Continuous Sensors

11 Glycemic Levels and Rates of Change Around Meals During a 40-Day Home-Use Study with the FreeStyle Navigator Continuous Glucose Monitoring System

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Background: Average blood glucose (BG) levels and variability are linked to the development of complications in patients with diabetes mellitus (DM).
Objective: To present an analysis of BG values and variability around mealtimes documented with the FreeStyle Navigator Continuous Glucose Monitoring System, an investigational device.
Methods: In 123 patients, BG levels were recorded every 10 minutes and meals were logged in this 40-day, home-use study. Meals were analyzed if they occurred between 6 AM and midnight and >4 hours after an earlier meal. BG levels and rates were determined 0 to 40 minutes before meals and 80 to 120 minutes after meals and fit to a multiple linear-regression model.
Results: After 20 days, both hypoglycemic and hyperglycemic ranges decreased significantly ($P < 0.05$, blinded vs unblinded study phase) based on American Diabetes Association guidelines. BG traces included 6627 analyzable meals. BG rates after meals decreased significantly more ($P < 0.05$) than before meals independent of study phase. However, BG levels before and after meals were slightly but significantly higher ($P < 0.05$) during the blinded period (avg ± SD, 154 ± 65 mg/dL, n = 3528 before, 180 ± 71 mg/dL, n = 3540 after) compared with the unblinded period (150 ± 61 mg/dL, n = 2908 before, 176 ± 67 mg/dL, n = 2869 after).
Conclusion: The availability of real-time continuous BG data may help improve BG control in patients with DM. Extended studies are needed to further assess the overall impact of continuous BG monitoring.