

## 日本のスタディにおいて高用量のピタバスタチンによる治療は低用量の治療を上回った (2017 AHA, Session LBS.02)

REAL-CAD: 高用量ピタバスタチンは安定CADを有する日本人患者において心血管イベントを有意に減少させた

REAL-CAD: High-dose pitavastatin significantly reduced cardiovascular events in Japanese patients with stable CAD

高用量スタチン療法はアジアの臨床現場ではあまり用いられていないが、安定冠動脈疾患(CAD)を有する日本人患者において有効であり忍容性に優れている、と2017 American Heart Association Scientific Sessions で発表された。REAL-CAD 試験には、日本の733施設から13,000人超が組み入れられた。5年後に、高用量群(4mg/日)においては、低用量群(1mg/日)に比べ、主要評価項目(心血管死、非致死性MI、非致死性脳卒中、および不安定狭心症による入院)の有意なリスク減少が認められた( $p=0.001$ )。5年間の治療必要数(NNT)は63であった。

### Full Text

Although high-dose statin therapy isn't widely used in clinical practice in Asia, it is efficacious and well-tolerated in patients from Japan who have stable coronary artery disease (CAD), according to research presented at the 2017 American Heart Association Scientific Sessions.

The Randomized Evaluation of Aggressive or Moderate Lipid Lowering therapy with Pitavastatin in Coronary Artery Disease (REAL-CAD) trial included more than 13,000 patients from 733 centers in Japan, making it one of the largest to compare high- and low-dose statin therapy—and the first randomized controlled trial in Asia to do so.

The open-label study found that high-dose (4 mg/day) as compared with low-dose (1 mg/day) pitavastatin therapy significantly reduced CV events in Japanese patients with stable CAD ( $P=0.01$ ).

Despite ACC/AHA and ESC guidelines, the high-intensity statins are not widely used in daily clinical practice, particularly in Asia. No clear evidence regarding "more versus less statins" has been established in Asian populations. Most of the doses of high-intensity statin therapy defined in the ACC/AHA guidelines are not approved in Japan.

Furthermore, the incidence of CV events is lower in Asian patients than in Western patients. The benefits of high-intensity statins demonstrated in Western patients with relatively high CV event risk might not be clinically relevant in patient populations at relatively low event risk.

The REAL-CAD clinical trial evaluated the efficacy of high-intensity Pitavastatin therapy in patients with stable coronary artery disease in relatively low risk population.

13,054 patients from 733 institutions in Japan were randomized to high-intensity (pitavastatin 4 mg/day) or low-intensity (pitavastatin 1 mg/day) statin therapy for 5 years. Six months after randomization, mean LDL-C was  $73.8 \pm 20.3$  mg/dL in the high-intensity group and  $89.4 \pm 21.4$  mg/dL in the moderate-intensity group.

"Current guidelines call for high-intensity statin therapy in patients with . . . CAD based on several previous 'more-or-less-statin' trials," write the investigators.

"However, no clear evidence regarding more vs less statin has been established in Asian populations," said Dr. Hiroaki Shimokawa of Tohoku University Graduate School of Medicine, Sendai, Japan during a press briefing.

In October 2015, the steering committee decided to terminate the study 2 years early, "despite the original event-driven trial design, because a substantial number of centers were reluctant" for the study to be extended further, reported Shimokawa. This led to the noncompletion of the final follow-up in "a substantial proportion" of patients.

Even with this limitation, there was a significant risk reduction for the primary endpoint (a composite of cardiovascular death, non-fatal myocardial infarction (MI), non-fatal stroke, and hospitalization for unstable angina). The hazard ratio (HR) was 0.81 for the high- vs low-dose statin group (95% CI 0.69–0.95,  $P=0.01$ ). In addition, 4.3% vs 5.4%, respectively had a CV event. The number needed to treat (NNT) for 5 years was 63.

"The present study provides support for the notion that administration of higher doses of statins within the range of local approval would be the preferred therapy in patients with established CAD regardless of the baseline LDL-C levels," summarized Shimokawa.

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## Cardiology特集

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