

The efficacy of insulin degludec in children and adolescents with type 1 diabetes.

AUTHORS HAVE NOTHING TO DISCLOSE

P. BRUZZI¹, G. MALTONI², B. PREDIERI¹, S. ZUCCHINI², L. IUGHETTI¹

¹ Department of Medical and Surgical Sciences of the Mother, Children and Adults; University of Modena and Reggio Emilia, Modena;
² Department of Pediatrics, Sant'Orsola-Malpighi Hospital, University of Bologna, Bologna - Italy

BACKGROUND - OBJECTIVES

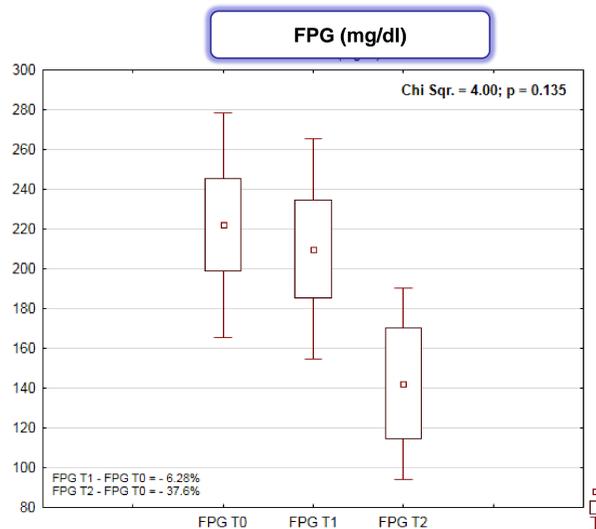
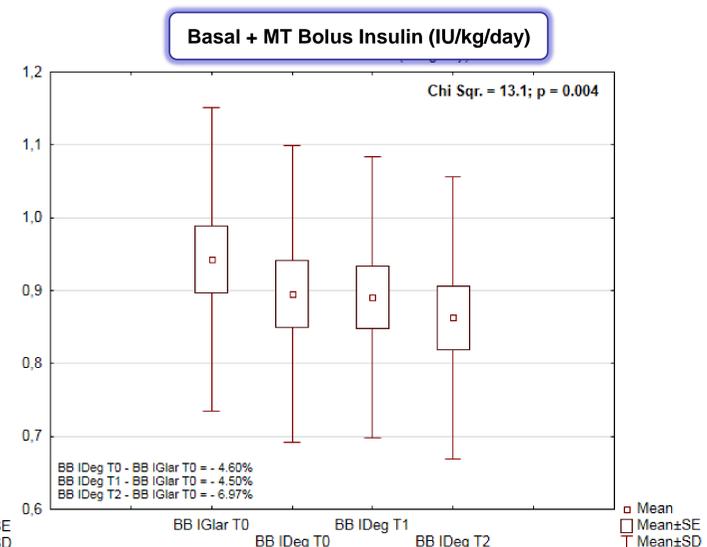
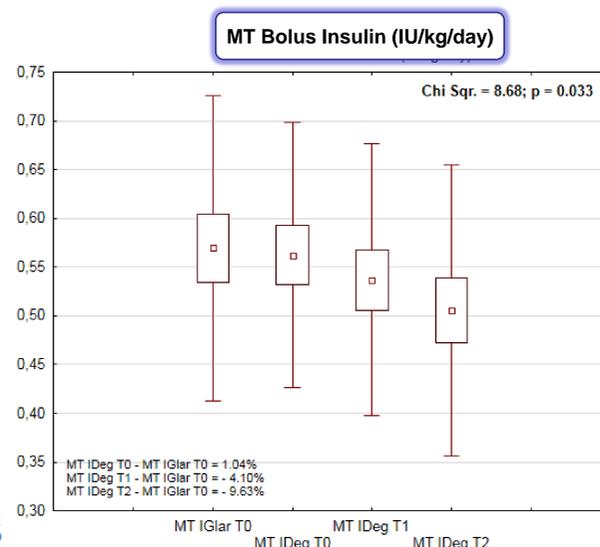
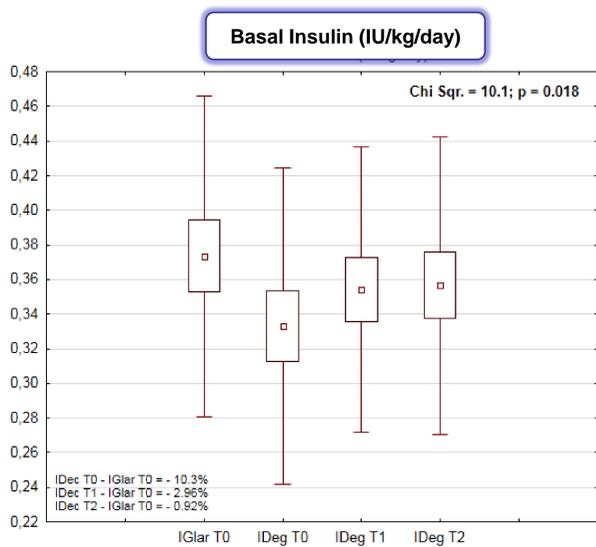
Insulin degludec (IDeg) is a new basal insulin with an ultra-long duration of action and a mechanism of protraction that induces a flat and stable action profile with low variability.

In adults with type 1 diabetes (T1DM) it provides a more consistent glucose-lowering effect and lower rates of hypoglycemia than insulin glargine (IGlar). To date, few data have been published on IDeg effects in children and adolescents. The aim of this study was to evaluate the efficacy and safety of IDeg as basal-bolus therapy after switching from IGlar during a 6-month period in children and adolescents with T1DM.

METHODS – We determined...

- What?**
- Anthropometric data (height SDS, z-score BMI)
 - Metabolic data [glycated hemoglobin (HbA1c), fasting plasma glucose (FPG) and severe hypoglycaemia rates (n)]
 - Daily doses of insulin subcutaneous injection [IGlar, IDeg, and short-acting/regular at meal-time (MT)]
- Who?**
- Twenty children and adolescents [age 15.1±4.0 yrs; 9 males (45%); 7 prepubertal (35%)] who had been diagnosed with T1DM 7.25±3.75 years before and had been treated with basal IGlar for at least 1 year
- Patients were switched from their once-daily injection of IGlar (Lantus® 100 U/mL, Sanofi, Paris, France) to once-daily injection of IDeg (Tresiba®100 U/mL, Novo Nordisk, Bagsvard, Denmark)
 - Safety variables were insulin dose, body weight, severe hypoglycemic episodes, and adverse events
- How?**
- All data were checked using the Kolmogorov-Smirnov test: despite we found a normal distribution, considering the few patients included in the study, non-parametric statistical analysis (STATISTICA™ software, StatSoft Inc., Tulsa, OK, USA) was performed. All results are reported as the mean±SD. Between group comparison (gender, pubertal status) of metabolic data and daily subcutaneous insulin were evaluated using Mann-Whitney's U-test. Longitudinal changes were analyzed using the Friedman ANOVA.
- When?**
- Data were collected at basal insulin switch (T0) and after both 3 (T1) and 6 months (T2) from the start of IDeg

RESULTS



- Despite the lack of statistical significant longitudinal improvement in HbA1c (Chi Sqr. 1.66; p=0.435) we found that its levels had fallen by 0.35% points (SE 0.23) at T1 and 0.20% points (SE 0.19) at T2 with IDeg, as compared with IGlar.
- The mean body weight was 58.6±21.0 kg, the BMI was 21.2±4.64 kg/m², and the z-score BMI was 0.05±1.17 SDS at the beginning of the study. All these variables did not longitudinally change on IDeg.
- The switch from IGlar to IDeg allowed a significant decreased of the number of insulin injection (4.45±0.78 vs. 4.15±0.58, respectively; p=0.043)
- As IGlar, 6-months after the start of IDeg we found no episodes of severe hypoglycemia.
- No side effect was found.
- Results did not change analyzing data according to gender and pubertal status.

CONCLUSIONS

- IDeg administered once-daily as part of basal-bolus therapy seems to improve the glycemic control reducing both FPG and HbA1c than therapy with IGlar
- Despite data from adults with T1DM, our results in childhood suggest that the dose of IDeg should be reduced by median 5% and the meal-time insulin appropriate replacement doses should be lowered by 10% for patients who previously received IGlar

IDeg might be considered a useful and well tolerated basal insulin for children and adolescents with T1DM

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