

Original Research Article

Study of efficacy of epidural methylprednisolone acetate and triamcinolone acetate for treatment of low back pain and radiculopathy

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ABSTRACT

Background: Epidural steroids have been proven to be one of the most effective non-operative managements of back pain. The present study entailed evaluation of the efficacy of epidural methylprednisolone acetate and triamcinolone acetate for treatment of low back pain and radiculopathy.

Methods: The two groups of 25 participants, formed on the basis of the injectable epidural steroid used {80mg of methylprednisolone acetate (group 1) or 40mg of triamcinolone acetate (group 2)}, were enrolled after following due selection criteria. After detailed history taking, examination and requisite investigations, 15 ml volume of the drug was injected epidurally with the patient lying in lateral position. The patients were followed-up at 3 weeks, 6 weeks and 3 months and pain assessment and percentage of pain relief was noted in comparison with the level of pain before epidural injection. Sleep quality, activity score, days in bed, analgesic requirement, complications and requirement of surgical intervention were all assessed at each follow-up.

Results: The mean pain score was significantly less in group 1 after 6 weeks and 3 months period, with 60% in group 1 having “good” pain relief, while 69.56% amongst group 2 participants reported “fair” pain relief. Eighty four percent group 1 participants required 2 injections, while 64% participants in group 2 required 3 injections. There was overall improvement in the activity score, quality of sleep and decrease in bed rest and analgesic requirement.

Conclusions: Epidural steroid therapy is highly efficacious and methylprednisolone acetate is more effective than triamcinolone acetate; with negligible complications.

Keywords: Efficacy, Epidural steroid, Low back pain, Methylprednisolone acetate, Radiculopathy, Triamcinolone acetate

INTRODUCTION

Of all the pain syndromes of benign etiology, back pain is one of the most incapacitating to the patient, promptly affecting his activities of daily living and thus making prompt management imperative. At the same time, it remains one of the most enigmatic entity to the physician etiologically, diagnostically and therapeutically. Many treatment options for acute and chronic low back pain are

available, but little is known about the optimal treatment strategy. Surgical procedures have provided disappointing results and, with the inherent risk of morbidity and mortality and inevitable protracted period of recuperation, nonsurgical approaches have come in to vogue off-late.¹ Epidural injections for managing debilitating back pain are gaining wider acceptance year-on-year for being a safe, effective and economical alternative with lesser chances of systemic side effects.² In

the past, opioids, local anaesthetics, saline and distilled water have been used in different combination and volume via epidural route.³ Epidural steroids have been proven to be one of the most effective non-operative managements of back pain and are now recommended in debilitating back pain, especially in those with features of nerve root irritation.⁴⁻⁶ The relief of pain is mainly attributed to the anti-inflammatory effect of the steroid.

The present study was undertaken with the objective of evaluation and comparison of the efficacy of two steroid preparations with different duration of action, i.e. methylprednisolone acetate and triamcinolone acetate, when injected epidurally for back pain and radiculopathy.

METHODS

The present comparative observational study was carried out at a tertiary care government hospital in central India over the period of two years (January 2013 to December 2014). The study population consisted of all the patients visiting the orthopaedics OPD of the hospital with primary complaint of low back pain and radiculopathy.

Following selection criteria were employed for the study:

Inclusion criteria

- All American society of anaesthesiologists (ASA) class I and II patients⁷
- Patients between the ages of 20-60 years.

Exclusion criteria

- Patients with progressive neurological deficit
- Patients with abnormal coagulation profile
- Patients with localised infection
- Patients with tumour involvement of spine, compression fracture, osteoporotic vertebral collapse or spinal deformity
- Patients with diabetes
- Patients with psychiatric disorder
- Pregnant patients
- Patients refusing to consent for the study

A total of 50 patients fulfilling the selection criteria constituted the study sample. All the 50 participants were subjected to detailed history taking and examination as per protocol, after written informed consent. The back pain was classified as 'acute' (duration of symptom less than 6 months), 'chronic' (duration of symptom more than 6 months) or 'recurrent' (history of relapse and remission with treatment with fresh onset of pain at the time of presentation). All the necessary investigations like complete blood count (CBC), bleeding time, clotting time, random blood sugar and ECG were carried out on OPD basis before the procedure.

The participants were randomly divided into two groups of 25 participants each on the basis of the injectable

epidural steroid used. The two study groups thus formed were as follows:

- *Group 1:* Patients received 80mg of methylprednisolone acetate diluted with normal saline up to total 15ml volume.
- *Group 2:* Patients received 40mg of triamcinolone acetate diluted with normal saline up to total 15ml volume.

On arrival of the patient in the operation theatre, baseline BP and pulse were checked and intravenous line set. The patient was asked to lie in lateral position with the side having radiation of pain dependent. The site of injection was elected as close to the site of pathology as possible. Under all aseptic precautions, epidural space was identified by loss of resistance test (LORT) and hanging drop method using 18G Tuohy needle. Fifteen ml volume of desired drug was injected slowly followed by flushing of needle with one ml of normal saline. The patient was kept in the same position for five minutes before turning supine, indicating completion of the procedure. The patient was monitored for half an hour post-procedure and then discharged. Complications during or after the procedure, if any, were duly noted.

All the patients were called for follow-up at 3 weeks, 6 weeks and 3 months and pain assessment was done as per visual analogue scale.⁸ The percentage of pain relief was noted at each follow-up in comparison with the level of pain before epidural injection and classified as 'excellent' (>80% pain relief), 'good' (60-80% pain relief), 'fair' (40-60% pain relief) and 'poor' (<40% pain relief). Straight leg raising (SLR) test, sleep quality, activity score, days in bed, analgesic requirement, complications and requirement of surgical intervention were all assessed and recorded at each follow-up.

The study was commenced after ethical approval from the Institutional Ethics Committee. All the data was analysed using SPSS (version 17) by employing hi-square test and Analysis of Variance (ANOVA).

RESULTS

The two groups of 25 participants formed on the basis of the injectable epidural steroid used (80mg of methylprednisolone acetate or 40mg of triamcinolone acetate) were observed to be comparable for age (mean age: group 1- 37.9±9.9, group 2- 41.1±7.9), with most of the participants belonging to third or fourth decade of life. Males significantly outnumbered females, with the M:F ratio for group 1 and group 2 being 5.25 and 2.13 respectively. Two patients from group 2 were lost to follow-up subsequently.

Prolapsed intervertebral disc (68% in group 1, 64% in group 2) was by far the commonest diagnosed entity in the study, followed by lumbar spondylosis (LS), lumbar spinal stenosis (LSS), PID with LS, post spinal surgery

back pain (PSSP); which were also evenly distributed between the two groups.

The groups were compared for duration of back pain and were found not to differ significantly. The mean pain score before injection and at 3 weeks follow up was not significantly different between the two groups. But the mean pain score was observed to be significantly less in group 1 after 6 weeks and 3 months period. Majority (60%) reported having “good” pain relief in group 1, while as many as 69.56% amongst group 2 participants reported “fair” pain relief, and the difference was significant (Table 1).

Table 1: The causes of death.

Characteristics	Group 1	Group 2	Total (‘P- value’ for mean pain score difference)
Duration of pain [n (%)]			
Acute	13(56.52)	10(43.4)	23(100)
Recurrent	3(60)	2(40)	5(100)
Chronic	9(40.9)	13(59.09)	22(100)
Mean pain score (mean \pm SD)			
Before injection	8.44 \pm 0.69	8.24 \pm 0.427	P >0.05
After 3 weeks	4.6 \pm 1.6	4.76 \pm 1.63	P >0.05
After 6 weeks	2.95 \pm 1.14	3.6 \pm 1.11	P <0.05
After 3 months	1.78 \pm 0.83	2.76 \pm 1.01	P <0.05
Pain relief [n (%)]			
Excellent	4(16)	1(4.34)	5(10.41)
Good	15(60)	3(13.04)	18(37.5)
Fair	4(16)	16(69.56)	20(41.66)
Poor	2(8)	3(13.04)	5(10.41)

Patients between 30-50 years of age reported better pain relief in both the groups. Females had generally better pain relief in both the groups. Amongst the group 1 patients with acute symptoms, majority (61.5%) had good pain relief, with no patient having poor relief. While in group 2 patients with acute pain, 60% had fair results. Amongst those with chronic symptoms, 44.4% had good and 33.3% had fair results in group 1; while majority (72.7%) in group 2 had fair results. In patients suffering from PID, 64.7% of the participants in group 1 had good pain relief, while 73.3% in group 2 reported fair results.

Difference in the number of injections required was significant between the groups; with 84% group 1 participants requiring 2 injections, as opposed to 64% participants in group 2 requiring 3 injections. Only 2 patients each in group 1 and group 2 required referral for surgery.

Study of changes in activity score revealed that 23 (92%) patients in group 1 and 21 (91.3%) participants in group 2 became more active, the difference between groups being insignificant. The sleep quality of those with sleep

disturbances improved in both the groups in almost equal proportion. As for the analgesic medications requirement in the patients taking them before study, 87.5% in group 1 and 71.42% in group 2 no longer required analgesics for back pain by the end of 3 months. Bed rest was also no longer required in 5 out of 6 patients (83.33%) in group 1 and 3 out of 4 patients (75%) in group 2 (Table 2).

Table 2: The overall outcome of patients.

Parameters	Group 1 [n (%)]	Group 2 [n (%)]
Activity Score		
More active	23(92)	21(91.3)
Same level of activity	2(8)	2(8.69)
Less active	-	-
Total	25(100)	23(100)
Quality of sleep (in patients with sleep disturbances)		
Better	10(83.33)	11(84.61)
Same	2(16.66)	2(15.38)
Worse	-	-
Total	12(100)	13(100)
Analgesic Requirement (by the end of 3 months)		
Not required	14(87.5)	10(71.42)
Less	-	2(14.28)
Same	2(12.5)	2(14.28)
More	-	-
Total	16(100)	14(100)

Localised pain was the commonest side effect observed (11 patients each in both the groups). One patient in group 1 had dural tap, which was managed appropriately. No other complications were observed in either of the groups.

DISCUSSION

In the present study conducted over two years, epidural methylprednisolone acetate and triamcinolone acetate were evaluated and compared in 50 patients visiting orthopaedics OPD for their efficacy in back pain and radiculopathy. The age range of 20-60 years was focussed in the present study, as the prevalence of discogenic back pain is more in this age group. The age group was similar to those studied by White AH et al (21-87 years) and Mam MK et al (25-70 years).^{2,9} The male preponderance observed in the present study is also in line with previous evidence.^{10,11}

The distribution of low back pain causing disease entities studied and analysed in the present study i.e., PID (68% in group 1, 64% in group 2), lumbar spondylosis (LS), lumbar spinal stenosis, PID with LS and post spinal surgery back pain were similar to the observations of White AH.³

The pain assessment was done by visual analogue pain scale and there was immediate sense of subjective well-

being and increase in angle of straight leg raising. The groups were compared for duration of back pain and there were no significant intergroup differences there. The pain relief was assessed and classified, as detailed above, at subsequent follow-ups. The categorization of pain relief differed slightly from the one adopted by Goebert HW et al, who had classified results as 'good' (>60% pain relief), 'fair' (40-60% pain relief) and 'poor' (<40% pain relief), and Mam MK et al, who classified results as 'excellent' if patients had complete pain relief, 'good' if there was near complete pain relief, 'fair' if patients had moderately reduced pain and 'poor' for no relief.^{9,11} The mean pain score was observed to be significantly less in group 1 after 6 weeks and 3 months follow-up. Patients between 30-50 years of age and females were the two groups reporting better pain relief in both the groups, which is similar to study by Mam MK et al in which they observed patients in the age group of 41-50 years as well as females as having better results.⁹ The plausible explanation could be the higher tendency of people in this age group to abuse the back and the fact that most of the female participants were housewives with heavy household chores taking toll over the back.

Majority (60%) reported having "good" pain relief in group 1, while as many as 69.56% amongst group 2 participants reported "fair" pain relief. The results were better in the acute cases than recurrent or chronic ones, with majority (61.5%) of the group 1 participants with acute symptoms reported having good pain relief while 60% had fair results among group 2 patients. More than 90% PID patients had excellent to good results in group 1, as against 26.6% in group 2. Hundred percent patients with lumbar spondylosis had excellent results in group 1, while no one from group 2 reported the same. The results are in agreement with the observations of DePalma MJ et al and Goebert HW et al.^{10,11}

The difference between the groups with respect to the number of injections required was highly significant. This may be due to the fact that methylprednisolone acetate is less soluble, less extensively protein bound than triamcinolone acetate. Thus, it is absorbed slowly into the circulation and has a prolonged effect as compared to triamcinolone acetate. The results regarding number of injections are comparable to the findings of Rivest et al and Hickey RF et al.^{12,13} There was overall improvement in the activity score, quality of sleep and decrease in bed rest and analgesic requirement, indicating overall improvement in the quality of life. This is in agreement with the observations of Bush K et al, who had studied similar parameters of quality of life and reported significantly better results with methylprednisolone acetate.¹⁴

The incidence of complications in the present study was relatively less with localised pain being the commonest one and easily ameliorable to a maximum of 3 days of analgesic therapy. The rate of complications, particularly dural puncture and meningitis, was observed to be low in

comparison to previous similar study.^{10,12-15} Only one patient had dural puncture with no long term sequelae.

CONCLUSION

In conclusion, it can be said that epidural steroid therapy is safe and effective and methylprednisolone acetate is more effective than triamcinolone acetate with negligible treatment or technique related complications.

Epidural steroid therapy is highly efficacious and methylprednisolone acetate is more effective than triamcinolone acetate; with negligible complications.

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