Abstract

BC Combo is a co-formulation of prandial insulin lispro (25%) and basal insulin glargine (75%) in a fixed ratio (5:4) that has been designed to improve glycemic control in patients with type 2 diabetes. In this study, the effects of BC Combo on postprandial glucose (PPG) levels were evaluated in subjects with type 2 diabetes. The primary endpoint was the difference in area under the glucose curve (AUC) of glucose excursion over the 1st hour post-insulin administration (AUCGlu-1h) in subjects receiving BC Combo (50% lispro insulin lispro [LisproMix]) vs. Lantus (Lantus). The difference between treatments was calculated as the mean difference, with 95% confidence intervals. The primary endpoint was met with a p-value <0.0001 (Table 1). The time to peak response was 2.0 hours with BC Combo and 0.5 hours with Lantus. The overall time in target range (≥72 ≤180 mg/dL) was higher with BC Combo than with Lantus (60.1 vs. 42.9%; p=0.0007). The results of this study suggest that BC Combo is an effective and safe treatment option for patients with type 2 diabetes.

Introduction & Background

Postprandial glucose (PPG) excursions are of great importance in the management of type 2 diabetes. Hyperglycemia after meals is associated with an increased risk of microvascular and macrovascular complications. The use of prandial insulin in a fixed ratio with basal insulin glargine (BC Combo) has been shown to reduce postprandial glucose levels significantly compared to basal insulin alone (Lantus). In this study, the effects of BC Combo on postprandial glucose (PPG) levels were evaluated in subjects with type 2 diabetes. The primary endpoint was the difference in area under the glucose curve (AUC) of glucose excursion over the 1st hour post-insulin administration (AUCGlu-1h) in subjects receiving BC Combo (50% lispro insulin lispro [LisproMix]) vs. Lantus (Lantus). The difference between treatments was calculated as the mean difference, with 95% confidence intervals. The primary endpoint was met with a p-value <0.0001 (Table 1). The time to peak response was 2.0 hours with BC Combo and 0.5 hours with Lantus. The overall time in target range (≥72 ≤180 mg/dL) was higher with BC Combo than with Lantus (60.1 vs. 42.9%; p=0.0007). The results of this study suggest that BC Combo is an effective and safe treatment option for patients with type 2 diabetes.

Pharmacokinetics

- BC Combo showed a shorter time to peak glucose excursion compared to Lantus, with a time to peak of 2.0 hours compared to 0.5 hours for Lantus.
- Total exposure to glucose was lower with BC Combo than with Lantus, with total exposure after 6 hours being 23.7 mg/dL with BC Combo and 68.0 mg/dL with Lantus.

Safety

- All insulin regimens were well-tolerated, with no serious adverse events reported.
- Hypoglycaemia was considered as an adverse event and was noted in 13.5% of patients receiving BC Combo and 20.8% of patients receiving Lantus.

Results

- The time to peak response was 2.0 hours with BC Combo and 0.5 hours with Lantus.
- The overall time in target range (≥72 ≤180 mg/dL) was higher with BC Combo than with Lantus (60.1 vs. 42.9%; p=0.0007).

Conclusions

- BC Combo showed a faster rise in insulin concentrations and a higher early insulin exposure than both Humalog Mix and separate gliclazide and lispro in improved postprandial control in the first two hours after a test meal. The late PK-exposure from 2 to 6 hours was lower with BC Combo which reduced the decline of BG concentrations below baseline and the rate of postprandial hypoglycaemia compared to LMx.