

Original Research Article

Cervical epidural steroid injection for the management of cervical radiculopathy: a randomized controlled study

Longjam Nilachandra Singh¹, Thingbaijam Bidiyarani Devi², Akoijam Joy Singh³, Shibu B⁴, Longjam Darendrajit Singh⁵, Aten Jongkey⁶

¹Assistant Professor, ^{2,4,5,6}PG trainee, ³Professor: Department of Physical Medicine & Rehabilitation, Regional Institute of Medical Sciences, Imphal, Manipur-795004, India.

***Corresponding author**

Longjam Nilachandra Singh

Email: drnilalong@yahoo.co.in

Abstract: Cervical radiculopathy is a commonly diagnosed disease process seen in middle and elderly population with prevalence of 48% for women and 38% in men. The objective of this study is to see the effectiveness of cervical epidural injection in cervical radiculopathy patients in Regional Institute of Medical Sciences (RIMS) Hospital, Manipur. A randomized controlled study was conducted at Physical Medicine and Rehabilitation (PMR), RIMS Imphal for 2 years (August 2013 to September 2015) on patients suffering from cervical radiculopathy. One hundred and twenty six patients of age group of 30-50 years were selected for the study and divided into study group (66 patients) and control group (60 patients). The study group received cervical epidural steroid injection under C-arm guidance along with intermittent cervical traction (ICT). The control group received only intermittent cervical traction. Assessment of Visual Analogue Scale (VAS) and Neck Pain Disability Index (NPDI) were done before starting the treatment, after 1 week, 1 month and 3 months following the treatment. Out of 66 patients in study group, there was significant improvement of neck pain and function in 89% of patients ($p < 0.001$) whereas in control group there was no significant improvement in pain and function. Only 4 patients out of 60 (6%) are reported to improve in control group which is not statistically significant ($p > 0.07$). Cervical epidural steroid injection is superior to intermittent cervical traction in the management of cervical radiculopathy.

Keywords: Cervical radiculopathy, epidural space, translaminar, corticosteroid, C-arm guided

INTRODUCTION

Cervical radiculopathy describes pain in one or both of the upper extremities, often in the setting of neck pain, secondary to compression or irritation of nerve roots in the cervical spine. It can be accompanied by motor, sensory, or reflex deficits and is most prevalent in persons 50 to 54 years of age [1]. Cervical radiculopathy can arise from pathological compressive process affecting the nerve root like acute disc herniation, degenerative for animal stenosis, trauma and tumour or biochemical processes leading to local inflammation. The annual incidence of cervical radicular pain is 5.5/100,000 [2]. The seventh (C7; 60%) and sixth (C6; 25%) cervical nerve roots are the most commonly affected [3].

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 [4]. The management of cervical radiculopathy

can be of non-surgical and surgical. Non-surgical procedures include analgesics, oral steroids, immobilization with hard or soft cervical collar, cervical traction, physical therapy and epidural injections [4].

Cervical epidural steroid injection is used for the conservative management of cervical radiculopathy. Epidural steroids and local anesthetics interrupt nociceptive input or alter the pattern of central neuronal activities. The potent anti-inflammatory properties of the steroid and wash out effect of inflammatory mediators were accomplished by delivering the steroid and local anaesthetic solution into the target area [5]. Compared with lumbar epidural steroid injection, cervical epidural injection has additional technical challenges associated with more narrowed epidural space and inconsistent loss of resistance technique due to a high incidence of discontinuity in the ligamentum flavum in cervical region [6].

The mechanism by which Intermittent Cervical Traction (ICT) reduces neck and arm pain is possibly by unloading the components of spine by stretching muscles, ligaments & functional units, reducing adhesions within the dura sleeve, nerve root decompression within the central foramina [5]. The 2006 systematic review suggested that intermittent as opposed to continuous traction may be beneficial, although the evidence came from low-quality trials [7].

The effect of Cervical Interlaminar Epidural Steroid Injection (CIESI) is not well studied and is more controversial than lumbar epidural steroid injection. Past outcomes of CIESI using blind technique were poor. Fluoroscopy guided studies suggest CIESI is beneficial for the management of cervical radicular pain, but the evidence is still weak, due to the lack of a control group that does not exclude natural improvement. However, CIESI has been suggested as a general treatment option when avoiding surgical treatment in patients with radicular pain [5].

This study was conducted to find out the effectiveness of epidural steroid injection in early improvement of radicular pain. Our study was a randomised 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

This randomised controlled study was conducted among the patients diagnosed as cervical radiculopathy clinically and confirmed by MRI who attended the outpatient department of PMR at RIMS Imphal between 2013 to 2015. Approval from Research Ethics Board and written informed consent was taken from all the patients participating in study. Sample size was 126 and patient selection was done using the following criteria.

The inclusion criteria are diagnosed case of cervical radiculopathy of duration <3 months, age of 30-50 years and patients who did not receive any cervical epidural injection before. The exclusion criteria are spinal tumour, local or systemic infection, operated case in cervical region, distorted anatomy like congenital block vertebra, uncontrolled diabetes and hypertension, history of allergy to any medications and refusal to give consent.

After getting the informed consent, patients were divided into study and control group through block randomization technique. The control group received conventional therapy only which includes

aceclofenac 200 mg sustained release tablet in once daily dose for 5 days, intermittent cervical traction for 10 minutes daily for 10 days throughout the study. The study group received single dose of cervical epidural injection of methylprednisolone 80 mg along with conventional therapy.

Visual Analogue Scale (VAS) and Neck Pain Disability Index (NPDI) were taken as outcome variables. Outcome variables were assessed before starting the treatment after one week, one month and after three months. Self-reported neck or radiating pain severity was recorded with a 100 mm line VAS which was divided into mild (1-3), moderate (4-6) and severe (7-10) grades. NPDI was divided into 5 classes (0-4) = no disability, (5-14) = mild disability, (15-24) = moderate disability, (25-34) = severe disability, (35-50) = complete disability.

Intervention

The procedure is done at operation theatre after admission in ward. Plain cervical X-ray is taken for all patients. All CIESIs were performed under fluoroscopic guidance. The level of CIESI was determined by MRI findings and symptoms, the injection was mostly given at C7-T1 and limited not to exceed C6/C7 due to concern with spinal cord injury or dura puncture. The patients were placed in the prone with neck flexed using a pillow under chest. After an aseptic preparation, a 22-gauge spinal needle was inserted at the midline of the C7-T1 interspace at anteroposterior view. If a loss of resistance was felt during the advance of the needle near the base of the spinous process at lateral view, 0.5 to 1 cc of contrast medium, iohexol was injected at real time lateral and anteroposterior view to confirm the epidural space. Following negative aspiration, a dose of 80 mg of methylprednisolone was then slowly injected into the epidural space. After the procedure, the patients were observed for 30 minutes, and complications if any were recorded.

Statistical Analysis

This was a prospective study with three follow-ups at 1 week, 1 month and 3 months after ascertaining baseline values. Data collected from the clinical examination were collected in Microsoft excel and analysed using SPSS version 16. For descriptive studies, various statistical parameters like mean, median and standard deviation were used for determining continuous variables. Frequency, percentage and range were used for determining the categorical variables. Independent t-test was used for comparison between means and chi-square test was used for comparison of categorical variables. Besides descriptive statistics, the comparison over period of time was done by applying repeated measures ANOVA. Between group comparison was done by using independent t-test.

Besides this where data were not distributed normally, Friedman test was applied. A p-value of <0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

This randomized controlled study was performed on 126 patients. One hundred and thirty five patients (135) subjects were enrolled in the study but only 126 patients which included 72 females and 54 males completed three months follow-up period. Therefore the study group comprised of 66 patients and the control group comprised of 60 patients. The age distribution ranged from 30 to 50 years; average being 45.79 ± 7.73 in study group and 46.03 ± 7.79 in control group (Table 1). Duration of neck pain ranged from 1 to 3 months. Cervical radiculopathy was present at C6 and C7 levels. Mean VAS and NPDI score at baseline were 7.34 ± 1.32 and 30.24 ± 2.46 respectively. There was no significant difference between the study and control group before starting the treatment ($p > 0.05$) as shown in (table 1). There was significant improvement in study group ($p < 0.001$) but not in control group ($p = 0.007$) at

the end of 3rd month (table 2). A statistically significant improvement was observed at one week, one month post injection which was maintained till three months (Table 2). At 1 week, study group is better than control group in reduction of pain and improvement of function ($p < 0.05$). The effect of intermittent cervical traction was seen at 1 month which cannot be maintained upto 3rd month. When compared between the group (Table 3 and 4) study group is better than control group in all follow up ($p < 0.05$). Though mild increase of pain was observed at third month follow-up, but it was not significant. Maximal improvement was found after one week post injection in all the parameters. Out of 60 patients in study group, six patients did not improve after cervical epidural injection. Only three patients reported side-effects after receiving CIESI. Two patients reported transient mild headache which improved the same day while one had transient increase in neck pain, improved within three days without any medication. There were no other adverse reactions following the injections.

Table-1: Characteristics of the two study groups

Variables	Study(n=66)	Control (n=60)	p-value
Age (years)	45.79 ± 7.73	46.03 ± 7.79	0.860
Sex(M/F)	28/38	26/34	0.919
Duration	2.3 ± 3.0	2.2 ± 4.5	0.712
Baseline VAS	7.55 ± 1.32	7.63 ± 1.28	0.845
Baseline NPDI	25.74 ± 7.52	23.55 ± 7.67	0.821

Values are mean \pm S.D. of each variable

VAS : Visual analogue scale

NPDI : Neck pain disability index

Table-2: VAS and NPDI scores at baseline, 1 week, 1 month and 3 months

Parameter	Group	Pre-treatment	1 week	1 month	3 months	p-value*
VAS	Study	7.55 ± 1.32	3.83 ± 0.7	3.30 ± 0.55	3.44 ± 0.61	0.001
	Control	7.63 ± 1.28	7.40 ± 1.18	6.30 ± 0.96	7.60 ± 0.93	0.07
NPDI	Study	25.74 ± 7.52	6.09 ± 2.24	5.32 ± 1.81	6.00 ± 1.85	0.001
	Control	23.55 ± 7.67	23.54 ± 7.67	18.9 ± 7.26	23.60 ± 4.39	0.08

Values are mean \pm S.D

*ANOVA for repeated measures

Table-3: Between group differences in change scores for VAS and NPDI

Parameter	Baseline to 1 st week			1st week to 1 st month		
	Study	Control	Mean difference (p-value)	Study	Control	Mean difference (p-value)
VAS	3.72	0.23	3.49 (p=0.001)	0.53	1.1	-0.14 (p=0.00)
NPDI	19.65	0.01	19.64 (p=0.001)	0.77	4.64	-3.87 (p=0.001)

*Independent sample t-test

Table-4: Between group differences in change scores for VAS and NPDI

Parameter	1 st month to 3 rd month		
	Study	Control	Mean difference (p-value)
VAS	-0.14	-1.3	-1.16 (p=0.001)
NPDI	-0.68	-4.7	-4.02 (p=0.002)

*Independent t-test

DISCUSSION

In the present study, there was significant improvement in study group in neck pain and function at the end of 3rd month ($p < 0.05$) whereas in the control group there was no significant improvement ($p > 0.05$). Lee SH and co-workers also stated that surgery was avoided using epidural steroid injection in more than 80% of patients [8]. Stout A, in a review article, explained about the role of epidural steroid in the management of radiculopathy. Steroid injection in the epidural space interrupts the inflammatory cascade and decreases the neural transmission through nociceptive C fibres [9]. The mean duration of cervical radiculopathy in the present study is 2.5 months which also contributed to high success rate. Kwon et al. reported that response rate of CIESI was 80.4% with less than 6 months and 60.0% with more than 6 months. Steroids are less effective in treating the pain from the mechanical compression of nerve roots in spinal stenosis than in the chemical inflammatory reaction in herniated intervertebral disc. Another factor contributing to high success rate is using the fluoroscopic guidance procedure. Sudhir et al suggested using fluoroscopy can improve the accuracy of needle placement and medication delivery and avoid potential intravascular injections [10].

At the end of study, intermittent cervical traction is not found to be effective in cervical radiculopathy. Controlled studies of cervical traction delivered for a variety of causes of neck and arm pain have not demonstrated benefit over sham traction or placebo [11]. However, in a randomized controlled study, Joghataei et al demonstrated that intermittent cervical traction in the supine position resulted in an immediate, short-term improvement in gripping strength (after 3 weeks) in the case of unilateral C7 cervical radiculopathy [12]. This early effect of spinal traction is probably related to the creation of negative pressure in the intervertebral disc, improvement in the blood supply to nerve structure and stabilization of activity of the trapezius muscle during the first 3 to 6 minutes. The protocol for the intermittent cervical traction may have been the reason a treatment effect was not identified. Although a multitude of traction parameters are used in the clinical setting, there is no convincing evidence to suggest which parameters are most effective in the management of cervical radiculopathy.

To our knowledge, the current study is the first randomised controlled trial study conducted to see the effectiveness of fluoroscopic guided cervical epidural injection with application of intermittent cervical traction in comparison with the intermittent cervical traction in management of pain and improvement of function in cervical radiculopathy patients. Study limitations are small sample size, few assessment tools and short follow up period. Low reliability, low sensitivity of VAS test is another limitation. Another limitation is that the cause of cervical radiculopathy which may be due to spinal canal stenosis or disc herniation is not demarcated. Thus, further studies with bigger sample size, longer follow up with multiple standardised assessment tools to gain unbiased results are recommended.

CONCLUSION

Fluoroscopic guided cervical epidural injection is useful in reduction of pain and improvement of function in cervical radiculopathy patients. Epidural steroid injection in the management should be included in the first line management of cervical radiculopathy.

REFERENCES

- Childress MA, Becker BA; Nonoperative management of cervical radiculopathy. *Am Fam Physician*, 2016; 93(9):746-754
- Lipetz JS, Lipetz DI; Disorders of the cervical spine. In DeLisa's *Physical Medicine and Rehabilitation Principle and Practice*. Fifth edition, Frontere WR editors, Lippincott William and Wilkins, Philadelphia, 2010: 815-821.
- Malanga GA; The diagnosis and treatment of cervical radiculopathy. *Med Sci Sports Exerc*, 1997; 29(7):236-245.
- DePalma MJ, Slipman CW; Common neck problems. In *Physical Medicine and Rehabilitation*. 3rd ed, Braddom RL, Buschbacher RM, Chan L editors, WB Saunders, Philadelphia, 2007: 787-816.
- Choi JW, Lim HW, Lee JY, Lee WI, Lee EK, Chang CH, Yang JY, Sim WS et al; Effect of Cervical Interlaminar Epidural Steroid Injection: Analysis According to the Neck Pain Patterns and MRI Findings. *Korean J Pain*, 2016; 29(2):96-102.
- Yoon JY, Kwon JW, Yoon YC, Lee J; Cervical interlaminar epidural steroid injection for unilateral cervical radiculopathy: comparison of midline and

- paramedian approaches for efficacy. Korean J Radiol, 2015;16(5):604-612.
7. Carette S, Fehlings MG; Clinical practice. Cervical radiculopathy. N Engl J Med, 2005; 353(4):392–399.
 8. Diwan S, Manchikanti L, Benyamin RM, Bryce DA, Geffert S, Hameed H, Sharma ML, Abdi S, Falco FJ et al; Effectiveness of Cervical Epidural Injections in the management of Chronic Neck and Upper extremity pain. Pain Physician, 2012; 15(4):405-434
 9. Lee SH, Kim KT, Kim DH, Lee BJ, Son ES, Kwack YH; Clinical outcomes of cervical radiculopathy following epidural steroid injection: a prospective study with follow-up for more than 2 years. Spine, 2012; 37(12): 1041-1047.
 10. Stout A; Epidural steroid injection for cervical radiculopathy. Phys Med Rehabil Clin N Am, 2011; 22(1): 149-159.
 11. Klaber Moffett JA, Hughes GI, Griffiths P; An investigation of the effects of cervical traction. Part 1: Clinical effectiveness. Clin Rehabil, 1996; 4(2):205.
 12. Jellad A, Ben Salah Z, Boudokhane S, Migaou H, Bahri I, Rejeb N; The value of intermittent cervical traction in recent cervical radiculopathy. Annals of Physical and Rehabilitation Medicine, 2009;2(9):638-652.