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Original article

Impact of the New American and British Guidelines on the Management and Treatment of Dyslipidemia in a Spanish Working Population

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ABSTRACT

Introduction and Objectives: The guidelines of the American College of Cardiology/American Heart Association and the British National Institute for Health and Clinical Excellence on the management and treatment of dyslipidemia recommend significant changes, such as the abolition of therapeutic targets and the use of new risk tables. This study aimed to evaluate the impact of the use of these new guidelines compared with the application of European guidelines.

Methods: Observational study conducted among Spanish workers. We included all workers registered with the *Sociedad de Prevención de Ibermutuamur* in 2011 whose cardiovascular risk could be evaluated. Cardiovascular risk was calculated for each worker using the Systematic Coronary Risk Evaluation cardiovascular risk tables for low-risk countries, as well as the tables recommended by the American and British guidelines.

Results: A total of 258 676 workers were included (68.2% men; mean age, 39.3 years). High risk was found in 3.74% of the population according to the Systematic Coronary Risk Evaluation tables and in 6.85% and 20.83% according to the British and American tables, respectively. Treatment would be needed in 20 558 workers according to the American guidelines and in 13 222 according to the British guidelines, but in only 2612 according to the European guidelines. By following the American guidelines, the cost of statins would increase by a factor of 8.

Conclusions: The new recommendations would result in identifying more high-risk patients and in treating a larger fraction of the population with lipid-lowering drugs than with the European recommendations, which would result in increased costs.

Impacto de las nuevas guías estadounidense y británica en el manejo y el tratamiento de las dislipemias en una población laboral española

Palabras clave:
Enfermedades cardiovasculares
Fármacos cardiovasculares
Guía de práctica clínica

RESUMEN

Introducción y objetivos: La guía para el manejo y el tratamiento de las dislipemias del *American College of Cardiology/American Heart Association* estadounidense y la del *National Institute for Health and Clinical Excellence* británico recomiendan cambios importantes, como la supresión de los objetivos terapéuticos o la utilización de unas tablas de riesgo nuevas. Este estudio pretende evaluar el impacto de utilizar estas nuevas guías en comparación con lo que supone la aplicación de la guía europea.

Métodos: Estudio de tipo observacional realizado en trabajadores españoles. Se incluyó a todos los trabajadores reconocidos por la Sociedad de Prevención de Ibermutuamur durante el año 2011 y cuyo riesgo cardiovascular era evaluable. De cada sujeto, se calculó el riesgo cardiovascular utilizando las tablas *Systematic Coronary Risk Evaluation* para países de bajo riesgo y las tablas recomendadas por las guías estadounidense y británica.

Resultados: Se incluyó a 258.676 trabajadores (el 68,2% varones; media de edad, 39,3 años). Según las tablas *Systematic Coronary Risk Evaluation*, el 3,74% de la población resultó ser de alto riesgo, mientras que según las tablas británicas eran el 6,85% y según las tablas estadounidenses, el 20,83%. Se debería tratar a más de 20.558 trabajadores si se sigue la guía estadounidense, 13.322 con la británica y 2.612 siguiendo las recomendaciones de las sociedades europeas. Con la guía estadounidense, el coste diario de estatinas se multiplicaría casi por 8.

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Conclusiones: La nuevas recomendaciones supondrían identificar a más pacientes de alto riesgo y tratar con hipolipemiantes a más población que con las recomendaciones europeas, lo que aumentaría los costes.

Abbreviations

ASCVD: atherosclerotic cardiovascular disease
LDL-C: low density lipoprotein cholesterol

INTRODUCTION

The European guidelines on the management of dyslipidemia and on cardiovascular prevention published in 2011 and 2012, respectively, by a joint committee from distinct European scientific societies[1,2] have been translated, debated and adapted, with broad circulation in Spain[3,4]. The guidelines of the ACC/AHA (American College of Cardiology/American Heart Association)[5] on the management and treatment of dyslipidemias were published at the end of 2013, and immediately gave rise to intense debate, both in the United States and in the European Union and other countries. Specifically, the American guidelines, focused their recommendations on the use of statins, and defined 3 treatment levels: high-, moderate-, and low-intensity, depending on the statin and its dosage. These guidelines abandon low-density lipoprotein cholesterol (LDL-C) targets and implicitly assume that, for each treatment level, there will be a specific percentage reduction in LDL-C.

Another new, and also controversial, aspect of these guidelines is the publication of new risk tables that measure the risk of atherosclerotic cardiovascular disease (ASCVD tables) based on different American cohorts and make specific recommendations on statin therapy for primary prevention in people with cardiovascular risk $\geq$ 7.5%.

The British National Institute for Health and Clinical Excellence (NICE) is another internationally prestigious group that has recently published a draft document on the management of dyslipidemias, which is similar to the American guidelines in that it does not recommend therapeutic targets and also defines treatment intensity. This document recommends the use of the QRISK2 risk tables, which are derived from primary care databases in England,[6] and statin therapy in primary prevention among people with cardiovascular risk $\geq$ 10% ($\geq$ 20% in the previous guidelines).

If the new American guidelines in the United States, with the risk factor profile of the NHANES-III (Third National Health and Nutrition Examination Survey) 2005-2010 cohort (3773 participants) were extrapolated to the entire US population aged between 40 years and 75 years (115.4 million people), the number of individuals to be treated with statins would increase from 43.2 million (37.5%) to 56 million (48.6%), and most of this difference (10.4 million/12.8 million) would consist of individuals without cardiovascular disease.[7] In the subgroup aged 60 years to 75 years (primary prevention), this fraction would increase from 30.4% to 87.4% among men and from 21.2% to 53.6% among women. Another Swiss study, in a sample of 3297 people aged 50 years to 75 years, estimated that the use of the new American tables rather than the European guidelines would double the number of persons eligible for lipid-lowering therapy, a difference that was much higher in the group aged 50 years to 60 years.[8] Extrapolating these data to the Swiss population, the application of the American guidelines would increase the annual cost of cardiovascular prevention treatment by €333.7 million.

Studies have recently been published that evaluate LDL-C control in patients with a prior coronary event according to the recommendations of secondary prevention guidelines.[9,10]

The aim of this study was to evaluate the impact of using the American and British guidelines versus the European guidelines on the percentage of patients requiring statin therapy in a Spanish working population in primary prevention.

METHODS

The methodology of this study has been previously described as part of the ICARIA (Ibermutuamur CArdiovascular RIsk Assessment)[11] study. For this particular study, we included all workers whose companies had contracted health monitoring services from the *Sociedad de Prevención de Ibermutuamur*, who underwent a medical review between January 4th and December 30th 2011, and who had complete information in all fields required for cardiovascular risk assessment. All autonomous regions of Spain were represented in the study sample, including Ceuta and Melilla. Incomplete cases, ie, those with unverified outliers, and previously diagnosed cases of cardiovascular disease were excluded. For each worker, the risk of cardiovascular disease was calculated using the SCORE (Systematic Coronary Risk Evaluation) tables for low-risk countries,[12] and using the QRISK2[13] and ASCV[14] tables. The risk functions were developed from the original formulas, and the workers' cardiovascular risk was calculated using StataSE 12. To calculate risk according to the QRISK2 formula, a number of assumptions were made: by default, race was considered to be "WHITE"; UK postcode was not applicable; and the responses to questions on atrial fibrillation, rheumatoid arthritis, and history of cardiovascular disease before 60 years of age in first-degree relatives were considered negative, since this information was not recorded.

Depending on the risk estimation obtained from the various tables, we calculated the percentage of patients who achieved the therapeutic goals, and who were undergoing lipid-lowering therapy according to SCORE. Specifically, following the recommendations of the Fourth Joint Document of the European Guidelines on Cardiovascular Prevention,[2] LDL-C treatment targets for patients at high or very high risk according to SCORE are as follows: for a risk of 5%-9% and $\geq$ 10%, an LDL-C concentration of $<$ 100 mg/dL and $<$ 70 mg/dL is recommended, respectively. For the QRISK2 and ASCV tables, since the NICE and ACC/AHA recommendations do not stipulate therapeutic targets for LDL-C, all patients at high risk were considered to be candidates for lipid-lowering therapy.

To estimate the additional costs associated with statin therapy in high-risk individuals according to the various tables, the following statins were considered: 40 mg simvastatin, €2.17; 20 mg atorvastatin, €9.21; and 10 mg rosuvastatin, €25.95; all these drugs were offered in packs of 28 tablets.

All analyses were carried out using StataSE 12.