For slumbering diabetics, a way to detect low blood sugar and stop insulin delivery

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New research could soon make it easier for people with type-1 diabetes to get a safe night's sleep, says a Stanford University School of Medicine scientist who led the study.

In a large trial conducted in patients' homes in the United States and Canada, scientists demonstrated that they could predict and prevent dangerously low overnight blood sugars in adolescents and adults with type-1 diabetes.

Very low blood-sugar levels can cause seizures or even, in rare cases, death. People with type-1 diabetes often sense warning signs of low blood sugar when they are awake, but not during sleep, explaining why 75 percent of diabetic seizures occur at night.

The new study, which will be published online May 7 in *Diabetes Care*, coupled a glucose sensor worn under the skin to an insulin pump that was connected wirelessly to a computer at the bedside. The computer ran an algorithm that calculated when a low blood-sugar level might occur and then temporarily suspended insulin delivery until the sugar level was trending upward. This occurred without waking the patient. The shutoffs reduced the cumulative time patients spent with low blood sugars during sleep by 81 percent, with only a minimal increase in nighttime glucose levels.

"A system like this should dramatically decrease diabetics' risk of having a seizure overnight," said Bruce Buckingham, MD, professor of pediatric

endocrinology at Stanford, who led the trial and is a co-author of the study. "Patients and parents will be able to have a better night's sleep, knowing that there is a much lower risk of severe hypoglcyemia at night." Buckingham is also a pediatric endocrinologist at Lucile Packard Children's Hospital Stanford.

Diabetics who use insulin pumps usually receive a low dose of insulin throughout the night; it is delivered by the pump through a small catheter inserted under the skin. In the past, researchers have tried other approaches to prevent low blood sugar during sleep, such as having glucose sensors trigger an alarm for a low blood-sugar level. This has only been partly successful because patients sleep through about 70 percent of the alarms. Since a person with diabetes would shut off their insulin pump if they had a low blood glucose, the next approach was to use the sensors' glucose values to suspend insulin delivery when low blood glucose was detected.

The new study involved 45 people, ages 15-45, with type-1 diabetes. Each person participated for about 42 nights, for a total of 1,912 nights. The patients slept in their own homes. Their insulin pumps were wirelessly connected to a laptop computer near their beds.

Each night, the algorithm on the computer was randomly assigned to be active or inactive and participants did not know whether the algorithm was active before they went to sleep. On treatment nights, the computer algorithm predicted whether blood sugar would fall below 80 milligrams per deciliter in the next 30 minutes, a threshold slightly above the 60 mg/dl level at which complications of low blood sugar set in. If the computer predicted lows, the subject's insulin pump was shut off until the subject's blood sugar was increasing.

In addition to the 81 percent reduction in time spent with low blood sugar, there were several other indicators that the treatment was useful.

The insulin pumps were shut off at least once during 76 percent of the treatment nights, and the time spent in episodes of low blood sugar that lasted two hours or more was reduced by 74 percent.

In the morning, median blood glucose was slightly higher after treatment nights, but still within a safe range. The blood-glucose sensors recorded similar percentages of nights with high blood-glucose values in both treatment and control conditions. Subjects checked their urine and blood each morning for ketones, an indicator of whether their sugar levels had become too high during the night. Ketone levels were similar after control and treatment nights. These results indicated that the insulin pump shutoffs were not putting subjects at risk from high blood sugars.

The research team is now expanding their investigations to a larger age group, including children ages 3-15. "A lot of parents whose children have diabetes are getting up night after night at midnight and 3 a.m. to check their children's blood-sugar levels," Buckingham said. "We think this type of system is going to make it much easier for them to feel comfortable about letting their child with diabetes sleep through the night with fewer overnight sugar tests. Parents will be able to get a better night's sleep, too."

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