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COMPARATIVE ASSESSMENT OF QUALITY OF LIFE ACCORDING TO THE FAS SCALE AND THE KSQ QUESTIONNAIRE IN PATIENTS WITH NEWLY DIAGNOSED AND RECURRENT PULMONARY SARCOIDOSIS

State Organization "National Scientific Centre of Phthisiology, Pulmonology and Allergology named after F. G. Yanovsky of the National Academy of Medical Sciences of Ukraine"

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Abstract

The cause of sarcoidosis is unknown, so treatment is aimed at granulomatous inflammation. For this purpose, glucocorticosteroids (GCS) are the most widely used. At the same time, the study of long-term results of GCS therapy showed a high incidence of disease relapses, which is currently one of the most acute problems in the management of patients with pulmonary sarcoidosis.

In 2021, the ERS Official Document "Clinical practice guidelines on the treatment of sarcoidosis" was published [16], which defined completely new approaches to the treatment of patients with sarcoidosis. The mere presence of sarcoid granulomas in the lung parenchyma is not yet an indication for specific therapy, since granulomas in sarcoidosis, unlike infectious granulomas, are not a source of pathological process spread. In order to make a decision about the treatment of a particular patient, it is necessary to determine whether they are at high risk of disability, mortality from sarcoidosis, or to assess the level of decline in their quality of life. In recent years, the criteria for assessing the treatment results of patients with pulmonary sarcoidosis have been revised, including the concept of 'clinical remission', which was based primarily on the normalisation of lung computed tomography. Nowadays, quality of life indicators are increasingly used as the primary point of evaluation of treatment effectiveness. The Fatique Assessment Scale (FAS) and the King's College Hospital Questionnaire (King's Sarcoidosis Questionnaire — KSQ) have been developed to assess the quality of life specific to sarcoidosis.

The aim of the study: to conduct a comparative assessment of quality of life according to the FAS scale and the KSQ questionnaire in patients with newly diagnosed and recurrent pulmonary sarcoidosis in combination with computed tomography of the lungs, ventilation function and lung diffusion capacity.

Materials and methods. The study included 32 patients (women: 12, men: 20; aged: 22 to 66 years). All patients were divided into two groups. group 1: 16 (women: 4, men: 12; mean age: (35.0 ± 2.1) years) with newly diagnosed stage II pulmonary sarcoidosis, group 2: 16 (women: 8, men: 8; mean age: (47.0 ± 2.7) years) in the active phase of stage II sarcoidosis relapse. Along with the clinical examination, all patients were examined by high-resolution computed tomography (CT) using Aquilion TSX-101A multislice CT scanner (Toshiba). The results of CT were evaluated using the criteria described by M. Veltkamp, J. C. Grutters (2015). The state of pulmonary function was assessed on the basis of spirometry, study of the structure of the total capacity, diffusion capacity of the lungs using the 'Diffustic' diagnostic complex (Geraterm Respiratory GmbH).

Statistical methods. The hypothesis that the studied numerical samples follow the normal law of distribution was tested using the D'Agostino D-test. The significance of differences in mean values was assessed using the Student's t-test. All tests were two-sided with the significance level set at $p < 0.05$.

Results. Patients with active relapse of pulmonary sarcoidosis, compared with patients with newly diagnosed disease, had more pronounced CT signs of lung parenchyma lesions in the form of micronodular dissemination, decreased lucency, signs of interstitial lung fibrosis, which most likely had a negative impact on ventilatory function and lung diffusion capacity — the formation of restrictive pulmonary ventilation disorders, and decreased rate of pulmonary diffusion.

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ПОРІВНЯЛЬНА ОЦІНКА ЯКОСТІ ЖИТТЯ ЗА ДАНИМИ ШКАЛИ FAS ТА ОПИТУВАЛЬНИКА KSQ У ХВОРИХ НА ВПЕРШЕ ДІАНОСТОВАНИЙТА РЕЦИДИВУЮЧИЙ САРКОЇДОЗ ЛЕГЕНЬ

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Abstract

Причина саркоїдозу невідома, тому лікування спрямоване проти гранульоматозного запалення. З цією метою найбільш широко застосовуються глюкокортикостероїди (ГКС). Разом з тим вивчення віддалених результатів ГКС-терапії показало високу частоту рецидивів захворювання, які в даний час є однією з найбільш гострих проблем у веденні хворих на саркоїдоз легень.

У 2021 році опубліковано Офіційний документ ERS «Clinical practice guidelines on treatment of sarcoidosis», в якому визначено абсолютно нові підходи до лікування хворих на саркоїдоз. Сама по собі присутність саркоїдних гранульом у паренхімі легень ще не є показанням для призначення специфічної терапії, оскільки гранульоми при саркоїдозі, на відміну від інфекційних, не є джерелом поширення патологічного процесу. Для того, щоб прийняти рішення про лікування конкретного пацієнта, необхідно визначити, чи належить він до групи високого ризику інвалідності, смертності від саркоїдозу або оцінити рівень зниження якості його життя. В останні роки переглядаються критерії оцінки результатів лікування хворих на саркоїдоз легень, саме поняття "клінічна ремісія", основу якого становила, перш за все, нормалізація показників комп'ютерної томографії легень. В даний час все частіше як первинна точка оцінки ефективності лікування використовуються показники якості життя. Розроблено специфічні для саркоїдозу інструменти оцінки якості життя – шкала оцінки рівня втоми (Fatique Assessment Scale — FAS) та опитувальник Госпіталю королівського коледжу в Лондоні (King's Sarcoidosis Questionaire — KSQ).

Мета дослідження: провести порівняльну оцінку якості життя за даними шкали FAS та опитувальника KSQ у хворих на вперше діагностований та рецидивуючий саркоїдоз легень у комплексі з показниками комп'ютерної томографії легень, вентиляційної функції та дифузійної здатності легень.

Матеріали та методи дослідження. До дослідження було включено 32 хворих (жінок —12, чоловіків — 20; вік — від 22 до 66 років). Усі пацієнти були розподілені на дві групи: група 1 — 16 (жінок — 4, чоловіків — 12; середній вік — (35,0 ± 2,1) років) з вперше діагностованим саркоїдозом легень II стадії, група 2 — 16 (жінок — 8, чоловіків — 8; середній вік — (47,0 ± 2,7) років) в активній фазі рецидиву саркоїдозу II стадії.

Поряд з клінічним обстеженням всі пацієнти обстежені методом комп'ютерної томографії (КТ) високої роздільної здатності на мультислайсовому КТ-сканері Aquilion TSX-101A (Toshiba). Оцінку результатів комп'ютерної томографії проводили за допомогою критеріїв, описаних M. Veltkamp, J. C. Grutters (2015). Стан ФЗД оцінювали на основі даних спірометрії, дослідження структури загальної ємності, дифузійної здатності легень на діагностичному комплексі "Diffustic" (Geraterm Respiratory GmbH).

Статистичні методи. Гіпотезу про відповідність досліджуваних числових вибірок нормальному закону розподілу перевіряли за допомогою D-критерію Д'Агостіно. Оцінку значущості відмінностей середніх величин проводили за t-критерієм Ст'юдента. Усі тести були двосторонніми з рівнем значущості, встановленим при $p < 0,05$.

Результати. У пацієнтів з активним рецидивом саркоїдозу легень у порівнянні з пацієнтами з вперше діагностованим захворюванням більшою мірою виражені КТ-ознаки ураження паренхіми легень у вигляді мікровузликової дисемінації, зниження її прозорості, ознаки інтерстиціного фіброзу легень, що з найбільшою ймовірністю мало негативний вплив на вентиляційну функцію та дифузійну здатність легень — формування рестриктивних порушень легеневої вентиляції, зниження швидкості легеневої дифузії.

More pronounced CT signs of sarcoidosis, the degree of impaired ventilatory function and lung diffusion capacity in patients with recurrent pulmonary sarcoidosis were accompanied by more pronounced impairment of their quality of life according to the FAS scale and the KSQ questionnaire.

Conclusion. The recommendations of the literature based on the study of the validity of the FAS scale and the KSQ questionnaire, as well as the results of this study, give grounds to recommend these quality of life assessment tools as criteria for determining the timing of the start of specific therapy, if necessary, the correction of its regimens and the timing of treatment completion.

Key words: pulmonary sarcoidosis, relapsing course, computed tomography of the lungs, ventilatory function and diffusion capacity, quality of life, FAS, KSQ.

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Більш виражені КТ-ознаки саркоїдозу, ступінь порушень вентиляційної функції та дифузійної здатності легень у хворих з рецидивуючим саркоїдозом легень супроводжувалися і більш вираженими порушеннями їх якості життя за показниками шкали FAS та опитувальника KSQ.

Висновок. Рекомендації літератури, отримані на основі вивчення валідності шкалі FAS та опитувальника KSQ, а також результати даного дослідження дають підстави рекомендувати ці інструменти оцінки якості життя як критерії визначення термінів початку специфічної терапії, при необхідності корекції її режимів та термінів закінчення лікування.

Ключові слова: саркоїдоз легень, рецидивуючий перебіг, комп'ютерна томографія легень, вентиляційна функція та дифузійна здатність, якість життя, FAS, KSQ.

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Sarcoidosis is a multisystem disease of unknown nature characterised by the formation of granulomas in various epithelioid organs without caseous necrosis [2].

Sarcoidosis with lung parenchyma involvement in most countries of the world ranks first in the structure of interstitial lung diseases. According to generalised statistics, the prevalence of sarcoidosis in the world is on average 20 per 100,000 [2]. Since the 70s of the last century, there has been a steady increase in the incidence of sarcoidosis and mortality [3–5].

The cause of sarcoidosis is unknown, so treatment is aimed at granulomatous inflammation. For this purpose, glucocorticosteroids (GCS) are the most widely used [6] — their effectiveness in assessing short-term results has been proven in numerous studies [7–10]. At the same time, the study of long-term results of GCS therapy showed a high incidence of disease relapse, which is currently one of the most acute problems in the management of patients with pulmonary sarcoidosis [11]. The rate of sarcoidosis relapse ranges from 13 to 75 %, depending on the population studied [12–15]. Relapses usually occur from 1 month to 1 year after the end of therapy [14, 15].

In 2021, the ERS Official Document "Clinical practice guidelines on the treatment of sarcoidosis" was published [16], which defines completely new approaches to the treatment of patients with sarcoidosis. According to this document, the main principle of treatment of patients with pulmonary sarcoidosis is to achieve a balance between: a) minimising the risk of disability, death due to lung damage or reduced quality of life; and b) the risk of comorbidity and reduced quality of life due to GCS and other therapies.

The mere presence of sarcoid granulomas in the lung parenchyma is not yet an indication for specific therapy, since granulomas in sarcoidosis, unlike infectious granulomas (e.g., tuberculosis), are not a source of pathological process spread. In order to make a decision about the treatment of a particular patient, it is necessary to determine whether they are at high risk of disability, mortality from sarcoidosis, or to assess the level of decline in their quality of life. The Guideline presents the main high-risk criteria (extensive interstitial process, severe pulmonary fibrosis, pulmonary hypertension, clinical symptoms, impaired pulmonary ventilation and diffusion).

In recent years, the criteria for assessing the treatment outcomes of patients with pulmonary sarcoidosis have been revised, including the concept of 'clinical remission', which was based primarily on the normalisation of lung computed tomography. Currently, quality of life indicators are increasingly used as the primary point of evaluation of treatment effectiveness, including the level of recovery of working capacity and normalisation of social status of patients who prioritise quality of life issues over most objective clinical tests to assess their disease.

The Fatique Assessment Scale (FAS) and the King's College Hospital Questionnaire (King's Sarcoidosis Questionnaire — KSQ) have been developed to assess the quality of life specific to sarcoidosis.

Fatigue is one of the most important factors causing a decrease in the quality of life in patients with sarcoidosis [17]. Fatigue is a common complaint among patients with sarcoidosis [18–22], with a frequency of 50-70 % [17, 18] (53.7 % in our data). Fatigue associated with sarcoidosis is recognised worldwide as a disabling symptom [17].

The causes of this symptom remain unclear and are multifactorial. Fatigue can be a consequence of treatment, including as a complication of administering GCS. The formation of granulomas and the release of certain cytokines may be relevant. However, despite adequate treatment of sarcoidosis, many patients continue to feel fatigued. Comorbidities associated with sarcoidosis, including depression, anxiety, hypothyroidism, and sleep disturbances, can all contribute to fatigue [16].

De Vries J. et al. [22] developed the Fatigue Assessment Scale (FAS) for patients with sarcoidosis, consisting of 10 questions.

The KSQ (King's College Hospital Questionnaire) is also a sarcoidosis-specific quality of life assessment tool. It was

developed in 2012 in a study of 207 patients with sarcoidosis with multiple organ involvement [24]. Unlike the FAS, the KSQ allows you to assess the impact on the overall health of not only fatigue, but also respiratory symptoms (cough, shortness of breath, chest pain, chest tightness). KSQ is considered one of the most appropriate for assessing quality of life in sarcoidosis [25]. According to Moor C.C. et al. (2023), KSQ can be used as a standard in assessing quality of life in patients with pulmonary sarcoidosis [26]. The KSQ consists of modules: General Health, Lungs, Medications, Skin and Eyes. The ERS Guidelines [16] recommend using the General Health and Lungs modules to assess quality of life in patients with pulmonary sarcoidosis.

The aim of the study: to conduct a comparative assessment of quality of life according to the FAS scale and the KSQ questionnaire in patients with newly diagnosed and recurrent pulmonary sarcoidosis in combination with computed tomography of the lungs, ventilation function and lung diffusion capacity.

Materials and methods

The study was conducted at the certified department of interstitial lung diseases of the SO "National Scientific Centre of Phthisiology, Pulmonology and Allergology named after F.G. Yanovsky of the NAMS of Ukraine". All studies were approved by the Ethics Committee of the SO "National Scientific Centre of Phthisiology, Pulmonology and Allergology named after F.G. Yanovsky of the NAMS of Ukraine". All patients were familiarised with the list of procedures and signed an informed consent to participate in the study.

The study included 32 patients (women: 12, men: 20; aged: 22 to 66 years). All patients were divided into two groups. group 1: 16 (women: 4, men: 12; mean age: (35.0 ± 2.1) years) with newly diagnosed stage II pulmonary sarcoidosis, group 2: 16 (women: 8, men: 8; mean age: (47.0 ± 2.7) years) in the active phase of stage II sarcoidosis relapse.

Along with the clinical examination, all patients were examined by high-resolution computed tomography (CT) using Aquilion TSX-101A multislice CT scanner (Toshiba). The results of computed tomography were evaluated using the criteria described by M. Veltkamp, J. C. Grutters [27].

CT data were evaluated using the K-Pacs software.

A scoring system was used for statistical processing of CT signs: 0 points — absence, 1 point — slight degree of severity, 2 points — moderate and 3 points — severe. The following CT signs were analysed:

1) bilateral symmetrical hilar lymphadenopathy, degree of nodal enlargement;

2) micronodular dissemination in the parenchyma with perilymphatic distribution, presence, extent and density;

3) formation and consolidation, presence and severity;

4) pulmonary lymph nodes, presence and degree of enlargement;

5) signs of interstitial fibrosis, presence and severity.

Computerised densitometry of the parenchyma in the hilum area (in Hounsfield units — HU) was also performed.

The state of pulmonary function was assessed on the basis of spirometry, study of the structure of the total lung capacity, diffusion capacity of the lungs using the 'Diffustic' diagnostic complex (Geraterm Respiratory GmbH). The following spirometry parameters were analysed: vital capacity of the lungs (VC, % of the normal value), forced vital capacity of the lungs (FVC, % of the normal value), forced expiratory volume in the first second (FEV_1, % of the normal value), FEV_1/FVC (%), inspiratory capacity (IC).

The study of the structure of total lung capacity (TLC, % of the normal value) was carried out with the calculation of residual lung volume (RV, % of the normal value) and the RV/TLC index. The diffusion capacity of the lungs was assessed using the single breath method with the calculation of the diffusion coefficient (DLCO, of the normal value).

Evaluation of FAS results

The total score ranges from 10 to 50, with a higher score indicating more severe fatigue. A score above 22 indicates significant fatigue [22].

General fatigue assessment

- a score of less than 22 indicates a 'normal' (i.e. healthy) level of fatigue,
- from 22 to 34 indicates mild to moderate fatigue,
- 35 or more indicate severe fatigue [23].

Two assessment sub-scales:

1. Mental fatigue (sum of items 3, 6, 7, 8, and 9, sum of items 3, 6, 7, 8, and 9 marked with a blue asterisk) is an indicator of the cognitive effects of fatigue (e.g., lack of motivation, problems starting tasks, problems thinking).

2. Physical fatigue (sum of items 1, 2, 4, 5 and 10) is an indicator of the physical effects of fatigue (e.g. physical tiredness, lack of energy).

Evaluation of KSQ results

The total score ranges from 10 to 70 for the General Health module and from 6 to 42 for the Lungs module.

Unlike the FAS, the literature does not provide a total score of the survey results by the degree of impact of sarcoidosis on the general health and lung function. In this regard, the total score used to form the answers to the question "Does sarcoidosis affect your health?" and "Does Sarcoidosis Harm Your Lungs?" by the degree of exposure (similar to the FAS scale) was conducted on the basis of a consensus opinion of the specialists of the Department of Interstitial Lung Diseases of the "National Scientific Centre of Phthisiology, Pulmonology and Allergology named after F.G. Yanovsky of the NAMS of Ukraine".

1. General Health status:

Sarcoidosis affects your health:

60 to 70 points — very little or not at all;

30 to 60 points — little or moderate;

10 to 30 points — strongly or very strongly.

2. Lungs

Sarcoidosis harms your lungs:

36 to 42 points — very little or not at all;

18 to 36 points — little or moderate;

6 to 18 points — strongly or very strongly.

Statistical methods

The hypothesis that the studied numerical samples follow the normal law of distribution was tested using the D'Agostino D-test. The significance of differences in mean values was assessed using the Student's t-test. All tests were two-sided with the significance level set at $p < 0.05$.

Results and Discussion

Table 1 shows the results of a comparative assessment of CT lung data in patients with newly diagnosed and recurrent sarcoidosis.

As can be seen from the table, in patients with newly diagnosed disease, the cardinal CT symptom of sarcoidosis — bilateral symmetrical hilar lymphadenopathy — was more pronounced than in patients with active relapse. In patients of group 2, there was a tendency to increase the severity of micronodular dissemination, the frequency and severity of consolidations, and the degree of pulmonary nodule enlargement, but these changes were statistically insignificant. In patients with recurrent pulmonary sarcoidosis, signs of interstitial lung fibrosis were observed significantly more often and to a more pronounced extent, and the lucency of the parenchyma in the hilar area was significantly reduced.

Table 1

Chest CT scan parameters in patients with newly diagnosed and recurrent lung sarcoidosis

Indicators	Patient groups		Coefficient of statistical significance, p
	Group 1 (n=16)	Group 2 (n=16)	
Bilateral symmetrical hilar lymphadenopathy, degree of nodal enlargement(points, M ± m)	1.94 ± 0.15	1.44 ± 0.13	0.017*
Dissemination in the parenchyma, degree of spread and density (points, M ± m)	1.31 ± 0.23	2.00 ± 0.27	0.061
Consolidations, presence and severity (points, M ± m)	0.38 ± 0.23	0.63 ± 0.28	0.495
Pulmonary lymph nodes, presence and degree of enlargement (points, M ± m)	0.56 ± 0.16	0.75 ± 0.26	0.538
Signs of interstitial fibrosis, presence and severity (points, M ± m)	0.25 ± 0.18	1.31 ± 0.23	0.0001*
Densitometry of parenchyma in the hilum area (HU)	–795.7 ± 17.8	–721.1 ± 19.9	0.009*

Note: * — The differences are statistically significant.

Table 2

Indicators of spirometry, TLC structure and DLCO in patients with newly diagnosed and recurrent pulmonary sarcoidosis, (M ± m)

Indicators	Patient groups		Coefficient of statistical significance, p
	Group 1 (n=16)	Group 2 (n=16)	
VC (% of the normal value)	88.1 ± 2.9	79.5 ± 4.1	0.090
FEV_1 (% of the normal value)	86.5 ± 3.4	73.8 ± 4.1	0.021*
FVC (% of the normal value)	85.1 ± 5.8	78.9 ± 3.6	0.372
FEV_1/FVC (%)	79.8 ± 1.97	77.4 ± 2.3	0.433
IC (% of the normal value)	88.2 ± 3.22	76.4 ± 4.7	0.047*
TLC (% of the normal value)	87.1 ± 2.9	76.4 ± 3.3	0.021*
RV (% of the normal value)	83.1 ± 3.22	71.2 ± 3.5	0.018*
DLCO (% of the normal value)	86.4 ± 4.2	74.6 ± 4.1	0.048*

Note: * — The differences are statistically significant.

Table 3

Comparative characteristics of FAS and KSQ scores in patients with newly diagnosed and recurrent lung sarcoidosis

Indicators	Patient groups		Coefficient of statistical significance, p
	Group 1 (n=16)	Group 2 (n=16)	
Fatigue Assessment Scale (FAS)			
General fatigue (points, M ± m)	23.1 ± 1.53	28.0 ± 2.3	0.086
Mental fatigue (points, M ± m)	9.6 ± 0.8	12.1 ± 0.9	0.046*
Physical fatigue (points, M ± m)	13.3 ± 0.9	15.4 ± 1.2	0.172
King's College Hospital Questionnaire (KSQ)			
General Health (points, M ± m)	48.3 ± 2.1	44.4 ± 2.6	0.252
Lungs (points, M ± m)	33.1 ± 2.6	25.8 ± 2.4	0.048*

Note: * - The differences are statistically significant.

Table 2 shows the results of a comparative assessment of CT lung data in patients with newly diagnosed and recurrent sarcoidosis.

The table shows that in patients with newly diagnosed pulmonary sarcoidosis, all average spirometry parameters, TLC structure and DLCO were within the normal range. In patients with recurrent sarcoidosis, there was a significant decrease in TLC, RV, IC, indicating the formation of restrictive pulmonary ventilation disorders. The significant decrease in FEV1 is the result of a decrease in static volumes, not bronchial obstruction, as the FEV1/FVC ratio remained within the normal range. At the same time, a significant decrease DLCO was observed in patients of group 2.

Table 3 demonstrates the differences in FAS and KSQ scores in patients with newly diagnosed and recurrent lung sarcoidosis.

The table shows that the level of fatigue according to the FAS scale in patients of group 2 was higher than in patients with newly diagnosed pulmonary sarcoidosis (the level of mental fatigue was statistically significant). At the same time, patients in group 2 reported a greater negative impact of sarcoidosis on their general health and lung condition, as indicated by differences in KSQ scores.

Thus, more pronounced CT signs of sarcoidosis, the degree of impaired ventilatory function and lung diffusion capacity in patients with recurrent pulmonary sarcoidosis are accompanied by more pronounced impairment of their quality of life.

In studies of the validity of the FAS scale and the KSQ questionnaire [22, 24, 25, 26], the dependence of their indicators on many objective parameters, including spirometry and DLCO, was investigated, the results of which allowed the authors to recommend the FAS and KSQ as reliable tools for assessing the quality of life of patients with sarcoidosis.

Conclusion

Patients with active relapse of pulmonary sarcoidosis, compared with patients with newly diagnosed disease, had more pronounced CT signs of lung parenchyma damage in the form of micronodular dissemination, decreased transparency, signs of interstitial lung fibrosis, which most likely had a negative impact on ventilatory function and lung diffusion capacity — the formation of restrictive pulmonary ventilation disorders, and decreased rate of pulmonary diffusion.

More pronounced CT signs of sarcoidosis, the degree of impaired ventilatory function and lung diffusion capacity in patients with recurrent pulmonary sarcoidosis were accompanied by more pronounced impairment of their quality of life according to the FAS scale and the KSQ questionnaire.

The recommendations based on the study of the validity of the FAS scale and the KSQ questionnaire [22, 24, 25, 26], as well as the results of this study, give grounds to recommend these quality of life assessment tools as criteria for determining the timing of the start of specific therapy, if necessary, the correction of its regimens and the timing of treatment completion.

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