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Meta-Analysis comparing Hypoglycemia Rates of Insulin Degludec with Insulin Glargine across Clinical Trials with up to 2 years' Duration

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Insulin degludec (IDeg), is a basal insulin with a long and stable glucose-lowering effect with low day-to-day variability. A comparison of the rate of hypoglycemia with IDeg vs. insulin glargine (IGlar) across phase 3a trials, including all available trial extensions (n=4) plus one new trial was performed post hoc; IDeg: n=3454; IGlar: n=1709; T1D: 2 trials; T2D: 6 trials. Hypoglycemia was defined as rates of self-reported confirmed hypoglycemia (BG <56 mg/dL or severe hypoglycemia requiring assistance) and nocturnal confirmed hypoglycemia (00:01-05:59 both incl.). Rates were analyzed with a negative binomial regression model on patient level data. IDeg resulted in statistically significantly lower rates of confirmed and nocturnal confirmed hypoglycemia vs. IGlar in T2D, and for nocturnal confirmed hypoglycemia in T1D. Analyses of the maintenance period (from 16 weeks onwards), demonstrated more pronounced benefits with IDeg vs. IGlar in both T1D and T2D. In conclusion, this post hoc meta-analysis confirms and extends the outcomes of a previously published pre-specified meta-analysis. Even with the inclusion of additional trial data for up to two years' duration, the lower rates of both overall (T2D) and nocturnal confirmed (T1D and T2D, respectively) hypoglycemia with IDeg vs. IGlar are maintained.