

## 高齢者においては基礎疾患により降圧薬を選択すべきである

OSCAR: 高齢高血圧患者において併用療法はアンジオテンシンII受容体拮抗薬単独と同様の結果をもたらす

OSCAR: Combination therapy produces similar outcomes compared to angiotensin II receptor blocker alone for elderly hypertensive patients

高齢高血圧患者をアンジオテンシンII受容体拮抗薬 (ARB) とカルシウム拮抗薬 (CCB) の併用で治療した場合の心血管イベントおよび死亡は高用量ARB単独で治療した場合と同様であると第60回American College of Cardiologyで発表された。日本人の研究者らは心血管疾患または2型糖尿病を有する高リスクの高齢高血圧患者1,164人を組み入れた。患者らは高用量オルメサルタン (1日40mg、578人) またはCCBとオルメサルタン (1日20mg、586人) 併用を投与された。36ヵ月後に両群ともに血圧は適切にコントロールされていたが、血圧は併用療法の方が単剤療法よりも有意により低下した (平均SBPおよびDBPはそれぞれ2.4mmHg [ $p=0.0315$ ] と1.7mmHg [ $p=0.0240$ ])。一次エンドポイント (心血管イベントおよび総死亡) 発現数は単剤療法群で58、併用療法群では48であり有意差はなかった ( $p=0.1717$ )。既存の心血管疾患を有する患者におけるサブ解析では、併用療法群の方が単剤療法群よりも心血管イベントおよび死亡発現数が有意に少なかった (それぞれ34および51、 $p=0.02610$ )。

### Full Text

Treating elderly hypertensive patients with a combination of an angiotensin II receptor blocker (ARB) and a calcium channel blocker (CCB) leads to similar rates of cardiovascular events and death compared to therapy with a high-dose ARB alone, according to research presented at the American College of Cardiology's 60th Annual Scientific Session. The findings add to a growing body of knowledge on the best hypertension treatment for elderly patients.

Although CCBs have generally been recommended as the first-line treatment, ARBs have also been shown to exert beneficial effects on this patient population, especially in the SCOPE trial. The CASE-J trial - a Japanese study conducted in elderly patients - showed that a CCB and an ARB were equally effective in preventing cardiovascular morbidity and mortality.

"The CASE-J trial supported the idea that ARBs and CCBs are both beneficial as first-line agents for the treatment of hypertension in elderly patients," said Hisao Ogawa, M.D., Ph.D., lead study author and professor in the Department of Cardiovascular Medicine at Kumamoto University in Japan. "However, our research team did not know of any studies comparing the efficacy of high-dose ARB monotherapy with standard-dose combination therapy in terms of preventing cardiovascular morbidity and mortality in elderly patients. Thus, the OSCAR study may have a significant impact on determining the best antihypertensive therapeutic strategy for these patients."

For the study, Ogawa's research team enrolled 1,164 high-risk elderly hypertension patients at 134 centers throughout Japan from June 2005 to May 2007. To meet the inclusion criteria, patients must have been unable to manage their high blood pressure through standard-dose monotherapy with the ARB olmesartan (Benicar<sup>®</sup>, manufactured by Daiichi Sankyo) and had to have at least one of the cardiovascular diseases or type 2 diabetes. Patients were randomized to receive either: 1) high-dose olmesartan at 40 mg per day ( $n=578$ ) or 2) a CCB combined with olmesartan at 20 mg per day ( $n=586$ ).

The study's primary endpoint was a composite of cardiovascular events - including cerebrovascular disease, coronary artery disease, heart failure, other atherosclerotic disease, diabetic complications, and the deterioration of renal function - and all-cause death.

At a follow-up point of 36 months, the researchers found that blood pressure was adequately controlled by both treatment groups, although the combination therapy reduced blood pressure to significantly lower levels than monotherapy (mean SBP and DBP were lower by 2.4 mmHg [ $p=0.0315$ ] and 1.7 mmHg [ $p=0.0240$ ], respectively). However, no significant difference was seen between the two cohorts in the number of primary endpoints, with 58 events occurring in the monotherapy group and 48 occurring in the combination group (Hazard ratio [HR] 1.31; 95 percent confidence interval [CI] 0.89 - 1.92,  $p=0.1717$ ).

The team did find a statistically significant difference, however, when conducting a subgroup analysis only on patients with pre-existing cardiovascular disease. In the subgroup analysis, study subjects randomized to the combination therapy group had significantly fewer occurrences of cardiovascular events and death than those in the monotherapy group, at 34 and 51, respectively (HR = 1.63; 95 percent CI, 1.06 - 2.52;  $p=0.02610$ ).

Conversely, another subgroup analysis including patients with only diabetes showed a higher incidence of the primary endpoint in the combination therapy group, at 14 events compared to seven events in the monotherapy group, although this difference was not statistically significant (HR = 0.52; 95 percent CI 0.21 - 1.28;  $p=0.1445$ ).

According to Ogawa, the data show that cardiologists should consider the type of risk factors that patients may have - such as cardiovascular disease or type 2 diabetes - before prescribing high-dose ARBs.

"The OSCAR study provides the first evidence showing that a standard dose of ARB plus CCB combination is superior to high-dose ARB treatment in reducing adverse events in elderly hypertensive patients with cardiovascular disease," Ogawa said. "However, high-dose ARB better prevented adverse events in diabetic patients in spite of its weaker antihypertensive effect."

The researchers received grant support for the OSCAR study from the Japan Heart Foundation. Ogawa has received grant support over the past five years from Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Daiichi-Sankyo, Eisai, Kowa, Kyowa Hakko Kirin, MSD, Novartis, Pfizer, Sanofi-Aventis, Schering-Plough, and Takeda.

## ACC2011特集

[News01]  
カテーテルを用いた大動脈弁手術の開心術に対する非劣性が認められた

[News02]  
Mitraclipは手術と比較し有効性は低い及安全性は高い

[News03]  
薬剤溶出ステントは予後を改善する

[News04]  
橈骨動脈からのアクセスにより血管系合併症が減少する

[News05]  
スタティの結果、心不全患者において薬物療法よりもCABGの方が成績は良好であった

[News06]  
バイパスグラフトには橈骨動脈の方が成績は良好である

[News07]  
エコーによりペースメーカーリードの最良の設置部位が得られる

[News08]  
2剤併用抗血小板薬療法は6ヵ月で十分である

[News09]  
Rivaroxabanはエノキサパリンと比較し正味の臨床上の有益性は認められない

[News10]  
高齢者においては基礎疾患により降圧薬を選択すべきである

[News11]  
バルサルタンとアムロジピンの有効性は同等

[News12]  
Phase IIIの結果から、従来の治療が無効な高血圧の治療に圧反射活性化が有望であることが示された

[News13]  
ヨガにより心房細動発作頻度が低下する

[News14]  
小児における広範な脂質スクリーニングが推奨される

[News15]  
新たなポリマーにより1年後の標的病変不全が軽減できる

[News16]  
宇宙での心臓超音波検査により地球上での心臓管理が改善する可能性がある

[News17]  
抗うつ薬は動脈壁肥厚と関連がある

[News18]  
ハリケーンカトリーナから数年経っても慢性ストレスは持続している