ORIGINAL INVESTIGATIONS

Factors associated with achieving an acceptable health-related quality of life in the treatment of patients with psoriatic arthritis

Tremaskina P.O.[1], Korotaeva T.V.[1], Loginova E.Yu.[1], Glukhova S.I.[1], Lila A.M.[1,2]

[1]V.A. Nasonova Research Institute of Rheumatology, Moscow; [2]Department of Rheumatology Russian Medical Academy of Continuing Professional Education, Ministry of Health of Russia, Moscow

[1]34A, Kashirskoe Shosse, Moscow 115522, Russia; [2]2/1, Barrikadnaya Street, Build. 1, Moscow 125993, Russia

Objective: *to analyze factors associated with the achievement of acceptable health-related quality of life (HRQoL) in patients with psoriatic arthritis (PsA) 7 years after the start of observation.*

Material and methods. *The study included 53 patients (28 women, 25 men) with PsA who met the 2006 CASPAR criteria. The mean age of patients was 45.7±12.0 years, the median duration of PsA was 90 [72; 99] months, and the observation period was 81 [61; 91] months. The study included patients in early stage of PsA (duration up to 2 years), who were treated according to the "treat-to-target" strategy (T2T) for 24 months. Subsequently, all patients continued therapy according to the standards of medical care under the supervision of the treating physician.*

Over time, a standard rheumatological examination was performed. Activity of PsA was assessed by DAPSA, psoriasis by BSA, HRQoL by Psoriatic Arthritis Impact of Disease (PsAID-12); body mass index (BMI, kg/m^2) and functional status by HAQ were also assessed. PsAID-12 ≤4 corresponded to achieving a Patient Acceptable State Status (PASS). The results were analyzed in two groups of patients: PsAID-12 ≤4 and PsAID-12 >4. The number of patients (%) who achieved minimal disease activity (MDA) after 1–2 years of active treatment and after 7 years was assessed. X-rays of the hands and feet (n=42) were performed using standard methods, changes were assessed using the Sharp/van der Heijde method modified for PsA (m-Sharp/van der Heijde).

Results and discussion. *After 7 years, 38 (71.7%) of 53 patients were found to have PASS. Patients who achieved PASS had significantly lower PsA and psoriasis activity, lower CRP levels, lower m-Sharp/van der Heijde scores, better functional status and HRQoL, and lower BMI at baseline. Factors associated with achieving PASS were identified: absence of nail psoriasis, BSA ≤3%, CRP ≤5 mg/l, number of swollen joints ≤3, number of painful joints ≤5, HAQ ≤0.5 at baseline and after 24 months, and achievement of MDA during the first 12 months of treatment.*

Conclusion. *The majority of PsA patients treated at an early stage according to T2T principles had PASS, which is associated with low disease activity, fewer joint erosions, better functional status and achievement of MDA during the first 12 months of therapy. These factors should be considered when predicting disease progression*

Keywords: *psoriatic arthritis; T2T strategy; health-related quality of life; PSAID-12.*

Contact: *Polina Olegovna Tremaskina;* ***polinatrem@yandex.ru***

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Psoriatic arthritis (PsA) is a chronic immunoinflammatory disease from the group of spondyloarthritis (SpA), which is accompanied by damage to the musculoskeletal system (peripheral arthritis, dactylitis, enthesitis, inflammation of the spine), as well as psoriatic lesions of the skin and nails [1, 2]. According to the recommendations of EULAR (European Alliance of Associations for Rheumatology) and GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis - International Group for the Study of Psoriasis and PsA), the main goals of PsA treatment are to achieve remission and/or the minimal disease activity (MDA) in all clinical domains (arthritis, dactylitis, enthesitis, spondylitis, psoriasis), improved health-related quality of life (HRQoL), and delayed radiographic progression [3, 4].

Recently, when assessing PsA activity and achieving treatment goals, attention has been paid not only to total activity indices (Disease Activity In Psoriatic Arthritis, DAPSA; DAS28, DAS), criteria for response to therapy (ACR20/50/70; Psoriasis Area and Severity Index, PASI 75/90/100) and laboratory signs of inflammation (CRP and ESR), but also to subjective parameters that the patient determines independently (Patient-Reported Outcomes, PROs) [5]. These include assessment of pain, disease activity on a visual analogue scale (VAS), fatigue, sleep disturbance, social activity, work ability, and general activity. These parameters are used as independent indicators or as part of questionnaires characterizing HRQoL. One of these questionnaires is PsAID (Psoriatic Arthritis Impact of Disease) [6], developed specifically for patients with PsA.

PsAID-12 consists of 12 scales that cover the physical, social, psycho-emotional spheres of the patient's life: pain; fatigue/weakness; skin problems; work or leisure; physical performance; discomfort; sleep disturbance; coping; nervousness/fear and uncertainty; feeling of embarrassment and/or shame; social activity; depression [7]. PsAID-12 is actively used in randomized controlled trials and in clinical practice, including for assessing the achievement of remission and MDA. Patient-acceptable symptom state (PASS) is considered one of the indicators char-

Table 1. Patient characteristics and comparison of groups achieving/not achieving PASS after 7 years of follow-up

Index	Group as a whole (n=53)	achieving PASS (n=38)	not achieving PASS (n=15)	p
Age, years, M±σ	45.7±12	44.4±11.7	49.2±12.5	0.12
Duration of PsA, months, Me [25th; 75th percentile]	90 [72; 99]	88 [72; 99]	90 [71; 110]	0.89
Duration of psoriasis, months, Me [25th; 75th percentile]	132 [96; 180]	132 [91; 180]	120 [96; 216]	0.93
Female, n (%)	28 (52,8)	19 (50)	9 (60)	0.36
TJC of 68, Me [25th; 75th percentile]	4 [0; 7]	1 [0; 4]	8 [6; 12]	**0.001**
SJC of 66, Me [25th; 75th percentile]	2 [0; 4]	1 [0; 2]	4 [2; 7]	**0.001**
Patient-reported global disease activity VAS, Me [25th; 75th percentile]	30 [10; 50]	20 [5; 30]	67 [50; 70]	**0.001**
Patient-reported pain intensity VAS Me [25th; 75th percentile]	20 [10; 50]	10 [2; 30]	65 [45; 80]	**0.001**
CRP, mg/L, Me [25th; 75th percentile]	3 [1.2; 7.6]	2.4 [1.2; 5.5]	16.2 [5.5; 43.5]	**0.001**
BSA, %, Me [25th; 75th percentile]	1 [0.2; 4]	0.5 [0.1; 3]	3.5 [0.5; 70]	**0.016**
HAQ, Me [25th; 75th percentile]	0 [0.375; 0.875]	0.125 [0; 0.375]	1.125 [0.75; 1.5]	**0.001**
DAPSA, Me [25th; 75th percentile]:				
currently	10.8 [2.7; 21]	5.2 [1.6; 13]	26.2 [19; 39.2]	**0.001**
after 24 months of follow-up	4 [0.7; 22]	3 [0.4; 14.1]	19.6 [3.4; 29.7]	**0.04**
BMI, kg/m^2, Me [25th; 75th percentile]				
at baseline	27.1 [23.3; 30.8]	25.9 [22.7; 28.9]	29 [26.6; 34.5]	**0.012**
currently	27.6 [23.8; 32.4]	26.5 [23.4; 32]	30 [27.1; 35.5]	0.16
Time to achieving remission, months, Me [25th; 75th percentile]	6 [3; 12]	6 [3; 9]	6 [0; 15]	0.95
Time to achieving MDA, months, Me [25th; 75th percentile]	6 [3; 9]	6 [3; 9]	3 [0; 12]	0.16
TSS, Me [25th; 75th percentile]:				
at baseline	27 [12; 56]	26 [10; 49]	48 [27; 56]	0.1
currently	56 [31; 90]	34 [24; 89]	90 [78; 98]	**0.004**
ER, Me [25th; 75th percentile]:				
at baseline	1 [0; 4]	0 [0; 1]	4 [0; 10]	**0.02**
currently	4 [1; 12]	2 [0; 8]	19 [4; 29]	**0.001**
JSN, Me [25th; 75th percentile]:				
at baseline	26 [12; 55]	24 [10; 49]	39 [20; 62]	0.16
currently	50 [29; 88]	32 [23; 88]	79 [56; 88]	**0.007**

acterizing disease activity and response to therapy [8]. In 2022, the PsAID-12 questionnaire was validated in the Russian Federation for use in clinical practice [9].

Until now, in Russia, HRQoL in patients with PsA has not been assessed using the PsAID-12 questionnaire, as well as the association of achieving PASS with MDA and structural changes in the joints in the long term in patients with early PsA who received therapy in accordance with the Treat-to-Target strategy (T2T).

The purpose of the study was to analyze the factors influencing the achievement of acceptable HRQoL in patients with PsA 7 years after the start of observation.

Material and methods. The study included 53 patients (28 women, 25 men) diagnosed with PsA, who met the CASPAR criteria (ClaASification criteria for Psoriatic Arthritis) 2006. The average age of the patients was 45.7±12 years, the median duration of PsA was 90 [72; 99] months, duration of psoriasis – 132 [96; 180] months, observation duration – 81 [61; 91] months. Patients were selected for the study at an early stage of PsA (duration of peripheral arthritis - up to 2 years); After signing informed consent, they received treatment for 24 months in accordance with the T2T strategy (REMARCA cohort).

Initially, all patients were prescribed methotrexate (MTX) monotherapy in subcutaneous form at 10 mg/week, with the dose increasing by 5 mg every 2 weeks to 20–25 mg/week. In the absence of low disease activity, remission according to DAPSA, and MDA after 3–6 months, adalimumab (40 mg once every 2 weeks) or ustekinumab (45 mg according to the regimen) was added to MTX (20–25 mg/week). The total duration of therapy was 24 months [10].

After 2 years of intensive follow-up, patients continued treatment in accordance with the standards of care. 7 years after the start of observation, all patients were examined. A standard rheumatological examination was performed, the prevalence and severity of psoriasis, body mass index (BMI, kg/m2), HRQoL, functional status were assessed, and radiography of the hands and feet was performed. The tender joint count (TJC) out of 68, the swollen joint count (SJC) out of 66, patient-reported pain intensity

and global disease activity on the visual analogue score (VAS), physician-reported disease activity (VAS, 0–100 mm), functional index HAQ (Health Assessment Questionnaire), the presence of enthesitis, dactylitis, nail psoriasis, as well as the level of CRP (in mg/L) were assessed. The area of psoriatic skin lesions was assessed using the BSA index (Body Surface Area, in %). PsA activity was determined by DAPSA: remission – 0–4; low disease activity – 5–14; moderate activity – 15–28; high activity – >28 [11]. The number of patients (in %) who achieved MAB was assessed: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3, patient-reported pain intensity on VAS ≤15 mm, patient-reported global disease activity on VAS ≤20 mm, HAQ ≤0.5, number of inflamed entheses ≤1. MDA was considered to be achieved when a patient had 5 of 7 criteria [12]. HRQoL was assessed using PsAID-12: score ≤4 points corresponded to the achievement of PASS [6]. The results were analyzed in two groups of patients: PsAID-12 ≤4 and PsAID-12 >4.

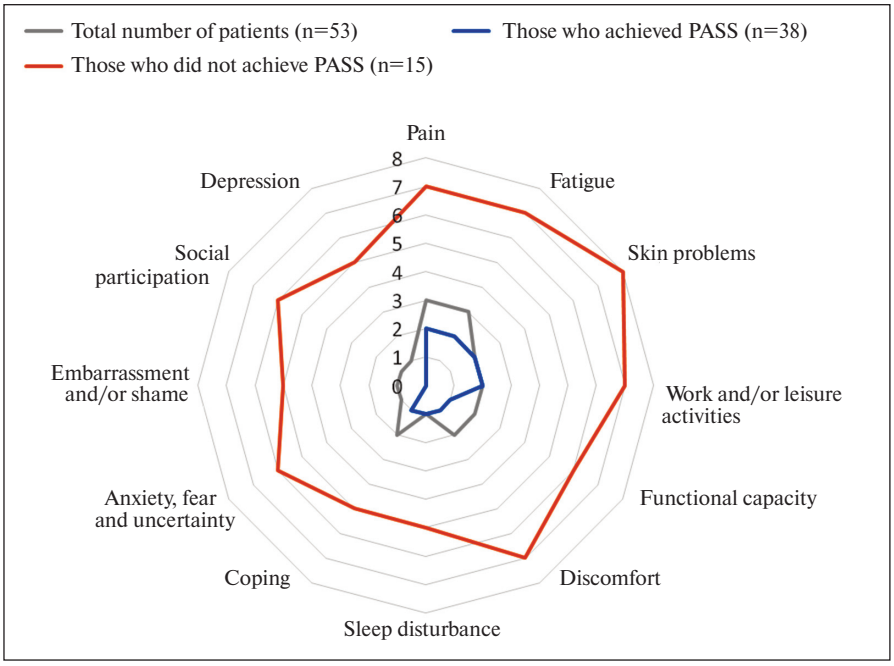

Fig. 1. *Comparison of the PsAID-12 scales*

Table 2. Comparison of clinical characteristics of patients who achieved and did not achieve PASS after 7 years of follow-up, Me [25th; 75th percentile] (n=53)

Index	Group as a whole (n=53)	achieving PASS (n=38)	not achieving PASS (n=15)	p
At baseline:				
TJC	9 [6; 12]	8 [5; 12]	11 [8; 15]	0.07
SJC	7 [6; 11]	7 [5; 10]	10 [6; 15]	**0.04**
patient-reported global disease activity VAS	54 [45; 65]	52 [44; 58]	69 [52; 72]	**0.008**
patient-reported pain intensity VAS	54 [50; 67]	52 [40; 62]	67 [52; 74]	**0.008**
CRP, mg/L	15.5 [8.9; 31]	15 [8.6; 27]	16.6 [10.2; 53.5]	0.29
BSA, %	1.5 [0.5; 5]	1 [0.5; 4.5]	3 [0.5; 17]	0.19
HAQ	0.875 [0.5; 1.125]	0.625 [0.5; 1]	1 [0.75; 1.875]	**0.01**
DAPSA	29.3 [24.3; 36]	26.7 [22.8; 32.4]	35.9 [31; 46.4]	**0.002**
After 24 months of follow-up:				
TJC	0 [0; 6]	0 [0; 3]	4 [0; 8]	0.14
SJC	0 [0; 0]	0 [0; 2]	4 [0; 8]	0.14
patient-reported global disease activity VAS	11 [0; 48]	9 [0; 28]	28 [10; 63]	**0.03**
patient-reported pain intensity VAS	15 [0; 50]	6 [0; 45]	35 [10; 63]	0.052
CRP, mg/L	4 [1.2; 16.2]	2.7 [1.1; 14.6]	8.8 [1.6; 32.3]	0.12
BSA, %	0.5 [0; 2]	0.5 [0; 1]	0.5 [0; 13]	0.7
HAQ	0.25 [0; 0.5]	0 [0; 0.375]	0.625 [0.75; 1.875]	**0.002**
DAPSA	4 [0.7; 22]	3 [0.4; 14.1]	19.6 [3.4; 29.7]	**0.044**

In 42 patients, radiography of the hands and feet was performed over time (after 7 years) using standard methods, assessed by two independent radiologists using the Sharp/van der Heijde method modified for PsA (m-Sharp/van der Heijde). In accordance with the generally accepted methodology, we counted erosions (ER) in the hands and feet (maximum score 320), joint space narrowing (JSN) in the hands and feet (maximum score 208), as well as the total Sharpe score (TSS), which implies summing ER and JSN for the hands and feet (maximum score 528) [13].

Statistical data processing was performed using the Statistica 10 software package (StatSoft Inc., USA). Differences were considered statistically significant at $p<0.05$. Odds ratios (OR) with 95% confidence intervals (CI) for each variable were estimated. The mean values of the indicators (M) and standard deviation (SD) were calculated. If the distribution differed from normal, the median and interquartile range (Me [25th; 75th percentile]) were calculated. Data were compared over time using the Mann–Whitney and Wilcoxon tests.

Results. 7 years after the start of follow-up, PASS was detected in 38 (71.7%) out of 53 patients. General clinical and laboratory characteristics of patients included in the study and comparison of groups that achieved/did not achieve PASS are presented in Table. 1.

As can be seen from the presented data, patients who achieved PASS had significantly lower TJC, SJC, pain level according to VAS, functional impairment according to the HAQ index, prevalence of psoriasis, BMI, and CRP level. Patients who did not achieve PASS were characterized by a significantly higher number of

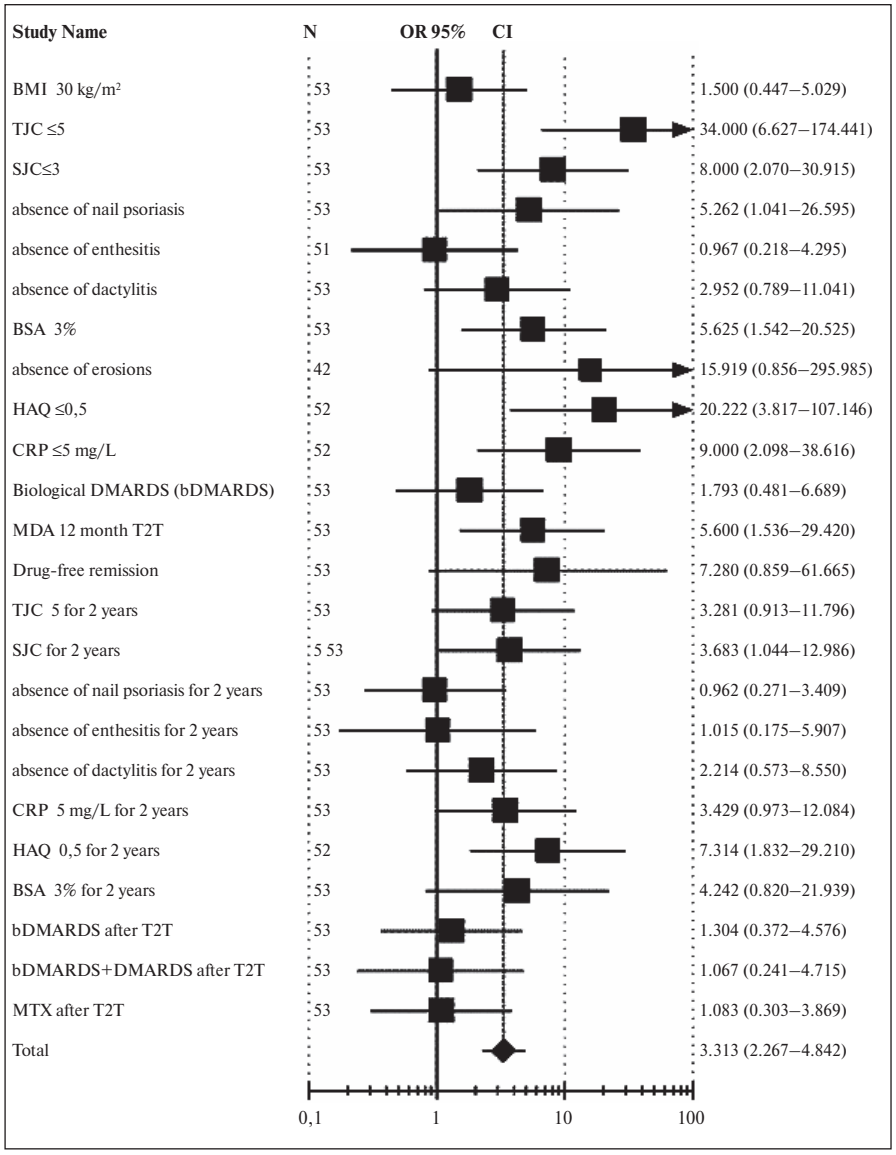

Fig. 2. *Factors associated with achieving PASS after 7 years. DMARDs – disease modifying antirheumatic drugs*

erosions on radiographs of the hands and feet at the onset of the disease and after 7 years.

The median PsAID-12 total score was 2.1 [0.95; 4.6]. At the same time, individual analysis of the scales demonstrated significantly worse HRQoL indicators in the group of patients who did not achieve PASS (Fig. 1).

Comparative clinical characteristics of patients before the start of therapy and after 2 years of treatment, depending on the presence or absence of PASS after 7 years of follow-up, are presented in Table. 2.

As can be seen from Table 2, patients who did not achieve PASS had higher disease activity and worse functional status according to HAQ both before the start of therapy and at week 24 of follow-up. The group of patients who subsequently achieved PASS, at the early stage of PsA was characterized by lower SJC and pain levels (according to VAS), and better functional status. After 24 months of treatment, the groups also differed significantly in terms of patient-reported global disease activity on VAS and HAQ index.

Interestingly, disease activity according to DAPSA in the groups that achieved and did not achieve PASS was significantly different not only after 7 years of treatment, but also at the onset of the disease and after 24 months of treatment for PsA.

Logistic regression analysis was performed to identify factors associated with achieving PASS at an average of 7 years of follow-up (Fig. 2).

The most significant indicators associated with achieving PASS in patients with PsA are: absence of nail psoriasis (OR 5.262; 95% CI 1.041–26.595); BSA <3% (OR 5.625; 95% CI 1.542–20.523); CRP <5 mg/L (OR 9.000; 95% CI 2.098–38.616), low level of functional impairment according to HAQ after 7 years (OR 20.222; 95% CI 3.817–107.146) and 24 months of treatment (OR 7.314; 95% CI 1.832 – 29.210), achievement of MDA in the first 12 months of treatment (OR 5.600; 95% CI 1.536–20.420).

Characteristics of pharmacotherapy. During the first 24 months of treatment, all patients who achieved PASS received MTX, including 34 (89.5%) – s/c. The median duration of MTX treatment before discontinuation of therapy was 36 [4; 52] months. Sulfasalazine (SS) was taken by 2 patients (5.3%), leflunomide (LEF) by 1 patient (2.6%); non-steroidal anti-inflammatory drugs (NSAIDs) were regularly received by 34 (89.5%), glucocorticoids orally by 4 (7.9%) and intra-articularly by 14 (36.8%) patients.

In the first 24 months of treatment, biological drugs (bDMARDS) were prescribed to 10 (66.7%) of 15 patients who did not achieve PASS, and 17 (44.7%) of 38 who achieved PASS (p=0.15). These data may indicate that the group of patients with a worse quality of life initially had a more severe course of PsA, which necessitated the addition of bDMARDS to MTX monotherapy. Twelve (31.6%) of 38 patients who achieved PASS and 8 (53.4%) of 15 patients who did not achieve PASS received combination therapy with bDMARDS + MTX. The median duration of bDMARDS use was 24 [6; 48] months.

Currently, out of 38 patients who achieved PASS, 12 (31.6%; p = 0.55) receive MTX (31.6%; p = 0.55), 15 (39.5%; (p = 0.38) receive bDMARDS, 2 patients receive tofacitinib and SS (5.3%), 1 patient - LEF (2.6%). The need in regular use of NSAIDs in patients with PASS is significantly lower (47.4%, n=18) than in the group who did not achieve PASS (86.7%, n=13), p=0.008, as well as the need in oral glucocorticoids, p=0.004.

Drug-free remission of PsA during the entire follow-up period was achieved in 14 (26.4%) out of 53 patients and was associated with achieving PASS after 7 years of follow-up (p=0.04).

Discussion. Improving patients' HRQoL is one of the goals of PsA therapy, along with achieving remission or MDA [14].

A recent meta-analysis found that the PsAID-12 has high psychometric and constructive properties, which allows it to be considered a key tool for assessing HRQoL in PsA [15].

Recently, the possibility of using PsAID-12 to assess remission, MDA or very low disease activity has been shown. It was found that in patients who achieved MDA, the total PsAID-12 score corresponds to better HRQOL [16].

The effectiveness of the T2T strategy and escalation of therapy in the absence of remission or MDA in patients with PsA was first demonstrated in the TICOPA trial, in which the results were assessed according to the response criteria for peripheral arthritis ACR20/50/70, as well as the achievement of MDA. L.C. Coates et al. [17], presenting the results of a 5-year follow-up in the TICOPA trial, noted the need to analyze the impact of the T2T strategy on HRQoL.

The previously published results of the REMARKA observational study, also devoted to evaluating the use of the T2T strategy, showed the high effectiveness of this approach in the treatment of patients with early PsA: after 24 months, there was a statistically significant improvement in all clinical and laboratory parameters of PsA activity and the functional state of patients; more than a half of the patients had MDA and remission according to DAPSA [18].

For the first time, we analyzed the long-term results of using the T2T strategy in patients with early PsA from the perspective of achieving PASS, assessed by PsAID-12. It was shown that after 7 years of follow-up, HRQoL according to PsAID-12 remained generally good. However, individual analysis of the rating scales revealed significant differences between patients who achieved and did not achieve PASS.

Our study is the first to identify factors influencing the achievement of patient-acceptable HRQoL. It was found that achieving PASS is associated with damage to a limited number of joints (TJC ≤5, SJC ≤3), low level of functional impairment (HAQ ≤0.5), low level of CRP (≤5 mg/l), mild skin psoriasis (BSA ≤3%) and absence of nail psoriasis. This coincides with the results of R. Queiro et al. [19], who using multivariate logistic regression analysis showed that patients with high CRP levels were significantly less likely to achieve PASS, and HAQ ≤0.5 was associated with achieving PASS.

In recent years, the benefit of early diagnosis and early active treatment of patients with PsA has been discussed in the rheumatology community [20]. In this regard, the most interesting result, from our point of view, is the identification of the association between the achievement of short-term goals of the T2T strategy and HRQoL in the long term.

In the present study, achieving MDA in the first 12 months of T2T-based therapy in early PsA was associated with the presence of PASS after 7 years of follow-up. These data are consistent with the results of S.V.J. Snoeck Henkemans et al. [21], who demonstrated the association between rapid achievement of MDA and better PROs (pain, HRQoL, etc.) after 3 years of follow-up. K. Wervers et al. [22] also note that patients who achieved MDA very early (in the first 3 months of therapy) had more favorable HRQoL indicators than patients who achieved MDA at a later date.

Structural damage to the joints of the hands and feet in PsA can lead to functional impairment and poor HRQoL [23]. According to our data, patients who achieved PASS had significantly less pronounced radiographic changes in the joints (fewer erosions at the onset of the disease and after 5 years, fewer narrowed gaps and TSS).

Conclusion. Despite the growing interest in assessing HRQoL in patients with PsA during a long course of the disease, as well as the impact of the T2T strategy on the quality of life of patients, few studies have been published that address this issue. Further studies, including larger cohorts of patients, are needed to gain a more precise understanding of the impact of PsA on HRQoL. These data can be used to predict treatment outcomes in patients with PsA.

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Tremaskina P.O. https://orcid.org/0000-0003-4005-1745
Korotaeva T.V. https://orcid.org/0000-0003-0579-1131
Loginova E.Yu. https://orcid.org/0000-0001-6875-4552
Glukhova S.I. https://orcid.org/0000-0002-4285-0869
Lila A.M. https://orcid.org/0000-0002-6068-3080