

## 587-P / 587 - Sitagliptin and Risk of Fractures in Type 2 Diabetes: Results from the TECOS Trial

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### Disclosures

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An increased risk of fractures is associated with type 2 diabetes, and some diabetes treatments, such as thiazolidinediones (TZDs) and sodium-glucose cotransporter 2 (SGLT2) inhibitors, may further elevate this risk; data regarding dipeptidyl peptidase 4 inhibitors (e.g., sitagliptin) are mixed. The Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS) randomized 14,671 patients to the addition of sitagliptin (N=7,332) vs. placebo (N=7,339) to existing diabetes treatments. At baseline, mean (SD) age was 65.5 (8.0) years and diabetes duration 11.6 (8.1) years, HbA1c was 7.2% (0.5%), 29.3% were women and 32.1% were non-white. In a prespecified intent-to-treat analysis we examined the self-reported incidence of clinician- or radiograph-verified fractures. Over a median of 3.0 years, 3.9% of patients had a non-fatal myocardial infarction, 1.7% were hospitalized for heart failure, 2.1% had a non-fatal stroke and 375 (2.6%) had a fracture, including 146 major fractures (hip: N=34; upper extremity: N=81; spine: N=31). An increased fracture risk was associated independently, in adjusted analyses, with older age ( $p<0.001$ ), female sex ( $p<0.001$ ), white race ( $p=0.001$ ), lower blood pressure ( $p<0.001$ ), diabetic neuropathy ( $p=0.002$ ) and use of TZDs ( $p=0.015$ ) or insulin ( $p<0.001$ ). 189 fractures (0.5 per 100 person-years) occurred with sitagliptin vs. 186 (0.6 per 100 person-years) with placebo (hazard ratio 1.01 [95% CI 0.82-1.23],  $p=0.94$ ). In TECOS, fractures were not uncommon, especially in older patients, and occurred at rates similar to heart failure hospitalization or stroke. There was no significant difference in fracture rates between sitagliptin and placebo, and sitagliptin was not associated with major fractures ( $p=0.78$ ) or hip fracture specifically ( $p=0.75$ ). This finding should help inform clinicians' choice of second-line diabetes treatments in patients at high fracture risk.