

Pilot Evaluation of a Prototype Critical Care Blood Glucose Monitor in Normal Volunteers

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Abstract

Background:

Availability of a highly accurate in-hospital automated blood glucose (BG) monitor could facilitate implementation of intensive insulin therapy protocols through effective titration of insulin therapy, improved BG control, and avoidance of hypoglycemia. We evaluated a functional prototype BG monitor designed to perform frequent automated blood sampling for glucose monitoring.

Methods:

Sixteen healthy adult volunteer subjects had intravenous catheter insertions in a forearm or hand vein and were studied for 8 hours. The prototype monitor consisted of an autosampling unit with a precise computer-controlled reversible syringe pump and a glucose analytical section. BG was referenced against a Yellow Springs Instrument (YSI) laboratory analyzer. Sampling errors for automated blood draws were assessed by calculating the percent of failed draws, and BG data were analyzed using the Bland and Altman technique.

Results:

Out of 498 total sample draws, unsuccessful draws were categorized as follow: 11 (2.2%) were due to autosampler technical problems, 21 (4.2%) were due to catheter-related failures, and 37 (7.4%) were BG meter errors confirmed by a glucometer-generated error code. Blood draw difficulties or failures related to the catheter site (e.g., catheter occlusion or vein collapse) occurred in 6/15 (40%) subjects. Mean BG bias versus YSI was 0.20 ± 12.6 mg/dl, and mean absolute relative difference was 10.4%.

Conclusions:

Automated phlebotomy can be performed in healthy subjects using this prototype BG monitor. The BG measurement technology had suboptimal accuracy based on a YSI reference. A more accurate BG point-of-care testing meter and strip technology have been incorporated into the future version of this monitor. Development of such a monitor could alleviate the burden of frequent BG testing and reduce the risk of hypoglycemia in patients on insulin therapy.

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Abbreviations: (ANOVA) analysis of variance, (BG) blood glucose, (BMI) body mass index, (FP) functional prototype, (IIT) intensive insulin therapy, (IV) intravenous, (MARD) mean absolute relative difference, (POCT) point-of-care testing, (YSI) Yellow Springs Instrument

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