Safety and efficacy of insulin detemir in type 2 diabetic patients previously treated with oral antidiabetics alone: Results from the Tunisian A$_1$chieve cohort

Sir,

Due to the natural history of type 2 diabetes (T2D), timely modification of therapeutic regimens is required when glycemic targets are not met.[1] Insulin detemir (IDet) therapy is associated with improved glycemic control and a low incidence of hypoglycemia compared to neutral protamine Hagedorn insulin.[2] We report the results of a Tunisian cohort switching from oral antidiabetic drugs (OADs) alone to IDet ± OADs, as a sub-analysis of A1chieve: a 24-week, international, prospective, multicenter, observational, non-interventional study.[3]

Tunisian T2D patients transferred from OADs alone to IDet ± OADs were included. The primary endpoint was the analysis of serious adverse drug reactions (SADRs), including major hypoglycemic events. Secondary endpoints included changes in the frequency of hypoglycemic events and efficacy assessments (glycated hemoglobin A_{1c} [HbA_{1c}]), fasting plasma glucose (FPG), postprandial plasma glucose (PPPG), systolic blood pressure (SBP), body weight, blood lipid, and quality of life evaluation (EQ-5D 20 cm visual analog scale).

A total of 169 patients (mean age ± SD = 60 ± 11. 7 years; body mass index = 28.4 ± 5.3 kg/m^2) with a mean diabetes duration of 11.8 ± 6.8 years and mean duration on OADs of 11.1 ± 6.7 years were included in this analysis. The most commonly used OADs at pre-study were sulfonylurea and metformin (94% and 73% of patients, respectively). After switching to IDet, 78% and 68% of patients continued using sulfonylurea and metformin, respectively. For 91% of patients, IDet therapy was initiated to improve glycemic control. The mean IDet dose at baseline was 14.2 ± 6.3 U/day (0.19 ± 0.08 U/kg) titrated up to 25.7 ± 15.7 U/day (0.32 ± 0.16 U/kg) after 24 weeks. In total, 97% of patients initiated IDet dosing once daily (OD) at baseline and 84% continued OD dosing at week 24. No SADRs or major hypoglycemic events were reported during the study. No significant changes from baseline were noted in the proportions of patients reporting overall, minor, and nocturnal hypoglycemia at week 24. Mean HbA_{1c} levels improved significantly from 10.2 ± 1.5% to 8.1 ± 1.2% ($P < 0.001$) over 24 weeks. Mean FPG and PPPG levels also reduced significantly (change from baseline: 93.8 ± 64.6 mg/dL and 114.5 ± 69.5 mg/dL, respectively, $P < 0.001$). There was a statistically significant increase in mean body weight (change from baseline: +1.2 ± 3.6 kg, $P < 0.001$), which could perhaps be explained by the high proportion of patients who continued secretagogue treatment after initiating IDet. No significant changes in blood lipids or SBP were observed. Quality of life was improved (change from baseline: +8.2 ± 13.0, $P < 0.001$).

In this Tunisian cohort with T2D poorly controlled on OADs, initiation of IDet therapy (± OADs) significantly improved glycemic control with no major hypoglycemia or SADRs.

Larbi Chaib

Department of Endocrinology and Diabetology, Farhat Hached University Hospital, Ibn Jazzar Street, 4002 Sousse, Tunisia

Corresponding Author: Dr. Larbi Chaib, Department of Endocrinology and Diabetology, Farhat Hached University Hospital, Ibn Jazzar Street, 4002 Sousse, Tunisia. E-mail: l.chaieb@rns.tn

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