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DYNAMIC CHANGES IN THE ACTIVITY INDEX AND THE TOTAL SEVERITY INDEX IN PATIENTS WITH SYSTEMIC SCLERODERMA AND INTERSTITIAL LUNG DISEASE OVER A 5-YEAR FOLLOW-UP PERIOD

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ABSTRACT: Systemic scleroderma (SSD) is a systemic disease based on microcirculation disorders, inflammation and generalized fibrosis. Interstitial lung disease (IPL) is one of the main manifestations of SSD. Determining the activity and severity of SSD is difficult, since it is very difficult to distinguish between fibrous and inflammatory changes, which in most cases are interrelated and have a similar clinical picture.

The aim of the study was to evaluate the value of the activity index (IA) and the total severity index (SIT) for the dynamic observation of patients with SDS with different course of IPL.

Material and methods. The study included 77 patients with SSD and IPL who were observed At the SaMMU The Department of Rheumatology, the average age at the time of inclusion was 46± 13 years. All patients underwent high-resolution computed tomography (CTVR) of the chest organs, the value of SIT and IA was determined upon inclusion in the study and after an average of 59 ± 12 months. Depending on the dynamics of pulmonary changes over a 5-year follow–up period, according to CTVR data, patients were divided into three groups: the first included patients with positive dynamics (n=16), the second – without dynamics (n=39); the third - with negative dynamics (n=22). The disease was regarded as active with an IA value of ≥3 points.

Results and discussion. The average IA values for the entire cohort of patients were low and did not change significantly during the follow-up period, amounting to 2.1±1.55 and 2.37±1.55 ($p>0.05$) at the beginning and at the end of the study, respectively. After 5 years, only in group 3, IA values were > 3 points. When included in the study, the values of IA in the groups did not significantly differ, however, after 5 years in group 3, IA became significantly higher than in groups 1 and 2 ($p=0.004$ and $p=0.03$, respectively). The sieves during the observation period did not significantly it changed and averaged 6.5 ± 2.5 and 6.9±2.3, respectively, at inclusion and at the end of the study. At the same time, in groups 1 and 2, the SIEVE tended to decrease, and in group 3 it significantly increased ($p=0.006$) and at the end of the study was significantly higher than in group 1 ($p=0.002$). There was a direct correlation between IA and SIT in the general cohort of patients, both at the time of inclusion and after 5 years ($R=0.57$ and $R=0.53$ at $p<0.05$). Direct correlations were found between the indices within groups 2 ($R=0.51$ and $R=0.37$) and 3 ($R=0.67$ and $R=0.71$ at the time of inclusion and at the end of observation, respectively; $p<0.05$).

Conclusion. In our work, IA and SIT reflected the dynamics of IPL in patients with SSD. The progression of IPL according to the CTVR data was accompanied by a significant

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increase in the values of IA and SIT, they directly correlated with each other. Thus, IA and SIT can be used for dynamic monitoring, reflecting the progression of the disease.

Key words: Systemic scleroderma; interstitial lung lesion; atherogenicity index; total severity index.

INTRODUCTION

Scleroderma is a systemic disease based on microcirculation disorders, inflammation and generalized fibrosis. SSD is accompanied by characteristic changes in the skin, musculoskeletal system, internal organs (lungs, heart, digestive tract, kidneys) and widespread vasospastic disorders such as Raynaud's syndrome. SSD is characterized by a variety of clinical forms and the flow options. Lung damage in SSD includes interstitial lung disease (IPL) and pulmonary hypertension (PH). It is known that IPL and LH are the main causes of death in SSD, accounting for 33 and 28% of deaths, respectively. IPL is one of the main manifestations of SSD, its frequency varies from 16 to 100% depending on the ethnicity of patients and examination methods. IPL is characterized by damage to the interstitial lung tissue with a different combination of processes inflammation and fibrosis. The morphological picture of changes in lung tissue is described in detail in the works of domestic and foreign authors and consists in the proliferation of connective tissue in the interalveolar septa, vascular walls, perivascularly, peribronchially, mainly in the basal sections and subpleural. With the help of high-resolution computed tomography (CTVR) of the chest organs, IPL is detected in more than 90% of cases. Reduction of the forced vital capacity of the lungs, the diffusion capacity of the lungs (DSL), restrictive changes in According to functional pulmonary tests, they are detected in 40-75% of patients.

Determining the activity and severity of SSD is difficult, since it is very difficult to distinguish between fibrous and inflammatory changes, which in most cases are interrelated and have a similar clinical picture. In 2003, T.A. Medsger et al. definedthe severity and activity of SSD: the severity of the disease reflects its overall effect on organ function, including It includes reversible and irreversible components; activity is a reversible component of severity, which may disappear during the course of the disease or lead to minor or severe organ damage.

Difficulties in determining activity in SSD arise due to a number of factors. Firstly, many patients, especially those with a limited form of the disease, have a slow progressive course, without clear signs of inflammation. Secondly, laboratory indicators of inflammatory activity, such as ESR and the level of C-reactive protein, rarely elevated in SSD and therefore uninformative. In 2001, the European Scleroderma Study Group – ESkSG) has developed an activity index (IA), which

includes 10 signs with a "weight" of each from 0.5 to 2 points. The sum of the points corresponds to the total activity of the disease, its maximum possible value is 10. With IA $\geq$ 3 points, the disease is regarded as active, with IA $<$ 3 – as inactive. At an early stage of the disease, when there is a potential opportunity to prevent the development of severe fibrotic and vascular pathology, improve the quality of life of patients and the prognosis of SSD, in addition to determining activity, an assessment of the severity of the disease is of particular value.

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In 1999, T.A. Medsger et al. developed and presented their own severity scale for SSD. They identified 9 systems that were included in the scale, and developed an account of the severity of the lesion for each of them. At the same time, the progression of cutaneous, vascular-trophic manifestations, and internal pathology were taken into account organs (lungs/heart) subjectively assessed by the patient, as well as data from physical, instrumental (for example, DSL) and laboratory examination methods. The purpose of our study is to evaluate the value of the total severity index (SIT) and IA for the dynamic observation of patients with SDS with different course of IPL according to CTVR data.

MATERIALS AND METHODS OF RESEARCH

The study included 77 patients (72 women and 5 men) with a reliable diagnosis of SSD in accordance with the classification criteria of the American College of Rheumatology (ACR). Their age at the time of inclusion averaged 46±13 years, the duration of the disease from the first non-Raynaud's syndrome was 7.4±6.6 years, the duration of follow–up was 5 years (59±11 months). 24 patients had a diffuse and 53 had a limited form SSD. All patients received treatment with vascular, anti-inflammatory and/or immunosuppressive drugs in accordance with international recommendations. To assess the activity and severity of the disease, IA and SIT were used, which were determined upon inclusion in the study and after 5 years. The clinical and laboratory parameters of IA were evaluated in points, after which the overall index of SSD activity was calculated. The severity of the skin lesion was assessed using a modified Rodnan skin score, representing the sum of points for 17 anatomical areas of the body (face, chest, abdomen, symmetrical sections in each of these areas, the degree of skin compaction was assessed in points (from 0 to 3), where 0 – there is no compaction, 1 – insignificant (the skin gathers into a fold), 2 – moderate (the skin does not gather into a fold), 3 – significant compaction (the skin does not gather into a fold). Changes in the skin (Δ of the skin), Raynaud's syndrome (Δ of blood vessels), heart and lungs (Δ of the heart/lungs) in the month preceding hospitalization were detected during the patient's interview. The presence of sclerodema (dense swelling of the hands), digital necrosis and arthritis it was determined during examination. The study of the function of external respiration was carried out using the Master apparatus

Viasys company's Screen PFT. DSL was evaluated by the single inhalation method and expressed as a percentage of the required values; 80-120% were considered normal values. The level of complement components (C3 and/or C4) was determined in the patient's blood serum by immunonephelometry on a Simens device. When analyzing the clinical manifestations of SSD, the severity of the lesion was taken into account according to 9 severity indices developed by T.A. Medsger et al. The authors suggested to determine the severity indices of common symptoms and affected organs and systems based on the totality of the results

of clinical, laboratory and instrumental examination methods. For each system, the index is determined on a 4-point scale: 0 – no changes, 1 – mild, 2 – moderate, 3 – pronounced, 4 – extremely severe changes. The assessment of the skin, joints and muscles is carried out according to clinical parameters, as well as the results of ultrasound examination (ultrasound). To characterize the pathology of the lungs, data from functional pulmonary tests, CTVR of the lungs, assessment of shortness of breath by NYHA; heart function was assessed according to electrocardiography and echocardiography. The conclusion on the

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involvement of the gastrointestinal tract (GI tract) is based on the complaints of patients and/or the results of esophagogastroduodenoscopy. Subsequently, it was proposed to summarize the scores for calculating the SIT. The maximum value of sieves for all systems is 36 points; the higher the sum of the points, the higher the severity of the disease. In our work, when evaluating all organs and systems using the severity index, we did not register kidney damage, therefore we did not include this system in sieves, and the maximum value of sieves in our study was 32 points. Data processing was carried out using the Statistica 10.0 statistical software package (Statsoft, USA). To analyze the significance of differences in quantitative indicators with a normal distribution of the studied parameter, the Student's t-test was used. For the analysis of qualitative data, the method of conjugacy tables with the calculation of the Fisher criterion was used. The differences were considered statistically significant at $p<0.05$.

THE RESULTS AND THEIR DISCUSSION

To objectify changes in the pulmonary parenchyma in dynamics, we used CT scan of the chest organs performed on one device, and its results were evaluated by one radiologist expert. The analysis of the KTVR data showed that the dynamic changes were of a multidirectional nature. Positive dynamics (improvement) was noted in 16 (21%) patients; in half of the cases (39 patients, 50%), no distinct changes were detected over 5 years, and in 22 (29%) cases, the progression of IPL was observed. The age of patients with positive dynamics of changes in the lungs was significantly less than in other groups. At the same time, the duration of the disease and the prescription of Raynaud's syndrome at the time of inclusion in the study did not significantly differ from those in other groups ($p>0.05$). The limited form prevailed in all groups. The ratio of patients with diffuse and limited forms was as follows: group 1 – 1:7, group 2 – 1:2, group 3 –1:1.75. The number of patients who had antibodies to SCL-70 at the time of inclusion was higher in group 3, and only in this group it increased and became significantly higher after 5 years, than in groups 1 and 2 ($p=0.004$ and $p=0.02$, respectively). At the time of inclusion in the study, anti-centromeric antibodies (ACA) were detected only in groups 1 and 2. The number of patients receiving cyclophosphane at the end of follow -up in group 1 was significantly lower than in group 3 ($p=0.01$) The frequency of glucocorticoid (HA) intake in the three groups did not differ, both at the time of activation and at the end of observation. Thus, the group with positive dynamics of IPL included younger patients, in whom the limited form was 7 times more common, the more diffuse, and less often than in others, antibodies to SCL-70 were detected. In the groups without dynamics and with negative dynamics of IPL, the ratio of patients with limited and diffuse forms was 2:1 and 1.75:1, respectively. In patients with negative dynamics, antibodies to SCL-70 were significantly more common than in other groups. The SIT for the entire cohort of patients did not change significantly during follow-up and averaged 6.5±2.5 and 6.9±2.3, respectively, at the time of inclusion and at the end of the study. In the general cohort of patients, IA practically did not change during the follow-up period and averaged 2.1±1.56 at the beginning and 2.36±1.54 at the end of the study ($p>0.05$).

When included, the values of IA in groups 1, 2 and 3 did not differ significantly

At the time of inclusion, the values of sieves in our patients were not high and significantly increased during the follow -up period only in the group with negative dynamics IPL

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(p=0.006). The highest values of sieves after 5 years were recorded in group 3, and the lowest in group 1. At the same time, sieves in group 3 after 5 years became significantly higher than in group 1 (p=0.002). Thus, An increase in SIT was associated with negative dynamics in lung CTVR. There was a direct correlation between SIT and IA both at the time of inclusion and after 5 years for the entire cohort of patients, the correlation coefficient according to R. Kendall was 0.57 ($p<0.05$) and 0.53 ($p<0.05$), for the second group – 0.51 ($p<0.05$) and 0.37 ($p<0.05$), for the third – 0.67 ($p<0.05$) and 0.71 ($p<0.05$), respectively. Only in the first group of IA and the sieves were not correlated with each other.

Thus, IA and SIT reflect the dynamics of IPL according to KTVR data. In patients with negative dynamics, a significant increase in IA was recorded, so SIT. SIT was directly correlated with IA in the entire cohort, as well as in patients in groups without dynamics and with negative dynamics of IPL. The work carried out is based on the analysis of the results of 5-year follow-up of patients with SDS with IPL according to CTVR data. In 50% of them, the pattern of ILE did not change significantly during this period, according to KTVR data, 21% had positive and 29% had negative dynamics. During the follow-up period, only patients with negative dynamics of IPL had a significant increase in IA ($p<0.04$), and its average value at the end of the study was >3 points, which indicates an increase in the activity of the disease. At the end of the study, the average IA values in group 3 were significantly higher than in groups 1 and 2 ($p<0.01$ and $p<0.04$, respectively).

Thus, the deterioration of the X-ray picture in the lungs was accompanied by an increase in the overall activity of the disease.Patients with positive dynamics of IPL were significantly younger than the rest of the patients, they had a limited form of SSD 7 times more often than diffuse, and antibodies to SCL-70 were detected less frequently than in other groups. This is consistent with the data of other authors: so, N.G. Guseva et al. showed that for patients with SSD with the late onset of the disease, the development of more severe visceral pathology in the first 3 years of the disease is characteristic. In the works of J.D. Reveille et al. and G. Spencer Green et al. antibodies to SCL-70 were found in 40% of patients with diffuse, less than 10% with limited form, and approximately 45% of patients with IPL.

CONCLUSIONS

Our patients did not have high SIT values at the time of inclusion in the study, which may reflect the benign nature of the disease. Progression According to the KTVR data, IPL was accompanied by a significant increase in SIT, while in groups with and without positive radiological dynamics it did not change significantly. In the work of M. Radic et al. the relationship of Helicobacter pylori with the severity of SSD has been shown. In the presence of this microorganism, skin changes, The gastrointestinal tract and tendon-ligamentous apparatus were significantly more pronounced, and the SIT was significantly higher than in its absence. In our work, IA and SIT correlated with each other both at the time of inclusion and after 5 years in the entire cohort of patients: in the absence of IPL dynamics and with negative dynamics, and only in the group with positive dynamics there was no such correlation. The negative dynamics of IPL according to KTVR data was accompanied by a significant increase in IA and SIT. Thus, IA and SIT can be used for dynamic monitoring of patients with SSD, reflecting the progression of both IPL and the disease as a whole.

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