Late-Breaking Clinical Trial

Session Title/Time/Location:
General Session/Thursday, May 7, 2015, 11:30 am-12:15 pm (Pacific Time)/General Session/Coronary Track (Indigo Level ABEF)

Impact of Combined Lipid Lowering with Calcium Channel Antagonist-based Blood Pressure Control on Coronary Plaque Regression: MILLION Study

Category: Pharmacotherapy

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Background: Recent clinical studies showed that aggressive LDL-C lowering therapy using statins could regress coronary atheroma and reduce major cardiovascular events. Additionally, therapy that controlled calcium channel antagonists such as amlodipine-based blood pressure reduced major cardiovascular events in patients with hypertension compared with an atenolol-based regimen.

Methods: An open-label randomized multicenter study is primarily planned to evaluate the changes in coronary atheroma volume using intravascular ultrasonography (IVUS) 18 - 24 months after LDL-C lowering by atorvastatin-based therapy and blood pressure lowering by amlodipine-based therapy. Percent atheroma volume is calculated by the formula:

{External elastic membrane EEM_{area} - $lumen_{area}$}/EEM_{area} x 100, where EEM_{area} is the cross-sectional area of the EEM, and $lumen_{area}$ is the cross-sectional area of the lumen.

Patients after area successful PCI with LDL-C levels more than 100 mg/dL with or without cholesterol-lowering therapy are included. The participants are divided into intensive treatment group, the target LDLC and blood pressure is 70 mg/dL and 120/70 mmHg, and standard treatment group, 100 mg/dL and 140/90 mmHg, indicated by current guidelines in Japanese patients with CAD. The patients with cardiogenic shock, diabetes mellitus under insulin injection therapy, hypertension treated with dihydropyridine calcium channel blockers for more than 6 months and familial hypercholesterolemia are excluded. The patients already under cholesterol-lowering therapy with atorvastatin, pitavastatin and rosuvastatin are also excluded. In total, 100 subjects with CAD who are undergoing PCI will be tested.

Results: The results will be presented on site.

Conclusions: Conclusion. The MILLION study will provide new evidence and therapeutic standards for the prevention of CAD in Japanese patients by controlling both LDL-C levels and blood pressure.

Author Disclosures:

1. Masa-aki Kawashiri: This author has nothing to disclose.
2. Kenji Sakata: This author has nothing to disclose.
3. Tadatsugu Gamou: This author has nothing to disclose.
4. Honin Kanaya: This author has nothing to disclose.
5. Kenji Miwa: This author has nothing to disclose.
6. Kosei Ueda: This author has nothing to disclose.
7. Toshinori Higashikata: This author has nothing to disclose.
8. Sumio Mizuno: This author has nothing to disclose.
9. Ichiro Michishita: This author has nothing to disclose.
10. Masanobu Namura: This author has nothing to disclose.
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20. Mitsuyasu Terashima: This author has nothing to disclose.
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