

High Prevalence of Self-Reported Hypoglycemia Rates for Diabetes Medications Among Adults With Type 2 Diabetes Mellitus

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BACKGROUND

- Hypoglycemia often causes recurrent physical morbidity, recurrent or persistent psychosocial morbidity, or both and in extreme cases may be fatal¹
- Hypoglycemia is a leading limiting factor in the glycemic management of adults with T2DM who are treated with insulin² or a sulfonylurea (SU) agent³
- Patients taking SU agents and insulin treatment are at risk of developing hypoglycemia,³ with previous investigations estimating the prevalence at 11%–17% for SU and 36%–64% for insulin^{4,6}
- Hypoglycemia is a barrier to achievement of glycemic control, and as a result, risk of microvascular complications may increase in spite of attempts to optimize metabolic control
- This investigation was designed to assess current rates of hypoglycemia among adults with T2DM by diabetes treatment regimen

OBJECTIVE

- To ascertain the rate of self-reported hypoglycemia among adults with T2DM for each class of antidiabetic medication

METHODS

Study Design

- Cross-sectional analysis among SHIELD T2DM respondents with hypoglycemia in the previous 12 months
- 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, and 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. Since 2005, annual SHIELD surveys have captured self-reported information on health status, attitudes and behaviors, quality of life, and medications from this representative sample of the US population
 - The 2008 survey collected information from 14,921 individuals (71% response rate), and data from respondents with T2DM (n = 3,000) were used in the analysis

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,” as reported in the 2008 survey

METHODS (Continued)

Study Measures

- Hypoglycemia was defined as self-reported low blood sugar in the past 4 weeks and in the past 12 months
 - The number of episodes of hypoglycemia were reported for the past 4 weeks
- Anti-diabetic medications were classified into 3 major groups
 - Those receiving oral anti-diabetic medications (OADs) either as monotherapy or combination oral therapy
 - Those receiving OADs were stratified by whether they received an SU or not
 - Those receiving insulin alone
 - Those receiving insulin + OADs
- Respondents were considered overweight if their BMI was 25.0–29.9 kg/m² and obese if their BMI was ≥30 kg/m²
- Comorbid conditions were self-reported based on survey questions as to having been told by a healthcare professional that they had the condition

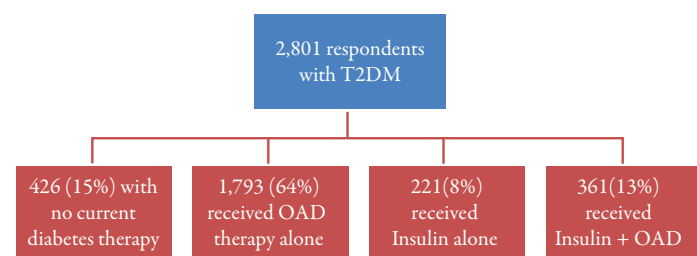
Statistical Analyses

- The proportion of T2DM respondents reporting at least 1 episode of hypoglycemia was tabulated
- Comparisons between respondents with and without use of SU were conducted using chi-square test for categorical variables and *t*-tests for continuous variables
- Statistical significance was set *a priori* as *p* < 0.05

RESULTS

Medication Groups

Figure 1. T2DM respondents by medication regimen



- There were 2,801 respondents with T2DM and medication history in the 2008 SHIELD survey (Figure 1)
- 15% of respondents with T2DM reported not receiving any current diabetes therapy at the time of the survey
- 64% of T2DM respondents received OAD therapy alone and 13% received insulin + OAD therapy
- 8% of T2DM respondents reported receiving insulin alone
- Among T2DM respondents receiving OAD therapy with or without insulin, 48% reported receiving an SU, and 52% did not receive an SU

RESULTS (Continued)

Table 1. Characteristics of T2DM respondents by medication group

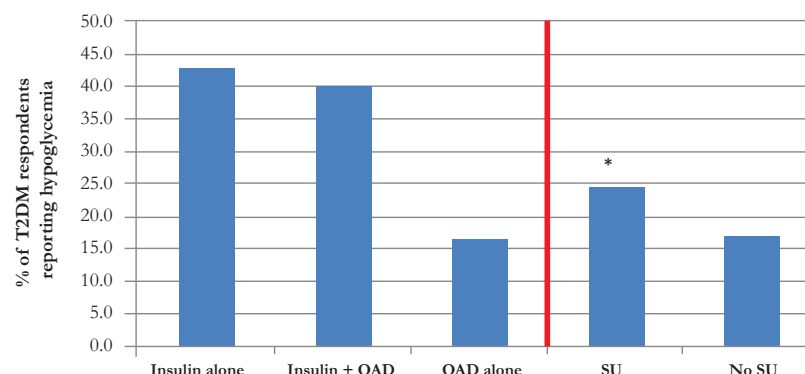
Characteristics	Insulin alone N = 221	Insulin + OAD N = 361	OAD alone N = 1,793
Age, years, mean (SD)	65.3 (12.0)*	60.9 (11.0)	63.5 (11.7)
Women, %	63.8	58.4	59.5
White, %	72.4	71.7	74.5
Education, % with high school degree or less	39.2	31.7	33.3
Income, % <\$30,000/year	48.0*	37.1	34.0
Overweight, % with BMI 25.0–29.9 kg/m ²	23.6*	16.0	28.0
Obese, % with BMI ≥30 kg/m ²	63.9*	78.4	62.3

**p* < 0.01

- Significantly greater proportion of T2DM respondents who received insulin alone had low household income compared with the other 2 groups (*p* = 0.001) (Table 1)
- Significantly more T2DM respondents who received insulin + OADs were younger and obese than T2DM respondents who received insulin alone or OADs alone (*p* < 0.0001)

Prevalence of Hypoglycemia

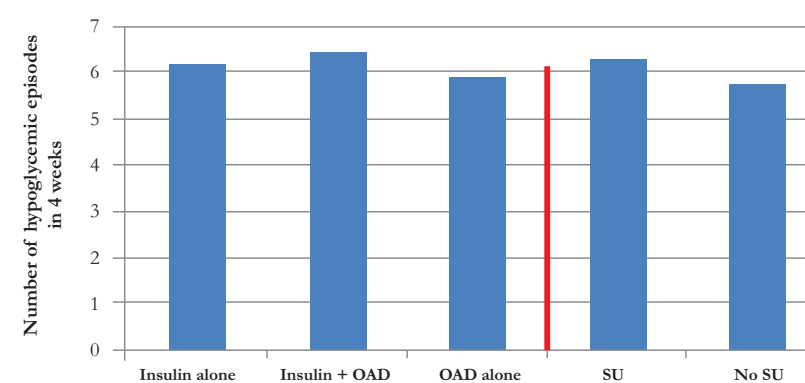
Figure 2. Prevalence of self-reported hypoglycemia in past 4 weeks



**p* < 0.001

- Among T2DM respondents who reported receiving insulin alone, 43% reported having hypoglycemia in the past 4 weeks (Figure 2)
- Among those who received insulin + OAD therapy, 40% reported having hypoglycemia, whereas only 17% of those who received OAD therapy alone reported hypoglycemia in the past 4 weeks
- A greater proportion of T2DM respondents who received SU reported hypoglycemia in the past 4 weeks than those who did not receive an SU, 24% vs. 17% (*p* < 0.001)

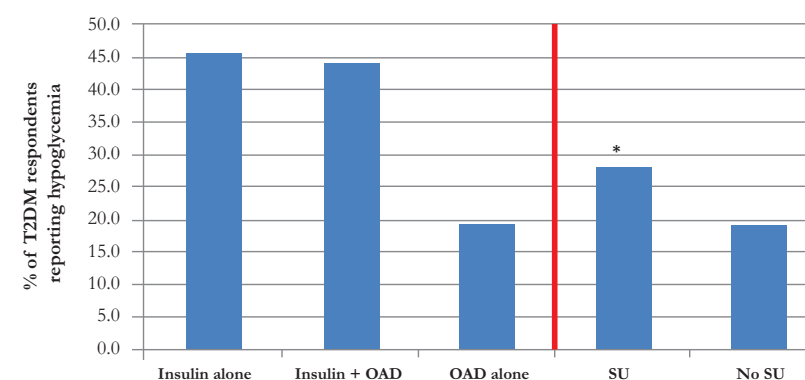
Figure 3. Mean number of self-reported hypoglycemic episodes in the past 4 weeks



- T2DM respondents reported a mean of 6 episodes of hypoglycemia in the past 4 weeks, and this did not differ across therapy groups (Figure 3)

- There was no difference (*p* > 0.05) in mean number of hypoglycemic episodes between T2DM respondents who did and did not receive SU

Figure 4. Prevalence of self-reported hypoglycemia in the past 12 months



**p* < 0.001

- Rates of hypoglycemia in the past 12 months ranged from 45% among T2DM respondents receiving insulin alone to 19% of T2DM respondents receiving OADs alone (Figure 4)
- A greater proportion of T2DM respondents who received SU reported hypoglycemia in the past 12 months than those who did not receive SU, 28% vs. 19% (*p* < 0.001)
- Rates of hypoglycemia in the past 12 months for each therapy group were similar to those reported for the past 4 weeks

LIMITATIONS

- Diagnosis of diabetes and other comorbid conditions, and episodes of hypoglycemia were self-reported and could not be validated with medical record review or administrative claims data. However, this bias is anticipated to be balanced between the groups compared in this study
- Information on the severity of hypoglycemia, blood glucose levels around the time of the hypoglycemia, and causes of hypoglycemia were not collected in the SHIELD survey, thereby limiting the understanding of the impact of hypoglycemia
- Household panels, like the TNS/NFO panel, tend to under-represent the very wealthy and very poor segments of the population and do not include military or institutionalized individuals

SUMMARY

- 40%–43% of T2DM respondents treated with insulin ± OADs and 17% of T2DM respondents treated with OADs alone reported experiencing hypoglycemia in the past 4 weeks
- SU users reported more hypoglycemia in the past 4 weeks and over the past 12 months than non-SU users
- Hypoglycemic episodes were frequent – more than once a week – among all treatment groups

CONCLUSIONS

- There was a high prevalence of self-reported hypoglycemia in respondents receiving medication to manage their T2DM
- Risk of hypoglycemia was substantially increased in patients with T2DM who received either SU or insulin, compared with OAD regimens without an SU alone
- Consideration should be given to using classes of medication with lower rates of hypoglycemia when treating T2DM adults to reduce the potentially serious adverse outcomes associated with hypoglycemia

References

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Abbreviations

BMI	Body mass index
SHIELD	Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes
SU	Sulfonylurea
T2DM	Type 2 diabetes mellitus
TNS/NFO	Taylor Nelson Sofres/ National Family Opinion

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