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DUAL VIII: longer time to intensification with insulin degludec/liraglutide (IDegLira) vs. insulin glargine in a 104-week randomised trial mirroring clinical practice

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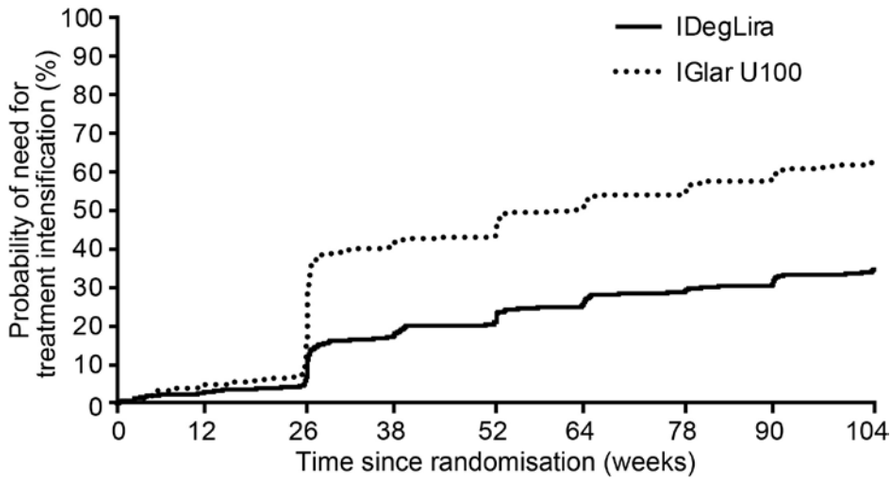
Background and aims: Long-term glycaemic control is key to avoid type 2 diabetes (T2D) complications. Few trials have studied treatment durability and impact on time to intensification, which affects overall maintenance of glycaemic control. The aim of DUAL VIII was to compare the durability of glycaemic control of insulin degludec/liraglutide (IDegLira) vs. insulin glargine 100 units/mL (IGlar U100) in a trial mirroring clinical practice.

Materials and methods: Patients (n=1012) with T2D (HbA_{1c} 7–11%) on oral antidiabetic drugs (OADs) were randomised 1:1 to open-label IDegLira or IGlar U100 in a 104-week trial to assess treatment durability. The primary endpoint was time from randomisation to treatment intensification (HbA_{1c} ≥7.0% at 2 consecutive visits including Week 26); patients who met the primary endpoint discontinued study drug.

Results: Baseline characteristics were similar. Over 104 weeks, fewer patients with IDegLira required intensification vs. IGlar U100 (37.4% vs. 66.2%). Patients treated with IDegLira had a significantly longer time to intensification (median: >2 years/~1 year for IDegLira/IGlar U100; **Figure**). There was a greater effect with IDegLira vs. IGlar U100 after 104 weeks, had patients remained on treatment and intensification not been needed, in terms of: patients achieving HbA_{1c} <7% (55.7 vs. 28.5%), and HbA_{1c} <7% with no weight gain (20.9 vs. 6.3%), lower estimated mean insulin dose (36 vs. 51 U; estimated treatment difference –14.9 U), and 56% lower rate of severe or blood glucose-confirmed symptomatic hypoglycaemia (0.38 vs. 0.86 events/patient-year of exposure), p<0.0001 for all. Safety results were similar.

Conclusion: Improved long-term glycaemic control, evidenced by significantly longer time to treatment intensification, was achieved with IDegLira vs. IGlar U100 in patients previously uncontrolled on OADs.

DUAL VIII trial
Kaplan–Meier curve of time to need for treatment intensification (HbA_{1c} ≥7% at two consecutive visits including Week 26)



IDegLira, insulin degludec/liraglutide; IGlar U100, insulin glargine 100 units/mL
Data based on full analysis set. Patients discontinuing treatment contributed to analyses as having needed treatment intensification from time of discontinuation. The primary analysis used a stratified log-rank test where treatment, baseline HbA_{1c} group (<8.5, ≥8.5%) and previous oral antidiabetic treatment (sulphonylurea/non-sulphonylurea) were included as strata in the model (stratified log-rank test p<0.0001, in favour of IDegLira)

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