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Real-life effectiveness and tolerability of initial combination therapy with Vildagliptin/Metformin in drug-naive patients with type-2 DM (initial): A 24-week study from Asia

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Background & Aim: Type-2 diabetes mellitus (T2DM) prevalence in South-East Asia region is on the rise and there is currently limited evidence assessing early therapeutic interventions. We assessed the effectiveness and safety of initial combination therapy with vildagliptin/metformin in drug naive type-2DM patients in a real life (initial) study.

Methods: Initial study was a 24-week non-interventional, prospective study in drug-naive type-2 DM patients across Asia (Bangladesh, India, Philippines, South Korea) with documented HbA1c>7.5% (>8.0% in India), who were prescribed vildagliptin/metformin initial combination within 4 weeks of study entry according to local label. The primary endpoint was change in HbA1c (ΔHbA1c) from baseline to week 24. Key secondary endpoints were achievement of HbA1c≤7.0% and ΔHbA1c by baseline subgroups (varying HbA1c category and dosage).

Results: Out of 532 enrolled patients, 457 (85.9%) completed the study. Overall study population was relatively young with mean age 49.6±11.27 years, mean HbA1c-9.3±1.57%, diabetes duration-0.8±2.47 years, BMI-26.7±4.50 kg/m2. At baseline, approximately 30% patients had hypertension, dyslipidemia or diabetes family history and 17.9% were obese. Most patients (70.6%) received twice daily vildagliptin/metformin (mostly 50/500 mg in 53.5%) with minimal dose changes. Overall ΔHbA1c from baseline was statistically significant (p<0.001) both at week 12 (−1.6±1.59%) and 24 (−1.9±1.70%) and meaningful across baseline HbA1c categories and drug dosages. Overall 39.6% patients achieved HbA1c≤7.0% and mean change in body weight was −1.1±2.62 kg. About 48 (9.0%) AEs including 1 (0.2%) hypoglycemic episode were reported with no SAEs or deaths.

Conclusion: Overall in these relatively young drug-naive type-2 DM Asian patients with high baseline HbA1c and often associated with CV risk factors vildagliptin/metformin combination was associated with significant and clinically relevant HbA1c reduction from baseline. This effect was seen early at week 12 was maintained over 24 weeks and was accompanied with good glycemic control and tolerability.

Biography

M F Pathan is an eminent Endocrinologist and Diabetologist. He is the Head of the Department of Endocrinology at BIRDEM General Hospital, Dhaka, Bangladesh. He has published several research articles and review articles including the South Asian consensus guidelines on various aspects of management of diabetes and presented research papers at various national and international conferences.

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