Session GPS02 - Sunday General Poster Session

1183-P / 1183 - Time to Insulin in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS)

June 11, 2017, 12:00 PM - 1:00 PM | Hall B

Authors

M. A. BETHEL, SAMUEL S. ENGEL, JYOTSNA GARG, SUSANNA R. STEVENS, YULIYA LOKHNYGINA, ROBERT G. JOSSE, JENNIFER B. GREEN, ERIC D. PETERSON, RURY R. HOLMAN, TECOS STUDY GROUP, *Oxford*, *United Kingdom*, *Rahway*, *NJ*, *Durham*, *NC*, *Toronto*, *ON*, *Canada*

Disclosures

M.A. Bethel: *Research Support*; *Author*; Merck & Co., Inc., AstraZeneca. *Other Relationship*; *Author*; Merck & Co., Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Novo Nordisk Inc., GlaxoSmithKline, Merck Serono S.A.S., Janssen Pharmaceuticals, Inc., Sanofi-Aventis. S.S. Engel: *Employee*; *Author*; Merck & Co., Inc.. J. Garg: None. S.R. Stevens: None. Y. Lokhnygina: *Research Support*; *Author*; Merck & Co., Inc., Janssen Research & Development, AstraZeneca, GlaxoSmithKline, Bayer AG. R.G. Josse: *Research Support*; *Author*; Amgen Inc., AstraZeneca, Boehringer Ingelheim GmbH, Eli Lilly and Company, Janssen Pharmaceuticals, Inc., Merck & Co., Inc. J.B. Green: *Research Support*; *Author*; Merck & Co., Inc., AstraZeneca, GlaxoSmithKline. *Other Relationship*; *Author*; Merck & Co., Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Bioscientifica, The Endocrine Society. E.D. Peterson: *Research Support*; *Author*; Janssen Pharmaceuticals, Inc., Eli Lilly and Company. *Other Relationship*; *Author*; AstraZeneca, Bayer AG, Janssen Pharmaceuticals, Inc., Sanofi US. R.R. Holman: *Research Support*; *Author*; Merck & Co., Inc., Bayer AG, AstraZeneca, Bristol-Myers Squibb Company. *Other Relationship*; *Author*; Amgen Inc., Bayer AG, Intarcia Therapeutics, Inc., Merck & Co., Inc., Novo Nordisk Inc., GlaxoSmithKline, Janssen Pharmaceuticals, Inc., Takeda Pharmaceutical Company Limited, Novartis AG.

Background: TECOS was a randomized, placebo-controlled trial assessing the impact of sitagliptin on cardiovascular outcomes when added to usual care in patients with type 2 diabetes (T2DM). Among those not using insulin at baseline (n=11,263), we report the risk for progression to insulin during follow-up.
Methods: TECOS enrolled 14,671 participants with HbA1c 6.5-8.0% on monotherapy with metformin (MET), pioglitazone, sulfonylurea (SU) or insulin, or dual combination with two oral agents or insulin with MET. They were randomized double-blind to sitagliptin or placebo, with subsequent diabetes management by the participants' usual care physician. Time to initiation of insulin was estimated using a Cox proportional hazards model.
Results: 5,739 and 5,472 participants were on mono- (MET 4,435 [77%], SU 1246 [22%]) and dual- (SU + MET 5152 [94%]) oral agent therapy, respectively. Monotherapy patients had similar mean age (66 vs. 65 years) but shorter median T2DM duration (6 vs. 11 years), compared to dual therapy patients. MET monotherapy users were slightly younger (65 vs. 68 years), had shorter T2DM duration (6 vs. 8 years), similar HbA1c (7.1% vs. 7.2%) and higher eGFR (77.4 vs. 70.7) compared to SU monotherapy users. Overall, 4.7% of MET monotherapy users, 11.0% of SU monotherapy users and 17.2% of MET + SU users initiated insulin over a median duration of 3.1 years. Randomization to sitagliptin delayed the time to progression to insulin when added to MET monotherapy (1.3 vs. 2.0 events per 100 pyrs; HR 0.67 [95% CI 0.51-0.89]) or SU + MET dual therapy (5.1 vs. 7.8 events per 100 pyrs; 0.64 [0.56-0.73]), but not to SU monotherapy (4.0 vs. 4.2 events per 100 pyrs; 0.96 [0.68-1.34]).
Conclusion: Among a cohort of international clinical trial participants with T2DM well controlled with MET or SU mono- or dual oral agent therapy, the rate of initiation of insulin was higher among SU users (as mono- or dual therapy). Randomization to sitagliptin treatment delayed progression to insulin among MET and MET + SU users.