

**CAREFUL MONITORING —THE WAY TO OPTIMIZE THE TREATMENT OF
PATIENTS RHEUMATOID ARTHRITIS**

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ABSTRACT: Goal. To evaluate the dynamics of clinical symptoms of rheumatoid arthritis (RA) and the activity index under careful control in routine clinical practice.

Material and methods. 112 patients with a reliable (according to the criteria of the ACR) diagnosis of RA were observed (88 women and 24 men, average age 37.8 ± 1.9 years). The patients were divided into 2 groups: Group I was observed for 2 years by a rheumatologist in real clinical practice, 1 time every 3-4 months, group II was under the careful supervision of a rheumatologist-researcher (control of NPV, BBS, NEO, VAS pain, ESR level, counting DAS 28 and the functional index according to HAQ) 1 time per month. The reliability of the differences between the groups was assessed using the t-test Student (significant difference at $p < 0.05$).

Results. In group I, 32.8% of patients achieved acceptable activity ($< \text{grade II}$) of RA within 2 years. Remission was registered in 8.6% of cases. Functional activity according to HAQ did not reach the target level (after 12 months — 1.8 ± 0.4 ; after 24 months — 1.7 ± 0.8). In group II ($n=54$), tight control, remission was observed in 47 patients (87%): "induced" in 17 cases (31.5%) and "remission during therapy" — in 30 patients (55.6%). The rate of decrease in all clinical parameters of RA is significantly higher in group II. The changes were noted already by the 3rd month, a significant improvement was achieved by the 6th month ($p < 0.05$), and by the 12th and 24th months this difference is obvious ($p < 0.01$ and $p < 0.001$).

Conclusion. Thus, with careful monitoring, there is a great opportunity for timely and adequate correction of treatment under the control of DAS 28 and HAQ, remission or decrease in RA activity is achieved faster.

Keywords: Rheumatoid arthritis, RA activity index, quality of life, remission, careful monitoring.

INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune rheumatic disease of unknown etiology characterized by chronic erosive arthritis (synovitis) and systemic damage to internal organs. RA is heterogeneous both in terms of disease activity and the degree of bone destruction. This is the most common autoimmune human disease that develops without any apparent connection with infection. Rheumatoid lesions are more often observed in the most mobile joints. It has been shown that the cost of RA treatment is comparable to such is the case with coronary heart disease. The life expectancy of a patient with RA is 10-15 years shorter than in the population. It is the same as in cases of lymphogranulomatosis, type 2 diabetes mellitus and three-vessel coronary artery disease. More than half of the patients become disabled already in the first 5-7 years of the disease. After 20 years from the beginning of

RA, the number of disabled people increases to 60-90%. Back in the early 80s of the XX century, most rheumatologists considered RA as a "benign"

disease, usually controlled by nonsteroidal anti-inflammatory drugs (NSAIDs).

This is how the pyramid of treatment was built. Only in severe RA or the ineffectiveness of NSAIDs, aminoquinoline drugs were prescribed first, and then other basic drugs, including glucocorticoids (HA). However, it has now been proven that early administration of basic anti-inflammatory drugs (HDL) significantly improves the outcome of RA, and therefore RA is considered an "urgent" disease, the clinical signs of the disease are only the tip of the iceberg of a far-reaching immunological imbalance. Back in the 90s of the last century, the concept of early appointment of HDL was put forward (in the first 2 years — during the so-called two-year therapeutic window, "2-year therapeutic window"). Currently, the concept of "window of opportunity" (window of opportunity).

The change in the treatment paradigm made it possible to change the main goal of therapy from relieving clinical symptoms to achieving remission. Since the beginning of the XXI century, the question has arisen what is considered remission, what signs characterize the definition of "remission" (a low degree of RA activity, or its absence, or the absence of radiological progression of articular destruction). Of course, the main goal of treatment is not only to stop signs of RA activity, but also to stop radiological progression. However, it is currently unrealistic in conventional clinical practice to include the radiological progression of RA in the definition of "remission". Comparison of the conducted studies is impossible on the principle of "it seems to me" or "by eye", which is often found among rheumatologists in clinical practice. For this purpose, a single tool for assessing RA activity, the activity index (DAS and DAS 28 modified for clinical practice, etc.) is used. The CAMERA study proved that with careful monitoring, remission is achieved more often, faster and lasts longer. The purpose of our work is to evaluate the dynamics of RA clinical symptoms and activity index under conditions of careful monitoring and routine clinical practice.

MATERIALS AND METHODS OF RESEARCH

The work is based on data from clinical, laboratory and instrumental examination and treatment of 112 patients (88 women and 24 men) with a reliable (according

to the criteria of the ACR) diagnosis of RA. The average age of the patients was 37.8 ± 1.9 years (from 17 to 68 years). The duration of RA is 10.5 ± 4.4 years (from 6 months to 23 years). The diagnosis was established on average 2.3 ± 1.6 years after the onset of the disease (from 3 months to 4 years). In the formulation of the diagnosis, the domestic classification adopted at the plenary session was used

Associations of Rheumatologists. The joint configuration was assessed during the examination (swelling, defiguration, deformation), were determined BBS and BPS — a total of 28 joints. RA activity was assessed by the DAS 28 index, which was calculated in points: >5.1 — high (III) RA activity; $3.3—5.1$ — medium (II) activity; $2.6—3.2$ — low (I) RA activity; the index corresponded to remission <2.6 . The quality of life of RA patients was assessed using the HAQ questionnaire. The minimum value of the HAQ functional

index could be zero, the maximum - 3 points. In addition to NSAIDs, patients were offered HDL, after that, the patient signed an informed consent to participate in this study. The management tactics of the RA patient was standard and consistent with clinical recommendations. After clarifying the diagnosis and determining the prognosis, the first—line drugs were MT (starting dose of 10 mg / week followed by escalation) in combination with folic acid or leflunomide (100 mg / day for the first 3 days, then 20 mg / day). If treatment was ineffective, therapy with a combination of MT with leflunomide or other HDL was performed. Statistical processing of research results it was carried out using an application software package Microsoft Excel, version 11.0, 2005, Statistical for Windows, version 6 on a Pentium 4 type PC. Standard parametric criteria (Student's t-criterion) were used. The reliability of the differences between the groups when comparing continuous quantitative parameters was assessed using the Student's t-test. The difference in values of 95% was taken as reliable at $p < 0.05$.

THE RESULTS AND THEIR DISCUSSION

All patients ($n=112$) were divided into two groups. Group I ($n=58$) was observed by a rheumatologist at the polyclinic without monitoring the RA activity index and without additional interventions by the researcher (real clinical practice) according to the standards of management of a patient with RA. The rheumatologist carried out the correction of treatment according to the patient's treatment, on average 1 time in 3-4 months. The analysis of the patient's management was carried out according to outpatient charts. In group II ($n=54$), monitoring was carried out by a rheumatologist researcher on a monthly basis with monitoring of RA activity

according to DAS 28. The calculation of BBS, NPV, NEOS (according to YOUR) was carried out, quality of life according to HAQ and clinical tests (general blood analysis, biochemical blood tests). In addition to visits, group II patients had the opportunity to consult with the researcher by phone. The condition of patients in group II was more severe than in group I. Higher levels of ESR and pain intensity (according to YOUR) were revealed. The number of swollen and painful joints was initially higher. They had significantly higher average RA activity according to DAS 28. The quality of life according to the HAQ of this group is significantly lower. Group I patients received the following therapy: 40 patients (69.0%) — MT, the dose of which varied from 12.5 up to 15 mg /week, with folic acid, 8 people (13.8%) received combination therapy (MT + sulfasalazine), in 3 cases (5.2%) a combination of glucocorticoids (HA) and NSAIDs, as well as infliximab at a dose of 3 mg / kg weight were used bodies (according to the protocol); 2 patients (3.4%) were treated with prospidin and 1 (1.7%) with delagil + NSAIDs. Of group II, in 23 patients (42.6%), HDL therapy changed. In 17 patients (31.5%), the dose of MT was increased to 20 mg Parenterally, once a week, in 6 cases (11.1%), a combination of MT at a dose of 20 mg / week and leflunomide (arava) 10 mg / day was treated. The treatment lasted for 2 years. Thirty-one patients (57.4%) with the ineffectiveness of the therapy with first-line drugs of HDL GIBP was prescribed: 22 patients received infliximab at a dose of 3 mg/kg of body weight and 9 people received rituximab 2000 mg according to the protocols for the management of severe RA patients. The most severe were 31 patients (57.4%) who were transferred to high-tech treatment of GBS. As can be seen from Table 3, reflecting the clinical characteristics of patients with the appointment of infliximab and rituximab, this was the most severe group of middle -aged patients (44.5 ± 4.7 years), the majority were women,

the diagnosis of RA was verified 2.7 years after the onset of symptoms. All patients received HDL: 18 people received MT at a dose of 7.5 to 20 mg / week (average dose 12.7 ± 1.2 mg / week), 4 people received leflunomide at a dose of 20 mg / day. In 6 cases , systemic GC was added to the treatment. The duration of therapy before the appointment of infliximab was 22.6 ± 1.3 months. The patients had a high degree of RA activity: pain by YOURS was up to 85.4 ± 3.8 mm, morning stiffness lasted 234.5 ± 32.8 minutes. The disease occurred with polyarthritis and extraarticular manifestations in most patients.

High inflammatory activity was indicated by such indicators as BBS, BPS, ESR level, RA activity index. In patients of group I, the dose of MT was adjusted (increased to 15 mg/ week). The therapy was carried out in combination with sulfasalazine, GK, in 3 cases, patients were transferred to infliximab. After 3 months of treatment, only 1 patient achieved remission. By 12 months, this number had grown to 5 people (significantly higher compared to the initial data). During monitoring, it turned out that by 6-12 months , the number of patients with a high degree of activity significantly decreased. By 24 months, a decrease in the number of patients with high activity was revealed to 19 (by 5.5%). On the contrary, the number of patients with a minimal degree of activity increased by 13.8%, i.e. it was observed in 14 cases. In group I, the number of patients with a high degree of DAS 28 activity significantly decreased only by 24 months of treatment, a significant increase in the number of patients with the achieved target level of DAS 28 <3.2 and remission was also noted by 24 months. Nevertheless, only 32.8% of patients reached the level of acceptable RA activity within 2 years. Remission was registered in 8.6% of cases. The level of quality of life also did not reach the target value. So, according to our data, HAQ after 12 months was 1.8 ± 0.4 ; after 24 months — 1.7 ± 0.8 , although its change turned out to be statistically significant.

In group II (n=54), in which monthly monitoring (tight control) was performed with the calculation of the activity index and appropriate treatment correction,

a low level of activity (DAS 28 <3.2) was achieved in all patients. Remission was observed in 47 patients (87%): "induced" in 17 cases (31.5%) and "remission during therapy" in 30 patients (55.6%). Drug-free remission (drug-free remission) was not observed. The remaining patients (13%) showed a low level of RA activity. Against the background of the therapy, after 6 and 12 months, pain significantly ($p<0.01$) decreased (both according to the doctor's assessment and according to the patient's assessment), morning stiffness (after 6 months — by 2 times, after 12 months — to the target value of 30 minutes), the activity of RA decreased significantly DAS 28. By 12 and 24 months, the number of painful and swollen joints significantly decreased, after a year, no swollen joints were found. The average value of the ESR decreased to 12 mm/h. Accordingly , the activity index has normalized. The quality of life significantly improved ($p<0.0001$): the functional index according to the HAQ questionnaire decreased to 0.38 ± 0.02 . The analyzed group did not include 2 patients who developed pulmonary tuberculosis after the 6th and 7th infliximab infusions. In 3 patients after achieving remission after 1 A year of follow-up, refractoriness to infliximab was noted, and therefore patients were transferred to rituximab. Despite the improvement in laboratory parameters and rapid CD19 depletion, significant clinical improvement was obtained only by 3 months of rituximab therapy, which continued to grow by 6 months. The NPV decreased faster than CHBS. By 3 months, the average pain indicators for VAS decreased to 28.7 ± 0.6 mm, ESR to 23.4 ± 1.2 mm/h. Software activity

DAS 28 significantly decreased to 4.1 ± 0.9 , which led to a decrease in the functional HAQ index to 0.9 ± 0.2 . By 12 months, the DAS 28 index corresponded to remission — 2.2 ± 0.2 , the HAQ index ranged from 0 to 1.5. All patients continue to work and consider themselves practically healthy. NSAIDs are taken in the "demand" mode — on demand. Two patients receive leflunomide at a dose of 20

mg / day, the rest receive MT 10 mg / week with folic acid. Comparison of functional activity by HAQ and NEO by 6-12 months in two groups of outpatient follow-up shows that in the absence of the target achievement of DAS 28 < 2.6 , the quality of life was significantly worse in group I (n=58) compared with group II (n=54), and the best indicators were obtained when using GIBP (n=31). The comparative dynamics of the main clinical indicators, laboratory data, RA activity and quality of life of patients of the two groups are presented graphically in Fig.

3, from which it follows that the rate of decline of all clinical data on RA activity (NPV, BBS, pain according to VAS), laboratory data (ESR level), DAS 28 activity and functional status according to HAQ are significantly higher in group II. Positive changes were noted by 3 months, significant improvement was achieved by 6 months ($p < 0.05$), and by 12 and 24 months this difference was obvious ($p < 0.01$ and $p < 0.001$). In group II, all average indicators practically returned to normal, which convincingly proves the effectiveness of using the method of careful monitoring during the treatment of RA patients.

CONCLUSIONS

Thus, for the management of newly diagnosed RA patients (especially during the "window of opportunity" period), first of all, training is required, and then observation of the patient in an intensive mode with the calculation of disease activity according to DAS 28 and the functional index according to HAQ, not only in inpatient conditions, but also in outpatient practice, which leads to reducing the activity of the disease, significantly improving the quality of life of patients and adherence to treatment. "The main task (of domestic rheumatologists) The goal is to introduce these achievements into clinical practice as soon as possible, creating conditions under which new medical technologies will be available to the population of our country" .

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