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A Prospective, Randomized Study of Cocktail Block and Selective Nerve Root Block in the Management of Lumbar Radicular Pain from Prolapsed Intervertebral Disc

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ABSTRACT

Background: Minimally invasive epidural injections are a cornerstone in the management of lumbar radicular pain due to prolapsed intervertebral disc (PID). The "cocktail block" (CB), a non-targeted epidural injection, and the Selective Nerve Root Block (SNRB), a fluoroscopically guided precise injection, are common techniques. Direct comparative studies on their efficacy are limited.

Objective: To prospectively compare the clinical efficacy, functional improvement, and safety of CB versus SNRB in patients with unilateral lumbar radiculopathy secondary to PID.

Methods: 64 patients meeting stringent inclusion criteria were randomly allocated into two equal groups (n=32 each). Group A received a lumbar interlaminar epidural injection of a corticosteroid-local anesthetic "cocktail." Group B received a fluoroscopically guided transforaminal SNRB with the same medication. Primary outcome was the reduction in leg pain assessed by the Visual Analog Scale (VAS) at 4 weeks. Secondary outcomes included Oswestry Disability Index (ODI) scores, patient global impression of change (PGIC), and medication use at 4 and 12 weeks.

Results: Both groups showed significant intra-group improvement in VAS and ODI scores from baseline ($p<0.001$). However, the SNRB group demonstrated a statistically superior reduction in VAS leg pain at 4 weeks (mean reduction: 5.4 vs. 3.8 in CB group, $p=0.012$). Functional improvement (ODI) was also greater in the SNRB group at 4 weeks ($p=0.023$). A higher proportion of SNRB patients reported "much improved" on PGIC at 4 weeks (75% vs. 47%, $p=0.032$). The difference in outcomes narrowed but remained in favor of SNRB at the 12-week follow-up. No major adverse events were reported in either group.

Conclusion: While both interventions are safe and effective, fluoroscopically guided SNRB provides significantly better short-term pain relief and functional improvement compared to the non-targeted cocktail block in patients with PID-induced radiculopathy.

Key Words: *Prolapsed Intervertebral Disc, Radiculopathy, Selective Nerve Root Block, Epidural Steroid Injection, Cocktail Block, Minimally Invasive.*

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INTRODUCTION

Lumbar radicular pain, commonly resulting from a prolapsed intervertebral disc (PID), represents a pervasive and debilitating clinical challenge, contributing significantly to global disability and healthcare expenditure.[1] The pathophysiological cascade involves not only the mechanical compression of the spinal nerve root but also a potent biochemical insult mediated by the leakage of inflammatory mediators such as phospholipase A2, tumor necrosis factor-alpha, and interleukins from the herniated nucleus pulposus.[2] This inflammatory milieu leads to edema, altered nerve conduction, and heightened pain sensitivity. When a trial of conservative management—including physical therapy, pharmacotherapy, and activity modification—fails to provide adequate relief, interventional spinal procedures become a pivotal therapeutic bridge, potentially averting the need for invasive surgical intervention.[3]

Epidural steroid injections (ESIs) are the most widely performed interventional procedures for this indication, aiming to deliver potent anti-inflammatory corticosteroids close to the site of pathology.[4] These injections, however, are not a monolithic entity and vary considerably in their technical approach, precision, and underlying philosophy. The "cocktail block" (CB), often administered via an interlaminar or caudal route, epitomizes a non-targeted, volume-dependent

strategy.[5] It involves depositing a larger-volume mixture of corticosteroid, local anesthetic, and often saline into the posterior epidural space, relying on passive diffusion and hydrodissection to reach the affected anterior neural structures. Its advantages include technical simplicity, lower cost, and the avoidance of fluoroscopy.[6]

In stark contrast, the Selective Nerve Root Block (SNRB), or transforaminal epidural steroid injection, represents a paradigm of precision medicine in interventional pain management.[7] Performed under real-time fluoroscopic guidance, it facilitates the targeted delivery of a smaller, high-concentration volume of medication directly into the "ventral epidural space" and the immediate vicinity of the symptomatic dorsal root ganglion and nerve root. This approach maximizes the therapeutic agent's concentration at the exact epicenter of the pathophysiological process—the interface between the herniated disc and the inflamed nerve.[8]

Despite the compelling anatomical and pharmacological rationale favoring targeted delivery, the clinical superiority of SNRB over the more generalized CB approach remains a subject of active debate.[9] Proponents of CB argue that its larger volume can bathe multiple segments, potentially address more diffuse inflammation or central sensitization, and cite a favorable safety profile with a lower risk of vascular injection.[10] Critics of SNRB, while acknowledging its precision, point to its technical complexity, greater cost, mandatory ionizing radiation exposure, and a historically documented (though rare) risk of catastrophic neurological complications from particulate steroid embolism.[11] The existing literature is fragmented, with studies often comparing different medications, volumes, or endpoints, and few provide a direct, prospective, randomized comparison of these two fundamental techniques in a homogeneous patient population.[12] This gap in high-quality evidence leads to significant variation in clinical practice, often driven by physician preference, resource availability, or training background rather than robust comparative data.

The primary objective is to compare the reduction in leg pain intensity at 4 weeks post-procedure between the two techniques.

Methodology

Study design, settings and population

This study employed a prospective, randomized, controlled, single-blind, parallel-group design. The study was conducted at the Department of Orthopaedics. The target population consisted of adult patients (aged 25-60 years) presenting with chronic, unilateral lumbar radicular pain secondary to a single-level, whose symptoms had persisted despite a minimum of 6 weeks of structured conservative management.

Inclusion Criteria:

1. Age between 25 and 60 years.
2. Clinical presentation of unilateral radicular pain (leg pain > back pain) in an L5 or S1 dermatomal distribution.
3. Correlating single-level lumbar PID (contained herniation or protrusion) at L4-L5 or L5-S1 confirmed on MRI within the last 3 months.
4. Positive straight leg raise test or femoral nerve stretch test correlating with the affected level.
5. Baseline leg pain intensity of ≥ 6 on the Visual Analog Scale (VAS).
6. Failure to respond to at least 6 weeks of conservative therapy (including NSAIDs, physical therapy, and/or oral corticosteroids).
7. Willingness to provide informed consent and comply with follow-up schedules.

Exclusion Criteria:

1. Previous lumbar spine surgery or instrumentation.
2. Clinical evidence of significant or progressive neurological deficit (e.g., motor weakness ≤ 3/5, cauda equina syndrome).
3. Multi-level symptomatic spinal stenosis or spondylolisthesis (> Grade I).
4. Evidence of infection, tumor, or fracture at the target site.
5. Coagulopathy or current use of anticoagulant therapy that could not be safely paused.
6. Known allergy to corticosteroids, local anesthetics (bupivacaine), or radiographic contrast media.
7. Pregnancy.
8. Systemic or local infection at the planned injection site.
9. Severe cardiopulmonary disease precluding safe procedure performance.
10. Inability to comprehend study procedures or outcome measures.

Sample Size Calculation

The sample size was calculated a priori based on the primary outcome measure: the mean change in VAS leg pain score at 4 weeks post-procedure. Assuming a clinically meaningful between-group difference of 1.5 points on the VAS (with a standard deviation of 1.8, based on previous literature), a power (1-β) of 80%, and a two-sided alpha (α) level of 0.05, the calculation yielded a required sample size of 28 patients per group. To account for an anticipated attrition rate of

approximately 10-15% over the 12-week follow-up period, the sample size was inflated to 32 patients per group, resulting in a total sample size of **N = 64**.

Randomization & Blinding

Randomization was implemented to minimize selection bias and ensure the equitable distribution of known and unknown confounding variables between the two intervention groups. An active-control model was used, comparing the standard "Cocktail Block" (CB) to the more precise "Selective Nerve Root Block" (SNRB). The single-blind protocol ensured that the patients and the outcome assessor were blinded to the group allocation, while the interventionalist performing the procedure was necessarily unblinded. This design allows for a direct, head-to-head comparison of the efficacy and safety profiles of the two techniques under controlled conditions.

Procedure for Data Collection

1. **Screening & Baseline:** Eligible patients were identified from the outpatient clinic. After informed consent, a detailed clinical history, neurological examination, and review of MRI were performed. Baseline VAS and ODI scores were recorded.
2. **Randomization & Intervention:** Eligible patients were randomized (1:1) into Group A (CB) or Group B (SNRB) using computer-generated random numbers sealed in sequentially numbered opaque envelopes opened just prior to the procedure. The assigned procedure was performed by an experienced interventionalist following the standardized protocol detailed in section 2.4 of the main manuscript.
3. **Follow-up Assessments:** A blinded research assistant conducted follow-up evaluations via scheduled clinic visits at **4 weeks (± 3 days)** and **12 weeks (± 7 days)** post-procedure. At each visit, the VAS and ODI were re-administered, and the PGIC and details of any analgesic use or adverse events were recorded using a standardized case report form (CRF).
4. **Data Recording:** All data, including procedural details (needle placement, contrast spread, volume injected) and outcomes, were meticulously recorded in the patient's CRF.

Statistical analysis

Data from the paper CRFs were entered into a secure, password-protected Microsoft Excel spreadsheet by a dedicated data entry operator. The final anonymized dataset was exported to IBM SPSS Statistics (Version 25.0) for statistical analysis.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Cocktail Block (CB) Group (n=32)	Selective Nerve Root Block (SNRB) Group (n=32)	p-value
Age (years), Mean ± SD	48.3 ± 8.7	46.9 ± 9.1	0.542
Gender, n (%)			0.813
Male	18 (56.3%)	17 (53.1%)	
Female	14 (43.8%)	15 (46.9%)	
BMI (kg/m²), Mean ± SD	26.5 ± 3.2	27.1 ± 3.8	0.498
Symptom Duration (weeks), Mean ± SD	10.4 ± 3.2	11.1 ± 4.0	0.432
Affected Level, n (%)			0.796
L4-L5	13 (40.6%)	14 (43.8%)	
L5-S1	19 (59.4%)	18 (56.3%)	
Baseline VAS Leg Pain (0-10), Mean ± SD	7.9 ± 1.0	8.1 ± 0.9	0.382
Baseline ODI (%), Mean ± SD	58.4 ± 7.2	59.7 ± 8.0	0.486

p-values from independent t-tests (continuous) or Chi-square tests (categorical).

The two groups were well-matched at baseline, with no statistically significant differences in any demographic or clinical parameter. The mean age was approximately 48 years in the CB group and 47 years in the SNRB group (p=0.542). Gender distribution, Body Mass Index (BMI), and mean symptom duration (approximately 10-11 weeks) were also comparable. The distribution of the affected spinal level (L4-L5 or L5-S1) was similar between groups. Most importantly, the baseline mean Visual Analog Scale (VAS) score for leg pain (CB: 7.9; SNRB: 8.1, p=0.382) and Oswestry Disability Index (ODI) scores (CB: 58.4%; SNRB: 59.7%, p=0.486) were equivalent, confirming successful randomization.

Table 2: Primary Outcome – Leg Pain Intensity (VAS) Over Time

Time Point	**Cocktail Block (CB) Group**	**Selective Nerve Root Block (SNRB) Group**	**Between-Group p-value**
	Mean VAS (0-10) ± SD	**Mean VAS (0-10) ± SD**	**(Independent t-test)**
Baseline	7.9 ± 1.0	8.1 ± 0.9	0.382
4 Weeks	4.1 ± 1.6	2.7 ± 1.4	**0.001**
12 Weeks	3.5 ± 1.8	2.4 ± 1.7	**0.012**
Mean Change from Baseline to 4 Weeks (95% CI)	**-3.8 (-4.4 to -3.2)**	**-5.4 (-5.9 to -4.9)**	**<0.001**
p-value (Within-Group vs. Baseline)	**<0.001** (Paired t-test)	**<0.001** (Paired t-test)	

Both groups demonstrated a statistically significant reduction in leg pain from baseline to the 4- and 12-week follow-ups (within-group p<0.001 for both time points). However, the magnitude of pain relief was significantly greater in the SNRB group. At the primary 4-week endpoint, the mean reduction in VAS score was 5.4 points in the SNRB group compared to 3.8 points in the CB group (between-group p<0.001). The mean VAS score at 4 weeks was 2.7 in the SNRB group versus 4.1 in the CB group (p=0.001). This superior analgesic effect in the SNRB group persisted, though the difference narrowed slightly, at the 12-week follow-up (mean VAS: 2.4 vs. 3.5, p=0.012).

Table 3: Secondary Outcomes – Functional Disability and Global Impression

Outcome Measure	**Cocktail Block (CB) Group**	**Selective Nerve Root Block (SNRB) Group**	**p-value**
ODI Score (%), Mean ± SD			
Baseline	58.4 ± 7.2	59.7 ± 8.0	0.486
4 Weeks	36.0 ± 9.8	28.6 ± 10.2	**0.004**
12 Weeks	32.1 ± 11.4	25.3 ± 12.1	**0.026**
% ODI Improvement at 4 Weeks	38.4%	52.1%	**0.003**
PGIC at 4 Weeks, n (%)			**0.032** (Chi-square)
Very Much Improved	3 (9.4%)	9 (28.1%)	

Outcome Measure	Cocktail Block (CB) Group	Selective Nerve Root Block (SNRB) Group	p-value
Much Improved	12 (37.5%)	15 (46.9%)	
Minimally Improved	14 (43.8%)	7 (21.9%)	
No Change/Worse	3 (9.4%)	1 (3.1%)	
Patients Requiring Rescue Analgesics at 4 Weeks, n (%)	18 (56.3%)	9 (28.1%)	**0.025**

Functional improvement mirrored the pain relief results. The SNRB group exhibited a significantly greater reduction in ODI scores at both 4 weeks (28.6% vs. 36.0%, p=0.004) and 12 weeks (25.3% vs. 32.1%, p=0.026). The percentage improvement in ODI at 4 weeks was 52.1% for SNRB compared to 38.4% for CB (p=0.003). Patient-reported outcomes also favored the SNRB group. A significantly higher proportion of patients in the SNRB cohort reported being "Much Improved" or "Very Much Improved" on the Patient Global Impression of Change (PGIC) scale at 4 weeks (75.0% vs. 46.9%, p=0.032). Consequently, the need for rescue analgesic medication at 4 weeks was significantly lower in the SNRB group (28.1% vs. 56.3%, p=0.025).

Table 4: Procedure-Related Outcomes and Adverse Events

Parameter / Event	Cocktail Block (CB) Group (n=32)	Selective Nerve Root Block (SNRB) Group (n=32)	Notes
Procedure Time (min), Mean ± SD	8.5 ± 2.1	14.3 ± 3.5	p < 0.001
Contrast Used	No	Yes (100%)	Integral to SNRB technique
Minor Adverse Events, n (%)	2 (6.3%)	3 (9.4%)	p = 0.642
- Transient Headache (Non-postural)	2 (6.3%)	0	
- Transient Paresthesia during procedure	0	2 (6.3%)	Resolved in <2 minutes
- Vasovagal Reaction	0	1 (3.1%)	Resolved with supine positioning
Major Adverse Events	0	0	

As expected, the SNRB procedure, performed under fluoroscopic guidance, took significantly longer than the CB procedure (mean time: 14.3 vs. 8.5 minutes, p<0.001). The safety profile was favorable in both groups, with no major adverse events such as infection, hematoma, or neurological injury reported. Minor, transient adverse events occurred infrequently and were not significantly different between groups (CB: 6.3%, SNRB: 9.4%, p=0.642). These included two cases of non-postural headache in the CB group and transient paresthesia during needle placement (n=2) and a single vasovagal episode in the SNRB group, all of which resolved spontaneously or with simple measures.

Discussion

This prospective, randomized study demonstrates that while both the non-targeted Cocktail Block (CB) and the image-guided Selective Nerve Root Block (SNRB) are safe and effective interventions for lumbar radicular pain secondary to a prolapsed intervertebral disc, the precision of the SNRB technique confers a significant clinical advantage. Our primary

finding—that SNRB resulted in a significantly greater reduction in leg pain at the 4-week primary endpoint—supports the central hypothesis that targeted drug delivery to the site of pathology is superior to a volume-dependent, non-specific epidural spread.[13] This outcome is not merely statistically significant but clinically meaningful, as the between-group difference in VAS reduction (1.6 points) exceeds the commonly accepted minimal clinically important difference of 1.5 points for VAS in radicular pain.[14]

The superior efficacy of SNRB can be attributed to its direct pathoanatomical rationale. The transforaminal approach facilitates the deposition of a high-concentration bolus of corticosteroid and local anesthetic into the ventral epidural space, precisely at the interface between the herniated disc material and the inflamed dorsal root ganglion.[8] This ensures maximal anti-inflammatory effect at the primary site of nociception and neural compromise. In contrast, the interlaminar CB relies on the passive diffusion of a larger, more diluted volume through the dorsal epidural fat and connective tissue to reach the anterior pathology, a process that is less efficient and more variable.[5] Our findings align with and extend those of previous comparative studies. Ghai et al. (2013), in a double-blind trial, reported significantly better pain relief and functional recovery at 2 and 12 weeks with a transforaminal approach compared to an interlaminar approach using similar medication, attributing the result to more reliable ventral epidural spread.[15] Similarly, a systematic review by Buenaventura et al. (2009) concluded that transforaminal injections provided superior short-term pain relief and reduced the need for surgery compared to interlaminar injections, reinforcing the principle of targeted delivery.[16]

The significant secondary outcomes in our study further validate the primary result. The greater improvement in ODI scores and the higher proportion of patients reporting "much improved" on the PGIC in the SNRB group indicate that the enhanced pain relief translated into tangible functional benefits and higher patient satisfaction.[17] The reduced consumption of rescue analgesics in the SNRB group at 4 weeks provides additional objective evidence of its superior therapeutic effect, potentially reducing the risks associated with chronic NSAID use. The convergence of these outcome measures—pain, function, global impression, and analgesic use—strengthens the internal validity of our conclusions and paints a coherent picture of a more rapid and robust recovery facilitated by the targeted intervention.

Our safety data are reassuring and consistent with the broader literature when procedures are performed by experienced hands under appropriate guidelines.[18] The absence of major complications, such as spinal cord infarction or nerve injury, is critical. While SNRB carries a theoretical risk of vascular injection, the meticulous use of live fluoroscopy with contrast confirmation in our protocol likely mitigated this risk.[19] The minor adverse event profile was similar between groups, suggesting that the added complexity of SNRB does not translate into a higher rate of clinically significant side effects in a controlled setting. It is noteworthy, however, that the SNRB procedure required significantly more time and mandatory fluoroscopy, implicating higher resource utilization and radiation exposure, factors that must be weighed against its clinical benefits in resource-constrained environments.[20]

The observed narrowing of the outcome gap between groups at the 12-week follow-up is an important finding. It suggests that while SNRB provides a more powerful initial suppression of inflammation—effectively "jump-starting" the healing process—both techniques can facilitate the natural history of recovery from an acute exacerbation of discogenic radiculopathy over time.[21] This pattern has been observed in other studies, such as the work by Riew et al. (2000), which highlighted the potent therapeutic effect of transforaminal steroids but within a context where natural recovery also plays a role.[22] This does not diminish the value of SNRB's early superiority; faster pain relief and functional recovery have profound implications for reducing disability, improving quality of life, and potentially preventing the chronicization of pain.[23]

Conclusion

In conclusion, this randomized controlled trial provides Level I evidence that for patients with well-defined, unilateral lumbar radiculopathy from a prolapsed intervertebral disc, a fluoroscopically guided Selective Nerve Root Block offers statistically and clinically superior short-term pain relief and functional improvement compared to a non-targeted Cocktail Block. The precision of medication delivery directly to the site of neuroinflammation is the key determinant of this enhanced efficacy. While both procedures are safe, SNRB should be considered the interventional technique of choice when the clinical and radiological presentation is focal and the necessary expertise and imaging resources are available. Future research should focus on cost-effectiveness analyses and long-term outcomes, including the need for repeat procedures or ultimate surgical intervention.

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