CLINICAL AND RADIOLOGICAL CORRELATION OF DEGENERATIVE LUMBAR CANAL STENOSIS WITH OUTCOME OF VARIOUS MODALITIES OF TREATMENT

Dissertation submitted in partial fulfillment of the requirements for the degree of

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NEUROSURGERY(5 YEARS COURSE)

Examination in AUGUST 2012

THE TAMILNADU DR.M.G,R. MEDICAL UNIVERSITY

DEPARTMENT OF NEUROSURGERY,

STANLEY MEDICAL COLLEGE

CHENNAI-1

CERTIFICATE

This is to certify that this dissertation entitled **CLINICAL AND RADIOLOGICAL CORELATION OF DEGENERATIVE LUMBAR CANAL STENOSIS WITH OUTCOME OF VARIOUS MODALITIES OF TREATMENT** submitted by **Dr.G.Rajkumar** appearing for **M.Ch**. Degree examination in **August 2012** is a bonafide record of work done by him under my direct guidance and supervision in partial fulfillment of regulations of the Tamil Nadu Dr.M.G.R. Medical University,Chennai,Tamil Nadu,India.

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DECLARATION

I,Dr.G.Rajkumar solemnly declare that this dissertation **CLINICAL AND RADIOLOGICAL CORELATION OF DEGENERATIVE LUMBAR CANAL STENOSIS WITH OUTCOME OF VARIOUS MODALITIES OF TREATMENT** was prepared by me in the Department of Neurosurgery,Stanley medical college and Government Stanley Hospital,Chennai under the guidance and supervision of Prof.Ranganathan Jothi M.Ch, D.N.B(N.S),Professor of neurosurgery, Department of Neurosurgery,Stanley medical college and Government Stanley Hospital,Chennai between 2007 and 2012.

This dissertation is submitted to the Tamilnadu Dr.M.G.R.Medical University, Chennai in partial fulfillment of the University requirements for the award of degree of M.Ch. Neurosurgery.

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(G.Rajkumar)

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CONTENTS

S.NO	TITLE	Page No.
1.	Introduction	1
2.	Aim of study	3
3.	Material and Methods	5
4.	Review of Literature	9
5.	Treatment of cases in this study.	25
6.	Outcome and Analysis-1(surg.treatment)	31
7.	Outcome and Analysis-1(conserv.treatment)	49
8.	Discussion	56
9.	Statistical Analysis.	67
10.	Conclusion	75
11.	References	
11.	Appendix	

INTRODUCTION

INTRODUCTION

Descriptions of treatment for low back pain (LBP) date to Hippocrates (460-370 BCE), who reported joint manipulation and use of traction. Onset of LBP often is associated with bipedal ambulation.

Lowback pain is extremely prevelant and is the second most common for people to seek medical attention. LBP accounts for the most of the sick leave from work and is the most common cause of disability of persons less than 45 years of age. As life expectancy continue to increase, prevalence of symptomatic spinal stenosis will increase. Although lumbar stenosis is not life threatening it can cause chronic and sustained pain and can limit activity severely. Early, accurate diagnosis and treatment of lumbar stenosis is important in preserving activity in elderly population[14].

Lumbar spinal stenosis is a progressive and degenerative process that causes narrowing of spinal canal, lateral recess or neural foramina and is divided into 2 groups, congenital & acquired. The narrowing results in the compression of lumbosacral roots by bony canal or soft tissues including the intervertebral disc, facet joints & ligamentum flavum. This narrowing causes axial lumbar pain, radicular pain & cauda equina syndrome when thecal sac & nerve roots are compressed.Even though nonoperative treatment is the main stay of treatment, surgery is

indicated in patients who have progressive neurological decline or when non- operative maneuvers have failed adequately to address the symptoms.

The Present dissertation is going to be a prospective study of 80 cases of lumbar canal stenosis to be treated for a period of one year(2011-2012) by conservative treatment and operative modalities such as decompressive laminectomy, discectomy, foraminotomy / medial facectomy, excision of hypertrophied ligamentum flavum.

AIMS AND OBJECTIVES

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Aims and objectives

1. To evaluate the age and sex incidence, distribution of pain, presence or absence of Laseque sign(SLRT +VE), motor/sensory/DTR disturbances in case of LCS.

2. To measure spinal canal at the level of disc, lateral recess, interpedicular distance using digital/ plain x ray LS spine, CT LS spine, MRI LS spine &correlation with clinical findings and outcome of various modalities of treatment.

3. To measure body/canal ratio(jones Thompson index)& correlation with clinical findings &outcome of surgery.

4. To illustrate the variations in spinal canal &lateral recess measurements using CT scan,MRI scan & study the statistical significance of the variations.

5. To evaluate the results of surgical treatment in LCS and its correlation with lumbar canal measurement by radiological investigations &clinical findings.

6. To evaluate the improvement in sciatica, claudication pain, neurological deficit in follow up of patients at 2 weeks,1 month,3 months,6 months following surgical intervention and conservative treatment.

7. To compare the results of conservative and surgical treatment.

MATERIALS

AND METHODS

MATERIALS AND METHODS

Source of data

This is a randomized study of 80 patients of lumbar canal stenosis of age between 20-60 years which was carried out in department of neurosurgery during the year 2011-2012 at govt Stanley hospital & college, Chennai.

Methods of collection

Data will be collected from the patients by their history telling, clinical examination & appropriate investigation.

Clinically patient had neurogenic caudication, backpain and/or sciatica as their main complaints. Sensory symptoms precede the motor manifestations in majority of the patients. The examination may disclose sensory deficits and/or loss of reflexes. As the disease progresses some pain may be experienced at rest &weakness on effort become a prominent symptoms. There may be varying degree of paravertebral muscle spasm with limitation of spine movements &occasionally restriction of SLRT. Impairment of DTR occurs in most patients, ankle jerk being more commonly affected. Sensory changes if present are predominant in 4, 5^{th} lumbar&1 st sacral dermatomes. If there is an associated disc prolapse

pain is aggravated by coughing, sneezing, straining at stools, lifting heavy weights etc. They have a restricted SLRT &have sensory &motor deficit pertaining to involved roots.

Careful history is taken to rule out vascular insufficiency (vas. claudication), trochantric bursitis, juxtafacet cyst, arachnoiditis, intraspinal tumors, functional etiology &diabetic neuritis.

All patients clinically subjected to be suffering from lumbar canal stenosis were subjected to the following radiological investigations- digital/plain x ray LS spine(AP &LATERAL VIEW),CT LS spine & MRI LS spine. In x-ray, parameters like disc space, facet joint, pars interarticularis, I.V foramen, interpedicular distance, lateral recess, spinal canal measurements, presence of listhesis/osteophytes/LSTV, presence of deformities like kyphosis, scoliosis, loss of lordosis, body/canal ratio(jones Thompson index) studied. CT LS SPINE is done to study spinal canal measurements at disc level& lateral recess were measured from L1 to L5 levels and also the status of facet joint. MRI LS SPINE with myelography is also done for the measurement of spinal canal &lateral recess, presence of HNP& their types, presence/absence of disc extrusion, root compression, ligamentum flavum hypertrophy, facet joint

hypertrophy, disc dehydration, endplate changes, deformity, presence/absence of listhesis& status of pars.

Documentation of patients information consisting of the patients particulars, history, clinical findings, investigations, operative procedures &its findings, follow up were recorded on a proforma.

Study design

Prospective study.

Inclusion criteria

1. age 20-60years.
2. sex-both males and females.
3. above mentioned cases of LCS with LBA,sciatica are included
4. stable form of lumbar canal stenosis such as lig.flavum hypertrophy, neural foraminal narrowing, facet hypertrophy, lateral recess stenosis, herniated/bulging intervertebral disc are included.
5. above form of LCS presented with neurological deficit like EHL weakness,footdrop are included.
6. above form of LCS presented with neurogenic claudication pain are included.

Exclusion criteria

1. unstable form of degenerative LCS-degenerative spondylolisthesis, degenerative scoliosis, multisegmental form are excluded.
2. congenital forms like achondroplasia, morquio syndrome, hurlers syndrome are excluded.
3. spondylolytic forms are excluded.
4. vertebral body compression# (trauma, metabolic diseases) are excluded.
5. iatrogenic postlaminectomy, post fusion are excluded.
6. spinal tumors like lymphomas, meningioma, schwanomma, neurofibroma, conus medullaris tumors are excluded.
7. miscellaneous conditions like pagets disease, spinal epidural hematoma & abscess are excluded.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

ANATOMY

There are five lumbar vertebrae and each vertebra has following components , Vertebral body – Designed to bear weight, Neural arch – To protect the neural elements. The body is connected by discs above and below and the arches are connected by facet joints (Zygapophyseal joints). The neural arch is composed of two pedicles and two laminae. The pedicle is attached to the cephalad end of the body. The ligamentum flavum fills in the inter laminal space at each level.(fig 1)

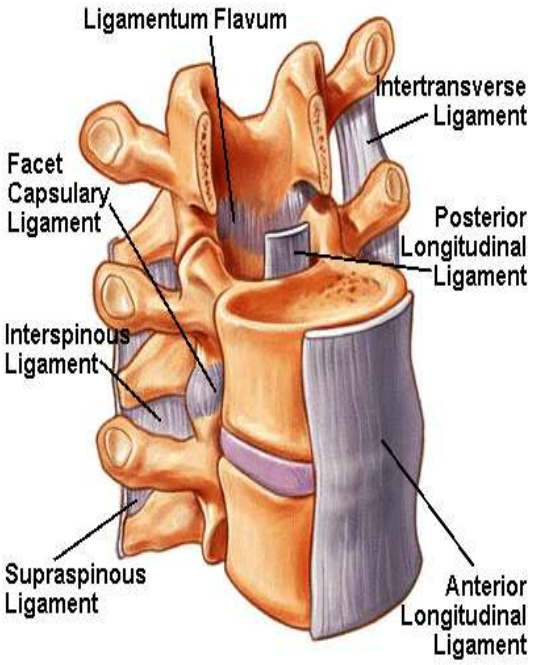


Fig1

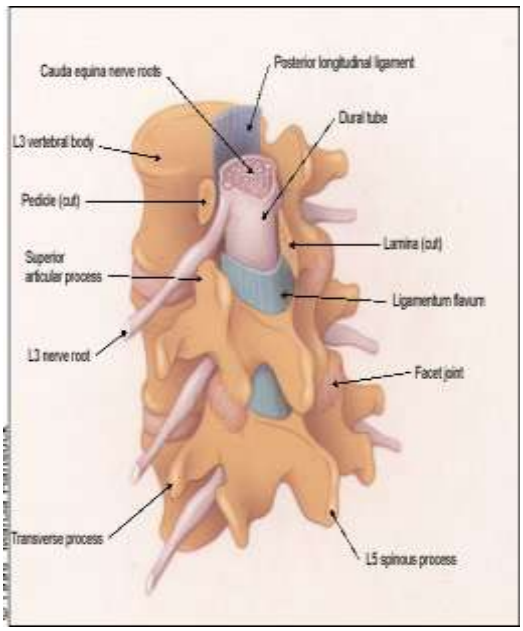
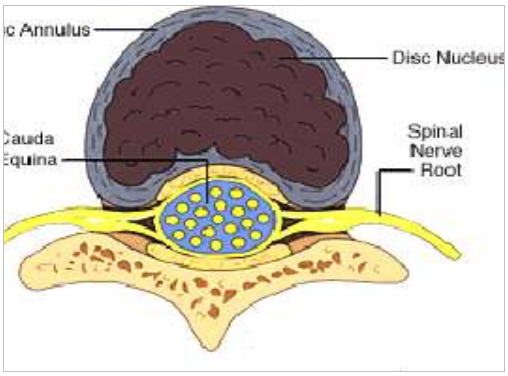


fig2

NERVE DISC RELATIONSHIP

The lumbar nerve exists from the intervertebral foramina below the corresponding numbered vertebral body but sufficiently above the disc and so will not commonly be affected by disc herniation at the same level except in case of a far lateral disc. Usually in the most common type of postero-lateral disc herniation, the traversing nerve root is compressed. (fig 2)



BIOMECHANICS OF THE DISC

The liquid and elastic properties of the nucleus and the annulus together provide great ability for withstanding large stresses. The distortion of the nucleus and the redistribution of the vertical forces into horizontal forces give the disc its compressibility and the resilience which makes the disc a very essential part in the bio-mechanic of weight transmission of the spine.

BASIC SPINAL CANAL ANATOMY[14]

Understanding spinal canal anatomy is fundamental to understanding the pathophysiology of degenerative lumbar stenosis. The posterior edge of the vertebral bodies and intervertebral discs form the anterior border of the spinal canal. The posterior bony arches (laminae) and the ligamentum flavum form the posterior border of the spinal canal. The lateral borders of the spinal canal are composed of the pedicles, the bony attachments of the posteriorarches to the vertebrae anteriorly. The spinal nerves exit segmentally through the neural foramina, the spaces between the pedicles. Facet joints are located bilaterally at each level of the spine posterolaterally at the disc space level. Degenerative enlargement of the facet joints may result in central impingement on the spinal canal (central stenosis) or more laterally, where the nerve root moves toward the foramen (lateral recess stenosis). Narrowing of the neural foramen may compress the exiting nerve root (foraminal stenosis)

CLASSIFICATION[14]

Spinal stenosis is classified according to

1. Etiology
2. According to stability.
3. Site of stenosis
4. Anatomical classification.

ETIOLOGICAL CLASSIFICATION

1. Congenital / Developmental stenosis

Idiopathic

Dwarfism

Achondroplasia

Morquio's syndrome (mucopolysaccharidosis)

Hurler's syndrome (mucopolysaccharidosis

2. Acquired stenosis

A. Degenerative

B. Spondylolisthetic / Spondylolytic

C. Combined

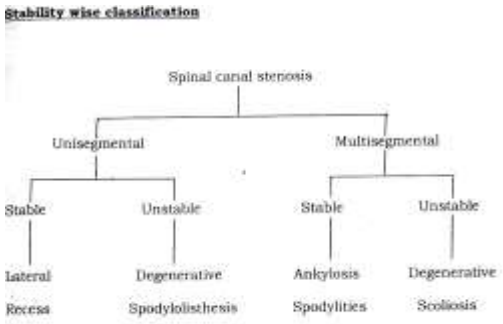
D. Iatrogenic

1. Post – laminectomy

2. Post-fusion

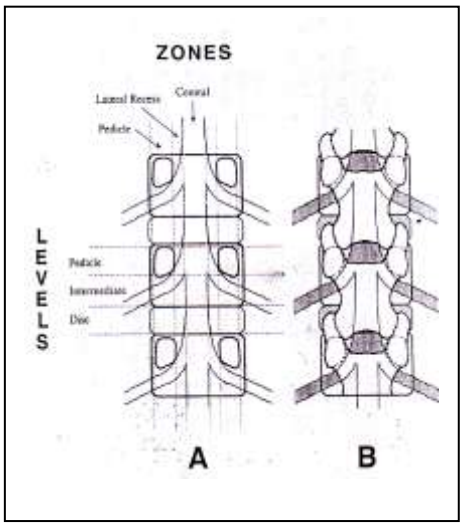
E. Post traumatic

3. Miscellaneous , spinal tumors.



ANATOMICAL CLASSIFICATION[22]:

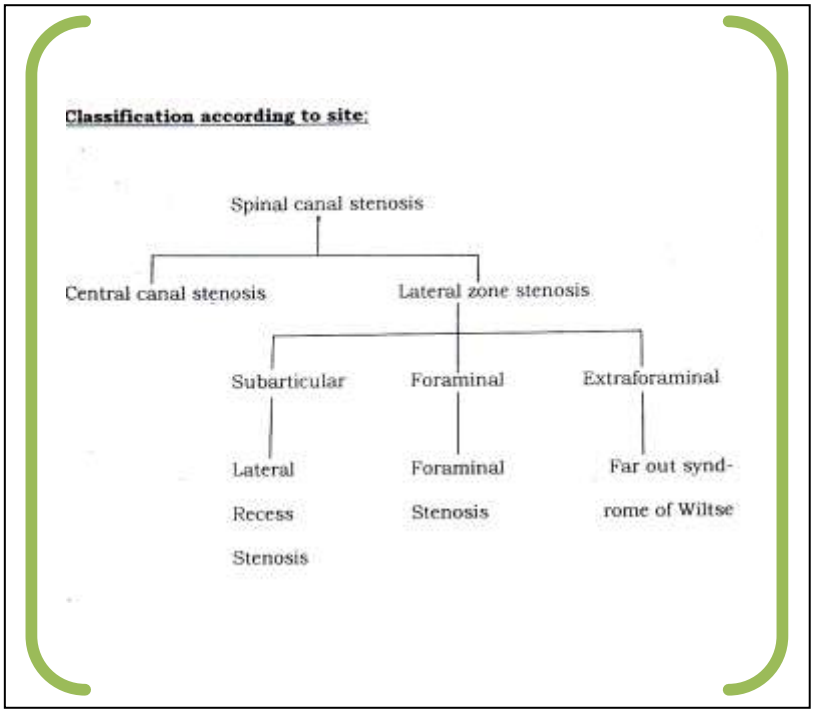
LINE DIAGRAM DEMONSTRATING GRID LIKE SUBDIVISION OF LUMBAR CANAL INTO THREE ZONES AND THREE LEVELS.



Anatomical classification of lumbar canal stenosis is used to identify specific areas of narrowing of spinal canal and is particularly useful as guides for operative decompression. Spinal canal is divided in grid like manner into series of transverse (three levels from cephalad to caudad and sagittal region (three zone from midline laterally).

- The three transverse levels from cephalad to caudad are the pedicle level, the intermediate level (body) and the disc level. The pedicle level extends from the superior to the inferior border of the pedicle. The intermediate level extends from inferior border of the pedicle to inferior end plate of the vertebra caudally. The disc level begins at the inferior end plate and extends caudally to the superior border of the next pedicle.

- From midline laterally the three sagittal zones are central zone, lateral recess zone, and the pedicle zone. The central zone is the area between normal lateral borders of non-compressed dural sac. The lateral recess zone is the area between the lateral border of the dural sac medially and longitudinal line connecting the medial edges of the pedicle laterally. The pedicle zone is the area between medial and lateral borders of the pedicle. This grid like subdivision of spinal canal helps in anatomical localization of stenotic element and consequent effective decompression.



PATHOGENESIS OF LCS

Each motion segment of the spine consists of two adjacent vertebrae and the intervening intervertebral disc, facet joints, and supporting ligaments. Degeneration of this joint complex commonly begins as disc desiccation. Mechanical failure of the disc then alters motion segment kinematics with subsequent facet joint osteoarthritis and hypertrophy.

As Segmental instability increases, the pedicles and laminae thicken, and the supporting ligamentous structures undergo hypertrophy. Bulging of the disc in the anterior spinal canal and infolding of the ligamentum flavum posteriorly also result in disc space narrowing. In most people who develop symptoms of spinal stenosis, the cross-sectional area of the spinal canal begins in the low-to-normal range, with limited capacity to accommodate the additional narrowing associated with degenerative changes.

CLINICAL PRESENTATION[17]

Most of our patients who have lumbar spinal stenosis presented with classical neurogenic claudication characterized by activity-related intermittent pain, numbness, and paresthesias radiating down the leg.

Symptoms occurred &worsened with prolonged standing, activity, or positions involving lumbar extension and are relieved by sitting, recumbency, or positions that reduce the degree of lumbar lordosis, such as bending forward. Patients give a long history of low-back pain which is more vague than the radiculopathy associated with a focal disc herniation. Most of our Patients assumed a simian posture, stooped with flattening of normal lumbar lordosis. Progressive reduction in distances walked or standing time was often reported. The classic history is that of symptom relief when pushing a grocery cart (upper-extremity weight-bearing with lumbosacral and hip flexion) as compared with walking upright.

NEUROGENIC CLAUDICATION

Table 1

Neurogenic Claudication[23]

All patients in this study had 'classic' neurogenic claudication defined as:

1. Bilateral posterior thigh and, often, calf discomfort characterized by pain, parasthesias, tiredness, and heaviness.
2. Brought on by walking (usually < a city block) and standing (usually < five minutes).
3. Relieved by sitting or lying down.
4. Positive MRI demonstrating canal stenosis.
5. Absence of significant vascular impairment to the lower extremities, absence of peripheral neuropathy, absence of severe DJD of hips, and absence of cardiopulmonary insufficiency.

REF.14

Symptom or Sign	Neurogenic Claudication	Vascular Claudication
Distal pulses	Normal	Diminished or absent
Skin changes	None	Mottled or atrophic Loss of pretibial hair growth
Positional change	Pain improved with lumbar flexion (eg, sitting, stooping)	Pain unaffected by lumbar posture
Riding stationary bicycle	Pain relieved	painful
Relationship of pain to cessationof ambulation	Prolonged time for pain resolution	Pain typically subsides immediately

OTHER CAUSES OF PAIN IN SPINAL STENOSIS[14]

Position-related radiculopathy.

Patients who have degenerative lumbar spinal stenosis often present with position-related radiculopathy rather than true neurogenic claudication.

Extension of the lumbarspine causes pain or paresthesias. Cadaver studies have demonstrated significant increases in dural sac capacity with **lumbar flexion** as compared with extension, which buckles the ligamentum flavum, increases disc protrusion, decreases interlaminar distance, and narrows the spinal canal by as much as 60% when compared with lumbar flexion.

Acute disc herniation.

A more constant radicular pain resulting from affected nerve root often occurs in addition to the more long-standing symptoms of activity-related numbness, weakness,and pain in the lower extremities. Sensory deficits are more common in patients who have spinal stenosis. Diminished motor reflexes may represent normal aging, but, because degenerative spinal stenosis usually affects lumbosacral spine, diminished/absent ankle jerk associated with grip weakness may be noted .Extensor hallucis longus weakness is seen with equal frequency in patients who have either lumbar spinal stenosis or a herniated lumbar disc, but a diminished ankle jerk is more common in patients with spinal stenosis. Limited spinal mobility and nerve root tension signs, such as a positive passive straight-leg raise or femoral stretch test, more commonly indicate a disc herniation than spinal stenosis.

- **Cauda equina syndrome.**

Acute cauda equina syndrome, characterized by extensive bilateral neurologic symptoms (eg, saddle anesthesia, bilateral motor weakness, fecal or urinary incontinence, sexual dysfunction), is uncommon with lumbar spinal stenosis.The rapid onset is more characteristic of an acute lumbar disc herniation than the gradual onset of positional symptoms associated with lumbar spinal stenosis. Nonetheless,

these symptoms require a complete neurologic evaluation with rectal examination of tone and sensation. Clinicians should maintain a high index of suspicion for all progressive neurologic disturbances, because acute disc herniation may occur with long-standing lumbar stenosis. Confirmed symptoms and signs should prompt urgent evaluation of the spinal canal with magnetic resonance imaging (MRI) or computed tomography (CT) myelography. Urgent (within 48hours of onset) surgical decompression may be necessary.

chronic cauda equina syndrome may develop from gradually progressing spinal stenosis, and most often results in bladder dysfunction and perineal pain. Because of the slowly progressive nature of the neurologic decline, urgent decompression is not often necessary before full diagnostic evaluation.

DIAGNOSTIC IMAGING[14]

Plain radiography for suspected lumbar spinal stenosis should include anteroposterior (AP) and lateral radiographs of the lumbosacral spine. In most patients who have suspected degenerative lumbar spinal stenosis, **multilevel spondylosis i**s seen on x-ray

XRAY FINDINGS IN LCS[18]

The following finding on plain x-rays were suggestive of lumbar canal stenosis:

(1) **Presence of hypertrophy of facet joint**

(2) Reduced distance between the pedicle and the facet joint

(3) Laterally aligned and irregular facet joint

(4) Reduced distance between the posterior border of vertebral body and anterior border of the superior facet.

(5) Short stout spinous process and the laminae.

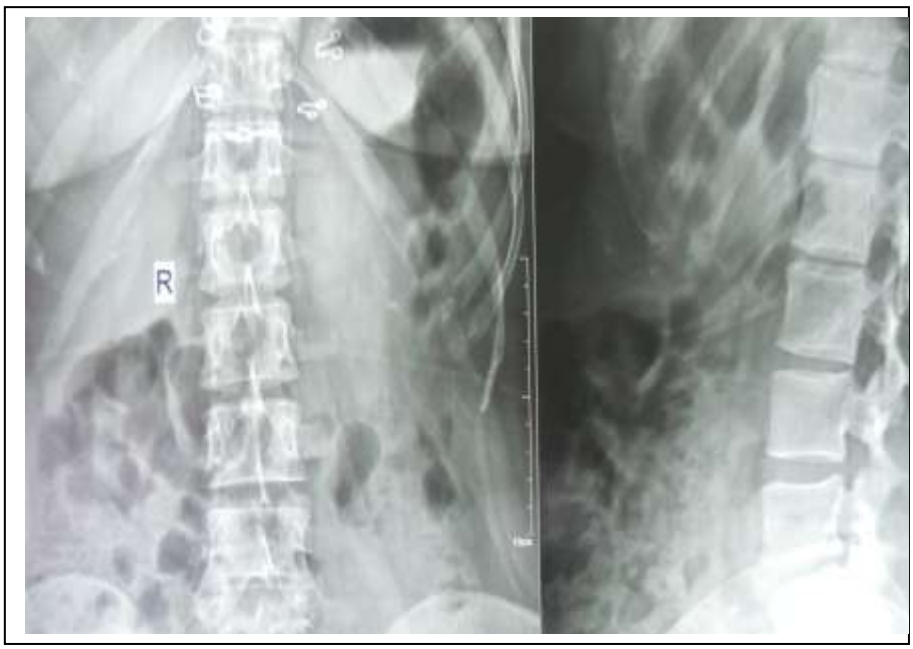
(6) **Reduced distance between the pedicles of adjoining vertebrae**.

(7) Associated features of prolapsed disc viz.

Reduced inter-vertebral disc space

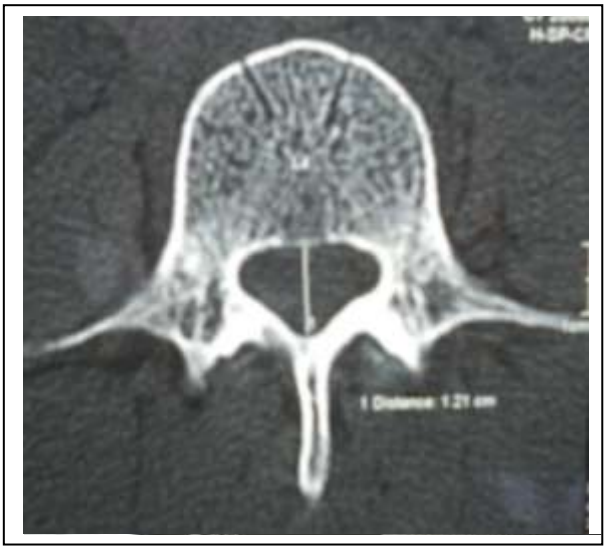
Posterior osteophytes etc

(8) jones Thompson index-evaluation of spinal canal stenosis



DIAGNOSTIC IMAGING

CT is used to determine canal dimensions and configuration and to identify disc abnormalities and herniation, facet degeneration and hypertrophy, ligamentous hypertrophy and redundancy, and spondylosis or occult fractures. Advantages of this technique include excellent osseous detail,especially of the lateral recess; ability to differentiate between disc, ligamentum flavum, and thecal sac(within the dura mater); and visualization of far lateral disc abnormalities and the neural foraminal architecture.The addition of intrathecal, water-soluble contrast media with CT is more sensitive than myelography alone and may improve the evaluation of patients who have persistent symptoms. A better assessment of central spinal and lateral recess stenosis and improved visualization of foraminal and far lateral disc abnormalities can be obtained. The combination of MRI and CT provides both bony and soft-tissue detail for preoperative anatomic analysis and can obviate the need for myelography in most cases.



MRI is especially effective for the evaluation of the intervertebral disc, neural elements, and soft-tissue elements of the spinal canal. Despite its higher cost compared with CT and plain radiography, its advantages include lack of radiation, direct multiplanar image reconstruction, and increased sensitivity in detecting soft-tissue and disc pathology. Also, sagittal images help visualize the lower end of the spinal cord, including the conus medullaris. MRI has been shown to be as accurate as CT myelography, and diagnostically superior to either myelography or CT alone.Careful interpretation is necessary, however, because overestimation of canal stenosis may occur if sclerotic osteophytes cause regions of low signal intensity on T2-weighted images.

OTHER TESTS

- **Electrophysiologic studies, such as electromyography, nerve-conduction velocities, and** somatosensory evoked potentials are not routinely used for establishing the diagnosis of degenerative lumbar spinal stenosis.

- The clinical utility of such studies lies in their ability to help differentiate active denervation from chronic, inactive changes in peripheral nerves, or to help rule out diffuse, peripheral neuropathic abnormalities secondary to other conditions, such as diabetes mellitus.

- Normal neurophysiologic studies do not rule out symptomatic lumbar spinal stenosis, because the radiculopathy may be intermittent and activity-related.

CLINICAL CORRELATION[14]

Despite the increasing reliance on diagnostic tests, correlation of any radiographic abnormalities with clinical signs and symptoms cannot be overemphasized. In a CT study of asymptomatic patients, 50% of those older than 40 demonstrated findings that were consistent with spinal stenosis, disc herniation, and facet joint degeneration. MRI demonstrated lumbar spinal stenosis in 3 of 14 asymptomatic subjects older than 60.

- Our diagnostic evaluation of lumbar spinal stenosis begins with AP and lateral views of the X RAY lumbosacral spine. If the

history, physical examination, and X RAY evaluation suggest spinal stenosis, we obtain MRIs with sagittal and coronal reconstructions to characterize the level of stenosis and to further evaluate neurologic deficits, such as those caused by herniated disc.

- If a patient is considered a surgical candidate, we obtain CT scans to better delineate osseous architecture for preoperative planning.

- In postsurgical patients, MRI with gadolinium contrast is used to differentiate pathology from scar tissue.

- When the pathology is unclear based on MRI findings, we obtain CT myelograms to further characterize the stenosis. CT myelography is also useful in patients who cannot undergo MRI (eg, patients with cardiac pacemakers) or in whom spinal instrumentation, such as metal rods, would obscure or distort the images. We do not routinely obtain electrophysiologic studies except in cases with mixed neurologic deficits with multiple causes, such as patients with concomitant lumbar stenosis and peripheral neuropathy caused by diabetes mellitus.

TREATMENT OF CASES IN THIS STUDY

TREATMENT OF CASES IN THIS STUDY

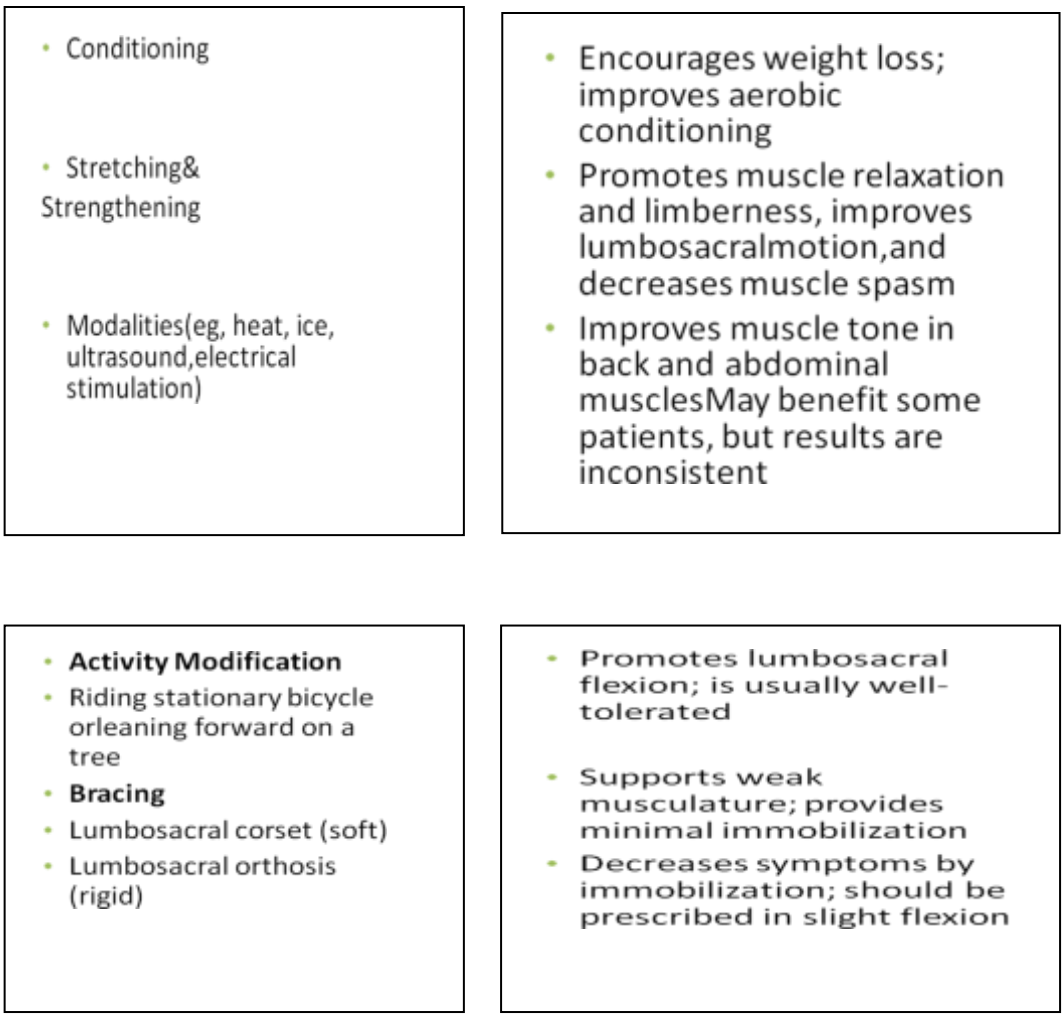
NON OPERATIVE MANAGEMENT[14]

Nonoperative treatment has been successful for patients who have lumbar spinal stenosis.Most patients who have symptoms of degenerative lumbar stenosis will respond to nonoperative treatment and not need surgery, at least initially. In the absence of acute focal neurologic deterioration or the development of acute cauda equina syndrome, all patients should be treated with a trial of nonoperative therapy before consideration for surgical treatment.

CONSERVATIVE TREATMENT

MEDICATIONS	MECHANISM OF ACTION
NSAIDs	Decrease inflammation, provide pain relief
Acetaminophen	Provides pain relief
Oral corticosteroids	Decrease inflammation; diminish radicular symptoms and pain
Muscle relaxants	Decrease paravertebral muscle spasm
Narcotics	Not routinely used, but may help in acute flares
Tricyclic antidepressants (eg, nortriptyline hydrochloride)	Decrease radicular symptoms
Anticonvulsants (eg, gabapentin	Decrease radicular symptoms
Calcitonin injections	Decrease pain; increase ambulatory capacity in some patients

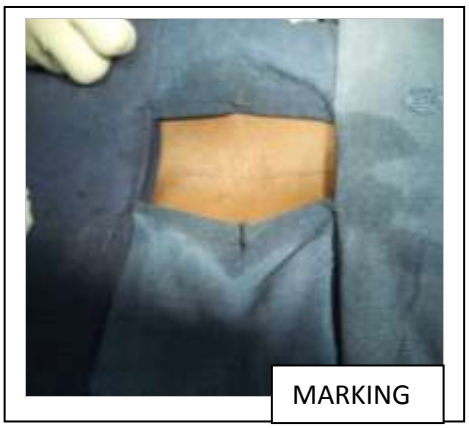
PHYSICAL THERAPY



OPERATIVE MANAGEMENT

Because degenerative spinal stenosis is not life-threatening and catastrophic neurological deterioration is very rare, operative treatment should be considered only when non operative treatment has failed to improve function or provide adequate pain relief to allow daily activities. Much less commonly, urgent surgery is indicated to address progressive neurological deficits or the development of the cauda equina syndrome.

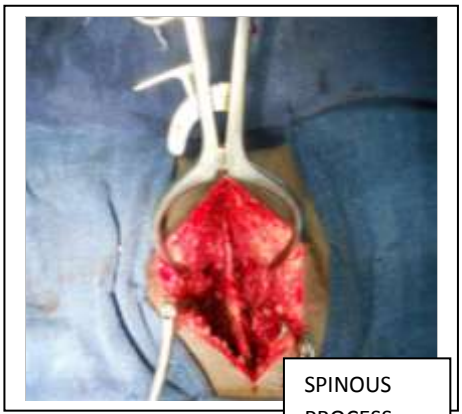
The main goal in the operative treatment of lumbar spinal stenosis is to decompress the affected neural elements throughout their entire course from the central canal to their exit through the neural foramina. The secondary goal of surgery is to maintain spinal stability or to restore stability in cases of preoperative degenerative instability. The standard decompression procedure, called laminectomy, involves removal of the spinous processes and central portion of the laminae overlying the affected stenotic segments. Hypertrophic arthritic facet joints are shaved to relieve compression and medial facectomy(foraminotomy) are also done.



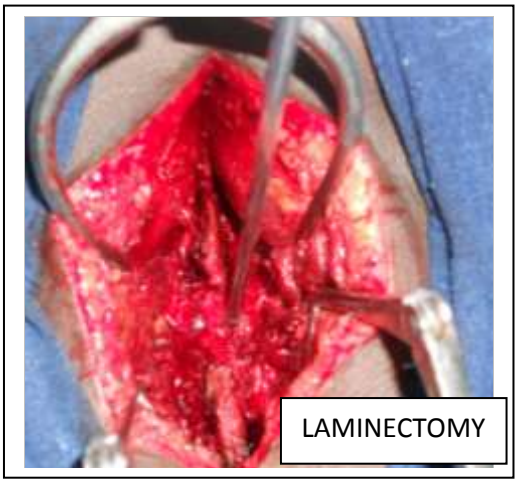
MARKING

INCISION

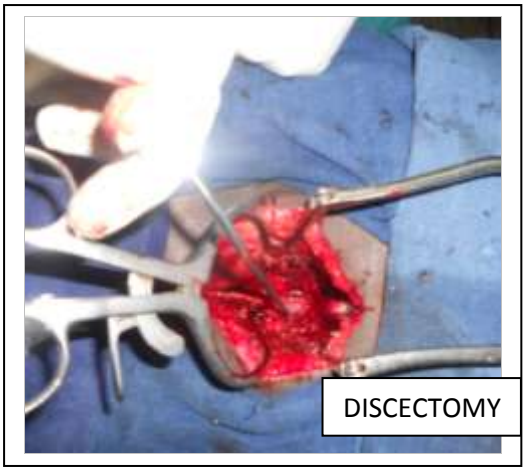
PARAVERTEBRAL MUSCLE RETRACTION



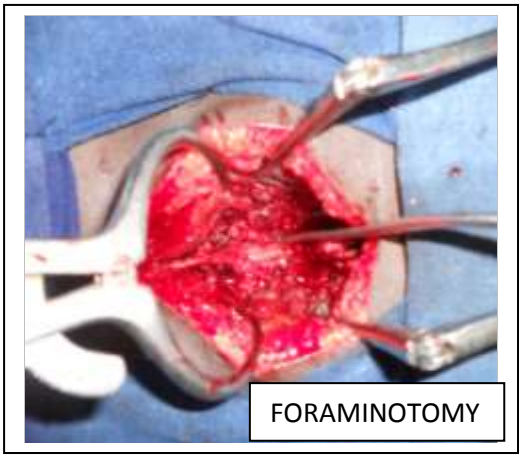
SPINOUS PROCESS &LAMINA EXPOSURE



LAMINECTOMY



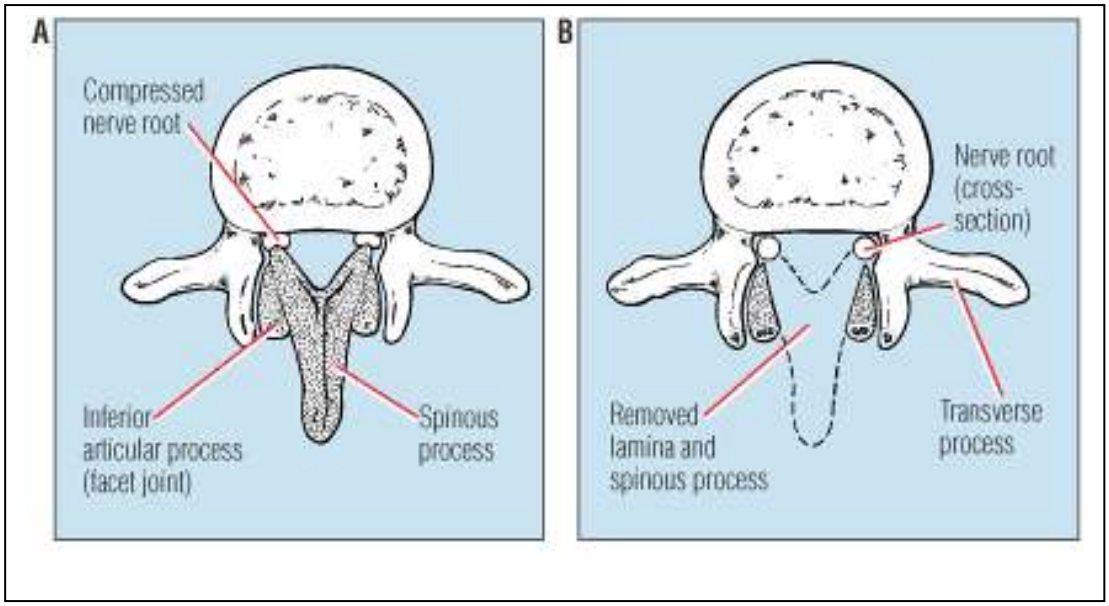
DISCECTOMY



FORAMINOTOMY

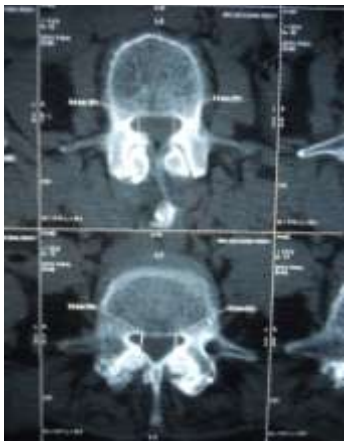
SKIN CLOSURE

DIAGRAMATIC REPRESENTATION OF LAMINECTOMY



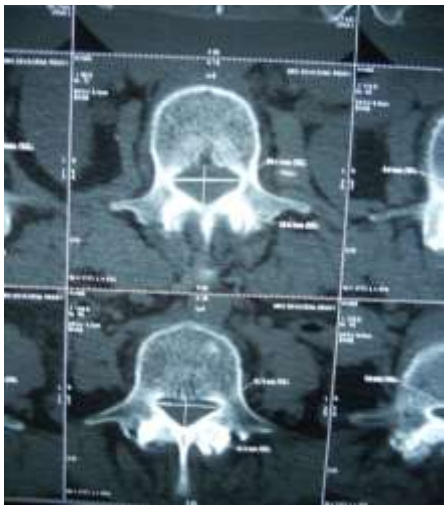
PREOP CT

L4(4.7,4.6)



L3(5.4,5.6)

L3 AP-11.7
TRA-20.4
L5 AP-10.4
TRA-23



L2-AP-13.6
TRA-20.4
L4-AP-12.3
TRA-21.3

POST OP CT

L3 (7.5,7.5)

L4(7.1,6.7)

L5(6.3,5.9)

CENTRAL CANAL WIDENED

COMPLICATIONS OF LAMINECTOMY

- Postoperative spondylolisthesis is a potential complication of lumbar decompression without fusion of the operative segments. An increased risk of instability is associated with total facetectomy and preexisting degenerative spondylolisthesis at the operative level.

- To minimize the risk of postoperative instability, some surgeons advocate multiple laminotomies (partial removal of lamina) to decompress the lateral recesses and neural foramina and to maintain the central posterior elements for stability. Maintaining the integrity of these structures is believed to improve postoperative structural stability, but this has not been confirmed in any prospective randomized studies.

- Dural injury with CSF leakage and meningitis.

- Root injury with footdrop &bladder incontinence.

Surgical complications in this study are few constituting about 1%.(2 cases of dural injury,1 case of footdrop,1 case of wound infection &discitis).

OUTCOME & ANALYSIS-1 (SURGICAL MANAGEMENT)

OUTCOME & ANALYSIS-1

(SURGICAL MANAGEMENT)

The findings of our study of 40 cases of operated degenerative lumbar canal stenosis were as follows-

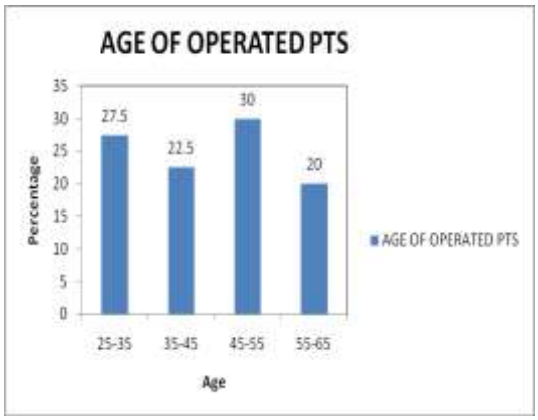


Fig 1

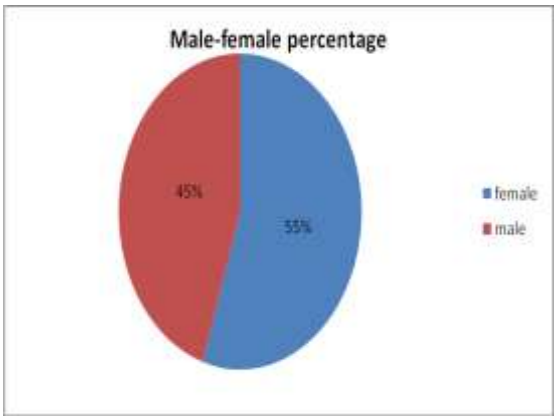


Fig 2

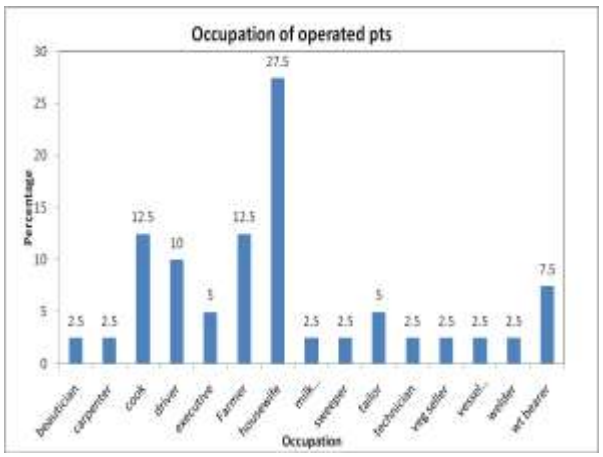


Fig 3

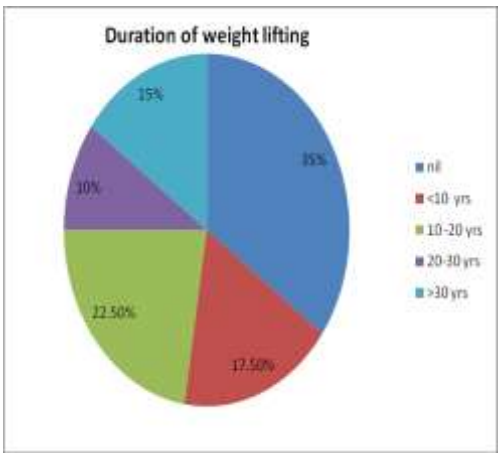


Fig 4

The youngest case is 26 years and oldest being 65 years.The mean age incidence is 42 years. The distribution in different age groups is given in Fig 1 with maximum of 30 patients in 45-55yrs age group and minimum of 20 patients in 55-65yrs age group.

There is female preponderance in this study(fig 2).Occupation of patients are given in fig 3 with maximum duration of duration of weightbearing being 10-20 years(fig 4).

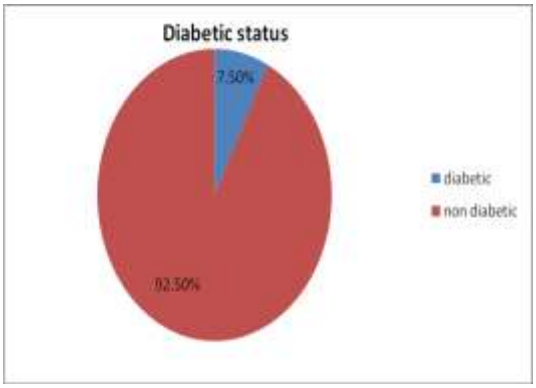


Fig 5

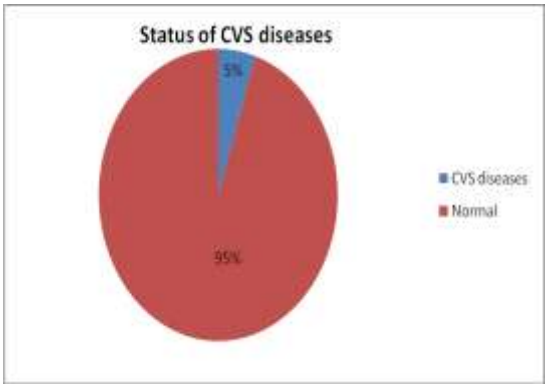


Fig 6

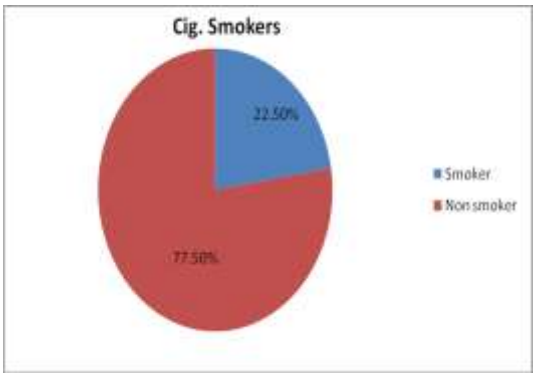


Fig 7

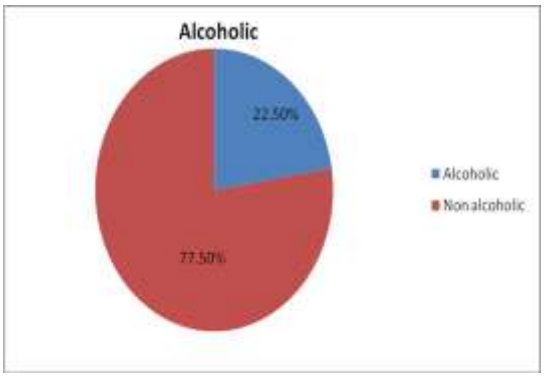
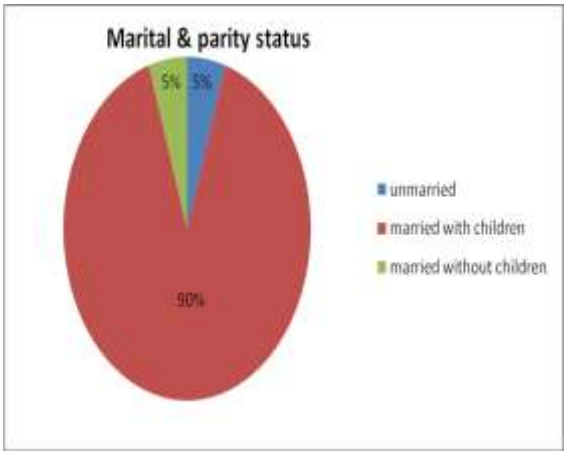


Fig 8

In this study of 40 patients,7.5% are diabetic(fig 5), 5% are hypertensives[19](fig 6), 22.5% are cigarette smokers[20] (fig 7) and 22.5% are alcoholics (fig 8).



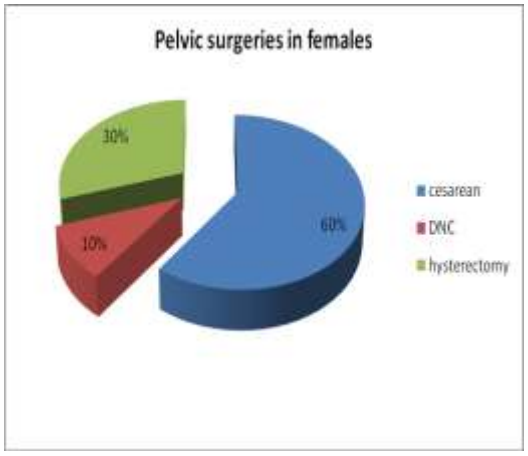


Fig 9 **Fig 10**

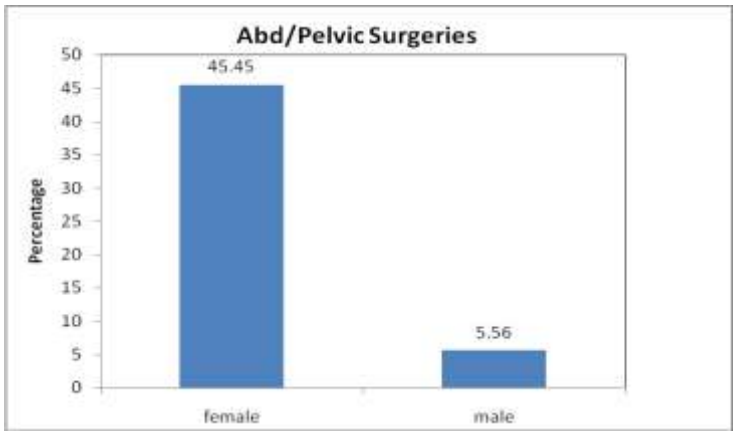


Fig 11

In this study 90% of patients are married with children(fig 9).45.5% of female patients undergone abdominal/pelvic surgeries(fig11) with maximum being cesserian surgery(60%)(fig10).However only 5.5% of male patients have undergone abdominal surgeries(fig 11).

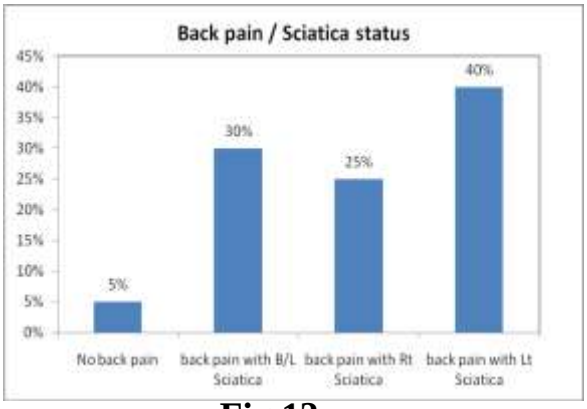


Fig 12

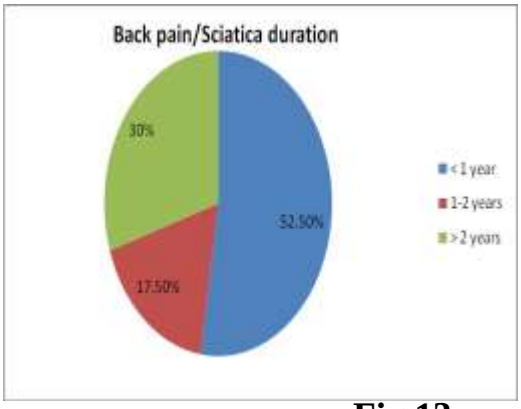


Fig 13

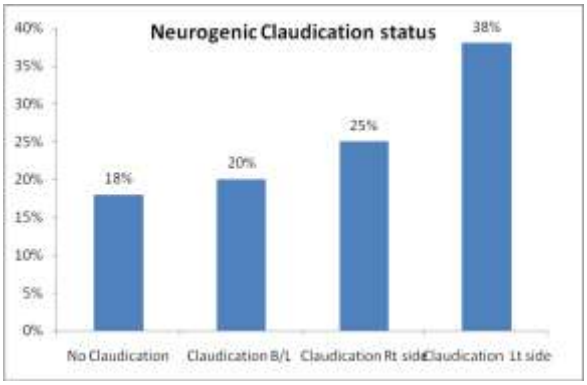


Fig 14

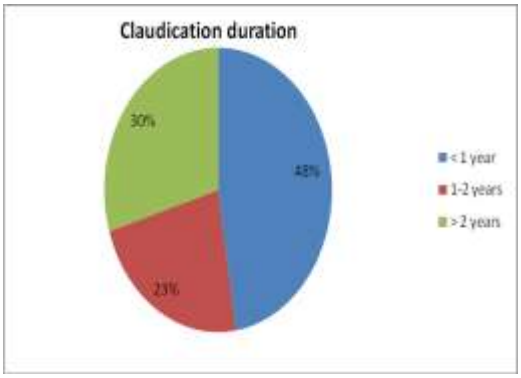


Fig 15

Most of the patients(95%) presented with backpain[27,29,30,31] among which 40% have left sided sciatica(fig 12) with minimum duration of 1month and maximum duration of 12 years.In this study most of the patients(52.5%) suffered from backpain for a period of less than 1 year(fig 13).[13]

In this study about 38% of patients has lt sided neurogenic claudication(fig 14) with most of patients(48%) with duration of less than 1 year(fig 15).[13]

SYMPTOMOTOLOGY

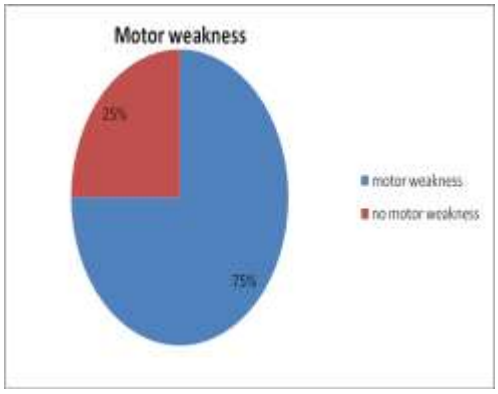


Fig 16

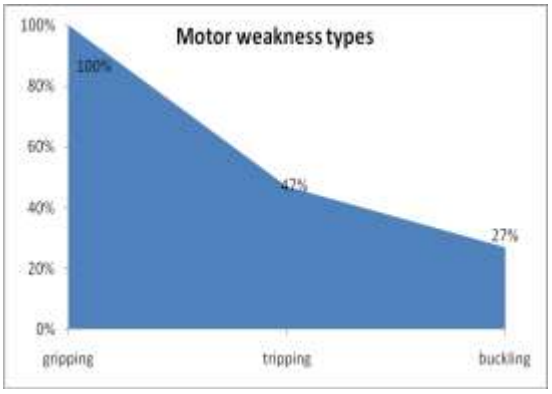


Fig 17

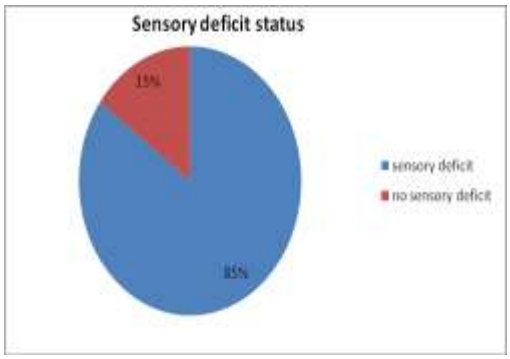


Fig 18

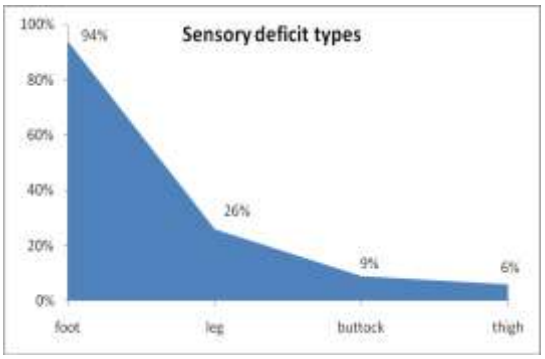


Fig 19

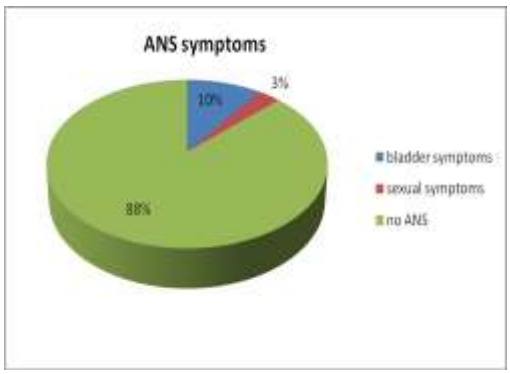


Fig 20

Most of the patients presented with sensory symptoms(85%) with commonest being foot numbness(90%) (fig 18&19).

Motor symptoms constitute about 75% with gripping weakness in aimost all the patients(fig 16,17).Bladder and sexual disturbances occurred in 10% and 3% of the patients respectively(fig 20).

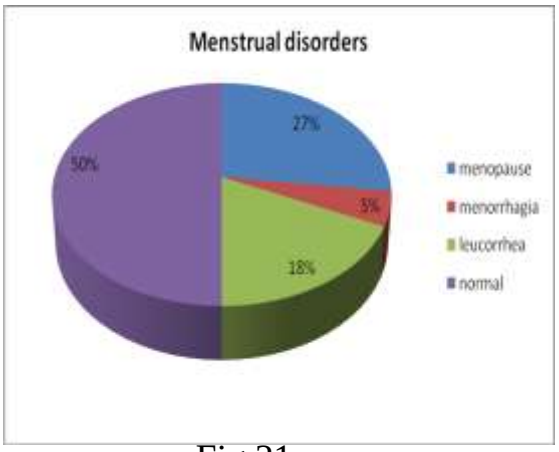


Fig 21

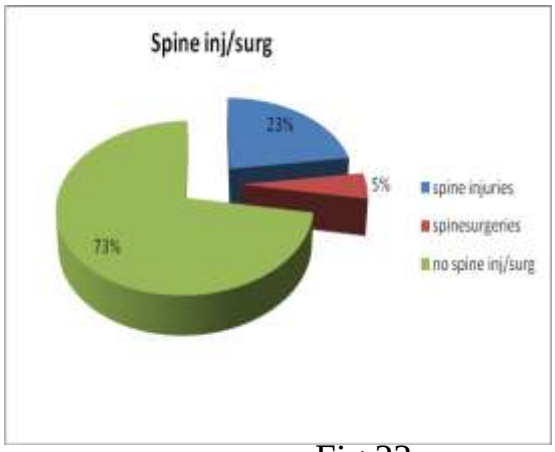


Fig 22

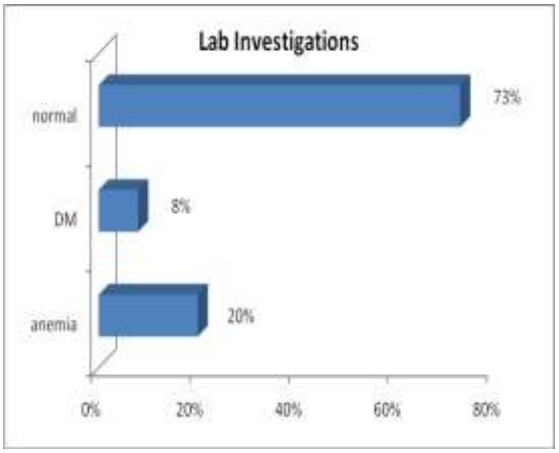


Fig 23

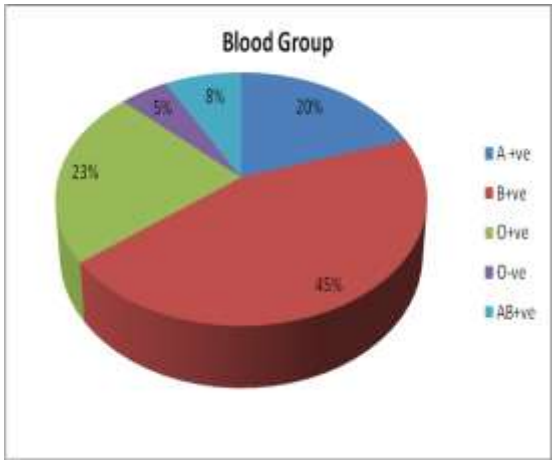
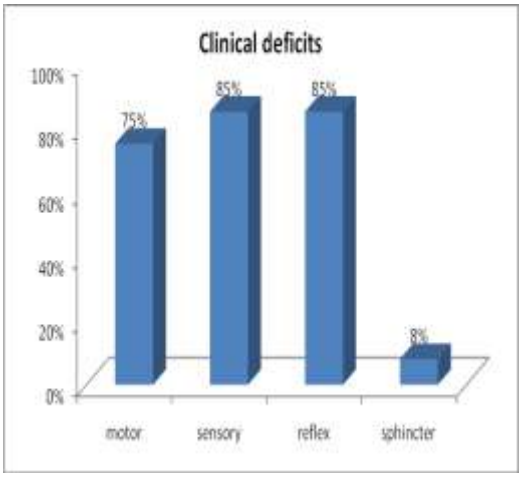


Fig 24

In this study 18% &5%of female patients had leucorrhoea and menorrhagia respectively(fig21).Trivial spine injuries were seen in 23%and failed back surgery syndrome in 5% patients(fig22).

Lab investigations revealed 20% are anemic and 8% are diabetic(fig23). Incidence of deg.lumbar canal stenosis are common in B +ve and least common in O –ve bloodgroup(fig24) in this study.

CLINICAL SIGNS



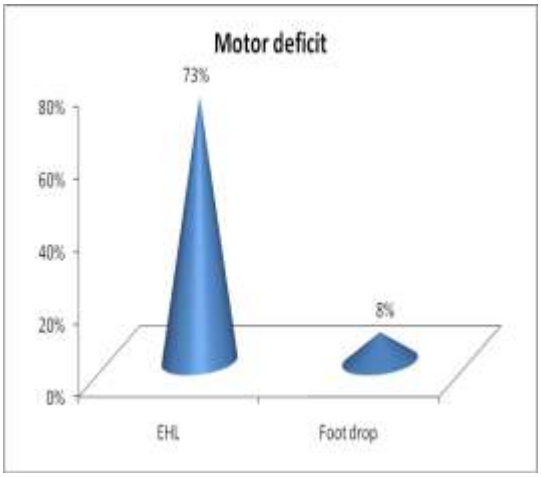
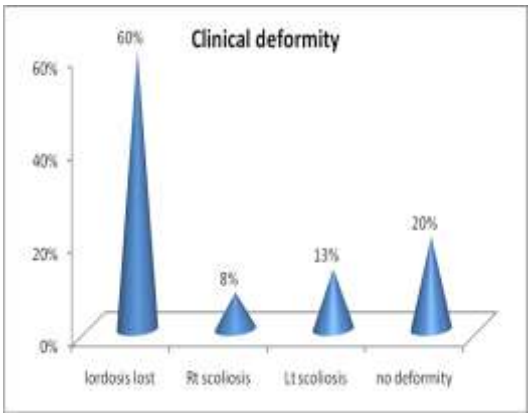


Fig 25 **Fig 26**



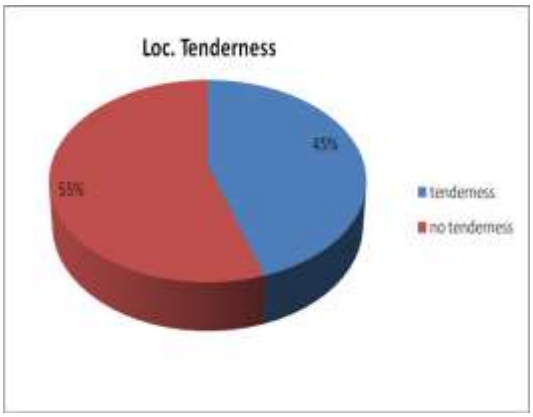


Fig 27 **Fig 28**

Like symptomotology,sensory deficits are common(85%).Among motor deficits EHL weakness is common(73%) and foot drop is least common(8%).Diminished deep tendon reflex especially ankle jerk is seen in 85% of patients.All these parameters correspond to involvement of L4L5,L5S1 levels.(fig 25,26)

About 80% of patients presented with clinical deformity among which loss of lordosis being the commonest(60%)(fig 27).Localised spine tenderness in lower lumbar region is felt in 45% of patients(fig 28).

X RAY LS PARAMETERS

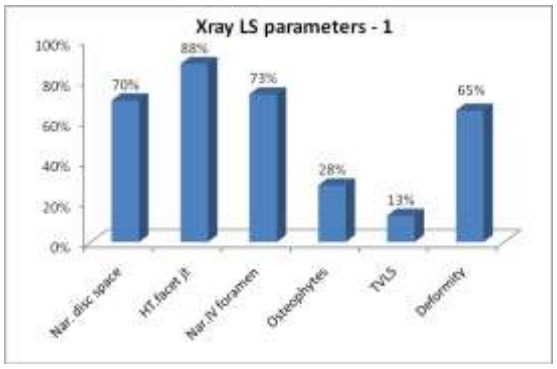


Fig 29

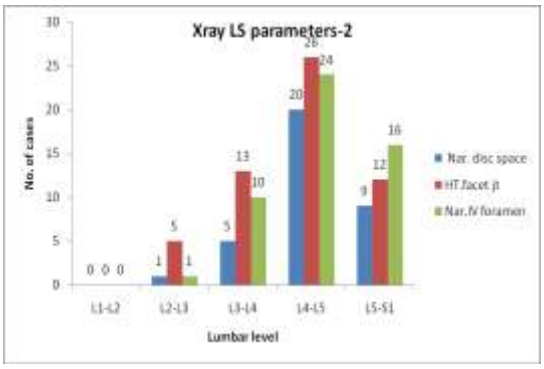


Fig 30

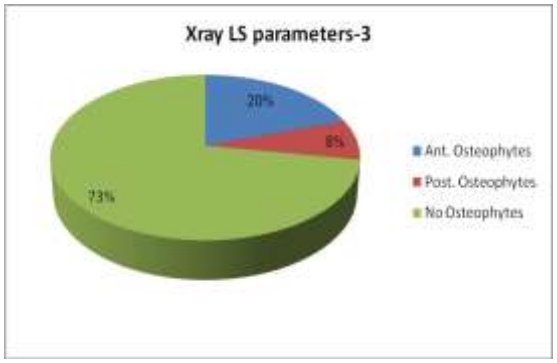


Fig 31

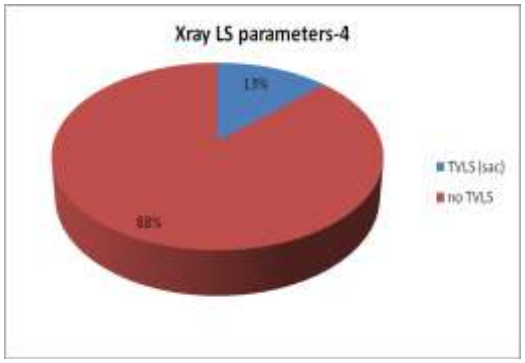


Fig 32

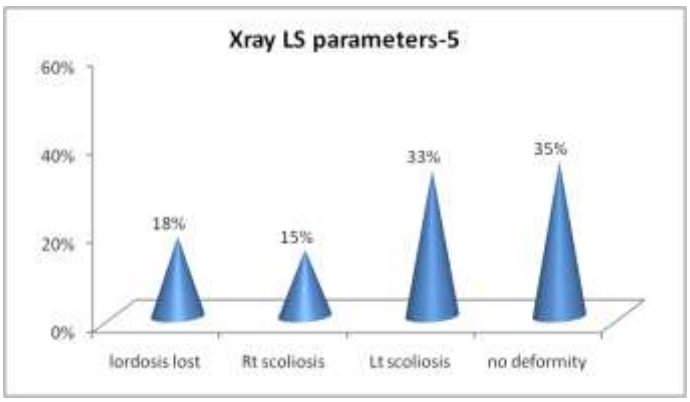


FIG33

X RAY LS PARAMETERS

In this study,most common finding in X ray lumbosacral spine is hypertrophied facet joint constituting about 88%. Hyp.facet joint is common in L4L5 level(26 out of 40 cases).(fig29,30).

Narrow intervertebral foramen is seen in 73% of patients being commonest at L4L5 level(24 out of 40 cases).(Fig29,30)

Narrow disc space is seen in 70% of patients being commonest at L4L5 level(20 out of 40 cases).(fig 29,30).

Osteophyte changes is seen 28% of patients,anterior osteophytes being the commonest.(fig31)

TVLS is seen in 13% of cases which is one of the reason for failed back syndrome in this study(fig32).

Deformity is seen in 65% cases with LT.Scoliosis being commonest(33%) (fig33)corresponding to common symptomotology of backpain with lt sciatica&lt side claudication pain in this study.

MRI LS PARAMETERS

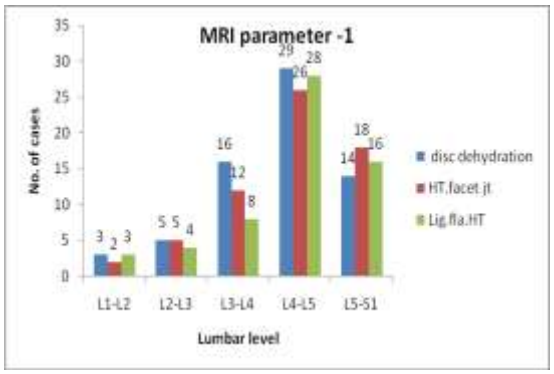


Fig 34

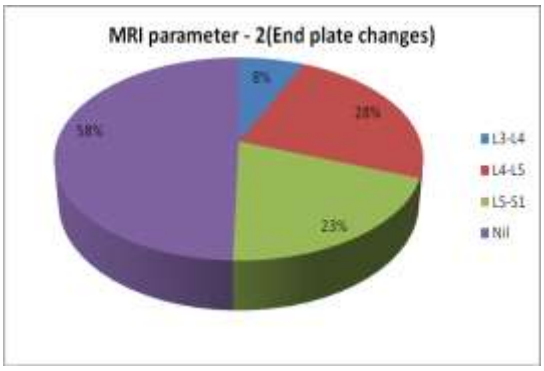


Fig 35

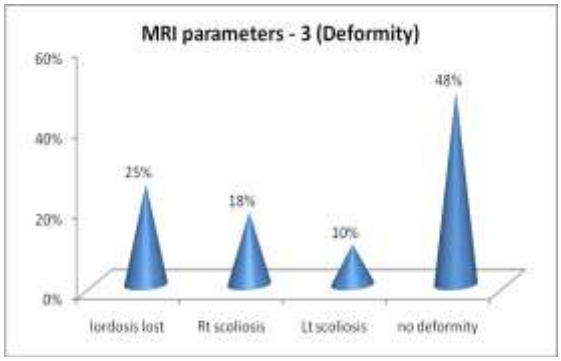


Fig 36

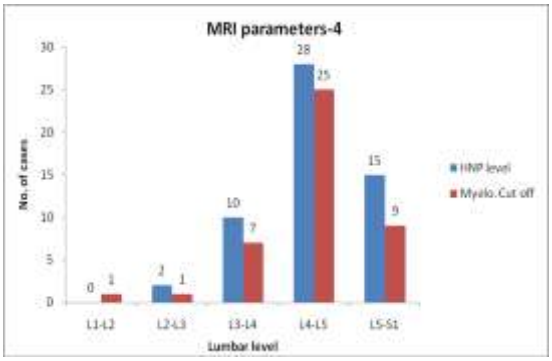


Fig 37

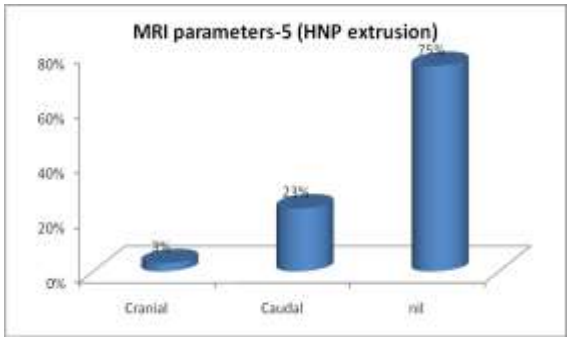


Fig 38

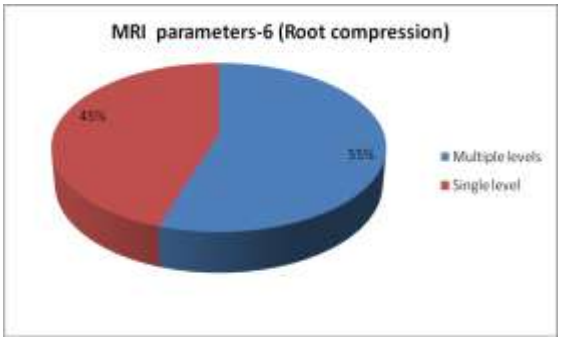


Fig 39

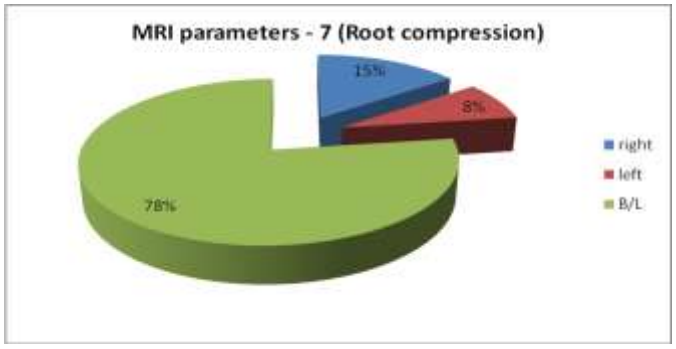


Fig. 40

MRI LS PARAMETERS

In this study, most common finding in MRI lumbosacral spine is disc dehydration. Disc dehydration is common in L4L5 level(29 out of 40 cases).(Fig 34).

Hypertrophied ligamentum flavum is commonest at L4L5 level(28 out of 40 cases).(fig 34)

Hypertrophied facet joint is seen in commonly at L4L5 level(26 out of 40 cases).(fig 34).

Endplate changes is seen in 42%cases,commonest at L4L5 level.(fig 35)

Deformity is seen in 52% cases with Lost lordosis being commonest(25%) (fig36).

HNP is commonest at L4L5 level(28 out of 40 cases) and myelogram cut off sign corresponds to L4L5 level(25 out of 40 cases)(fig37)

Disc extrusion is seen in 5% cases with commonest being caudal extrusion.(fig38)

Root compression is common at multiple levels in 55% cases and bilaterally in 78% cases& commonest level being L4L5 level.(fig 39,40)

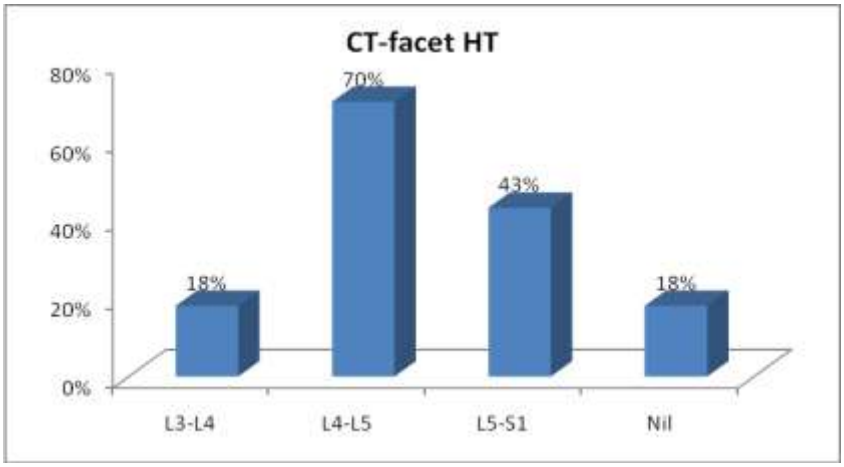


Fig 41

CT LS shows facet hypertrophy in 82%cases,commonest at L4L5 level (70%) (fig 41).

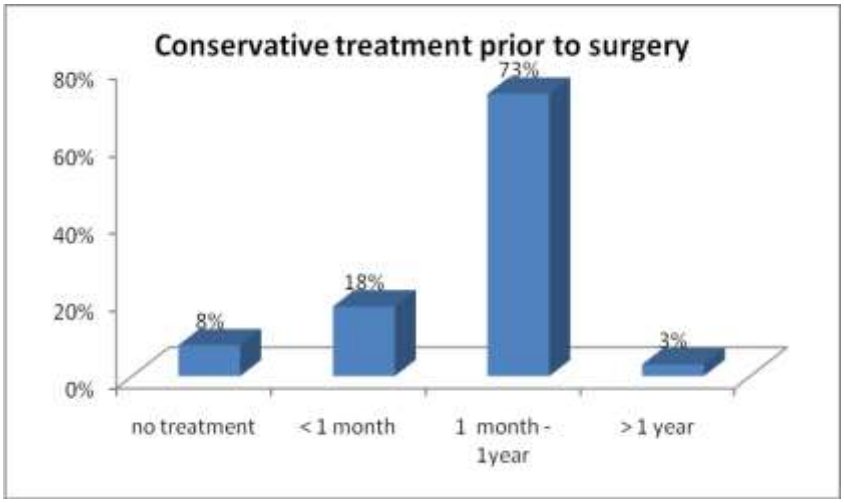


Fig 42

Prior to surgery 73% of patients undergone trial of conservative treatment between 1 month to 1 year. 26% of patients undergone no treatment/ less than 1 month conservative treatment prior to surgery due to presence of motor/autonomic deficits which required urgent surgical intervention.

SURGICAL MANAGEMENT OF DEG.LUMBAR CANAL STENOSIS

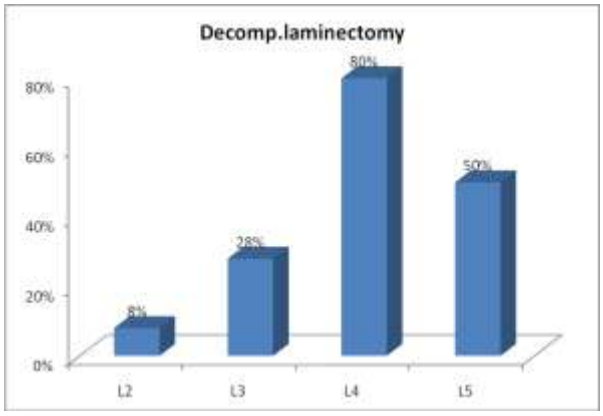


Fig 43

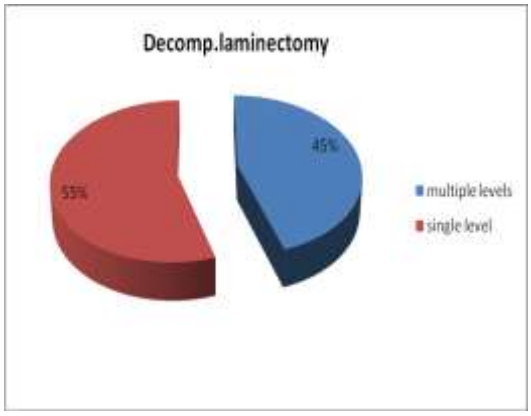


Fig 44

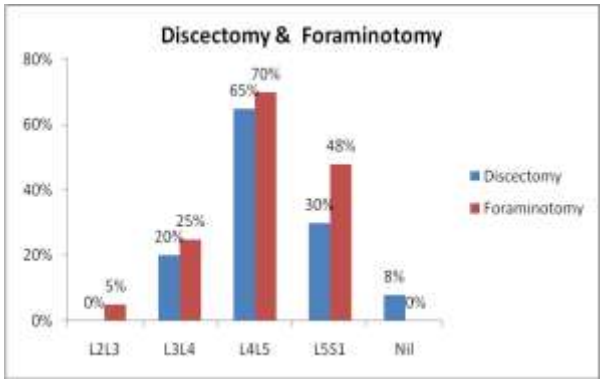


Fig 45

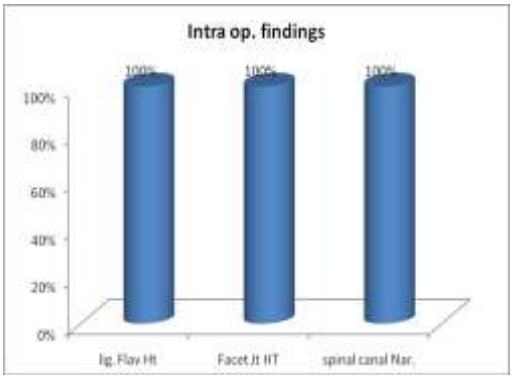


Fig 46

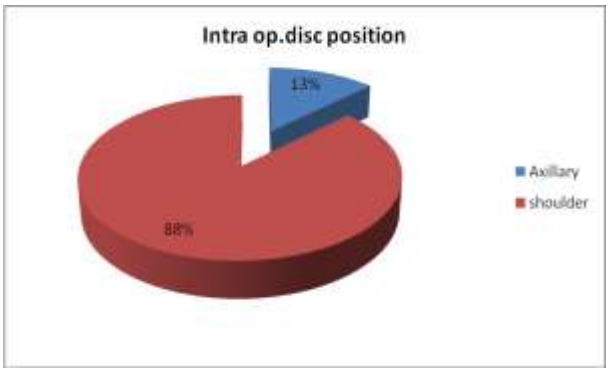


Fig 47

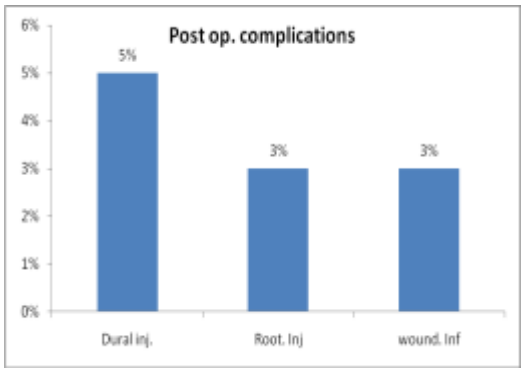


Fig 48

SURGICAL MANAGEMENT OF DEG.LUMBAR CANAL STENOSIS

Decompressive laminectomy is performed in all cases involving multiple levels in 45% cases and single level in 55% cases. Commonest single level being L4 constituting about 80% cases & least being L2 lamina constituting about 8% cases.(fig43,44). Discectomy is done in 90%cases and L4L5 being commonest level(65%)(fig 45) Foraminotomy is done in all cases and L4L5 being commonest level(70%) (fig 45). Intraoperatively ligamentum flavum hypertrophy, facet joint hypertrophy, spinal canal narrowing is seen in all cases corresponding to clinical and radiological levels, commonest being L4L5 level.(fig 46).

Intraoperatively, Shoulder disc is seen in 88% of cases corresponding to ipsilateral scoliosis and axillary disc is seen in 12% cases corresponding to contralateral scoliosis. (fig 47). Surgical complications in this study are few constituting about 1%. (2 cases of dural injury, 1 case of footdrop,1 case of wound infection &discitis). (fig 48)

FOLLOW UP OF OPERATED PATIENTS

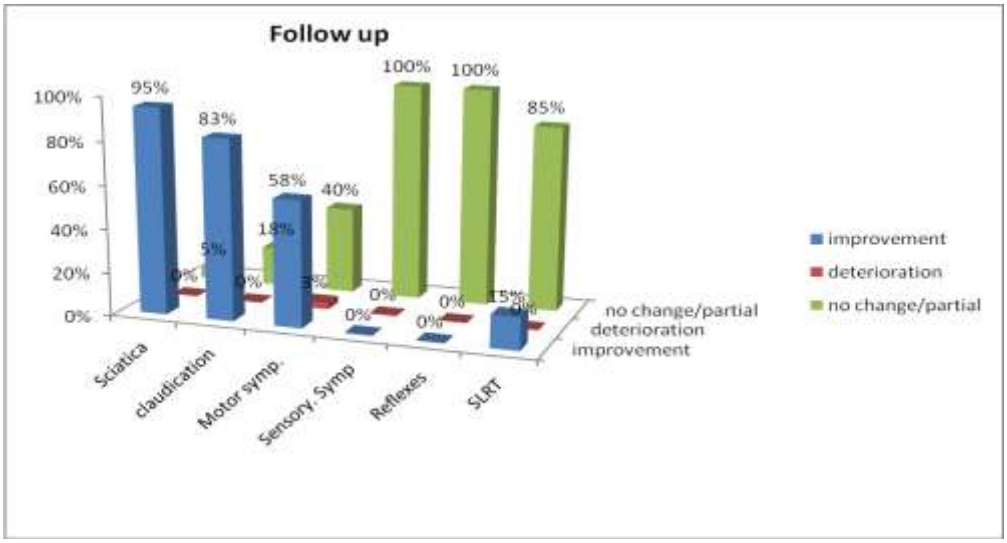


Fig 49

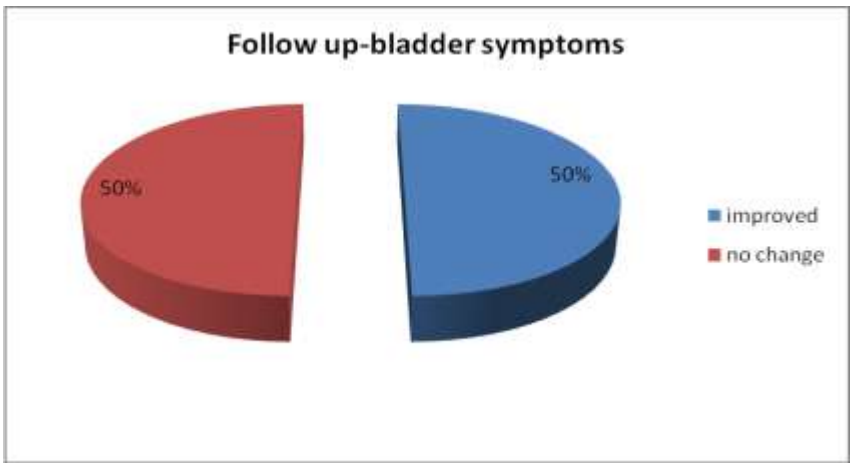


Fig 50

FOLLOW UP OF OPERATED PATIENTS

In regular follow up of operated patients for one year,83% cases shows improvement in neurog.claudication pain,95% cases for sciatica especially in patients with duration of symptom/deficit less than 1 year. Beyond 1 year, patient has partial or no improvement. (fig 49).

Motor weakness improved in 58% cases, deteriorated in 2%cases, partial/no improvement in cases who presented with deficit more than 1 year, constituting about 40%cases. (fig 49) Whatever may be the duration of symptoms / deficit in patients, there were no changes in sensory symptoms nor reflexes. (fig 49).

In patients with duration of SLRT +VE less than 1 year there is improvement in 15% cases. Beyond 1 year, patient has partial or no improvement in 85%cases.(fig 49).

Out of 4 cases presented with urinary incontinence, 2 cases showed improvement and no change is seen in other 2 cases in one year follow up. (fig 50). There is no change seen in the case presented with erectile disturbances for 1 year follow up. (fig 50).

SATISFACTION MEASURES IN SURGICAL TREATMENT[23]

Satisfaction Measures

1. Overall, how successful has your operation been?

a. Very successful, complete relief

b. Fairly successful, a good deal of relief

c. Not very successful, only a little relief

d. Failure, no relief

e. Worse than before

If you had a friend with the same trouble you had, would you recommend the operation? Yes/No

'Satisfaction' requires **a** or **b** and **Yes** to the above questions.

Weiner *et al. Journal of Orthopaedic Surgery and Research* 2007 **2**:3
doi:10.1186/1749-799X-2-3

	CLAUD.PAIN	**SCIATICA**	**DEFICITS**	**SLRT+VE**	**URI.INC0NT**
EXCEL	24	32	19	4	2
GOOD	3	4	4	2	0
FAIR	0	0	0	0	0
SAME	6	2	5	7	2
WORSE	0	0	2	0	0
TOTAL	33	38	30	13	4
SATISF%	81%	94%	77%	46%	50%

This table proves surgical treatment yields good satisfaction results for patients with complaints of claudication pain&sciatica.[30,31,32,33]

SATISFACTION MEASURES 1N SURGICAL TREATMENT

	SURGICAL TREATMENT FOR BACKPAIN ONLY	SURGICAL TREATMENT FOR BACKPAIN WITH DEFICITS
EXCEL	2	20
GOOD	1	4
FAIR	0	4
SAME	7	0
WORSE	0	2
TOTAL	10	30
SATISF%	30%	80%

This table shows patients who were operated for backpain with associated neurological deficits had good satisfactory results when compared to patients who were operated only for backpain[34].

OUTCOME & ANALYSIS-2 (CONSERVATIVE MANAGEMENT)

OUTCOME &ANALYSIS-2

(CONSERVATIVE MANAGEMENT)

The findings of our study of 40 cases of conservatively managed degenerative lumbar canal stenosis were as follows-

AGE DISTRIBUTION:

The youngest case is 28 years and oldest being 65 years. The mean age incidence is 40 years. The distribution in different age groups is given in Fig 51 with maximum of 16patients in 25-35 yrs age group and minimum of 4 patients in 55-65yrs age group.

AGE GROUP	NO OF PATIENTS
25-35 YEARS	16
35-45 YEARS	8
45-55 YEARS	12
55-65 YEARS	4
TOTAL	40

FIG 51

SEX DISTRIBUTION:

There is female preponderance in this study,there were 23 females and 17 males in this study.

OCCUPATION OF PATIENTS:

In this study most of patients are housewife (9 in number), followed by cook (8) & farmer(7).

DURATION OF WEIGHTBEARING:

In this study most of patients has weightbearing duration less than 10 years. (fig 52).

DURATION OF WEIGHTBEARING IN YEARS	NO OF CASES
<10	17
10-20	3
20-30	5
>30	5
NO WEIGHT LIFTING	10

Fig 52

COMORBID FACTORS:

In this study of 40 patients,10% are diabetic, 7.5% are hypertensives,12.5% are cigarette smokers and 10% are alcoholics.

MARITAL&PARITY:

In this study 92.5% of patients are married with children.22% of female patients undergone abdominal/pelvic surgeries with maximum being cesserian surgery(60%)(fig10).However no male patients have undergone abdominal surgeries.

BACKPAIN:

ALL the patients presented with backpain with minimum duration of 1month and maximum duration of 12 years. In this study most of the patients (55%) suffered from backpain for a period of less than 1 year.

NEUROGENIC CLAUDICATION:

In this study about 100% of patients has neurogenic claudication with most of patients (72%) with duration of less than 1 year.

SYMPTOMATOLOGY:

Most of the patients presented with sensory symptoms (87.5%) with commonest being foot numbness (66%). Patients had no motor, bladder and sexual disturbances.

MENSTRUAL SYMPTOMS:

In this study 4% of female patients had leucorrhoea. 30% cases attained menopause & rest of cases had normal menstruation.

TRAUMA HISTORY:

Trivial spine injuries were seen in 25% cases.

LAB RESULTS:

Lab investigations revealed 20% are anemic and 7.5% are diabetic. Incidence of deg. lumbar canal stenosis are common in B +ve and least common in O –ve bloodgroup.

CLINICAL DEFICITS:

Like symptomotology, sensory deficits are common (70%). Diminished deep tendon reflex especially ankle jerk is seen in 90% of patients. There are no motor, bladder or sexual symptoms.

CLINICAL DEFORMITY:

Only 20% of patients presented with clinical deformity(loss of lordosis)

X RAY LS PARAMETERS

In this study, most common finding in X ray lumbosacral spine is narrow disc space constituting about 70%. Narrow disc space is common in L4L5 level(21 out of 40 cases).

Hypertrophied facet joint is seen in 42% of patients being commonest at L4L5 level(12 out of 40 cases).

Osteophyte changes is seen 27% of patients,anterior osteophytes being the commonest.

TVLS is seen in 5% of cases.

Deformity(Loss of lordosis) is seen in 10% cases.

MRI LS PARAMETERS

In this study,most common finding in MRI lumbosacral spine is disc dehydration. Disc dehydration is common in L4L5 level (28 out of 40 cases).

Hypertrophied ligamentum flavum is commonest at L4L5 level (19 out of 40 cases).

Hypertrophied facet joint is seen in commonly at L4L5 level (11 out of 40 cases).

Endplate changes is seen in 12%cases,commonest at L4L5 level.

Deformity (Lost lordosis) is seen in 15% cases.

Minimal disc bulge is commonest at L4L5 level(28 out of 40 cases) and no myelogram cut off sign.

CT LS PARAMETERS:

CT LS shows facet hypertrophy in 42%cases,commonest at L4L5 level (76%).

CONSERVATIVE TREATMENT:

DURATION OF TREATMENT	NO OF CASES
<6 MONTHS	36
6MONTHS-1 YEAR	3
>1 YEAR	1

FIG 53

In this study most of the patients(90%) are under 6 months of treatment.

FOLLOW UP OF CONSERVATIVELY TREATED PATIENTS

In regular follow up of conservatively treated patients for one year,47% cases shows improvement in neurog. claudication pain,62%cases for sciatica especially in patients with duration of symptom/deficit less than 1 year. Beyond 1 year, patient has partial improvement of 53% & 38% respectively. Whatever may be the duration of symptoms / deficit in patients, there were no changes in sensory symptoms nor reflexes

SATISFACTION MEASURES 1N CONSERVATIVE TREATMENT

	CLAUD.PAIN	SCIATICA
EXCEL	12	10
GOOD	4	10
FAIR	3	5
SAME	21	15
WORSE	0	0
TOTAL	40	40
SATISF%	40%	50%

FIG 54

This table shows patients who are presenting only with backpain when managed conservatively produces good results when compared to surgical treatment[34].

DISCUSSION

DISCUSSION

A Study of 80 cases(40 cases of surgical management &40 cases of conservative management) was made of patients with lumbar canal stenosis. The diagnosis of lumbar canal stenosis was based on clinical findings and supported by radiological investigations. **Following is the comparision of surgical and conservatively managed cases in this study.**

PARAMETERS	SURGICAL TREATMENT	CONSERVATIVE TREATMENT
AGE DISTRIBUTION	youngest case is 26 years , oldest being 65 years.mean age incidence is 42 years.	youngest case is 28 years, oldest being 65 years, mean age incidence is 40 years.
SEX DISTRIBUTION	female preponderance with 55%	female preponderance with 58%
OCCUPATION OF PATIENTS	most of patients are housewife (11 in number),followed by cook(5)&farmer(5).	most of patients are housewife (9 in number),followed by cook(8)&farmer(7).
DURATION OF WEIGHTBEARING	most has weightbearing duration of 10-20 years.	most has weightbearing duration less than 10 years.
COMORBID FACTORS	7.5% are diabetic, 5% are hypertensives, 22.5% are cigarette smokers, 22.5% are alcoholics.	10% are diabetic,7.5% are hypertensives,12.5% are cigarette smokersand 10%are alcoholics.
MARITAL&PARITY	90% of patients are married with children,45.5% of female patients undergone pelvic surgeries.	92.5% of patients are married with children.22% of female patients undergone pelvic surgeries.

	SURGICAL TREATMENT	CONSERVATIVE TREATMENT
BACKPAIN	95% presented with backpain among which 40% have left sided sciatica with minimum duration of 1month and maximum duration of 12 years.	All the patients presented with backpain with minimum duration of 1month and maximum duration of 12 years
NEUROGENIC CLAUDICATION	82% of patients has neurogenic claudication	100% of patients has neurogenic claudication .
SYMPTOMATOLOGY	sensory symptoms(85%) with commonest being foot numbness(90%). Motor symptoms(75%)with gripping Weakness in all patients,Bladder and sexual disturbances occurred in 10% and 3% of the patients respectively	sensory symptoms(87.5%) with commonest being foot numbness(66%). Patients had no motor,bladder and sexual disturbances.
MENSTRUAL SYMPTOMS	18% &5%of female patients had leucorrhoea and menorrhagia respectively.	4%of female patients had leucorrhoea.
TRAUMA HISTORY	Trivial spine injuries were seen in 23%and failed back surgery syndrome in 5% patients.	Trivial spine injuries were seen in 25% cases
LAB RESULTS	20% are anemic , 8% are diabetic.Incidence are common in B +ve and least common in O –ve bloodgroup	20% are anemic, 7.5% are diabetic.Incidence are common in B +ve and least common in O –ve bloodgroup.

	SURGICAL TREATMENT	CONSERVATIVE TREATMENT
CLINICAL DEFICITS	Sensory deficits are common(85%).Among motor deficits EHL weakness is common(73%) and foot drop is least common(8%).Diminished deep tendon reflex especially ankle jerk is seen in 85% of patients.	sensory deficits are common(70%).Diminished deep tendon reflex especially ankle jerk is seen in 90% of patients.There are no motor,bladder or sexual symptoms.
CLINICAL DEFORMITY	80% of patients presented with clinical deformity (loss of lordosis 60%)	20% of patients presented with clinical deformity(loss of lordosis).
X RAY LS PARAMETERS	common finding in X ray LS spine is hypertrophied facet joint (88%)	most common finding in X ray lumbosacral spine is narrow disc space(70%.).
MRI LS PARAMETERS	common finding in MRI LS spine is disc dehydration and it is common in L4L5 level(72%). HNP is commonest at L4L5 level(70%) and myelogram cut off sign corresponds to L4L5 level(62.5%)	most common finding in MRI LS spine is disc dehydration and is common in L4L5 level(70%). Minimal disc bulge is commonest at L4L5 level(70%) and no myelogram cut off sign.
CT LS PARAMETERS	facet hypertrophy in 82%cases,commonest at L4L5 level (70%).	facet hypertrophy in 42%cases,commonest at L4L5 level (76%).

TREATMENT	Decompressive laminectomy involving multiple levels in 45% cases and single level in 55% cases, Discectomy is done in 90%cases and L4L5 being commonest level(65%).Foraminotomy is done in all cases and L4L5 being commonest level(70%).	Among conservatively treated patients 90% are under 6 months of treatment
FOLLOW UP	83% cases improves in neurog.claudication ,95% for sciatica .Motor weakness improved in 58% cases,.SLRT improves in 15% .biadder imp in 50%cases. ,no changes in sensory symp nor reflexes	47% cases shows improvement in neurog.claudication pain,62%cases for sciatica. no changes in sensory symptoms nor reflexes.
SATISFACTION MEASURES	Claudication pain-81% Sciatica-94%	Claudication pain-40% Sciatica-50%

FIG 55

COMPARISION WITH IVANOV AT AL STUDY[21]

	IVANOV AT AL STUDY-1998(34 PATIENTS)	**THIS STUDY 2011-2012(80 PATIENTS)**	
		SURG	**CONSERV**
LSS&FACET HYPERTROPHY	95%	83%	43%
IATROGENIC LSS	5%	5%	0
LSS&HNP/DISC BULGE	32%	92%	95%
LSS ONLY	45%	7.5%	5%
3 LEVEL LSS	11%	2.5%	25%
4 LEVEL LSS	3%	7.5%	0

FIG 56

Comparison of age distribution[18,20,21,27,29,30,31](fig 56)

AGE	KATZ ET AL	CAPUTY ET AL	EPSTEIN ET AL	YAMADA ET AL	NEERAJ	PRESENT STUDY	
						Sur	Cons
MINIMUM	55	43	17	58	35	26	28
MAXIMUM	89	84	51	70	69	65	65
MEAN	69.3	67	35	62.5	45	42	40

Compared to most of the studies mean age distribution in this study is low.

Comparison of sex distribution[18,20,21] (FIG57)

AGE	JOHNSON AL	HOPP ET AL	CAPUTYET AL	KATZ ET AL	NEERAJ	PRESENT STUDY	
						sur	Cons
MALES	24	38	46	26	16	18	17
FEMALES	8	62	54	62	24	22	23

Like most of the studies there is Female preponderance.

Comparison of duration of pain prior to operation[27,29,30,31] (FIG58)

DURATION IN MONTHS	CAPUTY ET AL	CIRIC ET AL	JOHNSON ET AL	YAMADA ET AL	NEERAJ	PRESENT STUDY	
						sur	Cons
MINIMUM	1	6	4	7	4	1	1
MAXIMUM	144	120	96	144	72	24	24
MEAN	6	48	22	44	22	12	12

Compared to most of the studies mean duration of pain prior to operation in this study is low.

Comparison of SLR restriction[30,31,32](FIG 59)

SLR RESTRICTION	CIRIC ET AL	EPSTEIN ET AL	YAMADA ET AL	NEERAJ	PRESENT STUDY	
					sur	cons
TOTAL CASES	16	12	5	40	40	40
RESTRICTED SLR	2	8	1	10	13	0

Compared to most of the studies Restricted SLRT in this study is relatively high.

COMPARISION WITH JAFFREY STUDY IN SURGICAL RESULTS[34](FIG60)

CLINICAL PARAMETERS	RADIOLOGY PARAMETERS	SURGICAL RESULTS OF JAFFREY STUDY	SURGICAL RESULTS OF THIS STUDY
BACKPAIN ONLY	POSITIVE	40%	30%
BACKPAIN WITH DEFICIT	POSITIVE	74	80%

Compared to Jaffrey study surgical results for patients with BACKPAIN WITH DEFICIT are quiet high.

COMPARISION OF SURGICAL OUTCOME WITH VARIOUS STUDIES[34](FIG61)

	MAUERSBERGER ET AL	SILVERS ET AL	KATS ET AL	DEAN ET AL	JOSEPH BERNSTE IN ET AL	THIS STUDY
OVER ALL IMPROVEMENT	80%	75%	75%	_	65-85%	89%
BLADDER IMPROVEMENT	_	_	_	60%	_	50%

Compared to most of the studies surgical results in this study is relatively high.

COMPARISION OF SURGICAL OUTCOME WITH CONSERVATIVE TREATMENT(FIG62)

	FRITZEL ET AL 2001	THIS STUDY
SURGICALLY TREATED	46%	89%
CONSERVATIVELY TREATED	18%	45%

Like fritzel study[34] surgical outcome is better than conservative treatment.

COMPARISION OF RADIOLOGICAL PARAMETERS WITH HIRAYASU STUDY[24](FIG63)

THIS STUDY	X RAY LS	CT LS	MRI LS	Ct% this study	Ct% hirayasu study
Mean diameter of canal in mm	35.8	33.2	30.2	110	>119
Lateralrecess in mm	17.9	13.8	8.8	162	>111

Like hirayasu study CT diameter of spinal canal and lateral recess is significantly larger& more the stenosis higher will be the difference[24].

COMPARISION OF SURGICALLY MANAGED CASES WITH PARAMETERS OF JOSEPH BERNSTEIN 2O11 STUDY[15]:(FIG64)

PARAMETERS	JOSEPH BERNSTEIN STUDY	THIS STUDY
Mean diameter of canal	12mm	16.3mm
Mean age in women	73 years	42 years
Commonly affected level	L3L4,L4L5	L4L5
Radicular pain	20%	95%
L5 weakness	90%	75%
Surgical success	65-85%	89%

Sagital canal diameter,radicular pain%,surgical success% in this study is relatively high.

COMPARISION WITH IVERSON AT AL STUDY[16](2001)(FIG65)

PARAMETERS		IVERSON ET AL	THIS STUDY(SURGICAL)	THIS STUDY (CONSERVATIVE)
FEMALES%		65%	55%	58%
MEDIAN AGE IN FEMALES		73.6	42	40
MEAN DURATION OF LBA		24 MONTHS	12 MONTHS	12 MONTHS
LOWER EXTREMITY DEFICIT	MOTOR	51%	73%	NIL
	SENSOR	81%	85%	70%
	REFLEX	91%	85%	90%
CLAUDICATION PAIN		66%	82%	100%
DM		21%	7.5%	10%
ALCOHOLICS		5%	22.5%	10%
PREVIOUS SPINE SURGERY		16%	5%	NIL
NO DEFORMITY		16%	20%	80%
LOSS OF LORDOSIS		65%	60%	20%
SCOLIOSIS		23%	20%	NIL
SPINOUS TENDERNESS		26%	45%	NIL
BACKPAIN		65%	95%	100%

Compared to Iverson study backpain and deficits occurrence is more common in this study,however incidence in females,mean age in females and LBA duration is relatively low.

NEUROGENIC CLAUDICATION OUTCOME SCORE[23]

Neurogenic claudication outcome score(NCOS) preoperatively is 25 (average) & it improved to 60 after surgery & on regular follow up for 1 year. MRI measurement of spinal canal in this study at L4 level is 17.3mm. (NORMAL-20MM)

COMPARISION 0F SPINALCANAL STENOSIS&NCOS&SATISFACTION MEASURES FOLLOWING SURGERY.(fig 66)

	SPINAL CANAL STENOSIS(MRI)	NCOS(POSTOP)	SATISFACTION MEASURES(POSTOP)
BRADLEY STUDY	>50%STENOSIS <50%STENOSIS	75% 49%	100% 50%
THIS STUDY	15% STENOSIS	60%	89%

According to Bradley study[23] surgery done for LSS with stenosis more than 50% produce 100% satisfaction &75% improvement in NCOS, however stenosis lesser than 50% stenosis are expected to produce 50% satisfaction & 49% improvement in NCOS.

But in this study even less than 50%stenosis(i.e 15%) produces 89% satisfaction &60% NCOS improvement with surgery, which is more than expected. This is probably due to foraminotomy done in all cases in addition to laminectomy.

NEUROGENIC CLAUDICATION OUTCOME SCORE (NCOS)[23]

1. *How far can you walk before having to stop and rest ?*

   a. <100 yards b.Between 100 yards and ½ mile

   c.Between ½ and 1 mile d.> 1 mile

2. *How long can you stand still before having to sit down ?*

   a. <5 min. b.5 to 15 min c.15 to 45 min d.As long as I please

3. *Once your symptoms arise, you have :*

   a.Severe b.Moderate c.Mild d.None

   Rank <u>each</u> : Back pain, Leg pain, Numbness/Tingling, Heaviness/Weakness

4. *The symptoms affect the following activities :*

   a.Severely b.Moderately c.Mildly d.Not at all

   Rank <u>each</u> : Sports or activities, Household or odd jobs, Walking, Standing

   Sitting, Sex Life.

5. *How long must you rest before the symptoms resolve ?*

   a. >10 min b.between 5 and 10 min c.<5 min

6. *How frequently do you take pain medicine for these symptoms ?*

   a. Frequently b.Daily c.Occaisionally d.Never

7. *How frequently do you see a doctor for these symptoms ?*

   a. Frequently b.Monthly c.Rarely d.Never

8. *Rank your pain on the following scale :*

0 1 2 3 4 5 6 7 8 9 1

No Pain *Worst Pain*

The score is calculated by adding :

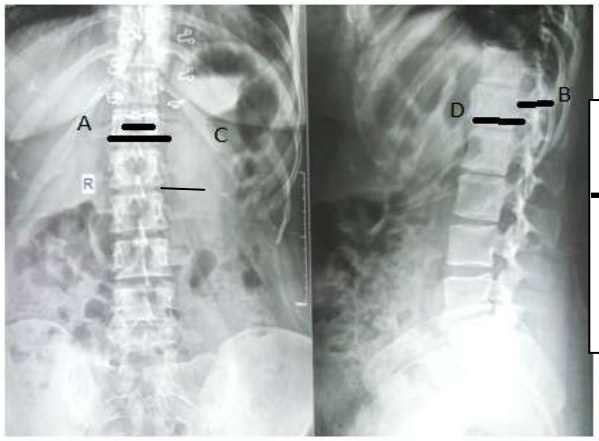
'a' answers = 0 points, 'b' answers = 2 points,

'c' answers = 4 points, 'd' answers = 6 points

---plus the pain scale added as 10-X

Total possible points = 100 (asymptomatic, full function).

JONES THOMPSON INDEX[25]



INTERPEDICULAR DIMENSION(A) X SAGITTAL CANAL DIMENSION(B)

TRANSVERSE BODY DIMENSION(C) X SAGGITAL BODY DIMENSION (D)

A X B/ C X D

Fig67

NORMAL VALUES FOR THE LUMBAR CANAL TO BODY RATIO[25]

LEVEL	MINIMUM	MAXIMUM
L3	1:3.0	1:6.0
L4	1:3.0	1:6.0
L5	1:3.2	1:6.5

Fig 68

Normal JONES THOMPSON INDEX at L4 Level is 1/6.0, any value above 1/6.0 indicates lumbar canal stenosis. In this study average JONES THOMPSON INDEX is 1/10 at L4 Level which corresponds to clinical neurological deficit. Following decompressive surgery jones Thompson index is measured using Postop X ray LS spine and there is a reversal of index to 1/6 corresponding to recovery of neurological deficits.

STATISTICAL ANALYSIS

STATISTICAL ANALYSIS

(A)Statistical Analysis of sag canal diameter for a sample of Surgically treated 40 patients measured by XRay, CT Scan and MRI is given below.

General factorial design was carried for three different levels namely X ray (Level 1), CT Scan(Level 2) and MRI (Level 3) for forty replicates. Explanation of important statistical terms is given below.

Coefficient Estimate: Regression coefficient representing the expected change in response y per unit change in x when all remaining factors are held constant. In orthogonal designs, it equals one half the factorial effect. Coefficients for multi-level categorical factors are not as simple to interpret. They do not have a physical meaning, but do have a mathematical meaning. Beta1 is the difference of level 2 from the overall average. Beta2 is the difference of level 3 from the overall average. Beta k is the difference of level (k+1) from the overall average. The negative sum of the coefficients will be the difference of level 1 from the overall average.

DF: Degrees of Freedom – equal to one for testing coefficients.

Standard Error: The standard deviation associated with the coefficient estimate.

95% CI High and Low: These two columns represent the range that the true coefficient should be found in 95% of the time. If this range spans 0 (one limit is positive and the other negative) then the coefficient of 0 could be true, indicating the factor has no effect.

Values of "Prob > |t|" less than 0.0500 indicate the difference in the two treatment means is significant. Values of "Prob > |t|" greater than 0.1000 indicate the difference in the two treatment means is not significant

	Coefficient		**Standard**	**95% CI**	**95% CI**
Term	**Estimate**	**DF**	**Error**	**Low**	**High**
Intercept	0.83045	1	0.035607089	0.759931785	0.90096774
A[1]	0.071989	1	0.050042888	-0.02711805	0.17109658
A[2]	0.00205	1	0.050350782	-0.09766685	0.10176733

Fig 69

Treatment Means		
	Estimated	**Standard**
	Mean	**Error**
1-Level 1 of A	0.902439024	0.060904
2-Level 2 of A	0.8325	0.06166
3-Level 3 of A	0.756410256	0.062446

Fig70

Treatment	Mean difference	DF	Standard error	t for H0 Coeff=0	Prob > |t|
1 vs 2	0.069939024	1	0.086667679	0.806979312	0.4213
1 vs 3	0.146028768	1	0.087228287	1.674098766	0.0968
2 vs 3	0.076089744	1	0.087758225	0.867038318	0.3877

Fig71

Inference: Prob > t larger than 0.10 indicates that there is no difference between the mean of the different treatments X-ray and CT Scan & CT and MRI. But the Prob > t less than 0.10 for X-ray Vs MRI which indicates that the difference between the mean of these two treatments is significant.

Also the check of the normality assumption may be made by constructing a normal probability plot of the residuals, as in Fig. Since the residuals plot approximately along a straight line, hence the normality assumption is satisfied.

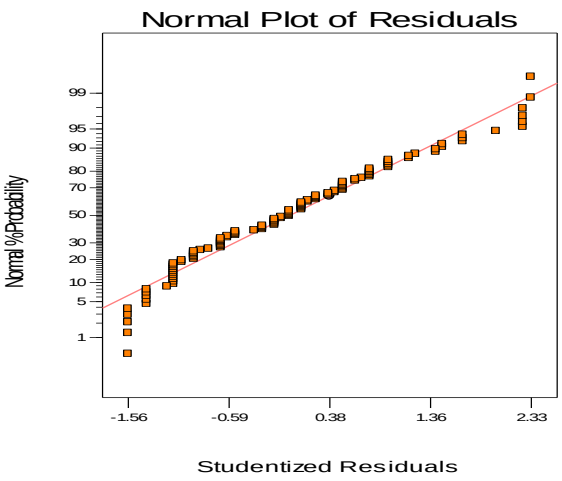


Fig72

VARIATION IN XRAY & MRI MEASUREMENT OF SPINAL CANAL IN MEASURING SPINAL CANAL STENOSIS IS STATISTICALLY SIGNIFICANT BY STUDENT T TEST(t < 0.10)

(B)Statistical Analysis of Lateral recess for a sample of Surgically treated 40 patients measured by XRay, CT Scan and MRI is given below by STUDENT T TEST

	Coefficient		Standard	95% CI	95% CI
Term	Estimate	DF	Error	Low	High
Intercept	0.338333	1	0.019261	0.300188	0.376478
A[1]	0.109167	1	0.027239	0.055222	0.163112
A[2]	0.006667	1	0.027239	-0.04728	0.060612

Treatment Means		
	Estimated Mean	Standard Error
1-Level 1 of A	0.4475	0.033361
2-Level 2 of A	0.345	0.033361
3-Level 3 of A	0.2225	0.033361

Fig73

Treatment	Mean difference	DF	Standard Error	t for H0 Coeff=0	Prob > |t|
1 vs 2	0.1025	1	0.047179	2.172578	0.0318
1 vs 3	0.225	1	0.047179	4.769075	< 0.0001
2 vs 3	0.1225	1	0.047179	2.596496	0.0106

Fig74

Inference: Prob > **t lesser than 0.05 indicates that the difference between the mean of the different treatments X-ray, CT and MRI for LATERAL RECESS is significant.** Also the residuals plot approximately along a straight line, hence the normality assumption is satisfied.

(C) Chi-square test of independence

Null hypothesis: Output of Xray, CT Scan and MRI are independent.

Alternative hypothesis: Output of Xray, CT Scan and MRI are dependent.

Level of significance: alpha = 0.05

Criterion: Reject the null hypothesis if Chi-square value is greater than 99.08, the value of Chi-square at alpha =0.05 for degree of freedom (3-1)*(40-1) =78 is given by the formula below

Chi square = $(o_{ij}-e_{ij})^2/e_{ij}$

Where o_{ij} = observed frequency, e_{ij} = expected frequency

Fig75

Expected frequencies						
sag canal diameter				Lateral recess		
	X-RAY	CT	MRI	X-RAY	CT	MRI
1.0	1.0	0.9	0.9	0.3	0.2	0.1
2.0	0.8	0.8	0.7	0.6	0.5	0.3
3.0	0.6	0.6	0.5	0.3	0.2	0.2
4.0	1.2	1.1	1.0	1.2	0.9	0.6
5.0	0.7	0.7	0.6	0.4	0.3	0.2
6.0	0.6	0.6	0.5	0.3	0.2	0.2
7.0	0.7	0.7	0.6	0.4	0.3	0.2
8.0	0.9	0.8	0.8	0.4	0.3	0.2
9.0	0.6	0.6	0.6	0.4	0.3	0.2
10.0	0.8	0.7	0.6	0.4	0.3	0.2
11.0	0.4	0.3	0.3	0.4	0.3	0.2
12.0	1.0	1.0	0.9	0.4	0.3	0.2
13.0	0.8	0.8	0.7	0.3	0.2	0.2
14.0	0.6	0.6	0.5	0.3	0.2	0.2
15.0	0.8	0.8	0.7	0.3	0.2	0.2
16.0	1.0	1.0	0.9	0.7	0.5	0.4
17.0	0.6	0.6	0.5	0.4	0.3	0.2
18.0	0.6	0.5	0.5	0.4	0.3	0.2
19.0	0.8	0.7	0.6	0.3	0.2	0.2
20.0	1.2	1.1	1.0	1.2	0.9	0.6
21.0	0.7	0.7	0.6	0.4	0.3	0.2
22.0	1.0	1.0	0.9	0.7	0.5	0.4
23.0	1.5	1.4	1.3	0.4	0.3	0.2
24.0	0.8	0.7	0.7	0.5	0.4	0.2
25.0	0.7	0.6	0.6	0.4	0.3	0.2
26.0	0.7	0.6	0.6	0.3	0.2	0.2
27.0	0.8	0.7	0.6	0.4	0.3	0.2
28.0	1.1	1.0	0.9	0.4	0.3	0.2
29.0	1.2	1.1	1.0	0.6	0.4	0.3
30.0	1.3	1.2	1.1	0.5	0.4	0.3
31.0	0.9	0.8	0.8	0.4	0.3	0.2
32.0	0.9	0.8	0.8	0.5	0.4	0.3
33.0	1.1	1.0	0.9	0.4	0.3	0.2
34.0	1.0	1.0	0.9	0.3	0.2	0.2
35.0	0.7	0.6	0.6	0.3	0.2	0.1
36.0	0.7	0.7	0.6	0.3	0.2	0.2
37.0	0.9	0.8	0.8	0.4	0.3	0.2
38.0	1.3	1.2	1.1	0.5	0.4	0.3
39.0	1.5	1.4	1.3	0.4	0.3	0.2
40.0	1.2	1.1	1.0	0.5	0.4	0.3

Fig76

chi2

	sag canal diameter			Lateral recess		
	X-RAY	CT	MRI	X-RAY	CT	MRI
1.0	0.1	0.2	0.0	0.0	0.0	0.0
2.0	0.0	0.0	0.0	0.2	0.1	0.1
3.0	0.2	0.0	0.1	0.0	0.0	0.0
4.0	0.0	0.3	0.4	0.0	0.3	0.3
5.0	0.0	0.2	0.1	0.0	0.0	0.0
6.0	0.1	0.0	0.0	0.0	0.0	0.0
7.0	0.2	0.2	0.0	0.0	0.1	0.0
8.0	0.0	0.1	0.2	0.0	0.0	0.0
9.0	0.0	0.2	0.1	0.0	0.0	0.1
10.0	0.3	0.1	0.9	0.0	0.1	0.0
11.0	0.0	0.0	0.0	0.0	0.0	0.0
12.0	0.0	0.1	0.0	0.0	0.1	0.0
13.0	0.0	0.3	0.5	0.0	0.0	0.0
14.0	0.0	0.0	0.1	0.0	0.0	0.0
15.0	0.0	0.3	0.5	0.0	0.0	0.0
16.0	0.0	0.3	0.3	0.1	0.0	0.1
17.0	0.1	0.1	0.0	0.0	0.0	0.0
18.0	0.1	0.0	0.0	0.1	0.0	0.1
19.0	0.0	0.1	0.0	0.0	0.0	0.0
20.0	0.0	0.3	0.4	0.0	0.3	0.3
21.0	0.2	0.2	0.0	0.0	0.1	0.0
22.0	0.0	0.3	0.3	0.1	0.0	0.1
23.0	0.1	0.0	0.0	0.1	0.0	0.1
24.0	0.0	0.0	0.0	0.0	0.0	0.1
25.0	0.3	0.1	0.1	0.0	0.0	0.0
26.0	0.1	0.1	0.0	0.0	0.0	0.0
27.0	0.0	0.0	0.0	0.0	0.0	0.0
28.0	0.1	0.1	0.0	0.1	0.1	0.0
29.0	0.0	0.2	0.3	0.0	0.0	0.0
30.0	0.0	0.2	0.1	0.0	0.0	0.1
31.0	0.0	0.0	0.1	0.0	0.0	0.0
32.0	0.0	0.2	0.1	0.0	0.0	0.2
33.0	0.0	0.0	0.1	0.0	0.0	0.0
34.0	0.3	0.2	0.0	0.0	0.1	0.1
35.0	0.0	0.0	0.0	0.1	0.1	0.0
36.0	0.1	0.0	0.0	0.0	0.0	0.0
37.0	0.0	0.0	0.1	0.0	0.0	0.0
38.0	0.0	0.2	0.1	0.0	0.0	0.1
39.0	0.1	0.0	0.0	0.1	0.0	0.1
40.0	0.0	0.0	0.0	0.0	0.0	0.1

Decision: Since Chi square value = 12.73(Sag canal diameter), 4.12(lateral recess) not greater than 99.08, null hypothesis must be accepted;

We conclude that the output of Xray, CT Scan and MRI are independent implying **VARIATION IN XRAY,CT & MRI MEASUREMENT OF SPINAL CANAL & LATERAL RECESS IN MEASURING SPINAL CANAL STENOSIS IS STATISTICALLY SIGNIFICANT.**

CONCLUSION

CONCLUSIONS

Variations seen in the spinal canal and lateral recess diameter measured by Xray,CT,MRI lumbosacral spine in this study is satistically more significant than any other studies.MRI has smaller spinal canal and lateral recess diameter due to more accurate measurement of soft tissue changes associated with degenerative lumbar canal stenosis.

Significant neurological deficit occurs even with mean spinal canal diameter of 15.1mm in this study when compared to diameter of 12 mm of other studies. This is probably due higher incidence of lateral recess stenosis in this study implying the importance of lateral recess stenosis in the pathology of degenerative lumbar canal stenosis.

As Mean spinal canal stenosis is only 15% (i.e less than 50%) in this study, 49% satisfactory surgical results are expected based on Bradley study, but still 89% satisfactory results are obtained.

Overall good surgical outcome compared to other studies and better surgical results when compared to conservative treatment in this study is due to foraminotomy/medial facectomy done in all cases in addition to laminectomy and discectomy thereby dealing the lateral recess stenosis which is the

important pathology in degenerative lumbar canal stenosis ,which has already been dealt previously.

Patients with degenerative lumbar canal stenosis presenting with only backpain are better managed conservatively and patients presenting with backpain with associated neurological deficit are successfully managed with surgical treatment in this study.

Similar to other studies, there is a female preponderance and Factors like smoking,alcoholism,hypertension,diabetis mellitus has no significant influence in the outcome of treatment of degenerative lumbar canal stenosis.

Jones Thompson index applied in this study correlates well with clinical neurological deficit as well as with surgical outcome.

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APPENDIX

APPENDIX – I

PROFORMA

CLINICAL AND RADIOLOGICAL CORRELATION OF DEGENERATIVE LUMBAR CANAL STENOSIS WITH OUTCOME OF VARIOUS MODALITIES OF TREATMENT.

PATIENT PARTICULARS: NAME. AGE/SEX

I.P/OP NO: UNIT:

ADDRESS:

D.O.A D.O.D

CONTACT NUMBER:

OCCUPATION:

PERSONAL HISTORY:

PAST HISTORY:

H/O PRESENTING ILLNESS:

1.LOWBACKACHE+/-SCIATICA 2.CLAUDICATION PAIN 3.NUMBNESS/PARESTHESIA 4.BLADDER/BOWEL DISTURBANCES 5.U.T.I 6.MENSTRUAL IRREGUARITIES/LEUKORRHOEA 7.ERECTILE DISTURBANCES/ IMPOTENCY 8.H/O LIFTING HEAVY WEIGHTS.

CLINICAL EXAMINATION:

1.BULK 2.TONE 3.POWER 4.SENSATION 5.REFLEXES 6.SLRT 7.SPINE TENDERNESS 8.DEFORMITY.

BASIC INVESTIGATIONS:

RADIOLOGIAL INVESTIGATIONS :

X RAY LS SPINE-1.BODY/CANAL RATIO(JONES &THOMPSON INDEX) 2.LORDOSIS ANGLE 3. INTERPEDICULAR DISTANCE 4.LATERAL RECESS.

CT LS SPINE- 1.SPINAL CANAL&LATERAL RECESS MEASUREMENT(L1-L5) 2.HNP 3.FACET JOINT 4LISTHESIS 5.LIG.FLAVUM HT.

MRI LS SPINE-1.DISC DEHYDRATION 2.HNP 3.FACET JOINT 4LISTHESIS 5.LIG.FLAVUM HT. 6.ENDPLATE CHANGES 7.ROOT COMPRESSION. 8. SPINAL CANAL&LATERAL RECESS MEASUREMENT(L1-L5)

DIAGNOSIS:

TREATMENT: CONSERVATIVE-
SURGICAL- 1.PROCEDURE 2.INTRAOP FINDINGS. 3. COMPLICATIONS. 4. POSTOP PERIOD.

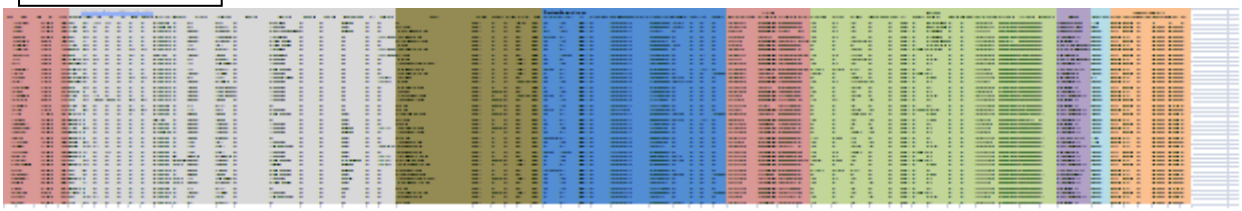
NEUROLOGICAL STATUS ON DISCHARGE:

FOLLOW UP:

APPENDIX-2

GROUP A

GROUP B



APPENDIX-3

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

சிதைவாக்கப்பட்ட கீழ் முதுகு குழாய் குறுக்கத்தை நோய்படுக்கை தொடர்பியல் மூலமாகவும், மற்றும் ஊடுகதிர் கதிரியக்க மருத்துவத்தோடும், பற்பல சிகிச்சை முறையின் விளைவோடும் சம்மந்தப்படுத்தும் ஆய்வு

ஆராய்ச்சி நிலையம் : அரசு ஸ்டான்லி மருத்துவமனை, சென்னை - 600 001.

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பங்கு பெறும் நோயாளியின் எண் : பாலினம் : ஆண் ☐ பெண் ☐

பங்கு பெறும் நோயாளியின் விலாசம் :

நோயாளி இதனை (✓) குறிக்கவும்.

மேலே குறிப்பிடப்பட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது ☐

நான் என்னை இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்க அனுமதிக்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் என்னை இவ்வாய்வில் இருந்து விலக்கி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன். ☐

இந்த ஆய்வில் என்னை ஈடுபடுத்த முழுமனதுடன் ஒப்புக் கொள்கிறேன். இந்த ஆய்வின் போது செய்யப்படும் அறுவை சிகிச்சையின் போதோ, அறுவை சிகிச்சைக்குப் பிறகோ ஏற்படக் கூடிய பின் விளைவுகள் மற்றும் எதிர்பாராத விளைவுகள் பற்றி எனக்கு விளக்கமாகத் தெவிக்கப்பட்டது. ☐

இந்த ஆய்வின் போது கீழ் முதுகில் அறுவை சிகிச்சை மேற்கொள்ளப்படும். அறுவை சிகிச்சை செய்த பின் ஏற்படும் விளைவுகளை ஆய்வு செய்ய முழு மனதுடன் சம்மதிக்கிறேன். ☐

என் நலன் கருதியே இந்த ஆய்வு மேற்கொள்ளப்பட்டது என்று தெரிந்து இந்த ஆய்விற்கு ஒப்பளிக்கின்றேன். ☐

நோயாளியின் கையொப்பம் ..... இடம் ..... தேதி

கட்டைவிரல் ரேகை (இந்த படிவம் படித்து காட்டப்பட்டு புரிந்து கைரேகை அளிக்கின்றேன்)

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி

ஆய்வாளரின் பெயர் .....

APPENDIX-4

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Clinical and Radiological correlation of Degenerative Lumbar Canal Stenosis with outcome of various modaities of treatment

Principal Investigator : Dr.G.Rajkumar

Designation : PG in M.Ch (Neuro Surgery)

Department : Department of Neuro Surgery
Government Stanley Medical College,
Chennai-1

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 12.10.2011 at the Modernized Seminar Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate form the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

13/10/11

MEMBER SECRETARY,
IEC, SMC, CHENNAI