Equivalence of Venous and Capillary Point-of-Care Clozapine Levels

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Background – Clozapine is the most effective medication for treatment-resistant schizophrenia. Measurement of clozapine concentrations is critical for treatment decisions due to high pharmacokinetic variability and the risk of adverse drug reactions. Therapeutic drug monitoring of clozapine levels is strongly recommended in guidelines. However, for clinical utility, rapid turnaround time is essential. With point-of-care (POC) results are immediate, but require a finger stick. To eliminate the finger stick when a venous whole blood sample is available from the patient, we investigated the feasibility of measuring venous K_2EDTA whole blood clozapine levels using the MyCare Insite Clozapine Test on a POC device, MyCare Insite by comparing them to (1) venous serum and (2) capillary whole blood clozapine values. Methods - Matched venous serum, venous K_2EDTA whole blood, and capillary whole blood samples from patients taking clozapine were collected according to an IRB-approved protocol. Serum samples were measured in singlicate on a Beckman Coulter AU480 using a CE marked, Health Canada licensed, and FDA-cleared immunoassay. Whole blood (venous and capillary) samples were measured immediately after collection in duplicate using the MyCare Insite Clozapine Test immunoassay on the POC device. Passing-Bablok regression analysis was used to compare clozapine results between sample types. Results – Good agreements between all sample types were obtained, as evaluated by Passing-Bablok regressions. The regression line between venous serum results (x-axis) and capillary whole blood results (y-axis) was $y=1.052*x - 0.8$ ng/mL, $r=0.925$. The regression line between venous serum results (x-axis) and venous K_2EDTA whole blood results (y-axis) was $y=1.089*x + 4.9$ ng/mL, $r=0.947$. The regression line between capillary whole blood results (x-axis) and venous K_2EDTA whole blood results (y-axis) was $y=1.012*x + 10.5$ ng/mL, $r=0.914$. Precision of venous K_2EDTA whole blood samples was equivalent to precision of capillary whole blood samples (CV $\leq$ 11.3%). Conclusions - This study demonstrated that venous K_2EDTA whole blood clozapine samples show equivalent results to venous serum and capillary whole blood samples, and may be a suitable sample type for clozapine TDM measurements. Key words - clozapine, point-of-care, immunoassay, schizophrenia