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ORIGINAL ARTICLE

The Efficacy of Epidural Depo-Methylprednisolone And Triamcinolone Acetate In Relieving The Symptoms Of Lumbar Canal Stenosis: A Comparative Study

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ABSTRACT

Objective: To compare the efficacy of depo-methylprednisolone and triamcinolone acetate in pain relief and in the improvement in claudication distance after two doses of epidural injections in patients with clinically diagnosed lumbar canal stenosis.

Material and Methods: This prospective, randomized trial was performed in seventy patients with the clinical features of lumbar canal stenosis, who received epidural medications for pain relief. The patients were grouped into two; the T group receiving an injection of 80mg triamcinolone acetate with bupivacaine (0.125%) diluted in normal saline and the M group receiving 80 mg methylprednisolone acetate with bupivacaine (0.125%) diluted in normal saline solution (total volume of 20 ml in each group). The pain relief was assessed at 1, 3 and 6 months post-procedurally for improvement in the VAS pain scores and for the increase in the claudication distance.

Results: Of the 70 patients who were included in the study, 40% were females (n=28) and 60% were males (n=42). In the M group, 24 patients (68.5%) reported improvement in the VAS pain scores at the end of 6 months, as compared to 14 (40%) patients in the T group. The pre-intervention mean claudication distance was 163 meters in the group M and 170 meters in the group T, which improved to 637 metres and 350 meters in groups M (P < .001) and T (P>0.05) respectively, at the end of a 6 month follow up. In group M, the average VAS scores decreased from 7.34 in the pre-treatment phase, to 3.64 at the end of a 6 month follow up, which was significantly low (P=0.02). Comparatively, in group T the pre-treatment VAS score value decreased from 6.4 to 4.8 after 6 months of treatment (P< 0.05).

Conclusion: Both triamcinolone and methylprednisolone are effective epidural medications for symptomatic relief in lumbar canal stenosis, though depo-methylprednisolone showed better long term pain relief and improved walking distance at long term intervals as compared to triamcinolone.

Key Words: Lumbar canal stenosis (LCS), Epidural steroid injection (ESI), triamcinolone acetate, depo-methylprednisolone.

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Introduction

Lower back pain is the most common of all chronic pain disorders, with a life time

prevalence of 54% to80% [1]. It is one of the most common health problems worldwide and a leading cause of disability in persons older than 45 years [2]. Lumbar canal stenosis (LCS) is a common source of lower back pain and disability in almost all the age groups, with a strong preponderance in the elderly population. The disease encompasses a wide array of triggering factors including most commonly, the prolapsed intervertebral disc, followed by ligamentum flavum hypertrophy and facet joint arthropathy. All these factors lead to chronic inflammation, thus causing compression of the nerve root and ischaemia, oedema and eventually scarring, with perineural fibrosis [3].

Due to ignorance, lack of regular health check-ups and financial constraints, the disease largely remains undiagnosed in the general population until a later stage, where conservative treatment is left with a subtle role. The disease starts as vague backaches or sometimes as thigh or leg pain. Delay in treatment in the early stages leads to progression of the disease to the stage of neurogenic claudication that becomes a hallmark symptom in the fully established stenosis of the spinal canal. The pain classically presents in the buttock and the bilateral lower limbs, which is initiated by walking, prolonged standing or walking downhill (relative lumbar extension) and is relieved by sitting, bending forward or pushing a grocery cart.

The treatment approaches to lumbar stenosis consists of bed rest, non steroidal anti-inflammatory drugs, muscle relaxants, opioids and corticosteroids which are administered through the oral or the epidural route [4]. Intravenous infusion of infliximab or the subcutaneous perispinal administration of etanercept has also been associated with a dramatic response [5],[6]. The surgical mode of treatment consists of the removal of the prolapsed disc or laminectomy. Surgery may be contraindicated in many stenotic patients due to associated medical illnesses or co-morbidities. Conservative management therefore remains as a necessary and viable treatment option for such patients.

Only few studies have been conducted to evaluate the effectiveness of the various modalities available. In the Maine lumbar spine study, patients with lumbar stenosis reported better results with the surgical mode of treatment in the initial years post operatively; however, with progressing time period, the results of surgery somewhat declined.

The use of epidural injections was first described by Evans in 1930 [7]. Epidural injections of local anaesthetics, with or without steroids, have been widely used for the treatment of radicular pain, with encouraging results. There are multiple mechanisms of action of pain relief for corticosteroids. These include the inhibition of nerve root oedema with improved microcirculation [8], reducing ischaemia by increased blood flow to the neural elements [9], an anti-inflammatory effect by inhibiting prostaglandin synthesis [10] and direct inhibition of the nociceptive C-fiber neuronal membrane excitation [11].

Though used frequently, the epidural steroid injection (ESI) procedure for the treatment of LSS is controversial. Most of the studies which have been done so far compared epidural steroids with anaesthetics or normal saline. The steroids reported to have been of beneficial use through the epidural route include methylprednisolone, triamcinolone acetate and betamethasone acetate.

To our knowledge, no published study has compared the efficacy of epidural, depo-methylprednisolone and triamcinolone acetate, for providing pain relief in the patients of LSS. Moreover, their role in improving claudication distance has largely been unexplored. However, in controlled trials, both have been reported to be equally effective and safe [12].

The aim of our study was to compare the efficacy of epidurally administered depo-methylprednisolone and triamcinolone acetate in providing long term pain relief and in improving claudication distance at varying time intervals in patients suffering from lumbar canal stenosis.

Material and Methods

This prospective, double blinded study was conducted in the Department of Orthopaedics of our institute from May 2009 to April 2010 (12 months), after approval from the

institutional ethical committee. Seventy patients (n=70) with clinically diagnosed signs and symptoms of lumbar canal stenosis, with refractory pain even after taking a full dose of NSAIDs or physiotherapy for more than two weeks of duration, were included in the study. The exclusion criteria included patients with prior back surgery, back or leg pain due to other aetiologies (e.g. spinal fracture, metastasis, neuropathy, vascular claudication etc.) pregnancy, breast feeding status or medical disorders like bleeding diathesis, diabetes, connective tissue disorders, excessive smoking and severe COPD.

The cases enrolled in the study were planned for treatment with epidural injections through the caudal route. The patients were randomly distributed to the T or M groups by using computer generated numbers. In the M group, patients received 2ml of depo-methyl prednisolone (80mg) mixed with 5ml of bupivacaine and diluted in 13 ml of normal saline. In the T group, the patients were given 2ml of triamcinolone acetate (80 mg) with 5ml of bupivacaine diluted in 13ml of normal saline. Thus, the concentration of bupivacaine was standardized to 0.125% and the volume was made to 20 ml in both the groups.

After completing the history taking and clinical examination, an informed consent was taken and the patient was asked to lie down in the lateral position with the knees and hips fully flexed. The skin was cleaned with betadine and a 22 gauge needle, about one and a half inches long, was inserted into the sacral hiatus, which was located as a v-shaped depression, about an inch or more proximal to the coccygeal vertebrae. The epidural space was sensed using the "loss of resistance" and was confirmed by "woosh test". A 20ml syringe containing the treatment drug was prepared by an independent investigator who was not involved in the management of the patients. All injections were given under aseptic precautions through the caudal route by a single operator who was blinded to the chemical nature of the drug and thus, the study was double-blinded.

The cases were followed up fortnightly for the first month and then at monthly intervals for 6 months. The second ESI was given 2 weeks after the first injection. The response was measured in terms of improvement in the claudication distance and the visual analogue scale (VAS) pain scores at 1, 3 and 6 month intervals and was compared with the initial values. To measure the claudication distance, the patient was asked to walk along a 100 metre long straight line. Claudication distance was defined as the distance for which the patient could walk before stopping because of pain. Any decrement in the VAS pain scores of more than two scales was considered to be significant. Any increase in the claudication distance for more than 100 meters was defined as significant improvement. All the cases were screened for any complications during the study period. The patients were given NSAIDs as rescue medications on an as and when needed basis.

The data were analyzed by using the statistical software SPSS, version 17.0. The categorical data was analyzed by using the x^2 test, while the continuous variables were analyzed by using the Student t-test. The results were presented as median (range) and number (percentage) for continuous variables. A *P*-value <0.05 was considered as statistically significant and *P* values <0.001 as highly significant.

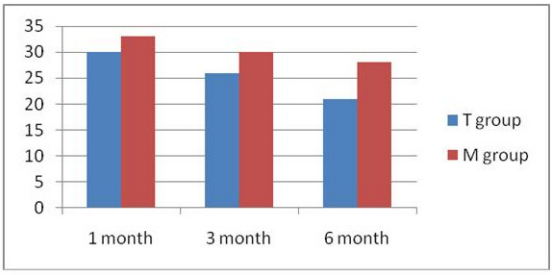
Results

Of the 70 cases, 28 were females (40%) and 42 were males (60%). The patient characteristics were comparable in both the groups (*P*= 0.92) prior to intervention [Table/Fig 1] .

(Table/Fig 1) Patient characteristics of the two groups prior to ESI

Characteristics	T group (n=35)	M group (n=35)
Male/ female ratio	19/16	23/12
Mean age (yrs)	45	42
Mean duration of symptoms (month)	17.5	16.8
Mean claudication distance (mtr)	170	163
Average VAS scores	6.4	6.34

A significant number of cases (n= 33, 30 and 28 cases, respectively) reported improvement in the VAS pain scores at 1, 3 and 6 months intervals (*P*= 0.012, 0.021, 0.029, respectively) in the M group. In the T group, 30 (85.7%), 26 and 21 cases reported significant improvement in the VAS pain scores at 1, 3 and 6 months respectively (*P*= 0.02, 0.026, 0.038 respectively) [Table/Fig 2] .



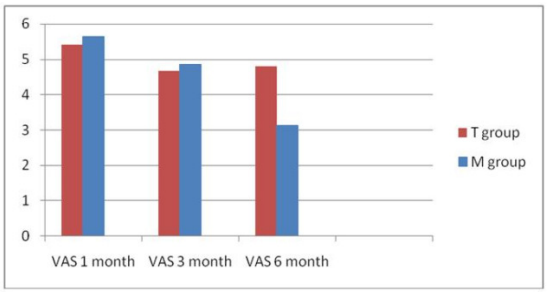
(Table/Fig 2) No. of patients in M and T group showing improvement in VAS pain scores at 1, 3 and 6 months of follow up.

In the M group, the mean claudication distance was 467 meters at 1 month, 587 meters at 3 months and 637 meters at 6 months follow up, which was significantly high (*P*=0.034; 0.013 and 0.001 respectively); however, it was 280m at 1 month (*P*<0.05), 312 meters at 3 months and 350 meters at 6 months in the T group (*P*>0.05) [Table/Fig 3] (Table 2).

(Table/Fig 3) Average pain scores and claudication distance at various time intervals in both the groups.

	T - GROUP		M- GROUP	
	Average VAS scores	Mean claudication Distance (mtrs)	Average VAS scores	Mean claudication Distance (mtrs)
Pre-intervention	**6.4**	**170**	**6.34**	**163**
1 Month	**5.42**	**280**	**5.65**	**467**
3 Month	**4.66**	**312**	**4.87**	**587**
6 Month	**4.80**	**350**	**3.64**	**637**

The average VAS score in group M was 6.34 pre-intervention, 5.65 at 1 month follow up and 3.64 at the end of 6 months of follow up, which showed a significant improvement (*P* =0.02) [Table/Fig 4] (Fig. 2). In the T group, the average pre-injection VAS score was 6.4. At 1 month follow-up, it was 5.42 and 4.80 at 6 months of follow up, which depicted an insignificant improvement (P>0.05). No serious complications like epidural abscess, infection or haematoma were reported in any patient of either group during the study period of 12 months.



(Table/Fig 4) Mean VAS pain scores in M and T group at 1 month, 3 months and 6 months follow up.

Discussion

Due to spinal canal stenosis, mechanical compression of the nerve roots causes oedema producing pain. Pro-inflammatory agents such as the tumour necrosis factor alpha (TNF-α), phospholipase A2 [13] and the interleukins (IL) [14] have been shown to play a significant role in producing pain due to damaged discs. Accordingly, anti-inflammatory agents have been found to have a role in controlling the signs and symptoms of lumbar radicular pain. Epidural steroid injections are a mode of direct delivery of the anti-inflammatory agents to the site of inflammation. This type of therapy ensures the delivery of a higher concentration of drug to the diseased area and lower rate of systemic effects such as neuro-endocrine axis suppression, hyperglycaemia and osteoporosis.

To date, many studies have been undertaken to compare the efficacy of different types of steroids for treating lumbar radicular pain. Jeffery S *et al* [15] in their retrospective study on 597 patients of low back pain, compared the efficacy of triamcinolone and betamethasone and reported that though both the steroids were effective in reducing lower back and radicular pain, triamcinolone was found to reduce pain in a significantly larger number of patients than betamethasone at 1 and 2 weeks after injection. Epidural steroid injections do not correct the anatomical abnormalities which cause canal stenosis, but rather provide only symptomatic relief. Our results indicated that depo-ethylprednisolone is superior to

triamcinolone in providing short and long term pain relief. A greater percentage of cases in the M group (94.2%) as compared to the T group (85.7%), showed pain relief at the end of 1 month. The improved efficacy of depo-methylprednisolone was clearly apparent at 3 and 6 months of follow up, when pain relief was seen in 85.7% and 80% of patients respectively, as compared to the T group, where only 74.2% patients showed improvement at 3 months and 60% patients at 6 months of follow up. Pirubdak *et al* [16] conducted a prospective randomised study to compare the effectiveness of the epidural, triamcinolone and betamethasone on 70 patients of discal radiculalgia. They reported significantly lower VAS values at the first, second and sixth weeks in patients who received 80 mg of triamcinolone by epidural injections.

Only a few articles have previously reported the efficacy of steroids in improving the claudication distance. Fukusaki *et al* [17] conducted a study on 53 patients of spinal stenosis with features of claudication and injected 8ml of mepivacaine plus 40mg of methylprednisolone in 19 patients. They reported good to excellent results in improving claudication distance in 3 patients after 3 months and only 1 patient at 6 months of follow up. Our results showed that, though initially the results were not very encouraging, they tended to improve on long term follow up, probably due to the halting of the disease process in the early stages. Moreover, the role of physiotherapy has not been studied in improving the outcome in the study group, though it was advised to all patients with back pain as a part of the routine treatment. Koc *et al* [18] conducted a randomized controlled trial to compare the effects of epidural steroid injections and the physical therapy program on pain and function in patients with lumbar spinal stenosis. Both epidural steroids and physical therapy groups have demonstrated significant improvement in pain and the functional parameters and no significant difference was noted between the 2 treatment groups. Pain and the functional assessment scores (RMDI and NHP physical activity subscore) were significantly more improved in the ESI group as compared to the controls at the second week. Our results have shown that epidural steroid administration improved physical ability and claudication distance by more than 200 metres at 6 month intervals in both groups, thus aiding an early return to routine activities.

A few shortcomings of our study were that a large sample sized study over a prolonged duration could have added more precision to our results. Secondly, the diagnosis of lumbar canal stenosis was purely clinical and the objective measurement of spinal canal diameter was not done; so, a few patients with other disorders could have been categorised with the same diagnosis. Moreover, the calculation of the reduction in analgesic requirements could have added new dimensions to our results, while an increase in the follow up time for years could have helped to evaluate the long term efficacy of steroids in providing permanent relief or halting the disease process.

Conclusion

We conclude that two doses of depo-methylprednisolone given epidurally creates more effective intervention as compared to triamcinolone acetate in providing long term pain relief in a high percentage of patients who suffer from lumbar canal stenosis. It improves walking distance in these patients and facilitates an early resumption of daily activities on a long term basis. We recommend the use of depo-methylprednisolone for epidural injections as a safe, minimally invasive and long term method of alleviating the symptoms of lumbar canal stenosis.

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