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研究課題名（和文）冠動脈プラーク退縮におけるコレステロール吸収阻害薬および合成阻害薬の効果

研究課題名（英文）Plaque Regression with Cholesterol absorption Inhibitor or Synthesis inhibitor Evaluated by IntraVascular UltraSound

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研究成果の概要（和文）：研究計画書に則り、熊本大学を中心に本研究参加施設からプロトコル I、II 合わせて 250 例の登録を得、登録患者の画像データを本院に設置されたコアラボに収集し定量的 IVUS 画像解析および定量的冠動脈造影解析を行った。中間解析結果では、一般的な二次予防法であるアトルバスタチン単独療法と比較してエゼチミブ追加療法における低い副作用発現率、より強力な LDL-C 低下効果、同等以上のプラーク退縮効果が確認されている。

研究成果の概要（英文）：Based on the study protocol, 250 cases (including protocol I and II) have been enrolled from Kumamoto University and collaborating centers. Coronary angiography (CAG) and intravascular ultrasound (IVUS) images were collected to our core laboratory, quantitative CAG and IVUS analysis was done. Interim analysis revealed that low incidence of drug adverse reaction, greater lowering effect of low-density lipoprotein cholesterol, and equivalent or greater plaque regression effect in atorvastatin + ezetimibe group than in atorvastatin alone group.

交付決定額

（金額単位：円）

	直接経費	間接経費	合計
2010年度	1,600,000	480,000	2,080,000
2011年度	1,400,000	420,000	1,820,000
年度			
年度			
年度			
総計	3,000,000	900,000	3,900,000

研究分野：医歯薬学

科研費の分科・細目：内科系臨床医学・循環器内科学

キーワード：臨床心血管病態学

1. 研究開始当初の背景

積極的な LDL コレステロール（LDL-C）低下療法が冠動脈プラークを退縮させることが報告され、欧米では冠動脈疾患二次予防目的に LDL-C < 70mg/dl の達成が推奨されているが、LDL-C 低下療法には、HMG-CoA 還元酵素阻害薬（スタチン）によるコレステロール合成抑制と小腸コレステロールトランスporter阻害薬：エゼチミブによるコレステロール吸収阻害の2つの治療戦略が存在

する。

2. 研究の目的

本研究の目的は、広く一般に行われているコレステロール合成抑制薬（スタチン）と比較して、コレステロール吸収阻害薬が冠動脈疾患患者の冠動脈プラーク退縮効果と冠動脈プラーク性状の安定化に及ぼす影響について、血管内超音波法や生化学的マーカーを用いて検討すること。

3. 研究の方法

(1)迅速な目的達成のため国内関連施設との間で他施設共同として実施。

(2)冠動脈インターベンション (PCI) 治療を受ける患者で LDL-C<100mg/dL に達していない患者が対象。

(3)PCI時にIVUSにて対象プラークを観察し、下記の無作為割付試験および前向き観察研究を行い、全症例で LDL-C<70mg/dLを目指す。プロトコール I:アトルバスタチン単独療法群 vs アトルバスタチン+エゼチミブ併用投与群

プロトコール II:ストロングスタチン+エゼチミブ併用療法

(4)9-12 ヶ月の薬物療法後、確認造影検査の際に定量的冠動脈造影と IVUS を再施行し、対象冠動脈プラークの退縮、組織性状の変化を評価。

4. 研究成果

(1)研究計画書に則り、熊本大学を中心に本研究参加施設からプロトコール I、II 合わせて 250 例の登録を得、登録患者の画像データを本院に設置されたコアラボに収集し定量的 IVUS 画像解析および定量的冠動脈造影解析を行った。

(2)中間解析結果では、一般的な二次予防法であるアトルバスタチン単独療法と比較してエゼチミブ追加療法における低い副作用発現率、良好な LDL-C 低下効果、同等のプラーク退縮効果が確認されている。

5. 主な発表論文等

(研究代表者、研究分担者及び連携研究者には下線)

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6. 研究組織

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