J. Dairy Sci. 96:4514–4518
http://dx.doi.org/10.3168/jds.2012-6533

Short communication: Validation of a point-of-care glucometer for use in dairy cows

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ABSTRACT

The purpose of this study was to evaluate the diagnostic performance of a hand-held electronic glucometer (Precision Xtra; Abbott Diabetes Care Inc., Mississauga, ON, Canada) for cow-side use in dairy cattle. This device has been validated for measuring blood concentrations of β-hydroxybutyrate in dairy cows. This study was designed to assess the accuracy of whole-blood glucose measurements from the glucose meter relative to a reference chemical analyzer in a diagnostic laboratory. Duplicate samples were taken from the same cows at the same time, into blood tubes with either the glycolysis-inhibiting preservative sodium fluoride (NaF) or without preservative. Glucometer readings were taken on whole blood with no preservative, and laboratory measurements were conducted on serum preserved with NaF. Blood samples were collected from cows between 3 wk before and 5 wk after calving, including during a glucose tolerance test conducted 1 wk before expected calving. Passing-Bablok and Bland-Altman data analyses were used to evaluate the performance of the glucometer relative to the laboratory results. A strong correlation was observed in 709 samples from 81 cows between the hand-held meter and serum from samples preserved with NaF ($R^2 = 0.95$). Overall, 96% of measurements with the glucometer fell within the 95% confidence limits of analysis in the laboratory, although at higher-than-physiologic glucose concentrations (>5.2 mmol/L) the glucometer tended to overestimate. The hand-held glucometer appears suitable for rapid measurement of glucose under field conditions in dairy cattle.

Key words: glucometer, insulin resistance, glucose tolerance test, peripartum

Short Communication

Beginning in late gestation and continuing into early lactation, dairy cows are insulin resistant as glucose produced is partitioned primarily to the mammary gland (Hayirli, 2006). Changes in the responsiveness (hormone release in response to stimuli) or sensitivity (tissue responsiveness to hormone), or both, may result in insulin resistance (**IR**; Kahn, 1978). Due to the difficulty in discerning the relative importance of responsiveness and sensitivity in most cases, particularly in the transition period when different tissues are involved, IR is used as a general term for the phenomenon (Schoenberg and Overton, 2010). Glucose tolerance tests (**GTT**) can be used to measure IR (Lozner et al., 1941; Hayirli, 2006). This procedure consists of an intravenous bolus infusion of 50% glucose and monitoring of serum concentrations of glucose and insulin at regular intervals. A simplified GTT has been suggested by Matteo et al. (2009), whereby the ratio of glucose concentration 80 min after glucose infusion to that before infusion are compared, with a ratio of 1.05 proposed as an interpretive cut point. The same research group (Riuzzi et al., 2012) reported an association between the GTT ratio and postpartum BHBA concentration. However, the utility of the simplified GTT in general, and the predictive value of particular cut points for subsequent health outcomes have not been validated. Additionally, recent data indicate that glucose concentration at 3 DIM may be a useful predictor of pregnancy at first AI (Garverick et al., 2013). The ability to rapidly and inexpensively measure blood glucose concentrations cowside would be useful in assessing the metabolic status of dairy cows.

Several studies have reported the use of a variety of hand-held human electronic glucometers in dairy cattle, but few report data on validation or test characteristics (Leury et al., 2003; Fall et al., 2008; Galvão et al., 2010). One glucose and ketone hand-held meter (Precision Xtra; Abbott Diabetes Care Inc., Mississauga, ON, Canada) has been validated for diagnosis of subclinical ketosis in dairy cows, with a Pearson correlation coefficient of 0.95 (Iwersen et al., 2009). The ability of this device to accurately measure glucose in dairy cows was briefly evaluated with a reported coefficient of determination value of 0.56 (Oetzel and McGuirk, 2008).

The purpose of this study was to evaluate the diagnostic performance of a hand-held glucometer (Pre-

Received December 28, 2012.
Accepted April 2, 2013.
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cision Xtra) for cowside use in dairy cattle. Specific objectives were to (1) assess the accuracy of whole-blood glucose measurements from the Precision Xtra glucometer relative to the gold standard of a reference chemical analyzer in a diagnostic laboratory and (2) assess the suitability of the glucometer to classify cows as insulin resistant with a GTT.

A hand-held electronic glucose measuring system (Precision Xtra; Abbott Diabetes Care Inc.) was used in this experiment according to the label descriptions of the manufacturer. The system consists of a hand-held meter and electrochemical test strips. A 0.6-μL blood sample is applied to the sensor after the test strip is inserted into the meter. Once the blood progresses through the test strip via capillary action, it reacts with glucose oxidase to form gluconic acid, which then reacts with the potassium ferricyanide to create potassium ferrocyanide, which reacts with the metal of the test strip electrodes, creating an electrical current. The current generated is directly proportional to the amount of glucose present in the blood. After 5 s, the monitor displays the glucose concentration (mmol/L). The limits of quantification of the glucometer according to the test strip package insert are 1.1 to 27.8 mmol/L.

This experiment included 81 peripartum Holstein dairy cows housed at the University of Guelph (Guelph, ON, Canada) dairy research herds. These animals were part of an observational study reported separately (Wittrock et al., 2012). Animals were cared for according to the Canadian Council on Animal Care guidelines (CCAC, 2009) and fed and managed conventionally. Data were collected on enrolled animals from 3 wk before due date until 5 wk after calving between November 2010 and October 2011.

Duplicate blood samples (n = 709) were taken from the coccygeal vein or artery into vacuum tubes (Vacutainer; Becton Dickson, Franklin Lakes, NJ) with the preservative sodium fluoride potassium oxalate (NaF; the gold standard for glucose analysis, as NaF stops enzymatic activity of the glycolytic pathway; Peakman and Elliott, 2008) or without any preservative. After samples were obtained, the tubes were gently inverted 10 times to ensure thorough mixing with the preservative and placed in a chilled container. Glucometer readings were taken on the whole blood with no preservative immediately following collection. The glucose concentration (mmol/L) displayed on the glucometer was recorded. One meter was used for all of the glucose measurements. Blood was separated through centrifugation (1,000 × *g* for 30 min). Serum was collected, frozen, and stored at −20°C until submission to the Animal Health Laboratory (University of Guelph) for determination of glucose concentrations using a commercial reagent kit (GLUC3; Roche Diagnostics Corp., Indianapolis, IN) and auto-chemistry analyzer (Cobas c311; Roche Diagnostics Corp.). The analytical sensitivity of the glucose assay was 0.1 mmol/L, and the inter- and intraassay coefficients of variation were 2.9 and 2.4%, respectively.

Fifty-nine simplified GTT (Matteo et al., 2009) were conducted 1 wk before calving and consisted of an intravenous bolus infusion of 0.25 g/kg dextrose (Dextrose 50%; Vétoquinol Canada Inc., Lavaltrie, QC, Canada) based on standard estimated BW of 650 kg. Duplicate blood samples were taken immediately before dextrose infusion and at 10 and 80 min after. Animals were classified as insulin resistant if the ratio of blood glucose concentration at 80 min after dextrose infusion to before infusion was ≥1.05 (Matteo et al., 2009). We emphasize that this cut point is preliminary, under investigation, and requires validation.

Statistical analyses were performed using SAS (version 9.2; SAS Institute Inc., Cary, NC). Glucose concentrations obtained from the serum preserved with NaF and analyzed in the laboratory were considered the gold standard for all analyses. Samples from both routine data collection (at −3, −2, −1, 1, 2, 3, 4, and 5 wk relative to calving) and GTT were used, including 59 observations of circulating glucose at peak concentrations 10 min after the bolus infusion associated with the GTT. Pearson correlation coefficients were calculated. A Passing-Bablok linear regression correlation plot was performed, comparing the values from the glucometer to the gold standard laboratory measurements (Passing and Bablok, 1983). Using only correlation coefficients may not be suitable for evaluation of diagnostic test performance (Bland and Altman, 1986); therefore, a Bland-Altman plot was used to assess the residuals between the results from the Precision Xtra meter and the laboratory.

Using a GTT ratio of 1.05 (i.e., glucose concentration 80 min after infusion vs. just before infusion), the suitability of the Precision Xtra meter for assessing IR was assessed. The GTT ratios calculated from Precision Xtra glucose concentrations were compared with those calculated from the NaF samples analyzed in the laboratory. To identify an optimal test threshold for the glucometer relative to the proposed 1.05 laboratory result-based GTT ratio, glucometer GTT ratios were dichotomized. The optimal cut point was the value that produced the highest sum of sensitivity and specificity. Differences between GTT ratios measured by the glucometer and in the laboratory were evaluated using a paired *t*-test.

Figure 1 depicts a Passing-Bablok correlation plot between the glucose concentrations as measured by the laboratory and the glucometer. The Pearson correlation coefficient was 0.95 ($P < 0.001$). The intercept