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Sleep quality and blood pressure variability after anti-TNF-α treatment in axial spondyloarthritis patients: A prospective preliminary study

Aksiyel spondiloartropati hastalarında anti-TNF- α tedavisi sonrası uyku kalitesi ve kan basıncı değişkenliği: Prospektif bir ön çalışma

Abstract

Objective: Anti-tumor necrosis factor- α (TNF- α) agents are known to improve inflammation and may reduce cardiovascular risk in axial spondyloarthritis (axSpA). This study prospectively evaluated their effect on sleep quality and ambulatory blood pressure parameters.

Methods: Twenty-eight anti-TNF-α–naïve patients with axSpA (57% female) were enrolled. Clinical activity, sleep quality, and ambulatory blood pressure monitoring—including blood pressure real variability (ARV) and dipping patterns—were recorded at baseline and after three months of therapy.

Results: Participants had a mean age of 40.0±10 years and a median disease duration of 6.5 years. Following treatment, both disease activity indices and sleep quality scores improved significantly. ARV did not change significantly. The proportion of patients with a dipper pattern rose from 46% to 61%, though this change was not statistically significant (p=0.388). Nighttime systolic blood pressure, however, decreased significantly (p=0.020).

Conclusion: Despite improvements in sleep quality, no impact was noted on ARV and dipper patterns. While anti-TNF- α therapy may enhance sleep quality, its long-term effects on cardiovascular morbidity require further validation through larger, long-term studies.

Keywords: Axial spondylitis, anti-TNF- α , ambulatory blood pressure, sleep quality

Özet

Amaç: Anti-tümör nekroz faktörü-α (TNF-α) tedavisi, aksiyel spondilitli (axSpA) hastalarda hastalık aktivitesini, uyku kalitesini ve kan basıncı parametrelerini iyileştirerek kardiyovasküler morbiditeyi azaltabilir. Bu prospektif çalışmada, axSpA hastalarında anti-TNF-α tedavisinin uyku kalitesi ve ambulatuvar kan basıncı izleme parametreleri üzerindeki etkisi araştırılmıştır.

Yöntem: Bu çalışmaya 28 (%57 kadın) anti-TNF- α naif axSpA hastası dahil edildi. Hastalık aktivitesi, uyku kalitesi, kan basıncı değişkenliği (ARV) ve dipper paternleri dahil olmak üzere ambulatuvar kan basıncı izleme parametreleri başlangıçta ve üç aylık anti-TNF- α tedavisinden sonra değerlendirildi.

Bulgular: Hastaların ortalama yaşı 40,0±10 yıl ve tanıdan sonraki ortanca hastalık süresi 6,5 (4-11) yıldı. Hastaların anti-TNF- α tedavi sonrası, hastalık aktivite skorları ve uyku kaliteler anlamlı olarak iyileşti. Ancak ARV'de anlamlı bir değişiklik görülmedi. Dipper paterni sergileyen hastaların yüzdesi %46'dan %61'e yükselmesine rağmen, bu değişiklik istatistiksel olarak anlamlı değildi (p=0,388). Bununla birlikte, gece sistolik kan basıncında da anlamlı bir düşüş gözlendi (p=0,020).

Sonuç: Anti-TNF- α tedavisi, axSpA hastalarında uyku kalitesini anlamlı düzeyde iyileştirmiştir. Ancak, kan basıncı değişkenliği ve dipper paternleri üzerinde anlamlı bir etkisi gözlenmemiştir. Anti-TNF- α tedavisinin kardiyovasküler morbidite üzerindeki etkilerini daha iyi değerlendirecek uzun süreli ve daha geniş kapsamlı çalışmalara ihtiyaç vardır.

Anahtar Kelimeler: Aksiyel spondilit, anti-TNF- α , ambulatuar kan basıncı, uyku kalitesi

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Introduction

Spondyloarthritis refers to a group of inflammatory rheumatic disorders that share common genetic predispositions, clinical characteristics, and radiological features. [1] It has been reported that aortitis, cardiac conduction defects, valve failure, ischemic heart disease, metabolic syndrome, obesity, hypertension, and dyslipidemia occur with greater frequency in individuals with ankylosing spondylitis (AS) than in the normal population. [2,3]

Sleep disorders are also a significant comorbidity, and poor sleep quality, insomnia, morning sleep inertia, and obstructive sleep apnea have been reported in 50-65% of individuals with AS.[4-6] Chronic inflammation and sleep disorders may contribute to an elevated likelihood of cardiovascular complications among individuals with AS. Beneficial impacts of anti-tumor necrosis factor- α (TNF- α) treatment on chronic inflammation and sleep quality have been documented in individuals with AS.[7] Blood pressure measurement variables such as blood pressure variability (ARV) and dipper patterns are directly related to adverse cardiovascular outcomes.^[8,9] These parameters can be positively affected by decreasing inflammation, reducing pain, and improving sleep quality. The current literature does not contain any studies that have examined the influence of anti-TNF-α therapy on ambulatory ARV, dipper patterns,

and sleep quality in patients with AS. This study aimed to evaluate how anti-TNF- α treatment influences sleep quality and ambulatory blood pressure parameters.

Materials and Methods

Study Population

Patients with axial spondyloarthritis (axSpA) who meet the ASAS 2009 criteria and applied to our rheumatology outpatient clinic between March 1, 2021, and December 1, 2021, were included in this study. They were planned to receive anti-TNF-α treatment for the first time. During this period, 127 TNF-naïve patients with axSpA were scheduled to receive anti-TNF therapy. Of these patients, 74 declined to participate in the study because of an application outside Ankara, unsuitable working hours, or time constraints. In addition, 23 patients with hypertension and/or cardiovascular disease were excluded from the study. The study population consisted of 30 individuals diagnosed with axSpA. One patient was excluded from the analysis because the first ambulatory blood pressure measurement (ABPM) was insufficient, and another patient refused a controlled blood pressure measurement at the 3rd month (Figure 1). Age, sex, age at diagnosis, disease duration, use of drugs, erythrocyte sedimentation rate (ESR), C-reactive

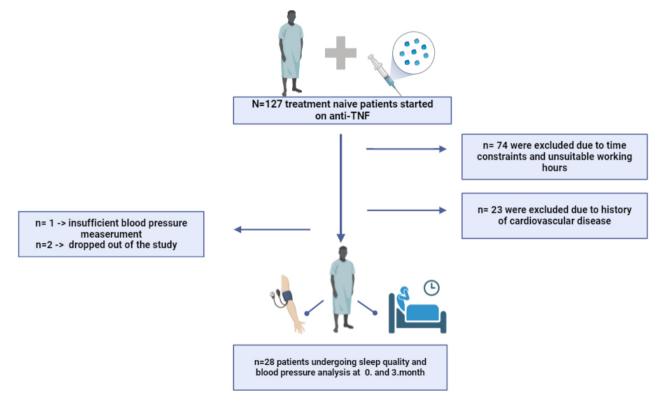


Figure 1. Flow chart of the study *TNF: Tumor necrosis factor*

protein (CRP), and disease activity parameters such as the Bath ankylosing spondylitis disease activity index (BASDAI) and Bath ankylosing spondylitis functional index (BASFI) were analyzed at 0 and 3rd month. Sleep quality was assessed using the Pittsburgh sleep quality questionnaire (PSQI), and ambulatory blood pressure monitoring was performed at months 0 and 3. Furthermore, body mass index, concomitant non-steroidal anti-inflammatory drugs (NSAID), conventional disease-modifying antirheumatic drugs (DMARD), and steroid usage was also recorded. This was a single-center, prospective, non-randomized, descriptive study.

Approval was granted by the Hacettepe University Ethics Board (2021/02-04-KA-20092), with all patients giving informed consent. The study adhered to the ethical standards of the Declaration of Helsinki.

Ambulatory Blood Pressure Measurement

ABPM was performed with a Mobil-O-Graph NG (Industrielle Entwicklung Medizintechnik, Germany) portable blood pressure monitor using the oscillometric method, which has met the validation protocols. Measurements were taken every 15 minutes between 07:00 and 23:00 during the day and every 20 minutes between 23:00 and 07:00 at night. Patients were told to continue with their normal daily activities and remain immobile during the measurement, if possible. If the measurements were ≥70% valid, the 24-hour blood pressure measurement was considered to be sufficiently valid. Three parameters were calculated for ambulatory ARV: systolic BP, diastolic BP, and mean blood pressure. The dipper patterns were also examined.

Dipper, Non-dipper and Reverse Dipper

In healthy individuals, nighttime blood pressure values were lower than daytime blood pressure values. A decrease of 10-20% or more in nighttime blood pressure compared to daytime mean blood pressure is considered a "dipper" pattern. A non-dipper was defined as a reduction in nighttime blood pressure of <10%, and a reverse dipper was defined as experiencing no decrease or even an increase in nighttime blood pressure. The non-dipper and reverse dipper patterns are linked to higher cardiovascular mortality.^[10]

Blood Pressure Variability

Variations in blood pressure throughout the day are influenced by respiratory dynamics, regulation by the nervous system, and humoral as well as vasomotor control within the vascular bed.

Increased ARV is linked to end-organ damage and cardiovascular mortality. ARV is a sensitive and specific tool for determining blood pressure variability. [11] ARV was determined by averaging the absolute differences between successive blood pressure readings (Figure 2).

Assessment of Sleep Quality

There are several questions regarding the determination of sleep quality in patients. We used the PSQI to determine sleep quality, which was validated in Turkish.^[12] The PSQI includes items evaluating perceived sleep quality, time taken to fall asleep, total sleep period, efficiency of sleep, use of insomnia drugs, and impairment in daily activities due to sleep deprivation. A total score ≥5 indicated poor sleep quality. As the total score increased, the sleep quality deteriorated further.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26.0. Normality of the variables was assessed with the Shapiro-Wilk test. Categorical data were expressed as frequencies and percentages, while normally distributed continuous variables were summarized as mean ± standard deviation, and non-normally distributed data as median, range, and interquartile range. Within-group comparisons between baseline and the third month were carried out using the paired Student's t-test or the Wilcoxon signed-rank test, as appropriate. Between-group comparisons were performed with the independent samples t-test or the Mann-Whitney U test. Associations between continuous variables were explored using Pearson or Spearman correlation analyses. A two-sided p value <0.05 was considered statistically significant.

Results

Twenty-eight patients with axSpA were recruited for the study. Sixteen (57%) patients were female and 12 (43%) were male. The mean patient age was 40.0 ± 10.4 years, and the median disease duration after diagnosis was 6.5 (4-11) years. Thirteen (46%) patients were current smokers, and nine (32%) were considered obese. Before the anti-TNF- α therapy, all patients were using intermittent or continuous

$$ARV = \frac{1}{\sum_{w}} \sum_{k=1}^{n-1} w \times |BP_{k+1} - BP_{k}|$$

Figure 2. Formula for ambulatory blood pressure variability

NSAIDs, while 17 (60%) patients were taking DMARDs and 4 (14%) were taking prednisolone at doses below 7.5 mg/day. The baseline demographic and clinical profiles of the participants at the initiation of anti-TNF- α therapy are presented in Table 1.

Initially, 29% of the patients experienced good sleep quality, while 71% reported poor sleep quality. Following anti-TNF therapy, the proportion of patients with good sleep quality increased to 57%, and those with poor sleep quality decreased to 43%, which was statistically significant (p<0.05). Prior to anti-TNF therapy, the sleep quality score was 8.5, indicating poor sleep quality. Following anti-TNF treatment, this score decreased to 4, demonstrating a significant improvement in sleep quality (p<0.001) (Table 2).

The patients had normal 24-hour systolic blood pressure (112.8±8.2), 24-hour diastolic blood pressure (70.3±8.1) and 24-hour mean blood pressure (89.8±7.1) at month 0. In correlation with these results, the day and night systolic/

diastolic/mean values were found to be in the normotensive range. By the third month, 24-hour systolic blood pressure, 24-hour diastolic blood pressure, and 24-hour mean blood pressure values were also within normotensive limits. A statistically significant decrease was found in the comparison between 0 and 3 months in systolic night and mean night values [respectively: 109.1±9.5 vs. 105.6±10.7 p (0.042) vs 86.6±8.1 vs. 83.3±9.2 p (0.028)]. ARV did not differ significantly between the initial and 3rd months (Table 3).

At the baseline before anti-TNF- α treatment, 46% of the patients were dippers (n=13), and 57% (n=15) were non-dipper/reverse dippers. The dipper ratio was 61% (n=17) and the non-dipper/reverse dipper ratio was 39% (n=11) at the 3rd month after anti-TNF- α treatment; however, the change did not reach statistical significance (p=0.388). When comparing 0th and 3rd month, the decrease in night time systolic blood pressure reached statistical significance [4.8% (-7to -9.2) vs. 9.2% (4.7 to 11.1); p=0.020],

Table 1. Baseline characteristics of patients with axSpA

Table 1. Daseline Characteristics of	patients with axspA		
Men/women n (%)		12 (43%)/16 (57%)	
Age* year	40.0±10		
Disease duration** year		6.5 (4-11)	
HLA-B27 positivity n (%)		13 (59%)	
Peripheric arthritis n (%)		11 (39%)	
VAS pain**		7.5 (5.3-9.0)	
BASDAI** (0-10)		5.8 (3.5-7.1)	
BASFI** (0-10)		6.4 (3.6-7.3)	
ESR** (mm/st)		14.0 (6.3-30.0)	
CRP** (mg/dL)		0.8 (0.3-2.3)	
BMI* (kg/m²)		27±6	
LDL (mg/dL)*		123±38	
HDL (mg/dL)*		50±10	
Triglycerides (mg/dL)*		118±72	
Smoking n (%)		13 (46%)	
Obes n (%)		9 (32%)	
	NSAID n (%)	28 (100%)	
Drugs*	kDMARD n (%)	17 (61%)	
	Steroid# n (%)	4 (14%)	

^{*: (}Mean ± standard deviation), **: (Median 25-75%), *: <7.5 mg prednisone or equivalent, axSpA: Axial spondyloarthritis, BASDAI: Bath ankylosing spondylitis disease activity index, BASFI: Bath ankylosing spondylitis functional index, BMI: Body mass index, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate, HDL: High-density lipoprotein, HLA: Human leukocyte antigen, LDL: Low-density lipoprotein, NSAID: Non-steroidal anti-inflammatory drug, kDMARD: Conventional DMARD, VAS: Visual analog scale, Steroid (users under <7.5 mg), Obesity is considered as having a BMI >30

Table 2. Comparison of baseline and 3rd month sleep quality (n=28)

Variable		0. month	3. month	р
Class avalitudes (0/)	Good	8 (29%)	16 (57%)	0.008**
Sleep quality* n (%)	Bad	20 (71%)	12 (43%)	
Sleep quality point [median (25-75%)]		8.5 (4.0-12.8)	4.0 (1.0-5.8)	<0.001&

The decrease in nocturnal diastolic blood pressure, however, failed to attain statistical significance [6.4% (1.5-14.7%) vs. 9.6% (5.0-15.8%); p=0.112] (Table 4). When the clinical features of patients with dipper and non-dipper, before anti-TNF-α treatment were compared, the BASFI scores (4.32±2.49 vs. 6.33±1.84, p=0.021) and PSQI scores [5 (2.5-11)] vs. 10 (8-13) p=0.049] were considerably lower in the dipper group (Table 5). Three months after initiating anti-TNF-α therapy, clinical features did not differ between dipper and non-dipper patients (p>0.05 for all).

Discussion

In the present study, sleep quality was significantly better at the 3-month follow-up following anti-TNF- α therapy, while no significant alterations in ARV were noted relative to pretreatment. In addition, 46% of the patients were dippers before anti-TNF- α treatment. However, after the anti-TNF- α treatment, the dipper rate increased to 61%. Although the difference was not statistically significant, this suggests that anti-TNF- α treatment could have had an effect on patients' dipper status.

Table 3. Comparison of ambulatory blood pressure parameters (0. and 3. month)

Variable (mean ± standard deviation)	0. month	3. month	р
Systolic 24 hour (mmHg)	112.8±8.2	111.4±9.3	0.354 ^{&}
Diastolic 24 hour (mmHg)	70.3±7.2	69.9±8.6	0.701 ^{&}
Mean 24 hour (mmHg)	89.8±7.1	89.04±8.3	0.547 ^{&}
Systolic day (mmHg)	114.2±9.0	113.9±9.3	0.865 ^{&}
Diastolic day (mmHg)	71.8±8.1	72.3±9.1	0.749 ^{&}
Mean day (mmHg)	91.4±8.1	91.4±8.6	0.980 ^{&}
Systolic night (mmHg)	109.1±9.5	105.6±10.7	0.042 [®]
Diastolic night (mmHg)	67.1±8.3	64.7±9.2	0.108 ^{&}
Mean night (mmHg)	86.6±8.1	83.3±9.2	0.028 [∞]
ARV systolic	9.8±2.3	10.7±2.6	0.092*
ARV diastolic	8.4±2.1	8.4±1.8	0.912 ^{&}
ARV mean	7.0±1.8	7.4±2.0	0.088*
&: T-test was used in dependent groups, *: Wilcoxon te	st was used, ARV: Average real variability		

Table 4. Comparison of dipper/non-dipper ratios of axSpA patients (0. and 3. month) (n=28)

0. month	3. month	р
13 (46%)	17 (61%)	
15 (54%)	11 (39%)	0.388*
4.8 [(-7) -9.2]	9.2 (4.7-11.1)	0.020**
6.4 (1.5-14.7)	9.6 (5.0-15.8)	0.112**
	13 (46%) 15 (54%) 4.8 [(-7) -9.2]	13 (46%) 17 (61%) 15 (54%) 11 (39%) 4.8 [(-7) -9.2] 9.2 (4.7-11.1)

^{*:} Mc Nemar, **: T-test in dependent groups, axSpA: Axial spondyloarthritis

Table 5. Comparison of laboratory and parameter values of dipper and non-dipper patients

Variable 0. month	0. month Dipper n=13	0. month non-Dipper n=15	р
	Mean ± standard deviation and median (25-75%)		
Disease duration (year)	7 (4-15)	6 (4-8)	0.816 ^{&}
Age (year)	36.4 (26.6-42.6)	43.6 (34.6-51.1)	0.152*
VAS pain (0-10)	6.08±3.09	7.80±1.42	0.083*
BASDAI (0-10)	4.99±2.28	5.96±1.87	0.226*
BASFI (0-10)	4.32±2.49	6.33±1.84	0.021*
ESR (mm/st)	9 (4-18)	21 (12-41)	0.088&
C-reaktif protein (mg/dL)	0.71 (0.25-1.11)	1.41 (0.39-3.34)	0.134 ^{&}
Sleep quality (PSQI)	5 (2.5-11)	10 (8-13)	0.049 ^{&}

^{*:} t-test, *: Mann-Whitney U test, BASDAI: Bath ankylosing spondylitis disease activity index, BASFI: Bath ankylosing spondylitis functional index, ESR: Erythrocyte-sedimentation rate, PSQI: Pittsburgh sleep quality questionnaire, VAS: Visual analog scale

At baseline, poor sleep quality was identified in 71% of patients as assessed by the PSQI; however, this rate decreased to 43% at the 3rd month (p<0.05). Following treatment with anti-TNF- α , a statistically significant decrease in the Pittsburgh Sleep Scale scores was observed at the third month (p<0.001). Sleep disturbances, in addition to pain and fatigue, are serious comorbidities in patients with AS, with 50-65% of patients reporting sleep disturbances. [13,14] Multiple studies indicate that elevated disease activity correlates with impaired sleep quality and that sleep disturbances increase cardiovascular mortality. In a prospective study involving 60,586 people followed for cardiovascular events, Lao et al.[15] reported that poor sleep quality was linked to a higher risk of coronary artery disease. Anti-TNF-α therapy has the potential to improve sleep quality in individuals with AS by decreasing disease activity

In this study, 46% of the patients were categorized as dippers before anti-TNF- α treatment. By the third month after treatment, this percentage had increased to 61% (p=0.388), although the increase was not statistically significant. On the other hand, a significant reduction in systolic nocturnal blood pressure was observed, consistent with the dipper pattern. (p<0.05). Lo et al. [16] investigated the connection between sleep quality and hypertension through a meta-analysis of 29 articles and 45,041 patients.

Poor sleep quality was strongly related to hypertension, with patients showing greater systolic and diastolic values than individuals with normal sleep quality. [17] Evidence from another study indicated that enhanced sleep quality corresponded to decreased nighttime blood pressure (dipper pattern). [18] Several investigations have suggested that the link between hypertension and sleep quality may be bidirectional. These findings imply that anti-TNF- α therapy could exert beneficial effects on pain and sleep quality, in addition to lowering nocturnal blood pressure and reducing cardiovascular risk. [6]

In our study, anti-TNF- α treatment did not have a statistically significant impact on ARV. Our results align with previous research. In a prospective study, Capkin et al. [19] examined 28 AS patients both at the start of therapy and after a six-month course of TNF treatment. Although there was a significant reduction in the BASDAI, ESR, and CRP levels, no change was observed in pulse wave velocity (PWV) before and after treatment. Although the authors did not demonstrate a significant improvement in PWV in this study, they suggested that anti-TNF- α therapy could modulate these parameters over the long-term emphasizing the need for long-term studies to assess this hypothesis.

Study Limitations

The limited number of patients, short follow-up periods, and absence of cardiovascular comorbidities in our study group could explain the lack of change in ABPM parameters. It is also possible that blocking the TNF-pathway is not sufficient to modulate cardiovascular risk in these patients.

Conclusion

While anti-TNF- α therapy may modulate cardiovascular risk factors in patients with AS by improving sleep quality, its effect on blood pressure parameters needs to be clarified. Further research is required to evaluate the immediate and long-range impacts of anti-TNF therapy on cardiovascular risk in patients with AS.

Ethics

Ethics Committee Approval: Approval was granted by the Hacettepe University Ethics Board (2021/02-04-KA-20092). The study adhered to the ethical standards of the Declaration of Helsinki.

Informed Consent: All patients gave informed consent.

Footnotes

Authorship Contributions

Surgical and Medical Practices: K.M., L.K., Concept: K.M., T.Y., S.K., L.K., Design: K.M., T.Y., S.K., L.K., Data Collection and Processing: K.M., L.K., Analysis or Interpretation: K.M., T.Y., S.K., L.K., Literature Search: K.M., S.K., L.K., Writing: K.M., L.K.

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