Home Use of Artificial Beta Cells

By Veronica Hackenthal, MD [2]

Artificial beta cell systems and insulin pumps went head-to-head in two trials with type 1 diabetes patients.

Home use of a closed-loop artificial beta cell system could improve glycemia in patients with type 1 diabetes mellitus (T1DM), according to an article published online in the New England Journal of Medicine.

The article reports on two studies that included 33 adults and 25 children and adolescents who used artificial beta cells for 12 weeks at home. Participants who used the artificial beta cell had better glucose control, less hypoglycemia, and lower Hba1c (adults only) than those who used an insulin pump.

The artificial beta cell uses a control algorithm to independently monitor and increase or decrease insulin delivery based on real-time sensoring of glucose levels. In contrast, insulin pumps that link insulin delivery to sensors that continuously monitor glucose levels can only temporarily suspend insulin delivery based on preset glucose thresholds. These systems can decrease the risk of hypoglycemia, but cannot respond to hyperglycemia.

“The advantage of a closed-loop system is the responsive, graduated modulation of insulin delivery, both below and above the present pump regimen, which allows for improvements in the proportion of time spent in target glucose range and lowering of the mean glucose level without increasing the risk of hypoglycemia,” wrote lead author Roman Hovorka, MD, of the University of Cambridge and colleagues in the APCam Consortium and AP home Consortium.

Past studies of the artificial beta cell have suggested that it can improve glucose control and decrease the risk of hypoglycemia, but these studies have been limited to 6 weeks at most. The results come from two open-label multicenter, crossover randomized controlled trials. In each trial the artificial beta cell was used for 12 weeks, and insulin pumps were used for about the same amount of time. Participants were randomly assigned to use either the artificial beta cell system for 12 weeks, followed by sensor-augmented insulin pumps, or vice versa. The artificial beta cell did calculations every 12 minutes to figure out the insulin infusion rate needed to reach target glucose levels, then automatically sent these results wirelessly to the insulin pump.

The first study included 33 adults from UK, Germany, and Austria. Participants used the artificial beta cell day and night, and administered mealtime insulin using a standard bolus calculator.

The second study included 25 children and adolescents from three sites in the UK. Participants used the artificial beta cell overnight only.

Participants in both trials received no remote monitoring or supervision, and could perform their usual activities and eat foods of their choice. After the first two weeks, they could travel and use the system while driving. Target glucose levels were 70-180 mg/dL in adults, and 70-145 mg/dl in children.

Key results for the artificial beta cell vs. the pump:
• Adults:
  ♦ Amount of time spent in the target glucose range: 11% higher (95% CI 8.1-13.8, P<0.001)
  ♦ Mean glucose level: 11 mg/dL lower (-17to -6, P<0.001)
  ♦ Mean HbA1c: 0.3% lower (-0.5 to -0.1, P=0.002)
  ♦ Area under the curve for the period when glucose was <63 mg/dL (estimates the burden of hypoglycemia): 39% lower (24-51, P<0.001)
• Children and adolescents:
  ♦ Amount of time spent in the nighttime glucose target range: 24.7% higher (20.6-28.7, P<0.001)
  ♦ Mean nighttime glucose: 29 mg/dL lower (-39 to -20, P<0.001)
  ♦ Area under the curve for the time when day-and-night glucose levels were <63 mg/dL: 42% lower (4-65, P=0.03)
  ♦ Three severe episode of hypoglycemia happened with the artificial beta cell, all when the system was not in use because of low battery or the system was not turned on.
“[W]e found that extended use of a closed-loop system at home over a period of 12 weeks during free daily living without close supervision is feasible in adults, children, and adolescents with type 1 diabetes,” the authors concluded, “Improvements in glucose control and reduction in the burden of hypoglycemia were observed. Among adults, the glycated hemoglobin level was lower with the use of a closed-loop system day and night than with a sensor-augmented insulin pump, even when the insulin pump was adjusted appropriately.”

**Take-home Points**

- The closed-loop artificial beta cell uses a control algorithm to independently monitor and increase or decrease insulin delivery based on real-time sensing of glucose levels.
- Insulin pumps that use continuous blood glucose monitoring can decrease the risk of hypoglycemia, but do not respond to hyperglycemia.
- Two open-label multicenter, crossover randomized controlled trials in 33 adults and 25 children and adolescents found that using the artificial beta cell for 12 weeks resulted in better glucose control, less hypoglycemia, and lower HbA1c (adults only) than the insulin pump.

The study was sponsored by Abbott Diabetes Care, and DIasend. Two of the authors hold patents for closed-loop insulin delivery systems and a system for insulin delivery that uses various measurements-error models.


**Links:**

[2] [http://www.physicianspractice.com/authors/veronica-hackenthal-md](http://www.physicianspractice.com/authors/veronica-hackenthal-md)