Olmesartan Delayed Microalbuminuria in Type 2

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FROM THE ANNUAL MEETING OF THE EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES

STOCKHOLM – Olmesartan was shown to significantly reduce the time to microalbuminuria in a randomized, placebo-controlled, double-blind multicenter study of 4,447 patients with type 2 diabetes.

The Randomized Olmesartan and Diabetes Microalbuminuria Prevention (ROADMAP) trial investigated whether early treatment with the angiotensin receptor blocker olmesartan would delay the occurrence of microalbuminuria in patients with type 2 diabetes who had at least one other cardiovascular risk factor but who had normal albumin excretion at baseline.

At baseline, the patients had a mean age of 58 years, diabetes duration of 6 years, body mass index of 30 kg/m^2, and hemoglobin A_{1c} of 7.6%.

Correction for the small differences in blood pressure between groups showed that most of the effect was BP-independent.

DR. HALLER

Mean blood pressure at baseline was 137/80 mm Hg, and the mean estimated glomerular filtration rate was 85 mL/min per 1.73 m^2.

The patients received 40 mg of olmesartan or placebo once daily for a median of 3.2 years.

In both groups, additional antihypertensive drug treatment other than ARBs or ACE inhibitors was used to reach the target blood pressure of less than 130/80 mm Hg.

That goal was reached by 78% of the olmesartan group and 71% of the placebo group by 48 months, Dr. Hermann Haller reported at the meeting.

The cumulative incidence of microalbuminuria, which was defined as excretion of more than 35 mg albumin/g urine creatinine for women and more than 25 mg albumin/g urine creatinine for men in morning spot urine, was 8.2% of the olmesartan patients vs. 9.8% of the placebo group.

This amounts to a highly significant risk reduction of 23%, said Dr. Haller of Hannover (Germany) Medical School.

Correction for the small differences in blood pressure between the two groups showed that the majority of the effect was blood pressure–independent, he said.

Overall cardiovascular morbidity and mortality rates were low and they were similar between the two groups, with just 4.3% of the olmesartan group and 4.2% of the placebo group experiencing any cardiovascular event or death, Dr. Haller noted.

Total mortality occurred in 1.2% and 1.7%, respectively.

Cardiovascular mortality, however, was higher in the olmesartan group (15 deaths vs. 3 deaths, or 0.7% vs. 0.1%), possibly because of hypotensive episodes among patients with preexisting cardiovascular disease, Dr. Haller said.

There were no adverse effects of olmesartan on hard renal outcomes.

An observational follow-up study is ongoing to further elucidate the long-term benefits of microalbuminuria prevention, Dr. Haller said. ■

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Major Finding: The cumulative incidence of microalbuminuria was 8.2% of the olmesartan patients vs. 9.8% of the placebo group, for a highly significant risk reduction of 23%.

Data Source: Randomized, placebo-controlled, double-blind, multicenter ROADMAP trial of 4,447 patients with type 2 diabetes and one or more other cardiovascular risk factors but with normoalbuminuria.

Disclosures: The study was funded by Daiichi-Sankyo, which manufactures olmesartan under the name Benicar.