Oral presentation 90

Reduced risk of hypoglycaemia and lower HbA_{1c} with degludec compared to glargine U300 in insulin-treated patients with type 2 diabetes

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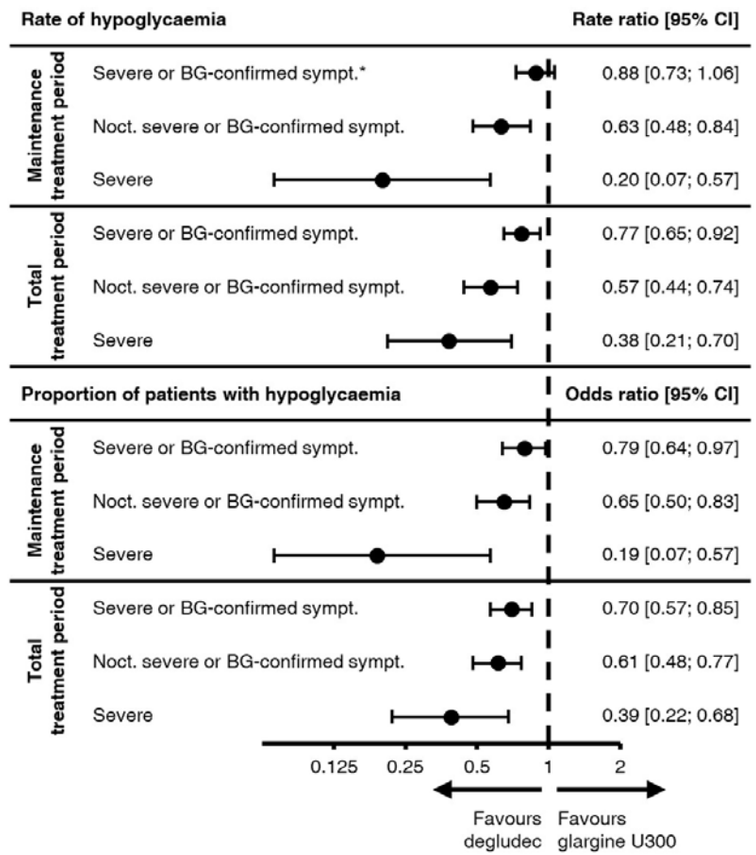
Background and aims: Minimising hypoglycaemia is an important aim of insulin therapy. Long-acting basal insulins, degludec and glargine U300 have been shown to have a lower risk of hypoglycaemia than glargine U100. A head-to-head trial was conducted to evaluate the risk of hypoglycaemia with degludec compared with glargine U300 in insulin-treated patients with type 2 diabetes (T2D).

Materials and methods: This randomised (1:1) open-label, treat-to-target, multinational trial, included T2D patients ≥18 years with HbA_{1c} ≤9.5% and BMI ≤45 kg/m^2. Patients were previously treated with basal insulin ± oral antidiabetic drugs (excluding insulin secretagogues) and fulfilled at least one criterion that placed them at a risk of hypoglycaemia. Both degludec and glargine U300 were similarly titrated to a fasting blood glucose (BG) target of 4.0–5.0 mmol/L. All endpoints related to hypoglycaemia were assessed during a 36-week maintenance treatment period and the total treatment period of up to 88 weeks.

Results: Of 1609 randomised patients, 703 patients in the degludec arm and 706 patients in the glargine U300 arm completed the treatment. Baseline characteristics were comparable between the treatment arms. The rate ratio (RR) of severe or BG-confirmed symptomatic hypoglycaemia with degludec compared to glargine U300 was 0.88 (NS) during the maintenance period and a statistically significant RR of 0.77 was seen during the total treatment period (**Figure**). During the maintenance and total treatment periods, the RR was statistically significant in favour of degludec for severe hypoglycaemia (RR: 0.20 and 0.38, respectively) and for nocturnal hypoglycaemia (RR: 0.63 and 0.57, respectively). The proportions of patients with hypoglycaemia were statistically significant in favour of degludec during both periods for all hypoglycaemic endpoints (**Figure**). The *post hoc* assessed change from baseline to end of treatment in HbA_{1c} was statistically significantly greater in patients treated with degludec compared to glargine U300 (estimated treatment difference [95% CI]: –0.10% –0.18; –0.02]).

Conclusion: Degludec showed an overall lower risk of hypoglycaemia compared to glargine U300 accompanied by significantly lower HbA_{1c}.

Figure. Hypoglycaemia endpoints



*Primary endpoint. Severe episodes classified as per the American Diabetes Association definition. BG-confirmed episodes defined as BG <3.1 mmol/L. Nocturnal episodes were between 00:01 and 05:59.
BG: blood glucose; CI: confidence interval; Noct: nocturnal; sympt: symptomatic.

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