Fatigue Assessment Using FACIT-F Scale in Spondyloarthropathy Patients and its Correlation with BASDAI and BASFI Scores

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ABSTRACT

Objective: To measure fatigue in axial spondyloarthropathy patients and find its correlation with the disease activity measures.
Study Design: Cross-sectional, descriptive study.
Place and Duration of the Study: Rheumatology Unit, Federal Government Polyclinic Hospital, from November 2021 to May 2022.
Methodology: This study included 45 patients fulfilling the ASAS criteria for spondyloarthropathy. Bathankylosing spondylitis disease activity (BASDAI), Bath ankylosing spondylitis functional index (BASFI), and functional assessment of chronic illness therapy- fatigue (FACIT-F) scores were measured for each patient.
Results: In this study, there were 9 (20%) female patients and 36 (80%) male patients. There were 39 (86.7%) patients who had ankylosing spondylitis, 4 (8.9%) had axial spondyloarthropathy with peripheral arthritis and 2 (4.4%) had enthesitis-related juvenile idiopathic arthritis. The mean duration of the disease was 5.45 ± 4.19 years. Active disease with a BASDAI score of ≥4 was found in 16 (35.6%) patients while 29 (64.4%) had a BASDAI score <4. Severe fatigue with a FACIT-F score of <30 was found in 31 (68.9%) of the patients while less fatigue with FACIT-F score >30 was found in 14 (31.1%). The mean BASFI score of the cohort was 3.23 ± 2.01. Spearman's rho correlation analysis showed a significant strong correlation between the FACIT-F score, BASDAI and BASFI scores ($p<0.001$).
Conclusion: Patients with active disease and higher BASFI scores had a lower FACIT-F score suggesting more fatigue, thus correlating with the disease activity.

Key Words: *Bath ankylosing spondylitis disease activity (BASDAI), Functional assessment of chronic illness therapy-fatigue (FACIT-F), Ankylosing spondylitis (AS), Bath ankylosing spondylitis functional index (BASFI), Assessment in ankylosing spondylitis (ASAS).*

How to cite this article: Shah SA, Khaliq T, Saleem S. Fatigue Assessment Using FACIT-F Scale in Spondyloarthropathy Patients and its Correlation with BASDAI and BASFI Scores. *J Coll Physicians Surg Pak* 2024; **34(01)**:63-67.

INTRODUCTION

Axial spondyloarthritis (AxSpA) is a chronic inflammatory rheumatologic disease with variable clinical manifestations. Dactylitis, enthesitis, and peripheral joint involvement are other musculoskeletal manifestations of axial spondyloarthropathies. Anterior uveitis, apical fibrosis, and heart involvement like conduction abnormalities and valve disease can also be present in AxSpA.[1] Also, these patients are prone to develop skeletal deformities which negatively impact the well-being and quality of life of these patients.[2]

The overall prevalence of inflammatory rheumatic diseases is around 5%,[3] while in Europe the prevalence of axial spondyloarthritis is 0.2 to 1.61%.[4] The male-to-female ratio is found to be 3:1 as per the latest research.[5]

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Received: April 02, 2023; Revised: November 23, 2023; Accepted: December 19, 2023
DOI: https://doi.org/10.29271/jcpsp.2024.01.63

In Pakistan, COPCORD study carried out in the suburbs of Lahore, found that 3% of the local population had inflammatory backache, of which 1% were found to have radiographic AxSpA.[6]

Fatigue is also recognised as a prominent feature of the disease, defined as a state of extreme tiredness, and exhaustion typically resulting from exertion i.e. either physical or mental illness.[7] It has been found to be one of the most disabling symptoms affecting patients and has a great impact on their quality of life.

There are different scales to measure the quality of life and fatigue in patients suffering from different chronic diseases. Functional assessment of chronic illness therapy (FACIT) measurement system 23 is one of them and has been validated in different populations. Thirteen fatigue-related questions (FACIT fatigue) were added to the FACIT-F. A 4-point Likert scale was used to assess the response to each of the thirteen items of the questionnaire. The total score range was 0-52 and a patient was said to have less fatigue when the score was high.[8]

The FACIT-F scale had been used in different patient populations and had also been validated.[9]

Similarly, another study done in France, on patients suffering from AxSpA, showed that fatigue levels were high in this population and this score correlated well with their disease activity as well.[10]

The rationale of the study was that AxSpA are chronic ailments that lead to fatigue which in turn is an important factor affecting the quality of life and hence, it is important to consider it while managing the patients using a holistic approach. The objective of this study was to find out fatigue in AxSpA patients using the FACIT-F scale, its correlation of fatigue with disease activity using the Bath ankylosing spondylitis disease activity index (BASDAI) score and also the impact on functional status using the Bath ankylosing spondylitis functional index (BASFI) score.

METHODOLOGY

This descriptive, cross-sectional study was conducted in the Rheumatology Unit of the Federal Government Polyclinic Hospital from 20th November 2021 to 20th May 2022. The sample size calculated by the WHO calculator was found to be 45 with a confidence interval of 95% and a margin of error of 0.05, taking the prevalence of AxSpA to be 1%.[6] Consecutive, non-probability sampling was done to enrol patients in the study.

All diagnosed cases of AxSpA according to the ASAS criteria were included in the study.[11] Any patients suffering from other rheumatologic disorders like rheumatoid arthritis, SLE, mixed connective tissue diseases, and gout were excluded from the study. Patients suffering from other chronic disorders like Diabetes mellitus, thyroid disorders, ischaemic heart disease, chronic kidney problems, asthma or chronic obstructive lung diseases, malignancies, haematologic abnormality, infection of acute or chronic nature, and pregnancy were also excluded as these would have acted as confounders.

The data collection was started after getting the approval from the hospital's Ethical Review Board. Informed written consent was obtained from study participants and filled on the questionnaires. BASDAI and BASFI scores,[12] were obtained for each of the patients using the online calculators. The Urdu version of FACIT-F questionnaire was filled by the patient and the score was calculated by the researcher for which license agreement was taken from the FACIT.org.

BASDAI for AxSpA was calculated with score <4 representing inactive or mild disease, and ≥4 representing active disease.[13]

The BASFI consisted of ten questions that assessed the functional limitation in terms of a visual analog scale scored from 0 - 10 cm. The mean of these 10 scales gave a BASFI score for the patient.[12]

The FACIT-fatigue scale used a 13-item questionnaire for assessing fatigue in the last seven days before the assessment. A 0 - 4 score was used to score each item, with 0 being not at all to 4 equalling very much so. All the thirteen-item scores were added to give a final score range of 0 - 52. Items seven and eight are reverse scored i.e. higher scores representing less fatigue. To assess the severity of fatigue, four grades of severity were made based on the total score, the higher the score the lesser the fatigue; 40 - 52 represented no or little fatigue, 27 - 39 represented some fatigue, 14 - 26 showed quite a lot of fatigue while a score of 0-13 suggested extreme fatigue.[9]

Data were recorded on a pre-designed structured proforma and FACIT questionnaires were filled by the patients after an informed written consent. The FACIT proforma was then scored by the researcher. Data were analysed by using IBM SPSS i.e. Statistical Package for Social Sciences (version 23.0). The descriptive statistics were reported using frequencies and percentages for the categorical data, while mean and standard deviations for the continuous variables were reported. Spearman's rho correlation analysis, Chi-square test and Independent sample t-tests were performed, and p-values <0.05 were considered significant.

RESULTS

This study included a total of 45 patients out of which 9 (20%) were females and 36 (80%) were males. The mean age of the patients was 33.77 ± 7.63 years, with 39 (86.7%) having ankylosing spondylitis, 4 (8.9%) having peripheral AxSpA, and 2 (4.4%) having enthesitis-related juvenile idiopathic arthritis. The mean duration of the disease was 5.45 ± 4.19 years. There were 8.9% patients who had a disease duration <1 year, 48.9% with duration of 1-5 years, 31.1% with disease duration of 6-10 years, while 11.1% had disease duration of >10 years. Active disease, that is a BASDAI score >4, was found in 16 (35.6%) while 29 (64.4%) had inactive disease. FACIT-F score of <30 representing severe fatigue was found in 31 (68.9%) while >30 representing less fatigue was found in 14 (31.1%). The mean BASFI score was 3.23 ± 2.01.

Based on the FACIT-F grades of severity of fatigue, there were 44.4% patients with quite a lot of fatigue having a score of 14-26, 37.8% with some fatigue (27-39) while 8.9% each belonged to the groups with either extreme fatigue (0-13) or little or no fatigue (40-52).

There was a strong significant negative correlation among the FACIT-F score [-0.450 (0.002)], BASDAI [0.495(0.001)], and BASFI [-0.521 (<0.001)].

There were significant differences among the values of the BASFI and the FACIT-F functional scores among the active and inactive disease groups based on their BASDAI scores as shown in Table I. Patients in the active group had a higher BASFI and lower FACIT F score as compared to the group with inactive disease as shown in Table II.

Table I: Severity of fatigue and relationship with BASDAI activity.

FACIT-F Functional score	BASDAI Inactive <4	BASDAI Active ≥4	Total	p-value*	p-value**
<30 Severe fatigue	17 (54.84%)	14 (45.16%)	31	0.045	0.001
>30 Less fatigue	12 (85.7%)	2 (14.3%)	14		
Total	29	16	45		

** Chi-square test. ** Spearman's rho correlation analysis for FACIT-F score and BASDAI (0.001**).*

Table II: Mean and standard deviations of FACIT-F score and BASFI among those with active and inactive disease based on BASDAI activity.

	BASDAI Activity	n	Mean	Std. deviation	Std. error mean	p-value*
FACIT functional score	<4 Inactive	29	28.9655	9.08	1.68	0.003
	≥4 Active	16	20.6250	7.47	1.86	
BASFI score	<4 Inactive	29	2.46	1.62	0.30	<0.001
	≥4 Active	16	4.6375	1.92	0.48	

**Independent sample t-test.*

DISCUSSION

AxSpA predominantly including ankylosing spondylitis (AS) is a chronic inflammatory disease presenting with backache, early morning stiffness, restriction in mobility and fatigue as the main clinical features.[14] The underlying mechanism for these symptoms specifically of the restricted mobility is the replacement of subchondral bone marrow by repair tissue which ultimately stimulates the new bone formation and thus the syndesmophytes.[15] It is an ailment that affects males more than females and the usual age group involved is less than 45 years.[16] Fatigue occurs in 50-70% of AS patients thus making it the most common systemic symptom. Fatigue assessment while assessing disease activity in AxSpA had been added as a component since 2009 and ever since clinical trials had been focusing on improving this as a separate outcome in spondyloarthropathy patients. Its assessment in clinical trials increased from 17.1 to 84%.[17]

There are several scoring systems for assessing the disease activity like BASDAI, ASDAS-CRP, BASFI, and BASMI. For assessment of fatigue, numeric rating scale (0 - 10), BASDAI--fatigue scale (0-10), multidimensional assessment of fatigue (MAF) scale, and FACIT-F scale are commonly used. In this study, BASFI and BASDAI were used to measure the clinical disease activity and FACIT-F scale assessed the fatigue in the participants.

Li *et al.* used the BASDAI-fatigue component as a fatigue measurement tool, and they found that 85.8% of their study population had some degree of fatigue including 32% having severe fatigue.[18] FACIT-F scale was validated by Cella *et al*. in their study as the most feasible and reliable measure of fatigue assessment in patients with active AxSpA.[19] A study done in Denmark showed that 46% had no or little fatigue, 33% had some fatigue, 28% had quite a lot of fatigue and 3% had extreme fatigue.[9] Using the FACIT-F scale in this study, it was found that 8.9% had no or little fatigue (40 - 52), 37.8% had some fatigue (27 - 39), 44.4% had quite a lot of fatigue (14 - 26), and 8.9% had extreme fatigue (0 - 13).

It was also found that the FACIT-F score correlated with the activity of the disease and the functional status using the BASDAI and BASFI score, respectively, as shown in Table II. Those having high disease activity ≥4 had a lower FACIT-F score as compared to those with inactive disease. Similar findings were observed with the BASFI score being higher in those who had higher disease activity but had a lower FACIT-F score indicating severe fatigue. Similar findings were observed in the French DESIR cohort in 2016, where a higher fatigue level was associated with high disease activity, but the only difference from the current study was that it employed numeric rating as the fatigue assessment tool.[9]

Several researchers like Wagan *et al.* in Pakistan,[20] Edurado J Santos in Portugal[21] and Bianchi *et al.* in Brazil,[22] found that the fatigue score had a direct correlation with the activity of the disease in rheumatoid arthritis as well and similar findings were also reported for psoriatic arthritis,[12] and systemic lupus erythematosus,[23] thus supporting the fact that FACIT-F scale is a reliable tool for assessing fatigue in all inflammatory rheumatic diseases. Very few studies had been done on AxSpA fatigue assessment using the FACIT-F scale and in authors' knowledge, this is the first study of this type on AxSpA in Pakistan.

The mean FACIT-F score in this study was 26 ± 9.37, active disease had a score of 20.62 ± 7.47 while inactive disease 28.96 ± 9.08, majority of the patients were either on Salfasalzine with NSAIDS (28.9%), Etanercept (20%), or a combination of these options (13.3%). The results from the current cohort were comparable to those found in studies done on Secukinumab of 150 mg in MEASURE 1 and MEASURE 2 (25.6 ± 10.7),[24] Tofacitinib (27.2 ± 10.7). A 4-point increase from the baseline FACIT-F score was labelled as a minimal and clinically important difference (MCID) in all these trials.[25] A significant improvement in the FACIT-F scores was observed in all these trials when the disease was controlled, thus suggesting that the FACIT-F scale can be used as a tool for assessing fatigue in itself, improvement in the patient reported outcomes and also control of the disease activity in AxSpA.

There were several limitations to this study. First of all, the sample size was small. Secondly, there were generalised results as per active and inactive disease, not taking into account if the patient was on the biological treatment group or only on NSAIDS. The authors also did not individualise each component of the BASDAI score, rather took a composite score dividing patients into active and inactive groups, thus, not taking the BASDAI-fatigue score separately which could have impacted the composite score.

In future, the results of this study could be further worked upon to assess the effect of different treatment modalities on the overall FACIT-F score, the BASFI, and the BASDAI scores, and also their correlation with radiological progression.

CONCLUSION

Fatigue assessment using the FACIT-F scale was impacted by the disease activity of the patient assessed by the BASDAI and BASFI scores. Those having active disease had lower FACIT-F scores indicating severe fatigue as compared to those who had inactive disease. The BASDAI and BASFI scores also correlated with each other; the higher the BASDAI score, the higher the functional limitation and thus, the severity of fatigue.

ETHICAL APPROVAL:

An approval was taken in the 84th meeting of the Ethical Review Committee held on 20th November 2021.

PATIENTS' CONSENT:

A well-informed written consent was taken from the participants of the study.

COMPETING INTEREST:

The authors did not declare any conflict of interest.

AUTHORS' CONTRIBUTION:

SAS: Conceptualisation of the article, data collection, drafting, and data analysis.
TK: Data collection, drafting, proofreading, critical analysis and referencing.
SS: Data collection and referencing.
All authors agreed to the final version of the manuscript for publication.

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