Combination of Saxagliptin and Metformin Is Effective as Initial Therapy in New-Onset Type 2 Diabetes Mellitus With Severe Hyperglycemia

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Abstract

Context:
The efficacy/safety of combination oral agents in those with stable newly diagnosed type 2 diabetes (T2DM) with severe hyperglycemia is unknown.

Objective:
The objective of the study was to assess glycemic and β-cell outcomes of two oral regimens.

Design:
This was an open-label, randomized controlled trial with patients enrolled from 2011 through 2014 and followed up for 12 weeks.

Setting:
The study was conducted at a major public hospital in Chicago.

Patients:
One hundred adults with newly diagnosed T2DM and severe hyperglycemia (300–450 mg/dL) participated in the study.

Intervention:
One hundred patients were randomized to receive Kombiglyze XR (saxagliptin 5 mg/metformin 2000 mg) daily (K group) vs glipizide XL 10 mg daily (G group).

Main Outcome Measures:
The measure was to maintain fasting/premeal glucose of less than 300 mg/dL up to 6 weeks and less than 250 mg/dL after 6 weeks until study end, and to have no return acute care-site visits. Those not meeting criteria were discontinued. Other outcomes included continuous glucose monitoring (CGM) and β-cell function estimates at start and study end.

Results:
Baseline characteristics and primary outcome (K group 94%, G group 98%) were similar in both groups. The enrollment glucose (K group 343 mg/dL, G group 341 mg/dL) and glycated hemoglobin (K group 10.8%, G group 11%) declined by week 12 (K group 137 mg/dL, G group 129 mg/dL, and K group 6.8%, G group 6.9%), respectively. Homeostasis model assessment to assess basal insulin secretion and early insulin response improved severalfold (K group ×5.8, G group ×5.9, and K group ×9.5, G group ×13.1). In follow-up, the incidence of hypoglycemia was lower in the K group (self-monitored blood glucose: K group 8.0%, G group 24%; CGM: K group 20%, G group 46.5%) as were the number of episodes of hypoglycemia (self-monitored blood glucose: K group 4 in 12 weeks, G group 27 in 12 weeks; CGM: K group 0.28 per 24 h, G group 0.31 per 24 h).

Conclusions:
Kombiglyze XR and glipizide XL are efficacious in improving glycemia and β-cell function in stable newly diagnosed T2DM with severe hyperglycemia. The K group had less hypoglycemia. These results suggest that certain oral medications could be appropriate alternatives in treating severe hyperglycemia.

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