

Incidence of hypoglycemia with glimepiride/metformin fixed-dose combination in patients with type 2 diabetes inadequately controlled on metformin monotherapy in Peru: a prospective, active pharmacovigilance cohort study Short running title: Hypoglycemia with glimepiride plus metformin in Peru

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Abstract

Purpose — To evaluate hypoglycemia incidence rate during treatment with a fixed-dose combination of glimepiride and metformin in patients non-responders to metformin monotherapy. Data were collected during customary specialized practice in Peru where access to effective and safe, but low-cost medications, is needed. **Methods**— This was an observational, prospective, active pharmacovigilance, cohort study with in-person medical assessments. Medical assessments were conducted every 3-months, with monthly follow-up through phone calls. Data regarding use and administration of treatment were recorded by patients. Adverse events (AE) reported by patients and/or ascertained by attending physicians during the period of 18 months along with treatment-related events were identified. Cumulative incidence and hypoglycemia incidence rate were estimated. Poisson and logistic regression models were applied to study their relationship with risk factors and patterns of use. **Results**— 206 patients were enrolled in the study from 10 centers and were followed for a median duration of 12 months (range, 2-18 months). Forty treatment-related AEs were reported (cumulative incidence = 19.4%). No severe hypoglycemic events were observed. Most common AE found was non-severe hypoglycemia (cumulative incidence = 2.4%; incidence rate = 2.6/100 person-years). Self-administration of a higher dose than prescribed was associated with a higher probability of an AE ($p=0.03$). **Conclusions**— Administration of a fixed-dose combination of glimepiride plus metformin was associated with low incidence of non-severe hypoglycemia, and no incidence of severe hypoglycemia. These results advocate the use of fixed-dose combination of glimepiride plus metformin in low- and middle-income countries with limited resources, even more so in wake of COVID-19 pandemic.

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