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Patient-Reported Outcomes

Health-Related Quality of Life in Psoriatic Arthritis: Findings and Implications



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ABSTRACT

Objectives: To assess the quality of life (QOL) and its associated factors in patients with psoriatic arthritis (PsA) who would start treatment with biologic drugs at the Brazilian Unified Health System.

Methods: A cross-sectional study was performed at a single center pharmacy in Belo Horizonte, State of Minas Gerais, Brazil. EQ-5D was used to assess the patients' QOL. The functional status was assessed using the Health Assessment Questionnaire-Disability Index, whereas disease activity was evaluated through the Bath Ankylosing Spondylitis Disease Activity Index and the Clinical Disease Activity Index. Simple and multiple linear regression analyses were performed to assess the factors associated with QOL.

Results: A total of 212 patients with PsA were included, of which 185 (87.3%) reported having some pain/discomfort, and 148 (69.8%) presented some level of anxiety/depression. Patients with PsA had a mean QOL score of 0.651 (SD 0.12) with a significant reduction in female patients, concomitant use of nonsteroidal anti-inflammatory drugs, comorbidity, and worse clinical and functional status. Poor QOL was associated with worse functional status by the Health Assessment Questionnaire-Disability Index, disease activity by the Bath Ankylosing Spondylitis Disease Activity Index, and with diagnoses of osteoporosis, hypothyroidism, and depression.

Conclusion: PsA and its associated comorbidities negatively affect the QOL, evidencing the need for a comprehensive and effective clinical approach.

Keywords: cross-sectional study, health system, psoriatic arthritis, quality of life.

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Introduction

Psoriatic arthritis (PsA) is a chronic, immune-mediated, inflammatory disease associated with psoriasis that presents a worldwide prevalence of 0.02% to 0.25%. PsA affects both men and women equally, with a higher incidence in the age group of 40 to 50 years.¹

PsA has musculoskeletal clinical manifestations with peripheral and axial joint involvement, tenosynovitis, enthesitis, dactylitis, bone neoformation, and nail dystrophy. The most frequent signs and symptoms are pain, swelling, morning stiffness, fatigue, and pruritus, and it is more pronounced in the most active states of the disease, with consequent impairment of functional capacity and negative impact on quality of life (QOL).^{2,3}

Greater negative impacts on functional status and QOL are observed in patients with PsA compared with patients who received a diagnosis of psoriasis without PsA.⁴ When compared with the general population, patients with PsA present decreased QOL, impairment of functional capacity, psychosocial disability,

and significantly increased mortality rate.^{5,6} This impact on QOL is directly related to the physical signs and symptoms of the disease and to emotional and social aspects.⁷

In this context, this study aimed to evaluate QOL and its associated factors in patients with PsA who would start treatment with a biologic disease-modifying antirheumatic drug (bDMARD) at the Brazilian Unified Health System (*Sistema Único de Saúde* in Portuguese).

Methods

Type and Setting of the Study

This was a cross-sectional study performed at a single center pharmacy in Belo Horizonte, the capital of the State of Minas Gerais, Brazil. This center is the largest of 28 regional pharmacies in Minas Gerais state and assists about 320 patients with PsA being treated with biologic drugs from 39 municipalities. These regional pharmacies are outpatient and public, specialized to

Table 1. Sociodemographic and clinical characteristics of patients with PsA included in the study.

Variables	Female n = 125		Male n = 87		Total n = 212		P value
Age mean (SD)	50.58 (11.10)		51.65 (12.04)		51.20 (11.48)		.631
Disease duration mean (SD)	6.05 (7.75)		5.46 (6.86)		5.81 (7.39)		.570
Ethnicity n (%)							
White	65	52.4	44	50.6	109	51.7	.847
Brown	42	33.9	31	35.6	73	34.6	
Other	17	13.7	12	13.8	29	13.7	
Marital status n (%)							
Married	63	51.2	55	63.2	118	56.2	.588
Single	34	27.6	21	24.1	55	26.2	
Other	26	21.1	11	12.6	37	17.6	
Schooling n (%)							
Undergraduate	45	36.6	23	26.4	68	32.4	.043
High school	49	39.8	33	37.9	82	39.0	
Elementary	29	23.6	31	35.6	60	28.6	
csDMARD n (%)							
Yes	62	49.6	36	41.4	98	46.2	.239
No	63	50.4	51	58.6	114	53.0	
Corticosteroids n (%)							
Yes	42	33.6	17	19.5	59	27.8	.025
No	83	66.4	70	80.5	153	72.2	
NSAIDs n (%)							
Yes	29	23.2	23	26.4	52	24.5	.591
No	96	76.8	64	73.6	160	75.5	
bDMARD n (%)							
Adalimumab	64	51.2	49	56.3	113	53.3	.927
Etanercept	43	34.4	27	31.0	70	33.0	
Golimumab	3	2.4	2	2.3	5	2.4	
Infliximab	15	12.0	9	10.3	24	11.3	
bDMARD previous n (%)							
Yes	33	26.8	19	21.8	52	24.8	.507
No	90	73.2	68	78.2	158	75.2	
Comorbidities n (%)							
0	28	22.4	23	26.4	51	24.1	.673
1	35	28.0	26	29.9	61	28.8	
≥2	62	49.6	38	43.7	100	47.2	
CDAI mean (SD)	26.38 (16.78)		17.03 (15.55)		22.54 (16.89)		<.001
BASDAI mean (SD)	5.72 (2.33)		4.41 (2.61)		5.18 (2.53)		<.001
HAQ-DI mean (SD)	1.38 (0.62)		0.93 (0.73)		1.20 (0.71)		<.001
EQ-5D mean (SD)	0.61 (0.18)		0.71 (0.18)		0.65 (0.18)		<.001

BASDAI indicates Bath Ankylosing Spondylitis Disease Activity Index; bDMARD, biologic disease-modifying antirheumatic drugs; CDAI, Clinical Disease Activity Index; csDMARD, conventional synthetic disease-modifying antirheumatic drugs; HAQ, Health Assessment Questionnaire-Disability Index; NSAID, nonsteroidal anti-inflammatory drug; PsA, psoriatic arthritis.

supply high-cost drugs, such as biologic drugs, and cover a health administrative region, which comprises a list of municipalities and a defined population.

This study was conducted between January 2012 and December 2018.

Eligibility Criteria and Data Collection

Patients aged 18 years or older, who received a diagnosis of PsA according to the Classification Criteria for Psoriatic Arthritis⁸ and would start treatment with adalimumab, etanercept, golimumab, and infliximab were included in the study. A convenience sampling was adopted, and the patients that received the authorization of their treatment by the state were invited to participate in the study.

A team of pharmacists and undergraduate pharmacy students trained at a rheumatology specialty center conducted the interviews for data collection using a standardized questionnaire.

Variables

The European Quality of Life five dimensions (EQ-5D) was used to assess QOL based on the health status, estimated by the time trade-off method for the population of Minas Gerais.⁹

The EQ-5D evaluates the QOL according to 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, there are 3 alternatives according to the level of severity (no problems, some problems, and extreme problems/unable to perform) that allow patients to describe their

Table 2. Utility scores of patients with PsA.

Variables	Utility score	Δ in overall patients with PsA	P value*
Overall patients with PsA	0.6514 [†]	-	-
Patients with PsA by	-	-	-
Sex			
Female	0.6128	-0.0386	<.001 [‡]
Male	0.7068	0.0554	
Age group			
<50 years	0.6607	0.0094	.538
50-59 years	0.6565	0.0051	
≥60 years	0.6258	-0.0256	
Diagnosis time			
≤3 years	0.6616	0.0103	.364
>3 years	0.6387	-0.0126	
Race			
White	0.6568	0.0055	.932
Brown	0.6495	-0.0019	
Black/others	0.6443	-0.0071	
Schooling			
Elementary	0.6309	-0.0204	.400
High school	0.6466	-0.0048	
Undergraduate	0.6735	0.0221	
Marital status			
Single	0.6488	-0.0026	.701
Married	0.6584	0.0070	
Others	0.6297	-0.0216	
Glucocorticoid			
Yes	0.6179	-0.0335	.097
No	0.6643	0.0129	
NSAIDs			
Yes	0.6052	-0.0462	.035 [‡]
No	0.6664	0.0150	
csDMARD			
Yes	0.6298	-0.0215	.110
No	0.6699	0.0185	
bDMARD previous			
Yes	0.6521	0.0007	.966
No	0.6508	-0.0005	
CDAI			
Remission/LDA (≤10)	0.7861	0.1347	<.001 [‡]
MDA (10.1-22)	0.6846	0.0332	
HDA (>22)	0.5405	-0.1109	
BASDAI			
Inactive disease (<4)	0.8018	0.1505	<.001 [‡]
Active disease (≥4)	0.5818	-0.0695	
HAQ-DI			
Mild disability (0-1)	0.7961	0.1448	<.001 [‡]
Moderate disability (1-2)	0.5721	-0.0793	
High disability (2-3)	0.4425	-0.2088	
Comorbidities			
No	0.7166	0.0652	.003 [‡]
Yes	0.6307	-0.0207	

BASDAI indicates Bath Ankylosing Spondylitis Disease Activity Index; bDMARD, biologic disease-modifying antirheumatic drugs; CDAI, Clinical Disease Activity Index; csDMARD, conventional synthetic disease-modifying antirheumatic drugs; HAQ-DI, Health Assessment Questionnaire-Disability Index; HAD, high disease activity; LDA, low disease activity; MDA, minimal disease activity; NSAID, nonsteroidal anti-inflammatory drug; PsA, psoriatic arthritis.

*Mean utility score for the 212 patients with PsA including in the study.

[†]A significance level of 5% for comparison into each variable (eg. female sex versus male sex) was adopted.

[‡]P value ≤.05

health condition. The higher the EQ-5D score, the better the QOL.¹⁰

In addition, the following instruments were used to measure disease activity: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) to assess axial involvement and Clinical Disease Activity Index (CDAI) to evaluate peripheral involvement. Functional status was assessed through the application of the Health Assessment Questionnaire-Disability Index (HAQ-DI) to verify the patients' difficulty in performing usual activities.^{11,12}

Data on sociodemographic characteristics, such as age, sex, municipality of residence, schooling, marital status, and ethnicity, were collected. Patients also reported disease duration since the diagnosis by the physician, current and previous use of medications for PsA, and comorbidities.

Statistical Analysis

Descriptive analysis was performed using measures of frequency distribution, mean, and SD. Differences between the groups were verified using the Pearson chi-squared or the Fisher exact tests for categorical variables and the *t*-test for continuous variables. Additionally, the mean EQ-5D score and the proportions of patients with PsA with problems in each domain were compared with the values of the general Brazilian population.¹³

Simple and multiple linear regression analyses were performed to verify the factors associated with QOL. Sociodemographic (age, sex, education level, marital status, and ethnicity) and clinical (disease duration, type of medication, CDAI, BASDAI, and HAQ-DI) variables were included in the model as independent variables. Statistical significance levels of 20% and 5% were adopted for the simple and multiple linear regression analyses, respectively. The variables that showed statistically significant association in the simple regression were included in the multiple regression model.

Ethical Considerations

The Research Ethics Committee of the Federal University of Minas Gerais approved the study under protocol number 0069.0.203.000-11, and all participants signed an informed consent form.

Results

Patient Characteristics

A total of 212 patients with PsA were included in the study, of which 125 (59.0%) were female and 65 (51.7%) white. Most patients were married (56.2%) and had at least completed high school (71.4%) (Table 1).

It was observed that 59 (27.8%) individuals were using glucocorticoids, 52 (24.5%) nonsteroidal anti-inflammatory drugs (NSAIDs), and 98 (46.2%) conventional synthetic disease-modifying antirheumatic drugs (csDMARDs). Regarding the previous use of medication, 46.2% and 24.8% of the participants reported taking csDMARDs and bDMARDs, respectively. The most requested bDMARD was adalimumab (53.3%), followed by etanercept (33.0%), infliximab (11.3%), and golimumab (2.4%) (Table 1).

Women presented worse disease activity, functional status, and QOL; used more glucocorticoids; and had a higher education level than men (Table 1).

QOL and Its Associated Factors

The mean QOL score was 0.651 (SD 0.12). It was observed that female patients and patients with concomitant use of NSAIDs,

Table 3. Utility scores of the main comorbidities of patients with PsA.

Comorbidities	n	%	Utility score	Δ without comorbidity
No	51	24.1	0.7166	–
Yes	161	75.9	0.6307	–0.0859
Hypertension	67	31.6	0.6353	–0.0813
Dyslipidemia	48	22.6	0.6041	–0.1125
Depression	38	17.9	0.5267	–0.1899
Diabetes mellitus	32	15.1	0.6169	–0.0997
Hypothyroidism	17	8.0	0.5605	–0.1561
Gastritis	14	6.6	0.5255	–0.1911
Fibromyalgia	9	4.2	0.5548	–0.1618
Anxiety	8	3.8	0.7060	–0.0106
Obesity	7	3.3	0.5430	–0.1736
Herniated disc	6	2.8	0.5547	–0.1619
Osteoporosis	5	2.4	0.5114	–0.2052

PsA indicates psoriatic arthritis.

comorbidities, and worse clinical and functional status had a significant reduction in QOL (Table 2).

Among the main comorbidities reported by patients with PsA, osteoporosis, gastritis, depression, obesity, herniated disc, fibromyalgia, and hypothyroidism had a higher negative impact on QOL, as shown in Table 3.

Finally, multiple linear regression analysis showed that worse disease activity (BASDAI), worse functional status (HAQ-DI), and experiencing depression, hypothyroidism, and osteoporosis were the factors associated with a worse QOL in patients with PsA ($P<.050$) (Table 4).

Problems Reported According to EQ-5D Domains

Analysis using EQ-5D showed that most patients did not have problems with self-care ($n = 142, 67.0\%$), and approximately 54.0% ($n = 115$) of them presented some difficulty in mobility and carrying out usual activities. The most prevalent dimensions were pain/discomfort ($n = 185, 87.3\%$) and anxiety/depression ($n = 148, 69.8\%$), with major impact on the patients' QOL. In addition, it was found that women had more problems in the dimensions of mobility, usual activities, and pain/discomfort than men ($P<.050$) (Table 5).

Table 4. Factors associated with HRQOL in patients with PsA.

Variables	Simple				Multiple			
	Coefficient	95% CI		P value	Coefficient	95% CI		P value
	β	Lower limit	Upper limit		β	Lower limit	Upper limit	
Female sex	–0.094	–0.142	–0.045	<.001	-	-	-	-
csDMARD	–0.040	–0.089	–0.009	.110	-	-	-	-
Corticosteroids	–0.046	–0.101	0.008	.097	-	-	-	-
NSAIDs	–0.061	–0.118	–0.004	.035	-	-	-	-
BASDAI	–0.048	–0.055	–0.041	<.001	–0.020	–0.028	–0.011	<.001
CDAI	–0.006	–0.007	–0.005	<.001	-	-	-	-
HAQ-DI	–0.193	–0.216	–0.169	<.001	–0.133	–0.164	–0.103	<.001
Dyslipidemia	–0.061	–0.119	–0.003	.041	-	-	-	-
Depression	–0.152	–0.212	–0.091	<.001	–0.060	–0.101	–0.020	.004
Gastritis	–0.135	–0.233	–0.037	.007	-	-	-	-
Hypothyroidism	–0.099	–0.189	–0.009	.032	–0.073	–0.129	–0.016	.012
Fibromyalgia	–0.101	–0.223	0.021	.104	-	-	-	-
Herniated disc	–0.100	–0.248	0.049	.188	-	-	-	-
Osteoporosis	–0.143	–0.305	0.018	.082	–0.107	–0.208	–0.005	.039
Obesity	–0.112	–0.250	0.025	.109	-	-	-	-

BASDAI indicates Bath Ankylosing Spondylitis Disease Activity Index; bDMARD, biologic disease-modifying antirheumatic drugs; CDAI, Clinical Disease Activity Index; CI, confidence interval; csDMARD, conventional synthetic disease-modifying antirheumatic drugs; HAQ-DI, Health Assessment Questionnaire-Disability Index; HRQOL, health-related quality of life; NSAID, nonsteroidal anti-inflammatory drug; PsA, psoriatic arthritis.

Table 5. Assessment of the health status of patients with PsA by EQ-5D dimensions.

Dimension	Difficulty level	Female		Male		Total		P value
		n	%	n	%	n	%	
Mobility	No problems	50	40.0	47	54.0	97	45.8	.044*
	Some problems	75	60.0	40	46.0	115	54.2	
	Unable to do	0	0.0	0	0.0	0	0.0	
Self-care	No problems	78	62.4	64	73.6	142	67.0	.090
	Some problems	47	37.6	23	26.4	70	33.0	
	Unable to do	0	0.0	0	0.0	0	0.0	
Usual activities	No problems	41	32.8	48	55.2	89	42.0	.003*
	Some problems	78	62.4	36	41.4	114	53.8	
	Unable to do	6	4.8	3	3.4	9	4.2	
Pain/discomfort	None	8	6.4	19	21.8	27	12.7	<.001*
	Moderate	94	75.2	62	71.3	156	73.6	
	Extreme	23	18.4	6	6.9	29	13.7	
Anxiety/depression	None	33	26.4	31	35.6	64	30.2	.107
	Moderate	69	55.2	45	51.7	114	53.8	
	Extreme	23	18.4	11	12.6	34	16.0	

PsA indicates psoriatic arthritis.

*A significance level of 5% was adopted (P value $\leq .05$).

Patients with PsA presented worse results in all dimensions of the EQ-5D scale and a lower mean score (0.651) when compared with the general population of Brazil (0.793) ($P < .001$) (Fig. 1).

Discussion

This study verified the profile of patients who would start treatment with bDMARDs and evaluated the impact of PsA on their QOL and its associated factors.

Most evaluated patients were female, white, married, and had at least completed high school, corroborating the findings of others studies.¹⁴⁻¹⁷

Despite the use csDMARDs and NSAIDs, patients remained with disease activity by the BASDAI (BASDAI ≥ 4) and with moderate or high activity by the CDAI, which justifies the request of bDMARD for PsA.^{16,18} Most patients in this study requested adalimumab, which has also been reported in other studies.^{15,19-21}

The patients investigated in this study presented a QOL score of 0.651, which is lower than that of the general population assisted at primary care in Brazil (0.793),¹³ thus, confirming the impact of the disease on the QOL of affected patients. It has been reported that patients with PsA have a worse QOL than that of patients with psoriasis without PsA, similar to that of patients with ankylosing spondylitis and better than that of patients with rheumatoid arthritis.^{4,14,22} In Brazil, the utility observed in patients with PsA was better than that observed in patients with rheumatoid arthritis and ankylosing spondylitis and similar to patients with PsA naïve in biologic therapy.^{17,23,24}

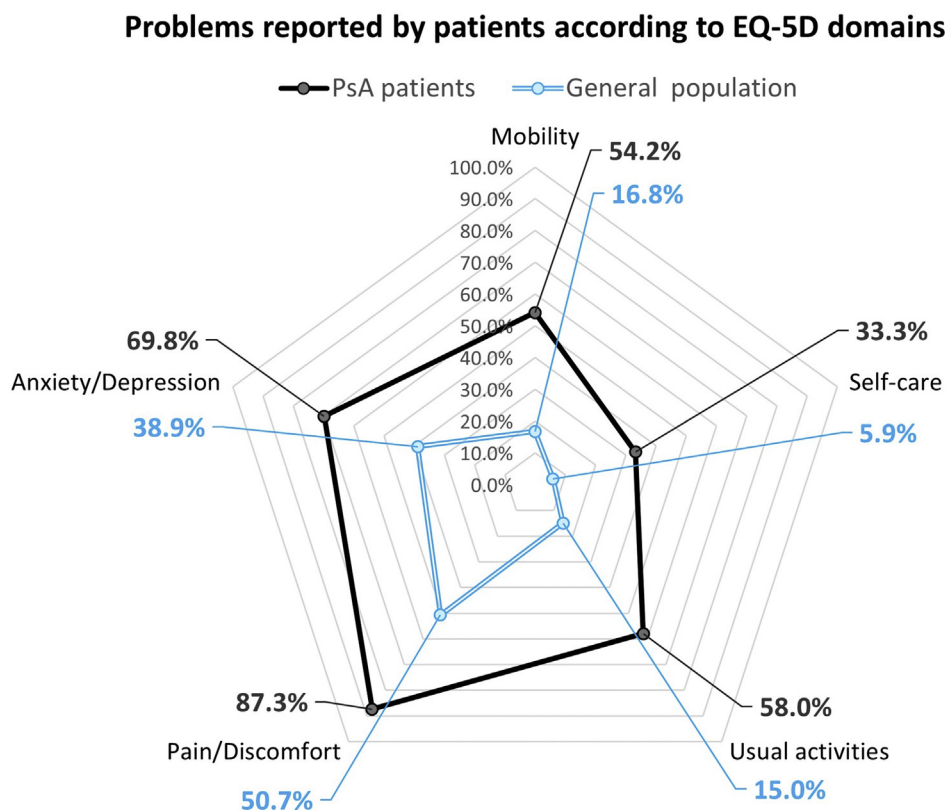
Worse functionality and worse disease activity significantly reduced QOL of patients with PsA, which reinforces the results of other studies. This worse clinical status is associated with a loss of productivity, limitation of physical and social activities, and greater pain for patients, which justified the negative impact on QOL.^{14,25,26}

Patients with PsA also presented problems in 3 of 5 dimensions evaluated, which were mobility difficulties, problems to perform usual activities, and suffering from pain/discomfort, which affected the QOL. Pain is one of the symptoms that interferes the most with physical capacity because it is an indication that patients present high disease activity. Some studies have demonstrated that the state of pain influences the patient's global assessment of disease activity, which is associated with worse functional status and QOL.^{27,28} Other studies have shown that depression in patients with PsA is related to an increased state of pain, affects self-esteem, and generates debilitating disorders, such as stress, embarrassment, and physical discomfort, with a consequent negative impact on productivity and QOL.^{3,28,29}

It was found that women presented worse disease activity, functional status, and QOL and used more corticosteroids. In addition, they were more likely to experience pain/discomfort and reported greater difficulties in the mobility and usual activities dimensions, also corroborating the findings of other studies.^{4,14,30}

Considering the comorbidities presented by the patients, it was observed that depression, osteoporosis, and hypothyroidism greatly affected their QOL. In addition, fibromyalgia, dyslipidemia, herniated disc, obesity, and gastritis could have had some impact on it. In this sense, studies have shown that comorbidities in patients with PsA can influence disease management and, occasionally, worsen the disease state. It has been observed that the presence of comorbidities and other symptoms such as fatigue and sleep disorders may be associated with depression and a tendency for isolation in these patients.^{27,31} Moreover, it has been observed that some comorbidities contribute to persistent inflammation in PsA.^{29,31-33} Patients with associated fibromyalgia present moderate-to-severe disability, which is associated with greater pain intensity and psychological factors, such as alexithymia and depression.³⁴ Thus, comorbidities increase the levels of physical disability, worsen the mental health and functional status, and lead to decline in patient QOL.^{29,35}

Figure 1. Problems with the HRQOL in patients with PsA compared with general patients of primary care in Brazil.



HRQOL indicates health-related quality of life; PsA, psoriatic arthritis.

In a Brazilian context, some factors can contribute to poor disease control and negatively affect the QOL, such as the difficulty to access rheumatologists, delay in the diagnosis, lower medication persistence in the csDMARD use, and the 2 months median time to receive medicines for the PsA treatment by *Sistema Único de Saúde*.^{15,16,36} Thus, expanding the early diagnosis and treatment of the disease is a fundamental action to ensure a good prognosis. Nevertheless, the effective implementation of these stages is still a challenge.^{15,37}

A limitation of this study refers to its convenience sample, that is, only patients who agreed to participate were included. Therefore, more severe patients may not have participated in the study because of difficulty in attending the pharmacy to seek their medication. In addition, the population of this study is from a single center and does not represent the entire Brazilian population with PsA. Therefore, the results should be generalized with caution. As for strengths, the evaluation of QOL was performed using a generic instrument that has a high correlation with specific instruments used in PsA,³⁸ thus, allowing comparison with the general population and other health conditions. Furthermore, it was possible to know the QOL profile in the population with PsA in Brazil, its associated factors, and implications of the disease on the health of these patients. Finally, utility metrics from EQ-5D have been used in economic evaluations of rheumatic diseases, reinforcing the importance of generating QOL data.^{17,23}

Conclusion

The results showed the impact of PsA on the patients' QOL. Patients with PsA presented worse results in all dimensions of the

EQ-5D and a lower mean utility score when compared with the general population. Worse disease activity by BASDAI, worse functional status by HAQ-DI, and diagnoses of depression, hypothyroidism, and osteoporosis negatively affected the QOL of patients with PsA. The implementation of measures to improve patient health status, such as early diagnosis, immediate inclusion of the patient for the treatment, and monitoring by a multidisciplinary health team, is necessary to improve the QOL of patients with PsA.

Article and Author Information

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