

## バルサルタンとアムロジピンの有効性は同等

冠動脈バイパス術後1年間の開存率は伏在静脈グラフトと橈骨動脈グラフトとで同等である

Angiotensin II receptor blocker and calcium channel blocker produce similar results in patients with hypertension and glucose intolerance

高血圧と耐糖能障害を有する患者の心血管イベントに対するアンジオテンシンII受容体拮抗薬（ARB）とカルシウム拮抗薬（CCB）の有効性を比較した初めての無作為化スタディにおいて、これらの2種類の薬剤間に有意差がないことが示されたと第60回 American College of Cardiologyで発表された。日本の研究チームが2型糖尿病または耐糖能異常を有する高血圧患者1,150人をファーストライン治療として ARB（バルサルタン、575人）またはCCB（アムロジピン、575人）を投与する群に組み入れた。平均3.2年後に一次アウトカム項目（心筋梗塞、脳卒中、冠動脈血行再建術、うっ血性心不全による入院、および心臓突然死の合計）が発現したのはバルサルタン群で54人（9.4%）であり、アムロジピン群で56人（9.7%）であった（ $p=0.85$ ）。これらの5項目のうち4つの発現率においても有意差はなく、唯一うっ血性心不全による入院のみ有意差が認められ、バルサルタン群で3人（0.5%）に発現し、アムロジピン群では15人（2.6%）であった（ $p=0.01$ ）。総死亡率—このスタディの二次アウトカム—または有害事象に関しても有意差は認められなかった。

### Full Text

In the first randomized study to compare the effects of an angiotensin II receptor blocker (ARB) to a calcium channel blocker (CCB) on cardiovascular outcomes in patients with hypertension and glucose intolerance, researchers found no significant difference between the two drug classes, according to research presented at the American College of Cardiology's 60th Annual Scientific Session.

The study follows several non-randomized analyses that also compared ARBs to CCBs, but because of conflicting results and a lack of a randomized trial, a definitive answer has yet to be established for the preferred first-line treatment for patients with hypertension and glucose intolerance. Both drug classes lower blood pressure by dilating blood vessels, but they accomplish this by blocking two distinct chemicals, calcium and angiotensin II.

"Angiotensin II receptor blockers were shown to reduce onset of type 2 diabetes and lower renal events, and so many treatment guidelines recommended them as the first-line medication for hypertensive patients with diabetes," said study researcher Toyooki Murohara, M.D., Ph.D., professor at the Department of Cardiology at Nagoya University Graduate School of Medicine in Nagoya, Japan. "However, no study confirmed superiority of ARBs over CCBs in terms of the prevention of major cardiovascular events."

For the study, a Japanese research team enrolled 1,150 hypertensive patients with either type 2 diabetes or impaired glucose tolerance at 46 facilities across the country. Between October 2004 and July 2010, the patients were randomized to receive either an ARB (valsartan [Diovan?, manufactured by Novartis];  $n = 575$ ) or a CCB (amlodipine [Norvasc?, manufactured by Pfizer];  $n = 575$ ) as their first-line treatment.

The researchers followed the patients for an average of 3.2 years, conducting follow-up analysis every month for the first three months and every one to three months thereafter. As part of this follow-up, the team tested blood pressures and HbA1c levels to gauge how each patient's blood pressure and glucose intolerance progressed. In addition, they recorded cardiovascular events that occurred. Specifically, the team's primary outcome measure was a composite of acute heart attack, stroke, coronary revascularization, hospital admission due to congestive heart failure, and sudden cardiac death.

The team found that the primary outcome occurred in 54 patients (9.4 percent) who were taking valsartan and 56 patients (9.7 percent) who were taking amlodipine (hazard ratio, 0.97; 95 percent CI, 0.66 to 1.40;  $p = 0.85$ ), an insignificant difference. When the team examined each component of the primary outcome individually, they also found no significant differences in four of the five events; only hospital admission for congestive heart failure showed a significant difference, with three patients (0.5 percent) in the valsartan group and 15 patients (2.6 percent) in the amlodipine group experiencing this outcome [HR, 0.20; 95 percent CI, 0.06-0.69;  $p = 0.01$ ]. The researchers also found no significant difference in all-cause mortality - the study's secondary outcome - or in adverse events.

After analyzing the changes in blood pressure and HbA1c levels, the researchers once again found no significant differences between the two groups. Blood pressure was reduced to 131/73 mmHg in the valsartan group and 132/74 mmHg in the amlodipine group at 54 months. Both groups showed a steady decrease in HbA1c levels to 6.7 percent across the same time period.

"Our study showed no difference in the efficacies between ARBs and CCBs in terms of prevention of major cardiovascular events, although the ARB was superior to the CCB regarding the prevention of heart failure," Murohara said. "These results highlight the safety and efficacy of ARBs, especially in preventing heart failure in diabetic hypertensive patients."

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