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.

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T ype 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

See editorial by Vinicor, p. 483.

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. systematic investigation of treatment Furthermore, 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 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 χ^2 tests of independence. Although ratings of burden were skewed, our sample size was large enough that nonparametric methods were not necessary.¹⁴ 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.^{15,16}

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.¹⁷ 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 selfmonitoring 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.

Treatment	Rating [*] Mean (SD)	Rating with Experience	Rating Without Experience
Oral agents twice a day	1.4 (1.9)	1.4	1.8
Periodic self-monitoring of blood glucose	1.9 (2.0)	1.6	3.0^{\dagger}
Moderate diet	2.2 (2.0)	2.0	2.6^{\dagger}
Self-monitoring of blood glucose once a day	2.3 (2.1)	2.0	3.5^{\dagger}
Insulin once a day	3.5 (2.5)	1.8	4.7^{\dagger}
Combination bedtime insulin and daytime oral agents	3.8 (2.4)	3.1	4.3^{\dagger}
Self-monitoring of blood glucose 3 times a day	3.9 (2.3)	3.7	4.7^{\dagger}
Insulin twice a day	3.9 (2.4)	2.4	4.9^{\dagger}
Insulin twice a day + self-monitoring of blood glucose 3 times a day	4.4 (2.2)	3.5	5.1^{\dagger}
Insulin 3–4 times a day	4.8 (2.1)	4.1	5.2^{\dagger}

Table 1. Ratings of Treatment Burden

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

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

Table 2.	Adjusted	Probability	of A	dherence	to	Self-management*
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Treatment Regimen	Proportion Always Adherent, %					
	Burden =0	Burden =3	Burden =6	P Value [†]		
Diet	8.2	3.5	1.5	<.001		
Self-monitoring of bl	ood glucose					
Three times/day	53.2	38.2	22.5	.020		
Once/day	58.5	34.6	19.0	<.001		
Periodic	37.6	19.7	8.7	.001		
Oral agents	82.4	74.4	67.1	.006		
Insulin	85.3	79.0	76.1	.023		

*Probabilities are based on multivariate analyses that adjusted for demographics, diabetes education, and primary diabetes provider (specialist vs generalist).

[†]P value based on the regression coefficient of rating of burden.

In multivariate analyses of predictors of adherence to selfmanagement, subjects' views of treatment burden were the primary predictor of treatment adherence (Table 2). Multivariate analyses also showed that receiving care from a specialist (almost all endocrinologists), as opposed to a generalist, was an independent predictor of higher adherence to diet and self-monitoring of blood glucose, but not for medication treatments. No other factors, including demographics, were significant independent predictors of adherence for any of the 4 self-management modalities. Similarly, patient rating of burden was the only significant predictor of acceptance of insulin therapy in multivariate analyses (OR of acceptance =0.58 per 1 unit increase in rating of burden; 95% CI, 0.48 to 0.69).

DISCUSSION

We examined patients' views of the burden of diabetes therapy, and found that patients view several aspects of diabetes therapy as very burdensome, especially insulin injections and self-monitoring of blood glucose. Those who were not on insulin viewed insulin therapy as very burdensome; in contrast, for those on insulin, the rating of insulin burden was lower, but increased dramatically based upon the frequency of injections. The finding that experience mitigates views of burden suggests that people are adaptable to new treatments, but only to a point-the more burdensome treatments, such as multiple daily injections with self-monitoring of blood glucose, are considered quite burdensome even when patients have direct experience with insulin. Nonetheless, this has important implications for treatment and counseling in diabetes. For example, providers can minimize patients' fears of insulin by sharing this information with patients, or even by giving patients an early experience with insulin in the setting of a less threatening "temporary trial."

A critical finding of our study is that patient views of burden were the strongest (and indeed, only) consistent independent predictor of both self-rated level of adherence to therapy and willingness to accept insulin therapy. We found, as have others, that overall self-rated adherence to nonpharmaceutical management, such as diet and self-monitoring of blood glucose, was particularly low.^{18,19} Most studies trying to identify causes of low adherence in diabetes have focused on predictors such as elements of the health belief model, psychological factors, and social-environmental barriers.^{19–23} Few have focused, as our study did, on patients' perceptions of the burdens of treatment. This study has several weaknesses. Although our sample size is relatively large, the sample is drawn from a VA population, which is not representative of the general population; in particular, we had few Hispanics or Native Americans, who have increased risks of diabetes, and there were few women in the sample. This population also has good access to care in a VA system that is increasingly focused on chronic disease management, which may not reflect the diabetes population in the United States, particularly the uninsured. In addition, we relied on self-report of adherence, which likely overestimates of the effect of burden on adherence are conservative. Further, self-reported adherence does correlate with actual adherence and metabolic control.^{8–11,24}

It is clear from our findings that patient views of burden are related to both willingness to accept and self-rated adherence to treatment. We must recognize that in some instances, informed patients may find treatments burdensome enough that they elect to choose treatment regimens that would lead to glycemic control that does not meet widely cited standards of care.²⁵ Our study suggests that these types of choices occur quite often; about 13% of our study sample had refused insulin when recommended, primarily because of their views of the burden of the regimen. As many have argued, the best way to optimize patient adherence may be by encouraging patient participation in decision-making processes, where patient views of the burdens and the relative importance of treatment are directly considered.^{26,27} Given that the ultimate goal of interventions is to maximize quality of life, treatment burden should be explicitly considered and weighed against potential benefits on an individual basis. The benefits of treatment are likely to be minimized if patients are nonadherent to a burdensome therapeutic regimen or if patients' quality of life is significantly limited by the treatment. An appropriate juxtaposition between treatment guidelines, standards, and patient preferences requires that treatment burden be explicitly considered when making clinical and policy decisions about the management of chronic diseases.

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