THE EFFICACY AND SAFETY OF INSULIN DEGLUDEC AS BASAL-BOLUS INSULIN THERAPY IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES IN ROUTINE CLINICAL PRACTICE.

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Background and Aim

Insulin degludec (IDeg) is an ultra-long action (>42 h) basal insulin analogue with flat and stable action profile and low variability, that approved for use in both type 1 (T1D) and type 2 diabetic adults and children >1 years. In adults with T1D it provides a more consistent glucoselowering effect and lower rates of hypoglycemia than insulin glargine. The aim of this study was to evaluate the efficacy and safety of IDeg as basal-bolus therapy after switching from other basal insulin analogues in T1D paediatric patients.

Materials and Methods

This was a 12-week trial carried out in 12 patients 9–15 years (75% male; Tanner Stage ≥2) with T1D (duration 1 to 5 years) previously treated with glargine (50%) or detemir as basal-bolus regimen. Baseline HbA1c was 8.4% (75% patients have HbA1c >7.5%); FPG - 8.69 mmol/l; daily amplitude of plasma glucose (DAPG) - 8.8 mmol/l; all of patients experienced hypoglycemia (plasma glucose<3.1 mmol/l) at least 1 time per week. Outcomes were evaluated by change in HbA1c level, number of patients who achieved HbA1c<7.5%, change in FPG and DAPG, rate of overall and nocturnal hypoglycemia, body weight, mean daily insulin doses (in Units (U) and doses per kg body weight (U/kg)) and other safety assessments. The data presented as median, lower and upper quartiles [Q25; Q75], minimum and maximum.

Results

At 12 weeks degludec administration there were significant reduce of HbA1c (-1.43%; w=2.62; p=0.007), FPG (-1.44 mmol/l; w=2.35; p=0.018) and DAPG (-2.35 mmol/l; w=2.43; p=0.015) with using lower basal daily insulin doses (by 19.5% in U (p=0.05) and by 14% in U/kg (p=0.04)) (Figures1-3).

Figure 1. Change in HbA1c

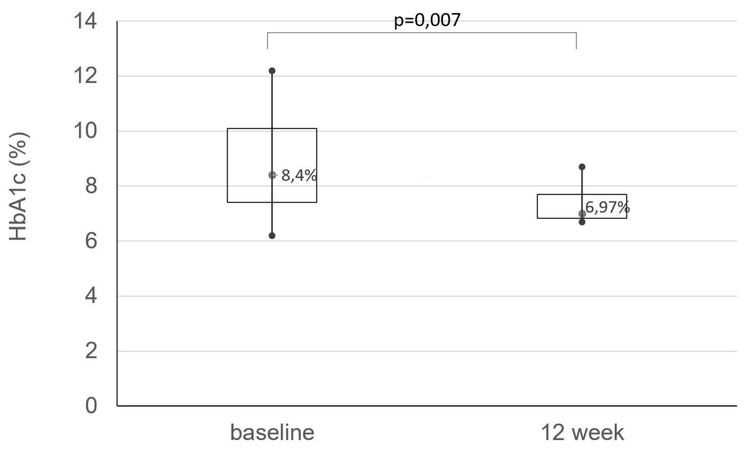


Figure 2. Change in mean daily amplitude of plasma glucose

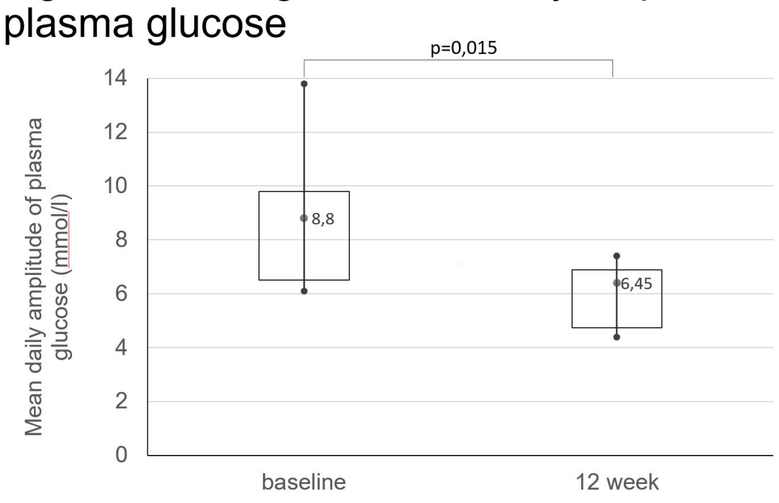
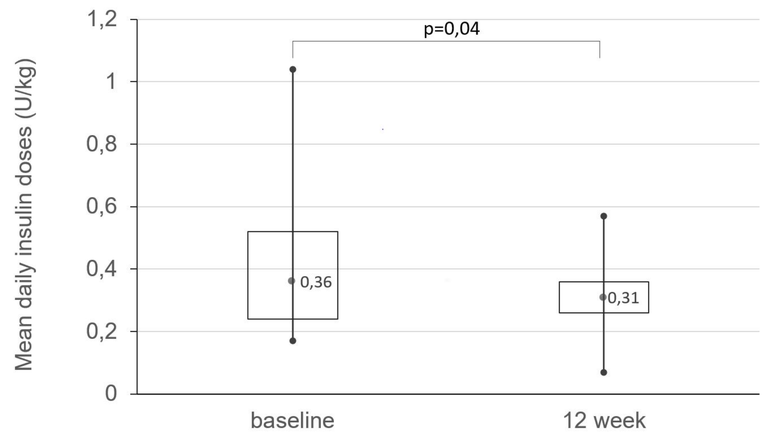


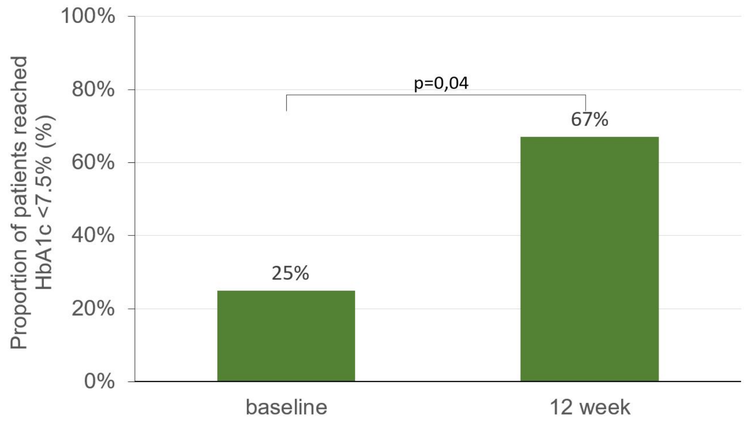
Figure 3. Change in mean basal daily insulin doses (U/kg)



At the study end the number of patients achieved HbA1c<7.5% were increased up to 67% (+42%; χ^2=4.2; p=0.04) (Figure 4).

At 12 weeks there were reduced of rate of any hypoglycemic events (0.24 to 0.03 events per patient for 7 days; w=2.8; p=0.005) and number of patients experiencing hypoglycemia (up to 25%; χ^2=14.4; p=0.001). There were no severe (requiring the assistance of another person) and nocturnal (between 23:00 and 06:00) hypoglycemia as well as any other side effects across trial period.

Figure 4. Changing the number of patients achieving targets (HbA1c <7.5%)



Conclusions

In paediatric patients with T1D switching to degludec as part of basal-bolus therapy allows to significant improve the glycemic control, as measured by HbA1c with a significant FPG and DAPG reduction, with using lower basal daily insulin doses, and reduce the rate of hypoglycemia.

Duality of interest: The authors declare there are no duality of interest associated with this work.
Acknowledgments: The authors are grateful to Dr. Yana Alekseeva (Novo Nordisk, Russia) for scientific input and editorial support under the direct supervision of Dr. Alexey Kiiaev.

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