How Does Treatment Satisfaction Work?

Modeling determinants of treatment satisfaction and preference

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OBJECTIVE — This study tested a model hypothesizing that treatment affects objective clinical outcomes, which in turn affect perceived consequences, which in turn affect satisfaction and preference judgments.

RESEARCH DESIGN AND METHODS — The model was tested in a double-blind, randomized clinical trial in which 266 patients with type 1 diabetes added active or placebo pramlintide to their insulin regimens. Objective clinical outcomes included changes in glucose and weight control, insulin requirements, incidence of hypoglycemia, and study drug tolerance. At the end of the trial, patients completed the validated PRAM-TSQ questionnaire measuring treatment satisfaction and preference and perceived medication benefits and side effects.

RESULTS — Statistical modeling demonstrated that active pramlintide was significantly associated with greater treatment satisfaction, preference, and perceived benefits (all except hypoglycemia prevention), as well as objective clinical outcomes (weight loss, lower postprandial glucose [PPG], lower medication tolerance, more hypoglycemia). Perceptions of treatment consequences were sensitive and specific to their cognate objective clinical outcomes (no halo effects). Clinical outcomes (especially PPG) accounted for almost half of the effect of the study medication on treatment satisfaction and preference. Treatment satisfaction and preference were strongly related to the perceived benefits/side effects of the study medication, and these perceptions (especially glucose control) mediated most of the association of clinical outcomes with satisfaction and preference.

CONCLUSIONS — This model received substantial empirical support. Improvements in objective clinical outcomes accounted for a large part of the association of pramlintide treatment with higher treatment satisfaction and preference. Perceived treatment consequences mediated the effect of objective clinical benefits on satisfaction with and preference for the study medication.

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Assessment of patient-reported outcomes (PROs), especially treatment satisfaction, is increasingly recognized as important in determining the efficacy of new therapies (1,2). Treatment satisfaction may be associated with adherence to treatment (3), glycemic control (2,4,5), and treatment preference (6). Most studies of treatment satisfaction and preference assess differences between groups using different treatments, but the diabetes literature reveals little effort to determine how treatment affects treatment satisfaction and preference. We have begun to develop a model that conceptualizes this process (Fig. 1, *top panel*). Treatment (e.g., initiation of a new medication) affects objective clinical outcomes (e.g., A1C levels), which in turn affect perceived consequences (e.g., better glucose control, more frequent hypoglycemia), which in turn affect treatment satisfaction (e.g., belief that the benefits of treatment outweigh the burden) and preference judgments (e.g., desire to continue taking the new medicine). Other perceived consequences of treatment that are not driven by objective clinical outcomes (e.g., convenience, pain, etc.) also may influence satisfaction and/or preference judgments (7).

Our research has provided preliminary support for this model. We found that several objective clinical outcomes were associated with perceived benefits (8) and treatment satisfaction and/or preference (7,9). We also found that perceived benefits of treatment were associated with treatment satisfaction/preference (6,7) and accounted for most of the difference between groups in treatment satisfaction/preference (6). However, several key research questions should be more fully addressed:

1. Do objective clinical outcomes account for group differences in treatment satisfaction or preference? Just because a group differs on both types of factors does not demonstrate that the factors are necessarily related to each other; such an assumption is an example of the "ecological fallacy" (10,11). Demonstrating the effect of improved clinical outcomes on PRO requires that they be linked at the individual level (i.e., by correlation/regression analysis) (8). Moreover, where studies include several clinical outcomes, it is important to assess the relative contribution of each outcome to differences between treatment groups in satisfaction and preference. It is important to note that the clinical outcome most responsive to treatment is not necessarily the one with the largest effect on treatment satisfaction or preference (6).
2. How do objective clinical outcomes affect patients' subjective perceptions of treatment consequences (benefits and side effects)? For example, does an objective clinical benefit such as weight reduction give rise to only one specific perceived benefit (perceived weight control), or, as we found earlier (8), does an objective clinical benefit have a halo effect and contribute to other perceived benefits?
3. Do perceived treatment consequences mediate the relationship between objective clinical outcomes and treatment satisfaction or preference (e.g.,

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How treatment satisfaction works

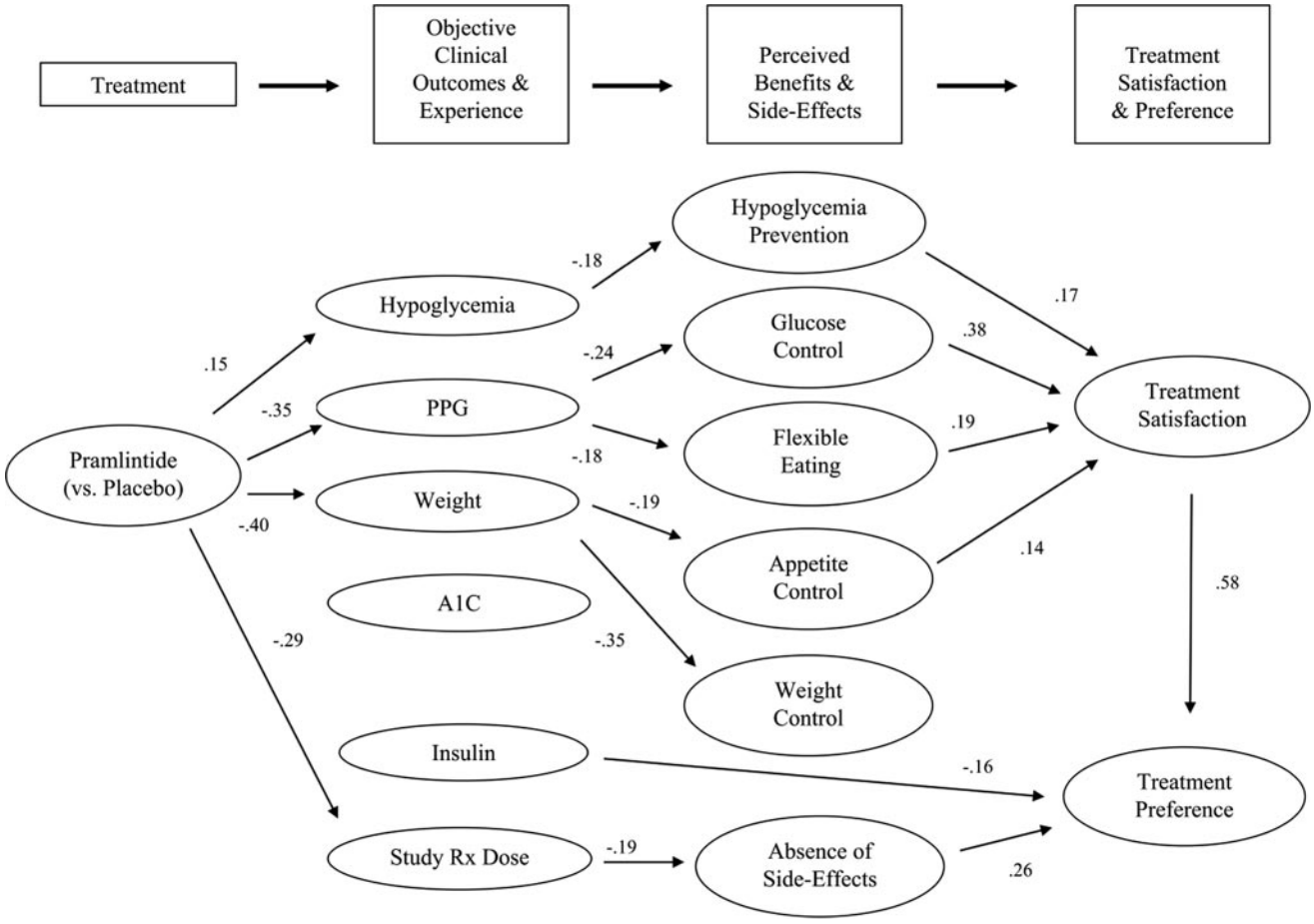

Figure 1—*Associations among model elements: objective clinical outcomes, perceived treatment consequences, treatment satisfaction, and treatment preference. Only paths with significant standardized regression coefficients from Table 2 are shown. Direct paths from treatment arm to PROs are not shown in order to simplify the diagram.*

Does perceived glucose control mediate the relationship between objective glucose and treatment satisfaction or preference?), and, if so, how much does each perceived consequence contribute to treatment satisfaction and preference? We have some evidence regarding the relative contribution of specific perceived consequences to treatment satisfaction/preference (6,7) but not in the context of a randomized clinical trial (RCT) and not whether perceived benefits and side effects mediate the relationship of clinical outcomes to satisfaction and preference.

4. For a particular treatment, are satisfaction with and preference for the treatment differently related to the various objective clinical outcomes and perceived consequences of treatment, or are these two PROs interchangeable?
5. Does treatment satisfaction mediate the relationship of the various objective clinical outcomes and perceived treatment consequences with treatment preference, or do some perceived consequences have direct relationships with preference?

The current report examines the proposed model in the context of a study of patients with type 1 diabetes participating in an RCT comparing the effects of adding pramlintide or placebo with patients' insulin regimen. This study is well suited for testing our model because *1*) the RCT design allows us to be confident that the observed group differences are a result of the study medication rather than uncontrolled factors, and *2*) the study medication (pramlintide, an analog of human amylin) is hypothesized to effect multiple clinical outcomes, including lower A1C and postprandial glucose (PPG) levels, weight reduction compared with taking insulin alone, and reduced doses of mealtime insulin (12,13). Pramlintide also has some potential drawbacks; it requires an injection before each meal in addition to the patient's insulin regimen (14), and its use is associated with gastrointestinal side effects, including nausea, in some patients (15,16).

This study incorporates both objective and subjective measures of all these potential treatment effects, thereby permitting an analysis of the interrelationships among these factors and their association with treatment satisfaction and preference. The PRO measure (9,17) was designed to assess perceived clinical side effects and benefits of the study medication, as well as overall judgments of satisfaction and preference. The instrument did not assess some of the more traditional determinants/components of treatment satisfaction (e.g., convenience, comfort), which are less central to the proposed model.

RESEARCH DESIGN AND METHODS

— A total of 266 adults with type 1 diabetes completed the 29-week, double-blind, placebo-controlled, multicenter trial. A full description of the

study protocol, including inclusion and exclusion criteria, medication, self-monitored blood glucose regimen, and data collection procedures, can be found elsewhere (12). The study protocol was approved by an institutional review board, and all participants provided written informed consent before participating in the trial. The study was conducted in accordance with the principles of the Declaration of Helsinki (1964), including all amendments through the South Africa revision (1996).

Clinical measures

Clinical parameters assessed at baseline and at the end of the trial were daily total insulin dose, weight, A1C, and PPG (measured as the average of the daily averages over 2 weeks). Diary data were used to obtain the measures of PPG and insulin dose. Also measured were hypoglycemia and study medication dose (pramlintide or placebo). Hypoglycemia incidence was the natural log of the actual number of events (taken after adding one to the number to correct for the log of zero). Severe hypoglycemia incidence was a binary yes/no (1/0) measure defined using the Diabetes Control and Complications Trial criteria (18). Study medication dose was a binary yes/no (1/0) variable indicating whether the participant was able to take the maximum (60 μg/meal) dose.

PRO measures

PROs were assessed at the end of the trial, with the double-blind protocol still in place, using a 14-item questionnaire, the PRAM-TSQ (9,17). Response options were on a 6-point Likert scale from strong agreement with the item (scored 6) to strong disagreement (scored 1), with equal increments between response options.

PRO measures included several individual items measuring specific perceived benefits of the study medication (items 1–5: perceptions of blood glucose control, flexible eating, weight control, hypoglycemia prevention, and appetite control, respectively) and absence of side effects (item 6 with reverse scoring). Two multi-item scales were calculated as the means of their constituent items: treatment satisfaction (items 7–12: perceptions of benefits greater than insulin alone, less worries about having diabetes, more confidence managing diabetes, benefits that outweighed the burden of extra injections, improved ability to function, feeling better overall) and treatment preference (items 13 and 14: desire to continue taking the study medication and willingness to recommend it to others). Reliability was adequate for the two multi-item scales: treatment satisfaction ($\alpha = 0.92$) and treatment preference ($\alpha = 0.69$).

Statistical analysis

Only the 263 cases with complete data for all PRO measures were included in the analysis. The last-observation-carried-forward method was used for missing data on the clinical outcome measures. For all variables with missing data after using these techniques, we assigned participants the mean value of that variable in their treatment arm. The only clinical outcomes for which more than one value was imputed were PPG ($n = 39$) and insulin dose ($n = 52$).

The model's hypothesized independent associations among treatment group, clinical outcomes, perceived consequences, satisfaction, and preference were assessed with hierarchical ordinary least squares (OLS) regression using forced entry (19,20). The first block of variables included respondent characteristics, baseline values of clinical outcomes, and treatment arm. The second block of variables included the measures of objective clinical outcomes. For the analyses of treatment satisfaction and preference, the third block of variables included perceived consequences of the study medication. Finally, in the analysis of treatment preference, treatment satisfaction was entered in the final block to assess whether it made an additional contribution to explanatory power and mediated the association of treatment preference with other explanatory variables.

Note that clinical outcomes and perceived consequences can affect satisfaction or preference even though they are not related to treatment arm; these associations account for within-treatment-group variation rather than between-treatment-group variation. Only factors related both to treatment assignment and to satisfaction or preference can mediate the effect of treatment assignment on satisfaction or preference.

RESULTS

Baseline characteristics

Study participants were mostly white (93%), female (55%), and using continuous subcutaneous insulin infusion (54%). Respondents were middle-aged ([means ± SD] 41.1 ± 13.2 years) and had diabetes of long duration (20.2 ± 11.9 years). Participants were somewhat overweight (81.4 ± 17.3 kg) and in suboptimal glycemic control (PPG = 185.9 ± 38.3 mg/dl; A1C = 8.1 ± 0.8%). Total daily insulin dose was substantial (55.1 ± 28.1 units). There were no statistically significant differences between the treatment arms at baseline (results not shown).

Objective clinical outcomes and perceived treatment consequences differed by treatment group

A precondition for assessing our conceptual model was the existence of significant treatment arm differences in clinical outcomes, perceived treatment consequences, satisfaction, and preference. Table 1 presents the analyses of group differences in objective clinical outcomes and PROs demonstrating that these preconditions were met. For clinical outcomes, the placebo medication arm experienced significantly less hypoglycemia during the trial, and more placebo participants were able to tolerate the maximum dosage of study medication. The active medication arm experienced statistically significant advantages in two objective clinical outcomes: weight and PPG. There were no significant differences for A1C or insulin requirements.

The pramlintide arm had a statistically significant advantage for all PRO measures except hypoglycemia prevention and absence of side effects; not surprisingly, those taking placebo reported lower side effects. For the six measures on which there was a statistically significant benefit for the active medication, four of the effect sizes (glucose control, weight control, appetite control, and treatment satisfaction) met the one-half SD criterion for a "minimally detectable difference" (21), the criterion representing a "moderate" effect (22).

Clinical outcomes were associated with perceived benefits and side effects

Although none of the perceived treatment consequences were associated with change in A1C or insulin requirements, as hypothesized, each perceived consequence was associated with a corresponding clinical outcome (see Table 2*A*–*F*). Improved postprandial glucose levels were associated with better perceived glucose control and flexibility in eating, improved weight was associated with better perceived weight and appetite control,

Table 1—*End of the trial measures by treatment group*

	Active pramlintide	Placebo pramlintide	Unadjusted effect size (η, SDU)	Adjusted effect size (β, SDU)
n	129	134		
Clinical outcomes				
Log number of hypoglycemic events	3.67 ± 1.09	3.40 ± 1.04	0.12*, 0.25	0.15*, 0.28
Severe hypoglycemic event	27.1%	13.4%	0.13*, 0.28	0.17†, 0.34
Maximal pramlintide dose	72.1%	93.3%	0.28‡, 0.55	−0.29‡, 0.58
Change in insulin requirement (units/day)	0.59 ± 74.04	4.76 ± 34.34	0.04, 0.07	0.04, 0.07
Change in weight (kg)	−1.60 ± 3.80	1.28 ± 2.94	0.39‡, 0.79	−0.40‡, 0.81
Change in A1C (%)	−0.38 ± 0.86	−0.45 ± 0.85	0.04, 0.08	0.03, 0.06
Change in PPG (mg/dl)	−38.27 ± 39.18	−7.40 ± 38.25	0.37‡, 0.74	−0.35‡, 0.71
Patient reported outcomes				
Glucose control	4.18 ± 1.44	3.15 ± 1.65	0.32‡, 0.63	0.34‡, 0.67
Flexible eating	3.42 ± 1.53	2.89 ± 1.63	0.17†, 0.33	0.20†, 0.39
Weight control	3.70 ± 1.74	2.33 ± 1.41	0.40‡, 0.80	0.41‡, 0.83
Appetite control	4.00 ± 1.71	2.63 ± 1.53	0.39‡, 0.78	0.41‡, 0.82
Hypoglycemia prevention	2.84 ± 1.40	2.72 ± 1.41	0.04, 0.09	0.04, 0.09
Absence of side effects	4.71 ± 1.66	5.31 ± 1.22	0.20‡, 0.41	−0.19‡, 0.39
Treatment satisfaction	3.79 ± 1.35	2.83 ± 1.43	0.33‡, 0.65	0.35‡, 0.69
Treatment preference	4.77 ± 1.49	4.22 ± 1.75	0.17†, 0.33	0.17‡, 0.34

Data are means ± SD, unless otherwise indicated. Effect sizes for study outcomes were measured by ANOVA with the η-statistic (unadjusted) and ANCOVA with the β-statistic (adjusted for race, sex, age, duration of diabetes, multiple daily injections/continuous subcutaneous insulin infusion, and baseline values of insulin, weight, A1C, and PPG), as well as by the difference between treatment groups in SD units (SDU). *$P < 0.05$; †$P < 0.01$; ‡$P < 0.001$.

fewer hypoglycemic events was associated with better perceived hypoglycemia prevention, and ability to tolerate the maximal pramlintide dose was associated with fewer perceived side effects. These associations demonstrate the sensitivity/responsiveness of the perception of benefits/side effects to objective clinical outcomes. The associations also manifested content specificity; no patient assessment was significantly associated with an objective clinical outcome to which it did not correspond.

Clinical outcomes were associated with treatment satisfaction and preference

Independent associations of treatment satisfaction and preference with clinical outcomes (controlling for baseline measures) are presented in Table 2. Higher treatment satisfaction was associated with improved PPG (see model TS1). Higher preference for the study medication was associated with improved PPG and reduced insulin requirements (see model TP1).

Objective clinical outcomes partially mediated the relationship between treatment group and PROs

Of seven PRO measures for which there were statistically significant differences between treatment arms, introduction of objective clinical outcomes into the models accounted for 20–49% (median = 46%) of the PRO difference (compare each β in Table 1 to the corresponding β for treatment arm in Table 2, models *A–F*, TS1, TP1) (see Fig. 1 for a representation of all mediations). Four of five significant associations between treatment arm and perceived consequences remained significant after controlling for clinical outcomes.

Perceived treatment consequences mediated the association of objective clinical outcomes with treatment satisfaction and preference

Perceived glucose control and flexibility of eating were associated with higher treatment satisfaction and mediated the association of PPG change with treatment satisfaction (compare model TS1 to model TS2). Perceived glucose control also was associated with treatment preference and mediated the association of PPG change with preference (compare model TP1 to model TP2). Introduction of perceived consequences did not mediate the significant association of treatment preference with change in insulin requirements (see model TP2).

Treatment satisfaction mediated the association of perceived benefits with treatment preference

Treatment satisfaction mediated the association of treatment preference with perceived glucose control but not with perceived side effects or objective change in insulin requirements (see model TP3). Sensitivity analyses performed using data for which missing values were not imputed revealed no meaningful differences in results compared with those reported here for the imputed data.

CONCLUSIONS — The purpose of this study was to test a model of objective and subjective determinants of treatment satisfaction and preference, specifically that treatment affects objective clinical outcomes, which in turn affect perceived consequences, which in turn affect satisfaction and preference judgments. The results of our analyses are illustrated in Fig. 1.

The results show that the study medication raises treatment satisfaction by reducing postprandial glucose levels, which increases perceived glucose control and ability to eat flexibly. The effect of improved postprandial glucose and perceived glucose control on treatment preference is mediated by treatment satisfaction, which outweighs the negative effect of lowered medication tolerance and perceived side effects. Reduction of insulin dose makes an independent contribution to increased preference for the study medication but does not contribute to the treatment group difference in medication preference.

The results illustrated in Fig. 1 address the research questions identified

Table 2—*Regression analysis of patient-reported outcomes at the end of the trial (standardized OLS regression coefficients)*

	Glucose control (A)	Flexible eating (B)	Weight control (C)	Appetite control (D)	Hypo prevent (E)	Absence of side effects (F)	Treatment satisfaction (TS1)	Treatment satisfaction (TS2)	Treatment preference (TP1)	Treatment preference (TP2)	Treatment preference (TP3)
Race (white)	−0.14*	−0.15*	−0.01	−0.04	−0.03	−0.06	−0.09	0.01	0.05	0.13*	0.12*
Sex (male)	0.03	0.00	0.03	−0.02	−0.03	−0.15*	0.01	0.01	−0.14	−0.10	−0.10
Age (years)	−0.02	−0.02	0.01	−0.05	0.10	0.12	0.05	0.05	0.15*	0.13*	0.10
Diabetes duration (years)	0.08	0.02	−0.07	0.06	−0.05	0.01	−0.01	−0.04	0.02	−0.01	0.01
Multiple daily injections§	−0.03	0.04	0.02	0.04	0.04	−0.02	0.05	0.04	−0.03	−0.02	−0.05
Baseline insulin (units/day)	0.20*	0.21*	0.20†	0.27†	0.11	−0.06	0.22†	0.04	0.05	−0.04	−0.07
Baseline weight (kg)	−0.14*	−0.16	−0.20*	−0.13	0.05	0.17	−0.12	−0.02	0.09	0.10	0.11
Baseline A1C (%)	−0.01	0.02	−0.03	−0.02	0.01	0.07	0.05	0.05	−0.03	−0.05	−0.08
Baseline PPG (mg/dl)	−0.22†	−0.21*	−0.10	−0.04	−0.14	−0.14	−0.17*	−0.00	−0.12	0.02	0.02
Treatment arm (active)	0.22†	0.10	0.21†	0.26‡	0.04	−0.15*	0.19†	0.04	0.09	0.04	0.02
Log number of hypoglycemic events	−0.09	−0.07	−0.03	−0.01	−0.18*	0.06	−0.00	0.07	0.02	0.04	−0.00
Severe hypoglycemic event	−0.02	0.12	0.10	0.10	−0.09	−0.03	0.08	0.06	0.05	0.04	0.01
Maximal pramlintide dose	−0.01	−0.02	−0.05	−0.08	0.04	0.19†	−0.04	−0.03	0.06	0.01	0.03
Change insulin (units/day)	−0.08	−0.02	−0.04	−0.01	−0.06	−0.07	−0.05	0.01	−0.16*	−0.11*	−0.12*
Change weight (kg)	−0.12	−0.05	−0.35‡	−0.19†	0.00	−0.03	−0.10	0.01	−0.01	0.04	0.04
Change A1C (%)	−0.12	−0.09	−0.01	−0.03	0.08	0.10	−0.01	0.04	−0.02	−0.00	−0.03
Change PPG (mg/dl)	−0.24†	−0.18*	−0.09	−0.11	−0.14	0.01	−0.27‡	−0.10	−0.22*	−0.13	−0.07
Glucose control								0.38‡		0.25†	0.04
Flexible eating								0.19†		0.14	0.03
Weight control								0.08		−0.04	−0.09
Appetite control								0.14*		0.13	0.05
Hypoglycemia prevention								0.17‡		0.04	−0.06
Absence of side effects								0.07		0.30‡	0.26‡
Satisfaction											0.58‡
R^2	0.23	0.16	0.34	0.27	0.10	0.13	0.23	0.71	0.13	0.39	0.49

Each column reports the results of a separate multiple regression analysis, each of which includes all variables for which coefficients are presented. For treatment satisfaction there are two models (TS1 and TS2), with the TS2 model adding perceived consequences to the TS1 model. For treatment preference, there are three models (TP1, TP2, and TP3), with the TP2 model adding perceived consequences to the TP1 model and the TP3 model adding treatment satisfaction to the TP2 model. *$P < 0.05$; †$P < 0.01$; ‡$P < 0.001$; §reference category is continuous subcutaneous insulin infusion.

earlier. First, results demonstrated that the individual-level clinical outcomes (hypoglycemia, pramlintide dose, change in postprandial and long-term glucose levels, weight, and insulin required) accounted for almost half of the effect of the study medication on perceptions of treatment consequences and judgments of treatment satisfaction and preference. Improved postprandial glucose had the strongest effect on treatment satisfaction and preference; lowered insulin requirements also had a significant effect on preference.

Second, our results showed that the effects of objective clinical factors on specific perceived benefits and side effects were as hypothesized (each measure of perceived consequences was significantly associated with the particular clinical outcome to which it corresponded [sensitivity] and only with that outcome [specificity]). For the one perceived consequence (glucose control) with two relevant clinical outcomes (changes in A1C and PPG), only PPG had a significant independent association. Elsewhere (8), we have offered several explanations of this pattern, including the fact that A1C levels and changes are not experienced as directly or as frequently by the patient as the PPG levels and changes revealed by blood glucose self-monitoring, which provides immediate and powerful feedback to patients about treatment efficacy compared with the feedback from A1C, which is less frequent and after the fact.

Third, our results showed how various perceived treatment consequences mediate the relationship between objective clinical outcomes and treatment satisfaction or preference. Treatment satisfaction and/or preference were independently related to each of the perceived consequences of the study medication, with perceived improvement in glucose control having the strongest association (as might be expected for an antihyperglycemic medication). In one benefit domain represented by two relevant measures (appetite/weight control), only the appetite-control measure was related to treatment satisfaction, perhaps because appetite control comprises a more frequent, visceral, and immediate subjective experience than weight control (paralleling the experiential primacy of PPG over A1C noted above).

Fourth, results showed that, despite some similarities, treatment satisfaction and preference for the study medication were differently related to clinical outcomes and perceived consequences. Satisfaction was independently related more to perceived benefits, while preference was related more to perceived side effects and objective clinical outcomes.

Finally, we demonstrated that treatment satisfaction mediated the association of perceived glucose control with treatment preference and produced a substantial increment to explanatory power. The latter finding suggests that either the measure of treatment satisfaction incorporates unmeasured treatment consequences, or it represents synergistic effects of measured factors. Interestingly, treatment satisfaction did not mediate the relationship between perceived absence of side effects and preference. Our earlier research (9) indicated that perceptions of side effect absence and treatment benefits do not cluster together, and these results demonstrate that it is important to retain a separate measure of perceived side effects because it may play an important role in treatment preference.

Research implications

The model investigated here can provide a foundation for future research. For example, controlling for clinical outcomes did not eliminate all treatment arm differences in perceived consequences, treatment satisfaction, or preference. This indicates that patients' subjective perceptions and judgments about treatment are more complex than our empirical model (e.g., perceived hypoglycemia prevention did not mediate the effect of reducing insulin dose, implicating negative perceptions of insulin beyond hypoglycemia risk) (23); these should be studied in future research. Relatedly, this study did not capture all the potential perceived consequences that might be relevant to patients' judgments about treatment satisfaction and preference. Perhaps unmeasured perceived consequences that do not have a corresponding objective clinical outcome (e.g., convenience, comfort/pain, safety, etc.) would account for additional variance or some of the variance now attributed to the measured consequences (6,7); these factors should be incorporated into future tests of this model. Finally, we do not know whether the factors in this model would have the same influence with different medications; research with other medications should include measures of the specific objective and perceived effects of those medications. Analysis of PROs in studies of a treatment intervention should analyze each perceived consequence separately to obtain a unique perceived risk/benefit profile for that intervention.

Clinical implications

Our findings suggest that patients recognize the objective clinical benefits and side effects of their treatments and that they are especially likely to recognize those that are most immediate (e.g., changes in PPG rather than changes in A1C; changes in appetite rather than changes in weight). Our findings also suggest that perceived benefits are powerfully associated with treatment satisfaction, which is related to treatment adherence (4) and clinical outcomes (2,5,6). Clinicians should consider helping patients identify immediate, perceptible benefits of prescribed treatments and heighten the salience of these benefits as a means to improve treatment adherence, treatment satisfaction, and clinical outcomes (23). In addition, the finding that treatment satisfaction did not mediate the relationship between perceived absence of side effects and treatment preference suggests that patients' concerns about side effects should be addressed specifically in order to enhance treatment adherence.

Limitations

Our model hypothesizes causal pathways from perceived consequences to satisfaction and preference. However, all data for these pathways were collected at the end of the study, and these relationships are cross-sectional. Without knowing the temporal dynamics of these associations, we cannot confidently assert causal pathways. Moreover, the study population is not necessarily representative; patients who enroll in RCTs tend to differ from the general patient population. Thus, the generalizability and validity of the results may be limited. Finally, the study medication has a particular effect profile that, if known to patients, may have significantly influenced their perceptions, satisfaction, and preferences and might not be present in other studies.

Summary

This report developed a model that identifies objective and subjective determinants of treatment satisfaction and preference and the linkages among them. The model states that treatment affects objective clinical outcomes, which in turn affect perceived consequences, which in turn affect satisfaction and preference

judgments. This model received substantial empirical support and performed reasonably well in accounting for treatment satisfaction and preference. Additional research will be required to further develop the model and determine its generalizability.

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