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Original Article

Gabapentin versus Pregabalin for management of chronic inflammatory demyelinating polyradiculoneuropathy

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Abstract: Introduction: Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a chronic autoimmune demyelinating peripheral neuropathy that leads to symmetrical muscular weakness, sensory deficit, hyporeflexia, chronic fatigue, and impaired quality of life (QoL). The current study aims to investigate the effects of gabapentin versus pregabalin on pain, sleep disturbances, and QoL in CIDP patients. Methods: This clinical trial was conducted on 40 patients diagnosed with CIDP randomly allocated to treatment with 100-500 mg gabapentin (n=20) or 50-300 mg pregabalin (n=20) both co-medicated with 37.5 mg venlafaxine. The dose of gabapentin/pregabalin was adjusted based on the patient's tolerability/response to the treatment. Visual analogue scale (VAS), Pittsburg Sleep Quality Questionnaire and Short Form Health Survey (SF-36) were filled at baseline, within three, six, nine and 12 months after the interventions to assess pain severity, sleep quality and QoL, respectively. The Iranian Registry of Clinical Trials (IRCT) code: IRCT20200217046523N16, https://fa.irct.ir/search/result?query=IRCT20200217046523N16. Results: Gabapentin revealed a dose-dependent efficacy in pain severity (*P*-value =0.004, r=0.287), sleep quality (*P*-value <0.001, r=0.387) and QoL (*P*-value =0.001, r=-0.378), but pregabalin (*P*-value >0.05). Co-medication of gabapentin plus venlafaxine could significantly improve sleep quality (*P*-value =0.009) and QoL (*P*-value =0.004), but pain severity (*P*-value =0.796). Pregabalin plus venlafaxine showed statistically significant improvement in pain (*P*-value =0.046), sleep quality (*P*-value <0.001) and QoL (*P*-value <0.001). The comparison of the two medications revealed the superiority of pregabalin in pain relief (*P*-value >0.001) and QoL (*P*-value =0.03) to pregabalin. Conclusion: Based on this study, the co-medication of pregabalin and venlafaxine led to remarkable superior outcomes compared to venlafaxine plus gabapentin in the management of pain, sleep quality, and QoL due to CIDP.

Keywords: Pregabalin, gabapentin, chronic inflammatory demyelinating polyradiculopathy

Introduction

Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a chronic autoimmune demyelinating peripheral neuropathy that, in general, develops over the least period of 8 weeks; however, it may have a progressive or relapsing course [1]. Studies in the literature have estimated various rates of prevalence for this disorder ranging from one to nine per 1,000,000 people [2]. This disorder generally involves the motor and sensory nerve roots, and also peripheral nerves, while the cranial nerves are less often affected, and the involvement of autonomic nerves is sparse [3].

A review in the literature shows up to 50% negative impact of strength and sensory deficit on the CIDP patients' quality of life expectations. Besides, remained 50% is attributed to other factors such as pain, fatigue, and anxiety due to this disorder [4]. The best management approach of pain and CIDP mood-related adverse effects has not been unified yet and is

one of the most critical issues in research as it considerably affects the patients' quality of life [5].

Gabapentin is a structural analogue of gamma-aminobutyric acid that acts by the inhibition of calcium influx through calcium channels in the peripheral and central nervous system, and therefore, restricts the release of the neurotransmitters in pain pathways. Although gabapentin has emerged as an anticonvulsant agent, further evaluations revealed its efficacy in pain control, neuropathic types in particular [6].

Pregabalin is another gabapentinoid agent that acts by the modulation of stimulatory neurotransmitters release, glutamate, norepinephrine, and substance P and also inhibition of neural overstimulation. Similar to gabapentin, this agent was introduced as an anticonvulsant, while showed remarkable analgesic actions, as well [7].

Numerous studies investigated the efficacy of these agents in neuropathic pain management due to diverse etiologies such as postherpetic neuralgia and diabetic neuropathy [8-10]. It has been previously reported that gabapentin could have significant effects on pain relief in patients with neuropathic pain syndromes and polyradiculoneuropathy [1, 11] and also pregabalin could have significant results [12] but to the best of our knowledge there is no report in the English literature comparing the use of gabapentin versus pregabalin for CIDP. Since pregabalin acts at a lower dose than gabapentin and has fewer dose-dependent effects, as well as it is easier for patients to tolerate than gabapentin, and due to fewer side effects, we aimed to compare the effect of this drug with gabapentin. Therefore, in the current study, we aimed to compare these two agents in terms of pain, sleep disturbances and quality of life in CIDP patients.

Methods and material

Study population

The current clinical trial has been conducted on 40 patients with the diagnosis of CIDP referred to the outpatient neurology clinic of Alzahra Hospital affiliated at Isfahan University of Medical Sciences from April 2017 to March 2019.

The Ethics Committee of Isfahan University of Medical Sciences approved the study protocol (Ethics code: IR.MUI.MED.REC.1398.070, Iranian Registry of Clinical Trials (IRCT) code: IRCT20200217046523N16). The study protocol was explained to the patients, and they were reassured about the confidentiality of their personal information. Eventually, they were requested to sign the written form of participation in the study.

Inclusion and exclusion criteria

The inclusion criteria were age over 18-year-old, definite diagnosis of CIDP based on the European Federation of Neurological Societies/Peripheral Nerve Society 2010 (EFNS-2010) [13] and signing the written informed consent to participate in this study. The exclusion criteria were diagnosis of other neuropathies, including intoxication with heavy metals, vitamin B12 deficiency, gammopathies, nutritional-related neuropathies, diabetic neuropathy, and neuropathy due to hypothyroidism, patients with drug-related adverse effects or hypersensitivity to venlafaxine, gabapentin, or pregabalin that led to drug discontinuation.

Randomization

The patients with CIDP neuropathy that met the study inclusion criteria were recruited through convenience sampling. Then, they were randomly allocated to one of the medication approaches using Random Allocation software; thus, each of the participants was provided with a particular number allocated her/his to one of the treatment approaches. The person who interviewed the patients was blinded to the type of regimen used by each of them.

Medication approaches

The study population was divided into two groups of treatment. The first group was treated with the daily 37.5 mg of venlafaxine (Tehran Chemistry, Iran) plus 100-500 mg of gabapentin (Hakim, Iran); while the latter one was treated with the daily 37.5 mg of venlafaxine (Tehran Chemistry, Iran) plus 50-300 mg of pregabalin (Osveh, Iran).

The therapeutic regimens were continued for 12 months, and the patients' responses to the treatments were assessed five times, including

Table 1. Demographic data of patients

Variable		Gabapentin group (N=20)	Pregabalin group (N=20)	*P*-value
Age (year) (mean ± SD)		50.25±13.22	45.45±13.22	0.26
Sex (n (%))	Male	11 (55%)	15 (75%)	0.19
	Female	9 (45%)	5 (25%)	
Initial VAS (mean ± SD)		4.20±2.52	5.35±1.92	0.24
Initial sleep quality (mean ± SD)		17.60±6.91	10.55±8.10	0.18
Initial SF-36 (mean ± SD)		97.35±10.19	74.90±10.24	0.18

baseline and every three months until the end of the study.

The evaluations included pain complaints assessed using the Visual Analogue Scale (VAS), sleep quality based on the Pittsburg Sleep Quality Questionnaire, and quality of life (QoL) based on the Short Form Health Survey (SF-36).

Means of assessment

Visual analogue scale (VAS): This is a scale to assess the intensity of pain sensation, which ranges from 0 to 10 as the least to the most severe complaint of pain [14].

Pittsburg sleep quality questionnaire: This questionnaire contains 24 questions and seven subscales, including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficacy, sleep disturbances, use of sleep medications, and daytime dysfunction. Each of the questions is scored from 0-3, and the final scores are summed. The higher score represents the worse quality of sleeping [15]. The Persian version of this questionnaire has been validated by Farrahi and colleagues with Cronbach's alpha of 0.89 in 2009 [16].

Short form health survey (SF-36): This questionnaire is a generic self-reported health-related quality of life instrument consisting of 36 items in entities, including physical functioning (10 items), physical problems (4 items), bodily pain (2 items), general health perceptions (5 items), social functioning (2 items), role limitation due to emotional problems (3 items), vitality (4 items) and perceived mental health (5 items). Also, there is an item assessing the perceived change in general health status within a year that is the 36th item of SF-36 [17]. This questionnaire was turned to Persian in 2005 by Montazeri and others, which presented the remarkable Cronbach's alpha of 0.77 to 0.90 [18].

Using these three tools, we tried to evaluate the patient's response: VAS score, score of Pittsburg Sleep Quality Questionnaire and SF-36.

Statistical analysis

The obtained data were entered into the Statistical Package for Social Sciences (SPSS) version 25. The descriptive data was presented in mean, standard deviation, percentages, and absolute numbers. For analytics, Chi-square, T-test, ANCOVA, and Repeated measure ANOVA were used. *P*-value of less than 0.05 was considered as a significant level.

Results

Study population

In the current study, 40 patients fulfilled the study protocol, among which 20 patients were allocated to treatment with gabapentin, and the latter 20 patients were treated with pregabalin.

The mean age of gabapentin treated patients was 50.25±13.22 years (range: 32-79 years) with a predominance of male gender (11 (55%):9 (45%)), while those under pregabalin treatment had the mean age of 45.45±13.22 years (range: 25-72 years) with male gender predominance again (15 (75%):5 (25%)). The comparison of the two groups in terms of gender distribution (*P*-value =0.19) and age (*P*-value =0.26) revealed insignificant differences. There were also no significant differences between groups of patients regarding pain (P=0.24), sleep quality (P=0.18) and QOL (P=0.18). These demographic data are summarized in **Table 1**.

Table 2. The distribution of gabapentin and pregabalin dose per day in combination with venlafaxine

Dose per day	Number	Percentages
Gabapentin		
100 mg	4	20
300 mg	13	65
500 mg	3	15
Pregabalin		
50 mg	6	30
75 mg	5	20
100 mg	8	40
300 mg	1	5

Table 3. The effect of medication dose on pain, sleep quality and quality of life in the study groups

		P-value	r
Gabapentin dose	Pain	0.004	0.287
	Sleep quality	<0.001	0.378
	Quality of life	0.001	-0.326
Pregabalin dose	Pain	0.566	0.058
	Sleep quality	0.440	-0.078
	Quality of life	0.715	0.037

Response to treatments

The distribution of co-medications doses used with venlafaxine is demonstrated in **Table 2**. Based on this table, the highest prevalence for gabapentin was 300 mg per day (65%) and for pregabalin 100 mg per day (40%). Assessment of dose-effect on the pain, sleep quality, and QoL showed an insignificant role in the pregabalin treated group, while the dose of gabapentin could effectively affect all of the assessments (**Table 3**).

Changes in pain, sleep quality, and QoL scores

The trends of changes in pain scores, sleep quality scores, and QoL scores are demonstrated in **Table 4**. As it is shown, co-medication with gabapentin plus venlafaxine could significantly improve sleep quality and QoL, while the pain scores did not change remarkably at the end of the treatment. Assessments of pregabalin revealed statistically significant improvement in all of the entities. The comparison of the two medications showed the superiority of pregabalin in pain relief and QoL to pregabalin, while an insignificant difference was found between the two medications in terms of sleep quality improvement.

Discussion

Similar to the reports in the literature, we found that most of the affected cases with CIDP were male and in their fifth and sixth decades of life; however, there is no scientific hypothesis logically find the reason for male gender predominance in CIDP [19].

Apart from the CIDP progression control, the management of disease-related adverse effects such as pain, mood-related disorders, and eventually, quality of life is a notifying field of research. Our findings were in favor of pregabalin use as compared to gabapentin. Although both of the regimens could fulfill our desire, not only the outcomes of pregabalin were superior to gabapentin, we found a dose-dependent effect for gabapentin. On the other hand, despite the higher efficacy of gabapentin in terms of pain relief in higher doses, it was inversely associated with QoL representing the patients' reluctance to multiple uses of remedies as compared to single doses per day.

Pain is a considerable complaint of CIDP occurring in 49-72% of the patients [20, 21]. Agents such as tricyclic antidepressants (TCA), gabpentinoids, opioids, duloxetine, and immunomodulators have been raised lonely or mostly in combination with pain management [22-24]. These findings were in line with the results of our study showing the effectiveness of gabpentinoids on pain reduction in patients.

Studies in terms of gabapentin use for pain management in CIDP are controversial and similar to our study, they represented the requirement of multi-medication therapies and even using an injecting agent to control the pain [22, 23, 25]. In other words, gabapentin as a popular agent for neuropathic pain therapies could only efficiently lead to pain relief in CIDP when used as an adjuvant to immunotherapy [26]. Neuropathic pain due to CIDP management with pregabalin has not been well-established; however, data in access showed a higher rate of improved pain and even treatment cessation in pregabalin monotherapy or combination with other agents [26, 27].

Table 4. The efficacy of gabapentin versus pregabalin in pain relief, sleep quality and quality of life in the study groups

		Baseline	Within three months	Within six months	Within nine months	Within 12 months	*P*-value*	*P*-value**
		Mean ± standard deviation						
Pain	Gabapentin	4.20±2.52	4.20±2.52	3.65±2.73	2.85±2.05	2.70±1.89	0.796	<0.001
	Pregabalin	5.35±1.92	3.20±1.93	2.50±1.35	1.95±0.99	1.60±0.99	0.046	
Sleep quality	Gabapentin	17.60±6.91	17.60±6.91	15.25±7.36	15.75±6.81	15.45±6.66	0.009	0.083
	Pregabalin	10.55±8.10	14.75±9.19	12.40±8.64	9.70±6.53	8.50±6.34	<0.001	
Quality of life	Gabapentin	97.35±10.19	97.35±10.19	100.55±11.06	105.75±11.04	108.80±10.77	0.004	0.03
	Pregabalin	74.90±10.24	90.78±12.08	107.15±14.81	121.30±16.06	132.05±19.20	<0.001	

*ANCOVA, **Repeated measure ANCOVA test.

Despite lacking data comparing pregabalin with gabapentin for pain management in CDIP, these two agents have been widely discussed for other neuropathies. Dolgun and others conducted a study to compare these agents for pain relief following discectomy in lumbar surgery. Similar to our study, both of the agents could effectively improve pain within a year postoperatively, while they found an insignificant difference between the drugs in terms of pain control [28]. The other study by Ghai and colleagues represented significantly lower post-transabdominal hysterectomy pain complaints by pregabalin use as compared to gabapentin. Besides, the first request for analgesia was longer in pregabalin-treated patients, while the overall outcomes of the two regimens were comparable [6]. In the study by Devi and colleagues, the comparison of pregabalin, gabapentin, and duloxetine revealed the superiority of pregabalin in terms of pain complaint and sleep quality among patients with diabetic neuropathy. Also, drug-related adverse effects were considerably lower in this group [8]. Our data were also in line with these findings.

Interruption in the daily chores and attendance in social activities, in addition to the disabilities occurrence due to CIDP, poses a significant burden on these patients' life. Impaired quality of life and sleep disturbances are remarkably high among patients with CIDP [20, 29, 30]. Surfing the literature revealed only studies representing the values of immune or steroid therapy on the patients' rehabilitation and improvement of the life quality [20, 31]; while we observed that both of the agents could successfully improve sleep disturbances and QoL, however, pregabalin was superior. One of the limitations of our study is not to assess the drug-related adverse effects. In general, consistent with our findings, pregabalin seems superior to gabapentin because of better pharmacokinetics, dose-independence absorption, better potency, and fewer adverse effects [32].

Taken together, we assume that either pain relief and improved sleep quality, or maybe treatment with venlafaxine is the factors associated with improved QoL. On the other hand, we have not assessed the disease progression status within the year of assessment, as by rehabilitation of the disease in this period, patients may become more satisfied with their daily life. Therefore, a remarkable limitation of this study is not to assess the CIDP status, and further studies with better control of variables are recommended.

Conclusion

Based on this study, both pregabalin and gabapentin could efficiently lead to pain relief and improve QoL in CIDP patients, while the comparison of the two regimens revealed the superiority of pregabalin in terms of pain relief, sleep quality and life quality improvement.

Disclosure of conflict of interest

None.

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