

Effect of Caudal Epidural Injection for management of Lumbar Spinal Stenosis: A randomized controlled Trial

Dr. Padam Meena¹, Dr. Sunil Goenka², Dr. Nitin Pandey³, Dr Rajeshwari Jindal⁴,
Dr. Mrinal Joshi⁵, Dr. Rajeev Yadav^{6§}

¹Resident doctor, Department of PMR, SMS Medical College Jaipur (Rajasthan) India

^{2,4,5}Senior Professor, Department of PMR, SMS Medical College Jaipur (Rajasthan) India

³Assistant Professor, Department of PMR, SMS Medical College Jaipur (Rajasthan) India

⁶Associate Professor, Department of PSM, JLN Medical College Jaipur (Rajasthan) India

§Corresponding Author: Dr. Rajeev Yadav

Abstract—Chronic low back pain (LBP) is a common cause of morbidity and work absenteeism worldwide. This hospital based randomized, controlled, interventional study is conducted to assess the effectiveness of caudal epidural steroid injection in lumbar spinal stenosis. Study subjects were chronic low back pain patients attending at department of Physical Medicine and Rehabilitation (PMR), Sawai Man Singh Hospital, Jaipur (Rajasthan) India. For study purpose, 60 LBP cases were taken in Study group and 60 cases were taken for control group. To compare the effect between conservative treatment alone and added with caudal epidural injection of steroid plus saline in lumbar spinal stenosis, in study group, a mixture of MPA (3mg/kg body wt.) plus 16 ml of normal saline was injected in epidural space along with conservative treatment and in control group only conservative treatment was given. It was observed in this study that patient had more significant improvement in low back pain, leg pain, walking distance and functional activity after caudal epidural block in the study group than control group for a period of 3-6 months. So it was concluded that when conservative treatments were combined with interventional methods in form of caudal epidural steroid injection the amount of relief gets augmented as compared to the conservative treatment alone resulting in the patient benefiting in terms of much better symptom control and pain relief, improvement in anxiety, depression and activity limitations and quality of life.

Keywords: Chronic low back pain (LBP), Methylprednisolone Acetate.

I. INTRODUCTION

Chronic low back pain (LBP) is a common cause of morbidity and work absenteeism worldwide and a very common presenting complaint in out-patient departments dealing with geriatric patients. The prevalence of LBP is 5-20% in USA, 25-45% in Europe and 23.09 % in India,¹ Among various causes lumbar spinal stenosis (LSS) is a common cause in elderly for spinal surgery. LSS is a growing concern with the aging of the population.²

Spinal stenosis can be primary (congenital) or secondary (acquired stenosis). The natural history of spinal stenosis remains poorly understood. Prevalence of congenital LSS is 4.7% for relative and 2.6% for absolute. Acquired LSS is 22.5% and 7.3% for relative and absolute respectively. Acquired LSS showed increasing prevalence with age ≥ 40 years, the prevalence of relative and absolute LSS found 20.0% and 4.0%, respectively; in those 60–69 years the prevalence found 47.2% and 19.4%, respectively.³

Degenerative LSS involve central canal, lateral recess, foramina or combination. Central canal stenosis results from decrease in antero-posterior, transversal or combined. Entrapment of cauda equina roots by hypertrophy of the osseous and soft tissue structure surrounding the lumbar spinal canal. Foraminal

stenosis more frequently involves the L5 nerve root, as L5-S1 foramen has smaller foramen/root area ratio. The available space in the central canal decreases in loading and extension and increases in axial distraction and flexion.^{4,5}

Signs and symptoms results from vascular compromise to the vessels supplying the cauda equina (central stenosis) or from pressure on the nerve root complex (lateral stenosis). Till now no widely accepted diagnostic or classification criteria for the diagnosis of LSS is established. Standardized questionnaires and radiological imaging studies are used for the diagnosis of central, lateral recess and foraminal stenosis. Stenosis is relative if diameter is between 10 and 12 mm whereas a diameter less than 10 mm is absolute. However various pain rating scales, imaging criteria & patient administered were used in different studies.³

Treatment options include analgesics, NSAIDs, muscle relaxants, opioid and gabapentine. Conservatively, manual therapy, splinting, stretching, and strengthening exercises for the lumbar spine and hip region were used. Surgically cases are managed by decompressive laminectomy, epidural injections includes corticosteroids, normal saline. Few studies had used epidural steroid injections for management of these cases with increasing frequency as a less invasive, potentially safer and more cost-effective treatment than surgery.^{6,7,8}

This present study was conducted to find out the added effect of Methylprednisolone Acetate over conservative treatment alone in lumbar spinal stenosis (LSS) cases in a tertiary level setting.

II. METHODOLOGY

A hospital based longitudinal, prospective, randomized, controlled, clinical interventional study was carried out on lumbar spinal stenosis (LSS) cases from March 2015 to December 2016 at department of PMR, SMS Medical College, Jaipur (Rajasthan) India.

All patients aged 40 years or older with chronic low back pain attending at the Physical Medicine and Rehabilitation (PMR) center outpatient department (OPD) of SMS hospital, Jaipur during the study period were enrolled. Patients having Lumbar spinal canal stenosis diameter of <10 mm in MRI, Radiological evidence of stenosis at L4-5 & L5-S1 levels and qualified as LCS with neurogenic claudication cases were included in this study. Following inclusion and exclusion criteria were used for the patients to be included in the study. Patients on any contraindication to steroid, active local or systemic infection, spinal instability requiring surgery or who had gone for spinal surgery, history of epidural injection in the previous 6 month, excessive alcohol consumption and/ or with diseases like Diabetes mellitus, Metastatic disease, Psychiatric illness, severe vascular, pulmonary or coronary artery disease that limits ambulation including recent myocardial infarction (within the last 6 months) were excluded from study.

All patients clinically suspected to be suffering from lumbar canal stenosis were subjected to following radiological investigations: Plain X-rays lumbo-sacral spine. MRI of lumbosacral spine was performed for all patients. Once the diagnosis of lumbar canal stenosis was made patient were subjected to conservative line of management. After taking written informed consent from all 120 study subjects, baseline information was taken as per pre-designed and semi-structured Performa. These eligible subjects were randomized in two groups by a computer generated random number and trial will be done accordingly i.e. study and control group.

In other control group patients were kept only on conservative treatment whereas in study group, along with conservative treatment patients were given steroid injection. Every study group patient is placed in the prone position with a pillow under the pelvis. The patient is prepared in a standard aseptic fashion over an area large enough to allow palpation of landmarks and sterile technique is used throughout the procedure. Skin and subcutaneous tissue around sacral hiatus which is usually palpable roughly 4 cm from the upper end of the natal cleft. Under strict aseptic precaution a needle is passed through sacral hiatus. Aspiration is performed to ensure that the needle has not penetrated a blood vessels or a dura. Whoosh test is used to confirm needle placement. A stethoscope is placed over the thoraco-lumbar region in the middle line as approximately 2 ml of air injected. If the needle is truly in the epidural space then a whoosh is heard with stethoscope confirming the passage of air proximally in the epidural space. The epidural space is injected with mixture of MPA (3mg/kg body wt) plus 16 ml of normal saline. Injection should be slow. Following the injection, the patient remains flat for 4 hour with regular monitoring of pulse, BP and temperature. After injection, every patient is given 5 days of antibiotic therapy with Cefixime 200mg BD.

All patients of both the groups were examined thoroughly at baseline, 2week and finally at 3 months on basis of RMDS (Roland Morris Disability Score) and GAD 7 (Generalized Anxiety Disorder 7). RMDS questionnaire was used to assess health status measure for low back pain and GAD 7 - questionnaire for screening and severity measurement of generalized anxiety disorder.

Chi-square test was used to assess the significant of difference in proportion in both the groups. For significance p value <0.05 was considered significant.

III. RESULTS

Both groups i.e. study and control group were not having significant difference as per age and sex wise.

When mean changes in RMDS (Roland Morris Disability Score) pain score of both group was compared from baseline to 1st follow up and 2nd follow up, it was observed that mean changes in RMDS score were found significantly more (p value<0.001) in study group than control group at 1st follow up as well as in 2nd follow up (p value<0.001). (Table 1)

Table 1
Comparison of Roland Morris Disability Scores (RMDS) in study and control group

| Time Interval | Group | N | Mean | SD | 'p' Value* |
|-------------------------------------|---------|----|-------|-------|------------|
| Change at 1 st Follow Up | Study | 60 | 11.07 | 3.199 | <0.001 |
| | Control | 60 | 5.283 | 2.034 | |
| Change at 2 nd Follow Up | Study | 60 | 9.45 | 2.971 | <0.001 |
| | Control | 60 | 4.6 | 2.738 | |

* *Chi-square test*

When mean changes in GAD-7 pain score of both group study and control group was compared from baseline to 1st follow up and 2nd follow up, it was observed that mean changes in GAD-7 score were found significantly more (p value<0.001) in study group than control group at 1st follow up as well as in 2nd follow up (p value<0.001). (Table 2)

Table 2
Comparison of Generalized Anxiety Disorder 7 (GAD-7) Scores in study and control group

| Time Interval | Group | N | Mean | SD | 'p' Value* |
|-------------------------------------|---------|----|-------|-------|------------|
| Change at 1 st Follow Up | Study | 60 | 12.12 | 4.043 | <0.001 |
| | Control | 60 | 5.7 | 1.825 | |
| Change at 2 nd Follow Up | Study | 60 | 9.367 | 4.025 | <0.001 |
| | Control | 60 | 3.683 | 1.535 | |

* *Chi-square test*

IV. DISCUSSION

Lumbar canal stenosis is a common problem for the elderly limiting their ambulation and day to day activities. Worldwide it's a significant problem in the elderly population increasing the demand of extra caution and dependence for this age group. Studies revealed the effectiveness of surgical and non surgical means to get rid of the neurological claudication and suffering to make quality of life better. In our search of print and electronic publication no study was found relieving the prevalence of back pain due to spinal stenosis in India in elderly population.

In developing country like India the need of low cost treatment is often felt. In our country the infrastructural facilities and technology support are less as compared to the western world. The investigators here have kept in mind that the majority of the population dealt here were not very capable of affording a higher cost of treatment. Inclusions like imaging modalities for guided procedures are not available everywhere in Indian rural health setup and they also increase the cost of treatment.

So the investigators explored the blind procedure and its accuracy in the available literature, which was found to be in range of 74-91%²⁵ according to Stitz M Y et al.⁹ This encouraged the investigators to go with the blind procedure, which is reasonably accurate. The cost of this whole procedure comes around Rs. 350, which can be afforded.

In the present study after matching the samples and excluding bias in methodology the observations were statistically analyzed and concluded. In the present study low back pain was decreased in both conservative and treatment group. Roland Morris Disability Score (RMDS) questionnaire was administered in the study population which is a widely used health status measure for low back pain. It was found that the mean score of RMDS (Roland Morris pain Disability Score) decreased significantly when analyzed statistically in both the groups. Reduction in mean RMDS score at 2 weeks and 3 months follow up was found to be statistically significant from the baseline. These observations are in accordance with other studies conducted by Jordan K et al,¹⁰ Brain W B et al,¹¹ Ciocon JO et al,⁸ Delport EG et al¹² and Bicket M C et al.¹³

When the RMDS score in both groups at follow ups were compared at 2 weeks and 3 months there is significant reduction in score from the baseline but the reduction in score was more significant in test (intervention) group as compared to the control (conservative) group. It can be stated that pain and disability decreased in both conservative and interventional treatment regime but the amount of relief is higher in the interventional group. So the activity limitations, dependence and confinement to indoors and quality of life get benefitted more in the interventional group. A short term symptom management can accelerate the pace of life better in the spinal stenosis sufferers. The present study is similar in observations with Kocz, Ozcakil S et al¹⁴ as both conservative treatment regime and caudal epidural

steroid provide relief in symptoms with spinal stenosis and on comparison caudal epidural steroids provide better symptom control .

GAD7 (Generalised Anxiety Disorder) is a questionnaire for screening and severity measurement of generalized anxiety disorder. In the present study GAD 7 score decreased significantly when analyzed statistically in both the groups. Reduction in mean GAD7 score at 2 weeks and 3 months follow up was found to be statistically significant from the baseline. This observation is in accordance with the similar study done by Robert Le et al.¹⁵

When the GAD7 score in both groups at follow ups were compared at 2 weeks and 3 months there is significant reduction in score from the baseline but the reduction in score was more significant in test (intervention) group as compared to the control (conservative) group. It can be stated that anxiety and depression decreased in both conservative and interventional treatment regime but the amount of relief is higher in the interventional group. Thus patients in the interventional group benefit more in terms of improvement in activity limitations, and quality of life.

The present study analyzed the cases of spinal stenosis in terms of pain, walking distance, activities of daily living, anxiety, depression and physical impairment. These factors improved for short term in people taking physical and pharmacological treatments on a short term basis, when the above treatments were combined with interventional methods in form of caudal epidural steroid injection the amount of relief get augmented as compared to the conservative treatment alone. This can very well be supported by the studies conducted by Friedly J L et al,⁶ and Ammendolia C et al⁷ who are of the opinion that if caudal epidural steroids is added to the conservative treatments , it provides a much better control of symptoms and makes the morbid productive for family and society life in much less time with better frame of mind in terms of disease related anxiety and depression.¹⁵

This study is an initiative for exploring low cost treatment regimes in developing countries for management of common problems in elderly people. Spinal stenosis is a common problem that alters the outdoor mobility, functional independence and other activities of daily living along with increased anxiety and depression. Presently the sufferers are purely dependant on exercise and pain reliving pills, if one injection can provide symptom control for 3 months or more it is worth having it as it curtails the adverse effects of pain medication and improves the mentation of the sufferer. This can help the great grey army to become independent and socially productive.⁸

V. CONCLUSION

It was concluded that when conservative treatments for lumbar canal stenosis were combined with caudal epidural steroid injection the amount of relief gets augmented as compared to the conservative treatment alone resulting in the patient benefiting in terms of much better symptom control and pain relief, improvement in anxiety, depression and activity limitations, and quality of life. So This caudal epidural may be opted for treatment of lumbar canal stenosis as it is cost effective and reasonably accurate and hence appropriate for the Indian scenario.

CONFLICT OF INTEREST

None declared till now.

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