

Retrospective Comparative Study of Analgesia and Complications between Particulate (Triamcinolone) v/s Non-Particulate (Dexamethasone) Steroid in Transforaminal Epidural Injection at Tertiary care Hospital

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Abstract

Transforaminal epidural steroid injection (TFESI) is frequently used for the treatment of lumbar radiculopathy. A retrospective analytical study was conducted at a pain clinic among 100 adult patients more than 18 years of age who underwent 'Transforaminal epidural injection' for Lumbar radiculopathy from November 2017 to December 2020. Group A (50 patients) received Transforaminal epidural injection with Particulate corticosteroid (Triamcinolone) and Group B (50 patients) received non-Particulate corticosteroid (Dexamethasone). Pain intensity was assessed using the NRS score. T-test was used as a test of significance. The intensity of analgesia as measured by NRS score is similar in particulate (triamcinolone) and non-particulate (dexamethasone) in transforaminal epidural injection done for Lumbar radiculopathy patients immediately after the procedure as well as at three months follow-up.

Key Words: lumbar radiculopathy, TFESI, particulate steroids, non-particulate steroids

Introduction

Lumbar radicular pain due to a herniated intervertebral disc is a common and debilitating problem worldwide. A study conducted by Kuppaswamy S et al [1] reported a high prevalence (28.2%) of lumbar disc degeneration and herniation in asymptomatic Indian subjects using MRI. One of the early experimental studies conducted by Wilder DG et al. in 1988 showed that lumbar disc herniation's can be a direct mechanical consequence of prolonged sitting in static or vibration environments.[2]

A review article suggested strong evidence for transforaminal injections in the treatment of lumbar radicular pain for both short and long-term relief.[3] A transforaminal epidural steroid injection (TFESI) is frequently used for the treatment of Lumbar radiculopathy in patients that have not responded to conservative treatment. TFESIs are thus becoming a common procedure in pain management. Various studies have reported a significantly greater proportion of patients treated with a transforaminal injection of steroids achieve relief of pain than patients treated with a transforaminal injection of local anaesthetic. [4,5] Clinical studies evaluating the efficacy of different

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types of steroid injections have shown variable results without a definite conclusion.^[6]

Aim:

Comparison of analgesia between Particulate steroid vs. Non-particulate steroid in transforaminal epidural injection done for Lumbar radiculopathy patients.

Comparison of incidence of complications of Particulate steroid vs. Non-particulate steroid in transforaminal epidural injection done for lumbar radiculopathy patients.

Objectives:

To compare the intensity of Analgesia Immediately post-procedure and after 3 months of TFESI with triamcinolone and dexamethasone.

To compare complications like changes in blood pressure and inadequate analgesia immediately post-procedure and after 3 months of TFESI.

Material and Methods

Type of study: This is a retrospective analytical study.

Study setting: Pain Clinic, Department of Anaesthesia, Medical College and tertiary health care Centre.

Study duration: Jan 2021 to June 2021

Study Population: Adult patients more than 18 years of age who underwent 'Transforaminal epidural injection' for Lumbar radiculopathy from November 2017 to December 2020.

Sample size: By using the formula,

$$n_1 = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right)^2 \left[\sigma_1^2 + \frac{\sigma_2^2}{r} \right]}{\Delta^2} \quad r = \frac{n_2}{n_1}, \quad \Delta = \mu_1 - \mu_2$$

Where: n = sample size

$Z_{1-\frac{\alpha}{2}} = 1.96$ (level of significance)

$Z_{1-\beta} = 0.84$ (critical value or power of test)

σ = standard deviation

Δ = difference of two means (0.5)

r = ratio of two means (1.007)

A sample size of 50 in each group was calculated.

Inclusion criteria:

- Adult (more than 18 years) patients with lumbar radiculopathy with pain intensity >4/10 on Numerical Rating Scale (NRS) and pain more than six months duration.
- The patients diagnosed on MRI with single level herniated nucleus pulposus below L3 that corresponded with the patient's clinical features.
- Patients with follow up record up to 3 months
- American Society of Anaesthesiologists (ASA) Grade I or II patients.

Exclusion criteria:

- Patients having Lumbar facetar arthropathy, Sacroiliac joint pain, Inflammatory spine disease like ankylosing spondylitis.
- Previous history of spine surgery.
- Bleeding disorders, and patients on anticoagulants.

Methodology

This is a record-based study conducted at a tertiary care centre. To retrieve the data Medical Records Department was approached. A pre-designed proforma was prepared for the documentation of required data. The Required sample size was 50 in each group. To achieve the required sample size and after application of inclusion and exclusion criteria data was screened retrospectively from December 2020 to November 2017. We found 231 records with lumbar radiculopathy.

No. of adult patients with lumbar radiculopathy = 231

No of patients with pain duration more than 6 months = 184
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No of patients with pain intensity more than 4/10 = 173

No of patients in whom complete records with f/u data upto three months was available = 148

Among 148 study subjects, 83 underwent procedure with triamcinolone

Among 83 study subjects, 50 study subjects were selected randomly

Among 65 study subjects who received dexamethasone 50 study subjects were selected randomly

The demographic profile of patients was recorded along with detailed history regarding the site of pain, intensity and duration along with the history of comorbidities. Numerical Rating scale (NRS) score was recorded prior to the procedure, immediate post-procedure, at one month follow-up and three months follow-up. General examination was done. Routine blood investigations and radiological investigations were done. Pre anaesthesia evaluation of patients was done prior to the procedure.

Patients in both groups were selected using computer generated random number table. Group A had received fluoroscopically guided transforaminal Triamcinolone acetate 40 mg epidural steroid injection whereas Group B received fluoroscopically guided transforaminal dexamethasone 8 mg epidural steroid injection. Written informed consent was taken from patients prior to the procedure.

An intravenous line was secured and Injection Ringer Lactate (10 ml/ kg) was given. Patients were placed in the prone position on the injection table. After sterile preparation, the area was draped and anaesthetized using 1 % lidocaine. Using fluoroscopic guidance, a spinal needle was advanced in an oblique view to the safe triangle. Both anterior-posterior and lateral views were obtained to confirm precise needle placement within the intervertebral foramen at 6 O'clock position under the pedicle; ideally, the needle was placed adjacent to the back of the vertebral body immediately inferior to the pedicle. At the target level, approximately 1 ml of

contrast medium (Omnipaque 240) was injected while being visualized with real-time fluoroscopy to assure target medication flow and the absence of vascular or subdural or subarachnoid flow. After waiting for two minutes, to assure no adverse events, patients were injected with the 2ml of 0.5% Bupivacaine and treatment corticosteroid. Group A had received one ml of Triamcinolone acetate 40 mg/ml epidural whereas Group B received one ml of dexamethasone phosphate 8 mg/ml. These doses were chosen to have equal volumes of injectate as well as equal potency.

Data were entered in an excel sheet and analysed using Epi Info Version 7.2.5.0. Frequency and percentages were calculated for categorical data. Mean and standard deviation was calculated for continuous data. The Chi-square test was used as a test of significance for categorical data. An unpaired t-test was used to compare two means. P value less than 0.05 was considered to be statistically significant.

Results

The present retrospective study was conducted to compare analgesia between Particulate steroid (Triamcinolone acetate) vs. Non-particulate steroid (dexamethasone) in transforaminal epidural injection done for Lumbar radiculopathy patients.

Table 1 depicts the baseline characteristics of both groups. Both the groups were comparable concerning baseline characteristics like age, gender, level of vertebral involvement, duration of pain. Both the groups were similar when compared with the number of injections required for pain relief with most of the patients requiring a single injection.

Table 2 depicts a comparison of numerical rating scale scores between the two groups pre and post-procedure. There was a significant reduction in the mean NRS score immediately after the procedure, at one month and three months follow up ($P < 0.001$).

There was no significant difference when intergroup comparison of mean NRS scores was done. Both the groups had comparable NRS scores.

Table 3 shows a comparison of complications among both groups. The incidence of complications was similar in both groups. Complications recorded immediately after the procedure was classified as

changes in blood pressure and inadequate analgesia. Both the groups had a comparable incidence of all the complications. At three months follow up, inadequate

analgesia in the form of increased radicular pain was found among 4 (8%) participants in Group A and 3 (6%) participants in Group B which is similar.

Table 1: Baseline characteristics of both the groups

Sr No	Variable	Group A (n= 50)	Group B (n=50)	P value
1	Age (Mean \pm SD) years	41.96 \pm 10.8	42.24 \pm 12.0	0.46*
2	Gender (Males: Females)	32:18	27:22	0.31#
3	Involvement of L4 or L5 vertebra n (%)	36 (72%)	33 (66%)	0.51#
4	Duration of pain (Mean \pm SD) months	3.78 \pm 1.53	3.70 \pm 1.58	0.82*
5	The proportion of Protrusion n (%)	36 (72%)	31 (62%)	0.28#
6	The proportion of patients requiring two injections for intervention n (%)	10 (20%)	7 (14%)	0.42#

* t test # Chi square test

Table 2: Comparison of numerical rating scale scores between the two group's pre and post-procedure

	Group A (n= 50)	Group B (n= 50)	Intergroup P value (t-test)
Pre procedure	6.36 \pm 1.43	6.26 \pm 1.38	0.72
Immediate Post Procedure	2.27 \pm 1.31	2.26 \pm 1.29	0.96
1 month f/u	1.12 \pm 0.75	1.41 \pm 0.83	0.07
3 month f/u	0.92 \pm 1.00	1.16 \pm 0.91	0.21

Table 3: Incidence of complications among both the groups

	Group A (n= 50)	Group B (n= 50)	P value
Immediate Post Procedure	n (%)	n (%)	
Changes in blood pressure			
Hypotension	2 (4%)	3 (6%)	0.50#
Increased BP	5 (10%)	6 (12%)	0.74*
Vasovagal	3 (6%)	2 (4%)	0.99#
Analgesia			
Increased back pain	2 (4%)	0 (0)	0.49#
Increased local pain	12 (24%)	9 (18%)	0.46*
Increased radicular pain	4 (8%)	3 (6%)	0.99#
No complication	27 (54%)	30 (60%)	
Three months follow up			
Increased radicular pain	4 (8%)	3 (6%)	0.97#

* Chi-square test, # Fisher exact

Discussion

The present study found that the mean NRS score decreased significantly in both the groups (Group

A Triamcinolone v/s Group B Dexamethasone) immediately post-procedure at one month and three months follow-up. In a study conducted by Madavi SK et al [7] after one month of intervention, the VAS score was 2.85 \pm 0.83 in group Triamcinolone and 5.76

± 0.75 in group Dexamethasone and the difference was found to be statistically significant.

A randomized controlled trial conducted by Kennedy DJ et al^[8] to determine if there was a major difference in effectiveness between particulate and nonparticulate corticosteroids for acute radicular pain due to lumbar disc herniation; Both triamcinolone and dexamethasone resulted in statistically significant improvements in pain and function at two weeks, three months, and six months, without clear differences between groups.

El-Yahouchi C et al^[9] conducted a retrospective observational study to assess whether a nonparticulate steroid (dexamethasone, 10 mg) is less clinically effective than the particulate steroids (triamcinolone, 80 mg; betamethasone, 12 mg) in lumbar transforaminal epidural steroid injections (TFESIs) in subjects with radicular pain with or without radiculopathy and revealed no evidence that dexamethasone is less effective than particulate steroids.

Shau DK et al^[10] conducted a randomized controlled trial to compare the clinical efficacy of transforaminal epidural injection of dexamethasone and triamcinolone in the management of chronic low back pain with or without radiculopathy due to herniated intervertebral disc and found improvement in pain score was significantly better with transforaminal epidural injection of triamcinolone acetate compared to dexamethasone.

The present study found that there were no major complications following the procedure in both groups. Serious complications can be avoided by the accuracy of the procedure using fluoroscopic guidance, use of dye spread for the confirmation of epidural space, placement of the needle in the safe triangle and negative aspiration of blood. Although various case reports and case series have reported paraplegia following infarction as a major complication following TFESI.^[11,12,13,14] Few studies have reported that particulate steroids contain aggregates that can act as emboli. And therefore, lead to serious complications.^[15,16]

The rate of complications with these types of epidural techniques is low.^[17,18,19,20] Complications are related either to the procedure itself—mostly

inadvertent placement of the needle off target— or the administration of the corticosteroid or local anaesthetic.^[21]

Although the proportion of minor complications immediately after the procedure was slightly higher among triamcinolone group 28 (56%) as compared to dexamethasone group 23 (46%); this difference was not statistically significant. Also, there was no statistically significant difference between the incidences of radicular pain at three months follow up. A similar finding was noted by Madavi SK et al.^[7]

Conclusion

The intensity of analgesia as measured by NRS score is similar in particulate (triamcinolone) and non-particulate (dexamethasone) in transforaminal epidural injection done for Lumbar radiculopathy patients immediately after the procedure as well as at three months follow-up.

There are no major complications in a carefully monitored procedure. The incidence of minor complications including changes in blood pressure and inadequate analgesia in both the groups are similar.

Limitations: The study has all the inherent limitations of an observational study.

Conflict of Interest: None.

Source of funding: Self

Ethical clearance: Approval of the Institutional Ethics Committee at Vasantropawar medical college and research hospital, Nashik (Maharashtra) was sought (vide letter no: 62/2020-21 dated 21.01.2021). Permission from the head of the Institute as well as the medical record department was sought prior to the collection of data.

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