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QT/QTc safety and efficacy evaluation of Tenueligliptin in Indian type 2 diabetes mellitus patients: the “thorough QT/QTc” study (Q-SET study)

Therapeutic armamentarium of T2DM has been rapidly expanding over last decade & dipeptidyl peptidase IV inhibitors (gliptins) have emerged as safe, efficacious, durable class. In this same timeframe, ADA-EASD guidelines have become more patient centric & the USFDA has given a mandate to prove cardiovascular safety before marketing any antidiabetic drug.

Tenueligliptin is a very widely used drug for T2DM in India since 2015. Therapeutic doses of tenueligliptin (20 or 40 mg/day) have not been known to alter the QT interval in ECG, but, suprathreshold doses (160mg/day) may prolong the same. Similar observations are made with sitagliptin (50 or 100 mg/d safe-but-400mg/d may prolong QT interval). Since prolongation of QT interval can increase risk of polymorphic ventricular tachyarrhythmia Torsade de Pointes, this scrutiny is essential.

Since there is no devoted study to assess if routine doses of tenueligliptin (20 or 40mg/day) are safe with respect to effect on QT interval, we undertook this exercise.

We selected 66 adult nonpregnant T2DM patients (age >18 yrs <65 yrs) who were gliptin naïve & on standard antidiabetic treatment, but, uncontrolled (HbA1c > 7%). Tenueligliptin 20mg/day was added to therapy & if needed, doubled to 40mg/day. Other drugs were unchanged through the study duration (unless compelling clinically). Baseline 12 lead ECG


was recorded & also within 120 minutes of the 1st, 15th & 90th day of tenueligliptin. Glycemic parameters were recorded alongwith other laboratory tests. QT interval was measured for each of these 4 ECGs (baseline, day 1, day 15 & 90) & QTc was calculated as per Bazett's formula ($QTc = QT / \sqrt{\text{RR}}$ interval).

It was observed that there was no increase in QT/QTc interval after 3 months of tenueligliptin treatment (along with other antidiabetic drugs like glimepiride, pioglitazone, metformin). The drug improved glycemic parameters & without noteworthy adverse events. Larger studies & longer observation periods may help in future.

Speaker Biography

Suhas Gopal Erande is a practicing consultant who is having own Diabetes centre & Insulin Pump Clinic at Akshaya Hospital, India. He has been writing Diabetes Patient Education books over 2 decades. Felicitated for social services for diabetes by 'Diabetes Mitra' award. He has written academic articles for physicians at National & International levels. Publications in National & International journals. He has been writing chapters in textbooks over years. Invited for poster presentation on Intensive Glucose Monitoring in Bethesda Baltimore 2016 Diabetes Technology Society Meet invited for Global Diabetes Conference. For Diabetes in Women lecture in Prague August 2017. His recently published studies Prevalence of depression in T2DM in India (DEPTH study) & effect of tenueligliptin on QT-QtC interval (Q SET study) have got International acclaim.

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