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MiniMed 530G: An Insulin Pump with Low-Glucose Suspend Automation

The FDA has approved the MiniMed 530G (Medtronic), an insulin pump used in combination with a continuous glucose monitoring sensor (Enlite) that can stop delivery of insulin when interstitial glucose reaches a prespecified low level. It is the only sensor-augmented insulin pump available in the US with this capability.

THE DEVICE — The MiniMed 530G system is approved in the US for patients ≥16 years old. It has been available in Europe as the Paradigm Veo since 2009. When interstitial glucose reaches a preset low-glucose threshold, an alert sounds and the pump automatically stops insulin delivery. After 2 hours, the insulin infusion starts again automatically, but the patient can override the suspension and restart insulin delivery at any time. The MiniMed 530G system, including the Enlite sensor and threshold suspend feature, costs about $7000, according to the manufacturer.

CLINICAL STUDIES — In a 3-month trial (ASPIRE), 247 patients 16-70 years old with type 1 diabetes and nocturnal hypoglycemia were randomized to sensor-augmented insulin pump therapy with the threshold-suspend feature (Paradigm Veo) or to standard sensor-augmented insulin pump therapy (the control group). The threshold glucose values were set at ≤70 mg/dL initially and then to 70-90 mg/dL. After 3 months, the incidence of nocturnal hypoglycemic events was 32% lower (1.5 vs. 2.2 per patient-week) in the threshold-suspend group compared to the control group. The number of nights with ≥2 hypoglycemic events was 60% lower in the threshold-suspend group. There were 4 episodes of severe hypoglycemia, all occurring in the control group, and no episodes of diabetic ketoacidosis.¹

In another trial, 95 adults and children with type 1 diabetes were randomized to use of a sensor-augmented insulin pump with threshold suspension or to a standard insulin pump. After 6 months, the combined incidence of moderate and severe hypoglycemic events was significantly lower in patients using the pump with threshold suspension (9.5 vs. 34.2 per 100 patient-months).²

ARTIFICIAL PANCREAS SYSTEMS — The MiniMed 530G system has been described as an artificial pancreas. True artificial pancreas systems use computerized algorithms and data from real-time continuous glucose monitoring to automate insulin delivery from an insulin pump to prevent hypo- and hyperglycemia. No artificial pancreas systems are currently approved by the FDA. A 2-night, randomized, crossover trial compared an experimental artificial pancreas system (MDLogic) to a sensor-augmented insulin pump for nocturnal glucose control in 56 children with type 1 diabetes. There were significantly fewer episodes of nocturnal hypoglycemia with the artificial pancreas system than with the sensor-augmented pump (7 vs. 22).³

CONCLUSION — The MiniMed 530G system can suspend insulin delivery at a preset low-glucose threshold and has been shown to reduce the frequency of nocturnal hypoglycemic events.
