

**SEVERITY INDEX IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS**

Uralov Rustam Sherbekovich
Eshmuratov Sardor Eldorovich
Samarkand State Medical University, Samarkand, Uzbekistan

Abstract

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with multiple organ damage and variable symptoms. SLE is characterized by alternating periods of stable condition (remissions) and active manifestations (exacerbations). Assessment of activity and identification of prognostically unfavorable factors is the main task in monitoring patients with SLE, however, the "golden the standard" has not yet been developed. Existing methods determine either the activity of SLE at the time of examination and the dynamics of this parameter during observation and treatment, or the development of irreversible damage. The assessment of the severity index (IT) of the disease allows you to combine all the components.

The aim of the study was to assess the clinical significance and prognostic informativeness of IT in patients with SLE.

Material and methods. 146 male patients with a reliable diagnosis of SLE aged 15 to 64 years, observed over a 15-year period, were analyzed. The patients underwent a generally accepted clinical, laboratory and instrumental examination using standard methods for assessing the activity of the disease. To characterize the course and outcomes of SLE, IT and the SLICC/ACR Damage Index (SDI) were used. IT and damage index for the 1st, 5th, and 10th years of the disease were analyzed in dynamics in 133, 91, and 63 patients, respectively.

Results. Significant correlations were found between IT at the time of activation and indicators reflecting the course and activity of SLE. The analysis of IT dynamics showed that during the first 5 years of the disease, its maximum increase was observed in patients with SLE onset age <20 years. In combination with SLE and secondary antiphospholipid syndrome, there was a more pronounced increase in IT compared to patients who did not have such disorders. The highest survival rates were observed in patients with "early" IT equal to 0.

Conclusion. IT is a good indicator reflecting the "accumulated" activity of the disease. It increases with an increase in the prescription of the disease, while its increase can occur at any stage of the disease. This dynamics depends on the course of the disease, the timing of diagnosis, and concomitant pathology. IT correlates well with the indicators of activity and damage traditionally used in SLE, as well as the frequency of exacerbations of the disease, which indicates the possibility of using IT as a prognostic marker.

Keywords: systemic lupus erythematosus; monitoring of patients; assessment of activity and damage; severity index; prognosis.



Introduction

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with a multi-organ lesion and a variable course. The symptoms are extremely diverse, the clinical picture of each patient is individual, therefore SLE is called a "multifaceted disease". The course of SLE is characterized in most patients by alternating periods relative to stable condition and recurrence of activity and is often unpredictable. SLE was previously considered a fatal disease, but in the 21st century, against the background of the use of modern treatment methods, the development of complete and persistent remission is often recorded. Recent advances in treatment have significantly increased the survival rate of patients with the most severe and life-threatening manifestations. At the same time, the percentage of irreversible damage to internal organs is quite high due to both the disease itself, as well as the ongoing therapy. The problem of reducing life expectancy and quality of life has not lost its relevance – some patients develop severe exacerbations or concomitant conditions leading to death or permanent disability. The cornerstone of patient curation and the development of new treatments for SLE is patient monitoring. At the same time, rheumatologists constantly need to evaluate current activity with mathematical accuracy, analyze the course of the disease and predict outcomes.

It differs from the activity indices. The latter represent an assessment of the patient's condition at the time of examination, whereas OT reflects the cumulative activity of the disease and the fact of damage to vital organs and systems such as the kidneys and central nervous system.

According to the authors of the index, it may also be useful in studying the influence of demographic and socio-economic factors on the course of SLE and in comparing the characteristics of the disease in different groups. We managed to find the only job in which the assessment of IT SLE in men and women was carried out. When comparing 18 men and 36 women, who did not differ in age, duration of the disease and ethnicity, IT was found in men higher than that of women. Male patients had a higher frequency of some parameters included in IT, compared with women: proteinuria (78 and 53%), increases in creatinine (50 and 31%), lesions Central nervous system (28 and 3%) and lungs (11 and 3%). More than 7 criteria ACR during the disease period was observed in 39% of men and 19% of women. Antibodies to cardiolipin and venous thrombosis in male patients with SLE were recorded more often, than in women (56 and 28%; 31 and 6%, respectively). The authors themselves noted that due to the small number of patients and the retrospective analysis of the group, it is too early to draw final conclusions, and only a prospective study of a sufficient number of patients included in the onset of the disease can be considered ideal for studying the issues of sexual dimorphism of SLE (including disease variants).

The above-mentioned study did not address a number of issues. How did IT correlate with the traditionally used indices of disease activity? What predictive value can this index have? Allows can IT solve the issue of the need to change or intensify therapy? Having a sufficiently large group of patients SLE, traced over a long period, we calculated IT at various stages of the disease, determined its correlation with the parameters of SLE activity and tracked its dynamics during the disease.



MATERIALS AND METHODS OF RESEARCH

The study included 146 male patients aged 15 to 64 years who were followed up over a 5-year period. All patients met the ACR diagnostic criteria.

The patients underwent a generally accepted clinical, laboratory and instrumental examination using standard methods. The activity of SLE was determined according to the classification of V.A. Nasonova and using the SLEDAI-2K and SLAM indices. To assess the course and outcomes of the disease, OT and the SLICC/ACR Damage Index (SDI) were used. OT and SDI for the 1st, 5th, 10th years of the disease were analyzed in dynamics in 133, 91 and 63 patients, respectively. The survival rate of patients was assessed using the Kaplan–Meyer method. Statistical data processing was carried out using the Statistica 6.0 application software package, the results are presented in the form of $M \pm SD$, differences were considered statistically significant at $p < 0.05$.

THE RESULTS AND THEIR DISCUSSION

Correlation of the severity index with the features of the clinical picture of systemic lupus erythematosus at the time of inclusion. At the time of inclusion, the group was dominated by patients with IT 1-4 points (73.3%), the average IT in the whole group was 3.29 ± 1.85 points. Low IT values (0-2 points) were recorded in 52 (35.6%), moderate (3-5 points) – in 74 (50.7%), high – in 20 (13.7%) patients. Patients with high IT (6-8 points) had a younger age of disease onset than patients with low and moderate IT values.

A significant correlation between IT and the moment of activation and indicators reflecting the course and activity of SLE: age of onset of the disease ($r = -0.24$; $p < 0.01$), duration of the disease ($r = 0.19$; $p < 0.05$), the number of ACR criteria for the period of the disease ($r = 0.46$; $p < 0.001$), SLAM indices ($r = 0.42$; $p < 0.001$), SLEDAI ($r = 0.46$; $p < 0.001$), SLICC ($r = 0.43$; $p < 0.001$), as well as the number of exacerbations (4.23 ± 2.48 ; $r = 0.3$; $p < 0.05$). Association of the "early" severity index with the parameters of systemic lupus erythematosus. In the first year of the disease, 58 (39.7%) patients had IT equal to 0 (group 1), 61 (41.8%) had 1-2 points (group 2), 27 (18.5%) had 3 points or more (group 3). Patients with the highest IT values (≥ 3 points) in the first 12 months of the disease had a shorter duration of the disease before diagnosis, a high incidence of acute SLE, a lower frequency of secondary AFS (which indirectly reflects the rarity of chronic SLE in this group), higher damage index values in the first year of the disease and higher rates lethality in the future. The dynamics of the severity index.

According to the criteria, IT may increase over time (which occurs with the development of exacerbations of the disease and primarily with the involvement of new organs in the pathological process) or remain unchanged (with the development of persistent remission of SLE). Both took place in our group. However, an increase in IT could be observed at any time of the disease. The absolute majority of patients in the group received immunosuppressive therapy aimed at suppressing the activity of the disease and achieving remission. This explains a fairly large percentage of patients whose IT did not change during the observation process. However, in some cases, even against the background of ongoing therapy, exacerbations were noted and an increase in IT was recorded, which is well consistent with the unpredictability of the course characteristic of SLE and the possibility of involving new organs in the pathological process at any stage of the disease. It should also be noted that during the first 5 years of the disease, the maximum increase in IT was observed in young patients with the age of SLE onset < 20 years. With a combination of SLE and secondary AFS, there was also a more pronounced increase in IT over a ten-year period



compared with patients with SLE without AFS. The relationship of the dynamics of the severity index with the parameters characterizing the activity and course of the disease. We divided patients into several groups depending on the IT score in the 1st, 5th, 10th years of the disease and analyzed the association of IT dynamics over 5 and 10 years with some parameters characterizing SLE and the treatment being carried out. 91 patients were analyzed in the 1st and 5th years of the disease. During this period, IT remained unchanged in 40 (group 1), increased by 1-2 points in 36 (group 2) and by 3 points or more in 15 patients (group 3).

Important parameters for assessing the outcomes of SLE are the survival rate, topic and degree of irreversible organ damage, frequency, rate of development and duration of remission, as well as quality of life. In randomized clinical trials, scientific papers and in describing clinical situations, the activity of SLE is assessed mainly using various indices. The most common and widely used are SLAM scales, SLEDAI, ECLAM and BILAG. Along with good reproducibility and comparability, ease of use these methods have a number of disadvantages that limit their use to describe the course of the disease. Firstly, it is the "weight" of indicators reflecting damage to organs and systems that varies in different indices, and therefore, for example, active lupus nephritis can be assessed by a different number of points using different methods. Secondly, within the same counting system, the same patients with active lupus nephritis may have a lower score than patients with less adverse skin and joint lesions. Thirdly, the indices are most sensitive to changes in disease activity within the framework of cohort studies of drug efficacy or over short follow-up periods, poorly characterizing the disease as a whole in long-term studies. These disadvantages in no way detract from the advantages of modern methods for calculating SLE activity, however, activity indices may not always be applicable to characterize the disease. Impossible and wrong to evaluate the relationship of certain conditions, the occurrence of which is associated with the duration of SLE (for example, atherosclerotic vascular lesion or osteoporosis) with the result of simultaneous determination of SLE activity using indices, since the initial indicators for their calculation, as already noted, are different in importance and may decrease or increase in a short period of time.

CONCLUSIONS

In our study, IT reflected the "accumulated" activity of the disease well. The analysis showed that OT increased with increasing prescription of SLE, while its growth could occur at any stage of the disease and depended on the variant of its course, the timing of diagnosis, concomitant pathology. OT correlated well with the indicators of activity and damage traditionally used in SLE, as well as with the frequency of exacerbations of the disease. Numerous studies have shown that the activity of SLE and the fact of recurrence are good predictors of the development of irreversible organ damage and adverse outcomes of SLE. The correlation of OT with activity and damage indicators indicates the possibility of using OT as a predictive marker.

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