Efficacy and Safety of Co-Formulation (IDegAsp) Insulin : A Real world Clinical Audit

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Background :

Insulin degludec/insulin aspart (IDegAsp) is a co-formulation of the ultra-long-acting insulin degludec (IDeg) and the rapid-acting analog insulin aspart (IAsp) in 70:30 ratio.

The individual properties of basal and prandial insulin are preserved in this co-formulation and present an opportunity to correct both fasting and post-prandial glucose with an advantage of single prick and simple regime in type 2 diabetic (T2D) patients.(1)

Aims:To evaluate the efficacy and safety of co-formulation (IDegAsp) insulin in patients poorly controlled on multiple oral anti-diabetics (OADs).

Methods:

► Multi-centered, retrospective, real world, medical registry based observational study.

► All patients received treatment as per routine standard of care

► All patients were followed up for minimum of 12 weeks

Inclusion Criteria:

► Non pregnant T2D patients diagnosed as per ADA criteria(HbA1c > 6.5%)

► T2D patients were initiated with once daily IDegAsp after multiple (2 or more) OAD failure

Exclusion criteria:

► Type 1 diabetes

► Patients who were dropped out before 12 weeks

► Patients who were on additional prandial insulin

► Patients who had incomplete dataset

► Patients with a history of hospitalization for malignancy

Results-

Baseline characteristics

► Total 83 patients (53 male and 30 female) with hyperglycaemia (mean FPG 236.08 ± 86.31 mg/dl, mean PPPG 309.06 ± 106.76 mg/dl and mean HbA1c 9.61± 2.12 %) treated with once daily IDegAsp were included in the study.

► The mean age of the patients were 59.49 ± 11.31 and the mean duration of follow up 24.77 ± 12.31 weeks

► Demographic characteristics are enlisted in Table 1 and the Laboratory Parameters at baseline are enlisted in Table 2

Table 1:Demographic characteristics

Male, n (%)	53 (63.86)
Female, n (%)	30 (36.14)
Age(years), Mean ± SD	59.49 ± 11.31
Height (centimetres), Mean ± SD	161.73 ±8.99
Body weight (Kg), Mean ± SD	68.51±11.88
BMI (kg/m2), Mean ± SD	27.22± 3.58
Mean Duration of Follow-up, Weeks	24.77 ± 12.31

Table 2: Laboratory Parameters at baseline

FPG(mg/dl), Mean ± SD	236.08±86.31
PPPG(mg/dl), Mean ± SD	309.06±106.76
HbA1c (%), Mean ± SD	9.61± 2.12
Serum Creatinine, mg/dL	1.01± 0.33

Most patients of our cohort was male (63.86%). Mean age and mean BMI of our cohort was 59.49 years and 27.22 respectively (Table-1). Statistical significant improvement in FPG (p <0.001), PPPG (p <0.001) and HbA1c (p <0.001) were observed over an average of 24 weeks follow up, without any significant changes in weight, BMI and serum creatinine value (Table-3). There were 3 events of asymptomatic, 16 events of symptomatic and 5 events of severe hypoglycemia but no event of nocturnal hypoglycaemia.

Table 3: Changes in study parameters after 26 weeks

Parameter	Baseline Mean ± SD	Follow-up Mean ± SD	p (paired t-test)
Weight	68.51 ± 11.88	69.04 ± 11.19	0.702
BMI (kg/m2)	26.22 ± 3.58	26.53 ± 3.42	0.812
Scr (mg/dl)	1.01 ± 0.33	1.03 ± 0.39	0.897
FPG (mg/dl)	236.08 ± 86.31	154.31 ± 56.41	<0.001
PPPG (mg/dl)	309.06 ± 106.76	220.56 ± 85.12	<0.001
HbA1c (%)	9.61 ± 2.12	8.09 ± 1.74	<0.001

Discussion: The introduction of IDegAsp, in T2D patients with multiple OAD failure, consistently improved all parameters of glucose control. Unlike basal insulin, IDegAsp provides a significant improvement in postprandial glucose excursions also, a distinct advantage with a single prick. Some weight gain is expected with all forms of insulin therapy including IDegAsp (1), but no significant gain in weight (p =0.702) or BMI (p=0.812) was observed in our cohort. Though the total hypoglycaemic events were 28.9 %, only few patients (6%) suffered severe hypoglycaemia. Nocturnal hypoglycaemia, a recognised barrier to treatment intensification for some patients, was absent with IDegAsp in our cohort (2). IDegAsp, the novel pharmaceutical coformulation, offer clinical advantages over currently available insulin preparations.

References :

1. Kalra S. Insulin Degludec Aspart: The First Co-formulation of Insulin Analogues. Diabetes Ther. 2014;5(1):65–72.
2. Philis-Tsimikas, A. et al. Similar glycaemic control with less nocturnal hypoglycaemia in a 38-week trial comparing the IDegAsp co-formulation with insulin glargine U100 and insulin aspart in basal insulin-treated subjects with type 2 diabetes mellitus. Diabetes Research and Clinical Practice , Volume 147 , 157 - 165