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Research Article

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Comparative Efficacy of Lefno in the Treatment of Rheumatoid Arthritis

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Abstract In the treatment of rheumatoid arthritis (RA), it is recommended to use methotrexate or leflunomide as the first synthetic basic anti-inflammatory drug. The study included 27 patients from February to November 2019.According to the instructions for use, LEFNO was prescribed in the first 3 days at 100 mg / day, then at 20 mg / day. During the visit to the doctor, the number of painful, swollen joints, the severity of pain was assessed using a visual analogue scale (VAS); carried out laboratory examination: clinical blood test, determination of ESR and CRP level. RA activity was judged by the DAS 28 index. For 6 months. on therapy with LEFNO the average number of swollen joints decreased from 11.7 to 4.1, and the number of painful joints - from 12.7 to 8.5; the intensity of pain according to the VAS decreased on average from 72.3 to 32.1 mm; ESR - from 41.5 to 25.8 mm / h, CRP - from 28.9 to 14.5. The study did not reveal any serious side effects of the drug. The drug was discontinued only in 3 patients: in 1 due to the development of adverse events, in 1 due to insufficient efficacy, and in 1 for non-medical reasons.

Thus, we can conclude that the results obtained in patients with rheumatoid arthritis indicate a fairly high clinical efficacy of the drug LEFNO. Allows you to achieve a rapid clinical response, which may be of particular interest for general clinical practice.

Keywords rheumatoid arthritis; LEFNO (leflunomide)

Introduction

The progression of rheumatoid arthritis (RA) leads to the generalization of the pathological process by involving new joints and extra-articular structures, the formation of irreversible changes and resistance to therapy. RA therapy has undergone significant positive changes in the current century. First of all, this applies to the early administration of drugs that can prevent the development of destructive changes in the joints and systemic manifestations of the disease caused by autoimmune inflammation [1].

In 2010, the European Anti-Rheumatic League (EULAR) published recommendations on the use of synthetic and biological disease-modifying drugs in RA, in which the goal of therapy is designated as achieving remission or low disease activity, which requires not only the appointment of an adequate drug, but also careful monitoring of disease activity [2, 3]. As the drug of choice for RA patients who have not previously received basic anti-inflammatory drugs (HDL), EULAR experts recommend using methotrexate (MT) in optimally high tolerated doses (20-30 mg/week). An alternative to it is leflunomide (LF), sulfasalazine, hydroxychloroquine or their combinations. LF was introduced into clinical practice much later than MT, but the results of numerous randomized clinical trials have shown the comparability of these drugs in terms of efficacy and tolerability (4).

In 2012, the drug LEFNO (leflunomide, KusunHelskare, India) was registered and approved for use in Uzbekistan. (UA registration certificate/6367/01/02 from 24.10.2012).

The aim of this observational study was to evaluate the efficacy and tolerability of LEFNO in clinical practice in patients with RA.

Material and Methods

The study included patients who met the classification criteria of RA in 1987, with different disease duration. 27 patients were observed from February to November 2019. According to the instructions for use, the drug LEFNO was prescribed for the first time for 3 days at 100 mg / day, then at 20 mg / day. In case of adverse events, it was recommended to reduce the daily dose to 10 mg. Patients were examined before prescribing the drug, as well as after 1, 3 and 6 months of treatment. During the visit to the doctor, the number of painful, swollen joints, the severity of pain were evaluated using a visual analog scale (VAS); laboratory examination was performed: a clinical blood test, determination of ESR and CRP levels. RA activity was judged by the DAS28 index.

The statistical processing included data from 27 (20 women and 7 men) patients, whose average age was 48.1± 9.1 years, and the average duration of the disease was 3.5 years. The activity of the disease was moderate in 3 patients and high in 24. 15 patients had II and 9 – III X-ray stage of the disease. 16 (59.3%) patients were found to be positive for rheumatoid factor (RF) and antibodies to cyclic citrullinated peptide.

Patients were examined before treatment and then every 3 months. Determined by the severity of the arthralgia, the number of painful joints (CHBS), number of swollen joints (NPV), overall assessment of the health status of patients (Sz), overall assessment of disease activity by the physician (AOAV), erythrocyte sedimentation rate, number of leukocytes, number of platelets. The main indicator of the effectiveness of treatment was the ACR criteria.

Prior to inclusion in the study, patients received HDL: MT-13 (48.2%), sulfasalazine -5 (18.5%), LF – 9 (33.3%), as well as nonsteroidal anti–inflammatory drugs -22 (81.5%) and glucocorticoids-5 (18.5%). The effectiveness of treatment was evaluated by DAS28 and CDAI.

Statistical data processing was performed using standard methods of descriptive statistics using the statistical processing package Statistica 6.0.

Results of the Study

During 6 months of therapy with LEFNO, the NPS decreased on average from 11.7 to 4.1, and the NPS-from 12.7 to 8.5. The intensity of VAS pain decreased on average from 72.3 to 32.1 mm. Laboratory parameters reflecting the activity of the inflammatory process, also have undergone statistically significant changes: erythrocyte sedimentation rate decreased on average from 41.5 to 25.8 mm/h, CRP levels – from 28.9 to 14.5 mg/l (table. 1).

The effectiveness of drug therapy LENO is confirmed by the dynamics of the indices of RA activity is the mean value of DAS28 decreased from 6.03±of 1.05 to 4.02±1.35 ($p<0.0001$), CDAI – from 42.22±14.02 to 30.29±18.42 ($p<0.0001$).

The number of patients with low and moderate activity increased significantly during treatment and after 6 months was 58 for DAS28 and 42 for CDAI. The results obtained indicate a fairly high clinical efficacy of the drug LEFNO (Table 2).

An important task of the study was to assess the safety of the drug, which turned out to be high: no significant deviations from the norm of laboratory parameters and blood pressure (BP) were observed.

During the study, no pronounced adverse events were noted. Non-serious adverse events were recorded in 5 (18.5%) patients: nausea (in 2), dyspepsia (in 1), increased blood pressure (in 1), increased liver enzymes (in 1), urticaria (in 1), hair loss (in 1). These changes were observed mainly by the 2nd visit. All of them had a mild or moderate degree of severity. The drug was discontinued in only 3 patients: 1 due to the development of adverse events, 1 due to insufficient effectiveness and 1 for non-medical reasons.

Table 1: Dynamics of RA activity according to DAS28 for 6 months of therapy with LEFNO

Activity by DAS28	Before therapy	At the time of completion of the study
Low	0	5 (18,5)
Moderate	5 (18,5)	16(59,3)
High	22(81,5)	6 (22,2)

Note. In parentheses – indicators as a percenta; $p<10^5$.

The frequency of adverse events in this study was close to the previously obtained data [3,5,6]. The results of this study indicate a fairly high clinical efficacy and tolerability of the drug LEFNO.

The most favorable conditions for its treatment are available at the beginning of the disease in patients who have not received basic anti-inflammatory therapy. Therefore, the solution of practical issues of medical care for patients with early stage RA is very relevant. It is necessary to decide as soon as possible whether there are basic anti-inflammatory drugs

(HDL) should be used in patients with verified RA or with a real risk of developing it. At the first stage of therapy, conventional HDL is usually preferred. Until recently, methotrexate was the gold standard of treatment for such patients. However, the latest guidelines from the American College of Rheumatology on the use of biological and non-biological BAIDs recommend giving MT leflunomide (LF) at the discretion of the physician. The standard scheme of LF administration in metered doses allows to ensure the therapeutic concentration of the drug in the blood only during the first week of therapy and a noticeable clinical improvement during the first month.

Thus, the appointment of a standard treatment regimen for LEFNO (leflunomide, KusunHelskare, India) allows for a rapid clinical response, which may be of particular interest to a wide clinical practice. LF acts much faster than other conventional HDLs may be of particular interest in the treatment of RA.

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