Who Benefits From Intensive Therapy in Type 1 Diabetes?

A fresh perspective, more questions, and hope

Our assumptions about what kinds of patients benefit most from intensive therapy (IT) are rarely questioned. Thanks to the empirical evidence provided by Wysocki et al. (1) in this issue of Diabetes Care, we now have a fresh perspective on the critical question of who benefits from IT. In the landmark study that established the benefits of IT for people with type 1 diabetes, the Diabetes Control and Complications Trial (DCCT) employed strict eligibility criteria and screened out patients who were assessed as too unstable or unmotivated to follow through on the rigorous demands of IT. Each DCCT participant had to complete a series of demanding behavioral tasks during the run-in period before randomization. Thus, the DCCT study population was a “young, generally healthy, and highly motivated” sample (2) that was also steadily employed and lived in a stable home environment. The assumption that IT was best suited for the highly adherent and informed patient, which guided the DCCT screening procedure and subsequent decisions about who would adhere to and benefit from IT, has become dogma (2).

This legacy is turned upside down by the empirical data of Wysocki et al. Their data suggest that patients/parents with the lowest levels of diabetes knowledge and adherence had the greatest glycemic benefits from IT. As one part of a larger pediatric randomized trial of IT versus usual care (UC), the authors sought to identify and objectively characterize the subgroup of youth (and their families) that experienced the most significant glycemic benefits from participation in IT. As in the DCCT, very different levels of support and services were available to families in the IT condition as compared with UC. Families randomized to UC received quarterly clinical visits with the nurse and physician, one annual clinical visit with a dietitian and a psychologist, and participation in systematic diabetes education. Families randomized to IT were provided with weekly telephone contact with a dietitian and psychologist without charge, monthly clinical visits with a dietitian nurse, quarterly clinical visits with the physician, participation in advanced diabetes education, and access to a monthly multifamily diabetes support group.

The sample comprised 147 youth with type 1 diabetes who were 6–16 years of age and their parents, who consented to be randomized to either UC or IT for 18 months. Families in both treatment conditions were divided into three groups based on the classification of their self-management competence (SMC). SMC was conceptualized as a composite of the skills needed for effective family management of type 1 diabetes. SMC scores were calculated on three measures, assessed every 6 months of the 18-month study period. These measures consisted of 1) a valid, reliable measure of diabetes knowledge based on the Diabetes Information Survey for Children (3), 2) a valid, reliable measure of treatment adherence based on the Diabetes Self-Management Profile (4), and 3) a clinician rating of the quality of health care interactions with the family based on the Physician Satisfaction Questionnaire (5). Scores in each of these individual measures were transformed into standardized T-scores. This provided a distribution of SMC composite scores that the investigators divided into tertiles to categorize families as high, moderate, or low with respect to SMC. The authors hypothesized that “patients with moderate SMC would benefit more from IT than would those with either high or low SMC, since patients with moderate SMC possess some prerequisite self-management skills while also having room for glycemic improvement” (1).

However, the resulting data on glycemic “benefits” yielded three quite unexpected and dramatic findings:

1) Within the IT condition, at the end of the 18-month trial, there were no significant differences among the high-, moderate-, and low-SMC groups with respect to final HbA1c level achieved (see Fig. 1, Wysocki et al.).

2) Within the IT condition, over the course of the 18-month trial, low-SMC patients had greater glycemic benefit (improvement in HbA1c) from IT than the moderate- or high-SMC patients (see Fig. 2, Wysocki et al.).

3) Within the UC condition, over the 18-month trial, glycemic control deteriorated significantly for patients with low SMC, but not for patients with moderate and high SMC (see Fig. 1, Wysocki et al.).

The authors interpret their findings with a fresh perspective. They suggest that SMC is more important to the success of UC, which does not provide as much support for the pediatric patient and/or family, than to the success of IT. In contrast to UC, IT provided medical follow-up three times more frequently, free psychological and nutritional services, weekly phone calls from the certified diabetes educator, and monthly family support groups. The authors conclude that patients should not be screened out of or steered away from IT due to “limited competence in diabetes self-management.”

The findings of Wysocki et al. indicate that with IT, all patients experienced glycemic benefits, and that the least adherent patients and least informed patients (and parents) experienced the greatest glycemic benefit. This contradicts the usual consensus about behavioral risk factors for IT as outlined in the exclusion criteria during the DCCT feasibility phase, i.e., “behavioral problems or characteristics that in the opinion of the investigator are likely to result in poor compliance with treatment regimens of DCCT” (6). Several questions, however, remain from this research.

1) Did patients/families from low-, moderate-, and high-SMC groups in the...
IT condition participate equally in these extra supports? In other words, which subgroup of families made and kept appointments with the dietitian and psychologist and participated in monthly family groups most frequently in the IT groups, the low-, moderate-, or high-SMC families? We know from our recent research (7,8) at Joslin that extended contact can have a powerful role in facilitating diabetes management and improving health outcomes in youth with type 1 diabetes.

2. Will these glycemic benefits last over time, once families no longer have access to IT?

Long-term follow-up of the DCCT participants revealed that glycemic control in the IT patients deteriorated within the first year after concluding their participation in the resource-rich clinical trial. In fact, the significantly different average HbA1c levels of the IT patients and conventionally treated patients maintained over the DCCT (7.2 vs. 9.1%) converged at the end of the 4-year follow-up (7.9 vs. 8.2) (9). This raises the question: what will happen to the patients in the IT group of Wysocki et al. after participation in this clinical trial? Is it the intensive follow-up contact, intensive support, and more intense relationship with health care providers that drive glycemic improvement? Clearly, we hope that Wysocki et al. have the funding to continue to follow-up with their pediatric patients; doing so will allow them to investigate the stability and sustainability of the glycemic effect in IT patients across the three SMC groups in the absence of the intensive support provided over the 18-month study period. These findings raise larger and more daunting questions. How do we implement programs of IT in this era of shrinking resources and necessary resource allocation in chronic disease management? How do we translate and fund diabetes care of the quality and multidisciplinary scope seen in the DCCT and in the research of Wysocki et al. in our current health care marketplace outside the context of a clinical trial?

3. How did the level of physician satisfaction vary between the IT and UC group providers?

This is an important question because one-third of the SMC score was composed of physician satisfaction with the patient’s visit. Is there a possibility that patients/parents seeing improvement in blood glucose levels and with full access to multidisciplinary support felt encouraged to work together on diabetes management within the family? Is it also possible that clinicians seeing improvement in the family teamwork and glycemic control of these previously less well-controlled patients and families became more hopeful (about their own effectiveness as well as the child’s health prognosis), and thus were more positive in their interactions with patients and parents?

“Hope” is the thing with feathers—
That perches in the soul—
And sings the tune without the words—
And never stops— at all—
And sweetest— in the Gale— is heard—
And sore must be the storm—
I’ve heard it in the chillest land—
And on the strangest Sea—
Yet, never, in Extremity,
It asked a crumb— Of Me.
Emily Dickinson, 1861 (10)

Hope and encouragement fuel motivation for both patients and providers. Experienced diabetes clinicians have pointed out that the chronic nature and complexities of diabetes management affect providers as well as patients (11,12). Moreover, behavioral researchers have documented the profound importance of the patient-provider relationship to the success of patients’ diabetes management (13,14). In the IT group of the DCCT, the patient-provider relationship has been described as one where, “in many cases, participants and professionals became ‘family’” (2). In addition to the intensive treatment (self-management) required and extra health care support and follow-up contact afforded in IT, the encouragement and hope at the heart of IT may bring this sense of “family” to patient and provider, and may elusively contribute to important glycemic outcomes. The research of Wysocki et al. raises this unasked question: how is the patient-provider relationship changed during a clinical trial of IT in which neither patient nor provider is blinded as to the treatment group assignment? The possibility exists that mutual encouragement, the hope described by poet Emily Dickinson, persists in the “chillest land and on the strangest Sea” (clearly a picture of the challenging landscape of type 1 diabetes management), and plays a profound role in determining health outcomes by bringing much needed psychological benefit, “the tune without the words,” to both patient and provider.

BARBARA J. ANDERSON, PHD

From the Baylor College of Medicine, Texas Children’s Hospital, Children’s Nutrition Research, Houston, Texas.

Address correspondence to Barbara J. Anderson, PhD, Baylor College of Medicine, Texas Children’s Hospital, Children’s Nutrition Research, 1100 Bates St., Room 2054, Houston, TX 77030. E-mail: bja@bcm.tmc.edu.

© 2003 by the American Diabetes Association.

References


