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A Comparative Study of the Therapeutic Effectiveness of Lamictal™ and Neurontin™ in Managing Trigeminal Neuralgia Patients with Related Levels of Subjective Acceptance: An Original Research Study

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KEYWORDS

Trigeminal Neuralgia, Gabapentin, Tic Douloureux, Magnetic Resonance Imaging (MRI), Magnetic Resonance Angiography (MRA)

ABSTRACT:

Aim: This study aims to determine the effectiveness of Lamictal™ and Neurontin™ in managing trigeminal neuralgia patients with related levels of subjective acceptance

Materials and Methods: This study involved 40 patients aged 35 to 60 with facial pain, eligible regardless of their trigeminal neuralgia (TN) diagnosis status. Exclusion criteria included psychiatric disorders, serious medical conditions, malignancies, pregnancy, substance abuse, and infectious diseases. A clinical history, examination, and MRI confirmed the TN diagnosis. The effectiveness of Lamictal™ and Neurontin™ was evaluated using the Visual Analog Scale (VAS) and Verbal Rating Scale (VRS) for pain relief. Patients were divided into two groups: 20 received escalating doses of Lamictal™ (75 mg to 200 mg over 9 weeks), and 20 were treated with Neurontin™ (1200 mg to 1800 mg over the same period). Post-treatment scores were analyzed to assess treatment effectiveness and monitor complications.

Statistical Analysis and Results: This study involved 40 patients aged 35 to 60 diagnosed with trigeminal neuralgia, excluding those sensitive to Lamictal™ or Neurontin™ and those with serious health issues. Patients gave informed consent and were divided into two groups: Group 1 received escalating doses of Lamictal™ (75 mg, 125 mg, 200 mg) over 9 weeks, while Group 2 received Neurontin™ (1200 mg, 1500 mg, 1800 mg) at the same intervals. Treatment outcomes were assessed using the Visual Analog Scale (VAS) and Verbal Rating Scale (VRS). After 9 weeks, Group 1 had a VAS score of 10.7±4.28 and Group 2 had 20.3±7.35. VRS scores were 0.84±0.46 for Group 1 and 1.28±0.54 for Group 2. Post-treatment complications included 6 uncomplicated patients in Group 1 and 4 in Group 2. One-way ANOVA estimates are detailed in Table 8.

Conclusion: The authors found that Lamictal™ was more effective than Neurontin™ for

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neuropathic pain. While Neurontin™ is effective for diabetic neuropathic pain, lamotrigine excels in chemotherapy-induced pain. These differences may stem from the unique mechanisms of action of the medications, indicating a need for further research on targeted neuropathic pain treatments.

Introduction

Trigeminal Neuralgia, often called Tic Douloureux, is a chronic pain disorder characterized by sudden, intense episodes of pain that feel like electric shocks. This condition affects areas served by the Fifth Cranial Nerve, especially the V2 and V3 branches, and the pain usually occurs on one side of the face. Patients often describe the sensation as lightning-like, and these painful episodes can happen multiple times throughout the day. Understanding the implications of Trigeminal Neuralgia is crucial for developing effective treatment and management strategies for those affected.[1-3] TN is a neurological condition marked by sharp, sudden facial pain often described as electric shocks. This pain usually results from pressure on the trigeminal nerve root, mainly caused by nearby blood vessels like the superior Cerebellar Artery. In some cases, other factors such as tumors, cysts, or Demyelinating diseases like multiple sclerosis can also cause the condition.[4,5] Its prevalence is estimated at between 4 and 13 cases per 100,000 people annually. The condition shows a significant gender disparity, being diagnosed more frequently in women. While TN mainly affects older adults, especially those over 50, it can also appear in younger adults and, rarely, in children.[6,7] The condition often damages the nerve and causes abnormal electrical signals within the trigeminal nerve, leading to excruciating pain triggered by minor stimuli like light touch, brushing teeth, or exposure to wind. The International Classification of Headache Disorders divides trigeminal neuralgia into three types: classical trigeminal neuralgia, which is idiopathic; secondary trigeminal neuralgia, caused by other health conditions; and Idiopathic Trigeminal Neuralgia, where the exact cause is unknown.[8,9] Diagnosis usually starts with a detailed medical history and physical exam by a healthcare professional. Advanced imaging techniques like Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA) are often used to visualize the Trigeminal Nerve and identify structural abnormalities.[10,11] First-line treatment typically includes antiepileptic drugs such as Carbamazepine and Oxcarbazepine, which have proven effective in reducing nerve pain. If these treatments don't work, other medications like Gabapentin and additional anticonvulsants may be considered. When medications are ineffective, surgical options such as Microvascular Decompression can be performed to relieve pressure on the trigeminal nerve by relocating or removing the offending blood vessels. Overall, understanding the causes, diagnosis, and treatment options for Trigeminal Neuralgia is vital for managing the condition effectively and improving the quality of life for those suffering from this painful disorder.[12,13] This study aims to determine the effectiveness of Lamictal™ and Neurontin™ in managing trigeminal neuralgia patients with related levels of subjective acceptance.

Materials and Methods

This study initially commenced with a cohort of 50 patients who presented with pain localized in and around the facial region. From this initial pool, 40 patients qualified for treatment and were enrolled based on the study's carefully defined inclusion criteria, which specified an age range of 35 to 60 years. Both male and female patients were considered eligible, irrespective of whether they were newly diagnosed or had a previous diagnosis of trigeminal neuralgia (TN), a condition characterized by severe facial pain. To maintain the integrity of the study, certain exclusion criteria were established. Patients suffering from psychiatric disorders, serious liver or cardiovascular diseases, renal insufficiency, or significantly low white blood cell counts were ruled out to avoid complicating factors. Furthermore, individuals with malignancies, those who were pregnant or nursing, and those with a history of alcohol or recreational drug abuse were also excluded to ensure the safety and reliability of the results. Additionally, patients who tested positive for infectious diseases such as HIV or hepatitis B and C were not included. Lastly, participants who exhibited hypersensitivity to medications like lamotrigine or gabapentin were also excluded from the study. Consent

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was obtained from all patients included in the study before starting the treatment plan. Before initiating treatment, a thorough clinical history and examination were conducted, along with magnetic resonance imaging (MRI) to confirm the diagnosis of trigeminal neuralgia. The outcome measures related to the efficacy of the medications (pain relief) were assessed using various valuation tools, such as the visual analog scale (VAS) and the verbal rating scale (VRS).Patients were asked to rate their pain on a Visual Analog Scale (VAS), which is a 100mm vertical line. One end is labeled "no pain" and the other end is labeled "worst pain." The ratings were categorized as follows: 0-4mm means no pain; 5-44mm means mild pain; 45-74mm means moderate pain; and 75-100mm means severe pain. For pain assessment, a VAS rating of 0-4mm is complete relief, 5-44mm is fair relief, and 45-100mm is incomplete relief. For the Verbal Rating Scale (VRS), pain intensity is scored based on severity: 0 means no pain, 1 means mild pain, 2 means moderate pain, and 3 means severe pain. To assess the effectiveness of pain relief and identify any complications associated with the medications Lamictal™ and Neurontin™, a total of 40 patients suffering from trigeminal neuralgia were carefully divided into two distinct groups. Group 1 comprised 20 patients who were prescribed Lamictal™. Over the course of the study, they received escalating daily doses—75 mg at 3 weeks, followed by 125 mg at 6 weeks, and ending with a dose of 200 mg at 9 weeks. Meanwhile, Group 2, also consisting of 20 patients, was treated with Neurontin™, with dosages structured at daily 1200 mg till 3 weeks, increasing to 1500 mg at 6 weeks, and reaching 1800 mg by week 9.To evaluate the outcomes of the treatment, rigorous assessments were performed to calculate post-treatment scores, derived from the variations in each patient's Visual Analog Scale (VAS) and Verbal Rating Scale (VRS) scores. These scores provided quantitative measures of pain relief experienced by the patients. The results of the study were then subjected to comprehensive statistical analysis to ascertain the effectiveness of Lamictal™ and Neurontin™ in the management of trigeminal neuralgia, as well as to monitor for any potential complications arising from their use.

Statistical Analysis and Results

In this study, we conducted all statistical analyses using SPSS software version 29.0. To assess the significance of our findings, we employed the chi-square test, which effectively examines differences in proportions across groups. This method facilitated a rigorous comparison of categorical data, accurately reflecting trends within the dataset.

Results

This study involved 40 patients aged 35 to 60 who sought treatment for facial pain and were diagnosed with trigeminal neuralgia through clinical examination, clinical history, and MRI. Inclusion criteria entailed both genders diagnosed with trigeminal neuralgia, while exclusion criteria comprised individuals sensitive to Lamictal™ or Neurontin™, and those with HIV, hepatitis B or C, pregnancy, or serious health issues. Informed consent was obtained from all participants. Table 1 presents the age and gender distribution of the participating patients, while Graph 1 illustrates the demographic distribution, indicating that there were 23 females and 17 males in the study. The 40 patients diagnosed with trigeminal neuralgia were divided into two distinct groups. Group 1 consisted of 20 patients who were prescribed Lamictal™. Over the course of the study, they received escalating doses: 75 mg at 3 weeks, followed by 125 mg at 6 weeks, and reaching a maximum dose of 200 mg at 9 weeks. Group 2 also included 20 patients who were treated with Neurontin™, with dosages set at 1200 mg at 3 weeks, increasing to 1500 mg at 6 weeks, and finally 1800 mg by week 9. To evaluate treatment outcomes, rigorous assessments were conducted to compute post-treatment scores based on the changes in each patient's Visual Analog Scale (VAS) and Verbal Rating Scale (VRS) scores. These scores provided quantitative measures of the pain relief experienced by the patients. Table 2 shows the results for Group 1 (n=20) patients diagnosed with trigeminal neuralgia who received treatment with Lamictal™. Pain levels were assessed using the VAS at titrated doses of 75 mg, 125 mg, and 200 mg at three designated time intervals: 3 weeks, 6 weeks, and 9 weeks. Statistical significance was evaluated using the Pearson Chi-Square test, yielding a score of 10.7±4.28 at 9 weeks. Table 3 reflects the results for Group 2 (n=20) patients with trigeminal neuralgia who were treated with Neurontin™. Pain levels were assessed using the VAS at doses of 1200 mg, 1500 mg, and 1800 mg at the same time intervals. Statistical significance, assessed with the Pearson Chi-Square test, resulted in a

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score of 20.3±7.35 at 9 weeks. Table 4 outlines the pain relief for Group 1 (n=20) patients treated with Lamictal™, as assessed through the VRS at the same titrated doses and time intervals. Statistical analysis using the Pearson Chi-Square test indicated a score of 0.84±0.46 at 9 weeks. Table 5 shows the pain relief for Group 2 (n=20) patients receiving Neurontin™, assessed through the VRS at the designated doses and time intervals. Statistical significance, evaluated using the Pearson Chi-Square test, yielded a score of 1.28±0.54 at 9 weeks. Table 6 presents the evaluation of post-treatment complications for Group 1 (n=20) patients treated with Lamictal™. Statistical significance, analyzed using the Pearson Chi-Square test, indicated that 6 patients remained uncomplicated post-treatment. Table 7 details the evaluation of post-treatment complications for Group 2 (n=20) patients treated with Neurontin™, with statistical significance determined using the Pearson Chi-Square test, revealing that 4 patients were uncomplicated post-treatment. Finally, Table 8 provides estimates across all studied groups using one-way ANOVA

Table 1: Age & gender based statistical description of contributing patients

Age Group (Yrs)	Male	Female	Total	P value
35-40	3	4	7	0.03*
41-45	4	3	7	0.06
46-50	3	4	7	0.01*
51-55	4	5	9	0.80
56-60	3	7	10	0.30
Total	17	23	40	*Significant
*p<0.05 significant				

Graph 1: Patients demographic distribution and associated details

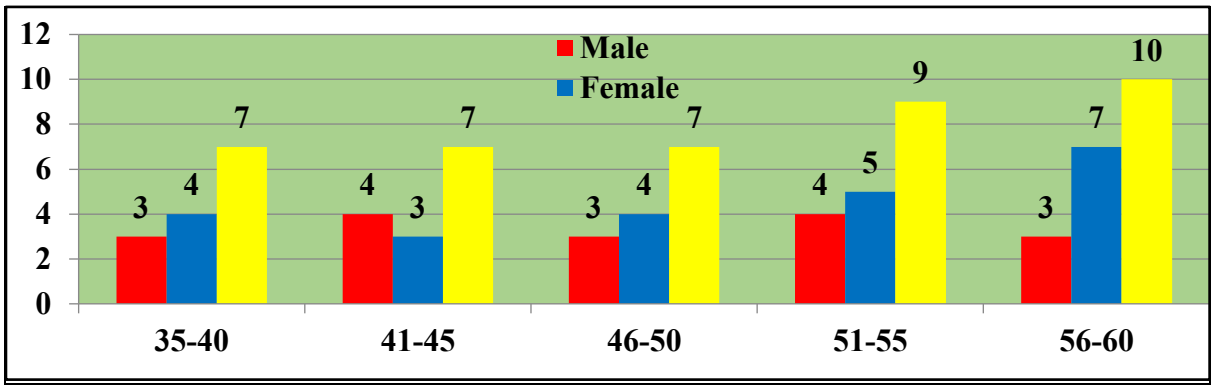

Table 2: Group 1 (n=20) Patients diagnosed with trigeminal neuralgia received therapeutic management with Lamictal™. Pain levels were assessed utilizing the Visual Analog Scale (VAS) at titrated doses of 75 mg, 125 mg, and 200 mg at three designated time intervals: 3 weeks, 6 weeks, and 9 weeks. Statistical significance was evaluated employing the Pearson Chi-Square test

Time interval	Visual Analog Scale (VAS)	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
3 weeks	14.8±8.21	2.29	2.14	2.428	2.124	1.23	1.119	0.03*
6 weeks	12.7±6.25	1.12	2.04	1.098	1.130	1.02	1.032	1.0

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9 weeks	10.7±4.28	1.34	1.01	1.025	1.120	1.24	1.015	0.02*
*p<0.05 significant								

Table 3: Group 2 (n=20) Patients diagnosed with trigeminal neuralgia received therapeutic management with Neurontin™. Pain levels were assessed utilizing the Visual Analog Scale (VAS) at titrated doses of 1200 mg, 1500 mg, and 1800 mg at three designated time intervals: 3 weeks, 6 weeks, and 9 weeks. Statistical significance was evaluated employing the Pearson Chi-Square test

Time interval	Visual Analog Scale (VAS)	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
3 weeks	27.6±12.30	2.12	2.17	1.38	2.68	1.12	1.063	0.01*
6 weeks	24.5±9.33	1.28	1.14	1.108	1.142	1.24	1.220	1.0
9 weeks	20.3±7.35	1.48	1.23	1.036	1.140	1.14	1.501	0.03*
*p<0.05 significant								

Table 4: Group 1 (n=20) Patients diagnosed with trigeminal neuralgia received therapeutic management with Lamictal™. Pain relief was assessed utilizing the Visual rating Scale (VRS) at titrated doses of 75 mg, 125 mg, and 200 mg at three designated time intervals: 3 weeks, 6 weeks, and 9 weeks. Statistical significance was evaluated employing the Pearson Chi-Square test

Time interval	Visual rating scale(VRS)	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
3 weeks	1.02±0.521	2.21	2.13	1.02	1.016	1.01	1.024	0.04*
6 weeks	0.98±0.670	1.09	1.21	1.036	1.121	1.14	1.023	0.02*
9 weeks	0.84±0.46	1.20	1.23	1.024	1.271	1.22	1.612	1.0
*p<0.05 significant								

Table 5: Group 2 (n=20) Patients diagnosed with trigeminal neuralgia received therapeutic management with Neurontin™. Pain relief was assessed utilizing the Visual rating Scale (VRS) at titrated doses of 1200 mg, 1500 mg, and 1800 mg at three designated time intervals: 3 weeks, 6 weeks, and 9 weeks. Statistical significance was evaluated employing the Pearson Chi-Square test

Time interval	Visual rating scale (VRS)	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
3 weeks	1.12±0.61	2.34	2.22	1.08	1.098	1.11	1.080	0.04*

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6 weeks	1.21±0.59	1.28	1.23	1.109	1.230	1.22	1.942	1.0
9 weeks	1.28±0.54	1.28	1.39	1.460	1.036	1.40	1.231	0.02*
*p<0.05 significant								

Table 6: Group 1 (n = 20) patients with a diagnosis of trigeminal neuralgia underwent treatment with Lamictal™, and the post-treatment complications were evaluated. The statistical significance was analysed using the Pearson Chi-Square test

Post-Treatment Complications	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Shaking and tremors	3	2.45	2.32	1.18	1.058	1.14	1.280	0.03*
Difficulty in sleeping	4	1.24	1.20	1.09	1.290	1.23	1.023	0.06
Diarrhoea	3	2.45	2.32	1.18	1.058	1.14	1.280	0.03*
Aggression	2	1.20	1.16	1.076	1.045	1.19	1.045	1.0
Skin rashes	1	1.09	1.07	1.006	1.009	1.20	1.015	0.01*
Swollen arms	1	1.09	1.07	1.006	1.009	1.20	1.015	0.01*
Mood changes	0	-	-	-	-	-	-	-
Dry mouth	0	-	-	-	-	-	-	-
Uncomplicated	6	3.50	2.67	2.88	2.168	2.54	2.680	0.03*
*p<0.05 significant								

Table 7: Group 2 (n = 20) patients with a diagnosis of trigeminal neuralgia underwent treatment with Neurontin™, and the post-treatment complications were evaluated. The statistical significance was analysed using the Pearson Chi-Square test

Post-Treatment Complications	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Shaking and tremors	1	1.09	1.07	1.006	1.009	1.20	1.015	0.01*
Difficulty in sleeping	2	1.20	1.16	1.076	1.045	1.19	1.045	1.0
Diarrhoea	3	2.45	2.32	1.18	1.058	1.14	1.280	0.03*

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Skin rashes	1	1.09	1.07	1.006	1.009	1.20	1.015	0.01*
Swollen arms	2	1.20	1.16	1.076	1.045	1.19	1.045	1.0
Mood changes	3	2.45	2.32	1.18	1.058	1.14	1.280	0.03*
Dry mouth	3	2.45	2.32	1.18	1.058	1.14	1.280	0.03*
Uncomplicated	4	1.24	1.20	1.09	1.290	1.23	1.023	0.06
*p<0.05 significant								

Table 8: Estimation amongst all studied groups using one-way ANOVA

Variables	Degree of Freedom	Sum of Squares ∑	Mean Sum of Squares m∑	F	Level of Sig. (p)
Between Groups	4	2.240	10.097	1.7	0.001*
Within Groups	17	1.280	1.653	_	
Cumulative	124.15	12.044	*p<0.05 significant		

Discussion

Anwar, et al reviewed in their study that trigeminal neuralgia (TN) is a severe neuropathic pain condition that profoundly affects quality of life. Patients experience intense, electric shock-like facial pain that can occur unpredictably and is often excruciating. This debilitating pain not only causes significant physical distress but also leads to psychological challenges, including anxiety, depression, and disrupted sleep. The unpredictable nature of TN can result in episodes triggered by even minor stimuli, such as brushing teeth or feeling a breeze, further intensifying its impact on daily living.[14,15] BoraN et al showed in their study that recent advancements in magnetic resonance imaging (MRI) technology have provided deeper insights into TN, revealing notable neurovascular contact at the trigeminal nerve root. This contact is often correlated with compression caused by adjacent blood vessels or tumors. The trigeminal nerve, due to its unique anatomical structure and location, is particularly susceptible to such compressive forces. This leads to Demyelination of nerve fibers, which subsequently become Hyperexcitable, resulting in spontaneous pain episodes.[16,17] Sessle, B.J. et al included in their study that diagnosis of TN primarily hinges on a comprehensive clinical history and careful physical examination to rule out other potential causes of facial pain, including dental issues, sinus infections, or migraines. While neuro-imaging can assist in supporting the diagnosis, it is not definitive. TN is typically classified into three distinct categories: classical, secondary, and idiopathic. Classical TN requires demonstrable evidence of neurovascular compression. In contrast, secondary TN is associated with identifiable underlying conditions, including multiple sclerosis or structural lesions affecting the nerve.[18,19] Zakrzewska JM et al reviewed in their stud that managing acute exacerbations of Trigeminal Neuralgia (TN) presents significant challenges that demand nuanced approaches. Currently, the range of pharmacological treatments available for the long-term management of this condition is quite limited. First-line therapies predominantly include well-established antiepileptic medications such as Carbamazepine and Oxcarbazepine, both of which have demonstrated considerable efficacy in significantly reducing the

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frequency and intensity of painful episodes associated with TN.[20,21] Liu JK et al reviewed in their study that, nevertheless, there are alternative medications like Gabapentin and Nortriptyline that hold promise; however, their effectiveness and safety profiles require further rigorous investigation to fully understand their potential role in TN management. Moreover, the advent of Botulinum Toxin Type A as a potential treatment option represents a groundbreaking and innovative venture into non-traditional therapeutic approaches, challenging and expanding the conventional methods used to manage this debilitating condition. This exploration could redefine the standard care protocols for TN, offering hope for enhanced relief and improved quality of life for patients suffering from this agonizing disorder. The ongoing research and clinical trials aimed at discovering new treatment modalities reflect the pressing need for enhanced management strategies. These efforts are crucial for improving the quality of life for individuals suffering from TN, helping to address not only the physical pain but also the significant emotional and psychological impacts of this challenging condition.[22,23]

Conclusion

The study conducted by the authors examined a comprehensive investigation into the effectiveness of two medications, Lamictal™ (Lamotrigine) and Neurontin™ (Gabapentin), in the management of trigeminal neuralgia, a condition characterized by intense facial pain. The findings revealed that both medications serve as valuable treatment options; however, Lamictal™ exhibited a moderately greater effectiveness compared to Neurontin™. Particularly noteworthy was Lamictal™'s potential in treating neuropathic pain that arises as a side effect of anticancer therapies, suggesting its promising role in improving the quality of life for patients undergoing cancer treatment. On the other hand, Neurontin™ has been recognized for its efficacy in managing diabetic neuropathic pain, yet in cases of neuropathic pain caused by cancer chemotherapy, Lamotrigine outperformed it. This variation in effectiveness may be attributed to the distinct analgesic mechanisms inherent in different antiepileptic medications. The study underscores the critical need to delve deeper into the underlying mechanisms that drive neuropathic pain across diverse causes, enabling healthcare professionals to develop more tailored and effective treatment strategies for those suffering from these debilitating conditions.

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