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(54) **COMPOSITION AND/OR METHOD FOR PREVENTING ONSET AND/OR RECURRENCE OF CARDIOVASCULAR EVENTS**

(75) Inventors: **Mitsuhiro Yokoyama**, Hyogo (JP); **Hideki Origasa**, Toyama (JP); **Masunori Matsuzaki**, Yamaguchi (JP); **Yuji Matsuzawa**, Hyogo (JP); **Yasushi Saito**, Chiba (JP); **Yuichi Ishikawa**, Hyogo (JP); **Shinichi Oikawa**, Tokyo (JP); **Jun Sasaki**, Fukuoka (JP); **Hitoshi Hishida**, Aichi (JP); **Hiroshige Itakura**, Tokyo (JP); **Toru Kita**, Kyoto (JP); **Akira Kitabatake**, Nara (JP); **Noriaki Nakaya**, Tokyo (JP); **Toshiie Sakata**, Fukuoka (JP); **Kazuyuki Shimada**, Tochigi (JP); **Kunio Shirato**, Miyagi (JP)

Correspondence Address:
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747 (US)

(73) Assignee: **MOCHIDA PHARMACEUTICAL CO., LTD.**, Tokyo (JP)

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(57) **ABSTRACT**

Provided are composition and/or methods useful in preventing onset and/or recurrence of cardiovascular events, especially in patients who have escaped the unstable period after cardiovascular angioplasty or in hyperlipidemia patients who have been treated with HMG-CoA RI.

COMPOSITION AND/OR METHOD FOR PREVENTING ONSET AND/OR RECURRENCE OF CARDIOVASCULAR EVENTS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to Japan Patent Application No. 2005-200503, filed on Jul. 8, 2005, which is incorporated herein by reference.

TECHNICAL FIELD

[0002] This invention relates to compositions and/or methods for preventing onset and/or recurrence of cardiovascular events which contain at least ethyl icosapentate (hereinafter abbreviated as EPA-E).

BACKGROUND ART

[0003] Westernization of diet has resulted in the increase of patients suffering from lifestyle-related diseases such as diabetes, hyperlipidemia, and hypertension. Some of these diseases finally lead to arteriosclerotic diseases such as myocardial infarction, angina pectoris, and cerebral infarction and sometimes results in death. As treatment of arteriosclerotic diseases, for example, drugs or surgical methods such as vascular angioplasty are generally utilized.

[0004] For prevention of arteriosclerotic diseases or improvement of quality of life, it is important to reduce risk factors such as hyperlipidemia, diabetes, hypertension, and smoking habit. In the major epidemiological survey where incidence rates of hyperlipidemia and coronary artery disease were examined, positive correlation was found between serum total cholesterol (hereinafter abbreviated as T-Cho) concentration or serum triglyceride (hereinafter abbreviated as TG) concentration and the onset of the coronary artery disease. More specifically, even stronger positive correlation was found for the serum low density lipoprotein cholesterol (hereinafter abbreviated as LDL-Cho) concentration, while negative correlation was found for the serum high density lipoprotein cholesterol (hereinafter abbreviated as HDL-Cho) concentration.

[0005] Pharmacotherapy of hyperlipidemia has become relatively easy, and suppression of onset of coronary artery diseases by a strong therapy of hyperlipidemia using 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor (hereinafter abbreviated as HMG-CoA RI) has been proved in a large scale clinical trial. For example, when male hyperlipidemia patients with no history of myocardial infarction were orally administered with pravastatin sodium for an average period of 4.9 years, serum T-Cho concentration decreased by 20%, serum LDL-Cho concentration decreased by 26%, serum HDL-Cho concentration increased by 5%, and serum TG decreased by 12%, and as a consequence, the total incidence rate of nonfatal myocardial infarction and cardiovascular death decreased by 31% (The New England Journal of the Medicine, 1995, vol. 333, pp. 1301-1307). When patients with history of angina pectoris or myocardial infarction were orally administered with simvastatin for an average period of 5.4 years, serum T-Cho concentration decreased by 25%, and serum LDL-Cho concentration decreased by 35%, serum HDL-Cho concentration increased by 8%, and serum TG decreased by 10%, and as a consequence, the incidence rate of major cardiovascular events decreased by 34% (The Lancet, 1994, vol. 344, the issue of, pp. 1383-1389). The decrease in the incidence rate of the cardiovascular events was also approximately 20 to 30% in other large scale clinical trials using HMG-CoA RI (Archives of Internal Medicine, 1999, vol. 159, No. 1, pp. 1793-1802). These results may not be sufficient for clinical practice.

[0006] It has been reported that when a capsule that includes a ω-3 polyunsaturated fatty acid composition containing EPA-E and ethyl docosahexaenoate (hereinafter abbreviated as DHA-E) in a total amount of 850 to 882 mg was orally administered to patients within three months from the onset of acute myocardial infarction every day for 3.5 years, the combined incidence rate of cardiovascular death, nonfatal myocardial infarction, and nonfatal cerebral infarction decreased by 20%, and that, while cardiovascular death decreased by 30%, no significant effect was observed on nonfatal cardiovascular events (The Lancet, vol. 354, Aug. 7, 1999, pp. 447-455). It was also reported that their death rate decreased when 1 g of essential fatty acids containing EPA-E and DHA-E in a total amount of 85% was administered to patients with history of myocardial infarction every day for 3.5 years (WO00/48592 (JP 2002-537252 A)). It is also disclosed that the use of EPA or DHA in combination with a cholesterol synthesis inhibitor represses cardiovascular events (U.S. Pat. No. 6,159,993).

[0007] High purity EPA-E is commercially available in the trade names of Epadel and Epadel S (manufactured by Mochida Pharmaceutical Co., Ltd.) as the therapeutic drug for hyperlipidemia. It has been reported that when such high purity EPA-E is orally administered at 600 mg per administration and three times a day immediately after meal (when serum TG is abnormal, the dose can be increased to the level of 900 mg per administration and three times a day), serum T-Cho concentration and serum TG can be reduced by 3 to 6% and by 14 to 20%, respectively (Drug Interview Form "EPA preparation, Epadel capsule 300", revised in July, 2002; January, 2003; pp. 21-22.), and that, based on such action, such high purity EPA-E is expected to exert effects on cardiovascular events of hyperlipidemia patients (American Heart Journal, 2003, vol. 146, No. 4, pp. 613-620.).

[0008] On the other hand, as an option for treatment of Ischemic heart disease, a surgical treatment, cardiovascular angioplasty such as PTCA, and coronary stent implantation has been widely carried out mainly for serious patients, but cardiovascular events are easy to occur after the angioplasty. For example, the cardiovascular event after PTCA is due to resetenosis at the PTCA site, which generally means progression of stenosis in more than 50% of the region expanded by PTCA, or generation of new lesion in many cases. The resetenosis rate is approximately 30-40% and the resetenosis is usually observed at or within six months. The resetenosis rate can be reduced by using stent but it is not always reliable (T. Yamaguchi & M. Kitahara, Kon-nichi no tiryoushishin, published by IGAKUSHOIN, pp. 237, 2003).

[0009] As medical treatment with drugs after cardiovascular angioplasty, anti-platelet agents are often used. For example, combination of aspirin and Ticlopidine (Clopidogrel) is administered as a matter of course when a stent is inserted. For prevention of stent thrombi, combination of aspirin and cilostazol is administered (T. Yamaguchi & M. Kitahara, Kon-nichi no tiryoushishin, published by

IGAKUSHOIN, pp. 245-246, 2003). In particular, care after the surgery is considered important.

[0010] Although fish oil or omega-3 fatty acids have been administered to the patients with resetenosis in the unstable period after cardiovascular angioplasty, there are controversial reports regarding their efficacy, while there is a view that they have to start to be administered before the cardiovascular angioplasty (J Am Coll Cardiol. 2005 May 17;45(10):1723-8; Am Heart J. 2002 June; 143(6):E5; J Am Coll Cardiol. 1999 May; 33(6):1619-26; Am J Cardiol 77,31-36 (1996))

[0011] Although it was reported that two-year administration of HMG-CoA RI, plavastatin, after PTCA had reduced the resetenosis rate and thus been effective for repression of the cardiovascular events (Am J Cardiol. 2000 Oct. 1; 86(7):742-6) as well as that three- to four-year administration of fluvastatin from immediately after Percutaneous Coronary Artery intervention repressed the onset of the the cardiovascular events (JAMA. 2002 Jun. 26; 287(24):3215-22), an improved treatment is expected which enable more repression of the cardiovascular events.

SUMMARY OF THE INVENTION

[0012] In view of the situation that death from the cardiovascular diseases is still a major cause of death, and it is a serious problem that many cardiovascular events are still impossible to prevent by the HMG-CoA RI therapy, an object of the present invention is to provide a composition and/or method for preventing onset and/or recurrence of the cardiovascular events.

[0013] In order to solve the problems described above, the inventors of the present invention made an extensive study and found that EPA-E has an effect of preventing onset and/or recurrence of the cardiovascular events, and in particular, an effect of preventing onset and/or recurrence of the cardiovascular events in patients who have escaped the unstable period after cardiovascular angioplasty. The present invention has been thus completed on the basis of such findings. Accordingly, the present invention is directed to:

(1) composition for preventing onset and/or recurrence of cardiovascular events comprising at least EPA-E as its effective component; specifically,

[0014] (2) composition for preventing onset and/or recurrence of cardiovascular events in a hyperlipidemia patient to whom HMG-CoA RI treatment has been carried out, comprising administrating to the patient the composition containing ethyl icosapentate as its effective component;

[0015] (3) method for preventing onset and/or recurrence of cardiovascular events in a patient who has history of acute myocardial infarction, comprising administrating to the patient the composition containing ethyl icosapentate as its effective component;

[0016] (4) method for preventing onset and/or recurrence of cardiovascular events in a patient who has escaped the unstable period after cardiovascular angioplasty, comprising administrating to the patient the composition containing ethyl icosapentate as its effective component;

(5) method according to (4), in which the composition starts to be administered after the patient has escaped the unstable period;

[0017] (6) method for preventing onset and/or recurrence of cardiovascular events in a patient beyond six months after the cardiovascular angioplasty, comprising administrating to the patient the composition containing ethyl icosapentate as its effective component;

(7) method according to any of (4) to (6), in which the administration of the composition is started beyond six months after the cardiovascular angioplasty and is continued at least for two years;

[0018] (8) method according to any of (4) to (7), in which the cardiovascular angioplasty is selected from a group consisting of percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal coronary recanalization (PTCR), directional coronary atherectomy (DCA), coronary stent implantation (coronary artery stenting), and coronary artery bypass grafting (AC bypass grafting);

(9) method according to any of (1) to (8), in which the patient suffers from hyperlipidemia;

(10) method according to any of (1) to (9), in which the proportion of the ethyl icosapentate in the total content of fatty acids and derivatives thereof is 96.5% by weight or more;

(11) method according to any of (1) to (10), in which the ethyl icosapentate is orally administered at an amount of 0.3 g/day to 6.0 g/day immediately after meals;

(12) method according to any of (1) to (11), in which the composition is used in combination with an inhibitor for 3-hydroxy-3-methylglutaryl coenzyme A reductase;

(13) method according to (12), in which the inhibitor is pravastatin or simvastatin; and

(14) method according to any of (1) to (13), further comprising DHA-E.

DESCRIPTIION OF THE PREFERRED EMBODIMENT

[0019] Next, the present invention is described in detail.

[0020] A first embodiment of the present invention is a composition and/or a method for preventing onset and/or recurrence of the cardiovascular events which contains EPA-E as its effective component.

[0021] Although any composition for prevention of any onset and/or recurrence of cardiovascular events at least containing EPA-E as its effective component is within the scope of this invention, preferred examples include compositions for prevention of cardiovascular death, fatal myocardial infarction, sudden cardiac death, nonfatal myocardial infarction, cardiovascular angioplasty, new onset of rest angina and effort angina, and destabilization of angina pectoris. The subject of the administration of the composition includes all humans requiring prevention of onset of cardiovascular events, and preferred examples include hyperlipidemia patients. While EPA-E content in the total fatty acid and dosage of administration are not particularly limited as long as intended effects of the present invention are attained, high purity EPA-E is preferred; for example, the composition having a proportion of the EPA-E of preferably 40% by weight or more, more preferably 90% by weight or more, and still more preferably 96.5% by weight or more in

total of the fatty acids and their derivatives. The daily amount in terms of EPA-E is typically 0.3 to 6.0 g/day, preferably 0.9 to 3.6 g/day, and still more preferably 1.8 to 2.7 g/day.

[0022] Other preferable fatty acid contained is any omega-3 unsaturated fatty acid, especially DHA-E. The ratio of EPA-E/DHA-E in the composition, the content of EPA-E and DHA-E in the total fatty acids and administration amount of EPA-E and DHA-E are not limited but the ratio is preferably 0.8 or more, more preferably 1.0 or more, still more preferably 1.2 or more. The composition is preferably highly purified; for example, the proportion of EPA-E+DHA-E in the fatty acids and their derivatives is preferably 40% by weight or more, more preferably 80% by weight or more, and still more preferably 90% or more. The daily amount in terms of EPA-E+DHA-E is typically 0.3 to 10.0 g/day, preferably 0.5 to 6.0 g/day, and still more preferably 1.0 to 4.0 g/day. The low content of other long chain saturated fatty acids is preferred, and among the long chain unsaturated fatty acids, the content of ω-6 fatty acids, and in particular, the content of arachidonic acid is preferably as low as less than 2% by weight, and more preferably less than 1% by weight.

[0023] A second embodiment of the present invention is a composition and/or a method for preventing onset and/or recurrence of cardiovascular events of hyperlipidemia patients who is undergoing HMG-CoA RI therapy, which contains at least EPA-E as its effective component. While HMG-CoA RI includes all inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase, a pharmaceutically administrable inhibitor is preferably used, which is preferably pravastatin, simvastatin, lovastatin, fluvastatin, cerivastatin, atorvastatin, pitavastatin, rosuvastatin, and salts and derivatives thereof, and more preferably, pravastatin, lovastatin, simvastatin, fluvastatin, atorvastatin, pitavastatin, or rosuvastatin, and most preferably, pravastatin or simvastatin.

[0024] All pharmaceutically administrable salts can be used, and preferred are sodium and potassium salts such as pravastatin sodium, fluvastatin sodium, cerivastatin sodium, atorvastatin calcium, pitavastatin calcium, and rosuvastatin calcium. In the present invention, "pravastatin", for example, also includes the pravastatin in the form of a salt unless otherwise noted.

[0025] A third embodiment of the present invention is a composition and/or a method for preventing onset and/or recurrence of cardiovascular events in patients who have history of acute myocardial infarction, which contains at least EPA-E as its effective component.

[0026] In the second and third embodiments of the present invention, preferred embodiments of the type of the cardiovascular events, proportion of the EPA-E in the total fatty acid, daily amount, and proportion of other long chain fatty acids are the same as those of the first embodiment of the present invention as described above.

[0027] A fourth embodiment of the present invention is a composition and/or a method for preventing onset and/or recurrence of cardiovascular events in patients who have escaped the unstable period after cardiovascular angioplasty, which contains at least EPA-E as its effective component. The patients who underwent cardiovascular angioplasty have a high possibility to show the symptoms due to the cardiovascular angioplasty itself within about six months and a higher possibility within about three months, after the cardiovascular angioplasty. This period is referred to as the unstable period in this specification. Therefore, a fourth embodiment of the present invention is preferably a composition for preventing onset and/or recurrence of cardiovascular events in patients beyond six months after the cardiovascular angioplasty. Thus the cardiovascular events such as resetenosis during the unstable period, which are caused by the cardiovascular angioplasty itself, are excluded from the scope of this invention. The type of the cardiovascular angioplasty is not particularly limited, and examples include percutaneous transluminal coronary angioplasty (hereinafter abbreviated as PTCA), percutaneous transluminal coronary recanalization (hereinafter abbreviated as PTCR), directional coronary atherectomy (hereinafter abbreviated as DCA), coronary stent implantation (coronary artery stenting), and coronary artery bypass grafting (hereinafter abbreviated as AC bypass grafting).

[0028] A fifth embodiment of the present invention is a composition and/or a method for preventing onset and/or recurrence of cardiovascular events in patients who have escaped the unstable period after cardiovascular angioplasty, which contains at least EPA-E as its effective component, and preferably a composition for preventing onset and/or recurrence of cardiovascular events in patients beyond six months after the cardiovascular angioplasty.

[0029] The composition according to the fourth and fifth embodiments is administered to the patients who have escaped the unstable period after cardiovascular angioplasty and preferably to the patients beyond six months after the cardiovascular angioplasty.

[0030] The cardiovascular events that occur after the unstable period are thought to generate by a mechanism which is different from that of the cardiovascular events such as resetenosis during the unstable period, which are caused by the cardiovascular angioplasty itself. The rate of the cardiovascular events that occur after the unstable period is relatively high. The composition according to the fourth and fifth embodiments is administered after the unstable period, specifically beyond after cardiovascular angioplasty. The composition is preferable to be administered continuously for a long time, specifically for two years or more, more preferably for three years and a half or more, still more preferably for five years or more and thus is effective for preventing onset and/or recurrence of cardiovascular events which occur after the unstable period.

[0031] While EPA-E content in the total fatty acid and dosage of the compositions according to the fourth and fifth embodiments of the present invention are not particularly limited as long as the composition contains EPA-E as its effective component and intended effects of the present invention are attained, high purity EPA-E is preferably used; for example, the composition having a proportion of the EPA-E of preferably 40% by weight or more, more preferably 90% by weight or more, and still more preferably 96.5% by weight or more in total of the fatty acids and their derivatives. The daily amount in terms of EPA-E is typically 0.3 to 6 g/day, preferably 0.9 to 3.6 g/day, and still more preferably 1.8 to 2.7 g/day.

[0032] Other preferable fatty acid contained is any omega-3 unsaturatedfatty acid, especially DHA-E. The ratio

of EPA-E/DHA-E in the composition, the content of EPA-E and DHA-E in the total fatty acids and administration amount of EPA-E and DHA-E are not limited but the ratio is preferably 0.8 or more, more preferably 1.0 or more, still more preferably 1.2 or more. The composition is preferably highly purified; for example, the proportion of EPA-E+DHA-E in the fatty acids and their derivatives is preferably 40% by weight or more, more preferably 80% by weight or more, and still more preferably 90% or more. The daily amount in terms of EPA-E+DHA-E is typically 0.3 to 10.0 g/day, preferably 0.5 to 6.0 g/day, and still more preferably 1.0 to 4.0 g/day. The low content of other long chain saturated fatty acids is preferred, and among the long chain unsaturated fatty acids, the content of ω-6 fatty acids, and in particular, the content of arachidonic acid is preferably as low as less than 2% by weight, and more preferably less than 1% by weight.

[0033] The compositions according to the first to fifth embodiments of the present invention have the effect of preventing onset and/or recurrence of cardiovascular events when orally administered to a normal person, a person suffering from hyperlipidemia, diabetes or hypertension with the risk of cardiovascular events, or a patient to whom HMG-CoA RI treatment has been carried out, although those whom the compositions are administered are not limited thereto. The composition of the present invention also has a combined effect when used with HMG-CoA RI, and accordingly, onset and/or recurrence of the cardiovascular events can be even more effectively prevented by using in combination with the HMG-CoA RI.

[0034] The compositions of the present invention contain a smaller amount of impurities such as saturated fatty acids and arachidonic acid, which are unfavorable for cardiovascular events, than fish oil or fish oil concentrate, and intended effects can be attained without causing problems like overnutrition or excessive intake of vitamin A. In addition, since the effective form of the present composition is an ester, which is more stable to oxidation than that in fish oil in which its effective form is a triglyceride, a sufficiently stable composition can be produced by adding a conventional antioxidant. Thus the use of the EPA-E has enabled production of a composition for preventing onset and/or recurrence of cardiovascular events which can be used in clinical practice.

[0035] In the present invention, the term "icosapentaenoic acid" designates all-cis-5,8,11,14,17-icosapentaenoic acid.

[0036] In the present invention, the term "cardiovascular events" is used to generally refer to pathological changes of cardiovascular system, and includes cardiovascular death (fatal myocardial infarction and sudden cardiac death), non-fatal myocardial infarction, cardiovascular angioplasty (PTCA, PTCR, DCA, coronary stent implantation (coronary artery stenting), and AC bypass grafting), new onset of rest angina or effort angina, and destabilization of angina pectoris (hospitalization, and PTCA, PTCR, DCA, coronary stent implantation (coronary artery stenting), AC bypass grafting, or other cardiovascular angioplasty).

[0037] In the present invention, the term "hyperlipidemia patient" designates the patient experiencing increase in serum T-Cho concentration, increase in serum LDL-Cho concentration, decrease in serum HDL-Cho concentration, or increase in serum TG. In the narrow sense, the term "hyperlipidemia patient" designates, a patient who suffers from any one of hypercholesterolemia (with the serum T-Cho concentration of about 220 mg/dl or higher, and in the narrower sense, with the serum T-Cho concentration of 250 mg/dl or higher), hyper-LDL cholesterolemia (with the serum LDL-Cho concentration of 140 mg/dl or higher), hypo-HDL cholesterolemia (with the serum HDL-Cho concentration of less than 40 mg/dl) and hypertriglyceridemia (with the serum TG of 150 mg/dl or higher).

[0038] In the present invention, the term "use in combination with HMG-CoA RI" includes both the embodiment in which the composition containing EPA-E as its effective component and the HMG-CoA RI are simultaneously administered and the embodiment in which both agents are separately administered. When these agents are simultaneously administered, they may be formulated either as a combination drug, or separate drugs. When these agents are separately administered, the composition containing EPA-E as its effective component may be administered either before or after the HMG-CoA RI. The administration amount and ratio of the the composition containing EPA-E as its effective component and the HMG-CoA RI may be adequately selected. Preferable examples of use of HMG-CoA RI which is administered in combination is the similar to those shown in the second embodiment as example.

[0039] The compositions and/or methods according to the first to fifth embodiments of the present invention has the action of preventing onset and/or recurrence of the cardiovascular events by sole administration of the composition, and in particular, the present composition is expected to exert an effect of preventing onset and/or recurrence of the cardiovascular events which cannot be prevented by administration of the HMG-CoA RI. In addition, EPA-E has not only the action of reducing the serum T-Cho concentration and the serum TG, but also the action of suppressing platelet aggregation based on inhibition of arachidonic acid cascade, which is a pharmacological action different from the HMG-CoA RI. Therefore, the stronger action of preventing onset and/or recurrence of the cardiovascular events of the present composition can be exerted by using in combination with the HMG-CoA RI.

[0040] The compositions according to the first to fifth embodiments of the present invention can pharmaceutically accepted carriers as well as its effective component. Since EPA-E and DHA-E are highly unsaturated, inclusion of an effective amount of an antioxidant such as butylated hydroxytoluene, butylated hydroxyanisole, propyl gallate, gallic acid, and pharmaceutically acceptable quinone, and α-tocopherol is preferable.

[0041] The preparation may be orally administered to the patients in the dosage form of tablet, capsule, microcapsule, granules, fine granules, powder, oral liquid preparation, syrup, or jelly. Preferably, the preparation is filled in a capsule such as soft capsule or microcapsule and is orally administered.

[0042] It is to be noted that high purity EPA-E soft capsule (Epadel™ and Epadel S™) are commercially available in Japan as safe therapeutic agents for arteriosclerosis obliterans and hyperlipidemia with reduced side effects, and the proportion of EPA-E in the total fatty acid is at least 96.5% by weight. Further, soft capsule (Omacor™, Ross products) containing about 46% by weight of EPA-E and about 38%

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