Difficulties in Monitoring the Glucose Status of Patients Undergoing Hematopoietic Stem Cell Transplantation

We were pleased to read the article by Hammer et al. in the March edition of *BBMT* [1], which complements and vastly expands on our earlier abstract [2]. Recognizing the need for a prospective randomized clinical trial to provide more insight into the relationship between transplantation mortality/morbidity and glycemia control, we embarked on such a trial in 2007. We randomized patients undergoing hematopoietic stem cell transplantation (HSCT) to “tight” blood glucose control, with a goal of < 125 mg/dL, using insulin/glucose infusions and the best available “real-time” glucose monitoring system (Guardian REAL-Time Monitor; Medtronic, Minneapolis, MN) versus a traditional insulin sliding scale. Our transplantation unit’s nurses underwent extensive training in glucose management using the monitor, and our local Medtronic representative provided excellent onsite support. In addition, a diabetologist evaluated the study patients during daily rounds. Unfortunately, despite these efforts, we were unable to complete the trial. The Medtronic device was unable to provide reliable, actionable glucose readings in the inpatient transplantation setting. This lack of reliability in glucose readings resulted in the need for frequent fingersticks to recalibrate and validate the monitoring device. Patients found this bothersome, and some eventually withdrew consent to participate in the study. This problem was addressed in the device’s Food and Drug Administration approval document, with the admonishment that monitor “values are not to be used directly for making therapy adjustments.” More worrisome than the frequent fingersticks were the numerous episodes of asymptomatic and symptomatic hypoglycemia occurring in patients assigned to the ”tight” glucose control regimen. These episodes were considered secondary to the fluctuations of oral intake seen as patients experienced gastrointestinal distress, mucositis, and corticosteroid use, making it very difficult to anticipate their insulin needs and safely maintain a blood glucose level < 125 mg/dL.

The unacceptably high rate of hypoglycemia, in combination with the technical limitations inherent with the implantable real-time glucose monitor, led to the termination of our trial. We would caution other investigators that the available real-time implantable glucose monitoring device remains unapproved and inadequate by itself for monitoring the blood glucose levels of patients undergoing HSCT.

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REFERENCES


George B. Selby, MD
Melody Mosallaei-Benjamin, MD
Venkataraman Kalyanaraman, MD
Andrew Lancaster, MD
Robert H. Scofield, MD
Oklahoma University Health Sciences Center
Oklahoma City, OK