

## Investigation of the effect of low back pain severity on functional level, quality of life and fear-avoidance behavior in women with hip osteoarthritis

*Kalça osteoartritli kadınlarda bel ağrısı şiddetinin fonksiyonel düzey, yaşam kalitesi ve korku kaçınma davranışına etkisinin incelenmesi*

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### Abstract

**Purpose:** The objective of the this study was to investigate the effect of low back pain (LBP) severity on functional level, quality of life (QoL), and fear-avoidance behavior in patients with hip osteoarthritis (HOA).

**Material and methods:** A cross-sectional study conducted on a total of 43 female patients diagnosed with HOA. The patients were divided into two groups according to pain intensity; Group 1 consisted of patients with moderate-to-high intensity low back pain (VAS:3.5-10 cm; n=21), Group 2 consisted of patients with mild back pain (VAS:0.5-3.49 cm; n=22) occurred. Functional level (Lumbar Spine Mobility, Harris Hip Score, Timed Up and Go Test), quality of life (Nottingham Health Profile) and kinesiophobia (Tampa Scale of Kinesiophobia) were evaluated.

**Results:** When the groups were compared, it was found that the QoL, QoL-pain and emotional reactions sub-parameters scores of Group 1 were significantly higher than Group 2 ( $p=0.001$ ,  $p=0.002$ ,  $p=0.002$ ). However, there was no statistically significant difference between the two groups in terms of functional level and kinesiophobia ( $p>0.05$ ).

**Conclusion:** The results of the study showed that the QoL-pain and emotional reaction sub-parameters and QoL were negatively affected in patients with moderate-high severity of LBP in HOA in comparison with mild severity of LBP.

**Keywords:** Hip osteoarthritis, low back pain, quality of life, pain, assessment.

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### Öz

**Amaç:** Bu çalışmanın amacı kalça osteoartritli (KOA) hastalarda bel ağrısı şiddetinin fonksiyonel düzey, yaşam kalitesi ve korku kaçınma davranışı üzerine etkisini incelemektir.

**Gereç ve yöntem:** Yapılan kesitsel çalışmaya KOA tanısı konmuş toplam 43 kadın hasta dahil edilmiştir. Hastalar ağrı şiddetine göre iki gruba ayrılmış; Grup 1 orta-yüksek şiddette bel ağrısı olan hastalardan (VAS:3,5-10 cm; n=21), Grup 2 ise hafif bel ağrısı olan hastalardan (VAS:0,5-3,49 cm; n=22) oluşturulmuştur. Fonksiyonel düzey (Lumbar Bölge Hareketliliği, Harris Kalça Skoru, Zamanlı Kalk ve Yürü Testi), yaşam kalitesi (Nottingham Sağlık Profili) ve kinezyofobi (Tampa Kinezyofobi Ölçeği) değerlendirilmiştir.

**Bulgular:** Gruplar karşılaştırıldığında Grup 1'in yaşam kalitesi, yaşam kalitesi-ağrı ve emosyonel reaksiyonlar alt parametre skorlarının Grup 2'ye göre anlamlı derecede yüksek olduğu görüldü ( $p=0,001$ ,  $p=0,002$ ,  $p=0,002$ ). Ancak fonksiyonel düzey ve kinezyofobi açısından iki grup arasında istatistiksel olarak anlamlı fark yoktu ( $p>0,05$ ).

**Sonuç:** Çalışmanın sonuçları, KOA'da orta-yüksek şiddette bel ağrısı olan hastalarda, hafif şiddette bel ağrısına kıyasla yaşam kalitesi-ağrı ve emosyonel reaksiyonlar alt parametrelerinin ve yaşam kalitesinin olumsuz etkilendiğini göstermiştir.

**Anahtar kelimeler:** Kalça osteoartriti, bel ağrısı, yaşam kalitesi, ağrı, değerlendirme.

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## Introduction

Hip osteoarthritis (HOA) is an important source of morbidity that causes pain, gait abnormalities, and functional disorders [1]. In the literature, hip osteoarthritis is reported to occur particularly after the age of 50, with a prevalence of approximately 10%, and it is predicted to increase [2-4]. The prevalence of HOA is higher in women than in men after 50 years of age [5].

Symptomatic HOA, which significantly impairs both quality of life (QoL) and daily activities, frequently coexists with lumbar spine issues, even when occurring in isolation [6]. Individuals who experience low back pain (LBP) throughout their lives often encounter a decline in their QoL due to diminished physical, mental, and social functioning [7]. The perception of pain is closely linked to fear-avoidance beliefs [8]. Fear of movement negatively impacts both pain experience and functional impairment in osteoarthritis patients [9]. Furthermore, it has been demonstrated that fear of movement at the onset of LBP serves as a mediator in the correlation between pain severity and functional decline [10].

Patients diagnosed with HOA typically exhibit an abnormal spine-hip relationship [11]. In 1983, Offierski and MacNab introduced the concept of Hip-Spine Syndrome, characterizing the co-occurrence of lumbar spine and hip disorders [12]. Offierski and MacNab proposed that hip flexion deformities lead to gradual anteversion of the pelvis, resulting in compensatory lumbar hyperlordosis and subsequent subluxation of the lumbar posterior facets, thereby eliciting LBP [12]. It is thought that there may be other factors that play a role in the mechanism of LBP secondary to HOA. Severe osteoarthritis of the hip joint, abnormal sagittal spine alignment and disordered balance may cause trudge and are associated with LBP [13].

The aim of the present study was to investigate the effect of LBP severity on functional level, QoL, and fear-avoidance behavior in women with HOA.

## Material and methods

### Study design and sample

This is a cross-sectional study, and approval was obtained from the Pamukkale University Non-Interventional Clinical Research Ethics Committee (date: 03.08.2017, number: 60116787-020/49863). The study was performed in accordance with the rules of the Declaration of Helsinki. Informed consent forms were obtained from the participants in the study. The study was conducted with 43 female patients who were diagnosed with stage 2 and 3 HOA according to Kellgren-Lawrence Stage on their radiographs taken in the last 6 months between October 2017 and January 2018 at Pamukkale University Department of Orthopedics and Traumatology. Patients were required to have LBP along with HOA. Patients with HOA were divided into 2 study groups according to the severity of non-specific LBP as a result of the evaluation with Visual Analog Scale (VAS) (0-10 cm) [14]. Group 1 included patients with moderate-high LBP (VAS:3.5-10 cm; n=21) and Group 2 included patients with mild LBP (VAS:0.5-3.49 cm; n=22), respectively [15]. The inclusion criteria for both groups, other than having LBP, were patients over 50 years of age, being diagnosed with HOA according to the American College of Rheumatology Criteria, having at least stage 2 according to the Kellgren-Lawrence Staging on radiographs taken in the last 6 months, patients with pain problems around the groin and hip for at least 3 months, and having a hip pain severity of 3.5 cm or higher on the VAS. Patients who had undergone knee and/or hip replacement, had spinal surgery, received physiotherapy for hip, knee, or waist in the last 6 months, had a neurological diagnosis, and had secondary HOA were not included in the assessment.

### Sample size

Power analysis results from the study conducted by French et al. [16] (2015) were utilized. According to the study result, they had a large effect size ( $d=1.45$ ). Assuming we can achieve a lower effect size ( $d=0.9$ ), a power analysis was performed before the study. Accordingly, when at least 42 participants (21 per each group) were included in the study, that

would result in 80% power with 95% confidence level (5% type 1 error rate). A total of 48 patients were enrolled during the study's duration. Exclusions from the study encompassed one patient who declined to participate, 2 patients who did not complete the assessment, and 1 patient who encountered a health issue during the evaluation. Of the 44 total patients who met criteria, only one was male.

## **Data collection**

### **The patient information form**

For the participants in the study, information regarding age, weight, height, body mass index, and radiological stage of HOA were recorded on a prepared form.

### **Pain**

The duration of hip and LBP (in months) was queried for the patients participating in the study. The severity of both LBP and hip pain for the patients was assessed using the Visual Analog Scale (VAS) [14]. Additionally, participants were asked to specify the duration (in months) of their hip pain complaints.

### **Functional level**

The functional level measurement of the patients was determined by evaluating lumbar region mobility with the Modified Schober Test [17], range of the motion (ROM) of hip [18], Harris Hip Score [19], and performance-based functional mobility measurement with the Timed Up and Go Test [20, 21].

#### **a. The Modified Schober Test (MST)**

The MST was employed to assess the active flexion range of motion in the lumbar region [22]. To conduct this assessment, the upper edge of the sacrum was identified and marked over both spina iliaca posterior superior. The marked area was determined to be 5 cm below and 10 cm above the vertical line, resulting in a 15 cm difference. The distance between the two marked points was then measured while patients were instructed to lean forward as far as possible. The increase in the distance between the marks functioned as a quantitative gauge of the normal range of motion for lumbar flexion [17].

#### **b. The Range of Motion of Hip**

The range of motion of hip flexion, extension, and abduction was measured using a standard two-arm goniometer [18].

**Flexion/in supine position:** The pivot point of the goniometer was positioned at the greater trochanter, while the stationary arm was held parallel to the axilla. The flexion value was recorded by following the lateral midline of the femur with the moving arm of the goniometer [23].

**Extension/in prone position:** The patient was asked to extend the hip while keeping the knee extended on the side being measured [23].

**Abduction/in supine position:** The stationary arm of the goniometer was kept parallel to the anterior superior iliac spines. The abduction value of the hip joint was recorded by tracking the anterior midline of the femur with the moving arm of the goniometer [23].

#### **c. Harris Hip Score (HHS)**

Hip function was evaluated with HHS; it consists of four subsections: pain, function, deformity, and range of motion [24, 25]. 90-100 points: excellent, 80-89 points: good, 70-79 points: medium, below 70 points: poor [26].

#### **d. The Timed Up and Go Test (TUGT)**

The TUGT was employed to determine the functional performance levels of the patients based on objective measures. The test commenced with the individual rising from a chair and concluded when the person walked a distance of 3 meters and returned to the the chair. Timing was initiated upon issuing the "go" command to the patient and concluded when the person made contact with the back of the chair [20, 21].

#### **Quality of Life (QoL)**

The Nottingham Health Profile (NHP) was used to determine QoL [27]. The NHP encompasses 38 statements that assess subjective distress across six domains: physical activity, pain, sleep, energy, social isolation, and emotional reactions [28]. Each section is scored between 0-100. In this scale, 0 represents the best health, while a score of 100 signifies the worst health [29].

## Kinesiophobia

Kinesiophobia behaviors related to low back pain of the patients were evaluated with the Tampa Scale of Kinesiophobia (TSK). The scale consists of 17 items, which encompass parameters related to injury/re-injury and fear avoidance in work-related activities. It employs a 4-point Likert scoring system. In TSK, where the possible score varies between 17-68, high scores indicate that kinesiophobia is also high [30]. The scores greater than 37 indicate a high degree of kinesiophobia [31].

## Statistical analysis

Statistical analyses were conducted using the 'IBM SPSS Statistics 24 software (Armonk, NY: IBM Corp.)'. The variables were provided as mean, standard deviation (SD), and percent. Whether the obtained data was suitable for normal distribution was evaluated by the Shapiro-Wilk test. When parametric test assumptions are provided, a t test in Independent Groups is used to compare differences. When the parametric test assumptions were not met, the Mann-Whitney U test was employed to compare

independent group differences. The difference between categorical variables was examined by Chi-Square analysis. In all analyzes,  $p < 0.05$  was considered statistically significant.

## Results

There was no statistically significant difference between the two groups in terms of sociodemographic and clinical data [age, height, body mass index (BMI), radiological stage of hip osteoarthritis ( $p=0.099$ ,  $p=0.921$ ,  $p=0.466$ ,  $p=0.391$ ) (Table 1). Pain severity of low back was  $8.2 \pm 1.8$  cm in Group 1 and  $1.6 \pm 1.0$  cm in Group 2. There was no statistically significant difference between the two groups in terms of hip pain severity and pain duration ( $p=0.187$ ,  $p=0.075$ ) (Table 1).

The results obtained from the HHS indicate that hip function was poor in the groups. There was no statistically significant difference between the groups regarding pain, function, deformity, and joint motion sub-parameters and total score of HHS, MST, and TUGT ( $p=0.563$ ,  $p=0.243$ ,  $p=0.274$ ,  $p=0.682$ ,  $p=0.284$ ,  $p=0.128$ ,  $p=0.654$ ) (Table 2).

**Table 1.** Comparison of sociodemographic and clinical data between groups

	Group 1 (n=21)	Group 2 (n=22)	p (Z/t)
	Mean $\pm$ SD	Mean $\pm$ SD	
<b>Age (years)</b>	62.6 $\pm$ 8.0	66.6 $\pm$ 7.4	0.099 <sup>a</sup> t:(-1.690)
<b>Height (cm)</b>	157.5 $\pm$ 0.1	157.4 $\pm$ 0.1	0.921 <sup>a</sup> t:(0.102)
<b>Weight (kg)</b>	81.0 $\pm$ 11.2	78.9 $\pm$ 8.1	0.486 <sup>a</sup> t:(0.703)
<b>BMI (kg/m<sup>2</sup>)</b>	32.8 $\pm$ 5.2	31.9 $\pm$ 3.0	0.466 <sup>a</sup> t:(0.737)
<b>Hip</b>			
<b>Pain</b>	9.2 $\pm$ 1.2	8.8 $\pm$ 1.0	0.187 <sup>b</sup> Z:(-1.319)
<b>Severity (VAS)</b>			
<b>Hip</b>			
<b>Pain</b>	125.1 $\pm$ 129.8	67.3 $\pm$ 108.8	0.075 <sup>b</sup> Z:(-1.779)
<b>Duration (Month)</b>			
<b>Kellgren Lawrence Classification</b>	n (%)	n (%)	p
<b>Grade 2</b>	16 (76.2)	19 (86.4)	0.391 <sup>c</sup>
<b>Grade 3</b>	5 (23.8)	3 (13.6)	

BMI: Body Mass Index, VAS: Visual Analog Scale, <sup>a</sup>T-test in Independent Groups, <sup>b</sup>Mann-Whitney U Test, <sup>c</sup>Fisher exact test, t value is used to describe the T test of the comparison of the normal distribution variables. Z value is used to describe the Mann-Whitney U Test of the comparison of the non-normal distribution variables

**Table 2.** Comparison of ROM of Hip, HHS parameters, MST and TUGT values between groups

	Group 1 (n=21) Mean $\pm$ SD	Group 2 (n=22) Mean $\pm$ SD	p (Z/t)
<b>ROM of Hip Flexion</b>	82.1 $\pm$ 13.8	84.7 $\pm$ 13.8	0.544 <sup>a</sup> Z: (-0.612)
<b>Extension</b>	4.7 $\pm$ 3.2	4.5 $\pm$ 2.2	0.802 <sup>b</sup> t: (0.253)
<b>Abduction</b>	24.4 $\pm$ 5.3	22.4 $\pm$ 6.1	0.266 <sup>b</sup> t: (1.128)
<b>HHS Pain</b>	12.4 $\pm$ 4.4	13.1 $\pm$ 4.1	0.563 <sup>a</sup> Z: (-0.578)
<b>Function</b>	23.2 $\pm$ 9.2	26.1 $\pm$ 6.6	0.243 <sup>b</sup> t: (-1.185)
<b>Deformity</b>	3.6 $\pm$ 0.5	3.5 $\pm$ 0.5	0.274 <sup>a</sup> Z: (-1.094)
<b>Joint Motion</b>	4.3 $\pm$ 0.4	4.4 $\pm$ 0.4	0.682 <sup>a</sup> t: (-0.413)
<b>Total Score</b>	43.6 $\pm$ 12.2	47.2 $\pm$ 9.0	0.284 <sup>b</sup> t: (-1.088)
<b>MST (cm)</b>	3.6 $\pm$ 1.5	4.3 $\pm$ 1.6	0.128 <sup>a</sup> Z: (-1.551)
<b>TUGT (Sec)</b>	17.5 $\pm$ 4.1	18.2 $\pm$ 5.9	0.654 <sup>b</sup> t: (-0.452)

ROM: Range of motion, HHS: Harris Hip Score, MST: Modified Schober Test, TUGT: Timed Up and Go Test, SD: Standard Deviation

<sup>a</sup>: Mann-Whitney U Test, <sup>b</sup>: T-test in Independent Groups

t value is used to describe the T test of the comparison of the normal distribution variables

Z value is used to describe the Mann-Whitney U Test of the comparison of the non-normal distribution variables

Statistically, Group 1's total scores of QoL, QoL- emotional reactions, and pain sub-parameters were significantly higher than Group 2 ( $p=0.001$ ,  $p=0.002$ ,  $p=0.002$ ).

There were no statistically significant differences in QoL-physical activity, sleep,

energy level, social isolation sub-parameters between the groups ( $p=0.458$ ,  $p=0.066$ ,  $p=0.306$ ,  $p=0.147$ ). The results obtained with the TSK indicate high kinesiophobia in the groups. There was no statistically significant difference between the two groups regarding kinesiophobia ( $p=0.241$ ) (Table 3).

**Table 3.** Comparison of NHP sub-parameters and kinesiophobia between groups

	Group 1 (n=21) Mean $\pm$ SD	Group 2 (n=22) Mean $\pm$ SD	p (Z/t)
<b>NHP Physical Activity</b>	65.8 $\pm$ 17.8	61.8 $\pm$ 16.3	0.458 <sup>a</sup> t: (0.749)
<b>Pain</b>	94.9 $\pm$ 9.1	79.9 $\pm$ 17.5	0.002 <sup>a</sup> Z: (-3.142)
<b>Sleep</b>	64.5 $\pm$ 26.1	47.1 $\pm$ 33.4	0.066 <sup>b</sup> t: (1.891)
<b>Energy Level</b>	62.8 $\pm$ 8.5	61.0 $\pm$ 0.0	0.306 <sup>a</sup> Z: (-1.024)
<b>Social Isolation</b>	52.4 $\pm$ 25.5	39.5 $\pm$ 29.5	0.147 <sup>b</sup> t: (1.479)
<b>Emotional Reaction</b>	75.9 $\pm$ 20.6	52.9 $\pm$ 24.3	0.002 <sup>b</sup> t: (3.328)
<b>Total Score</b>	416.1 $\pm$ 64.2	342.5 $\pm$ 70.3	0.001 <sup>b</sup> t: (3.576)
<b>TSK</b>	49.8 $\pm$ 6.2	47.6 $\pm$ 6.2	0.241 <sup>b</sup> t: (1.191)

NHP: Nottingham Health Profile, TSK: Tampa Scale of Kinesiophobia, <sup>a</sup>: Mann-Whitney U Test<sup>b</sup>: T-test in Independent Groups,  $^*p<0.05$ . t value is used to describe the T test of the comparison of the normal distribution variables

Z value is used to describe the Mann-Whitney U Test of the comparison of the non-normal distribution variables



## Discussion

In this study, it was found that the QoL sub-parameters associated with pain and emotional reactions and the total QoL were negatively affected in patients with moderate-high severity of LBP in HOA compared to mild severity of LBP. This result showed that the severity of LBP is an important factor in QoL in patients with HOA.

The study aims to investigate the mechanisms underlying the co-occurrence of HOA and LBP, provide prognostic information to clinicians associated with this condition, and examine the impact of varying levels of low back pain in patients with HOA on health-related parameters.

The findings from the restricted number of studies examining lumbar region mobility in patients with HOA and concurrent LBP appear to be inconclusive. For instance, French et al. [16] conducted a comparison between groups of patients with HOA, with and without LBP. De Araújo et al. [32] similarly made a comparison between sailors with and without LBP. They reported no statistically significant difference in lumbar spine mobility, a result that is in line with the study. In a study by Moll and Wright [33], it was noted that the flexion values according to the Modified Schober Test ranged from 4 to 8.5 cm for women aged 55-64 and from 3.5 to 6.5 cm for women aged 65-74. These values suggest a decrease in lumbar spine mobility in the group experiencing moderate-high LBP, while it remained within normal limits for the group with mild LBP. Therefore, even though there was no statistically significant difference in lumbar spine mobility between the groups, we can infer from this distribution that an increase in the severity of LBP negatively impacts lumbar spine mobility. In substantiation of this situation, Tateuchi et al. [34] reported that hip degeneration and LBP severity negatively affect lumbar spine mobility. Latimer et al. [35] and Shirley [36] noted an association between increased pain intensity, decreased voluntary mobility, and abnormal spinal stiffness. While both study groups in this research were comprised of individuals with HOA, it is possible that lumbar spine mobility was more impacted in the group experiencing moderate-high levels of LBP severity. Furthermore, it has been noted that a decrease in mobility can occur as a result

of muscle spasms in painful conditions [37]. The reasons for the lack of an influence of LBP severity on lumbar region mobility in patients with HOA in our study may be attributed to several factors. Firstly, it is possible that HOA, independently of the severity of LBP, exerts a negative impact on lumbar biomechanics. Secondly, both study groups have experienced issues related to LBP, albeit with varying degrees of severity.

In this study, it was observed that the severity of LBP did not have an impact on hip function based on the results of the HHS and hip ROM isolated from HHS in patients with HOA. Parvizi et al. [38] conducted a study involving a significant number of participants with HOA, encompassing both those with and without LBP. Similarly, Staibano et al. [39] conducted a comparison between individuals with HOA who did not experience LBP or had mild LBP and those with moderate-high LBP. In both of these studies, similar to the research, it was reported that the groups exhibited similar HHS, and it was noted that the hip function in these groups was deemed "poor." Furthermore, Ran et al. [40] observed that improvements in hip function, as assessed by the HHS, correlated with enhancements in spine function and a reduction in LBP. In our study, hip involvement caused by osteoarthritis was similar between the groups. HOA may affect hip function more than LBP severity. Therefore, it can be asserted that hip function exhibits similarity between the groups, irrespective of the severity of LBP.

In the literature, the duration of the TUGT applied to patients with HOA varies; Arnold and Faulkner [41] (2007) recorded the duration of the TUGT as 12.8 seconds, while Ceballos Laita et al. [42] (2021) determined it as 10.5, 9.63, and 9.5 seconds. In our study, compared to the literature, it was observed that the duration of the TUGT was higher in both groups. The presence of LBP indicates that the performance-based functional level is negatively affected in HOA, regardless of the severity of LBP. In addition, it has been found in our study that the severity of LBP had no effect on performance. Results of performance-based tests were correlated with the strength of hip abductors and knee extensors [43]. Similar HOA involvement and hip function may result in a similar loss of muscle strength in the lower extremity.

The QoL was poor in both groups; however, it was significantly worse in the group with moderate to severe LBP. In our study, the QoL score showed that moderate-high LBP negatively affected the QoL compared to mild pain. It was also noted that pain and emotional reactions related to QoL were more negatively affected in the group with moderate-high LBP. High pain level is associated with significant physical limitations and worse prognosis; these sub-parameters have a negative impact on health-related QoL [44]. Our study results confirm this situation. However, there are different results in the literature. Parvizi et al. [38] reported that the QoL of patients with and without LBP was similar in a study in which most of the participants were HOA patients. Stupar et al. [45] stated that patients with hip and knee OA with LBP had a lower QoL related to physical function, mental, and general health parameters compared to patients without LBP. In studies examining HOA and LBP together in the literature, heterogeneity is observed among patient groups. There is a need for more homogeneous studies in this regard.

The study shows that kinesiophobia is high in both groups, but there is no significant difference between the two groups. This result shows that HOA, regardless of the severity of LBP, and in addition to osteoarthritis, LBP, regardless of its severity, can cause kinesiophobia. In order to better elucidate this issue, future studies should include HOA patients with different LBP severities as well as a group without LBP, which will further clarify the situation. From a different perspective, Kopp et al. [46], in their study, the limitation and pain caused by HOA, reported that it is more strongly correlated with individual and psychological aspects, especially cognitive coping strategies such as kinesiophobia, rather than pathological and anatomical factors such as the location and severity of arthritis. This may be why kinesiophobia is mainly associated with hip pain, and anatomically, hip-related LBP severity has no effect on kinesiophobia.

In this study, the effect of LBP of different severity in HOA on health-related parameters was examined. However, people without LBP were not included in the study. Therefore, it has become challenging to make interpretations regarding certain parameters. This can be seen

as a limitation of our study. We believe that future studies including individuals with HOA who do not have LBP can provide more conclusive results. At the same time, no biomechanical evaluation was made in our study. We believe that biomechanical changes caused by HOA and LBP, as well as the small sample size in the study, could potentially influence the outcomes.

In conclusion, the presence of moderate to high levels of LBP in patients with HOA revealed a significant adverse impact on various sub-parameters of QoL, particularly on quality of life in relation to pain and emotional reactions, when compared to patients with mild LBP. It is crucial for clinicians to assess the severity of LBP in patients with HOA and subsequently incorporate comprehensive evaluation and management of all aspects of QoL, including physical activity, pain, sleep, energy, social isolation, and emotional reactions, into the treatment plan.

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