ORIGINAL RESEARCH PAPER

Cervical epidural steroid injection for the management of radiculopathy: A prospective randomized controlled study

Medicine

KEY WORDS: Radiculopathy, Epidural space, Transforaminal, Translaminar, Corticosteroid

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BSTRACT

Background: Cervical radiculopathy is a commonly diagnosed disease process seen in middle and elderly population. Role of epidural steroid injection in the management of cervical radiculopathy is still under debate due to absence of properly conducted studies. **Aim:** The purpose of the study is to find out the superiority of epidural steroid injection over conventional therapy.

Methods: One hundred and twenty six patients were selected for the study between the age group of 40-60 years and included under 'study' and 'control' groups. The study group received epidural steroid injection along with conventional therapies while the control group received conventional therapies only. Assessment of Visual Analogue Scale (VAS) and Neck Pain Disability Index (NPDI) were done before starting the treatment, after one week, one month, three months, six months following the treatment. Study was conducted for the period of 2 years after receiving Institutional Ethical clearance.

Results: There was significant (p<0.001) improvement of the VAS score and NPDI during the follow up period in the study group. Six patients from the control group were lost during follow ups. Three patients had aggravated symptoms following injection. No adverse reaction was noticed following injections except local pain.

Inference: Cervical epidural steroid injection is superior to conventional exercise program in the management of radiculopathy. It is cheap but needs expert hand. There are no long term side effects as seen with analgesics and anti-inflammatory drugs. Epidural steroid should be included in the first line management of cervical radiculopathy.

Introduction

Cervical radiculopathy is a dysfunction of cervical nerve roots. The causes of cervical radiculopathy can be pathological compressive process affecting the nerve root, like acute disc herniation, degenerative foraminal stenosis, trauma and tumour or biochemical processes leading to local inflammation. The annual incidence of cervical radicular pain is 5.5/100,000. The most commonly affected nerve roots are C7 followed by C6. Patients younger than 55 years usually present with acute disc herniation whereas older than 55 years usually presents with degenerative foraminal or central canal stenosis.¹

Patients usually present with pain, paraesthesia and weakness in upper limb and neck region of either side. Symptoms and signs are presented in the distribution of the affected nerve root. Diagnosis of cervical radiculopathy is usually done clinically. Radiography can be used as an initial screening tool and MRI is the imaging modality of choice.\(^1\)

The management of cervical radiculopathy can be of non-surgical and surgical. Non-surgical procedures include analgesics, collar application, traction, physical therapy and epidural injections. Cervical epidural injections are indicated in case of severe pain or in failed other non-surgical procedures.¹

The rationale of corticosteroid injection in the epidural space is its anti-inflammatory effect. Herniated disc specimens showed increased level of matrix metalloproteinase activity, nitric oxide, prostaglandin E2 and interleukin 6. Phospholipase A2 also plays

role in inflammation of the nerve roots. Epidural steroids have been shown to inhibit phospholipase A2 activity, thus reducing symptoms. Corticosteroid mitigates nerve conduction slowing due to inflammation. Corticosteroids also affect cell-mediated activity and cytokines, which may be involved in the pathogenesis of radicular pain. Besides its anti-inflammatory effects, corticosteroids stabilize nerve membranes inhibiting ectopic impulses, inhibits ion conductance, hyperpolarizes spinal neurons, and inhibits C fibre transmission. All these properties are involved in relief of pain in non-inflammatory causes.²

This study was conducted to find out the effectiveness of epidural steroid injection in early improvement of radicular pain. Few studies were performed earlier with injection of epidural steroid and local anaesthetic agents with mixed responses. Our study was a case controlled study and we injected only methylprednisolone in the study population. There were no adverse reactions observed in any of the patients besides local pain. Most of the studies were conducted without a control group. That's why our study has definite significance for future management protocols in cervical radicular pain.

Materials and Methods

The study was a prospective, randomized controlled study, conducted in the Department of Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences, Imphal, for the period of two years (October, 2012-September 2015). Patients between the age of 40-60 years, diagnosed as cervical radiculopathy clinically and confirmed by radiography and MRI in

the outpatient department were included in the study. Patients with features of medical instability, cervical myelopathy, local or systemic infection, refusal were excluded from the study. All diagnosed patients attending the OPD fulfilling the inclusion criteria were included in the study. Ethical clearance was obtained from the Regional Institute of Medical Sciences, Imphal. Participants were informed about the study, and both verbal and written informed consent was obtained. The Helsinki Declaration was strictly followed for data collection.³

After getting the informed consent, patients were divided into study and control group through block randomization technique. The study group received single dose of epidural injection of methylprednisolone along with conventional therapy. The conventional therapy includes aceclofenac 200 mg sustained release tablet in once daily dose for 5 days, intermittent cervical traction for 10 minutes daily for 10 days, isometric strengthening exercise of neck muscles throughout the study. The control group received conventional therapy only. Visual analogue scale and neck pain disability index were taken as outcome variables. Outcome variables were assessed before starting the treatment, after one week, after one month, after three months and after six months. Visual analogue scale was divided into mild (1-3), moderate (4-6) and severe (7-10) grades. Neck pain disability index was divided into 5 classes (0= no disability, 1= mild disability, 2= moderate disability, 3= severe disability, 4= complete disability). Paired t test and ANOVA were used to analyse the data. A p value of < 0.05 was considered statistically significant.

Results

There was no significant difference between the study and control group at baseline (Table 1).

Improvement of pain assessed by VAS score was seen in both the groups but more significant in the study group (p<0.05). Patients were assessed after 1 week, 1 month, 3 months and 6 months following the treatment and improvement was noticed every time without any recurrence during the follow ups. Neck pain disability index was also assessed in patients and showed significant (p<0.001) improvement in the study group compared to the control group during follow ups.

Table 2 shows the VAS score improvement in both the groups throughout the follow ups. There was significant (p<0.05) improvement in the study group compared to the control group. Neck pain disability index was also shows significant improvement during the follow ups **(Table 3)**.

Discussion

This randomized controlled study was performed on 126 patients. The study group comprised of 66 patients and the control group comprised of 60 patients. There was loss of 6 patients in the control group during follow up. Three patients had increased neck pain following injection but improved in few hours. There were no other adverse reactions following the injections.

Lee SH and co-workers conducted a prospective study with follow up period more than 2 years. Epidural steroid injection was applied in 98 patients with cervical radiculopathy without major neurodeficit. A total of 3 or fewer epidural steroid injections were administered, using either the interlaminar or transforaminal technique. At the final follow-up, 79 of the patients (80.6%) did not undergo surgery, whereas the other 19 patients (19.4%) underwent surgery. From this study, they concluded that, in more than 80% of patients with cervical radiculopathy who were surgical candidates, surgery was avoided using epidural steroid injection.⁴

Huston CW did a review on cervical epidural steroid injection and compared between the interlaminar and transforaminal approach. He concluded that cervical epidural steroid injection are frequently utilised in the management of radicular pain. Observational

studies are also supportive of cervical epidural injections in the management of cervical disk herniation and atraumatic cervical spondylotic foraminal stenosis. Transforaminal approach was found more effective due to delivery of the drug directly at the pathology site. He also concluded that both procedures should be performed under fluoroscopy to reduce risk of serious complications and to ensure appropriate delivery of medication into the epidural space. ⁵

Hirpara KM and co-workers in there review article, regarding the non-operative management of cervical spondylosis, concluded that, there is stronger evidence supporting the use of steroids selectively, in the form of cervical epidurals with moderate improvement of symptoms though cervical epidurals are not without risk.⁶

Stout A, in a review article, explained about the role of epidural steroid in the management of radiculopathy. He mentioned that, injection of steroid along with local anaesthetic drug causes decrease of pain and inflammation at the site of injection. He made the hypothesis that steroid injection in the epidural space interrupts the inflammatory cascade. In addition, it decreases the neural transmission through nociceptive C fibres.²

Lin EL and co-workers did a retrospective study in cases of symptomatic cervical disc herniation patients to see the effectiveness of epidural steroid injection. They studied in 70 patients. Of the 70 treated patients, 44 (63%) had significant relief of their symptoms and did not wish to proceed with surgical treatment. Of the 26 patients who underwent surgical decompression, 92% had successful resolution of their symptoms. The nonsurgical and surgical groups were similar in terms of gender, pre-injection symptoms, or number of injections. However, significant differences between the two groups were found with regard to age (p<0.05) and time from initial consultation to initial injection (p<0.05). With an average of 13-month follow-up, 45 (65.3%) patients reported a good/excellent result per Odom criteria.⁷

Benyamin R and co-workers conducted a systemic review of cervical interlaminar epidural injections in managing upper extremity and neck pain. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria as utilized for interventional techniques for randomized trials and the criteria developed by the Agency for Healthcare Research and Quality (AHRQ) criteria for observational studies. The primary outcome measure was pain relief (short-term relief = up to 6 months and long-term > 6 months). Secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake. Results showed the indicated evidence was of Level II-1 in managing chronic neck and upper extremity pain.⁸

We applied the blind technique with approximate assessment of the length of the spinal needle through plain lateral radiograph of cervical spine. Injection of only methyl-prednisolone was given to the epidural space without any local anaesthetic injection to reduce the rate of hypersensitivity. Although guided injections are preferred, blind technique with expert hand is very useful in treating patients even in remote corners. It is a cheap but useful procedure which only needs a clean and sterile operation theatre. Epidural injections are still used in conservative failure cases in case of cervical radiculopathy. It's the time to change epidural injection to the first line management of cervical radiculopathy.

CONCLUSION

Effectiveness of epidural steroid in the management of cervical radiculopathy has been proven through different studies. It is cheap and without the side effects of long term use of analgesics. Our study also shows significant improvement of symptoms of cervical radiculopathy following epidural injection. Use of methylprednisolone without any adjuvant reduces the

complication rate in terms of hypersensitivity reactions. Epidural steroid injection in the management should be included in the first line management of cervical radiculopathy.

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Table 1: Comparison of baseline characteristics between study and control groups.

Groups Variables	Study (n= 66)		Control (n= 60)		p-value
Age (Years)	45.79±7.73		46.03±7.79		
Sex	Male	28	Male	26	>0.05
	Female	38	Female	34	
Baseline VAS	Severe (7-10)	56	Severe (7- 10)	52	>0.05
	Moderate (4- 6)	10	Moderate (4-6)	08	
	Mild (1-3)	0	Mild (1-3)	0	
Baseline NPDI	Mild	4	Mild	3	>0.05
	Moderate	22	Moderate	21	
	Severe	36	Severe	33	
	Complete	4	Complete	3	

VAS- visual analogue scale; NPDI- Neck pain disability index

Table 2: Visual Analogue Scale (VAS) score during follow up.

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	Group	Total		
	Study	Control		
VAS at 1 week	No improvement	4	9	13
	1 grade improvement	26	51	77
	2 grade improvement	34	0	34
	3 grade improvement	2	0	2
Total	66	60	12	26
VAS at 1 month	1 grade improvement	12	57	69
	2 grade improvement	30	3	33
	3 grade improvement	24	0	24
Total	66	60	126	
VAS at 3 month	1 grade improvement	0	18	18
	2 grade improvement	10	42	52
	3 grade improvement	56	0	56
Total	66	60	126	
VAS at 6 month	1 grade improvement	2	0	2
	2 grade improvement	10	60	70
	3 grade improvement	54	0	54
Total	66	60	126	

Table 3: Neck Pain Disability Index (NPDI) during follow ups

		Group		Total
		Study	Control	
NPDI at1	non-significant improvement	14	24	38
week	1 grade improvement	48	36	84
	2 grade improvement	4	0	4
Total	66	60	126	
NPDI at 1	non-significant improvement	2	6	8
month	1 grade improvement	22	51	73
	2 grade improvement	20	3	23
	3 grade improvement	20	0	20
	4 grade improvement	2	0	2

Total	66	60	126	
NPDI at 3 month	non-significant improvement	2	3	5
	1 grade improvement	10	42	52
	2 grade improvement	20	15	35
	3 grade improvement	32	0	32
	4 grade improvement	2	0	2
Total	66	60	126	

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