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Subject:

A randomised controlled trial of linagliptin monotherapy vs initial combination with metformin in newly diagnosed type 2 diabetes patients

Abstract:

Aims: The incidence of type 2 diabetes (T2D) has risen dramatically in recent decades and glycaemic control in early stages of T2D is crucial to prevent long-term complications. While antihyperglycaemic monotherapy could be sufficient in mild to moderate hyperglycaemia, initial combination of glucose-lowering agents may be considered in pronounced hyperglycaemia. We compared 2 common treatment strategies (monotherapy or initial combination) for controlling marked hyperglycaemia in previously untreated patients with newly diagnosed T2D by utilising the DPP-4 inhibitor linagliptin.

Methods: This international double-blind clinical trial randomised 316 treatment naïve subjects with recently diagnosed (≤12 months) and uncontrolled T2D (baseline HbA1c 8.5–12.0%) to receive linagliptin 5 mg QD (n=157) or the initial combination of linagliptin 5 mg QD + metformin BID (uptitrated in the first 6 weeks; maximal dose 2000 mg/d) (n=159) for 24 weeks. The primary endpoint was the difference in change from baseline HbA1c between groups in the per-protocol cohort of subjects completing the trial exclusively on study drug (linagliptin, n=113; linagliptin + metformin, n=132).

Results: Subjects (54% females) were mainly Whites (58%) or Asians (38%) with a mean (±SD) age, HbA1c, and BMI of 48.8 (11.0) years, 9.8 (1.1) %, and 29.7 (5.6) kg/m^2. After 24 weeks both linagliptin monotherapy as well as the initial combination of linagliptin and metformin significantly reduced HbA1c (±SE) levels by –2.0% (0.1) and –2.8% (0.1), respectively. The treatment difference of –0.8% (95% CI –1.1 to –0.5) showed superiority for the initial combination over monotherapy ($p<0.0001$). Notably, 40% and 61% of patients in the monotherapy and combination arms achieved HbA1c <7.0%. Treatments were well tolerated overall with very few drug-related or serious adverse events. Hypoglycaemia occurred in ≤3.2% of each arm. Body weight was stable with linagliptin and decreased in the combination arm (–1.3 kg between group difference; $p=0.0033$).

Conclusion: Linagliptin as monotherapy or in initial combination with metformin achieved clinically significant improvements in glucose control in patients with newly diagnosed T2D and marked hyperglycaemia; the large HbA1c reductions were notable, particularly with the dual therapy. This previously untreated cohort was chosen to explore the efficacy of oral DPP-4 inhibition in T2D patients with short disease duration.

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