNE tests as defined by MRI.

In phase three, which formed the main study of the research project, a total of 102 participants were recruited in this study with a gender distribution of 57% females and 43% males. The majority (67%) had neuropathic pain according to the S-LANSS scale and their pain intensity ranged from moderate (4-6) to severe (7-9) as recorded on a Numeric Pain rating Scale (NPRS), and was more common among manual workers. Similarly, patients whose pain had a neuropathic component had moderate to severe disability. The S-LANSS scale and lower limb neuro-dynamic tests were the most sensitive tests 0.79 and 0.75 respectively, while deep tendon reflexes were the most specific tests (0.87). The S-LANSS and CNE correlated fairly but significantly with MRI ($r=0.36$, $P=0.01$).

LSR is a common condition and its assessment and diagnosis remains a clinical challenge among physiotherapists. MRI is a high-cost diagnostic tool but is being used by many clinicians in making decisions regarding the management of patients. Rapid and low-cost neuropathic pain screening by the use of the S-LANSS scale, together with use of evidence-based CNE of neuro-conduction and neuro-dynamic tests may be used in confirming nerve-root related MRI findings.

These may be used in making a decision on whether to manage a patient conservatively using pharmacological agents and manual physiotherapy and therapeutic exercise, or consider surgery in the initial management of patients with clinical suspicion of LSR. This is especially valuable in the resource-poor settings like Kenya and other sub-Saharan African countries where MRI is costly or unavailable.

November, 2014.

**PRESENTATIONS BY THE AURTHOR AT CONFERENCES, ON THE
OUTCOME OF THE RESEARCH STUDY.**

1. Accuracy of clinical neurological examination in diagnosing lumbar radiculopathy: A systematic review. Poster presentation at WCPT-Africa, Nairobi Kenya. June, 2012
2. Diagnostic correlation of S-LANSS score, clinical neurological examination and MRI in patients with lumbar radiculopathy (presented as work in progress). Kenya Society of Physiotherapists (KSP) Congress, Thika, Central Kenya. November, 2012
3. Lumbo-sacral radiculopathy: Evidence-based diagnostic options. Kenya Society of Physiotherapists (KSP) Congress, Machakos University College, Machakos County. Kenya. December, 2013.
4. The correlation of the Self-reported Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) score, Clinical Neurological Examination Findings and Magnetic Resonance Imaging findings in patients with lumbo-sacral radiculopathy. Submitted for platform presentation at WCPT conference, Singapore, May 2015.

DECLARATION

I declare that research study and report on *THE CORRELATION OF THE SELF-REPORTED LEEDS ASSESSMENT OF NEUROPATHIC SYMPTOMS AND SIGNS SCORE, CLINICAL NEUROLOGICAL EXAMINATION FINDINGS AND MAGNETIC RESONANCE IMAGING FINDINGS IN PATIENTS WITH LUMBO-SACRAL RADICULOPATHY* is my own work, that it has not been submitted before for any degree or examination in any other University, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Full name: Nassib Tawa Ndune.

Date: November 2014.

Signature.....



ACKNOWLEDGEMENTS

1. God the almighty for making me realise my dreams in academia against all odds.
2. Dr. Diener for her motivation and belief in me, and for the lead role she played.
3. Prof Rhoda for her immense inputs and guidance throughout the process.
4. Prof Frantz for the finances she made available, I highly appreciate it.
5. My wife Grace for her unwavering support and encouragement.
6. My parents, family and friends for their prayers and moral support.
7. JKUAT for their financial commitment towards completion of this work.
8. All my clinical research assistants, and the patients who participated, I highly appreciate your contributions.



TABLE OF CONTENTS

Title page.....	i
Key words.....	ii
Abstract.....	iii
Papers presented by the author at conferences, on the outcomes of the study.....	iv
Declaration.....	v
Acknowledgements.....	vi
List of appendices.....	ix
List of tables.....	x
List of figures.....	xi
List of abbreviations.....	xii
CHAPTER ONE: BACKGROUND.....	1
1 Introduction.....	1
1.1 Prevalence of Lumbo-Sacral Radiculopathy.....	2
1.2 Aetiology and pathogenesis of Lumbo-Sacral Radiculopathy.....	2
1.3 Clinical signs and symptoms.....	4
1.4 Diagnosing Lumbo-Sacral Radiculopathy.....	5
1.4.1 Neuropathic pain screening tools.....	6
1.4.2 Clinical neurological examination (CNE).....	8
1.4.3 Magnetic resonance imaging (MRI).....	11
1.5 Problem statement.....	13
1.6 Research question.....	14
1.7 Aim of the study.....	14
1.8 Specific objectives of the study.....	14
1.9 Summary.....	15
1.10 Outline of thesis.....	16
1.11 Summary of chapters.....	17
1.12 Definition of key terms.....	19

CHAPTER TWO: METHODOLOGY.....	22
2 Introduction.....	22
2.1 Theoretical framework.....	22
2.2 Research setting.....	23
2.3.1 Phase 1: Systematic literature reviews.....	25
2.3.2 Definition and purpose of SLR.....	25
2.3.3 Properties and components of a SLR.....	25
2.3.4 Sources of information.....	26
2.3.5 Procedure of conducting SLR.....	26
2.4 Phase 2: Development, validation and reliability testing of clinical diagnostic tools.....	29
2.4.1 Development of evidence-based clinical diagnostic tools.....	29
2.4.1.1 Protocol development process.....	30
2.4.1.2 Features of an evidence-based clinical protocol.....	31
2.4.2 Validation of evidence-based clinical diagnostic tools.....	32
2.4.2.1 Face and content validity.....	32
2.4.2.2 Reliability testing of clinical diagnostic tools (test-re-test)....	33
2.5 Phase 3: Correlation of clinical diagnostic tools.....	33
2.6 Ethical considerations.....	35

CHAPTER THREE: ACCURACY OF CLINICAL NEUROLOGICAL EXAMINATION IN DIAGNOSING LUMBO-SACRAL RADICULOPATHY: SYSTEMATIC REVIEW.....37

3. Introduction.....	37
3.1 Clinical diagnosis of Lumbo-Sacral Radiculopathy.....	37
3.2 Review question.....	39
3.3 Aim of the systematic review.....	39
3.4 Methodology.....	39
3.4.1 Search strategy.....	40
3.4.2 Study selection and inclusion criteria.....	40
3.5 Data analysis.....	42
3.6 Results.....	43
3.7.1 Quality assessment.....	48
3.7.2 Data extraction.....	49
3.8 QUADAS scores of reviewed studies.....	52
3.9 Inter-observer agreement.....	53
3.10 Diagnostic accuracy of index tests.....	54
3.10.1 Summary of diagnostic accuracy of individual tests.....	54
3.11 Discussion.....	59
3.12 Conclusion.....	61

CHAPTER FOUR: ACCURACY OF MRI IN DETECTING LUMBO-SACRAL NERVE ROOT COMPROMISE: SYSTEMATIC REVIEW..... 62

4. Introduction.....62

4.1 Utilisation of MRI in diagnosing radiculopathy.....62

4.2 Aim of the systematic review.....64

4.3 Review question.....64

4.4 Methodology.....65

4.4.1 Search strategy.....65

4.4.2 Study selection.....65

4.4.3 Inclusion criteria.....66

4.5 Data analysis66

4.6 Results.....68

4.7 Quality assessment.....71

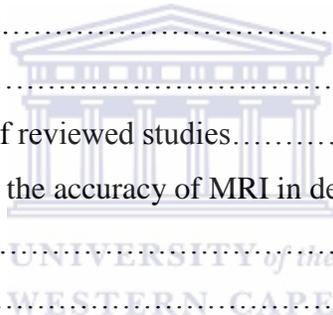
4.8 Data extraction.....71

4.9 QUADAS scores of reviewed studies.....73

4.10 Discussion on the accuracy of MRI in detecting lumbar nerve root
compromise.....73

4.11 Discussion.....74

4.12 Conclusion.....75

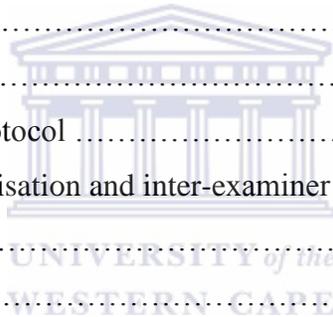


**CHAPTER FIVE: VALIDATION AND RELIABILITY OF THE S-LANSS
PAIN SCALE AMONG A KENYAN POPULATION.....76**

5. Introduction.....	76
5.1 Neuropathic pain screening.....	76
5.2 Methodology.....	78
5.2.1 Location and setting.....	78
5.2.2 Validation of the original S-LANSS scale.....	78
5.2.3 Inclusion and exclusion criteria.....	79
5.2.4 Study design.....	79
5.2.5 Data collection tools and materials.....	79
5.2.6 Data collection procedure.....	80
5.2.7 Data analysis.....	81
5.3 Results.....	81
5.3.1 Demographic and professional qualities of participating physiotherapists.....	81
5.3.2 Adaptations on the S-LANSS scale.....	82
5.3.3 Demographic and clinical characteristics of the patient sample.....	83
5.4 Reliability testing of the adapted S-LANSS scale.....	84
5.4.1 Location and setting.....	84
5.4.2 Population and sampling.....	85
5.4.3 Inclusion and exclusion criteria.....	85
5.4.4 Data collection tools and materials.....	85
5.4.5 Data collection procedure.....	85
5.4.6 Data analysis.....	86
5.4.7 Results (Test-re-test stability).....	87
5.5 Discussion.....	88
5.6 Conclusion.....	89

**CHAPTER SIX: DEVELOPMENT, STANDARDISATION AND
RELIABILITY TESTING OF AN EVIDENCE-BASED LUMBAR SPINE CNE
PROTOCOL90**

6. Introduction.....	90
6.1 Clinical diagnosis of Lumbo-Sacral Radiculopathy.....	90
6.2 Methodology.....	94
6.2.1 Lumbar CNE protocol development.....	94
6.2.2 Clinical standardisation of the lumbar CNE protocol	96
6.2.3 Sampling of physiotherapists.....	97
6.2.4 Standardisation procedure of the lumbar CNE Protocol	99
6.2.5 Sampling of patients.....	100
6.2.6 Inter-examiner reliability of pre-trained physiotherapists.....	100
6.3 Data analysis.....	100
6.4 Results.....	101
6.4.1 Lumbar CNE protocol	101
6.4.2 Clinical standardisation and inter-examiner reliability.....	105
6.5 Discussion.....	106
6.6 Conclusion.....	106



CHAPTER SEVEN: VALIDATION AND RELIABILITY TESTING OF AN ADOPTED LUMBAR MRI REPORTING PROTOCOL107

7. Introduction	107
7.1 Utility of MRI in diagnosing Lumbo-Sacral Radiculopathy.....	107
7.2 Research question.....	108
7.3 Study aims.....	108
7.4 Methodology.....	109
7.4.1 Setting.....	109
7.4.2 Sampling.....	109
7.4.3 Clinical validation and adaptation.....	109
7.4.3.1 Data collection materials.....	109
7.4.3.2 Procedure.....	110
7.4.3.3 Data analysis and results.....	111
7.4.4 Reliability testing.....	111
7.4.4.1 Data collection materials.....	111
7.4.4.2 Procedure.....	112
7.4.5 Data analysis.....	112
7.5 Results.....	113
7.6 Discussion.....	113
7.7 Conclusion.....	114



CHAPTER EIGHT: THE CORRELATION OF THE SELF-REPORTED LEEDS ASSESSMENT OF NEUROPATHIC SYMPTOMS AND SIGNS SCORE, CLINICAL NEUROLOGICAL EXAMINATION FINDINGS AND MAGNETIC RESONANCE IMAGING FINDINGS IN PATIENTS WITH LUMBO-SACRAL RADICULOPATHY.....116

8. Introduction.....116

8.1 Examining methods for identification of neuropathic pain.....116

8.2 Diagnostic value of examining methods for neuropathic pain.....120

8.3 Methodology.....122

8.3.1 Study design.....122

8.3.2 Sample size determination.....124

8.3.3 Participants’ recruitment procedure.....125

8.3.4 Inclusion and exclusion criteria.....125

8.3.5 Data collection tools and materials.....125

8.3.5.1 Pain and socio-demographic questionnaire.....126

8.3.5.2 The Oswestry Disability Index (ODI) questionnaire.....126

8.3.5.3 Adapted S-LANSS scale.....127

8.3.5.4 Lumbar spine CNE protocol.....127

8.3.5.5 Adapted lumbar MRI reporting protocol.....128

8.3.6 Data collection process.....128

8.3.7 Data processing and analysis.....131

8.4 Results.....133

8.4.1 Socio-demographic and clinical characteristics of participants.....133

8.4.1.1 Participants’ job category.....134

8.4.1.2 Intensity (NPRS) and type (S-LANSS) of pain.....135

8.4.1.3 Level of disability (ODI).....135

8.4.2 Diagnostic findings participants.....	136
8.4.2.1 S-LANSS Scores.....	136
8.4.2.2 Clinical neurological examination.....	136
8.4.2.3 MRI findings.....	137
8.5 Bivariate analysis.....	137
8.5.1 Pain intensity and age.....	137
8.5.2 Pain intensity and level of disability.....	138
8.5.3 Correlation of intensity and type of pain.....	138
8.5.4 Association between CNE and MRI findings on nerve root compromise.....	138
8.6 Logistic regression and odds ratio.....	139
8.7 Diagnostic accuracy of S-LANSS and CNE compared to MRI.....	139
8.8 Summary of the study findings.....	141
8.9 Discussion.....	142
8.9.1 Correlation of S-LANSS scores, evidence-based CNE findings and lumbar MRI reports.....	142
8.9.2 Diagnostic accuracy and utility of the individual diagnostic tools and procedures.....	143
8.9.2.1 Diagnostic accuracy correlations compared to MRI findings.....	144
8.9.2.2 The Lumbar CNE.....	144
8.9.2.3 Combining neuro-conduction with neuro-dynamic testing.....	145
8.9.3 Clinical features (symptomatology) of patients with LSR.....	146
8.9.4 Prevalence and socio-demographic characteristics of patients with LSR...	146

CHAPTER NINE: SUMMARY, CONCLUSION AND RECOMMENDATIONS.....	148
9. Introduction.....	148
9.1 Summary.....	148
9.2 Conclusion.....	150
9.3 Implications of the study findings in clinical practice.....	150
9.4 Limitations of the study.....	151
9.5 Recommendations.....	152
9.5.1 Further research.....	152
9.5.2 Clinical practice.....	152
9.5.3 Policy.....	152
BIBLIOGRAPHY.....	153



APPENDICES

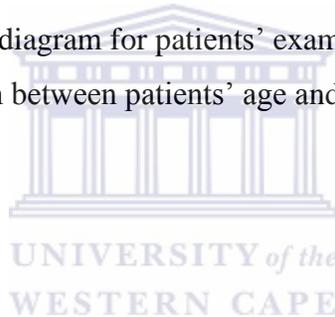
Appendix I:	PICO guideline
Appendix II:	QUADAS criteria
Appendix III:	Self-developed data extraction form
Appendix IV:	Consent form
Appendix V:	Information sheet (Physiotherapists)
Appendix VI:	Information sheet (Patients)
Appendix VII:	Original S-LANSS scale
Appendix VIII:	Self-developed short questionnaire (S-LANSS scale validation)
Appendix IX:	Adapted S-LANSS score
Appendix X:	Evidence-based Lumbar CNE Protocol
Appendix XI:	Consent form (Radiologists)
Appendix XII:	Information sheet (Radiologists)
Appendix XIII:	Lumbar MRI reporting protocol (Original)
Appendix XIV:	Self-developed short questionnaire (MRI protocol validation)
Appendix XV:	Adapted lumbar MRI reporting protocol
Appendix XVI:	Oswestry Disability Index (ODI)
Appendix XVII:	Demographic and pain questionnaire
Appendix XVIII:	Lumbar CNE protocol peer review questionnaire
Appendix XIX:	Lumbar CNE review data
Appendix XX:	MRI review data

LIST OF TABLES

- Table 1.1:** Neuropathic pain screening tools.
- Table 3.1a:** PICO analysis on retrieved studies: Assessment of neural conduction.
- Table 3.1b:** PICO analysis on retrieved studies: Assessment of neural mechano-sensitivity.
- Table 3.2:** Characteristics of included studies.
- Table 3.3:** QUADAS scores of included studies.
- Table 3.4:** Definition of test accuracy terms.
- Table 3.5:** Diagnostic accuracy of sensory tests.
- Table 3.6:** Diagnostic accuracy of motor tests.
- Table 3.7:** Diagnostic accuracy of tendon reflex tests.
- Table 3.8:** Diagnostic accuracy of lower limb neuro-dynamic tests.
- Table 4.1:** PICO analysis of retrieved studies.
- Table 4.2:** Characteristics of included studies.
- Table 4.3:** Methodological quality assessment of reviewed studies using QUADAS criteria.
- Table 5.1:** Characteristics of participating physiotherapists (n=64).
- Table 5.2:** Socio-demographics and clinical characteristics of patients (n=60).
- Table 6.1:** Sampling frame-work for physiotherapists.
- Table 6.2:** Lumbar CNE protocol standardisation.
- Table 6.3:** Socio-demographic and professional characteristics of participating physiotherapists (n=18).
- Table 8.1:** Application of the STARD framework guidelines
- Table 8.2:** Data codes
- Table 8.3:** Participants' socio-demographics and clinical characteristics (n = 102)
- Table 8.4:** Diagnostic predictive values and odds ratios.
- Table 8.5:** Diagnostic performance of S-LANSS and CNE compared to MRI

LIST OF FIGURES

- Figure 1.1:** Schematic illustration of the study procedure.
- Figure 2.1:** SLR procedure.
- Figure 2.2:** Procedure for developing clinical protocols.
- Figure 3.1:** Search history (CNE Review).
- Figure 4.1:** Search history (MRI Review).
- Figure 5.1:** Applicability of the S-LANSS scale in Kenya.
- Figure 5.2:** Appropriateness of the S-LANSS scale in Kenya.
- Figure 5.3:** Test-re-test procedure.
- Figure 6.1:** CNE protocol development process.
- Figure 6.2:** Recruitment of participating physiotherapists.
- Figure 6.3:** Evidence-based dermatomes.
- Figure 8.1:** Flow chart diagram for patients' examination.
- Figure 8.2:** Association between patients' age and pain intensity.



LIST OF ABBREVIATIONS

CNE:	Clinical Neurological Examination
CT Scan:	Computed Tomography Scan
DRG:	Dorsal Root Ganglia
DTA:	Diagnostic Test Accuracy
EMG:	Electro-myography
FNST:	Femoral Nerve Stretch Test
HNP:	Herniated Nucleus Pulposus
IASP:	International Association for the Study of Pain
IVDH:	Inter-vertebral Disc Hernia
LLNDT:	Lower Limb Neuro-dynamic Test
LSR:	Lumbo-Sacral Radiculopathy
MRI:	Magnetic Resonance Imaging
ODI:	Oswestry Disability Index
QAUDAS:	Quality Assessment of Diagnostic Accuracy Studies
RICs:	Resisted Isometric Contractions
S-LANSS:	Self-report Leeds Assessment of Neuropathic Symptoms and Signs
SLRT:	Straight Leg Raise Test

CHAPTER ONE

BACKGROUND

1. Introduction

Lumbar spinal pain is one of the most common musculo-skeletal reasons for seeking medical care and referrals for advanced imaging investigations globally (Van Tulder et al 2003; Brooks 2006; Iversen et al 2013).

Lumbo-Sacral Radiculopathy (LSR) is clinically defined as the objective loss of sensory and motor function with or without accompanied spinal and radicular pain (IASP 2014). According to the United Nations and World Health Organisation categorisation (Woolf and Pfleger 2003), Lumbo-Sacral Radiculopathy (LSR), osteoarthritis, rheumatoid arthritis and osteoporosis, are ranked second in the global burden of disease. The pain, disability and impact on patients' quality of life due to functional limitations and participation restrictions, is considerably high (Brooks 2006; Schafer et al 2007; Capra et al 2011). Options available for diagnosing LSR include neuropathic pain screening questionnaires, clinical neurological tests and imaging (Al Nezari et al 2013; Kreiner et al 2014). However, the diagnostic utility and correlation of these tests have not been fully explored in the available scientific literature. In this chapter, the health and socio-economic impact of LSR is presented and motivation for the need for early and accurate diagnosis of LSR is discussed.

1.1 Prevalence of Lumbo-Sacral Radiculopathy

Despite the efforts by clinicians and researchers to classify and define pain patterns, there is still controversy on case definition of LSR (Govind 2004; Bogduk 2009).

The exact prevalence of LSR is therefore not provided in published literature, however, the prevalence of a neuropathic component in adults with low back pain has been estimated at 50% among black South Africans (Ouedraogo et al 2011) and 55% in the Arabian Gulf region (El Sissi et al 2010).

The estimates of the prevalence of low back pain with neuropathic characteristics in the general population in the developed countries was reported as 8 % in the United Kingdom (Torrance et al 2006), 7% in France (Bouhassira et al 2008), 9% in the United States (Yawn et al 2009) and 18% in Canada (Toth et al 2009).

To date, there are no published reports on the prevalence of LSR in African countries, including Kenya. Moreover, neuropathic pain disorders including LSR are, in most primary health care settings of Africa, misdiagnosed and inappropriately treated, hence compounding the already existing burden of this debilitating condition (Meyer-Rosberg et al 2001; Chetty et al 2012).

1.2 Aetiology and pathogenesis of Lumbo-sacral Radiculopathy

LSR is one of the aetiology-based sub-types of painful peripheral neuropathies which occur as a direct consequence of disease or injury to the somatosensory system (Chetty et al 2012; IASP 2014). The clinical features include dermatomal anaesthesias, paraesthesias or dysaesthesias; myotomal fasciculation, weakness, spasms, atrophy; and loss or altered deep tendon reflexes (Schaffer, Hall and Brifa 2007). LSR differs from nociceptive pain in respect of cause, underlying mechanism and symptomatology, as well as the assessment and therapeutic approaches required for accurate diagnosis and successful management (Chetty et al 2012).

The various causes and mechanisms underlying LSR are broadly classified into two categories namely: anatomical/bio-mechanical and bio-chemical factors.

Lumbar intervertebral disc (IVD) herniation has been reported to be the most common bio-mechanical cause underlying lumbo-sacral nerve root irritation and subsequent radiculopathy (Nee and Butler 2006; Schafer et al 2007). However, a report by Hoogendoorn et al (2000) indicates that other bio-mechanical factors, including spinal canal stenosis, lumbar vertebrae osteophytes, lumbar facet joint hypertrophy or ligamentum flavum hypertrophy, may also compromise the lumbo-sacral nerve roots and cause radiculopathy.

In the event of a lumbar IVD herniation causing nerve root irritation the involved lumbar/sacral spinal nerve roots are subjected to sustained compression and they eventually become stretched and hyper-sensitised to mechanical stimulation without involvement of any bio-chemical mediators (Nee and Butler 2006; Schafer et al 2007). Upon structural compression of the lumbar/sacral nerve roots, according to Hoogendoorn et al (2000) and Govind (2004), the following sequence of events occur and eventually leads to radiculopathy, focal demyelination, intra-neural oedema, impaired intra-radicular blood flow, increased endo-neural fluid pressure and nerve fibre deformation.

According to Scharfer et al (2007), the sensory and motor dysfunctions together with radicular symptoms which are common among patients with LSR are as a result of neuronal ischemia and breakdown of axonal myelin sheaths caused by the combination of increased endo-neural fluid pressure and decreased blood flow.

The bio-chemical cause of LSR includes inflammatory reactions of the neural or surrounding musculo-articular structures like facets joint capsules (Tachihara et al 2007). As demonstrated by Pelletier, Martel-Pelletier and Abramson (2001) and Ozaktay et al (2006) in experimental studies on rat models, the reaction caused by pro-inflammatory bio-chemical mediators like tumour necrosis factor (TNF- α) and Interleukin (IL- β) from the herniated nucleus pulposus or inflamed facet joint capsule plays a vital role in the development of radicular pain by causing an increase in conductance in the nerve root and associated dorsal root ganglia (DRG), which in turn contributes to increased ectopic discharges and nerve trunk mechano-sensitivity. These research findings therefore suggest that LSR is not always mechanically mediated, and that mechanical nerve root compression (as visible on MRI films) on its own does not necessarily determine radicular symptoms.

1.3 Clinical signs and symptoms

The clinical manifestations of LSR are often described in terms of positive and negative symptoms (Zhuo 2007). Positive symptoms reflect an abnormal level of excitability in the nervous system and include pain, paraesthesia, dysaesthesia, and spasm.

Negative symptoms, on the other hand, indicate reduced impulse conduction in the neural tissues or denervation and include hypoaesthesia or anaesthesia, muscle weakness and diminished or loss of deep tendon reflexes. The classical features of the pain associated with patients with LSR include spontaneous and/or paroxysmal pain, commonly described by patients as burning, shooting, electric shocks or a strong prickling sensation.

Paraesthesia is an abnormal sensation which may be spontaneous or evoked but not unpleasant while dysesthesia is one which is unpleasant (IASP 2014). Muscle spasm, which is a common clinical presentation among patients with LSR, refers to a state of increased resting muscle tone as a result of hypersensitivity of the peripheral neural system to stimulation. While on the other hand, muscle weakness and impaired tendon reflexes are as a result of a nerve conduction block.

Hypo- and anaesthesia refer to a decrease or absence of sensitivity to stimulation on a dermatome (specific area of skin supplied by a spinal nerve root). Movements or positions of the lumbar spinal segment and/or lower limbs that expose sensitised lumbar-sacral neural tissues to compressive, friction or tensile stimuli can be symptomatic for patients experiencing a musculoskeletal presentation of LSR (Wright 1999; Walsh and Hall 2005).

1.4 Diagnosing LSR

Due to the complexity of the patho-physiology and patho-mechanics of lumbar nerve root compression and radiculopathy, there is currently no particular reference standard that can specifically diagnose LSR under its current definition by the IASP (IASP 2011; Al Nezari et al 2013; Kreiner et al 2014), therefore several diagnostic tools and strategies including, neuropathic pain screening questionnaires, clinical neurological examination (CNE) and radiological imaging tests are widely utilised in the assessment and diagnosis of LSR.

In the assessment and diagnosis of LSR, clinicians currently utilise various tools and procedures including patients' medical history and physical examination, diagnostic pain screening questionnaires, electro-diagnostics and radiological imaging (Bennett et al 2007; Bertilson et al 2010; Coster et al 2010).

1.4.1 Neuropathic pain screening tools

There are several diagnostic neuropathic pain screening questionnaires which have been developed in the recent past. These tools include the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) (Bennett 2001), Neuropathic Pain Questionnaire (NPQ) (Krause and Backonja 2003), *Douleur Neuropathique en 4 Questions* (DN4) (Bouhassira et al 2005), and neuropathic pain screening questionnaire named ID-Pain (Portenoy 2006).

Table 1.1 presents a summary of the psychometrical qualities of these tools. The NPQ (Krause and Backonja 2003) is a diagnostic and measurement tool, however, unlike the seven item S-LANSS, the NPQ assesses the intensity of 12 neuropathic pain symptoms and requires complex calculations to score. The DN4, developed by Bouhassira et al (2005) in France, has ten questions classified into two sections of patient interview and physical examination, a total of 4 or more yes responses is diagnostic of neuropathic pain. The neuropathic pain screening questionnaire commonly known as ID-Pain which was developed by Portenoy (2006) has a total score of 35 and its structure is not user friendly for a rapid bedside screening.

The LANNS scale Bennette (2001) is the most commonly used diagnostic pain screening questionnaire found in the literature, probably due to its easy to use, user friendly, simple scoring and good psychometric properties. This tool has also been translated into various native languages and validated in different settings of the world (Yucel et al 2004; Kaki et al 2005; Koc and Erdemoglu 2010; Elzahaf et al 2013).

The LANNS comprises of five questions on pain symptoms namely dysesthesia, autonomic, evoked, paroxysmal and thermal, and two items on sensory examination of allodynia and hyperalgesia.

The inclusion of a physical examination of the two sensory items of allodynia and hyperalgesia by a clinician when using the LANSS was later seen as a limitation for its use as a neuropathic pain screening tool, especially in large community-based research or busy primary care clinical settings (Backonja et al 2002).

This necessitated revisions on the original LANSS scale which led to the development of a patient-administered short version S-LANSS scale by Bennett et al (2005). The S-LANSS is a valid and reliable seven item tool with a maximum score of 24.

The cut-off for a positive score is 12 which imply pain of predominantly neuropathic origin (POPNO). The S-LANSS scale has a reported superior sensitivity and specificity of 89% and 94% respectively (Bennett et al 2005). This scale has been validated in various settings including Turkey (Yucel et al 2005), Saudi (Kaki et al 2005) and Brazil (Schestatsky et al 2011) and has been reported to be the simplest and easiest to administer in clinical practice, by these authors. The S-LANSS scale is therefore a modification of the original version, with similar psychometric properties and has also been translated into Turkish (Koc and Erdemoglu 2010), Portuguese (Schestatsky et al 2011), Spanish (Perez et al 2006) and Arabic (Elzahaf et al 2013). Therefore, the short version makes it easy and possible for self-completion in clinical setting and for research and has acceptable reported capability to identify pain of predominantly neuropathic origin (POPNO) (Bennett 2005; Yucel et al 2005; Koc and Erdemoglu 2010). The S-LANSS pain scale, based on analysis of data obtained during bedside examination aimed at distinguishing neuropathic (radiculopathy) pain from somatic pain when used on low back pain patients, is a scale with a simple graphical outlook and easy scoring process.

Also, S-LANSS has been widely translated in to various local official languages including Spanish, Portuguese, Arabic and Turkish; and has been clinically validated in different settings of the world with a consistent report of good sensitivity and specificity in diagnosing neuropathic pain compared to other available diagnostic pain screening tools (Perez et al 2006; Schestatsky et al 2011; Elzahaf et al 2013). The reliability and validity of the S-LANSS scale will be further discussed in Chapter Five of this thesis.

Table 1.1: Neuropathic pain screening tools

Tool	Purpose	No. of items	Total score	Positive cut-off	Sensitivity	Specificity
S-LANSS	Diagnostic	7	24	12	85%	80%
NPQ	Diagnostic & Assessment	12	-1.3	≥ 0	66%	74%
DN4	Diagnostic	4	10	4	83%	90%
ID-Pain	Diagnostic	6	5	3	97%	72%
Pain Detect	Diagnostic	15	38	19	85	80

Source: (Bennet et al 2007)

1.4.2 Clinical neurological examination (CNE)

Clinical neurological examination (CNE) is also used for early diagnosis of LSR. It constitutes testing of dermatomal sensation, myotomal motor strength, myotomal deep tendon reflexes as neuro-conduction tests (Butler 2000), and neuro-dynamic tests for mechanical sensitivity of the lower limb peripheral neural structures (Elvy and Hall 1999; Shacklock 2005; Nee and Butler 2006).

Sensation testing is one test used in detecting a change in conduction in a nerve. Sensation testing is considered capable of detecting the level of nerve root involvement through testing the soft touch and superficial pain sensation of specific cutaneous innervation fields of lumbo-sacral spinal nerve roots (Vroomen et al 2002; Bertilson et al 2010; Suri et al 2011). The procedure and sequence of sensory testing by most authors (Bertilson et al 2010; Coster et al 2011; Suri et al 2011) is described as testing light touch sensation with a soft brush or cotton wool, and superficial pain sensation with a light prick by a sterile pin.

Although there have been concerns regarding the variations in published dermatome maps which are used to guide examiners in locating the dermatomal areas (Lee, McPhee and Stringer 2008), there is some consensus amongst researchers regarding the dermatomes for the lumbar and sacral spinal nerve roots.

The anatomical areas used in studies for testing sensation in different dermatomes are mid-anterior thigh for L2 nerve root, medial knee for L3, medial boarder of the foot for L4, dorsum foot for L5 and lateral boarder of the foot for S1 (Bertilson et al 2010; Coster et al 2011; Suri et al 2011; Iversen et al 2013).

Various studies (Albeck 1996; Vroomen et al 2002; Robinson et al 2003) used different strategies to assess the integrity of motor function of the lumbar and sacral spinal nerve roots. The specific tests used include assessment of lower limb muscle atrophy, muscle power and muscle weakness/paresis of specific muscles or muscle groups. The number of target muscles or muscle groups together with the grading system is variable depending on the protocol being followed, for example, the American Spinal Injury Association physical examination protocol recommends motor testing to be done on seven muscles or muscle groups and which are then graded in a five point scale (Iversen et al 2013), while others recommend the Oxford manual muscle testing grading system which uses six points (Coster et al 2010; Suri et al 2011).

The muscles which are commonly assessed include psoas major, rectus femoris, tibialis anterior, tibialis posterior and soleus and extensor halucis longus for L2, L3, L4, L5 and S1 and S2 nerve roots respectively. Other protocols propose the use of functional tests and results are graded as normal or diminished strength (Vroomen et al 2002; Robinson et al 2003). Such methodological disconnect creates a potential basis for poor diagnostic performance of motor tests which makes it difficult to compare results of different studies. Deep tendon reflex tests form the third component of the neuro-conduction assessment of lumbo-sacral spinal nerve roots. Deep tendon reflex tests are conducted to establish hypo-reactivity or complete absence of nerve conductivity in patients who are suspected of having LSR. In the diagnosis of LSR using deep tendon reflex tests, literature (Maggie 2007; Coster et al 2010; Suri et al 2010; Al Nezari et al 2013) recommends that clinicians observe appropriate positioning of the subjects, correct execution of the tests and proper interpretation of the test results so as to improve the diagnostic credibility of the tests.

The patellar tendon reflex has been used in the clinical diagnosis of lumbar radiculopathy, and the Tendon Achilles reflex for sacral radiculopathy (Bertilson et al 2010; Suri et al 2011). Clinical neuro-dynamic tests, also known as clinical neural provocation tests are part of the examination procedures for lumbar and sacral spinal nerves and include the straight leg raise test (SLR) and the femoral nerve stretch test (Elvy and Hall 1999; Butler 2000; Shacklock 2005; Nee and Butler 2006). These specific movement tests assess the mechanical sensitivity of neural structures to longitudinal loading (Shacklock 2005).

In order to determine the accuracy of the CNE tests in diagnosing LSR, a systematic literature review was conducted by the researcher and is presented in Chapter Three of this thesis.

1.4.3 Magnetic resonance imaging (MRI)

Magnetic resonance imaging of lumbar spine is preferred in the medical field as a non-invasive method of diagnosing lumbar disc herniation and radiculopathy (Pfirrmann et al 2004; Bajpai et al 2013; Hasankhani and Omid-Kashani 2013; Kreiner et al 2013).

MRI might have become a diagnostic tool of choice to many musculo-skeletal clinicians due to the fact that it uses non-ionising radiation and has a superior ability of visualization of soft tissues.

MRI is a high technology modern imaging diagnostic tool in health care and therefore the equipment used together with image acquisition procedures are fairly standard across the world. The commonly used MRI machine is the 1.5 Tesla scanner, the Philips Intera (Bertilson et al 2010; Coster et al 2010; Suri et al 2011).

In the field of spinal musculo-skeletal health care, it is well documented that there is an emerging trend in over-utilisation and over-dependency on MRI among clinicians because of varied reasons ranging from availability of the imaging technology especially in the developed countries to diagnostic uncertainties and individual preferences by clinicians.

Also, lumbar spinal patients have strong confidence and high expectations that MRI would always identify the primary source of their problem which should then lead to appropriate treatment and subsequent recovery (Hollingworth et al 2002; Weiner and Patel 2008; Carrino et al 2009; Lysdahl and Hofmann 2009). There are, however, several limitations to the detection of LSR with MRI investigation.

MRI has been reported to be incapable of diagnosing far out extra-foraminal spinal stenosis lesions (Al Nezari et al 2013) which could also cause radiculopathy. Even in surgery, when used as a gold standard, it is not clear whether the actual intra-operative findings reflect the true pathologic state of the nerve root or whether varying degrees of exposure of the operative field in different surgical fields affect the validity of observations made during the procedure (Suri et al 2011). Similarly, EMG which is considered the most useful test in diagnosing radiculopathy (Albeck et al 2000; Szabela and Zawirski 2002), is limited to identifying the root with neuro-pathophysiology and not the actual anatomic site.

In order to determine the accuracy of MRI in diagnosing LSR, a systematic literature review was conducted by the researcher and is presented in Chapter Four of this thesis.

Therefore, it is important to note that early and accurate diagnosis of LSR by musculoskeletal clinicians is crucial to ensure target-specific treatment in order to avoid chronicity, disability and work loss. However, for clinicians to embrace this in practice, there is need for the use of research-proven clinical tests and the adoption of an evidence-based diagnostic approach, which is in line with the current advocacy by health care financiers and consumers (Al Nezari et al 2013; Kreiner et al 2014). It is important therefore that early accurate diagnosis at a primary care level is desirable to ensure that appropriate measures regarding therapy or referrals for further investigations or surgery are undertaken (Trainor and Pinnington 2011). However, there is currently no documented evidence as to which of the above diagnostic tests are most accurate in the diagnosis of LSR. In addition, the correlation between the S-LANSS score, CNE tests and MRI findings in diagnosing LSR has not been investigated.

Therefore, it is imperative that the diagnostic correlation between the S-LANSS scale and MRI and evidence-based CNE tests and MRI is established so as to enable clinicians to make decisions regarding the management of a patient in the event that MRI investigation is medically contra-indicated, unaffordable or even unavailable.

1.5 Problem statement

LSR has been established as a positive indicator of chronic pain syndromes, disability and severity of low back pain (Woolf and Pfleger 2003; Brooks 2006). There is therefore a need for early accurate diagnosis that would underpin appropriate cost-effective treatment of this condition. Currently there is a clinical challenge with regard to diagnosis of LSR. Clinicians are often faced with a delicate balance between not missing a treatable pathology and avoiding unnecessary investigation which may increase patients' fears about their condition (Jarvik and Deyo 2002).

This has led to excessive utilization and high dependency on the use of MRI as a diagnostic tool of choice among clinicians in the assessment and diagnosis of LSR (Lysdahl and Hofmann 2009). This is even the case although there are discrepancies and variability of experts' opinions regarding the sensitivity and reliability of MRI findings in detecting nerve root involvement and radiculopathy (Bertilson et al 2010; Capra et al 2011; Van Boxem et al 2011; Wassenaar et al 2012; Kreiner et al 2014).

There is currently no acceptable reference standard for detecting lumbo-sacral nerve root compromise in patients with low back pain (Pfirrmann et al 2004; Wassenaar et al 2012; Hasankhani and Omidi-Kashani 2012; Lee and Lee 2012). However, MRI is often used in making the decision as to whether to manage a patient conservatively, using physiotherapy or pharmacological agents or surgery. This is despite the fact that MRI reports have shown low levels of sensitivity, poor to moderate inter-tester reliability due to variations in image acquisition methods and reporting protocols and weak agreement with standardised clinical tests (Kim et al 2009; Carrino et al 2009; Bertilson et al 2010). Added to these shortcomings, the high cost and unavailability of MRI especially in resource poor countries, makes MRI a less ideal tool to identify patients with LSR.

Some evidence is emerging about the use of CNE and screening tools in diagnosing LSR. In embracing the principles of evidence-based clinical practice and as a cost-effectiveness public health concern, it has therefore become feasible to evaluate how MRI reports correlate with S-LANSS scores and clinical neurological examination (CNE) findings, in detecting LSR among patients presenting with low back and referred leg symptoms.

1.6 Research question

Is there a correlation between S-LANSS scores, CNE findings and MRI findings in diagnosing LSR among patients with low back and referred leg symptoms?

1.7 Aim of the study

To determine a correlation between S-LANSS scores, CNE findings and MRI reports in the diagnosis of LSR among patients with low back and referred leg symptoms, referred for physiotherapy in selected Kenyan hospitals.

1.8 Specific objectives of the study

- 1.8.1 To establish the current evidence-based reliability and validity of clinical neurological examination findings in diagnosing LSR through a systematic literature review.
- 1.8.2 To establish the current evidence-based reliability and validity of magnetic resonance imaging findings in diagnosing LSR through a systematic literature review.
- 1.8.3 To establish face and content validity of the original S-LANSS questionnaire among a Kenyan population.
- 1.8.4 To establish the test-re-test reliability of an adapted S-LANSS questionnaire among a Kenyan sample of patients with low back and referred leg symptoms.

- 1.8.5 To develop and standardise an evidence-based clinical neurological examination protocol for patients with low back and referred leg symptoms.
- 1.8.6 To determine the validity and reliability of a lumbo-sacral MRI interpretation protocol by Kenyan radiologists.
- 1.8.7 To correlate the S-LANSS scores, standardised CNE findings and MRI reports in patients presenting with lumbo-sacral pain and referred leg symptoms.

1.9 Summary

LSR is emerging as a public health concern due to its adverse impact on patients' health, functional, socio-economic status, level of activity and participation and quality of life. It also remains highly imperative that clinicians at all levels of health care delivery do early identification of patients with LSR in order to avoid miss-classification and miss-diagnosis, so as to minimize the likelihood of chronicity and disability.

Rapid diagnosis using neuropathic pain screening tools and evidence-based clinical neurological tests could therefore be used to identify patients with LSR, especially in resource-scarce primary health care settings like Kenya. Similarly, in tertiary and specialised health care settings, identification of patients with LSR based on imaging results should always be done with the patient's clinical picture in mind and in correlation with findings on physical examination and neuropathic pain screening.

This may serve to minimise the likely risk of patients misdiagnosed/misclassified by false coincidental imaging results. Ultimately, this would facilitate a mechanism-based approach in treatment and improved health and functional outcomes.

This study therefore aimed at establishing the diagnostic correlation of the S-LANSS pain score, structured CNE tests and MRI findings among a Kenya population of patients who presented with low back and referred leg symptoms consistent with LSR.

1.10 Outline of thesis

The overall structure and phases of this research project and report is described and discussed in Chapter Two. This study was conducted in three phases.

In phase one, two structured systematic literature reviews were conducted. The first one aimed at establishing the current evidence regarding the accuracy of CNE tests, and the second at establishing the current evidence for MRI in diagnosing LSR. The results of the CNE review were used as part of the evidence in the development of the CNE protocol in Chapter five. Both reviews are presented as Chapter Four and Five of this thesis.

Phase two consisted of three different studies. Firstly, the original S-LANSS pain scale was validated among a Kenyan population of patients and physiotherapists.

Secondly, a protocol was developed and standardised for CNE of lumbo-sacral nerve root function, using the best evidence tests identified through the first systematic literature review, as well as clinical expert opinions of lecturers in musculoskeletal medicine worldwide. Thirdly, an adopted MRI lumbar reporting protocol was standardised, and tested for validity and reliability among a population of Kenyan radiologists. These three studies are presented separately as Chapters Five, Six and Seven respectively, and they were intended to pre-test and standardise the three diagnostic tools prior to the main study of Chapter Eight.

In phase three, the main study, the correlation of S-LANSS scores, CNE findings and MRI reports in diagnosing LSR among patients with low back and referred leg symptoms, was established. This is described in Chapter Eight.

The thesis ends with Chapter Nine, which includes a summary, conclusion and recommendations based on the key findings of the study.

Figure 1.1 below illustrates a schematic presentation of the research project.

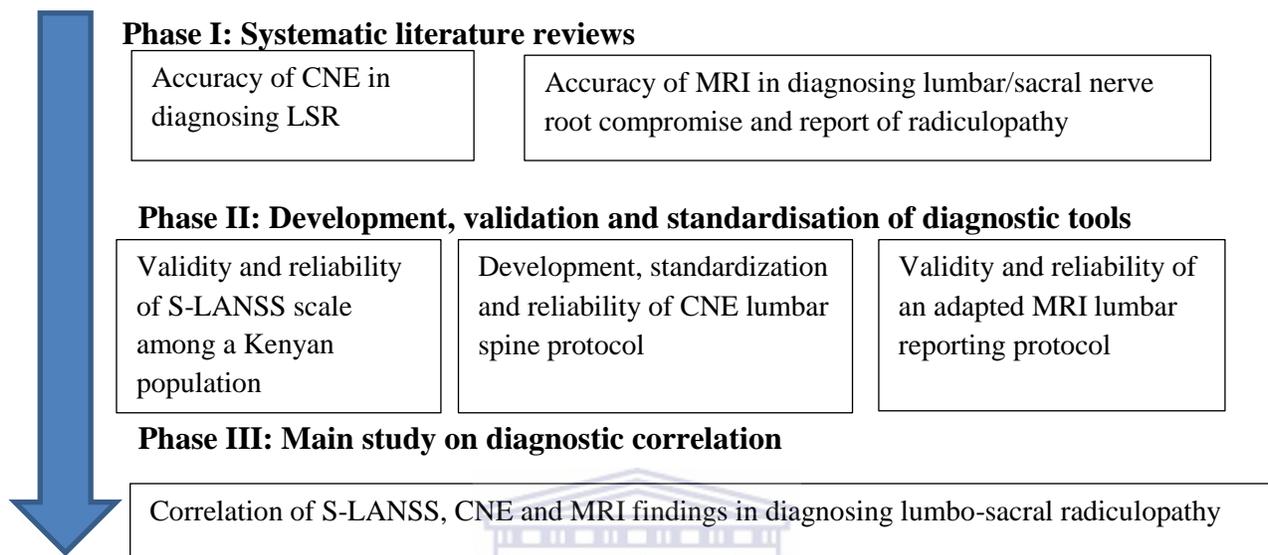


Figure 1.1 Schematic illustration of the research project

1.11 Summary of chapters

Chapter One of this thesis provides the background information on lumbo-sacral radiculopathy; including case definition, aetiology, patho-genesis and the key clinical features. The impact of LSR on patients' health, function and quality of life is discussed followed by the current diagnostic options which are commonly used by clinicians in practice. The chapter concludes by presenting the primary aim of the current research study, specific objectives and the significance of the study findings.

Chapter Two presents the methodology and designs which were chosen in undertaking each specific objective of the entire research project. The chapter begins by providing the overall conceptual framework within which the research project was based on, together

with description of and justification for each design which was chosen in the different phases of the study.

Chapters Three and Four presents the systematic literature reviews on the accuracy of CNE and MRI respectively, in diagnosing LSR. In both chapters, the review aim and research question are presented, followed by the key search terms and electronic data bases which were used. The search strategy, search results, study selection criteria and quality assessment are described. The chapters end by conclusions drawn from key findings of the reviewed studies.

Chapter Five describes the processes which were followed in establishing face and content validity of the original S-LANSS score in the Kenyan clinical setting. The graphical and linguistic adaptations which were made on the S-LANSS score after the validation procedures are presented, followed by the procedure and results of a reliability study on the adapted version of the S-LANSS score.

Chapter Six of this thesis presents the procedures which were followed in developing an evidence-based lumbar spine CNE protocol. This is followed by the process of clinical standardisation of the developed protocol and inter-examiner reliability test which was conducted among a sample of Kenyan physiotherapists. The chapter concludes by reporting the key outcomes of the CNE protocol development and reliability testing and the clinical implications.

Chapter Seven describes the procedures followed in establishing face and content validity of an adopted lumbar MRI reporting protocol in the Kenyan clinical setting. This is followed by a description of the inter-rater reliability test which was done among a sample of Kenyan radiologists. The results and conclusion of both the validity and reliability studies are also presented.

Chapter Eight of this thesis forms the final study of the research project on the correlation of S-LANSS score, CNE findings and MRI findings in patients with LSR. The conceptual framework of the main study is presented, followed by the study design, sampling techniques, data collection tools and procedures. Both primary and secondary findings of the correlation study are described. The chapter concludes with a discussion drawn from the key findings.

Chapter Nine provides a summary of the entire research project. This chapter highlights the key findings from each stage of the study based on the specific objectives. The chapter also links the findings of the preliminary chapters to the main study on correlation. Finally, conclusions and recommendations are made based on the key findings and in line with the primary aim of the research project.

1.12 Definition of key terms



Binary test data: Diagnostic test results reported in a dichotomised format of positive or negative.

Comparator/Reference standard: A test routinely used to detect the target condition, which the diagnostic accuracy of the index test(s) is compared to.

Diagnostic Test Accuracy (DTA): Ability of a diagnostic or screening test to detect the presence of the target condition.

Diagnostic test sensitivity: The sensitivity of a test is defined as the probability that the index test result will be positive in a diseased subject. Sensitivity is sometimes referred to as Detection Rate (DR), True Positive Rate (TPR) or True Positive Fraction (TPF).

Diagnostic test specificity: The specificity of a test is defined as the probability that the index test result will be negative in a non-diseased subject. Specificity is occasionally referred to as the True Negative Rate (TNR) or True Negative Fraction (TNF).

Disease status: Refers to the true state of nature of an individual, normally dichotomised into diseased or non-diseased by the comparator test.

False negative test results: A negative index test result on a diseased subject.

False positive test results: A positive index test result on a non-diseased subject.

Index test(s): The diagnostic or screening test/procedure whose accuracy in detecting the target condition is being evaluated.

Lumbo-Sacral Radiculopathy: Low back and referred leg symptoms accompanied by an objective sensory and/or motor deficit due to nerve root compromise (Bogduk 2009; IASP 2011).

ODI: The Oswestry Disability Index is a self-report questionnaire used to capture the participants' pain-related disability. It contains questions regarding information on pain intensity and limitations in personal care, walking, standing, lifting, travelling, home-making and employment. (Fairbank et al 1980).

Positive predictive value of a test: Defined as the probability that a subject with a positive index test result is diseased. Positive predictive values are reported either as proportions or percentages.

QUADAS: Quality assessment of diagnostic accuracy studies is a critical appraisal checklist for the methodological quality of primary diagnostic studies (Whiting et al 2004).

S-LANSS: The Self-report Leeds Assessment of Neuropathic Symptom and Signs questionnaire is a neuropathic pain screening tool which contains 5 symptom items and 2 clinical examination items used to identify patients whose pain experience is dominated by a neuropathic mechanism (Bennett et al 2007).

STARD: The Standards for Reporting of Diagnostic test framework is used to assess the quality of design and reporting of diagnostic tests (Simel et al 2008).

Target condition: The condition, stage of condition or sub-type of a condition of interest.

The negative predictive value of a test: Defined as the probability that a subject with a negative index test result is non-diseased.



CHAPTER TWO

METHODOLOGY

2. Introduction

This chapter begins by describing the setting of the research project. In order to address the research question, this thesis is divided into three different phases as mentioned in the previous chapter. This chapter provides the theoretical basis for the methodologies used in the different phases of the study. Firstly, a discussion on systematic literature reviews is presented, secondly, the steps involved in the development and determination of psychometric properties and adaptation of clinical diagnostic protocols are explained, and thirdly, correlation of clinical diagnostic tools is described. The chapter ends with the ethical considerations adhered to during the implementation of the study.

2.1 Research setting

Phase two and phase three were hospital-based clinical studies which were conducted at six different hospitals in the Republic of Kenya which is a country in the East African region with an estimated multi-ethnic population of 44.4 million people. According to the Kenya bureau of statistics, the country has a multi-ethnic population of approximately 44.4 million people majorly composed of black Africans and a minority of Asians, Europeans and Arabs. The official languages of communication in Kenya are English and Kiswahili which are spoken across the country.

The healthcare system in Kenya is organised in tandem with the government administrative levels. This is similar to many other countries across the African region including the United Republic of Tanzania and South Africa. The Kenyan healthcare system is organised in four levels namely; national, regional, county and community.

The community healthcare facilities mainly offer promotive and preventative healthcare services while the county health care facilities offer primary healthcare services. The regional and national healthcare facilities form the secondary and tertiary or referral levels, which offer specialised referral healthcare services together with other hospitals in the private sector.

Participants (patients, physiotherapists and radiologists) in the clinical studies of phase two and phase three were drawn from both public and private health care facilities at secondary and tertiary health care levels. The study sites included six hospitals: Coast General Referral Hospital, Mater Hospital, Kenyatta National Hospital, Mbagathi District Hospital, Thika level V Hospital and Jomo Kenyatta University Hospital. The Coast General Referral Hospital in Mombasa is a public secondary health care facility offering healthcare services in most specializations, including musculo-skeletal health and orthopedics.

The Coast General Referral Hospital is a regional referral and teaching hospital for the coast region which offers specialised health care at government subsidised rates. The facility is in close proximity to radiological imaging centres in the port-city of Mombasa and most patients with low back-related disorders are referred to the hospital's physiotherapy department for treatment. Kenyatta National Hospital in Kenya's administrative and commercial capital city of Nairobi is a tertiary health care facility serving as national referral hospital and teaching hospital for Nairobi University and Kenyatta University's schools of health sciences respectively. Kenyatta National Hospital has specialised musculo-skeletal and radiological imaging services and most patients with low back-related disorders are referred to the hospital's physiotherapy departments by the resident specialists, mostly after MRI evaluations.

The Thika level V Hospital is a referral hospital for the Kiambu County while Mbagathi District Hospital is a referral hospital for the Nairobi County. Mater Hospital is a private hospital within Nairobi city.

These hospitals offer a wide range of highly specialised health care services including; neurology, neuro-surgery, rheumatology, orthopaedics, traumatology and diagnostic imaging.

2.2.1 Phase 1: Systematic literature reviews (SLRs)

2.2.2 Definition and purpose of SLR

A systematic literature review is a structured and comprehensive process of evaluating and comparing previous research work in a particular topic (Cochrane 2009). This process is always aimed at answering a topical clinical challenge/question. It also employs critical analysis of the methodologies and reports of previous work in order to identify knowledge gaps in the field or topic of interest. Through a structured and comprehensive SLR, researchers could identify the key areas of consensus and/or controversy among clinicians/researchers with regard to a particular clinical challenge/question. The use of evidence obtained through systematic literature review in clinical practice however has some limitations resulting from study inclusion criteria, analytical methods, heterogeneity and generalization of review results.

2.2.3 Properties and components of a SLR

According to the Australian National Health and Medical Research Council (NHMRC) (2000), a good SLR therefore should have the following basic properties:

Comprehensive: Meaning the coverage of literature should be extensive enough so as to minimise the likelihood of missing out on important pieces of previous work in the field.

Selective: The information to be included in the analysis should be selected through strict in- and ex-clusion criteria to ensure relevance of the literature with regard to the clinical question which is being answered through the SLR.

Synthesis: The SLR should generate new trends, understanding or perspectives out of the documented literature. The new information may be supportive of previous knowledge or sometimes it may be contrary to previous knowledge and understanding.

Critical: Reviewers should gauge the findings of previous research studies based on the methodological soundness of the research conducted.

Analytical and summative: The findings from a SLR should be an outcome of statistical analysis of the reviewed studies and in case of a narrative review, the outcome should be a descriptive commentaries from other people's work. The key findings are summarised in order to point out what has emerged as new knowledge or information which responds to the clinical question which necessitated the SLR.

2.2.4 Sources of information

The types of information for a SLR are broadly classified into primary literature and grey literature (NHMRC 2000). Primary literature include published peer-reviewed articles and conference proceedings, while the grey literature includes unpublished conference proceedings, theses, bibliographies, references and where necessary opinions of experts in the field. Based on the aim of the SLR which is being conducted, these various sources of information could be used in generating relevant literature to address the review question.

2.2.5 Procedure of conducting SLR

The process of conducting a SLR is rigorous and complex, involving several steps. Systematic review of the literature begins with identification of the scope and selection of a topic. The choice of a topic for review is informed by many factors including the prevalence rate of the condition, the health and socio-economic impact on patients and society or the morbidity and/or mortality.

Once the topic is identified, the reviewer then formulates a clinical question using a format which is based on the category of the topic regarding whether the review is looking for information of the accuracy of a diagnostic test, effectiveness of an intervention, prognosis of a condition or health economics. The next step involves identification of the key search terms from the clinical question and choosing of topic-relevant data bases. This is followed by development of a search strategy, which incorporates the various key search terms, based on the review question, related terms and synonyms.

The actual search process then follows and selection of relevant studies from the search results is done using defined inclusion criteria which is based on the aim of the review.

The studies which qualify for inclusion in a review are prior to analysis exposed to critical appraisal using standardised criteria. The process of critical appraisal involves assessment of the quality of the design and methodology of the included studies which is aimed at ensuring that only studies which were conducted using acceptable protocols are included for review. When conducting critical appraisal of the included studies, reviewers always focus on the following specific items; sample size, clinical similarities of the study participants, in- and ex-clusion criteria, participants' recruitment procedure and period, clinicians' professional qualifications and experience, tools and materials used, execution of diagnostic test or therapeutic intervention, and, interpretation of test results or treatment outcome.

Finally, data extraction from qualified studies is done, which is followed by analysis and writing up the review findings. Figure 2.1 below illustrates the major steps followed in planning, executing and writing up a SLR.

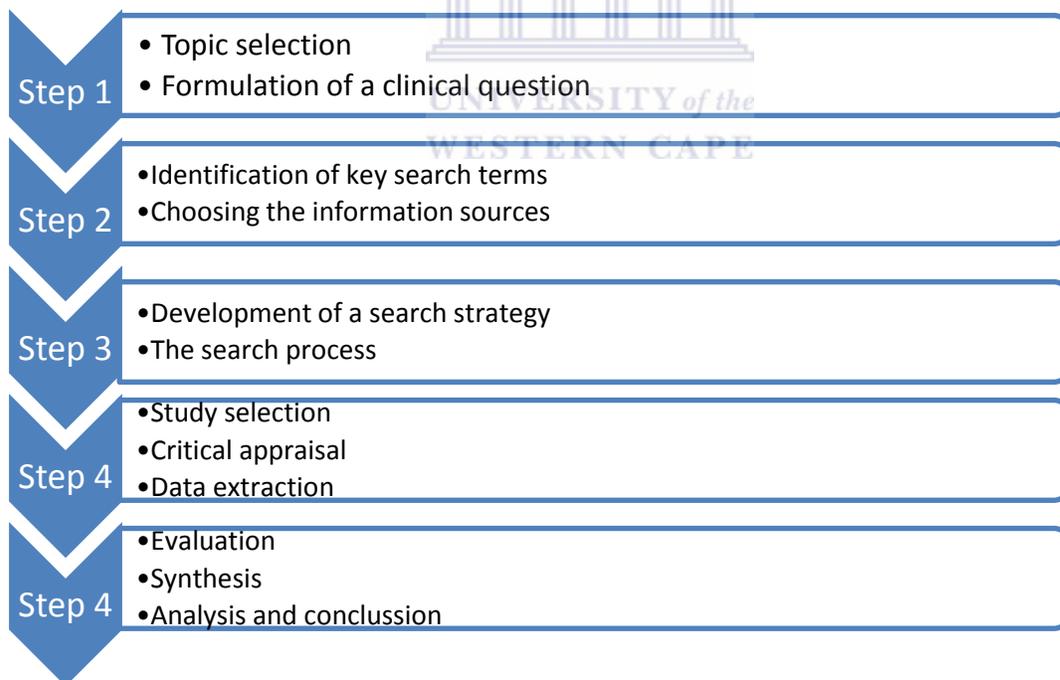


Figure 2.1: SLR procedure (Source Cochrane 2007)

Therefore, for the purposes of this research, two systematic literature reviews were conducted to establish the accuracy of: firstly, CNE, and secondly, MRI in diagnosing LSR. The first systematic review answered the research question: *In patients with low back and referred leg symptoms, is CNE accurate in detecting and diagnosing LSR?* While the second systematic review answered the research question: *In patients with low back and referred leg symptoms, is MRI accurate in detecting nerve root involvement and diagnosing LSR?*

The two reviews were conducted using the diagnostic tests accuracy (DTA) protocol of the Cochrane Collaboration (2007). The Cochrane DTA protocol was preferred in this study because it offers guidance on the structure and composition of a review.

The protocol also highlights the main characteristics of included studies which are supposed to be reported including the patients' clinical characteristics, duration of symptoms, patient recruitment period, clinical examiners' attributes and execution and interpretation of both index test and the reference standard.

The protocol also offers guidelines on the process and criteria of assessing the methodological quality of all included studies together with analytical techniques and data presentation styles on the sensitivity and specificity of each investigated test using 2×2 contingency tables, forest plots and receiver operating characteristics (ROC) plots. The reviewers adopted the Cochrane DTA format because it helps readers to find the results of reviews quickly, especially when needed for clinical application.

The methodology and results of the systematic literature reviews on the accuracy of CNE and that on the accuracy of MRI in diagnosing lumbo-sacral radiculopathy are described in detail in Chapters Three and Four of this thesis respectively.

2.3 Phase 2: Development, validation and reliability testing of clinical diagnostic tools

2.3.1 Development of evidence-based clinical diagnostic tools

Evidence-based clinical diagnostic tools offer a summary of theoretical knowledge on a given topic and synthesises innovations from theory to actual clinical practice. Evidence-based protocols are in most cases intended to minimise variations in the various areas of clinical practice including assessment, diagnosis and treatment (Connis et al 2000).

Through the use of standardised protocols, clinicians are therefore able to promote evidence-based clinical practice which ultimately improves the quality of patient care and treatment outcomes (Haamstede 2004). This satisfies the need for transparency and professional accountability in modern health care practice.

2.3.1.1 Protocol development process

According to Connis et al (2000), the procedure used in developing evidence-based clinical diagnostic protocols involves a number of key steps. The process begins by identification of relevant sources of literature. This is followed by formulation of a search strategy and execution of the search. Selection of topic-relevant studies and grading of evidence based on the type of study (Randomised controlled trial, case-control or systematic literature review) and methodological quality (adequate sample size, blinding of examinations or use of appropriate reference standard) of the selected studies is then performed.

Data extraction is then performed and the information which is generated is compiled so as to produce the first draft of an evidence-based clinical diagnostic tool. The National Institute of Clinical Excellence (NICE) guidelines (2001) recommends that the draft protocol is disseminated for peer review, after which amendments are done based on the feedback from the peer reviewers.

A second draft is then developed and disseminated for endorsement by stakeholders in the field including professional societies. Following this process, a protocol is then declared suitable for adoption and use in clinical practice. Figure 2.2 below illustrates the process of developing a clinical diagnostic protocol.

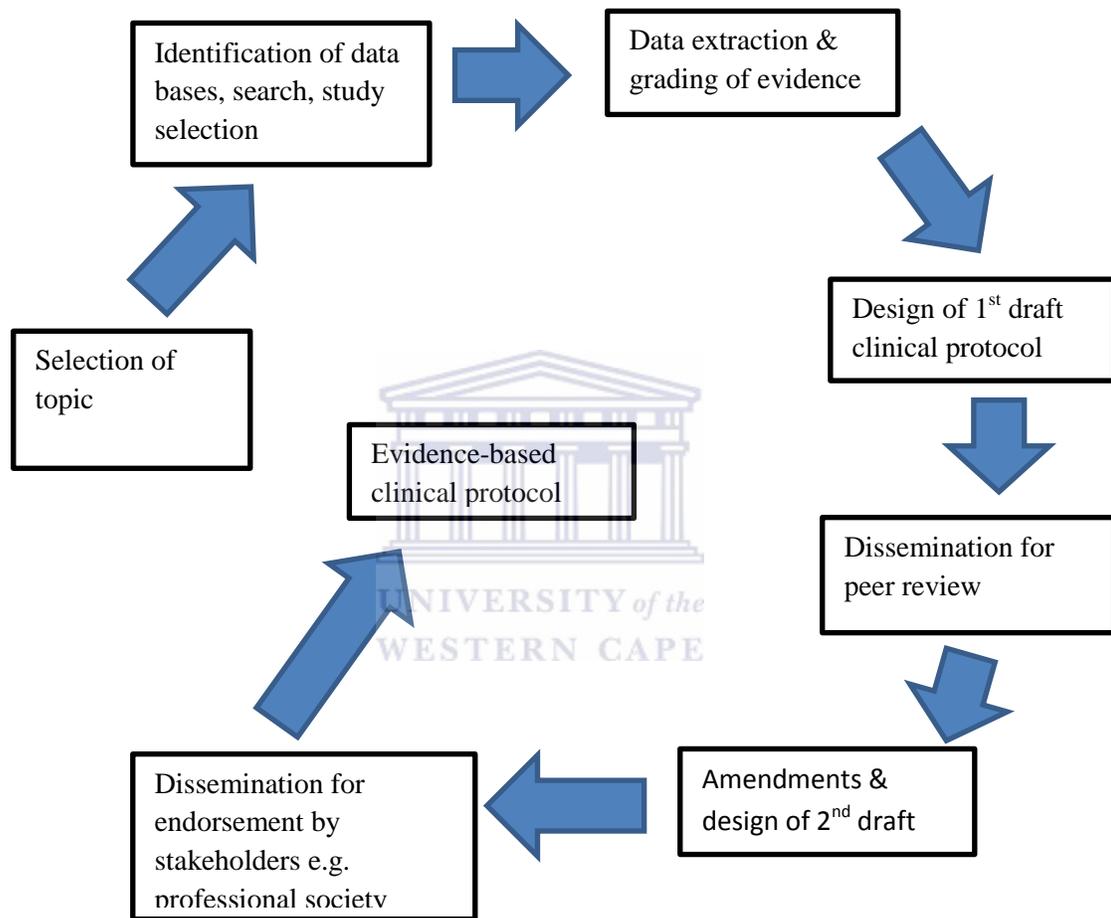


Figure 2.2: Procedure for developing clinical protocols (Source: Connis et al 2001)

2.3.1.2 Features of an evidence-based clinical protocol

There are basic features of a clinical protocol which demonstrate the credibility of the design and methodology used in the development process. These properties facilitate compliance to, and utilisation of the developed protocol by the target consumers or users.

The features of a good clinical protocol therefore include among others: involvement of end users in the development process for purpose of ownership, balance and diversity among the individuals involved in the development process with regard to level of professional qualifications, clinical experience and areas of specialisation, systematic review of the literature, combination of scientific evidence and expert consensus, external peer review and clear strategies for dissemination and implementation.

For the purpose of this study, the evidence-based lumbar spine clinical neurological examination protocol was developed using the New Zealand Guidelines Group (NZGG) framework (NZGG 2011). The NZGG framework was preferred in developing the lumbar spine CNE protocol because it clearly highlights the key steps to be followed and also explains the specific activities to be conducted during each step of the guideline development process as earlier illustrated in Figure 2.2. The methodology and results of the lumbar spine CNE protocol development, standardisation and reliability testing is described and presented in detail in Chapter Six of this thesis.

2.4.1 Validation of evidence-based clinical diagnostic tools

2.4.1.1 Face and content validity

Face validity and content validity of a diagnostic measurement tool is the ability of a tool to assess the desired qualities in a subject (Fairbank and Pynsent 2000). Clinical validation of diagnostic measures is done when the tool which is intended to be used was developed and has been used in a different setting from the target setting. The difference between the source setting and the target setting may be the language of communication and/or culture.

Therefore, the validation process involves two key steps namely translation process and culture adaptation process (Beaton et al 2000). The cross-cultural adaptation process is done once a tool has been translated from the original language to the target language and is aimed to maximise attainment of equivalence of the face and content validity between the two versions of the tool.

For the purpose of this study, the face and content validity, and reliability of the S-LANSS scale and the lumbar MRI reporting protocol was established in the Kenyan clinical setting. The methodology and results of the S-LANSS and lumbar MRI reporting protocol are presented in Chapters Five and Seven respectively.

2.4.1.2 Reliability testing of clinical diagnostic tools (test-re-test)

Reliability of clinical diagnostic tools refers to the degree of consistency with which a tool measures the target variable. Test-re-test reliability therefore refers to the stability of a clinical diagnostic test outcome over time when applied on subjects in whom the target condition is stable (Ramsey et al 2008). Therefore, in most cases, a test-re-test reliability study of the new version of a diagnostic tool is always conducted after clinical validation and adaptation of a tool, in order to assess the repeatability and stability of the test results among subjects in the target setting. Chapter Five of this thesis presents a reliability test study of an adapted version of the S-LANSS score in the Kenyan clinical setting. The reliability of the tool was assessed using a test-re-test procedure. Similarly, Chapter Seven of this thesis presents another reliability study on the adapted lumbar MRI reporting protocol among a sample of Kenyan radiologists. This second reliability study was also conducted using the test-re-test procedure.

2.5 Phase 3: Correlation of clinical diagnostic tools

Correlation is a statistical method used to assess a reciprocal relationship between two or more variables (Mukaka 2012). Therefore in medical research, correlation of clinical diagnostic tools involves assessment of the agreement between two or more tests with regard to detection of a certain target condition. Correlation therefore examines the convergence of the psychometric properties or constructs of the various tests in detecting specific attributes in subjects (Foxcroft and Roodt 2010).

According to Ruffano et al (2012), the specific diagnostic parameters whose agreement may be investigated in a diagnostic correlation study include: sensitivity which refers to the probability of a positive test result on a subject with the target condition, specificity which refers to the probability of a negative test result on a subject without the target condition, positive likelihood ratio which refers to the probability that a subject with a positive test result has the target condition and negative likelihood ratio which refers to the probability that a subject with a negative test results does not have the target condition.

Diagnostic correlation studies are conducted in order to establish evidence which may be used to support the use of certain tests as equal substitutes in cases of medical contra-indications, unavailability of high costs.

In this thesis, a diagnostic correlation study is presented in Chapter Eight, on the correlation of S-LANSS score, CNE and MRI findings in diagnosing LSR among patients who presented with low back and referred leg symptoms. This was the final and main study, a diagnostic test accuracy (DTA) study which was conducted in conformity to the guidelines of the Standards for Reporting of Diagnostic Tests (STARD) framework (Simel et al 2008). The primary objective of the main study was to determine the correlation of S-LANSS score, CNE findings and lumbar MRI findings in diagnosing LSR. This study was conducted using a cross-sectional multi-centre design. The methodology and results of this phase of the study is described and presented in detail in Chapter Eight of this thesis.

2.6 Ethical considerations

Before commencement of any clinical data collection activity, the principal researcher obtained ethical clearance for the study from the Senate Higher Degrees and the Senate Research Grants and Study Leave Committee, University of the Western Cape. Permission from the selected participating centres country-wide was obtained from their respective administrations. The study purpose, issues of confidentiality and anonymity were explained to all the participants using the participants' study information sheet prior to data collection.

The researcher observed confidentiality and anonymity of all participants in this study by using initials and serial numbers to identify all data collection tools and storage of all completed data collection materials in safe and locked cabinets. The data which was captured from all questionnaires were stored in password protected computer files.

The participating healthcare professionals including physiotherapists and radiologists together were voluntarily recruited and were free to withdraw from the study at any stage and without any liable prior notification of the researcher. Such an occurrence would not have had any negative consequences in their practice or administratively.

The participating patients were also voluntarily recruited and were made aware about their freedom to withdraw at any stage of the study without necessarily notifying the researcher, and that such an occurrence would not amount to any negative implications on their further medical care. At each of the participating hospitals, the principle researcher had in place special referral arrangements for participants in cases of medical emergencies during the course of the study. These measures were organised through collaboration between the appointed research assistants, heads of Physiotherapy Department and the Medical Superintendent at each of the participating hospitals. Informed consent was obtained from all study participants, both healthcare professionals and patients prior to participation.

Completed data collection materials including demographic and pain questionnaires, S-LANSS questionnaires and copies of patients' MRI reports were acquired by the researcher and stored under lock and key.

For purposes of confidentiality and anonymity, a secret coding system and initials were used to identify participants. Part of the study results have been disseminated through conference presentations, physiotherapy professional development workshops and manuscripts will be submitted for publication in peer reviewed journals.



CHAPTER THREE

ACCURACY OF CLINICAL NEUROLOGICAL EXAMINATION IN DIAGNOSING LUMBO-SACRAL RADICULOPATHY: SYSTEMATIC REVIEW.

3. Introduction

This chapter presents the first systematic literature review of this thesis. The aim of this systematic literature review was to establish the reliability and validity of clinical neurological examination (CNE) in diagnosing Lumbo-Sacral Radiculopathy (LSR). This review also represents step 2 of the CNE protocol development process as previously illustrated in Chapter two. The final draft CNE protocol was used as one of the diagnostic tools in the main study in Chapter eight. This chapter starts with background information regarding the current practice trends in the assessment of patients who present with clinical signs and symptoms consistent with LSR. This is followed by the review question, key search terms, the search strategy, and description of quality assessment and analysis of the reviewed studies. Lastly, the results on the diagnostic accuracy of the various clinical neurological tests in diagnosing LSR, and the clinical implications of the key findings are discussed.

3.1 Clinical diagnosis of Lumbo-Sacral Radiculopathy

Early and accurate diagnosis of LSR is crucial especially at primary health care settings in resource-poor countries like Kenya where advanced diagnostic testing is either unaffordable or sometimes unavailable. This would underpin timely effective interventions which ultimately minimise the chances of chronicity and the impact of the condition of the patients' level of activity and participation restrictions and quality of life.

There is thus a need for a cost-effective, accurate and non-invasive method for clinicians at all levels of health care, to confirm the diagnosis of LSR, and to determine whether the patient can be adequately treated conservatively using pharmacological and physiotherapeutic interventions, or requires advanced imaging like CT scan and MRI or possible surgery.

In musculo-skeletal medicine, a clinical neurological test is defined as a procedure designed to assess the physiological and bio-mechanical status of a specific neural structure thought to be responsible for the patient's pain or dysfunction resulting from compromise of the neural structure by its own 'mechanical interface' or 'bed'(Magee 2007).

Determination of the presence or absence of radiculopathy is dependent upon the examiner's ability to identify the clinical signs and symptoms, by taking a thorough history of the mechanism of injury or possible pathology, and a physical examination, as well as the clinician's ability to perform the tests correctly and accurately (Magee 2007; Majlesi et al 2008; Trainor and Pinnington 2011). The tests of a CNE are easy to perform, cost-effective and have a relatively low health risk to patients. However, the literature presents numerous variations on the execution of CNE tests and interpretation of results, which makes it difficult to establish the best-evidence clinical tests as a result of the methodological disparities in the primary diagnostic studies (Butler 2000; Vroomen et al 2002; Capra et al 2009). There is thus a need for researchers and clinicians in the field of musculo-skeletal healthcare to establish consensus on the tests to include and the specific procedure of CNE, to make it possible for clinicians to identify and conduct tests which have an acceptable diagnostic sensitivity and/or specificity in detecting lumbo-sacral nerve root dysfunctions. The clinical usefulness of a neurological test is largely determined by the accuracy with which it identifies its target dysfunction (Simpson and Gemmelle 2006).

The ideal clinical neurological test would give a positive result in those subjects who have radiculopathy (true-positive), and a negative result in those subjects who do not have radiculopathy (true-negative), therefore considering the sensitivity and specificity of the neurological tests, which could constitute an evidence-based CNE.

3.2 Review question

This systematic literature review answered the following research question: *'In patients with low back and referred leg symptoms, what is the reported diagnostic accuracy of CNE in identifying patients with LSR?'*

3.3 Aim of the systematic review

The aim of the current systematic literature review was to determine the diagnostic accuracy of CNE in detecting LSR. The diagnostic accuracy measurements which were established in the current review included validity, reliability, sensitivity and specificity.

3.4 Methodology

The review was conducted using the diagnostic tests accuracy (DTA) protocol of the Cochrane Collaboration (2007). For the purposes of this study, the DTA protocol was considered appropriate because this was a diagnostic review which aimed at examining the accuracy of a diagnostic test (CNE) in detecting a specific condition of interest (LSR).

The Cochrane DTA protocol offers review authors with guidance on the structure and composition of a review. It also highlights the main characteristics of included studies which are supposed to be reported together with the process and criteria of assessing the methodological quality of all included studies. The protocol also offers guidelines on how to analyse and present data on the sensitivity and specificity of each investigated test using the 2×2 contingency tables, forest plots and receiver operating characteristics (ROC) plots. In the current study, the Cochrane DTA format was adopted in planning and undertaking the review because this format helps readers to find the results of reviews quickly and to assess the validity, clinical applicability and implications of those results.

It also guides review authors to report their work explicitly and concisely, and facilitates the production of statistical summary figures and tables, which are highly informative.

3.4.1 Search strategy

The reviewers conducted a structured literature search from May up to September 2012 to identify relevant studies in various electronic databases including MEDLINE, CINAHL, Biomed Central, Science Direct, Springerlink, Google scholar, Pubmed, and Embase. No publication date limitation was imposed, thus all databases were searched since inception. The search was performed by one reviewer (NT), who also performed reference tracing of potentially relevant articles which were retrieved, complemented by hand searching of field- and topic-relevant journals, including reference lists of potentially relevant articles.

The key search terms as derived from the review question were: low back and leg pain, clinical neurological examination, accuracy and lumbo-sacral radiculopathy.

The search strategy incorporated synonyms, related terms, variant spelling, truncation and Boolean operators and therefore the search terms used were as illustrated below;

1st set

Physical OR clinical OR neurological OR Sensory OR dermatome OR motor OR myotome* OR deep tendon reflex OR neurodynamic OR provocative OR nerve palpation*

2nd set

Examination OR assessment OR diagnosis OR detect* OR identify**

3rd set

Lumbar OR lumbar spine OR lumbo-sacral OR low back OR back OR back-related OR leg Pain OR referred pain OR radiating pain OR radicular pain OR symptoms Radiculopathy OR nerve root irritation OR compression OR compromise

3.4.2 Study selection and inclusion criteria

Selection of studies for the purpose of this review was independently performed by two reviewers (NT and ID) using the PICO analysis (Booth and Fry-Smith 2003) and disagreements were resolved through discussion and the opinion of a third reviewer (AR).

The studies were pre-screened according to:

- **Participants:** For studies to be included in this review, the sample must have been patients aged 18 years and older presenting with low back and referred leg pain and not previously diagnosed with specific serious pathologies like fractures, tumors and infections of the lumbar/sacral spine causing low back and/or referred leg symptoms.
- **Index tests:** This review only included studies which examined the diagnostic accuracy of any of the following CNE tests in detecting LSR: sensory testing, motor testing, deep tendon reflex testing and neural mechano-sensitivity testing, in either individual or combined sets.

- **Target Condition:** This review targeted primary diagnostic studies whose main aim was to detect LSR due to nerve root compromise using CNE. Studies in which the target condition was other specific causes of LSR (like tumors or infections of the spine) other than nerve root compromise were excluded.
- **Outcomes: Reference standards:** The reviewers included diagnostic studies which compared the accuracy of clinical neurological tests against acceptable comparators like radiological imaging (Magnetic Resonance Imaging, Computed Tomography and Electro-myelography) and intra-operative findings.

The reviewers included primary diagnostic studies which examined the sensitivity and/or specificity of CNE in detecting LSR, compared to a reference standard. Only full reports of cohort and case control studies were included in order to minimise potential sources of heterogeneity, because inclusion of studies whose primary aim was not to examine the accuracy of CNE in diagnosing LSR would confound the results of the review and the conclusions and recommendations drawn thereof.

Selection of relevant studies was independently performed by two reviewers (NT and ID) using the PICO analysis (Booth and Fry-Smith 2003) following exclusion of studies which did not address the primary aim of the review as stated above. Disagreements were resolved through discussion and the opinion of a third reviewer (AR).

3.4.2 Quality assessment

Two reviewers (NT and AR) independently assessed the quality of the twelve included studies using the QUADAS criteria. Each of the included studies was separately assessed for each of the twelve items.

Studies were scored as 'positive' (+), when the described methodology was of good quality according to the guidelines of the QUADAS criteria, as 'negative' (-), when the described methodology was not of acceptable quality, and 'not sure' (?), when the methodology was inadequately described.

In order to familiarise the reviewers with the process and standards of quality assessment using the QUADAS criteria and to improve on the level of agreement between the two reviewers, the aforementioned tool was first discussed in a meeting between the two reviewers using the QUADAS guideline manual (National Institute for Health and Clinical Excellence 2009).

The manual elaborates each item and also provides an explanation and justification on when to score a positive, negative or unclear. After establishing a common understanding on each item, the tool was then piloted using two studies which had assessed the accuracy of upper limb provocative tests in diagnosing cervical radiculopathy (Shah and Rashekar 2004 and Tong, Hig and Yamakawa 2002). The reviewers independently rated the methodological quality of the two pilot studies and compared the scores. The scoring disagreements in the pilot study were discussed and resolved before the quality assessment of the main studies was conducted. This was in conformity with recommendations by the developer of the QUADAS tool (Whiting et al 2002). A cumulative percentage across all included studies was then scored per item, and per study. Scoring disagreements between the two reviewers for each of the twelve included studies ranged from 2 items in the Vroomen et al (2002) study to 7 items in the Lee-Robinson et al (2010) study.

All scoring disagreements were then resolved by a discussion arbitrated by the third reviewer (ID) until a consensus was reached.

3.7. Data extraction

The first reviewer (NT) independently extracted data from the originally included studies using a self-developed data sheet which covered: Participants (number, age, gender, clinical characteristics, clinical setting), examiners (profession and expertise) and clinical test(s).



Table 3.2: Characteristics of included studies

Author (year) Country	Sample size (gender, age)	Setting (period of recruitment)	Patients' description	Examiners	Index tests
Iversen (2013) Norway	N=116 Male=68 Female=48 Mean age=42	Out-patient multi-disciplinary back clinics	History and clinical presentation suggestive of chronic lumbar radiculopathy	Orthopaedic manual physiotherapists and neurologists	FNS, SLR, sensory, motor, knee reflex, ankle reflex
Suri (2011) USA	N=54 Male =28 Female = 26 Mean age = 54	Hospital spine centre (January 2008 – March 2009)	Lower extremity radiating pain < 12 weeks	Physiatrists specialized in spine care	SLR, Crossed SLR, FNST, sensory, motor, patella & Achilles reflexes
Trainor (2011) UK	N=16 Male =7 Female = 9 Mean age = 49	Orthopedic spinal clinic (6 months)	Pain radiating into one or both legs distal to the groin or gluteal fold Distribution of pain in dermatomal pattern	Physiotherapists	Slump knee bend test
Coster (2010) Netherlands	N=202 Male =92 Female = 110 Mean age = 46	Neurology department (January 2006 – March 2007)	Clinical suspicion of Lumbo-Sacral Radicular Syndrome	Neuro-physiologist	Sensory, motor, reflex and SLR tests
Suri (2010) USA	N=51(independent group) Male =40 Female = 11 Mean age = 54	Hospital spine centre (January 2008 – March 2009)	Lower extremity radiating pain	Physiatrists specialized in spine care	Sensory, motor, reflex and neural provocation tests
Bertilson (2010) Sweden	N=61 Male =12 Female = 49 Mean age = 60	Radiology clinic (February - September 2004)	Clinical signs and symptoms consistent with lumbar nerve root involvement	Orthopedic surgeon & certified radiologist	Sensory, motor, tendon reflex and tender point palpation

Lee-Robinson (2010) USA	N=70 Male =31 Female = 39 Mean age = 65	Electro-diagnosis, physical medicine & rehabilitation clinic (January to October 2009)	Low back pain and radicular lower extremity symptoms of weakness, numbness and pain	Physician (specialist in electro-diagnostics & physical medicine & rehab)	Ankle reflex, pin wheel examination, motor testing
Majlesi (2008) Turkey	N=85 Male =55 Female =30 Mean age =39	Neuro-surgery department (January – June 2005)	Complaints suggestive of lumbar disc herniation with low back, leg, or low back and radicular symptoms	Neuro-surgeons	Slump and SLR tests
Rabin (2007) USA	N=38 (MRI +) Male =30 Female = 8 Mean age = 38	Neuro- and orthopedic surgery clinic	Low back pain or paraesthesia radiating below the knee	Physiotherapists	Seated SLRT and supine SLRT
Vroomen (2002) Netherlands	N=274 Male =67 Female = 207 Mean age =46	Neurology department	A new episode of pain radiating into the leg below the gluteal fold.	Neuro-radiologist	Paresis, finger floor distance, tendon reflexes, sensory tests
Albeck (1996) Denmark	N=80 Male =48 Female = 32 Mean age = 40	Neuro-surgery clinic	Mono-radicular pain from L5 or S1	Neuro-surgeon	sensory, motor, tendon reflexes
Haldeman (1988) USA	N=100 Male = Not provided Female = Not provided Mean age =Not provided	Neurology and surgery	Patients with complaints of low back pain and leg pain, consistent with a diagnosis of sciatica	Certified neuro-radiologist and orthopaedic surgeon	SLR, motor, sensory and reflex tests

Ten of the twelve studies which were reviewed were published between 2002 and 2013 (Vroomen et al 2002; Iversen et al 2013) while two were published between 1988 and 1996 (Haldeman 1988; Albeck 1996). Five studies (Haldeman et al 1988; Suri et al 2010; Lee-Robinson et al 2010; Suri et al 2011; Rabin et al 2011) were conducted in specialised health care settings in the United States of America, while the rest were conducted in Norway (Iversen et al 2013), United Kingdom (Trainnor and Pinnington 2011), Netherlands (Coster et al 2010 and Vroomen et al 2002), Turkey (Majlesi et al 2008), Sweden (Bertilson et al 2010) and Denmark (Albeck 1996). The clinicians who conducted the clinical neurological examination in the reviewed studies included physiotherapists, neurologists, neurosurgeons, orthopedic surgeons and neuro-radiologists who were all experienced in their fields of specialisation.

3.5 Data analysis

The reviewers extracted, and where unavailable, re-calculated the common parameters of diagnostic test accuracy including; sensitivity, specificity, positive likelihood ratio (+LR) and negative likelihood ratio (-LR). However, as suggested by Pepe et al (2004), diagnostic odds ratios were not calculated in this review due to its limitations in gauging the performance of a diagnostic marker. A meta-analysis was also not conducted given the minimal numbers of included studies in this review. In order to establish the level of agreement between the two observers, statistical technique was applied by using un-weighted Cohen's Kappa test with 2 x 2 cross-tabulation in SPSS computer software version 21. The inter-observer agreement was assessed using the QUADAS criteria, and Kappa (k) values and P-values were considered as indicators in determining the statistical significance of the observed agreement. The inter-observer agreement was considered poor if $k \leq 0$, slight $k \leq 2$, fair $k \leq 4$, moderate $k \leq 6$, good $k \leq 8$ and perfect $k > 8$ (Viera and Gareth 2005).

Scoring disagreements were resolved through a consensus discussion between the two reviewers (NT and ID) with the arbitration of the third reviewer (AR) until agreement on all items for all the studies was reached. Where necessary, and in cases where raw data were incomplete, a 2 x 2 contingency table was used to re-calculate the diagnostic accuracy values.

3.6 Results

The search on relevant electronic data bases retrieved a total of 1568 articles (Figure 4.1) by the first hit of the key search terms and the mesh terms. After screening the title, key words and abstract of all articles and removal of duplicates, 39 articles were selected as potentially suitable for inclusion and were retrieved as full articles for further analysis. Out of the 39 articles, 24 were selected from those that were generated by the entry of the key search terms while 15 were selected from the output of the mesh terms.

Full screening of the 39 articles was independently done by two reviewers (NT & ID) using a PICO analysis and disagreements were resolved through adjudication by a third reviewer (AR).

Twenty-seven studies were further excluded for not meeting the inclusion criteria of this review (primary aim of the study was not to diagnose lumbo-sacral radiculopathy n=6, use of an inappropriate reference standard n=4, patients' clinical characteristics not consistent with lumbo-sacral radiculopathy n=11, reviews n=6). The reference lists of all included studies were hand-searched by one reviewer (NT) for possible additional references to studies which could be included in the review but the process did not yield any more relevant studies. A total of 12 studies met the inclusion criteria and were analysed for the purposes of this review. Seven of the studies examined neurological conduction and the remaining five studies examined mechanical neural sensitivity. Of the 12 studies included in this review, 11 were cohorts and one a case control study.

The clinical neurological examination tests assessed by the included studies were the standard CNE tests as described in handbooks (Petty and Moore 1998; Butler 2000; Hengeveld and Banks 2013): Sensory (soft touch and superficial pain), motor power (functional motor tests and resisted isometric muscle contractions) and deep tendon reflexes as well as neuro-dynamic tests for the lower quadrant neural structures. MR imaging was used as a reference standard in eight of the included studies while two used EMG, one electro-diagnostics and CT, and the other one used intra-operative surgical findings.

Eleven studies were carried out in secondary and tertiary health care settings while 1 was a primary care diagnostic study. See a diagram of the search procedure and results in Figure 3.1.

Seven primary diagnostic studies (Vroomen et al 2002; Bertilson et al 2010; Coster et al 2010; Lee-Robinson et al 2010; Suri et al 2010; Suri et al 2011; Iversen et al 2013) which had evaluated the neuro-conduction function of lumbar and sacral spinal nerve roots qualified for inclusion after the PICO analysis, which was independently done by two reviewers (NT and ID). See results in Table 3.1a.

The seven studies recruited patients with clinical signs and symptoms consistent with lumbar nerve root compromise and radiculopathy and evaluated the diagnostic accuracy of standard clinical neuro-conduction tests (sensory, motor and tendon reflexes) in detecting lumbar radiculopathy as defined by MRI and/or EMG.

Five studies (Haldeman et al 1988; Albeck 1996; Rabin et al 2007; Majlesi et al 2008; Trainor and Pinnington 2011) and were pre-qualified after the PICO analysis which was conducted by two reviewers (NT and ID).

These five studies evaluated the diagnostic performance of clinical neuro-dynamic tests (SLR and FNST) in detecting lumbar radiculopathy on a sample of patients aged 18 and older who presented with clinical signs and symptoms suggestive of lumbo-sacral nerve root compression and radiculopathy using MRI (Rabin et al 2007; Majlesi et al 2008; Trainor and Pinnington 2011), electro-diagnostics and CT scan (Haldeman et al 1988) and Surgery (Albeck 1996). See results in Table 3.1b.

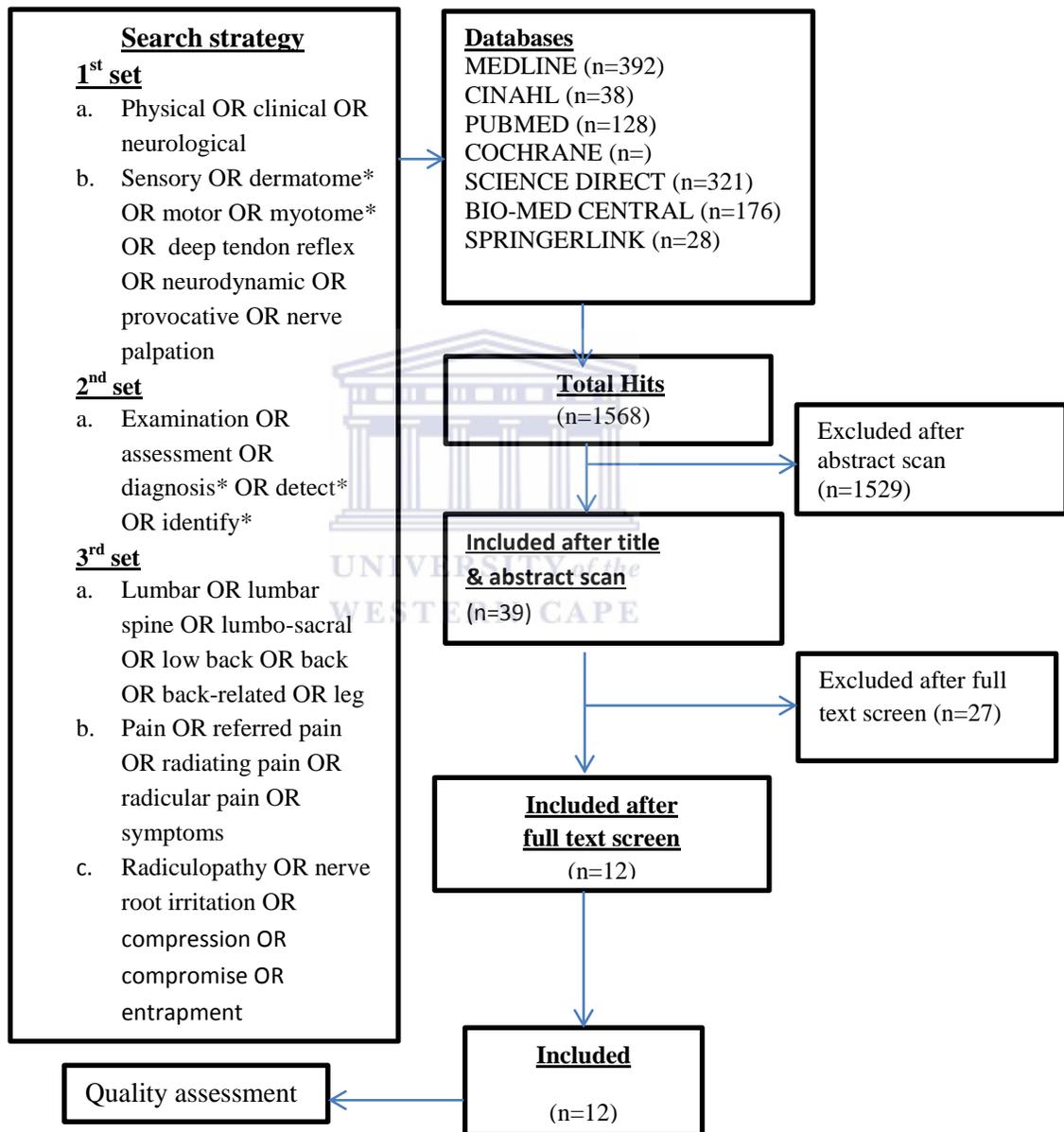


Figure 3.1: Search history

Table 3.1a: PICO analysis on retrieved studies: Assessment of neural conduction

Author (Year)	Patients	Index test	Comparison	Outcome
Iversen (2013)	18 and older 116 patients with symptoms of lumbar radiculopathy \geq 12 weeks	CNE	MRI	Knee flexion motor test for L5, S1 and S2 and SLR test were more sensitive in detecting radiculopathy in the light of MRI compared to other CNE tests.
Suri (2011)	18 and older 54 patients with lower extremity radiating pain < 12 weeks	CNE	MRI	Mid-lumbar impingement, femoral stretch test (FST), crossed FST, medial ankle pinprick sensation, and patellar reflex testing demonstrated LRs \geq 5.0 while for Low lumbar impingement, Achilles reflex test demonstrated an LR \geq 5.0..
Bertilson (2010)	18 and older 61 patients with long-standing nerve root symptoms	CNE and simplified pain drawing	MRI	Structured physical examination (including CNE), and simplified pain drawing showed more sensitivity than MRI for nerve involvement
Coster (2010)	20 and older 202 patients with suspicion of lumbo-sacral radicular syndrome \geq 3 weeks	Medical history and CNE	EMG and MRI	Positive SLR test, paresis and unilateral absence of ankle tendon reflex were predictors for radiological nerve root compression.
Lee-Robinson (2010)	18 and older 70 patients with low back pain and radicular lower extremity symptoms of weakness, numbness and pain	Medical history, electro-diagnosis and CNE	MRI	Patient reports of neuropathic symptoms with findings of distal muscle weakness, distal decreased sensation to sharp pin, and diminished ankle reflex, were the most consistent indicators of lumbar radiculopathy.
Suri (2010)	18 and older 160 patients with lower extremity radiating pain \leq 12 weeks	CNE (blinded to MRI)	CNE (not blinded to MRI)	Sensitivity of pin prick test was significantly higher with prior knowledge of MRI than without.
Vroomen (2002)	18 and older 274 patients with a new episode of pain radiating into the leg.	Standardized CNE	MRI	Paresis, a finger-floor distance of \geq 25cm, absence of ankle and knee tendon reflexes and a positive SLR test were predictors of nerve root compression on MRI.

Table 3.1b: PICO analysis on retrieved studies: Assessment of neural mechano-sensitivity

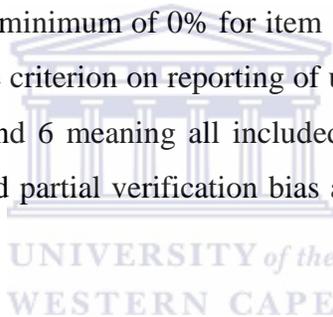
Study (Year)	Patients	Index test	Comparison	Outcome
Trainor (2011)	18 and older 16 patients with radicular leg pain For a period of between 3 weeks and 3 months	Slump knee bend (SKB) test	MRI	The SKB test correctly confirmed or negated the presence of L4 nerve root compression in 14 out of the 16 patients (88%). Sensitivity was 100% while specificity was 83%.
Majlesi (2008)	18 and older 75 patients with complaints suggestive of lumbar disc herniation with low back, leg, or low back and leg pain \leq 12 weeks	The Straight Leg Raising (SLR) and SKB tests	MRI.	The Slump test was more sensitive (0.84) than the SLR (0.52) in the patients with lumbar disc herniations. While the SLR was slightly more specific test (0.89) than the Slump test (0.83).
Rabin (2007)	18 and older 71 patients with signs and symptoms consistent with lumbar radiculopathy for \geq 4 weeks	Supine and seated SLR tests	MRI	Myotomal weakness, dermatomal sensory loss, deep tendon reflex diminution or abolishment were predictors of lumbar radiculopathy. The supine SLR test was more sensitive (0.67) in detecting MRI-visible nerve root compression compared to the seated SLR test (0.41).
Haldeman (1998)	18 and older 100 patients with complaints of low-back pain and leg pain consistent with a diagnosis of sciatica \geq 6 months	CNE	Electro-diagnostics and CT scan	SLR test was insensitive in detecting radiculopathy in the light of CT scan. Sensory testing was sensitive in detecting radiculopathy based on electro-diagnostic findings.
Albeck (1996)	18 and older 80 patients with mono-radicular pain corresponding to the 5 th lumbar or the 1 st sacral nerve root. Conservative treatment should have failed	CNE	Surgery	SLR test, paresis and hypoesthesia are highly sensitive in diagnosing radiculopathy but poor in excluding the diagnosis of radiculopathy (low specificity) using intra-operative findings as a comparator.

3.8 QUADAS scores of reviewed studies

The final QUADAS scores for each of the twelve included studies across all QUADAS items which is presented horizontally in Table 3.3, was calculated as a percentage of the sum of all positive scores divided by the total number of QUADAS items (12). Therefore, the quality scores ranged from a minimum of 50% for the Coster et al (2010) study to a maximum quality score of 92% for the Bertilson et al (2010) study. See Table 3.3 for results.

In this review, the researcher also assessed the quality performance of all included studies per QUADAS items, presented vertically in columns (Table 3.3). This gives a picture of how for example all the included studies avoided partial verification bias, (item 5). The final score was calculated as a percentage of the sum of positive scores divided by the number of studies (12).

The scores ranged from a minimum of 0% for item 11 meaning none of the included twelve studies fulfilled the criterion on reporting of un-interpretable index test results to 100% for item 1, 5 and 6 meaning all included studies fulfilled the criteria on avoidance of spectrum and partial verification bias and clarity of execution of index test.



3.9 Inter-observer agreement

Inter-observer agreement between the two reviewers (NT and AR) was determined for each item in all the twelve included studies by calculating the Kappa coefficient using the un-weighted Cohen's Kappa statistic test. The mean of the level of agreement between the two independent reviewers was fair ($k = 0.3$) ranging from $k = -0.03$ for the Lee-Robinson et al (study) which was rated as poor to $k = 0.7$ for the Suri et al (2011) study which was rated good.

Most disagreements between the two reviewers were observed in items 7 and 8 which concern index test and reference standard review bias respectively.

Table 3.3: QUADAS scores of included studies

Author (year)	Criteria number												12 (%)
	1	2	3	4	5	6	7	8	9	10	11		
Iversen (2013)	+	+	+	?	-	+	+	+	+	+	-	+	75
Suri (2011)	+	+	+	?	+	+	+	?	+	+	-	+	75
Trainor (2011)	+	+	?	-	+	+	-	?	+	-	-	+	50
Coster (2010)	+	?	+	?	+	+	+	?	-	+	-	-	50
Suri (2010)	+	+	+	?	+	+	+	?	+	+	-	+	75
Bertilson (2010)	+	+	+	+	+	+	+	+	+	+	-	+	92
Lee-Robinson (2010)	+	+	?	?	+	+	+	+	+	?	-	+	67
Majlesi (2008)	+	?	+	?	+	+	+	?	-	+	-	-	50
Rabin (2007)	+	+	?	-	+	+	+	+	+	+	-	+	75
Vroomen (2002)	+	+	?	-	+	+	+	+	+	+	-	+	75
Albeck (1996)	+	?	+	?	+	+	+	?	-	+	-	+	58
Haldeman (1988)	+	+	?	-	+	+	+	+	+	+	-	+	75
% of maximum	100	72	55	9	100	100	90	45	72	82	0	82	

3.10 Diagnostic accuracy of the index tests

Table 3.4: Definition of test accuracy terms

Index test	Gold standard	
	Positive	Negative
Positive	A	b
Negative	C	d

a=True positive (TP)

b=False positive (FP)

c= False negative

d= true negative

Sensitivity = $a / (a + c)$

Specificity = $d / (b + d)$

Positive predictive value (PPV) = $a / (a + b)$

Positive likelihood ratio (+ LR) = $\text{sensitivity} / (1 - \text{specificity})$

Negative likelihood ratio (- LR) = $\text{specificity} / (1 - \text{sensitivity})$

3.10.1 Summary of diagnostic accuracy of individual tests

Table 3.5: Diagnostic accuracy of sensory tests

Author (year)	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	+ LR	-LR
Suri (2010) L2	MRI	0.08(0.01-0.27)	0.96(0.82-1.00)	2.0	1.0
L3	MRI	0.17(0.05-0.37)	0.96(0.82-1.00)	4.3	1.2
L4	MRI	0.17(0.05-0.37)	1.00(0.88-1.00)	0.2	1.2
L5	MRI	0.13(0.03-0.34)	0.82(0.63-0.94)	0.7	0.9
S1	MRI	0.08(0.01-0.27)	0.79(0.59-0.92)	0.4	0.9
Iversen (2013)	MRI & CT	0.33(0.06-0.79)	0.88(0.81-0.93)	2.8	1.3
Bertilson (2010) (L4)	MRI	0.07(0.01-0.22)	0.81(0.63-0.93)	0.4	0.9
L5		0.17(0.06-0.35)	0.58(0.39-0.75)	0.4	0.7
S1		0.20(0.08-0.39)	0.84(0.66-0.95)	1.3	1.1
Albeck (1996)	Surgery	0.61(0.47-0.73)	0.63(0.38-0.84)	1.6	1.6
Vroomen (2002)	MRI	0.14(0.09-0.21)	0.93(0.87-0.97)	2.0	1.1

Diagnostic accuracy of sensory tests in identifying nerve root impingement was evaluated in five studies (Albeck 1996; Vroomen et al 2002; Bertilson et al 2010; Suri et al 2011; Iversen et al 2013) by establishing the sensitivity (true positive) and specificity (true negative) values of sensory testing as defined by the reference standard (MRI, CT scan or surgical findings).

The various aspects of sensory testing whose diagnostic performance was assessed included hypo-aesthesia, paraesthesia and anaesthesia. The actual procedures were not well reported in most of the studies. Dermatome maps were used to guide the procedures. The Albeck (1996) study which was the oldest among the five, reported the best sensitivity 0.61(0.47-0.73) CI 95% with a relatively moderate specificity of 0.63(0.38-0.84). This, comparing to the other studies which evaluated sensibility to touch using MR imaging as a reference standard, may be attributed to the fact that patients who undergo surgery are routinely carefully selected compared to those who are sent for imaging.

Hence the probability of a positive index test results becomes relatively higher in the surgical than imaging group. A more recent study by Suri et al (2010) presented the best specificity for sensibility testing in detecting nerve root impingement at 0.96 (0.82-1.00) CI 95%.

Table 3.6: Diagnostic accuracy of motor tests

Author (year)	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	+LR	-LR
Suri (2010)	MRI	0.39(0.32-0.52)	0.83(0.78-0.87)	2.3	1.4
Iversen (2013)	MRI & CT	0.33(0.06-0.97)	0.68(0.59-0.76)	1.0	1.0
Suri (2011) L3	MRI	0.50(0.19-0.81)	0.77(0.62-0.89)	2.2	1.5
L4	MRI	0.54(0.25-0.81)	0.80(0.65-0.91)	2.7	1.7
L5	MRI	0.61(0.36-0.83)	0.86(0.71-0.95)	4.4	2.2
S1	MRI	0.29(0.10-0.56)	0.97(0.85-1.00)	1.0	1.4
Albeck (1996)	Surgery	0.34(0.23-0.48)	0.47(0.24-0.71)	0.6	0.7
Vroomen (2002)	MRI	0.27(0.20-0.35)	0.93(0.87-0.97)	3.9	1.3
Bertilson (2010) L4	MRI	0.13(0.04-0.31)	0.87(0.28-3.76)	1.0	1.0
L5	MRI	0.27(0.12-0.46)	0.68(0.49-0.83)	0.8	0.9
S1	MRI	0.17(0.06-0.35)	0.81(0.63-0.93)	0.9	1.0

The diagnostic accuracy of motor tests in identifying nerve root impingement was evaluated in twelve studies (Haldeman et al 1988; Albeck 1996; Vroomen et al 2002; Rabin 2007; Majlesi et al 2008; Bertilson et al 2010; Suri et al 2010; Lee-Robinson et al 2010; Coster et al 2010; Suri et al 2011; Trainor and Pinnington 2011; Iversen et al 2013) by establishing the sensitivity (true positive) and specificity (true negative) values of motor testing as defined by the reference standard (MRI, CT scan or surgical findings). The specific tests which were evaluated were functional motor tests and resisted isometric contractions (RICs), to determine paresis or muscle weakness.

None of the studies reported detailed information regarding execution and criteria for positivity. Generally, motor tests across all primary diagnostic studies reported a relatively poor sensitivity. The highest 0.61(0.36-0.83) CI 95% was for great toe extension test in detecting L5 nerve root impingement reported in the Suri et al (2011) study. Similarly, dorsiflexion and great toe extension had the highest specificity 0.93(0.87-0.97) CI 95%, as reported in the only primary care study (Vroomen et al (2002), however, this was not ascribed specifically to any segmental nerve root level.

Table 3.7: Diagnostic accuracy of tendon reflex tests

Author (year)	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	+ LR	-LR
Patella reflex					
Suri (2010)	MRI	0.32(0.31-0.53)	0.90(0.89-0.95)	3.2	1.3
Iversen (2013)	MRI & CT	0.67(0.21-0.94)	0.83(0.75-0.89)	4.0	2.5
Coster (2010)	EMG	0.18(0.10-0.18)	0.66(0.58-0.71)	0.5	0.8
Achilles reflex					
Albeck (1996)	Surgery	0.61(0.47-0.73)	0.63(0.38-0.84)	1.8	1.6
Vroomen (2002)	MRI	0.14(0.09-0.21)	0.93(0.87-0.97)	2.0	1.1
Suri (2011)	MRI	0.33(0.13-0.59)	0.91(0.77-0.98)	3.7	1.4
Iversen (2013)	MRI & CT	0.67(0.21-0.94)	0.60(0.51-0.69)	1.7	1.8

Diagnostic accuracy of tendon reflex tests in identifying nerve root impingement was evaluated in six studies (Albeck 1996; Vroomen et al 2002; Coster et al 2010; Suri et al 2010; Suri et al 2011; Iversen et al 2013) by establishing the sensitivity (true positive) and specificity (true negative) values of deep tendon reflex tests as defined by the reference standard (MRI, CT scan, EMG or surgical findings). Deep tendon reflex tests were conducted to establish hypo-reactivity or complete absence. Three of the reviewed studies (Coster et al 2010; Suri et al 2011; Iversen et al 2013) evaluated patella reflex or knee jerk, while four examined the accuracy of the Achilles or ankle reflex.

Most of the studies did not provide a detailed explanation regarding test execution and definition of positivity. The most recent study (Iversen et al 2013) reported the highest sensitivity of patella reflex (0.67(0.21-0.94)) in detecting L4 nerve root impingement with a relatively good specificity of 0.83(0.75-0.89), though this was slightly lower compared to a 0.90 (0.89-0.95) specificity rate reported in an earlier study by Suri et al (2010).

The recent Iversen et al (2013) study also reported the highest specificity 0.67(0.21-0.94) of the Achilles tendon reflex test in detecting lower lumbar (L5 S1) nerve root impingement compared to the other three studies which investigated the accuracy of the same test. However, the best specificity 0.93(0.87-0.97) of the Achilles tendon reflex was found in the much earlier primary study (Vroomen et al 2002).

Table 3.8: Diagnostic accuracy of lower limb neuro-dynamic tests

Type of index test (Author, year)	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	+LR	-LR
SLR & Lassegu's sign					
Majlesi (2008)	MRI	0.52(0.42-0.58)	0.89(0.79-0.95)	4.7	1.9
Vroomen (2002)	MRI	0.64(0.56-0.71)	0.57(0.47-0.66)	1.5	1.6
Albeck (1996)	Surgery	0.84(0.72-0.92)	0.21(0.06-0.46)	1.1	1.3
Haldeman (1988)	CT and electro-diagnostics	0.37(0.19-0.58)	0.78(0.67-0.87)	1.7	1.2
Suri (2010)	MRI	0.64(0.47-0.82)	0.48(0.45-0.50)	1.2	1.3
Coster (2010)	EMG	0.44(0.38-0.52)	1.00(0.48-1.00)	0.4	1.8
Suri (2011)	MRI	0.29(0.28-0.32)	0.57(0.48-0.58)	0.7	0.8
Rabin (2007)	MRI	0.67(0.53-0.79)	0.43(0.38-0.46)	1.0	1.3
Slump test					
Majlesi (2008)	MRI	0.84(0.74-0.90)	0.83(0.73-0.90)	5.0	5.2
Trainor & Pinnington (2011)	MRI	1.00(0.40-1.00)	0.83(0.52-0.98)	5.9	0.8

The diagnostic accuracy of lower limb neuro-dynamic tests was also evaluated in most of the reviewed studies. This was done through establishing the sensitivity (true positive) and specificity (true negative) values of neuro-dynamic tests as defined by the reference standard (MRI, CT scan, electro-diagnostics or surgical findings). Researchers used provocative tests to establish the level of disc herniation and subsequent exiting or traversing nerve root impingement, and not the response of the lower limb peripheral neural system towards mechanical loading as argued by Butler (2000) and Schacklock (2005).

Similarly, SLR test and Lassegue's sign were used inter-changeably in one study (Albeck 1996), describing the latter and reporting about the former. The diagnostic performance of the SLR test however had the highest sensitivity of 0.93(0.87-0.97) reported in both Albeck (1996) and Majlesi et al (2008) studies.

The difference between these two studies being the reference standard where the former used intra-operative findings while the later used MR imaging. On the other hand, a specificity rate of 1.00(0.48-1.00) was reported in the relatively current Suri et al (2011) study.

3.11 Discussion

In contrast to previous reviews which examined sciatica due to lumbar disc herniation (Vroomen et al 1999; Van der Windt et al 2010; Al Nezari et al 2013); this review aimed at establishing the accuracy of clinical neurological tests in diagnosing LSR due to any lesion or dysfunction of the somatosensory system. The main findings of this review are that the diagnostic accuracy of clinical neurological tests in detecting LSR range from low to moderate and that there is no standard definition of a positive SLR test and grading of tendon reflex test results.

This review evaluated twelve primary diagnostic test accuracy (DTA) studies that specifically assessed the performance of various clinical neurological tests in detecting nerve root impingement.

Deep tendon reflex testing focused on evaluation of the patella and Achilles' reflexes. Generally, diagnostic performance of reflex tests across the studies which evaluated reflexes was notably good with specificity ranging from 0.60 (0.51-0.69) in the recent Iversen et al study (2013) to 0.93(0.87-0.97) in the Vroomen et al (2002) study. However, the sensitivity was moderate with the highest being 0.67(0.21-0.94) in the Iversen et al (2013) study.

The procedure of reflex testing was either not provided in some of the studies, and where provided, there were outright procedural similarities in all the reviewed studies. However, the grading system varied from a four point scale (Suri et al 2011) to a five point scale (Iversen et al 2013). According to the North American Spine Society (NASS 2012) guidelines on diagnosis of lumbar radiculopathy, there is insufficient evidence on the actual diagnostic utility of positive tendon reflex tests in detecting lumbar radiculopathy.

In our opinion, the low to moderate accuracy of clinical neurological tests seen in this review stem from several factors ranging from variations in operational case definition of the target condition and outcome of clinical testing, that is, detection of radiculopathy due to disc-related nerve root compression amongst others. Inconsistencies in previous systematic reviews (Vroomen et al 1999; Deville et al 2000; Rebain et al 2002) regarding primary study selection where similar studies appears in different reviews with different aim and specific objectives posing a number of questions on the criteria used to select studies.

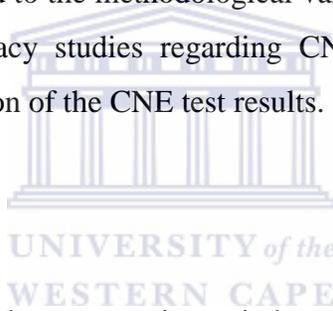
Verification bias may also contribute towards the scarce research reporting on clinical neurological tests since the commonly utilised reference standard is MR imaging which the value and accuracy is known only in detecting visible structural nerve root impingement which does not necessarily mediate radicular symptoms yet the evaluated index tests are intended to detect radicular symptoms (Bertilson et al 2010).

Lumbo-Sacral Radiculopathy is a common condition encountered by physiotherapists in practice. Early and accurate diagnosis and effective management of LSR especially at primary health care settings in countries like Kenya, is critical in order to prevent chances of chronicity and minimise the impact on patients' health, function and quality of life.

Rapid, low cost and non-invasive diagnostic options like CNE tests should be promoted in practice as opposed to the use of advanced imaging which is costly or in some settings may be unavailable, not omitting the false positive and false negative findings commonly seen in imaging examinations (Jensen et al 2004). However, this review indicates that the accuracy of CNE tests in diagnosing LSR ranges from low to moderate, and according the opinion of the reviewers, this relatively low diagnostic accuracy may be attributed to the methodological variations among researchers of the primary diagnostic accuracy studies regarding CNE test execution, definition of positivity and categorisation of the CNE test results.

3.12 Conclusion

While clinical neurological tests remain a vital component of the initial diagnostic procedure of patients suspected of LSR, the current evidence shows a low to moderate accuracy of CNE tests in diagnosing LSR. However, a common ground must be reached in terms of operational definition of LSR (target condition), and CNE (index test outcome). This would improve the reported accuracy and ultimately the credibility of clinical neurological tests in the diagnosis of LSR.



CHAPTER FOUR

ACCURACY OF MRI IN DETECTING LUMBO-SACRAL NERVE ROOT COMPROMISE: SYSTEMATIC REVIEW.

4. Introduction

This systematic literature review was aimed at establishing the reliability and clinical validity of Magnetic Resonance Imaging (MRI) in detecting lumbo-sacral nerve root compromise. Background information regarding the current practice trends in diagnostic imaging and radiculopathy is followed by the review question, together with the key search terms, search strategy, and the electronic and print literature sources. The search process, management of search results, study selection process and criteria used for data extraction are provided. Lastly, the quality assessment and analysis of the reviewed studies together with the key results are discussed.

4.1 Utilization of MRI in diagnosing radiculopathy

MRI is frequently used in examining patients with Lumbo-Sacral Radiculopathy (Bertilson et al 2010; Kreiner et al 2014). Access to imaging tests is proposed to improve diagnostic accuracy and facilitate effective treatment for better health outcomes (Hilal et al 2013), but the relationship between MRI-visible anatomical abnormalities, clinical history and patients' treatment outcomes remain controversial (Wainer and Patel 2008; Carrino et al 2009). Similarly, there are documented reports of high prevalence of MRI-visible lumbar spine abnormalities in asymptomatic subjects (Jensen et al 2004). Over-utilisation and over-dependency on imaging has been attributed to technological advances and availability of medical imaging, clinicians' uncertainty and patients' expectations (Jarvik and Deyo 2002). These may all result from clinicians' attempt to address the delicate balance between not missing a treatable pathology and avoiding unnecessary investigation which may increase patients' fears about their condition (Lysdahl and Hofmann 2009).

MRI examination is proposed to provide detailed anatomic assessment of the spine, however, it has a high potential of identifying incidental findings which are morphologically abnormal but not responsible for, or even related to, patients' symptoms (Bajpai, Saini and Singh 2013). MRI findings may sometimes be irrelevant in clinical decision making and ultimate treatment outcomes (Carrino et al 2009). Such findings may influence further investigations, unnecessary treatment options, increased cost of care and possibly poor outcomes (Carrino et al 2009; Bajpai et al 2013). MRI of the lumbo-sacral spine has been proven to be able to detect alterations in both the anatomy (disc herniations and spinal canal stenosis) and tissue properties (disc desiccation and reactive marrow changes), which then need to be considered within a clinical context (Weiner and Patel 2008). Other characteristics investigated by MRI include disc contour abnormalities (bulge and herniations), and degenerative changes of the inter-vertebral discs, bone marrow, neuro-foramina, spinal canal and facet joints (Carrino et al 2009). The diagnostic value of MRI in assessing normal lumbar anatomy, internal disc chemistry and architecture, features of lumbar spine degeneration, and in diagnosing herniated lumbar discs have been well documented (Jarvil and Deyo 2002; Weiner and Patel 2008; Carrino et al 2009). However, it's accuracy in detecting nerve root involvement remains questionable as evident by conflicting reports by Bertilson et al (2010) that MRI is insensitive and Kreiner et al (2014), that MRI is sensitive and thus recommended for diagnosing LSR.

Abnormal imaging findings in patients with LSR are in some instances coincidental, hence the need to correlate imaging findings with the patient's clinical picture (Hoogendorn et al 2000; Wainer and Patel 2008; Carrino et al 2009). This shortcoming, on the likelihood of false positive findings on MRI, coupled with high economic cost of radiological imaging, and the surgical interventions they may trigger, has invoked consistent criticism among authorities in the fields of neurology and musculo-skeletal health care as indicated earlier in the American Agency for Health Care Policy and Research (AHCPR) recommendations by Bigos et al (1994), and recently by Weiner and Patel (2008); Lysdahl and Hofmann (2009).

These authors recommended that clinicians should correctly apply and understand the limitations of MRI examination in the assessment of patients suspected with LSR.

Another major concern regarding the reported variability in the interpretation of the identified abnormalities is the non-uniformity of MRI reporting protocols which cause heterogeneity in the reported findings (Bertilson et al 2010; Coster et al 2010). Previous work in the field of radiology confirmed observer performance as an important source of variability in imaging-based diagnostics (Ketler et al 2006). These factors put to question the reliability of MRI findings in detecting nerve root involvement, especially when used to make treatment recommendations or as a prognostic indicator. This is further complicated by the fact that there is not a gold standard diagnostic tool to which MRI can be compared. Even though conventional electro-diagnostic procedures which include current perception threshold testing, electro-myelography and lumbar medial branch blocks are sometimes used as a gold standard for detecting nerve involvement, some researchers have argued that the above tests leave the function of small caliber afferent fibers unexplored, and therefore there is no basis for positive findings (Nygaard et al 2000; Yamashita et al 2002; Manchikanti et al 2003; Coster et al 2010). The current review of the literature therefore sought to establish the sensitivity and specificity of MRI in detecting lumbo-sacral nerve root involvement among patients with low back and referred leg pain.

4.2 Aim of the systematic review

The aim of this review was to determine the accuracy of MRI in detecting lumbo-sacral nerve root compromise, as reported in the literature. The diagnostic accuracy measurements which were established in this review included validity, reliability, sensitivity and specificity.

4.3 Review question

This review answered the following research question: *“In patients with low back and referred leg symptoms, is MRI accurate in detecting nerve root compromise?”*

4.4 Methodology

This review was conducted using the diagnostic tests accuracy (DTA) protocol of the Cochrane Collaboration (2007).

4.4.1 Search strategy

The reviewers developed and conducted a structured literature search from May 2012 up to February 2014 to identify relevant studies in various electronic databases including MEDLINE, CINAHL, Biomed Central, Science Direct, Springerlink, Google scholar, Pubmed, and Embase. No publication date limitation was imposed, thus all databases were searched since inception up to February 2014. The search was performed by the first reviewer (NT), followed by reference tracing of potentially relevant articles complemented by hand searching of field- and topic-relevant journals including reference lists of potentially relevant articles. The search strategy incorporated synonyms, related terms, variant spelling, truncation and Boolean operators.

4.4.2 Study selection

Selection of studies for the purposes of this review was independently performed by two reviewers (NT and ID) using the PICO analysis (Booth and Fry-Smith 2003) and disagreements were resolved through discussion and the opinion of a third reviewer (AR). The studies were pre-screened according to:

- **Participants:** For studies to be included in this review, the sample must have been patients aged 18 years and older presenting with low back and referred leg pain or back-related leg pain, and not previously diagnosed with specific serious pathologies like fractures, tumors and infections of the lumbar/sacral spine causing low back and/or referred leg symptoms.

- **Index tests:** This review only included studies which examined any aspect of MRI parameters relevant to nerve root compromise using screening or limited protocol MRI, routine full protocol MRI, or diffusion-weighted imaging (DWI). The parameters which are relevant to nerve root compression are significant protrusion of inter-vertebral disc material (nucleus pulposus) and spinal stenosis, compromising nerve roots. The reviewers thought it was necessary to only focus on MRI parameters which are specific to nerve root compromise so as to conform to the ISAP definition of radiculopathy.
- **Target Condition:** This review targeted primary diagnostic studies whose main aim was to detect LSR due to nerve root compromise using MRI. Studies whose target condition was other specific causes of LSR (like tumors or infections of the spine) other than nerve root compromise were excluded.
- **Outcomes: Reference standards:** The reviewers included diagnostic studies which compared the accuracy of MRI against acceptable comparators like clinical neurological examination (testing of sensory, motor, tendon reflex and neuro-dynamic properties), pain drawing, fluoroscopic radiculography, electro-diagnostics (EMG), lumbar medial nerve blockade, plain Computed Tomography (CT), CT myelography and intra-operative findings.

4.4.3 Inclusion criteria

The reviewers included primary diagnostic studies which examined the sensitivity and/or specificity of MRI in detecting LSR, compared to a reference standard. Only full reports of cohort and case control studies were included in order to minimise potential sources of heterogeneity.

4.5 Quality assessment

Two reviewers (NT and ID) independently assessed the quality of the four included studies using the Quality assessment of Diagnostic Accuracy Studies (QUADAS) criteria and scoring disagreements between the two reviewers were resolved by a discussion until a consensus was reached.

Each of the included studies was separately assessed for each of the twelve items. Studies were scored as ‘positive’ (+), when the described methodology was of good quality according to the guidelines of the QUADAS criteria, as ‘negative’ (-), when the described methodology was not of acceptable quality, and ‘not sure’ (?), when the methodology was inadequately described.

4.6 Data extraction

The first review author (NT) independently extracted data from the original studies using a self-developed data sheet. Data extraction covered participants (total number, age, gender, clinical characteristics, clinical setting and recruitment period), examiners (number, expertise and experience) and assessment procedure/tools. See appendix XX for this data.



Table 4.2: Characteristics of included studies

Author (year) Country	N (gender, age)	Participants description	Imaging tool	Test results
Hasankhani & Omid-Kashani (2013) Iran	N=152 Male= 96 Female=52 Mean age=43	Radicular pain \geq 6 weeks	Not described	High accuracy (89.5%) of MRI in detecting nerve root involvement.
Eguchi (2011) Japan	N=10 Male =8 Female = 2 Mean age =48.0	Unilateral radicular symptoms caused by a lumbar herniated disk	1.5-T scanner (Achieva 1.5 T Nova Dual; Philips Medical Systems, Japan)	The mean apparent Diffusion Coefficient (ADC) in patients was greater at compressed DRG and distal spinal nerves than in the controls.
Bertilson (2010) Sweden	N=61 Male =12 Female = 49 Mean age = 60	Low-back and referred leg pain	1.0 Tesla scanner (Philips Intera)	MRI-visible nerve involvement at any location and segment was less compared to physical examination.
Thornbury et al (1993) USA	N=63 Male=42 Female=21 Mean age=42	Acute low back and radicular pain	Not described	No difference between the accuracy of MRI, plain CT and CT myelography in diagnosing HNPNC.

4.7 Data analysis

The reviewers extracted, and where unavailable re-calculated the common parameters of diagnostic test accuracy including; sensitivity, specificity, positive likelihood ratio (+LR) and negative likelihood ratio (-LR). Also, true positive, false positive, true negative and false negatives values of all investigated index tests were recorded.

However, as suggested by Pepe et al (2004), diagnostic odds ratios were not calculated in this review due to its limitations in gauging the performance of a diagnostic marker. A meta-analysis was also not conducted given the minimal numbers of included studies in this review. In order to establish the level of agreement between the two observers, a statistical technique was applied by using un-weighted Cohen's Kappa test with 2x2 cross-tabulation in SPSS computer software version 21. The inter-observer agreement between the two reviewers was assessed for each QUADAS item for all included studies. The QUADAS criteria which were developed by Whiting et al (2004) are a methodological checklist which is used to assess the quality and design of primary diagnostic studies. The checklist comprises of questions on the spectrum of the participants who were included in the study, the inclusion criteria, description of target condition, index test and reference standard and interpretation of test results. Kappa (k) values and P- values were considered as indicators in determining the statistical significance of the observed agreement. The inter-observer agreement was considered poor if $k \leq 0$, slight $k \leq 2$, fair $k \leq 4$, moderate $k \leq 6$, good $k \leq 8$ and perfect $k > 8$. Scoring disagreements were resolved through a consensus discussion between the two reviewers (NT and AR) with the arbitration of the third reviewer (ID) until agreement on all items for all the studies was reached. Where necessary, and in cases where raw data were incomplete, a 2 x 2 contingency table was used to re-calculate the diagnostic accuracy values.

4.8 Results

The search on relevant databases yielded a total of 769 articles which were generated by the first hit of the key search terms and the MeSH terms. After removal of duplicates, a screening procedure was done by scanning the abstracts and titles of the search results, twenty-seven articles were pre-qualified as suitable for PICO analysis. Out of the twenty-seven articles, twelve were selected from those that were generated by the entry of the key search terms while fifteen were selected from the output of the MeSH terms.

Full screening of the twenty-seven articles was independently done by two reviewers (NT & ID) using a PICO analysis and nineteen studies were further excluded.

A discussion was held between the two reviewers (NT and ID) with adjudication by the third reviewer (AR) regarding the specific objectives of the eight remaining studies and a further four were excluded because their primary objective was simply to assess the accuracy of MRI in detecting disc herniation and not nerve root compromise. Only four studies were finally qualified for inclusion in this review. Three of the studies (Bertilson et al 2010; Eguchi et al 2011; Hasankhani and Omidi-Kashani 2013) are relatively recent and were done in Iran, Japan and Sweden respectively. The fourth and older study (Thornbury et al 1993) was done in USA. All four studies assessed the accuracy of MRI in detecting lumbar nerve root compromise among patients who presented with signs and symptoms consistent with LSR. Three studies (Thornbury et al 1993; Bertilson et al 2010; Hasankhani and Omidi-Kashani 2013) were cohort studies and used electro-diagnostics, clinical examination and simplified pain drawing and CT myelography as reference standards while the Eguchi et al (2011) was a case control study which used healthy volunteers as controls according to findings on an ordinary MRI. Figure 4.1 below illustrates the search process.

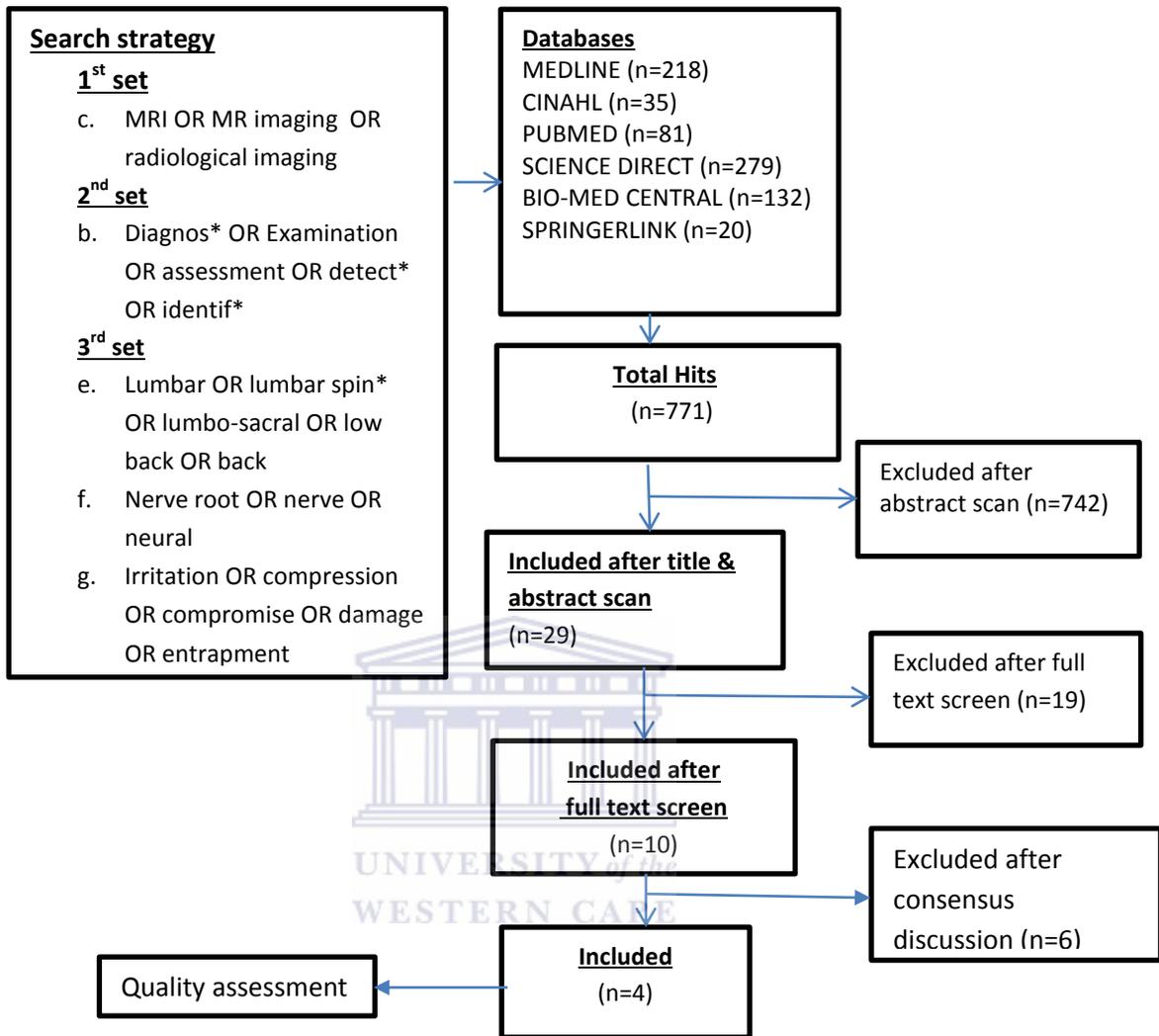


Figure 4.1: Search history

Table 4.1: PICO analysis of retrieved studies

Author (year)	Patients Description	Index test	Comparison	Outcome
Hasankhani & Omidi-Kashani 2013	152 patients 15 years and older Radicular low back pain	MRI	CNE & electro-diagnostics	MRI showed a high + likelihood ratio for nerve root involvement indicating that it is a better modality to confirm radiculopathy.
Eguchi (2011)	18 years and older 10 patients with mono-radicular symptoms	Diffusion-Weighted Imaging (DWI)	Routine MRI	Mean ADC values were significantly greater in the compressed DRG and distal spinal nerves than in intact nerves.
Bertilson (2010)	18 and older 61 patients with long-standing nerve root symptoms	MRI	CNE and simplified pain drawing	Structured physical examination (including CNE), and pain drawing showed more sensitivity than MRI for nerve involvement.
Thornbury et al (1993)	18 and older 95 patients with acute low back and radicular pain	MRI	Plain CT and CT myelography	No statistically significant difference in the diagnostic accuracy of MRI, plain CT and CT myelography in the diagnosis of nerve root compression caused by HNP.

4.9 QUADAS scores of reviewed studies

The final QUADAS scores for the four included studies across all QUADAS items are presented horizontally in Figure 4.4 below and this was calculated as a percentage of the sum of all positive scores divided by the total number of QUADAS items (12). Therefore, the quality scores were 50%, 58% and 75% for Hasankhani and Omidi-Kashani 2013; Eguchi et al (2011) and Bertilson et al (2010) respectively. All studies did not fulfil criteria items 4 and 11, meaning there was no clear explanation regarding the delay between MRI examination and application of the reference standard which might have caused disease progression or recovery bias and also the authors in all four studies did not report uninterpretable results.

Table 4.3: Methodological quality assessment of reviewed studies using QUADAS criteria

Author (year)	Criteria Number												%
	1	2	3	4	5	6	7	8	9	10	11	12	
Hasankhani & Omidi-Kashani 2013	+	+	+	?	+	+	-	-	?	?	+	-	50
Eguchi, et al (2011)	+	?	+	-	+	+	+	+	-	+	-	-	58
Bertilson et al (2010)	+	+	?	-	+	+	+	+	+	+	-	+	75
Thornbury et al, 1993	+	+	?	-	+	+	-	+	?	-	-	+	50
% of maximum	100	75	50	0	100	100	50	75	25	50	25	50	

4.10 Discussion on the accuracy of MRI in detecting lumbar nerve root compromise

The sensitivity and specificity of MRI in detecting lumbar nerve root compromise were extracted from included studies. Diffusion-weighted Imaging (DWI) which uses similar principles and techniques like routine MRI was used in the other reviewed study. It is a recent technological advancement in the field of medical imaging which offers an alternative means to assess the morphology of suspected nerve roots through measurement of the apparent diffusion coefficient (ADC) (Eguchi et al 2011). The two studies which were reviewed gave a satisfactory and elaborate explanation of the imaging equipment and process.

In the Eguchi et al (2011) study, a 1.5-Tesla scanner (Achieva 1.5 T Nova Dual; Philips Medical Systems, Japan) was used for image acquisition. During the examination process, subjects were scanned in supine position using a sense XL Torso coil, and diffusion-weighted imaging (DWI) was performed with a background body signal suppression and short T1 inversion recovery-echo planar imaging sequence. The results indicated that the mean apparent Diffusion Coefficient (ADC) was greater at compressed DRG and distal spinal nerves than in the controls. In this reviewed study, MRI could detect compromises at and below site of compression. In the Bertilson et al (2010) cohort study, a 1.0 Tesla scanner (Philips Intera) was used for image acquisition. Patients were positioned in supine and a phased array spinal coil was used to produce sagittal and axial T1 and T2 spin and turbo spin echo sequences (slice thickness 3mm, inter-slice gap 0.3mm, fields of view 25 cm for sagittal and 16v cm for axial images). The reported outcome was that MRI-visible nerve involvement at any location and segment was less compared to the reference standard of physical examination findings. The sensitivity of MRI in detecting lumbar nerve root compromise was very low at 0.25 (95% CI) while the specificity, which is the probability of getting a negative MRI test result on a patient with negative findings for nerve root compromise by physical examination, was relatively high at 0.92 (95% CI).

4.11 Discussion

This review aimed at establishing the accuracy of MRI in diagnosing lumbosacral nerve root compromise as one of the causes of radiculopathy, and not detection of disc herniation and sciatica. The main finding of this review is that there is not sufficient high quality evidence for or against the use of MRI in diagnosing Lumbo-Sacral nerve root compromise and Radiculopathy. Most previous primary diagnostic studies and reviews focused on the accuracy of MRI in detecting lumbar disc herniation and sciatica, which according to literature (Govind 2004; Carrino et al 2009), is not the only possible bio-mechanical cause of nerve root compromise and radiculopathy, since even bio-chemical agents may also cause nerve root compromise and radiculopathy.

Similarly, it has been reported that MRI cannot detect far-out possible extra-foraminal causes of radiculopathy and that MRI-visible nerve root compromise does not necessarily mean radiculopathy, and vice versa (Pfirrmann 2004).

Therefore, the use of MRI by clinicians in the diagnosis of LSR could only be attributed to various factors ranging from availability of imaging equipment to mere personal preference by clinicians. Because, on the contrary, very little high quality scientific research has been done to investigate the accuracy of MRI in detecting nerve root compromise and radiculopathy.

Also, the results of the Bertilson et al study (2010) indicate that MRI is rather insensitive in detecting nerve root compromise compared to clinical examination. This runs a risk of registering false negatives contrary to a long held notion that MRI (Bertilson 2010).

4.12 Conclusion

MRI is regularly used by clinicians in making a decision of whether to treat a patient conservatively using physiotherapy, rehabilitation and pain medication or consider surgical intervention. There is a documented trend on increasing excessive utilisation and over-dependency on MRI in assessing lumbar spine disorders among clinicians. Therefore, based on the findings of this review, the lack of sufficient high quality scientific evidence in support or against the use of MRI, the on-going debate among experts regarding the cost, diagnostic utility and accuracy of MRI in diagnosing nerve root compression and radiculopathy, clinicians should always correlate the findings of MRI with the patients' medical history and clinical presentation in clinical decision making.

CHAPTER FIVE

VALIDATION AND RELIABILITY OF THE S-LANSS PAIN SCALE AMONG A KENYAN POPULATION.

5. Introduction

The aim of this study was to establish whether the S-LANSS scale is valid and reliable amongst Kenyan nationals with low back and referred leg symptoms. This chapter gives an account of the procedure followed in establishing face and content validity of the original S-LANSS questionnaire, among physiotherapy clinicians and patients in Kenya. Finally, the procedure and statistical tests used to determine the reliability of the slightly adapted version of the S-LANSS tool among a sample of Kenyan patients is presented.

5.1 Neuropathic pain screening

The need for a pathological mechanism-based diagnosis for lumbar spinal and referred pain among clinicians necessitated the development of pain screening tools for research and clinical use (Bennett et al 2001). Pain is widely considered by clinicians as a subjective description and since it is one of the chief manifestations of neuropathic dysfunctions, consideration of patients' verbal descriptors like aching, radiating or lancinating, and the quality of pain could form the basis of clinical differentiation (Bennett et al 2001).

Neuropathic lumbar spinal pain occurs in 23-57% of patients with low back pain and 75% of these cases involve L5 and S1 spinal nerve roots (Robinson et al 2003). The prevalence of lumbar radiculopathy is increasing as the population ages (Smith and Torrance 2012), while diagnosis and treatment remain a challenge in daily practice. Diagnosis and measurement of neuropathic symptoms and signs have evolved in the recent past (Smith and Torrance 2012). Neuropathic pain has a unique patho-physiology and it clinically manifests in specific patterns (spontaneous, paroxysmal or evoked) indicating a particular underlying mechanism (Govind 2004).

It is clinically relevant to recognise neuropathic pain, since it facilitates effective interventions through identification of the underlying patho-mechanisms. There is an apparent agreement in documented reports by various authorities that, differentiating lumbar spinal pain according to the underlying mechanism/source is highly necessary since it would inform clinical decision-making in terms of the structure/mechanism-based treatment (Bennett 2005; Nee and Butler 2006; Schafer et al 2007).

The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) was the first neuropathic pain screening tool to be developed (Bennett et al 2001) compared to all the other neuropathic pain screening tools established in the current literature. A self-report version (S-LANSS) was later developed by Bennett et al (2005). The S-LANSS tool has been widely used both in postal research and clinical settings in countries like Brazil, Turkey, Saudi Arabi and Algeria, to identify patients whose pain is predominantly of neuropathic origin as distinct from somatic nociceptive pain (Yucel et al 2004; Kaki et al 2005; Koc and Erdemoglu 2010; Elzahaf et al 2013). The S-LANSS tool has however not been used for research in any sub-Saharan African countries including Kenya whose socio-cultural demographics differ from those of the United Kingdom which is the source country and Brazil, Turkey, Saudi Arabi and Algeria where the tool has been used.

Clinical application of the S-LANSS tool requires that a patient marks the area(s) of most pain on a body chart and responds to seven questions which assess the patients' back pain regarding the presence of dysaesthesia, autonomic reaction, evoked sensation, paroxysmal reaction, thermal sensation allodynia and hyperalgesia. The psychometric properties of the S-LANSS as reported in the current literature are; sensitivity and specificity ranging from 82% to 91% and 80% to 94% respectively (Bennett et al 2007). When compared to a gold standard procedure like clinical examination in diagnosing pain of pre-dominantly neuropathic origin (POPNO), S-LANSS has a discriminant validity of 73% to 75% when used unaided and 79% to 80% when used in interview format. This indicates a superior diagnostic ability of the S-LANSS tool in detecting POPNO among patients who present with low back pain.

Similarly, the construct validity and Odds ratio for each positive response on the seven items have a mean average of 4.5 (2.2-7.3) towards a total S-LANSS positive score suggestive of POPNO (Bennett et al 2007).

Therefore the S-LANSS tool was the first diagnostic neuropathic tool to be developed and has been widely utilised in most parts of the world other than the African region.

Compared to the other neuropathic pain screening tools, S-LANSS is simple and highly applicable during bedside examination, making it an important and valuable diagnostic tool especially in resource scarce clinical settings of Kenya. Although the S-LANSS scale has been widely used and translated into various local official languages across the world, to our knowledge, the S-LANSS scale has not been translated into a local official African language or clinically validated in an African population. Therefore, by using the procedure explained in Chapter Two of this thesis, the researcher established the face and content validity and reliability of the S-LANSS scale in the Kenyan clinical setting.

5.2 Methodology

5.2.1 Location and setting

The clinical validation and reliability testing of the S-LANSS tool was done in six different hospitals namely Jomo Kenyatta University Hospital, Coast General referral Hospital, Thika Level V Hospital, Kenyatta National Hospital, Mater Hospital and the Aga Khan University Hospital. This study was therefore conducted at the physiotherapy departments of the six hospitals after permission was obtained from the relevant authorities at each of the hospitals. These hospitals were chosen by the researcher because of the reported high capacity of patients with low back and referred leg symptoms consistent with LSR on a daily basis. Also, since all the hospitals are teaching, referral or private hospitals, it was feasible for the researcher to get physiotherapists with clinical experience of five years and more especially in the field of musculoskeletal health.

5.2.2 Validation of the original S-LANSS scale

Population and Sampling

There were approximately 130 registered physiotherapists working in the six selected study centres. A purposive sample of 64 physiotherapists was recruited by the researcher using defined inclusion criteria which are explained below. Furthermore, at least ten prospective patients who presented with low back and referred leg symptoms as indicated by the referring clinician were randomly recruited at each of the participating hospitals. The researcher targeted a sample size of approximately 60 patients based on the minimum daily attendance average of six patients per study centre.

5.2.3 Inclusion and exclusion criteria

All physiotherapists who participated in the S-LANSS validation study were Kenyan citizens who had practiced in an out-patient setting for not less than 5 years, and had expressed voluntary willingness to participate. All patients who participated were aged 18 years and older, had been referred for physiotherapy with low back and leg symptoms and clinical suspicion of LSR, by a referring clinician, and had expressed voluntary willingness to consent and participate in the study. The exclusion criteria for physiotherapists in the S-LANSS validation study were non-citizens, less than five years of clinical experience in musculoskeletal health care, and working or having been working in other specialised areas other than musculoskeletal. For patients, the criteria for exclusion were inability to read and write in English, below the age of 18 years and confirmed state of mental instability by the referring clinician.

5.2.4 Study design

This study composed of two main stages; In stage one, the researcher established the face and content validity of the S-LANSS tool using both quantitative and qualitative methods, while in stage two, the reliability of the adapted S-LANSS scale was tested using a quantitative methodology. The tools and materials, together with the procedures which were used in both stage one and stage two of this study are explained in detail in the subsequent sections of this chapter.

5.2.5 Data collection tools and materials

The data collection tools and materials used for the S-LANSS validation study were the original S-LANSS questionnaire (Appendix VII), a self-developed validation questionnaire (VIII), which was used for recording participants' comments and suggestions regarding the appropriateness of the terms used in the S-LANSS tool and the applicability of the S-LANSS tool in the Kenyan clinical and research setting. Also, consent forms, both for patients and physiotherapists (Appendix IV), participants' information sheets for both patients (Appendix VI) and physiotherapists (Appendix V), an audio recorder for recording the proceedings of the focus group discussions and stationary for verbatim transcription of the audio data was also used in this study.

5.2.6 Data collection procedure

The data collection process for the S-LANSS validation study was conducted from May to August 2012 at different occasions in each of the six participating study centres. The process started with an explanation by the researcher, to the selected physiotherapists, regarding the aim and objective of the process, using the participants' study information sheet (Appendix V). This was followed by obtaining formal written consent from all willing physiotherapists. The researcher then distributed the original S-LANSS tool to all participating physiotherapists together with the self-developed validation questionnaire (Appendix VIII) which was used to capture the participants' responses regarding appropriateness of terms used and applicability of the tool in the Kenyan setting. Immediately after collection of all completed data capture forms a structured focus group discussion was conducted with the participating physiotherapists. The proceedings of the focus group discussions were recorded by the researcher using a voice recording application of a cellular device (Samsung, Duos) and later transcribed verbatim.

On a different occasion at each of the study centres, an appointed research assistant conveniently recruited ten prospective patients with low back and referred leg symptoms, referred for physiotherapy by a clinician.

The aim and objectives of the study together with the expected roles of the study participants was explained by the research assistant to each of the selected patients using the patients' study information sheet (Appendix VI) and formal written consent was obtained from those who expressed voluntary willingness to participate. All recruited patients were then booked on the same day according to their convenience. The original S-LANSS tool was given to the patients for self-completion and returned to the research assistant who then conducted a structured focus group discussion with the same group of patients who had all completed the questionnaire earlier. The proceedings were also recorded using a similar application of a cellular device.

All completed questionnaires and audio materials from all the study centres were kept under safe custody of the appointed research assistant before they were collected by the principal researcher for analysis.

5.2.7 Data analysis

The S-LANSS validation study generated both quantitative and qualitative data. The quantitative data was descriptively analysed and results are presented in frequencies and percentages in a table. While the qualitative data which was collected from both physiotherapists and patient participants were qualitatively analysed by looking at the connections, trends and patterns from the respondents for each of the S-LANSS scale items, while the audio-recorded data from the focus group discussions of both physiotherapists and patients were first transcribed verbatim and then qualitatively analysed by considering emerging common themes and trends from participants' contributions during the discussions. The final results of the face validation process were used as basis for making adaptations to the original S-LANSS score in order to come up with the adapted Kenyan version of the S-LANSS scale.

5.3 Results

5.3.1 Demographic and professional qualities of participating physiotherapists

A total of 64 physiotherapists from the six hospitals in Kenya participated in the S-LANSS validation study. All participating physiotherapists were Kenyan citizens and had a minimum of five years clinical experience in musculoskeletal practice. The demographic and professional characteristics of the physiotherapists who participated in the S-LANSS validation study are presented in Table 5.1 below.

Table 5.1: Characteristics of participating physiotherapists (n=64)

Variable	Category	Frequency	%
Gender	Male	44	69
	Female	20	31
Clinical experience	5– 10	26	41
	11- 14	18	28
	15-20	12	19
	20 and above	8	12
Professional qualifications	Diploma	38	59
	Bachelor's Degree	22	35
	Masters' Degree	4	6

The physiotherapists who participated in the S-LANSS validation process comprised of a majority (69% n= 64) of males compared to females (31 %). Most of the group (41 % n=64) had practised for a period ranging from five to ten years at the time of the study. The majority (59%) of the participating physiotherapists in this current study were holders of a College Diploma in Physiotherapy.

5.3.2 Adaptations on the S-LANSS score

This section provides results of the qualitative data. The changes which were made on the S-LANSS tool were arrived at after considering the similarities on suggestions and recommendations which had been provided by the participants.

The necessary adaptations which were made to the original S-LANSS tool following the group discussion included the following;

- *Replacing the words; “draw” with “mark” in the instructions section of the tool*
- *Replacing the word “bad” with “severe” in the pain scale*
- *Replacing the word “mottle” with spotted in item 2, and*
- *Replacing the word “still” with “at rest” in item 4.*

Similarly, an indication that there are minimal linguistic changes on the original S-LANSS tool following a validation process was put at the top of the adapted version. (Appendix IX).

Figure 5.2 below illustrates the responses of participating physiotherapists regarding the applicability and appropriateness of the S-LANSS tool in the Kenyan clinical context.

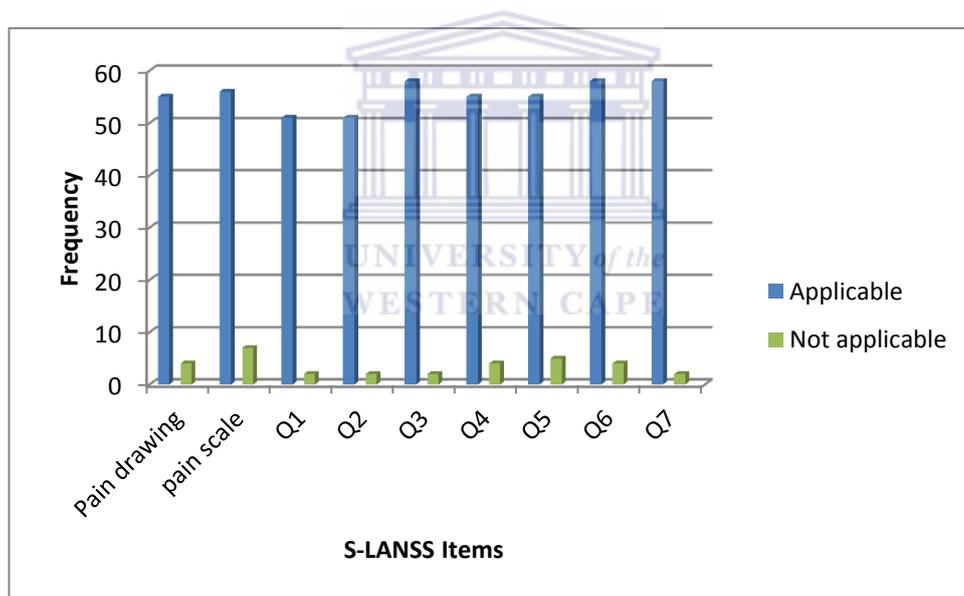


Figure 5.1: Applicability of the S-LANSS scale in Kenya (n=60)

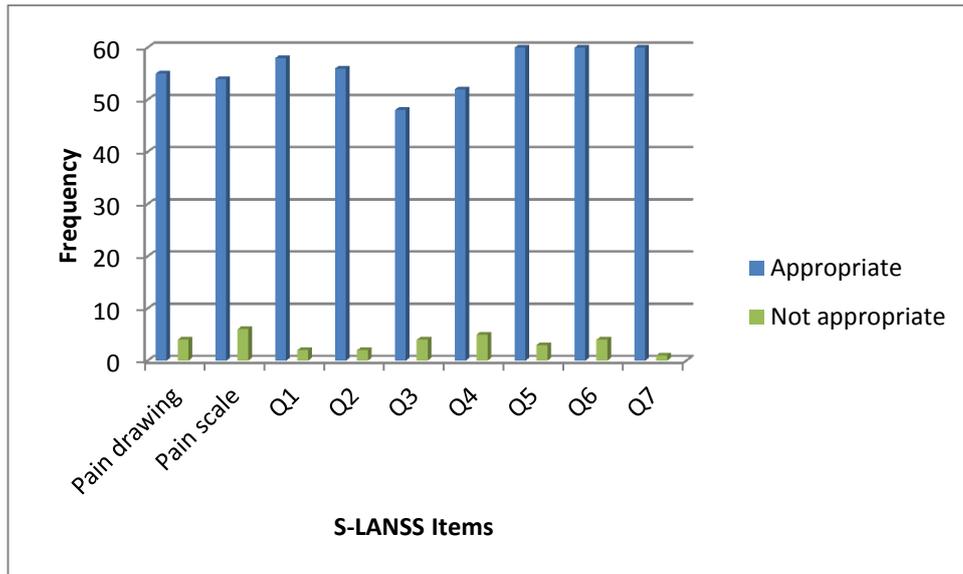


Figure 5.2: Appropriateness of the S-LANSS scale in Kenya (n=60)

5.3.3 Demographic and clinical characteristics of the patient sample

A total of 60 patients (21 males and 39 females) participated in the validation study. All patients at each of the participating study centres had been referred for physiotherapy treatment with low back and referred leg symptoms consistent with LSR.

The majority 72% (n=60) of the patients who participated in the validation study were aged between 42 and 63 years. The patient self-reported pain intensity according to the numerical pain rating scale ranged mainly from moderate (52%) to severe (45%), while 53% of the patients were considered to have pain of predominantly neuropathic origin (POPNO) while the remaining 47% had somatic pain type according to categorisation by the overall S-LANSS score.

Table 5.2 below illustrates the patients' demographics and clinical characteristics.

Table 5.2: Socio-demographics and clinical characteristics of patients (n=60)

Variable	Category	Frequency	%
Age	20-30	5	8
	31-41	12	20
	42-52	24	40
	53-63	19	32
Gender	Male	21	35
	Female	39	65
Numerical Pain Rating Scale	1-3	2	3
	4-6	31	52
	7-9	27	45
S-LANSS pain type	Neurogenic	32	53
	Somatic	28	47

Results from the S-LANSS validation study indicates that there was over 78% (n=60) positive response regarding the appropriateness of the terminologies and words used in the original S-LANSS tool and the applicability of the tool in the Kenyan clinical and research settings. This explains the very minimal and mainly linguistic adaptations which were made in coming up with the generic local version.

5.4 Reliability testing of the adapted S-LANSS scale

5.4.1 Location and setting

The reliability study of the adapted version of the S-LANSS scale was conducted at one study centre which was conveniently selected by the researcher due to its strategic geographical location, easier access for the researcher and also due to its relatively higher out-patients capacity.

5.4.2 Population and sampling

During the reliability testing of the adapted version of the S-LANSS scale, the researcher recruited a convenient sample of twenty prospective patients who had not taken part in the validation study.

5.4.3 Inclusion and exclusion criteria

All patients who participated in the reliability study were aged 18 years and older, had been referred for physiotherapy with low back and leg symptoms and clinical suspicion of LSR by a referring clinician, and had expressed voluntary willingness to consent to participate in the study. The exclusion criteria were inability to read and write in English, and confirmed state of mental instability by the referring clinician such as in the preceding validation study.

5.4.4 Data collection tools and materials

The data collection tools and materials used during the reliability study included the adapted version of the S-LANSS questionnaire (Appendix IX), patients' consent forms (Appendix IV) and participants' information sheets for patients (Appendix VI).

5.4.5 Data collection procedure

In this study, the researcher used a test-re-test procedure in order to determine the reliability of the adapted version of the S-LANSS scale among a sample of twenty prospective Kenyan patients who during the time of data collection presented with low back and referred leg symptoms. For the purposes of this study, participants were conveniently recruited in one study centre. In this stage, patients were invited to participate in the study immediately after they had been registered at the physiotherapy department. An information sheet was used to brief each participant regarding the aim of the study and the expected roles. A willing patient was then requested to complete a formal written consent after which the adapted S-LANSS tool was self-administered for the initial evaluation and an appointment was made for the follow-up evaluation after seven days.

In order to minimise bias and improve independence between the initial and the subsequent S-LANSS evaluations during the reliability testing of the tool, the researcher ensured that the delay between the two evaluations was not too short to allow recall bias or too long to allow disease progression or treatment effects bias which is caused by a change in the attribute or condition under investigation.

According to Streinor and Norman (2003), the researcher therefore used a time interval of seven days between the initial and the subsequent S-LANSS evaluations. Figure 5.1 below illustrates the test-re-test procedure.

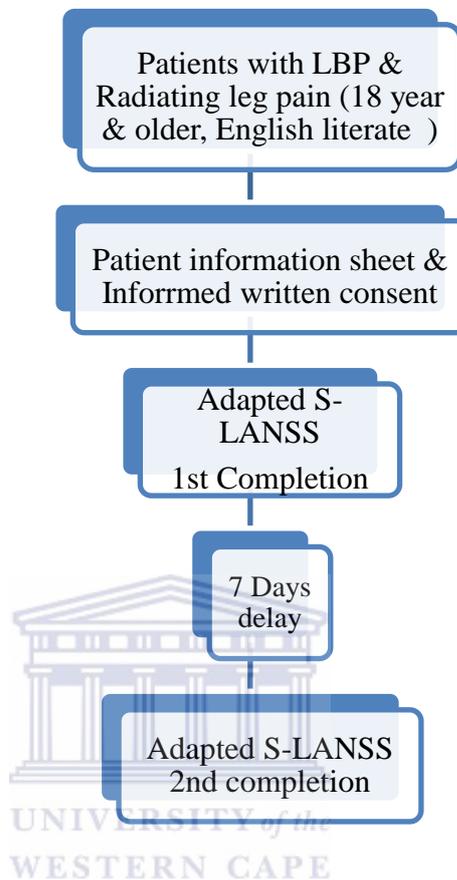


Figure 5.3: Test-re-test procedure

5.4.6 Data analysis

Data from the two S-LANSS evaluations were separately captured on two excel spread sheets of the windows computer software. The researcher extracted nine variables namely: area of pain, pain intensity and S-LANSS questions 1 to 7 in that order.

This was followed by data cleaning where the researcher re-captured the same data on different spread sheets and did a comparison so as to detect any variations. Data coding was also done by assigning numerical values for each variable response, for example 1= low back and 2= low back and leg for variable number two (area of pain). The numerically coded data was then imported to SPSS software version 19 for statistical analysis.

Descriptive statistics were utilised to analyse patients' demographics and clinical characteristics. The researcher also used the un-weighted Cohen's Kappa statistical test to correlate the agreement between the first and the follow-up S-LANSS evaluations. The Kappa correlation coefficient is recommended for establishing reliability of diagnostic ratings in musculo-skeletal research (Sim and Wright 2005). In order to determine the correlation between the initial and the follow-up S-LANSS overall scores of the patients', the intra-class correlation coefficient (ICC) was used. Data from the initial and follow-up S-LANSS evaluations were paired on a nominal scale and computed using a 2×2 cross-tabulation for each variable to evaluate the correlation as judged by the k values, while the statistical significance of the differences detected for each variable was considered using the P values. The test-re-test agreement was interpreted as follows; poor if $k \leq 0$, slight $k \leq 2$, fair $k \leq 4$, moderate $k \leq 6$, good $k \leq 8$ and perfect $k > 8$.

5.4.7 Results (Test-re-test stability)

The test-re-test reliability of the adapted version of the S-LANSS scale had a good intra-class correlation coefficient of $r = 0.81$, 95% CI, while the Kappa correlation coefficient for the measurement of agreement between the individual seven S-LANSS items (dysesthetic pain, autonomic response, evoked sensation, paroxysmal pain, thermal sensation, allodynia and hyperalgesia) was perfect $k = 0.91(0.68 \text{ to } 1.00)$.

5.5 Discussion

This study aimed at establishing the face and content validity of the S-LANSS pain scale in the Kenyan clinical setting. The validation process resulted into minimal linguistic adaptations on the S-LANSS scale which included replacement of the terms "draw, bad, mottle and still" with the words "mark, severe, spotted and at rest, respectively. Also, an indication that there are minimal linguistic adaptations was put at the top of the adapted version of the S-LANSS scale (Appendix IX). Reliability testing demonstrated a good correlation of the overall score of the adapted version of the S-LANSS scale.

The main finding of this study is that the adapted version of the S-LANSS score is valid and reliable for use in the Kenyan setting, both in research and clinical practice, to identify patients whose lumbo-sacral pain has a predominantly neuropathic origin as distinct from those whose pain originates from the musculoskeletal structures. This is clinically relevant because of the fact that the S-LANSS scale is a rapid, low-risk and cost-effective but accurate screening tool which could be used in primary health care settings for early identification of patients with LSR, and considering that Kenya is one of the resource-poor countries in Africa. These findings are in line with similar previous studies which translated or adapted the tool and subsequently evaluated the reliability of the new versions, like in Brasil (Schestasky et al 2011), Turkey (Koc and Erdemoglu 2010), Saudi Arabia (Kaki et al 2005) and more recently Libya (El Zahaf et al 2013). In this study, both the construct validity and discriminant validity of the adapted version of the S-LANSS scale were not calculated because the changes which were made were very minimal and were mainly linguistic and so the psychometric properties of the tool were assumed to have remained constant.

The limitations of this study are: firstly, the sample composed of patients who had been referred for physiotherapy with low back and referred leg symptoms which are highly suggestive of LSR. Therefore the pre-test probability of neuropathic pain among this population was high. Secondly, the high internal consistency of the tool may have been influenced by recall bias caused by the seven days' interval which was preferred by the researcher for fear that the status of the patients' conditions could change if the delay was to be extended beyond seven days or treatment would take effect since patients were allowed to continue with their treatment during the study.

5.5 Conclusion

The adapted version of the S-LANSS scale is a valid and reliable neuropathic pain diagnostic tool. It is suitable for use in busy resource-poor primary care settings of Kenya due to its low cost and user-friendliness.

The S-LANSS scale has the capacity to diagnose the presence of pain of predominantly neuropathic origin (POPNO) among patients with low back and referred leg symptoms, as distinct from somatic low back pain.



CHAPTER SIX

DEVELOPMENT, STANDARDISATION AND RELIABILITY TESTING OF AN EVIDENCE-BASED LUMBAR SPINE CLINICAL NEUROLOGICAL EXAMINATION PROTOCOL

6. Introduction

The aim of this study was to develop and standardise an evidence-based clinical neurological examination (CNE) protocol for patients with low back and referred leg symptoms. This chapter provides an account of the process which was followed in developing an evidence-based lumbar spine CNE protocol using best evidence clinical neurological tests which were identified from selected primary diagnostic accuracy studies, topic-relevant textbooks and opinions of consulted experts in the field. Also, the procedure used to recruit and pre-train the participating physiotherapists on the lumbar spine CNE protocol is explained. The chapter concludes with an account on the inter-examiner reliability testing done to establish the level of agreement among physiotherapists on performing the evidence-based CNE on patients.

6.1 Clinical diagnosis of lumbo-sacral radiculopathy (LSR)

Patients who present with signs and symptoms suggestive of LSR are often at some point in their clinical course referred for physiotherapy when a CNE must detect the presence or absence of nerve root involvement and radiculopathy. The decision of whether to manage conservatively, refer for imaging or consider surgical intervention is largely informed by the patient's medical history and findings on CNE. (Laslet et al 2005; Van Rijn et al 2006; Lee and Lee 2012; Chetty et al 2012). However, the validity and reliability of the clinical neurological findings mainly depends on the examining clinicians' knowledge, clinical skills on execution of the tests and interpretation of the results (Laslet et al 2005). CNE of patients with clinical suspicion of LSR is conducted in order to separate those patients whose pain is neuropathic from those whose pain is of a somatic nociceptive origin. Similarly, CNE is conducted in order for the clinician to identify the specific spinal segmental level involved.

The diagnostic validity of any clinical test is heavily judged by the reliability and validity of the resultant data.

Greater variability among clinicians impacts negatively on the diagnostic accuracy of the clinical neurological tests in detecting lumbar and/or sacral nerve root involvement and ultimately the treatment outcomes (Landel et al 2008; De Luigi and Fitzpatrick 2011). A satisfactory level of inter-examiner reliability forms the basis for valid and uniform clinical decisions on patients' diagnosis and subsequent clinical management. For the purpose of this study, therefore, reliability was the extent to which different participating physiotherapy clinicians could diagnostically agree in distinguishing between neuropathic and somatic nociceptive low back and related leg pain. CNE traditionally consists of tests for the conduction function of the peripheral neural system. These include of dermatomal sensation, myotomal muscle power and deep tendon reflexes (Petty and Moore 2008; Coster et al 2010; Bertilson et al 2010; Lee-Robinson and Lee 2010; Al Nezari et al 2013).

Firstly, testing of skin sensation is always conducted aided by dermatome maps which are known to overlap and differ as evident by the variations among published dermatome maps (Butler 2000; Schaklock 2005; Apok, Gurusinghe, Mitchell and Emsley 2011). These differences are mostly attributed to use of different methodologies in the study of dermatomes. The lack of consensus among experts on dermatome mapping suggests that findings must be correlated with other test results as a guide in locating the symptomatic segmental level. However, this may not always be useful since in some cases the dermatomal sensory changes may not necessarily match the classical patterns of published dermatomes (Nitta, Tajima, Sugiyama and Moriyama 1993). These variations could partly stem from neuro-anatomical anomalies of the lumbar spinal nerve roots like extra-dural inter-segmental anastomosis and overlapping of adjacent spinal segments (Lee, McPhee and Stringer 2008; Taghipour, Razmkon and Hosseini 2009; Apok et al 2011).

Secondly, myotomal strength testing is clinically conducted using functional muscle strength tests and maximal resisted isometric contractions (RICs) (Petty and Moore, 2008 and Butler 2000).

Grading of muscle strength may be practically done using a hand-held dynamometer or the Oxford Manual Muscle Testing (MMT) system with the latter being more susceptible to considerable intra- and inter-examiner variability due to challenges in standardisation of the process (Nee and Butler 2006; Al Nezari et al 2013).

Thirdly, deep tendon reflex testing assesses both afferent input (Mooney and Robertson, in 1976, injected lumbar facet joints with hypertonic saline which abolished the ankle reflex, which could then be restored by a steroid injection), as well as general sensitivity of CNS (Robinson 2003; Schaffer et al 2007). According Suri et al (2011) there is a considerable inter-tester disagreement due to variability in body position, gravity, load on muscle and inhibitory and excitatory stimuli acting on CNS. Similarly, there seem to be no consensus among clinicians with regard to the number of times examiners are supposed to tap or briskly strike the tendon during assessment. Some older musculoskeletal physiotherapy text books (Grieve 1994; Petty and Moore 1998; Maitland 2008) proposed to do six repetitions, while neurology (McLeod et al 1993) and more recent musculoskeletal textbooks only suggest enough repetitions to elicit a good reflex (Butler 2000; Hengeveld et al 2005; Cook and Cook 2011). The grading system also varies from three point (hypo, normal and hyper) (Vroomen et al 2002) to four point (absent, reduced, normal and exaggerated) (Suri et al 2011) probably due to individual preferences by clinicians and researchers or otherwise unknown reasons. These variations in the execution of CNE tests and interpretation of the test results could probably explain the differences in the levels of sensitivity and specificity which has been reported in previous primary diagnostic test accuracy studies (Vroomen et al 2002; Coster et al 2010; Bertilson et al 2010).

Lastly, lower limb neural dynamic tests examine the mobility and mechanical sensitivity status of the lumbar and sacral nerve roots and their peripheral extensions, using the 'Prone Knee Bend' or 'Femoral Slump', and the 'Straight Leg Raise' and/or 'Sitting Slump' tests (Butler 2000; Shacklock 2005).

Neuro-dynamic testing mainly relies on patients' self-report of typical pain reproduction and palpation of protective muscle contraction, with longitudinal loading of the neural structures (Hall and Elvey 1999). Therefore, there is need for clinicians to cautiously interpret neuro-dynamic test results especially when considered in making a clinical diagnosis. The routine CNE of the lumbo-sacral spine has various aspects which include patient positioning, test execution, definition of a positive cut-off, interpretation and documentation of test results.

The patients' final diagnosis, treatment and ultimately the health and functional outcomes depend heavily on how well each aspect of the CNE is conducted. Moreover, each of the CNE components has more than a single specific test. It therefore became highly imperative to have a structured battery of clinical neurological tests which could be standardised among physiotherapists so as to achieve acceptable levels of reliability and for purposes of professional accountability, especially in this era of evidence-based clinical practice. These arguments necessitated the development of the evidence-based clinical neurological examination protocol which would focus on all aspects of clinical testing like appropriate positioning of the subject and the clinician, recommended testing tools and materials, explanation and demonstration of the procedure to the subject, sequence of test execution and interpretation and documentation of test results. The aim of the current study was thus to develop an evidence-based CNE protocol for patients with low back and referred leg pain; to train a sample of Kenyan physiotherapists to be able to follow the protocol and then to establish the inter-examiner reliability of the CNE protocol among the pre-trained Kenyan physiotherapists.

6.2 Methodology

6.2.1 Lumbar CNE Protocol development

The evidence-based CNE protocol for the lumbo-sacral spine was developed following the steps suggested by the New Zealand Guidelines Group (NZGG) framework (NZGG 2011) namely: preparation, design, external review and dissemination. In conformity to the NZGG framework, the evidence-based lumbar spine CNE protocol was developed using the following steps:

Preparation

The preparatory phase of the lumbar CNE protocol development involved formulation of an answerable clinical question, identification of relevant data bases and development of a search strategy as earlier explained in Chapter Two of this thesis.

Design

During this stage, the researcher incorporated the results of the first systematic literature review of Chapter Three on the accuracy of clinical neurological examination in diagnosing Lumbo-Sacral Radiculopathy. As the evidence from these studies was scarce, topic-relevant text books were also consulted (Bogduk and Twomey 1987; Butler 2000; Magee 2007; Petty and Moore 2008; Maitland 2008). Additionally, the opinions of three lecturers on university programmes in the field of musculoskeletal physiotherapy from Australia, New Zealand and the United Kingdom were sought.

All the sources of information included in the protocol development were assigned a level of evidence according to the Oxford Centre for Evidence-based Medicine Levels of Evidence (2001) and the Centre for Reviews and Dissemination Report Number 4 (2001). Relevant information that was extracted and recorded from all these sources covered: positioning of the subjects and clinical examiners, tools and materials used, test execution and interpretation of test results including cut-off for positivity. Where there was a severe gap in published information, opinions of the experts were consulted, and all these were together used as basis for generating the first draft of a CNE protocol for the lumbo-sacral spine.

The first draft CNE lumbar spine protocol was discussed between the principal researcher and the study leaders (ID and AR) and at this stage, any amendments deemed necessary were done in order to come up with the second draft CNE lumbar spine protocol.

External review

During this stage of the lumbar spine CNE protocol development process, the second draft was circulated to a sample of twelve Kenyan physiotherapists together with a peer review form (Appendix XIII) for recording their inputs regarding the relative merits of the protocol to Kenyan physiotherapists, feasibility of the protocol in the Kenyan clinical setting and the overall structure and presentation of the protocol. The physiotherapists who participated at this stage were conveniently selected by the researcher based on their considerable adequate clinical experience of not less than ten years in the field of musculoskeletal physiotherapy and professional qualifications of a Bachelor's degree or more. The protocol was modified where necessary, as a result of their feedback, and this led to the third and final draft CNE lumbar-sacral spine protocol (Appendix X) which was presented to members of the Kenya Society of Physiotherapists (KSP) for endorsement, and in fulfilling the dissemination phase.

Dissemination

The dissemination of the evidence-based lumbar CNE protocol for endorsement by professional colleagues was firstly done during a regional KSP congress on 13th March 2011 in Mombasa County and secondly, during a national KSP AGM and CME on 22nd November 2012 in Thika, Kiambu County. Figure 6.1 below illustrates the development cycle of the evidence-based lumbar spine CNE protocol.

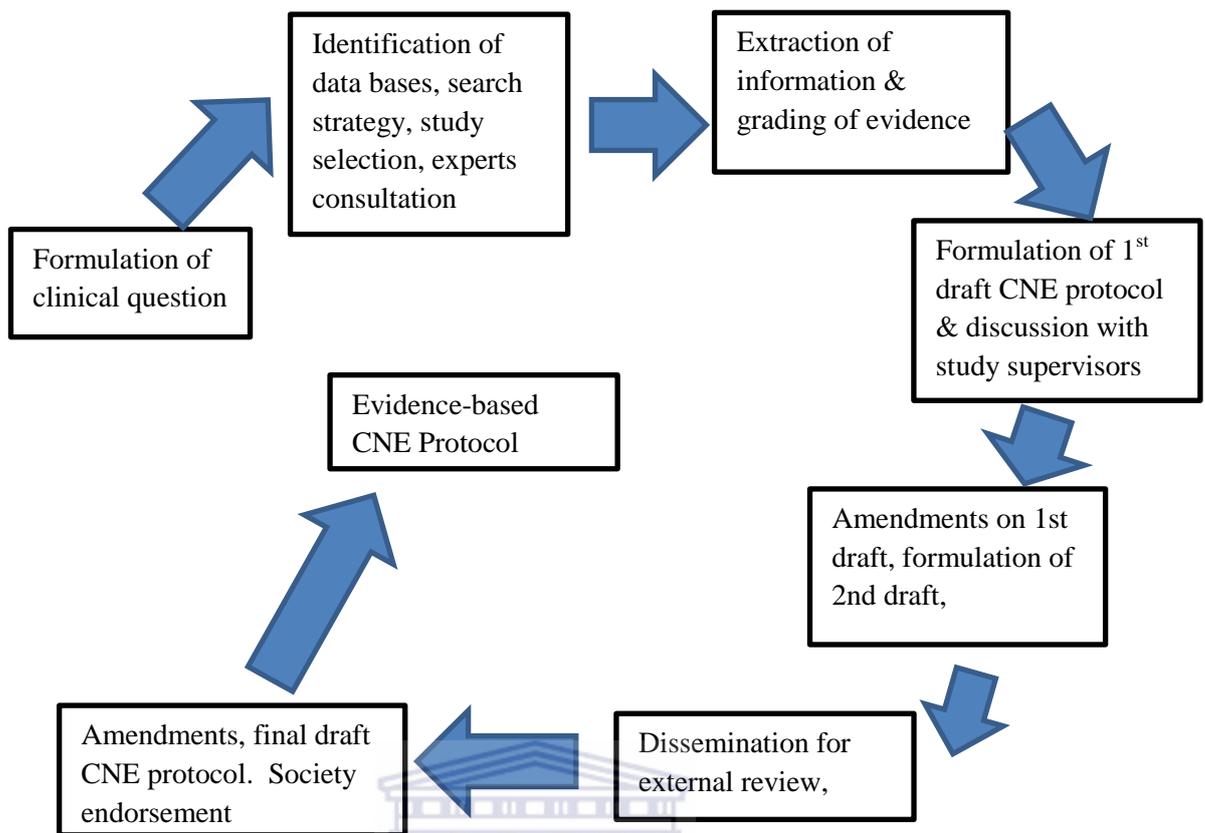


Figure 6.1 CNE protocol development process

6.2.2 Clinical standardisation of the lumbar CNE protocol

Following successful development of the lumbar CNE protocol, a clinical standardisation process among physiotherapists was embarked on, in order to ensure that there is some statistically acceptable degree of reliability in executing the CNE during the main study of chapter eight on correlation of S-LANSS score, CNE and MRI findings in diagnosing LSR. The reliability testing was done among physiotherapists who were going to participate in the main study.

6.2.3 Sampling of physiotherapists

At each of the six study centres, the researcher used a systematic random sampling (SRS) technique to develop a sampling frame of physiotherapists. The inclusion criteria were: five years or more of clinical experience in musculoskeletal physiotherapy and being a physiotherapist registered in Kenya. Every second physiotherapist from the sample frame which was alphabetically arranged, was selected. This criterion was intended to avoid any possible human bias.

Table 6.1: Sampling frame-work for physiotherapists

FACILITY	TOTAL POPULATION	SAMPLE	RECRUITS
Kenyatta National Hospital	46	26	4
Coast general referral Hospital	14	7	4
Aga Khan University Hospital	17	10	2
Mater Hospital	10	5	2
Thika level V Hospital	7	4	2
Jomo Kenyatta University Hospital	36	18	4

From a total population of approximately 130 physiotherapists derived from the six study centres, the CNE standardization process involved eighteen physiotherapists as illustrated in the flow chart diagram below.

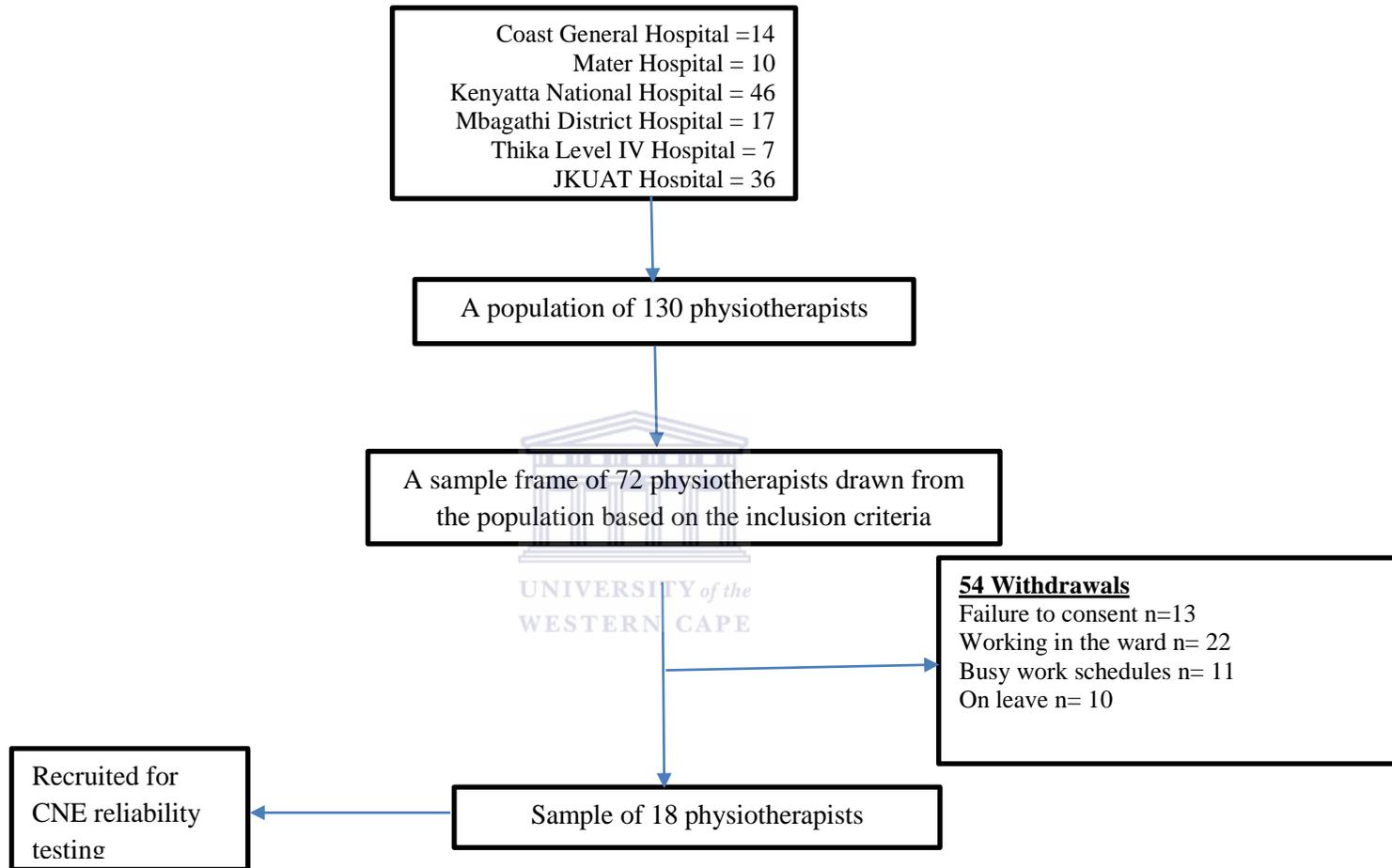


Figure 6.2: Recruitment of participating physiotherapists

6.2.4 Standardisation procedure of the lumbar CNE protocol

The standardisation process was implemented on different occasions at each of the participating study centres. All the recruited physiotherapists were given the participants' study information sheet (Appendix XXII) stipulating the aim, objectives, risks, benefits and expected roles for their participation. The standardisation process comprised of presentations and practical demonstrations by the principle researcher and return demonstrations by the participants until each of the participating physiotherapists acquired proper understanding of the procedures and could demonstrate each of the tests satisfactorily. Standardisation of the lumbar CNE protocol was implemented on different occasions at each of the study centres, as illustrated in Table 6.2 below.

Table 6.2 Lumbar CNE protocol standardization

STAGE	ACTIVITY
STEP 1	Introductory presentation of the main study to give participants a clear picture of the scope of work and significance of standardisation of the protocol through their participation.
STEP 2	Presentation and training on the evidence-based CNE protocol through demonstrations by the principal researcher on consenting models. Follow-up practicals by the participating physiotherapists on consenting models under supervision of the principal researcher.
STEP 3	Examination of consenting patients with the target condition by the researcher in the presence of participating physiotherapists with emphasis on patient's and clinician's positioning, tools/materials, test execution, interpretation and documentation of test results using the CNE data sheet. Re-examination of consenting patients with the target condition by participants witnessed by the researcher. Post-assessment consensus discussion between participants and the principal researcher

6.2.5 Sampling of patients

Using the patients' admission and daily attendance registers in the physiotherapy departments at each of the study centres, an appointed research assistant randomly selected ten prospective patients with the target condition who had been referred for treatment, using a strict inclusion criteria (aged 18 years and older and presenting with low back and referred leg symptoms). A total of sixty patients were recruited for participation from all the six study centres.

6.2.6 Inter-examiner reliability of pre-trained physiotherapists

Upon acquisition of a formal written consent following an explanation regarding the aim and objectives of the study using a patient study information sheet, the consenting patients at each centre were randomly grouped into two: A and B. The research assistant then randomly assigned patients per examiner per group for the initial CNE with the pre-trained examiners blind to the patients' history and the referring clinicians' provisional diagnosis. Without disclosing the initial findings to any of the examining physiotherapists, the research assistant on the same day alternated the patients between group A and B for re-examination by different participating physiotherapists. A coding system was used for participating physiotherapists to ensure confidentiality and anonymity while initials were used to identify patients. The findings were captured in two separate CNE data sheets and secured by the research assistant before they were collected by the principal researcher.

6.3 Data analysis

The data which was collected from the participating physiotherapists, together with that from the experts in the field of musculoskeletal physiotherapy, was qualitatively analysed by considering individual responses in relation to the available best scientific research evidence and clinical practice knowledge. To determine the inter-examiner reliability of the evidence-based lumbar spine CNE protocol among the pre-trained physiotherapists, a statistical technique by use of un-weighted Kappa coefficient test was employed using the SPSS version 21 computer package.

The data from the first and second examinations for each patient was paired in a nominal form and a 2×2 cross-tabulation performed to establish the level of agreement.

6.4 Results

6.4.1 Lumbar CNE protocol

The lumbar CNE protocol (Appendix X) was the outcome of the development process which involved the following steps: formulation of the clinical question, design and execution of the literature search, extraction and appraisal of evidence, designing and drafting the protocol, external review and finally dissemination of the protocol (NZGG 2011). The CNE lumbar spine protocol constitutes the following components in structure and content:

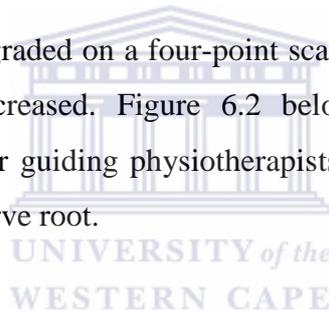
- Definition and abbreviations of the key terms which were used in the main text is provided in the preliminary pages of the protocol followed by brief background information of LSR.
- The main text, a description of the evidence-based CNE of the lumbo-sacral peripheral neural system which is presented as sensory testing, motor testing, deep tendon reflex testing and neuro-dynamic testing.

The *sensory integrity* of each lumbo-sacral nerve root is assessed using light touch sensation and superficial pain sensation by using a soft brush or a piece of cotton wool and a sterile flagged pin, respectively.

The protocol offers guidance on the specific areas of skin to be assessed for each spinal nerve root using a recent published evidence-based dermatome map (Butler 2000 and Lee et al 2008), and the procedure involved in executing the sensory tests as stipulated below:

1. *Establish baseline sensation to familiarize the patient with 'soft touch' sensation on the arm: 'This is how light touch feels' [No indent on skin]*
2. *Patient's eyes closed*
3. *Test one spot in 'signature zone' of the dermatome*
4. *Compare the affected side with the other side with: 'Does this' [touch/stroke twice lightly on a small surface], 'feel the same as this'? [repeat same procedure on other side at exactly the same area/direction/depth]*
5. *If soft touch sensation is impaired, assess superficial/light pain with a sterile flagged pin – touch or tap skin – following the same procedure as for light touch sensation*

Sensory test results are graded on a four-point scale of 0 = absent, 1 = reduced, 2 = normal and 3 = increased. Figure 6.2 below shows the evidence-based dermatome map used for guiding physiotherapists on the target areas of skin to assess for each spinal nerve root.



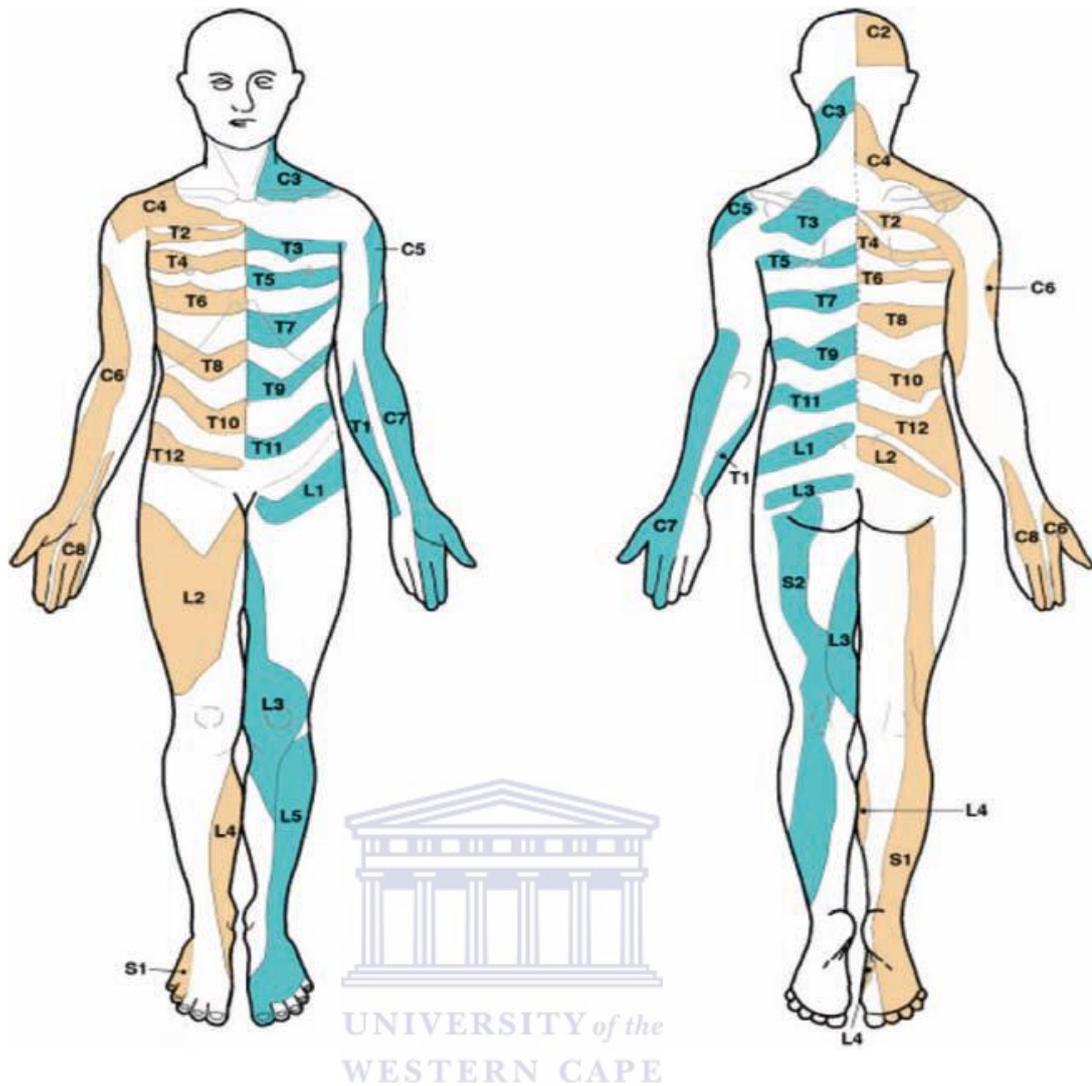


Figure 6.3: Evidence-based dermatomes (Source: Lee et al 2008)

The *motor function* of the lumbo-sacral spinal nerve roots (L₂ to S₂) were assessed using quick functional tests and resisted isometric contractions (RICs), and the test execution was as follows:

1. *Unaffected side, then affected side*
2. *Position the limb in the mid- range of movement, where the therapist can hold the position saying: 'Don't let me move you down/up/in/out'*
3. *Ascertain the correct direction of resistance given to the movement tested*
4. *The therapist gives just enough resistance to meet the motor power of the patient*
5. *The therapist holds the contraction and count: '6,5,4,3,2,1,let go'; and then let go slowly meeting the force of the patient's relaxation of the contraction*

Motor strength of the target muscle/muscle group was recorded on a two-point scale of 0 = diminished and 1 = normal.

Deep tendon reflex testing which makes up the third component of the neuro-conduction function of the peripheral neural system together with sensory and motor function testing was conducted using the routine procedure for both patella and Achilles tendon reflex tests as illustrated below:

1. *The patient is positioned in a stable posture with the tested tendon on slight stretch*
2. *The patella hammer 'fall' on the tendon fibers just next to where it attaches to the bone*
3. *The tendon is tested once if a good contraction is elicited and can be repeated to assure the outcome of the test*

The results of deep tendon reflex testing were recorded in a four-point scale of 0 = absent, 1 = hypo, 2 = normal and 3 = hyper.

The *neuro-dynamic function* of the lumbo-sacral peripheral neural system was assessed using the femoral nerve stretch test (FNST) and the straight leg raise test (SLRT) for lumbar and sacral plexus respectively (Shacklock 2005).

The principles of test execution and documentation of the test results were well stipulated in the protocol as follows:

1. *Patient starting position is specified*
2. *Explain to patient that they must report symptoms [what and where] – note P₂*
3. *Measure height of heel from bed in SLRT and hip E ROM with goniometer in FNST*
4. *What is a positive test? [in this order of importance]*
 - a. *The symptoms of the patient reproduced– record *Sx*
 - b. *Symptoms diminished/increased with addition/subtraction of a distant movement component which does not change the underlying soft tissue stretch. Record which movement*
 - c. *Palpable increase in protective muscle spasm compared to other side – note MSp₂. Record MSp₂ at what ROM*

6.4.2 Clinical standardisation and inter-examiner reliability

The CNE lumbar spine protocol was clinically standardized among eighteen physiotherapists who were drawn from the six participating hospitals. The demographic and professional characteristics of the physiotherapists who participated in the clinical standardisation and inter-examiner reliability testing is provided in Table 6.3 below.

Table 6.3: Socio-demographic and professional characteristics of participating physiotherapists (n=18)

Variable	Category	Frequency	%
Gender	Male	9	50
	Female	9	50
Clinical experience	5– 10	3	17
	11- 14	5	28
	15-20	5	28
	20 and above	5	28
Professional qualifications	Diploma	11	65
	Bachelor's Degree	4	24
	Masters	2	12

The overall level of agreement among the pre-trained physiotherapists in detecting the presence or absence of lumbo-sacral nerve root compromise using the CNE protocol was good $k= 0.71(0.53-0.84)$.

6.5 Discussion

This study aimed at, firstly, developing an evidence-based protocol for clinical neurological examination of the lumbo-sacral spine, using available evidence on clinical tests as established in literature and from experts' opinions, secondly, clinical standardisation of the developed lumbar CNE protocol among a sample of Kenyan physiotherapists and, thirdly, reliability testing of the lumbar CNE protocol among pre-trained Kenyan physiotherapists. The main outcome of the first stage of this study was the evidence-based lumbar spine CNE protocol (Appendix X). This protocol could be used as a guideline for clinicians in the field of musculo-skeletal medicine in the assessment and diagnosis of LSR. In line with the recommendations by the NZZG (2011), the use of the protocol would improve the diagnostic accuracy of clinicians because it was based on best available scientific literature and the opinions of leading experts in the field. Similarly, harmonization of clinical practice through the use of protocols and guidelines is known to minimise variations hence improving professional credibility and patients' confidence (Connis et al 2000, National Institute for Clinical Excellence Guidelines 2001).

For the second and third stages of this chapter, the major outcome was the attainment of a good level of inter-examiner reliability of the pre-trained Kenyan physiotherapists in conducting CNE of the lumbo-sacral spine among patients with low back and referred leg symptoms using the protocol. The findings of the current study contradicts earlier reports of a systematic literature review by Van Trijffel et al (2005) which reported a poor to fair agreement between examiners in conducting passive assessment of intervertebral motion at the lumbar and cervical spine segments. The difference between the current findings of good inter-examiner agreement and the poor inter-examiner agreement reported in the review could be explained by the fact the studies which were included in the review were reported to be heterogeneous and of poor methodological quality.

The findings of the current study are clinically relevant especially in Kenya because it means that clinicians in the field of musculo-skeletal medicine could harmonise the way they conduct clinical neurological examination of the lumbosacral spine if they undergo pre-training using the evidence-based lumbar CNE protocol which was developed in this chapter. Similarly, for the purposes of this research project, the implication of the results is that those physiotherapists who underwent training on the protocol demonstrated an acceptable high level of agreement in detecting the presence or absence of LSR in patients who presented with low back and referred leg symptoms, using the clinical tests stipulated in the protocol and thus they were qualified in participating in the final study on correlation of S-LANSS score, CNE and MRI findings.

6.6 Conclusion

In this chapter, an evidence-based lumbar spine CNE protocol was developed for use by clinicians in diagnosing LSR. The sample of pre-trained physiotherapists demonstrated good inter-examiner agreement in detecting the presence or absence of LSR using the standardised lumbar CNE protocol. This demonstrated their suitability for participation in the final study on correlation of S-LANSS score, CNE and MRI findings in diagnosing LSR. Also, this is evidence that despite the fact that at the time of this study most Kenyan physiotherapists were diploma holders by professional training, the CNE protocol could be standardised among more physiotherapists in the field of musculoskeletal health care to improve the clinical diagnosis of LSR.

CHAPTER SEVEN

VALIDATION AND RELIABILITY TESTING OF A LUMBAR MAGNETIC RESONANCE IMAGING REPORTING PROTOCOL

7. Introduction

The aim of this study was to determine the validity and reliability of a lumbo-sacral Magnetic Resonance Imaging (MRI) interpretation protocol by Kenyan radiologists. A description of the process involved in determining the face and content validity of an adopted MRI reporting protocol by Kenyan radiologists is followed by the procedure regarding establishing reliability of the protocol.

7.1 Utility of MRI in diagnosing Lumbo-Sacral Radiculopathy (LSR)

The MRI has become an indispensable tool for most musculoskeletal health care professionals in the assessment of patients with back-related leg pain, in order to confirm nerve root impingement and radiculopathy (Hollingworth et al 2002; Lysdahl and Hofmann 2009). As seen in the main findings of Chapter four of this thesis on the diagnostic accuracy of MRI, there is not sufficient high quality evidence for or against the use of MRI in diagnosing Lumbo-Sacral nerve root compromise and radiculopathy.

However, there is an emerging trend in over-utilisation and over-dependency on diagnostic imaging, significantly impacting on the costs of musculoskeletal health care services and ultimate patient clinical outcomes (Lysdahl and Hofmann 2009). In attempting to address this clinical challenge, health care policy and practice authorities like the American Agency for Health Care Policy and Research (U.S Department of Health and Human Services 2009) and the New Zealand National Health Committee (National Health Committee 2006) have published referral guidelines for imaging in order to curtail inappropriate and unnecessary investigations.

While the diagnostic value of MRI in assessing normal lumbar anatomy, internal disc chemistry and architecture, features of lumbar spine degeneration and discs have been well documented (Jarvick and Deyo 2002; Weiner and Patel 2008; Carinno et al 2009), its validity and reliability in diagnosing nerve root compromise and radiculopathy is debated in the literature (Bertilson et al 2010; Coster et al 2010; Al Nezari et al 2013).

Experts in the field of neurology challenge the routine utilisation of imaging assessment tests in the evaluation of LSR since the relationship between anatomical and mechanical abnormalities found in the lumbar spine imaging and lumbar radiculopathy remains controversial.

(Hollingworth et al 2002; Weiner and Patel 2008; Bertilson et al 2010; Jensen et al 2007; Kinkade et al 2007) reported that MRI of the lumbar spine has a high rate of abnormal findings in asymptomatic subjects, questioning its diagnostic value in the assessment of LSR. Furthermore, there are documented concerns regarding variability in the interpretation of the abnormalities identified (Bertilson et al 2010; Suri et al 2010) due to various image acquisition methods and non-uniformity of MRI reporting protocols which cause heterogeneity in the reported findings (Coster et al 2010). Previous work in the field of radiology confirmed observer performance as an important source of variability in imaging-based diagnostics (Ketler et al 2006). These, among other factors, question the reliability of MRI findings in detecting nerve root involvement and radiculopathy, especially when used to make treatment recommendations or as a prognostic indicator. These reports indicate that MRI should be carefully applied and interpreted in the patient's clinical context, in the diagnosis of LSR.

7.2 Research question

Is the lumbar MRI reporting protocol developed by Bertilson et al (2010) a valid and/or reliable tool in the Kenyan clinical setting?

7.3 Study aims

7.3.1 To determine the face and content validity of the Bertilson et al (2010) lumbar MRI reporting protocol among selected Kenyan radiologists.

7.3.2 To adapt the Bertilson et al (2010) lumbar MRI reporting protocol, based on the outcome of the validation process.

7.3.3 To establish the inter-rater reliability of the adapted lumbar MRI reporting protocol among the selected Kenyan radiologists.

7.4 Methodology

7.4.1 Setting

This study was conducted at the Kenyatta National Hospital, which is located in Kenya's capital city of Nairobi. KNH is a tertiary healthcare facility which serves as a regional referral hospital for East Africa and teaching hospital for Nairobi University and Jomo Kenyatta University's schools of health sciences.

The researcher chose KNH because it is the largest public tertiary health care facility in the republic of Kenya with a modern radiology and imaging unit and residential specialists in radiology.

7.4.2 Sampling

During the time of data collection, there were twelve experienced radiologists at the Kenyatta National Hospital who were specialised in neuro-radiology. Invitation to participate in the study was extended to all but due lack of willingness to participation among most of the radiologists, a convenient sampling was done to select four independent radiologists. The recruitment of the four radiologists was purely based on clinical experience of not less than five years in the field of diagnostic imaging.

7.4.3 Clinical validation and adaptation

7.4.3.1 Data collection materials

The lumbar MRI reporting protocol developed by Bertilson et al (2010) is a standard protocol based on the author's standard examination methods and other specialized spine care units. For purposes of this study, in collaboration with the participating Kenyan radiologists, the Bertilson et al (2010) was used for recording patients' imaging-based findings of nerve root involvement in MRI tests. The protocol reports findings on disc water content, disc height, high intensity zone (HIZ), medulla signal, spinal canal stenosis, disco-ligament protrusion and bone protuberance (Appendix XIII). These findings are reported in a dichotomised fashion of positive or negative, the positive findings are further graded into grade 1 for slight and grade 2 for significant.

Since the MRI protocol is originally European, it was necessary to have the face and content validity of the tool established among Kenyan radiologists. The validation process focused on the graphical presentation of the protocol, examination coverage, diagnostic parameters, appropriateness of terms used, grading of findings, and applicability of the protocol in the Kenyan clinical practice and research. The reliability testing aimed to achieve acceptable levels of intra- and inter-rater agreement in reporting, as well establishing a standardised protocol among the participating radiologists during the main study. In order to establish the face and content validity of the lumbar MRI reporting protocol among Kenya radiologists, the radiologists' study information sheet (Appendix XII) and consent form (Appendix XI) together with the lumbar MRI reporting protocol and a short researcher-developed questionnaire (Appendix XIV), were used for capturing the responses from the participating radiologists. The researcher-developed questionnaire (Appendix XIV) comprised of seven sections which were assessing different aspects of the MRI lumbar reporting protocol namely; graphical outlook, examination coverage, examination parameters, appropriateness of the protocol in clinical and research application in the Kenyan setting and the grading system.

7.4.3.2 Procedure

The clinical validation process was conducted from June to August 2013. Firstly, the original lumbar MRI reporting protocol was sent to the four participating radiologists with the short researcher-developed face value evaluation form (Appendix XIV), radiologists' information sheet (Appendix XII) and consent form (Appendix IV). The researcher-developed face value evaluation form was used to capture inputs of the participating radiologists regarding the following specific items of the lumbar MRI reporting protocol which was developed by Bertilson et al (2010): graphical presentation, examination coverage, examination parameters, appropriateness of terms used in Kenyan context, applicability in clinical practice and research and the grading system.

The completed short questionnaires were then collected from the four radiologists for analysis. All questions, suggestions and recommendations which arose from the participating Kenyan radiologists during the validation process were shared with the lead author of the protocol (BC Bertilson) who is a specialist in musculo-skeletal medicine (Karolinska Institute, Sweden). The lead author then clarified the questions to the satisfaction of the participating Kenyan radiologists.

7.4.3.3 Data analysis and results

Data was qualitatively analysed by considering similarities in the responses provided by the participating radiologists for each of the seven items. The outcome was considered as basis of making the necessary amendments to the original lumbar MRI reporting protocol. The changes made were: translating the Swedish terms "*dexter*" and "*sin*" into "*right*" and "*left*", changing of "*Patient ID*" in the bio-data section of the protocol into "*O/P No.*", as out-patient number as commonly used in Kenya, and deleting spinal levels *T9-10*, *T10-11*, *T11-12*, *T12-L1* and *L5-6* because they were beyond the scope of the current study and not related to the aim of the current study. (See Appendix XV for the final protocol). The changes were mainly linguistic and partly graphical, an indication that the adapted version was not different from the original version in terms of psychometric properties.

7.4.4 Reliability testing

7.4.4.1 Data collection materials

The inter-rater reliability of reporting by the four participating radiologists on 20 MRI films of patients was tested. The clinicians used the adapted lumbar MRI reporting protocol, to retrospectively report on films of patients referred earlier by their clinicians for MRI due to low back and referred leg symptoms. All the MRI films used had been acquired using a 1.0 Tesla scanner (Philips Intera), an imaging device which has a dedicated phased array spinal coil which produces sagittal and axial T1 and T2 spin and turbo spin echo sequences.

This equipment also produces magnetic resonance images with a 3mm slice thickness, 0.3mm inter-slice gap and 25cm and 16cm fields of view for sagittal and axial images respectively, making it possible for a multi-level assessment of the lumbar and sacral spines (Bright 2011; Brown and Semelka 2011).

7.4.4.2 Procedure

The inter-rater reliability of the adapted lumbar MRI reporting protocol among the four participating Kenyan radiologists was assessed in November 2013. The process started with the research assistant administering the study information sheet to the participating radiologists followed by obtaining their formal written consent. The four participating radiologists were then randomly divided into group A and B. With each observer blind of the other, the research assistant randomly assigned five imaging films per radiologist per group who then performed the initial evaluation. The reports of the initial evaluation were collected by the research assistant for safe and secure storage, and on a different day, the research assistant then alternated the imaging films between radiologists in group A and B for them to perform the second evaluation of films which had been previously reported by another radiologist, without knowledge of the findings of the initial evaluation. The reports of the second evaluation were collected by the research assistant, and together with those of the first evaluation were confidentially sent to the principal researcher for analysis.

7.4.5 Data analysis

Data from radiologist group A and group B for each of the twenty lumbar MRI films were separately captured on two excel spread sheets of the windows computer software, the researcher extracted eight variables namely; disc water content, disc height, annular fissure, medulla signal, spinal canal stenosis, disc protuberance and disco-ligament and bone restriction. This was followed by data cleaning where the researcher re-captured the same data on different spread sheets and did a comparison so as to detect any variations. Data coding was also done by assigning numerical values for each variable response, for example, in the variable disc water content: 0= normal, 1= slight decrease and 2= significant decrease. The numerically coded data were then imported to SPSS software version 19 for statistical analysis. Simple descriptive statistics were used to analyse patients' imaging findings. The researcher also used the un-weighted Cohen's Kappa statistical test to establish inter-rater agreement per variable between the reporting radiologists for each of the fourteen imaging parameters including disc water content, disc height, annular tears, lateral recess among others, and to determine the concordance of the radiologists' final imaging report regarding the presence or absence of MRI-visible lumbo-sacral nerve root compromise. Data from radiologist A and radiologist B for each individual lumbar MRI film were paired on a nominal scale and computed using a 2×2 cross-tabulation for each of the fourteen variables to evaluate the level of agreement as judged by the k values. The statistical significance of the differences detected for each for each variable was considered using the P values. The inter-rater reliability was interpreted as follows; poor if $k \leq 0$, slight $k \leq 2$, fair $k \leq 4$, moderate $k \leq 6$, good $k \leq 8$ and perfect $k > 8$.

7.5 Results

The inter-rater reliability testing was done using twenty retrospective MRI films which were reported twice by the participating radiologists. The overall inter-rater agreement between the four participating radiologists on diagnosing LSR due to nerve root compromise (significant spinal canal stenosis and protrusion/protuberance grade) on lumbar MRI using the adapted reporting protocol was moderate $k = 6$.

7.6 Discussion

This study, firstly, aimed at establishing the face and content validity of an adapted lumbar MRI reporting protocol among Kenyan radiologists. The validation process resulted into minimal linguistic and graphical adaptations, while the reliability testing showed fair level of agreement between radiologists in diagnosing LSR due to nerve root compromise.

The linguistic and graphical adaptations which were incorporated in the protocol were meant to maximise attainment of equivalence between the original protocol and the adapted version of the protocol, since it was going to be used in the target clinical setting (Kenya) which is different from the source setting (Sweden). This is in line with the recommendations made by cross-cultural and linguistic validation guidelines for psychometric health measurement tools (Beaton 2000).

The main finding of this study is that there was a considerable level of variations in reporting of MRI-visible nerve root involvement by Kenyan radiologists using the adapted version of the MRI lumbar reporting protocol.

This is in line with similar previous studies by Bertilson et al (2010), who, when using the original version of the MRI reporting protocol, reported only poor to fair level of agreement among neuro-radiologists in detecting nerve root involvement at L4-L5 and L5-S1 segmental levels. The findings of this study and the Bertilson et al (2010) study are however contrary to those of Weiner and Patel (2008) and Carrino et al (2009) who reported sufficient agreement between radiologists in interpretation of general lumbar spine MRI characteristics. The difference between the poor to fair agreement reported in this study and that of Bertilson et al (2010) and the good to perfect agreement reported earlier by Weiner and Patel (2008) and Carrino et al (2009) could be that the current study focused on nerve root compromise-related parameters and not general characteristics like disc degeneration, modic changes or spondylolisthesis. The evident variations may also stem from the apparent lack of a standard cut-off for a nerve root compromise on MRI.

Therefore, the clinical implication of the key findings of this study agrees with previous studies (Ketler et al 2006; Wainer and Patel 2008; Carrino et al 2009) that MRI findings should be interpreted within the context of the patients' medical history and clinical examination findings, especially when considering to make a decision regarding the patients' management. However, a limitation of this current study could be that the examiners were general radiologists and not neuro-radiologists, as in previous similar diagnostic studies.

7.7 Conclusion

This study firstly established the face and content validity of a lumbar MRI reporting protocol which was developed by Bertilson et al (2010). Secondly, linguistic and graphical adaptations were made on the original protocol which lead to an adapted version of the lumbar MRI reporting protocol which was validated in the Kenyan setting prior to the main study of Chapter Eight on correlation of the S-LANSS score, CNE findings and MRI findings in patients with LSR. Thirdly, a moderate inter-rater agreement between participating Kenyan radiologists was established.

Therefore, the key findings of this study affirm the cautions suggested by authors of previous studies in the field that there is a significant variation in the detecting LSR due to nerve root compression-related MRI findings among radiologists. This questions the diagnostic credibility of MRI reports in diagnosing LSR, and therefore supports the need to correlate MRI findings with the patients' medical history and CNE findings, especially in making a decision of whether to manage the patient conservatively using pharmacological agents and physiotherapy, or to consider surgery.

Finally, for the purpose of this research project, this study prepared the participating radiologists to use the adapted lumbar MRI reporting protocol in the main study, as well as clinical settings for harmonization of MRI reporting among Kenyan radiologists, which may ultimately minimise variation in reporting.

CHAPTER EIGHT

THE CORRELATION OF THE SELF-REPORTED LEEDS ASSESSMENT OF NEUROPATHIC SYMPTOMS AND SIGNS SCORE, CLINICAL NEUROLOGICAL EXAMINATION FINDINGS AND MAGNETIC RESONANCE IMAGING FINDINGS IN PATIENTS WITH LUMBO-SACRAL RADICULOPATHY

8. Introduction

In order to make a clinical decision regarding the treatment of patients who present with Lumbo-Sacral Radiculopathy (LSR), clinicians consider the findings of various available diagnostic tools and procedures which include neuropathic pain screening tools, clinical neurological examination tests, radiological imaging and electro-diagnostic studies (Al Nezari et al 2013; Kreiner et al 2013). However, in the assessment of LSR, clinicians are encouraged to correlate the findings on patients' medical history, physical examination and imaging because of the shortcomings of each of these tests when considered individually (Modic et al 2005; Bajpai et al 2013). The correlation of all commonly used tools and procedures in the assessment and diagnosis of LSR has not been reported in the reviewed scientific literature.

8.1 Examining methods for identification of neuropathic pain

In the initial clinical assessment of patients who present with clinical suspicion of LSR at the primary healthcare level, a thorough medical history taking and clinical examination is sufficient for assessment and treatment since the primary purpose is to identify any 'red flags' and to make a specific diagnosis (Chou and Qaseem 2007; Kreiner et al 2013; Al Nezari et al 2014). Radiological examination (X-rays, Computerized Tomography and Magnetic Resonance Imaging) together with bio-chemical laboratory tests (full blood count and Erythrocyte Sedimentation Rate) are not recommended in the first 4-6 weeks of acute LBP since they do not provide any clinical benefit unless there are red flags (Qaseem et al 2007; National Institute of Clinical Studies 2008).

LSR pain has a unique patho-physiology and it clinically manifests in specific patterns, indicating a particular underlying mechanism (Robinson 2003; Govind 2004; Smart et al 2009), and needs to be differentiated from somatic or visceral referred leg pain. Therefore, early and accurate diagnosis of LSR is important to facilitate effective interventions through identification of the underlying patho-mechanisms.

Current clinical practice advocates for differentiation of lumbo-sacral spinal and leg pain according to the underlying mechanism and source as very necessary, since it would inform therapeutic clinical decision making in terms of a structure/mechanism-based treatment (Schafer et al 2007).

Diagnostic neuropathic pain screening by use of the S-LANSS has for the past decade become a quick and cost-effective bedside assessment option for clinicians in detecting the presence of a neuropathic source to patients' low back and/or leg pain (Yucel et al 2004; Bennett et al 2005; Kaki et al 2005). The S-LANSS score has been reported to have significant levels of sensitivity and specificity in detecting LSR (Koc and Erdmoglul 2010; El Zahaf et al 2013), and therefore, the diagnostic correlation of this low-risk and cost-effective tool with other commonly used tools and procedures like CNE and high-technology MRI should be investigated so that it can be considered as an option in the event that other tests are medically contra-indicated, unavailable or even to confirm or rule out the presence of LSR when used along-side other diagnostic measures (Bertilson et al 2010).

Clinical neurological examination is another method of diagnosing LSR. CNE is not only important for the identification of whether or not LSR is present, but also for anatomic localisation of radicular symptoms. If properly conducted, it could detect or exclude the presence of nerve root impingement based on particular physical findings (Jarvik and Deyo 2002). Determination of the presence or absence of LSR is dependent upon the examiner's awareness of typical clinical signs and symptoms, and knowledge of possible pathology and/or mechanisms of injury.

It also depends on the accuracy of physical examination and ability to perform the tests correctly (Coster et al 2010; Al-Nezari et al 2013; Kreiner et al 2014). However, clinical examination has been reported to have a high prevalence rate for positive symptomatic findings correlating poorly with MRI in the clinical prediction of the symptomatic spinal segmental level, a discrepancy that could be of great clinical concern to surgeons (Van Rijn et al 2006). Anatomical localisation of the symptomatic spinal structure responsible for patients' radicular symptoms is important when using targeted treatments like physiotherapy, manual therapy and surgery. These interventions often rely on clinical examination findings of dermatomal sensation, myotomal muscle power and tendon reflex testing, which are commonly used to diagnose LSR (Van Der Windt et al 2010; Van Boxem et al 2010). Therefore, since CNE tests are commonly used in diagnosing LSR, and neuropathic pain screening tools have shown significant levels of accuracy in diagnosing LSR, it becomes necessary to investigate the correlation of S-LANSS score, CNE findings and MRI findings in diagnosing LSR.

MRI is often used to detect nerve root involvement in patients who present with clinical suspicion of LSR (Bertilson et al 2010; Kreiner et al 2014). However, in a study on correlation of CNE, pain drawing and MRI (Bertilson et al 2010), it was noted that MRI is insensitive compared to CNE and pain drawing in detecting the symptomatic spinal level of LSR. Although there are no documented reports on a significant association between segmental distribution of back and leg pain and the presence of MRI-visible nerve root involvement (Beattie et al 2000), one study has shown that severe MRI-visible nerve root compromise is associated with distal leg pain which is a clinical sign of lumbar nerve root involvement and radiculopathy (Bertilson et al 2010). Even though the accuracy of MRI in diagnosing disco-genic radicular symptoms has been reported (Patel and Lauerman 1997; Pfirrmann et al 2004), it is known that radiculopathy could also be caused by far-out extra-foraminal spinal stenotic lesions of which MRI is incapable in detecting (Haigi et al 2006).

Therefore in patients with MRI negative findings on nerve root involvement, other diagnostic measures should be considered in detecting the presence of lumbosacral nerve root compromise and radiculopathy, hence the need to know which diagnostic tools correlate with MRI in diagnosing LSR.

On the other hand, not all MRI-visible reports of nerve root compression are symptomatic. Medical literature has consistently reported that abnormal imaging findings in patients with LSR are in some instances coincidental hence the need to correlate radiological imaging findings with the findings of other tests (Hoogendorn et al 2000; Van Rijn et al 2005; Weiner and Patel 2008). Hence correct application and understanding of the limitations of MRI examination is widely advocated for in the assessment of patients suspected with LSR (Chou and Qaseem 2007; Kreiner et al 2013; Al Nezari et al 2014). The routine utilisation of MRI in isolation, in diagnosing LSR has been consistently challenged in the fields of neurology and musculoskeletal health (Weiner and Patel 2008; Bertilson et al 2010). Even though there is no single gold standard diagnostic test for diagnosing LSR, this fact is contrary to the present clinical practice where MRI is used as the reference standard in making a clinical decision of whether or not to operate (Bertilson et al 2010). The results of studies (Weiner and Patel 2008; Bertilson et al 2010) indicate that MRI should be carefully applied in the diagnosis of LSR and that findings must be interpreted in the patient's clinical context and in relation to the findings of other tests.

Since there is evidence that not all MRI-visible nerve root compromise is clinically relevant (Modic et al 2005; Carrino et al 2009), and that MRI is relatively costly and may not be available in most primary care settings in resource-poor countries, it therefore becomes highly imperative to explore how MRI correlates with other quick and cost-effective bed-side diagnostic options like the S-LANSS pain scale and standardised CNE in diagnosing nerve root compromise and radiculopathy.

8.2 Diagnostic value of examining methods for neuropathic pain

The individual diagnostic utility and/or accuracy of the S-LANSS, CNE and MRI in diagnosing LSR has been explored in previous diagnostic accuracy studies (Bennett et al 2007; Coster et al 2010; Bertilson et al 2010). Firstly, the S-LANSS has been reported to have the ability to discriminate between patients whose low back pain has a neuropathic component as distinct from somatic pain type (Yucel et al 2004; Bennett et al 2007; Koc and Erdumoglu 2010; El Zahaf et al 2012). Diagnostic neuropathic pain screening using the S-LANSS (Bennett et al 2007; El Zahaf et al 2012) has high levels of accuracy in diagnosing pain of predominantly neuropathic origin (POPNO). Secondly, CNE tests has varied reported accuracy (Trainor and Pinnington 2011; Suri et al 2012; Iversen et al 2013) and has high levels of accuracy in diagnosis of radicular pain (Al Nezari et al 2013; Krenire et al 2014). Bed-side application of the S-LANSS and CNE in clinical practice is quick, low-risk and cost-effective (Bennett et al 2007; Al Nezari et al 2013; Kreiner et al 2014). Thirdly, while MRI is preferred for its non-ionizing radiation and superior soft tissue visualisation (Kreiner et al 2014), a systematic literature review (Chapter Four) on the accuracy of MRI in diagnosing lumbo-sacral nerve root compromise and radiculopathy, demonstrated that MRI is rather insensitive compared to CNE, and that there is a great paucity of high quality research evidence to support or refute the use of MRI in detecting nerve root compromise and radiculopathy. Despite this, MRI, a relatively expensive and often unavailable diagnostic option, has become a diagnostic tool of choice among clinicians (Bertilson et al 2010; Wassenaar et al 2011).

Assessment of the correlation of these commonly utilised diagnostic tools and procedures in diagnosing LSR has thus become highly imperative in order to establish whether, by using the S-LANSS and CNE, clinicians could predict MRI findings and make therapeutic decisions.

This is important especially in instances where MRI is unavailable, unaffordable or medically contra-indicated. In a study by Van Rijn et al (2006), on the correlation between clinical examination and MRI in detecting the level of disc-related nerve root compression, results indicated that there was no exact match on the level predicted by clinical examination and MRI findings, such discrepancies complicate the decision on the treatment of patients.

A more recent diagnostic correlation study (Hemmo et al 2012) which compared the agreement between clinical examination, MRI and epiduroscopy in detecting the spinal origin of leg pain indicated that epiduroscopy correlated fairly but significantly with both MRI and clinical examination in determining the spinal level where significant spinal pathology occurs in patients with LSR.

In the assessment and diagnosis of LSR, clinicians commonly use diagnostic tools and procedures in an attempt to establish the presence of nerve root involvement in order to make appropriate therapeutic decisions on whether to manage a patient conservatively or consider further investigations and surgery. A significant diagnostic correlation between clinical examination of the lumbo-pelvis region by physiotherapists, compared to radiologists' diagnostic technology, has been reported (Laslet et al 2005; Hansani and Omid-Kashani 2012). Information on the diagnostic correlation of the various tools and procedures is crucial to clinicians in order to facilitate clinical decision making in the event that a certain preferred diagnostic tool is contra-indicated on a particular patient or unaffordable or even unavailable. Therefore, the aim of the final and main study was to determine a diagnostic correlation between a clinically validated adapted version of the S-LANSS score, results of a developed evidence-based lumbar CNE protocol, and lumbar MRI reports, among patients with complaints of low back and referred leg symptoms. This chapter of the thesis addresses the sixth specific objective of the study.

8.3 Methodology

8.3.1 Study design

The correlation between the SLANSS score, CNE findings and MRI findings was investigated using a cross-sectional multi-centre blinded design. In this study, the researcher examined the diagnostic correlation of the three tools through a blinded test execution and interpretation of the test results. As a cross-sectional multi-centre research study, data collection was separately conducted from March 2014 to June 2014 in six different physiotherapy departments in Kenyatta National Hospital, Coast Province Referral Hospital, Jomo Kenyatta University Hospital, Thika Level 5 Hospital, Mbagathi District Hospital and The Mater Hospital, as mentioned in Chapter Two of this thesis.

The study was conducted within the Standards for Reporting of Diagnostic Tests (STARD) framework (Simel et al 2008), which is used for diagnostic test accuracy (DTA) studies. Table 8.1 below illustrates the application of the STARD framework in the current study.

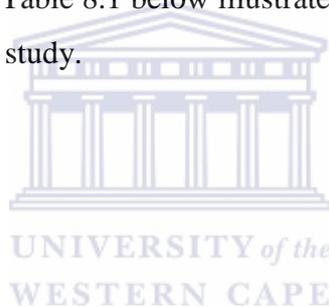


Table 8.1: Application of the STARD framework guidelines

STARD CRITERION	STARD GUIDELINES	APPLICATION IN THE MAIN STUDY
1	Specification of clinical examiner's attributes in terms of profession, qualifications and clinical experience.	Clinical examiners included Physiotherapists and radiologists who had clinical experience of 5 years and above. The physiotherapists had a minimum of a college diploma while the radiologists Masters in diagnostic radiology.
2	Clear description of patient's attributes including age and gender	Inclusion criteria were set for both male and female patients aged 18 years and older.
3	Clarity and specification of the target condition	Only subjects with low back pain and referred leg symptoms, which is a clinical suspicion of LSR were included in the main study.
4	Standardisation of measurement tools and processes through pre-training of participating clinicians	The participating physiotherapists were pre-trained on the lumbar CNE protocol and inter-examiner reliability was established prior to the main study. The participating radiologists were also pre-trained on the lumbar MRI reporting protocol, and inter-rater reliability was established prior to the main study.
5	Acceptable time-lapse between the index test and the comparator test or reference standard	The S-LANSS and CNE which comprised the index tests were performed on the same day, while the MRI (reference standard) had been performed maximally 48 hours prior.
6	Blinding of clinical examiners	The 1 st examination was the S-LANSS which was patient self-administered and the results were collected by an independent research assistant. The 2 nd examination was CNE which was performed by an independent physiotherapist blind to the S-LANSS score. The 3 rd examination was lumbar MRI reporting by an independent pre-trained radiologist blind to both the S-LANSS and CNE results. The principal researcher separately received the three sets of results from the collection points.

Key

STARD: Standards for reporting of diagnostic test

LSR: Lumbo-Sacral Radiculopathy

CNE: Clinical neurological examination

MRI: Magnetic resonance imaging

S-LANSS: Self-report Leeds assessment of neuropathic symptoms and signs

8.3.2 Sample size determination

Sample size calculation was performed by using both precision and power analyses which were aimed at controlling type-1 error (false positive) and type-2 error (false negative) (Bartlett, Kotrlik and Higgins 2001). In this study, both the S-LANSS scale and the lumbar CNE were used as index tests compared to MRI, the reference standard. Therefore, a type-1 error (false positive) was a positive test result on either S-LANSS or CNE or both in patients with negative MRI reports of lumbo-sacral nerve root compression and radiculopathy. On the other hand, a type-2 error was a negative test result on either S-LANSS or CNE or both in patients with positive MRI reports of lumbo-sacral nerve root compression and radiculopathy.

An appropriate sample size was informed by a retrospective review of physiotherapy admission and attendance records of patients who presented with low back and referred leg pain conducted at each of the six study centres for the preceding year 2013, to determine the monthly average attendance. The total average from all six study centres was then considered as the population (N) of patients with the target condition, from which the study sample (n) was derived from using the Cochran formula (Cochran 1977). The number of patients to be recruited from each department was calculated as a proportion of the department's monthly average from the population (N):

$$n = \left\{ \frac{NP(1-P)}{d^2/z^2 - \alpha/2(N-1) + P(1-P)} \right\}$$

where **n** = Sample size, **N** = Target population, **P** = Prevalence of target condition, **d** = Margin of error and **z** = Standard deviation. This study therefore targeted a total of approximately 104 participants from the six centres. The number of targeted participants for each of the six study centres was calculated as a proportion of the sum total from all study centres (N) from the monthly average for each study centres, and is as follows: nineteen from Jomo Kenyatta University Hospital, twenty-three from Thika Level V Hospital, seventeen from Coast province referral Hospital, twenty-two from Kenyatta National Hospital, ten from Mater Hospital and fourteen from Mbagathi District Hospital.

8.3.3 Participants' recruitment procedure

At each of the six study centres, a research assistant (a qualified physiotherapist) consecutively identified and recruited eligible patients who were receiving treatment at the physiotherapy departments and had met the inclusion criteria.

The recruitment was done until the intended target for each particular study centre was reached. Both the participants' recruitment and data collection processes were conducted from March to June 2014 in all six study centres.

8.3.4 Inclusion and exclusion criteria

This study recruited both male and female patients aged 18 years and older who, at the time of data collection presented with an acute episode of low back and radiating leg pain below the gluteal fold, as diagnosed by the referring physician, and who had been referred for physiotherapy treatment following an MRI examination done within the past 48 hours.

On the other hand, exclusion criteria were patients who had been diagnosed with a life threatening co-morbidities like cancer, serious medical and psychiatric conditions. Inability to read and write in English language was also an exclusion criterion because of the need to complete the S-LANSS scale independently.

8.3.5 Data collection tools and materials

Five different data collection tools were used in this phase of the study, and are described below: a pain and demographic questionnaire; the Oswestry Disability Index (ODI), an adapted Kenyan version of the S-LANSS scale, the researcher-developed evidence-based lumbar CNE protocol, and the adapted lumbar MRI reporting protocol.

8.3.5.1 Pain and socio-demographic questionnaire

This was a researcher-developed questionnaire (Appendix XVII) which was used to capture patients' clinical pain characteristics and their socio-demographics (also used in preceding studies). This tool was developed based on literature from subject-related textbooks in the field (Petty and Moore 2008; Maitland 2010) and the clinical assessment of the ATLAS study protocol (Konstantinou et al 2012). The tool captured data on patients' socio-demographic characteristics like age, gender and occupation, and clinical pain characteristics including the area(s) of symptoms, type or nature of symptoms, intensity and behaviour of pain, duration of symptoms, history of the presenting condition, relevant past medical, surgical, family and social history.

8.3.5.2 The Oswestry Disability Index (ODI) questionnaire

The ODI (Appendix XVI) was used to evaluate the level of functional limitations and participation restrictions on patients' activities of daily living (ADLs) by low back pain and referred leg symptoms.

The ODI has been extensively used in previous studies (Fairbank and Pynsent 2000; Kim et al 2005; Pekkanen et al 2011) and it is presented in a ten-section format focusing on pain intensity and functional limitations in personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. The tool has a maximum score of 5 for each of the ten sections and patients' disability index is rated as mild (up to 20%), moderate (21 – 40%), severe (41 – 60%), or bed-bound (61 – 100%) depending on the total percentage for all the sections. The ODI tool was used as a condition-specific measure of low back pain disability, and is a valid and reliable tool (Cronback's $\alpha = 0.87$ and Correlation Coefficient $r = 0.83$ respectively) (Fairbank and Pynsent 2000). Similarly, the ODI tool is easy to administer, thus making it suitable for use in research and clinical practice (Roland et al 2000; Davidson and Keating 2002; Walsh et al 2003; Vivian 2008).

8.3.5.3 Adapted S-LANSS scale

The adapted Kenyan version of the S-LANSS questionnaire (described in Chapter 5) is a local validated version of the original S-LANSS tool, as has been done in previous similar diagnostic studies on lumbar neuropathic pain in communities in Turkey and Brazil (Koc and Erdemoglu 2010; Schestatsky et al 2011). The purpose for the use of the adapted S-LANSS scale in this study was mainly to sub-classify patients with pain of predominantly neuropathic origin (a score of 12 and higher) and somatic pain types (a score of 11 and lower). In the validity and reliability studies of the tool in a Kenyan sample of patients, the tool exhibited a perfect internal consistency of 91%, and is thus ideal for research use in the Kenyan clinical setting. For purposes of this study, only the final score which indicated whether a patients' low back and/or leg pain was predominantly of neuropathic or somatic origin, was captured.

8.3.5.4 Lumbar spine CNE protocol

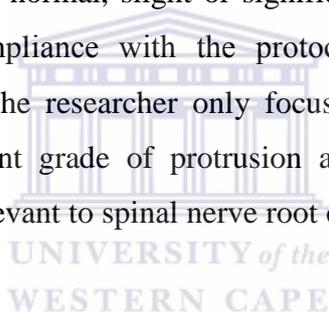
The lumbar spine CNE protocol which was developed and standardised (Chapter 6), was used to guide the participating physiotherapists in performing a structured assessment on patients. The CNE lumbar spine protocol stipulated the specific evidence-based tests for sensation, motor function, tendon reflex and neuro-dynamics for lumbar and sacral nerve roots to be conducted, including details on patients' and clinician's positioning, tools and materials to be used, test execution, interpretation of test results and documentation of the test results in a structured data capture sheet. The participating physiotherapists were pre-trained and the inter-examiner reliability among these physiotherapists was found to be 71% (Chapter Seven).

This was an indication that there was a good level of agreement between the pre-trained physiotherapists regarding implementation of the protocol, improving the credibility of the CNE test results during the main study. For purposes of this study, findings on sensory, motor, reflex testing for neuro-conduction assessment were captured in a binary fashion of positive or negative for each test.

Positivity of neuro-conduction tests was defined as and classified into: *weak*, when a patient had a single positive conduction test, *moderate*, when a patient had two positive conduction tests and *strong*, when a patient had positive results in all the three conduction tests. Results from neuro-dynamic tests of the lumbar and sacral plexi, the Femoral Nerve Stretch Test and Straight Leg Raise Test, were captured as negative or positive.

8.3.5.5 Adapted lumbar MRI reporting protocol

Participating radiologists who used the adapted MRI lumbar reporting protocol (Appendix XV) to report the imaging findings of the patients in the main study, were introduced to the protocol in the validation study (Chapter Seven). The protocol covered findings on parameters like disc (water content, height and rim sign), medulla signal, spinal canal stenosis, protrusion (paramedical, lateral, foraminal and extra-foraminal) and bone and disco-ligament restriction. Each parameter is recorded as normal, slight or significant. However, for purposes of this study, and in compliance with the protocol author's recommendations (Bertilson et al 2010), the researcher only focused on significant spinal canal stenosis and a significant grade of protrusion as the only lumbo-sacral MRI parameters which are relevant to spinal nerve root compromise and radiculopathy.



8.3.6 Data collection process

Prior to data collection for the current study, the researcher conducted a pilot study from November 2013 to December 2013, on thirty subjects who had low back and related referred leg symptoms using similar data collection tools, materials and procedures. Since there were no alterations necessary, the researcher incorporated the data from the earlier pilot study in to the main study.

The data was collected from March 2014 to June 2014 after approval by the relevant institutional authorities. At each of the participating physiotherapy departments, an appointed and pre-trained research assistant who was a qualified physiotherapist, used the patients' admission register to select every consecutive patient with low back and referred leg symptoms as diagnosed by the referring clinician.

The research assistant screened for inclusion and invited the participants into the study. The aim and objectives of the study was explained to the selected participants, and those who expressed voluntary willingness to participate were then requested to sign a formal written consent. For the purpose of this study, all the three different assessments of the participants' were done within a period of 48 hours. The clinical data collection process was conducted in three steps. Firstly, a pre-trained physiotherapist who was blind to the patients' medical history and referring clinicians' diagnosis, conducted a structured subjective examination procedure using the researcher-developed pain and socio-demographic questionnaire followed by administration of the adapted S-LANSS questionnaire and the Oswestry Disability Index (ODI) questionnaire. Secondly, a second pre-trained physiotherapist who was blind to the patients' subjective examination results, S-LANSS score and ODI report conducted a structured CNE of the lumbo-sacral nerve roots, using the standardised evidence-based CNE protocol and documented the findings of the same patients in the CNE data capture sheet. Thirdly, for purposes of this study, a radiologist completed the MRI reporting protocol which was validated in Chapter Seven. The radiologists who completed the MRI protocols were blind to the patient's medical history and initial diagnosis; although this is contrary to routine practice. Figure 8.1 below illustrates the data collection process.

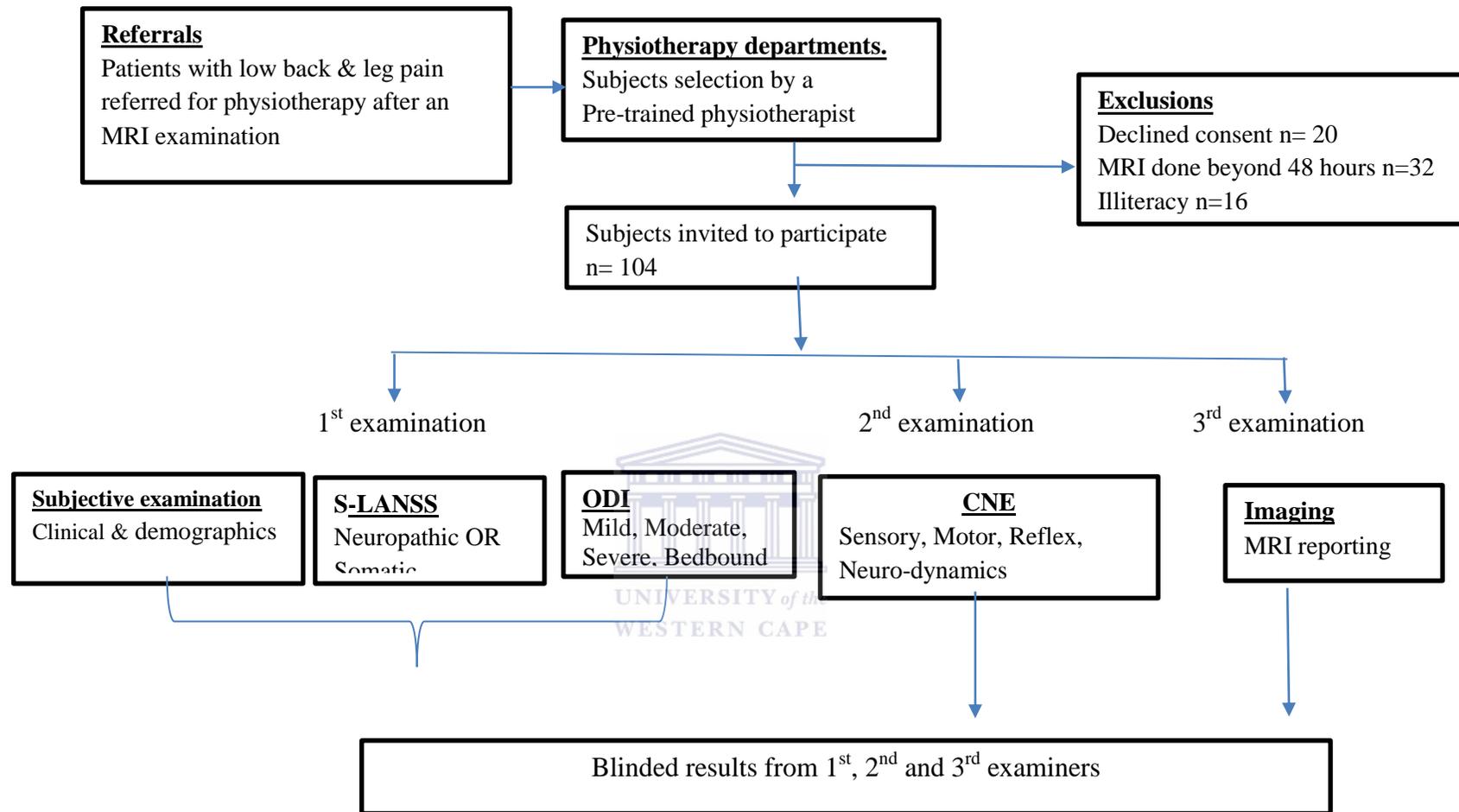


Figure 8.1: Flow chart diagram for patients' examinations

8.3.7 Data processing and analysis

The data collected from the three examinations was in quantitative format. The first data set included the patients' socio-demographics and pain-related clinical characteristics and presence or absence of neuropathic pain as identified by the S-LANSS score and the level of disability according to the ODI. The second data set included the findings on the testing of skin sensation, muscle power, deep tendon reflexes and neuro-dynamics, while data from the third assessment included the MRI reports on presence or absence of visible nerve root involvement.

All data was first captured from the raw materials into a Microsoft Office EXCEL spreadsheet using Windows 7 computer software. The data capturing process began with serialisation of all questionnaires for identification purposes followed by selection of variables for each of the five data collection tools which were used. The researcher extracted into an EXCEL spread sheet a total of fourteen variables namely; *age, gender, occupation, area, nature and intensity of symptoms from the pain and demographic questionnaire, presence or absence of neuropathic pain from the S-LANSS score, level of disability from the ODI, sensory, motor power, tendon reflex, total neuro-conduction and neuro-dynamic test, outcomes from the CNE and finally MRI-visible nerve root compromise from the MRI reports.* The data from the EXCEL spread sheet was then imported into SPSS computer software version 21.0, and was then cleaned by running two paired data sheets in order to check for any differences. A data coding procedure was performed where each variable status was translated into a numerical code as illustrated in Table 8.2 below.

Table 8.2: Data Codes

Variable Number	Variable Name	Variable code
1	Age	N/A
2	Gender	1=male 2 = female
3	Occupation	1 = manual 2 = office
4	Area of symptoms	1 = LBP and anterior thigh/groin 2= LBP and posterior thigh/buttock
5	Nature of symptom	1= pain 2= numbness 3= paraesthesia 4= pain and numbness
6	Pain intensity (NPRS)	N/A (Continuous numerical)
7	S-LANSS	1= (S-LANSS +) neuropathic pain 2= (S-LANSS -) somatic pain
8	ODI	1=mild disability 2=moderate disability 3=severe disability 4=bed-bound
9	Sensory testing	1=positive 2=negative
10	Motor testing	1=positive 2=negative
11	Deep tendon reflex	1=positive 2=negative
12	Neuro-conduction testing	0=negative 1= weak positive 2=moderate positive 3=strong positive
13	Neuro-dynamic testing	0=negative 1=positive
14	MRI-visible nerve root compromise	0=negative 1=positive

Statistical data analysis started with calculating the means and frequencies of all clinical and demographic variables. Before any further analyses were conducted, the Kolomogorv Simirnov tests were performed to determine the normality of the data.

The results indicated a non-parametric distribution, so the researcher therefore used the Spearman's rank correlation coefficient r test to perform bivariate analysis in order to establish the correlation between S-LANSS score and MRI findings, and, CNE findings and MRI findings, in diagnosing LSR.

Also, the linear regression and odds ratio analyses were performed to establish possible correlations between the various socio-demographic, clinical and diagnostic parameters like gender, pain intensity and sensory test. Finally, Receiver Operating Characteristics (ROC) curves were used to determine the diagnostic accuracy of individual or combined sets of CNE tests in diagnosing nerve root compromise and radiculopathy in light of MRI as the reference standard. The results of this study are presented in both a descriptive and inferential manner using tables, figures and scatter plots.

8.4 Results

Firstly, a descriptive analysis of the clinical and demographic characteristics of the study participants is presented, by use of frequencies and means. Inferential statistics between socio-demographics, functional and clinical characteristics and are drawn together with linear associations between paired variables. Finally, the agreement between S-LANS scores, aspects of CNE and MRI is presented.

8.4.1 Socio-demographic and clinical characteristics of participants

This study involved 102 participants whose mean age was 44.7 (19 – 86 years) with a standard deviation of 14.0 and gender distribution of 57% females and 43% males. Table 8.3 below illustrates the frequencies and means of the various clinical and socio-demographic characteristics of the respondents.

Table 8.3: Participants’ socio-demographics and clinical characteristics (n = 102)

Variable	Category	Frequency (n)	Percentage (%)
Gender	Male	44	43
	Female	58	57
Age	18 – 25	10	10
	26 -35	17	16
	36 -45	35	35
	46 -55	16	15
	56 -65	17	16
	66 – 75	5	5
	76 and older	2	3
Occupation	Manual work	52	51
	Office work	50	49
Pain intensity (NPRS)	≤3 (mild pain)	5	5
	4-6 (moderate pain)	52	51
	7-9 (severe pain)	39	38
	=10 (excruciating pain)	6	6
Nature of pain (S-LANSS)	Neuropathic	67	66
	Somatic	35	34
Level of disability (ODI)	Mild	13	13
	Moderate	37	36
	Severe	38	37
	Bed-bound	14	14
Neuro-conduction tests	Negative	33	32
	Mild deficit (one +ve test)	30	29
	Moderate deficit (two +ve tests)	18	18
	Severe deficit (three +ve tests)	21	21
Neuro-dynamic tests	Positive	64	63
	Negative	38	37
MRI-visible nerve root compromise	Positive	56	55
	Negative	46	45

8.4.1.1 Participants’ job category

The results indicate that 51% (N=102) of the respondents were manual workers while 49% were office workers. For the purpose of this study, participants’ jobs were categorised into manual and office. The former category included; domestic workers, army/police officers, drivers, industry workers, constructors, farmers and nurses while the latter category included bankers, teachers and administrators.

In the subsequent sections of this chapter, the findings of bivariate analysis between participants' job category and other clinical characteristics will be presented to explore possible significant associations.

8.4.1.2 Intensity and area (NPRS) and type (S-LANSS) of pain

This section presents results on the intensity and type of low back and/or leg pain as reported by the study participants as rated and classified by the NPRS and S-LANSS respectively. The findings indicate that a majority (52 %, n=102) of the respondents experienced moderate pain followed by severe pain (39%, n=102). The results on the participants' pain type indicate that most of the participants (66 %, n=102) had lumbo-sacral spinal pain of predominantly neuropathic origin (POPNO) which is a distinct clinical presentation from somatic pain type which was recorded in 35% of the respondents. Most of the respondents (60% n=102) presented with low back and posterior leg pain consistent with L4, L5 and S1 radiculopathies.

8.4.1.3 Level of disability (ODI)

In this study, the extent to which participants' ADLs were restricted by their low back and/or leg pain was determined using the ODI. The results indicate that the level of disability ranged from moderate among 37% (n=102) to severe among 38% (n=102) of the participants. The level of disability among the neuropathic pain patients (n=67) was, 31% were classified as having moderate disability, 45% as having severe disability and 21% were bed-bound. While for the somatic group (n=35), 45% were classified as having moderate disability and only 22% had severe disability. No patient in the somatic group was bedbound as a result of their condition.

8.4.2 Diagnostic findings on participants

8.4.2.1 S-LANSS scores

According to the results of the current study, 66% (n=102) of the participants were diagnosed with LSR, as a result of a positive S-LANSS score while the remaining 34% (n=102) were diagnosed with somatic nociceptive low back and referred leg pain as a result of negative S-LANSS scores. The positivity cut-off for S-LANSS scale is 12 points.

8.4.2.2 Clinical neurological examination

This section presents results on the findings of nerve root compromise and radiculopathy as detected by CNE tests. Results indicate that 68% (n=102) of the respondents presented with nerve conduction deficits as indicated during the CNE using the standardised evidence-based CNE protocol while 32% (n=102) had a normal neuro-conduction function on the symptomatic side. Those who had mild nerve conduction deficit (in this study identified as having a single positive test result) were 29% of the group. Those who had a moderate nerve conduction deficit (two positive test results during the clinical examination) were 18% while those who had a severe nerve conduction deficit (decrease in skin sensation, muscle power and deep tendon reflex tests) were 21%.

On the other hand, results on the neuro-dynamic function of the lumbar and sacral nerve roots indicated that a majority (64%, n=102) were positive for neuro-mechano-sensitivity indicating an exaggerated or patho-mechanical level of reactivity of the lumbar and sacral plexus towards mechanical stretch/loading. Similar to the results on nerve conduction, 36% of the respondents had normal levels of mechanical excitability of the lower limb peripheral neural structures despite the typical clinical manifestation of low back and referred leg symptoms, possibly indicating somatic referred pain into the legs.

8.4.2.3 MRI

In this study, MRI-visible nerve root compromise (defined as significant spinal canal stenosis and/or IVD protrusion or protuberance) was present among 55% (n=102) of the respondents, while 45% of the respondents had negative MRI findings on nerve root compromise despite the classical presentations of a lumbosacral spinal and referred leg pain

8.5 Bivariate analysis

This section presents results on the associations between socio-demographic characteristics of the study participants and their clinical presentations and functional status, and between CNE and MRI findings on nerve root compromise.

8.5.1 Pain intensity and age

The results of this study expressed no significant association between high self-reported pain intensity scores and age of the subjects. This is illustrated in the scatter plot below, demonstrating that although the majority of the respondents had moderate to high levels of pain there was not a clear trend with advanced age.

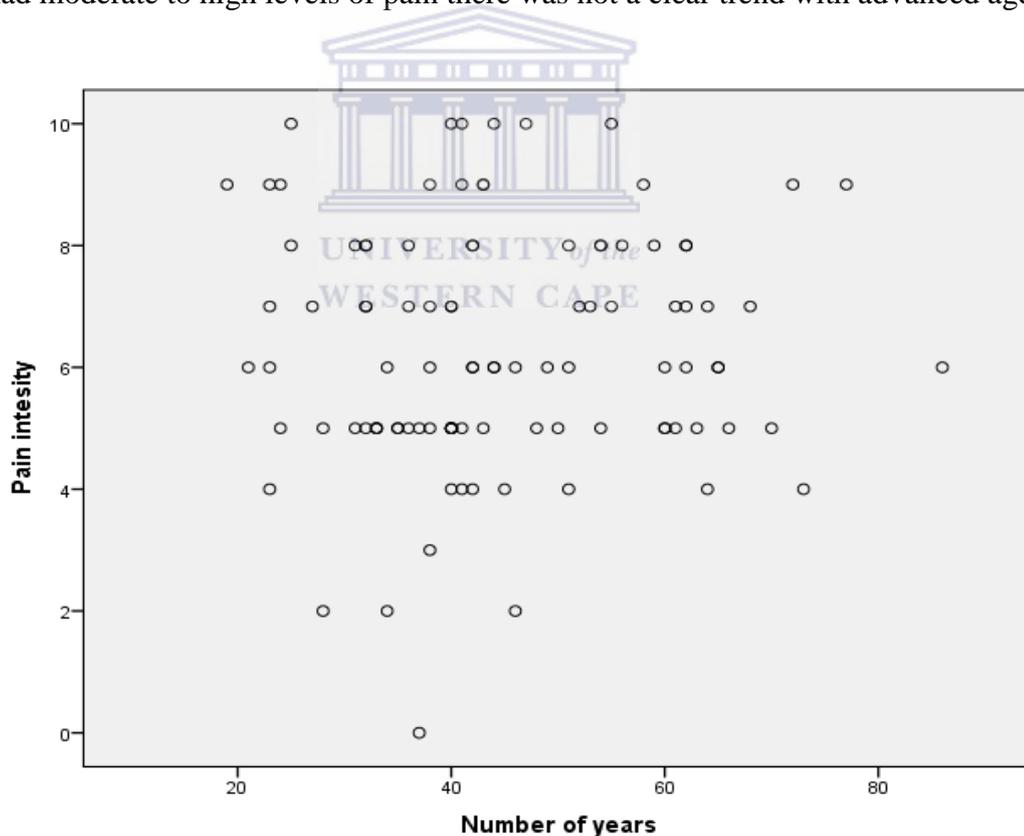


Figure 8.2: Association between patients' age and pain intensity

8.5.2 Pain intensity and level of disability

The correlation between pain intensity (NPRS) and the level of disability (ODI) was assessed using the Spearman's' rank correlation coefficient r statistical test. The results of the analysis indicated a significant positive linear correlation ($r = 0.43$). This implies that patients with self-reported high intensity pain experienced high levels of reported functional limitations in their ADLs. Most of the respondents (60%) presented with low back and posterior leg pain consistent with L4, 5 S1 radiculopathies.

8.5.3 Correlation of intensity and type of pain

The results of this study reveal that patients who reported low levels of pain intensity as graded by the NPRS had low scores on the S-LANSS pain scale, possibly indicating that somatic referred pain is of lower intensity than POPNO.

8.5.4 Association between CNE and MRI findings on nerve root compromise

The association between nerve conduction and neuro-dynamic testing, which were categorical variables, and MRI findings on nerve root compromise, which in this study was dichotomised into positive or negative using the Spearman's' rank correlation coefficient r , were established. Results indicated a positive relationship ($r = 0.36$, $P = 0.01$) between the two diagnostic tests (neuro-conduction and neuro-dynamic) and MRI in detecting LSR. The results also expressed a positive agreement between combined neuro-conduction tests (sensory, motor and reflex) and neuro-dynamic testing (SLRT and FNST) in detecting LSR. This may imply that in the assessment of patients with low back and referred leg symptoms, both neuro-conduction and neuro-dynamic tests should be considered in making a clinical diagnosis of the presence or absence of a possible underlying nerve root compromise and radiculopathy. Individual CNE tests did not correlate well with MRI findings of nerve root compromise. However, the agreement between CNE and MRI in detecting nerve root compromise at specific spinal segmental levels was not explored in the current study.

8.6 Logistic regression and odds ratio

The binary logistic regression analysis was used to explore the diagnostic value of S-LANSS pain scale and the various aspects of CNE in predicting the outcome of MRI reports on patients with clinical suspicion of LSR. Results indicated that the neuro-dynamic test component of the CNE, which in this study was composed of SLRT and FNST for lumbar and sacral nerve roots respectively, has a significant association ($p=0.05$) with MRI findings. Patients who had positive neuro-dynamic test results were according to this study eight times more likely (odds ratio 8.3) to have reports of MRI-visible nerve root compromise compared to those who had negative neuro-dynamic test results.

On the other hand, there was no significant association between CNE tests of nerve conduction (sensory, motor and reflexes) in predicting the possible outcome of MRI in detecting nerve root compromise and radiculopathy. Table 8.4 below illustrates the diagnostic predictive values and odds ratios.

Table 8.4: Diagnostic predictive values and odds ratios.

Diagnostic test	Predictive value	CI	Odds Ratio
S-LANSS	-.534	.269	1.510
Sensory test	-.260	.617	2.133
Motor test	-.201	.692	2.210
Tendon reflex	-1.478	.010	.698
Neuro-dynamic	1.155	.019	8.301

8.7 Diagnostic accuracy of S-LANSS and CNE compared to MRI

The diagnostic accuracy of S-LANSS and CNE tests in detecting LSR was assessed with the MRI report as a reference standard. This section presents results on the diagnostic accuracy of the S-LANSS pain scale and the various aspects of CNE in diagnosing LSR as defined by MRI, the reference standard.

Figures on true positive (TP), false positive (FP), false negative (FN), and true negative (TN) are presented alongside sensitivity, specificity, positive likelihood ratio (+LR) and negative likelihood ratio (-LR). See Table 8.5 and 8.6 below.

Table 8.5: Diagnostic performance of S-LANSS and CNE compared to MRI

Diagnostic test	TP	FP	FN	TN	Sensitivity	Specificity	+LR	-LR
S-LANSS	42	25	14	21	0.75	0.6	1.87	2.4
Skin sensation	27	13	29	33	0.48	0.71	1.66	1.37
Motor power	35	16	21	30	0.63	0.65	1.8	1.76
Tendon reflex	29	6	27	40	0.52	0.87	4	1.8
LLNDTs	44	20	12	26	0.79	0.57	1.84	2.71

Key: TP True positive, FP False positive, FN False negative, TN True negative, +LR Positive likelihood ratio, -LR Negative likelihood ratio.

Lower limb neuro-dynamic tests (used in this study to assess the mechanical sensitivity of both the femoral and sacral plexus towards stretch), recorded the best sensitivity of 0.79. This is followed by S-LANSS (used to sub-classify patients' pain into POPNO and somatic type) which had a sensitivity of 0.75. Deep tendon reflex testing of the Patellar and Achilles tendons were the most specific CNE (nerve conduction) tests (0.87).

8.8 Summary of the study results

This chapter presented results of a correlation and diagnostic test accuracy study which was conducted in the Republic of Kenya. The primary findings of the current study were:

- There is significant positive correlation between neuropathic pain screening using the adapted S-LANSS scale, CNE and lumbar MRI findings on nerve root compromise and radiculopathy.

- The strongest diagnostic accuracy correlations compared to MRI findings on nerve root compromise are firstly, neuro-dynamic tests (SLRT and FNST) (0.8), secondly, the S-LANSS score (0.8) and thirdly, the CNE components of motor power (0.6) and deep tendon reflex changes (0.5).
- A multi-test score of skin sensation tests, muscle power tests and deep tendon reflexes are superior to individual nerve conduction tests in diagnosing LSR.
- There is a positive agreement between combined neuro-conduction tests (sensory, motor and reflex) and neuro-dynamic testing (FNST and SLRT) in detecting LSR.

Secondary results of the study:

- In the group of patients in whom the correlation was established, the majority of patients who were diagnosed by S-LANSS, CNE and MRI as having neuropathic pain presented with moderate to severe levels of pain intensity and disability, compared to those whose low back and leg pain was somatic nociceptive.
- The majority of the participants who were diagnosed with LSR were females by gender, and people who were involved in manual labour-intensive occupations, and aged between 36 and 45 years.

8.9 Discussion

8.9.1 Correlation of S-LANSS score, Evidence-based CNE findings and lumbar MRI reports

As the main aim of this research project was to establish a correlation between the three diagnostic tools (S-LANSS, CNE and MRI) in diagnosing LSR among patients with low back and referred leg symptoms, the main finding was that diagnostic neuropathic pain screening using the adapted S-LANSS score and combined sets of the evidence-based CNE testing and neuro-dynamic tests (SLRT and FNST) showed a significant positive correlation with lumbar MRI findings on nerve root compromise and radiculopathy.

Clinically, this observation implies that S-LANSS scale and evidence-based CNE tests could be used to predict MRI findings on nerve root compromise and radiculopathy, and make therapeutic decisions, in the event that MRI is medically contra-indicated, unaffordable or even unavailable. Similarly, this finding supports the reports by (Bennet et al 2007; El Zahaf et al 2013) for use of quick, low-risk and cost-effective diagnostic options in the assessment and diagnosis of LSR especially in the primary care settings of resource-poor countries of Africa. Also, since radiological imaging is not recommended within the first four to six weeks of an acute episode of low back pain (Chou and Qaseem 2007; Kreiner et al 2013; Al Nezari et al 2014), S-LANSS and CNE tests could therefore be used to confirm or refute a clinical suspicion of LSR.

No studies on correlation of all three diagnostic tools were found in the published scientific literature in the field of musculoskeletal medicine. There are however reports on correlation of two of the three assessment procedures. In a correlation study between MRI, physical examination and pain drawing (Bertilson et al 2010), it was observed that there was a better correlation between MRI and pain drawing compared to MRI and physical examination in detecting nerve root involvement.

Findings of the current study could agree with those of the Bertilson et al (2010) on correlation between MRI and pain drawing, given that one section of the S-LANSS scale and pain drawing (Appendix XXI) both involve mapping of the area(s) of pain or discomfort on a body chart and use of pain descriptors like numbness and stinging. A recent correlation study (Lee and Lee 2012), reported that MRI findings of nerve root involvement showed no significant correlation with CNE test of muscle weakness. These findings are contrary to the earlier reports by Bertilson et al (2010) and those of the current study. The discrepancy may stem from the fact that in the study which was conducted by Lee and Lee (2012), physical examination was done with knowledge of the MRI findings, a source of possible verification bias which has been reported by Suri et al (2010).

8.9.2 Diagnostic accuracy and utility of the individual diagnostic tools and procedures

The results of the study indicated that the strongest diagnostic accuracy correlations compared to MRI findings are firstly, neuro-dynamic tests (SLRT and FNST) which examines the mechanical sensitivity of the lumbo-sacral nerve roots as opposed to nerve conduction, secondly, the S-LANSS score and thirdly, the CNE component of deep tendon reflex changes. The results also showed that combined sets of skin sensation tests, muscle power tests and deep tendon reflexes are superior to individual nerve conduction tests in diagnosing LSR.

Contrary to previous similar diagnostic test accuracy studies (Bertilson et al 2010; Coster et al 2010; Suri et al 2010), in this study, the researcher separately considered the femoral nerve stretch test (FNST) and straight leg raise test (SLRT) for the clinical assessment of mechanical sensitivity (provocation) of the lumbar and sacral peripheral neural structures respectively in line with the scientific basis put forward by Butler (2000); Schaclock (2005).

The findings on the accuracy of combined CNE tests agrees with reports of previous similar studies (Coster et al 2010; Suri et al 2011) that combined CNE tests improves the likelihood ratio for detecting LSR, and lastly the results expressed a positive agreement between combined neuro-conduction tests (sensory, motor and reflex) and neuro-dynamic testing (SLRT and FNST) in detecting LSR.

8.9.2.1 Diagnostic accuracy correlations compared to MRI findings

In this study, the S-LANSS score was used as an index test during the initial assessment of participants in diagnosing LSR. The findings indicate that S-LANSS score is more sensitive than specific compared to MRI in diagnosing LSR. In clinical practice, this finding mean that S-LANSS score could be used in identifying patients whose low back pain is predominantly neuropathic but not in ruling out the presence of LSR.

These findings are in line with previous studies on the validity and reliability of – SLANSS in diagnosing POPNO among patients with low back and/or referred leg pain (Yucel et al 2004; Kaki et al 2005). This is very important, given that S-LANSS is a quick, low-risk and cost-effective bed-side diagnostic tool which is ideal especially in resource-poor settings of Kenya.

8.9.2.2 The lumbar CNE

In this correlation and DTA study, which used MRI as reference standard, neuro-conduction tests of motor power and neuro-dynamic tests recorded acceptable levels of sensitivity in diagnosing LSR, while deep tendon reflex tests were the most specific neuro-conduction tests for nerve root compromise and radiculopathy.

These results are in agreement with previous reports by (Vroomen et al 2002; Trainor and Pinnington 2010; Bertilson et al 2010; Iversen et al 2013; Al Nezari et al 2013; Kreiner et al 2014) on the need for early and accurate diagnosis of LSR using evidence-based clinical tests, and that the use of high technology imaging be considered only when surgery is contemplated following failed conservative treatment or in case serious systemic pathologies are suspected. If embraced by clinicians, the use of these tests in confirming and ruling out the presence of LSR may address the delay in with-holding clinical decision-making until imaging reports are made available, thus minimising the likelihood of disease progression, chronicity and disability.

The clinical implication of this observation is that with a proper and standardised execution of the tests and accurate interpretation of the test results, CNE could be utilised for baseline assessment of patients to confirm the presence of LSR especially in instances where MRI is medically contra-indicated or un-available.

8.9.2.3 Combining neuro-conduction with neuro-dynamic testing

Combined sets of neural conduction and neuro-dynamic tests showed a significant positive correlation with lumbar MRI findings on nerve root compression and radiculopathy. This findings is in line with previous reports by Bertilson et al (2010) and Suri et al (2011) on the diagnostic utility of combined CNE tests compared to individual tests and also supports the current clinical practice as these CNE tests are never recommended for use in isolation but rather in combination (Butler 2000; Petty and Moore 2008; Maitland 2010). This confirmation gives us a strong clinical basis for a best practice guideline to the lumbar spine CNE protocol which was developed in Chapter Six of this thesis. This finding is in line with previous reports by Bertilson et al (2010) and Suri et al (2011) on the diagnostic utility of combined CNE tests compared to individual tests.

This also supports the current clinical practice as these CNE tests are never advocated in isolation but rather in combination (Butler 2000; Petty and Moore 2008; Maitland 2010). This confirmation gives us a strong clinical basis for a best practice guideline to the CNE of patients with low back and leg pain.

The findings of this study agree with several previous studies on the validity and reliability of the S-LANSS tool in identifying patients whose low back pain is predominantly of neuropathic origin (POPNO) (Yucel et al 2004; Kaki et al 2004; Bennett et al 2007; Koc and Erdemoglu 2010; El Zahaf et al 2013). Similarly, the results of the current study support advocacy for early accurate detection of neuropathic pain, to warrant appropriate intervention and prevent chronicity and disability.

The secondary results of the study demonstrated that in the group of patients in whom the correlation was established, the majority of the patients who were diagnosed as having neuropathic pain, presented with moderate to severe levels of pain intensity and disability, compared to those whose low back pain is somatic nociceptive. It was also shown that the majority of the participants who were diagnosed with LSR were females and people who were involved in manual labour-intensive occupations and aged between 36 and 45 years.

8.9.3 Clinical features (symptomatology) of patients with LSR

The majority of the participants in this study had moderate to severe pain accompanied by mild to moderate neuro-conduction deficits (sensory, motor and tendon reflex) and neuro-dynamic dysfunctions (SLRT and FNST). Clinically, this implies that patients whose low back pain has a neuropathic source are more likely to experience high levels of pain compared to patients whose pain is nociceptive musculo-skeletal. This finding supports the high levels of functional or activity limitations and disability among patients with LSR which has been consistently reported in previous studies (Suri et al 2010; Coster et al 2010; Bajpai et al 2013). The findings of this current study therefore affirms previous reports on the high levels of health and socio-economic impact of LSR to patients, family and society due to poor quality of life (QoL), work loss and cost of medical care (Brooks 2006; Katz 2006). Therefore, to prevent this, there is need for early and accurate diagnosis of LSR in order to facilitate effective treatment, this is important especially in developing countries such as Kenya where the health care system is already over-burdened.

8.9.4 Prevalence and socio-demographic characteristics of patients with LSR

A total of 56% (n=102) of the study participants had LSR as defined by MRI which was used as the reference standard in this study. Most of the participants who were diagnosed with LSR were involved in manual labor-intensive occupations like farming and were aged between 36 and 45. Also, there were more female participants who were diagnosed with LSR compared to males. These findings on the prevalence and socio-demographic characteristics of LSR indicates that LSR is a common condition especially among patients who are referred for physiotherapy with complaints of low back pain and referred leg symptoms.

Labour intensive manual workers like farmers and army officers whose jobs involve repetitive spinal movements, prolonged standing and/or walking are more predisposed to development of LSR. Also, LSR is common among people who are within the productive ages of 36 to 45 years, hence its high impact on workplace productivity and societal economic development.

These findings are in line with previous similar diagnostic test accuracy (DTA) studies (Bertilson et al 2010; Coster et al 2010; Lee and Lee 2012)

The current study revealed that low back pain and referred leg symptoms or radiculopathy is common among females and people involved in manually intensive occupations like farming, shop keeping and construction work. This is in line with previous reports by Louw et al (2007), on the prevalence on low back pain (LBP) in Africa, which stated that LBP-related conditions including LSR, are more common among workers compared to scholars. This is a concern given that majority of the population within the productive age in most developing countries like Kenya are involved in manual occupations.

Therefore, the high pain intensity and work loss imposed on patients by LSR may have a negative impact on health-related quality of life and socio-economic growth.

The results of this study therefore indicate that S-LANSS may be used to confirm the presence of a neurogenic source of referred leg symptoms as distinct from somatic referred leg symptoms, that neuro-dynamic tests could be considered in confirming nerve root compromise of both lumbar and sacral plexus, and that deep tendon reflex testing was the most specific CNE test in the clinical detection of nerve root compromise as defined by MRI.

CHAPTER NINE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

9. Introduction

In this chapter, a summary of the results of each specific objective of the entire research project is presented, followed by conclusions drawn from the key findings. The chapter also presents the limitations of the current study and a conclusion of the research project. The chapter concludes by giving recommendations for; further research activities, clinical practice and policy.

9.1 Summary

This research project was a diagnostic test accuracy study which explored psychometric convergence of three diagnostic tools (S-LANSS, CNE and MRI) in diagnosing LSR.

Results indicate that diagnostic neuropathic pain screening using the adapted version of the S-LANSS score is feasible in the Kenyan clinical setting. The tool is both valid and reliable in identification of patients whose lumbo-sacral pain has a predominantly neuropathic origin as distinct from those whose pain is somatic nociceptive. Moreover, the adapted S-LANSS scale is a simple, cheap and easy to administer, making it suitable for use in the busy resource-poor primary care settings of Kenya.

It was also observed that clinical neurological tests are a vital component of the initial diagnostic procedure of patients suspected of LSR. However, there is no consensus regarding the operational definition of LSR. Similarly, the execution of deep tendon reflex tests and the grading system for both tendon reflex tests and motor tests is varied. Another component of this study included the development and standardisation of an evidence-based lumbar spine CNE protocol.

The results of an inter-examiner reliability test indicated a good level of agreement between the pre-trained Kenyan physiotherapists in conducting CNE of the lumbo-sacral spine among patients with low back and referred leg symptoms using the protocol.

In the radiological imaging diagnosis of LSR which is commonly preferred by clinicians in practice, there is not sufficient evidence for or against the use of MRI. It was also noted as a concern that there is a great paucity of high quality scientific evidence on the diagnostic accuracy of MRI in detecting nerve root compromise and radiculopathy in line with a previous similar study (Bertilson et al 2010). However, the adapted Bertilson et al (2010) lumbar MRI reporting protocol is valid in the Kenyan clinical setting, although there were significant variations in the detecting LSR due to nerve root compression-related MRI findings among radiologists.

The results of the preceding chapters were preliminary to the main study of Chapter Eight on correlation of the three diagnostic tools (S-LANSS, CNE and MRI) in diagnosing LSR. The primary finding of the main study was the presence of a significant positive correlation between neuropathic pain screening using the adapted S-LANSS scale, CNE (skin sensation, motor power, tendon reflex and neuro-dynamic tests (SLRT and FNST) and lumbar MRI findings on nerve root compromise and radiculopathy.

LSR is a common condition encountered by physiotherapists and especially among people within the productive age. Females and people involved in manually intensive jobs are more susceptible to this condition than other groups in a population. LSR causes severe and debilitating pain which mostly leads to poor health-related quality of life and significant disability and work-loss. Early and acute diagnosis of LSR is desirable especially in primary care in order to prevent misclassification and misdiagnosis which are known to lead to chronicity.

9.2 Conclusion

This was the first correlation and diagnostic tests accuracy (DTA) study in the African continent to have used three diagnostic tools in the assessment and diagnosis of LSR. Diagnostic neuropathic pain screening using S-LANSS score is rapid, low-risk and cost-effective but accurate in diagnosing LSR. Evidence-based combined tests of motor, FNST and SLRT are sensitive in confirming LSR while deep tendon reflex tests of patella and ankle reflexes are specific in ruling out LSR.

Both the adapted S-LANSS score and the evidence-based CNE tests of motor, tendon reflex, SLRT and FNST have a significant positive correlation with MRI reports in diagnosing LSR and therefore are recommended for use especially in instances where MRI is medically contra-indicated, unaffordable or even unavailable.

9.3 Implications of the study findings in clinical practice

MRI findings and S-LANSS score correlates positively in diagnosing LSR, and MRI findings and CNE (motor power, tendon reflex, SLRT and FNST) correlate positively in diagnosing LSR. These key findings clinically imply that S-LANSS and CNE components of motor, tendon reflex and neuro-dynamics could be used to predict MRI findings and make therapeutic decisions on patients in the event that MRI is medically contra-indicated, unaffordable or even unavailable. This would facilitate timely effective treatment and ultimately prevent chronicity.

Deep tendon reflex tests (patella and ankle) are specific in ruling out LSR and therefore this test is recommended for use to differentiate between LSR and somatic referred nociceptive pain which may clinically mimic LSR.

The evidence-based lumbar spine CNE protocol which was developed in Chapter Six is a standard tool and exhibited a good inter-examiner reliability in diagnosing LSR, hence ideal for use in the Kenyan clinical setting. The use of evidence-based standardised diagnostic protocol would improve the accuracy of diagnosing LSR and minimise variations among physiotherapists.

The adapted Kenyan version of the S-LANSS scale is a quick, low-risk and cost-effective diagnostic pain screening tool which could be used for early and accurate diagnosis of LSR in most primary care settings of Kenya.

9.4 Limitations of the study

Like any other research process, there are unique limitations related to the current study. The majority of the physiotherapists who participated in performing the standardised evidence-based lumbar spine CNE, were holders of a Diploma in Physiotherapy which is a relatively junior professional qualification compared to the level of qualification of examiners in similar previous DTA studies.

This shortcoming was however minimised by clinical standardisation through pre-training of the participating physiotherapists in performing the tests. Secondly, the exclusion of patients who could not read and write in English language in the initial assessment might have eliminated a specific group with unique socio-demographics and clinical characteristics.

Thirdly, unlike in previous diagnostic test accuracy studies which used certified neuro-radiologists to report the MRI findings (Vroomen et al 2002; Bertilson et al 2010), this current study recruited non-specialist radiologists. These limitations may have negatively impacted on the quality of data generated, and ultimately the reported diagnostic utility of both the clinical and imaging tests.

9.5 Recommendations

9.5.1 Further research

The following recommendations for further investigations are suggested:

1. Translation and linguistic validation of the S-LANSS score into a Kenyan native Language (Swahili).
2. Correlation of CNE and MRI in detecting nerve root compromise at specific segmental levels.
3. Development and standardisation of evidence-based CNE protocols for other conditions in the field of musculoskeletal medicine.
4. Correlation of MRI findings and intra-operative findings in the diagnosis of LSR.

9.5.2. Clinical practice

1. Clinicians in the field of musculoskeletal medicine should always correlate patients' MRI findings with the medical history and findings of other diagnostic tools like S-LANSS and evidence-based clinical tests.
2. The adapted Kenyan version of S-LANSS scale is valid and reliable and thus suitable for use in clinical practice.
3. The evidence-based lumbar spine CNE protocol is valid and reliable and is recommended for country-wide standardization and clinical use.

9.5.3 Policy

1. Development of a national policy on imaging guidelines in the assessment and diagnosis of spinal disorders including LSR.
2. Development of national policy on evidence-based oriented training of health care personnel including physiotherapists and medical doctors.

BIBLIOGRAPHY

Al Nezari NH, Schneiders AG and Hendrick PA (2013). Neurological examination of the peripheral nervous system to diagnose lumbar spinal disc herniation with suspected radiculopathy: A systematic review and meta-analysis. *The Spine Journal*. 13:657-674.

Albeck M J, Taher G, Lauritzen M and Trojaborg W (2000). Diagnostic value of electrophysiological tests in patients with sciatica. *Acta Neurologica Scandinavica*. 101:4: 249–254.

Albeck MJ (1996). A critical assessment of clinical diagnosis of disc herniation in patients with monoradicular sciatica. *Acta Neurologica*. 138:1:40-44.

Andersson GBJ. (1997). The epidemiology of spinal disorders. In: Frymoyer JW. *The adult spine: Principles and Practice*. 2nd edition. New York: Raven Press. 93-141.

Apok V, Gurusinghe NT, Mitchell JD and Emsley HCA (2011). Dermatomes and dogma. *Practical Neurology*. 11: 100-105.

Backonja MM (2002). Need for differential assessment tools of neuropathic pain and the deficits of LANSS pain scale. *Pain*. 98:229-230.

Bajpai P, Saini S and Singh R (2013). Clinical Correlation of Magnetic Resonance Imaging with Symptom Complex in Prolapsed Intervertebral Disc Disease. *Web Publication*. 4:1:16-20

Beaton DE, Bombardien C, Guillemin F and Ferraz MB (2000). Guidelines for cross-culture adaptation of self-reported outcome. *Spine*. 35:24:3188-3191.

Beattie PF, Meyers SP, Stratford P, Millard RW and Hollenberge GM (2000). Association between patients self-report of symptoms and anatomic impairment visible on lumbar MRI. *Spine*. 25:7: 819-828.

Bennett MI (2001). The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and signs. *Pain*. 92:147-157.

Bennett MI, Attal M, Backonja MM, Baron R, Bouhassira D, Freynhagen R, Scholz J, Tolle TR, Wittchen H and Jensen TS (2007). Using screening tools to identify neuropathic pain. *Pain*. 127:3:119-203.

Bennett MI, Smith BH, Torrance N and Potter J (2005). The S-LANSS Score for Identifying Pain of Predominantly Neuropathic Origin: Validation for Use in Clinical and Postal Research. *The Journal of Pain*. 6:3:149-158.

Bertilson BC, Brosjo E and Strender L (2010). Assessment of nerve involvement in the lumbar spine: Agreement between Magnetic Resonance Imaging, physical examination and pain drawing findings. *BMC Musculoskeletal Disorders*. 11:202.

Bigos S, Bowyer O and Braen G (1994). Acute low back problems in adults. Clinical practice guideline no. 14. AHCPR publication no. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of health and Human Services.

Bogduk N (2009). On the definitions and physiology of back pain, referred pain, and radicular pain. *IASP*. Topical Issue.

Bogduk N and Twomey L (1991). Clinical anatomy of the lumbar spine. Churchill Livingstone.

Bouhassira D, Attal N, Alchaar H, Boureau F, Bruxelle J, Cunin G, et al (2005). Comparison of pain syndromes associated with nervous or somatic lesions and development of a new neuropathic pain diagnostic questionnaire (DN4). *Pain*. 114:29–36.

Bouhassira D, Lanteri-Minet M and Attal N (2008). Prevalence of chronic pain with neuropathic characteristics in the general population. *Pain*. 136:380-387

Brooks PM (2006). The burden of musculoskeletal diseases—a global perspective. *Clinical rheumatology*. 25:778-781

Butler DS (2000). The Sensitive Nervous System. Churchill Livingstone. 2nd Edition.

Capra F, Valti C, Donati R et al (2011). Validity of the straight-leg raise test for patients with sciatic pain with or without lumbar pain using magnetic resonance imaging results as a reference standard. *Journal of Manipulative Physical Therapy*. 34:231-8.

Carrino JA, Lurie JD, Tosteson ANA, Tosteson TD, Carragee EJ, Kaiser J, Grove MR, Blood E, Pearson LH, Weinstein JN and Herzog R (2009). Lumbar spine: Reliability of MR Imaging Findings. *Radiology*. 250:1:161-170

Chetty S, Baalbergen E, Bhigjee A I, Kamerman P, Ouma J, Raath R, Raff M and Salduker S (2012). Clinical practice guidelines for management of neuropathic pain: Expert panel recommendations for South Africa. *South African Medical Journal*. 102:5:312-325

Cochran WG (1997). Sampling Techniques (3rd edition). New York: John Wiley & Sons.

Cochrane Style Guide Working Group (2009). Cochrane Style Guide Basics.

Cohen J (1968). Weighted kappa: Nominal scale agreement with provision for scaled disagreement or partial credit. *Psychology Bulletin*. 70:213–220.

Connis T, Nickinovich DV, Caplan RA and Arens JM (2000). The development of evidence-based clinical practice guidelines. *International Journal of Technology Assessment in Health Care*. 16:4:1003-1012.

Cook CE and Cook AE (2011). Cervical myelopathy and radiculopathy. Neck and arm pain syndromes. Churchill Livingstone.

Coster S, de Bruijn FTM and Tavy TLJ (2010). Diagnostic value of history, physical examination and needle electromyography in diagnosing lumbosacral radiculopathy. *Journal of Neurology*. 257:332–337.

Deville W, Danielle W, Dzaferagic A, Bezemer PD and Bouter LM (2000). The test of Lasegue: Systematic review of the accuracy in diagnosing herniated discs. *Spine*. 25:1140-1147.

Deyo RA, Battie M, Beurskens AJ, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M and Waddell G (1998). Outcome measures for low back pain research. A proposal for standardized use. *Spine*. 23: 20-23.

Deyo RA; Rainville J, Kent DL. What can the history and physical examination tell us about low back pain. *JAMA* 1992; 268: 760-5.

Dooly JF, McBroom RJ, Taguchi T and Macnab I (1998). Nerve Root Infiltration in the Diagnosis of Radicular Pain. *Spine*. 13:1.

Dumitru D, Anthony A, Zwarts M (2001). Electrodiagnostic Medicine. Hanley & Belfus Inc. 18:713-734.

Eguchi et al (2011). Difusion-weighted magnetic resonance imaging of symptomatic nerve root of patients with lumbar disc herniation. *Diagnostic Neurology*. 53:633-641

El Sissi W, Arnaout A and Chaarani MW (2010). Prevalence of neuropathic pain among patients with chronic low-back pain in the Arabian Gulf Region assessed using the leeds assessment of neuropathic symptoms and signs pain scale. *Journal of International Medical Residence*.38:2135-2145.

Elvey RL and Hall TM (1999). Nerve trunk pain: physical diagnosis and treatment. *Manual Therapy*. 4:2:63-73.

Elzahaf RA, Tashani OA, Unsworth BA and Johnson MI (2013). Translation and Linguistic Validation of the Self-Completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) Scale for Use in a Libyan Population. *Pain Practice*. 3:3:198–205

Fairbank J, Couper J and Davies J (1980). The Oswestry low back pain questionnaire. *Physiotherapy*. 66:271–273

Fairbank JCT and Pynsent PB (2000). The Oswestry Disability Index. *Spine*. 25:22: 2940–2953

Foerster O (1993). The dermatomes in man. *Brain*. :56: 1-39.

Foxcroft C and Roodt G (2009). Introduction to psychological assessment in the South African context (3rd edition). Cape Town. South Africa: Oxford University Press.

Foxcroft C and Roodt G (2010). An introduction to psychological assessment in the South African context. 3rd Edition. Cape Town: Oxford University Press.

Frymoyer JW (1988). Back pain and sciatica. *New England Journal of Medicine*. 318: 291-300.

Govind J (2004). Lumbar radicular pain. *Australian Family Physician*. 33:6:409-412.

Greening J and Lynn B (1998). Minor peripheral nerve injuries: an underestimated source of pain? *Manual Therapy*. 3:4:187-194.

Grieve GP (1994). Mobilisation of the spine. Fifth edition. Churchill Livingstone.

Haig AJ, Geisser ME and Tong HC (2007). Electromyographic and magnetic resonance imaging to predict lumbar stenosis, low-back pain, and no back symptoms. *American Journal of Bone Joint Surgery*. 89:358-36

Haig AJ, Tong HC, and Yamakawa KS (2006) “Spinal stenosis, back pain, or no symptoms at all? A masked study comparing radiologic and electrodiagnostic diagnoses to the clinical impression,” *Archives of Physical Medicine and Rehabilitation*. 87:7:897–903

Hasankhani EG and Omid-Kashani F (2013). Magnetic Resonance Imaging versus Electrophysiologic Tests in Clinical Diagnosis of Lower Extremity Radicular Pain. *Neuro-science*.

Hengeveld E, Banks K and English K (2005). Maitland’s Vertebral Manipulation. 7th edition. Elsevier Butterworth Heinemann.

Hilal K, Sajjad Z, Sayani R and Khan D (2013). Utility of Limited Protocol Magnetic Resonance Imaging Lumbar Spine for Nerve Root Compression in a Developing Country, Is It Accurate and Cost Effective? *Asian Spine Journal*. 7:3:184-189

Hiltunen J, Suortti T, Arvela S, Seppa M, Joensuu R and Hari R (2005). Diffusion tensor imaging and tractography of distal peripheral nerves at 3 T. *Clinical Neurophysiology*. 116:2315-2323.

Hollingworth W, Todd CJ, King H, Males T, Dixon AK and Karia KR (2002). Primary care referrals for lumbar spine radiography: Diagnostic yield and clinical guidelines. *British Journal of General Practice*. 52:497: 475-480.

Hoogendoorn WE, van Poppel MNM, Bongers PM, Koes BW and Bouter LM (2000). Systemic review of psychosocial factors at work and private life as risk factors for back pain. *Spine*. 25: 2114-25.

IASP (2011). Commentary: A new definition of neuropathic pain. *Pain*.152:2204-2205

International Association for the Study of Pain (2014). Taxonomy. www.iasp-pain.org

Iversen T, Solberg T K, Romner B, Wilsgaard T, Nygaard O, Waterloo K, Brox J I and Ingebrigsten T (2013). Accuracy of physical examination for chronic lumbar radiculopathy. *BMC Musculoskeletal Disorders*. 14:206.

Jarvik JG and Deyo RA (2002). Diagnostic evaluation of low back pain with emphasis on imaging. *Annals of Internal Medicine*. 137: 586-97.

Jensen MC, Brant-Zawadzki MN, Obuchowski N, Modic MT, Malkasian D and Ross JS (1994). Magnetic Resonance Imaging of the Lumbar Spine in People without Back Pain. *New England Journal of Medicine*. 331:69-73.

Kaki AM, El-Yaski AM and Youseif E (2005). Identifying Neuropathic Pain Among Patients With Chronic Low-Back Pain: Use of the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale. *Regional Anaesthesia and Pain Medicine*. 30:5:420-422.

Katz JN (2006). Lumbar disc disorders and low-back pain: Socioeconomic factors and consequences. *Journal of Bone and Joint Surgery*. 88:21-24

Keegan JJ and Garreth FD (1948). The segmental distribution of the cutaneous nerves in the limbs. *Anatomy records*. 102:409-437.

Kendall NAS, Linton SJ and Main CJ (1997). Guide to assessing psychosocial yellow flags in acute low back pain: risk factors for long-term disability and work loss. Accident Rehabilitation & Compensation Insurance Corporation of New Zealand and the National Health Committee. Wellington, New Zealand.

Kettler A and Wilke HJ (2006). Review of existing grading systems for cervical or lumbar disc and facet joint degeneration. *European Spine Journal*. 15:6:705-18.

Kinkade S (2007). Evaluation and Treatment of Acute Low Back Pain. *American Academy of Family Physicians*. 75:8.

Klein R (2001). Understanding the burden of musculoskeletal Conditions. The burden is huge and not reflected in national health priorities. *British Medical Journal*. 322:1079-1080.

Koc R and Erdemoglu AK (2010). Validity and Reliability of the Turkish Self-Administered Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) Questionnaire. *Pain Medicine*. 11:1107-1114

Konstantinou K, Hider SL, Vogel S, Beardmore R and Somerville S (2011). Development of an Assessment Schedule for Patients with Low Back-Associated Leg Pain in Primary Care. *European Spine Journal: A Delphi consensus study*.

Konstantinou K; Beardmore R; Dunn KM; Lewis M and Hider SL. 2012. Clinical course, characteristics and prognostic indicators in patients presenting with back and leg pain in primary care. The ATLAS study protocol. *BMC Musculo-skeletal Disorders*. 13:4:1471-1780.

Krause SJ and Backonja MM (2003). Development of a Neuropathic Pain Questionnaire. *Clinical Journal of Pain*.19:306–14.

Kreiner et al (2014). An evidence-based guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy. *The Spine Journal*. 14:180-191.

Laslett M, McDonald B, Tropp H, Aprill CN and Oberg B (2005). Agreement between diagnoses reached by clinical examination and available reference standards: A prospective study of 216 patients with lumbo-pelvic pain. *BMC Musculoskeletal Disorders*. 6:28.

Lee JH and Lee SH (2012). Physical examination, Magnetic Resonance Imaging and Electrodiagnostic study of patients with Lumbo-sacral Disc Herniation or Spinal Stenosis. *Journal of Rehabilitative Medicine*. 44:845-850.

Lee MWL, McPhee RW and Stringer MD (2008). An evidence-based approach to human dermatomes. *Clinical Anatomy*. 21:363-373.

Louw QA, Morris LD and Grimmer-Somers K (2007). The prevalence of low back pain in Africa. *BMC Musculoskeletal Disorders*. 8:1471-2474.

Lysdahl KB and Hofmann BM (2009). What causes increasing and unnecessary use of radiological investigations? a survey of radiologists' perceptions. *BioMed Central Health Service Research*. 9:155:1186-1472.

Magee DJ (2007). Orthopedic Physical Assessment. 5th edition. Saunders.

Maitland GD (2010). Maitland's Vertebral Manipulation. Churchill Livingstone. Eight Edition.

Majlesi J, Togay H, Unalan H and Toprak S (2008). The sensitivity and specificity of the Slump and the Straight Leg Raising tests in patients with lumbar disc herniation. *Journal of Clinical Rheumatology: Practical Reports on Rheumatic & Musculoskeletal Diseases*. 14:2: 87-91.

Manchikanti L et al (2003). Are diagnostic lumbar medial branch blocks valid? Results of 2-year follow-up. *Pain Physician*. 6:2:147-53

McLeod JG, Lance JW and Davies L (1993). Introductory neurology. Blackwell Science.

Meyer-Rosberg K, Kvarnstrom A, Kinnman E, Gorth T, Nordfors LO and Kristofferson A (2001). Peripheral neuropathic pain--a multidimensional burden for patients. *European Journal of Pain*. 5:4:378-389

Minematsu K, Fisher M, Li L, Davis MA, Cotter RE, McBurney RN and Sotak CH (2005). Diffusion-weighted magnetic resonance imaging: Rapid and quantitative detection of focal brain ischemia. *Neurology*. 42:235-240

Modic MT, Obuchowski NA and Ross JS (2005). Acute low back pain and radiculopathy: MR imaging findings and their prognostic role and effect on outcome. *Radiology*. 237: 597-604.

Mooney V and Robertson J (1976). The facet syndrome. Clinical Orthopaedics and related research. *Musculoskelet Disorders*. 13: 4:115:149.

Mukaka MM (2012). Statistics corner: A guide to appropriate use of correlation coefficient in medical research. *Malawi Medical Journal*. 24:3:69-71.

Muller U, Duetz M, Roeder C and Greenough C (2004). Condition-specific measures of low back pain. Part 1: Validation. *European Spine Journal*. 13:4:301-313.

National Health and Medical Research Council (2000). Australia.

National Institute for Health and Clinical Excellence (2009)

National Institute of Clinical Excellence (NICE) (2001).

Nee RJ and Butler D (2006). Management of peripheral neuropathic pain: Integrating neurobiology, neurodynamics, and clinical evidence. *Physical Therapy in Sport*. 7: 36-49.

New Zealand Guidelines Group (NZGG) (2011).

Nita H, Tajima T, Sugiyama H and Moroyama A (1993). Study on dermatomes by means of selective lumbar spinal nerve block. *Spine*. 18:13:1782-1786.

Nygaard OP, Kloster R, Solberg T and Mellgren SI (2000). Recovery of function in adjacent nerve roots after surgery for lumbar disc herniation: use of quantitative sensory testing in the exploration of different populations of nerve fibers. *Journal of Spinal Disorders*. 13:5:427-431

Ouedraogo DD, Nonguierma V, and Napon C. (2011). Prevalence of Neuropathic Pain Among Black African Patients Suffering from common low back pain. *Rheumatol Int. Electronic Publication Ahead of Print*.

Ozaktay AC, Kallakuri S, Takebayashi T, Cavanaugh JM, Asik I and DeLeo JA (2006). Effects of interleukin-1 beta, interleukin-6, and tumor necrosis factor on sensitivity of dorsal root ganglion and peripheral receptive fields in rats. *European Spine Journal*. 15:10:1529–1537.

Patel PR and Laueran WC (1997). The Use of Magnetic Resonance Imaging in the Diagnosis of Lumbar Disc Disease. *Orthopedic nursing*.16:1:107-113

Pelletier JP, Martel-Pelletier J and Abramson SB (2001). Osteoarthritis, an inflammatory disease: potential implication for the selection of new therapeutic targets. *Arthritis Rheumatism*.44: 1237–1247.

Pepe MS, Janes H, Longton G, Leisenring W and Newcomb P (2004). Limitations of the odds ratio in gauging the performance of a diagnostic, prognostic, or screening marker. *American Journal of Epidemiology*. 159:9:882–890.

Pérez C, Galvez R, Insausti J, Bennett M, Ruiz M and Rejas J (2006). Linguistic adaptation and Spanish validation of the LANSS (Leeds Assessment of Neuropathic Symptoms and Signs) scale for the diagnosis of neuropathic pain. *Med Clin (Barc)* 127, 485-491.

Petty NJ and Moore AP (1998). Neuromusculoskeletal examination and assessment. A handbook for therapists. First edition. Churchill Livingstone.

Petty NJ and Moore AP (2008). Neuromusculoskeletal examination and assessment. A handbook for therapists. 5th Edition. Churchill Livingstone.

Pfirschmann CWA, Claudio D, Marius RS, Marco Z, Juerg H and Norbert B (2004). MR Image-based Grading of Lumbar Nerve Root Compromise due to Disk Herniation: Reliability Study with Surgical Correlation. *Radiology*. 230:583–588

Portenoy R (2006). Development and testing of a neuropathic pain screening questionnaire: ID Pain. *Current Medical Research and opinion*.22:1555-1565.

Ramsey R (2008). Validation of the Arabic version of ODI developed in Tunisia for low back pain patients in the UAE. Masters Thesis. Physiotherapy. University of Stellenbosch. South Africa.

Rebain R et al (2003). The passive straight leg raising test in the diagnosis and treatment of lumbar disc herniation: a survey of United Kingdom osteopathic opinion and clinical practice. *Spine*. 28:15:1717-1724.

Robinson JR (2003). Lower extremity pain of lumbar spine origin: Differentiating Somatic Referred and Radicular Pain. *Journal of Manual and Manipulative therapy*. 11:4:223-234.

Royal College of General Practitioners (1999). Clinical Guidelines for the Management of Acute Low Back Pain. London, Royal College of General Practitioners.

Ruffano LF, Hyde CJ, McCaffery KJ, Bossuyt PMM and JJ (2012). Assessing the value of diagnostic tests: A framework for designing and evaluating trials. *British Medical Journal*. 344:686:1-9

Scharfer A, Hall T and Briffa K (2007). Classification of low back-related leg pain—A proposed patho-mechanism-based approach. *Manual Therapy*. 14:2:222-230.

Schestatsky P, Félix-Torres V, Chaves F, Câmara-Ehlers B, Mucenic T, Caumo W, Nascimento O and Bennett MI (2011). Brazilian Portuguese Validation of the Leeds Assessment of Neuropathic Symptoms and Signs for Patients with Chronic Pain. *Pain Medicine*. 12:1544–1550

Shacklock M (2005). *Clinical Neurodynamics: A New System of Neuromusculoskeletal Treatment*. Butterworth-Heinemann.

Shah KC and Rajshekhar V (2004). Reliability of diagnosis of soft cervical disc prolapse using Spurling's test. *British Journal of Neurosurgery*. 18:5:480–483

Sim J and Wright CC (2005). The Kappa Statistic in Reliability Studies: Use, Interpretation, and Sample Size Requirements. *Journal of the American Physiotherapy Association and Royal Dutch Physical Therapy*. 85:257-268

Simel DL, Rennie D and Bossuyt P M (2008). STARD statement for reporting diagnostic accuracy studies: Application to the history and physical examination. *Journal of General Internal Medicine*. 23:6:7688-774.

Smart KM, Blake C, Staines A, and Doody C (2009). Clinical indicators of 'nociceptive', 'peripheral neuropathic' and 'central' mechanisms of musculoskeletal pain. A Delphi survey of expert clinicians. *Manual Therapy*. 1-8.

Smith BH and Torrance N (2012). *Epidemiology of Neuropathic Pain and its Impact on Quality of Life*. Springer Science.

Streiner DL and Norman GR (2003). Health Measurement Scales: A Practical Guide to their Development and Use. 3rd ed. Oxford, England: Oxford University Press.

Suri P, Hunter DJ, Katz JN, Li L and Rainville J (2010). Bias in the physical examination of patients with lumbar radiculopathy. *BMC Musculoskeletal Disorders*. 11:275:1471-2474.

Suri P, Rainville J, Katz JN, Jouve C, Hartigan C, Limke J, Pena E, Li L, Swaim B and Hunter DJ (2011). The accuracy of the physical examination for the diagnosis of mid-lumbar and low lumbar nerve root impingement. *Spine*. 36:1:63-73.

Szabela DA and Zawirski M (2002). "Use of needle electromyography for diagnosis of radiculopathies. *Journal of neurology*. 36:1:157–171.

Tachihara H, Kikuchi S, Konno S and Sekiguchi M (2007). Does Facet Joint Inflammation Induce Radiculopathy? An Investigation Using a Rat Model of Lumbar Facet Joint Inflammation. *Spine*. 32:4:406-412.

Terwee BC, Bot DMS, Boer RM, Windt AWMD et al (2007). Quality criteria proposed for measurement properties of health status questionnaires. *Clinical Epidemiology*. 60:34-42

Tong HC, Haig AJ and Yamakawa K (2002). The Spurling test and cervical radiculopathy. *Spine*. 27:2:156–15.

Torrance N, Smith BH and Bennett MI (2006). The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. *Journal of pain*. 7:281-289.

Toth C, Lnader J and Wiebe S (2009). The prevalence and impact of chronic pain with neuropathic pain symptoms in the general population. *Pain Medicine*. 10:918-929

Trainor K and Pinnington M (2011). Reliability and diagnostic validity of the slump knee bend neurodynamic test for upper/mid lumbar nerve root compression: a pilot study. *Physiotherapy*. 97:59–64.

Van Boxem, Cheng j, Patijn J et al (2010). Evidence-based medicine: Lumbo-sacral radicular Pain. *Pain Practice*. 10:4:339-358.

Van den Hoogen HMM, Koes BW, van Eijk JTM, Bouter LM (1995). On the accuracy of history, physical examination and erythrocyte sedimentation rate in diagnosis of low back pain in general practice. A criteria-based review of the literature. *Spine*. 20: 318-27.

Van Rijn JC, Klemetso JB and Reitsma (2006) et al., “Symptomatic and asymptomatic abnormalities in patients with lumbosacral radicular syndrome: clinical examination compared with MRI,” *Clinical Neurology and Neurosurgery*. 108:6:553-553.

Van Tulder MW, Furlan A, Bouter LM, Bombardier C and the Editorial Board of the Cochrane Back Review Group (2003). Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *Spine*. 28:1290-1299.

Viera A J and Garreth J M (2005). Understanding Interobserver Agreement: The Kappa Statistic. *Family Medicine*. 37:5:360-363.

Vroomen PCAJ, de Krom MCTFM, Wilmink JT, Kester ADM and Knottnerus JA (2002). Diagnostic value of history and physical examination in patients suspected of lumbo-sacral nerve root compression. *Journal of Neurology and Neuropathic Pain*. 72:630-634.

Walsh J and Hall T (2009). Classification of Low Back-Related Leg Pain: Do Subgroups Differ in Disability and Psychosocial Factors?. *Journal of manual and manipulative therapy*. 17:2:118-123.

Walsh WB and Betz NE (2001). Tests and Assessment. 4th Edition. New Jersey: Prentice Hall.

Wassenaar M, Rogier M, Van Rijn C, Raymond W and Ostelo JG (2010). Magnetic Resonance Imaging for diagnosing lumbar spinal pathology in adult patients with low back pain or sciatica: a diagnostic systematic review. *European Spine Journal*. 21:2:220-227

Weiner BK and Patel R (2008). The accuracy of MRI in the Detection of Lumbar Disc Containment. *Journal of Orthopaedic Surgery and Research*. 3:46.

Whiting P, Rutjes AW, Reitsma JB, Boyssut PM and Kleijnen J (2004). The development of QUADAS: A tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. *BMC Medical Research*. 3:1:25.

Woolf AD and Pfleger B (2003). Burden of major musculoskeletal conditions. Policy and Practice. *Bulletin of the World Health Organization*. 81:9.

Wright A (1999). Recent concepts in the neurophysiology of pain. *Manual Therapy*. 4:4:196-202.

Yamashita T, Kanaya K, Sekine M, Takebayashi T, Kawaguchi S, Katahira GA (2002). Quantitative analysis of sensory function in lumbar radiculopathy using current perception threshold testing. *Spine*. 27:14:1567-1570.

Yawn BP, Wollan PC and Weingarten TN (2009). The prevalence of neuropathic pain: Clinical evaluation compared with screening tools in a community population. *Pain Medicine*. 10:586-593.

Yucel A, Senocak M, Orhan EK, Cimen A and Ertas M (2004). Results of the Leeds Assessment of Neuropathic Signs and Symptom in Turkey: A validation study. *The Journal of Pain*. 5:8:427-432

Zhuo M (2007). Neuronal mechanism for neuropathic pain. *Molecular pain.*
3:14:1186-1744.



Appendix I: PICO Guideline

PICO Worksheet and Search Strategy

Name _____

PICO Worksheet and Search Strategy

1. Define your question using PICO by identifying: Problem, Intervention, Comparison Group and Outcomes. Your question should be used to help establish your search strategy.

Patient/Problem _____

Intervention _____

Comparison _____

Outcome _____

Write out your question: _____

1. Type of question/problem: Circle one:
 Therapy/Prevention Diagnosis Etiology Prognosis

3. Type of study (Publication Type) to include in the search: Check all that apply:
 Meta-Analysis Systematic Review Randomized Controlled Trial Cohort Study Case Control Study Case series or Case Report Editorials, Letters, Opinions Animal Research In Vitro/Lab Research

4. List main topics and alternate terms from your PICO question that can be used for your search

List your inclusion criteria –gender, age, year of publication, language
 List irrelevant terms that you may want to exclude in your search

5. List where you plan to search, i.e. EBM Reviews, Medline, AIDSLINE, CINAHL, PubMed

P	I	C	O
Patient, Population or Problem	Indicator	Comparison	Outcome
What are the characteristics of the patient or population? What is the condition or disease you are interested in?	What do you want to do with this patient (e.g. treat, diagnose, observe)?	What is the alternative to the intervention (e.g. placebo, different drug, surgery)?	What are the relevant outcomes (e.g. morbidity, death, complications)

Appendix II: QUADAS Criteria

Quality assessment of diagnostic accuracy studies (QUADAS) criteria

Item
1. Was the spectrum of subjects used in the study, representative of the patients who will receive the index test in clinical practice?
2. Were the in- and exclusion criteria of the subjects clearly described?
3. Was the reference standard used likely to correctly classify the target condition (i.e. lumbo-sacral radiculopathy)?
4. Was the time between the application of the reference standard and index test short enough to be reasonably sure that the disease status of the target condition did not change between administration of the two tests?
5. Did all patients receive the same reference standard, regardless of the index test results?
6. Was the execution of the index test described in sufficient detail to permit replication of the test?
7. Was the execution of the reference standard described in sufficient detail to permit its replication?
8. Were the index test results interpreted without knowledge of the results of the reference standard?
9. Were the reference standard results interpreted without knowledge of the results of the index test?
10. Were the same clinical data available when the index test results were interpreted as would be available when the index test is applied in clinical practice?
11. Were uninterpretable/intermediate/unclear index test results reported?
12. Were withdrawals from the study explained or reported?



Appendix III: Self-Developed Data Extraction Form

Author (year) Country	Sample size (gender, age)	Setting (period of recruitment)	Patients' description	Examiners	Index tests



Appendix IV: Consent Form (Physiotherapists)



UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959, 2542 Fax: 27 21-959, 1217

CONSENT FORM

Title of the study:

Validation of the Self-Administered Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) Scale in Kenya.

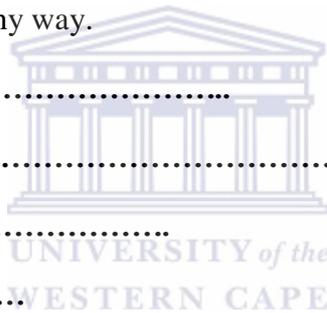
The study has been described to me in a language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name.....

Participant's signature.....

Witness.....

Date.....



Should you have any questions regarding this study or wish to report any problems you have experienced related to the study, please contact the principal researcher.

Mr. Nassib Tawa

College of Health Sciences

Jomo Kenyatta University of Agriculture & Technology

PO Box 62000-00200

Cell: +254 701 182 685

Appendix V: Information sheet (physiotherapists)



UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959, 2542 Fax:

INFORMATION SHEET

Study Title:

Validation of the Self-Administered Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) Scale in Kenya.

What is this study about?

This study is part of a PhD research project being conducted by **Mr Nassib Tawa** at the University of the Western Cape, South Africa. We are inviting you to participate because you are a Kenyan physiotherapist who on a regular basis attends to patients with low back and referred leg symptoms.

What is the purpose of this study?

The purpose of this study is to establish the face and content validity and reliability of the S-LANSS scale in the Kenyan setting.

What will I be asked to do?

You will be asked to read through the S-LANSS scale and indicate whether or not the questions asked could be well understood and answered accordingly by the patients you always attend to. You shall also be asked to make brief comments or suggestions you deem necessary as far as the content of the S-LANSS scale is concerned.

What benefits will I gain for participating?

This study is not designed to personally benefit you as an individual physiotherapist. However, the outcome shall assist physiotherapists in identifying patients whose LBP pain symptoms are dominated by neuropathic mechanisms as distinct from nociceptive mechanisms. This shall improve our diagnostic accuracy hence leading to provision of mechanism-based treatment options and improved patients' outcomes.

Is my confidentiality and anonymity guaranteed?

We will do our best to keep your personal information confidential. To help protect your anonymity we shall use your initials during the entire process. Data will be kept in a safe place having locked filing cabinets and storage areas, using identification codes on data and password-protected computer files. If we write a report or publish an article about this research project, your identity will be protected to the maximum extent possible.

What are the risks?

There are no known risks associated with participating in this research project. However, in case of any eventuality while participating, the researcher has put all necessary measures in place to assist appropriately.

Must I participate in this study?

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

This study is being conducted by **Mr Nassib Tawa** of the department of physiotherapy at the University of the Western Cape, South Africa. If you have any questions about the study, please contact

Mr. Nassib Tawa +254 701 182 685 e-mail nassibtawa@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Head of Department: Prof. Anthea Rhoda

Dean, Faculty of Community and Health Sciences: Prof. Jose Fratnz

University of the Western Cape

Private Bag X17

Bellville 7535

This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

Appendix VI: Information Sheet (Patients)



**UNIVERSITY OF THE WESTERN
CAPE**

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959, 2542 Fax: 27 21-959, 1217

INFORMATION SHEET

Study Title:

Validation of the Self-Administered Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) Scale in Kenya.

What is this study about?

This study is part of a PhD research project being conducted by **Mr Nassib Tawa** at the University of the Western Cape, South Africa. We are inviting you to participate because you present with low back and referred leg symptoms.

What is the purpose of this study?

The purpose of this study is to establish the applicability S-LANSS questionnaire in the Kenyan setting. This is a tool used to determine whether a patient's low back and leg pain originated from the nervous tissues.

What will I be asked to do?

You will be asked to read complete the S-LANSS scale and later participate in a discussion regarding the questionnaire together with other patients with a similar problem.

What benefits will I gain for participating?

This study is not designed to personally benefit you as an individual. However, the outcome shall assist physiotherapists in identifying patients whose LBP pain symptoms are dominated by neuropathic mechanisms as distinct from nociceptive mechanisms. This shall improve our diagnostic accuracy hence leading to provision of cost-effective treatment.

Is my confidentiality and anonymity guaranteed?

We will do our best to keep your personal information confidential. To help protect your anonymity we shall use your initials during the entire process. Data will be kept in a safe place having locked filing cabinets and storage areas, using identification codes on data and password-protected computer files. If we write a report or publish an article about this research project, your identity will be protected to the maximum extent possible.

What are the risks?

There are no known risks associated with participating in this research project. However, in case of any eventuality while participating, the researcher has put all necessary measures in place to assist appropriately.

Must I participate in this study?

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

This study is being conducted by **Mr Nassib Tawa** of the department of physiotherapy at the University of the Western Cape, South Africa. If you have any questions about the study, please contact

Mr. Nassib Tawa +254 701 182 685 e-mail nassibtawa@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Head of Department: Prof. Anthea Rhoda

Dean, Faculty of Community and Health Sciences: Prof. Jose Frantz

University of the Western Cape

Private Bag X17

Bellville 7535

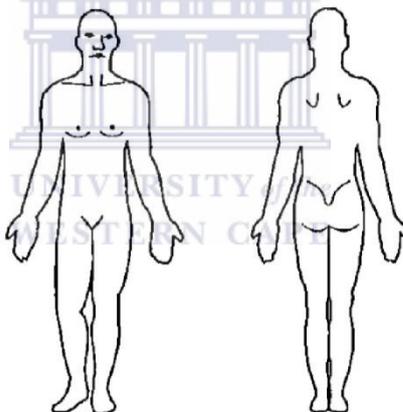
This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

Appendix VII: Original S-LANSS Scale

THE S-LANSS PAIN SCORE

NAME _____ DATE _____

- This questionnaire can tell us about the type of pain that you may be experiencing. This can help in deciding how best to treat it.
- Please draw on the diagram below where you feel your pain. If you have pain in more than one area, **only shade in the one main area where your worst pain is.**



- On the scale below, please indicate how bad your pain (that you have shown on the above diagram) has been in the last week where:
'0' means no pain and '10' means pain as severe as it could be.

NONE 0 1 2 3 4 5 6 7 8 9 10 SEVERE PAIN

-
- On the other side of the page are 7 questions about your pain (the one in the diagram).
 - Think about how your pain that you showed in the diagram has felt **over the last week**. Please circle the descriptions that best match your pain. These descriptions may, or may not, match your pain no matter how severe it feels.
 - Only circle the responses that describe your pain. **Please turn over.**

S-LANSS

1. **In the area where you have pain, do you also have 'pins and needles', tingling or prickling sensations?**
 - a) NO – I don't get these sensations (0)
 - b) YES – I get these sensations often (5)

2. **Does the painful area change colour (perhaps looks mottled or more red) when the pain is particularly bad?**
 - a) NO – The pain does not affect the colour of my skin (0)
 - b) YES – I have noticed that the pain does make my skin look different from normal (5)

3. **Does your pain make the affected skin abnormally sensitive to touch? Getting unpleasant sensations or pain when lightly stroking the skin might describe this.**
 - a) NO – The pain does not make my skin in that area abnormally sensitive to touch (0)
 - b) YES – My skin in that area is particularly sensitive to touch (3)

4. **Does your pain come on suddenly and in bursts for no apparent reason when you are completely still? Words like 'electric shocks', jumping and bursting might describe this.**
 - a) NO – My pain doesn't really feel like this (0)
 - b) YES – I get these sensations often (2)

5. **In the area where you have pain, does your skin feel unusually hot like a burning pain?**
 - a) NO – I don't have burning pain (0)
 - b) YES – I get burning pain often (1)

6. **Gently rub the painful area with your index finger and then rub a non-painful area (for example, an area of skin further away or on the opposite side from the painful area). How does this rubbing feel in the painful area?**
 - a) The painful area feels no different from the non-painful area (0)
 - b) I feel discomfort, like pins and needles, tingling or burning in the painful area that is different from the non-painful area (5)

7. **Gently press on the painful area with your finger tip then gently press in the same way onto a non-painful area (the same non-painful area that you chose in the last question). How does this feel in the painful area?**
 - a) The painful area does not feel different from the non-painful area (0)
 - b) I feel numbness or tenderness in the painful area that is different from the non-painful area (3)

Scoring: a score of 12 or more suggests pain of predominantly neuropathic origin

Appendix VIII: Self-Developed Short Questionnaire
S-LANSS VALIDATION QUESTIONNAIRE

Name
 (Initials).....Hospital.....Date.....

S-LANSS ITEM	APPLICABILITY IN KENYA	APPROPRIATENESS OF WORDS/TERMS	COMMENTS/SUGGESTIONS
Pain Drawing	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Pain Scale	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q1	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q2	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q3	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q4	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q5	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q6	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	
Q7	<input type="checkbox"/> Applicable <input type="checkbox"/> Not applicable	<input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	

Thank you for your participation

Appendix IX: Adapted S-LANSS Scale

THE S-LANSS PAIN SCORE

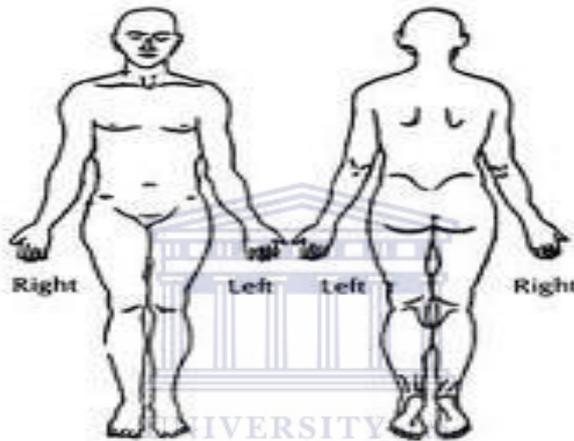
Leeds Assessment of Neuropathic Symptoms and Signs (Self-complete)

(Wording slightly adapted after focus group discussions with Kenyan experts in the field).

NAME.....DATE.....

This questionnaire can tell us about the type of pain you may be experiencing. This can help in deciding how best to treat it.

Please mark on the diagrams below where you feel your pain. If you have pain in more than one area, only shade in the one main area where your worst pain is.



On the scale below, please indicate how **severe** your pain (the one you have shown on the above diagrams) has been in the last week where:

0 = means no pain, 5 = means moderate pain and 10 = means pain as severe as it could be

NO PAIN 0 1 2 3 4 5 6 7 8 9 10 SEVERE PAIN

On the other side of the page are 7 questions about your pain (the one in the diagrams)

Think about how the pain that you showed in the diagrams has felt over the last week. Please circle the descriptions that best match your pain. These descriptions may or may not match your pain no matter how severe it feels.

Only circle the responses that describe your pain. Please turn over

1. In the area(s) where you have pain, do you also feel pins and needles, tingling or prickling sensations?
 - a) NO – I don't get these sensations (0)
 - b) YES – I get these sensations (5)

2. Does the painful area(s) change color (perhaps looks more red) when the pain is particularly severe.
 - a) NO - The pain does not affect the color of my skin (0)
 - b) YES - I have noticed that the pain does make my skin look different from normal (5)

3. Does your pain make the skin of the affected area abnormally sensitive to touch? Getting unpleasant sensations or pain when lightly stroking the skin might describe this.
 - a) NO- The pain does not make my skin in that area abnormally sensitive to touch (0)
 - b) YES - My skin in that area is particularly sensitive to touch (3)

4. Does your pain come on suddenly and in bursts for no apparent reason when you are completely at rest? Words like electric shocks, jumping and bursting might describe this.
 - a) NO – My pain doesn't really feel like this (0)
 - b) YES – I get these sensations often (2)

5. In the area(s) where you have pain, does your skin feel unusually hot like a burning pain?
 - a) NO – I don't have burning pain (0)
 - b) YES – I get burning pain often (1)

6. Gently rub the painful area(s) with your index finger and then rub a non-painful area (for example, an area of skin further away or on the opposite side from the painful area). How does the painful area(s) feel when rubbed?
 - a) The painful area feels no different from the non-painful area (0)
 - b) I feel discomfort like pins and needles, tingling or burning in the painful area (5)

7. Gently press on the painful area(s) with your finger tip then gently press in the same way onto a non-painful area (the same non-painful area that you chose in the last question). How does the painful area(s) feel when pressed?
 - a) The painful area does not feel different from the non-painful area (0)
 - b) I feel numbness or tenderness in the painful area that is different from the non-painful area (3)

Scoring: a score of 12 or more suggests pain of predominantly neuropathic origin

Appendix X: Evidence-Based Lumbar CNE Protocol

PROTOCOL
CLINICAL NEUROLOGICAL EXAMINATION OF
THE LUMBO-SACRAL SPINE

BY

Nassib Tawa, PhD Fellow (Physio)
University of the Western Cape
Cape Town, South Africa

Physiotherapy Lecturer
College of Health Sciences
Jomo Kenyatta University

Dr Ina Diener, PhD (Physio)
Physiotherapy lecturer & Clinician
University of Stellenbosch, South Africa

Prof. Anthea Rhoda, PhD (Physio)
Lecturer & Researcher
University of the Western Cape
Cape Town, South Africa

2012

TABLE OF CONTENTS

1. ABBREVIATIONS.....	3
2. DEFINITION OF KEY TERMS.....	4
3. INTRODUCTION AND BACKGROUND INFORMATION	5
4. PRINCIPLES AND RECORDING OF CLINICAL NEUROLOGICAL EXAMINATION.....	6
a. CONDUCTION TESTING	
i. SENSORY TESTING.....	8
ii. MOTOR STRENGTH TESTING	8
iii. TENDON REFLEX TESTING	9
b. NEURAL TISSUE PROVOCATION TESTING	
i. NEURO-DYNAMIC TESTING.....	10
5. CLINICAL NEUROLOGICAL TESTS FOR THE LUMBO-SACRAL NERVE ROOTS	
a. SENSORY TESTS.....	10
b. MOTOR TESTS.....	11
c. REFLEX TESTS.....	11
d. NEURO-DYNAMIC TESTS.....	11
6. BIBLIOGRAPHY.....	12



ABBREVIATIONS

CNE	Clinical neurological examination
DRG	Dorsal root ganglion
IVD	Inter-vertebral disc
ESR	Erythrocyte sedimentation rate
MRI	Magnetic resonance imaging
L1 – L5	Lumbar nerve roots 1 to 5
S1 & S2	Sacral nerve roots 1 and 2
NDTs	Neuro-dynamic Tests
ROM	Range of Motion
RICs	Resisted Isometric Contractions
MSp2	Muscle Spasms stopping movement
P1	Point in ROM where pain begins
P2	Point in ROM where pain stops movement
*	Reproduced patient's symptoms
SLR	Straight Leg Raise Test
E	Extension
F	Flexion



2. DEFINITION OF KEY TERMS

Neuro-conduction testing: Examination of the conduction function of the peripheral neural system

Dermatome: Area of skin supplied by a specific spinal nerve root

Signature zone: A dermatomal area distinctly supplied by a specific spinal nerve

Distal dermatomal area: The most distal part of a dermatome

Soft touch testing: examination of the conduction function of large caliber nerve fibers

Superficial pain testing: Examination of the conduction function of small caliber fibers

Myotome: A group of muscles supplied by a specific nerve root

Motor power testing: Examination of muscle strength

Tendon reflex testing: Examination of deep tendon reflexes

Neuro-sensitivity testing: Examination of the peripheral neural system's response towards mechanical loading

Mid-lumbar spine segment: Lumbar spinal segment from the 2ND to 4th vertebrae

Lower lumbar spine segment: Spinal segment from the 5th lumbar vertebrae to the 2nd sacral vertebrae

Straight leg raise test: Neuro-sensitivity testing of the lower lumbar segment

Slump knee bend test: Neuro-sensitivity testing of the mid-lumbar segment

3. INTRODUCTION AND BACKGROUND INFORMATION

Definition of lumbo-sacral radiculopathy: Lumbo-sacral radiculopathy is one of the three main clinical sub-categories of lumbar spinal dysfunctions according to the Quebec Task Force classification (Andersson, 1997). Lumbo-sacral radiculopathy is clinically defined as spinal and/or radiating leg pain accompanied by objective loss of sensory and motor function. The clinical features usually include dermatomal anesthesia, myotomal fasciculation, cramping, atrophy and loss or altered deep tendon reflexes (Schaffer, Hall and Brifa 2007). The radicular symptoms are caused by mechanical irritation, inflammation or ischemic damage of the lumbo-sacral nerve roots and their associated Dorsal Root Ganglia (DRGs) leading to release of ectopic nerve impulses perceived as pain in a dermatomal pattern accompanied by hypersensitization of the DGR to mechanical stimulation and stretching during normal functional activities (Andersson, 1997).

Causes of lumbo-sacral radiculopathy: Inter-vertebral disc (IVD) herniation is considered to be the major common cause of lumbo-sacral radiculopathy (Kendall, Linton and Main (1997), however, conditions like spinal stenosis, infestations, tumours and vascular abnormalities may also cause lumbo-sacral radiculopathy (Hoogendoorn et al, 2000). The resultant patho-anatomical, patho-mechanical and patho-physiological changes may vary depending on the underlying causative factors, however, the most common changes usually include focal demyelination of the affected nerve root, intra-neural oedema, impaired micro-circulation, and Wallerian degeneration (Andersson, 1997).

Assessment of lumbo-sacral radiculopathy: Clinical guidelines on the assessment of lumbo-sacral spinal dysfunctions recommend the application of diagnostic triage to differentiate *specific spinal pathologies* like tumors, *nerve root radiculopathies* and *NSLBP* (Jarvik and Deyo, 2002). However, for most patients with lumbar spinal dysfunctions, a thorough history taking and brief clinical examination is sufficient for assessment and treatment at the primary healthcare level since the primary purpose of the initial examination is to attempt to identify any 'red flags' and to make a specific diagnosis.

Radiological examination (x-ray, Computerized Tomography and Magnetic Resonance Imaging) together with bio-chemical laboratory tests (full blood count and Erythrocyte Sedimentation Rate) are not recommended in the first 4-6 weeks of acute lumbo-sacral radiculopathy since they do not provide any clinical benefit unless there are red flags (Frymoyer, 1988).

Clinical neurological examination which is a vital component of the assessment include dermatomal sensitivity testing (soft touch and superficial pain), myotomal strength testing, deep tendon reflex testing and neural mechano-sensitivity testing.

4. EVIDENCE-BASED CNE OF LUMBAR AND SACRAL NERVE ROOTS

For all neurological testing the patient is positioned comfortably and appropriately for the testing, with just enough skin exposure for meaningful testing. Prior to each test the testing procedure is explained to the patient, regarding **what is tested, what is expected** of the patient and **how the test** is going to be done.

A. Sensory testing [dermatomal]

A.1 Light touch sensation & A.2 Superficial pain sensation [only if light touch is impaired]

1. Establish base sensation to familiarize patient with 'soft touch' sensation on the arm: 'This is how light touch feels' [No indent on skin]
2. Patient's eyes closed
3. Test one spot in 'signature zone' and one spot at most distal part of the dermatome
4. Compare the affected side with the other side with: 'Does this' [touch/stroke twice lightly on a small surface], 'feel the same as this'? [repeat same procedure on other side at exactly the same area/direction/depth]
5. If soft touch sensation is impaired, assess superficial/light pain with a sterile flagged pin – touch or tap skin – following the same procedure as for light touch sensation

Recording [indicate on affected side on body chart]

Grade	Sensation
0	Absent
1	Reduced
2	Normal
3	increased

B. Motor power testing [myotomal]

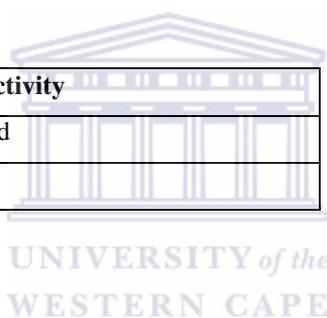
B.1 Functional tests

B.2 Isometric muscle contraction tests

1. Unaffected side, then affected side
2. Position the limb in the mid- range of movement, where the therapist can hold the position saying; 'Don't let me move you down/up/in/out'
3. Ascertain the correct direction of resistance given to the movement tested
4. The therapist give just enough resistance to meet the motor power of the patient
5. The therapist hold the contraction and count: '6,5,4,3,2,1,let go'; and then let go slowly meeting the force of the patient's relaxation of the contraction

Recording

Grade	Muscle Activity
0	Diminished
1	Normal



C. Deep tendon reflex testing

1. The patient is positioned in a stable posture with the tested tendon on slight stretch
2. The patella hammer 'fall' on the tendon fibers just next to where it attaches to the bone
3. The tendon is tested once if a good contraction is elicited and can be repeated to assure the outcome of the test

Recording on affected side:

Grade	Reflex activity
0	Absent
1	Hypo
2	Normal
3	Hyper

D. Neuro-sensitivity testing

Principles and Recording:

1. Patient is specified starting position
2. Explain to patient that must report symptoms [what and where] – note P2
3. Measure height of heel from bed in Sciatic nerve test and hip E ROM with goniometer in Femoral nerve test
4. What is a positive test? [in this order of importance]
 - a. The symptoms of the patient reproduces – record *Sx
 - b. Symptoms diminished/increased with addition/subtraction of a distant movement component which does not change the underlying soft tissue stretch. Record which movement
 - c. Palpable increase in protective muscle spasm compared to other side – note MSp2. Record MSp2 at what ROM

5. CLINICAL NEUROLOGICAL TESTS

A. SENSORY & MOTOR TESTING

L2 Nerve root

A. Sensory test: Dermatome		B. Motor strength test: Myotome	
Signature zone	Distal area	Functional test	RICs
Middle (medial thigh)	Lower (medial thigh)		Hip flexion (Ilio- psoas)

L3 nerve root

A. Sensory test: Dermatome		B. Motor strength test: Myotome	
Signature zone	Distal area	Functional test	RICs
Medial knee	Medial knee below	Sitting –to-standing	Supine: Quadriceps (Knee extension)

L4 Nerve root

A. Sensory test: Dermatome		B. Motor strength test: Myotome	
Signature zone	Distal area	Functional test	RICs
Medial lower leg above medial malleolus	Medial big toe	Heel walk x6	Tibialis anterior (dorsiflexion towards inversion)

L5 Nerve root

A. Sensory test: Dermatome		B. Motor strength test: Myotome	
Signature zone	Distal area	Functional test	RICs
Medial foot	Lateral big toe, Tip T2,3,4. Medial plantar surface forefoot		Big toe extension (Extensor hallucis longus)

S1 Nerve root

A. Sensory test: Dermatome		B. Motor strength test: Myotome	
Signature zone	Distal area	Functional test	RICs
Dorsum lateral foot	Lateral foot	Tip-toe standing	Planter-flexion (Gastrocnemius & solues)

S2 Nerve root

A. Sensory test: Dermatome		B. Motor strength test: Myotome	
Signature zone	Distal area	Functional test	RICs
Postero-medial upper thigh	Postero-medial lower leg	Tip-toe standing	Planter-flexion (Gastrocnemius & solues)

B. TENDON REFLEX TESTING

A. Mid-lumbar spine		B. Lower-lumbar spine	
Segmental level	Reflex test	Segmental level	Reflex test
L1, 2, 3	Patella tendon reflex	L4,L5,S1	Achilles tendon reflex

C. NEURAL SENSITIVITY TESTING

D. Femoral nerve longitudinal loading test (Side-lying slump) (asymptomatic side first and then symptomatic side).

- a. Patient is positioned in side lying (affected side uppermost)
- b. Patient holds the opposite knee by bending it towards chest
- c. Patient flexes neck with chin towards chest
- d. Therapist holds the uppermost leg in 90 degrees knee flexion resting on her arm and extend the hip until symptoms are provoked
- e. Therapist ask patient for neck extension

E.

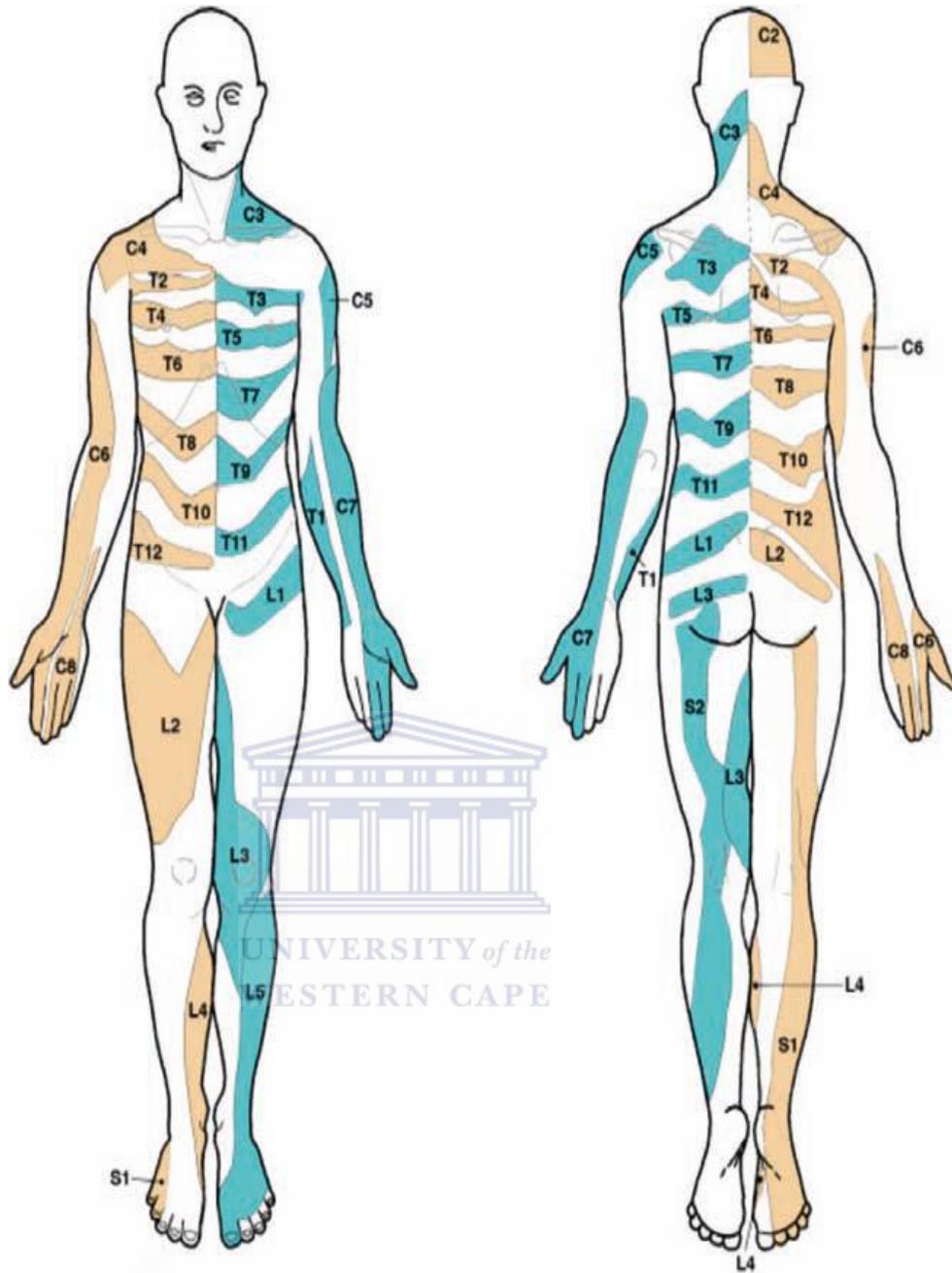
A. Mid-lumbar spine	
Segmental level	NDT
L1, 2, 3	Slump knee bend test for femoral nerve stretch

1. Sciatic nerve longitudinal loading test (Straight leg raise) (asymptomatic side first and then symptomatic side).

- a. Patient in supine - both legs extended
- b. Therapist places one hand under ankle and the other over patella
- c. Keeping knee extended, therapist flex hip in a perpendicular plane until *symptoms are evoked – measure distance of heel from bed
- d. If *symptoms are not evoked, and only a hamstring stretch is felt – measure the distance from the bed, and lower the leg
- e. Apply maximum dorsiflexion with one hand, maintain knee extension and flex the hip with a straight leg. Measure when * symptoms or hamstring stretch stops the movement (P2)

B. Lower-lumbar spine	
Segmental level	NDT
L4,L5,S1	SLR for sciatic nerve stretch

DERMATOME MAP



Appendix XI: Consent Form (Radiologists)



**UNIVERSITY OF THE WESTERN
CAPE**

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959, 2542 Fax: 27 21-959, 1217

CONSENT FORM

Title of the study:

Clinical validity and reliability of an adopted MRI lumbar reporting protocol.

The study has been described to me in a language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name.....

Participant's signature.....

Witness.....

Date.....

Should you have any questions regarding this study or wish to report any problems you have experienced related to the study, please contact the principal researcher.

Mr. Nassib Tawa

College of Health Sciences

Jomo Kenyatta University of Agriculture & Technology

PO Box 62000-00200

Cell: +254 701 182 685

nassibtawa@gmail.com

Appendix XII: Information Sheet (Radiologists)



UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959, 2542 Fax: 27 21-959, 1217

INFORMATION SHEET

Study Title:

Clinical validity and reliability of an adopted MRI lumbar reporting protocol.

What is this study about?

This study is part of a PhD research project being conducted by **Mr Nassib Tawa** at the University of the Western Cape, South Africa. We are inviting you to participate because you are a Kenyan radiologist who on a regular basis report MRI films of patients with low back and referred leg symptoms for the diagnosis of lumbar radiculopathy

What is the purpose of this study?

The purpose of this study is to establish clinical validity and reliability of an of the adopted protocol among Kenyan radiologists

What will I be asked to do?

1. You will be required to read through the tool and give feedback regarding its face and content validity.
2. You will be required to report patients' films using the protocol

What benefits will I gain for participating?

This study is not designed to personally benefit you as an individual radiologist. However, the outcome shall assist improving diagnostic workup for patients with low back and referred leg pains

Is my confidentiality and anonymity guaranteed?

We will do our best to keep your personal information confidential. To help protect your anonymity we shall use your initials during the entire process. Data will be kept in a safe place having locked filing cabinets and storage areas, using identification codes on data and password-protected computer files. If we write a report or publish an article about this research project, your identity will be protected to the maximum extent possible.

What are the risks?

There are no known risks associated with participating in this research project. However, in case of any eventuality while participating, the researcher has put all necessary measures in place to assist appropriately.

Must I participate in this study?

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

This study is being conducted by **Mr Nassib Tawa** of the department of physiotherapy at the University of the Western Cape, South Africa. If you have any questions about the study, please contact

Mr. Nassib Tawa: +254 701 182 685 e-mail nassibtawa@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Head of Department: Prof. Anthea Rhoda

Dean, Faculty of Community and Health Sciences: Prof. Jose Frantz

University of the Western Cape

Private Bag X17

Bellville 7535



This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

Appendix XIII: Lumbar MRI Reporting Protocol (Original)

MRI PROTOCOL Patient id: _____ Patient name: _____ Date: _____ LUMBAR SPINE

Examination quality: Good _____

Before reading patient history Suboptimal _____

After reading patient history Not conclusive _____

LEVEL	SPINE	DISC			ME-DULLA signal	SPINAL CANAL Spinal-stenosis	PROTRUSIO / PROTUBERANCE GRADE							RESTRICTION TYPE	
		Water content	Height	Rim Sign			dx extra-foraminal	dx foraminal	dx lat recess	MEDIAL paramedial	sin lat recess	sin foraminal	sin extra-foraminal	Disk Ligaments	Bone
Th 9-10															
Th 10-11															
Th 11-12															
Th12-L1															
L1-2															
L2-3															
L3-4															
L4-5															
L5-S1 (L5-6)															
Grading:		- normal decrease 1 slight 2 significant	- normal decreased: 1 slight 2 signif.	- absent 1 present	- normal 1 increa.	- absent 1 slight 2 signif.	- normal 1 slight 2 significant	- normal 1 slight 2 significant	- normal 1 slight 2 to nerve 3 deranging nerve	- normal 1 slight 2 to dura/medulla 3 deranging dura/med.	- normal 1 slight 2 to nerve 3 deranging nerve	- normal 1 slight 2 significant	- normal 1 slight 2 significant	- normal 1 bulging 2 hernia 3 sequest	- normal 1 vertebra 2 intervertebral

Appendix XIV: Self-Developed Short Questionnaire

**FACE VALUE EVALUATION FORM
MRI LUMBAR SPINE PROTOCOL**

Name

(Initials).....Hospital.....Date.....

ITEM	QUALITY	COMMENTS/SUGGESTIONS
Graphical presentation	Clear unclear	
Examination coverage	Adequate Inadequate	
Examination parameters	Fully relevant partially irrelevant Fully irrelevant	
Appropriateness of protocol	Totally appropriate Partially appropriate Totally inappropriate	
Clinical applicability (Kenya)	Applicable Inapplicable	
Research applicability (Kenya)	Applicable Inapplicable	
Grading system	Poor Faire Standard	

Thank you for participating.

Appendix XV: Adapted Lumbar MRI Reporting Protocol

MRI PROTOCOL LUMBAR SPINE

IP/OP No.: _____

Patient name: _____

Date: _____

Examination quality:

- Before reading patient history
- After reading patient history

- Good _____
- Suboptimal _____
- Not conclusive _____

LEVEL	DISC			ME-DULLA signal	SPINAL CANAL Spinal-stenosis	PROTRUSIO / PROTUBERANCE GRADE							RESTRICTION TYPE	
	Water content	Height	Rim sign			RT extra-foraminal	RT foraminal	RT lat recess	MEDIAL paramedial	LT lat recess	LT foraminal	LT extra-foraminal	Disk Ligaments	Bone
L1-2														
L2-3														
L3-4														
L4-5														
L5-S1														
Grading:	- normal decrease d: 1 slight 2 significant	- normal decrease d: 1 slight 2 signif.	- absent 1 present	- normal 1 increa.	- absent 1 slight 2 signif.	- normal 1 slight 2 significant	- normal 1 slight 2 significant	- normal 1 slight 2 to nerve 3 deranging nerve	- normal 1 slight 2 to dura/medulla 3 deranging dura/med.	- normal 1 slight 2 to nerve 3 deranging nerve	- normal 1 slight 2 significant	- normal 1 slight 2 significant	- normal 1 bulging 2 hernia 3 sequest	- normal 1 vertebra 2 intervertebral

Appendix XVI: Oswestry Low Back Pain Disability Questionnaire

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools.

Scoring instructions

For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, it = 5. If all 10 sections are completed the score is calculated as follows:

Example: 16 (total scored)
 50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

 16 (total scored)
 45 (total possible score) x 100 = 35.5%

Minimum detectable change (90% confidence): 10% points (change of less than this may be attributable to error in the measurement)

Interpretation of scores

0% to 20%: minimal disability:	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability:	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability:	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled:	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.



Section 1 – Pain intensity

I have no pain at the moment
The pain is very mild at the moment
The pain is moderate at the moment
The pain is fairly severe at the moment
The pain is very severe at the moment
The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

I can look after myself normally without causing extra pain
I can look after myself normally but it causes extra pain
It is painful to look after myself and I am slow and careful
I need some help but manage most of my personal care
I need help every day in most aspects of self-care
I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

I can lift heavy weights without extra pain
I can lift heavy weights but it gives extra pain
Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
I can lift very light weights
I cannot lift or carry anything at all

Section 4 – Walking*

Pain does not prevent me walking any distance
Pain prevents me from walking more than 2 kilometres
Pain prevents me from walking more than 1 kilometre
Pain prevents me from walking more than 500 metres
I can only walk using a stick or crutches

I am in bed most of the time

Section 5 – Sitting

I can sit in any chair as long as I like
I can only sit in my favourite chair as long as I like
Pain prevents me sitting more than one hour
Pain prevents me from sitting more than 30 minutes
Pain prevents me from sitting more than 10 minutes
Pain prevents me from sitting at all

Section 6 – Standing

I can stand as long as I want without extra pain
I can stand as long as I want but it gives me extra pain
Pain prevents me from standing for more than 1 hour
Pain prevents me from standing for more than 2 minutes
Pain prevents me from standing for more than 10 minutes

Pain prevents me from standing at all

Section 7 – Sleeping

My sleep is never disturbed by pain
My sleep is occasionally disturbed by pain
Because of pain I have less than 6 hours sleep
Because of pain I have less than 4 hours sleep
Because of pain I have less than 2 hours sleep
Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

My sex life is normal and causes no extra pain

My sex life is normal but causes some extra pain

My sex life is nearly normal but is very painful

My sex life is severely restricted by pain

My sex life is nearly absent because of pain

Pain prevents any sex life at all

Section 9 – Social life

My social life is normal and gives me no extra pain

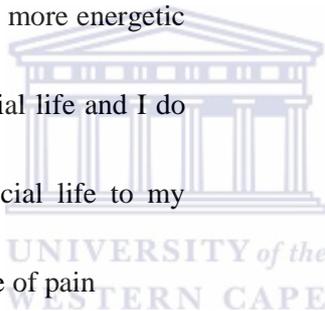
My social life is normal but increases the degree of pain

Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport

Pain has restricted my social life and I do not go out as often

Pain has restricted my social life to my home

I have no social life because of pain



Section 10 – Travelling

I can travel anywhere without pain

I can travel anywhere but it gives me extra pain

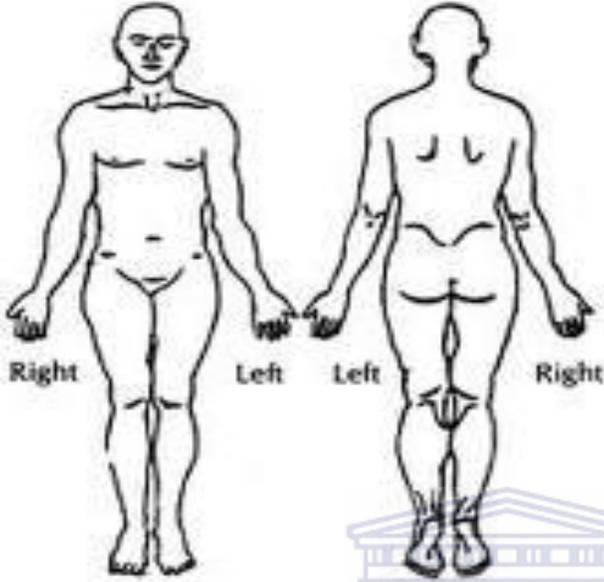
Pain is bad but I manage journeys over two hours

Pain restricts me to journeys of less than one hour

Pain restricts me to short necessary journeys under 30 minutes

Pain prevents me from travelling except to receive treatment

Appendix XVII: Demographic and Pain Questionnaire

<p>Indicate by shading the area(s) you experience pain</p> 	<p>Name (Initials).....</p> <p>Age.....Gender.....</p> <p>Occupation.....</p>
<p>What position or movement makes your pain worse</p>	<p>What time of the day/night is your pain worse</p> <p>Early morning <input type="checkbox"/></p> <p>Day long <input type="checkbox"/></p> <p>Evening <input type="checkbox"/></p> <p>Night <input type="checkbox"/></p>
<p>What position or movement makes your pain better</p>	<p>Has your pain affected your performance or productivity at;</p> <p>Home <input type="checkbox"/></p> <p>Work <input type="checkbox"/></p> <p>Leisure and recreation <input type="checkbox"/></p>
<p>Rate your pain in a scale of 0 = no pain, 5 = moderate pain and 10 = the worst pain</p>	<p>Indicate the status of your pain</p> <p>Improving Static Worsening</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p align="right"><input type="checkbox"/></p>

Appendix XVIII: Lumbar CNE protocol Peer Review Form

Title: Development of an evidence-based lumbar spine CNE protocol

Researchers:

Mr Nassib Tawa, Msc. PT

Dr Ina Diener, PhD. PT

Prof Anthea Rhoda, PhD. PT

Review Guideline 1: Merit of the protocol to Kenyan physiotherapists

- Important, worthwhile and justifiable.
- Addresses a clinical issue that is important in our daily practice.
- Aim of the protocol builds on and addresses a gap in existing knowledge among Kenyan physiotherapists.

Reviewer notes:

Review Guideline 2: Feasibility of the protocol in clinical practice

- The protocol is appropriate and could achieve the specific aim.
- The protocol is likely to improve clinical capacity among Kenyan physiotherapists in the field and contribute to accurate diagnosis, cost-effective treatments and improved health outcomes
- The protocol is highly applicable in the clinical settings
- The developers used robust scientific methods and have the appropriate experience and expertise

Reviewer notes:

Review Guideline 3: Structure and presentation of the protocol

- Appropriate overall presentation, including structure, ‘understandability’, clarity and readability

Reviewer notes:

Review Guideline 4: Other comments

- Any reviewer observations regarding the protocol that are not covered in the points above

Reviewer notes:

Reviewer (Initials).....signature..... Name

Appendix XIX: Lumbar CNE Review Data

Author (year)	N (gender, age)	Participants description	Setting & recruitment period	Examiners	Clinical test results
Suri et al (2011)	N=54 Male =28 Female = 26 Mean age = 54	Lower extremity radiating pain of ≤ 12 weeks	Hospital spine centre (January 2008 – March 2009)	Physiatrists specialized in spine care	SLR test or crossed SLR test, Femoral nerve stretch test or crossed FS test, motor testing, sensory testing, patellar tendon reflex and Achilles tendon reflex test.
Trainor & Pinnington. (2011)	N=16 Male =7 Female = 9 Mean age = 49	Radicular leg pain	Orthopedic spinal clinic (6 months)	Physiotherapists	SLR tests and slump knee bend test
Bertilson et al (2010)	N=61 Male =12 Female = 49 Mean age = 60	Low-back and referred leg pain	Radiology clinic (February September 2004)	Orthopedic surgeon and certified radiologist	Hypotrophy and sensibility to touch and pain prick, reflex and motor function, palpation of tender points and spine
Coster et al. (2010)	N=202 Male =92 Female = 110 Mean age = 46	Patients with clinical suspicion of Lumbo-sacral radicular syndrome.	Neurology department (January 2006 – March 2007)	Neurophysiologist.	Dermatomal sensory loss, myotomal weakness, reflexes and straight leg raising.
Lee-Robinson et al (2010)	N=70 Male =31 Female = 39 Mean age = 65	Low back pain and radicular lower extremity symptoms of weakness, numbness, and pain.	Electro-diagnosis, physical medicine & rehabilitation clinic (January to October 2009)	Physician specialized in Electro-diagnosis, Physical Medicine and Rehabilitation	Ankle reflexes, sensory tests, Distal muscle strength of ankle and toe extensors and flexors. Feet and lower extremities were closely inspected for evidence of muscle atrophy
Suri et al (2010)	N=51 Male =40 Female = 11 Mean age = 54	Lower extremity radiating pain of ≤ 12 weeks due to MRI-visible lumbar disk herniation.	Hospital spine centre (January 2008 – March 2009)	Physiatrists specialized in spine care	Provocative testing, motor strength testing, pin prick sensation testing and deep tendon reflex testing.

Vroomen et al. (2002)	N=274 Male =139 Female = 135 Mean age = 46	A new episode of pain radiating into the leg below the gluteal fold	Neurology department	Neuro-radiologist	Patella tendon reflex, SLR test, sensory test
Majlesi et al (2008)	N=38 Male =30 Female = 8 Mean age = 38	Low back, leg, or low back and leg pain	Neuro-surgery department (January – June 2005)	Medical doctor	Slump test and SLR test
Rabin A et al (2007)	N=58 (MRI +) Male =? Female = ? Mean age =?	Signs and symptoms consistent with lumbar radiculopathy	Neuro- and orthopedic surgery clinic	Orthopedic physiotherapist and neuro-surgeon	Lumbar range of motion, myotomal muscle strength, deep tendon reflexes, and dermatomal sensory testing
Haldeman S, et al (1998)	N=100 Male = ? Female = ? Mean age =?	Low-back pain and leg pain, consistent with a diagnosis of sciatica	Orthopedic surgery department	Neurologist and orthopedic surgeon	Slump knee bend test
Albeck (1996)	N=80 Male =48 Female =32 Mean age =40	Mono-radicular pain corresponding with L5 or S1 nerve root pathology.	Neurology clinic	Neuro-surgeon	Finger-floor distance and SLR test

Appendix XX: MRI Review Data

Author (year) Country	N (gender, age)	Participants description	Imaging tool	Imaging procedure	Test results
Eguchi et al (2011) Japan	N=10 Male =8 Female = 2 Mean age = 48.0	Unilateral radicular symptoms caused by a lumbar herniated disk	1.5-T scanner (Achieva 1.5 T Nova Dual; Philips Medical Systems, Japan)	Subjects scanned in supine using a sense XL Torso coil. Diffusion- weighted imaging (DWI) was performed with a background body signal suppression and short T1 inversion recovery-echo planar imaging sequence.	The mean apparent Diffusion Coefficient (ADC) in patients was greater at compressed DRG and distal spinal nerves than in the controls. MR neurography showed nerve abnormalities at and below site of compression in symptomatic nerves
Bertilson et al (2010) Sweden	N=61 Male =12 Female = 49 Mean age = 60	Low-back and referred leg pain	1.0 Tesla scanner (Philips Intera)	Patients in supine, phased array spinal coil was used to produce sagittal and axial T1 and T2 spin and turbo spin echo sequences (slice thickness 3mm, inter-slice gap 0.3mm, fields of view 25 cm for sagittal and 16v cm for axial images)	MRI-visible nerve involvement at any location and segment was less compared to physical examination. Decreased water content and disco- ligament protrusions were the most prevalent disc and space-restricting pathologies respectively. MRI findings were more prevalent at L4-S1 segment.

Hasankhani & Omid-Kasani (2013) Iran	N=152 Male=96 Female=52 Mean age=43	Radicular pain of not less than 6 weeks	Not Described	Not Described	High accuracy of MRI (89.5%) in detecting nerve root involvement
Thornbury et al (1993) USA	N=63 Male= 42 Female= 21 Mean age=42	Acute low back and radicular pain	Not described	Not described	No difference between the accuracy of MRI, plain CT and CT Myelography in diagnosing HNPNC

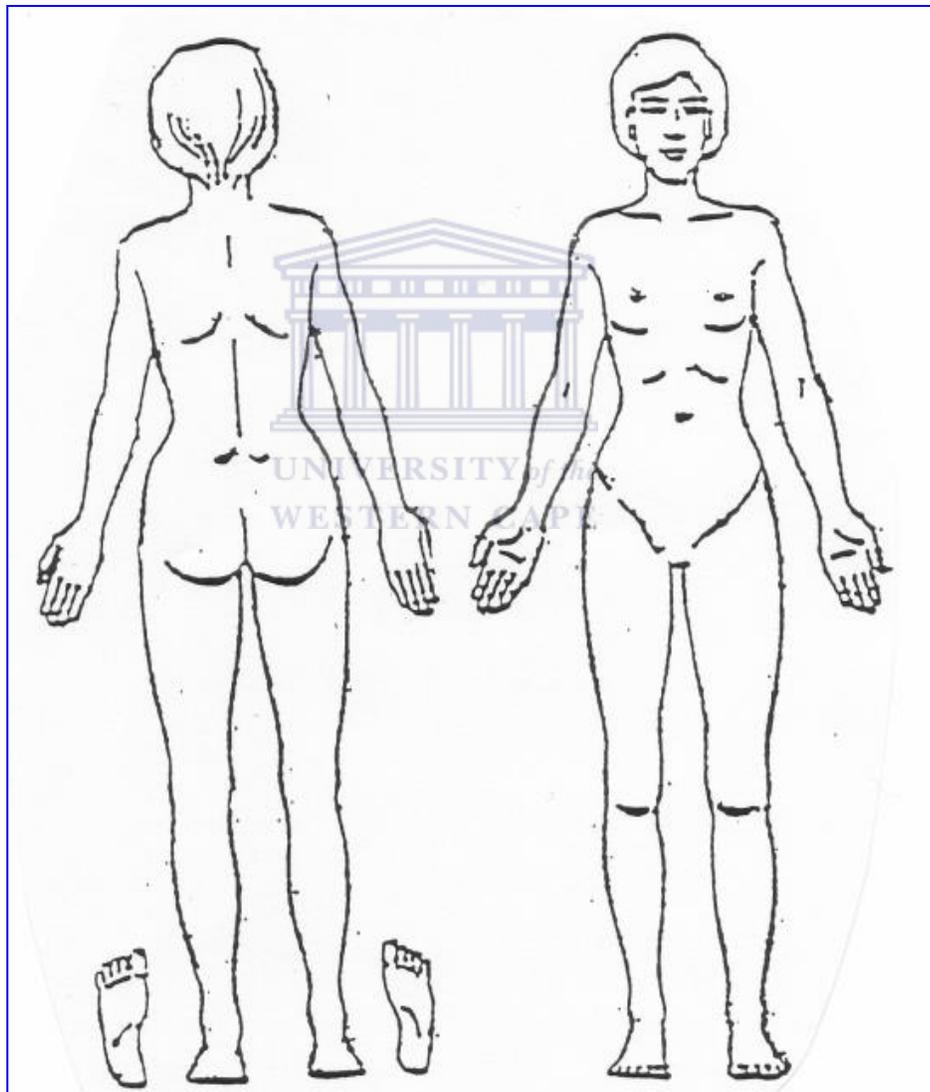


Appendix XXI

The simplified pain drawing

Drawing of discomfort

Where have you had discomfort and what kind of discomfort? Shade with a led pen ALL areas where you have experienced discomfort the last 3 months. Shade off the blackness according to the severity of the discomfort. Describe the kind of discomfort next to the figure, for example: ache, murmur, tingle, stinging, numbness, pain, cramp, buzz.



Appendix XXII: Information sheet (physiotherapists)



UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959, 2542 Fax:

INFORMATION SHEET

Study Title:

Clinical standardisation of an evidence-based lumbar spine CNE protocol.

What is this study about?

This study is part of a PhD research project being conducted by **Mr Nassib Tawa** at the University of the Western Cape, South Africa. We are inviting you to participate because you are a Kenyan physiotherapist who on a regular basis attends to patients with low back and referred leg symptoms.

What is the purpose of this study?

The purpose of this study is to standardise an evidence-based lumbar spine clinical neurological examination among a sample of Kenyan physiotherapists.

What will I be asked to do?

You will be required to attend some presentations and practical demonstrations by the researcher.

What benefits will I gain for participating?

This study is not designed to personally benefit you as an individual physiotherapist. However, the outcome shall assist physiotherapists in achieving a harmonised way of conducting a clinical neurological examination of patients with low back pain.

Is my confidentiality and anonymity guaranteed?

We will do our best to keep your personal information confidential. To help protect your anonymity we shall use your initials during the entire process. Data will be kept in a safe place having locked filing cabinets and storage areas, using identification codes

on data and password-protected computer files. If we write a report or publish an article about this research project, your identity will be protected to the maximum extent possible.

What are the risks?

There are no known risks associated with participating in this research project. However, in case of any eventuality while participating, the researcher has put all necessary measures in place to assist appropriately.

Must I participate in this study?

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

This study is being conducted by **Mr Nassib Tawa** of the department of physiotherapy at the University of the Western Cape, South Africa. If you have any questions about the study, please contact

Mr. Nassib Tawa +254 701 182 685 e-mail nassibtawa@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Head of Department: Prof. Anthea Rhoda

Dean, Faculty of Community and Health Sciences: Prof. Jose Fratz

University of the Western Cape

Private Bag X17

Bellville 7535

This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.