Impact of Type 2 Diabetes Mellitus on Prescription Medication Burden and Out-of-Pocket Expenses

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BACKGROUND

- Type 2 diabetes mellitus (T2DM) usually requires drug therapies to lower glucose levels and reduce the risk of complications

- Individuals with T2DM are prescribed numerous medications to treat not only their diabetes, but also comorbid conditions such as hypertension and dyslipidemia

- Compliance with prescribed medical therapy has been shown to be inversely related to the number of pills recommended daily[1]

- The annual US expenditure on care for diabetes and its complications is estimated to be $174 billion,[2] but little is known about the personal out-of-pocket healthcare expenses of individuals with T2DM

- It is important to understand whether having T2DM increases the burden of prescription medications and out-of-pocket expenses

OBJECTIVE

- Assess the increased burden of the number of prescriptions and out-of-pocket medical expenses of survey respondents with and without T2DM

METHODS

Study Design

- Data were derived from the Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes (SHIELD), a 5-year population-based survey conducted to better understand the risk for the development of diabetes, as well as disease burden

  - Based upon a screening questionnaire mailed to 200,000 nationally representative households, responses were obtained for 211,097 adults from 127,420 households (64% response rate)

  - A baseline survey was sent to a stratified random and representative sample of 22,001 individuals from the screening respondents (23% had T2DM) to understand heath status, health knowledge and attitudes, and current behaviors and treatments (72% response rate, n = 15,794)

  - Annual follow-up surveys were sent to individuals responding to the baseline survey. The 2006 survey was sent to 18,445 individuals, with a response rate of 75% (n=13,887). Individuals with T2DM represented 27% of the 2006 respondents

- This investigation is a cross-sectional analysis of the 2006 survey to determine the number of prescription medications and out-of-pocket expenses for respondents with and without T2DM

METHODS (Continued)

Study Population

- Respondents were categorized as having T2DM based upon self-report of having been told by a doctor, nurse or other healthcare professional that they had T2DM, and reported an age of onset > 21 years

- Respondents categorized as not having T2DM were those who reported no diagnosis of either T2DM, T1DM, gestational or unspecified diabetes

Study Measures

- Therapy Assessment:

  - Respondents reported the name of each medication currently prescribed to them. They were instructed to refer to their medication labels for accurate reporting

- Out-of-Pocket Expenditure:

  - Respondents provided their out-of-pocket cost based on the following questions:
    * In the past 12 months, what is the total amount you paid for your healthcare costs that is not covered by any health insurance (out-of-pocket cost)?
    * What is the total amount you pay each month that is not covered by any health insurance (out-of-pocket cost) for all your prescription medications?

- Health Insurance:

  - Respondents replied to the following questions:
    * Do you have health insurance?
    * Is any of the cost of prescription medications covered by your insurance?
    * Is any of the cost of medical supplies (such as monitoring tests [e.g., blood sugar or blood pressure monitors], syringes, oxygen or other medical supplies) covered by your insurance?

Statistical Analyses

- Fixed dose combination agents were counted as one medication in the prescription counts

- Comparisons between respondents with and without T2DM were made using ANOVA

- Multivariate linear regression models adjusted for age, gender, prescription insurance coverage, and household income

RESULTS

Table 1. Characteristics of SHIELD respondents with and without T2DM

Characteristics	T2DM n = 3,551	No T2DM n = 8,686
Age, years, mean (SD)	61.5 (12.4)*	55.6 (16.2)
Women, %	60*	62
Race, % white	85*	88
Income, % <$35,000/year	46*	36
Have health insurance, %	91	90
Insurance that covers prescription medications, %	94*	92
Insurance that covers medical supplies, %	86*	52

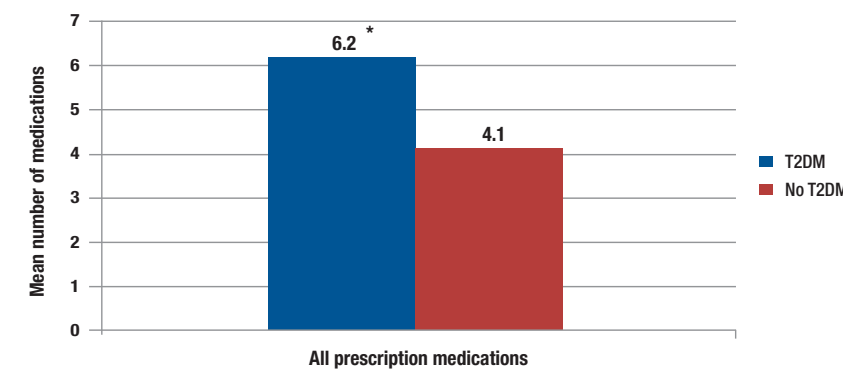*p < 0.05 for comparison of T2DM vs. No T2DM

- A significantly larger proportion of T2DM respondents were older, had low income, and had health insurance that covered prescription medications and medical supplies compared with No T2DM respondents

Figure 1. Distribution of anti-diabetes medications among T2DM respondents
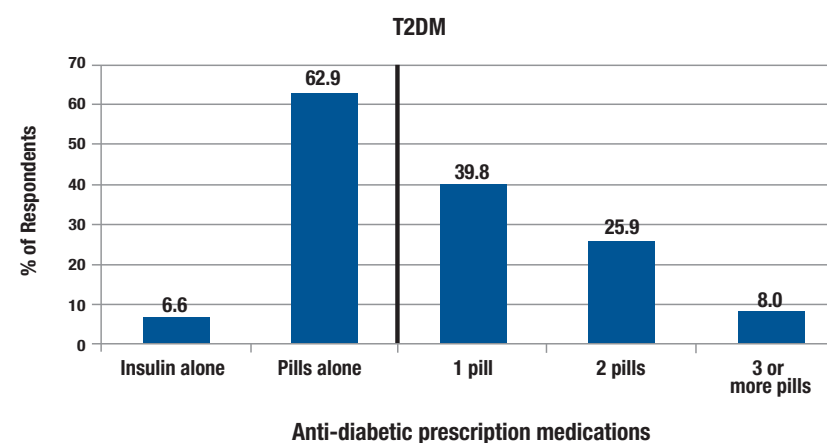
- Of the T2DM respondents, 62.9% were taking anti-diabetes pills as the sole prescription therapy for their T2DM, and 6.6% were taking insulin alone

- Among the T2DM respondents taking anti-diabetes pills, 40% were on one prescription anti-diabetes pill, 26% were on two anti-diabetes pills, and 8% were on three or more anti-diabetes pills

- Mean number of anti-diabetes pills was 1.3 among T2DM respondents

**Figure 2. Mean number of prescription medications§ for individuals with and without T2DM†**

§Adjusted for age, gender, insurance coverage, and income
†Combination anti-diabetes pills (and/or other combination drugs) were counted as one pill/prescription
*p < 0.001 for comparison of T2DM vs. No T2DM

- T2DM respondents had a significantly higher total number of prescription medications compared with respondents without T2DM, after adjusting for age, gender, insurance coverage, and income (p < 0.001)

- More than 40% of T2DM respondents were taking ≥7 prescription medications

Figure 3. Mean out-of-pocket expenditure§ for individuals with and without T2DM
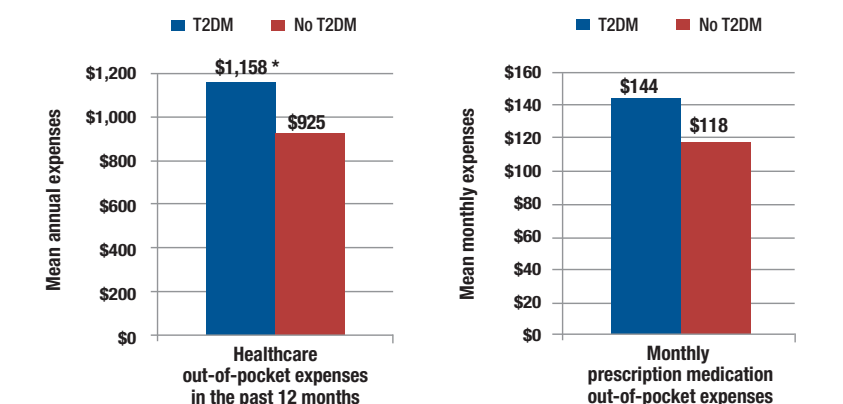
§Adjusted for age, gender, insurance coverage, and income; healthcare expenses may have included expenses for prescription medications
*p < 0.001 for comparison of T2DM vs. No T2DM

- T2DM respondents had significantly higher out-of-pocket expenditure for both annual healthcare and monthly prescription expenses compared with respondents without T2DM, after adjusting for age, gender, insurance coverage and income

LIMITATIONS

- The determination of T2DM was made based upon self-report rather than clinical or laboratory measures

- 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

- Self-selection bias may be present since respondents were those who could read and comprehend the survey

SUMMARY

- T2DM respondents were significantly more likely to be taking more prescription medications than respondents without T2DM, even after adjusting for age, gender, insurance coverage and household income differences

- T2DM respondents had significantly higher out-of-pocket healthcare costs than respondents without T2DM

- T2DM respondents had significantly higher out-of-pocket expenses for prescription medications than respondents without T2DM

- 90% of respondents reported having insurance coverage for prescriptions and supplies; therefore, the out-of-pocket costs in this survey represent the personal cost burden to respondents

CONCLUSIONS

- Individuals with T2DM face an increased burden of more prescription medications and higher out-of-pocket expenses than individuals without T2DM, even with a high percentage of insurance coverage for healthcare, prescriptions and supplies

- Increased out-of-pocket medical and medication costs in T2DM were due to the use of both anti-diabetes agents and other medications for treatment of comorbid conditions

References

1. Barnett AH. *Eur J Endocrinol* 2004; 151(Suppl 2):T3-7
2. American Diabetes Association. *Diabetes Care* 2008; 31:596-615

List of Abbreviations

ANOVA	Analysis of variance
SHIELD	Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes
T2DM	Type 2 diabetes mellitus
T1DM	Type 1 diabetes mellitus