Poster

[P27-2] P27-2: Anti-infective drugs (7): Antifungals

Chair: Yoh Takekuma, Japan

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[P27-2-1] Evaluation of the ARK Voriconazole II immunoassay on the Abbott Architect analyser

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Background

Therapeutic drug monitoring of voriconazole is necessary to ensure appropriate therapy. Aim:To evaluate the ARK voriconazole II immunoassay on the Architect-C8000 analyser for measuring human plasma voriconazole concentrations.

Methods

The study was performed following CLSI protocol(EP5-A3,EP9-A3,EP17-A2).Within-day imprecision:20 replicated analyses of three patient samples and of ARK voriconazole low(1mcg/mL), medium(5mcg/mL) and high(10mcg/mL) controls.Between-days imprecision:over a 20-day period using the three controls (low,medium,high) and patient samples; each sample was tested using two reagent lots and two runs per day.Limit of blank (LoB) and limit of detection (LoD):ten replicates of analyte-free sample (zero-calibrator) and low concentration calibrator (0.5mcg/mL). LoD= LoB+ 1.645 ($SD_{\text{low concentration calibrator}}$).Lower limit of quantification(LLoQ):a low concentration plasma sample was diluted with a voriconazole-free sample to ten different concentrations in 5 different analytical runs.Dilution linearity:five high voriconazole concentration plasma patients' pools were serially diluted with calibrator A. Analytical recovery:adding concentrated voriconazole into voriconazole-negative samples. Calibration curve stability tested on days 1,7,14 and 21 using the calibrators A-F and controls (low,medium,high) in duplicate, as were patient samples.Therapeutic range:1-5.5mcg/mL. Statistical analysis was carried out on SPSS 19.0.Plasma levels obtained with the ARK voriconazole were compared with serum levels generated with the LC-MS/MS from 50 patients ranging from 0.5 to 9mcg/mL.The concordance between these concentrations was evaluated with the intraclass correlation coefficient(CCI) with a 95% limit of agreement, and graphically with the Bland-Altman method.

Results

Within-assay coefficient of variation(CV) was 5.8% for low(mean:1.1mcg/mL), 4.1% for medium(mean:5.2mcg/mL) and 6.4% for high control(mean:9.9mcg/mL).The respective total CV for the patients' pool was 4.2% (mean:1.2mcg/mL), 4.8% (mean:3.4mcg/mL) and 5.3% (mean:6.6mcg/mL), respectively.Between-days imprecision was 6.2%, 5.7% and 6.5% for low, medium and high controls, respectively.LoB and LoD were 0.005 and 0.03mcg/mL, respectively. LLoQ was 0.5mcg/mL.Dilution linearity exhibited a high degree in the range studied (0.5-16mcg/mL,r=0.99).Recovery was 95%. Calibration curve was stable for 3 weeks.CCI was 0.97 (0.94;0.98) and this concordance was confirmed with the Bland-Altman analysis.

Conclusions

This study demonstrates that the ARK voriconazole immunoassay adapted to the Architect-C8000 analyser has a very good calibration curve stability, precision, reproducibility, sensitivity, specificity, and a good accuracy with the LC-MS/MS method. Therefore, this technology could be suitable for monitoring voriconazole in routine clinical practice.