EuroSciCon

7th World Congress on

DIABETES AND OBESITY

April 25, 2022
Webinar

Journal of Diabetic Complications & Medicine
ISSN: 2475-3211

Semaglutide and Cardiovascular outcomes in patients with Type 2 Diabetes

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Background

Regulatory guidance specifies the need to establish cardiovascular safety of new diabetes therapies in patients with type 2 diabetes in order to rule out excess cardiovascular risk. The cardiovascular effects of semaglutide, a glucagon-like peptide 1 analogue with an extended half-life of approximately 1 week, in type 2 diabetes are unknown.

Methods

We randomly assigned 3297 patients with type-2 diabetes who were on a standard-care regimen to receive once-weekly semaglutide (0.5 mg or 1.0 mg) or placebo for 104 weeks. The primary composite outcome was the first occurrence of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke. We hypothesized that semaglutide would be no inferior to placebo for the primary outcome. The no inferiority margin was 1.8 for the upper boundary of the 95% confidence interval of the hazard ratio.

Result

At baseline, 2735 of the patients (83.0%) had established cardiovascular disease, chronic kidney disease, or both. The primary outcome occurred in 108 of 1648 patients (6.6%) in the semaglutide group and in 146 of 1649 patients (8.9%) in the placebo group (hazard ratio, 0.74; 95% confidence interval [CI], 0.58 to 0.95; P<0.001 for noninferiority). Nonfatal myocardial infarction occurred in 2.9% of the patients receiving semaglutide and in 3.9% of those receiving placebo (hazard ratio, 0.74; 95% CI, 0.51 to 1.08; P=0.12); nonfatal stroke occurred in 1.6% and 2.7%, respectively (hazard ratio, 0.61; 95% CI, 0.38 to 0.99; P=0.04). Rates of death from cardiovascular causes were similar in the two groups.

Rates of new or worsening nephropathy were lower in the semaglutide group, but rates of retinopathy complications (vitreous hemorrhage, blindness, or conditions requiring treatment with an intravitreal agent or photocoagulation) were significantly higher (hazard ratio, 1.76; 95% CI, 1.11 to 2.78; P=0.02). Fewer serious adverse events occurred in the semaglutide group, although more patients discontinued treatment because of adverse events, mainly gastrointestinal.

Conclusion

In patients with type 2 diabetes who were at high cardiovascular risk, the rate of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke was significantly lower among patients receiving semaglutide than among those receiving placebo, an outcome

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that confirmed the no inferiority of semaglutide.

Biography

Hazem Rayyan is the Director of training program in Internal medicine in NWAFH. Previously, he worked as a consultant Endocrinologist in King Salman Military Hospital, Tabuk-KSA. Currently, he is working as a Endocrinologist in(JCDE) in Jordan Hospital. His main research

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Received: March 10, 2022; **Accepted:** March 14, 2022; **Published:** May 19, 2022