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## Esc pericardial disease guidelines

INTRODUCTION In accordance with the clinical practice policy guidelines previously established by the Executive Committee of the Spanish Society of Cardiology (Sociedad Española de Cardiología [SEC]).<sup>1</sup> This article aims to discuss the most important and new issues in 2015 recommendations of the European Society of Cardiology (ESC) for the diagnosis and treatment of pericardial diseases.<sup>2</sup> Guidelines update the recommendations contained in an earlier version of 2004,<sup>3</sup> and include new evidence of pericardial diseases who have come to light ever since. METHODS The SEC Guidelines Committee has set up a working group to review the evidence and recommendations included in European guidelines on pericardial diseases.<sup>2</sup> All members of the working group have been asked to review the guidelines using a questionnaire covering the following features: a) methodology analysis; b) new contributions and issues that are especially relevant for clinical practice; c) analysis of the most positive and most questionable aspects of these contributions; d) gaps in the guidelines; and e) conclusions and implications for clinical practice. Based on the experts' comments, all members of the working group developed and approved a consensus document. The document was reviewed by a second panel of experts proposed by both the Clinical Cardiology Unit and the DEC Guidelines Committee, and their comments were included in the final document. GENERAL COMMENTS AND METHODOLOGY ANALYSIS The main difference between the 2004 guidelines is that recommendations in the current version are expressed through recommendation classes (I, IIa, IIb and III) and evidence levels (A, B and C). In addition, the recommendations in the 2015 guidelines are shown in tables, with their respective classes and evidence levels, while the 2004 version contained several tables and evidence levels were reported in the text. The current guidelines contain a total of 135 recommendations. As shown in Table 1, the proportion of recommendations with evidence of A-level (based on expert consensus) is very high (99 out of 135 recommendations; 73%). Only 6 recommendations are supported by A-level evidence, and 29 are based on B-level evidence. Most recommendations are backed up by evidence of C-levels that are not annulled but leave a wide margin for critical assessment and individual medical judgment, and 8% - Grade Ia. Thus, the level of available evidence for the treatment of pericardial diseases is low, which should encourage new research on these diseases. The guidelines are organized in several sections (epidemiology, etiology, pericardial syndromes, diagnostic methods of work and imaging, specific etiology of pericardial syndromes, age and sex issues, surgery and interventional techniques, as well as prospects); this document will discuss the most effective, new and questionable aspects. CURRENT AND NEW ASPECTS The most beautiful and new of the current guidelines are listed in Table 2. Critical assessment of relevant and new aspects Epidemiology, Etiology and Classification of pericardial diseases In the new recommendations of 2015 include a new section on the epidemiology of pericardial diseases. Acute pericarditis accounts for 0.1% of hospital admissions and mainly affects young people (aged 16-65). Hospital mortality is 1.1% (associated with severe infectious diseases), and the risk of relapse is about 30% after 18 months. The latest statement is based on 2 studies by Imazio and others<sup>4,5</sup> and clearly deserves comment. To suggest that nearly a third of patients with acute pericarditis will have a relapse seems to be reassessing and certainly very far from our experience of daily clinical practice. The very high rate of relapse identified in these studies can be explained by 2 factors: population bias (15% of patients in the COPES study had autoantibodies-related pericardial disease), and high steroid use, which is difficult to justify (33% of patients with recurrences and 10.9% of patients without recurrence received steroids before randomization, and 16% also received steroids in Spain, relapse in patients with idiopathic acute pericarditis (representing 50% of cases of acute pericarditis in the overall series) below 10%.<sup>6</sup> In patients admitted to tertiary hospitals, after using a comprehensive diagnostic protocol, a higher proportion of comorbidities (up to 22% of secondary pericardial diseases) and relapse were found.<sup>8</sup> Pericardial syndromes Pericardial syndromes are classified in 7 groups: acute pericarditis, continuous and chronic pericarditis, recurrent pericarditis, myopericarditis, pericardial effusion, cardiac tamponade, and constructive pericarditis. There is no mention of the pericardial birth defects discussed in the 2004 guidelines. Acute pericarditis The current guidelines are a clearer definition of diagnostic criteria for acute pericarditis, and 2 of the following criteria are required: chest pain, pericardial rub friction, electrocardiogram changes (ECG) and pericardial effusion. 4 diagnostic tests are recommended for all patients with suspected acute pericarditis: ECG, transthoracic echocardiography (TT), chest X-rays, and inflammatory markers (i.e. C-reactive protein [CRP]) and myocardial damage (creatininase, troponin). Interestingly, all 4 tests to be used in all patients with suspected pericarditis have the same class of recommendations and evidence level (I-C); however, only ECG and echocardiography are useful for diagnosis of acute pericarditis. Compared to the 2004 guidelines, the level of evidence was lowered from I-B to I-C. The guidelines do not specify when 4 diagnostic tests should be carried out (this can be injected, however, that they should be performed by appointment) and the recommendation is not whether they should be repeated or at what interval. These omissions lead to several questions that are not specified by the current guidelines: Is the ECG sufficient for admission or should a repeat ECG be obtained to monitor the evolution of ECG changes? If serial ECGs are needed, when and how often should they be performed? Should TTE and X-rays be carried out immediately or within 24 hours? Should markers be determined both on tolerance and in subsequent serial measurements? How often and for how long? The clinical treatment and therapy section recommends returning to activity once symptoms are resolved and diagnostic tests normalized, suggesting that initial diagnostic tests with abnormal outcome should be repeated once or more times (not specified). A much more controversial issue is the recommendation for initial doses of anti-inflammatory therapy to be maintained to address symptoms and normalise CRP. In other words, after a 1-week course of therapy, at least 1 additional measurement of RRM should be obtained to document the normalization of CRP before reducing the dose of aspirin. If high CRP values persist (which is not uncommon due to poor specificity), should the dosage of anti-inflammatory drugs at aeternum and CRP measurements be maintained weekly, even if the patient is asymptomatic? In our opinion, the need to use CPR to diagnose acute pericarditis is very questionable, and the need to use CPR to guide treatment decisions is even more questionable. As for clinical treatment, current guidelines include a new proposal for a set of major and minor predictors of poor prognosis. The main risk factors are high fever (>38.3°C), subacute course, signs of significant (>20 mm) pericardial emanation, heart tamponade, and no response to nonsteroidal anti-inflammatory drugs (NSAIDs) within 7 days. Myopericarditis, immunosuppression, traumatic injuries, and the use of anticoagulants are considered minor risk factors. Most predictors are defined quite imprecisely. Moreover, all predictors play the same role in hospitalization decisions: any patient with a large predictor or one minor predictor must be admitted. However, these predictors of poor prognosis can have very different consequences. Two examples: first, fever 38.1 °C and cardiac swab are considered the main predictors of poor prognosis, but their value is different; secondly, it is difficult to recognize that 38.1 °C fever should be considered a major predictor, while myopericarditis associated with substantially elevated troponin levels is classified as a minor predictor. Undoubtedly, the most innovative point is drug therapy, based on the publication of 4 randomized multicenter studies on the use of colchicine in patients with acute<sup>4,5</sup> and recurrent pericarditis.<sup>9,10</sup> These studies allowed recommendations to use colchicine as a first-aid drug the highest level of recommendations and evidence (I-A). In acute pericarditis, colchicine is recommended as a first-line drug added to aspirin/NSAIDs (Fig. A). Importantly, in order to increase tolerance and improve adherence, recommended doses of colchicine are lower than in the 2004 guidelines. The recommended initial dose depends on the patient's weight: 0.5 mg once daily (<70kg) or 0.5mg rate (>70kg) for 3 months; narrowing of colchicine is not binding until discontinued. In athletes, physical activity should continue to be limited for at least 3 months after symptoms and normalization of CRP, ECG, and echocardiography (IIa-C) are resolved. A controversial issue in the current guidelines is a recommendation to define CRP as a guide to assessing the response to anti-inflammatory therapy, not just routine clinical criteria. Another important issue to be qualified in current guidelines is that while steroids are not recommended as first-line therapy (II-C), recommendations against steroid use, except in very specific cases are not clearly emphasized. In fact, the guidelines include a grade IIa-C recommendation for the use of low-dose steroids when aspirin/NSAIDs and colchicine are contraindicated or failed. In our opinion, it would be much more appropriate to highlight the numerous side effects associated with steroids and the high risk of recurrence or chronicization of pericarditis, essentially a benign disorder if properly treated. Continuous and chronic pericarditis Pericarditis is considered continuous when symptoms persist for more than 4-6 weeks, and chronic when it persists for more than 3 months (especially in patients with persistent pericardial emanation). Recurrent pericarditis Installations in 2004 discussed recurrent and continuous pericarditis in one section, while the 2015 version includes a separate section on continuous pericarditis and significantly expanded the section on recurrent pericarditis. Diagnosis of recurrence should be based on the same criteria as those used in acute pericarditis, with a minimum non-symptom interval of 4 to 6 weeks after the initial episode (otherwise a continuous pericarditis is considered to be present). If in doubt, CRP, computerized tomography (CT) and cardiac magnetic resonance imaging (CMR) may be useful for diagnosis. The main causes of inadequate treatment in the acute phase, which leads to continuous, chronic or recurrent pericarditis, are: premature return to exercise, non-use of colchicine on top of aspirin/NSAIDs, and, especially, the use of corticosteroids, which is often unwarranted. The key points for the treatment of recurrent pericarditis are well covered by the current guidelines. The main changes are: a) a higher level of evidence that prefers colchicine as a first-line treatment; b) recommend using CRP measurement as a guide to responding to treatment (we unreasonably); c) changes in immunosuppressive therapy, and d) less importance is assigned to intrapericardial administration of corticosteroids. Two multicenter randomized studies<sup>9,10</sup> clearly showed the value of colchicine (added to aspirin/NSAIDs) to treat recurrent pericarditis and confirmed the results of early studies, performed in Spain almost 30 years ago.<sup>11,12</sup> Corticosteroids should be used only as second-line therapy (in patients with inadequate response or contraindications to aspirin/NSAIDs + colchicine), at low doses, and always after careful exclusion of infectious cause (Fig. A). Pressing corticosteroids should be very slow. Immunosuppressants are third-line therapy. Cyclophosphamide is no longer recommended, while a recommendation for the use of azathioprine is preserved and new alternatives such as intravenous immunoglobulin and anakinra are added; expectations of non-steroid corticosteroid administration have been reduced due to insufficient experience. Myopericarditis Nariz on myopericarditis is completely new. However, the recommendations are supported by evidence of C. Patients are diagnosed with myopericarditis if the criteria for acute pericarditis are fully met and there is an increase in biomarkers of myocardial damage (troponin I or T, fraction of creatinase MB), without a newly developed focal or diffuse disorder of the function of the left stomach. Endomyocardial biopsy is not recommended due to benign pericarditis prognosis. On the other hand, an issue that can become highly contentious is the recommendation of coronary angiography in patients with myopericarditis in accordance with clinical presentation and assessment of risk factors to exclude acute coronary syndromes (I-C). It is an invasive and expensive test and entails a significant risk in patients with typically benign disorder. It should be noted that patients who are in intensive care with acute chest pain and constant elevation of the ST segment should be excluded acute coronary syndrome prior to diagnosis of myopericarditis; emergency coronary angiography should be carried out in case of doubt instead of waiting for myocardial damage markers to be raised. Finally, as far as anti-inflammatory therapy is concerned, the recommendation class has been downgraded to IIa-C. Aspirin or NSAIDs can be used for anti-inflammatory therapy, with recommended doses lower than those used in pericarditis, as models of myopericarditis animals showed lack of efficacy and increased mortality when using NSAIDs. Pericarditis with the new Pericardial Effusion function in the 2015 guidelines is that tamponade and pericardial effusion are presented under separate headings, and the dimensions of echocardiographic effusion are classified into 3 types (lightweight, <10 mm; moderate, 10-20 mm; and large, >20 mm) instead of 4. Recommendations and algorithms for the treatment of pericardial emanation (Fig. B) are notable. One of the 2 main support for these recommendations<sup>13,14</sup> comes from a neighboring country.<sup>14</sup> For symptomatic patients who have no evidence of inflammation or when NSAIDs have failed, guidelines recommend taking into account pericardiocentesis and prolonged catheter drainage based on a lower rate of recurrence. The prognosis depends on etiology. Moderate/large effusion is more commonly associated with bacterial and malignant causes. Idiopathic cases have a favorable prognosis for mild to moderate emanance, although a recent series including more than 9,000 patients has not confirmed a benign course of asymptomatic mild emanation.<sup>15</sup> Patients with a large chronic pericardial e-oopata have a high risk of cardiac swab; this also applies to subacromioclavicular and significant renal failure, as well as those with the disease, secondary disease. However, the degree of pericardium calcification does not affect survival. Child-Pugh score should be assessed because score >7 (B or C) is associated with high mortality. Diagnostic work and visualization. Added multimodality Imaging Additive section on the main contributions of different visualization methods, suggested a smart and easy to understand approach to diagnostic works. The two tables were included to summarize and compare results, strengths and limitations of echocardiography, CT and CMR. The terms of use of CT or CMR are not specified, and both are considered second-line tests for use when additional data is required. In Spain, access to these imaging tests, especially CMR, may still be limited in some institutions; however, they are increasingly becoming universally used methods. Echocardiography is a first-line imaging test and should be used in all patients with clinical suspected pericardial disease (recommendation I-C). For selected cases that do not fulfill any other severity criterion and without signs of cardiomegaly on chest X-rays, institutions without ultrasonic equipment may consider conducting this test. In addition, in some patients, such as those with suspected pericardial effusion, the use of a pocket ultrasound device may be adequate to rule out significant disease. The appropriate use of this new technology is not defined in the current guidelines. One important new feature is clear and informed recommendations for etiological testing in patients with pericarditis and pericardial e-oopata similar to those offered in Spanish a few years ago.<sup>7,8</sup> The proposed etiological study takes into account both the clinical relevance of etiological diagnosis (the reasons for which there is specific therapy, especially pericarditis, pericarditis associated with systemic diseases and neoplastic pericarditis) and regional epidemiological profile. In Europe, relevant and reliable epidemiological data were reported by Spanish, 7.8 Italian and French groups; thus, these recommendations are clearly in force in Spain. Some risk factors were associated with a higher proportion of selected etiology in epidemiological studies. However, we believe that not every risk factor is more likely to have the same impact, and the mere presence of a risk factor does not always guarantee the execution of aggressive tests. For example, a patient with typical clinical manifestations indicative of acute pericarditis and presenting with a large pericardial emanance that shows a rapid response to anti-inflammatory therapy is likely to have a benign cause, and pericardiocentesis can be avoided in many cases. In our opinion, a clear limitation of this section is the lack of a clear indication of when to suspect a specific cause and order aggressive diagnostic tests, and the appropriate sequence of these tests. Figure 1 Specific Etiology Educative specific etiology discusses: viral, bacterial, renal failure, autoimmunity or inflammatory diseases, post-trauma and neoplastic and others. Each subsection includes Pivotal Tables with recommendations for diagnosis and therapy, with a level of evidence (11 new tables). Diagnosis of viral pericarditis requires histological, cytological, immunogistochemical and molecular assessments in samples of pericardial fluid or pericardial/epicardial biopsy. By contrast, viral serology plays no role in diagnosis (excluding human immunodeficiency and hepatitis C viruses) (Grade III). Specific therapies included in previous guidelines have been eliminated because they are still under investigation. The recommendation against steroid use is included (II-C). As for tuberculosis pericarditis, the recommended duration of treatment decreased to 6 months. In bacterial pericarditis, intrapericardial antibiotic therapy is no longer recommended. The term autoactive pericarditis, which was supposed to include pericardial disorders due to inflammatory and autoimmune diseases in previous guidelines, is no longer used. The section on syndromes after heart injuries has been carefully reviewed. This section combines several forms of pericardial inflammation (e.g., post-infarction, post-pericardiotomy, and post-traumatic pericarditis) with the suppression of common autoimmune pathogenesis after initial myocardial injury. The new guidelines propose a new set of diagnostic criteria for these syndromes that differ from diagnostic pericarditis criteria.<sup>16</sup> Regarding prevention, a systematic review has shown that only colchicine is associated with a reduced risk of post-pericardiotomy syndromes. However, due to the increased risk of gastrointestinal adverse events, colchicine is not recommended if there is no sign of systemic inflammation. Age and sex issues in the diseases of the pericardium of a particular section are included in the child age group. Up to 5% of children who cited emergency departments with chest pain have pericarditis. Clinical and prognostic features, as well as recurrences and diagnostic criteria, are similar to those in adults. Online additional material includes a schedule for the treatment of children's patients. Relapse appears to double the colchicine (recommendation of IIa-C), and avoiding steroid use is more strongly stressed than in adults. Anakinra (interleukin-1 receptor antagonist) is also included as a therapeutic option, especially for steroid-dependent children (IIb-C recommendation class). The Grade III-C recommendation was prescribed aspirin and steroids. No new features regarding pregnancy, breastfeeding and women of reproductive age were included. However, the proposed treatment scheme in online additional material deserves a mention. High doses of aspirin (500-750 mg/8h) are still recommended as a first-line drug within the first 20 weeks of pregnancy, and NSAIDs may be considered during the first and second trimesters. After week 20, NSAIDs can cause narrowing of the arterial duct and renal impairment. They should always be withdrawn in week 32. As for elderly patients, only a brief comment is included to highlight the need to assess comorbidities and poor adherence to treatment. Indometacin is not recommended. Doses of colchicine should be halved, as well as care for renal function assessment and drug interaction. Interventional techniques and surgery have been added to describe pericardiocentesis managed by fluoroscopy or echocardiography, as well as pericardiotomy, but no new features have been added compared to previous recommendations. Relative contraindications in pericardiocentesis included in previous guidelines are no longer mentioned. Brief discussions on intrapericardial therapy and pericardial access to electrophysiology do not include important new functions. A specific section on the pericardial window and pericardiectomy is included in the current guidelines, instead of discussing these methods in different sections, as in the previous version, and surgical technique is now described. Prospects and failure to express needs Installation provide a very stimulating description of several unresolved problems in pericardial disease. Seventeen questions for future research are mentioned. The most pressing questions include: a) a better understanding of pathophysiology and risk factors for recurrence and narrowing pericarditis; b) should physical activity limits be applied to patients with acute and recurrent pericarditis?; a) is intrapericardial fibrinolysis really useful and safe in exudative pericarditis? and d) what is pericarditis and what is myocarditis? QUESTIONABLE ASPECTS AND GAPS IN GUIDELINES Manage and gap gaps were mentioned in the previous sections and summarized in Table 3. CONCLUSIONS YOU guidelines in 2015 on pericardial diseases condition an important gap in literature, because the previous edition was published 11 years ago. Although the document includes a large number of Class C recommendations (expert opinions and consensus) due to the lack of randomized studies on pericardial diseases, it provides a clearer diagnostic and therapeutic approach to different types of pericardial syndromes and the use of currently available techniques. New and broader evidence focuses on the use of colchicine as a first-line therapy for acute and recurrent pericarditis. Diagnostic, prognostic and therapeutic algorithms are mainly based on expert opinion. However, they are useful in managing different syndromes, despite the limitations and doubts discussed in the relevant sections. Overall, the 2015 guidelines will be an invaluable help to improve the treatment of pericardial diseases. The constraints and controversial issues listed in Table 3 do not detract from its value. On the contrary, they should encourage further research into the disease in the near future. Conflict of interest declared. SEC Working Group on Diagnosis and Treatment of Pericardial Diseases 2015: Josep Hino (coordinator), Manuel Angita (coordinator), Joaquín Alonso, Joaquín Aznar, Jaime Francisco Pascual, María Dolores Martínez Ruiz, Beatrice Ardóñez, Juan Keeles and Gabriel Vázquez. ESC Expert Reviewers 2015 On Diagnosis and Treatment of Pericardial Diseases: Gonzalo Barón Escrivias, Vivencio Barrios Alonso, Juan Koshin Sales, Covadonga Fernández-Gollin Loban, Jose Maria Gamez Martinez, Xavier Garcia-Mole Marinon, Luis Jimenez Borejero, Eva Larraudogolia Gorosiz, Federico Lombera Romero, Ana Peseet Kubera, Thomas Ripoll Vera and Jose Angel Rodriguez SEC Guidelines Committee: Manuel Angita (chairman), Ángel Cecier, Fernando Alfonso, Lina, Jose A. Barrabes, Ignacio Fernandez Lozano, Jose Juan Gomez de Diego, Luis Rodriguez Padial, Jose Alberto San Roman, Pedro-Luis Sanchez, Juan Sanchis and Alessandro Sionis. SEC Working Group on Diagnosis and Treatment of Pericardial Diseases 2015, ESC Expert Reviewers 2015 Guidelines for the Diagnosis and Treatment of Pericardial Diseases and the SEC Guidelines Committee. A full list of names of all authors is provided in the Appendix. Add-on.

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