

Research Article

Comparative efficacy of pregabalin and cyclobenzaprine in the management of lumbar prolapsed intervertebral disc with sciatica

Arnav Pankaj Rathod^{1*}; Yogesh Rathod²; Ganesh Pundkar³; Rajendra Baitule⁴; Hrishikesh Saodekar⁴

¹Resident, Department of Orthopaedics, Dr. Panjabrao Deshmukh Memorial Medical College, Amravati, India.

²Assistant Professor, Department of Orthopaedics, Dr. Panjabrao Deshmukh Memorial Medical College, Amravati, India.

³Head of Department, Department of Orthopaedics, Dr. Panjabrao Deshmukh Memorial Medical College, Amravati, India.

⁴Professor, Department of Orthopaedics, Dr. Panjabrao Deshmukh Memorial Medical College, Amravati, India.

***Corresponding Author: Arnav Pankaj Rathod**

Flat No.113/114, A-Wing, Tower A-5, Godrej Garden
Enclave, Pirojsha Nagar, Vikhroli East, Mumbai 400079,
India.
Tel: 8591962299; Email: rarnav95@yahoo.in

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Abstract...

Background: Prolapsed Intervertebral Disc (PIVD) is a common spinal disorder that may present with sciatica and can significantly impair pain, function, and quality of life. Conservative management includes pharmacological agents such as pregabalin, an anticonvulsant with analgesic properties, and cyclobenzaprine, a centrally acting skeletal muscle relaxant. Comparative data regarding the effectiveness and tolerability of these agents in patients with PIVD-associated sciatica remain limited.

Aim: To compare the efficacy of pregabalin and cyclobenzaprine in patients with lumbar PIVD-associated sciatica, with particular emphasis on pain relief, functional improvement, and adverse effects.

Methods: A prospective comparative study was conducted in 60 patients with MRI-confirmed lumbar PIVD and radiculopathy. Patients were divided into two groups of 30 patients each. Group A received oral pregabalin 75-150 mg/day, titrated according to response and tolerability, while Group B received oral cyclobenzaprine 10 mg once daily. Pain intensity was assessed using the Visual Analogue Scale (VAS), and functional disability was assessed using the Oswestry Disability Index (ODI) at baseline and at 2, 4, and 6 weeks. Adverse drug reactions and treatment discontinuations were recorded.

Results: Both groups demonstrated improvement in VAS and ODI scores during the 6-week follow-up period. Mean VAS scores decreased from 7.9 ± 0.9 to 2.3 ± 0.8 in the pregabalin group and from 7.8 ± 1.0 to 1.1 ± 0.7 in the cyclobenzaprine group at 6 weeks. Mean ODI scores decreased from 53.2 ± 7.8 to 26.7 ± 6.4 in the pregabalin group and from 52.6 ± 8.4 to 16.2 ± 5.8 in the cyclobenzaprine group. Adverse effects including drowsiness, dizziness, and peripheral edema were reported more frequently in the pregabalin group, whereas dry mouth was slightly more frequent in the cyclobenzaprine group. Treatment discontinuation occurred in 3 patients in Group A and 1 patient in Group B.

Conclusion: In this study population, both pregabalin and cyclobenzaprine were associated with improvement in pain and functional disability over 6 weeks. Cyclobenzaprine was associated with lower mean VAS and ODI scores at follow-up and fewer treatment discontinuations. These findings should be interpreted cautiously, and larger randomized comparative studies with appropriate statistical methodology and longer follow-up are required to establish the comparative effectiveness and safety of these medications.

Keywords: Prolapsed intervertebral disc; Sciatica; Pregabalin; Cyclobenzaprine; Visual analogue scale; Oswestry disability index; Lumbar radiculopathy.

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Introduction

Prolapsed Intervertebral Disc (PIVD), also commonly referred to as lumbar disc herniation, is a condition in which the nucleus pulposus protrudes through a tear or weakening in the annulus fibrosus. Disc herniation may result in compression or irritation of adjacent nerve roots and can produce low back pain, radicular pain, sensory disturbances, or motor deficits depending on the location and severity of the lesion [1]. PIVD commonly affects the lumbar spine, particularly the L4-L5 and L5-S1 levels, and may present clinically with low back pain, sciatica, numbness, tingling, or weakness in the lower extremities [2-4]. The clinical manifestations depend on the level and extent of disc pathology as well as the degree of neural compression. The prevalence of lumbar disc abnormalities varies according to the population studied and the diagnostic modality used. Magnetic resonance imaging studies have demonstrated that disc abnormalities may also be present in asymptomatic individuals, emphasizing the importance of correlating radiological findings with clinical presentation [5-7].

Conservative treatment remains an important component of management in patients without indications for urgent surgical intervention. Pharmacological treatment aims to reduce pain and improve functional status. Pregabalin is an anticonvulsant and analgesic agent that binds to the $\alpha 2\text{-}\delta$ subunit of voltage-gated calcium channels in the central nervous system, thereby reducing the release of excitatory neurotransmitters [8]. It has been used for neuropathic pain and has consequently been prescribed in patients with radicular pain. Cyclobenzaprine is a centrally acting skeletal muscle relaxant structurally related to tricyclic antidepressants. It is primarily used for short-term treatment of acute musculoskeletal pain associated with muscle spasm [9]. Its potential role in patients with PIVD-associated sciatica may be related particularly to the muscular component of pain and associated paraspinal spasm.

Although both medications may be used during conservative management, their comparative effectiveness in patients with lumbar PIVD-associated sciatica remains clinically relevant. Therefore, the present study was undertaken to compare pregabalin and cyclobenzaprine with respect to pain relief, functional disability, and adverse effects.

Aims and objectives

Aim: To compare the efficacy of pregabalin and cyclobenzaprine in the management of patients with lumbar PIVD-associated sciatica.

Objectives

1. To compare pain reduction between patients receiving pregabalin and those receiving cyclobenzaprine using the Visual Analogue Scale.
2. To compare functional improvement between the two groups using the Oswestry Disability Index.
3. To compare the adverse-effect profiles of pregabalin and cyclobenzaprine.
4. To compare treatment discontinuation between the two groups.

Materials and methods

Study design: A prospective comparative clinical study was conducted.

Study setting: The study was conducted in the Department of Orthopaedics at a tertiary care centre.

Study duration: The study was conducted over a period of 6 months, during which patients fulfilling the predefined inclusion criteria were enrolled.

Sample size: A total of 60 patients were enrolled and divided into two groups of 30 patients each.

Study population: The study population consisted of adult patients diagnosed with MRI-confirmed lumbar PIVD with associated radiculopathy/sciatica.

Treatment groups:

Group A - Pregabalin Group

Patients received oral pregabalin at a dose of 75-150 mg/day, titrated according to clinical response and tolerability.

Group B - Cyclobenzaprine Group

Patients received oral cyclobenzaprine 10 mg once daily.

Inclusion criteria

Patients fulfilling the following criteria were included:

- Age between 18 and 65 years.
- MRI-confirmed lumbar PIVD with nerve-root compression.
- Unilateral or bilateral sciatica with pain radiating below the knee.
- Duration of symptoms between 2 weeks and 3 months.
- Willingness to participate in the study and provide informed consent.

Exclusion criteria

Patients were excluded if they had:

- Previous spinal surgery.
- Chronic peripheral neuropathy or other neurological disorders.
- Severe renal or hepatic impairment.
- Pregnancy or lactation.
- Use of pregabalin or muscle relaxants during the preceding month.
- Known allergy or intolerance to either study medication.

Clinical assessment

After obtaining informed consent, baseline demographic and clinical information was recorded, including age, sex, and occupation. Patients were assessed at baseline and followed up at 2, 4, and 6 weeks after initiation of treatment. At each follow-up visit, pain intensity was assessed using the Visual Analogue Scale (VAS), and functional disability was assessed

using the Oswestry Disability Index (ODI). Adverse drug reactions, including drowsiness, dizziness, dry mouth, and peripheral edema, were recorded during follow-up. Treatment discontinuation was also documented.

Primary outcome

The primary outcome was change in pain intensity measured using the Visual Analogue Scale at baseline, 2 weeks, 4 weeks, and 6 weeks.

Secondary outcomes

Secondary outcomes included:

1. Change in functional disability measured using the Oswestry Disability Index.
2. Incidence of adverse drug reactions.
3. Treatment discontinuation.

Results

A total of 60 patients were included in the study, with 30 patients allocated to Group A and 30 patients to Group B.

Demographic characteristics: Reports a mean age of 41.8 ± 8.2 years in Group A and 42.4 ± 9.0 years in Group B.

The original sex table, reports 18 males and 12 females in Group A and 19 males and 11 females in Group B. These values total 30 patients in each group.

The reported baseline values were:

- Baseline VAS: 7.9 in Group A and 7.8 in Group B.
- Baseline ODI: 53.2% in Group A and 52.6% in Group B.

Pain relief - Visual analogue scale

Follow-up	Group A - Pregabalin	Group B - Cyclobenzaprine
Baseline	7.9 ± 0.9	7.8 ± 1.0
2 weeks	5.4 ± 1.1	4.0 ± 0.8
4 weeks	3.5 ± 1.0	2.1 ± 0.9
6 weeks	2.3 ± 0.8	1.1 ± 0.7

Both groups demonstrated progressive reduction in VAS scores during follow-up. The reduction was numerically greater in the cyclobenzaprine group at each follow-up assessment.

At 6 weeks, the mean VAS score was 2.3 ± 0.8 in the pregabalin group compared with 1.1 ± 0.7 in the cyclobenzaprine group.

Functional outcome - Oswestry disability Index

Follow-up	Group A - Pregabalin	Group B - Cyclobenzaprine
Baseline	53.2 ± 7.8	52.6 ± 8.4
2 weeks	43.4 ± 4.2	39.2 ± 2.4
4 weeks	36.8 ± 5.2	28.9 ± 3.1
6 weeks	26.7 ± 6.4	16.2 ± 5.8

ODI scores improved progressively in both groups. At 6 weeks, the mean ODI was 26.7 ± 6.4 in the pregabalin group and 16.2 ± 5.8 in the cyclobenzaprine group.

Adverse effects

Adverse effect	Group A - Pregabalin	Group B - Cyclobenzaprine
Drowsiness	32%	18%
Dizziness	22%	6%
Dry mouth	10%	14%
Peripheral edema	8%	0%
Treatment discontinuation	3 patients	1 patient

Drowsiness and dizziness were reported more frequently in the pregabalin group. Peripheral edema was reported in the pregabalin group but not in the cyclobenzaprine group. Dry mouth was slightly more frequent in the cyclobenzaprine group.

Treatment discontinuation occurred in 3 patients in Group A and 1 patient in Group B i.e., 3/30 (10%) in Group A and 1/30 (3.3%) in Group B.

Discussion

Lumbar PIVD with associated sciatica is commonly managed initially with conservative measures in the absence of progressive neurological deficit or other indications for surgical intervention. Pharmacological treatment is directed toward symptom control and restoration of function.

In the present study, both pregabalin and cyclobenzaprine were associated with improvement in pain and functional disability during the 6-week follow-up period.

The reduction in VAS scores was greater in the cyclobenzaprine group at each follow-up assessment. The mean VAS score decreased from 7.8 ± 1.0 at baseline to 1.1 ± 0.7 at 6 weeks in the cyclobenzaprine group, while the pregabalin group demonstrated a reduction from 7.9 ± 0.9 to 2.3 ± 0.8 .

Similarly, functional disability improved in both groups. The mean ODI decreased from 52.6 ± 8.4 to 16.2 ± 5.8 in the cyclobenzaprine group and from 53.2 ± 7.8 to 26.7 ± 6.4 in the pregabalin group.

The greater improvement observed with cyclobenzaprine may potentially reflect its effect on the muscular component of pain and associated paraspinal muscle spasm. However, because the current study does not provide detailed information regarding the presence or severity of muscle spasm at baseline, this explanation remains speculative.

Pregabalin acts primarily through modulation of voltage-gated calcium channels and has been used in the treatment of neuropathic pain [8]. However, the clinical effectiveness of pregabalin in lumbar radicular pain has been questioned in previous research. Therefore, the findings of the present study should be interpreted within the context of the existing evidence and should not be considered sufficient to establish pregabalin as inferior to cyclobenzaprine for all patients with sciatica.

Cyclobenzaprine is primarily used as a centrally acting muscle relaxant for short-term treatment of musculoskeletal pain associated with muscle spasm [9]. Its role in radicular pain may therefore differ from that of pregabalin. The comparison between the two drugs should consequently be interpreted as a comparison of two pharmacological approaches rather than evidence that one drug is universally appropriate for all patients with lumbar radiculopathy.

Regarding tolerability, drowsiness and dizziness were more frequently reported in the pregabalin group, while dry mouth was slightly more frequent in the cyclobenzaprine group. Peripheral edema was reported in the pregabalin group but not in the cyclobenzaprine group.

The study has several limitations. First, the sample size was relatively small, with only 60 patients. Second, follow-up was limited to 6 weeks, preventing assessment of longer-term outcomes. Third, the current manuscript does not clearly describe the method used to allocate patients to the two treatment groups. Fourth, the statistical methodology requires clarification, particularly regarding analysis of repeated VAS and ODI measurements.

Despite these limitations, the observed differences in VAS and ODI scores provide a basis for further investigation. Larger randomized comparative studies with standardized treatment protocols, appropriate statistical analysis, longer follow-up, and clearly defined patient subgroups are required to establish the comparative effectiveness and safety of pregabalin and cyclobenzaprine.

Limitations

The present study has several limitations.

1. The sample size was relatively small, with 60 patients.
2. The follow-up period was limited to 6 weeks.
3. The current manuscript does not clearly specify the method of allocation of patients to the two treatment groups.
4. Detailed information regarding concomitant analgesic or other conservative treatments is not provided.
5. The study was conducted at a single tertiary care centre, which may limit generalizability.

Conclusion

This prospective comparative study demonstrated improvement in pain and functional disability among patients with lumbar PIVD-associated sciatica treated with either pregabalin or cyclobenzaprine over a 6-week period.

Within the study population, cyclobenzaprine was associated with lower mean VAS and ODI scores at follow-up and fewer reported treatment discontinuations. However, these findings should be interpreted cautiously because of the relatively small sample size, short follow-up period, and methodological limitations.

Further adequately powered randomized controlled studies with standardized treatment protocols and longer follow-up are required to determine the comparative effectiveness, safety, and appropriate clinical role of pregabalin and cyclobenzaprine in patients with lumbar radiculopathy.

Declarations

Conflict of Interest: The authors declare no conflict of interest.

Funding: No external funding was received for this study.

Informed Consent: Written informed consent was obtained from all participants before enrolment in the study.

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