



ORIGINAL ARTICLE

Fibrates in the secondary prevention of cardiovascular disease (infarction and stroke). Results of a systematic review and meta-analysis of the Cochrane collaboration[☆]



Jesus Millan^{*}, Xavier Pintó, Angel Brea, Mariano Blasco, Antonio Hernández Mijares, Juan Ascaso, Angel Diaz, Teresa Mantilla, Juan Pedro-Botet

Grupo de trabajo de Dislipemia Aterogénica, Sociedad Española de Arteriosclerosis, Spain

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Abstract Fibrates are a group of drugs that are known mainly for reducing triglycerides, increasing high density lipoproteins (HDL), and reducing the fraction of small, dense LDL particles. The results of a Cochrane Collaboration study have recently been published on their efficacy and safety in the secondary prevention of severe cardiovascular accidents, including coronary and cerebrovascular disease.

The study included randomised clinical trials in which the fibrate was compared with placebo or with no treatment. Clinical trials comparing two different fibrates were excluded.

The clinical trials evaluated included a total of 16,112 patients (13 trials). The meta-analysis (including all the trials with fibrates) showed evidence of a protective effect of the fibrates compared with placebo as regards a compound objective of non-fatal stroke, non-fatal myocardial infarction, and death of cardiovascular origin (hazard ratio of 0.88, with a 95% confidence interval of 0.83–0.94; in 16,064 individuals included in 12 studies). Thus, the results showed, with a moderate level of evidence, that fibrates could be effective in secondary prevention considering a compound objective of non-fatal stroke, non-fatal myocardial infarction, and death of cardiovascular origin.

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^{*} Corresponding author.

E-mail address: jesus.millan@salud.madrid.org (J. Millan).

PALABRAS CLAVE

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Revisión

Los fibratos en la prevención secundaria de la enfermedad cardiovascular (infarto e ictus). Resultados de una revisión sistemática y metaanálisis de la colaboración Cochrane

Resumen Los fibratos son un grupo de fármacos que se caracterizan principalmente por reducir los triglicéridos, elevar las lipoproteínas de alta densidad (HDL) y reducir la fracción de partículas de LDL pequeñas y densas. Se ha publicado recientemente los resultados de un estudio de la Colaboración Cochrane sobre su eficacia y seguridad en la prevención secundaria de accidentes cardiovasculares graves, incluyendo enfermedad coronaria y cerebrovascular.

El estudio incluye ensayos clínicos aleatorizados en los que el fibrato se compara con placebo o con no tratamiento. Se excluyen ensayos clínicos comparando 2 fibratos diferentes.

Los ensayos clínicos evaluados incluyen un total de 16.112 pacientes (13 ensayos). El metaanálisis (incluyendo todos los ensayos con fibratos) muestra la evidencia de un efecto protector de los fibratos comparados con placebo en lo relativo a un objetivo compuesto de ictus no fatal, infarto de miocardio no fatal, y muerte de origen cardiovascular (tasa de riesgo de 0,88, con intervalo de confianza (95%) de 0,83 a 0,94; en 16.064 individuos incluidos en 12 estudios). Por tanto, los resultados muestran con una evidencia de grado moderado que los fibratos pueden ser efectivos en la prevención secundaria considerando un objetivo compuesto de ictus no fatal, infarto no fatal, y muerte de origen cardiovascular.

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Introduction

Fibrates are drugs with the fundamental effects of reducing the abnormalities characterising a specific group of dyslipidaemias. This pharmacological group includes: clofibrate, gemfibrozil, bezafibrate, ciprofibrate and fenofibrate; although, currently, the most used drugs in practice are fenofibrate and gemfibrozil, due to their effects and the capacity of the former to be combined safely in poly-medicated patients, and particularly in treatments combined with statins.

Consequently, fibrates have been used in the treatment of certain dyslipidaemias, primarily and fundamentally those characterised by increased triglycerides with or without a decrease in cHDL, either primary or secondary to very prevalent processes such as diabetes mellitus type 2, visceral obesity or metabolic syndrome. The paradigm of these dyslipidaemias is that known as atherogenic dyslipidaemia, in which the three basic characteristics outlined above converge: hypertriglyceridaemia, low cHDL, and presence of a large proportion of small, dense LDL particles.

The significance of this type of dyslipidaemia is that we know accurately that it is a decisive component of the residual cardiovascular risk of lipid origin once the cLDL levels are under control. Therefore, detection and treatment of atherogenic dyslipidaemia seems essential if lipid alterations are present; and especially in patients who present a high cardiovascular risk or who have had previous clinical manifestations of cardiovascular disease (secondary prevention), in whom strict control of each and every one of the risk factors becomes imperative.

A response to this interest in determining the clinical benefits of fibrates in secondary prevention has been provided in a systematic review by the Cochrane Collaboration

which was published with the meta-analysis of 13 clinical trials, which included 16,112 individuals.¹ Eleven of the trials refer to patients with a history of coronary heart disease, two refer to patients with a history of cerebrovascular disease; one of the trials refers to patients with a history of both. The study refers to the effects of fibrates with regard to the placebo, and the results on coronary episodes (fatal and non-fatal) and cerebrovascular episodes (fatal and non-fatal), as well as mortality (vascular and all-cause mortality) are analysed.

Review

Epidemiological studies have shown unequivocally that the increase in triglycerides and the decrease in cHDL are associated significantly with an increase in cardiovascular risk.²⁻⁴ In addition, these lipid factors are responsible for a residual risk in patients treated with statins, in whom the statin does not prevent the cardiovascular risk associated with hypertriglyceridaemia or the decrease in cHDL.^{5,6}

Fibrates, which have been used for decades, have proven to be effective in the prevention of cardiovascular accidents, but their benefit in cardiovascular prevention as a whole has been a matter of controversy. A recent meta-analysis⁷ made it very clear that they are useful for the prevention of cardiovascular accidents, but their role in primary or secondary prevention is not properly clarified.

In fact, and considering only secondary prevention in patients with a history of cardiovascular disease, the results have not always been consistent, and, while some studies have shown a benefit,^{8,9} other studies have called this benefit into question.^{10,11}

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