Section A-Research paper

PSQI (Pittsburgh Sleep Quality Index) is used to Evaluate Sleep Quality in Patients with Neuropathic Pain

Tusharkumar R Patel[1]*, Dr. Hirenkumar R Chaudhary[2]

[1] Research Scholar, Sankalchand Patel University, Visnagar – 384315, Gujarat, India**.**

[2]Associate Professor, Nootan Pharmacy College, Sankalchand Patel University, Visnagar – 384315, Gujarat, India**.**

*Corresponding author:

85, Aalayam-95,

Opp. Shailaja Homes,

Radhanpur Road,

Mehsana-384002, Gujarat, India.

E-mail address: tusharpatel.3011989@gmail.com

Tel: + 919408845755.

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ABSTRACT:

Objective: Gabapentinoid effects on sleep quality in patients with neuropathic pain have been evaluated in this study using the PSQI (Pittsburgh Sleep Quality Index).

Material and Methods: A total of 450 patients with a neuropathic pain diagnosis were selected. After a medical professional diagnosed the patients with neuropathic pain, they were given a detailed description of the study's approach and asked for their informed consent. Subjects who fit the inclusion and exclusion criteria and are willing to participate in the study. During Visit-01, the demographic baseline assessment and PSQI score were finished. Patients started receiving Gabapentinoid after Visit-01. The patient was being followed up on after four weeks had passed since the enrollment date. Four weeks later, the PSQI score was assessed. After examining the PSQI Questioner and Informed Consent form, the Independent Ethics Committee (IEC) gave its approval. Data was assessed statistically using SPSS ($p < 0.05$).

Results: The estimated marginal mean for the PSQI's baseline Sleep Quality was found to be Using 07 PSQI Components & Global PSQI Score, Gabapentinoid Pre-treatment was markedly improved in 4 weeks after Gabapentinoid Post-treatment. It was demonstrated that gabapentinoid pre- and post-treatment varied substantially.

Discussion: Using 07 PSQI Components and the Global PSQI Score, it was demonstrated that the effects of gabapentinoid were significantly different before and after therapy.

Conclusion: The results mentioned above show that Gabapentinoid improves sleep quality in patients being treated for neuropathic pain.

KEYWORDS: Neuropathic Pain, Sleep Quality, Pittsburgh Sleep Quality Index, Gabapentinoid.

INTRODUCTION :

The process that follows an initial injury or illness of the somatosensory nerve system is known as neuropathic pain[1]. The etiology or anatomic localisation of this syndrome, which is the outcome of numerous different pathogenic causes, is typically used to define it. Neuropathies caused by viral infections, such as post-herpetic neuralgia, HIV, and leprosy, autoimmune conditions that affect the central nervous system, such as multiple sclerosis and Guillain-Barre syndrome, chemotherapy-induced peripheral neuropathies, and damage to the nervous system as a result of trauma are the conditions and pathophysiological states that determine the onset of neuropathic pain [2].

Allodynia (pain caused by a stimulus that does not typically cause pain), hyperalgesia (an increase in the perception of pain generated by a stimulus that causes pain), and paraesthesia (a condition that determines the perception of anomalous sensations similar to needle bites, tingling, itching, reduced, or even loss of sensitivity) are among the signs and symptoms linked to the presence of neuropathic pain. The pain that neuropathic pain patients experience frequently manifests spontaneously, without the requirement for a stimulation. This pathological disease seriously degrades the patients' quality of life and jeopardizes their mental health [3].

The Food and Drug Administration (FDA) has authorized the use of Gabapentinoid to treat neuropathic pain. Due to their structural resemblance to the neurotransmitter gamma-aminobutyric acid, they attach to the Ca2+ voltage-dependent channels' 2-subunit, limiting Ca2+ input to the cells [4].

It has become clear that inadequate sleep has a complicated link with general health as a result of the growing number of issues that are known to be brought on by sleep disruption. It is now understood that a variety of neurological, physiological, psychological, and behavioural components interact in both directions with sleep disruption[5–8]. The crucial role that sleep plays in general health has thus highlighted the necessity for objective polysomnographic (PSG) assessment as well as trustworthy, validated subjective instruments in modern medical practice. Although they are quite distinct diagnostic methods, they are complementary in that subjective tools can detect psychological and behavioural aspects that PSG cannot detect. In both clinical and research contexts, self-rating questionnaires like the Pittsburgh Sleep Quality Index (PSQI) are crucial for assessing sleep health[9 & 10]. These questionnaires have the benefits of being affordable, having high patient compliance, and being simple to administer. Perhaps more significantly, they lessen the demand on the time of medical specialists because such surveys are self-explanatory and do not require supervision[5]. The reliability and validity of rating scale surveys must be proven beyond a reasonable doubt given the significant diagnostic role they play. The psychometric validation of the questionnaires' dimensionality, or whether the items are all connected and indicative of factors influencing sleep quality, is a crucial component of this quality assurance [9]. This article critically evaluates the PSQI, one of the most popular self-rating sleep quality instruments, on the basis of the evidence for its dimensionality[11].

METHODS AND MATERIAL:

Methods:

In sum 450 Patients who had been diagnosed with neuropathic pain and were male or female and more than 18 years old were eligible for the trial. The patient's inability to sleep for more

than three nights per week for at least one month prior to the screening interview indicates a history of sleep disturbances. Patient must follow a regular wake-up, sleep, and daily schedule with some variance in bedtime from night to night. At the time of the screening visit, [12] sleep entry criteria will be assessed using the PSQI Sleep Questionnaire. Participants in the study who are willing to participate. If a patient has a history of any sleep issue, they will be disqualified. Patients may have any illness that would not interfere with the evaluation of sleep or neuropathy symptoms. Severe medical issues that, in the investigator's opinion, disqualified the patient from participating in the clinical trial; use of any drugs that were known to have an impact on wakefulness or sleep [13]. Those who have a history of allergy or hypersensitivity to Gabapentinoid or any of its ingredients. Those who have a history of allergy or hypersensitivity to Gabapentinoid or any of its ingredients. Those who do not want to participate. Prescriptions that are worded poorly.

Baseline demographic and PSQI score assessments were made during Visit-1. After Visit-01, patients began receiving Gabapentinoid. After four weeks from the date of enrolment, the patient was being followed up. The PSQI score was evaluated four weeks later [12 & 14].

Material:

The most popular measure for evaluating sleep health in both clinical and non-clinical groups is the PSQI. It may also be the sleep questionnaire that has been translated the most [15]. A 19-item self-report questionnaire called the Pittsburgh Sleep Quality Index (PSQI) was created to assess sleep quality and disruptions over the course of a month. The initial PSQI questions ask participants about their typical bedtime, average time to fall asleep, average time to get up, and average amount of actual sleep. The remaining 15 Likert-type questions focus on subjective sleep quality and the frequency of sleep disruptions over the previous month. Each

object is given a difficulty rating from 0 to 3, with 0 denoting no difficulty and 3 denoting extreme difficulty. Seven component scores, or subscales, are created from the 19 items: subjective sleep quality (item 6), sleep latency (items 2 and 5a), sleep duration (item 4), habitual sleep efficiency (items 1 and 4), sleep disturbances (items 5b to 5j), use of sleep medications (item 7), and daytime dysfunction (items 8 and 9). Scores for each component vary from 0, which indicates no issue, to 3, which indicates significant challenges. Additionally, the sum of the seven component values results in a final score that runs from 0 to 21, with lower scores indicating poorer sleep quality. A cut-off of > 5 on the overall score has been used to separate bad sleepers from excellent sleepers. Scores 5 indicate sound sleepers, whereas scores > 5 indicate disturbed sleepers [6].

Ethical Consideration:

The local ethics committee granted approval for the study procedure's participant recruitment via informed consent form and PSQI [16] Questionnaire in accordance with the declaration of Helsinki[17]. The Drug Controller General of India (DCGI) approved Independent Ethics Committee (IEC) provided ethical approval[18].

Statistical Analysis:

All data will be entered into the SPSS program for additional analysis [19]. The PSQI component and overall scores were computed based on accepted scoring guidelines. $p<0.05$ will be considered significant. For continuous parametric variables, descriptive statistics are presented as percentages, frequencies, and means with standard deviations. Analysis of Variance (ANOVA) will be used to determine whether there is a significant difference in PSQI score between the two visits, and paired t-tests was followed [20].

RESULT:

Out of the 450 patients who were enrolled for the study, 358 (79.5%) men and 92 (20.4%) women with age ranges between 31 and 70 years [(31-40 Years 35 (7.8%), 41-50 Years 217 (48.2%), 51-60 Years 167 (37.1%), and 61-70 Years 31 (6.9%)] were those who experienced neuropathic pain are depicted in Table 01. However, relapse status of sleep quality based on PSQI scores Pre-treatment and Post-Treatment of Neuropathic Drug is given by demographic in Table 01 and clinical characteristics in Table 02.

Although there were statistically significant changes between Gabapentinoid pre- and post-treatment for patients with neuropathic pain, there were statistically significant variations between pre- and post-treatment sleep-related characteristics between patients treated with Gabapentinoid. At the post-intervention phase, Table 2 shows statistically significant improvements in the PSQI components for Subjective Sleep Quality (sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction) scores ($p < 0.05$), indicating a significant improvement in Neuropathic Pain Patients sleep quality.

Gabapentinoid treatment improved both the mean and standard deviation of the component and global scores on the PSQI-7, as shown in Table 02 and Figures 01 and 02. Gabapentinoid treatment improved the quality of sleep for patients with neuropathic pain, as evidenced by a noticeably PSQI global score.

Table 01. Participant Demography And Treatment Of Gabapentinoid With Different Clinical Variables.

Demographic Details		**Gabapentinoid (*n = 450*)**	
		f	**%**
Gender	Male	358	79.6
	Female	92	20.4
Age	31-40 Years	35	7.8
	41-50 Years	217	48.2
	51-60 Years	167	37.1
	61-70 Years	31	6.9

***n*= Sample size, f = Frequencies, %= Percentage.**

Table: 02. Comparison Of The Mean Values Of Pittsburgh Sleep Quality Index (PSQI): Components & Global Score Vs Pre & Post Treatment Of Gabapentinoid With Different Clinical Variables.

PSQI Components	**Gabapentinoid (*n = 450*)**		***t-Test***	***P-Value***
	Mean ± SD			
	Pre-Treatment Visit-01	**Post-Treatment Visit-02**		
Subjective Sleep Quality	1.54 ± 0.59	0.81 ± 0.43	21.64	0.00
Sleep Latency	1.87 ± 0.33	0.92 ± 0.44	35.70	0.00
Sleep Duration	0.62 ± 0.67	0.01 ± 0.010	18.98	0.00
Habitual Sleep Efficiency	0.00 [a] ± 0.00	0.00[a] ± 0.00	0.00	0.00
Sleep Disturbances	1.93 ± 0.39	0.99 ± 0.105	48.42	0.00
Use Of Sleep Medication	1.05 ± 0.57	0.50 ± 0.50	15.37	0.00
Daytime Dysfunction	1.91 ± 0.44	0.91 ± 0.35	37.20	0.00
Global Score	8.95 ± 1.44	4.15 ± 0.87	61.82	0.00

n*=** Sample size, **Mean ± SD=** Mean± Standard Deviation, ***t- Test = Paired t-Test, ***P-Value*** *<0.05*

a. The correlation and *t*-cannot be computed because the standard error of the difference is 0.

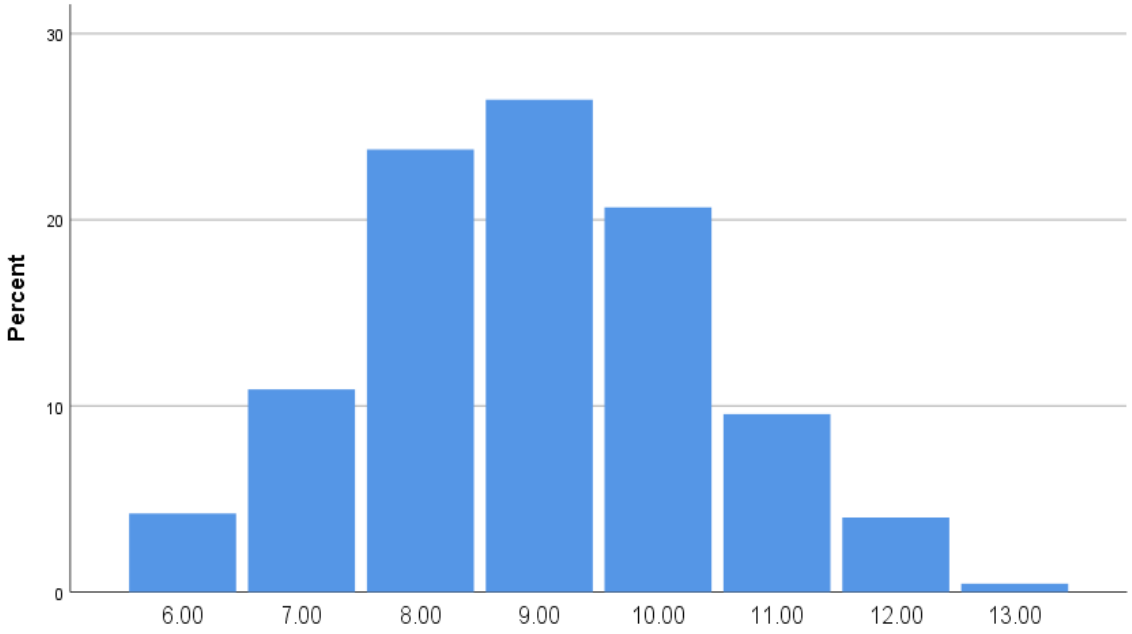

Figure: 01. Percentage (%) of Participant before Treatment of Gabapentinoid - Global Scoring 6-21 Represent As Bad /Poor Sleep. **V1GPSQI:** Visit-01 Global Pittsburgh Sleep Quality Index.

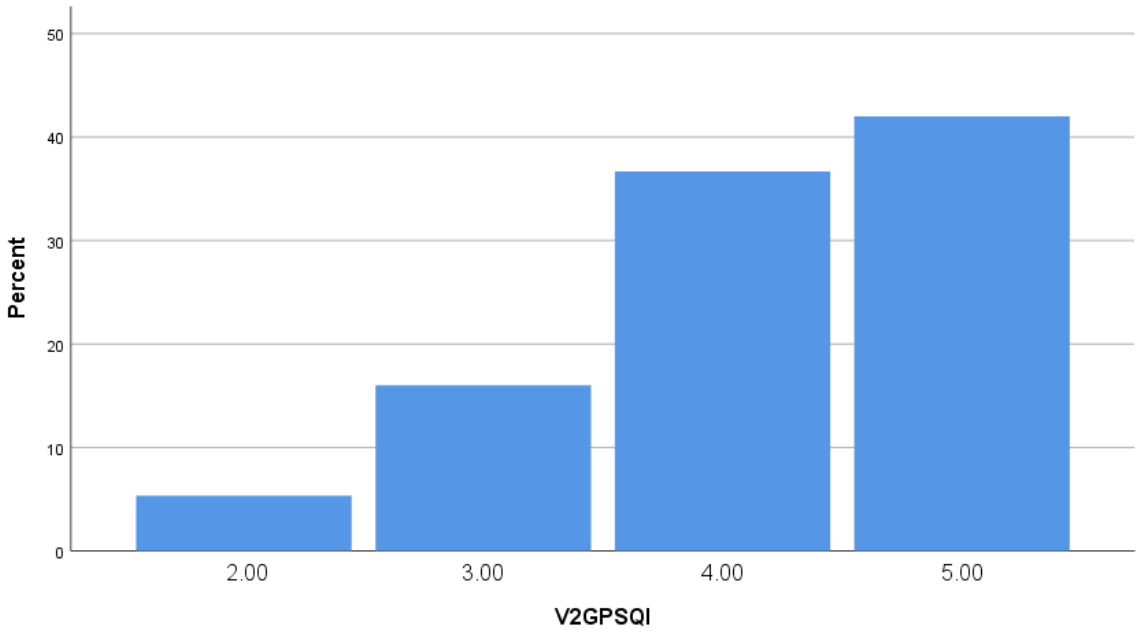

Figure: 02. Percentage (%) of Participants after Treatment of Gabapentinoid - Global Scoring 0-5 Represent As Good Sleep. **V2GPSQI:** Visit-02 Global Pittsburgh Sleep Quality Index.

DISCUSSION:

Sleeping problems may result from the neuropathic pain, which is frequently severe at night. Negative sensations like coldness, numbness, and a tightness around the feet are also possible in patients. Typically, distal and length-dependent symptoms occur [21]. Older persons frequently experience sleep disturbances, with more than 30% of them having poor sleep quality and ongoing problems sleeping. These issues might include difficulty falling asleep quickly, numerous night-time awakenings, and trouble settling back to sleep after waking. Such sleep abnormalities have an effect on how well people perform during the day, lower quality of life [22], and have been linked to worsening health status [23] and rising all-cause mortality, according to research [24].

Patients with Neuropathic Pain treated with Gabapentinoid have previously reported subjective improvements in sleep utilizing sleep quality diaries and sleep scales, such as the

Medical Outcomes Study sleep subscale, along with clinically significant improvements in pain [25 & 26].

Sleep disruption is a well-known and well-documented characteristic of neuropathic pain [27-29]. When treated with Gabapentinoid for 4 weeks compared to treatment (Vsit-02) against treatment (Vsit-01), patients with Neuropathic Pain demonstrated statistically significant improvements in sleep Quality, as evidenced by a reduction in Score of 0-5 in Sleep Quality as measured by the PSQI. Patients who used Gabapentinoid daily reported less pain, which is consistent with earlier research[30 & 31] and the use of the drug to treat Neuropathic Pain. Patients also noted improvements in their ratings of their sleep quality. During the course of four weeks of treatment, individuals with neuropathic pain had simultaneous improvements in sleep. This change may have an overall positive impact on the patients' daily disrupted sleep.

Gabapentinoid had positive benefits on sleep disruption in patients with chronic neuropathic pain, according to the findings of the current investigation. Gabapentinoid has been shown to be beneficial in treating pain-related sleep disruption in a review research[32]. In essence, the way that Gabapentinoid improves sleep quality is through reducing chronic pain. Gabapentinoid, however, has some beneficial benefits on sleep architecture as well, according to mounting research [33-35].

CONCLUSION:

Gabapentinoid had a good overall PSQI score for controlling sleep quality. In domains of neuropathic pain, Gabapentinoid was noticeably more effective. Gabapentinoid, was more successful in raising the PSQI's Seven Component Score and overall Global scoring. Gabapentinoid effects on patients with neuropathic pain may aid doctors in making a prescription decision.

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