Safety and efficacy of a pragmatic self-titration 1 unit/day (INSIGHT) algorithm for insulin glargine 300 U/mL (Gla-300)

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Background and aims: New basal insulin GLA-300 provides a flat and prolonged PK/PD profile with a comparable glycemic control and less hypoglycemia vs glargine 100 U/mL (GLA-100).

Materials and methods: In the phase III EDITION trials, insulin was titrated by the HCP based on the median of the last 3 fasting prebreakfast SMPGs. Titration was scheduled once weekly, no more often than every 3 days. However, with GLA-100, the INSIGHT pragmatic 1U/day self-titration protocol is widely used in Canada. The objective of this 12-week, randomized, descriptive pilot study was to compare safety and efficacy of two titration algorithms, INSIGHT and EDITION, for GLA-300 in T2DM patients (insulin-naïve or on basal insulin ± OAD) mainly in a primary care setting.

Results: Baseline characteristics of the 212 patients randomized in the study were similar: age 62.3 years, BMI 34.2 kg/m2, A1c 8.4%, insulin naïve 37.0%, prior basal insulin dose 57.2 U. Comparable number of patients in each titration group reached primary endpoint of a fasting SMPG ≤ 5.6 mmol/L without nocturnal (0:00-6:00 h) hypoglycemia (confirmed: SMPG ≤3.9 mmol/L or symptomatic or severe) at 12 weeks (INSIGHT algorithm 22.8%; EDITION 20.6%). No between treatment differences in number of severe hypoglycemia were noted (1 INSIGHT algorithm vs 3 EDITION). The percentages of patients achieving A1c ≤7% was 28.7% (INSIGHT algorithm) vs 28.4% (EDITION) with a similar mean A1c (SD) of 7.6% (0.9) at week 12. Similar number of patients experienced nocturnal hypoglycemia (INSIGHT algorithm 28.7%; EDITION 27.5%). Mean (SD) insulin dose at week 12 was comparable in both titration algorithms (INSIGHT algorithm 67.0 U (37.8); EDITION 70.0 U (43.1)). Mean change (SD) in weight from baseline was 0.41 kg with INSIGHT algorithm and 0.15 kg (2.4) with EDITION. No between groups differences in adverse events were noted.

Conclusion: In conclusion, application of a self-titration of 1 U/day algorithm with GLA-300 resulted in a good safety profile, was effective and comparable to the previously tested EDITION algorithm. Clinical Trial Registration Number: NCT02401243

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