Role Of High Dose Epidural Methylprednisolone In Lumbar Canal Stenosis: A Prospective, Randomized Control Study

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Citation

N Huda, P Bansal, M Rehman, M Jafri, S Gupta, H Siddiqui. *Role Of High Dose Epidural Methylprednisolone In Lumbar Canal Stenosis: A Prospective, Randomized Control Study*. The Internet Journal of Pain, Symptom Control and Palliative Care. 2009 Volume 8 Number 1.

Abstract

Objective: To determine pain relief and improvement in claudication distance after two doses of epidural steroid injections.Design: Prospective, randomised controlled trial performed in one hundred and twenty patients with clinical features of lumbar canal stenosis who received epidural medications for pain relief.Intervention: Patients were grouped into two; control group receiving injection of local anesthetic bupivacaine 4 ml (0.5%) diluted in normal saline and study group receiving 160mg methylprednisolone added to solution of bupivacaine 4ml (0.5%) and normal saline; both groups receiving equal volumes of 16 ml and bupivacaine in 0.125% concentrations. Pain relief was assessed post-procedurally by improvement in VAS pain scores and increase in the claudication distance. Results: Of the 120 patients followed for a period of 6 months 46% were females and 54% were males. In the study group 42 patients (70%) reported improvement in the VAS pain scores at the end of 6 months, compared to 9 (15%) patients in control group. The pre-intervention mean claudication distance was 128 meters in the study group and 130 meters in the control group; at the end of 6 month follow up was 694 m in the study group (P < .001) compared to 124 meters in the control group (P>0.05). In the study group, the average VAS scores decreased from 6.04 in pre-treatment phase to 3.14 at the end of 6 month follow up, which was significantly low (P<.05). Comparatively, in control group pre-treatment VAS score value decreased from 5.4 to 4.8 at 6 months of treatment (P>0.05). Conclusion: Injection of high dose of epidural steroids proved to be a safe, minimally invasive and cost effective method of treating lumbar canal stenosis and provided reasonably good relief for 6 months post-injection. We recommend using this intervention in routine clinical practice for treating lumbar canal stenosis.

INTRODUCTION

Lumbar spinal stenosis (LSS) is a common source of pain and disability in almost all the age groups, more so in the elderly population. Neurogenic claudication is the hallmark symptom of LSS, classically described as buttock and bilateral leg pain initiated by walking, prolonged standing or walking downhill (relative lumbar extension) and relieved by sitting, bending forward or pushing a grocery cart. This is contrasted with vascular claudication where pain is relieved solely by rest (not on sitting or bending forward) and aggravates on walking uphill.

LSS is a result of the degenerative spine cascade and thus, narrowing not only can affect the central spinal canal, but also the lateral recesses and intervertebral foramina. Due to the variable regions affected, patients may present with unilateral or bilateral and monoradicular or polyradicular symptoms. They can also present with frank radiculopathy, i.e. weakness, sensation loss and reflex loss in a myotomal and dermatomal distribution. Dull aching back pain and stiffness are common complaints consistent with osteoarthritis of the lumbar spine. Patients tend to default to a stooped-forward posture to alleviate pain by widening the spinal canal and decreasing the forces on the zygaphophyseal joints.

The treatment of lumbar stenosis consists of conservative or surgical method. Only a few outcome studies have been conducted to evaluate the effectiveness of various modalities available. In the Maine lumbar spine study, patients with lumbar stenosis reported better results with surgical mode of treatment in the initial years post operatively, however with progressing time period the results of surgery somewhat declined. Surgery may be contraindicated in many stenotic patients due to other medical illnesses. Conservative management therefore remains a necessary and viable

treatment option for such patients.

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 edema with improved microcirculation, reducing ischemia by increased blood flow to neural elements, anti-inflammatory effect by inhibiting prostaglandin synthesis, direct inhibition of nociceptive C-fiber neuronal membrane excitation.

Though, most of the studies have assessed the role of steroids using 80 mg of methylprednisolone in providing short term pain relief, only a few have studied their role in improving claudication distance. We conducted this trial to evaluate the role of high dose methylprednisolone (160 mg) in providing long term pain relief and improving claudication distance at varying intervals.

MATERIALS AND METHODS

This prospective study was conducted in the department of orthopaedics of our institute from June 2009 to March 2010 (10 months), after approval from institutional ethical committee. One hundred and twenty patients (n=120) of clinically diagnosed signs and symptoms of lumbar canal stenosis with refractory pain even after full dose of NSAIDs or physiotherapy for more than two weeks duration were included in the study. Exclusion criteria included patients with prior back surgery, back or leg pain due to other etiology (e.g. spinal fracture, metastasis, neuropathy, vascular claudication etc.) pregnancy, breast feeding status or medical disorders like bleeding diathesis, diabetes, connective tissue disorder, excessive smoking and severe COPD.

Patients enrolled in the study were planned for treatment with epidural injections through caudal route. Patients were randomly distributed to study or control group using computer generated numbers. In study group patients received 4ml of injection methyl prednisolone (160mg) mixed with 4ml of injection bupivacaine (0.5%) diluted in 8ml of normal saline. In control group, patients were given 4ml of bupivacaine (0.5%) diluted in12 ml of normal saline, final concentration of bupivacaine being 0.125% in volume of 16 ml in each group.

After completing the history taking and clinical examination, an informed consent was taken and the patient was asked to lie down in 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. Epidural space was sensed using the “loss of resistance” and confirmed by “woosh test”. A prepared 20ml syringe of long acting methylprednisolone acetate (160mg) with bupivacaine (4ml) diluted in normal saline in a total volume of 20ml was injected. In the control group the patients were given 4ml of bupivacaine plus 12ml of normal saline. All injections were given by caudal route by a single operator under all aseptic precautions.

Patients 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. Response was measured in terms of improvement in claudication distance and visual analogue scale (VAS) pain scores at 1, 3 and 6 month intervals and compared with 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 the patient could walk before stopping because of pain. Any decrement in VAS pain scores of more than two scales was considered significant. Any increase in claudication distance of more than 100 meter was defined as significant improvement. All the patients were screened for any complications. Patients were given NSAIDs as rescue medication on as and when needed basis.

The data was analyzed using statistical software SPSS, version 10.1. Categorical data was analyzed using x^2 test while continuous variables were analyzed using Student t-test. Results are presented as median (range) and number (percentage) and for continuous variables. A P-value<0.05 was considered as statistically significant and p <0.01 as highly significant.

RESULTS

Of the 120 patients 46% were females and 54% were males. The patient characteristics (age, sex, weight) were comparable in both the groups (P>0.05) prior to intervention (table 1).

Figure 1

Table 1: Patient characteristics of the two groups prior to ESI

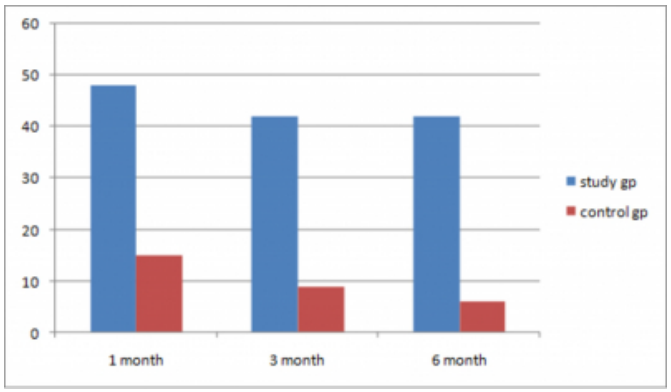
Characteristics	Control group (n=60)	Study group (n=60)
Male/ female ratio	33/27	32/28
Mean age (yrs)	45	42
Mean duration of symptoms (month)	15.5	14.8
Av. claudication distance (mtr)	130	128
Average VAS scores	5.4	6.04

Improvement in VAS pain scores at 2 week occurred in 45 patients (75%) in the study group and 15 patients (25%) in the control group. Significant number of patients reported improvement in VAS pain scores at 1, 3 and 6 months interval (P<0.05) in the study group.

In the control group, 15(25%) patients reported significant improvement in VAS scores at 1 month, while at 3 months 9 and at 6 months interval six patients reported improvement in pain scores (Fig.1).

Figure 2

Fig. 1: No. of patients in study and control group showing improvement in VAS pain scores at 1, 3 and 6 months of follow up.



In the study group, the mean claudication distance was 212 meters at 1 month, 437 meters at 3 months and 694 meters at 6 months follow up, which was significantly high (P=0.034; 0.013 and 0.001 respectively); however, it was 210m at 1 month (P<0.05), 175 meter at 3 months and 124 meter at 6 months in control group (P>0.05) (table 2).

Figure 3

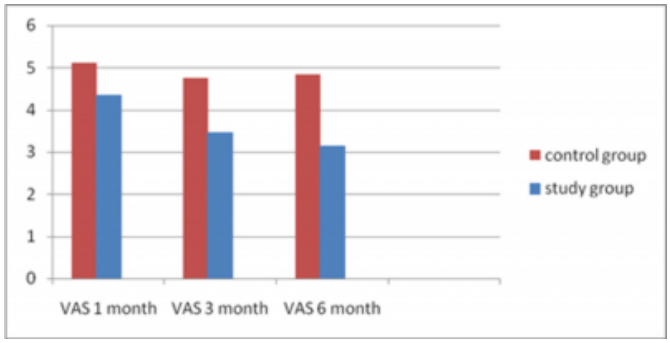
Table 2: Average pain scores and claudication distance at various time intervals in both the groups.

	Average VAS scores	Mean Claudication distance (mtrs)	Average VAS scores	Mean Claudication distance (mtrs)
Pre-intervention	5.4	130	6.04	128
1 month	5.12	210	4.35	212
3 month	4.76	175	3.47	437
6 month	4.84	124	3.14	694

In the study group average pre-intervention VAS score was 6.04, at 1 month follow up it was 4.35& at the end of 6 months follow up was 3.14 which was a significant improvement (P <0.01)(Fig. 2). In the control group the average pre injection VAS score was 5.4. At 1 month follow-up it was 5.12 and 4.8 at 6 month 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 10 months.

Figure 4

Fig 2: Mean VAS pain scores in study and control group at 1 month, 3 months and 6 months follow up.



DISCUSSION

Low back pain is one of the commonest disorders for which patients seek consultation from an orthopaedic surgeon. Chemical mediators of inflammation have been shown to play a significant role in the pathogenesis of intractable thigh or leg pain in patients of lumbar canal stenosis. Snal et al[5] suggested that the release of phospholipase A2 from the nucleus pulposus is the primary cause of pain. Burke et al[6] reported high levels of IL-6, IL-8 and prostaglandin E2 in the discs of patients undergoing surgery for discogenic pain. Accordingly anti-inflammatory agents play a significant role in the alleviation of pain. ESI is a method of local therapy in this regard. This type of therapy ensures delivery of a higher concentration of drug to the diseased area and lower rate of

systemic side effects such as neuro-endocrine axis suppression, hyperglycemia and osteoporosis.

Several investigations showed little to significant improvement in lumbar radicular pain after ESI. In a study conducted by Rivest et al[7] 38% of patients reported improvement after 2 weeks of receiving ESI. In our study 75% of patients in the study group reported improvement in VAS scores at 2 weeks whereas only 25% of patients in the control group reported improvement in 2 weeks VAS scores. This signifies that the addition of high dose (160mg) methylprednisolone significantly reduces the edema around the nerve root and causes relief in pain. The small percentage of patients reporting pain relief in the control group may be due to the local anaesthetic (bupivacaine). Hoogmartens and Morelle[8] reported that 48% of patients improved with ESI for lumbar spinal stenosis but they noted this was not significantly different from placebo. Ridley et al [9]reported that 90% of patients who received epidural injections of 80mg methylprednisolone plus 10m saline showed improvements at 1 week, 2 weeks and 3 months. Other authors reported success rates ranging from 63% – 80%.

Berivik et al[10] compared caudal epidural injections of bupivacaine and methylprednisolone with bupivacaine and saline and found that 56% of patients in the steroid group reported considerable pain relief as compared to 26% of patients in the bupivacaine group.

In a study undertaken by Ciocon et al[11] considerable improvement was seen in patients of lumbar spinal stenosis who received 3 consecutive caudal ESIs. Most of the patients reported sustained relief 6 months post treatment and had persistent, significant reduction in pain 10 months after injection. Rosen et al [12] conducted a retrospective study on 40 patients to evaluate the effect of ESI on spinal stenosis and reported that long term relief occurred in less than 25% of patients. Waldman et al[13] reported that in the ESI group the combined visual analog scale and verbal analog scale scores were reduced in 63% patients at 6 weeks, 67% patients at 3 months and 71% patients at 6 months. In our study, 70% of patients in the study group showed improvement in VAS scores and mean claudication distance at 6 months. Such a high rate of pain relief in our study may be due to early stage of presentation in patients at our setup or probably due to reversal of inflammatory changes by high dose steroids. Loy [14] conducted an analysis on 526 patients of sciatica who were given ESI and reported excellent to good pain relief in 93.35% of patients. This contrasts lumbar canal stenosis where the results are not so encouraging with conventional doses of steroids.

White et al [15] conducted a prospective study on 300 patients and reported good results in the early periods, there was 82% pain relief for one day and was reduced to 16% for two months. This brings to light the therapeutic decay phenomenon with ESI. For this reason many physicians recommend multiple injections. The time period between two injections is debatable with some suggesting an interval of 7-10 days while others fortnightly interval as sufficient. In our study the interval between the first and second injection was 2 weeks. Pirubdak et al[16] studied the role of epidural steroid injection and amitryptiline for the treatment of low back pain and sciatica and found that epidural steroid injection provided pain relief upto 6 months and additional oral amitryptiline increased pain relief to 9 months.

To the best of our knowledge, only a few articles have 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 mepivacaine plus 40mg of methylprednisolone in 19 patients. They reported good to excellent results in 3 patients after 3 months and only 1 patient at 6 month follow up. Our results show that though, initially the results are not very encouraging but tend to improve on long term follow up, probably due to halting of disease process in early stages. Moreover, the role of physiotherapy has not been studied in improving the outcome in study group, though it was advised to all patients with back pain as a part of routine treatment. Koc et al [18] conducted a randomized controlled trial to compare the effects of epidural steroid injections and physical therapy program on pain and function in patients with lumbar spinal stenosis. Both epidural steroid and physical therapy groups have demonstrated significant improvement in pain and functional parameters and no significant difference was noted between the 2 treatment groups. Pain and functional assessment scores (RMDI, NHP physical activity subscore) were significantly more improved in the ESI group compared with controls at the second week.

A few shortcoming of our study were that we could have studied a large sample size over a prolonged duration, calculation of reduction in analgesic requirements could have added precision to results and increase in follow up time for years could have helped evaluate its prolonged

efficacy.

CONCLUSION

High dose of epidural methylprednisolone in two doses is an effective intervention that provides long term pain relief in high percentage of patients suffering from lumbar canal stenosis. It improves walking distance in these patients and facilitates an early return to activities of daily living on long term basis. We recommend high dose ESI as a safe, minimally invasive and long term method of alleviating symptoms of lumbar canal stenosis.

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