### Special article

# Spanish Interdisciplinary Committee for Cardiovascular Disease Prevention and the Spanish Society of Cardiology Position Statement on Dyslipidemia Management. Differences Between the European and American Guidelines



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#### ABSTRACT

The publication of the 2013 American College of Cardiology/American Heart Association guidelines on the treatment of high blood cholesterol has had a strong impact due to the paradigm shift in its recommendations. The Spanish Interdisciplinary Committee for Cardiovascular Disease Prevention and the Spanish Society of Cardiology reviewed this guideline and compared it with current European guidelines on cardiovascular prevention and dyslipidemia management.

The most striking aspect of the American guideline is the elimination of the low-density lipoprotein cholesterol treat-to-target strategy and the adoption of a risk reduction strategy in 4 major statin benefit groups. In patients with established cardiovascular disease, both guidelines recommend a similar therapeutic strategy (high-dose potent statins). However, in primary prevention, the application of the American guidelines would substantially increase the number of persons, particularly older people, receiving statin therapy. The elimination of the cholesterol treat-to-target strategy, so strongly rooted in the scientific community, could have a negative impact on clinical practice, create a certain amount of confusion and uncertainty among professionals, and decrease follow-up and patient adherence. Thus, this article reaffirms the recommendations of the European guidelines. Although both guidelines have positive aspects, doubt remains regarding the concerns outlined above. In addition to using risk charts based on the native population, the messages of the European guideline are more appropriate to the Spanish setting and avoid the possible risk of overtreatment with statins in primary prevention.

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Posicionamiento del Comité Español Interdisciplinario de Prevención Cardiovascular y la Sociedad Española de Cardiología en el tratamiento de las dislipemias. Divergencia entre las guías europea y estadounidense

RESUMEN

Palabras clave: Prevención cardiovascular Guías clínicas Dislipemias La publicación en Estados Unidos de la guía de 2013 de *American College of Cardiology/American Heart Association* para el tratamiento del colesterol elevado ha tenido gran impacto por el cambio de paradigma que supone. El Comité Español Interdisciplinario de Prevención Cardiovascular y la Sociedad Española de Cardiología han revisado esa guía, en comparación con la vigente guía europea de prevención cardiovascular y de dislipemias.

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El aspecto más destacable de la guía estadounidense es el abandono de los objetivos de colesterol unido a lipoproteínas de baja densidad, de modo que proponen el tratamiento con estatinas en cuatro grupos de riesgo aumentado. En pacientes con enfermedad cardiovascular establecida, ambas guías conducen a una estrategia terapéutica similar (estatinas potentes, dosis altas). Sin embargo, en prevención primaria, la aplicación de la guía estadounidense supondría tratar con estatinas a un número de personas excesivo, particularmente de edades avanzadas. Abandonar la estrategia según objetivos de colesterol, fuertemente arraigada en la comunidad científica, podría tener un impacto negativo en la práctica clínica y crear cierta confusión e inseguridad entre los profesionales y quizá menos seguimiento y adherencia de los pacientes. Por todo ello, el presente documento reafirma las recomendaciones de la guía europea. Ambas guías tienen aspectos positivos pero, en general y mientras no se resuelvan las dudas planteadas, la guía europea, además de utilizar tablas basadas en la población autóctona, ofrece mensajes más apropiados para el entorno español y previene del posible riesgo de sobretratamiento con estatinas en prevención primaria.

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#### **Abbreviations**

ACC/AHA: American College of Cardiology/American Heart

Association
CVD: Cardiovascular disease

LDL-C: low-density lipoprotein cholesterol

#### INTRODUCTION

Hypercholesterolemia affects 1 in 2 adults in Spain<sup>1</sup> and is one of the major risk factors for atherosclerotic vascular disease. The major atherothrombotic complications of hypercholesterolemia lead to elevated morbidity and are the main cause of death worldwide.<sup>2</sup> Thus, the prevention and management of hypercholesterolemia in the context of cardiovascular risk management is a crucial issue for physicians and other health professionals. For this reason, various scientific institutions have developed clinical practice guidelines that discuss and summarize the available scientific evidence and provide recommendations in line with the guidelines. The European guidelines for dyslipidemia management and cardiovascular prevention, respectively published in 2011 and 2012 by the task force of the ESC/EAS (European Society of Cardiology/European Atherosclerosis Society),<sup>3,4</sup> were well received in Spain and prompted various initiatives for their implementation.<sup>5,6</sup> The American College of Cardiology/American Heart Association (ACC/AHA) guidelines were published in late 2013,7 and immediately sparked controversy on both sides of the Atlantic. Although the European and American guidelines agree in many respects, they also differ on other important points, such as the drastic change in the approach to the initial application of lipidlowering therapy and therapeutic targets, which has led to some confusion and uncertainty among many professionals, who question which approach is the best to follow. In response to this controversy, this article has been prepared by a group of physicians from different specialties and areas of work at the initiative of the Spanish Interdisciplinary Committee for Cardiovascular Disease Prevention (Appendix) and the Spanish Society of Cardiology.

#### COMMENTARY ON THE METHODOLOGY OF BOTH GUIDELINES

The European and American guidelines use a similar system for grading the strength of evidence and strength of recommendation. Both guidelines use the COR/LOE (Class of Recommendation/Level of Evidence); system. The ESC/EAS combines this system with the GRADE (Grading of Recommendations Assessment, Development,

and Evaluation) system<sup>3,4</sup> and recommendations can be strong or weak. The ACC/AHA uses the National Heart Lung and Blood Institute grading system, which ranges from class A (strong recommendation) to class E (expert opinion).<sup>7</sup>

The European guideline presents a wide range of clinical information that covers the entire spectrum of cardiovascular prevention, whereas the American guideline succinctly reviews the issues that the experts consider critical. The European guideline comprehensively discusses the process of the detection, management, and treatment of patients with dyslipidemia and addresses the assessment of cardiovascular risk and laboratory parameters, treatment goals, recommended lifestyle changes, and drugs that have proven useful in the treatment of dyslipidemia. It also addresses the issues of low values of high-density lipoprotein cholesterol and hypertriglyceridemia, the treatment of dyslipidemia in special situations, the follow-up of patients undergoing drug therapy, and finally, measures to improve treatment adherence among these patients. In contrast, the ACC/AHA guideline answers very specific clinical questions that are considered relevant regarding evidence on the use of therapeutic targets and the efficacy and safety of lipid-lowering drugs, particularly statins, in cardiovascular prevention.

A major limitation of the ACC/AHA guideline is that it only includes data from randomized clinical trials, as based on the recommendations of the Institute of Medicine. This makes it difficult to generalize the results to the general population, because participants in trials are usually high-risk individuals. Thus, the recommendations of the American guidelines, strictly interpreted, would only apply to individuals with similar characteristics. In addition, as drug therapy is easier to evaluate by randomized clinical trials than lifestyle modification interventions, the exclusion of other evidence from observational studies (cohort and casecontrol), surveys, and registries may result in guidelines that promote the excessive use of drugs at the cost of promoting healthy eating, physical activity, and tobacco cessation.

Asymptomatic individuals or those with subclinical disease perceive risk differently and their acceptance of and adherence to long-term drug therapy is more complicated than that of patients who require medical care after experiencing an acute cardiovascular event. In addition, the lower the cardiovascular risk, the lower the overall benefit-to-risk ratio of statin therapy. Therefore, in primary prevention, the decision to administer statin therapy should take into account the preferences of the individuals susceptible to intervention, after seriously assessing nondrug measures (diet, physical activity, and tobacco cessation), and the balance between the potential benefits and risks of intervention should be discussed in depth with the patient. However, the American guideline, despite its apparent patient-centered approach, in which the patient would have participated in decision-making, strongly recommends statin therapy for people with

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