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A PROSPECTIVE AND OBSERVATIONAL STUDY TO ASSESS THE EFFICACY OF PREGABALIN VERSUS DULOXETINE IN RELIEVING EARLY POST OPERATIVE NEUROPATHIC PAIN WITH RESPECT TO CLINICAL AND FUNCTIONAL OUTCOMES IN PATIENTS UNDERGOING LUMBAR SPINE SURGERY.

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ABSTRACT **Background:** Post-operative neuropathic pain is one of the most disabling complications following lumbar spine surgery and significantly affects patient recovery and functional outcome. Due to similarities in the underlying pathophysiological mechanisms of epilepsy and neuropathic pain, drugs such as pregabalin and duloxetine are frequently used for its management (Dworkin et al., 2007; Gajraj, 2007). **Methods:** This prospective and observational comparative study included a cohort of 60 patients undergoing single-level lumbar spine surgery who developed early post-operative neuropathic pain, diagnosed using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) score (≥12) (Bennett et al., 2005). Patients were allocated into two groups: pregabalin (n = 30) and duloxetine (n = 30). Clinical outcome was assessed using the Visual Analog Scale (VAS), functional outcome using the Oswestry Disability Index (ODI), and neuropathic pain severity using LANSS at predefined follow-ups. Total rescue analgesic consumption was also recorded. **Results:** Demographic variables and surgical levels were comparable between the two groups. Both groups demonstrated significant improvement in VAS and ODI scores compared to pre-operative status. Pregabalin showed statistically superior improvement at early follow-ups, while outcomes were comparable at longer follow-ups. Total analgesic consumption was lower in the pregabalin group. **Conclusions:** Both pregabalin and duloxetine are effective in the treatment of early post-operative neuropathic pain following lumbar spine surgery. Pregabalin demonstrated superior short-term clinical and functional outcomes, whereas both drugs showed comparable long-term benefits.

KEYWORDS : Neuropathic pain, Pregabalin, Duloxetine, VAS, ODI, LANSS

INTRODUCTION

Radiculopathy and degenerative disc disease frequently require lumbar spine surgery. Neuropathic pain is one of the most incapacitating types of pain, and despite advancements in surgical methods, a considerable percentage of patients continue to experience chronic pain following surgery (Yorimitsu et al., 2001; Atlas et al., 2005). Burning pain, shooting pain, paresthesia, hyperalgesia, and allodynia are hallmark features of neuropathic pain, which results from damage or dysfunction of the somatosensory nervous system (Bennett et al., 2005).

The pathophysiology of post-operative neuropathic pain involves demyelination of injured nerve fibers, increased expression of voltage-gated sodium and calcium channels, ectopic neuronal firing at the dorsal root ganglion, and central sensitization within the spinal cord (Devor & Wall, 1990; Woolf, 2011). These mechanisms distinguish neuropathic pain from nociceptive pain, explaining why conventional analgesics such as NSAIDs and opioids are often insufficient for effective symptom control (Baron, 2006).

Pregabalin, a structural analogue of gamma-aminobutyric acid, produces analgesia by binding to the α2-δ subunit of voltage-gated calcium channels, thereby reducing the release of excitatory neurotransmitters including glutamate, norepinephrine, and substance P (Field et al., 2000; Durkin et al., 2010). Duloxetine, a serotonin–norepinephrine reuptake inhibitor, enhances descending inhibitory pain pathways at both spinal and supraspinal levels, thereby modulating central pain processing (Goldstein et al., 2005; Lunn et al., 2014). Despite the fact that both medications are frequently used to treat a variety of neuropathic pain syndromes, there is currently little data comparing their effectiveness in treating early post-operative neuropathic pain after lumbar spine surgery. Therefore, the purpose of this study was to assess the effects of pregabalin and duloxetine on analgesic demand, functional recovery, and clinical pain alleviation.

AIMS AND OBJECTIVES:

The primary aim of this study was to compare the efficacy of pregabalin and duloxetine in relieving early post-operative neuropathic pain following lumbar spine surgery. The secondary objectives were:

- To assess neuropathic pain severity using the LANSS score
- To evaluate clinical outcome using the VAS score
- To evaluate functional outcome using the ODI score
- To compare total rescue analgesic consumption between the two groups

METHODS

This prospective and observational comparative study was conducted after obtaining approval from the Institutional Ethics Committee in MGM Medical College and Hospital, Chhatrapati Sambhajinagar. Patients aged between 25 and 60 years undergoing single-level lumbar spine surgery were screened post-operatively for neuropathic pain. Patients with LANSS score ≥12 on post-operative assessment were included in the study. Patients with multilevel spinal surgery, pre-existing peripheral neuropathy, severe systemic illness, psychiatric disorders, or prior use of antineuropathic medications were excluded.

Eligible patients were randomly allocated into two groups. Group A received pregabalin at a dose of 150 mg/day, while Group B received duloxetine at a dose of 60 mg/day. All patients received standard post-operative analgesia with NSAIDs. Rescue analgesic consumption was recorded quantitatively.

Patients were evaluated pre-operatively and post-operatively at 1 week, 1 month, 3 months, and 6 months using LANSS, VAS, and ODI scores.

Statistical analysis was performed using paired t-test for intra-group comparisons and unpaired t-test for inter-group comparisons. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 60 patients who developed post-operative neuropathic pain were included in the study, with 30 patients in each group. Baseline demographic variables, comorbidities, and surgical levels were comparable between the two groups, indicating adequate matching. Both pregabalin and duloxetine groups demonstrated a significant reduction in LANSS, VAS, and ODI scores compared to pre-operative

values. Pregabalin demonstrated statistically superior improvement in pain intensity and functional scores at early follow-ups, particularly at 1 and 3 months. However, at 6 months follow-up, the difference between the two groups was not statistically significant. Total rescue analgesic consumption was lower in the pregabalin group, suggesting an analgesic-sparing effect.

Table 1: Demographic Distribution And Surgical Levels Operated Upon Between The Two Groups

Demographic data	Group A (Pregabalin) n (%) / Mean ± SD	Group B (Duloxetine) n (%) / Mean ± SD
Cases	30 (100)	30 (100)
Age (years)	47.1 ± 8.6	46.3 ± 9.1
Male	12 (40)	13 (43)
Female	18 (60)	17 (57)
BMI (kg/m²)	27.2 ± 2.8	27.6 ± 3.1
Smokers	11 (36.7)	12 (40)
Diabetes mellitus	14 (46.7)	15 (50)
Hypertension	12 (40)	13 (43.3)
Surgical level		
L4–L5	13 (43.3)	12 (40)
L5–S1	17 (56.7)	18 (60)
p value	>0.05	>0.05

Table 2: Depicts The LANSS Scores Of The Two Groups At Different Time Frames.

Time frames	Group A (Pregabalin) Mean ± SD	Group B (Duloxetine) Mean ± SD	P value (unpaired t-test)
Pre-operative	9.4 ± 1.2	9.7 ± 1.4	>0.05
1st week post-operative	15.6 ± 1.5	15.9 ± 1.6	>0.05
1st month post-operative	11.4 ± 1.3	12.1 ± 1.4	<0.05
3rd month post-operative	8.9 ± 1.2	9.4 ± 1.3	<0.05
6th month post-operative	6.5 ± 1.1	6.9 ± 1.2	>0.05

Table 3: VAS Scores Of The Two Groups At Different Time Frames

Time frames	Group A (Pregabalin) Mean ± SD	Group B (Duloxetine) Mean ± SD	P value (unpaired t-test)
Pre-operative	8.3 ± 0.9	8.5 ± 1.0	>0.05
1st week post-operative	4.0 ± 0.7	4.3 ± 0.8	>0.05
1st month post-operative	2.0 ± 0.6	2.4 ± 0.7	<0.05
3rd month post-operative	1.1 ± 0.5	1.4 ± 0.6	<0.05
6th month post-operative	0.8 ± 0.4	0.9 ± 0.4	>0.05

Table 4: ODI Scores Of The Two Groups At Different Time Frames

Time frames	Group A (Pregabalin) Mean ± SD	Group B (Duloxetine) Mean ± SD	P value (unpaired t-test)
Pre-operative	42.0 ± 5.8	42.4 ± 6.1	>0.05
1st week post-operative	29.0 ± 4.2	30.1 ± 4.3	>0.05
1st month post-operative	21.1 ± 3.5	22.8 ± 3.6	<0.05
3rd month post-operative	15.8 ± 3.0	16.9 ± 3.1	<0.05
6th month post-operative	11.9 ± 2.6	12.4 ± 2.7	>0.05

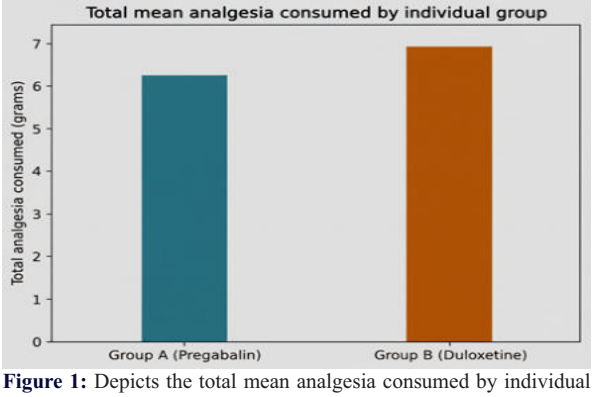

Figure 1: Depicts the total mean analgesia consumed by individual group.

DISCUSSION

The present study demonstrates that both pregabalin and duloxetine are effective in managing early post-operative neuropathic pain following lumbar spine surgery. The superior early outcomes observed with pregabalin may be attributed to its direct action on presynaptic voltage-gated calcium channels, leading to rapid suppression of ectopic neuronal firing at the dorsal root ganglion (Field et al., 2000; Durkin et al., 2010).

Duloxetine exerts its analgesic effect primarily by enhancing descending serotonergic and noradrenergic inhibitory pathways, thereby modulating central pain processing (Goldstein et al., 2005; Lunn et al., 2014). This centrally mediated mechanism explains its comparatively slower onset of action, although it provides sustained analgesic benefits. The convergence of outcomes observed at later follow-up intervals suggests that modulation of central sensitization plays a dominant role in long-term pain control (Woolf, 2011; Woolf & Salter, 2000).

Early identification and appropriate pharmacological intervention are crucial to prevent the progression of post-operative neuropathic pain into chronic pain states.

LIMITATIONS

The present study has certain limitations like the sample size was limited, follow-up duration was restricted to six months.

CONCLUSION

Both pregabalin and duloxetine are effective in the treatment of early post-operative neuropathic pain following lumbar spine surgery. Pregabalin provides superior short-term clinical and functional improvement, while long-term outcomes are comparable between the two drugs. Drug selection should be individualized based on patient profile and tolerability.

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Conflict Of Interest
None

Ethical Approval
Institutional Ethics Committee.

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