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The role of Distal Sodium Channel Blockers in the Management of Prolapsed Intervertebral Disc with Radiculopathy: A Mixed Cohort Study

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ABSTRACT
Sodium channel blockers and steroids are known to play a vital role in establishing pain relief in neuropathic pain. This is usually achieved by reducing inflammation of the involved nerve roots as well as by desensitizing them. In our study, we aim to establish the effectiveness of cocktail injections comprising of a combination of lignocaine 2%, Distill water and Triamcinolone acetate 40 mg for radiculopathy caused by Intervertebral Disc Prolapse. We conducted a mixed cohort study (prospective and retrospective) on 90 patients between the age groups of 18-60 years. attending the Out Patient Department of Orthopaedics, Kokrajhar Medical College and Hospital, Assam. These patients were diagnosed with Prolapsed Intervertebral Disc (PIVD) with lower limb radiculopathy with MRI findings of Disc prolapse at L4-L5 or L5-S1levels. The cocktail injection was injected into both the tarsal tunnel and superior tibio-fibular joint respectively in two divided doses in the affected lower limb. Patients were examined and evaluated clinically for VAS pain score, SLRT, sensory and motor examinations on Day 2, Day 7 and 1 month respectively. The mean pre-VAS score was 7.1 followed by the mean VAS score on Day 2 was 2.1 the mean VAS score was 2.7 on day 7 and 3.1 on day 30. There was a statistically significant difference in the mean VAS score ($p<0.001$). The use of distal sodium channel blockers injections could be cost effective, efficient and a game changer in the management of PIVD patients associated with lower limb radiculopathy.

INTRODUCTION

Prolapsed Intervertebral disc (PIVD) or herniation is one of the commonest cause of low back pain affecting approximately 10% of the population. Disc prolapse is more frequently seen in the lumbar region and is most common at L4-L5 and L5-S1 levels. Radicular pain is one of the most common and disabling symptoms which may lead to sensory and motor involvement and is a significant cause of morbidity. Magnetic Resonance Imaging (MRI) has a high sensitivity and specificity in the diagnosis of PIVD. Surgical intervention is required only when the patient does not respond to conservative management. Conservative management in the form of oral and injectable medications, spinal traction, spinal physiotherapy, electrotherapy etc. are currently recommended. Epidural steroid injections are one of the most commonly used treatment modalities for lumbo-sacral radiculopathy[1]. Despite providing quick relief, they are associated with well-known side effects, which includes allergic reactions, neurological deterioration, CSF leaks, intravascular injections, headaches, urinary retention, haematomas, seizures[2] etc. Therefore, a safer technique by utilising distal sodium channel blockers has been proposed for the treatment of radiculopathy associated with PIVD and thereby provide a safer and alternative to epidural lumbar injections.

MATERIALS AND METHODS

This was a mixed cohort study (including both prospective and retrospective) conducted between February 2023 to November 2023 at Department of Orthopaedics, Kokrajhar Medical College and Hospital, Assam. The study included patients aged between 18 to 60 yrs. of age coming to our OPD with symptoms of low back pain with lower limb radiculopathy, with MRI involvement of Lumbo-Sacral Spine showing Disc Prolapse at L4-L5 and/or L5-S1 levels, with VAS score more than 5. Patients diagnosed with listhesis, osteoporotic vertebral body collapse, tubercular and pyogenic infections were excluded. All the patients were assessed for neurological examinations which included the duration of symtoms, comfortable walking distance, Straight leg Raising test (SLRT), VAS score, sensory and motor examinations, bowel and bladder involvement. In cases where bilateral lower limb radiculopathy was there, injection was given in the more affected side.

The Two Injection Sites Were Marked Anatomically in the Affected Lower Limb as Shown in Figs 1 and 2:

Tarsal Tunnel Injection: Patient is positioned supine with external rotation of the hip in the same side of injection. The needle is introduced through a point just distal and posterior to the medial malleolus at an angle of 45 degrees to the horizontal plane with the needle tip facing towards the patient's head and facing posteriorly. The needle is progressed from distal to proximal with the needle going parallel to the tibial shaft. The injection volume was deposited at different depths as the needle was progressed deeper with aspiration before each injection in order not to miss the tarsal tunnel.

Proximal Tibio Fibular Joint Injection: The proximal tibio fibular joint is located inferior and slightly medial to the lateral aspect of the lateral tibial condyle. The patient is positioned supine with 90 degrees of knee flexion. The head of the fibula and the lateral tibial condyle are palpated and marked respectively. The midpoint between these two points is marked and the needle is introduced. The patients were injected with 10 ml of the cocktail injection in 2 divided doses at the above two sites respectively.

After injection, the patients were kept in observation in the OPD for 30 minutes. At the end of 30 minutes, the vitals were evaluated for any abnormalities or any adverse effects of the drugs. The patients were then allowed to go home and then asked for follow up on day 2, Day 15 and after 1 month. At each follow up, the Patients were evaluated clinically for VAS pain score, SLRT, sensory and motor examinations.

RESULTS

In this study, we analysed 90 patients in the OPD at Department of Orthopaedics, Kokrajhar Medical College and Hospital, Assam. 10 patients were lost to follow up. The mean age of patients is 40.35 years. There was 60% males with mean age of 43.23 years and 40% females with mean age of 46.76 years. In our study, 57% had injections on the left side and 43% had injections on the right side. Eleven patients had shown no improvement in pain VAS score and comfortable walking distance after one week of post injection. They were labelled as failed injections and repeat injection was given on day 7 after which all of them responded. Following the injections the main complaints of all the

Fig. 1: Tarsal tunnel injection

Fig. 2: Prox. Tibio-Fibular joint injection

patients was abnormal tingling sensation and mild numbness in the injected limb which lasted for about 6-8 hours. Around 10 patients were known cases of type 2 Diabetes Mellitus. But, prior to the injection, the sugar levels were all kept under control. There was no local irritation or local complication at the sites of injection (Table 1-3).

The mean pre VAS score was 7.10 followed by the mean VAS score on day 2 was 2.16. The mean VAS score was 2.73 on day 7 and 3.18 on day 30 and there was a statistically significant difference in the mean VAS score $p<0.001$. Before the start of treatment, 15 patients (18.75%) came to us in a wheelchair. 20 patients (25%) needed support for walking while the rest of the 45 patients (56%) had painful walking. After 1 month following the injection, only 3 patients (3.75%) needed wheelchair, 5 patients (6.25%) needed support for walking, 10 patients (12.5%) had painful walking and the rest of the 62 patients (77.5%) had comfortable painless walking.

DISCUSSIONS

Disturbance in the voltage-gated sodium channels was supposed to be the cause of pain in the cases of radiculopathy[3,4]. Till date, local anaesthetics were not used much for radiculopathy considering their short duration of action and the possible side effects it might cause. Following nerve injury, there is hyper-excitability and spontaneous firing which develops at the site of injury as well as in the cell bodies of the dorsal root ganglions. This hyper-excitability occurs owing to the accumulation of sodium channels at the site of injury and the correlation between the excitation of voltage gated sodium channels and the generation of pain has been stated in literatures[5].

The local anaesthetics (mainly lignocaine) which has been used for treating radicular pain works through the blocking of the sodium channels[6]. Local anaesthetics suppress oscillations of the resting membrane potential without significant sensory and motor blockage. Michel *et al*.[6] also found similar findings in their study that low dose local anaesthetics produced pain relief within short time and long duration of pain relief in their sub-therapeutic range. The aromatic ring of the local anaesthetics improves lipid solubility which makes the local anaesthetics to spread along the myelin sheath to the proximal site where pain is getting generated.

Hammodi[7] found that on injecting 0.6% lignocaine at anatomical gates A, B, C and D, there was significant pain relief. The epidural and trans-foraminal injections done for PIVD with radiculopathy have got well known side effects such as allergic reactions, neurological deterioration, CSF leaks, intravascular injections, headache, haematomas, seizures etc. To prevent these side effects, sterile conditions and controlled environment like Operation theatres were needed which indirectly increases the cost and duration of blocks. Many literatures have proven that the epidural or trans foraminal injections were ineffective and unsafe in controlling the pain associated with radiculopathy. In our study, we performed the procedures in the outpatient setting which resulted in the same level of pain control without the above mentioned side-effects.

TCAs (Tri Cyclic Antidepressants: Amitryptiline and nortryptiline), local anaesthetics (lignocaine, mexiletine) are currently used medications for the treatment of neuropathic pain that have proven actions against sodium channels. Triamcinolone, a corticosteroid has been used to eliminate inflammation. According to previous research studies, corticosteroid injections may provide short term relief from leg discomfort and sensory impairements but they may not lessen the need for surgery or provide significant functional benefit.

In a case series which was published in 1960, where distal to lesion block was studied to relieve pain from a large area supplied by the nerve by blocking the afferent from t hat area. Another study by Xavier *et al*.[11] highlights peripheral inputs as a cause of pain during distal block study. The effectiveness of common personal nerve block for lumbar disc herniation was evaluated in a double blind study by Tajiri *et al*.[10]. Manchikanti *et al*.[8,9] evaluated the efficacy of caudal epidural injections with or without steroids in treating chronic low back ache and lower extremity pain caused by disc herniation or radiculitis, as well as the differences between local anaesthetics with and without steroids in providing efficient and long lasting relief.

Table 1: Composition Details

Drug	Dose
Injection Lignocaine 2% (without adrenaline)	4mL
Injection Triamcinolone	40 mg (1 mL)
Distilled water	5 mL
Total dose	10 mL

Table 2: Vas score

Follow up	VAS score (Mean±SD)	Mean difference	p-value
Pre injection	7.10±0.76	-	-
Day 2	2.16±0.86	4.94	<0.001
Day 7	2.73±1.15	4.37	<0.001
Day 30	3.18±2.45	3.92	<0.001

Table 3: Ambulatory method

Ambulatory method	Pre injection	Day 30 (%)
Wheel chair	15 (18.75%)	3 (3.75)
Walking with support	20 (25%)	5 (6.25)
Painful walking	45 (56%)	10 (12.5)
Comfortable painless walking	0	62 (77.5)
Total	80	80

Patients undergoing discectomy for lumbar disc herniation often report a prompt reduction in leg pain and radiculopathy, but many complain of persistence of symptoms and in some cases worsening of low back pain after surgery[12,14]. Moreover, long term outcomes of conservative management have been reported to be better than surgical intervention in many studies[13]. Also, surgical intervention is not available for all symptomatic patients and may even lead to failure in approximately 25% of carefully selected cases.

Hence, we tried to resort to an alternative method that is based on non-operative treatment of Prolapsed intervertebral disc based on this concept of injecting distal sodium channel blockers. Following the injections, the radicular pain improved significantly in all the patients but the axial back pain persisted in some patients.

Limitation: In our study, patients were assessed for short period of time. Long term follow up is required for further evaluation

CONCLUSION

Injection of distal sodium channel blockers is very simple, non-operative and OPD based technique which could be reasonable, safe and efficient and eliminate the need for fluoroscopy guidance in the treatment of Prolapsed Intervertebral Disc Prolapse with radiculopathy.

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