



EFFICACY OF EPIDURAL STEROIDS FOR LOW-BACK PAIN AND COMPARISON WITH CONSERVATIVE MANAGEMENT : A PROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Low back pain, the ancient curse, is now presenting itself as a modern international epidemic. Back pain is the most common and complex type of chronic pain. Each year, 15 to 45 percent of adults suffer from low back pain, and one in 20 people present to a hospital with a new episode. This was a Randomised prospective study of one year duration where we studied the efficacy of epidural steroid injections for low back pain treatment against conservative treatment. In our study of 68 patients given conservative and 25 patients given injections it was inferred that injections gave significantly better results in the short term. They proved cost effective, decreased bed rest and better palliation when avoiding or awaiting spine surgery. The epidural injection therapy can therefore be called the 'middle wrung of the ladder' or the 'middle path'

KEYWORDS : low back pain, epidural steroid, conservative management, NSAIDS, Visual Analogue Score

INTRODUCTION

Low back pain is pain localized below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica). Non-specific low back pain is low back pain not attributed to a recognizable pathology, such as infection, tumour, osteoporosis, rheumatoid arthritis, fracture, or inflammation.¹ It is considered to be chronic when the pain is of more than six weeks duration.² Back pain is the most common and complex type of chronic pain.³ Many chronic back and extremity pain problems are thought to arise from musculoskeletal sources. It is most common between 35 and 55 years of age.⁴ A high prevalence of anxiety and depression is also associated with low back pain.⁵

Causes of low back pain are⁶ Structural defects of bone, Functional defects (leg length discrepancy, scoliosis, postural attitudes, etc.), Infections, Degenerative, Neoplastic and Traumatic. The treatments used for the relief from low back pain may be categorized as: 1. Conservative therapy 2. Injection therapy 3. Surgery.

The need for this study is to evolve a protocol for the treatment of low backache and to assess the efficacy of epidural steroid in the management of low backache as against conservative therapy, and to determine the role of epidural medication in postponing or avoiding the often irrational surgery.

MATERIALS AND METHODS

This was a Randomised prospective study conducted in Department of Orthopaedics, in a tertiary hospital conducted over a period of 12 months in Central India from October 2011 to September 2012.

All patients of low back pain who presented at the hospital during the study period and were receiving conservative treatment which comprised of bed rest, traction, physiotherapy and non-steroidal anti-inflammatory drugs for a minimum of 12 weeks were considered for inclusion in this study. The pain was assessed by *visual analogue pain scale* with markings from 0 to 100.^{7,8}



Fig.1 The visual analogue scale used in this study.

Exclusion criteria- Pregnancy, patients who required surgery, acute motor paresis, cauda-equina syndrome, massive disc prolapse with bladder and bowel involvement, primary or secondary malignant conditions were excluded from the study.

A choice was given to the patients to either continue conservative treatment or to undergo a series of a maximum of three corticosteroid, local anaesthetic solution injections in the epidural space. For ethical reasons, the patients who were improving with conservative measures were encouraged more to continue conservative management for another twelve weeks and were included in the conservative group. Those whose level of pain relief had reached a plateau were encouraged more to take the epidural injection and were included in the injection group.

Patients receiving conservative treatment were designated as group-1 and those receiving epidural injections were designated as group-2.

Patients in group-1 (conservative group) were put on bed rest and NSAIDS in the acute phase of pain and were later advised spinal extension, intermittent lumbar traction, interferential therapy and or short wave diathermy. Spinal orthosis were prescribed in a few patients to facilitate rest to the lumbar steroid injections (group-2)

Procedure.

A mixture of 4ml 2% lignocaine, 3ml of 0.5% bupivacaine and normal saline (total of 10cc) was loaded into a 10ml syringe. A 2nd syringe with 2ml of 40mg per ml methyl prednisolone acetate topped up with distilled water to make it 10ml was taken, and a 3rd syringe with 10 ml saline was taken. After proper investigations, part preparation, the 1st injection was given through the sacral hiatus after local anaesthesia. Keeping the needle in its place, 2nd and 3rd syringes were slowly emptied into the epidural space. Patients returned home after the injection.

Follow ups were done at 1, 3, 6 and 12 weeks after commencement of the conservative therapy in group-1 patients and after each injection in the group-2 patients. At these follow ups horizontal visual analog scale for pain assessment⁸. The patients were put in three categories based on the percentage of subjective pain relief as reported by the patient. Patients with 75% to 100% pain relief were classified as 'relieved'. 50% to less than 75% as 'assisted' and less than 50% were considered as 'failed'.

The observations of the first follow up, which was at one week

after the beginning of the study period in group-1 (conservative group) and at one week after the first injection in group-2 (injection group) were taken up for statistical analysis. The injection was repeated if there was incomplete relief in pain, at first follow up and such patients were called at 2 weeks after the first injection for the second injection. Similarly, if required a third injection was given two weeks after the second. A maximum of three injections were given in this study. Statistical tests were applied on observations e.g. student t-test, Chi-square test, Fischer exact test and Pearson correlation. The critical values for significance of the results were considered at 0.05 levels (95% confidence limits).

RESULTS

A total number of sixty eight patients were included in group-1 and a total of twenty five patients were included in group-2. The mean age of patients was 54.2 ± 14.48 years in Group-1 (conservative group) and 54.36 ± 12.74 years in Group-2 (injection group).

The sex distribution in group-1 was 32 males and 36 females. In group-2 there were 10 males and 15 females. Out of 25 patients in group -2, 9 patients had only back pain while 16 had back pain with leg pain out of which 15 had unilateral pain and 1 patient had bilateral pain.

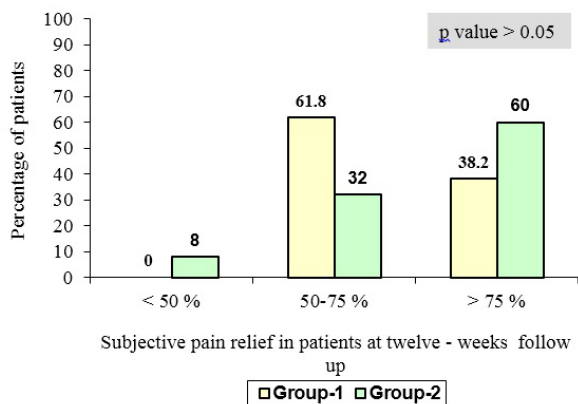
Out of 25 patients in group-2, 16 patients received one epidural injection each, 6 patients received two each and 3 patients received three each.

Table 1: Classification based on subjective pain relief at one week follow up.

	Failed (<50% relief)	Assisted (50-75% relief)	Relieved (>75% relief)
Group 1 (n = 68)	13 (19.1%)	47 (69.1%)	8 (11.8%)
Group 2 (n = 25)	2 (8%)	3 (12%)	20 (80%)

p value < 0.001

The table above shows the high relief rate in group-2 at the one - week follow up. A p-value of this data was tabulated and it was found to be p <0.001 which was highly significant showing that at one-week follow up, epidural injection was a much superior modality of treatment as compared to conservative management. (For statistical purposes the failed and assisted patients were together taken as 'not relieved')



Graph 1: percentage of subjective pain relief in patients at twelve-weeks follow up.

A p-value of this data was tabulated and it was found to be p >0.05 which was not significant showing that at twelve-week follow up epidural injection was a similar or not superior or inferior modality of treatment as compared to conservative management. (For statistical purposes the failed and assisted patients were together taken as 'not relieved') Although a

higher proportion of patients were 'relieved' in the epidural injection group at the twelve-week follow up, the results were statistically not significant (p>0.05); $\chi^2 = 3.55$. For $\chi^2 = 3.84$, p=0.05. Therefore although p is greater than 0.05 it is very close to being equal to it, it is possible that with a larger study group this value may reach a point that is significant statistically)

DISCUSSION

In our study, the mean age of patients was 54.2±14.48 years in Group-1 (conservative group) and 54.36 ± 12.74 years in Group-2 (injection group). In Cuckler's study on seventy three patients with lumbar radicular pain syndromes the average age in years was 49.5±2.8 years in the 'placebo group' and 48.5±1.3 years in the 'steroid group'. Other published data shows that low back pain is most common between 35 and 55 years of age. Our observations are consistent in the fact that low back pain affects the middle aged most. The duration of symptoms at inclusion in the study, in group-1 are 34.30±23.33 weeks (mean) and 24 weeks (median); and in group-2 are 34.08±22.61 weeks(mean) and 24 weeks(median) These figures are indicative of good randomisation of data.

In our study out of the 25 patients in group-2, 16 patients received one epidural injection each, 6 patients received two each and 3 patients received three each.

At the first-week follow up it was observed that there was 75% or more subjective pain relief in 80% of the epidural injection group (group 2) patients as against 11.8% of the conservative group (group 1) patients. The p value of p<0.001 for the data obtained at the first-week follow up proves that there is a highly significant difference in the efficacy of the two modalities of treatment at this point in time during the study. This clearly shows that epidural injections are much superior as compared to conservative therapy in providing a short term relief in pain.

At the twelve-week follow up it was observed that there was 75% or more subjective pain relief in 60% of the epidural injection group (group 2) patients as against 38.2% of the conservative group (group 1) patients. Although a higher proportion of patients were 'relieved' in the epidural injection group at the twelve-week follow up, the results were statistically not significant (p>0.05); $\chi^2 = 3.55$. For $\chi^2 = 3.84$, p=0.05. Therefore although p is greater than 0.05 it is very close to being equal to it, it is possible that with a larger study group this value may reach a point that is significant statistically).

At the late follow up 48% of the patients of the injection group (gp2) had pain relief of more than 75% and 48.5% of the patients of the injection group were 'relieved'. These results were equivalent and statistically 'highly not-significant'. (p>0.5) These observations prove beyond doubt that the effects of the injection therapy are short lived, but they do provide a good short term relief.

In the literature, the short and long-term efficacy of this treatment remains controversial^{9,10,11}.

Coomes (1961) compared the results of treatment by epidural injections and that by bed rest¹⁰. One group was put into bed and the other was given epidural injection of 50 to 60 ml of 5% procaine via the sacral hiatus. He observed that the epidural injection group did much better than the bed rest group. The epidural group had greater improvement in neurological signs than the bed rest group.

Analysis of the literature attests to the safety of the procedure. Experimental studies deny any neurotoxicity (Delaney et al.1980), and the reported complications of epidural

corticosteroid injection are few and far in between and relate mainly to the technical aspect of the injection technique and not to the corticosteroid drug itself¹¹. Our study confirms the clinical safety of steroid, local anaesthetic and saline solution. No serious complications occurred in our study.

From the analysis of our results, several features are worth further mention.

There were 40 patients of herniated nucleus pulposus in group 1 and 16 in group 2, 25% of the patients of group 1 were 'relieved' and 68.75% of the patients of group 2 were 'relieved' at twelve weeks. It is apparent that amongst the patients of herniated nucleus pulposus a much better result is obtained in the patients of the epidural steroid local anaesthetic solution injection group. (68.75% as against 25%) Therefore, it can be said that a lot of these patients who were potential candidates for surgery improved with the epidural injections, and the epidural steroid injections are of particular value in the patients with herniated nucleus pulposus. Cyriax (1957) used epidural injections extensively and laid down comprehensive indications regarding selection of patients for this form of treatment and advocated epidural anaesthesia as the conservative treatment of choice for patients who have a low lumbar disc lesion, with pressure on the nerve root and neurological signs in the affected leg¹².

Injection therapies for low back pain are still evolving. We feel that the steroid, local anaesthetic, normal saline solution injections definitely provide a high rate of short term relief as compared to conservative management and they are at the least equal in the long term. The duration of hospital stay and the cost to the patient or to the provider is significantly lower than in the conservative group. The epidural injection is therefore financially more viable and the hospital beds can be utilised for more serious patients leading to better utilization of resources. The surgical treatment can definitely be postponed and in a few cases avoided and especially so in the patients with herniated nucleus pulposus. Epidural injections are safe and no serious side effects have been seen in our study

We recommend that, up to three epidural steroid, local anaesthetic solution injections should be included in the protocol for the management of chronic low back pain. However, the third injection should be kept reserved for being administered at the 'late follow up'

SUMMARY

Epidural steroids are not a cure for the disc disease, but they do offer a relatively prolonged pain relief without excessive analgesic intake if non-surgical care is elected. Patients with low back pain who had received at least twelve weeks of conservative treatment were included if their pain was not relieved by at least 75% of the original using a visual analogue pain scale and after exclusion on the basis of specific illness requiring specific treatment. A total number of sixty eight patients were included in group-1 (conservative group) and a total of twenty five patients were included in group-2 (injection group). The analysis of the results showed that at one-week follow up, epidural injection was a much superior modality of treatment as compared to conservative management. It was further inferred that at twelve-week follow up epidural injection was a similar or not superior or inferior modality of treatment as compared to conservative management. It was also concluded that at late follow up the effect of epidural injection therapy and conservative therapy became equal.

With respect to efficacy of epidural medications for the treatment of low back pain and sciatica the literature is less definitive. Most of the studies show a higher short term success

and a significantly lower long term success, our study attests to this finding. The epidural injection is financially more viable and the hospital beds can be utilised for more serious patients leading to better utilization of resources. The surgical treatment can definitely be postponed and in a few cases avoided, especially so in patients of herniated nucleus pulposus. The patients are more comfortable while waiting for surgery and can carry out a physiotherapy regimen with greater ease and comfort and therefore compliance. Non-steroidal anti-inflammatory drug intake is greatly reduced. Epidural injections are safe and no serious side effects have been seen in our study We advocate a step-ladder pattern of approach in managing low back pain. Initially intensive conservative treatment followed by epidural steroid, local anaesthetic solution injection therapy and then if that fails surgery should be contemplated. The epidural injection therapy can therefore be called the 'middle rung of the ladder' or the 'middle path'.

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