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Study of Efficacy of Epidural Methyl Prednisolone Acetate in Lumbar Radiculopathy

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Abstract : *Chronic back pain with sciatica represents an important health problem in orthopaedic practice. The number of patients presenting with low back pain with radiculopathy constitute nearly 60% of OPD practice. Patients presenting to us are of rural background involved in heavy physical labour, these symptoms temporarily disables them in earning a livelihood. Our objective was to assess the efficacy of epidural steroid injection on pain relief and functional return in lumbar radiculopathy. All patients were given 80 mg Methyl Prednisolone Acetate (40mg/ml) along with 4cc of 2% Xylocard in lumbar epidural space. A total of hundred patients were included in this study. Efficacy was analysed using parameters like Straight Leg Raise Test (SLRT), Oswestry Disability Index Score(ODI) score, Visual Analog Scale (VAS) score. In the study it was observed that 65% of patients had symptoms less than 12 months. There was statistically significant improvement in SLRT. ODI & VAS also improved. We conclude that epidural steroid injection is an effective non surgical treatment option for patients with low backache and radicular leg pain. Epidural steroid should be considered before surgical intervention. It is only after adequate pain control that rehabilitation can be effective and function restored in many low backache patients.*

Keywords: *Lumbar radiculopathy, Epidural steroid, Oswestry Disability Index, Visual Analogue Scale*

I. Introduction

Back pain and related symptoms rank among the second most frequent medical complaints. Disability from low back pain is second only to the common cold as a cause of lost work time and is the most common cause of disability in people under 45 years of age [1].

Chronic back pain represents an important health problem in orthopaedic practice. The number of patients presenting with low back pain constitute nearly 80% of OPD practice. Patients presenting to us are of rural background involved in heavy physical labour. Low back pain temporarily disables them in earning a livelihood. So an approach has to be worked out to alleviate their symptoms early. Multiplicity of causes and difficulties in its treatment render low back ache one of the most frequent problems that an orthopaedic surgeon encounters. Decisions regarding optimal management are not easy. There are many therapeutic interventions available; however, none seems to be clearly superior [2]. At one end of the spectrum is the regime of bed rest and analgesics, forming the main pillar of the treatment while at the other, there is the operative removal of the prolapsed disc. Even in the conservative line of treatment, there is no universally accepted policy and the best form of treatment. This wide and haphazard spectrum of treatment suggests that there is no single satisfactory method of treatment that ensures permanent and long lasting cure [3] .

Radicular pain defined as pain that radiates from the site of a pinched nerve in the low back to the area of the body aligned with that nerve, such as the back of the leg or into the foot [4] . Radicular pain occurs due to an ectopic discharge physiologically generated in either the dorsal root or the dorsal root ganglion. An important cause of radicular pain is mechanical compression exerted by degenerative changes in the facet joint, the posterior longitudinal ligament or the herniated disc. Another cause is chemical irritation produced by phospholipase A2 or substance P secreted from the prolapsed intervertebral disc [5,6]. As a result, they contribute to pain mechanisms by triggering venous congestion and/or neural edema around the nerve root, for this reason, the local delivery of steroids seems to be a rational option [7].

Steroids inhibit the inflammatory response caused by chemical and mechanical sources of pain. They inhibit the formation of nerve root edema, have an anti-inflammatory effect, increase blood flow to neural elements thus improving ischemic neuritis and block conduction in nociceptive nerve fibers [8].Steroids also work by reducing the effect of the immune system to react to inflammation associated with nerve damage **[9]**.The purpose of epidural steroid injections is not to cure anatomic abnormalities but to improve symptoms. In this way, patients can commence rehabilitation, allowing a quicker return to a "normal" lifestyle with maximum

function and activity [10]. Our objective was to assess the efficacy of epidural steroid injection on pain relief and functional return in lumbar radiculopathy.

II. Material & Methods

A total of hundred patients satisfying the inclusion criteria from December, 2011 to July, 2013 were taken up for the study.Inclusion criteria are age more than 18 years and patients with low backache with lumbosacral nerve root pain which has not resolved within a minimum of six weeks and is of an intensity to warrant some intervention.Exclusion criteria are previous surgeries at the same motion segment,those with unclear topographical diagnosis,those with severely disabling neurological deficit,those with structural deformites like scoliosis,kyphosis,allergy to Steroids, bleeding diatheses,pregnancy,uncontrolled hypertension and uncontrolled diabetes mellitus.After selecting the cases,they were counselled about the study & were included after a written informed consent to participate in the study.All the patients underwent a thorough clinical evaluation in way of a history of the illness, including the details of pain, as well as the nature of the conservative treatment they have received in the past,examination including neurological assessment of the lower limb as per a proforma prepared for the study (attached later). They were subjected to questionnaires including the Visual Analogue Scale, Oswestry Disability Index Score(ODI) the scores were evaluated before & after the intervention and at follow up.

The investigations that were done for every patient included an X-ray Lumbo-Sacral Spine – AP and LAT,MRI Lumbosacral Spine, Routine Hemogram, HIV and HBsAg status,Bleeding and Clotting time.The procedure is carefully explained to the patient, who is told to expect increase in intensity of his symptoms during the injection.All the injections were carried out in the operation theatre with dry, sterile materials. Neurological Status & SLRT are re-assessed at this stage. With the patient in sitting or lateral decubitus posture(affected side down in those who could not sit),lumbo sacral region was prepared with spirit & povidine iodine several segments above & below the laminar interspace to be injected. The patient is draped in a sterile fashion. Sitting position was preferred as the fully flexed spine lead to opening of the interspinous spaces which were being used for the injection.

After positioning the patient & preparation of the skin, the target laminar interspace was identified. Commonly used anatomical landmarks were the highest point of the iliac crest, with L 4 spinous process. Using a needle, the skin over the target interspace was injected with 1 to 2 ml of 2% preservative-free Xylocaine without epinephrine & was anaesthetized.The target space was within one level above or below the levelof symptomatic disc.Then a 3½-inch, 18-gauge Tuohy epidural needle was inserted & advanced it vertically within the anesthetized soft tissue track until contact with the lamina has been made. "Walk off" the lamina with the Tuohy needle onto the ligamentum flavum was done. Stylet from the Tuohy needle was removed & attached to a 10-ml syringe filled with air. It was advanced into the epidural space using the loss of resistance technique.This was followed by securing the needle & then injecting 4ml
2% Xylocard and 2 ml of 40 mg/ml Methyl Prednisolone Acetate(Depomedrol) one after the other,a total of 6ml. Finally the tuohy needle is withdrawn & the spot was sealed with tincture benzoin.All the procedures were done by a anaesthetist.At the conclusion of the injection a note is made of the following: relief of pain & its extent measured subjectively as well as by straight leg raising test, & motor & sensory examination.The patient is advised that apart from a feeling of warmth in the legs & perhaps a sensation of walking on cotton wool, there should be no other neurological signs or untoward effect. The patient is further warned that after injection the pain may be worsened for a few days before it begins to settle. The patient is advised to lie flat for at least 45 min after the injection which helps to avoid headache developing on sitting up. The patient was advised to pass urine before leaving the hospital. Back extension exercises were continued after the injection as a routine protocol.

Clinical evaluations were performed immediately after the injection,at 1 &3 months. The Visual Analogue Score, Oswestry Disability Index score & the Straight Leg Raising Test (SLRT) were used to differentiate patients whose symptoms improved from those who remained symptomatic.Patient satisfaction was documented at 3months.Excellent->75% reduction of symptoms/disability,Good->50% reduction,Fair-<50% reduction,Poor-same or worse.

III. Results & Analysis

Data was entered into excel sheet after coding and analyzed using SPSS 11 version software. Frequencies and proportions were computed for qualitative data, Mean and Standard deviation was computed for quantitative data. Paired t test is the test of significance for Quantitative data to check the difference before and after treatment. Chi-square test is the test of significance for categorical data to check the association.

Table 1: Mean Scores of SLRT before and after treatment among the Patients with SLRT ≤ 70

SLRT	**Mean (n=65)**	**Std. Deviation**
Right side (Before treatment)	63.55	7.377
Right side (after 1 month)	77.10	7.97
Right side (after 3 months)	81.29	7.125
	Mean (n=52)	**Std. Deviation**
Left side (before treatment)	62.35	8.32
Left side (after 1 month)	74.71	11.01
Left side (after 3 months)	79.22	10.92

In the study it was observed that mean scores of SLRT improved on both sides after treatment.

Table 2: Mean scores of ODI (Oswestry Disability Index)

ODI score	**Mean**	**Std. Deviation**
ODI (before treatment)	45.65	5.508
ODI (after one month)	19.73	8.929
ODI (after 3 months)	9.1753	10.086

In the study it was observed that mean scores of ODI improved after treatment.

Table 3: Mean scores of VAS (Visual Analogue Score)

VAS score	**Mean**	**Std. Deviation**
VAS (before treatment)	7.45	.842
VAS (after 1 month)	2.95	1.278
VAS (after 3 months)	1.46	1.528

In the study it was observed that mean scores of VAS reduced after treatment.

Table 4: Association of ODI (Oswestry Disability Index) score after 3 month with Patient satisfaction

ODI After 3 month	**Patient satisfaction**				Total	
	Excellent	Fair	Good	Poor		
0 to 20%	38	10	39	3	90	X^2=49.277 df =6, p = 0.0001**
20 to 40%	0	4	0	5	9	
40 to 60%	0	0	0	1	1	
Total	38	14	39	9	100	

In the study it was observed that there was significant association between ODI score after treatment at 1 month and Patient satisfaction. *p* value <0.0001.

IV. Discussion

Low backache due to lumbar nerve root compromise is a debilitating problem frequently afflicting otherwise healthy individuals.Pain and reduced mobility severely compromise their quality of life.The aim of any therapy should be to return to a normal lifestyle as soon as possible,whether it be by treatment of the underlying cause or merely by symptomatic relief.It is recommended that surgery to be undertaken only when conservative management fails.[11]

Etiology of low backache remains controversial. Degeneration, herniation, or by an inflammatory reaction could be responsible for lower backache & sciatica[12]. An epidural injection can decrease inflammation in the epidural space as well as the pain in the affected nerve root. In this study,a total of hundred patients with lumbosacral radiculopathy were evaluated for a period of minimum 3 months post epidural injection of steroid,in terms of effectiveness.The mean age group was 42.53 yrs and 51% were in the middle age group between 30 to 50 years.In the study it was observed that the majority i.e. 65% of patients had symptoms <12 months.

There was statistically significant improvement in SLRT from 63.5 mean preintervention to 81.29 mean 3 months post steroid injection on right side,62.35 to79.22 on left side.These results were comparable to a study conducted by Karppinen [13] who studied results in 160 patients with sciatica,showed significant improvement in SLRT following epidural injection of methylprednisolone and anesthetic. We observed that 67% of patients had symptomatic lesion at single level,26% of patients had lesions at 2 levels and 6% of patients had lesions at multiple level.This was similar to the observation made by Wilson-MacDonald[14] where 80% patients showed single level ,16% at 2 levels and 4% multiple.We observed in 40% of patients S1 root was affected, in 36% of patients L5 root was affected.

In this study we observed that the mean scores of ODI improved from 45.65 prior to treatment to 9.17 at 3 months.Similar observation was made by N. K. Arden et al[27] who showed improvement from 44 to 12 at end of 3 months.VAS before treatment was 7.45 mean, 1.46 at 3 months.These results were comparable to a study conducted by Pirbudak et al[15] who showed significant improvement in 92 patients with sciatica treated with epidural steroid. In the study it was observed that 39% of patients had Good satisfaction, 38% had excellent satisfaction, 14% had fair satisfaction and only 9% had poor satisfaction after treatment.

There were no major complications like meningitis,allergic reactions or cauda equine syndrome.In the study it was observed that 15% of patients had Dural puncture, 27% of patients had pain at injection site and 10% had headache.these results were comparable to a study done by Michael J.DePalma[8] who showed injection site pain in 17.1% ,headache in 3.1%.

Karppinen et al[13] demonstrated that either local steroid injection or saline injection around a nerve root would improve referred pain, but found that when a combination of steroid and local anaesthetic were used there was a rebound phenomenon after three to six months, with increasing deterioration of symptoms the longer the period between the injection and follow-up.Our patients had significant improvement by 1 month and only 3 patients underwent surgery due to poor relief. It has been shown that epidural steroid injection with local anaesthetic is better than injection of local anaesthetic alone and thus the steroid does appear to be important in reducing pain in these patients.[15]

Many studies show that only 10% to 15% of patients with sciatica presenting to a specialist eventually require operation.The reason for the low take up of surgery may have been that many of the older patients did not wish to undergo surgical treatment. A small number of patients refused to have surgery despite the failure to improve over the course of time because of the perceived risks.

This study helps us to say that epidural steroid injection in early stage of back ache helps in relief of symptoms, early return to normal daily activities and work .Epidural steroid injection helps in patients in whom spontaneous improvement is expected by accelerating the rate of recovery.However in long term followup it may not preclude the need for surgery.

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V. Conclusion

This study was done to evaluate the efficacy of epidural steroid in low backache with radiculopathy. The results statistically showed significant improvement in terms of pain relief measured with Visual Analogue Scale score and patient satisfaction, clinical improvement measured by SLRT and functional return measured by Oswestry Disability Index. Complications encountered were injection site pain and headache.

We conclude that epidural steroid injection is an effective non surgical treatment option for patients with low backache and radicular leg pain.Epidural steroid should be considered before surgical intervention.After early adequate pain control, rehabilitation can be effective and function can be restored.Epidural steroid in selected cases fulfills this criteria.

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