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A Comparative Study on Low Back Pain with Radiculopathy treated with Conventional NSAIDs versus Combination of Caudal Epidural Steroid Injections and NSAIDs

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ABSTRACT

Background: Lumbar radicular pain (LBP) is a common and disabling condition affecting patients' quality of life and causing an economic burden on health systems. NSAIDs are the most common agents for the alleviation of pain due to radiculopathy, but are limited in their impact on such therapy, pointing to a need for adjunctive treatment such as caudal epidural steroid injections. The study compared the effectiveness of NSAIDs only and a combination of NSAIDs and CESIs for LBP with radiculopathy due to degenerative joint disease (DJD), acute disc prolapse (ADP), and paraspinal muscle spasm (PSMS).

Methods: A randomized controlled trial was conducted at the Department of Orthopaedics, Continental Medical College/Hayat Memorial Hospital, from September 15, 2022, to June 15, 2023, involving 100 adult patients with MRI-confirmed lower back pain (LBP) and radiculopathy using convenience sampling. Patients were randomized to receive either NSAIDs alone or NSAIDs with CESI. Pain relief was assessed at 1 and 3 weeks using the Numeric Pain Rating Scale (NRS). Statistical analysis (SPSS v. 23) used chi-square tests, with $p \leq 0.05$ considered significant.

Results: Patients with DJD experienced significantly greater pain relief with the combination therapy. By the third week, 94.1% (16) n=29 of DJD patients receiving CESIs with NSAIDs reported significant or complete pain relief compared to 58.3% (7) in the NSAIDs-alone group ($p < 0.05$). No significant differences were observed between the groups for ADP or PSMS ($p > 0.05$).

Conclusion: CESIs combined with NSAIDs are superior for managing DJD-related LBP, while NSAIDs alone may suffice for ADP and PSMS. Personalized treatment strategies are recommended based on underlying pathology.

Keywords: Low Back Pain, Radiculopathy, Degenerative Joint Disease, NSAIDS.

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INTRODUCTION

Low back pain (LBP) is defined as pain and discomfort localized below the costal margin and above the inferior gluteal folds, with or without radiating to the legs (sciatica). It is a pervasive musculoskeletal condition affecting individuals worldwide, with a prevalence ranging from 21% to 68% globally[1]. There are many causes of low back pain including muscle and ligament strain, traumatic injury, infections, tumors, and radiculopathy. One of the common causes of LBP is radiculopathy, which refers to the irritation or compression of spinal nerve roots. In the case of lumbar radiculopathy, this compressive force or nerve irritation may occur within the thecal sac, as the nerve root exits the thecal sac within the lateral recess, as the nerve root traverses the neural foramina or even after the nerve root as exited the foramina. It may be related to disc bulging or herniation, facet or ligamentous hypertrophy, spondylolisthesis, or even neoplastic and infectious processes. Radiculopathy significantly impairs quality of life and productivity and poses a substantial economic burden on healthcare systems[2].

The treatment for acute LBP (<12 weeks) is, NSAIDs and muscle relaxants which are more effective than placebo, while opioids, antibiotics, and antidepressants show limited evidence. Paracetamol offers no benefit. For chronic LBP (>12 weeks), NSAIDs, antidepressants, and opioids may help, but opioids carry significant risks. NSAIDs like ibuprofen and naproxen, commonly prescribed as first-line treatments, block cyclooxygenase to reduce pain and inflammation but can cause gastrointestinal, cardiovascular, and kidney side effects[3]. The effectiveness of paracetamol and muscle relaxants for chronic LBP remains unclear. While NSAIDs provide effective symptomatic relief for many individuals, their use is associated with potential gastrointestinal, cardiovascular, and renal adverse effects. Moreover, their efficacy in managing radicular pain, a hallmark feature of LBP with radiculopathy, may be limited[4]. As such, there is a need to explore alternative or adjunctive treatments to optimize outcomes in this patient population. The National Institute for Health and Care Excellence (NICE) guidelines recommend NSAIDs as first line analgesics for low back pain and sciatica and osteoarthritis. They are also used for musculoskeletal pain from acute injury[5]. In 2018, around 11.5 million oral NSAID prescriptions were issued in England. In the U.S., a 2008 claims database analysis showed that nearly 60% of patients with osteoarthritis or chronic low back pain were prescribed NSAIDs[6]. NSAIDs are commonly used for pain management in India, including for lower back pain. According to a study published in the Indian Journal of Medical Research, NSAIDs are among the most frequently prescribed medications in India. The availability of over-the-counter NSAIDs also contributes to their widespread use for various types of pain, including musculoskeletal conditions like lower back pain[7].

Caudal epidural steroid injections (CESIs) involve the percutaneous administration of corticosteroids into the epidural space via the sacral hiatus, targeting the inflamed nerve roots responsible for radicular pain. 82% patients had no backache or discomfort after a week 92% patients reported no discomfort after one month. By delivering high concentrations of steroids directly to the site of inflammation, CESIs aim to reduce nerve irritation, decrease inflammatory mediators, and alleviate pain[8]. When combined with NSAIDs, CESIs offer a multimodal approach to pain management, potentially enhancing efficacy while minimizing the need for systemic NSAID use and its associated adverse effects[9].

Despite the growing use of CESIs in clinical practice, the comparative efficacy of CESIs in combination with NSAIDs versus NSAIDs alone for treating radiculopathy-associated LBP remains a subject of debate. A study 'Synergistic effects of NSAIDs and caudal epidural steroid injections in the management of chronic low back pain,' concluded that the combined use of NSAIDs and caudal epidural steroid injections was associated with higher patient satisfaction, reduced economic burden due to decreased healthcare utilization, and lower bed occupancy rates. Furthermore, it provided superior pain control compared to NSAIDs alone for chronic low back pain[10]. Thus, there exists a need for robust comparative studies to elucidate the optimal pharmacological management strategy for this patient population.

This study aimed to conduct a comparative analysis of the efficacy and safety of conventional NSAIDs

versus the combination of CESIs and NSAIDs in the management of radiculopathy-related LBP. By systematically evaluating existing literature and synthesizing evidence from randomized controlled trials (RCTs) and observational studies, this study sought to provide clinicians and policymakers with valuable insights into the relative merits, like patient satisfaction, pain control duration, economic burden, and bed occupancy rate, of these treatment modalities.

METHODS

A randomized control trial was conducted in the Department of Orthopaedics at Continental Medical College/Hayat Memorial Hospital from September 15, 2022, to June 15, 2023, after taking IRB approval from the ethical board, IRB approval no 52/IRB/CMC. The procedures followed were by the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000, involving 100 adult patients diagnosed with low back pain and radiculopathy. The population proportion of lower back pain was 39.6 % [11]. Hence, Sample size was calculated using power analysis, set at 80% power and a 95% confidence level, to detect clinically significant differences in pain relief between the two treatment groups. This resulted in a minimum sample size of 50 patients per group. Convenience sampling was employed, enrolling eligible patients presenting with low back pain and radiculopathy during the study period.

Patients were divided into two groups: Group 1 received only nonsteroidal anti-inflammatory drugs (NSAIDs), while Group 2 was administered a combination of NSAIDs and caudal epidural steroid injections. Participants were between 19 and 64 years of age, and inclusion criteria required confirmed disc-related pathology on MRI. Exclusion criteria included patients with comorbidities such as diabetes, hypertension, cancer, spinal trauma, or no disc-related pathology. Written informed consent was obtained from all participants prior to their inclusion. In both groups, identical NSAIDs were administered to ensure consistency in treatment efficacy. The caudal epidural steroid injection for Group 2 consisted of 80 mg of Depo-Medrol (methylprednisolone acetate) combined with 3 cc of bupivacaine, delivered via an 18-gauge LP needle using a sacral hiatus approach.

The efficacy of treatments was evaluated at 1 and 3 weeks post-treatment using the Numeric Pain Rating Scale (NRS) to assess pain levels and functional improvements. Data were compiled and analyzed using SPSS version 23, with descriptive statistics generated for baseline characteristics. The chi-square test was applied to compare pain scores between groups, with a significance level of $p \leq 0.05$.

RESULTS

Table 1: Descriptive Statistics of Study Population

Variable	Mean	Standard Deviation
Age	57.78	13.66
Categorical Variable	**Frequency (N)**	**Percentage (%)**
Disease		
DJD (Degenerative Joint Disease)	29	58.0
ADP (Acute Disc Prolapse)	7	14.0
PSMS (Paraspinal Muscle Spasm)	14	28.0
Treatment Given		
NSAID	25	50.0
NSAID + Cuadial Epidural Injection	25	50.0
Pain Relief at 1 week		
Mild Pain Relief	11	22.0
Moderate Pain Relief	15	30.0
Appreciable Pain Relief	17	34.0

Complete Pain Relief	7	14.0
Pain Relief at 3rd week		
Mild Pain Relief	0	0.0
Moderate Pain Relief	1	2.0
Appreciable Pain Relief	12	24.0
Complete Pain Relief	37	74.0
Total	50	100

The study's patient population is moderately distributed in age, with an average age of 57.78 ±13.6 years. The disease distribution indicates that 58.0% of patients have DJD, whereas 14.0% and 28.0% of cases, respectively, are caused by ADP and PSMS. Treatment given to 50.0% of the patients was NSAID, and 50.0% got NSAID + Caudal Epidural Injection. Following significant pain relief (34.0%), moderate pain (30.0%), mild pain (22.0%), and total pain relief (14.0%), the majority of patients report significant pain alleviation after one week. The distribution dramatically changes by the third week, with a vast majority of patients reporting total pain reduction (74.0%), followed by noticeable alleviation (24.0%), and just a small number reporting moderate relief (2.0%) **(Table 1)**.

Table 2: Difference between the Pain Relief at Week 1 and Week 3 at Each Treatment

Disease	Time	Treatment Given	Pain	p-value
DJD	1st week	NSAID	1.8±0.7	0.004
		NSAID + Cuadial Epidural Injection	2.9±0.9	
	3rd Week	NSAID	3.5±0.5	0.021
		NSAID + Cuadial Epidural Injection	3.9±0.2	
ADP	1st week	NSAID	2±0.8	0.064
		NSAID + Cuadial Epidural Injection	3.3±0.5	
	3rd Week	NSAID	3.5±0.5	0.445
		NSAID + Cuadial Epidural Injection	3.0±1	
PSMS	1st week	NSAID	1.5±0.7	0.010
		NSAID + Cuadial Epidural Injection	3±0.7	
	3rd Week	NSAID	3.6±0.5	0.160
		NSAID + Cuadial Epidural Injection	4±0.1	

Table 2 showed that for DJD, NSAIDs initially provided a pain relief score of 1.8±0.7, which improved to 3.5±0.5 by the third week. The addition of a caudal epidural injection increased the first week's pain relief to 2.9±0.9, a significant improvement (p=0.004), and further to 3.9±0.2 by the third week (p=0.021). In ADP patients, NSAIDs alone achieved a score of 2±0.8 at the first week, increasing to 3.5±0.5 by the third. Combined treatment in ADP resulted in a first week score of 3.3±0.5, not significantly different (p=0.064), and decreased to 3.0±1 by the third week (p=0.445). PSMS patients treated with NSAIDs had an initial relief of 1.5±0.7, improving to 3.6±0.5 by the third week. With caudal epidural injections, initial relief rose significantly to 3±0.7 (p=0.010) and to the highest score of 4±0.1 by the third week, although the change was not statistically significant (p=0.160).

Table 3: Bivariate Analysis to Assess the Association between Dependent and Independent Variables

Disease	Time	Treatment Given	Pain Relief		p-value
			Yes	No	
DJD	1st week	NSAID	0	3	0.01
		NSAID + Cuadial Epidural Injection	5	2	
	3rd Week	NSAID	7	0	1
		NSAID + Cuadial Epidural Injection	16	0	
ADP	1st week	NSAID	0	1	0.48
		NSAID + Cuadial Epidural Injection	1	0	
	3rd Week	NSAID	2	0	0.05
		NSAID + Cuadial Epidural Injection	1	0	
PSMS	1st week	NSAID	0	5	0.029
		NSAID + Cuadial Epidural Injection	1	0	
	3rd Week	NSAID	6	0	0.025
		NSAID + Cuadial Epidural Injection	5	0	

Table 3 showed that Degenerative Joint Disease (DJD), Adhesive Capsulitis (ADP), and Post-Surgical Muscle Spasms (PSMS) across two time points (1st and 3rd week) and different treatment modalities. For DJD in the 1st week, NSAID treatment had resulted in no pain relief for all three patients, while NSAID combined with Caudal Epidural Injection had provided pain relief for 5 out of 7 patients, showing a statistically significant effect with a p-value of 0.01. In the 3rd week, NSAID alone had provided complete relief for 7 patients, and the combination therapy had benefited all 16 patients, though the p-value was non-significant at 1. For ADP, during the 1st week, NSAID alone had been ineffective for the single patient treated, whereas the combination therapy had relieved pain for the one patient it was administered to, with a p-value of 0.48. By the 3rd week, NSAID alone had relieved pain in both patients treated, and the combination had maintained its efficacy for one patient, with a borderline p-value of 0.05. In PSMS, NSAID treatment in the 1st week had relieved pain in one patient, but the combination therapy had worsened conditions for 5 patients, albeit with a statistically significant improvement noted in the p-value of 0.029. By the 3rd week, both NSAID alone and combined with the injection had relieved all patients treated, 6 and 5, respectively, both treatments showing significant effects with p-values of 0.025.

DISCUSSION

Lower back pain with radiculopathy can be a complex condition that can make it challenging to determine the most effective treatment plan. It's important to understand how different treatment approaches can impact pain relief and overall patient outcomes [11,12]. The study's patient population is moderately distributed in age, with a median age of 57.78± 13.66. A similar study conducted in Iran revealed that the groups with lower back pain having average ages of 57.8, 55.7, and 57.3 years were analyzed: received Gabapentin, Gabapentin and Naproxen respectively for as their treamtment[13].

The disease distribution indicates that 58.0% of patients have Degenerative Joint Disease, whereas 14.0% of cases are caused by Acute disc prolapse and 28% by Paraspinal muscular spasm. The treatment options are equally divided, with 50.0% of patients receiving NSAID and the remaining 50.0% receiving NSAID + Caudal Epidural Injection. Equal distribution of patients between NSAIDs alone and combination therapy allowed valid outcome comparison. A similar Indian study compared conservative management versus epidural steroid injections in two treatment groups[14,15].

The current study is conducted to report pain relief at 1 week and 3 weeks following NSAIDs and epidural injections. In Amsterdam a study showed treatment effects that were categorized into four-time frames: post-treatment (within 1 week after the last session), short-term (1 week to 3 months after the last session), medium-term (3 months to <1 year after the last session), and long-term (1 year or more after the last session)[16,17].

In patients with DJD, the combination of NSAIDs and caudal epidural injections showed significantly

superior pain relief compared to NSAIDs alone. After one week, 58.3% of patients on NSAIDs alone had moderate relief, while in the combination group, 47.1% reported significant and 29.4% complete pain relief. By the third week, the difference widened, with 94.1% of DJD patients in the combination group achieving significant relief, compared to 58.3% in the NSAIDs-only group ($p = 0.021$). These findings suggest a clear advantage of combination therapy, consistent with existing literature supporting the efficacy of combining anti-inflammatory drugs with localized steroid injections. The data highlights the sustained benefit of caudal epidural injections in DJD management, particularly in cases where inflammation is a major contributor to symptoms. The statistically significant outcomes at both week one ($p = 0.01$) and week three affirm the value of personalized treatment based on underlying pathology[18,19,20].

ADP patients showed no significant difference in pain relief between treatment groups, with $p = 0.233$ at week one and $p = 0.459$ at week three. This aligns with a 2020 U.S. study where 97% of herniated disc cases responded to conservative care like NSAIDs and LESIs. The limited benefit of steroid injections in ADP highlights the need to explore surgical or targeted noninvasive options for non-responders[21,22].

Results have been more complicated for patients with PSMS. In the first week, combination therapy showed a trend toward superior early pain relief in PSMS patients ($p = 0.058$). However, by week three, the difference between groups diminished, and treatment type was no longer significantly associated with pain relief ($p = 0.145$). Steroid injections may offer temporary relief in PSMS, but show limited long-term benefit. A difference finding study in that regard was in India. It demonstrated significant pain relief over the long term (VAS score reduction from 8.41 to 4.80, $p < 0.001$) and relief sustained at functional levels after six months, with 92.72% of patients rating their progress as positive in caudal epidural injections [23,24,25].

These findings support personalized treatment based on pathology. DJD patients showed strong response to caudal epidural injections, highlighting their role in inflammation control. However, limited benefit was observed in ADP and PSMS, suggesting the need for tailored or adjunctive therapies.

CONCLUSION

Combination of epidural steroid injections with nonsteroidal anti-inflammatory drugs significantly enhanced the management of low back pain due to radiculopathy, particularly in patients who have degenerative joint disease. The vast majority of patients under combination therapy reported a considerable or complete amount of pain relief by the third week, compared to those treated alone with NSAIDs. However, such patients with acute disc prolapse or with paravertebral muscle spasm who underwent CESIs did not benefit significantly. These findings attest to the relevance of an individualistic treatment approach as it indicates that while there is palpable gain for CESIs in terms of DJD-progressed radiculopathy, for other conditions like ADP and PSMS, NSAIDs alone may be sufficient. More research may be needed to further look at those alternative or adjunctive treatments for these specific subgroups.

LIST OF ABBREVIATIONS

ADP: Acute Disc Prolapse
CESIs: Caudal Epidural Steroid Injections
DJD: Degenerative Joint Disease
LBP: Lower Back Pain
NSAIDs: Non-Steroidal Anti-Inflammatory Drugs
NRS: Numeric Pain Rating Scale
PSMS: Paraspinal Muscle Spasm

CONFLICT OF INTEREST

None

FUNDING

None

ETHICAL APPROVAL

The study received ethical approval from the Institutional Review Board of Continental Medical College, under reference number (52/IRB/CMC).

PATIENT CONSENT

Consent was taken from the patients before the collection of data, and confidentiality was maintained throughout the collection of data and while writing the manuscript.

AUTHORS' CONTRIBUTIONS

IM conceptualized the project, while **RKL** collected data. **MUS** conducted the literature search, and **MUA** performed the statistical analysis. **MOI** handled drafting and revising the manuscript, while **FU** contributed to statistical analysis and writing.

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