ORIGINAL INVESTIGATIONS

Patient satisfaction with health status in rheumatoid arthritis based on remote assessment: a pilot OPTIMA study (Patient-reported Outcomes, Severity and Medical care in Arthritis)

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Leading Russian and international experts recognize the necessity of incorporating patient-reported outcomes (PROs) into the dynamic monitoring of rheumatoid arthritis (RA) patients. An integral indicator of general well-being and treatment satisfaction is the Patient Acceptable Symptom State (PASS).

Objective: *To assess patient satisfaction with their health status and treatment outcomes in RA and to evaluate its relationship with key disease manifestations through remote PROs assessment.*

Material and methods. *From January 2023 to November 2024, an online survey was conducted involving 2,115 RA patients (88.3% women, mean age 46.4±13.9 years, median disease duration 6 [3; 13] years). The survey assessed demographics, therapy, PASS, and PROs (pain, fatigue, anxiety, depression, daily activity limitations, patient global assessment [PGA], using a numerical rating scale [NRS], 0–10). Among respondents, 80% were receiving conventional synthetic disease-modifing antirheumatic drugs (DMARDs), 23.8% biologic DMARDs (bDMARDs) or Janus kinase inhibitors (JAKi). Glucocorticoids (GCs) were used by 39.7%, and nonsteroidal anti-inflammatory drugs (NSAIDs) by 67.9% of patients.*

Results and discussion. *A positive assessment of their health status (PASS+) was reported by 45.8% of patients. Mean NRS scores were: pain – 5.6±2.7, fatigue – 6.2±2.7, PGA – 5.5±2.5, median anxiety – 5 [3; 8], depression – 5 [2; 7], daily activity limitations – 5 [3; 7]. Dissatisfaction (PASS-) was associated with male gender, moderate (≥4) or high (≥7) NRS PRO scores, and the use of GCs and NSAIDs. bDMARD and JAKi therapy showed an inverse association with PASS-. A binary logistic regression model was developed to predict PASS- in RA patients with an accuracy of up to 71%. ROC curve analysis revealed a threshold value of the logistic function P at 49.6%, area under the curve (AUC) – 0.740 (95% CI 0.718–0.762), model sensitivity – 82%, specificity – 60%.*

Conclusion. *Fewer than half of RA patients were satisfied with their health status when assessed remotely. PASS is closely associated with PROs and may serve as an integral indicator of health status and treatment satisfaction in RA.*

Keywords: *rheumatoid arthritis; remote assessment; patient acceptable symptom state; patient-reported outcomes; pain; fatigue; daily activity limitation; depression; anxiety.*

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TheF modern concept of rheumatoid arthritis (RA) therapy, "Treat to Target," involves prescribing Disease-modifying antirheumatic drugs (DMARDs) as early as possible and regularly monitoring their effectiveness with an assessment of standard disease activity indices. However, the patient's opinion about the effectiveness of the treatment and the key parameters of the health assessment may differ significantly from the position of the doctor. Thus, according to a survey of patients with RA in the Netherlands, Great Britain, Austria, Denmark, France and the USA [1], the most important health parameters and criteria for successful therapy are the absence or low level of pain and fatigue, independence and physical activity. At the same time, a series of studies has shown that approximately one third of patients who achieved the standard indices (Disease Activity Score 28, DAS28; Clinical Disease Activity Index, [CDAI]; The Simplified Disease Activity Index [SDAI]) of remission or low activity of the disease continue to experience pain, fatigue, morning stiffness, anxiety, depression and functional disorders [2–4], which determines the need to include patient-reported outcomes (PROs) in the dynamic monitoring of health status and therapy effectiveness [5]. For this purpose, standard validated questionnaires are used to study individual parameters, such as the Hospital Anxiety and Depression scale (HADS), scales for assessing fatigue (Functional Assessment of Chronic Illness Therapy – Fatigue, FACIT-F; Fatigue Severity

Scale, FSS) and functional disorders (Health Assessment Questionnaire Disability Index, HAQ-DI) and others, multidimensional health assessment questionnaires (Routine Assessment of Patient Index Data 3, RAPID 3; European Quality of Life Instrument, EQ-5D; Medical Outcomes Study-Short Form 36, SF-36), as well as universal scales (visual analog scale, VAS, numerical rating scale, NRS) for assessing pain, general health, and disease activity. The assessment of the patient's overall well-being (patient acceptable symptom state, PASS) proposed by the OMERACT group (Outcome Measures in Rheumatoid Arthritis Clinical Trials) seems to be very useful [6–9]. This parameter, which is closely related to both PROs and disease activity (assessed by the standard DAS28, SDAI, and CDAI indices) is an integral indicator reflecting the patient's point of view on disease activity and subjective perception of the treatment outcome. It can be used in routine clinical practice, including for remote dynamic monitoring of patients. The COVID-19 pandemic has given a powerful stimulus to the development of remote technologies in medicine. The experience gained in this area shows that telemedicine surveillance provides valuable information about the patient's health status, reduces the need for visits to the doctor, and improves interaction between doctor and patient [10–12]. However, only a few studies have been conducted in Russia to assess patients' opinion about their condition and the effectiveness of treatment. Therefore, it was decided to identify the most significant indicators related to the satisfaction of RA patients with their condition, and thus optimize the tactics of remote monitoring.

The aim of the study was to assess patient satisfaction with their health status and treatment outcomes in RA and to evaluate its relationship with key disease manifestations through remote PROs assessment.

Material and methods

The study included 2,115 patients with RA who completed an online survey on the website of V.A. Nasonova Research Institute of Rheumatology (https://rheumatolog.su/) and those who filled out an electronic questionnaire (electronic questionnaires were sent out by the Public Organization of the Disabled People "Russian Rheumatology Association "Nadezhda") in the period from January 2023 to November 2024.

The criteria for inclusion in the study were: age over 18 years; RA diagnosis established by a rheumatologist (in accordance with criteria adopted by the Association of Rheumatologists of Russia); patient's consent to participate in a survey conducted as part of the OPTIMA study.

Criteria for non-inclusion: refusal to participate in the online survey.

The survey was completely anonymous, and there was no need to provide a name, phone number, or email address. Filling out the questionnaire took no more than 5-10 minutes. During the survey, patients noted their gender, age, duration of the disease, medications used to treat RA, and assessed their satisfaction with their condition using the PASS (the patient answered "Yes" or "No" to the question: "Do you consider your condition acceptable, given the pain, dysfunction, and other symptoms associated with the lesion of the joints?"). The main PROs (pain, fatigue, anxiety, depression, daily activity, patient global assessment, PGA) were assessed over the past 2 weeks using NRS values from 0 to 10, where 0 is the absence of a problem, and 10 is the maximum severity of a symptom that can be imagined.

The majority of patients were middle-aged women (88.3%) (46.4±13.9 years); the median duration of the disease was 6 [3; 13] years; 83.9% of patients received disease-modifying antirheumatic drugs (DMARDs), 80% of patients used conventional synthetic DMARDs (csDMARDs). Biological DMARDs (bDMARDs) and JAK inhibitors (JAKi), in combination with sDMARDs were used by 19.9% of patients; 3.9% of patients used them as monotherapy. Glucocorticoids (GCs) were taken by 39.7% of the respondents, nonsteroidal anti–inflammatory drugs (NSAIDs) – by 67.9% (Table 1). |

Table 1. Clinical and demographic characteristics and therapy (n=2115)

Indicator	Value
Gender:	
female/ male, n (%)	1868 (88.3)/247 (11.7)
Age, years, M±SD	46.4±13.9
Disease duration, years, Me [25; 75]	6 [3; 13]
Therapy, n (%):	
csDMARDs	1692 (80.0)
MTX	948 (44.8)
LEF	290 (13.7)
SSZ	197 (9.3)
GKH	93 (4.4)
csDMARDs combination	164 (7.8)
bDMARD:	504 (23.8)
TNFi	124 (5.8)
IL-6i	93 (4.4)
RTM	150 (7.1)
ABA	47 (2.2)
JAKi	90 (4.3)
GCs	840 (39.7)
NSAIDs	1437 (67.9)

Note. MTX – methotrexate; LEF – leflunomide; SSZ – sulfasalazine; HCQ – hydroxychloroquine; TNFi- Tumor necrosis factor inhibitors; IL-6i - interleukin-6 inhibitors; RTM – rituximab; ABA – abatacept, JAKi – JAK-inhibitors.

Statistical data analysis was performed using the Statistica 10 for Windows program (StatSoft Inc., USA). For the normality testing of the distribution function the Kolmogorov–Smirnov criterion was used. Parametric data were expressed as mean and standard deviation (M±SD), for nonparametric data median with the interquartile interval (Me [25th: 75th percentile]) were used. The Student's t-tests was used in the comparative analysis of quantitative indicators. In the case of non-compliance with the normal distribution law, quantitative indicators were analyzed using the Mann–Whitney U-test. The statistical significance of the differences in qualitative indicators was determined by the χ^2-Pearson criterion. To assess the impact of various factors on patient satisfaction with their condition, the Odds Ratio (OR) was calculated with the corresponding 95% confidence interval (CI) using regression analysis, a predictive model was formed using binary logistic regression. The differences at $p<0.05$ were considered statistically significant.

This study was approved by the local Ethics committee of V.A. Nasonova Research Institute (Protocol №17 dated 30.09.2021). All patients agreed to participate in the online survey.

Results

According to the survey data, only 45.8% of patients rated their health status related to RA as satisfactory (PASS+). Although

Table 2. Main PROs in RA patients (n=2115)

Indicator	NRS value	Number of patients with NRS score 4, n (%)
Joint pain M±SD	5.6±2.7	1637 (77.4)
Fatigue, M±SD	6.2±2.7	1765 (83.5)
Anxiety Me [25th; 75th percentile]	5 [3; 8]	1475 (69.7)
Depression, Me [25th; 75th percentile]	5 [2; 7]	1283 (60.7)
Restriction of daily activity, Me [25th; 75th percentile]	5 [3; 7]	1499 (70.9)
PGA, M±SD	5.5±2.5	1666 (78.8)

83.9% of patients regularly received DMARDs (including bDMARD and JAKi), most of them continued to complain of moderate to severe (≥4 NRS) joint pain, fatigue, anxiety, depression, and restriction of daily activity (Table 2). It is important to note that 63% of patients experienced joint pain "often or constantly", 31.8% – "sometimes", and only 5.2% of patients had no pain during the last 2 weeks before the survey. However, only 39.3% of respondents reported taking NSAIDs regularly (≥3 times a week), 41.9% used these drugs less than 3 times a week, and 18.8% did not use them.

According to the comparative analysis, patients who were satisfied (PASS+) and dissatisfied (PASS-) with their condition were comparable in age (46.4±13.6 and 46.3±14.2 years, respectively; p=0.91) and disease duration (median 6 [3; 13] and 6 [2; 13] years, respectively; p=0.71). There were more women in the PASS+ group than in the PASS- group (90.0% and 86.9%, respectively; p=0.03), there were lower levels of joint pain, fatigue, depression, and anxiety, less pronounced restriction of daily activity, and better PGA (for all values, p<0.001; Fig. 1).

The factors influencing the dissatisfaction of RA patients with their disease-related condition were analyzed. As it turned out, dissatisfaction (PASS-) was associated with male gender, moderate (≥4) or high (7) NRS PRO scores, and the use of GCs and NSAIDs. bDMARD and JAKi therapy showed an inverse association with PASS- (Fig. 2).

Based on the studied factors, using binary logistic regression, a model was formed that makes it possible to predict PASS- in patients with RA. The highest accuracy (71%) was obtained when the following indicators were included in the model: joint pain ≥4 NRS, fatigue ≥7; anxiety ≥7; PGA ≥4; treatment dissatisfaction (0 – no, 1 –yes), taking GCs and bDMARD/JAKi. The results of a stepwise multiple logistic regression are presented in Table 3.

The obtained predictive model is described by the equation:

$P = 1/(1 + e\text{-}z) \times 100\%$,

where $z = -2.031 + 0.865 \times X_{Pain4} + 0.278 \times X_{Fatigue}\ 7 + 0.1199 \times X_{Anxiety\ 7} + 0.321 \times X_{PGA\ 4} + 1.521 \times X_{Treatment\ dissatisfaction} + 0.186 \times X_{GCs} - 0.253 \times X_{bDMARD/JAKi}$; P is the probability of PASS- in %.

Using the analysis of ROC curves, the threshold value of the logistic function P was adjusted (Fig. 3). The area under the curve (AUC) was 0.740 (95% CI 0.718–0.762). The threshold value of the logistic function is 49.6%, thus, with P values equal to or greater than 0.4955, patients with RA have a high risk of dissatisfaction with their condition. The sensitivity of the model reached 82% at the threshold value used, and the specificity reached 60%.

Discussion

According to our survey of 2,115 RA patients, which reflects real clinical practice, less than a half of the respondents (45.8%) rated their condition as satisfactory, which is consistent with the results of our earlier study. Thus, in the work of A.S. Potapova et al. [13], based on a 6-month follow-up of a cohort of 521 patients with RA (among whom 69.8% received bDMARD/JAKi), 52% were satisfied with their condition (PASS+). In the works of foreign authors, the frequency of PASS + varies from 18.2% to 85%. The lowest estimate of the PASS was given by F. Salaffi et al. [9], who observed 303 patients, and only 18.2% of them had PASS+. According to D. Puyraimond-Zemmour et al. [7], in 531 patients with RA, the incidence of PASS+ was 60.4%, and in the study by T. Heiberg et al. [14] in 1496 patients included in the Norwegian NOR-DMARD registry, it reached 63%. In the work of W. Katchamart et al. [15], 85% out of the 443 patients included in the registers of Thailand considered their condition acceptable. This rather significant discrepancy in indicators may be due to differences in disease activity and the functional status of patients who participated in the studies, as well as to

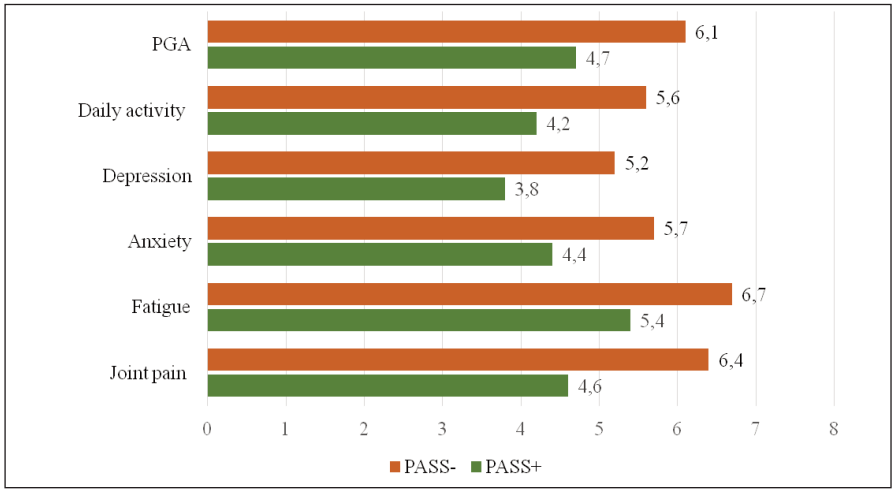

Fig. 1. *PROs in RA patients satisfied (PASS+) and not satisfied (PASS-) with their condition*

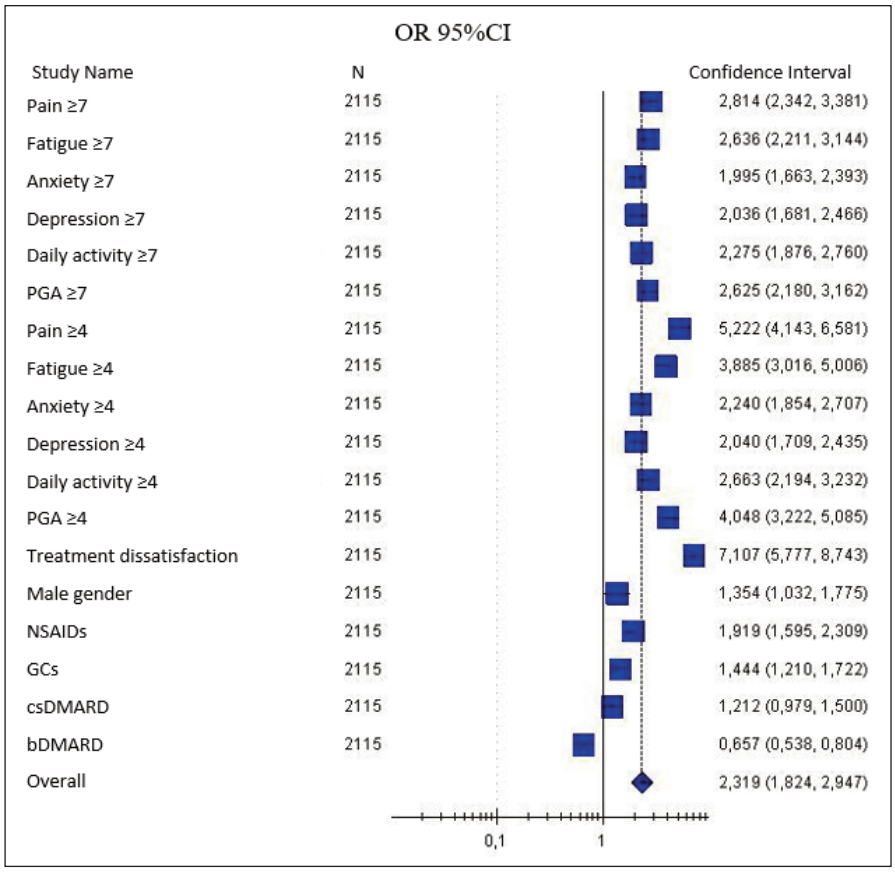

Fig. 2. *Factors associated with dissatisfaction (PASS-) in RA patients*

Table 3. Factors associated with PASS-according to stepwise logistic regression (n=2115)

Indicator		OR	95% CI	P
Pain ≥4, NRS		2.376	1.800–3.137	0.000
PGA ≥4, NRS	1.378	1.033–1.838	0.029	
Fatigue ≥7, NRS	1.320	1.062–1.642	0.012	
Anxiety ≥7, NRS	1.220	0.983–1.514	0.071	
Taking bDMARD/JAKi		0.777	0.613–0.983	0.036
Treatment dissatisfaction		4.575	3.655–5.726	0.000
Taking GCs	1.205	0.983–1.477	0.073	

the socio-cultural and economic characteristics of the assessed populations.

It should also be noted that a higher frequency of PASS+ was noted in the studies in which a larger number of patients received bDMARD/JAKi. The dependence of PASS on the therapy used was also noted in the present study. Thus, the dissatisfaction of patients with RA with their condition was associated with the use of GCs and NSAIDs.

This is especially interesting in the light of the latest recommendations of the Association of Rheumatologists of Russia, EULAR (European Alliance of Associations for Rheumatology) and ACR (American College of Rheumatology), which propose to strictly limit the use of GCs in RA [16]. These drugs are usually prescribed for patients with high inflammatory activity and systemic manifestations of RA. Unfortunately, serious problems arise with their discontinuation in the future – not only because of addiction (steroid dependence), but also because of the fears of attending physicians to cause an exacerbation and deterioration of patients' condition upon discontinuation of GCs. Therefore, in real practice in developed countries, including Russia, GCs are used by 40–50% of RA patients [16]. Our data once again emphasize an important point for practice – GCs do not improve the condition of most patients with RA, but, on the contrary, are associated with poor health and an unsatisfactory assessment of treatment results.

At the same time, bDMARD/JAKi therapy showed an inverse relationship with PASS- i.e., the use of these drugs provided PASS+ in most patients. Similar results were obtained in our previous studies. In the above–mentioned work by A.S. Potapova et al. [13], in patients receiving bDMARD/JAKi, PASS+ was noted in 65% of cases, and in those who did not receive these drugs – only in 33%. According to a telephone survey evaluating the results of the use of bDMARD/JAKi in 254 RA patients during the COVID-19 pandemic, the patients who continued and did

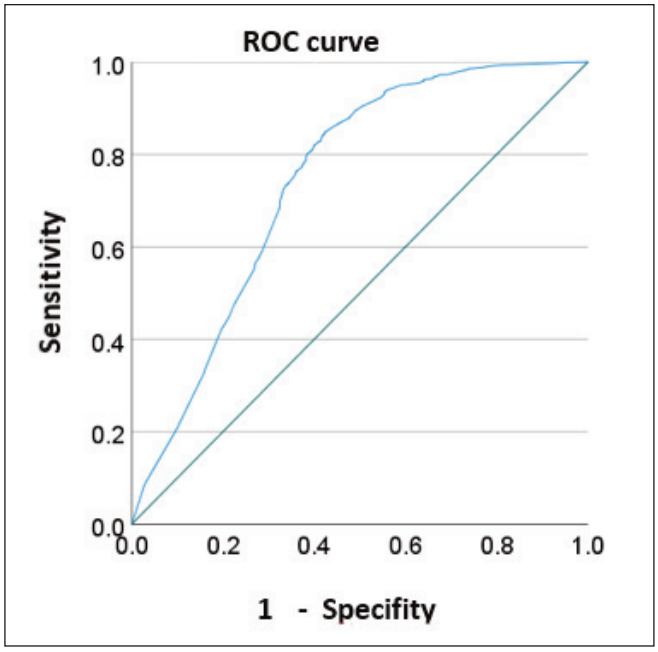

Fig. 3. *ROC curve illustrating the probability of dissatisfaction (PASS-) in RA patients based on predictive function values*

not continue this therapy, demonstrated PASS+ in 68% and 40% of cases, respectively [17].

A number of studies have also reported a significant change in the frequency of PASS+ as a result of treatment. Thus, M.K. Kvamme et al. [18] noted an increase in the proportion of PASS+ from 38% at the initial stage of therapy to 58% after 3 months of follow-up. In the work of L.D. Vorobyeva et al. [19] after 3 and 6 months of JAKi use, the number of patients with psoriatic arthritis who reported PASS+ increased from 25.6% to 66.7% and 71.8%, respectively.

In our study, the relationship between PASS and all the studied PROs was clearly demonstrated, however, the most significant factors associated with patients' dissatisfaction with their condition were joint pain, fatigue, anxiety and PGA. In the works of foreign authors, pain, as well as fatigue, functional disorders, sleep disorders, emotional well–being/ stability, and PGA are mentioned among the factors related to PASS [7, 20–23].

It should also be noted that satisfaction with one's condition significantly depends on the activity of the disease, which was determined using standard indices [14, 21]. T. Heiberg et al. [14] did not reveal PASS- in patients with remission or low disease activity, and S. Duarte et al. [21] reported that 20.2% of patients remained dissatisfied with their condition and noted pain, functional disorders, fatigue, physical and emotional state at the level of 5 points on the NRS. In a study by C. Garufi et al. [23], who analyzed the effectiveness of JAKi, patients with PASS + and PASS – with the same frequency achieved remission/low disease activity at the 4th and 12th weeks of treatment, however, in patients with PASS +, the positive dynamics turned out to be significantly more pronounced. At the same time, all patients who achieved remission according to the Boolean criteria noted PASS + in the first 4 weeks of therapy.

Conclusion. The results of this study allow us to consider PASS an effective tool for assessing the condition of patients with RA, including telemedicine follow-up. Our data highlight the importance of defining PROs as a necessary element for monitoring the results of antirheumatic therapy, including bDMARD/JAKi use.

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