

## Glycemic Control and Treatment Satisfaction in Type 2 Diabetes: Basal Plus Compared with Biphasic Insulin in the LANSCAPE Trial

Session Late Breaking Abstracts

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Late Breaking Posters

Number 47-LB | Sunday, June 23, 2013 at 12:00 PM – 2:00 PM | Location: Hall F1 - Posters

Category Clinical Therapeutics/New Technology–Insulins

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Biphasic insulin is a frequent intensification step when basal insulin alone provides inadequate glycemic control. Basal plus main-meal fast acting insulin may be equally effective and more acceptable. The LANSCAPE study tested whether “Basal Plus” insulin glargine (Lantus) once daily and insulin glulisine (Apidra) at main meal was non-inferior to twice daily “Biphasic” insulin aspart/aspart protamine 30/70 (NovoMix30) with respect to glycemic control (primary objective) and provided superior treatment satisfaction.

LANSCAPE was an international, controlled trial of adults with type 2 diabetes receiving basal insulin. Participants’ mean (SD) age was 61.6 (8.5) yrs, diabetes duration 12.9 (6.4) yrs and A1C 8.62 (0.94) %. During an 8-12 week run-in, oral agents except metformin were stopped and insulin glargine optimized. After run in, 335 participants with fasting glucose at target (<126mg/dl) but suboptimal A1C (>7%) were randomized to a “Basal Plus” (n=170) or “Biphasic” (n=165) regimen. Active insulin titration followed standardized algorithms; 89% of patients (91.8% and 86.1% respectively) completed treatment.

At 24 weeks A1C fell by 1.00% in the Basal Plus, 1.22% in the Biphasic arms; mean difference 0.21% (SE 0.09, upper 97.5% CL 0.38), implying non-inferiority of Basal Plus relative to the Biphasic regimen (pre-defined margin 0.4%). More subjects reached target A1C 7% with Basal Plus than Biphasic (76.5% vs 66.1%, p=0.049). There was no difference in overall hypoglycemia rates (15 vs. 18 events/patient-year respectively p=0.2), but slightly more nocturnal events with Basal Plus (5.7 vs 3.6 events/patient-year p=0.02). Significant advantages favoring Basal Plus were seen in DTSQc and ITSQ treatment satisfaction measures.

In type 2 diabetes Basal Plus provides comparable glycemic control to a Biphasic regimen, better patient reported outcomes, and may present a more acceptable option for insulin initiation/intensification.

NCT00965549

Keywords Insulin glargine (Lantus), Insulin glulisine (Apidra), Basal Plus

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