Glycaemic control in people with type 2 diabetes (T2D) switching from NPH to insulin glargine 300 U/mL (Gla-300): REALI pooled database

Author D. Müller-Wieland1, N. Freemantle 2, R. Bonadonna 3, C. Mauquoi 4, G. Bigot 5, M. Bonnemaire 6, P. Gourdy 7, D. Mauricio 8.

1 Department of Medicine, University Hospital, Aachen, Germany,

2 Institute of Clinical Trials and Methodology, University College London, London, UK,

3 University of Parma, Parma, Italy,

4 Clinical Trial Consulting, International Drug Development Institute, Louvain-la-Neuve, Belgium,

5 IVIDATA, Paris, France,

6 General Medicines, Sanofi, Paris, France,

7 Institute of Metabolic and Cardiovascular Diseases, Toulouse University, Toulouse, France,

8 Department of Endocrinology & Nutrition, Hospital of Santa Creu i Sant Pau,Barcelona, Spain.

Abstract:

Background and aims:

The effectiveness of Gla-300 in people with T2D switching from NPH is not widely documented.

Materials and methods:

The European REALI pooled database included patient-level data from 14 European prospective interventional and non-interventional studies inpeople with T2D treated with Gla-300. The present analysis evaluated the impact of Gla-300 on HbA1c improvements in people with T2D, previously uncontrolled on basal insulin (BI).

Results:

This analysis included data from people with T2D uncontrolled on prior BI: 1,282 switching from NPH and 2,899 from other non-NPH BIs (mainly glargine 100 U/mL,67%) to Gla-300. In the NPH group, mean±SD age was 63±9.4 years, BMI 32.5±5.8 kg/m², and median diabetes duration 12 years. The majority previously used biguanides(71%), followed by sulfonylureas (20%), and dipeptidyl peptidase 4 inhibitors (18%). HbA1c markedly improved after a 24-week Gla-300 therapy (Figure 1A). Mean±SD fasting plasma glucose (FPG) decreased from 188.8±55.9 mg/dL at Baseline to 143.3±45.5 at Week 24. Gla-300 was started at a mean dose of 29.4 U/day and titrated up to 35.6 at Week 24, with no body weight change. In the non-NPH BI group, baseline characteristics were comparable to those in the NPH group, except for higher baseline HbA1c and FPG in the latter. Figure 1B illustrates HbA1c improvement in the non-NPH BI group, at a mean Gla-300 starting dose of 35.4 U/day (0.37 U/Kg/day) increasing to 41.7 U/day (0.44U/Kg/day) at Week 24, with no body weight change. Hypoglycaemia was similarly low in both groups.

Conclusion:

This analysis shows that people with T2D, previously uncontrolled on BI, benefited from switching to Gla-300 in terms of HbA1c improvement, and this was especially observed in those previously treated with NPH.

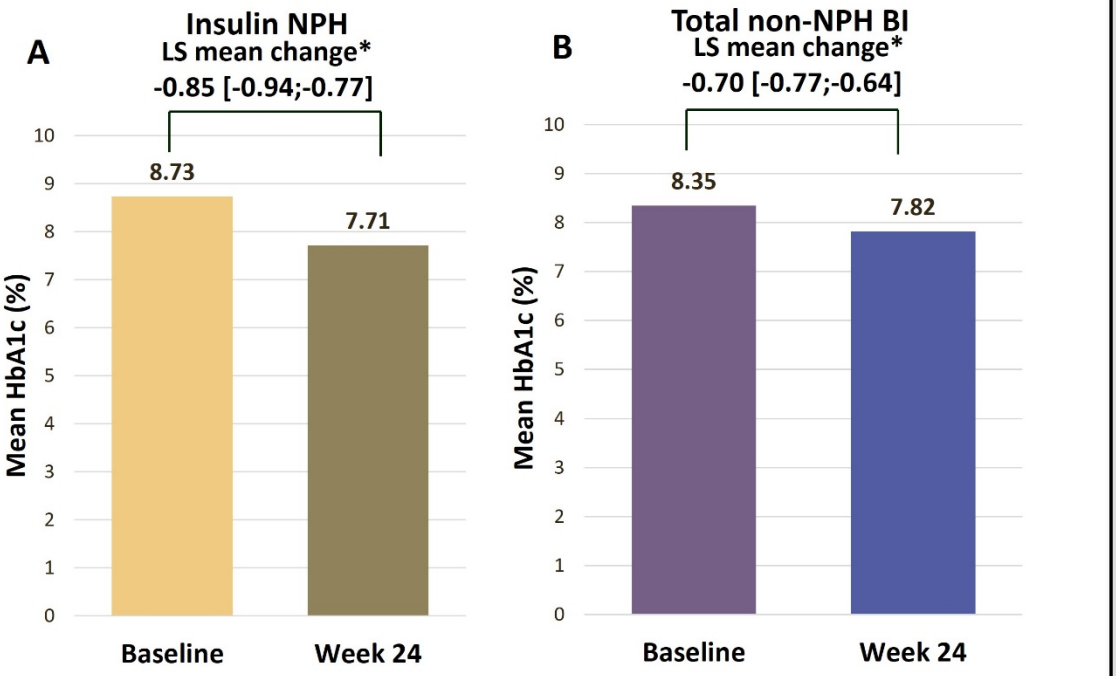

Figure 1. Mean HbA1c (%) Change from Baseline to Week 24 During Treatment with Insulin Glargine 300 U/mL in People with Type 2 Diabetes Previously Treated with **(A)** Insulin NPH and **(B)** non-NPH Basal Insulin. *LS mean change [95% CI] from Baseline to Week 24 derived from MMRM adjusted for study, baseline HbA1c, interaction baseline HbA1c by visit, age, interaction age by visit, BMI and interaction BMI by visit. ***Abbreviations*:** BI, basal insulin; BMI, body mass index; CI, confidence interval; HbA1c, hemoglobin A1c; LS, least square; MMRM, mixed-effect model with repeated measures; NPH, neutral protamine Hagedorn.