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Comparison of Methylprednisolone and Dexamethasone for trans-foraminal epidural steroid injections in Lumbar disc disease

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Abstract
Introduction: *Trans-foraminal epidural steroid injections (TFESI) have been extensively used for treatment of pain due to lumbosacral disc disease. There has been an ongoing debate regarding benefits and safety of non-particulate steroids over particulate steroids. We have studied outcomes following injection of methylprednisolone versus dexamethasone in symptomatic lumbosacral disc disease.*
Materials and Methods: *A total of 100 patients (50 in each group) were chosen and randomized to be included in either arm of the study. Patients were assessed at different time points following a one-timetrans-foraminal epidural steroid injection. Outcome was assessed using the Numerical Rating Scale (NRS).*
Results: *Overall, the extent, as well as duration of pain relief was significantly better in the methylprednisolone group, than in the dexamethasone group. Except for transient paraesthesias, there were no serious adverse effects in either group.*
Conclusion: *There is satisfactory pain relief with both the medications when used for TFESI, but the efficacy of epidural methylprednisolone is greater than dexamethasone, and the effects tend to last longer. There is no difference in adverse effects between both the drugs when used for lower lumbar epidural injections.*

Introduction

Trans-foraminal epidural steroid injections have been popular interventions for the treatment of lumbosacral radicular pain, and it has been shown to be effective[(1)].

Non-particulate steroid preparations have been proposed to be safer than particulate steroid preparations for epidural use. This is because particulate steroid preparations like methylprednisolone, triamcinolone, and betamethasone have been implicated in multiple cases of neurological injury[(2,3)].

Dexamethasone, in comparison, is a non-particulate steroid, and has a superior safety profile[(4)]. In light of this, the safe practice guidelines of the multi-disciplinary working group has recommended non particulate steroid dexamethasone (DEXA), as the initial choice for lumbar Trans-foraminal Epidural Steroid Injections (TFESI). Regarding benefits of DEXA over methylprednisolone in terms of pain relief, there is conflicting literature. Majority of literature provides evidence that quality of pain relief offered by DEXA is comparable to the particulate steroids.

However, there are studies that have revealed greater degree of pain relief by methylprednisolone (MP), and a comparatively shorter duration of action of DEXA[5,6].

The aim of the present study was to examine the comparative efficacy of DEXA, in comparison to MP in terms of extent and duration of pain relief, and improvement of disability.

Materials and Methods

The study was conducted in the Department of Orthopaedics, Government Medical College, Srinagar; a tertiary referral hospital in the Indian state of Jammu & Kashmir. Approval was obtained from the ethical committee of the medical college, and written, informed consent was taken from all patients for their inclusion in the study.

Only individuals with unilateral lower limb pain, of a radicular distribution along a dermatome secondary to single, or two level prolapsed intervertebral disc (PIVD) were included in the study. The patients should have undergone conservative treatment for at least 6 weeks, before opting for the injection.

Excluded, were patients with neurological deficit, history of back surgery for the same PIVD, or patients with evidence of osteophytes, spondylolisthesis, or spinal deformities, and patients with extruded discs. Patients with history of previous epidural steroid injection within the last 6 months, history of substance abuse, or suspected addictions, and patients with other contraindications for percutaneous spinal injections were also excluded.

A total of 100 patients were selected for inclusion into the study, over a period from July 2018 to July 2019. Randomization was done using random number tables, with 50 patients each assigned to DEXA, and MP group respectively.

Patients in the DEXA group received 8 mg of dexamethasone, and patients in the MP group received 40 mg of methylprednisolone. 2% lidocaine (preservative-free) was added to the preparations as well.

All the TFESIs were performed by the same surgeon.

Technique

TFESI was performed using a 22 gauge, 100mm spinal needle, under all aseptic precautions. Using fluoroscopy, accurate placement of the needle was achieved. Contrast (Iohexol-320) was used for confirmation of needle position, and the steroid-anaesthetic mixture was injected. Patients were observed for one hour in the recovery room post procedure, and subsequently discharged. All the patients were prescribed Aceclofenac 100mg SOS upon discharge. Topical adjuvants were allowed; however, no other analgesic, or neurotropic drugs were allowed according to the study protocol.

Treatment outcomes were measured using the 11-point Numerical Rating Scale (NRS). NRS score was collected pre-procedure, then at 14 days, 6 weeks, and 3 months. post procedure. The cumulative number of analgesic tablet consumptions was collected for each group at similar time periods.

Successful treatment outcome was defined as at least 50% improvement of NRS score, over the pre-procedure scores recorded.

Results

A total of 100 patients were enrolled and randomized in our study. The clinical and demographic characteristics between the two groups did not differ significantly.

	Group A (n=50)	Group B (n=50)
Age (mean, in years)	44.6	41.5
Sex (M/F)	29/21	23/27
Weight (mean, in kg)	72.8	76.2
Median duration of leg pain (weeks)		
Mean consumption of NSAID tablets/week	4.54	4.8
No of discs involved as per MRI		
Discs involved		
L3-L4/isolated L3-L4	10/0	12/2
L4-L5/isolated L4-L5	38/16	35/13
L5-S1/isolated L5-S1	24/12	25/13

Overall, the extent of pain relief was significantly better in the patients who were given methylprednisolone, than those who were given dexamethasone. The NRS scores in the MP group were significantly better at 14 days, 6 weeks, and 3 months following TFESI.

NRS Score at various time points	Mean ± SD		p-value
	Group I (MP)	Group II (Dexa)	
Pre-treatment	7.58 ± 1.59	7.66 ± 2.04	0.827
2 weeks	4.42 ± 1.43	5.48 ± 1.84	0.002
6 weeks	2.72 ± 1.59	3.18 ± 1.80	0.001
3 months	2.28 ± 1.37	4.78 ± 1.62	<0.0001

The consumption of Aceclofenac tablets was also significantly more in the dexamethasone group, at 6 weeks, and 3 months post injection.

Analgesic intake (tablets/day)	Mean ± SD		p-value
	Group I (MP)	Group II (Dexa)	
Pre-treatment	4.54	4.8	0.322
2 weeks	2.74	2.81	0.224
6 weeks	1.54	1.80	0.031
3 months	0.92	0.61	0.002

19 patients reported paraesthesias in the lower limb on the affected side immediately following injection. The paraesthesias resolved uneventfully in all patients.

None of our patients experienced motor weakness, or any of the other procedural complications associated with epidural injections.

Discussion

The magnitude of pain relief was better in patients belonging to the methylprednisolone group, and the difference was significant at all time points, i.e. 2 weeks, 6 weeks, and 3 months.

The relatively longer duration of action of methylprednisolone could be attributed to the fact that we have used the depot preparation, resulting in a potentially longer duration of action.[7] Dexamethasone is a non-particulate suspension, and consequently had faster clearance, and thereby, shorter duration of action.[8]

The literature on this discussion is divided in favour of both the steroids when used for TFESI.

Kim et al[9] and Noe et al[10] had shown better results with methylprednisolone. The study by Noe et al compared equipotent betamethasone with dexamethasone.

In another study by Kennedy et al[7], that compared equipotent doses of triamcinolone with dexamethasone for TFESI, there was no difference in pain scores and functional improvement until 6 months of post injection follow up. However, dexamethasone group required higher number of repeat injections to sustain the effects. Dreyfuss et al[11], in his study comparing varying doses of triamcinolone, and dexamethasone did not observe a significant difference in terms of pain scores at 1 month post-injection.

And on the other hand, there are a few studies that have revealed better short term pain relief with dexamethasone, as compared to triamcinolone[5,6]. In fact, El-Yahchouchi et al[6] have shown better functional outcome following use of non-particulate steroid at 2 months post-injection. However, it was not discussed in the study how a shorter acting drug that was administered in a less-than-equipotent dose could produce better functional results.

When using particulate steroids, there is a documented risk of intravascular injection of the drug, causing neurological injury. Particles of MP or triamcinolone have the ability to coalesce together into larger particles with a diameter of >100 microns. These bigger particles can occlude capillaries, arterioles, and rarely, even arteries; resulting in infarction of a section of neural tissue[12]. Dexamethasone, being non-particulate, has not been associated with any instance of neurological injury till now, except for a single instance of conus infarction, where the mechanism of injury was unclear[13]. Also, a report has described a 1:1 combination of Dexamethasone and ropivacaine as potentially dangerous, as they are capable of instantaneously forming crystals large enough to act as emboli[14]. Such crystallisation was not observed when dexamethasone was mixed with lignocaine or bupivacaine. Henceforth, the Food and Drug Administration issued a drug safety precaution in

2014, warning of the adverse effects of epidural steroid injections, which included vision loss, stroke, paralysis, and even death. This has resulted in significant concerns and controversies in the scientific community[15].

TFESI for lumbar disc disease could still be safely used with image guidance because of the wider Trans-foraminal area; however, in the cervical region, it has the potential to cause major disability[15]. A comprehensive safety analysis has favoured the use of dexamethasone as first-line choice for cervical TFESI, and lumbar TFESI at L3 and above, where the risks of permanent neurological compromise are greatest[4].

The present study has compared outcomes between methylprednisolone and dexamethasone in lower lumbar TFESI, therefore, occurrence of neurological injury was not high on the list of concerns.

The results of the present study were comparable to earlier studies, favouring the use of particulate steroids. Also, in a departure from protocols followed by earlier researchers[7], a one-time TFESI protocol was adapted, making this study more unambiguous, enabling a clearer illustration of the differences between the two drugs. However, the one-time injection protocol may not be acceptable in all the cases. Some patients had difficulties in maintaining accurate records of analgesic consumption, and might have supplied erroneous information.

Conclusion

There is satisfactory pain relief with both, methylprednisolone, and dexamethasone, in the immediate, and short term following trans-foraminal epidural steroid injections. The pain relief with dexamethasone, however, is milder, and tends to taper off at around 3 months post-injection.

Also, evidence regarding the possible complications of TFESI, and the associations of those complications with particulate and non-particulate steroids is limited at present. Hence, in our opinion, methylprednisolone can still be used for TFESI, involving the lower lumbar levels; provided all standardised safety recommendations are followed, and a careful calibration of individual risk-benefit ratio is done[16].

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