

Background

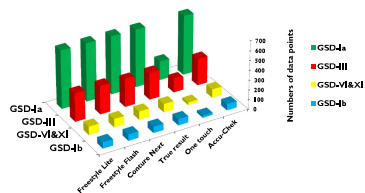
- The liver glycogen storage diseases (GSD) are marked by enzymatic deficiencies resulting in varying degrees of hypoglycemia
- Precise blood glucose measurements are required to determine treatment
- Euglycemia is essential for maintaining good metabolic values
- Glucometer accuracy can be affected by quality of sample, temperature, metabolites in the blood, etc.
- The accuracy of portable glucose meters is currently under scrutiny
- FDA is recommending that 95% of OTC glucose meters be accurate by $\pm 15\%$ at glucose concentrations < 100 mg/dL
- POC meters in the hospital setting should demonstrate 99% accuracy within $\pm 10\%$ for blood glucose concentrations > 70 mg/dL
- POC meters in the hospital setting should demonstrate 99% accuracy within ± 7 mg/dL at glucose concentrations < 70 mg/dL

Objectives

The purpose of the study was to compare the accuracy of over the counter meters (OTC) to standard lab results in the GSD population and to provide better recommendations of glucose meters to individual types of GSD affected patients

Methods

- 5296 venous blood glucose meter readings were performed from 35 patients with GSD during annual titration of their treatment
- Participants included 20 GSD Ia (56%), 7 GSD III (19%), 5 GSD VI & IX (14%), and 3 GSD Ib (8%) patients
- Metabolic control was assessed upon admission to the hospital
- Six commonly used meters were used to test hourly venous glucose concentrations
- Sample was applied to meters as outlined from predefined randomization
- Same sample was run simultaneously on a YSI glucose analyzer in a CLIA approved laboratory



Results I: Accuracy by GSD Types

Figure 1. Subjects' blood metabolites

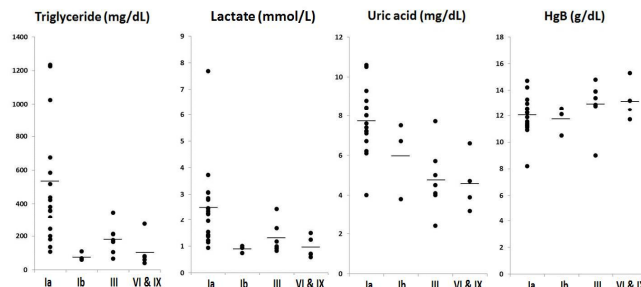
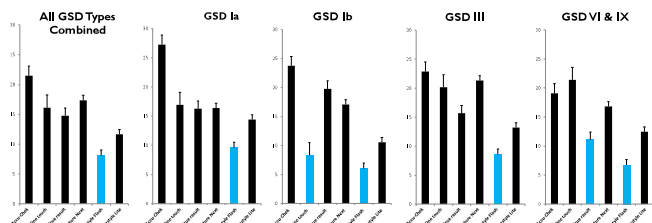


Figure 2. Percentage difference of meters from lab value



Results II: Accuracy by Metabolite in GSD Ia

Figure 3. Percentage difference by glucose level

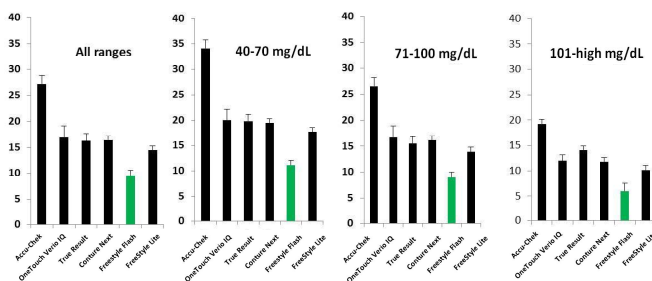
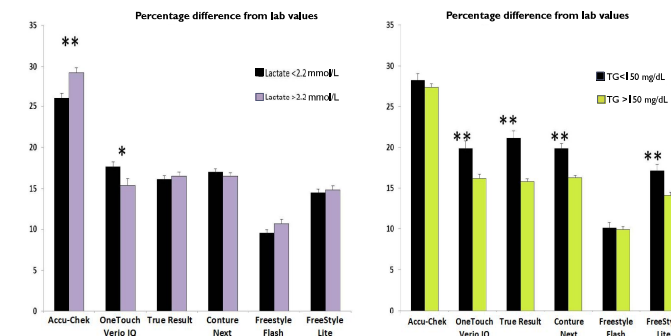


Figure 4. Percentage difference by lactate and triglycerides



*: $p < 0.05$ from t-Test, **: $p < 0.001$ from t-Test

Results Summary

- No significant interference from uric acid, cholesterol or hemoglobin
- All meters were less accurate in the hypoglycemic range
- Glucose meters are less accurate when blood glucose concentrations fall below 100 mg/dL
- Lactate can exacerbate inaccuracy in the Accu-Chek meter
- Elevated triglycerides lowered glucose readings on meters
- Inaccuracy in meters occurred across GSD types
- Few meters meet proposed FDA standard

Conclusion

- Significant meter to meter variability was documented
- Differences in meters may result in unrecognized hypoglycemia which can impact care in glycogen storage disease and other disorders of carbohydrate metabolism

Thank you to Emma Labrador RN, Dorothy Nichols RN and Charles Church RN for collecting and processing thousands of blood samples