

Evaluation of Treatment Results in Patients with Chronic Low Back Pain

Kronik Bel Ağrısı Olan Hastalarda Tedavi Sonuçlarının Değerlendirilmesi

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ABSTRACT Objective: Low back pain is one of the global ailments that negatively affect daily life activities and cause loss of workforce. The aim of this study was to compare the treatment outcomes of patients with chronic low back pain (CLBP) in terms of functionality and pain. **Material and Methods:** The study included 74 patients diagnosed with CLBP due to lumbar disc herniation. Patients were divided into 2 groups according to the treatment administered. Patients who received at least 75 mg and at most 300 mg of pregabalin were classified as Group 1, and patients who received nonsteroidal anti-inflammatory drugs (NSAIDs) and physical therapy were classified as Group 2. İstanbul Low Back Pain Scale (ILBPS) and Oswestry Scale (OS) scores were analyzed before and after treatment. Pre- and post-treatment values were compared. **Results:** It was observed that all participants benefited from the treatment and there was a statistically significant decrease in ILBPS and OS. ($p<0.001$). Pre-treatment ILBPS and OS stages were higher in Group 1. It was found that the change in ILBPS and OS after treatment was significantly higher in Group 1 patients than in Group 2 patients ($p<0.001$). **Conclusion:** In this study, it was observed that the use of pregabalin alone in the presence of radiculopathy in CLBP was beneficial in terms of functionality, whereas in patients with lumbar discopathy without radiculopathy, both NSAIDs and physical therapy applications could significantly improve functionality. Radiculopathy should be considered in the treatment planning of patients with CLBP due to lumbar discopathy, and pregabalin treatment should be considered in patients who do not respond to NSAIDs and physical therapy.

Keywords: Physical therapy; chronic low back pain; nonsteroidal anti-inflammatory drug; pregabalin; radiculopathy

ÖZET Amaç: Bel ağrısı, günlük yaşam aktivitelerini olumsuz yönde etkileyen ve iş gücü kaybına neden olan küresel rahatsızlıklardan biridir. Bu çalışmadaki amaç, kronik bel ağrısı (KBA) olan hastaların tedavi sonuçlarını fonksiyonellik ve ağrı yönünden karşılaştırmaktır. **Gereç ve Yöntemler:** Çalışmaya lomber disk hernisine bağlı KBA tanısı almış 74 hasta dâhil edildi. Hastalar uygulanan tedaviye göre 2 gruba ayrıldı. En az 75 mg en fazla 300 mg pregabalin kullanan hastalar Grup 1, nonsteroidal antiinflatuar ilaç (NSAİİ) kullanımı ile birlikte fizik tedavi uygulaması almış olan hastalar Grup 2 olarak değerlendirildi. Katılımcılara tedavi öncesi ve sonrası uygulanan İstanbul Bel Ağrısı Skalası [İstanbul Low Back Pain Scale (ILBPS)] ve Oswestry Skalası (OS) skorları incelendi. Tedavi öncesi ve sonrası değerleri karşılaştırıldı. **Bulgular:** Tüm katılımcıların tedaviden fayda gördüğü, ILBPS ve OS’de istatistiksel anlamlı düzeyde azalma meydana geldiği gözlemlendi ($p<0,001$). Tedavi öncesi ILBPS ve OS evreleri Grup1’de daha yüksekti. Grup 1 hastalarında tedavi sonrası ILBPS ve OS’deki değişimin Grup 2 hastalara göre anlamlı yüksek olduğu bulundu ($p<0,001$). **Sonuç:** Bu çalışmada, KBA’da radikülopati varlığında tek başına pregabalin kullanımının hastaya fonksiyonellik anlamında fayda sağladığı, radikülopati olmayan lomber diskopatili hastalarda ise hem NSAİİ’lerin hem de fizik tedavi uygulamalarının fonksiyonelliği önemli ölçüde iyileştirebildiği gözlemlendi. Lomber diskopati sebepli KBA olan hastalarda tedavi planlaması yapılırken, radikülopati göz önünde bulundurulmalı, NSAİİ ve fizik tedavi yanıtsız hastalarda pregabalin tedavisi düşünülmelidir.

Anahtar Kelimeler: Fizik tedavi; kronik bel ağrısı; nonsteroidal antiinflatuar ilaç; pregabalin; radikülopati

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Chronic low back pain (CLBP) is defined as persistent pain in the low back region that persists for 12 weeks or longer despite appropriate medical treatment and intervention. Those diagnosed with CLBP are affected psychologically as well as physical mobility disability. This situation significantly affects the quality of life, daily activities and general well-being of the individual.¹ Various factors can cause CLBP, including muscle strains, ligament sprains, herniated discs, degenerative disc disease, osteoarthritis, and spinal stenosis. Other factors that can contribute to CLBP include poor posture, sedentary lifestyle, obesity, stress, and psychological factors such as depression, anxiety, and emotional stress. In patients with CLBP, other than causes such as radiculopathy and spinal stenosis (85%), no specific reason can be found to explain this situation.²

The most load-bearing region of the spine is the lumbar region. Therefore, functional stresses, mechanical stresses, occupational and sports traumas mostly affect the lumbar region. Low back pain occurs due to strain on the muscles and ligaments in the lumbar spine, degeneration of the joints or compression of the nerve roots coming out of the spinal cord and inflammation. 70-80% of the society encounters low back pain at any time in their life. Although most of the low back pain heals, up to 30% of it can become chronic.³

CLBP causes a high rate of loss of workforce in the society, and an effective treatment has not been determined until today. Our aim in this study is to investigate which of the treatments given to patients with CLBP due to lumbar disc herniation is more effective.

MATERIAL AND METHODS

Patients who applied to the physical therapy and rehabilitation outpatient clinic and who had previously undergone magnetic resonance imaging and needle electromyography (ENMG) for CLBP were included in the study. Our study was conducted in accordance with the Declaration of Helsinki. 100 patients aged between 20 and 100 who applied to the outpatient clinic with CLBP were analyzed. Patients with discopathy who had vasculitis, inflammatory

disease, human immunodeficiency virus, herpes simplex, cirrhosis, malignancy that cause CLBP and who underwent lumbar disc herniation surgery were not included in the study. Seventy-four patients with CLBP were included in the study after obtaining verbal and written consent.

Demographic data of the patients included in the study were recorded. The İstanbul Low Back Pain Scale (ILBPS) and the Oswestry Scale (OS) were filled in to understand how CLBP affects the quality of life and whether the treatments received increase the quality of life.

The patients were divided into 2 groups according to the treatment they used. Group 1 was given pregabalin (minimum: 75 milligrams, maximum: 300 milligrams), Group 2 was given physical therapy and nonsteroidal anti-inflammatory drugs (NSAIDs). All of the 1st group had radiculopathy in their ENMG. In our country, pregabalin derivative drugs are usually given to patients with chronic musculoskeletal pain (fibromyalgia etc.) or neuropathy due to damage to the nervous system. The patients in Group 1 consisted of patients with radiculopathy due to lumbar discopathy and who had no benefit from other treatments. Group 1 patients did not use NSAIDs but only pregabalin.

ILBPS determines the degree of difficulty encountered due to low back and sciatic pain in daily activities in the last month without the help of any assistive device or person. This scale consists of 18 questions and gets 0 points if he/she can do the movements without any difficulty, 1 point if there is little difficulty, 3 points if there is little difficulty, 4 points if there is a lot of difficulty, 5 points if he/she cannot do it, and 6 points if he/she cannot do it at all. A high score indicates very severe CLBP, and a low score indicates better results.⁴ All our patients were categorized according to their scores.

The OS is a scale to understand how much your low back pain affects your daily activities. The scale consists of 10 questions and is evaluated by giving A=0, B=1, C=2, D=3, E=4, F=5 points for each answered question. Questions that the patient does not answer are not evaluated. Evaluation is made on the basis of the questions answered. For example, the pa-

tient answered all the questions of the test and the score he got was 38; Since the maximum score that can be obtained in a test with all questions answered is 50, the patient's score= $(38/50)*100$. If another patient with the same score does not answer the third question of the test, for example, the patient's score= $(38/45)*100$, since the maximum score is reduced by 5. The interpretation of the obtained percentage values is done as follows. 0% to 20% - minimal disability, 20% to 40% - moderate disability, 40% to 60% - severe disability, 60% to 80% - crippled, 80% to 100% - bed bound (or exaggerating symptoms).⁵

ETHICS COMMITTEE

Written permission was obtained from the Harran University of Medicine Clinical Research Ethics Committee (date: August 7, 2023; no: 14) and the institution where the study was conducted before the data were collected. In addition, all study participants were informed about the nature of the study and that participation was voluntary. Informed consent was obtained from all participants.

STATISTICAL ANALYSIS

Analyzes were evaluated by using IBM SPSS for Windows, Version 22.0 (Chicago, IL). In the study, descriptive data were shown as n and % values in categorical data, and mean±standard deviation values in continuous data. Wilcoxon analysis was used to compare sequential categorical data before and after treatment. Conformity of continuous variables to normal distribution was evaluated by Kolmogorov-Smirnov test. Mann-Whitney U test and were used to compare paired groups. Spearman correlation analysis was applied for the relationship of the measurement data. The statistical significance level in the analyzes was accepted as $p<0.05$.

RESULTS

A total of 74 patients, 30 (40.5%) male and 44 (59.5%) female, were included in the study and the mean age of the patients was 50.9 ± 13.8 (minimum=21-maximum=80) years. Thirty-five (47.3%) of the patients had radiculopathy. Pregabalin was given to 35 (47.3%) patients, and NSAID and physi-

cal therapy to 39 (52.7%) patients. Among the patients using pregabalin, 46% (n=16) were using 75 mg 2x1, 31% (n=11) were using 150 mg 2x1, 14% (n=5) were using 150 mg 1x1, and 9% (n=3) were using 75 mg 1x1. Percentage distribution of pregabalin use is shown in Figure 1.

ENMG results of the participants showed that 16 patients had L4-5 root compression, 15 patients had L5-S1 root compression, 1 patient had L3-4 root compression and 3 patients had both L4-5 and L5-S1 root compression.

Significant improvement was observed in the ILBPS and OS scales of all groups compared to pre-treatment. While the proportion of patients with radiculopathy (receiving pregabalin treatment) whose low back pain was very severe (Grade 6) according to ILBPS before treatment was 22.9%, this rate was 0% after treatment. After the treatment, the degree of difficulty in low back pain decreased significantly compared to ILBPS ($p<0.001$). In patients with radiculopathy, the rate of patients with low back pain before treatment was 54.3% according to OS (Stage 4), while the rate of patients who were bedridden (Stage 5) was 34.3%, while the rate of completely limited and bedridden patients after treatment was 0%. After the treatment, limitation due to low back pain decreased significantly compared to OS ($p<0.001$) (Table 1).

In patients without radiculopathy (who took physical therapy and NSAIDs), the rate of patients with low back pain at Stage 5 before treatment was

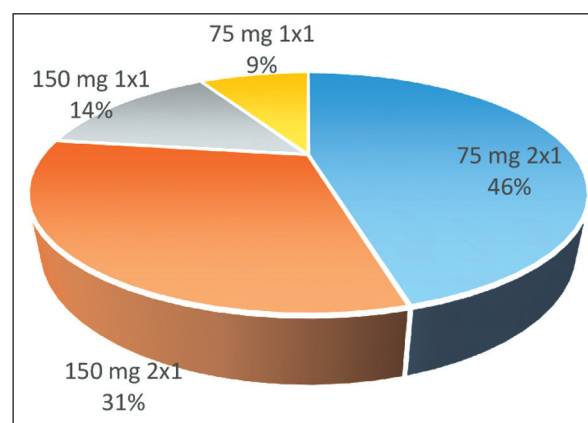


FIGURE 1: The distribution of 35 patients using pregabalin.

TABLE 1: Comparison of pre- and post-treatment scales in patients with radiculopathy.

		Before treatment		After treatment		p*
		n	%	n	%	
ILBPS	Not at all difficult (Stage 1)	0	0.0	0	0.0	<0.001
	Having little difficulty (Stage 2)	0	0.0	11	31.4	
	Struggling a bit (Stage 3)	0	0.0	19	54.3	
	Having a hard time (Stage 4)	7	20.0	5	14.3	
	Almost impossible (Stage 5)	20	57.1	0	0.0	
	Impossible or very severe symptoms (Stage 6)	8	22.9	0	0.0	
OS	No problem (Stage 1)	0	0.0	2	5.7	<0.001
	Mild limitation (Stage 2)	0	0.0	28	80.0	
	Advanced limitation (Stage 3)	4	11.4	5	14.3	
	Completely restricted (Stage 4)	19	54.3	0	0.0	
	Bedridden or very exaggerated symptoms (Stage 5)	12	34.3	0	0.0	

*Wilcoxon analysis has been applied; ILBPS: İstanbul Low Back Pain Scale; OS: Oswestry Scale.

20.5%, compared to 7.7% after treatment, according to ILBPS both before and after treatment. After the treatment, the degree of strain decreased significantly compared to the ILBPS ($p<0.001$). In patients without radiculopathy, the rate of people who were completely restricted (Stage 4) before treatment was 17.9%, while the rate of those who were bedridden (Stage 5) was 12.8%, while the rate of those who were completely limited (Stage 4) after treatment was 12.8% and bedridden. The rate of those who were dependent (Stage 5) was seen as 5.1%. After the treatment, the limitation decreased significantly compared to the OS ($p<0.001$) (Table 2).

The change in ILBPS was found to be significantly higher in women than in men ($p=0.002$). There was no significant difference between the genders in terms of the change in OS ($p=0.118$). In patients with radiculopathy, the change in ILBPS and OS was found to be significantly higher than those without radiculopathy ($p<0.001$). There was a significant difference between the treatments in terms of change in ILBPS and OS ($p<0.001$). This difference was due to the difference between those who received pregabalin and those who received the other treatment for both scales, and the level of change was higher for those who received pregabalin. There was a significant pos-

TABLE 2: Comparison of pre- and post-treatment scales in patients without radiculopathy.

		Before treatment		After treatment		p*
		n	%	n	%	
ILBPS	Not at all difficult (Stage 1)	0	0.0	9	23.1	<0.001
	Having little difficulty (Stage 2)	12	30.8	15	38.5	
	Struggling a bit (Stage 3)	13	33.3	7	17.9	
	Having a hard time (Stage 4)	6	15.4	5	12.8	
	Almost impossible (Stage 5)	8	20.5	3	7.7	
	Impossible or very severe symptoms (Stage 6)	0	0	0	0	
OS	No problem (Stage 1)	0	0	16	41.0	<0.001
	Mild limitation (Stage 2)	16	41.0	11	28.2	
	Advanced limitation (Stage 3)	11	28.2	5	12.8	
	Completely restricted (Stage 4)	7	17.9	5	12.8	
	Bedridden or very exaggerated symptoms (Stage 5)	5	12.8	2	5.1	

*Wilcoxon analysis has been applied; ILBPS: İstanbul Low Back Pain Scale; OS: Oswestry Scale.

itive correlation between ILBPS scale change and OS change ($r=0.861$; $p<0.001$), age ($r=0.458$; $p<0.001$) and body mass index ($r=0.235$; $p=0.044$). A significant positive correlation was observed between the scale change in OS and age ($r=0.443$; $p<0.001$) (Table 3).

DISCUSSION

The presence of radiculopathy in CLBP due to lumbar disc herniation may change the course of treatment. While a discopathy without radiculopathy can be easily treated with NSAIDs and physical therapy applications, the presence of radiculopathy may complicate the treatment process. In this study, we compared the treatment results of patients who underwent needle ENMG due to lumbar disc herniation, who used pregabalin due to radiculopathy, and who did not have radiculopathy on ENMG but received NSAIDs and physical therapy applications.

Radiculopathy and response to treatments given to patients with CLBP were examined. It was determined that the severity of CLBP was higher in patients accompanied by radiculopathy. Pregabalin was found to be a more effective treatment in these patients.

CLBP is common in our society due to the lack of conscious education and exercise habits about techniques to protect low back health. Most patients

with CLBP initially ignore low back pain. When there is a decrease in the quality of life and loss of work force, low back pain becomes important for the person.

Depending on the severity of symptoms of CLBP, patients apply to many treatments. Lumbar operations, physical therapy agents, exercises, epidural blocks, radiofrequency methods, yoga, back schools and medical treatments are some of these treatment options.⁶ Although these treatments reduce the person's symptoms, they do not provide a complete cure. In our study, it was determined that the symptoms decreased with the treatments received by the patients, but no cure was provided.

Physical therapy agents and exercises are the first treatment options for CLBP pain. However, it is necessary to investigate other pathologies accompanying CLBP in patients who benefit from this treatment. Radiculopathy is one of these pathologies and it mostly accompanies lumbar discopathy.^{7,8} All of the patients included in the study had lumbar discopathy and 35 patients had radiculopathy due to discopathy. Although all patients' daily activities and quality of life due to CLBP were affected by both ILBPS and OS, those with radiculopathy were more affected.

In our study, the quality of life and life activity of the group receiving pregabalin increased more in

TABLE 3: Comparison of scale changes and correlations according to gender, presence of radiculopathy and treatment.

		Change ILBPS		Change OS	
		$\bar{X}\pm SD$	p value	$\bar{X}\pm SD$	p value
Gender	Male	1.2 \pm 0.8	0.02*	1.3 \pm 0.7	0.118*
	Female	1.7 \pm 0.9		1.6 \pm 0.9	
Radiculopathy	Yes	2.2 \pm 0.5	<0.001*	2.1 \pm 0.6	<0.001*
	No	0.8 \pm 0.6		0.9 \pm 0.6	
Treatment	Pregabalin	2.2 \pm 0.5	<0.001*	2.1 \pm 0.6	<0.001*
	Other	0.8 \pm 0.6		0.9 \pm 0.6	
Change OS	r value	0.861			
	p value	0.000			
Age	r value	0.458		0.443	
	p value	0.000		0.000	
BMI	r value	0.235		0.155	
	p value	0.044		0.187	

*Mann-Whitney U analysis has been applied; SD: Standard deviation; ILBPS: İstanbul Low Back Pain Scale; OS: Oswestry Scale; BMI: Body mass index.

the other group. In addition, the baseline symptom severity of the group using pregabalin was greater in the group receiving physical therapy and NSAIDs. This might have resulted from the radiculopathy accompanying CLBP. Although physical therapy and NSAIDs reduced the symptoms of radiculopathy associated with low back pain, they were not as effective as pregabalin. According to our study, pregabalin was a better option than physical therapy and NSAIDs in patients with radiculopathy and low back pain.

In terms of CLBP due to lumbar disc herniation, the literature has shown that the use of pregabalin and gabapentin in the absence of radiculopathy is still under investigation, that the use of pregabalin is beneficial in the presence of radiculopathy, and that dose monitoring is important in the use of pregabalin in terms of potential side effects.^{9,10}

In our study, significant improvement was observed in the ILBPS and OS of both groups compared to pre-treatment. This improvement was greater in the pregabalin group. A significant difference was observed between the treatments in terms of change in ILBPS and OS and this difference was due to the difference between those who received pregabalin and those who received the other treatment for both scales, and the level of change was higher for those who received pregabalin. The quality of life of the pregabalin group improved more, and pregabalin may be a good treatment option in patients with CLBP.

Significant changes were found in the ILBPS and OS before and after treatment in patients with radiculopathy. This change was due to the fact that all patients with radiculopathy received pregabalin therapy.

A positive correlation was found between age and ILBPS and OS changes in both groups. Increasing age may have allowed an increase in response to

treatment due to increased mechanical low back pain. In addition, a positive correlation was observed between both groups, and it was seen that the patients responded positively to the treatment according to ILBPS and OS.

CONCLUSION

According to the results of our current study, the high severity of CLBP affects the quality of daily life negatively. When we compared the treatments used by the patients, the change in the pain scale of the pregabalin treatment group was higher than the other group.

Viewed from another perspective that the use of pregabalin has a positive effect on lumbar functions in the presence of radiculopathy in CLBP due to lumbar disc herniations. Considering the usage conditions of pregabalin in our country, possible radiculopathy should be tested with ENMG and neuropathic pain should be confirmed with tests in order to prevent potential side effects and pregabalin addiction. Considering the success of NSAIDs and physical therapy methods in CLBP due to lumbar disc herniation, pregabalin should not be recommended as first-line treatment, especially in the absence of radiculopathy.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

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