Original Article

Demographic and Clinical Characteristics of Chronic Low Back Pain Patients on Pregabalin: A Cross-Sectional Study at a Tertiary Care Hospital in Dhaka

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ABSTRACT:

Background: *Chronic low back pain (CLBP) is a leading cause of global disability. While pregabalin is a common off-label treatment for CLBP, there is a significant gap in the literature regarding the demographic and clinical characteristics of the patient population receiving this medication, particularly in tertiary care settings in developing countries. This study aimed to describe the profile of these patients and observe changes in their pain over time.*

Methods: *This was a cross-sectional study conducted at BIRDEM General Hospital in Dhaka from April to September 2024, involving 129 patients prescribed pregabalin for CLBP. Demographic, socio-economic, and clinical data were collected. The Visual Analog Scale (VAS) was used to measure self-reported pain intensity at baseline, and again at 6- and 12-week follow-up visits. The change in VAS scores was analyzed using a paired t-test by SPSS software (version 25.0) and then presented in tables and charts.*

Results: *The study population had a mean (± SD) age of 52.3 ± 11.5 years and was predominantly female (61.2%). Common comorbidities included hypertension (38.0%), diabetes mellitus (29.5%), and ischemic heart disease (24.8%). The mean (± SD) duration of CLBP was 21.3 ± 9.8 months. Mean (± SD) VAS scores showed a progressive and statistically significant reduction from baseline (7.8 ± 1.1) to the 6-week (5.5 ± 1.4) and 12-week (4.2 ± 1.5) follow-up visits ($p < 0.05$).*

Conclusion: *The findings characterize a complex and highly symptomatic patient cohort receiving pregabalin for CLBP. The significant reduction in pain intensity observed over a 12-week period is a promising real-world observation.*

Key Words:
Chronic Low Back Pain (CLBP), Pregabalin

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Introduction

Chronic low back pain (CLBP), defined as pain persisting for three months or longer, represents a major global health challenge and is a leading cause of disability worldwide [1]. This debilitating condition significantly impairs quality of life, reduces productivity, and places a substantial economic burden on healthcare systems [2]. The management of CLBP is often complex and requires a multi-modal approach, integrating pharmacological, physical, and psychological interventions [3]. Despite a wide array of treatment options, including non-steroidal anti-inflammatory drugs (NSAIDs) and opioids, many patients continue to experience persistent, refractory pain, leading to the exploration of alternative therapeutic agents [4].

Pregabalin is an anticonvulsant and analgesic medication approved for the management of various conditions with a neuropathic component, such as diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia [5]. Its mechanism of action involves binding to the alpha-2-delta subunit of voltage-gated calcium channels, which modulates the release of several pain-related neurotransmitters, including glutamate and substance P [6]. This action reduces hyperexcitability and nociceptive signaling, making it effective for pain with a neuropathic origin. While the etiology of CLBP is often non-specific, a significant proportion of patients present with a neuropathic pain component, a condition for which pregabalin is considered a viable treatment option [4,7,8]. Consequently, the off-label use of pregabalin for non-specific CLBP has become increasingly common in clinical practice, particularly in cases where first-line treatments have failed [9].

There is a notable gap in the literature regarding the use of pregabalin for chronic low back pain (CLBP) in Bangladesh. Specifically, there is a lack of information on the demographic and clinical profiles of patients receiving this medication, especially in tertiary care hospitals that handle complex cases. This knowledge is crucial for evaluating prescribing habits, identifying patient risk factors, and designing future studies on the drug's effectiveness and safety within the unique context of a developing country's healthcare system.

Therefore, this study was conducted to detail the demographic and clinical characteristics, including comorbidities and pain status, of CLBP patients prescribed pregabalin at a tertiary care hospital in Dhaka.

Methods

This was a cross-sectional study conducted over a six-month period, from April to September 2024. The study was carried out at the Department of Physical Medicine and Rehabilitation at BIRDEM General Hospital, a tertiary care academic hospital in Dhaka, Bangladesh. This setting was chosen due to its role as a key referral center for complex chronic pain cases.

A total of 129 patients with chronic low back pain (CLBP) were consecutively enrolled during their routine clinic visits. To be included, patients had to have a diagnosis of CLBP with a pain duration of at least three months, be 18 years of age or older, and have been prescribed pregabalin as the primary medication for CLBP management. All participants were required to provide informed consent. Patients were excluded if they had a known diagnosis of cancer-related pain, acute low back pain (less than three months), were pregnant or lactating, or had cognitive impairment that would prevent them from providing reliable information.

All data were collected meticulously by a specialist using a standardized data collection form to ensure consistency. The variables recorded included demographic characteristics such as age, gender, occupation, educational status, and socioeconomic status. Clinical characteristics documented were the duration of CLBP, clinical signs and symptoms, a history of previous pharmacological and non-pharmacological treatments, and the dosage of pregabalin. The comorbidity burden of each patient was also assessed by reviewing their medical charts for the presence of coexisting medical conditions such as diabetes mellitus, hypertension, and depression.

The intensity of pain at the time of the clinic visit was measured using the 10-point Visual Analog Scale (VAS), with a score of 0 indicating no pain and a score of 10 representing the worst possible pain. Patients were also asked to return for two follow-up visits at 6 weeks and 12 weeks. At each follow-up, their pain intensity was re-measured using the same VAS tool to describe any change in self-reported pain scores from the baseline measurement. It's important to note that this follow-up data was not used for a formal comparative efficacy

analysis, as the study's primary design was cross-sectional.

All participants provided written informed consent after receiving a full explanation of the study's objectives and procedures, and patient confidentiality was maintained throughout the study. The data were entered and analyzed using SPSS version 25. Descriptive statistics, including frequencies and percentages, were used for categorical variables, while mean and standard deviation were used for continuous variables. For inferential statistics, ANOVA was employed, with a p-value of < 0.05 considered as statistically significant.

Results

This study included 129 patients with chronic low back pain who were prescribed pregabalin. The results are presented in the following sections, summarizing the demographic, clinical, and pain-related characteristics of the study population.

a. Socio-demographic Characteristics of the Patients

The demographic profile of the patients is summarized in Table 1. The mean (± SD) age of the patients was 52.3 ± 11.5 years, with the majority being female (61.2%). The most common occupation reported was homemaker (35.7%), followed by daily wage laborer (21.7%).

Table 1: Socio-demographic Characteristics of the Patients (n= 129)

Characteristic	Mean ± SD or n (%)
Age (years)	52.3 ± 11.5
Gender	
Male	50 (38.8)
Female	79 (61.2)
Occupation	
Homemaker	46 (35.7)
Daily Wage Laborer	28 (21.7)
Salaried Employee	21 (16.3)
Business	15 (11.6)
Others	19 (14.7)
Educational Status	
Primary School	28 (21.7)
Secondary School	42 (32.6)
Higher Secondary	31 (24.0)
University Graduate	28 (21.7)

b. Baseline Clinical Characteristics of the Patients

The baseline clinical characteristics are shown in Table 2. The mean (± SD) duration of chronic low back pain was found to be 21.3 ± 9.8 months. A significant portion of patients had a documented history of comorbidities, with hypertension being the most prevalent (38.0%), followed by diabetes mellitus (29.5%) and ischemic heart disease (24.8%). Regarding previous treatment, NSAIDs was used by almost three-quarters of the study population (73.6%) and 45% reported of using physical therapy. The self-reported pain intensity at the first OPD visit measured using the Visual Analog Scale (VAS), had a mean (± SD) score of 7.8 ± 1.1.

Table 2: Baseline Clinical Characteristics of the Patients (n= 129)

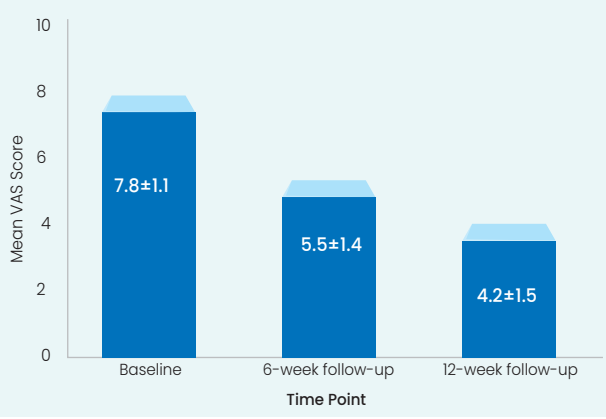
Characteristic	Mean ± SD or n (%)
Duration of CLBP (months)	21.3 ± 9.8
Baseline VAS Score (0-10)	7.8 ± 1.1
Comorbidities*	
Hypertension	59 (45.7)
Diabetes Mellitus	38 (29.5)
Ischemic Heart Disease	32 (24.8)
Other	18 (14.0)
Previous Treatment*	
NSAIDs	95 (73.6)
Physical Therapy	58 (45.0)
Other Opioids	31 (24.0)
Alternative treatment (Homeopathy, Acupuncture etc.)	14 (10.9)

* Multiple response

c. Changes in Self-Reported Pain Scores

The self-reported pain intensity at baseline, measured using the Visual Analog Scale (VAS), for all the patients had a mean (± SD) score of 7.8 ± 1.1. At the 6-week follow-up, the mean (± SD) VAS score decreased to 5.5 ± 1.4, and further decreased to 4.2 ± 1.5 at the 12-week follow-up. The change in mean (± SD) VAS score from baseline to 12 weeks was found to be statistically significant (Paired t-test; $p < 0.05$). The trend of pain reduction is illustrated in Figure 1.

Figure 1: Mean (± SD) VAS Scores at Baseline and Follow-Up Visits of the Patients (n =129)



Mean (± SD) VAS score	Baseline	6-week follow-up	12-week follow-up	p-value*
	7.8 ± 1.1	5.5 ± 1.4	4.2 ± 1.5	< 0.05

Discussion

This study provides a detailed observation regarding the demographic and clinical characteristics of a patient cohort with chronic low back pain (CLBP) who have been prescribed pregabalin at a tertiary care hospital in Dhaka. The findings offer a valuable, real-world perspective on prescribing patterns and patient profiles from Bangladesh, where such data is notably scarce.

The demographic profile of our cohort, with a mean (± SD) age of 52.3 ± 11.5 years and a clear female predominance (61.2%), is consistent with the global epidemiology of CLBP and other chronic pain conditions [10,11]. The higher prevalence of chronic pain in middle-aged women is a well-documented phenomenon, often attributed to hormonal, social, and psychological factors. The high proportion of homemakers and daily wage laborers highlights the significant socioeconomic burden of CLBP in this region, as these occupations are physically demanding and can predispose individuals to persistent musculoskeletal pain [12,13]. This is a crucial finding, as many studies from developed countries may not adequately capture this specific socioeconomic context.

A key finding is the significant comorbidity burden within the patient population. The high prevalence of hypertension (38.0%), diabetes mellitus (29.5%), and ischemic heart disease (24.8%) among our patients is higher than the general population and is consistent with studies that report a strong association between chronic pain and other non-communicable diseases [14,15]. The patients also presented with long-standing pain (mean (± SD) duration of 21.3 ± 9.8 months) and high baseline pain intensity (VAS 7.8 ± 1.1), suggesting they represent a population with refractory pain who have likely exhausted conventional first-line therapies. This is further supported by the high rates of prior treatment with NSAIDs (73.6%) and physical therapy (45.0%), which are typically recommended as initial management strategies [16]. The high prevalence of comorbidities and severe baseline pain underscores the complexity of this patient population and provides a strong rationale for the use of advanced pharmacological options like pregabalin [7,17,18].

The most notable finding is the statistically significant reduction in self-reported pain intensity observed over the 12-week follow-up period. The mean (± SD) VAS score decreased progressively from 7.8 ± 1.1 at baseline to 5.5 ± 1.4 at 6 weeks and further to 4.2 ± 1.5 at 12 weeks ($p<0.05$). This finding aligns with the known analgesic effects of pregabalin, particularly in pain with a neuropathic component [19]. While not a controlled trial, the results of this study are comparable to the outcomes observed in some randomized controlled trials that have shown a similar magnitude of pain reduction with pregabalin treatment for CLBP [4,20].

Despite these compelling descriptive findings, the study has several limitations. The primary limitation is the cross-sectional design, which prevents any causal conclusions regarding the efficacy of pregabalin. The absence of a control group means the observed reduction in pain could be influenced by a number of factors, including the placebo effect, concomitant therapies, or the natural history of the condition itself. The single-center setting and relatively small sample size also limit the generalizability of our findings. Data collection relying on self-reported pain scores and clinical records may also be subject to recall bias.

Conclusion

This study successfully characterized the demographic and clinical profile of chronic low back pain patients on pregabalin at a tertiary care hospital in Dhaka. The

patient population was highly symptomatic with a significant comorbidity burden and female predominance, confirming a complex patient profile. A promising finding was the statistically significant reduction in pain intensity over the 12-week follow-up period. While this single-center, cross-sectional design has limitations, these results provide a crucial foundation for future, larger-scale studies and randomized controlled trials to assess pregabalin's efficacy and safety in this specific patient population.

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