

Cyclosporine Drug Levels: Comparison of the Architect 1000i with the Siemens Dimension RXL System

Sir,

The process of organ and bone marrow transplantation requires suppression of immunity in the recipient to ensure a successful engraftment of the transplanted organ. Immunosuppressant drugs used for this purpose like cyclosporine A, tacrolimus, sirolimus have a narrow therapeutic index and maintaining the drug levels in the needed therapeutic range is of utmost importance.

Two hundred whole blood samples collected in EDTA anticoagulant from 29 posthematopoietic stem cell transplantation patients between the periods of March 2014 and July 2014 as part of the investigations during the course of treatment were processed simultaneously on Architect 1000i and Dimension RXL analyzers. Architect 1000i by Abbott Healthcare is based on chemiluminescent microparticle immunoassay principle involving a manual pretreatment process. The Siemens Dimension RXL uses an immunoassay technique with a pretreatment process performed by the automated analyzer. Values obtained were analyzed statistically. To study inter-operator bias, three operators independently processed samples of whole blood with mean values of 57.46, 230.7, and 518.5 ng/mL, respectively, in a blindfold study. Single operator reproducibility was studied with the single operator processing thrice a sample with mean value of 114.3 ng/mL; with separate pretreatment procedures each time.

The Passing-Bablok regression analysis showed R^2 value of 0.9181, slope of 0.939, and Y-intercept of 4.978. The mean difference observed in the Bland-Altman plot was 2.541. Coefficient of variation (CV) percentage observed for inter-operator bias was 8.35, 7.76, and 2.8 for low, medium, and high-value samples, respectively. The single operator CV% was 1.76. Linearity observed for Architect 1000i was 39.6–1387.5 ng/mL and within-run precision CV% of 3.45. For Dimension RXL, linearity was 15.6–1288 ng/mL

and within-run precision CV% of 4.27. Limit of blank was observed as 0 ng/mL for both analyzers. CV% for internal quality control (IQC) results on Architect was 12% and 11% and for Dimension RXL 9.9 and 6%, respectively, for level 1 and 2 controls. Good correlation between the two methods shown in our study correlates with the findings from a study by Maine *et al.*^[1] which showed R value of 0.93–0.98, slope of 0.69–1.08, Y-intercept of –20.1–26.1, and bias observed was –76.2 to –6.7 ng/mL. Another study^[2] by Marina *et al.* showed R value of 0.974, slope of 0.74, and Y-intercept of –15.61 in 104 samples from 70 kidney transplant patients. The linearity and imprecision for RXL analyzer found in our study are comparable to a study by Terrell *et al.*^[3] Compared to the Dimension RXL analyzer, higher CV % for IQC results were observed in Architect along with a high CV% for inter-operator study, probably due to manual pretreatment procedure. The procedure is also labor-intensive with higher turn-around-time (TAT). Our findings suggest that the fully automated procedure with no requirement for manual intervention and lesser TAT gives an edge to the Dimension RXL analyzer as compared to the Architect 1000i.

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