

A Self-Controlled Prospective Study between Methylprednisolone and Dexamethasone Inter-Laminar Epidural Steroid Injection in Radicular Pain for Prolapse Intervertebral Disc in Lumbar Vertebrae

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Abstract

Background: Previous studies have shown varying results with trans-foraminal approach epidural steroid injections performed with particulate versus non-particulate corticosteroids. The purpose of this study was to investigate the difference in pain relief and functional improvement between particulate and non-particulate lumbosacral (MIL) in patients who had undergone both injections through intra-laminar approach. Method: This was a self-controlled, prospective study of 40 patients who underwent both a methylprednisolone and a dexamethasone intra-laminar injection to the same vertebral level and side. Primary outcomes included pain relief according to the visual analogue scale (VAS) and functional improvement determined by a yes/no answer to questions regarding mobility and the activities of daily living. Post-injection data was recorded at 6, 12, and 24 weeks. Results: A decrease in VAS scores of -3.6 ± 3.1 , -3.2 ± 3.2 , -3.1 ± 3.1 is noted in methylprednisolone group as compared to better VAS score projected in patients with dexamethasone group as suggested -3.9 ± 3.2 , -3.1 ± 2.9 , -2.2 ± 3.2 at 6 weeks, 12 weeks and 24 weeks respectively. Conclusions: Findings positively supports the use of non-particulate steroids for lumbar prolapse inter-vertebral disc with radicular pain in contrast of safety use of particulate steroids for one of treatment modality in dealing with localized or radicular pain.

Keywords: Corticosteroids; Methylprednisolone; Dexamethasone; Epidural Injections; Low Back Pain; Radiculopathy.

Introduction

Lower back pain is considered to be the most commonest complaint of patients coming to the

orthopaedic OPD. Pain also impairs day to day living causing economical loss and lessens the quality of life. For lower back pain many treatment modalities have been come into implementation to overcome this problem. Epidural steroid injection has been considered as one of the modalities for pain management. Steroidal base in both particulate and non-particulate forms are used for pain relief. By local infiltration of steroids in epidural format shows a promising result in past. Epidural injections show an effective treatment for radicular pain¹⁻⁶. Particulate corticosteroids have a larger size ranging from

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(0.5-100 µg)⁷ and therefore it had lesser water solubility and they potential aggregate in crystalline hydrophilic environments. Some of these are prednisolone Acetate, methylprednisolone acetate, acetonidobetamethasone to triamcinolone acetate. Where as non particulate corticosteroids like dexamethasone are of profound smaller in size (0.5 µg)⁷ and water soluble due to their easy solubility property and hence do not aggregate. The safety use of particulate corticosteroids for epidural steroid injections is still uncertain because of many complications reported in past referral studies due to blockage of radiculomedullary arteries^{8,9} causing paraparesis or quadriparesis, paraplegia or quadriplegia, stroke, and even death¹⁰⁻¹⁷. Pathophysiology behind these absurd complications is still under evaluation and thought to be due to larger size molecules and less water solubility. U.S. Food and Drug Administration (FDA) in 2011 stated in public safety the use of drug triamcinolone acetonide is hazardous causing various complications like spinal cord infarction, paraparesis/paraplegia, quadriparasis/quadruplegia/stroke and even death in certain cases reported in association with steroid administration through epidural and intrathecal routes.

Some surgeons still the use of particulate corticosteroids for epidural steroid against cases reported by FDA complications arising. Some studies suggest amblozationtheoryand attributing complication of poor spinal needle placement¹⁸ In spite of above complication few studies suggested in pain relief for a longer duration with particulate corticosteroids¹⁹⁻²¹. The aim of study is to detect superior pain relief at follow up of 24 weeks post epidural injection with use of both types of corticosteroids

Materials and Method

It is a self control prospective study conducted in the department of Orthopaedics Datta Meghe maghe Medical College at Shalinitai Meghe Hospital and Research Centre, Nagpur in collaboration with JNMC DMIMS, Between July 2019 to April 2020. All the patients with single level PIVD with radicular pain had under-gone intra laminar epidural steroid infiltration. Inclusion criteria for this study includes patients ages more then 18 years of age, sign and symptoms suggestive of PIVD with radicular pain confirmed on MRI scan, history of no past epidural steroid infiltration given within 6 months. Patients with any past spinal surgery were excluded from this study. All patients undergone epidural steroid infiltration randomly basis with use of

either particulate or non-particulate steroid which later have been followed up at 6 weeks, 12 weeks, 24 weeks. At follow up functional data is collected from patients with the help of VAS score in view of pain assessment and simple yes/no questionnaire basis to assess the patients over all mobility and daily functional activity with use of either type of medication.

Procedure is performed by single doctor by safe triangle approach for epidural infiltration. A 12.7 cm long 22 gauge spinal needle used. After local infiltration with 4ml of 1% lidocaine hydrochloride, spinal needle placed at 4 o'clock position. A total mixture of 3 ml consisting of 2ml of 1% lidocaine mixed with either 40mg methyl prednisolone acetate or 1 ml of 10mg dexamethasone sodium phosphate is injected. Post op patients is hydrated with 2 units of ringer lactate or normal saline and later patients were kept under observation to watch out any development of complications for 24 hours post infiltration.

Results

A total of 40 patients were included in this study according to the inclusion criteria. All patients had come to orthopedic opd with complains of lower back pain with lower limb radiculopathy. All cases were diagnosed on MRI were central and paracentral disc with foraminal stenosis. On basis of stenosis patients were divided in mild (4/40), moderate (16/40), severe (20/40) groups. Patients with age group ranging from 63 +/- 16 years (methyl prednisolone group) versus 65 +/- 16 years (dexamethasone group) is included. Out of 40 patients, 28 were males and 12 were females with an average duration of symptoms of ranging from 5 years +/- 1. Pre injection VAS noted for both groups with mean values of 8.2 +/- 0.8 for methyl prednisolone group in comparison to 7.9 +/- 1.1 for dexamethasone group. Post injection opioids with was given for 3 days for extended pain relief.

The presentation of pre epidural and post epidural mean scores according the VAS score. The slop of the particulate steroid at 12 week was lower as compared to non-particulate steroid, but at 24 week both steroid show almost similar VAS score mean value.

Results shows changes in mean VAS score for both the groups at different intervals of follow up. A decrease of -3.6 +/- 3, - 3.2 +/- 3.2, -3 +/- 3.1 is noted in methyl prednisolone group as compared to better VAS score in patients with dexamethasone group as suggested -3.9 +/-

3.2,-3.1 +/- 2.9,- 2.2 +/- 3.2 at 6 weeks, 12 weeks and 24 weeks respectively. As suggested by the figures calculated the mean VAS scores is nearly equivalent in both group types of medication at any given point of time of follow up. Both the group shows improved functions at final follow up as compared to pre injection state.

Discussion

Aim of study to differentiate in terms of pain relief and function outcome by using corticosteroids i.e. particulate and non-particulate by using epidural steroid infiltration by intra laminar route. The primary outcome of our study show similar result in term of pain relief and functional betterment at end of 24 weeks. Few studies in past showed similar result between the two group in literature. One of the study conducted by Dennis et al²² concluded in his double blind randomized control trail(RCT) that there is no significant difference in functional outcome when patient treated with 7.5 mg of dexamethasone and 6 mg of betamethasone. Study showed significant change in VAS score and showed the promising result on basis of Oswestry disability index (ODI) showing statistically improvement by patient treated with dexamethasone group at 6 months follow.

Kennedy et. Al²³ also conducted a double blind RCT in 78 patient grouped in two treated with 15 mg of dexamethasone and 60mg of tramcinolone acetamide given by trans-foraminal route suggested no significant difference in terms of VAS score which showed clinical improvement in pain relief at the end of 6 months. Park et al²⁴ also conducted an RCT in 106 patients treated with either 40mg tramcinolone acetamide or 7.5mg dexamethasone showed clinical improvement on VAS score and McGill pain questionnaire as well as functional improvement as per ODI scoring. Study showed better results in particulate group as compared to non particulate group in accordance to VAS score at final follow up.

El-Yahchouchi et al²⁵ conducted a retrospective study in 2,634 patients who has been admitted with radicular pain and divided these patients into three groups treated with trans-foraminal epidural injection of 10mg dexamethasone, 80mg tramcinoloneacetamide and 12 mg betamethasone respectively. When patients follow up conducted showed a better pain relief and functional improvement by Numerical Rating scale (NRS) and Roland Morris disability questionnaire (R-M) in group treated with dexamethasone.

As our study conducted to compare the effectiveness of particulate and non particulate epidural steroid infiltration through inter laminar route shows a promising result in pain relief for radiculopathy. With few study in past literature have better functional outcome and clinical improvement from pain when treated with trans-foraminal epidural infiltration. Though the result of studies may show a difference in pain relief or duration of relief at any follow up it is important to note a varied clinical improvement in daily living and activity in subsequent follow ups post injection when compared to pre injection state. In this study statistically we noted there is no major significant difference in pain relief at final follow up done at 6 months but dexamethasone group showed a upper hand in relieving patient from pain when compared mean values of VAS scores and functionally assessing clinically showed a better daily living activity. But while considering safety of non – particulate steroid infiltration noted in literature, our study strongly suggest the use of non particulate steroid for treating radicular pain for upto 6 months and further follow up is needed to certain the final outcome of use of this treatment modality.

Few limitations of this study is small sample size and increased rise of selection bias is inherited. And also use of any statistical analysis is not taken into account for assessing functional outcome but considering any modality for this purpose would not solve any change in result even after enrolling a larger sample size. This study demonstrate a good efficacy with use of 10mg dexamethasone injected for relief of radicular pain and shows a good functional result in pleasuring daily living activity at 24 weeks of follow up. These findings positively supports the use of non-particulate steroids for cervico- lumbar prolapse inter-vertebral disc with radicular pain in contrast of safety use of particulate steroids for one of treatment modality in dealing with localized or radicular pain.

Conclusions

Findings positively supports the use of non-particulate steroids for lumbar prolapse inter-vertebral disc with radicular pain in contrast of safety use of particulate steroids for one of treatment modality in dealing with localized or radicular pain.

Ethical Clearance: Taken from institutional ethics committee.

Source of Funding: Self.

Conflict of Interest: Nil.

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