Users Extol Continuous Glucose Monitors' Benefits

BY MIRIAM E. TUCKER Senior Writer

WASHINGTON — Use of continuous glucose monitoring appeared to significantly improve diabetes control, reduce the incidence of hypoglycemia, and diminish levels of diabetes-associated stress among patients surveyed at a diabetes center in Idaho Falls, Idaho.

The results from two anonymous surveys of patients with type 1 diabetes at the Rocky Mountain Diabetes and Osteoporosis Center are among the first data on continuous glucose monitoring (CGM) to come from a real-life patient setting rather than an industry-sponsored study. Although the numbers are small—54 and 58 patients, respectively, responded out of 150 to whom surveys were sent—the results are statistically significant and can be used to petition third-party payers for reimbursement, Jean Halford said at the annual meeting of the American Association of Diabetes Educators.

Insurance coverage for CGM has increased over the last year with the establishment of new billing codes, but it is by no means universal. "The biggest roadblock to early adoption of this technology and more widespread reimbursement has been and continues to be the lack of long-term clinically significant outcome data demonstrating benefit," said Ms. Halford, a licensed dietitian and certified diabetes educator at the Rocky Mountain facility, which is the largest diabetes practice in the state of Idaho.

The first survey used two tools. One, the Diabetes Distress Scale (DDS), is a validated 17-item, single-page questionnaire designed to assess emotional burden (for example, "feeling overwhelmed by the demands of living with diabetes"), physicianrelated distress (for example, "feeling that my doctor doesn't take my concerns seriously enough"), regimen-related distress (for example, "feeling that I am not sticking closely enough to a good meal plan"), and diabetes-related interpersonal distress (for example, "feeling that my friends/family don't appreciate how difficult living with diabetes can be").

Respondents rate each on a scale of 1-5, with 5 being the highest distress level (Diabetes Care 2005;28:626-31). The other tool was a multipage quality of life questionnaire developed by the Rocky Mountain Diabetes Center, also using a 1-5 scale.

Of the 54 respondents, 27 had stopped using CGM and 27 were continuing to use it at the time of the survey. The difference in usage time was 6 vs. 14.4 months, respectively. Compared with those who quit using CGM, those who continued using it had significantly lower levels of both physician-related distress (1.22 vs. 1.67) and regimen-related distress (2.46 vs. 3.03). Emotional burden was also lower for those who continued (2.77 vs. 3.23), but that difference didn't reach statistical significance.

Among another 54 diabetic patients

who had never used CGM, scores on the DDS were just slightly lower than those of the patients who continued to use CGM, with a mean overall score of 2.08 for the never-users and 2.20 for those who continued, compared with 2.62 for those who stopped. This finding suggests that, contrary to what some have suggested, the CGM doesn't increase stress by "overwhelming" the user with data, Ms. Halford said.

Future studies could look at DDS scores before and after CGM use to determine whether there might be a way to predict how a given patient might do with CGM. "We may be able to identify patients who need a different type of education, or those who aren't the best candidates for CGM," she said.

The Rocky Mountain Center's questionnaire inquired retrospectively about hypoglycemia before and after CGM use. Among all CGM users, the reported fear of hypoglycemia dropped from a score of 3.30 to 2.52, a statistically significant difference. The drop was significant for both those who continued using CGM (3.44 vs. 2.64) and those who quit (3.19 vs. 2.41). Fear of severe hypoglycemia dropped from 2.48 to 1.67 overall, from 2.70 to 1.89 among the continuing users, and from 2.24 to 1.44 among those who quit. Those values were also all statistically significant.

It's possible that for the quitters, even the short 6 months of use might have improved glucose control enough that they felt more confident in managing it themselves, or that those with hypoglycemic unawareness regained their symptoms to the extent that their fear was diminished, Ms. Halford suggested.

A follow-up questionnaire was sent to the same 150 patients, this time asking about actual rates of severe hypoglycemia requiring assistance from individuals nearby or emergency personnel. Among the 58 who responded, 33 reported having had at least one episode of severe hypoglycemia in the 6 months prior to using CGM, and 25 had not.

Fourteen reported an episode of severe hypoglycemia while using CGM, and 44 said they had no such episodes. That 33% reduction in severe hypoglycemia was highly statistically significant, with a *P* value of .0006.

"The costs of CGM are easily justified by the avoidance of one emergency room visit or automobile accident," Ms. Halford said.

There was a statistically significant drop in self-reported hemoglobin A_{1c} of 0.65 percentage points (from a baseline of 7.69%) among those who continued using CGM, while there was virtually no change in HbA_{1c} among those who stopped using CGM, with a drop of just 0.04 percentage points from a baseline of 7.8%.

"[These findings] now give us the tools we need to go fight the insurance companies to get reimbursement for patients who want to use CGM," Ms. Halford said.

Educational Approaches Need To Be as Diverse as CGM Users

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WASHINGTON — Users of continuous glucose monitoring are a surprisingly diverse group.

That conclusion, from a survey conducted by researchers at the Rocky Mountain Diabetes Center, Idaho Falls, Idaho, suggests that different educational approaches may be needed for different types of patients, said Becky Sulik, R.D., a certified diabetes educator who works at the center.

The 26 men and 28 women had an average age of 45 years; 19% were older than age 60 years. Most (85%) had been trained

to use the CGM by a certified diabetes educator who was employed either by the center or by the device manufacturer. Threefourths of the patients came in for at least one follow-up visit after receiving their training, but only 41% of the group had down-loaded the information from their receiver to a computer. Of those who did download, 75% discussed the results with the educator or physician.

In the context of formal education, patients ranged from those having several advanced degrees to those who dropped out of school in the eighth grade. "It wasn't just the highly educated patients" who used CSM, Ms. Sulik noted at the annual meeting of the American Association of Diabetes Educators.

Both staff and patients were initially very excited about real-time CGM technology when it first became available in 2006, but over time a more realistic picture has emerged. Although the technology does provide valuable information about glucose trends and warnings of highs and lows, it's important for patients to be told at the outset that they will still need to do finger sticks, and that those finger-stick values will be different from those of the sensor. Otherwise, they will perceive the discrepancy as an accuracy issue, she cautioned.

Patients also need to be prepared for the annoyance of the alarms going off at inconvenient times. And overall, they need to know that "it's not going to fix everything. ... It only provides information. Judgment is still needed," Ms. Sulik said.

Good candidates for CGM will have taken the time to learn about the technology and how it works; they are already testing at least four times a day as well as when they are suspicious about how they feel, and they are committed to working with their health care providers. Ideally, they also have computer access for downloading the data, and have either good insurance coverage or disposable income to pay for the technology.

When educating patients, diabetes professionals should tailor terminology to the patient's level of understanding, as words such as "calibration," "interstitial," or "initializing" may be unfamiliar. To explain the calibration process and why it's necessary, Ms. Sulik shows patients a picture of a roller coaster, with the plasma glucose represented as the first car and the interstitial glucose as the caboose, lagging behind. She uses the terms "tissue sugar" instead of "interstitial," and "warm up" instead of "initialization."

And, although diabetes professionals tend to use the word "sensor" to refer to the entire CGM system, it's important to explain to patients that the CGM actually includes three separate parts: the sensor, the transmitter, and the receiver.

As with all diabetes education, CGM training must be tailored to the individual patient. However, Ms. Sulik described the following several broad patient "types" that she and her colleagues have identified over time, and the educational approaches that might work best for each:

▶ "Deer in the Headlights." These patients are overwhelmed with the amount of data yielded by the CGM and may feel helpless and frightened. Such patients are often older and

not as comfortable with technology. They may even become immobilized and end up doing nothing with the data.

For these patients, the key is to start simple. It may take more than one visit to teach them how to use the device, with several follow-up visits to reinforce the skills. Get them to practice the basics of pattern management, and build their confidence by focusing on small successes, Ms. Sulik advised.

▶ "The Analyzers." These patients "really like the data" and may become so preoccupied with individual readings that they miss overall trends. They are often quick to make multiple changes without waiting to see the effect of one change before making more. Sometimes it's the parent or spouse who is the analyzer, Ms. Sulik said.

With these patients it helps to focus on pattern management. Tell them to "experiment" with cause and effect before making more changes. Prioritizing the changes is also key. For example, reducing insulin doses at certain times to correct low blood sugars may take precedence over correcting highs. "Patients should make a change and then wait and watch," she advised.

▶ "The Complainers." Every practice has a few of these. They tend to see the downsides of the technology—such as the nuisance of the alarms or what they perceive as the CGM's accuracy problems—rather than its benefits. With these patients, it's important to reset their expectations, to make sure that they're doing the basics, such as blood glucose monitoring, and to remind them of the reasons they were interested in the device in the first place.

Ultimately, CGM isn't for everyone. "Patients need to be willing to do the work to make the device successful," Ms. Sulik said.