Real-World Cardiovascular Event Rates Among High-Risk Adults with Type 2 Diabetes Mellitus

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Background
- Cardiovascular disease (CVD) is a major complication of type 2 diabetes mellitus (T2DM) and is typically defined using the National Cholesterol Education Program Adult Treatment Panel III guidelines.
- T2DM increases the risk of CVD.
- A retrospective cohort study used data from the US population-based Study to Help Improve Early Evaluation and Management of Risk Factors Leading to Diabetes (SHIELD). High-risk respondents with T2DM were stratified into 2 cohorts: 1) established CVD (n = 1198) and 2) multiple risk factors cohort (n = 2005) established CVD cohort.
- An ongoing, multicenter, double-blind, placebo-controlled, Phase IV outcomes trial to evaluate the effect of Saxagliptin Assessment of Vascular Outcomes Recorded in patients with diabetes mellitus (SAVOR) is an ongoing, multicenter, double-blind, placebo-controlled, Phase IV outcomes trial to evaluate the effect of saxagliptin. The trial is sponsored by AstraZeneca LP.

Study Design
- A retrospective cohort study used data from the US population-based Study to Help Improve Early Evaluation and Management of Risk Factors Leading to Diabetes (SHIELD). High-risk respondents with T2DM were stratified into 2 cohorts: 1) established CVD (n = 1198) and 2) multiple risk factors cohort (n = 2005) established CVD cohort.
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Objective
- To ascertain the incidence and time to first non-fatal myocardial infarction (MI) or stroke over 3 and 5 years among adults with T2DM at high risk for CVD events.
- To evaluate the effect of saxagliptin on the incidence of myocardial infarction and stroke among adults with T2DM at high risk for CVD events.
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Methods
- A retrospective cohort study used data from the US population-based Study to Help Improve Early Evaluation and Management of Risk Factors Leading to Diabetes (SHIELD). High-risk respondents with T2DM were stratified into 2 cohorts: 1) established CVD (n = 1198) and 2) multiple risk factors cohort (n = 2005) established CVD cohort.
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Study Population
- Study population was comprised of 2 cohorts: 1) established CVD cohort and 2) multiple risk factors cohort.
- Established CVD cohort had a history of established CVD events (eg, CVD events of a different type, eg, stroke).
- Multiple risk factors cohort had at least 1 additional risk factor for CVD leading to Diabetes (SHIELD).

Study Measures
- Study measures included self-reported information on health status, attitudes, and behaviors.
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Results
- In the subsequent 5 years, any new reported MI or stroke was captured. For respondents with a history of CVD events (eg, MI), only CVD events of a different type (eg, stroke) were captured.
- Hazard rate (incidence) through 5 years peaked at: 0.8 in the established CVD cohort and 0.5 in the multiple risk factors cohort.
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Conclusions
- Saxagliptin is associated with a low risk of myocardial infarction and stroke events in high-risk adults with type 2 diabetes mellitus.
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Limitations
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