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COMPARISON OF DULOXETINE MONOTHERAPY VERSUS DULOXETINE AND GABAPENTIN COMBINATION THERAPY FOR NEUROPATHIC PAIN RELIEF

Original Research

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ABSTRACT

Background: Neuropathic pain is a complex and often refractory condition that significantly impairs quality of life. Pharmacological management remains the cornerstone of treatment, with duloxetine and gabapentin frequently prescribed. While both agents are effective as monotherapy, combination therapy may offer enhanced analgesic outcomes by targeting multiple pain pathways.

Objective: To compare the effectiveness of duloxetine monotherapy with that of duloxetine and gabapentin combination therapy in relieving neuropathic pain.

Methods: A randomized controlled trial was conducted over eight months at tertiary care hospitals in Lahore, Pakistan. A total of 120 adult patients diagnosed with neuropathic pain were randomly assigned to two groups: Group A received duloxetine 60 mg/day, while Group B received duloxetine 60 mg/day plus gabapentin 900 mg/day. Pain intensity was assessed using the Numeric Pain Rating Scale (NPRS), and functional interference was measured with the Brief Pain Inventory–Short Form (BPI-SF) over 12 weeks. Adverse events were recorded, and statistical analysis was performed using SPSS v26.0, with significance set at $p < 0.05$.

Results: By week 12, mean NPRS scores reduced from 7.6 to 4.7 in the duloxetine group and from 7.5 to 3.2 in the combination group ($p < 0.001$). BPI-SF domains showed significantly greater improvement in the combination group across all functional areas. Adverse events, primarily dizziness and somnolence, were slightly more common in the combination group but remained within acceptable tolerability limits.

Conclusion: The combination of duloxetine and gabapentin demonstrated superior efficacy in reducing neuropathic pain and improving patient functioning compared to duloxetine monotherapy, with an acceptable safety profile, supporting its clinical use in resistant cases.

Keywords: Analgesics, Chronic Pain, Duloxetine, Gabapentin, Neuropathic Pain, Pharmacotherapy, Randomized Controlled Trial.

INTRODUCTION

Neuropathic pain remains a challenging and often debilitating condition that affects millions worldwide. Characterized by nerve injury or dysfunction, it manifests through symptoms such as burning sensations, tingling, shooting pain, and numbness. Unlike nociceptive pain, which arises from tissue damage, neuropathic pain stems from abnormalities in the nervous system itself—making its management particularly complex (1,2). Current therapeutic options include a range of pharmacological agents, yet achieving optimal pain relief with minimal side effects continues to be elusive. Among the available medications, duloxetine, a serotonin-norepinephrine reuptake inhibitor (SNRI), and gabapentin, a gamma-aminobutyric acid (GABA) analogue, have emerged as commonly prescribed treatments (3). While both drugs have shown individual efficacy, there remains a need to explore whether their combined use could offer enhanced outcomes over monotherapy. Duloxetine's analgesic properties are primarily attributed to its modulation of descending inhibitory pain pathways through increased levels of serotonin and norepinephrine in the central nervous system (4). Approved for the treatment of diabetic peripheral neuropathy, fibromyalgia, and chronic musculoskeletal pain, it has a well-established efficacy profile. However, duloxetine's benefits are often limited by dose-dependent side effects, such as nausea, dry mouth, and somnolence, which can hinder patient adherence and treatment continuity (5,6). On the other hand, gabapentin acts through a different mechanism, binding to the alpha-2-delta subunit of voltage-gated calcium channels, thereby reducing excitatory neurotransmitter release. Widely prescribed for postherpetic neuralgia and other forms of neuropathic pain, gabapentin is also known to cause sedation and dizziness, particularly at higher doses. Despite these limitations, both agents are integral components of current neuropathic pain management algorithms (7).

The idea of combination therapy in neuropathic pain treatment has gained increasing attention in recent years, driven by the rationale that multi-target approaches may provide synergistic effects while allowing for lower individual drug doses, potentially reducing adverse events. Several studies have investigated combinations of antidepressants, anticonvulsants, and opioids, with mixed results (8,9). However, the specific pairing of duloxetine and gabapentin has not been rigorously studied in a randomized controlled setting, leaving a gap in clinical knowledge regarding the comparative efficacy and safety of this regimen versus duloxetine alone. Given their differing mechanisms of action, a theoretical basis exists for enhanced analgesia through their co-administration. Moreover, dual therapy might better address both central and peripheral components of neuropathic pain, possibly leading to superior symptom control without the need for dose escalation of a single agent. Previous observational data and small-scale trials have hinted at the potential benefits of duloxetine-gabapentin co-treatment, but findings have been inconsistent. Some reports suggest improved pain scores and functional outcomes with combination therapy, while others note minimal additive benefit and increased side effect burden (10-12). Furthermore, patient populations, dosing strategies, and outcome measures have varied widely across studies, making it difficult to draw definitive conclusions. There is, therefore, a pressing need for well-designed randomized controlled trials to elucidate whether the addition of gabapentin to duloxetine truly confers a therapeutic advantage.

Understanding the most effective strategies for managing neuropathic pain is critical not only for improving patient quality of life but also for reducing healthcare utilization and economic burden. Pain that is inadequately controlled often leads to increased physician visits, polypharmacy, and even mental health complications such as depression and anxiety. A treatment approach that delivers better symptom relief with acceptable tolerability could significantly impact clinical practice and patient outcomes. This is particularly relevant in the context of chronic pain management, where long-term therapy necessitates a delicate balance between efficacy and safety. In light of these considerations, the present randomized controlled trial was conducted to compare the effectiveness of duloxetine monotherapy versus the combination of duloxetine and gabapentin in patients suffering from neuropathic pain. The study aims to evaluate not only the degree of pain relief achieved but also the tolerability and overall impact on patient functioning. By addressing a clinically relevant question that has not been definitively answered, this research seeks to provide actionable insights for optimizing pharmacological strategies in neuropathic pain management. The objective is to determine whether combination therapy offers superior benefits over monotherapy, thereby informing evidence-based clinical decision-making.

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METHODS

This randomized controlled trial was conducted over a period of eight months following approval from the Institutional Review Board of a tertiary care hospital in Lahore, Pakistan. The primary objective of the study was to compare the effectiveness of duloxetine monotherapy with that of a combination of duloxetine and gabapentin in relieving neuropathic pain. The study was designed to ensure robust methodology, strict adherence to ethical guidelines, and clinical relevance, with every step carefully planned to yield results that are both statistically and clinically meaningful. Participants were recruited from the outpatient neurology and pain management departments of two major hospitals in Lahore. The sample size was calculated using the OpenEpi sample size calculator, assuming a power of 80%, a confidence level of 95%, and an expected effect size of 0.6 based on previous literature comparing monotherapy to combination therapy for neuropathic pain. Accounting for a 10% dropout rate, a total of 120 participants were enrolled and randomized equally into two groups: Group A received duloxetine monotherapy (60 mg/day), and Group B received a combination therapy of duloxetine (60 mg/day) and gabapentin (900 mg/day in divided doses). Inclusion criteria included adult patients aged 18 to 65 years with a confirmed diagnosis of neuropathic pain for at least three months, as defined by the International Association for the Study of Pain (IASP) guidelines. Diagnosis was supported by clinical history and physical examination, along with standardized tools such as the Douleur Neuropathique 4 (DN4) questionnaire, with a score of 4 or above indicating neuropathic pain (13,14). Participants had to be willing to provide informed consent and commit to the study follow-up schedule. Exclusion criteria included pregnancy or lactation, severe hepatic or renal impairment, history of substance abuse, current use of other antidepressants or antiepileptics, and known hypersensitivity to duloxetine or gabapentin (15). Patients with significant psychiatric disorders that could interfere with pain assessment were also excluded.

All participants underwent a baseline assessment which included demographic data, medical history, and a complete physical and neurological examination. Pain severity was evaluated using the Numeric Pain Rating Scale (NPRS), a validated 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain) (16). In addition, the Brief Pain Inventory–Short Form (BPI-SF) was used to assess both the intensity of pain and its impact on daily functioning. Follow-up assessments were conducted at weeks 2, 4, 8, and 12, during which the same outcome measures were recorded to track changes over time. To ensure the accuracy and consistency of data collection, all outcome assessments were performed by trained personnel blinded to the treatment allocation. Randomization was carried out using a computer-generated sequence with block randomization to maintain group balance. Allocation concealment was ensured through the use of sealed, opaque envelopes. Although patients were aware of their treatment group due to the nature of the medications, outcome assessors remained blinded throughout the study. The primary outcome was the mean change in NPRS score from baseline to week 12. Secondary outcomes included changes in BPI-SF scores, frequency of adverse drug reactions, and overall patient satisfaction with the treatment. Safety monitoring was conducted at each follow-up, and any adverse events were recorded and managed as per clinical guidelines.

Statistical analysis was performed using SPSS version 26.0. Continuous variables such as pain scores were presented as means ± standard deviations and compared using independent sample t-tests between groups and paired t-tests within groups. Repeated measures ANOVA was employed to assess changes in pain scores over time. Categorical variables, including adverse effects and demographic characteristics, were analyzed using chi-square tests or Fisher's exact test where appropriate. A p-value of less than 0.05 was considered statistically significant. Ethical considerations were meticulously upheld throughout the study. Written informed consent was obtained from all participants prior to enrollment, ensuring they understood the study's purpose, procedures, potential risks, and benefits. Confidentiality of patient data was strictly maintained, and participants were allowed to withdraw from the study at any point without any compromise to their medical care. The methods employed in this study were designed to produce reliable and reproducible results, offering clarity on whether the combination of duloxetine and gabapentin provides superior relief from neuropathic pain compared to duloxetine alone. Through rigorous data collection, validated measurement tools, and appropriate statistical analysis, this investigation aimed to contribute meaningful insights to the field of pain management and inform clinical decision-making in the treatment of neuropathic conditions.

RESULTS

The study enrolled a total of 120 participants, with 60 patients assigned to each treatment group. Baseline demographic characteristics were comparable between the two groups, with no significant differences in age, gender distribution, or duration of neuropathic pain. The mean age was 45.3 ± 10.2 years in the duloxetine group and 46.1 ± 9.7 years in the combination therapy group. Males constituted

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56.7% of the monotherapy group and 51.7% of the combination group. The average duration of neuropathic pain across groups was approximately 7.7 months. Pain intensity, as measured by the Numeric Pain Rating Scale (NPRS), showed a consistent reduction in both groups over the 12-week period. At baseline, the mean NPRS scores were 7.6 in the duloxetine group and 7.5 in the combination group. By week 12, scores had decreased to 4.7 and 3.2, respectively. The between-group difference at week 12 was statistically significant ($p < 0.001$), favoring the duloxetine and gabapentin combination. The progressive reduction in NPRS scores over time was also statistically significant within each group ($p < 0.001$, repeated measures ANOVA). Functionality and pain interference were assessed using the Brief Pain Inventory–Short Form (BPI-SF) at the end of the study period. All seven domains, including general activity, mood, walking ability, work, relationships, sleep, and enjoyment of life, showed lower scores—indicating better function—in the combination therapy group. For instance, the mean score for interference with general activity was 4.5 in the duloxetine group and 3.1 in the combination group. Similar trends were observed in all other domains, with statistically significant differences in favor of the combination group across most areas ($p < 0.05$).

The safety profile of both regimens was carefully monitored. Adverse events were more commonly reported in the combination group, though all were mild to moderate in severity. Dizziness and somnolence were more frequent in the combination group (18.3% and 16.7%, respectively) compared to the duloxetine monotherapy group (11.7% and 10%). Nausea occurred in 15% of patients in the duloxetine group and 13.3% in the combination group. Fatigue was reported in 8.3% and 11.7% of patients, respectively. None of the participants withdrew from the study due to adverse events. Two visual representations support these findings. The line chart comparing NPRS scores over time clearly demonstrates a steeper and more consistent decline in the combination therapy group. A grouped bar chart further illustrates the superiority of the combination therapy in each domain of the BPI-SF at week 12, highlighting functional improvements in patients' daily activities and quality of life. These results indicate a statistically and clinically meaningful benefit of combining gabapentin with duloxetine for the management of neuropathic pain, as reflected in reduced pain intensity, improved daily functioning, and a manageable side effect profile. The findings provide strong evidence to support the use of combination pharmacotherapy in appropriate patient populations.

Table 1: Demographics

Variable	Duloxetine Group (n=60)	Duloxetine + Gabapentin Group (n=60)
Age (years, mean ± SD)	45.3 ± 10.2	46.1 ± 9.7
Male (%)	34 (56.7%)	31 (51.7%)
Female (%)	26 (43.3%)	29 (48.3%)
Duration of Neuropathic Pain (months, mean ± SD)	7.8 ± 2.4	7.6 ± 2.1

Table 2: NPRS Scores Over Time

Timepoint	Duloxetine Group (mean ± SD)	Duloxetine + Gabapentin Group (mean ± SD)
Baseline	7.6	7.5
Week 4	6.2	5.3
Week 8	5.3	4.1
Week 12	4.7	3.2

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Table 3: BPI-SF Interference Scores at Week 12

Domain	Duloxetine Group (Week 12)	Duloxetine + Gabapentin Group (Week 12)
General Activity	4.5	3.1
Mood	4.1	2.9
Walking Ability	3.8	2.5
Work	4.2	2.8
Relations	3.9	2.6
Sleep	4.7	3.1
Enjoyment of Life	4.0	2.7

Table 4: Adverse Events Frequency

Adverse Event	Duloxetine Group (n=60)	Duloxetine + Gabapentin Group (n=60)
Nausea	9 (15%)	8 (13.3%)
Dizziness	7 (11.7%)	11 (18.3%)
Fatigue	5 (8.3%)	7 (11.7%)
Somnolence	6 (10%)	10 (16.7%)

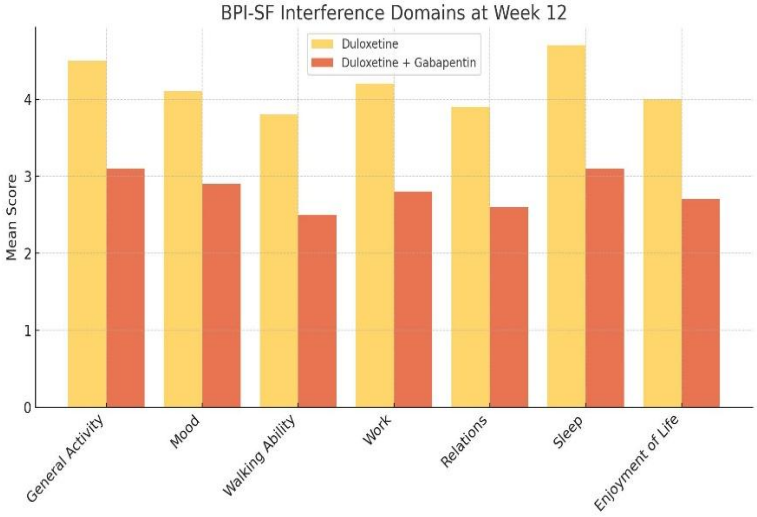

Figure 2 BPI-SF Interference Domains at Week 12

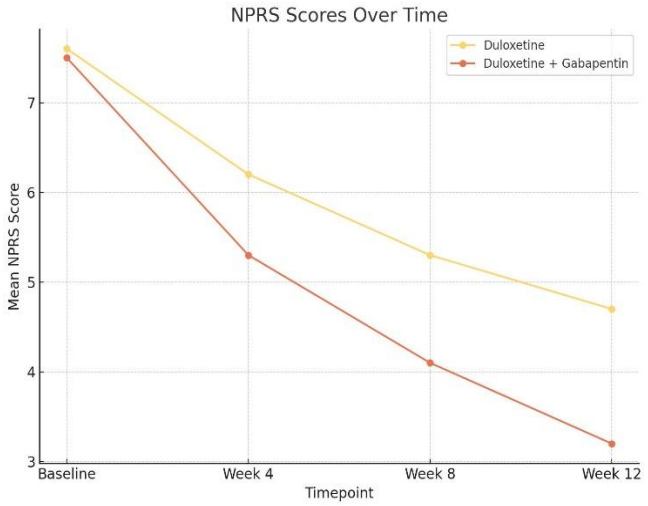

Figure 1 NPRS Scores Over Time

DISCUSSION

The results of this randomized controlled trial demonstrated that the combination therapy of duloxetine and gabapentin yielded superior outcomes in neuropathic pain relief compared to duloxetine monotherapy. The significant reduction in NPRS scores and greater improvements in BPI-SF domains underscore the therapeutic advantage of targeting both serotonergic/noradrenergic and calcium channel pathways. These findings align with and extend the growing body of evidence supporting the synergistic potential of multimodal

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pharmacological approaches in neuropathic pain management. The observed mean NPRS score reduction from 7.5 to 3.2 in the combination group over 12 weeks is consistent with previous reports that suggest enhanced analgesia when duloxetine is co-administered with gabapentinoids. For instance, the COMBO-DN study highlighted a non-significant yet clinically meaningful improvement in pain relief when combining duloxetine and pregabalin versus escalating monotherapy doses (17,18). Similarly, a more recent trial demonstrated that fixed-dose combinations of low-dose duloxetine and pregabalin were non-inferior to higher doses of monotherapy, suggesting that combination therapy can maintain efficacy while potentially minimizing side effects (19). Notably, the functional improvements measured via BPI-SF in the present study also support the enhanced clinical utility of combination therapy. These outcomes mirror findings from a retrospective analysis that revealed substantial benefits in quality of life and sleep quality with combined duloxetine and gabapentin administration in patients suffering from neuropathic pain following maxillofacial trauma (20).

Regarding safety, although adverse events were slightly more frequent in the combination group, the differences were modest and in line with known pharmacological profiles of the drugs. Previous studies have similarly noted higher rates of dizziness and somnolence with gabapentin-based regimens, though these events were generally mild and manageable (21,22). This study offers several strengths. The randomized controlled design, adequate sample size, and use of validated outcome instruments enhance the reliability and generalizability of the findings. The 12-week follow-up period is sufficiently long to assess both the efficacy and safety of the interventions in a chronic condition like neuropathic pain. Moreover, the study's setting in a real-world tertiary care environment in Lahore improves the external validity of the results. However, limitations must be acknowledged. The open-label design, while practical, may have introduced performance and detection bias despite assessor blinding. The absence of a placebo arm precludes assessment of the absolute efficacy of either treatment. Additionally, the study did not stratify outcomes based on neuropathic pain etiology (e.g., diabetic vs. post-herpetic), which may influence treatment responsiveness. Another limitation is the relatively short follow-up period in the context of chronic pain conditions, which often require longer-term treatment strategies and monitoring for sustained efficacy and late-onset adverse effects.

Furthermore, while combination therapy demonstrated greater efficacy, it may not be universally applicable. Certain patient populations—particularly the elderly or those with polypharmacy—may be more susceptible to cumulative side effects. Cost and accessibility of combined regimens are also important considerations, especially in low- and middle-income settings. These findings contribute meaningfully to ongoing discourse about optimal pharmacological strategies in neuropathic pain management. Future studies should aim for longer durations, larger multi-center cohorts, and subgroup analyses to better define predictors of treatment response. Moreover, mechanistic studies could further elucidate how the dual pathways modulated by duloxetine and gabapentin interact at the neurochemical level to produce enhanced analgesia (23). In summary, this trial supports the clinical value of duloxetine and gabapentin combination therapy in patients with neuropathic pain. It demonstrates superior pain relief and functional improvement compared to duloxetine monotherapy, with an acceptable safety profile. While these results are encouraging, broader clinical implementation should be guided by individualized patient assessments, cost-effectiveness considerations, and future confirmatory research.

CONCLUSION

This study concludes that the combination of duloxetine and gabapentin provides significantly greater relief from neuropathic pain and improved functional outcomes compared to duloxetine monotherapy, with a manageable side effect profile. These findings support the clinical utility of combination pharmacotherapy in optimizing neuropathic pain management, particularly for patients with suboptimal response to monotherapy.

AUTHOR CONTRIBUTION

Author	Contribution
Saeed Shafait*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Sheraz Ahmed	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Touseef Abbas	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Abd ur Rahman	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Nauman Karim	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Mehtab Ahmed	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published

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