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Overnight Blood Sugar Control Is Within Reach, Study Indicates

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Results from an ongoing study using Medtronic's *Paradigm* real-time insulin pump and continuous glucose monitoring system show early promise for overnight glucose control in diabetics.

The study - led by William Tamborlane, MD, deputy director of the Yale General Clinical Research Center -has tracked the experiences of 12 teenage patients with a prototypic mechanical pancreas based on the recently approved Medtronic technology (["The Gray Sheet" April 17, 2006](#), p. 8).

The patients used the system for roughly 36 hours, including one night's sleep and three meals, all within the clinic.

Medtronic's "open-loop" system - consisting of a subcutaneous glucose sensor, transmitter and insulin pump - requires confirmatory fingerstick testing and final dosage decisions from the user. But in the mechanical pancreas, a laptop relieves the patient of having to calculate and program the appropriate rate of insulin delivery.

The research has shown that short-term use of the mechanical pancreas allows for near-normal blood sugar control, co-investigator Stuart Weinzimer, MD, said at the Juvenile Diabetes Research Foundation's annual Global Diabetes Research Forum May 12.

"[Extreme] overnight blood sugars - [during] the time that one is most vulnerable to low blood sugar reactions - were almost completely eliminated, and meal-time blood sugar control was also quite superior to current...insulin therapy," Weinzimer noted.

The system isn't perfect, Tamborlane acknowledged in a May 17 interview with *The Gray Sheet*. "At times, some patients had undesirable glucose levels, ostensibly due to "delays in digestion, delays in glucose increasing in the interstitial space as opposed to the intravascular space, and then there's a delay because we're using a very practical route of insulin delivery,

which is under the skin," he said.

The doctors are now exploring the effectiveness of administering small "priming" doses of insulin "to get the insulin working a little bit," Tamborlane says. "Then you let the system take over."

Whatever its current shortcomings, diabetes management technology is approaching what at one time was considered, in Weinzimer's words, "just a dream": a closed-loop, fully automated artificial pancreas.

A first-generation artificial pancreas probably won't be 100% "closed," or self-sufficient, at all times, speculated Aaron Kowalski, JDRF director of strategic research projects. User intervention may still be necessary in some circumstances, he suggested.

But "if you can make automated insulin delivery overnight, [given that] the biggest worry [is] thinking about overnight glucose control when you put your child to bed...that would be a quantum step forward for people with diabetes," Kowalski observed.

In fact, he asserted, "the first company that crosses that threshold and puts out a product that says, 'You can put your child to bed overnight and run them at [near-normal glucose level] 100, and they'll go to sleep and wake up at that number' - every person with diabetes is going to want that product."

A home-based system of this kind may still be years away, JDRF says. In the interim, technology linking the glucose sensor and the insulin pump needs to be perfected, the group says.

Indeed, the predominant concern with a closed-loop system is "that you would have a sensor that was reading high and that, based on those data, the system would try to lower the blood sugar and actually drive the patient's actual blood sugar into the hypo[glycemic] range," Tamborlane said.

But that risk can be addressed fairly easily, he said, by allowing for a margin of error when setting a desired blood sugar value.

"Instead of trying to shoot for a normal blood sugar level of 80, where if you're off by 50% you might be [driven] into a low range...set it, the target, at 120," Tamborlane proposed. "If you could tell most families that their child would wake up on average at 120 every morning with no lows, they would be delighted."

In this study, investigators will use the mechanical pancreas in 15 patients. Further studies might use the technology outside the hospital setting, which will "truly be the proving ground for this type of technology," Weinzimer said.

- *Ryan Nelson*

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