

Transforaminal Epidural Injection of Dexamethasone vs Methylprednisolone in Reducing Low Back Pain and Disability in Prolapsed Lumbar Intervertebral Disc in Manipur, India: A RCT

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ABSTRACT

Introduction: Treatment for Low Back Pain (LBP) due to Prolapsed Intervertebral Disc (PIVD) includes conservative management, Epidural Steroid Injection (ESI), and surgery. Transforaminal Epidural Steroid Injection (TFESI) is a more recently described approach. All corticosteroid preparations used for TFESI are particulate except dexamethasone and betamethasone sodium phosphate. But while comparing methylprednisolone with dexamethasone, the latter has more potent anti-inflammatory action with least likelihood of causing embolic events and is also less expensive.

Aim: To compare the efficacy of transforaminal epidural injection of dexamethasone and methylprednisolone in reducing LBP and disability in prolapsed lumbar intervertebral disc amongst the indigenous population of Manipur, India.

Materials and Methods: This was a randomised controlled study on 80 patients with PIVD attending Outpatient Department (OPD) at physical medicine and rehabilitation was conducted from September 2016 to August 2018. A single dose of lumbar TFESI with dexamethasone in the study group and methylprednisolone in the control were given under C-arm guidance. The outcome

variables Visual Analog Scale (VAS) for pain and Oswestry Disability Index (ODI) for function were measured at one week, one month and six months. Statistical tests like t-test, Chi-square test were used for intra group and inter group analysis.

Results: In the total sample of 80 patients, 40 (15 males and 25 females, mean age: 38.28 ± 8.55 years) were categorised as Dexamethasone patients and 40 (17 males and 23 females; mean age: 39.28 ± 7.80 years) as methylprednisolone patients, there were significant improvement in mean score of VAS and ODI in both the groups (p -value <0.05). At six months, both treatment groups maintained initial observed improvements, with no significant differences between groups on the VAS {95% Confidence Interval (CI), -0.02 to 0.4; p -value=0.07} and ODI (95% CI,-0.21 to 3.43; p -value=0.08).

Conclusion: Non-particulate steroid dexamethasone was similar in efficacy to the particulate steroid methylprednisolone in lumbar TFESI. However, in view of the greater safety profile of dexamethasone, it is suggested that dexamethasone may be used as the preferred agent in lumbar TFESI.

Keywords: Functional improvement, Oswestry disability index, Steroids, Visual analog scale

INTRODUCTION

Lumbar prolapsed disc causes impairment of function by nerve root compression, compelling the patient to seek medical advice for low backache and leg pain [1]. The problem of LBP due to PIVD is fairly common in Manipur because the inhabitants are subjected to various physical stress either due to their living habits, low socio-economic status or are subjected to live or work at places with poor infrastructure [2]. In Manipur, LBP contributes to 16% of musculoskeletal complaints (community oriented program for control of rheumatic diseases- COPCORD 2008) [3]. Lifetime prevalence of LBP is as high as 84% [4]. The 2010 Global Burden of Disease Study estimated that LBP is among the top ten diseases and injuries that account for the highest number of disability adjusted life years worldwide [5].

The causes of LBP and radiating leg pain are complex. Initially, prolapsed disc was believed to cause pain by mechanically compressing the nerve roots. Now, it is well known that leakage of the contents of the nucleus pulposus, causes pain producing inflammatory reaction in the disc itself, around the facet joint and a chemical neuroradiculitis due to the synthesis of various inflammatory mediators like phospholipase A2, Tumor Necrosis Factor (TNF)- α , Interleukin (IL)-6, IL-8, and Glycoprotein G (GG)

E2 [1]. Corticosteroids are believed to decrease pain by reducing inflammation through inhibition of phospholipase A2 activity and by blocking the transmission of nociceptive C-fiber input [6]. The ESI is the most effective for lumbosacral radiculopathy associated with intervertebral disc herniation, bulging, or degeneration.

A comprehensive review has demonstrated the benefits of TFESI: functional improvement, avoidance of surgery, and cost savings [7] and has been a preferred method in treatment of radiating pain from disc herniation because it had the ability to place medication directly around the inflamed nerve root and dorsal root ganglion [8].

Commonly used corticosteroids in ESI include dexamethasone, betamethasone, methylprednisolone and triamcinolone. All corticosteroid preparations used for epidural injection are particulate except dexamethasone and betamethasone sodium phosphate [9]. Particulate corticosteroids are poorly soluble in water whereas dexamethasone sodium phosphate is considered as freely water soluble and soluble steroids are rapidly cleared, theoretically resulting in a short duration of action and less effective than a particulate corticosteroid [10]. Given the short duration of action of dexamethasone, some clinicians view particulate corticosteroids as more appropriate therapeutic choices. Accidental intra-arterial injection of particulates can cause spinal cord infarction [11]. A

non-particulate steroid is likely safer and in theory should not result in embolic infarction of the spinal cord. While there are studies of dexamethasone use for the cervical region [12-14], there are only a few studies of its use in the lumbar region [15,16] and has not been implicated in any of the embolic events associated with epidural injection [17].

As compared to methylprednisolone, the pharmacological property of dexamethasone as a potent anti-inflammatory, least likelihood of causing embolic events and being less costly contemplated the authors to conduct a study with an aim to assess the clinical results, with regard to decreasing pain and disability, of TFESI of dexamethasone and methylprednisolone in PIVD.

MATERIALS AND METHODS

A randomised controlled trial on 80 patients with PIVD attending OPD at Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences, Imphal was conducted from September 2016 to August 2018. Approval from the Research Ethics Board, RIMS, Imphal was taken before the start of the study {A/206/REB-Comm(SP)/RIMS/2015/187/55/2016} and written informed consent was obtained from all the subjects.

Sample size calculation: Taking into consideration from the study conducted by Kim D and Brown J, a prior power calculation was conducted and found that a sample size of 80 subjects was needed to detect between-group mean differences in an overall comparison between transforaminal methylprednisolone and dexamethasone [18].

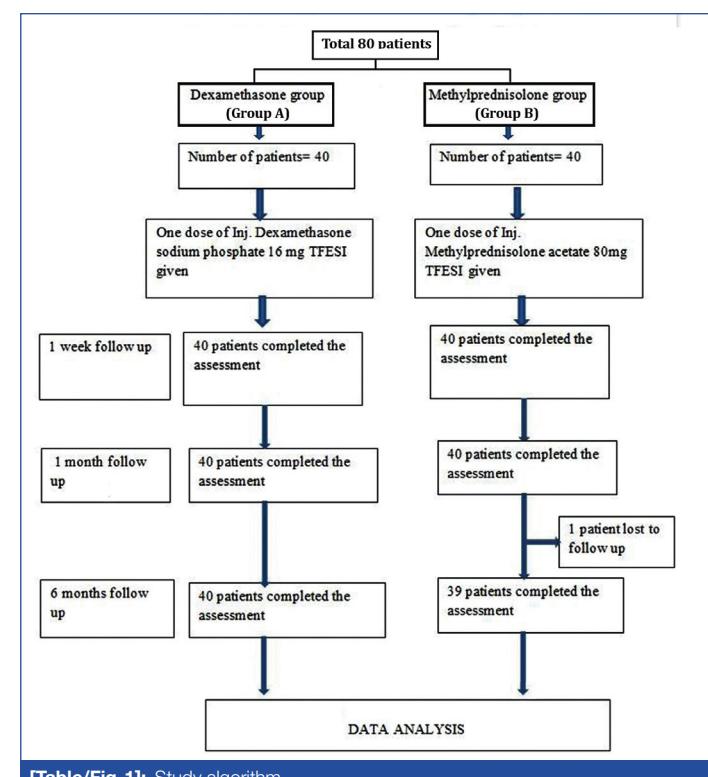
Inclusion criteria: Patients with prolapsed lumbar disc L4-L5 and L5-S1 less than three months duration, confirmed by MRI (Grade II and III) [19], 20 to 55 years, with Visual Analogue Scale (VAS) ≥5, Oswestry Disability Index (ODI) [20] score >40 and willingness to comply with treatment and follow-up assessments were included in the study.

Exclusion criteria: Patients with cauda equina syndrome, mental or physical condition that would invalidate evaluation results, prior lumbar surgery at any level, patients scheduled to have more than one level of steroid injection, pregnant patients, patients with systemic or local infection at site of injection, known allergy to corticosteroids, contrast dye or anesthetics, history of malignancy, bleeding disorders, uncontrolled diabetes mellitus/hypertension, patients who received any spinal injection in the past three months were excluded from the study.

Patients were assigned to two groups (Group A and B) by using block randomisation technique. Group A (Study Group) received Inj. Dexamethasone sodium phosphate 16 mg transforaminal epidural injection and group B (Control Group) received Inj. Methylprednisolone acetate 80 mg transforaminal epidural injection. The participants and physician who conducted follow-up were blinded to the treatment received [Table/Fig-1].

Interventions

Patient was placed in a prone position with a pillow under the abdomen to reduce lumbar lordosis. Using an ipsilateral oblique view, the X-ray tube (source) of the C-arm fluoroscope was angulated to square the inferior endplate of the vertebral body, and to place the superior articular process of the subjacent segment pointing at 6 o'clock of the pedicle of the above level that appears as a Scottie dog eye. Local skin was then prepped and draped in a sterile manner. A local skin wheal was raised with 1% lidocaine at the needle entry site and the subcutaneous tissue in the needle trajectory path infiltrated with 1% lidocaine. A 22 gauge spinal needle of appropriate length was inserted and directed down and parallel to the fluoroscopic beam toward the "safe triangle." To avoid deep needle placement and injury to the neurovascular structures in foramen, the needle was advanced until the tip touched the lower edge of the Scottie dog eye. The needle was then slightly withdrawn for 2 to 3 mm and redirected inferiorly just under the lower edge of the



[Table/Fig-1]: Study algorithm.

transverse process for about 0.5 mm. Further advancement of the needle was done under antero-posterior (AP) and lateral views. The final needle tip position was at the posterior half of the neuroforamen just under the pedicle in the lateral view to minimize injury to the neurovasculature structure. For the L5-S1 foramen, the C-arm source often needs to be tilted in a caudal direction to accommodate any remaining lumbar lordosis. An ipsilateral oblique projection was then used to visualise the Scottie dog and the target was identified as the region immediately under the pedicle, slightly lateral to the 6 o'clock position. This position leads to needle placement in the neuroforamen, ventral to the nerve root. Lateral imaging was used to demonstrate the needle depth, which was located at the superior portion of the intervertebral foramen, just under the pedicle. Once the needle was deemed at the proper position, approximately 1.0 mL of the contrast was injected under live fluoroscopic view. The needle was redirected if there was vascular uptake of the contrast. The injected contrast ideally outlined the nerve root and also show epidural spread.

For group A, 16 mg of Dexamethasone Sodium Phosphate, and for group B, 80 mg of Methylprednisolone Acetate, was slowly injected into the neuroforamen through the spinal needle.

Measures

Pain measured by VAS and functional disability measured by ODI were the outcome measures. Outcome variables were measured at baseline before intervention, one week, one month and six months. Paracetamol was given as rescue drug. Patients in both the groups received lumbar core muscles strengthening exercise and directions to engage in activity as tolerated.

STATISTICAL ANALYSIS

Data analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Descriptive analysis including mean, percentage, standard deviation, confidence intervals were used. Paired t-test and chi-square test were used for significant test. Value of $p < 0.05$ was considered to be statistically significant.

RESULTS

The present study analysed a total of 80 subjects (40 in Dexamethasone group and 40 in Methylprednisolone group) and the data was collected

and results were tabulated. [Table/Fig-2] shows that there were no statistical differences in the baseline characteristics between the dexamethasone and methylprednisolone groups ($p>0.05$).

Characteristics		Dexamethasone group (n=40) (Mean±SD) (n)	Methylprednisolone group (n=40) Mean±SD (n)	p-value
Mean age (years)		38.28±8.55	39.28±7.80	0.587
Gender	Male	15	17	0.820
	Female	25	23	
Side affected	Right	20	18	0.823
	Left	20	22	
Duration of pain (weeks)		6.25±2.52	5.63±2.92	0.309
Level	L4-L5	30	27	0.622
	L5-S1	10	13	
Occupation	Labourers	8	8	0.496
	Govt. employee	11	8	
	Housewife	13	16	
	Others	8	8	
Grading (MRI)	Grade 2	25	24	1.000
	Grade 3	15	16	
BMI (kg/m ²)		29.49±2.21	28.78±3.24	0.254
VAS		7.45±0.96	7.85±0.95	0.065
ODI		67.30±9.46	70.28±9.86	0.172

[Table/Fig-2]: Baseline characteristics of study groups.

BMI: Body mass index; VAS: Visual analog scale; ODI: Oswestry disability index; L: Lumbar vertebrae; S: Sacral vertebrae; *Chi-square test for categorical variables, independent t-test for continuous variables

[Table/Fig-3,4] show significant improvement in both mean VAS scores and ODI scores at one week, one month and six months of follow-up in both the groups. The comparison of mean within same group was compared using paired t-test (p -value <0.05).

Group	Parameter	Baseline	1 week	1 month	6 months	p-value
Dexamethasone	VAS	7.45±0.96	3.20±1.24	2.00±0.816	1.45±0.504	0.01
	ODI	67.30±9.46	35.71±9.71	20.67±6.27	15.03±4.47	0.02

[Table/Fig-3]: Intra-group comparison of mean scores of outcome measures at baseline, 1 week, 1 month and 6 months of dexamethasone group.

VAS: Visual analog scale; ODI: Oswestry disability index; *Paired t-test

Group	Parameter	Baseline	1 week	1 month	6 months	p-value
Methylprednisolone	VAS	7.85±0.95	2.83±1.30	1.65±0.834	1.25±0.494	0.01
	ODI	70.28±9.86	31.88±10.03	18.58±4.67	13.42±3.67	0.01

[Table/Fig-4]: Intra-group comparison of mean scores of outcome measures at baseline, 1 week, 1 month and 6 months of methylprednisolone group.

*Paired t-test

There was no statistically significant difference in terms of pain relief and improvement in functional disability between the two groups (p -value >0.05). At six months, both treatment groups maintained initial observed improvements, with no significant differences between groups on the VAS (95% CI, -0.02 to 0.42; p =0.07) and ODI (95% CI, -0.21 to 3.43; p =0.08) [Table/Fig-5].

Parameter		Dexamethasone	Methylprednisolone	95% CI	p-value
VAS	1 week	3.20±1.24	2.83±1.30	-0.18 to 0.94	0.188
	1 month	2.00±0.816	1.65±0.834	-0.01 to 0.71	0.062
	6 months	1.45±0.504	1.25±0.494	-0.02 to 0.42	0.077
ODI	1 week	35.71±9.71	31.88±10.03	-0.56 to 8.22	0.087
	1 month	20.67±6.27	18.58±4.67	-0.36 to 4.55	0.094
	6 months	15.03±4.47	13.42±3.67	-0.21 to 3.43	0.082

[Table/Fig-5]: Comparison of outcome measures between the two groups.

*Independent t-test

Twelve (15%) patients complained of pain at the injection site for a few days (mean duration 1.6 days, with a range of 0.4-3 days), 4 in dexamethasone group and 8 in methylprednisolone group. Three (3.75%) patients complained of headache after the injection,

1 in dexamethasone group and 2 in methylprednisolone group, but did not require medication for the same. Five patients reported mild nausea and giddiness, 2 in dexamethasone group and 3 in methylprednisolone group.

DISCUSSION

Lumbar ESI is one of the most commonly done interventional procedures for managing back and leg pain [21]. Indications for ESI include LBP associated with radicular symptoms, failure of medications, therapy and rest with persistence of functionally limiting back and leg pain, advanced imaging studies demonstrating nerve root compression with clinical correlation or physical examination findings consistent with nerve root irritation (i.e., positive dural tension signs and/or evidence of neurologic deficits) [21].

With this background, the present study was conducted on 79 patients with lumbar disc prolapse. The study revealed that mean age of the study population groups were 38.28±8.55 years in dexamethasone group and 39.28±7.80 years in methylprednisolone group. This is in par with a study of Tiwari RR et al., which claimed that age ≥35 years was found to have more risk to develop LBP [22]. This may be due to decrease in the elasticity of ligaments with advancing age resulting in decrease flexibility of vertebral column [23]. In the present study, there was significant improvement in VAS and ODI mean scores in a parallel pattern in both the groups at one week, one month and six months follow up (p <0.05). This is because as pain improved, patients were able to involve in daily activities without any disability.

Regarding gender, females (60%) were more commonly affected than men (40%) and among females housewives were most affected (60.4%). This finding is similar to a study conducted by Gupta G and Nandini N, of which 83% housewives were affected by LBP [23].

On comparing the two groups, no significant differences were noted with respect to either pain or functional improvement (p >0.05). This corroborates the existing literature as most studies show no statistically significant difference in outcomes between dexamethasone and particulate corticosteroids, although many have trends favouring particulate corticosteroids [18,24], but the study by Park CH et al., reported a statistically significant result [24]. In fact, from [Table/Fig-4], it is apparent that the vast majority of subjects had near complete pain relief by six months thereby clarifying that there is no indication for a routine series of three injections or multilevel injections for single disc herniation. However, in a study conducted by Kennedy DJ et al., it was found that dexamethasone possesses similar effectiveness when compared with triamcinolone but the dexamethasone group received slightly more injections than the triamcinolone group to achieve the same outcome [25].

The ultimate question when determining the ideal corticosteroid preparation is based on a risk to benefit calculation for a given patient and society as a whole. Methylprednisolone, with an intermediate duration of action, has sodium retaining potency half of cortisol and anti-inflammatory potency five times more. Dexamethasone has a long duration of action with higher anti-inflammatory and glucocorticoid potency as compared to other steroids. At equipotent anti-inflammatory doses, dexamethasone almost completely lacks the sodium retaining property of hydrocortisone. Also, dexamethasone is very cheap compared to methylprednisolone. Methylprednisolone has uniformly sized, densely packed particles with >50 µm in diameter and may form aggregations. Dexamethasone has particulate size <5 µm with the lowest density and the least tendency to aggregation among all the steroid preparations [26]. Theoretically, dexamethasone should have minimal neurological sequelae and a short duration of action [26]. Total dose should not exceed 3 mg/kg or 210 mg/year of methylprednisolone and equipotent doses of other steroids. Beyond this dosage, water and salt retention can occur [16]. None of the patients received steroid exceeding this dose. Particulate corticosteroids were regarded as

more suitable for therapeutic options because it was theorised that particulate steroid preparations may provide a local depot effect with constant release of the active drug from the administration site over a longer time period compared to non-particulate steroids [27].

Natural history of disc prolapse varies and so lack of long-term follow-up is one limitation in this study. Many studies reported short-term pain relief at 2-4 weeks and conflicting results in pain scores and operation rates by 12 months [26,28]. Also, plasma levels of steroid as well as evidence of suppression of the hypothalamo-pituitary-adrenal axis were not estimated. However, clinically there was no evidence of suppression or over-dosage of steroid.

Very few patients complained of pain at the injection site, headache, mild nausea and giddiness for a few days. There was no incidence of epidural haematoma, intravascular injection, nerve root injury or meningitis. To generalise the findings, this study showed that the non-particulate steroid dexamethasone was similar in efficacy to the particulate steroid methylprednisolone in lumbar TFESI in the management of herniated discs.

Limitation(s)

Lack of long-term follow-up is one limitation in this study. Also, plasma levels of steroid as well as evidence of suppression of the hypothalamo-pituitary-adrenal axis were not estimated. However, clinically there was no evidence of suppression or over-dosage of steroid.

CONCLUSION(S)

There is no statistically significant difference between transforaminal dexamethasone and methylprednisolone injection in reducing pain and disability in prolapsed lumbar intervertebral disc amongst the indigenous population of Manipur, India. However, in view of the greater safety profile of dexamethasone, it is suggested that dexamethasone may be used as the preferred agent in lumbar TFESI in the management of herniated discs.

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