

Automated Optical Glucose Measurement Comparison with Blood Gas and Clinical Laboratory Hexokinase Standard Methods

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ABSTRACT

Introduction

Management of blood glucose intraoperatively and perioperatively has been studied extensively over the past decade. Hyperglycemia and hypoglycemia negatively effect patient mortality and morbidity, and ability to maintain blood glucose at optimum concentration requires frequent and reliable measurements. The automated optical measurement technology embodied in TecMed, Inc.'s Surgical Suite Unit (the "SSU") was compared with hospital blood gas, and clinical laboratory hexokinase measurements in this limited human study.

Methods

Patient serum ultrafiltrate samples from hemoconcentrator effluent and blood samples were harvested and glucose measurements made utilizing a blood gas analyzer, a clinical laboratory hexokinase measurement method, a commercially available hand-held glucometer, and the SSU. Glucose measurements made with the SSU were statistically compared with the blood gas and hexokinase methods.

Results

All SSU measurements were within the FDA-preferred "A" area of the Clarke Error Plot, showed strong linear regression and correlation coefficients, and were within mean average deviation limits in Bland-Altman analysis.

Conclusions

The automated optical measurement system embodied in the SSU provided blood glucose measurement from patient serum ultrafiltrate that is a rapid, realtime, accurate alternative for laboratory glucose determination based on this data.