OLMESARTAN IN DIALYSIS PATIENTS: RESULTS OF THE OCTOPUS STUDY

Kunitoshi Iseki, MD for the Olmesartan Clinical Trial in Okinawan Patients Under OKIDS (OCTOPUS) Group*; Dialysis Unit, University Hospital of the Ryukyus, Nishihara, Okinawa, Japan

Introduction: In the chronic haemodialysis (HD) population, several clinical trials studying aspects such as increases in dialysis dosage, administration of erythropoiesis-stimulating agents, or statins failed to show improved survival. Such treatments may, however, be beneficial among subgroups of patients. The prevalent dialysis population is heterogeneous with regard to the duration of dialysis, co-morbid conditions and treatment regimens. Survival in dialysis patients depends not only on blood pressure (BP), but also on other significant confounders, such as nutritional status and chronic inflammation.

Hypertension is common and is not well controlled within the HD population [1]. Cardiovascular disease (CVD) thus remains the leading cause of death in this population. The available evidence, however, contradicts the guidelines for treating hypertension in non-HD patients. The prognosis of HD patients with hypertension is somewhat better than those with normal or low BP [2]. On the other hand, patients treated with a long and slow dialysis regimen show low to normal BP levels, and the prognosis is better than that for the majority of the dialysis population. A recent meta-analysis reported better survival among HD patients on antihypertensive medications regardless of their BP levels [3]. Only a few studies of HD patients have examined the effect of antihypertensive drugs on survival based on a prospective randomised controlled design. The Olmesartan Clinical Trial in Okinawa Patients Under Okinawa Dialysis Study (OCTOPUS) trial was designed to assess the effects of an angiotensin receptor blocker (ARB) olmesartan on the risks of cardiovascular disease and death [4].
Methods: In a multicentre, prospective, randomised, open-label, blinded-endpoint trial, we assigned 469 patients with chronic HD and elevated BP (140-199/90-99 mmHg) to receive an angiotensin receptor blockade olmesartan (at a dose of 10-40 mg daily; n=235) or other treatment except for angiotensin receptor blockers and angiotensin converting enzyme inhibitors (n=234). Primary outcomes were (1) composite of death, nonfatal stroke, nonfatal myocardial infarction, and coronary revascularization, and (2) all-cause death.

Findings: During a mean follow-up of 3.5 years, the mean BP was 0.9/0.0 mmHg lower in the olmesartan group than in the control group. A total of 68 patients (28.9%) in the olmesartan group and 67 patients (28.6%) in the control group had subsequent primary composite endpoints (hazard ratio [HR] in the olmesartan group 1.00, 95% confidence interval [CI] 0.71-1.40, P=0.99). All-cause deaths occurred in 38 patients (16.2%) in the olmesartan group and 39 (16.7%) in the control group (HR, 0.97; 95 % CI, 0.62-1.52, P=0.91). Olmesartan did not alter the risks of serious adverse events.

Interpretation: Blood pressure lowering treatment with olmesartan did not significantly lower the risks of major cardiovascular events or death among patients with chronic HD. The role of ARB in HD patients who are non-hypertensive, or have cardiomegaly and/or congestive heart failure requires further examination.
References

For further information please contact
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albersconcept
Dr. Bettina Albers
Jakobstrasse 38
D-99423 Weimar
press@era-edta.org
Tel.: +49(0)3643/ 776423
Fax: +49(0)3643/ 776452.