

Comparison of Epidural Steroid Injections with Conservative Management in Patients with Lumbar Radiculopathy

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ABSTRACT

Objective: To determine the difference in short- and long-term pain improvement between lumbar Epidural Steroid Injections (ESIs) and conservative management in patients with lumbar radiculopathy.

Study Design: Quasi-experimental study.

Place and Duration of Study: The Postgraduate Medical Institute of Hayatabad Medical Complex, Peshawar, from April 2005 to March 2007.

Methodology: Fifty elective patients fulfilling the inclusion criteria were randomly divided into two groups. Patients in the steroid group were treated with 80 mg of methylprednisolone injected in combination with 3 ml of 2% plain xylocaine and 3 ml of normal saline in the lumbar epidural space, while patients in the conservative group were treated with bed rest, non-steroidal anti-inflammatory agents, muscle relaxants, and opioids. All the 50 patients in the two groups were regularly assessed at 2 weeks, 1 month, 3 months and 6 months of periods for pain score by the Visual Analogue Scale (VAS), patients satisfaction score and any unwanted side effects.

Results: A marked improvement of the pain score and patients satisfaction score were noticed in the steroid group. Less significant improvement was seen in the conservative group during the initial period i.e 2 weeks and 1 month ($p < 0.05$). The difference in Visual Analogue Scale (VAS) and patients satisfaction score was non-significant in chronic stages of treatment in both groups ($p > 0.05$).

Conclusion: Epidural steroid injections in acute symptoms of sciatica are considered to be a better option compared to conservative treatment.

Key words: Epidural steroids. Sciatica. Lumbar radiculopathy.

INTRODUCTION

Sciatica is defined as radiating pain in the distribution of the sciatic nerve and is commonly felt in the foot and toes of the affected side. It is usually associated with numbness and an abnormal sensation along the distribution of the sciatic nerve. It is a common pathology responsible for work disability. It is more common in men (5.3%) than in women (3.7%). Work disability is noted to be 6%.¹ Although sciatica is considered to be a self-limiting condition with good prognosis, one-third of the patients remain symptomatic after one year, with 20% having work disability and 5-15% requiring surgery.²

Lumbar vertebral disc prolapse was initially considered to be the cause of sciatica, with resultant compression

of the nerve root, leading to impairment of blood supply, oedema and finally to chronic inflammation, scarring and perineural fibrosis. Recent studies have more precisely identified the cytokines responsible for this inflammatory process and indicate that inhibition of these cytokines may offer more specific and effective treatment for lumbar radicular pain.³ The approaches to treat lumbar radiculopathy or sciatica, include conservative treatment i.e bed rest, physiotherapy, non-steroidal anti-inflammatory agents, muscle relaxants, and even opioids.⁴ The mechanism of action by which corticosteroids act is to reduce inflammation by inhibiting the formation and release of a number of proinflammatory mediators (membrane stabilization) and by causing a reversible local anaesthetic effect, inhibition of phospholipase A2 activity, suppression of sensitization of dorsal horn neurons and neuronal discharges.^{5,6} Lumbar disc herniation is reported to be resorbed on follow-up MRI after epidural steroid injections as has been observed in several studies.⁷ Studies in both humans and animals showed only traces of steroids detected in blood with epidural steroid injections. Janicki found only traces of steroids at 6 and 12 hours after the administration of a therapeutic epidural dose of the drug (5 mg/kg) in rabbits; whereas, plasma steroids levels were undetectable at 24-72 hours.⁸

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The aim of this study was to compare the Visual Analogue Scale (VAS) improvement scores of epidural steroids with conservative treatment in patients having lumbar radicular symptoms.

METHODOLOGY

This clinical trial was conducted at the Postgraduate Medical Institute of Hayatabad Medical Complex, Peshawar, from April 2005 to March 2007, on 50 ASA II/III adult patients who presented with lumbar radicular pain. The trial was conducted after approval by the institutional ethical committee and informed written consent of the patients. Since each patient's allocation was determined in advance by their sequence of presentation, 52 sealed envelopes, 26 for each group, were made and a randomly-selected envelope was opened when the patient presented.

Patients in the steroid group were treated with 80 mg of Depomedrol (methylprednisolone) in combination with 3 ml of 2% plain xylocaine and 3 ml of normal saline in the lumbar epidural space. Patients in the conservative group were treated with bed rest, non-steroidal anti-inflammatory agents, muscle relaxants, and opioids. The exclusion criteria were known contraindications for epidural steroid injections, infection, bleeding tendency or malignancy, patient's refusal, previous lumbar epidural steroid injections, previous lumbar spine surgery, unstable neurological deficits, cauda equina syndrome and radiologically proven facet syndrome.

All patients with lumbar radicular pain, having pre-treatment visual analogue scale scoring of more than 6 and of more than 2 weeks duration, including low back and uni or bilateral leg pain were included in the study. Those with pain caused by lumbar intervertebral disc herniation and single level disc herniation on recent MRI (1 week), corresponding with the patient's clinical symptoms were also included in the study. After taking their complete history and careful neurological examination, pre-treatment assessment i.e. limitation of activity, SLR (straight-leg raising) test, sensory deficit (checking sensation of touch, temperature and skin prick) in all the dermatomal levels, muscle power (against the gravity, and external force) of both lower limbs, radiation of pain to right or left leg and any complaint of backache were noticed in all of the patients. Procedure of the treatment as well as visual analogue scoring was explained to each and every patient. Lumbar epidural injections were performed by a single expert anaesthetist, not involved in data collection. An intravenous line was established and a blood sample was taken for assessment of baseline of blood sugar. The patient was positioned in a lateral recumbent position with fully-flexed hip and knee joints.

The midline approach was used in all 25 patients. The skin was cleaned and draped with antiseptic solution.

Skin at the level of L4–L5 interspinous space was infiltrated with local anaesthetic. An 18-gauge epidural needle (Touhy) was inserted into the skin and advanced while a syringe containing air was attached to it. Epidural space was recognized by loss of resistance. The injection site was confirmed by injecting a test dose of 3 ml of 2% lidocaine with evidence of sensory (numbness) or even motor weakness. A solution containing 80 mg Depomedrol (methylprednisolone) and 3 ml of 2% plain xylocaine diluted with normal saline to a total volume of 8 ml was prepared in a 10 cc syringe before the start of the procedure, to be injected into the epidural space. After injecting into the epidural space, the needle was withdrawn and the patient laid in a supine position for at least 15 minutes. The patient's pulse, blood pressure and oxygen saturation were monitored throughout the procedure and thereafter for half an hour. Blood glucose levels were monitored 24 hours after the procedure and all the patients were screened thereafter for any major or minor complications. Patients were allowed to have tablet Ibuprofen (brufen) 400 mg as rescue medication on a need basis. Patients in the conservative group were treated with, tablet Ibuprofen (brufen) 400 mg thrice a day during first month, tablet Tramadol (tramol) SR 100 mg once a day during the first two months and tablet Tinizidine (ternalin) 2 mg twice daily, for a period of 1st three months. Tablet Famotadine (40 mg) was used throughout the treatment. Bed rest was initially advised with limited activity for a period of one month. Activity was gradually increased to walking 2-3 hours/day. Lifting of heavy weights and strenuous exercises were forbidden for 3-6 months. Patients were followed after the second week, one month, 3 months and 6 months for pain, patient satisfaction and for any side effects of the drugs (nausea, vomiting, heart burn) during their follow-up visits in both groups. Patients were advised to take analgesics, whenever needed after 3 months. A responsible person at home was advised to check for the compliance of medication and they completed a diary. Reduction of visual analogue scale by 50% were considered as successfully treated, while patients having no relief at all or very less reduction of VAS were referred to neurosurgery department for interventional management.

Sample size calculation was done as expected success rate in epidural steroid group and conservative group were 85% and 45% respectively. The ratio in the two groups was 1:1, for a risk of 5% and study power of 80. The sample size for each group was 26.

Statistical analysis was performed using statistical software (SPSS) version 10. An unpaired t-test was used to compare demographic variables (age, weight) and pain scores (VAS) between the two groups. All results were expressed as mean \pm SD (standard deviation). Patients' satisfaction score, symptoms of

radiculopathy and minor complications in both groups were compared by the chi-square test. A p-value less than 0.05 was considered statistically significant.

RESULTS

A total number of 52 patients who fulfilled the inclusion criteria were studied. Out of them, 2 patients – one in each group, were lost to follow-up and were excluded from the study. The male to female ratio was 17:8 and 15:10, the mean age was 40±2.15 and 41±2.45 years and mean weight of 75±6.55 and 78±7.45 kg was found in the steroid group and conservative group respectively. There was no significant statistical difference with respect to age (p=0.1316) and weight (p=0.137) in the two groups.

The symptoms and duration of sciatica i.e. limitation of activity, SLR, sensory deficit (sensation of touch, temperature and skin prick) in all the dermatomal levels, muscle power (against gravity and external force) of both lower limbs, radiation of pain to right or left leg and any complaint of backache were statistically not significant in the two groups (Table I).

Patients in both groups were assessed for improvements in pain score. A lower pain score on VAS was observed in the steroid group compared to the conservative group in acute stages of treatment i.e. after the second week and one month follow-up (p < 0.05), while less significant difference was observed in VAS in the chronic stages of treatment in both groups (p > 0.05, Table II). The patient's satisfaction after pain alleviation was noticed in 80% and 76% of the patients in the steroid group during the initial periods of 2 weeks and 1 month, while 52% and 68% of patients were satisfied after 3 months and 6 months of duration respectively. Patients satisfaction in the conservative group was comparatively less, with improvement in pain score after 2nd week, 1st month, 3 months and 6 months of duration. The percentage of patients were 52%, 48%, 56% and 64% respectively (Table III), for increasing duration.

No major complications were reported in the studied groups. The incidence of minor complications were small and were treated in time. Increases in blood glucose (> 180 mg/dl) were noted in 3 cases (12%), where their baseline blood sugar were < 180 mg/dl, and they had no history for diabetes. Flushing and headache were seen in 4 cases (16%) each, while only one patient (4%) had backache in the steroid group.

None in the conservative group had any complication except mild heart burn. All the events were resolved without morbidity. Out of 50 patients, 4 (16%) in the steroid group and 6 (24%) in the conservative group were referred to the neurosurgery department because of their increased intensity of pain (VAS > 6), for further interventional management.

Table I: Symptoms of radiculopathy in two groups.

Symptoms	Steroid group n=25 (%)	Conservative group n=25 (%)	P -value
Limitation of activity (%)	15 (60)	12 (48)	1.000 NS
SLR test positive (%)	20 (80)	21 (84)	1.000 NS
Sensory deficit (%)	3 (12)	4 (16)	1.000 NS
Decreased Ms power (%)	1 (4)	2 (8)	1.000 NS
Radiation to L/R (%)	10/15 (40/60)	12/13 (48/52)	1.000 NS
Sciatica/backache (%)	18/7 (72/28)	20/5 (80/20)	1.000 NS
Cauda eqina	nil	nil	

Table II: Visual Analogue Scale (VAS) in both groups.

Duration	Steroid group n=25 VAS (mean±SD)	Conservative group n=25 VAS (mean±SD)	P-value
2 nd week	2±1.4	4±1.2	< 0.0001 (significant)
1 month	2±1.5	4.5±1.48	< 0.0001 (significant)
3 months	4.5±1.50	5.0±1.10	0.1853 (NS)
6 months	6±1.45	6.5±1.30	0.2054 (NS)

Table III: Patient's satisfaction score with improvement of pain.

Duration	Steroid group n=25 (%)	Conservative group n=25 (%)	P-value
2 weeks	20 (80)	13 (52)	0.3757
1 month	19 (76)	12 (48)	0.3649
3 months	13 (52)	14 (56)	1.000
6 months	17 (68)	16 (64)	1.000

DISCUSSION

The intractable pain of sciatica is mainly caused and precipitated by inflammatory mediators.⁹ Roberts *et al.* showed a close relation between disk degeneration and matrix metalloproteinase release. Chronic nerve root compression due to lumbar stenosis has been shown to cause venous congestion, intramural edema, blockade of nerve conduction and the release of neurotoxic substances in animal studies. The role of steroids in such conditions is to impair prostaglandin synthesis, possibly improve nerve root blood supply and to alter chemotoxic mediator flow.¹⁰

Similarly, NSAIDS (non-steroidal anti-inflammatory agents) when given either locally or systemically play a role in abolishing the signs and symptoms of radiculopathy. In this regard, ESI is a kind of local therapy, It is preferable over systemic therapy, because has a lower rate of systemic side effects like adrenal suppression, increase in blood sugar level and osteoporosis, while it gets a higher concentrations of the drug at the diseased site. The incidence of serious complications such as epidural haematoma, abscess formation and arachnoiditis, are noticed to be very few in expert hands. Mild or less serious complications which may occur include flushing, post injection flare hyperglycemia, hypertension, backache, headache and central nervous system symptoms.¹¹ Runn reported that 59% of patients benefited from epidural steroid. They were able to perform daily living at the end of 3 months.¹² Loy reported excellent to good pain relief in

93.35% of epidurally-treated cases.¹³ Another study done by Buchner observed better results in patients treated with epidural steroids and recommended ESI in the acute phase of the conservative treatment of lumbosciatic pain.¹⁴ Postoperative pain decreased in the steroid treated group during the first postoperation week, but not at 12 months postoperation.¹⁵ The role of epidural steroid injections in the management of acute radicular pain due to herniated nucleus pulposus is to provide early pain relief.¹⁶ Valat *et al.* reported ESI to be effective in relieving pain due to sciatica.¹⁷ Delpont *et al.* showed sustained pain relief with ESI.¹⁸ According to Yang *et al.*, ESI reduces the need for surgical decompression.¹⁹

Buttermann *et al.* observed improved results after 1 month of ESI, and that the maximal beneficial effect of ESI was experienced in acute cases and was considered to be due to individual variations in receptor response to long-acting epidural steroids.²⁰ Although there was less improvement in chronic cases, even a 50% or less improvement in VAS after a 3 month post-injection period can reduce the need for surgery, if there is no neurological impairment.²⁰

The present results were similar to what is found in previous studies. Satisfactory results were achieved regarding improvement of VAS and patient satisfaction score, during the 2nd week and 1st month post-injection follow-up in patients studied with steroids. Patients in the conservative group were moderately improved with reduction of pain by 50%. Long-term treatment showed almost equal reduction of VAS and patient satisfaction in both the studied groups.

Some physicians prefer low dose epidural steroids in hypertensive and diabetic patients to reduce the incidence of post-injection flares, flushing, and hyperglycaemia compared to high dose steroids in epidural space. According to them, both doses are equally effective in improving VAS in patients having radiculopathy.²¹ Eighty milligrams of methylprednisolone was used in the studied group. Only 3 patients in the steroid group showed increased blood levels of sugar after 24 hours post-procedure (> 180 mg/dl), although they did not have any history of diabetes.

Epidural steroid injections under fluoroscopic control are found to be 93% effective in some studies because of the correct placement of the needle in the epidural space.²² Some physicians use more than one ESI at different time intervals. However, when placed in the correct position a single injection is as effective as multiple injections.²³

In order to provide the drug in adequate quantities to the affected nerve root, some clinicians favour transforaminal approaches. Although this is beneficial as it reduces the need for surgery, it is not recommended by

most clinicians due to its cost, complexity and complications.²⁴ A midline approach was used because of its simplicity and familiarity.

The volume injected is usually 1-5 ml, although some authors use 10 ml or more, but Carette demonstrated that injecting a larger volume did not provide additional efficacy.²⁵ In this study, a single lumbar epidural steroid injection of 8 ml was prepared to be injected into the epidural space by an expert anaesthetist during the follow-up of the patients from 2 weeks to 24 weeks, ESIs in acute stages of the symptoms were beneficial compared to the conservative treatment, while medium- or long-term benefit was not significant in either of the groups.

The persistence of pain and disability even after conservative management suggests that sciatica is not a self-limiting condition and these chronic conditions should be treated through multidisciplinary approaches, including bed rest, analgesics, physiotherapy and epidural steroids as part of the multidisciplinary package.²³

Although lumbar epidural steroids are effective treatment for sciatica, the importance of conservative management cannot be denied, specially in patients with a long history of radicular pain. A 50% improvement was noticed with initial treatment in the conservative group, while improvement of VAS with long-term treatment were almost equal in both groups.

CONCLUSION

The use of epidural steroid injections in this study offered short-term benefit but as sciatica is a chronic condition requiring a multidisciplinary approach including bed rest, analgesics, physiotherapy and epidural steroids as part of the multidisciplinary package, epidural steroids as well as conservative management should be the line of management. In order to fully investigate the value of epidural steroid injections, they need to be evaluated as part of a multidisciplinary approach.

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