Identifying High-Risk Populations in SHIELD with a 12-Item Screener Questionnaire

Susan Grandy, PhD,[1] Michael L. Reed, PhD,[2] and Richard Chapman, PhD,[3] for the SHIELD Study Group

[1]AstraZeneca, Wilmington, Delaware; [2]Vedanta Research, Chapel Hill, North Carolina; [3]ValueMedics Research, Falls Church, Virginia

Abstract

The Study to Help Improve Early management of risk factors Leading to Diabetes (SHIELD) is a large, longitudinal survey of US adults. SHIELD used a 12-item screener questionnaire to identify risk factors for diabetes diagnosis and to sample cohorts with or at risk for diabetes diagnosis for the longitudinal phase of the study (5 annual surveys). Candidate risk factors included in the screener were based on the literature, national guidelines and expert opinion. To determine occurrence of these risk factors, respondents were asked height, weight and waist circumference; if they had ever been told by a healthcare professional that they had high blood pressure, cholesterol problems or diabetes; if they had ever had certain cardiovascular (CV) events. The screener was mailed to 200,000 households representative of US adult population and completed by head of household, who answered for up to 4 adult members (≥18 years).

A total of 127,420 households (with responses for 211,097 adults) returned usable surveys (response rate=63.7%). Responses were weighted to match US census data for age, gender and household size. Self-reported prevalence of diabetes in SHIELD was 8.2% (5.8% type 2 diabetes, 0.3% type 1 diabetes, with remainder of unknown type). Multivariate logistic regression determined that the following factors from the screener were independently predictive of diabetes diagnosis in the past 36 months: abdominal obesity, high body mass index, dyslipidemia, hypertension, history of CV events ($p<0.001$ for all). Respondents were stratified by number of risk factors reported by each respondent. No risk factors were reported by 35% of respondents; 37% reported 1–2 risk factors; and 17% reported 3–5 risk factors.

The SHIELD screener was a useful tool to identify individuals with risk factors that could signal future diabetes diagnosis. Annual follow-up surveys will provide longitudinal data to determine the predictive power of these risk factors over time, and if and how these factors interact in diabetes development.

Introduction

- Diabetes is an epidemic disease in the US and worldwide, with enormous public health implications. Currently, there are approximately 20.8 million Americans with diabetes, including 6.2 million who are undiagnosed. An additional 41 million Americans aged 40–74 years have pre-diabetes (FPG >110 mg/dL but < 125 mg/dL) and carry an increased risk for CV events such as heart disease and stroke.[1] It has been projected that this disease will impact 29 million Americans by the year 2050.[2]
- Risk factors for diabetes include age >45, family history of diabetes, ethnicity (African Americans, Hispanic Americans, and Native Americans have higher rates of diabetes), high blood pressure, high cholesterol, and excess body weight/obesity. A number of studies have investigated the feasibility and effectiveness of strategies to prevent or delay the onset of diabetes, including lifestyle modifications as well as different therapeutic interventions.[3,4]
- Complementary to efforts directed toward prevention is the need to better define risk factors that may lead to diabetes mellitus. That is, there may be some risk factors that predict a future diagnosis of diabetes that would allow for earlier identification of those at risk and/or better screening to identify those who already have this condition but have not been diagnosed.
- SHIELD (the Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes) is a large, ongoing longitudinal study in the US adult population. SHIELD is the first survey of this size to examine risk factors that could be associated with a future diagnosis of diabetes.

Objectives

- To determine the feasibility of using consumer panel surveys to identify those individuals with diabetes and related risk factors
- To identify risk factors that are predictive of a future diabetes diagnosis

Methods

SHIELD

- SHIELD is a 5-year, national, longitudinal study of diabetes, CVD, and metabolic disease risks in US adults.
- As the first phase of the longitudinal SHIELD study, a screener questionnaire was developed by a panel of diabetes healthcare experts (the SHIELD Study Group) and mailed in 2004 to a stratified random sample of 200,000 US households that were part of the TNS NFO household panel.
  - TNS NFO maintains a survey panel of more than 600,000 households throughout the US, constructed to represent the US population in terms of geographic residence, age of head of household, and household size and income.
- The screener questionnaire consisted of 12 questions and was completed by the head of household, who answered for up to 4 adult household members (≥18 years of age).
- Respondents were asked if they had ever been diagnosed as having each of several conditions, including diabetes, high BP, or cholesterol problems.
- Respondents were also asked to provide their weight and height, which were used to calculate BMI, as well as waist circumference.
- SHIELD data on adults ≥18 years old were analyzed to determine self-reported prevalence of diabetes as well as risk factors that were associated with a self-reported diagnosis of diabetes.

Identifying conditions

Conditions were identified in the following manner:

- Self-report that a healthcare professional had diagnosed the condition (i.e., "conditions that you/other adult household members have ever been told you have by a doctor or nurse") was used for:
  - Diabetes (type 1 and type 2, but not gestational)
  - Hypertension ("high blood pressure")
  - Dyslipidemia ("problems with cholesterol" or specific components, e.g., "high total cholesterol")
- For CV events, respondents were asked to self-report whether they or other household members "ever had any of the following health problems or surgery for": narrowing or blocked arteries, stroke, heart attack, heart bypass surgery, angioplasty, stents, and circulation problems of any kind.
- BMI, in kg/m^2, was calculated using self-reported height and current weight.
- Waist circumference, in cm, was converted from "current waist size (in inches) measured at the navel."
- These measures were used to determine whether "high BMI" and "abdominal obesity" (defined below) were present.

Analyses

- The weighted data from the screener questionnaire responses were used to calculate the self-reported, national prevalence of diabetes.
  - The returned sample was weighted to match 2003 US census data on age, gender, and household size.[5]
- Logistic regression analyses were used to determine which BMI and waist circumference thresholds were most predictive of diabetes diagnosis in the past 36 months. These thresholds were used to create dichotomous variables for presence of "high BMI" and "abdominal obesity."
- Multivariable logistic regression analyses were then used to identify those risk factors associated with being diagnosed with type 2 diabetes, after adjusting for age, gender, race/ethnicity, geographic region and population size, and household size and income.
- All analyses were performed using SPSS version 13.0.1.

Results

- SHIELD yielded data on 211,097 adults from 127,420 households (63.7% response rate).
- A diagnosis of diabetes was reported by 17,375 respondents (8.2%), with most respondents reporting a diagnosis of type 2 diabetes (**Figure 1**)
  - 72.6% reported type 2 diabetes
    - Of these, 98% reported age of onset > 21 years and 2% ≤21 years
  - 14.5% reported type 1 diabetes
    - Of these, 29% reported age of onset ≤ 21 years and 71% >21 years
  - The remaining 12.9% includes unknown type or missing data

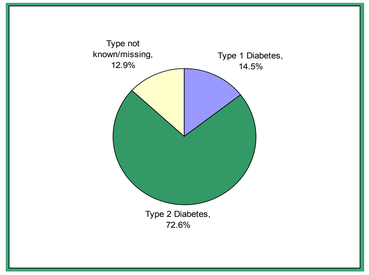
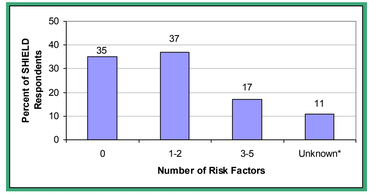


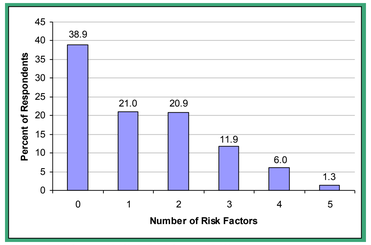
Figure 1. Percent of respondents by reported type of diabetes

- Logistic regression analyses determined which BMI and waist circumference thresholds were most predictive of diabetes diagnosis in the past 36 months:
  - High BMI = BMI ≥28 kg/m^2
  - Abdominal obesity = waist circumference ≥97 cm in men and ≥89 cm in women
- Multivariable logistic regression modeling determined that the following risk factors from the screener were independently associated with diabetes diagnosis in the past 36 months: abdominal obesity, high BMI, dyslipidemia, hypertension, and history of CV events ($p<0.001$ for all).
- After identifying these risk factors, respondents were stratified by the number of risk factors reported and placed into cohorts for low risk (0 or 1-2 risk factors) or high risk (3-5 risk factors) (**Figure 2**).
- **Figure 3** shows the percent of respondents reporting each number of risk factors individually, after removal of cases with missing data.



*Could not be classified due to missing data.

Figure 2. SHIELD respondents stratified into low-risk (0 or 1-2 risk factors) or high-risk (3-5 risk factors) cohorts



Note: 1–2 risk factors, 41.9%; 3–5 risk factors, 19.2%

Figure 3. Percentage of SHIELD respondents reporting each number of risk factors individually

Limitations

- The households participating in the TNS NFO panel had voluntarily elected to do so, leading to the possibility of bias due to self-selection.
- Household panels also tend to under-represent the very wealthy and very poor segments of the population and do not include military or institutionalized individuals.

Conclusions

- The SHIELD screener questionnaire was a useful tool to identify individuals with risk factors that could signal future diabetes diagnosis.
- Consumer panel surveys may represent an economical and timely alternative to other methods for identifying populations with conditions or diseases.

References

1. Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2003. Rev ed. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, 2004.
2. Boyle JP, et al. Projection of diabetes burden through 2050. Impact of changing demography and disease prevalence in the U.S. *Diabetes Care* 2001;24:1936-1940.
3. Tuomilehto J, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001; 344(18):1343-1350.
4. (Diabetes Prevention Research Group). Knowler WC, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346(6):393-403.
5. US Census Bureau. 2003 Annual Supplement to the Current Population Survey: Census Bureau Resident Population Estimates of the United States. Washington, DC: US Census Bureau; 2003.

Abbreviations

BMI = body mass index; BP = blood pressure; CHD = coronary heart disease; CV = cardiovascular; CVD = cardiovascular disease; FPG = fasting plasma glucose; SHIELD = Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes; SPSS = Statistical Product and Service Solutions; TNS NFO = Taylor Nelson Sofres National Family Opinion

This research was supported by AstraZeneca

Presented at the American Diabetes Association 66th Annual Scientific Sessions • Washington, DC • June 9-13, 2006