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Assessing the safety of sitagliptin in patients with type 2 diabetes and chronic kidney disease in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS)

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Background and aims: Chronic kidney disease (CKD) is a common sequela of type 2 diabetes (T2DM), and is evident in up to 40% of patients with T2DM. TECOS, a randomized, double-blind, placebo-controlled trial that assessed the impact of sitagliptin on cardiovascular outcomes, provides an opportunity to examine comparative safety-related outcomes in patients with T2DM and CKD.
Materials and methods: Baseline demographic, diabetes-related and cardiovascular characteristics of patients with chronic kidney disease (CKD), defined as an eGFR <60 ml/min/1.73m², were summarized. The incidences of severe hypoglycemia and diabetes-related complications were examined for sitagliptin- and placebo-assigned patients in the Intent to Treat population.
Results: TECOS included 3,324 CKD patients (1,667 sitagliptin, 1,657 placebo) with mean (SD) age 68.8 (7.9) years and diabetes duration 13.7 (9.0) years; 62% were male. Over ~2.8 median years' follow-up, sitagliptin-assigned patients, compared with placebo-assigned patients, had generally similar rates of diabetic eye disease, diabetic neuropathy, renal failure, malignancy, bone fracture and pancreatitis (Table). The proportions of patients with hypoglycemia requiring assistance was 3.4% and 3.3% in the sitagliptin and placebo groups, respectively.
Conclusion: In TECOS, no specific safety concerns were identified with the use of sitagliptin in T2DM patients with CKD.

Proportions of CKD patients in TECOS with:	Sitagliptin N=1667	Placebo N=1657
Any diabetes complication	40.1%	42.1%
Diabetic eye disease	3.1%	3.1%
Diabetic neuropathy	3.9%	3.6%
Renal failure	3.3%	3.6%
Malignancy	4.3%	5.1%
Bone fracture	3.7%	3.3%
Pancreatitis	0.1%	0.1%

Clinical Trial Registration Number: NCT00790205
Supported by: Merck & Co., Inc., Kenilworth, NJ, USA
Disclosure: **S.S. Engel:** Employment/Consultancy; Merck & Co., Inc., Kenilworth, NJ, USA. Stock/Shareholding; Merck & Co., Inc., Kenilworth, NJ, USA.