

Harmony 5 - year 3 results: albiglutide vs placebo and vs pioglitazone in triple therapy (background metformin and glimepiride) in people with type 2 diabetes

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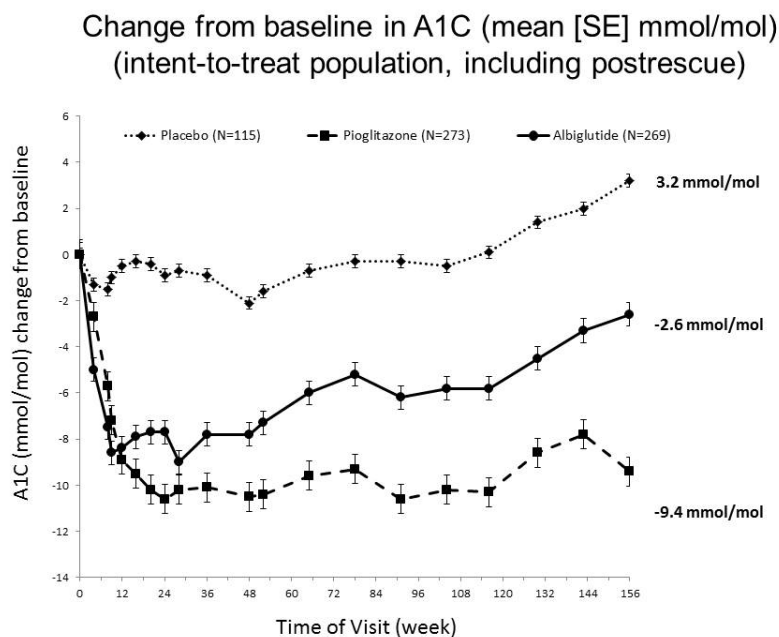
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Background and aims: A 3-year, randomized, double-blind, multicenter study evaluated once weekly (QW) GLP-1 receptor agonist albiglutide (Albi) vs placebo (Pbo) and vs pioglitazone (Pio) in people with A1C 53-85.8 mmol/mol [7.0-10.0 %] on background dual therapy of metformin and glimepiride.

Materials and methods: Uptitration of Albi 30 to 50 mg QW and Pio 30 to 45 mg QD was allowed if needed. If hyperglycemic rescue was required, people remained in the study.

Results: Baseline characteristics were similar between groups. At Week 52 (primary endpoint), Albi significantly decreased A1C vs Pbo but did not meet criteria for noninferiority vs Pio. Among people remaining in the study for 3-years (including those who received rescue medication), glycemic control was enhanced on Albi and Pio and maintained on Pbo (figure). Weight loss (kg) was observed on Albi and Pbo (-0.6 and -0.6), but weight increased on Pio (5.9 kg). Adverse events were higher on Albi than Pbo and Pio for injection site reactions (14.4%, 5.2%, 5.1% of participants, respectively), diarrhea (13.7%, 10.4%, 8.3%), and nausea (11.1%, 6.1%, 7.2%), but not vomiting (2.6%, 3.5%, 5.1%). The incidence of SAEs (14.4%, 18.3%, 17.3%) and AEs leading to withdrawal (8.1%, 10.4%, 10.5%) was lower on Albi than Pbo and Pio.

Conclusion: Albi in triple therapy gives effective glucose lowering to 3-years, was well tolerated, and was associated with less weight gain than Pio.



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