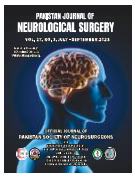

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Original Article

The Lower-Back Painkiller Challenge: Efficacy of Tramadol Versus Tapentadol

Naveed Gul[1], Kashif Ramooz[1], Yasir Shehzad[1], Soban Sarwar Gondal[2], Fraz Mehmood[3] Hafiz Muhammad Ali Khan[4], Eesha Yaqoob[5], Saad Javed[2]

Department of Neurosurgery, [1]Rawal Institute of Health Sciences, [2]DHQ Hospital, Rawal Institute of Health Sciences, Islamabad, [3]Department of Neurosurgery, Holy Family Hospital, Rawalpindi Medical University, Rawalpindi, [4]Department of Public Health Services Academy, [5]Department of Public Health, Health Services Academy, Ministry of National Health Services Regulations and Coordination, Government of Pakistan, Islamabad – Pakistan

ABSTRACT

Introduction: To reduce pain levels in people with lower back pain, the study looked at the comparative efficacy and tolerability of Tramadol and Tapentadol taken by oral route.

Materials & Methods: This comparative study consisted of a total of 126 patients divided into 2 groups, the Tapentadol and Tramadol groups for managing low back pain. Participants aged 18-60 with moderate or higher pain intensity were included. Data on pain intensity, adverse events, and patient-reported outcomes were collected at baseline, day 7, and day 14. Participants were randomly assigned to Tapentadol or Tramadol groups, receiving respective medications for 14 days. Data analysis involved t t-test to compare groups. Means and SD were also calculated.

Results: The mean age of the patients in the Tramadol group was 33.1 ± 19.1 and in the Tapentadol group was 37.6 ± 19.9, respectively. Sixty of the total participants were men and sixty-five were women. Participants were split equally between groups A and B, with 30 men and 33 women in group A and 30 men and 32 women in group B. The findings demonstrated that both medications considerably lessened moderate to severe chronic lower back pain (CLBP) patients' pain levels. At 28 days after the baseline, the mean VAS scores for groups A and B were 34.57 and 37.55, respectively. However, there was no significant difference (P= 0.007) in the mean reduction of pain intensity between the two groups.

Conclusion: According to the study's findings, these two medications effectively reduce pain in those with chronic lower back pain. Tapentadol is observed to be tolerated well and more effective than Tramadol.

Keywords: Lower back pain, Chronic lower back pain, Tramadol, Tapentadol, Visual Analogue Scale, Pain.

Corresponding Author: Dr. Saad Javed
Department of Neurosurgery,
Holy Family Hospital, Rawalpindi Medical University,
Rawalpindi, Pakistan

WFNS GNC Secretariat Team Member
Email: saadjaved10095@gmail.com

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INTRODUCTION

Low back pain (LBP) is a prevalent condition that is described as lumbar discomfort and soreness that may or may not radiate to the legs. Depending on how long the symptoms have been present, LBP can be divided into acute, sub-acute, and chronic pain.[1] In contrast to sub-acute LBP, which lasts between 6 and 12 weeks, chronic LBP lasts for 12 weeks or longer. LBP affects both sexes and practically all age groups, and the majority of occurrences are self-limiting.[2] LBP is thought to affect between 60 and 84 percent of people across their lifespan.[3]

Anxiety, despair, social isolation, and limited mobility are just a few of the social, mental, physical, and vocational distresses that people with chronic LBP may suffer. Estimates indicate that LBP has a substantial financial toll, costing billions of dollars annually in lost productivity and healthcare expenses.[5] Non-specific LBP is a form of persistent LBP that is not caused by a particular pathology or underlying ailment. This indicates that there is no known explanation for the pain, which makes it challenging to identify and treat. Many things, including bad posture, muscle strain, or degenerative changes in the spine, might result in non-specific LBP.[6] Non-specific LBP can nonetheless significantly affect a person's life despite the lack of a clear underlying cause. Pain, discomfort, and restricted mobility may result, which may cause social isolation and a decline in quality of life. Also, it may lead to lost workdays and decreased productivity, both of which can have a big financial impact.

Opioid use in the treatment of persistent low back pain is questionable. Opioids have been linked to several fatal reactions, including misuse, overdose, and respiratory distress, even though they may cater to some patients with constant and unrelenting CLBP with temporary support. As a result, opioids are generally not considered a first-line treatment for CLBP and are only used when other treatments have failed.[7] As a first line of treatment for CLBP, acetaminophen and no steroidal anti-inflammatory medications (NSAIDs) are frequently employed. These drugs have a good reputation for being well tolerated and effective in relieving pain, but some people may experience side effects such as gastrointestinal bleeding, kidney issues, or liver damage.[8] Other drugs, like muscle relaxants, benzodiazepines, Neurontin, and TCAs, may be taken into consideration when short-term therapy for persistent and unremitting CLBP is necessary. Although they may have adverse effects like sleepiness, dizziness, and dry mouth, these drugs can help with pain management and sleep improvement.[9]

Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used as the initial therapy for CLBP. I'm There is continuing research to create novel analgesics that can effectively treat CLBP pain without having the risk of addiction or major side effects.[10] This includes researching non-opioid drugs and complementary treatments like acupuncture and mindfulness-based stress reduction in addition to developing innovative opioid formulations.[11] Both Tapentadol and Tramadol are analgesics with central action that are used to alleviate the pain, however, their modes of action are different. Tramadol works by preventing norepinephrine and serotonin from being reabsorbed, as well as by weakly agonizing the opioid receptors. On the other hand, Tapentadol has extra effects on the monoaminergic system and is a greater agonist of the opioid receptor.[12]

Rationale and Objective: The main goal of the current study is to contrast Tapentadol with tramadol's efficacy and safety in treating low back

pain. The purpose of the study is to evaluate how Tapentadol and Tramadol affect the VAS scores used to measure changes in pain severity. The goal of the study is to fill the knowledge gap about the relative efficacy and safety of these two drugs for the treatment of low back pain, particularly in the Pakistani population. The study will also examine any Tapentadol and Tramadol adverse effects that may exist. The findings of this study may aid medical experts in Pakistan and other nations in selecting the best medication for their patients who are experiencing low back pain.

Materials and Methods

Study Design

This study was a comparative study to assess the efficacy and tolerance of Tapentadol versus Tramadol in the management of LBP.

Ethical Statement

The study was conducted after approval from the Ethical Approval Board and informed consent was taken from every patient before data collection.

Sampling

Participants for this study were recruited from patients experiencing low back pain. A total of 126 patients were selected for this study and divided into two groups. Patients in group A received Tramadol while patients in group B received Tapentadol.

Inclusion Criteria

Inclusion criteria included patients aged between 18 and 60 years, experiencing LBP of at least moderate intensity (VAS score of ≥4), and who had not received any analgesic medication for at least 48 hours before the study.

Exclusion Criteria

Participants with a history of allergy to Tramadol or Tapentadol, renal or hepatic impairment, addiction or dependence on opioids, and pregnancy or lactation were excluded from the study.

Clinical Management & Data Collection

Data was collected at baseline, day 7, and day 14 of treatment. Pain intensity was measured using the visual analog scale (VAS), and adverse events were recorded by study investigators. Patient-reported outcomes were assessed using questionnaires completed by the participants. Patients were randomly divided into either the Tapentadol group or the Tramadol group. The Tapentadol group was administered Tapentadol tablets (75 mg) twice daily having a half-life of 4 to 6 hours, while the Tramadol group received Tramadol extended-release tablets (50 mg) twice daily having a half-life of 5 to 6 hours. The duration of treatment was 14 days. The main outcome measure was the reduction in pain measured using the visual analog scale (VAS) at day 14 compared to baseline. Secondary outcomes included the proportion of participants achieving at least a 30% reduction in pain intensity, adverse events, and patient-reported outcomes such as global improvement and satisfaction with treatment.

Data Analysis

Data was analyzed using appropriate statistical tests. The qualitative variables were represented in the form of mean and SD and categorical variables were represented in the form of frequency and percentage. The difference between the groups was compared through an independent t-test.

RESULTS

Age Distribution

Table 1 displays the age-related demographic details for the two study groups. According to the

table, there were 63 patients in the trial in each of the groups A and Bs, and the average age was 42.6 ± 9.6 years for group A (Tramadol) and 44 ± 10.6 years for group B. (Tapentadol). The table also displays the frequency and percentage of patients in each age range.

Table 1: Age of the patients.

Age in Years	Group A: Tramadol	Group B: Tapentadol
18-20	2 (3.2%)	2 (3.2%)
21-30	8 (12.7%)	7 (11.1%)
31-40	16 (25.4%)	17 (27.0%)
41-50	22 (34.9%)	19 (30.1%)
51-60	15 (23.8%)	18 (28.6%)
Mean±SD	42.6±9.6	44±10.6

Gender Distribution

Table 2 showed that there was a total of 126 participants in the study, with sixty-three participants in each group. Table 2 shows that out of the total participants, 60 were male and 65 were female. In group A, 30 participants were male and 33 were female, while in group B, 31 were male and 32 were female.

Table 2: Gender.

Gender	Group-A Tramadol	Group-B Tapentadol
Male	30 (47.6)	31 (49.2)
Female	33 (53.9)	32 (50.8)

Table 3 shows the VAS for group A. The visual analog scale (VAS) was used to classify patients in both groups according to the severity of their pain at baseline and at various time periods, as shown in Table 3. In group A (Tramadol), at baseline, 73% of patients experienced moderate pain, 23.8% experienced severe pain, and 1% had no pain or mild pain. At the 7 days, 3.17% of patients had no pain, 74.6% had moderate pain, 9.52% had mild pain, and 9.5% had severe pain. At the 14 days, 60.3% had moderate pain, 25.4% had mild pain, and 6.3% had no pain. At 28 days, 55.5% had moderate pain, 31.7% had mild pain, 7.9% had no pain, and 4.7% had severe pain.

Table 3: VAS for Group A.

VAS	Baseline N (%)	Day 7 N (%)	Day 14 N (%)	Day 28 N (%)
No pain	1 (1)	2 (3.1)	4 (6.3)	5 (7.9)
Mild pain	1 (1)	6 (9.5)	15 (25.4)	20 (31.7)
Moderate pain	46 (73.0)	47 (74.6)	38 (60.3)	35 (55.5)
Severe pain	15 (23.8)	8 (9.5)	6 (7.9)	3 (4.7)

Table 4 shows the VAS pain scores in both study groups throughout the study. The mean VAS rating in Group A (Tramadol) at baseline was 74 ± 10.8, which decreased to 59.5 ± 13.6 on the 7 days, 51 ± 16.5 on the 14 days, and 41 ± 19.6 on 28 days. The mean VAS score in Group B (Tapentadol) at baseline was 75.2 ± 11.9, which decreased to 58.4 ± 12.4 on the 7 days, 49.8 ± 15.7 on the 14 days, and 37.6 ± 19.9 on 28 days. Overall, both Tramadol and Tapentadol were effective in reducing VAS pain scores over the four-week study period. However, Tapentadol appeared to be slightly more efficient than Tramadol in decreasing pain scores, particularly in the later weeks of the study. Since the mean difference in VAS scores between the two groups was similar, that shows that there was no difference between the groups.

Table 4: VAS for Group B.

VAS	Baseline N (%)	Day 7 N (%)	Day 14 N (%)	Day 28 N (%)
No pain	1 (1)	2 (3.1)	4 (6.3)	4 (6.3)
Mild pain	1 (1)	4 (9.5)	15 (23.8)	18 (23.8)
Moderate pain	43 (73.0)	48 (74.6)	40 (63.4)	35 (55.5)
Severe pain	18 (23.8)	9 (9.5)	6 (9.52)	6 (9.5)

According to Table 5, both groups' VAS scores dropped throughout the study, indicating a

reduction in pain levels. At 28 days, the mean VAS score in group A was 41 ± 19.6, while in group B, it was 37.6 ± 19.9. This shows that both Tramadol and Tapentadol were supportive and good in lowering study participants' pain levels. Moreover, group B's mean VAS score was slightly lower than group A's, suggesting that Tapentadol might be slightly more effective at reducing pain intensity.

Table 5: Total VAS scores for both groups.

VAS Scores	Group-A (Tramadol)	Group-B (Tapentadol)	P Value
Baseline	74±10.8	75.2±11.9	0.007
1st week	59.5±13.6	58.4±12.4	
2nd weeks	51±16.5	49.8±15.7	
4th weeks	41.1±19.6	37.6±19.9	

There was no significant diversity in the VAS scores among the two groups, as shown in Table 6. The VAS mean of group A was 33.119 while the standard deviation of group A was 37.619.

Table 6: Mean and SD of VAS score.

Variable	Group-A (Tramadol)	Group-B (Tapentadol)
Differences in VAS scores	33.1±19.1	37.6±19.9

Table 7: Adverse effects.

Side Effects	Group-A Tramadol	Group-B Tapentadol
Nausea	14 (22.2)	4 (6.3)
Dizziness	24 (38.1)	13 (20.6)
Constipation	2 (3.2)	2 (9.5)

Table 7 showed that Group A had a higher incidence of nausea and dizziness. Specifically, 14 out of 63 patients (22.2%) in Group A reported nausea/vomiting, while only 4 out of 63 patients (6.3%) in Group B experienced this side effect. Similarly, 24 out of 63 patients (38.1%) in Group A reported dizziness, while only 13 out of 63 patients (20.6%) in Group B experienced it. About 2 out of 63 participants reported constipation as an adverse effect.

DISCUSSION

Pain is a complex and multifaceted experience that can have a significant impact on a person's quality of life, functioning, and well-being. This study investigates the effectiveness and compliance of Tapentadol and Tramadol in the treatment of chronic low backache. It is evident from some studies that the incidence of lower backache is higher among females as compared to males and it increases with age.[13,14]

Based on the information provided, it seems that the study included a total of twenty-six patients, with sixty-three patients allocated to each treatment group. The main goal of the study was to measure changes in the Visual analog pain score values following administration of the medicine. It's not clear if there was a placebo or control group included in the study design. The data also shows that the age and sex distributions of the two treatment groups were similar, which suggests that any differences observed in the outcomes of the study could be attributed to the specific treatments being evaluated.

Based on the mean and SD values of the VAS scores for the two treatment groups, it appears that both groups experienced a significant improvement in pain scores throughout the research. Specifically, at the 28-day, the mean VAS score had decreased by approximately 33% in group A and 38% in group B. A further finding of the study was that there was not a significant difference (P=0.007) in the visual analog scores between the two treatment groups (baseline, 7, 14, and 28 days). This implies that both Tapentadol and Tramadol might be equally useful for treating severe LBP.

A comparison to a previous study conducted by Tomoko et al, it appears that both studies found a decrease in the visual analog score at 28

days with the use of tramadol, although the reduction was higher in the Tomoko et al study as compared to the present study.[15] Tramadol and Tapentadol were both tested for their ability to relieve low back pain. With Tapentadol showing a slightly higher reduction than tramadol, the average VAS score decreases for pain intensity were similar to those in the current trial. When compared to tramadol, Tapentadol was found to have fewer side effects in the current study, which is supported by the results of earlier trials. This implies that Tapentadol might be a safer and more well-tolerated option for treating chronic pain, though more research is necessary to confirm this. Tramadol monotherapy has been found to have only modest clinical symptomatic improvement in the treatment of chronic musculoskeletal pain in patients with gonarthrosis and coxarthrosis.[16]

Babita et al's, (2019) study compared the efficacy of Tapentadol and Tramadol in treating lower back pain in people with disc prolapse. One hundred patients who received either Tapentadol or tramadol for four weeks were enrolled in the study. Findings showed that both Tapentadol and Tramadol were found to be good and supportive at reducing the intensity of pain, but Tapentadol did so more quickly and with better results. For the treatment of Low Back Pain, a comparison of Tapentadol and Tramadol has been made. The findings showed that Tapentadol reduced pain intensity more adequately than tramadol, but it had fewer side effects.[17] When mixed with selective serotonin reuptake inhibitors (SSRIs), the percentage of developing serotonin syndrome-related life-threatening conditions like delirium, neuromuscular rigidity, and hyperthermia is lessened.[18–19] Additionally, studies have proved that Tapentadol has a lower ability for drug-drug interactions.[20,21]

CONCLUSION

Effective pain management options for chronic low back pain are crucial for enhancing quality of life, restoring functionality, and minimizing the emotional and physical toll on individuals.

Tapentadol and Tramadol have both been shown to significantly reduce pain in people with moderate to severe LBP. It has been demonstrated that Tapentadol is equally effective as Tramadol at reducing pain intensity, but it has a better tolerability profile and fewer side effects.

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Additional Information

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Human Subjects: Consent was obtained by all patients/participants in this study.
Conflicts of Interest:
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AUTHORS CONTRIBUTIONS

Sr.#	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Naveed Gul, Saad Javed	1. Study design and methodology.
2.	Kashif Ramooz & Fraz Mehmood	2. Paper writing.
3.	Yasir Shehzad & Soban Sarwar Gondal	3. Data collection and calculations.
4.	Eesha Yaqoob	4. Analysis of data and interpretation of results.
5.	Hafiz Muhammad Ali Khan	5. Literature review and referencing.
6.	Naveed Gul	6. Editing and quality insurer.