

**PSYCHOMETRIC ASSESSMENT OF THE QUESTIONNAIRE TO STUDY THE
ACTIVITY OF SYSTEMIC LUPUS ERYTHEMATOSUS**

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ABSTRACT: The validation and study of the psychometric properties of the questionnaire for self-assessment of disease activity in patients with systemic lupus erythematosus (SLE) was carried out. The study included 129 patients with different levels of activity and variable clinical manifestations. Factor and cluster analysis revealed the internal structure of the questionnaire, reflecting the activity of SLE in the musculoskeletal system, internal organs, constitutional manifestations, nervous system and skin. The conducted Rush analysis allowed us to confirm the uniformity and internal validity of the questionnaire with satisfactory parameters of separation and reliability of items. The external validity of the questionnaire was confirmed by correlation with the values of SLE activity obtained using generally accepted indices. It was found that the perception of SLE activity by the patient is influenced not only by the obvious clinical manifestations of the disease, but also by a number of laboratory parameters.

Keywords: Systemic lupus erythematosus, disease activity, activity index, questionnaire, validity, Rush analysis.

INTRODUCTION

Systemic lupus erythematosus (SLE) is a systemic connective tissue disease with variable clinical manifestations ranging from minor skin and joint inflammation to disabling lesions of the central nervous system, kidneys and other organs and systems. An unpredictable course with diverse involvement of almost all body systems has a significant negative impact on the quality of life of patients and it makes it difficult to assess the severity of the disease. The need for individualization and optimization of therapy forces researchers to use methods for assessing the impact of the disease based on the opinion of patients. We developed and initially validated a questionnaire for self-assessment of disease activity in patients with SLE (SLE), demonstrated its external, meaningful and divergent validity in a small cohort of patients. The OASC evaluates the patient's perception of SLE activity during the previous week by 10 points weighted on a scale The liqueur is from 0 to 3 and contains a numerical ordinal scale of the overall activity of the disease according to the patient. The OASC provides a result in the range of values from 0 to 40 points. The purpose of the work to evaluate the properties of SLE in a large cohort of patients with SLE with variable clinical manifestations, to carry out further external and divergent validation and study the psychometric parameters of the questionnaire.

MATERIALS AND METHODS OF RESEARCH

To assess the validity and psychometric parameters of SLE, it was studied in 129 patients with a verified diagnosis of SLE aged 18 to 69 years (114 (88.4%) women and 15 (11.6 %) men), with various clinical manifestations and variable activity of the disease. The age of the patients was (M (SD)) 35.67 (14.49) years, disease duration 7.06 (6.68) years (median 5,

range 0.5–27 years). To assess the external validity of the ASGV, the following methods were used indices of disease activity SLAM, SLEDAI-2K, BILAG 2004, ECLAM. All indexes had previously demonstrated good convergent validity, and their values were closely correlated with each other. Divergent validity was assessed by correlation with damage by index SLICC/ACR. To determine the internal structure of the questionnaire, a factor analysis based on the principal component model was applied with varimax rotation and hierarchical cluster analysis. The Kaiser criterion was used to determine the number of factors. Cluster analysis for analyzing the structure of the questionnaire was performed using the method of intergroup communication using questionnaire items as objects of classification, and proximity measures – Pearson correlation. A variant of the measurement theory, Rush analysis in a one-parameter model, was used for the psychometric assessment of the OASC. The results of the "calibration" of points and "personal measures" are presented in the form of logarithmic units (logits are the natural logarithm of the odds ratio), arranged on an ascending scale. A distance of 0.15 logits or more is accepted to conclude that the points are adequately separated. The model used uses emission-sensitive fitness statistics (outliersensitive fit statistical, OUTFIT) and information-weighted fitness statistics (information weighted fit statistical, INFIT). The values of INFIT and OUTFIT in the range from 0.7 to 1.4 were taken as acceptable consistent with the model. Descriptive statistics and correlation analysis were used for one-dimensional statistical analysis. For multidimensional analysis, a multiple linear regression model with a step-by-step calculation option was used, in which the dependent variable was the assessment of SLE activity by the patient, and the influencing variables were the main clinical manifestations and correlating laboratory parameters. Statistical analysis, including correlation and regression analysis, factor and cluster analysis was performed using the IBM SPSS Statistics software package, release 21.0. The rush analysis was performed using the program Winsteps version 3.90.0, by M. Linacre.

THE RESULTS AND THEIR DISCUSSION

The Kaiser criterion allowed us to identify 5 factors. Kettell's screening criterion also allowed us to assert the presence of 5 factors. The analysis of factor loads highlights the closely related points of the questionnaire, divided into 5 factors.

Cluster analysis, as well as factor analysis, led to the identification of 5 groups of variables, all 5 clusters were obtained at the 1st stage of the analysis. The clusters fully correspond to the factors obtained as a result of factor analysis and have a rational pathophysiological interpretation. These clusters reflect activity in organ systems: the musculoskeletal system (cluster 1, factor II), damage to internal organs (kidneys, heart, lungs – difficult to differentiate by the patient independently, but defined as pain and dysfunction) (cluster 2, factor V), constitutional symptoms (weakness, fever) (cluster 3, factor III), damage to the nervous system (visual impairment, headache) (cluster 4, factor I) and skin lesions (cluster 5, factor IV). Of particular interest is the analysis of distances to cluster unification. It can be seen that the convergence of clusters reflecting activity from the internal organs, musculoskeletal system and constitutional manifestations (previously combined with lesions of the integument and neuropsychic sphere)

occur at late stages, which reflects the partial independence of the contribution of lesions of different organs and systems to the overall assessment of activity. A similar effect on the

determinants of quality of life in patients SLE has been noted in some studies. M (SD) INFIT and OUTFIT were 1.08 (0.28) and 1.0 (0.24, respectively, which confirms the uniformity of the questionnaire. Separation Parameters (3.91) and the reliability of the questionnaire items (0.94) were satisfactory. When analyzing individual items in the questionnaire, it turned out that the values of the INFIT statistics exceeded 1.4 for two items – "edema" (1.42) and "skin rashes" (1.41), however, the excess was insignificant and did not indicate the need to exclude these items. An INFIT value of less than 0.7 is marked for one point – "weakness" (0.59). Such the results are quite understandable, since weakness is a non-specific manifestation, it is often observed and makes, perhaps, the least contribution to the objective picture of the assessment of SLE activity. At the same time, edema was a relatively rare manifestation and, therefore, is regarded as the most "difficult" point in the Rush analysis. The agreement of empirically observed and expected values was quite satisfactory, the differences, as expected, increased as the "complexity" of the questions increased. Characteristic curves for all The points of the OASC had a very close angle of inclination, indicating similar discriminant properties, and differed mainly by displacement relative to the zero values of the "complexity" axis. The distribution of activity estimates obtained with the use of OASC was shifted towards low values, however, a formal study showed the absence of significant deviations from the normal distribution, which allows the use of parametric statistics for analysis. The values of the OASC were closely correlated with the activity estimates for the indices, however, there was a weak but statistically significant correlation with damage, which indicates that patients do not always clearly distinguish between the concepts of activity and irreversible changes, indicating the "overall severity" of the disease. It is obvious that the activity of SLE negatively affects the quality of life and it should be expected that patients with poor quality For any reason, people will tend to attribute their suffering to active SLE. There was a positive correlation of the overall assessment of the OASC with the value of blood pressure ($r = 0.254$; $p = 0.004$) and a number of laboratory parameters (proteinuria, ESR, blood creatinine) and a negative one with the level of hemoglobin and total blood protein. Regression analysis allows us to explain 32.9% of the variance of the dependent variable. Interestingly, along with the obvious influencing factors – constitutional and cardiovascular manifestations, the "hidden" ones were preserved in the model influencing variables such as total blood protein and immunological manifestations that cannot be felt by patients. This fact testifies to the existence of a number of parameters that cannot be directly measured, affecting the perception of disease activity by patients, which has been noted in the literature.

CONCLUSIONS

The OASC developed by us is a valid, at the same time a simple tool that allows us to adequately assess the current severity of the condition of patients, the questionnaire has a reliable structure and an obvious pathophysiological justification for each item. The conducted psychometric assessment confirms the internal validity and reliability of the questionnaire. This tool can be recommended for clinical use along with other qualified questionnaires.

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