Performance Evaluation of the CSAN Pronto Point-of-Care Whole Blood Analyzer for Regular Hematological Monitoring During Clozapine Treatment

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Abstract : Objective: The key barrier in Clozapine treatment of treatment-resistant schizophrenia (TRS) includes frequent bloods draws to monitor neutropenia, the main drug side effect. WBC and ANC monitoring must occur throughout treatment. Accurate WBC and ANC counts are necessary for clinical decisions to halt, modify or continue clozapine treatment. The CSAN Pronto point-of-care (POC) analyzer generates white blood cells (WBC) and absolute neutrophils (ANC) through image analysis of capillary blood. POC monitoring offers significant advantages over central laboratory testing. This study evaluated the performance of the CSAN Pronto against the Beckman DxH900 Hematology laboratory analyzer. Methods: Forty venous samples (EDTA whole blood) with varying concentrations of WBC and ANC as established on the DxH900 analyzer were tested in duplicates on three CSAN Pronto analyzers. Additionally, both venous and capillary samples were concomitantly collected from 20 volunteers and assessed on the CSAN Pronto and the DxH900 analyzer. The analytical performance including precision using liquid quality controls (QCs) as well as patient samples near the medical decision points, and linearity using a mix of high and low patient samples to create five concentrations was also evaluated. Results: In the precision study for QCs and whole blood, WBC and ANC showed CV inside the limits established according to manufacturer and laboratory acceptability standards. WBC and ANC were found to be linear across the measurement range with a correlation of 0.99. WBC and ANC from all analyzers correlated well in venous samples on the DxH900 across the tested sample ranges with a correlation of > 0.95. Mean bias in ANC obtained on the CSAN pronto versus the DxH900 was 0.07× 109 cells/L (95% L.O.A -0.25 to 0.49) for concentrations <4.0 × 109 cells/L, which includes decision-making cut-offs for continuing clozapine treatment. Mean bias in WBC obtained on the CSAN pronto versus the DxH900 was 0.34× 109 cells/L (95% L.O.A -0.13 to 0.72) for concentrations <5.0 × 109 cells/L. The mean bias was higher (-11% for ANC, 5% for WBC) at higher concentrations. The correlations between capillary and venous samples showed more variability with mean bias of 0.20 × 109 cells/L for the ANC. Conclusions: The CSAN pronto showed acceptable performance in WBC and ANC measurements from venous and capillary samples and was approved for clinical use. This testing will facilitate treatment decisions and improve clozapine uptake and compliance.

Keywords : absolute neutrophil counts, clozapine, point of care, white blood cells