# ABSTRACT

Macrovascular complications of type 2 diabetes mellitus (T2DM) include myocardial infarction (MI) stroke, and coronary revascularization. This study ascertained the self-reported incidence rates of cardiovascular disease (CVD) events over 5 years among adults with and without T2DM. Respondents to the US Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes (SHIELD) surveys reported at baseline (2004) whether they had ever been told by a healthcare professional they had a heart attack, stroke, heart bypass surgery, angioplasty, or stents. In the subsequent 5 years, any new CVD events (incident event[s] reported subsequent to baseline) reported by T2DM respondents and those without diabetes were captured.

There were 2,305 T2DM respondents and 7,207 respondents without diabetes who reported no prior history of CVD events at baseline. A greater proportion of T2DM respondents had at least 1 incident CVD event over 5 years, compared with respondents without diabetes (16.7% vs. 10.3%, p <0.0001). In addition, 32.8% of T2DM respondents and 31.4% of respondents without diabetes had multiple CVD events (2 or more) over 5 years (p = 0.69). Among T2DM respondents with a prior history of CVD events (n = 898), 47.7% reported a new CVD event (different from baseline event) over the subsequent 5 years. For those without diabetes but with a prior history of CVD events (n = 1.744), 45.6% reported a new CVD event over 5 years (p = 0.33 in comparison with T2DM group). For those with a prior history of CVD events, 23.6% of T2DM respondents and 21.8% of respondents without diabetes had multiple CVD events over 5 years (p = 0.51).

There is a high prevalence of self-reported CVD events in respondents with T2DM. For T2DM respondents without a prior CVD history, there was a significantly higher incidence rate (62% relative increase), compared with those without diabetes and no prior history of CVD events. This study is consistent with previous reports suggesting that T2DM is a CVD risk equivalent.

# BACKGROUND

- Macrovascular and microvascular disease are well established complications of T2DM, with the risk of CVD and stroke 2 to 4 times higher among people with diabetes than among people without diabetes1,2
- Studies have indicated that the costs for patients with macrovascular complications were twice as high as those for patients with no complications<sup>3</sup>
- The ADA and the National Cholesterol Education Program recommend identification and aggressive treatment of cardiovascular risk factors, weight counseling and weight management, and more stringent target levels for lipids and blood pressure for individuals with T2DM than those recommended for the general population<sup>4, 5</sup>
- Current data for the incidence and prevalence of macrovascular disease among individuals with T2DM in the US are limited, with the latest figures based on data up to 2004<sup>2,6</sup>

# OBJECTIVE

To ascertain the self-reported incidence rates of CVD events over 5 years among adults with and without T2DM

# **METHODS**

#### Study Design

- Longitudinal analysis over 5 years was conducted using survey data among respondents with T2DM and those with no diabetes
- **Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes** (SHIELD) is a 5-year population-based survey conducted to better understand the risk for the development of diabetes, as well as diabetes disease burden
  - Based upon a screening questionnaire mailed to 200,000 nationally representative households (TNS NFO Household Panel), responses for 211.097 adults from 127.420 households were obtained (64% response rate)
- A baseline survey was sent to 22.001 selected individuals derived from the screening respondents, and the response rate was 72%. Since 2005, annual SHIELD surveys have captured self-reported information on health status, attitudes and behaviors, quality of life, and anthropometry from this representative sample of the US population
- Response rates to the 2005–2009 annual follow-up surveys were 69%–75%

## Study Population

- Respondents were 18 years of age or older
- Self-reported diagnosis of T2DM was based on being "told by a doctor, nurse or other healthcare professional that you have type 2 diabetes"
- Respondents who did not report a diagnosis of type 1 diabetes, T2DM, or unspecified diabetes in the baseline survey were included in the analysis as a comparison group without diabetes
- Respondents were included if they had completed the baseline survey and at least one follow-up survey through 2009

# Cardiovascular Event Rates in Adults with Type 2 Diabetes Mellitus: SHIELD 5-Year Perspective

Sandra J. Lewis, MD<sup>1</sup>, Kathleen M. Fox, PhD<sup>2</sup>, Elise Hardy, MD<sup>3</sup>, Susan Grandy, PhD<sup>3</sup>, for the SHIELD Study Group <sup>1</sup>Northwest Cardiovascular Institute, Portland, OR; <sup>2</sup>Strategic Healthcare Solutions, LLC, Monkton, MD; <sup>3</sup>AstraZeneca LP, Wilmington, DE

# **METHODS** (Continued)

#### Study Measures

- For macrovascular complications, respondents reported at baseline (2004) whether they had ever been told by a doctor, nurse, or other healthcare professional they had "a heart attack, stroke, heart bypass surgery, angioplasty, or stents"
- In the subsequent 5 years, any new CVD events reported were identified as incident events
- For respondents with a history of CVD events as reported at baseline, only different CVD events than the ones reported at baseline were counted as incident events during follow-up

#### **Statistical Analysis**

- Number of new CVD events reported between 2005 and 2009 was tabulated for respondents with T2DM and respondents with no diabetes
- Comparisons between respondents with and without diabetes were conducted using chi-square tests for categorical variables and *t*-tests for continuous variables
- Statistical significance was set *a priori* as p <0.05

# RESULTS

There were 3.203 respondents with T2DM, of whom 2.305 (72%) had no prior history of CVD events, and 8,951 respondents reported no diabetes, of whom 7,207 (80%) had no prior history of CVD events

Table 1. Characteristics of respondents with and without T2DM, stratified by prior history of CVD events

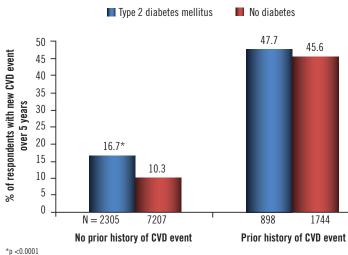
| Characteristics                              | Type 2 diabetes mellitus                      |                                     | No diabetes                                   |                                      |
|--|---|-------------------------------------|---|--------------------------------------|
|  | No prior history<br>of CVD events<br>N = 2305 | History of<br>CVD events<br>N = 898 | No prior history<br>of CVD events<br>N = 7207 | History of<br>CVD events<br>N = 1744 |
| Age, years, mean (SD)                        | 58.6 (12.5)*                                  | 65.4 (11.6)                         | 51.8 (15.7)                                   | 66.6 (13.1)                          |
| 18-44  | 14.6  | 3.5                                 | 33.7  | 6.2                                  |
| 44–54  | 23.7  | 15.5                                | 23.2  | 12.0                                 |
| 55-64  | 28.8  | 28.1                                | 20.8  | 21.4                                 |
| 65-74  | 21.0  | 26.6                                | 13.6  | 28.8                                 |
| 75 and older                                 | 11.9  | 26.3                                | 8.7   | 31.6                                 |
| Women, %                                     | 61.6  | 53.6                                | 63.3  | 50.1                                 |
| White, %                                     | 87.0*   | 89.3                                | 90.6  | 91.6                                 |
| Education, high school<br>diploma or less, % | 33.4*   | 41.5†                               | 28.0  | 36.2                                 |
| Household annual income<br><\$40,000, %      | 51.2*   | 59.0                                | 40.0  | 55.0                                 |
| Body mass index, kg/m²,<br>mean (SD)         | 34.3 (8.6)*                                   | 33.1 (8.1)†                         | 30.1 (7.1)                                    | 31.2 (6.7)                           |
| Duration of diabetes, years,<br>mean (SD)    | 8.5 (7.7)                                     | 11.1 (9.4)                          | NA  | NA                                   |

p < 0.0001 for comparison between T2DM and No diabetes with no prior history of CVD events: tp < 0.01 for comparison between T2DM and No diabetes with prior history of CVD event; NA = not applicable; CVD events include heart attack, stroke, angioplasty with or without stents, heart bypass surgery

- Age, gender, race, education, income, and BMI differed across the four groups of respondents (p <0.0001 for each) (Table 1)
- T2DM respondents with no prior history of CVD events were significantly older, fewer were white, and they had less education, lower income, and higher BMI, compared with respondents with no diabetes and no prior history of CVD events (p < 0.0001 for each)
- T2DM respondents with a prior history of CVD events were similar in age, gender, race, and income (p >0.05), but had significantly less education and higher BMI (p <0.01), compared with respondents with no diabetes and prior history of CVD events
- Among T2DM respondents, respondents with a history of CVD events were older, fewer were women, and they had less education than respondents with no prior history of CVD events. Similarly, for respondents without diabetes, respondents with a history of CVD events were older, fewer were women, and they had less education than respondents with no prior history of CVD events

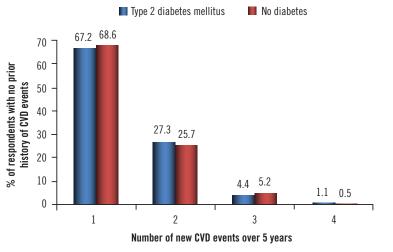
### **Incidence of CVD events**

Figure 1. Proportion of respondents with a new CVD event over 5 years stratified by history of **CVD** events



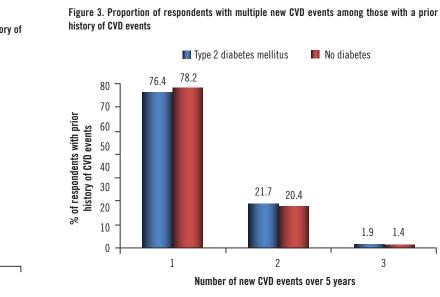
- For respondents with no prior history of CVD events, a greater proportion of T2DM respondents had at least 1 incident CVD event over 5 years, compared with respondents without diabetes (p <0.0001) (Figure 1)
- A similar proportion of respondents with a prior history of CVD events had an incident event over 5 years, 47.7% of those with T2DM and 45.6% of those without diabetes (p = 0.33)
- Regardless of diabetes status, the proportion of respondents with incident CVD events over 5 years was significantly higher (2.8–4.4 times higher) among respondents with a prior history of CVD events, compared with respondents with no prior history of CVD events (p < 0.001)

#### Figure 2. Proportion of respondents with multiple new CVD events among those with no prior history of CVD events



- A similar proportion of T2DM respondents and respondents without diabetes and no prior history of CVD events had 2, 3, and 4 new CVD events over the 5 years (Figure 2)
- Among respondents with no prior history of CVD events, 32.8% of T2DM respondents and 31.4% of respondents without diabetes had more than 1 new event over 5 years (p = 0.69)

# **RESULTS (Continued)**



■ A similar proportion of T2DM respondents and respondents without diabetes and prior

■ For respondents with prior history of CVD events, 23.6% of T2DM respondents and 21.8% of

Figure 4. Proportion of respondents with a new CVD event over 5 years, regardless of prior

Type 2 diabetes mellitus No diabetes

17.2

8951

history of CVD events had 2 and 3 new CVD events over the 5 years (Figure 3)

respondents without diabetes had more than 1 new event over 5 years (p = 0.51)

25.4 \*

3203

N =

history of CVD events

30 -

25

• Overall, significantly more T2DM respondents had an incident CVD event than respondents without diabetes (p < 0.0001) (Figure 4)

At least 1 incident CVD event over 5 years

LIMITATIONS

- Diagnoses of diabetes, heart attack, stroke, heart bypass surgery, and angioplasty were self-reported and could not be validated with medical record review or administrative claims data. However, this bias is similar between the groups compared in the study
- Mortality was not systematically captured in the SHIELD study, so fatal CVD events were not included, thereby underestimating the true incidence rate
- Household panels, like the SHIELD study, tend to under-represent the very wealthy and very poor segments of the population and do not include military or institutionalized individuals

# CONCLUSIONS

- Incidence of CVD events in respondents with T2DM is high
- For T2DM respondents without a prior history of CVD events, there was a significantly higher incidence rate of CVD events (62% relative increase), compared with respondents with no diabetes and no prior history of CVD events
- Incidence of CVD events during the 5-year period was high among respondents with a prior history of CVD events, in both those with T2DM (48%) and those without diabetes (46%)
- With current incidence estimates from 2004 through 2009, this study is consistent with previous reports indicating that CVD risk is higher in individuals with T2DM
- Effective therapies and approaches that address the concurrent comorbid conditions (i.e., A1c, BP, weight management, lipids) in patients with T2DM are necessary to prevent macrovascular complications and reduce the incremental cost burden of CVD events

#### References

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#### LIST OF ABBREVIATIONS

| ADA     | American Diabetes Association   |
|---------|---|
| BMI     | Body mass index   |
| CVD     | Cardiovascular disease  |
| SHIELD  | Study to Help Improve Early evaluation and management of risk factors |
|         | Leading to Diabetes   |
| T2DM    | Type 2 diabetes mellitus  |
| TNS NFO | Taylor Nelson Sofres National Family Opinion                          |
| US      | United States   |
|         |   |

This research was supported by funds from AstraZeneca LP

Presented at the 72nd Scientific Sessions of the American Diabetes Association Philadelphia, PA, June 8–12, 2012