Hypoglycaemia, irrespective of the definition used, is reduced when switching to insulin degludec from other basal insulins in routine clinical care: the ReFLeCT study

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Background

• Hypoglycaemia is a frequent event in patients with diabetes treated with insulin and has been linked to impaired glycaemic control.1-3

• Randomised controlled trials have demonstrated that degludec is associated with less hypoglycaemia than both other basal insulins and equivalent insulin glulisine, across a broad spectrum of patients with diabetes.1,4-7

• ReFLeCT (Results From Real-World Clinical Treatment with Tresiba®) was a prospective, observational study conducted across seven European countries.8,9

• Patients aged ≥18 years with T1D or T2D who were already on insulin, and whose physician advised that they should switch to degludec treatment, were eligible for inclusion.10

• The study comprised a baseline period (4 weeks prior to switching to degludec) and a follow-up period (up to 12 months after switching to degludec).10

• Patients were instructed to complete study diary cards prior to each visit, collecting day-by-day information on hypoglycaemic events.

• The primary endpoint was the number of overall hypoglycaemic events during the 12-month follow-up period.8,9

Methods

• ReFLeCT was a prospective, observational study conducted across seven European countries.8,9

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Results

• In ReFLeCT, switching to degludec from other basal insulins was associated with significantly reduced rates of overall hypoglycaemia in combination with improved glycaemic control in insulin-treated adults with T1D or T2D.10

• Hypoglycaemia definitions

  • Previous (pre-defined) ADA definitions.

  • As different hypoglycaemia definitions can impact study outcomes, as different hypoglycaemia definitions can impact study outcomes, the present analysis of the ReFLeCT study analysed previous (pre-defined) and updated (post-hoc) American Diabetes Association (ADA) hypoglycaemia definitions.10

• Statistical analysis

  • The numbers of hypoglycaemic events were converted to rates per person-month.

  • Rate ratios for hypoglycaemia between the 4-week baseline and 12-month follow-up periods, adjusting for covariates (visit number, duration of diabetes, type of diabetes; T1D, T2D), age, BMI, gender, body mass index, duration of diabetes, age, and country, in addition to bolus insulin (Neutral/sulphonylurea (HbA1c) for T1D).10

  • All statistical tests were two-sided with a significance level of p<0.05.

Conclusions

• Eighty-three (14.8%) patients in the T1D group and 70 (12.6%) in the T2D group experienced severe hypoglycaemia during the 12-month follow-up period.

• Switching to degludec from other basal insulins in routine clinical practice was generally associated with reduced rates of hypoglycaemia when using different hypoglycaemia definitions in patients with diabetes.4,5

• Definitions for Level 1, 2 and 3 hypoglycaemia were well-represented in the rate events and for the change between the baseline and follow-up periods (except for Level 4 hypoglycaemia for T2D), strengthening the generalisability of the results.8,10

• This analysis of ReFLeCT corroborates the findings of the primary study, that switching to degludec from other basal insulins is associated with reduced rates of overall hypoglycaemia in patients with T1D and T2D in routine clinical care.8,10

References:

5) et al., JAMA 2017;317:1061–70.
6) et al., JAMA 2017;317:1041–50.