

ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

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# Is Kinesiophobia Associated with Impaired Quality of Life in Patients with Ankylosing Spondylitis?

## Ankilozan Spondilitte Kinezyofobi Bozulmuş Yaşam Kalitesi ile İlişkili midir?

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**ABSTRACT Objective:** To evaluate the effect of kinesiophobia on quality of life in patients with ankylosing spondylitis (AS). **Material and Methods:** This study included 38 patients with AS and 38 controls. Patients were assessed according to the grades of radiographic sacroiliitis and kinesiophobia scores (high ( $\geq 37$ ) and low ( $< 37$ )). Short form-36 (SF-36) was used to evaluate the quality of life and the Tampa kinesiophobia scale (TKS) was used to evaluate the presence of kinesiophobia. The correlations were analyzed. The 'Bath Ankylosing Spondylitis Disease Activity Index' (BASDAI) was used to assess the disease activity and, the visual analogue scale (VAS) was used to evaluate the pain objectively. **Results:** In patient group, kinesiophobia score was significantly higher ( $40.92 \pm 6.65$ ) than in healthy controls ( $36.66 \pm 8.05$ ) ( $p < 0.05$ ). All SF-36 sub-parameters, especially general health and physical function, were significantly lower in patients compared to healthy controls ( $p < 0.05$ ). Patients with high kinesiophobia score had a higher pain score and lower general health score compared to the patients with low kinesiophobia score (for pain score  $4.83 \pm 3.09$ ,  $2.89 \pm 1.27$ , respectively, and for general health score ( $35.26 \pm 20.90$ ,  $57.22 \pm 20.02$ , respectively) ( $p < 0.05$ ). Emotional role limitation score was lower in patients with radiographic sacroiliitis ( $33.30$  ( $0-67.10$ )) compared to the patients with non-radiographic sacroiliitis ( $83.50$  ( $66.70-100$ )). Other SF-36 sub-parameters, BASDAI and VAS scores did not exhibit a significant difference between the groups ( $p > 0.05$ ). **Conclusion:** Kinesiophobia is more common in patients with ankylosing spondylitis compared to healthy controls, and quality of life is impaired. The presence of kinesiophobia is associated with quality of life variables, such as increased pain and impaired general health. Therefore, each patient should be evaluated for kinesiophobia and quality of life at the beginning of treatment.

**Keywords:** Ankylosing spondylitis; kinesiophobia; sacroiliitis; quality of life

**ÖZET Amaç:** Bu çalışmanın amacı ankilozan spondilit (AS)'li hastalarda gelişen kinezyofobinin yaşam kalitesi üzerine olan etkisini değerlendirmektir. **Gereç ve Yöntemler:** Çalışmaya 38 AS ve 38 sağlıklı kontrol dahil edildi. Hastalar kendi içinde radyografik sakroileit evrelerine göre ve kinezyofobi skoruna göre (yüksek ( $\geq 37$ ) ve düşük ( $< 37$ )) olarak değerlendirildi. Katılımcıların yaşam kalitesi Short form-36 (SF-36) ile kinezyofobi ise Tampa Kinezyofobi Skalası (TKS) ile değerlendirilerek korelasyon analizleri yapıldı. Hastaların hastalık aktivitesi Bath Ankilozan Spondilit Hastalık Aktivite İndeksi (BASDAI) ile ağrı durumları ise Vizüel Analog Skala (VAS) ile değerlendirildi. **Bulgular:** Hasta grupta kinezyofobi skoru ( $40.92 \pm 6.65$ ) sağlıklı kontrollerden ( $36.66 \pm 8.05$ ) daha yüksek bulundu. Hastalarda başta genel sağlık ve fiziksel fonksiyon olmak üzere tüm SF-36 alt parametreleri sağlıklı kontrollere göre anlamlı olarak daha düşük bulundu ( $p < 0.05$ ). Hasta grubunda kinezyofobi skoru yüksek olanlarla, düşük olanlar kıyaslandığında kinezyofobi skoru yüksek olanların, ağrı skorlarının daha yüksek ( $4.83 \pm 3.09$ ,  $2.89 \pm 1.27$ , sırasıyla) ve genel sağlık skorlarının daha düşük olduğu ( $35.26 \pm 20.90$ ,  $57.22 \pm 20.02$ , sırasıyla) gözlemlendi ( $p < 0.05$ ). Emosyonel rol güclüğü skorunun radyografik sakroileiti olan hastalarda ( $33.30$  ( $0-67.10$ )) non-radyografik olanlara ( $83.50$  ( $66.70-100$ )) göre daha düşük olduğu gözlemlendi. Bunun dışında diğer SF-36 alt parametreleri ile BASDAI ve VAS skorları açısından hasta grupları arasında farklılık saptanmadı ( $p > 0.05$ ). **Sonuç:** Ankilozan spondilitli hastalarda kinezyofobi sağlıklı kontrollerle karşılaştırıldığında daha fazla görülürken yaşam kalitesi azalmıştır. Kinezyofobi varlığı artmış ağrı ve genel sağlıkta bozulma gibi yaşam kalitesi değişkenleri ile ilişkilidir. Bu nedenle her hasta tedavi başlangıcında kinezyofobi ve yaşam kalitesi yönünden de değerlendirilmelidir.

**Anahtar Kelimeler:** Ankilozan spondilit; kinezyofobi; sakroileit; yaşam kalitesi

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Ankylosing spondylitis (AS) is a chronic rheumatic disease that typically affects the sacroiliac joints.<sup>1,2</sup> The main problems are inflammatory back pain, morning stiffness, and the limitation in spinal mobility.<sup>3,4</sup> As the disease progresses, spinal mobility and functions are gradually limited due to pain and structural deformities, and anxiety and depression occur as a result of impaired quality of life.<sup>5</sup> Clinical therapies aim to reduce pain and stiffness in patients and to prevent progressive structural deformities and to improve patients' quality of life.<sup>6,7</sup> Therefore, along with the pharmacological treatment, physiotherapy and exercise are essential in every step of the treatment, as EULAR/ASAS strongly points out.<sup>7</sup>

Increased stimulation to the central nervous system (CNS) as a result of continuous inflammation and exacerbation periods added on baseline pain in patients with AS may result in increased sensitivity to pain and central sensitization.<sup>3,8-10</sup>

Kinesiophobia is defined as the fear and anxiety of movement due to hypersensitivity caused by painful injury and/or re-injury.<sup>11</sup>

According to the Cognitive Fear Avoidance Model, people experience catastrophic cognitive changes in the presence of threatening painful stimulus, the feeling of pain gradually increases, and if this persists, anxiety and fear of physical activity occur, and people avoid physical activity. As a consequence of avoidance of physical activity, patients may suffer from non-use, disability and depression lead to a vicious circle.<sup>12</sup> There are few studies investigating the relationship between ankylosing spondylitis and kinesiophobia. Oskay et al. showed the impairment of the quality of life in the patients with ankylosing spondylitis due to the kinesiophobia.<sup>13</sup> In another study, no statistically significant relationship was reported between kinesiophobia scores and BASDAI ( $p>0.05$ ), but there was a weak correlation with Bath Ankylosing Spondylitis Metrology Index (BASFI).<sup>14</sup>

This study aims to determine kinesiophobia and its relationship with disease activity, quality of life, and pain scores in patients with AS.

## MATERIAL AND METHODS

This study included 38 patients with AS aged between 20-65 years diagnosed according to the new ASAS classification criteria and 38 healthy controls applying to Ankara University Rheumatology Outpatient Clinic and Selçuk University Physical Medicine and Rehabilitation Outpatient Clinic.<sup>15</sup> The ethics committee approval was obtained from Selçuk University Clinical Researches Ethics committee (08/04/2019-E.35944). All patients were provided information about the study and gave informed consent forms. The exclusion criteria were the presence of chronic diseases such as any kind of malignancy, infectious and other rheumatic diseases, psychiatric disorders, and fibromyalgia. Also, patients with surgery history, intraligamentary or intraarticular injection history or physical therapy within the last three weeks were excluded from the study. After recording the demographic characteristics, kinesiophobia and quality of life were evaluated. Furthermore, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores and pain scores in the morning, at noon, and in the evening according to visual analogue scale (VAS) were noted.

### PAIN ASSESSMENT

The VAS was used for pain detection. A line of 100 mm with two edges either written as "no pain" or "very severe pain" is drawn for this purpose. The patients are requested to mark the line. The score is assessed by measuring the distance between "no pain" point and the point marked by the patient, providing a score of 0-100. Distance is measured to determine the patient's pain severity.<sup>16</sup>

### DISEASE ACTIVITY

Turkish version of the BASDAI was used. The BASDAI consists of six VAS measurements of fatigue, spinal and peripheral joint pain, enthesal sensitivity, and morning stiffness. Each question is scored between 0 and 10, the total was divided by five after calculating the sum of the first four and the mean of the last two questions associated with morning stiffness.<sup>17,18</sup> This index is widely applied and provides a rapid evaluation with proven validity and re-

liability depending on good sensitivity to change and reproducibility.<sup>19</sup>

## KINESIOPHOBIA

Kinesiophobia was evaluated using the Turkish version of Tampa Kinesiophobia Scale (TKS). This scale consists of 17 items and used for acute and chronic back pain, fibromyalgia, injuries of the musculoskeletal system, and whiplash. A four-point likert scale is applied (1- "I fully disagree", 4- "fully agree"). After reversal of 4<sup>th</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 16<sup>th</sup> items a total score of 17-68 is calculated. The higher scores indicate higher kinesiophobia. The use of the total score is advocated in studies. The cutoff point is 37 and above, which is defined severe kinesiophobia and below mild kinesiophobia.<sup>20</sup>

## QUALITY OF LIFE

The Short Form 36 (SF 36) was used for determination of quality of life. SF 36 is a 36-item patient-reported outcome measure used with proven validity and reliability in patients with musculoskeletal diseases. These items include eight health-related functions. Physical component scores (PCS) is the sum of physical function, physical role limitations, bodily pain, and general health perception. Mental component score (MCS) is obtained summing up the social

functions, emotional role limitation, mental health, and vitality/energy scores. Every item is encoded separately and turned to a 0 (worst)-100 (best) points scale.<sup>21</sup>

## STATISTICAL ANALYSIS

All statistical analyses were performed using R Version 3.6.0 software. Histogram and p-p plots were examined and the Shapiro Wilk test was used to assess data normality before statistical analyses. The Levene test was used to check the variance homogeneity. Continuous variables were presented as mean±standard deviation and median (interquartile range) and tested by Student's T-test or Mann-Whitney U test. Categorical variables were described as numbers and percentages and tested by Chi-square or Fisher's Exact tests. Pearson and Spearman's Rho correlation coefficient were used to determine the relationship between continuous variables. A p level of <0.05 was considered as statistically significant.

## RESULTS

The patients and controls were similar in terms of age, height, weight and body mass index ( $p>0.05$ ). The mean duration of the illness was  $10.51\pm9.58$  years. The VAS scores and mean BASDAI scores

**TABLE 1:** Demographic data of patient and control groups.

| Variables                  | Patients (n=38) | Controls (n=38) | p-value |
|----------------------------|-----------------|-----------------|---------|
| Age (years)                | 43.76±9.45      | 39.47±9.95      | 0.058   |
| Height (cm)                | 165.26±8.50     | 169.13±9.02     | 0.058   |
| Body weight (kg)           | 77.79±13.82     | 75.82±14.74     | 0.549   |
| BMI (kg/m <sup>2</sup> )   | 28.49±4.78      | 26.46±4.33      | 0.057   |
| Duration of illness (days) | 10.51±9.58      |                 |         |
| VAS                        |                 |                 |         |
| Morning                    | 5.26±2.88       |                 |         |
| Noon                       | 4.37±2.88       |                 |         |
| Evening                    | 5.11±3.22       |                 |         |
| Sacroiliitis, n (%)        |                 |                 |         |
| Radiographic               | 28 (73.7%)      |                 |         |
| Non-radiographic           | 10 (26.3%)      |                 |         |
| BASDAI                     | 4.74±2.38       |                 |         |

VAS: Visual Analogue Scale, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, BMI: Body Mass Index.

Data are presented as mean±standard deviation.

p-value: student's t test.

$p<0.05$  was considered statistically significant.

were presented in Table 1. Of the patients, 73.7% had radiographic sacroiliitis.

In patient group, kinesiophobia scores were higher, and all of SF 36 sub-parameters were significantly lower compared to the control group (Table 2, Figure 1). When patients were divided into two groups according to the kinesiophobia scores, general health score was significantly lower and VAS noon pain score was significantly higher in patients with high kinesiophobia scores (Table 3).

When the intraclass correlation was analysed between kinesiophobia and SF 36 scores, physical functioning, energy, emotional well-being, pain and general health subparameters showed a significant negative correlation with kinesiophobia scores in patient group. Additionally BASDAI and VAS scores showed a positive correlation with kinesiophobia scores (Table 4).

Besides, the patients were classified into two groups according to the presence of radiographic and non-radiographic sacroiliitis. There was a significant difference in SF-36 emotional role limitation sub-parameter between the two groups, but no significant difference was found in the other SF-36 sub-parameters and VAS and kinesiophobia scores (Table 5).

## DISCUSSION

In this study, the level of kinesiophobia and its association with quality of life and pain was investigated. Our study showed that the patients with ankylosing spondylitis had a higher kinesiophobia score than controls. They had an impaired quality of life due to kinesiophobia. We found that higher kinesiophobia scores were correlated with increased pain scores and decreased scores in general health.

Kinesiophobia refers to the fear of movement developed due to recurrent injury and pain and causes inactivity in people.<sup>23</sup> In the studies it was stated that chronic musculoskeletal disorders involving the spine lead to higher kinesiophobia.<sup>23,24</sup> In a prior brain imaging study in ankylosing spondylitis showed that somatosensorial function, pain modulation, and motor planning areas had some abnormalities. This data may explain the pathophysiology of the kinesiophobia.<sup>9</sup> In our study, differently from the studies by Er et al. and Oskay et al., a significant correlation was

**TABLE 2:** The comparison of Short-Form 36 quality of life and kinesiophobia scores between groups.

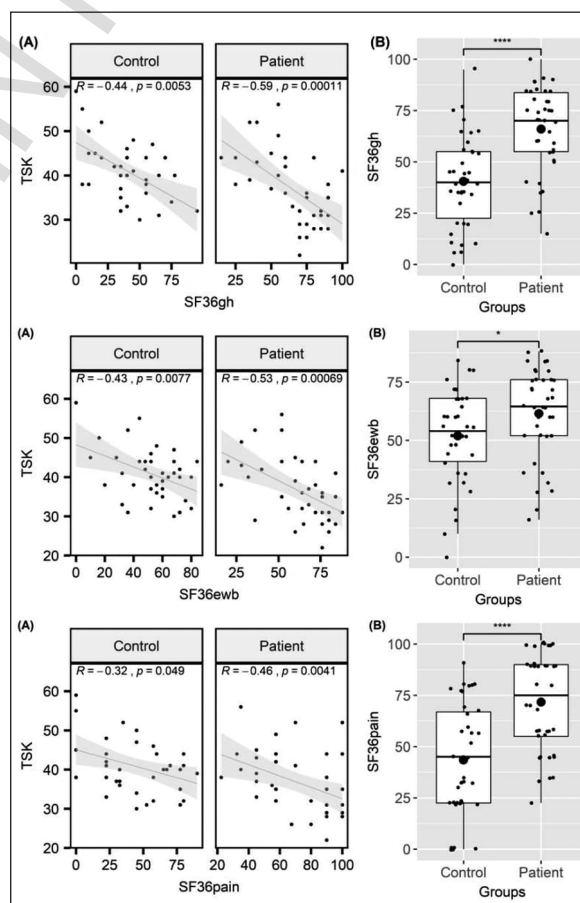
| Variables | Patients (n=38)  | Controls (n=38) | p-value |
|-----------|------------------|-----------------|---------|
| SF36pf    | 60 (45-85)       | 90 (85-100)     | <0.001* |
| SF36prl   | 25 (0-100)       | 100 (50-100)    | 0.001*  |
| SF36erl   | 66.70 (0-100)    | 100 (66.70-100) | 0.011*  |
| SF36eng   | 45 (25-60)       | 55 (40-75)      | 0.005*  |
| SF36ewb   | 51.95±20.01      | 61.50±19.81     | 0.040*  |
| SF36sf    | 50 (50-75)       | 75 (50-100)     | 0.034*  |
| SF36pain  | 45 (22.50-67.50) | 75 (55-90)      | <0.001* |
| SF36gh    | 40 (20-55)       | 70 (55-85)      | <0.001* |
| TKS       | 40.92±6.65       | 36.66±8.05      | 0.014*  |

SF-36: Short-Form 36, pf: physical functioning, prl: physical role limitation, erl: emotional role limitation, eng: energy, ewb: emotional well-being, sf: social functioning, gh: general health, TKS: Tampa Kinesiophobia Scale.

Data are presented as mean±standard deviation or median (interquartile range).

p-value: student's t test or Mann Whitney-U test.

\*p<0.05 was considered statistically significant.



**FIGURE 1:** Analysis of the correlation between the Tampa Kinesiophobia Scale (TKS) and SF-36 emotional well-being and general health parameters in patient and control groups.

**TABLE 3:** Comparisons of groups in terms of kinesiophobia levels and parameters.

|                                   | Low Kinesiophobia (n=9) | High Kinesiophobia (n=29) | p-value |
|-----------------------------------|-------------------------|---------------------------|---------|
| Age (years)                       | 42±10.07                | 44.31±9.37                | 0.529   |
| Height (cm)                       | 168.67±5.24             | 163.93±9.82               | 0.177   |
| Body weight (kg)                  | 74.56±8.93              | 78.79±15.01               | 0.429   |
| BMI (kg/m <sup>2</sup> )          | 26.21±3.01              | 29.29±5.01                | 0.196   |
| Duration of illness (days)        | 13 (4-20)               | 7 (3-15)                  | 0.309   |
| VAS                               |                         |                           |         |
| Morning                           | 4.89±3.22               | 5.38±2.82                 | 0.662   |
| Noon                              | 2.89±1.27               | 4.83±3.09                 | 0.010*  |
| Evening                           | 3.33±1.94               | 5.66±3.36                 | 0.016   |
| Sacroiliitis <sup>†</sup> , n (%) |                         |                           |         |
| Radiographic,                     | 6 (66.7%)               | 22 (75.9%)                | 0.673   |
| Non-radiographic                  | 3 (33.3%)               | 7 (24.1%)                 |         |
| SF36pf                            | 76.67±18.20             | 59.66±24.96               | 0.067   |
| SF36prl                           | 75 (25-100)             | 25 (0-100)                | 0.221   |
| SF36erl                           | 66.70 (0-66.70)         | 66.70 (0-100)             | 0.499   |
| SF36eng                           | 47.78±22.65             | 38.97±25.65               | 0.362   |
| SF36ewb                           | 59.11±16.94             | 40.09±28.30               | 0.224   |
| SF36sf                            | 62.50 (37.50-75)        | 50 (50-75)                | 0.919   |
| SF36pain                          | 54.44±20.64             | 40.09±28.30               | 0.169   |
| SF36gh                            | 57.22±20.02             | 35.26±20.90               | 0.009*  |
| BASDAI                            | 3.96±2.21               | 4.99±2.41                 | 0.261   |

SF-36: Short-Form 36, pf: physical functioning, prl: physical role limitation, erl: emotional role limitation, eng: energy, ewb: emotional well-being, sf: social functioning, gh: general health, VAS: Visual Analogue Scale, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, BMI: Body Mass Index.

Data are presented as mean±standard deviation or median (interquartile range).

p-value: student's t test or Mann Whitney-U test.

\*: Chi-square test.

p<0.05 was considered statistically significant.

found between kinesiophobia level and disease activity compared to the control group.<sup>13,14</sup> Although, when we categorized the patients into two groups according to the sacroiliitis grade and kinesiophobia level, there was no significant relationship between disease activity and higher scores. This could have been occurred due to the small sample size in the present study.

The difference of this study from the other studies is that it includes a healthy control group. When we evaluated the association between kinesiophobia and SF 36 sub-parameters, we found that quality of life scores, especially general health, pain and emotional well-being scores were significantly lower among patients compared to controls. We considered this condition may be a consequence of social limitation which occurred due to kinesiophobia and inactivity. In this study, BASDAI and VAS scores were significantly correlated with kinesiophobia scores in

patient group. Similarly to our study, Oskay et al. found a positive correlation between kinesiophobia scores and pain.<sup>14</sup> Furthermore, depression evolving with chronic pain may held responsible to reduce the pain threshold and alleviate the symptoms.<sup>25</sup> In this study, there was no significant relationship between emotional well-being scores and the degree of kinesiophobia but patients with higher kinesiophobia scores had statistically lower general health scores. However depending on small patient numbers, further studies are warranted to evaluate this factor.

To the best of our knowledge, this is the first study to evaluate kinesiophobia according to degree of radiographic sacroiliitis. According to this non-radiographic and radiographic patients did not differ in terms of disease activity, pain, and kinesiophobia scores. As for SF-36 sub-parameters, only emotional role limitation scores were lower in patients with radiographic sacroiliitis. To make clear conclusions on



**TABLE 4:** The results of intraclass correlation between TKS, SF-36 parameters, BASDAI, and VAS scores.

| TSK                      | Patients (n=38) |         | Controls (n=38) |         |
|--------------------------|-----------------|---------|-----------------|---------|
|                          | r               | p-value | r               | p-value |
| SF36pf                   | -0.415          | 0.010*  | -0.694          | <0.001* |
| SF36prl                  | -0.298          | 0.069   | -0.523          | 0.001*  |
| SF36erl                  | -0.067          | 0.688   | -0.405          | 0.012*  |
| SF36eng                  | -0.350          | 0.031*  | -0.400          | 0.013*  |
| SF36ewb <sup>†</sup>     | -0.426          | 0.008*  | -0.526          | 0.001*  |
| SF36sf                   | -0.057          | 0.734   | -0.457          | 0.004*  |
| SF36pain                 | -0.322          | 0.049*  | -0.455          | 0.004*  |
| SF36gh                   | -0.443          | 0.005*  | -0.586          | <0.001* |
| BMI (kg/m <sup>2</sup> ) | 0.310           | 0.068   | 0.062           | 0.710   |
| BASDAI <sup>†</sup>      | 0.362           | 0.025*  |                 |         |
| VAS                      |                 |         |                 |         |
| Morning <sup>†</sup>     | 0.244           | 0.140   |                 |         |
| Noon                     | 0.463           | 0.003*  |                 |         |
| Evening                  | 0.393           | 0.015*  |                 |         |

SF-36: Short-Form 36 , pf: physical functioning, prl: physical role limitation, erl: emotional role limitation, eng:energy, ewb: emotional well-being , sf: social functioning, gh:general health, VAS:Visual Analogue Scale, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, BMI: Body Mass Index, TKS: Tampa Kinesiophobia Scale.

<sup>†</sup>: Pearson correlation coefficient.

\*p<0.05 was considered statistically significant.

**TABLE 5:** Comparisons of the patients with non-radiographic and radiographic sacroiliitis in terms of SF-36 parameters, BASDAI, TKS, and VAS scores.

|          | Radiographic (n=28) | Non-radiographic (n=10) | p-value |
|----------|---------------------|-------------------------|---------|
| SF36pf   | 62.86±24.44         | 66±25.58                | 0.732   |
| SF36prl  | 12.50 (0-100)       | 62.50 (50-100)          | 0.125   |
| SF36erl  | 33.30 (0-67.10)     | 83.50 (66.70-100)       | 0.023*  |
| SF36eng  | 39.46±25.54         | 45.50±23.97             | 0.519   |
| SF36ewb  | 49.64±21.34         | 58.40±14.75             | 0.240   |
| SF36sf   | 50 (37.50-75)       | 75 (62.50-75)           | 0.056   |
| SF36pain | 43.57±27.94         | 43.25±26.20             | 0.975   |
| SF36gh   | 38.48±21.12         | 46±26.44                | 0.372   |
| BASDAI   | 4.60±2.54           | 5.14±1.90               | 0.546   |
| TKS      | 40.96±7.05          | 40.80±5.71              | 0.948   |
| VAS      |                     |                         |         |
| Morning  | 5.54±3.08           | 4.50±2.17               | 0.336   |
| Noon     | 4.32±3.01           | 4.50±2.64               | 0.869   |
| Evening  | 5.43±3.24           | 4.20±3.16               | 0.307   |

SF-36: Short-Form 36, pf: physical functioning, prl: physical role limitation, erl: emotional role limitation, eng: energy, ewb: emotional well-being, sf: social functioning, gh: general health, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, TKS: Tampa Kinesiophobia Scale, VAS: Visual Analogue Scale.

Data are presented as mean±standard deviation or median (interquartile range)

p-value: student's t test or Mann Whitney-U test

<sup>†</sup>: Chi-square test.

p<0.05 was considered statistically significant.

this issue, further studies with a higher patient allocation should be conducted.

In this study, when the association between physical function level and kinesiophobia was considered, the physical function score was lower in patients compared to the controls. In other words, these patients tend to stay inactive and avoid moving due to the pain. With regard to this factor in the study of Leeuw et al., it was shown that individuals with catastrophic thought and fear of pain predisposition showed excessive avoidance behavior against the risk of re-injury.<sup>26</sup>

The main limitation of this study is the low patient number. Further studies are needed to reveal an association between kinesiophobia and degree of radiographic or non-radiographic sacroiliitis.

The role of regular exercise is substantial in ankylosing spondylitis and axial spondyloarthritis in addition to pharmacologic treatment.<sup>7</sup> These patients should be directed to exercise as well as pharmacological therapies.

## CONCLUSION

Ankylosing spondylitis patients had a higher kinesiophobia score compared to healthy controls, and the presence of kinesiophobia is associated with increased pain and lower general health scores. Therefore, these results suggest that kinesiophobia should keep in mind at the beginning of treatment.

## Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

## 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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