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Diabetes Oral Medication Initiation and Intensification:

Patient Views Compared to Current Treatment Guidelines

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Abstract

Purpose—The purpose of this study was to compare patient perceptions about medication management to principles underlying American Diabetes Association (ADA) published treatment algorithms.

Methods—Six focus groups (4 English and 2 Spanish) were conducted with 50 patients with type 2 diabetes. Patients were asked about their prior experiences with initiating and changing oral medicines. They were also shown a medication plan for a hypothetical patient depicting future potential changes to achieve glycemic control. Coded responses were mapped to 3 concepts implicit in the ADA recommended treatment algorithm: (1) prescribing medicines to achieve A1c goal is beneficial, (2) medical regimens are generally intensified, and (3) intensification should be timely.

Results—Patient perceptions contrasted markedly with the treatment algorithm: (1) most patients had negative perceptions of medication initiation, viewing this event as evidence of personal failure and an increased burden; (2) patients equated medication intensification with increased risk for diabetes-related complications (rather than a step to reduce future risk) and viewed de-escalation as a primary goal; and (3) no patients expressed concerns about delays in medication intensification. Patients responded very favorably to an individualized medication plan depicting future potential changes.

Conclusions—Patients in this study described a conceptual model for medication therapy that contrasted in critical ways from the principles of current treatment guidelines. Underscoring the key role of patient-provider communication, the results suggest that effective counseling should also include an informed discussion of future medication intensification.

The incidence of type 2 diabetes (T2D) is increasing in the United States, particularly among Latinos.[1–3] Glycemia and related risk factors such as hypertension remain suboptimally controlled despite clear clinical trial evidence that effective treatment reduces both microvascular- and macrovascular-associated complications.[4,5] Despite an increasing number of approved medications, evidence from clinical practice reveals that there are frequent delays in medication initiation and regimen intensification over time.[6,7] This delay in optimizing treatment has been attributed to barriers at the level of the care system (eg,

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cost), physician (eg, competing demands during brief clinic visits), and patient (eg, lack of medication adherence).[8–10]

In an effort to encourage more effective diabetes care, the American Diabetes Association (ADA) published a consensus treatment algorithm to help guide health care providers in the process of medication initiation and intensification.[11,12] The primary goals of this treatment algorithm are to achieve and maintain A1c levels of <7% and to titrate medications rapidly when target glycemic goals are not being achieved. Implicit in the algorithm are 3 core principles: (1) prescribing medications to achieve glycemic control is beneficial, (2) medical regimens generally will require intensification, and (3) medication intensification should occur at timely intervals.

Discordance between patient and provider models of medication management may represent an important barrier to effective care that could be remedied by more effective patient-provider communication. Groups of patients (both English and Spanish speaking) were interviewed to gain further insight into their experiences with initiating and titrating oral medications for glycemic control. The purpose of our study was to compare patient perceptions of medication management to principles underlying published ADA treatment algorithms.

Methods

Participants and Recruitment

Six 90-minute patient focus groups were conducted from March to May 2008. English- and Spanish-speaking patients with T2D were recruited from the primary care practices of the Massachusetts General Hospital Practice–based Research Network, Boston, Massachusetts.[13] All patients were currently taking oral medicines for glycemic control and had experienced medication intensification during the course of their illness. Twenty-two patients were also currently prescribed insulin (these patients were specifically requested to consider their oral medications rather than insulin when discussing their experiences with medical regimen changes). Medical chart review and phone screening were used to exclude patients with significant mental health problems or other barriers to effective communication. Patients received a letter cosigned by their primary care physician and the study principal investigator (RWG) inviting them to participate in the study. Patients who did not call to opt out were subsequently contacted by phone.

On the basis of research linking medication adherence to glycemic control,[14,15] it was inferred that views about glycemic medications might differ between patients with higher or lower A1C control; similarly, it was considered that poorer glycemic control seen in US Latinos may in part reflect different views about medications compared to non-Latinos.[16] Accordingly, purposive sampling was used to recruit 3 groups with A1C ≥8.0% (2 English, 1 Spanish) and 3 groups with A1C <8.0% (2 English, 1 Spanish) to contrast patients: (1) with evidence for good versus poor current metabolic control and (2) who spoke primarily English versus Spanish. All participants received a $40 stipend. The study protocol was approved by the Massachusetts General Hospital Institutional Review Board.

Goals of Focus Groups

The goal of these groups was to understand patients' views regarding their experience with first starting oral medicines and with subsequent medication adjustments over the course of their illness. Medication intensification was defined for patients as either an oral medication dose increase or the addition of a second oral medicine. Patients were also specifically asked about their perceptions regarding the pace of medication change for diabetes. Near the end of each session, participants' feedback was sought after viewing an example of a

"Medication Treatment Pathway" for a hypothetical patient that depicted a sequence of potential future medication changes designed to achieve and maintain glycemic control over time. This example pathway was derived from the ADA treatment algorithm.

Data Collection

A semistructured interview guide was developed based on a literature review[17,18] and expert consensus and consisted of questions designed to ascertain current medication-taking beliefs and attitudes. This interview guide was pilot tested and refined before implementation. Group interviews were digitally recorded, transcribed, and (for the Spanish groups) translated into English for subsequent qualitative analysis. The moderator reviewed the transcripts for accuracy.

Data Analysis

Two members of the research team coded all data independently using NVivo 7.0. software (SdG Associates, London, UK); data were analyzed using content analysis to identify major concepts and axial coding to group and connect data.[19,20] At each analysis phase, the coders compared their results to confirm intercoder reliability, resolving discrepancies through discussion and comparison of the raw data. Themes within each content area were identified, and responses were categorized into codes. The coders then refined their definitions and the content of the codes and compared their coding lists. The following steps were taken to maximize dependability (reliability) and credibility (internal validity) of study conclusions: a multidisciplinary research team participated in each stage of data collection and analysis; facilitators and team members discussed their impressions and debriefed following each session; co-facilitators took notes at each session to record interactions, nonver-bal language, and environmental factors; and the coders discussed these other data sources to minimize bias in the interpretation of data.[21]

Results

Study Participants

Fifty patients (15 Spanish-speaking Latinos, 7 African Americans, and 28 non-Hispanic whites) participated in the focus groups (range, 6–11 participants/group). Mean age was 61.4 ± 11.4 years, and 54% were women (Table 1). Participants in the "higher A1C" groups (n = 23) had higher mean A1C levels (9.1% ± 1.4% vs 7.5% ± 0.5%, $P < .001$) and longer diabetes duration (10.7 ± 7.7 years vs 7.1 ± 4.7 years, $P = .05$) compared to participants in the "lower A1C" groups (n = 27). All patients reported personal experience with oral medication initiation and regimen intensification.

Medication Initiation

Provider model—The ADA treatment algorithm was developed based on clinical trial evidence that prescribing medicines for glycemic control reduces subsequent risk for disease complications. Implicit in this model is that the net balance of benefit to risk is favorable, and this benefit accrues through the delay or elimination of future adverse events.

Patient model—In contrast, when discussing their experiences with medications, most focus group participants described the negative connotations of medication initiation. A major theme in all groups was that medication initiation was perceived as evidence of personal failure rather than as a positive therapeutic step to reduce future risk. One patient's response typified most participants' reactions: "I was very disappointed, because I thought, well, I had been controlling it through diet for years. And when I went on the pills, it was a real step back for me. It was VERY disappointing." Another patient reported in response to

her physician prescribing a new medication, “I was just shocked, because I thought I was doing what I was supposed to be doing on my diet.” Other respondents found the news to be “frustrating,” reporting that they felt “shocked” and “disappointed” and that medication initiation was “another cross to bear” that “lowered self-esteem.”

Participant perceptions were typically reactive and reflected a past-rather than future-looking interpretive orientation. That is, patients mainly focused on the new prescription as a consequence of *prior* self-management behavior rather than as a step to reduce *future* complications.

Medical Regimen Intensification

Provider model—Although disease progression may be ameliorated by significant weight reduction and other lifestyle changes, most patients will inevitably require medical therapy intensification over time due to progressive beta cell failure. The ADA treatment algorithm reflects this clinical understanding in its emphasis on titrating medicines upwards until glycemic control is achieved and to return to the algorithm should initial control be lost.

Patient model—In contrast, many study participants identified treatment intensification as associated with increased risk of diabetes-related complications. For example, 1 participant commented, “Especially when they *add* medications on top of what you’re already taking, it makes you feel like you’re getting worse.” Another respondent explicitly linked treatment intensification to future mortality: “I felt sad because I already knew that my whole family had died from it. And so, I thought that the same thing was going to happen to me.” Thus, whereas in the medical model, increasing medical regimen intensity reduces a patient’s future risk, many patients in this study related medication intensification to increased current risk.

Given this association of medication intensification with increased risk, a major goal of therapy voiced by most respondents was to reduce treatment intensity. In a typical comment, 1 respondent reported, “I know if I do everything I’m supposed to do … the more weight I lose, the less medicine I take.”

The Timing of Titration

Provider model—Because the benefits of treatment are attenuated by subtherapeutic medical regimens, the ADA algorithm emphasizes that the process of medication titration should occur in a timely fashion.

Patient model—In contrast, when explicitly asked about the timing of regimen changes by their physicians, patients did not express enthusiasm for expediency. Rather, respondents tended not to have a strong opinion about the timing of medication adjustments and preferred to defer this aspect of care to their physician’s discretion (“I trusted my doctor. Whatever he said”; “The doctors are the experts”; “My health care was strictly in his [the doctor’s] hands”). In contrast to the future planning codified in the ADA treatment algorithm, most respondents emphasized the daily nature of living with diabetes (“I’ve always taken it one day at a time”) rather than the future goals of treatment.

Planning Future Medication Changes

Provider model—A key strength of the ADA treatment algorithm is that it specifies a sequence of treatment steps that can be taken over time until control is obtained. Thus, providers can anticipate recommended next steps in treatment.

Patient model—To further investigate patient perceptions about future medication changes, participants were shown a paper handout illustrating what a medication adjustment sequence might look like for a hypothetical patient. Participants responded positively to seeing medical regimens presented as a planned sequence of changes. The 2 main benefits identified were: (1) knowing what to expect ("It eliminates the anxiety you have when the doctor suddenly announces something to you. You can see the gradual buildup or gradual decline") and (2) the potential to reduce therapy ("Any improvement that I can make in exercise, diet, whatever, to get down a step is only going to encourage me to do it more").

Group Contrasts: Higher Versus Lower A1c and English Versus Spanish Speakers

Consistent agreement regarding the main themes reported above was found between the higher and lower A1c focus groups. Similarly, both Spanish- and English-speaking participants expressed similar general reactions to medication initiation and intensification. Differences between these 2 groups related primarily to logistical issues such as a greater prevalence of medication cost concerns and language barriers among the Spanish-speaking participants.

Conclusions

In a qualitative analysis involving a wide range of primary care patients with T2D, significant areas of discordance were found between patients' conceptual models of diabetes medication therapy and 3 core principles underlying the ADA medication treatment algorithm followed by providers. This contrast between patient perception and the provider model of medication management highlights the importance of effective communication between patients and providers and may help explain some of the persistent gap between ideal and actual care. Furthermore, the study suggests that interventions designed to more clearly convey the role of medication initiation and adjustment over time may be needed.

Analyses focused on 3 principles implicit in the ADA medication treatment algorithm developed to support more effective T2D pharmacotherapy. The contrasts between patient views and each treatment principle provide an instructive template for where patient-provider communication efforts may need greater focus:

1. *Medications as a benefit versus penalty*. Whereas treatment guidelines are based on clinical trial evidence that medications beneficially reduce future diabetes-related adverse events, most patients focused primarily on the immediate negative impact of adding a new oral medicine. In particular, patients tended to emphasize the link between initiation of medical therapy and prior inadequate behavior change. Because weight loss is seen as primarily a patient responsibility, "failing" to achieve this goal may have significant emotional impact on patients. These results suggest that counseling at the time of medication initiation should emphasize the future benefit that is being created by starting medication therapy.
2. *Medication intensification versus de-intensification as a goal*. Providers, with a focus on achieving goals of care, tend to see medical regimen intensification as an expected event in response to inevitable beta-cell decline. In contrast, patients in the study highlighted the negative response they felt toward medication intensification, emphasizing instead the goal of reducing medical therapy if possible. The result of these differing perspectives is that providers and patients to a large extent tend to have opposing medication goals (regimen intensification vs regimen reduction). This contrast in perspective may reflect the difference between providers and patients in the expectation of whether intensive lifestyle modification will be successful.

Patients associated intensification with increased risk for diabetes-related complications. For some study participants, intensification served as a signal that their disease was worsening. Others appeared to more closely link the intensification itself to increased risk of diabetes-related complications. The latter may represent an example of reverse causality (eg, medication prescription leads to increased risk of subsequent diabetes-related complications rather than increased risk of complications leads to medication prescription). For some patients, medication intensification may serve as tangible evidence of their disease progressing. These patient perspectives may explain why medication initiation and intensification carry such a negative connotation for many patients: rather than helping, the medication increase implies disease worsening and therefore increases patient fears of the very complications that the medication intensification is working to reduce.

3. *Long-term versus short-term perspective*. Implicit in the ADA algorithm is that changes need to be made in a timely manner (eg, every 3 months based on regular A1C monitoring). In contrast, patients reflected both a lack of awareness of the need for frequent medication adjustment and a perspective that seemed to focus more on the "here and now" of diabetes. Thus, many patients do not share the urgency codified in the ADA treatment algorithm. This contrast can be explained in part by the negative connotations associated with medications and suggest the need to more clearly explain the connection between medication intensification and future risk reduction. The lack of apparent concern about the timeliness of medication adjustment may also reflect a lack of knowledge on the patient's part. Indeed, when shown an example of an individualized, long-term medication plan for a hypothetical patient with T2D, patients were enthusiastic about seeing what might happen in the future with their medical regimens.

Given reported disparities in diabetes control between Latinos and non-Latinos in the United States,[16] it is somewhat surprising that this study found few differences between English-speaking and Spanish-speaking patients with regards to conceptual models of medication initiation and intensification. Spanish-speaking patients were drawn from an academically affiliated community health center within a primary care network. This health center has extensive resources for Spanish speakers, including many Spanish-speaking primary care physicians, bilingual staff, and professional interpreters. Thus, the Spanish speakers in this study may not have been representative of Latinos receiving care in less culturally concordant settings. However, the constancy of results between groups suggests that among patients with access to high-quality care, similarities in the experience of medication initiation and intensification may outweigh cultural differences between Latinos and non-Latinos.

This study is unique in its focus on the initiation and dose titration of oral medications for T2D glycemic control. Prior research has found many similar themes as applied to insulin initiation. The cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study, for example, found that many patients blamed themselves when insulin therapy had to be started.[22] Other studies have linked patient resistance to insulin therapy to beliefs such as the feeling that insulin initiation means that the patient's diabetes is getting worse, the patient has failed, and initiation will lead to poor outcomes such as weight gain and diabetes-related complications.[23–26] It was somewhat surprising that this view was not limited to insulin but extended to oral medications as well.

The results must be interpreted in the context of the study design. Because focus group participants may not be representative of the general population, qualitative studies should be considered "hypothesis-generating" research. Indeed, the results suggest several

promising avenues for intervention development, including educational interventions for patients and changes in medication counseling to include subsequent planned medication steps. Future, population-based survey research is needed to investigate the generalizability and predictors of the views discovered in this study. Another limitation of the group interviews is that patients were asked about oral medications but not about A1C levels or goals. Thus, this study cannot report the extent to which patient views about medications are influenced by their understanding of their A1C levels.

Prior studies have shown that (1) diabetes patients with greater medication-related concerns were less likely to be adherent,[17] (2) providers with concerns about patient motivation and adherence are less likely to intensify diabetes therapy,[10] and (3) both poor adherence[14] and lack of intensification[7] are associated with poorer diabetes-related outcomes. Taken together, these lines of research underscore the critical role of effectively educating patients about the goals and consequences of medication initiation and intensification.[27]

Implications

The results from this study suggest a framework for structuring medication-specific counseling. In keeping with the theme of setting the stage for effective diabetes care through early education,[28] providers should also consider “mapping out” an expected course of diabetes progression and a planned sequence of medication initiation and changes over time. This reframing of diabetes prognosis could reduce the surprise and disappointment many patients express when confronted with the need to intensify medical therapy.[29] In this study, when presented with a hypothetical example of such a planned medication sequence, patients expressed a much more positive view of the medication adjustment process. This hypothetical example illustrates the potential for improving communication by providing patients with greater perceived control and increased engagement with a domain of care—oral medication management—that has not traditionally been emphasized in diabetes self-management education.

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Table 1

Participant Demographic Characteristics

	All Participants (N = 50)	" Higher" A1C Group (n = 23)	" Lower" A1C Group (n = 27)
Women, n (%)	27 (54.0)	14 (60.9)	13 (48.1)
Spanish speaking, n (%)	15 (30.0)	6 (26.1)	9 (33.3)
Age, y (SD)	61.4 (11.4)	61.4 (9.7)	61.4 (12.8)
Diabetes duration, y (SD)	8.8 (6.5)	10.7 (7.7)	7.1 (4.7)
Last A1c%, mean (SD)	8.2 (1.3)	9.1 (1.4)	7.5 (0.5)
Currently prescribed insulin, n (%)	22 (44)	15 (65)	7 (26)
Insurance type, n (%)			
Commercial	22 (44.0)	13 (56.5)	9 (33.3)
Medicare	25 (50.0)	8 (34.8)	17 (63.0)
Medicaid	3 (6.0)	2 (8.7)	1 (3.7)

"Higher" A1C ≥8.0%; "lower" A1C <8.0%. All participants were taking 1 or more oral glycemic medications.