BRIEF REPORT: The Burden of Diabetes Therapy

Implications for the Design of Effective Patient-centered Treatment Regimens

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BACKGROUND: Management of diabetes, and in particular blood glucose, can be complex and burdensome.

OBJECTIVE: To evaluate patient views of the burdens of therapy and its impact on self-management.

PATIENTS: Veteran patients with type 2 diabetes.

DESIGN: Mailed survey.

MEASUREMENTS: Patients described their views of the burden of diabetes treatments, adherence, and clinical and demographic status. Factors associated with ratings of burden and adherence to therapy were examined using multivariate regression methods.

RESULTS: The response rate was 67% (n = 1,653). Patients viewed pills as the least burdensome treatment and insulin as the most burdensome. Ratings of the burden of insulin were lower if a patient had prior experience with therapy. Adherence to prescribed therapy varied substantially; for example, patients followed medication recommendations more closely than other areas of self-management. Multivariate analyses showed that the main predictor of adherence was patients’ ratings of the burden of therapy.

CONCLUSIONS: Injected insulin regimens are viewed as highly burdensome by patients, although this burden is attenuated by experience. Adherence to self-management is strongly and independently correlated with views of treatment burden. The burden of diabetes-related treatments may be a source of suboptimal glucose control seen in many care settings. Providers should consider the burden of treatment for a particular patient and its impact on adherence as part of a decision-making process to design effective treatment regimens.

KEY WORDS: diabetes; self-management; patient preferences.

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Type 2 diabetes is a common illness with substantial associated morbidity, mortality, and health expenditures. Although optimal medical care can prevent many diabetes complications, there is evidence that many patients with diabetes do not achieve treatment goals commonly cited to be standards of care,1 despite diabetes care being a major target for various quality improvement and disease management interventions.2–5

The premise of many disease management programs is that interventions aimed at the provider or the health care system will improve adherence to standards.2–5 There is little doubt that patient self-management is a critical factor in achieving optimal care.5,6 As a result, disease management programs often involve cooperative goal setting and encourage patients to be active partners in their care. However, there is at present surprisingly limited information on patients’ views of the burden of self-management and how these views may affect treatment adherence. Understanding these preferences is critical to developing clinical guidelines and quality standards that are in line with patients’ wishes. Furthermore, systematic investigation of treatment burden and the impact that it has on adherence is critical for designing effective disease management programs. Thus, we examined patients’ views of the burdens of common diabetes therapies, the predictors of ratings of burdens, and the relationship between patients’ perception of the burden of treatment and their adherence to their treatment regimen.

METHODS

We designed a self-administered, mailed survey to address patient views of the burdens of various glucose-lowering therapies in type 2 diabetes. The survey was designed to obtain patients’ ratings of the burdens of various hypoglycemic treatments, including dietary modification, oral hypoglycemic agents, and insulin, along with combinations of these in various frequencies. Ratings of the burdens of self-monitoring of blood glucose, again in various frequencies, were also collected. These views were collected on a 7-point scale, based on the question, “Please circle a number from 0 to 6 to show how much you would dislike doing each of the following for the next year,” ranging from do not dislike at all to dislike very much. The measures of burden were pilot tested in a sample of patients from an academic medical center, and refined using focus groups.7

Demographic information, health status, experience with treatments, physician recommendations for treatments, and self-reported adherence with treatment (using a 7-point ordinal scale with 1 = always followed, 4 = followed about half the time, and 7 = never followed) were also collected.8–11 Information on demographics, diabetes treatments, and health status were collected using previously validated measures from the Diabetes Patient Outcomes Research Team surveys.12

Patient recruitment occurred from the primary care population of two Veterans Affairs hospitals. Institutional Review Board approval was obtained at both sites; all data were collected anonymously. Patients at these facilities were identified as having diabetes using a previously validated algorithm that used a combination of diagnosis and pharmacy database information.3,12 Patients under the age of 30 were assumed to have type 1 diabetes and were excluded from the study.

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We randomly sampled subjects to survey. We used the modified Dillman technique repeatedly mailing surveys and postcard reminders to optimize response rate. There were 147 returned surveys that were ineligible because the patient had died or did not have diabetes, or the address was incorrect.

We first explored factors associated with patient ratings of burden of therapy. In initial bivariate analyses, continuous variables were compared using t tests; categorical variables were compared using contingency tables and \( \chi^2 \) tests of independence. Although ratings of burden were skewed, our sample size was large enough that nonparametric methods were not necessary. We explored several a priori hypotheses, namely that patient views of burden would be related to demographic factors (particularly age) or clinical factors such as experience with treatment, diabetes education, comorbidities, and provider specialty.

We then performed multivariate analyses using linear regression with burden as the dependent variable. Independent variables included demographic characteristics and factors that were found in bivariate analyses to be associated with ratings of burden. Because of heteroskedasticity of residuals which was not amenable to transformation of the data, we used robust Huber-White estimators of standard error.

We then examined predictors of 2 measures of adherence: self-reported adherence to therapy, and acceptance of insulin therapy when prescribed. We again examined bivariate associations between the 2 measures of adherence and possible predictors such as ratings of burden and demographic and clinical factors using contingency tables for categorical measures or one-way ANOVA for continuous measures. We then conducted multivariate analyses using measures that were found to be associated with adherence in bivariate analyses with a \( P \) value of less than .10. Because self-rated adherence was collected on an ordinal (e.g., each possible response was discretely labeled, in order) rather than continuous scale, we used ordinal logistic regression to conduct multivariate analyses with adherence as the dependent variable. For acceptance of insulin therapy when prescribed, we used logistic regression. Our primary independent variable was the rating of burden, while covariates included demographic factors and other clinical factors found to be associated with adherence in bivariate analyses.

RESULTS

After excluding those not eligible to participate, the response rate to the survey was 67% (1,653 responses). Patients had a mean age of 64 years (SD 11); they had completed 12 years of education (interquartile range 11–14); and had median yearly income of U.S. $10,000–$15,000. They were predominantly male (98%) and white (64%); 63% attended diabetes education, and 76% received primary diabetes care from a generalist. Treatment for diabetes was diet for 77% of participants, oral agents for 68%, and insulin for 44%; 88% reported self-monitoring their blood glucose.

The mean and median ratings of the burden of various types of glucose-lowering therapies (on a 0–6 scale) are listed in Table 1. All regimens were more burdensome than taking oral agents twice daily \( (P < .001) \); the largest increase in perceived burden occurred between the use of oral agents and any insulin regimen. The burden of various insulin regimens increased in a fairly linear pattern based on increasing frequency of administration.

Prior experience with the treatment had a large effect on ratings of burden in insulin therapy and in self-monitoring of blood glucose (Table 1). However, experience had less of an effect on ratings of the more intensive and frequent insulin and self-monitoring regimens. In multivariate analyses controlling for demographics, diabetes education, and type of primary diabetes provider (specialist vs generalist), prior experience with insulin remained a significant predictor of ratings of burden, with differences ranging from 1.2 to 2.8 points lower on the 0–6 scale \( (P < .001 \) for all differences). Views of burden were minimally or not at all related to other factors, such as having attended diabetes education classes or demographics.

We also evaluated self-reported adherence to self-management in the subsets of patients who stated that they had been prescribed each type of therapy. Levels of adherence were generally high for medication management, but much lower for other aspects of self-management such as diet and self-monitoring of blood glucose. For example, only 5.4% of subjects reported being always adherent to diet and 39.9% to self-monitoring of blood glucose, but 79.1% reported always following prescriptions for oral agents and 78.8% for insulin. However, 12.6% of subjects who had been recommended insulin had refused it altogether.

### Table 1. Ratings of Treatment Burden

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Rating(^a) Mean (SD)</th>
<th>Rating with Experience</th>
<th>Rating Without Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral agents twice a day</td>
<td>1.4 (1.9)</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Periodic self-monitoring of blood glucose</td>
<td>1.9 (2.0)</td>
<td>1.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Moderate diet</td>
<td>2.2 (2.0)</td>
<td>2.0</td>
<td>2.6(^1)</td>
</tr>
<tr>
<td>Self-monitoring of blood glucose once a day</td>
<td>2.3 (2.1)</td>
<td>2.0</td>
<td>3.5(^1)</td>
</tr>
<tr>
<td>Insulin once a day</td>
<td>3.5 (2.5)</td>
<td>1.8</td>
<td>4.7(^1)</td>
</tr>
<tr>
<td>Combination bedtime insulin and daytime oral agents</td>
<td>3.9 (2.4)</td>
<td>3.1</td>
<td>4.3(^1)</td>
</tr>
<tr>
<td>Self-monitoring of blood glucose 3 times a day</td>
<td>3.9 (2.3)</td>
<td>3.7</td>
<td>4.7</td>
</tr>
<tr>
<td>Insulin twice a day</td>
<td>3.9 (2.4)</td>
<td>2.4</td>
<td>4.9(^1)</td>
</tr>
<tr>
<td>Insulin twice a day + self-monitoring of blood glucose 3 times a day</td>
<td>4.4 (2.2)</td>
<td>3.5</td>
<td>5.1(^1)</td>
</tr>
<tr>
<td>Insulin 3–4 times a day</td>
<td>4.8 (2.1)</td>
<td>4.1</td>
<td>5.2(^1)</td>
</tr>
</tbody>
</table>

\(^a\)Ratings are on a 0–6 scale; higher ratings reflect greater burden \((0=\text{lowest burden}, 6=\text{greatest burden})\). Perceived burden for each treatment choice was significantly \( P < .001 \) different from the burden of oral agents twice a day.

\(^1\)Compared to patients with experience with the treatment, patients without experience with the treatment perceived it as significantly more burdensome \( P < .001 \).