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Safety and effectiveness of pregabalin controlled-release in Korean patients with peripheral neuropathic pain

A post-marketing surveillance data

Seong-il Oh, MD, PhD[a,b], Jin Hoon Park, MD, PhD[c], Sun-Young Oh, MD, PhD[d], Jee-Youn Moon, MD, PhD[e], Ji-Young Kang, MD[f], Jong Bum Choi, MD, PhD[g], Byung-Wan Lee, MD, PhD[h,*]

Abstract

Chronic pain, including neuropathic pain (NP), significantly affects quality of life in 7% to 10% of the general population. The prevalence of NP is rising owing to factors such as aging, obesity, and enhanced cancer survival rates. Effective management of NP is essential to improve patient outcomes. This study aimed to assess the safety and effectiveness of controlled-release (CR) pregabalin in Korean patients with peripheral NP . An open-label, non-comparative, multicenter study was conducted with 623 participants across 18 institutions. The patients received pregabalin CR as part of their routine treatment. Safety and efficacy data were collected over 12 weeks. Pain severity was assessed using the 11-point numeric rating scale (0 = no pain, 10 = worst imaginable pain), and sleep interference was assessed using an 11-point Likert scale (0 = did not interfere, 10 = unable to sleep). Safety was evaluated through adverse event (AE) reporting. Among the 617 participants evaluated for safety, 6.32% reported AEs, primarily dizziness and somnolence. Serious AEs were rare (0.32%). The efficacy analysis included 363 participants, with significant reductions in daily pain (from 5.05 ± 2.41 to 3.16 ± 2.26, $P < .0001$) and sleep interference scores (from 2.32 ± 2.70 to 1.42 ± 2.18, $P < .0001$) at week 12. Both the patients' and clinicians' global impressions demonstrated meaningful improvements in over 26% of the participants. The efficacy was reduced in patients with a medical history and in those receiving high doses (>165 mg/d). Pregabalin CR effectively reduced NP and sleep interference, with a manageable safety profile. These findings support the use of this drug as first-line treatment for NP. Personalized treatment and continuous monitoring are recommended to optimize patient outcomes.

Abbreviations: ADRs = adverse drug reactions, AEs = adverse events, CR = controlled-release, NP = pregabalin neuropathic pain, PMS = post-marketing surveillance.

Keywords: controlled-release formulation, diabetic peripheral neuropathy, neuropathic pain, postherpetic neuralgia, pregabalin

1. Introduction

Chronic pain is a major health problem affecting 1 in 5 people in Europe.[1,2] The prevalence of neuropathic pain (NP) ranges from 7% to 10% in the general population.[3–5] The increase in NP prevalence is likely influenced by risk factors such as an aging population, rising obesity prevalence, and improved survival of patients with cancer due to chemotherapeutics.[4,6–8]

Chronic pain can persist for a long time, resulting in a diminished health-related quality of life, often accompanied by depression, anxiety, sleep disturbances, fatigue, and decreased overall physical functioning.[9,10] NP can result from injury to either the central or peripheral nervous system.[2,7] The

All the investigators participating in this study are listed in the table. The study sites were written at the time of the study in alphabetical order. This study was funded by Pfizer Inc. in 2020, and Pfizer Upjohn merged with Mylan to form Viatris.

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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[a] Department of Neurology, Kyung Hee University Hospital, Kyung Hee University College of Medicine, Seoul, Republic of Korea, [b] Formerly, Inje University Busan Paik Hospital, Busan, South Korea, [c] Department of Neurosurgery, University of Ulsan College of Medicine, Gangneung Asan Hospital, Gangneung, Republic of Korea, [d] Department of Neurology, Chonbuk National University College of Medicine, Jeonju, Republic of Korea, [e] Department of Anesthesiology and Pain Medicine, Seoul National University Hospital, Seoul National University College of Medicine, Seoul, Republic of Korea, [f] Jangsarang Internal Medicine Hospital, Asan, Republic of Korea, [g] Department of Anesthesiology and Pain Medicine, Ajou University School of Medicine, Suwon, Republic of Korea, [h] Department of Endocrinology, Yonsei University College of Medicine, Seoul, Republic of Korea.

** Correspondence: Byung-Wan Lee, Division of Endocrinology and Metabolism, Department of Internal Medicine, Yonsei University College of Medicine, Seoul 03722, Republic of Korea (e-mail: bwanlee@yuhs.ac).*

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conditions commonly associated with NP include diabetic neuropathy, postherpetic neuralgia, trigeminal neuralgia, painful radiculopathy, peripheral nerve injury pain, spinal cord injury, multiple sclerosis, and stroke (in the form of central poststroke pain).[7,11]

Guidelines, including NeuPSIG, recommend various treatment modalities for NP, including antiepileptics such as gabapentinoids, tricyclic antidepressants, and serotonin-norepinephrine reuptake inhibitors as first-line therapies.[12,13] Notably, some drugs, initially developed for other indications (e.g., depression and epilepsy) were later evaluated for NP. Antiepileptic drugs are primarily used in the management of NP, such as painful diabetic neuropathy, rather than nociceptive pain (such as arthritis).[14]

Pregabalin, a ligand of α2-δ type voltage-gated calcium channel subunit, possesses analgesic, anxiolytic, and anticonvulsant activities. Moreover, pregabalin has been approved in more than 130 countries for both peripheral and central NP treatment.[15,16] Rapid effects of the drug are typically noted within the first week of treatment at doses ranging from 150 to 600 mg/d.[9] Controlled-release (CR) dosage forms (82.5, 165, and 330 mg) for once-daily dosing have been investigated in several phase 1 and 2/3 studies.[15,17]

However, the CR formulation of pregabalin can experience absorption variability, which is influenced by calorie intake, owing to the narrow absorption window of the drug.[18]

Despite evidence from previous studies, real-world data on pregabalin CR, particularly in Korea, are limited. This study addressed these gaps by evaluating both the safety and effectiveness of pregabalin CR under routine clinical conditions in Korean patients with peripheral NP.

2. Methods

2.1. Study design

This open-label, non-comparative, non-interventional, prospective, multicenter study was conducted in Korean healthcare centers by accredited physicians (i.e., investigators). The study was conducted on participants who were administered pregabalin CR as part of routine treatment and complied with local labeling guidelines. As this study aimed to demonstrate the safety and effectiveness of the product in a routine treatment setting, no additional visits or activities were mandated. This study did not require a screening procedure and Pfizer did not provide the investigational product, which was prescribed based on the investigator's clinical decisions in a real clinical practice setting.

Data privacy consent was obtained from the patients before enrollment, and the investigators collected clinical data by monitoring the participants' clinical status and recording information on case report forms. Enrollment was continued until the required number of cases per site was achieved according to the inclusion and exclusion criteria detailed below.

We recommend an initial dosage of 165 mg once daily, which can be based on individual patient responses and tolerability. The dosage was increased to 330 mg once daily after 3–7 days and, if necessary, to a maximum of 660 mg/d after an additional 7-day period. When switching from pregabalin capsules to pregabalin CR, patients received their final morning dose of pregabalin capsules before starting pregabalin CR after an evening meal.

Participants were included in this study if they were Korean individuals who had been administered pregabalin CR for the first time, according to the current local labeling.

Patients who met any of the following criteria were excluded from the study: deviation from local labeling regarding indication, dosage, or administration. Severe renal impairment with an estimated glomerular filtration rate <30 mL/min or those undergoing hemodialysis. Patients with hypersensitivity to the active substance (pregabalin) or excipients were also excluded. Other patients who were terminated by the investigator did not receive medication based on the risk assessment, such as those with suicidal behavior and ideation, pregnancy, or lactation.

2.2. Data collection and assessment

Clinical data including demographic characteristics, medical history (allergic history and other past/present diseases, including comorbidities such as liver or renal disorders, classified relative to the initiation of pregabalin CR), and current medication, were collected from the initial administration of pregabalin CR through a 12-week period (±2 weeks). If treatment was discontinued prematurely, the reasons were recorded and relevant data were collected until discontinuation. Gradual discontinuation over a minimum of 1 week was recommended according to the local labeling guidelines.

This study was designed as a short-term post-marketing surveillance to evaluate the safety and effectiveness of pregabalin CR during a 12-week period. Long-term surveillance was not included, as extensive safety data already exist for pregabalin capsules. Baseline creatinine clearance results were recorded within 3 months before the first administration of pregabalin CR.

2.3. Effectiveness evaluation

Pain severity was assessed using an 11-point numeric rating scale, with daily average pain scores collected at least at the 12-week endpoint (0 = no pain, 10 = pain as bad as you can imagine). Baseline daily average pain scores were collected prior to the first administration of pregabalin CR, and follow-up scores were measured at the 12-week endpoint (±2 weeks). The location of symptoms was recorded (left and/or right, arm, leg, foot, chest, face, back, and other areas), or radiation status was indicated.

Sleep interference was assessed using an 11-point Likert scale based on the question, "How much did the pain interfere with your sleep during the past 24 hours?" (0 = did not interfere, 10 = was unable to sleep). Baseline sleep interference scores were obtained prior to treatment initiation, and follow-up scores were collected at the 12-week endpoint (±2 weeks).

2.4. Safety evaluations

Adverse events (AEs) were recorded for each participant who was administered pregabalin CR at least once. The AE data included severity, seriousness, and causality, coded using the World Health Organization Adverse Reaction Terminology or MedDRA preferred terms. The seriousness of AEs was classified according to ICH E2A criteria (death, life-threatening event, hospitalization, persistent or significant disability/incapacity, congenital anomaly, or other medically important conditions). The severity of AEs was categorized as mild, moderate, or severe, based on their impact on daily activities and clinical course. Causality was assessed by investigators using standard pharmacovigilance categories (certain, probable/likely, possible, unlikely, or unassessable/unclassifiable). All AEs deemed to have more than 1 "unlikely" causal relationship were considered adverse drug reactions (ADRs).

2.5. Statistical analysis

Participants were classified into the safety evaluation set, which included all patients who received at least 1 dose of pregabalin CR, and the efficacy evaluation set, which included all patients who received at least 1 dose of pregabalin CR and had both baseline and at least 1 post-baseline efficacy assessment. The analysis included the occurrence rates of abnormal safety events and effectiveness based on demographic

factors, using the chi-square or Fisher exact tests. For the logistic regression analysis, potential influencing factors (e.g., demographic variables, baseline pain severity, concomitant medications, and comorbidities) were first assessed in univariate analyses. Variables with clinical relevance or statistical significance in univariate analyses were subsequently entered into the multivariate logistic regression model. Analyses were performed using SAS version 9.2 software, with significance set at $P < .05$.

2.6. Ethics statement

The study protocol was reviewed and approved by the ethics committees at each participating site. All the participants provided written informed consents. A full list of participating sites and ethics committees can be found in Table S1, Supplemental Digital Content, https://links.lww.com/MD/Q148.

3. Results

3.1. Demographics and baseline characteristics

The survey included 623 participants from 18 institutions. Safety evaluations were performed in 617 patients who received at least 1 dose of pregabalin CR and completed a safety follow-up. Six participants were excluded for violating the selection/exclusion criteria or failing to follow-up (Fig. 1).

For the efficacy evaluation, 363 participants were assessed according to the study protocol. This group excluded 149 individuals without a final efficacy evaluation and 105 individuals who received <10 weeks of medication. The baseline demographics and clinical characteristics, including medical history, primary pain diagnosis, and treatment regimens, are summarized in Table 1. The sample comprised 55.3% male participants, with an average age of 64.3 years (±11.3). Additionally, participants' ages ranged from 19 to 99 years, with age distributions of 21.4% (50–59 years), 36.1% (60–69 years), and 27.9% (70–79 years). None of the female participants was pregnant or lactating.

3.2. Safety

AEs were reported in 39 patients (6.3%), comprising of 49 events. Moreover, ADRs potentially linked to pregabalin CR were reported in 36 participants (5.8%), for a total of 45 events. Serious AEs were reported in 2 patients (0.32%), consisting of asthenia and adnexa uteri mass. One of these cases (0.16%) was classified as a serious adverse drug reaction (asthenia).Unexpected serious AEs occurred in 1 participant (0.2%); however, no unexpected serious adverse drug reactions were noted. Nonserious unexpected AEs were observed in 7 patients (1.13%).

Dizziness was the most cited AE (1.9%, 12 participants), followed by somnolence (1.3%, 8 participants), with other less frequent ADRs involving gastrointestinal and psychiatric disorders.

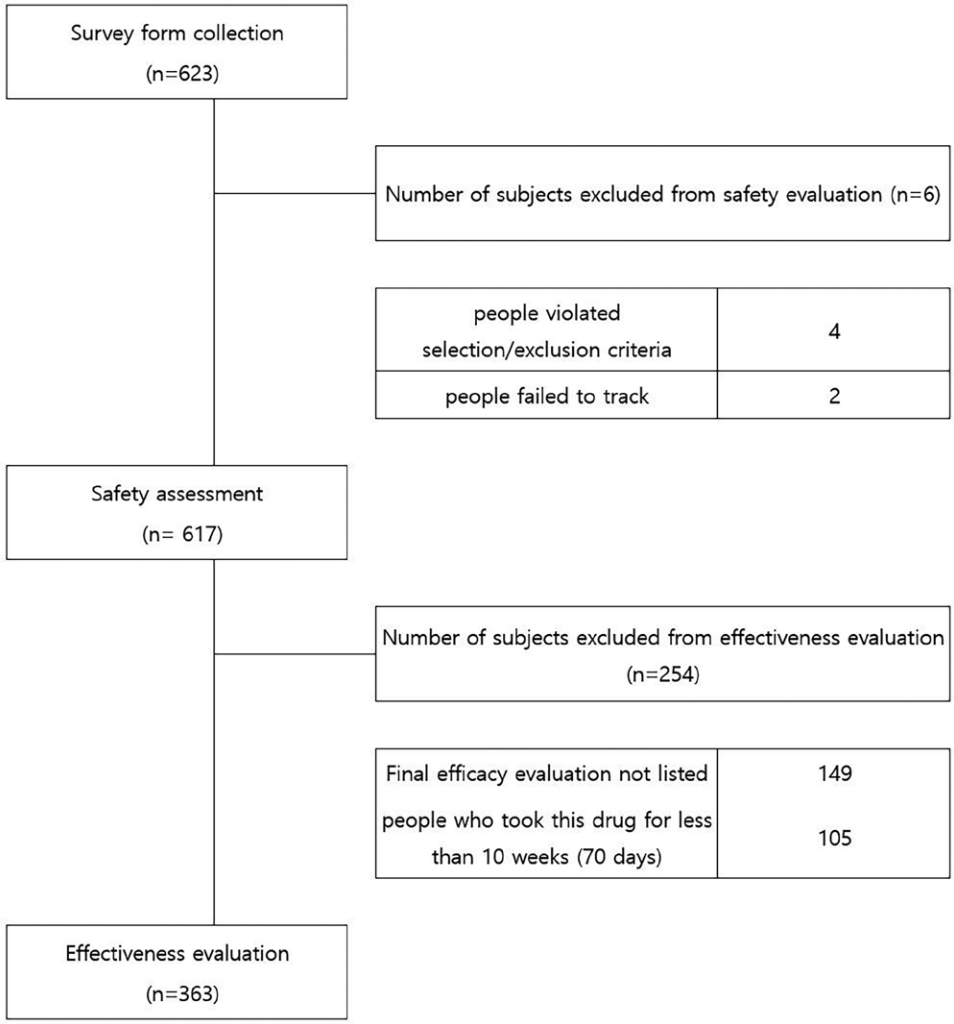

Figure 1. The composition of the post-marketing surveillance study participants.

Table 1

Demographics and baseline characteristics of participants.

Factor	Classification	Number of participants (n = 617)	
		n	(%)
Sex	Male	341	(55.3)
	Female	276	(44.7)
Age (yr)		64.3	±11.3
	≤50 yr	52	(8.4)
	50–59 yr	132	(21.4)
	60–69 yr	223	(36.1)
	70–79 yr	172	(27.9)
	≥80 yr	38	(6.2)
Geriatric	≥65 yr	335	(54.3)
	<65 yr	282	(45.7)
Height (cm) (n = 473)		163.5	±8.4
Weight (kg) (n = 503)		65.3	±11.6
Past medical history	Yes	200	(32.4)
	No	417	(67.6)
Renal impairment	Yes	18	(2.9)
	No	599	(97.1)
Hepatic impairment	Yes	15	(2.4)
	No	602	(97.6)
Allergy	Yes	20	(3.2)
	No	597	(96.8)
Purpose of treatment	Diabetic peripheral	222	(36.0)
	Postherpetic neuralgia	117	(19.0)
	Cancer-related	4	(0.7)
	Postoperative	42	(6.8)
	Compression-mediated	164	(26.6)
	Drug/toxic chemical-related	11	(1.8)
	Other	57	(9.2)
Duration of symptoms (mo) (n = 609)		21.1	±33.7
	<1 mo	160	(26.3)
	1–24 mo	290	(47.6)
	>24 mo	159	(26.1)
Location of symptom*	Arm	53	
	Hand	155	
	Leg	176	
	Foot	225	
	Chest and back	117	
	Face	20	
	Other area	79	
Peripheral neuropathic pain treatment history	Yes	395	(64.0)
	No	222	(36.0)
Concomitant medication	Yes	527	(85.4)
	No	90	(14.6)
Total duration of administration (n = 361)	10–14 wk	285	
	>14 wk	76	
The daily average dose of administration (n = 361)	165 mg/d	271	
	>165 mg/d	90	

*Overlapped.

Most AEs were mild (91.8%), with only a small number being classified as moderate or severe. The incidence of AEs showed no significant differences according to sex, although a low incidence was noted in older individuals. However, significant associations were identified with the treatment purpose, notably in patients with postherpetic neuralgia (9.4%, 11/117; $P = .0155$).

Multivariate logistic regression identified the treatment purpose and duration of drug administration as significant factors affecting AE occurrence. Specifically, compression-mediated NP treatment was less likely to result in AEs ($P = .0333$). Additionally, prolonged drug administration significantly reduced the odds of AE compared to shorter durations ($P < .0001$, odds ratio [OR] = 0.12) (Table 2).

3.3. Efficacy

Analysis of 347 individuals revealed the average daily pain score dropping from 5.05 (±2.41) at baseline to 3.16 (±2.26). Sleep interference scores also decreased significantly from 2.32 (±2.70) to 1.42 (±2.18), demonstrating marked improvement (both $P < .0001$) (Table S2, Supplemental Digital Content, https://links.lww.com/MD/Q148, Fig. 2).

The patient global impression of change demonstrated that 26.5% of patients experienced clinically meaningful improvement, with 15.6% reporting "very much improved" and 84.4% reporting "much improved." An additional 52.2% of patients reported slight improvement, while 19.6% reported no change and 1.6% reported worsening.

The clinician global impression of change yielded similar results, with 27.6% of patients experiencing meaningful improvement, including 14.0% "very much improved" and 86.0% "much improved." In addition, 55.1% of patients were rated as having slight improvement, 15.4% no change, and 2.0% worsening.

Overall, treatment was considered effective in 82.6% of patients, while 17.4% were rated as ineffective (Table S3, Supplemental Digital Content, https://links.lww.com/MD/

Table 2

Multivariable analysis of adverse events.

Factor	Classification	Estimate	SE	*P*-value	Odds ratio	[95% CI]
Intercept		-0.65	0.53	.2154		
Purpose of treatment	Neuropathic pain associated with diabetic peripheral neuropathy (DPN)	Reference				
	Postherpetic neuralgia (PHN)	0.01	0.58	.9801	1.01	[0.33, 3.15]
	Cancer-related neuropathic pain	-13.56	1191.83	.9909	–	–
	Postoperative neuropathic pain	-1.11	0.90	.2170	0.33	[0.06, 1.92]
	Compression-mediated neuropathic pain	-1.33	0.62	.0333*	0.26	[0.08, 0.90]
	Drug/toxic chemical-related neuropathic pain	-12.63	617.71	.9837	–	–
	Other neuropathic pain	0.09	0.62	.8799	1.10	[0.32, 3.72]
Total duration of administration (d)	<10 wk	Reference				
	10–14 wk	-3.15	0.55	.0000*	0.04	[0.01, 0.13]
	>14 wk	-2.12	0.64	.0009*	0.12	[0.03, 0.42]

CI = confidence interval, SE = standard error.

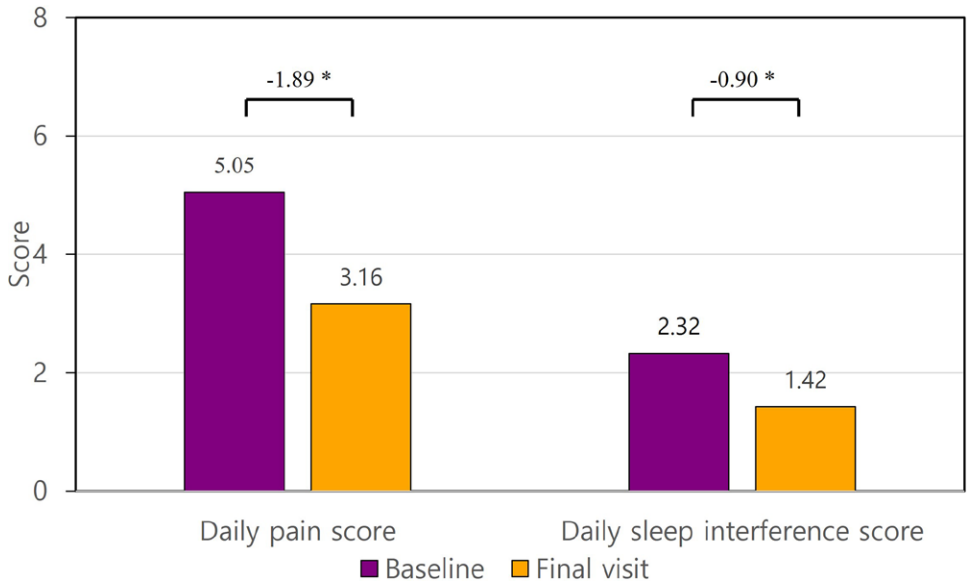

Figure 2. Reduction in average daily pain and daily sleep interference scores from baseline to those at final visit following treatment with pregabalin controlled-release.

Q148, Fig. 3). Efficacy evaluations demonstrated no significant differences based on sex; however, a reduced effectiveness rate was observed in patients who received higher daily doses (>165 mg/d), with 71.1% effectiveness (95% CI: 60.60–80.18), compared to 86.4% (95% CI: 81.68–90.20) in those receiving ≤165 mg/d (P = .0010) (Table S4, Supplemental Digital Content, https://links.lww.com/MD/Q148).

Multivariate logistic regression analysis was performed to evaluate predictive factors for efficacy. The presence of past disease was associated with lower response (OR 0.50, 95% CI: 0.28–0.88, P = .0156), as was a high daily average dose of pregabalin CR (>165 mg/d; OR 0.39, 95% CI: 0.22–0.70, P = .0016) (Table 3).

4. Discussion

Pregabalin is an important pharmacological therapeutic modality for both peripheral and central NP and is used globally.[12,13] Compared to 3-times-a-day dosing of traditional gabapentin and twice-daily dosing of immediate-release pregabalin, which offers enhanced convenience, pregabalin CR provides even greater medication convenience with its once-daily dosing, potentially enhancing patient's compliance or medication adherence.[9,15] However, caution should be exercised regarding potential safety issues that might arise from this dosing method.[19] The clinical relevance of post-marketing surveillance (PMS) studies lies in evaluating the long-term safety and efficacy of new drugs. This PMS study provided real-world insights into the efficacy and safety of pregabalin CR in Korean patients with peripheral NP. This study demonstrated the effectiveness of pregabalin CR in reducing pain severity and improving sleep, supporting its role as a first-line treatment in Korean patients with peripheral NP.

In this study, we confirmed the efficacy of pregabalin CR, accompanied by a favorable safety profile with stable adverse reaction outcomes. The findings from patient global impression of change and clinician global impression of change were consistent with the improvements observed in pain and sleep measures, supporting the robustness of the treatment effect. Multivariate logistic regression further demonstrated that past medical history and higher daily dosage (>165 mg/d) were associated with reduced effectiveness, emphasizing the importance of initiating therapy at lower doses and titrating gradually. Taken together, these results suggest that pregabalin CR can serve as an effective first-line treatment option for patients with peripheral neuropathic pain in real-world clinical practice.Adverse reactions occurred in 6.3% of patients, most of which were mild, with dizziness and drowsiness being common. In terms of safety, factors including the treatment purpose and total duration of administration were significant. Treatment for compression-mediated NP was associated with a lower incidence of AEs than that observed

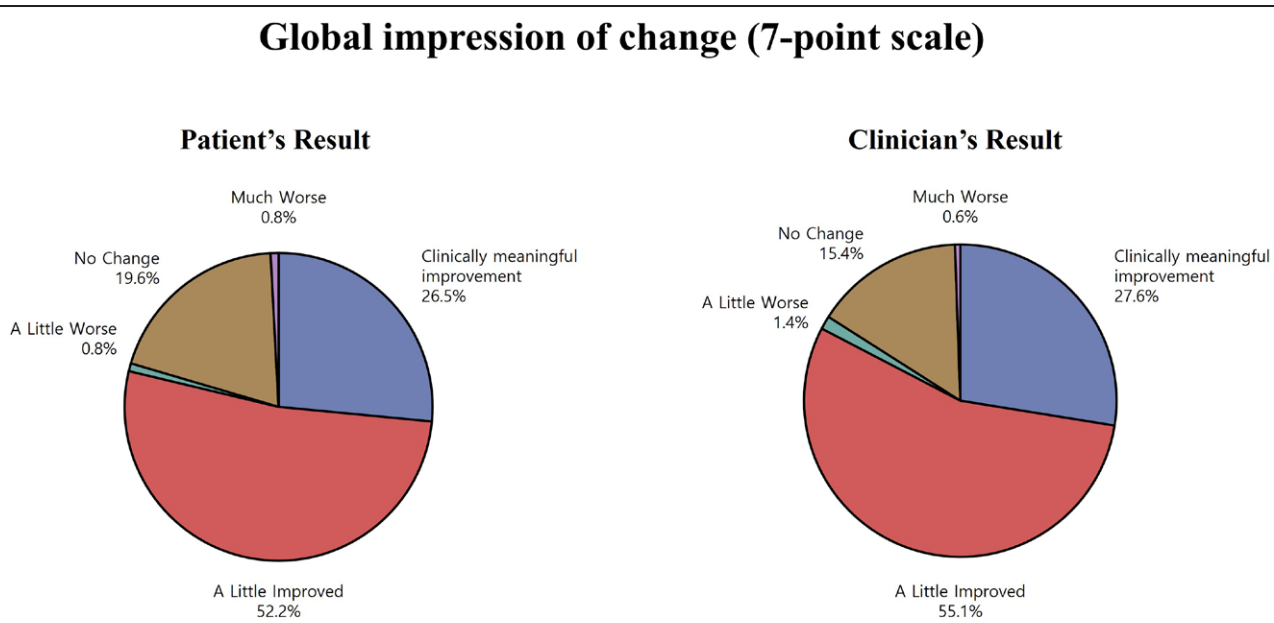

Figure 3. Patients and clinicians reported improvements in global impressions following treatment with pregabalin controlled-release.

Table 3

Multivariable analysis for the effectiveness rate according to clinical characteristics of participants.

Factor	Classification	Estimate	Standard error	*P*-value	Odds ratio	[95% CI]
Intercept		2.10	0.22	.0000*		
Past disease	No	Reference				
	Yes	-0.70	0.29	.0156*	0.50	[0.28, 0.88]
Daily average dose of administration	165 mg/d	Reference				
	>165 mg/d	-0.93	0.30	.0016*	0.39	[0.22, 0.70]

Response variable: occurrence status of adverse events.

CI = confidence interval, N = number of participants in the safety analysis set.

*$P < .05$.

with diabetic peripheral neuropathy ($P = .0333$). A total administration duration of 10 to 14 weeks and more than 14 weeks was associated with a lower incidence of AEs than a duration of <10 weeks ($P < .0001$ and $P = .0009$, respectively). Educating patients about potential side effects, especially dizziness and somnolence, and advising them on managing these symptoms can enhance adherence and improve the overall treatment experience. Participants with medical history and those receiving a high daily dose (>165 mg/d) experienced reduced efficacy. Multiple logistic regression analysis revealed a decreasing trend in the incidence of side effects with prolonged treatment duration.

This study has several limitations. The relatively short observational period and the non-randomized, open-label design typical of PMS studies may have contributed to an underestimation of adverse events and make it difficult to fully disentangle the independent effects of pregabalin CR. The incidence rate of AEs appeared lower than that reported in randomized controlled trials, which could be due to the real-world setting and potential underreporting. Furthermore, as a non-interventional study, laboratory data collection was left to the discretion of physicians, limiting standardization. Despite these methodological limitations, the consistent improvements in pain, sleep, and global impression scales support the clinical significance of pregabalin CR in real-world practice.

5. Conclusion

In conclusion, pregabalin CR was effective in managing NP in adults with an overall efficacy rate of 82.6% among evaluated individuals. Most AEs were consistent with the existing safety information, and no significant safety concerns were identified. Continuous monitoring through ongoing safety surveillance and pharmacovigilance is recommended to ensure the safety and efficacy of pregabalin CR therapy. Future research should focus on generating long-term real-world data specific to the CR formulation, to better understand its sustained efficacy and safety profile. Additionally, investigating the molecular mechanisms underlying the variable responses to pregabalin

Author contributions

Conceptualization: Seong-il Oh, Byung-Wan Lee.
Data curation: Seong-il Oh, Jin Hoon Park, Sun-Young Oh, Jee-Youn Moon, Ji-Young Kang, Jong Bum Choi, Byung-Wan Lee.
Formal analysis: Seong-il Oh, Jin Hoon Park, Sun-Young Oh, Jee-Youn Moon, Jong Bum Choi, Byung-Wan Lee.
Funding acquisition: Byung-Wan Lee.
Investigation: Seong-il Oh, Jin Hoon Park, Sun-Young Oh, Jee-Youn Moon, Ji-Young Kang, Jong Bum Choi, Byung-Wan Lee.
Methodology: Seong-il Oh, Jin Hoon Park, Sun-Young Oh, Jee-Youn Moon, Jong Bum Choi, Byung-Wan Lee.
Project administration: Byung-Wan Lee.
Supervision: Byung-Wan Lee.
Validation: Byung-Wan Lee.
Visualization: Seong-il Oh, Byung-Wan Lee.

Writing – original draft: Seong-il Oh, Jin Hoon Park, Sun-Young Oh, Jee-Youn Moon, Ji-Young Kang, Jong Bum Choi, Byung-Wan Lee.

Writing – review & editing: Seong-il Oh, Jin Hoon Park, Sun-Young Oh, Jee-Youn Moon, Ji-Young Kang, Jong Bum Choi, Byung-Wan Lee.

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