Effectiveness of Distal Sodium Channel Block in Managing Lumbosacral Radicular Syndrome: A Pilot Study

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ABSTRACT

Objective: To find the effectiveness of distal sodium channel blocks in managing lumbosacral radicular syndrome.
Study Design: Open-labelled, non-randomised, single-group, prospective, pilot study.
Place and Duration of the Study: Pain Clinic of Armed Forces Institute of Rehabilitation Medicine (AFIRM) Rawalpindi, Pakistan, from January to June 2022.
Methodology: Patients having low back pain radiating to L5/S1/both dermatomes with severity of numerical rating scale (NRS) score of more than 4/10 were included. Straight leg raise (SLR) and NRS score were noted down at baseline and at 30 minutes, 24 hours, 1 week, and 4 weeks post-distal sodium channel block (DSCB). DSCB was performed at beta 1, 2, 3, and 5 portals using 2 ml of 2% injection plain lignocaine + 1 ml (40 mg) injection triamcinolone + 7 ml distilled water. Statistical analysis was done using Statistical Package for Social Sciences (SPSS) 21.
Results: Out of 50 patients, 24 (48%) were females and 26 (52%) were males. No serious procedural complications were noted. Post-DSCB, follow-up was done for 4 weeks. A significant fall in NRS and an increase in SLR score were observed at every visit. Results were statistically significant ($p<0.001$) when mean NRS and SLR scores at every follow-up were compared for pre- and post-DSCBs.
Conclusion: DSCB reduced pain and improved SLR in patients even at 4 weeks of follow-up. Advantages included immediate pain relief, easy to perform as outdoor procedure, cost-effective and a time buying alternative procedure allowing for the analgesic effect of medicine to kick in.

Key Words: *Radiculopathy, Low-back pain, Epidural spinal injection, Sciatica, Pain management, Distal sodium channel blocks*.

How to cite this article: Shafaat HK, Jilani S, Younas U, Khalil MT, Rashid M, Irshad I. Effectiveness of Distal Sodium Channel Block in Managing Lumbosacral Radicular Syndrome: A Pilot Study. *J Coll Physicians Surg Pak* 2023; **33(12)**:1449-1453.

INTRODUCTION

In 2020, the International Association for the Study of Pain (IASP) defined pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."[1] Low back pain (LBP) is pain, stiffness, or muscle tension between the lower ribs and the gluteal crease, with or without sciatica.[2] As per Global Burden of Disease study (2019), LBP remains the leading cause of years lived with disability (YLDs) worldwide (568.4 million).[3] Up to 36% of patients with LBP also complain of pain radiating below the knee. It may be referred or radicular. Former initiates from intervertebral disc/intervertebral joints/ligaments, whereas, later involves spinal nerve or its roots or other neuropathic mechanisms.[4]

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Received: February 01, 2023; Revised: August 14, 2023; Accepted: September 02, 2023
DOI: https://doi.org/10.29271/jcpsp.2023.12.1449

Low back-related radicular leg pain has been designated as lumbosacral Radicular Syndrome (LRS, commonly known as sciatica).[5,6] Clinical diagnosis of LRS is based upon medical history and physical examination. Routine diagnostic imaging is not recommended and is needed only when there is a neurological deficit, suspected serious pathology, or failure to non-invasive treatment / planning surgical treatment.[4,6] Treatment of LRS can be divided into non-invasive (patient education, physical activity, exercise/physical therapy), pharmacological (paracetamol, non-steroidal anti-inflammatory drugs, opioids, anticonvulsants, muscle relaxants, antidepressants, corticosteroids) and invasive management (epidural injections, surgery).[2,4-6]

LBP poses a serious socioeconomic burden worldwide, especially in low and middle-income countries including Pakistan.[3] There has always been a need for more cost-effective and non-invasive pain management strategies which are affordable for the majority of patients. Effectiveness of distal sodium channel blockers (DSCBs) like lignocaine is based upon the theory that radicular pain results from hyperexcitability / hypersensitisation of voltage-gated sodium channels in nerve fibers at the level of dorsal root ganglia (DRG) and nerve root.[7-10] As DRG neurons are pseudo-unipolar type with communicating peripheral and

central processes, so injecting sodium channel blockers in the periphery of the nerve can block hypersensitive sodium channels proximally.[8-10] In recent years, some authors reported their experience with the use of DSCBs like lignocaine for managing radicular pain in the upper and lower extremities.[7,8,10]

For a developing country like Pakistan, DSCBs seem to be a very cost-effective alternative for pain management. However, no local data is available to show the efficacy of DSCBs to date. This pilot study aimed to find the effectiveness of DSCBs in managing patients with LRS.

METHODOLOGY

This open-labelled single-group pilot study with a non-randomised unblinded prospective design was conducted at the Pain Clinic of Armed Forces Institute of Rehabilitation Medicine (AFIRM) Rawalpindi, Pakistan, for a duration of six months from January to June 2022. An ethical approval was obtained from the institutional review board (reference number, 04/2021). A sample size of 45 was calculated using a WHO calculator (5% margin of error, 95% confidence level) and prevalence of 3%.[11] Sampling was done using the nonprobability consecutive sampling technique. A maximum number of available participants (50) during the study period were recruited after getting informed consent from each participant.

Inclusion criteria was patients reporting to the outdoor department, aged 18 years or more, having sciatica (unilateral/bilateral), pain radiating to L5/S1/both dermatomes with pain severity of numerical rating scale (NRS) score more than 4/10 that persisted for seven days or more. Exclusion criteria was patients with vertebral fracture, inflammatory LBP, fibromyalgia, polymyalgia rheumatic, psychiatric disorders/on psychiatric treatment, presence of neurological deficit, suspicion of cauda equina syndrome, using steroids, history of cardiac arrhythmias/ischemic heart disease, previous epidural injection / spinal surgery, bleeding disorders, dementia, peripheral neuropathy, spinal malignancy, congenital spinal deformity, and pregnancy.

Detailed history and complete physical examination were done. Distal target sites for injection were chosen after reviewing available literature on DSCBs. Two important studies were identified wherein the dedicated work of respective authors helped in finalising 4 target sites for injections.[8,10] Diwaker-Prakash nomenclature was used to replicate 4 portals as target sites in the patients (Figure 1).[10]

NRS and SLR scores were documented at baseline (pre-DSCB) and 30 minutes, 24 hours, 1 week, and 4 weeks post-DSCB. NRS was documented for severity of pain and SLR (Lasegue test) for clinical diagnosis of lumbosacral nerve root irritation.[12,13] An imaging study was not required.

Patients were given sub-cutaneous injections in supine position under aseptic conditions. Injection mixture included: 2 ml of 2% injection plain lignocaine + 1 ml (40 mg) injection triamcinolone + 7 ml distilled water making a total volume of 10 ml containing 0.4% lignocaine. A solution of 2.5 ml was injected at each of the Beta 1, Beta 2, Beta 3, and Beta 5 portals using 3 cc syringes (1.5 inches, 25 G needles). Patients were re-evaluated at 30 minutes, 24 hours, 1 week, and 4, weeks, and fresh scores for NRS and SLR were noted down.

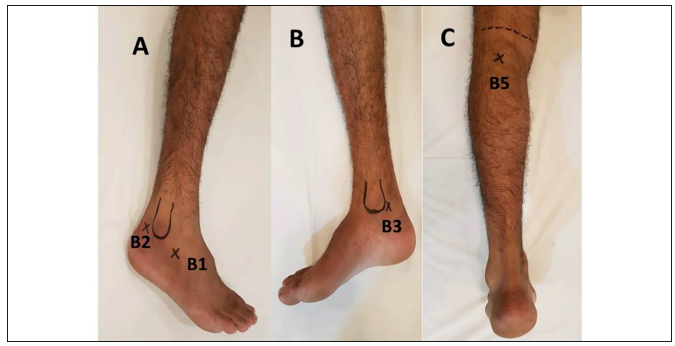

Figure 1: DSCB injection sites; (A) Beta 1 (2 cm anterior and inferior to lateral malleolus) and Beta 2 (between Achilles tendon and posteroinferior aspect of lateral malleolus); (B) Beta 3 (behind the posteroinferior border of medial malleolus); (C) Beta 5 (midline, between 2 heads of gastrocnemius, 5 cm distal to popliteal crease).

Effective pain relief was defined as 50% or more of improvement in NRS score at 24 hours and 1 week, post-DSCB. If a patient reported less than 50% relief at 24 hours and/or 1 week, DSCBs were repeated (i.e. at 24 hours and/or 1 week, as indicated). Repeat-DSCBs injection mixture was steroid-free and included 2 ml of 2% plain lignocaine + 8 ml distilled water.

Data were analysed using Statistical Package for Social Sciences (SPSS) 21.0 (IBM - Illinois). Descriptive statistics were expressed as mean ± standard deviation (SD), frequency, and percentages. A paired sample t-test was applied between pre- and post-DSCB results, and p-values ≤0.05 were considered significant.

RESULTS

The mean age of patients was 45.86 ± 1.928, mean weight was 73.30 ± 11.752 kgs and mean BMI was 25.71 ± 3.606 kg/m^2. The highest frequency of cases was noted among males in the age group of 18-40 years and among females in the age group of 41-60 years (Table I).

Table I: Demographic data and symptoms of patients.

Variable	Frequency n (%)
Age group (years)	
18-40	19 (38%)
41-60	27 (54%)
>60	4 (8%)
Gender	
Male	24 (48%)
Female	26 (52%)
Dermatomal distribution	
L5	7 (14%)
S1	19 (38%)
L5, S1	24 (48%)
Lower limbs involved	
Right	24 (48%)
Left	24 (48%)
Both	2 (4%)

Table II: Comparison of means – pre and post-DSCB NRS / SLR scores using paired samples t-test.

Parameters	Pre-DSCB Mean ± SD	Follow-up	Post-DSCB Mean ± SD	Difference (Pre-Post) Mean ± SD	p-value
NRS	8.00±1.471	After 30 minutes	4.16±2.103	3.840±1.754	<0.001
	8.00±1.471	After 24 hours	3.68±2.420	4.320±2.004	<0.001
	8.00±1.471	After 1 week	2.84±2.179	5.160±1.910	<0.001
	8.00±1.471	After 4 weeks	2.16±2.385	5.840±2.342	<0.001
SLR	45.80±12.631	After 30 minutes	62.50±10.013	-16.700±8.428	<0.001
	45.80±12.631	After 24 hours	65.80±11.79	-20.000±12.037	<0.001
	45.80±12.631	After 1 week	71.10±10.799	25.300±12.265	<0.001
	45.80±12.631	After 4 weeks	74.20±9.655	28.400±13.569	<0.001

Table III: Comparison of means – total number of injections and NRS / SLR scores using paired samples t-test.

Parameters	Pre-DSCB Mean ± SD	Follow-up	Post-DSCB Mean ± SD	Difference (Pre-Post) Mean ± SD	p-value
Total No. of	8.00±1.471	After 30 minutes	4.16±2.103	-6.320±1.558	<0.001
injections	8.00±1.471	After 24 hours	3.68±2.420	-2.480±1.764	<0.001
vs NRS	8.00±1.471	After 1 week	2.84±2.179	-2.000±1.927	<0.001
	8.00±1.471	After 4 weeks	2.16±2.385	-0.480±1.951	0.088
Total No. of	45.80±12.631	After 30 minutes	62.50±10.013	-60.820±10.303	<0.001
injections	45.80±12.631	After 24 hours	65.80±11.79	-64.120±12.173	<0.001
vs SLR	45.80±12.631	After 1 week	71.10±10.799	-69.420±11.292	<0.001
	45.80±12.631	After 4 weeks	74.20±9.655	-72.520±10.144	<0.001

Post-DSCBs, follow-up was done for 4 weeks. No serious procedural complications were noted except temporary injection site pain. Results were statistically significant (<0.001) when mean NRS and SLR scores at every follow-up were compared for pre and post-DSCBs (Table II).

Regarding number of sessions of DSCBs, 25 (50%) patients underwent only 1 session, 16 (32%) patients underwent 2 sessions and 9 (18%) underwent 3 sessions. No current guidelines / recommendations are avaialble on total number of DSCBs/injections. On comparing total number of injections (mean 1.68 ± 0.768) with mean NRS scores at every follow-up, results remained statistically significant (<0.001) at 30 minutes, 24 hours and 1 week post-DSCBs. However, results were insignificant (0.088) at 4 weeks. On comparing total number of injections (mean 1.68 ± 0.768) with mean SLR scores at every follow-up, results remained statistically significant (<0.001) at 30 minutes, 24 hours, 1 week and 4 weeks post-DSCBs (Table III). This highlighted clinical significance of number of injections in improving mean SLR value, while showing its insignificance in improving mean NSR score at 4 weeks.

On comparing total number of injections (mean 1.68 ± 0.768) with duration of symptoms (120.58 ± 208.443) and BMI (25.71 ± 3.606), results were statistically insignificant (p=0.613 and p=0.567, respectively).

DISCUSSION

IASP defines radicular pain as the "pain perceived as arising in a limb or the trunk wall (lancinating in quality, travels along a narrow band), caused by ectopic activation of nociceptive afferent fibers in a spinal nerve or its roots or other neuropathic mechanisms."[14] Recommendations suggest that SLR test, dermatome mapping of pain spread and heel gait evaluation (to check the strength of ankle dorsiflexors) should be done as part of clinical evaluation.[4]

The present results showed significant fall in NRS pain score and an increase in SLR score after DSCBs at every visit upto 4 weeks (Table II). As per the experience of authors, DSCB resulted in immediate pain relief and could be easily performed as outdoor procedure without the need of any special equipment. It can be used as a cost-effective, time-buying alternative procedure allowing for the analgesic effect of medicine to kick in. The analgesic effect of peripherally administered local anaesthetic in relieving radicular pain has also been demonstrated by the previous studies.[7,8] Adabala *et al*. also reported significant reduction in pain relief for L5 and S1 radiculopathy using tibial and sural nerve blocks with local anaesthetic.[8]

In animal studies, local anaesthetics when administered perineurally around dorsal root ganglion resulted in decreased expression of tissue necrosis factor-alpha resulting in decreased mechanical allodynia.[15] Since DRGs are pseudo-unipolar neurons with communicating peripheral and central processes, so local anaesthetic administered peripherally can have the same effect in theory but data is limited to support this hypothesis.[7,10] More studies are needed to exactly comment on the mechanism of pain relief by peripherally administered local anaesthetics.

There is low evidence for short-term efficacy of non-steroidal analgesic drugs and opioids in acute lumbar radiculopathy.[16] Such patients are often recommended to maintain routine physical activity as compared to bed rest because the positive effects of routine mobility outweigh the negative effects of rest.[15] In acute setting, although extraforaminal glucocorticoid injections decrease lumbar radicular pain, however, it is not clinically significant.[16] Hence, DSCB can be used as a time-buying procedure in acute settings to enable the patient to

regain routine mobility. But this needs to be further tested by randomised controlled trials with sufficient sample size.

Epidural steroid injection (ESI) is commonly being used for pain management of LRS.[17] However, ESI has no cost-effect benefit as compared to conservative management at 3 months.[17-19] Moreover, improvement in quality of life (QOL) of patients managed with ESI at 3 months was the same as that of a conservative management.[17,20] DSCB is a cost-effective alternative for radicular pain management, and further studies can be designed to see the effects of DSCB on QOL of patients.

This study was not without limitations. The study design and small sample size prevent from generalisation of the results. Moreover, the patients were taking oral analgesics as a part of usual care which are possible confounding factors. These issues can be addressed in future studies with randomised controlled trial using larger sample size which can address the confounding factors. Nonetheless, the study highlighted the possible role of DSCB in acute care settings which can serve as a food for thought for the fellow colleagues to design further studies to address the limitations of this study.

CONCLUSION

DSCBs have emerged as another reliable option for effective and immediate pain management without the need of a special equipment. Patients with LRS showed significant reduction in NRS pain score and improvement of SLR score even at 4 weeks of follow-up. It can be used as a time-buying alternative procedure allowing for the analgesic effect of medicine to kick in.

ETHICAL APPROVAL:
An ethical approval was obtained from the Institutional Review Board of the Armed Forces Institute of Rehabilitation Medicine, Rawalpindi (reference number, 04/2021).

PATIENTS' CONSENT:
Written informed consents were taken from the participants.

COMPETING INTEREST:
The authors declared no competing interest.

AUTHORS' CONTRIBUTION:
HKS, SJ, UY: Conception of work, data acquisition.
UY, MTK: Data analysis and interpretation.
HKS, SJ, UY, MTK, MR, II: Drafting the work, critical revision, final approval.
All authors approved the final version of the manuscript to be published.

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