A real-life experience with a new insulin co-formulation Degludec/Aspart for one year in poorly controlled children and adolescents with Type 1 Diabetes

Tarık Kırkgoz[1], Mehmet Eltan[1], Sare Betül Kaygusuz[1], Zehra Yavaş Abalı[1], Tülay Guran[1], Abdullah Bereket[1], Serap Turan[1]
[1]Marmara University School of Medicine, Pediatric Endocrinology and Diabetes Department İstanbul, Turkey

P3-007

Introduction: Achieving optimal metabolic control can be extremely challenging in some children and adolescents with Type 1 diabetes mellitus (T1DM) due to a complex mix of lifestyle factors. Difficulties in adherence to basal-bolus regimen which requires minimum of 4-5 injections/day is among the leading causes of suboptimal control and frequent hypo-hyperglycemias in these group of patients. The ISPAD guidelines acknowledge that premixed analog insulins, may help reducing the number of injections when adherence is a problem. A Recently, insulin degludec/aspart co-formulation (70% IDeg and 30% IAsp: IDegAsp) has become available to use in pediatric patients. Because of the long-duration of Insulin degludec, and retained individual pharmacokinetic characteristics of degludec and aspart, we wanted to test insulin degludec's efficacy in our patients with poor glycemic control and frequent hypo-hyperglycemias.

Objective: We investigated the number of hypoglycemic episodes, diabetic ketoacidosis frequency, and HbA1c levels before and after changing from basal-bolus to insulin degludec.

Methods: Patients > 4 years of age who had diabetes duration of > 1 year and on poor control on basal-bolus insulin regimens (at least 4 injections/day) were included in the study. IDegAsp treatment were offered to the patients with HbA1c of >8.5%, or having DKA while on insulin treatment or having frequent hypoglycemia episodes, labile diabetes and those with history of omitting insulin injections. Their insulin regimen were changed to one IDeg/Asp injection and two IAsp injections (total of three injections/day) with dose titration.

Results: Forty-six patients (20 girls) were included in the study. The mean age and the age of onset of diabetes were 12.9±3.4 (4-18) and 5.2±3.1 years (1.0-13.7), respectively. The reasons for the transition to IDeg/Asp were requirement of two doses of basal insulin (thus 5 injections/day) and resultant non-adherence (18), frequent episodes of hypoglycemia (9), daily glucose variability (9), frequent DKA (6). Ten patients discontinued IDeg/Asp and returned to the previous regimen due to continuing hyperglycemias (n=5), difficulty in dosing(n=3), transition to pump(n=1) or development of DKA (n=1).

Table 1: Follow-up parameter changes before and one year after insulin Degludec / Aspart combined preparation

	0. month	12. months	p
HbA1c	9,43±1,71	9,43±1,81	0,96
BMI (SDS)	0,49±1,146	0,34±1,19	0,13
İnsulin U/kg	1,22±0,36	1,01±0,24	p<0.05
Mean mild hypoglecmia / week	2,09±1,98	0,7±1,06	p<0.05
Severe Hypoglecima (Years/Patient)	0,05±0,23	0,05±0,23	0,141
DKA (Year/Patient)	0,22±0,48	0,08±0,28	0,159

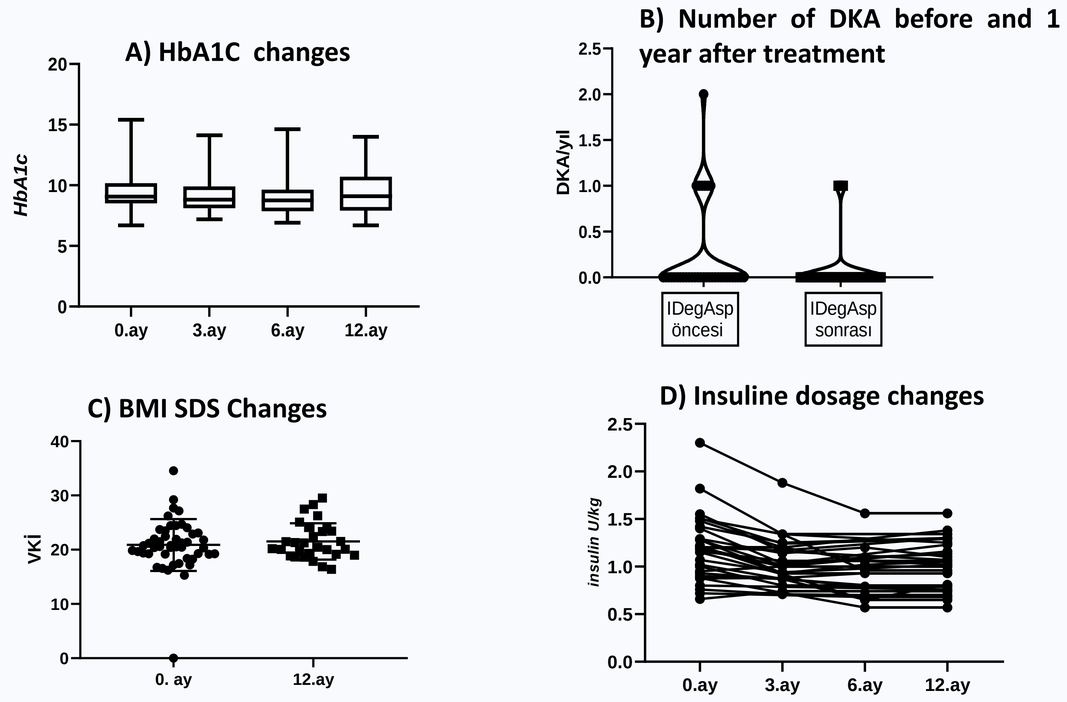

Figure 1: Follow-up parameter changes before and one year after insulin Degludec / Aspart combined preparation

Thirty-six patients were evaluated at the 1st year of IDeg/Asp treatment. Their metabolic control parameters were compared to that of the previous year (while on basal-bolus regimen). No change in HbA1c levels has been detected after switching to IDegAsp regimen (p:0.96). However, the number of self-reported mild-moderate hypoglycemia decreased significantly (p<0.05). There was only one episode of severe hypoglycemia before and after the regimen change. In previous year before regimen change, 8 DKA attacks in 7 patients were detected while on the basal-bolus regimen which decreased to 3 DKA attacks in 3 patients during the year on IDegAsp treatment (p:0.15). No significant change in BMI-SDS (p:0.13), but the decrease in insulin doses (unit/kg) (P<0.05) were detected (Table 1).

Conclusion : IDegAsp regimen could be useful in patients with frequent hypoglycemia and DKA attacks, who have poor compliance with basal-bolus regimen. Better adherence to treatment because of less injection number and longer duration of insulin degludec could prevent DKA in some cases.