EPIDURAL STEROID REDUCES DISCOGENIC PAIN IN ACUTE FLARE UP OF DEGENERATIVE DISC DISEASE WITH MODIC CHANGES THAN CONSERVATIVE MANAGEMENT

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ABSTRACT

BACKGROUND

Epidural Steroid Injection for radicular pain is an Effective method of treatment. No conclusive evidence exists to compare the efficacy of Epidural steroid injections (ESI) and conservative Management in Acute Flare up of Discogenic Pain in Degenerative Disc Disease (DDD).

The aim and objective of the study is to determine the efficacy of Epidural Steroid injections and to compare the outcome with conservative mode of treatment in patients with acute flare up of DDD and to determine whether patients with inflammatory end plate changes are a unique subgroup in terms of treatment response.

MATERIALS AND METHODS

Pain and function in patients with DDD were prospectively assessed in 89 patients for a period of 1year by an outcomes questionnaire (VAS pain score, Oswestry Disability index [ODI]), Use of pain medication and Opinion of treatment success before and after ESI and a course of conservative management. Further correlation was made with end-plate inflammatory (Modic Type 1) changes identified on Magnetic Resonance Imaging (MRI) and compared.

RESULTS

ESI was effective in improving pain and function, as assessed by outcomes scores at short-term follow-up .Patients had significant improvement in the 6 months follow up when compared to conservative group ($p<0.05$). Patients with inflammatory end-plate changes seem to represent a subgroup of DDD patients who respond better to steroid injections.

CONCLUSION

Spinal Epidural steroid injections are low risk and rapid treatment option for acute flare up of Discogenic Pain in DDD. It is beneficial and more effective in patients with Modic type 1 adjacent inflammatory end plate MRI findings when compared to conservative management.

KEYWORDS

Epidural steroid Injections, Degenerative Disc Disease, Modic changes.

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BACKGROUND

Disc degeneration is an important cause of chronic low back pain (CLBP). There are number of mechanisms that are involved, including inflammation and instability. A discogenic aetiology exists in a subgroup of patients suffering with chronic low back pain.[1,2,3,4] In some cases, low back pain may become chronic due to progressive degenerative disc disease (DDD), a condition in which a degenerating disc becomes painful. The pain is thought to be the result of the disc itself rather than of nerve root irritation or impingement.[5] Crock et al[6] also reported a condition that is characterized by internal disruption of the disc, discogenic lumbar pain in the absence of disc abnormality, absence of nerve root compression, and no obvious abnormality seen with computed tomography (CT) or myelography. Signal changes of degenerative lumbar end plates and adjacent bone marrow appeared on magnetic resonance imaging (MRI) were reported at the time of Discogenic pain by de Roos et al.[7] and the disc changes named as end plate Modic changes.[8,9]

Many studies demonstrated a strong linkage between end plate Modic changes and discogenic low back pain.[10,11,12] Modic changes are inflammatory lesions, characterized by vascularized fibrous tissue in Type 1 Modic changes and by high levels of tumor necrosis factor–reactive chondrocytes and nociceptive nerve fibers in both Type 1 and 2. Modic changes are a plausible marker for inflammatory disc pain.[8,9] Treatment for "discogenic" pain is typically conservative but is not successful in all cases. Surgical treatment may also be an option for selected patients; however, the indications vary among spine surgeons and range from performing surgery after only 3 months of failed non-operative treatment to no surgical treatment at all.[13,14,15] Epidural

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steroid is another valuable option for treatment of Degenerative Spine Disease. A number of studies have found improved pain symptoms in the short term, but with longer follow-up, the initial improvement after Epidural Steroid Injections (ESI) deteriorated over time.[16,17] Meta-analysis studies of spinal steroid injections for chronic axial back pain are inconclusive.[13,18,19] Cao's study provides Level 1 evidence that intradiscal steroids are an effective treatment for a subgroup of CLBP patients with Modic changes on magnetic resonance imaging.[4] No conclusive evidence exists to compare the efficacy of Epidural steroid injections (ESI) and conservative Management in Discogenic Pain with Degenerative Disc Disease (DDD). Our Aim of the study is to compare the outcome of Epidural Steroid injections with conservative treatment in patients with acute flare up of DDD and whether patients with inflammatory end plate changes are a unique subgroup in terms of treatment response.

MATERIALS AND METHODS

This clinical study was conducted at the Department of Orthopaedics, Assam Medical College, Dibrugarh from April 2016 to March 2017 on 89 adult patients who presented with low back ache with radicular pain. The trial was conducted after approval by the institutional ethical committee and informed written consent of the patients. Since each patient's allocation was determined in advance by their sequence of presentation, 100 sealed envelopes, 50 for each group, were made and a randomly-selected envelope was opened when the patient presented to our department. 89 patients were included in the study and others were ruled out due to loss of follow up and end of study period.

All patients with lumbar radicular pain, having pre-treatment visual analogue scale scoring of more than 6 and of more than 2 weeks duration, including low back with unilateral or bilateral leg pain, presence of disc degeneration on MRI, either L3–L4, L4–L5, or L5–S1; end plate Modic changes either Type I or Type II at the same level were included in the study.

The exclusion criteria were patients younger than 20 years or older than 60 years, known contraindications for epidural steroid injections, infection, bleeding tendency or malignancy, patient's refusal, previous lumbar epidural steroid injections, previous lumbar spine surgery, neurological deficits, cauda equine syndrome, high inflammatory marker (High ESR and C–Reactive protein) and local skin infection.

After taking their complete history and careful neurological examination, pre-treatment assessment i.e. limitation of activity, SLR (straight-leg raising) test, sensory deficit, sensation in all the dermatomal levels, muscle power of both lower limbs, radiation of pain to right or left leg were noted in all of the patients.

Patients who met the inclusion criteria were allocated into two groups- Group A- (Conservative group) were explained about the nature of disease and need for operative intervention if treatment fails. Patients were allowed to have tablet Tramadol 50 mg twice daily for pain relief till 15 days and if needed further. Pregabalin (75 mg) and Nortriptyline (10 mg) once daily for a period of 06 weeks. Bed rest was initially advised with limited activity for a period of one month. Activity was gradually increased to walking 2-3 hours/day. Lifting of heavy weights and strenuous exercises were forbidden for 3-6 months. Patients were followed after the second week, one month, 3 months and 6 months for VAS Score, ODI (%) and for any side effects of the drugs (nausea, vomiting and Heart burn) during their follow-up visits. Patients were advised to take analgesics, whenever needed after 3 months.

Reduction of visual analogue scale by 50% and reduction in ODI scores less than 20% or reduction in one stage were considered as successfully treated.

Group B - (Epidural Steroid group) were treated with 80 mg of Depomedrol (Methyl Prednisolone) in combination with 3 ml of 2% plain xylocaine and 3 ml of normal saline in the lumbar epidural space. An intravenous line was established, and a blood sample was taken for assessment of baseline of blood sugar. The patient was positioned in a lateral recumbent position with fully-flexed hip and knee joints. The midline approach was used in all 45 patients. The skin was cleaned and draped with antiseptic solution. Skin at the level of pathology was infiltrated with local anaesthetic. An 18-gauge epidural needle (Touhy) was inserted into the skin and advanced while a syringe containing air was attached to it. Epidural space was recognized by loss of resistance technique. The injection site was confirmed by injecting a test dose of 3 ml of 2% lidocaine with evidence of sensory (numbness) or even motor weakness. A solution containing 80 mg Depomedrol (methylprednisolone) and 3 ml of 2% plain xylocaine diluted with normal saline to a total volume of 8 ml was prepared in a 10 cc syringe before the start of the procedure, to be injected into the epidural space. After injecting into the epidural space, the needle was withdrawn, and the patient laid in a supine position for at least 15 minutes. The patient's pulse, blood pressure and oxygen saturation were monitored throughout the procedure and thereafter for half an hour. Blood glucose levels were monitored 24 hours after the procedure and all the patients were screened thereafter for any major or minor complications.

Bed rest was initially advised with limited activity for a period of one month. Activity was gradually increased to walking 2-3 hours/day. Lifting of heavy weights and strenuous exercises were forbidden for 3-6 months.

All patients were followed up using an outcomes questionnaire that included a visual analog scale (VAS, range of 0 to 10) for back pain and referred leg pain VAS; Oswestry Disability Index (ODI). Higher scores for VAS, ODI indicate greater pain severity, worse function or greater pain area, respectively. The survey also assessed the use of pain medication (much more, more, same, less, much less), and overall opinion as to whether patients thought their injection was successful in the treatment of their symptoms. The questionnaires were completed by patients in a prospective fashion at every clinic visit by 1 week, 1 month, 3 months, 6 months from onset of treatment.

Statistical methods Statistical analysis was conducted by using SPSS 11.0 software (SPSS Inc, Chicago, IL, USA). A paired t test was used to compare the pre- and post-injection results of average VAS scores and Oswestry Disability Index measurements at baseline versus 1 week, 1 month, 3 and 6 months. Independent-sample t test was used to detect the difference of VAS pain scores and Oswestry function scores at various time points between subgroups. A $p < 0.05$ was considered statistically significant.

RESULTS

The patient distribution among the groups with or without inflammatory end plates is described in Table 1. VAS scores, ODI (%) scores and intake of pain medication were compared in between two groups.

Of the patients in steroid group (n - 45), nearly seventy percent of the patients expressed a positive opinion and ESI was successful in the treatment of their symptoms during the first 3 months. Over the subsequent follow-up periods, the success rate declined. The use of pain medication (NSAIDs, Narcotics and Anti-depressants) was found generally to have decreased during the follow-up periods. During the first 3- month follow-up, 3 of 45 patients were using more pain medication, 8 were using the same, 30 were using less and 4 considered themselves to have been using much less. The VAS Scores and ODI (%) scores of patients in subsequent follow up is shown in fig. 1 and fig. 2 respectively.

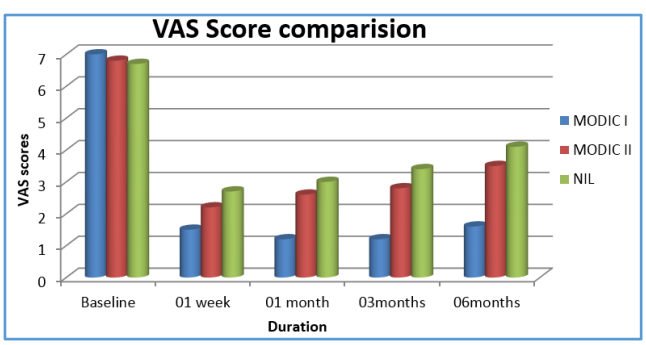

Figure 1. Visual Analog Scale (VAS) in Patients Receiving Epidural Spinal Injection Over Time

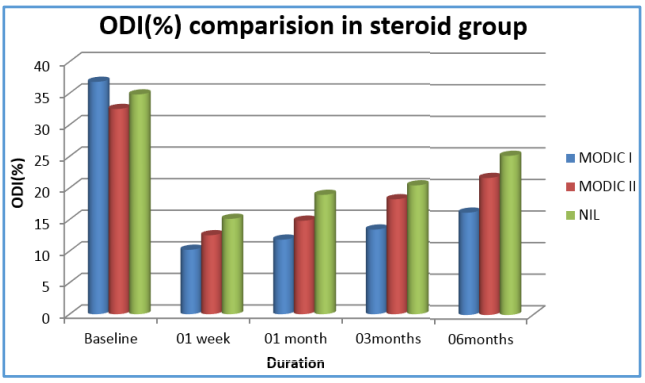

Figure 2. ODI (%) Scores in Patients Receiving Epidural Spinal Injection Over Time

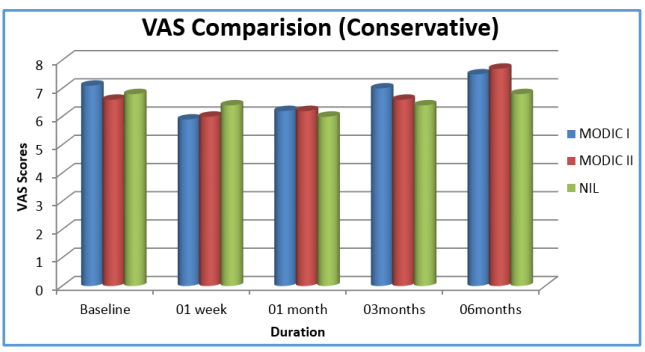

Figure 3. Visual Analog Scale (VAS) of Patients in Conservative Group Over Time

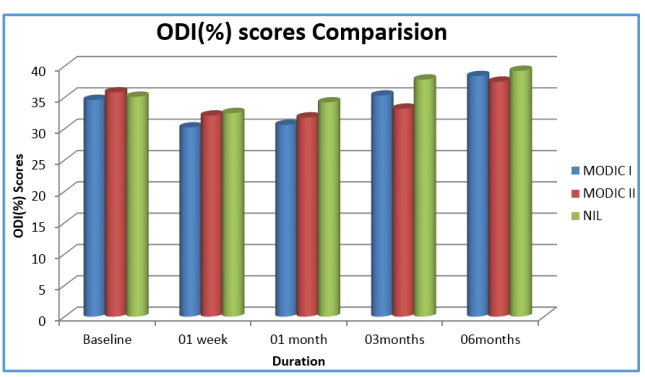

Figure 4. ODI (%) Scores of Patients in Conservative Group Over Time

Group	Inflammatory End Plates		Non Inflammatory End plates	Total
	MODIC I	MODIC II		
Conservative	9	9	26	44
Steroid	9	9	27	45
Total	18	18	53	89

Table 1. Distribution of patients among groups with respect to end plates and Treatment modality

CLINICAL OUTCOMES		CONSERVATIVE			STEROID		
		MODIC I	MODIC II	NIL	MODIC I	MODIC II	NIL
	Baseline	7.1	6.6	6.8	7	6.8	6.7
	01 week	5.9	6	6.4	1.5	2.2	2.7
VAS	**01 month**	6.2	6.2	6	1.2	2.6	3
	03 months	7	6.6	6.4	1.2	2.8	3.4
	06 months	7.5	7.7	6.8	1.6	3.5	4.1

	Baseline	34.6	35.8	35.1	36.8	32.5	34.8
	01 week	30.2	32.1	32.5	10.2	12.5	15.1
ODI %)	**01 month**	30.6	31.8	34.2	11.8	14.8	18.9
	03months	35.3	33.2	37.84	13.4	18.2	20.4
	06months	38.4	37.5	39.24	16.2	21.7	25.2

Table 2: The Mean values of VAS Score and ODI (%) in Conservative and Steroid groups

A comparison of the two ESI subgroups (inflammatory versus non-inflammatory end plates) revealed greater improvement for ODI scores for the patients with inflammatory end plates at follow-up periods.

Of the patients in conservative group (n - 44), nearly thirty percentage of the patients expressed a positive opinion and conservative management was successful in the treatment of their symptoms during first week in 30 patients and 6 patients in first month follow up, then declined further. During the first 3- month follow-up, 35 of 44 patients were using more pain medication, 6 were using the same, 3 were using less pain medications when compared to time of presentation. The VAS Scores and ODI (%) scores were compared and shown in fig. 3 and fig. 4 respectively. The mean values of scores in different sub groups are listed in table 2.

On statistical analysis, P value was significant ($p<0.05$) in Steroid group patients in 1 week, 01 month and 03 month when compared to Baseline values of VAS Score and ODI (%). Patients with Modic Type I changes had significant pain relief with Epidural steroid when compared to Conservative management. Patients without inflammatory endplate changes benefited with steroid therapy for 1 month and in subsequent follow ups, p value (>0.05) was not significant.

DISCUSSION

This study compared the efficacy of conservative management and ESI in patients with low back ache of acute presentation due to DDD and demonstrated that ESI have short-term benefit in discogenic pain mostly in patients with inflammatory end plate changes (mainly in Modic I). Initially, more than 70% of patients had decreased pain and improved function in ESI group. Patients who responded usually within weeks of the injection; of these, one-fourth to one-third had lasting improvement.

Injections were performed in the epidural space, which would presumably affect the posterior longitudinal ligament and posterior annulus fibrosis. The effectiveness of spinal steroid injections may be limited not only by the dosage applied but by whether the therapeutic agent disperses by spreading longitudinally within the epidural space. Basic scientific studies have identified enzymes and inflammatory mediators in degenerated disc tissue specimens. Thus, one can rationalize the use of steroids because of their anti-inflammatory properties in the treatment of discogenic pain.[13,20,21]

Specifically, disc specimens have been found to contain elevated levels of enzymes capable of degrading protein within the disc, such as enzymes and inflammatory mediators in degenerated disc tissue have also been found to be elevated. This inflammatory process may then stimulate neural pain elements in the periphery of the disc or posterior longitudinal ligament by means of tears in the annulus, which may then contribute to low back pain. If these factors act on noxious pain-generating nerve endings, pain transmission will start. Evidence suggests not only nerve in growth into the annulus by means of the tears, but pain may also be the result of disruption (eg, fissures) of the vertebral end plate, which may allow inflammatory agents to act on vertebral interosseous neural receptors.[22,23]

The current study focused on whether this MRI finding of inflammatory end-plate changes and if ESI could reduce pain in this subgroup of patients with DDD. This study has also so many limitations like small number of patients, lack of randomization and short follow up period to conclude about the efficacy of steroids. Even if only a minority of patients receives a beneficial effect from spinal injections, because of their low complication rate, spinal injections are an attractive treatment option before surgical intervention

Patients with inflammatory end-plate changes seem to represent a subgroup of DDD patients respond more favourably to steroid spinal injections than conservative management though there was small number of patients in our study. In this subgroup, ESI were considered successful in approximately 70% at 1 month follow up and about 40% in 6 months follow up.

Fayad et al.[24] observed the clinical response to intradiscal injection of corticosteroids in a total of 74 patients with low back pain and inflammatory Modic changes who showed no response to the 3-month conservative treatment. They found that pain was significantly relieved in patients with more end plate Modic changes at 1 month after intervention. The therapeutic efficacy remained after 3 and 6 months but without significant difference.

Intradiscal steroid injection could be a short-term efficient treatment for patients with chronic low back pain and predominantly inflammatory end plate changes when conservative treatments have failed.[13]

Recent studies have shown that the types of Modic changes are interchangeable. In the follow-up of lumbar spine end plate Modic changes, Kuisma et al.[25] found that at 3 years, 10 of 70 discs with Modic changes at baseline displayed another type.

Marshman et al.[26] also reported reverse transformation of Modic changes Type II to Modic changes Type I during sustained chronic low back pain. Therefore, Modic change Type I or Type II may represent a certain phase of a continuous process of end plate pathology. Meanwhile,

Mitra et al[12] pointed out that Modic changes Type I were dynamic lesions that either increased in size or converted to

Type II in most cases and evolution of Type I change related to change in patient's symptoms.

CONCLUSION

Spinal Epidural steroid injections are low risk and rapid treatment option for acute flare up of Discogenic Pain in DDD. Patients with inflammatory end-plate changes seem to represent a subgroup of DDD patients; ESI is beneficial and more effective in patients with Modic type I adjacent inflammatory end plate MRI findings when compared to conservative management.

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