Original Research Paper Medical Science

CONSERVATIVE MANAGEMENT OF "LUMBAR CANAL STENOSIS" : A PROSPECTIVE COMPERATIVE TRIAL

Dr. Sanyal Kumar*	MD (PMR), Dept of Physical Medicine and Rehabilitation King George Medical University, Lucknow, (UP), INDIA
Dr. V.P.Sharma	MS (Ortho), DNB (PMR), FICS, FACS, FIMSA, MAMS, PG (Spine) (Aus) Professor Department of Physical Medicine and Rehabilitation King George's Medical University, Lucknow, U.P., India
Dr. Anil Kumar Gupta	MD (PMR), DNB (PMR), CEPC Associate Professor,Department of Physical Medicine and Rehabilitation, KGMU, Lucknow
Dr. Dileep Kumar	MS (Ortho) Assistant Professor, Department of Physical Medicine and Rehabilitation, KGMU, Lucknow
Dr. Sudheer Mishra	DNB (PMR) Assistant Professor,Department of Physical Medicine and Rehabilitation, KGMU, Lucknow
Dr. Ganesh Yadav	MD (PMR) Lecturer,Department of Physical Medicine and Rehabilitation, KGMU, Lucknow

ABSTRACT

Introduction: Lumbar canal stenosis has various primary or secondary causes but secondary degenerative changes affect the global burden in the disability.

Objective & Aim: To compare outcome of physical therapy alone (PT) and physical therapy with Drug therapy (PT+DT) in nonsurgical management of subjects with lumber canal stenosis.

Methodology: This prospective randomised comperative study was performed in a tertiary care teaching institution of North India. Age and sex matched, subjects with Lumbar canal stenosis with neurogenic claudication were enrolled in this study. Subjects were assessed for pain by Numerical pain rating scale (NPRS), severity of disease by Claudication Distance (by Treadmill walking), Oswestry Disability Index (ODI) and Roland Morris Diability Index (RMDI) at 3weeks, 6 weeks and 3 months interval.

Results: A total of 68 subjects were enrolled. The age of PT(30 subjects) and PT+DT (38 subjects) groups ranged from 45-72 yrs and 48-70 yrs respectively with mean (± SD) 54.00 ± 9.55 yrs and 58.21 ± 10.24 yrs respectively, and median 50 yrs and 52 yrs respectively. Mean Claudication Distance, NPRS, ODI and RMDI scores were 565.50 ± 322.387.29 ± 1.47, 47.76 ± 12.48 and 47.63 ± 12.21 respectively at initial evaluation which improved to 1340.79 ± 541.50, 1.63 ± 1.22, 15.39 ± 9.27and 18.37 ± 11.48 respectively at 12 weeks in PT+DT group which was significantly improved($p<0.001$) as compared to PT alone group.

Conclusion: This study demonstrates significant improvement in evaluated parameters in PT + DT group as compared to PT group. Physical therapy in combined with drug therapy has greater impact than physical therapy alone.

KEYWORDS : Lumbar canal stenosis, Physical therapy, physical with drug therapy, randomized comparative study

INTRODUCTION

Lumbar canal stenosis is a narrowing or stricture of the spinal canal, with potential for nerve impingement, which may occur in the central canal, in the lateral recess, or at the neural foramen.[1, 2] It typically affects persons over 50 years of age.[3] **Lumbar canal** narrowing may be multifactorial. Degenerative changes are typically involved, including facet hypertrophy, ligamentum flavum thickening, and disc bulging and protrusion, alone or in combination. Degenerative spondylolisthesis, a distinct clinical feature characterized by forward displacement of vertebra due to disc and facet degeneration, is another frequent factor, further compromising the diameter of the lumbar canal.[4]

Pathophysiology behind LSS is due to inadequate oxygenation and accumulation of metabolite in the cauda equine resulting ischemia of the central canal and nerve root. In the presence of two low pressure blocks, there will be venous congestion in the intervening segments and reduction of blood flow by 64%.[5]

Classical symptoms seen are pseudoclaudication, also known as neurogenic claudication, paresthesia, weakness, or heaviness in the buttocks radiating into the lower extremities with walking or prolonged standing, relieved with flexion or sitting.[1,3,4] Detailed Clinical history and findings on physical examination, Spinal imaging by MRI or CT Myelography are usually performed to confirm the clinically suspected diagnosis.[6]

This study is based on the literature review in Lumbar spinal stenosis favourably influence the conservative treatment including back care, exercise programs, physical theray & medication alone or in combination yield to give good results in patients having mild to moderate symptoms of LSS. [6-10] Aim of this study to reduce the pressure over spinal cord and improve the spinal blood flow in the ischemic area resulting prevention from further damage of spinal nerve roots.

MATERIAL AND METHODS

A total of 68 subjects were enrolled in this study after written informed consent and clearance from institutional ethics committee. All subjects were randomly allotted into two groups by computer generated system. All subjects satisfying the **inclusion criteria were enrolled which included** age between 45 to 75 years, subjects having neurogenic claudication, pain, parasthesia, heaviness in the buttock radiating into the lower extremities with walking or prolonged standing and radiological finding of lumbar spine show narrowing of spinal canal diameter which are grade A and B, Grading of lumbar canal stenosis into four grades (A, B, C & D) through morphology of dural sac in MRI based on literature reiview **Constantin et al**.

Subjects who **excluded** from study presented with malignancy of lumbar spine (primary or secondary), infection of spine or surrounding structure, vascular claudication, Pott's spine,

peripheral neuropathy, prior surgery or fractures of lumbar spine, hip disease and severe peptic ulcer disease, subjects with an inappropriate diagnosis of Lumbar canal stenosis and subjects with neurological deficit or other inappropriate medical conditions complicating the pathology or MRI grade c and d.[8]

38 subjects were given Aspirin 75 mg sustained release orally at bed time and Xanthinol nicotinate 150mg 12 hourly after meal by oral route which formed the PT+DT group, whereas 30 were treated with physical therapy alone which also served as PT group. Drug therapy was continued at same dosage till the end of study period of 3 months. All patients took part in physical therapy, exercise and treadmill session. Physical therapy consisted hot pack (20min) + Short wave diathermy (10min) over the lumbar region, 5 days a week for 15 sessions.[9] Flexion exercise based on subject tolerance on the specific day consisted of pelvic tilt, single knee to chest, double knee to chest, partial sit-ups, hamstring stretch, hip flexor stretch, and squat (15 repetitions, three times in a day, and three days in a week for three months). Exercise were taught and performed by physiotherapist during hospital session and patients were instructed to repeat the same exercise twice a day at home. Treadmill session based on the patients tolerance on the specific day and could extend up to 45 min three times per week for three months. [10] Treadmill session were performed during hospital session under supervision .Outcome measures were assessed by numerical pain rating scale (NPRS), Claudication distance (CD), Oswestry Disability Index (ODI) and Roland Morris Disability Index (RMDI) at 1st visit, 3 weeks, 6 weeks and 3 months.

All subjects were explained about the procedure to dispel fear and misconception. They were explained about the procedure and regular follow up.

Determination of neurogenic claudication distance: The patient was placed over treadmill walker with zero inclination (explaining the procedure before) and walks over treadmill with a comfortable walking speed until the appearance of claudication pain and distance walked was recorded from treadmill display at the point of appearance of claudication.[9]

RESULTS

A total of 68 subjects were included in this study, randomize in to two groups PT group (n=30) and PT+DT group (n=38), 22 patients having concomitant disease like hypertension, coronary artery disease, type 2 DM. In PT+DT group no adverse effect reported by the patient, and outcome parameters were assessed. At baseline there is no significant difference between groups Patient's age, sex, MRI grading, Claudication distance, NPRS, RMDI and ODI (Table 1). Comparing the mean claudication distance within the groups, Tukey test showed significant ($p<0.05$ or $p<0.001$) increase in PT group at 12 wk as compared to other periods (0 wk, 3 wk and 6 wk) while in PT+DT group it increase significantly ($p<0.001$) at all periods except 0 wk and 3 wk . Similarly, comparing the mean claudication distance between the groups, showed significantly ($p<0.001$) different and higher claudication distance in PT+DT group as compared to PT group at 12 wk while at other periods it did not differed ($p>0.05$) between the two groups i.e. found to be statistically the same. At final evaluation net improvement in claudication distance was 27.1% higher in PT+DT group as compared to PT group (Figure 1). Comparing the mean NPRS within the groups, showed significant ($p<0.001$) decrease in NPRS in both groups between all the periods. Similarly, comparing the mean NPRS between the groups, showed significantly ($p<0.001$) different and lower NPRS in PT+DT group as compared to PT group at both 6 wk and 12 wk while at other periods (0 wk and 3 wk) it did not differed ($p>0.05$) between the two groups i.e. found to be statistically the same. At final evaluation improvement in NPRS was 37.2% in PT+DT group as compared to PT group (figure 2). Comparing the mean RMDI within the groups, showed significant ($p<0.001$) decrease in RMDI in both groups between all the periods. Similarly, comparing the mean RMDI between the groups, showed significantly ($p<0.001$) different and lower RMDI in PT+DT group as compared to PT group at 12 wk while at other periods (0 wk, 3 wk and 6 wk) it did not differed ($p>0.05$) between the two groups i.e. found to be statistically the same. Comparing the mean ODI within the groups, showed significant ($p<0.01$ or $p<0.001$) decrease in ODI in both groups between all the periods. Similarly, comparing the mean ODI between the groups, showed significantly ($p<0.001$) different and lower ODI in PT+DT group as compared to PT group at 12 wk while at other periods (0 wk, 3 wk and 6 wk) it did not differed ($p>0.05$) between the two groups i.e. found to be statistically the same. At final evaluation net improvement in both the disability index was 20.2% and 25.2% respectively in PT+DT group as compared with PT group (Table 2).

DISCUSSION

Lumbar canal stenosis is a common cause of neurogenic claudication pain and disability. The readily accepted treatment of mild to moderate level of LSS is largely conservative with surgery reserved for severe symptoms or failed conservative therapy. Many studies have reported reasonable effectiveness of conservative therapy as first line treatment plan and practiced with mixed result. Numerous option are available in conservative treatment include physical therapy including exercise programme, orthoses, electrical modalities, traction, manual therapy, epidural block, injection with or without steroids, NSAID's, Calcitonin, muscle relaxants, methylcobalamine, prostaglandins, gabapentine and multimodal treatments.

Most of the pharmacological treatment used focus on symptomatic and suppression of pain pathways. Epidural steroid injections, calcitonin and NSAID's aim to reduce nerve root inflammation. Drugs acting on ischaemia or vascular component of disease are few in number. This study has used combination of Xanthinol nicotinate with Aspirin for the first time as a pharmacologic treatment option. In our study, group treated with drug therapy had significant improvement in all assessed parameters. Calcitonin is another drug considered to be effective by increasing the blood flow.

In our study, we evaluated the effect of a drug regime in combination physical therapy and exercise. We used Xanthinol nicotinate and Aspirin with aim to decrease the viscosity of blood along with dilatation of small sized arterioles, combined action of these drugs help to reverse the ischaemia of central canal by decreasing sludging, increased blood flow and wash out painful metabolites.

Fritz *et al* [12] in their study used Visual Analogue Scale for pain and Oswestry Disability Index and Roland Morris Disability Index used for outcome assessment. At 10 week of follow up period and net improvement was noted 20%, 18%, and 25% respectively while Numerical Pain Rating Scale for pain, Oswestry Disability Index and Roland Morris Disability Index were used in this study. **Onel *et a*** [13] use combined physical therapy with superficial heat and deep heat modalities with calcitonin and exercise programme for one month at the end of study he found 70% of patients achieved good outcomes. **Fusan Sahin *et al*** [9] studied 45 subjects who received 8 weeks of treatment of concomitant use of calcitonin with physical therapy reporting no beneficial effect on the claudication distance. In this study net mean improvement in claudication distance of PT+DT group 27.1% higher as compared to PT group. **Ammendolia *et al*** [14] showed significant improvement in the NPRS from 0 week to 6 week nonsurgical multimodal programme which is consistent with results of this study. **Fritz JM, Irrgang JJ *et al*** [15] measured physical impairment at 1st visit and after 4 weeks follow up physical therapy by using Oswestry Disability Index and Quebec Back Pain Disability Scale. In this study, the mean change in ODI of PT+DT group was 25.2% higher as compared to PT group. **Fusan Sahin *et al*** [9] concluded that subjects having LSS who received 8 weeks of treatment with calcitonin with physical therapy had no change in RMDI. While this study showed improvement in RMDI of PT+DT group was 20.2% higher as compared to PT group. Comparison between conservative and surgical treatment favour surgical

option. **Johansson *et al*** [16] reported 19 untreated patients with spinal stenosis were compared to 44 patients treated surgically. In the follow up period one third of treated and one half of un-treated patients still had neurogenic claudication and VAS estimation 60% of surgically treated patients and 33% of un-treated patients felt better. **Atlas *et al*** [17] compare surgical and non-surgical management LSS in 4 years outcome. Initially they enrolled 148 patients and follow 119 patients out of which 67 treated surgically and 52 treated non-surgically. After 4 years surgically treated patients had more severe symptoms at baseline compared with non-surgically treated patients showed better outcome in their symptoms, treatment satisfaction and functional status. In non-surgically treated patients improvement is little and stable during 4 years period. Possible limitation of this study is lack of control group, small sample size & follows up period.

CONCLUSION

This study thus clearly shows that the subjects with Physical therapy combined with drug therapy have more improvement then physical therapy alone for lumbar canal stenosis. Multimodal conservative approaches are more beneficial. Educating the patient about back care is also equally important. It's effective and safe to be administered in outpatient clinics considering that the top priority of a pain control program is restoration of function to perform usual ADL.

Table:-1 Comparison of patient Age, Gender, MRI Grading & follow up parameters during baseline

	PT group (n=30)	PT+DT group (n=38)	P value
Age	54.00 ± 9.55	58.21 ± 10.24	> 0.05
Gender Male	18 (60.0)	20 (52.6)	> 0.05
Female	12 (40.0)	18 (47.4)	
MRI grading A	17 (56.7)	15 (29.1)	> 0.05
B	13 (43.3)	23 (60.5)	
CD	563.33 ± 336.4	309.61 ± 322.8	> 0.05
NPRS	6.43 ± 1.52	7.29 ± 1.47	> 0.05
RMDI	39.04 ± 13.11	47.63 ± 12.21	> 0.05
ODI	36.20 ± 12.99	47.47 ± 12.21	> 0.05

Fig.1:- Improvement in claudication distance.

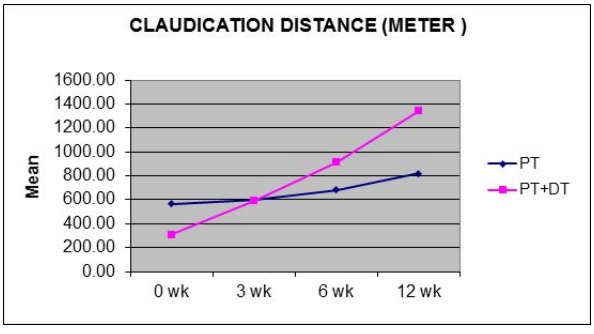
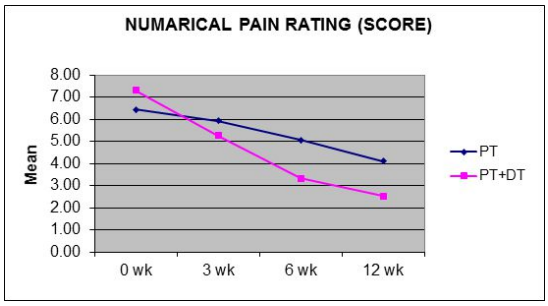


Table:-2 Comparison of Pre & Post-treatment in follow up parameters

		Pre-treatment	Post-treatment	P value
CD	PT	563 ± 336.4	818.33 ± 591.10	<0.001
	PT+DT	309.61 ± 322.38	1343.42 ± 541.50	
NPRS	PT	6.43 ± 1.52	4.03 ± 1.35	<0.001
	PT+DT	7.29 ± 1.47	2.53 ± 1.22	
RMDI	PT	39.04 ± 13.11	28.43 ± 12.20	0.002
	PT+DT	47.63 ± 12.11	18.37 ± 11.48	
ODI	PT	36.20 ± 12.99	27.57 ± 13.18	0.026
	PT+DT	47.47 ± 12.48	15.37 ± 9.27	

Fig. 2:- Improvement in NPRS



REFERENCES

1. Arbit E, Pannulo S. Lumbar stenosis—a clinical review. Clin Orthop 2001; 384:137–143.
2. Herkowitz H. Degenerative lumbar spondylolisthesis. Spine 1995; 20:1084–1090.
3. Baker AR, Collins T, Porter RW, Kidd C. Laser Doppler study of porcine cauda equina blood flow: The effect of electrical stimulation of the rootlets during single and double site, low pressure compression of the cauda equina. Spine 1995; 20:660-4.
4. Arnoldi C, Brodsky A, Cauchoix J. Definition and classification of lumbar spinal stenosis and nerve root entrapment syndromes. Clin Orthop 1976; 115:4–5.
5. Ricard W Porter.Spinal Stenosis and Neurogenic Claudication. SPINE 1996; 2046-2052.
6. Modic M, Masaryk T, Boumphrey F, Goormastic M, Bell G. Lumbar herniated disc disease and canal stenosis: prospective evaluation by surface coil MRI, CT, and myelography. Am J Radiol 1986; 7:709–717.
7. Janna L Friedly, Brian W Bresnahan, Bryan Comstock. Study Protocol- Lumbar Epidural Steroid Injections for Spinal Stenosis (LESS): a doubleblind randomized controlled trial of epidural steroid injections for lumbar spinal stenosis among older adults. BMC Musculoskeletal Disorders 2012, 13:48.
8. Constantin S, Nicolas T, Alexandre B, Rosamond T, Douglas W, Francis W,Gerit K, Qualitative Grading of Severity of Lumbar Spinal Stenosis Based on the Morphology of the Dural Sac on Magnetic Resonance Images. Spine 2010; 35: 1919-1924.
9. Fusun S, Figen Y, Nurdan K, Banu K, The Efficacy of Physical Therapy and Physical Therapy Plus Calcitonin in the Treatment of Lumbar Spinal Stenosis, Yonsei Med J 2009; 50(5): 683-688.
10. Whitman JM, Flynn TW, Childs JD, et al. A comparison between two physical therapy treatment programs for patients with lumbar spinal stenosis: a randomized clinical trial. Spine 2006; 31:2541-9.
11. Johnsson KE, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis. A comparison of surgically treated and untreated patients. Spine 1991; 16:615–619.
12. Fritz JM, Erhard RE, Vignovic M. A Nonsurgical Treatment Approach for patients with Lumbar spinal stenosis. Phys Ther. 1997; 77(9):962-73.
13. Onel D, Sari H, Donmez C. Lumbar spinal stenosis: clinical/radiologic therapeutic evaluation in 145 patients. Conservative treatment or surgical intervention? Spine 1993; 18:291–298.
14. Ammendolia C, Chow N, et al. Clinical Outcome For Neurogenic Claudication Using A Multimodal Program For Lumbar Spinal Stenosis: A Retrospective Study. J Manipulative and Physiological Therapeutics 2015; 38:3-4.
15. Fritz JM, Irrgang JJ. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. Phys Ther. 2001; 81(2):776-88.
16. Johnsson KE, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis. A comparison of surgically treated and untreated patients. Spine 1991; 16:615–619.
17. Atlas SJ, Keller RB, Robson D, et al. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the Maine Lumbar Spine Study. Spine 2000; 25:556–562.