

Comparison of Lumbar Transforaminal Epidural Dexamethasone and Triamcinolone for Lumbar Radiculopathy

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ABSTRACT

BACKGROUND

Epidural blockade is becoming one of the most useful and versatile procedures in modern anaesthesiology. What is unique is its application to clinical practice, as it can be placed virtually at any spinal level of vertebral column that allows considerable flexibility. Epidural steroid injections through lumbar transforaminal route to treat pain in lower back where radiculopathy is also associated with, are used widely. It has been reported that these procedures in lumbar spine are effective clinically for improved physical function in patients as well as relief of pain of short- and long-term duration. We wanted to determine as to whether there is a difference in the efficacy between nonparticulate (e.g. dexamethasone phosphate) and particulate (e.g. triamcinolone acetate) steroids in Lumbar Epidural via transforaminal approach for acute radicular pain in lumbar region and adverse effects of the drugs if any.

METHODS

66 patients, 33 in each group, with dexamethasone phosphate 8 mg or triamcinolone acetate 40 mg for lumbar transforaminal approach epidural steroid injection, were randomized. Observation was done through visual analog scale, short McGill pain questionnaire, revised Oswestry Disability Index before intervention and a month later.

RESULTS

A difference which was significant statistically in the visual analog score (2.85 ± 0.83 in group T, 5.76 ± 0.75 in group Dx), McGill Pain Questionnaire (3.73 ± 1.15 in group T, 6.55 ± 0.51 in group Dx) and Oswestry Disability Index (18.67 ± 7.13 in group T, 35.83 ± 5.10 in group Dx) was found in both but was more in triamcinolone group.

CONCLUSIONS

Efficacy is more in particulate (triamcinolone) than non-particulate (dexamethasone) in epidural injection through lumbar transforaminal with no drug related complication, performed for radiculopathy in lumbar region.

KEY WORDS

Corticosteroid, Dexamethasone, Lumbar Radiculopathy, Transforaminal Epidural Injection, Triamcinolone

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BACKGROUND

Pain is defined as “an unpleasant sensory and emotional experience associated with potential or actual tissue damage or described in terms of such damage” by the International Association for the Study of Pain (IASP).¹ The nerve roots during the process of exit from the spinal column if compressed, pain which occurs may be referred towards inferior extremity. This is the condition being noted as lumbar radiculopathy.² The term lumbosacral radiculopathy describes a syndrome of pain which can be caused by irritation or compression of nerve roots due to degeneration of the vertebral spine, herniation of lumbar disc and narrowing of the foramen from where the nerves exit the spinal canal in the lower back. Any process which causes irritation of the spinal nerves, however, can cause symptoms of radiculopathy which may include low back pain that radiates in a dermatomal pattern into the lower extremities. Other symptoms which can accompany are weakness, numbness, abnormalities in gait and loss of reflexes. This disorder causes pain in the hip and lower back radiating down the back of the thigh into the leg. Radiculopathy (lumbar-sacral radiculopathy) is most common in the lower back but can occur in any part of the spine.

The health problem of backpain with radicular component affecting male and female in general population is quite significant. An incidence of 3 % to 5 % of patient population has been reported with lumbar radiculopathy.³ The compression of the nerve roots while exiting L1 - S4 spinal levels is one of the causative factors of pain due to lumbar radiculopathy which creates ectopic nerve signals due to the release of noxious stimulus from a spinal nerve. This can result in numbness, tingling, paraesthesia, occasional shooting of pain, also radiation of pain. Depending on the affected nerve root (s) corresponding to the dermatome or myotome, patients can present with predictable patterns of symptoms.

Inflammation and injury of spinal nerve root can also cause the disease. Treatment options in a stepwise approach include conservative management, epidural steroids and surgery. Conservative management consists of exercise, weight reduction, physiotherapy and medication.

The patients who do not respond to the management conservatively,⁴ epidural steroids are tried. The idea behind the administration of steroids epidurally is to produce higher concentrations locally at the inflamed nerve root and also at other areas of inflammation in the spinal canal.

Steroid causes decrease in pain as the inflammation along the nerve affected gets reduced, ectopic discharge is repressed and flow of blood to the ischemic nerve root gets enhanced. The three most common methods of epidural routes are via the approach of interlaminar, transforaminal and caudal.

To relieve pain in leg and / or back and improve mobility without surgery in patients, glucocorticoid injections via epidural route are commonly given. After other conservative (non-surgical) treatment approaches fail and / or to avoid a surgical attempt, these steroid injections allow healing to occur by buying time. Two types of preparation of steroids used in the epidural injection are non-particulate like dexamethasone and particulate such as triamcinolone, betamethasone and methylprednisolone. To have a longer duration of action, the particulate group of steroids must undergo hydrolysis for lowering their solubility. The particulate steroids, due to a depot effect locally, release the

active form of drug continuously over a prolonged period of time from the injection site.⁵

On the other hand, the non-particulate steroids are small sized particles, water soluble having limited aggregation property⁶ which causes a duration of action for a short period and a quick clearance from the spinal canal.⁷ Complications of the drugs are generally not there but may cause headache, changes in B.P., irritation at the needle injection site, bleeding and infections. Steroids while used via epidural route commonly does not cause a rise in the level of blood sugar, B.P. or swelling of lower limb. Paraplegia, a vital complication, due to injury to a nerve root is not frequent. Epidural technique if applied with a blunt needle, may reduce the risk of this complication.

So, we anticipated a relief of symptoms of long duration in patients who received epidural injection with particulate steroids than those who received non-particulate steroids.

We wanted to determine as to whether there was any significant difference in the efficacy of non-particulate versus particulate corticosteroid and any complication occurred related to the drugs in lumbar transforaminal epidural injection to treat low back pain due to lumbar radiculopathy

METHODS

The present prospective randomized control study was carried out in the DMIMS School of Advanced Studies, Department of Anaesthesia Jawaharlal Nehru Medical College & Acharya Vinoba Bhave Rural Hospital, Wardha, Maharashtra during the period 2018 - 2019, having taken prior permission from the Institutional Ethical Committee.

Inclusion Criteria

1. age between 18 and 80 years,
2. either gender
3. who had failed conservative treatment for lumbar radiculopathy
4. willing for lumbar (Transforaminal Epidural Steroid Injection) TFESI for radicular pain in lumbar region,
5. diagnosis clinically based on pain distribution and compression of nerve root in MRI.

Exclusion Criteria

1. previous lumbar spine surgeries
2. disease of degeneration of spine
3. steroid medication used chronically through oral, peripheral or epidural route in the previous three months
4. allergy to myelographic contrast, steroid and local anaesthetic.

Patients were allocated randomly into two groups of 33 each (group Dx and T) based on random number table generated through computer. #Group Dx (33 subjects) – Fluoroscopically guided transforaminal dexamethasone 8 mg epidural steroid injection #Group T (33 subjects) – Fluoroscopically guided transforaminal triamcinolone acetate 40 mg epidural steroid injection. Informed written consent

taken. Before giving epidural injection, baseline pain score was recorded by McGill pain questionnaire⁸ and functional assessment done using the Revised Oswestry Disability Index (RODI).⁹

Sample Size Calculation

OpenEpi.com was used for calculation of sample size. Keeping the confidence interval at 95 % (α error at 0.05), power at 80 % and assuming the effectiveness (VAS Score) of non-particulate corticosteroid 7.4 ± 1.4 as per a previous study⁷ to assess the efficacy of particulate and non-particulate corticosteroids a sample size of at least 54 patients would be required. We included 66 patients to compensate for possible dropouts.

Procedure

Patients who fulfil the inclusion criteria for the study and confirmed nil by mouth (NBM) of 8 hours was accepted in the operating room. An intravenous cannula of 18 G was secured over the flexor aspect of forearm and normal saline / ringer lactate fluid infusion was started at the rate of 15 - 20 ml / kg. The patient was attached to all the routine monitors and baseline readings were recorded. Standard anaesthesia monitoring was done which includes:

- *heart rate, *respiratory rate, *systolic, diastolic blood pressure, *mean arterial pressure, *SPO2 (Saturated Percentage of Haemoglobinated Oxygen) with pulse oximetry, *Electrocardiogram

Before giving epidural injection, baseline McGill pain questionnaire for pain score and Oswestry Disability Index for functional assessment were recorded. With all aseptic precautions, local infiltration lignocaine 2 % 2 ml given. The same anaesthesiologist performed all injections to avoid any discrepancy. Prone position placement was given to each patient. With all sterile preparations, draping and local anaesthetic injection, a spinal needle of length 3.5 inch, gauge 23 had been advanced cautiously under fluoroscopic (real-time x'ray) guidance towards the oblique view of the 'safe-triangle' which is formed by the lateral border of the body of vertebra, the pedicle which forms the roof of the triangle, a tangential base corresponding the nerve root exiting. Proper placement of needle was confirmed by fluoroscopic projections of both anteroposterior and lateral aspect. This technique applied, causes the drug glucocorticoid to be injected nearer to the irritated nerve root than the conventional approach where epidural via interlaminar route was used. The technique we adopted, has minimal exposure to radiation.

The position of needle was confirmed by injecting contrast dye (iohexol) of 0.5 mL at each level. Using real-time fluoroscopy, documentation was done once an adequate flow of contrast dye was seen to the area targeted, neither cerebrospinal fluid nor blood could be aspirated, the anaesthesiologist then injected the study group steroid allocated, diluting it with 1 mL of lignocaine 1 %.



Figure 1. Image-Position of Patient during the Procedure

Epidural Transforaminal Injection

An epidural through transforaminal approach or SNRB (Selective Nerve Root Block) is done under x-ray guidance, with an injection of a steroid diluted with local anaesthetic into the area where the nerve exits the spinal column.

Statistical Analysis

All the data was expressed as mean + SD. Statistical analysis was performed with software program SPSS version 17.0 for analysis of demographic data and comparison of groups, x2. Unpaired student's t-test and paired-t-test was applied. P < 0.05 was considered as statistically significant (S), p > 0.05 statistically not significant (NS).

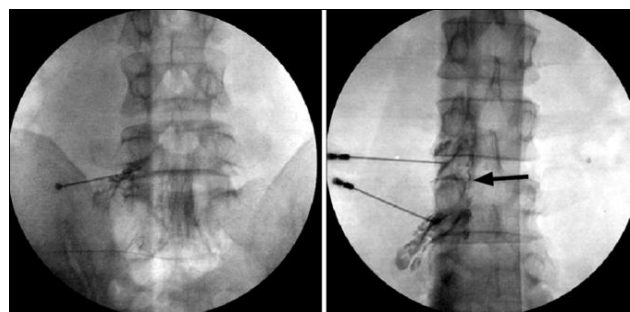


Figure 2. A B

- A. Antero-Posterior View**
Conventional approach of epidural steroid injection at the level of L5 - S1 via transforaminal route.
- B. Anteroposterior View**
Supplementary preganglionic approach of epidural steroid injection [arrow indicates preganglionic flow] at the level of L3 - 4 and L4 - 5 via transforaminal route after the intervention, the patient was observed for 2 hrs. if any complication there and was asked to come 4 weeks later for a check-up. McGill Pain questionnaire used for pain assessment, Oswestry Disability Index (ODI) for functional assessment.

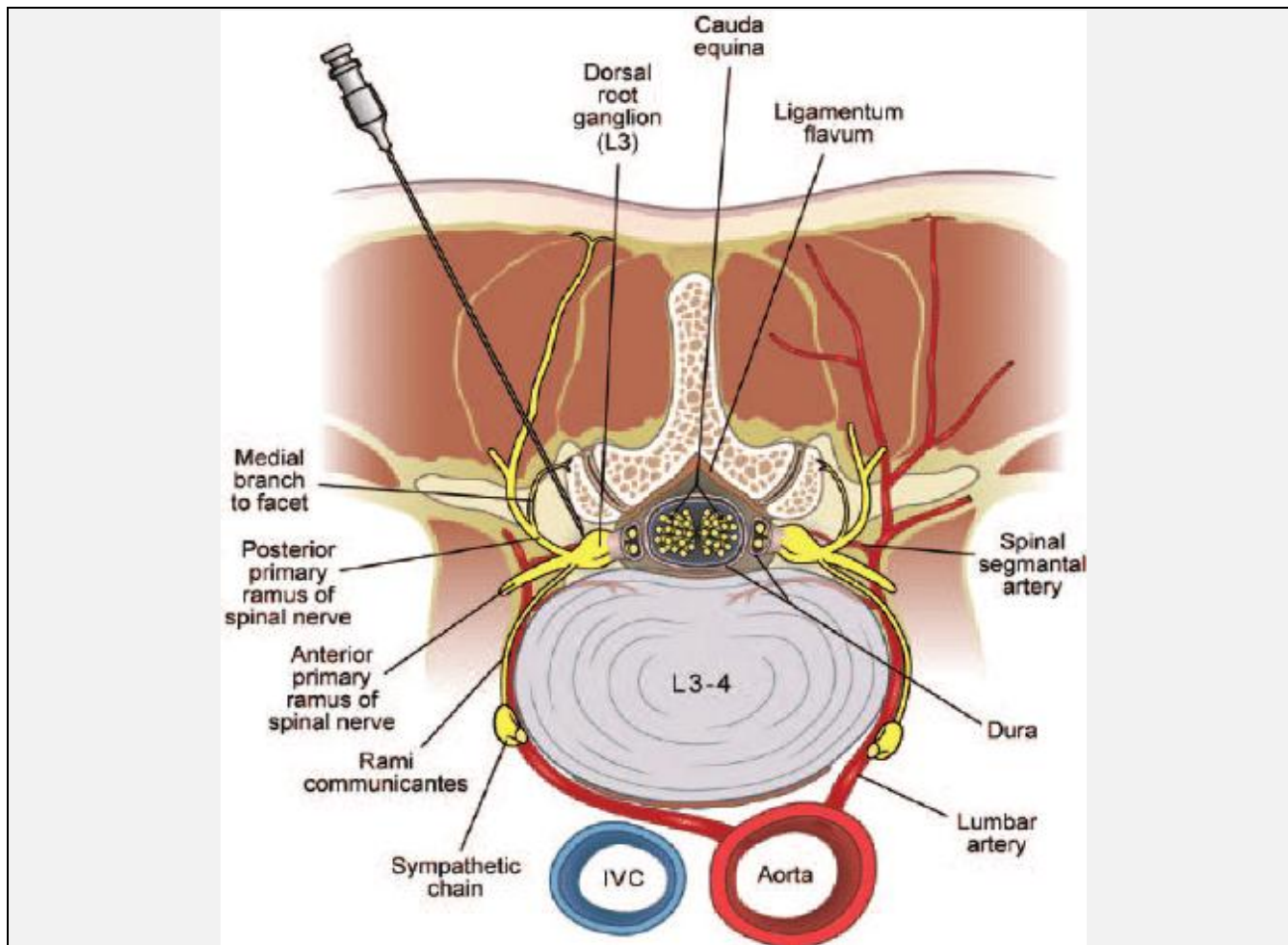


Figure 3. Axial View of Selective Nerve Root and Lumbar Transforaminal Epidural Injection for Transforaminal at Right L3 / L4, the Anatomy as well as Proper Needle Position (Axial View) Depicted. 10 Inferior Vena Cava [IVC] ¹⁰

RESULTS

Variables	Triamcinolone (N = 33)	Dexamethasone (N = 33)
Age (Yr.)	45.48 ± 14.73	49.27 ± 13.18
Male	59.2 ± 13.4	58.4 ± 17.6
Female	63.1 ± 9.1	53.1 ± 12.1

Table 1. Patients' Demographic Data in the Study Groups T and Dx

Demographically, the two groups of 33 patients each were not significantly different in respect to age and gender.

Variable	Group T			Group Dx			P Value
	N	Mean	± S.D.	N	Mean	± S.D.	
1 VAS Score BASELINE	33	8.21	0.86	33	8.24	0.90	> 0.001, NS
2B After 1 Month of Epidural	33	2.85	0.83	33	5.76	0.75	< 0.001, S

Table 2. Comparison of VAS Score in Group T and Group Dx

	Group T		Group Dx		N	P value
	Mean	± SD	Mean	± SD		
1 Baseline	8.61	0.61	8.61	0.61	33	> 0.001, NS
2 After 1 Month	2.70	0.81	5.09	0.80	33	< 0.001, S

Table 3. Comparison of Sensory Descriptor between Group T and Group Dx

The baseline VAS score was 8.21 ± 0.86 in group T and 8.24 ± 0.90 in group Dx showing insignificant difference statistically. After 1 month of intervention VAS score was 2.85

± 0.83 in group T and 5.76 ± 0.75 in group Dx which was statistically significant.

The baseline of sensory descriptor of McGill pain score was 8.61 ± 0.61 in group T and 8.61 ± 0.61 in group Dx with insignificant difference statistically. 1 month after intervention the score was 2.70 ± 0.81 in group T and 5.09 ± 0.80 in group Dx. The difference was statistically significant.

		Group T		Group Dx		N	P Value
		Mean	± SD	Mean	± SD		
1	Baseline	2.67	0.69	2.61	0.61	33	> 0.001, NS
2	After 1 Month	1.03	0.77	1.48	0.51	33	< 0.001, S

Table 4. Comparison of Affective Descriptor between Group T and Group Dx

		Group T		Group Dx		N	P Value
		Mean	± SD	Mean	± SD		
1	Baseline	69.36	7.68	70.12	6.42	33	> 0.001, NS
2	After 1 Month	18.67	7.13	35.82	5.10	33	< 0.001, S

Table 5. Comparison of RODI between Group T and Group Dx

The baseline of affective descriptor of McGill pain score was 2.67 ± 0.69 in group T and 2.61 ± 0.61 in group Dx with no statistically significant difference. 1 month after intervention the score was 1.03 ± 0.77 in group T and 1.48 ± 0.51 in group Dx having a statistically significant difference.

The baseline of score of RODI was 69.36 ± 7.68 in group T and 70.12 ± 6.42 in group Dx with no statistically significant

difference. 1 month after intervention the score was 18.67 ± 7.13 in group T and 35.83 ± 5.10 in group Dx with a statistically significant difference.

DISCUSSION

In India very commonly, more than 1 crore patients per year do suffer from severe pain from the lower back to the buttocks and leg that radiates along the sciatic nerve pathway. Pinched nerve, also referred to commonly as radiculopathy, is a set of conditions in which one & / or more nerves can be affected and cause neuropathy as the nerves do not work properly. As a result, there can be (radicular pain) pain, numbness, weakness, & / or difficulty in controlling some specific muscles.¹ Most often, radiculopathy is caused when a nerve root gets compressed mechanically usually at its exit from foramen or lateral recess of spine. Radiculopathy may also occur secondary to degenerative disc disease, degeneration or hypertrophy of facet joint, osteoarthritis, spondylolisthesis, hypertrophy of ligaments or a combination of all these factors.¹¹ Epidural steroids are used to treat radicular and other pain originated from of spine due to inflammation arising from the cervical, thoracic and lumbar spine.

Studies have been undertaken about various steroid preparations regarding the microscopic size of the particles.^{7,12} Tiso et al¹³ found that the particles of dexamethasone and betamethasone were like a rod in shape, lucent, having lowest density and least tendency for aggregation with size of a particle of less than 5 μm . The particles of triamcinolone and methylprednisolone were amorphous, opaque and congregate into bigger particles of size more than 100 μm . This size of particles could obstruct capillaries of diameter 5 – 8 μm , metarterioles of diameter 20 – 50 μm and even arteries of diameter > 50 μm at times, which might cause infarction of that artery supplying the neural tissue. Steroid particles of size greater than 1000 μm cause faster precipitation as noted by Benzon et al,⁷ who also found that before administration of the steroid, shaking of the solution resulted in formation of small sized particles which aggregated into a bigger size and then got precipitated. Thus, on entering the vessel it becomes possible for any steroid particle to occlude any size of a blood vessel. The use of dexamethasone, on the other hand, did not have any report of serious neurological complication. However, its effectiveness is limited in patients with radiculopathy. Triamcinolone preparations have a particle of intermediate and betamethasone has the smallest size of the particulate steroids.¹³ Steroid preparations of dissimilar types have different physicochemical properties which may lead to unanticipated side-effects and outcomes.

While expressing the results of our study, the demographic distribution in group Dx and Group T was found to be statistically insignificant. (Table 1) Table 2 in our study presented the values of VAS pain scores ($M \pm SD$) before the treatment which was found to be statistically insignificant between the groups. Significant improvement in pain relief was obtained in both the groups after 1 month of epidural injection. But the (particulate) triamcinolone group had better outcome than dexamethasone (nonparticulate) group. The baseline McGill pain score ($M \pm SD$) between the two groups

was too insignificant statistically. 1 month after intervention the score among the groups was found to be significant statistically (Table 3, 4). Functional improvement after 1 month of transforaminal epidural injection observed was significant in both the groups though more in triamcinolone group than dexamethasone group by using RODI. (Table 5) The first randomized controlled trial of the comparison between dexamethasone and triamcinolone for pain of lumbar radiculopathy following TFESI by Park et al¹⁴ in 2010, in 106 patients stated that decrease in visual analog scale, was significant statistically in triamcinolone as compared to dexamethasone. However, as per the McGill Pain Questionnaire or the ODI, there was insignificant difference between the study groups even after the treatment and follow-up of 1 month. In our study also triamcinolone group had statistically significant improvement compared to dexamethasone. In 2016, Jeetinder Kaur Makkar, Preet Mohinder Singh, Divya Jain et al,¹⁵ found improved VAS score of statistical significance, while conducting a study on non-particulate vs. particulate steroids for epidural injections via transforaminal route which was more with particulate steroid. This was similar to our study (Table 2).

David J. Kennedy, Christopher Plataras, Ellen Casey¹⁶ in 2019 used transforaminal particulate (triamcinolone) 40 mg and nonparticulate (dexamethasone) 7.5 mg for lumbar radiculopathy patients, studied at 2 weeks, 3 months, and 6 months and found statically significant improvements in pain and function with both triamcinolone and dexamethasone with no apparent difference between the groups. In our study, statically significant improvement was found in both the groups, but more significant improvement was in triamcinolone group than the dexamethasone group. Kim et al¹⁷ found a small reduction in VAS ($M \pm SD$) comparing the particulate group (- 27.2 %) vs. non-particulate group (- 19.7 %) which supports our study. In 2020, Christine El-Yahouchi, Jennifer R. Geske¹⁸ in a similar study found that dexamethasone was equally similar as the particulate steroids in relief of pain [response difference (95 % CI): 6.0 (- 0.7, 12.8)] as well as in functional improvement [5.6 (- 0.9, 12.2)] which was different from that of our study. Dreyfuss et al¹⁹ in one prospective study involving only 30 subjects and Lee JW et al,²⁰ Shakir A et al²¹ in two small retrospective studies between dexamethasone and triamcinolone in TFESIs via cervical route, showed similar effectiveness with no difference statistically in the self-reported pain scores by the patients. The study, due to small sample size, did not reach statistically significant level though a better effectiveness of the particulate steroids was informed by the treated subjects after one month follow up via phone call. No complication was reported with the use of both the drugs in any group.

CONCLUSIONS

By comparing triamcinolone (40 mg) and dexamethasone (8 mg) for epidural injection, for the duration of analgesia of pain in lumbar radiculopathy, injection of triamcinolone has been found to be more effective than injection of dexamethasone

through transforaminal route and no complication was reported with the use of both the drugs.

Limitation

The strength of the study is the fact that the participants were homogenous between two groups. Patients belonged to either ASA physical status I and II; results cannot be generalized as ASA physical status III and IV patients were excluded. Our sample size 66 (n = 33 in each group), free of significant comorbidities, did not alter haemodynamic status significantly either.

Data sharing statement provided by the authors is available with the full text of this article at jemds.com.

Financial or other competing interests: None.

Disclosure forms provided by the authors are available with the full text of this article at jemds.com.

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