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Management Strategy for Patients With Idiopathic Recurrent Pericarditis. Position Statement of the Experts of the Russian Society of Cardiology and Eurasian Association of Therapists

Pericarditis as an inflammatory heart disease is rarely discussed in the cardiology community. The latest European guidelines on pericarditis were published in 2015, and Russian clinical guidelines are dated 2022. However, in recent years, a number of publications have appeared that have forced the scientific community to take a fresh look at this problem. This is mainly due to a change in the paradigm of the treatment of idiopathic recurrent pericarditis (IRP) registered in the Russian Federation as a rare (orphan) disease. According to most experts, IRP is an underestimated cardiac disease, which, due to the lack of specific symptoms and the physicians' alertness regarding the IRP diagnostics, is rarely the subject of scientific discussions. The issues of diagnosis and therapy of IRP in light of the latest reports became the matter under discussion for a group of leading Russian experts chaired by Corresponding Member of the Russian Academy of Sciences, Professor G. P. Arutyunov.

Keywords Pericarditis; idiopathic; recurrent

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What is idiopathic recurrent pericarditis?

In accordance with the definitions provided in the 2015 ESC guideline and the 2022 guideline of the Ministry of Health of the Russian Federation, recurrent pericarditis is understood as a variant of the course of an inflammatory disease of the pericardium, wherein a recurrence of the disease occurs after acute pericarditis with an interval of 4–6 weeks or more [1, 2]. The estimated incidence of acute pericarditis is 27.7–168 cases per 100,000 population per year, with 20–50% of patients experiencing a recurrence of the disease [3].

The onset of recurrent pericarditis is often attributed to autoimmune and autoinflammatory diseases (familial Mediterranean fever, cryopyrin-associated periodic syndrome, tumor necrosis factor receptor-associated periodic syndrome, Still's disease), and the treatment of acute pericarditis without the use of colchicine [4]. In the majority of cases of recurrent pericarditis, the underlying cause remains undetermined (> 80%), which lends support to the diagnosis of idiopathic recurrent pericarditis (IRP) [5]. The majority of experts concur that innate immunity plays a significant role in the pathogenesis of IRP. The autoinflammatory nature of IRP is indicated by the similarity of the clinical manifestations of familial Mediterranean fever and periodic syndrome, in which cases of recurrent pericarditis have been described. In

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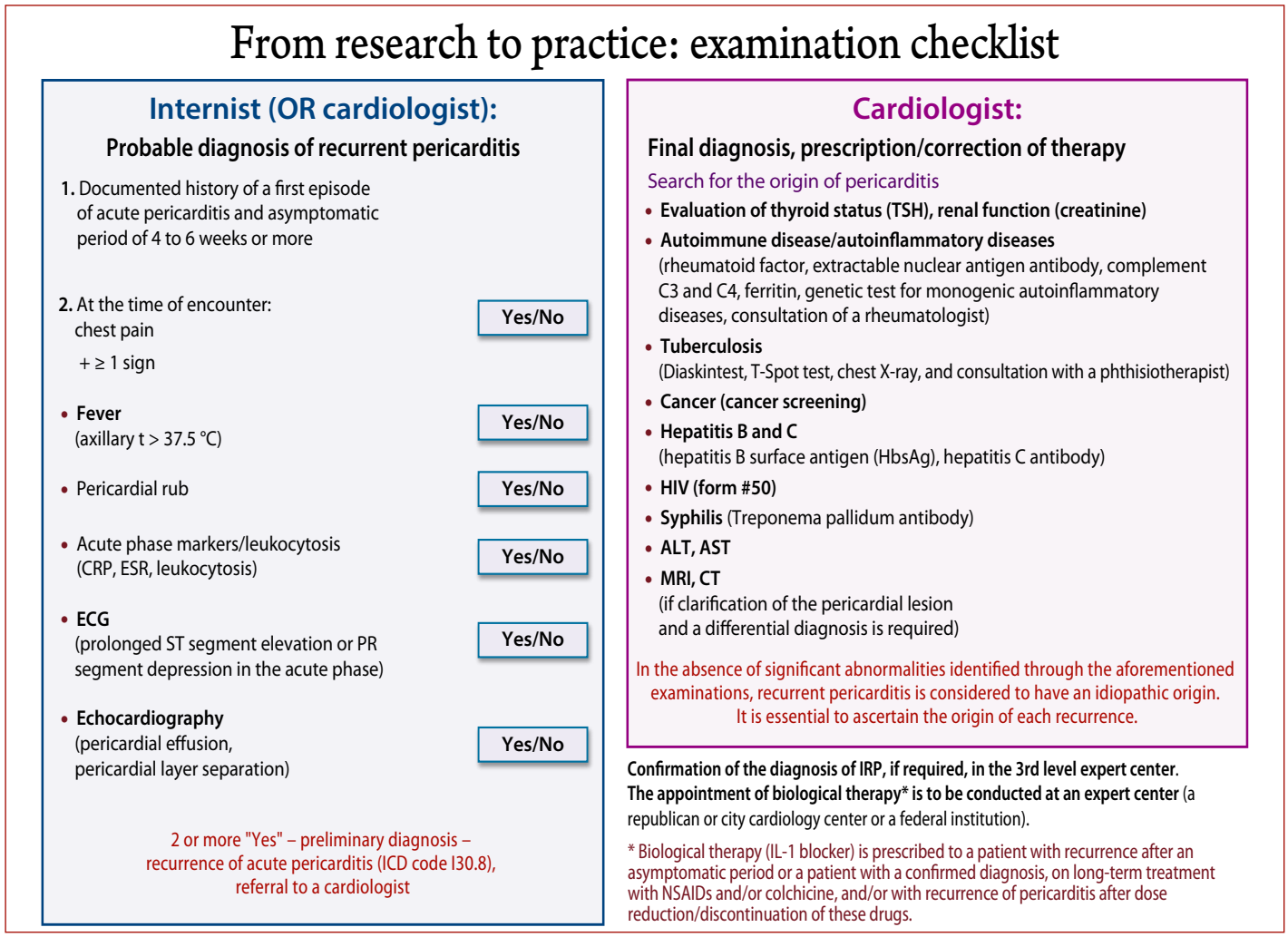
light of these considerations, it is advised that patients with IRP who have not responded to standard therapy undergo genetic testing for the presence of pathological variants in the MEFV, TRAPS, and TNFRSF1A genes [1, 6]. Moreover, patients with classic autoinflammatory diseases may have pathological variants in the gene encoding the NLRP3 inflammasome molecule, which is associated with a lower threshold for its activation [7] and exhibit the associations between the onset of pericarditis and two independent allelic variants of interleukin-1 (IL-1) genes (chromosome 2q14) [8].

Moreover, the immunohistochemical study of pericardial biopsies and the modeling of pericarditis using intrapericardial injection of Zymosan A yielded compelling evidence substantiating the activation of the NLRP3 inflammasome in pericarditis in experimental animals [8].

There is a paucity of data regarding the incidence and prevalence of recurrent pericarditis. The estimated prevalence of IRP in Europe is between 5.4 and 8.1 cases per 100,000 individuals [5]. A retrospective analysis of databases belonging to US insurance companies yielded objective data characterizing the burden of idiopathic pericarditis [9]. The ICD-10 disease codes (I30.8, I30.1, I31.9) were selected as inclusion criteria to encompass patients with idiopathic or post-viral origin of the disease. Nevertheless, the absence of a precise ICD code for IRP renders it challenging to ascertain the actual prevalence of this disease. The analysis revealed that the incidence of recurrent pericarditis was 6.0 cases per 100,000 patients per year, with a prevalence of 11.2 cases. Consequently, the authors of the study calculated the incidence of recurrent pericarditis in the United States to be approximately 20,000 cases per year, with a prevalence of approximately

Central illustration. Management Strategy for Patients With Idiopathic Recurrent Pericarditis



The examination plan is a description of the criteria to be used to diagnose and determine the origin of pericarditis. It is based on the 2022 clinical guidelines and the latest scientific publications on the criteria for determining pericarditis and . The plan represents the agreed position of the authors of the publication.

CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; ECG, electrocardiogram; ICD, the International Classification of Diseases; HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; ALT, alanine aminotransferase; AST, aspartate aminotransferase; MRI, magnetic resonance imaging; CT, computed tomography; IRP, idiopathic recurrent pericarditis.

37,000 cases. In 50% of patients who experienced a first recurrence of the disease, recurrent episodes occurred on multiple occasions. Furthermore, the probability of recurrence generally increased with each subsequent episode, and the time between recurrences steadily decreased, which had a negative impact on the quality of life of patients. The mean annual recurrence rate of ≥3 per year was observed in 6.1% of patients, with a frequency of 15% among patients with inadequate response to standard therapy. Among patients with long-term glucocorticoid use, the recurrence rate was 42%, indicating a more severe disease course in those dependent on steroids. The proportion of patients who received standard drug therapy at the time of the first recurrence of the disease was 71%. This figure declined to 63% and 56%, respectively, for the third and fourth recurrence episodes. In light of the data obtained, the authors have made the conclusion that there exists a cohort of patients for whom the currently available therapies are insufficient to reduce the risk of recurrence. This is evidenced by the recurrent nature of the disease, the prolonged use of glucocorticoids, or the need for surgical intervention, such as pericardial fenestration or pericardectomy.

A review of the medical database of the Almazov National Medical Research Center for the period from January 1, 2015, to January 1, 2020, revealed 6,000 case records of patients with pericardial effusion of various origins. Among these, 34 patients with IRP were identified [10]. The authors extrapolated the data obtained to the adult population, thereby estimating the prevalence of IRP in the Russian Federation to be 1.1 cases per 100,000 population. It is evident that this calculated indicator does not accurately represent the actual prevalence of IRP. A more detailed account of the prevalence could have been provided by the national register. Nevertheless, the analysis enabled the registration of IRP in the Russian Federation as a rare (orphan) pathology, designated by the ICD-10 code I09.2.

Consequently, the hypothesis of the autoinflammatory nature of IRP has been corroborated by compelling evidence derived from recent studies. The principal clinical manifestations of IRP are chest pain in conjunction with elevated body temperature and acute phase marker levels, in addition to electrocardiographic and echocardiographic signs that are characteristic of all variants of pericarditis. In the absence of specific symptoms, a multidisciplinary approach is required to diagnose and treat patients with IRP. This approach should involve cardiologists, rheumatologists, radiologists, and pathologists, and cardiovascular and thoracic surgeons.

In accordance with existing guidelines, non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are recommended as the first-line treatment for patients with recurrent pericarditis [1, 2]. The effect of colchicine is associated with its impact on the assembly of the inflammasome, the formation of the active form of IL-1, and an inhibitory effect on chemotaxis, phagocytosis, and degranulation of neutrophils [11]. According to a meta-analysis of 6 randomized clinical trials evaluating the efficacy of colchicine in acute and recurrent pericarditis, colchicine was associated with a reduction in the rate of recurrence compared with the control group (hazard ratio 0.37, 95% confidence interval 0.27–0.51) [12]. Glucocorticoids, recommended as second-line therapy in the presence of contraindications to NSAIDs or inefficacy of previous therapy, are considered one of the risk factors for the development of recurrent pericarditis when used without prior administration of colchicine, as well as when high doses are used with rapid discontinuation of the drug [13].

The efficacy of colchicine in patients with recurrent pericarditis justifies, from a pathophysiological point of view, the continued search for effective drugs targeting direct IL-1 blockade. Three IL-1 blockers (anakinra, rilonacept, and goflikicept) have demonstrated efficacy in randomized clinical trials in patients with recurrent pericarditis [14]. The Russian IL-1 blocker goflikicept is the sole pharmaceutical agent in the Russian Federation and worldwide that has been approved for the treatment of recurrent pericarditis. The patient population enrolled in the COURSE study (a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of the IL-1 blocker goflikicept for the treatment of patients with IRP) included patients with IRP who were either experiencing disease recurrence (n = 9) or in remission during background therapy (n = 13). In the AIRTRIP study (a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of the IL-1 blocker anakinra), all patients were dependent on steroids, and 57% continued colchicine therapy. Nevertheless, only two patients received glucocorticoids in the COURSE study, which presents an opportunity to discuss the potential benefits of earlier initiation of therapy with IL-1 blockers in IRP. In the randomized withdrawal phase of the study under goflikicept monotherapy, there were no instances of disease recurrence. In contrast, the AIRTRIP study reported 18% of recurrences in the anakinra group, while the RHAPSODY study documented 7% of patients in the rilonacept group experiencing disease recurrence. The safety profile of goflikicept in general did not differ from the outcomes observed in studies of other IL-1 blockers. However, adverse events related to drug administration were observed in only 1 (4.5%) patient undergoing goflikicept therapy, 4 (18.2%) patients receiving rilonacept, and 95.2% of patients on anakinra [15].

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Despite its benign course with rare life-threatening conditions such as cardiac tamponade and constrictive pericarditis, IRP is associated with frequent episodes of temporary disability. According to several studies, healthcare costs were 74% higher for patients with ≥2 recurrences than for patients with a first episode (total healthcare costs are due to higher rates associated with hospitalization) [16]. More than 50% of patients with recurrent pericarditis reported general disability. The IRAP registry indicates that anakinra resulted in a 7-fold reduction in hospitalizations, including a 11-fold reduction in intensive care unit admissions [17]. In the COURSE study, 50% of patients who received goflikicept returned to work.

The emergence of a new drug has the potential to alter the current paradigm for the treatment of pericarditis. However, this also presents a number of challenges that require the input of experts. The current issues related to the algorithm for diagnosing IRP, coding the disease as part of the provision of mandatory or specialized medical care, and the prospects for introducing this nosology into the first group of high-tech medical care for biological therapy, as well as the absence of pericarditis as a nosological form in the medical check-up schedules (Order No. 168n of the Ministry of Health of the Russian Federation «On approval of the procedure for medical check-ups of adults» dated March 15, 2022) remain unresolved.

In this regard, the following issues were addressed by the expert council:

1) Review, adjust, and approve the diagnostic criteria and checklist for the evaluation of a patient with suspected recurrent pericarditis (checklist);
2) Discuss the possibility of incorporating goflikicept (Arcerix) into clinical guidelines in order to provide patients with IRP with effective pathogenetic therapy;
3) Discuss the role of goflikicept in the treatment of IRP, with a particular focus on the potential benefits of initiating goflikicept therapy prior to the use of glucocorticoids in patients undergoing long-term combination therapy with colchicine; elucidate the optimal (sufficient for decision-making) duration of previous background therapy;
4) Evaluate the potential duration of goflikicept therapy in cases where the course of the disease is recurrence-free;
5) Evaluate the potential for the development of a novel clinical statistical group within the context of the Obligatory Medical Insurance/Specialized Medical Care program, specifically for the ICD-10 code I09.2 (rare pathology, recurrent pericarditis) or consider an alternative option of coding IRP within the Obligatory Medical Insurance/Specialized Medical Care program;
6) As an alternative, consider the potential inclusion of this nosology (ICD-10 code I09.2) in the high-tech medical care program.

Following a comprehensive deliberation on the criteria for recurrence and the resolution of recurrence, a consensus was reached on a compromise conclusion:

1. A preliminary diagnosis of recurrent pericarditis requires the presence of a documented history of an episode of acute pericarditis in conjunction with the patient's complaints of chest pain. A period of at least 4–6 weeks must elapse between the initial episode of acute pericarditis and the onset of symptoms, with the intensity of pain being > 3 points on the Numeric Rating Scale. To confirm the diagnosis of recurrent pericarditis, it is necessary to perform additional diagnostic procedures, including an electrocardiogram (to identify characteristic phenomena prolonged ST segment elevation or PR segment depression in the acute phase), echocardiography (to assess the separation of pericardial layers, regional wall movement, and the presence of a constrictive pattern), and acute phase marker tests (C-reactive protein (CRP), erythrocyte sedimentation rate, and leukocytosis). Additional supportive criteria may include the presence of fever (axillary temperature above 37.5 °C) and pericardial rub. The recurrence of the disease is diagnosed when two or more of the three listed signs are present: a CRP level greater than 5 mg/L, a pain score of less than 3 on the Numeric Rating Scale, and the appearance of new or the progression of existing pericardial effusion. The presence of all three main indicators is proposed as a criterion for determining the recurrence resolution: a chest pain score of 3 or less on the Numeric Rating Scale, a CRP level of 5 mg/L or less, and the absence or insignificant level (10 mm or less) of pericardial effusion as determined by echocardiography. The expert group also concurred upon a methodology for the examination of patients with suspected IRP (Central figure).
2. During the meeting, the experts deliberated on the potential inclusion of the IL-1 blocker goflikicept in the clinical guidelines. It was resolved that a distinct chapter on IRP should be included as part of the forthcoming revision of the clinical guidelines on pericarditis and the introduction of goflikicept as a treatment for the pathogenetic therapy of patients with IRP.
3. In light of the recently acquired scientific data, the experts reached a consensus on the revised approach to therapy. They determined that, given the current understanding of the role of IL-1 in the pathogenesis of IRP in cases where combined therapy with NSAIDs and colchicine is ineffective, the administration of

pathogenetic therapy with the IL-1 blocker goflikicept can be considered as the subsequent stage of therapy.

Prior to the administration of the IL-1 blocker goflikicept, the medical commission has determined that a second-line combination therapy comprising low-dose glucocorticoids and colchicine can be initiated.

It is recommended that goflikicept be considered as a potential treatment option in cases where the IRP course is being controlled with NSAIDs and colchicine six months after the initiation of the therapy. In the event of an uncontrolled course of IRP (multiple recurrences of the disease despite the administration of first- and second-line therapies), it is recommended to promptly initiate goflikicept therapy through a comprehensive medical consultation involving experts from specialized centers.

In consideration of the findings derived from the scientific data analysis, which included the results of randomized clinical trials, retrospective analyses of medical databases and registers, the experts have made recommendations regarding the duration of therapy with the IL-1 blocker goflikicept, which should be continued for a minimum of 18 months.

IRP is classified as a nosological form included in the list of rare diseases in the Russian Federation, with the corresponding ICD-10 code I09.2. At the time of writing, this code cannot be used by practicing physicians (cardiologists, internists) who manage patients with pericarditis. The inability to correctly encode this disease renders it «invisible» to health authorities, preventing an accurate estimation of its prevalence. The lack of a clinical statistical group for this disease precludes the provision of high-quality medical care to patients with IRP following diagnosis, including the administration of necessary pathogenetic therapy.

In the context of discussing topical issues of clinical practice, such as clinical issues (late appealability attributable to the unclear clinical picture; uncontrolled use of NSAIDs in the presence of chest pain; late echocardiography to verify the pericardial effusion; the absence of a comprehensive list of mandatory parameters in the clinical guidelines to assess the efficacy of the therapy) and organizational issues (the absence of an algorithm for the utilization of ICD-10 codes I30; I31; I32, leading to IRP hypodiagnosis; the absence of medical and economic standards for IRP to pay for inpatient services; the absence of a tariff for expensive outpatient biological therapy for patients with IRP), the experts reached the following conclusions:

Establish an IRP clinical statistical group (or the development of a flow chart in the event that the creation of a clinical statistical group is not applicable), for which it is recommended to include the IL-1 blocker goflikicept in the List of Life-Saving and Essential Drugs.

Develop a medical and economic standard for ICD-10 code I09.2, with the possibility of its use in therapeutic, cardiological, and day hospitals.

Put forward an initiative on the potential temporary utilization of the code I30.8 (other forms of acute pericarditis) for the diagnosis of IRP, in order to collect statistical data within the registers and to be able to provide patients with pathogenetic therapy with an IL-1 blocker.

There are several issues pertaining to the diagnosis and treatment of IRP, such as a lack of awareness among medical professionals regarding IRP as an independent nosology, insufficient awareness of modern methods of treatment, including IL-1 blockers, and a dearth of data on the prevalence of this disease.

In light of the findings presented by the expert council, it is important to highlight the significant shortcomings in the evaluation of IRP incidence and prevalence and the fact that patients with this pathology constitute an exceptionally vulnerable cohort. The high medical and social significance of the problem is determined by the high prevalence of the disease, the resulting temporary disability, and the necessity for frequent hospitalizations, including those in the intensive care unit. In order to obtain a reliable assessment of the burden of IRP, it is essential to establish a national IRP register, analyze electronic case records with the correct coding of the disease, and evaluate the long-term prognosis.

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