Oral

# [O26-1] O26-1: Immunosuppressive drugs: assey and genotyping

Chairs: Stein Bergan, Norway / Maria Shipkova, Germany

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## [O26-1-1] Assessment of automated electrochemiluminescence immunoassay for everolimus

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### Background

Therapeutic drug monitoring (TDM) of everolimus is essential to maintain the safety and efficacy in personalized immunosuppressive therapy. Several methodologies to measure the blood levels of everolimus are available. This study was to evaluate a new automated electrochemiluminescence immunoassay (ECLIA, Roche Diagnostics, Co. Ltd.) for measuring blood concentrations of everolimus in clinical practice.

### Methods

Spiked whole blood samples were used to evaluate performance of ECLIA (linearity, lower limit of quantification, within-run and intermediate imprecision). Residual EDTA whole blood concentrations of everolimus in transplant patients were measured by ECLIA, latex agglutination (LA, Sekisui Medical, Co. Ltd.) (n = 116), and liquid chromatography with tandem mass spectrometry (LC-MS/MS, AB Sciex, Co. Ltd.) (n = 126). Characteristics of blood concentration measurement system on everolimus were shown in Table 1. In addition, we examined whether simultaneous measurement of everolimus and tacrolimus was available or not using residual EDTA whole blood samples (n = 51).

### Results

Linearity from 0.5 to 30 ng/mL was observed, and lower limitation of quantification of 0.22 ng/mL at 20% coefficient of variation was determined. Imprecision testing gave coefficients of variation less than 6% for both within-run and intermediate imprecision. Values obtained with the ECLIA were highly correlated with the LA (ECLIA= 0.98× LA + 1.25; r=0.96), and with the LC-MS/MS (ECLIA=1.13× LC-MS/MS + 0.99; r=0.95). A good correlation between simultaneous measurement and independent measurement was observed for everolimus and tacrolimus, respectively ($r > 0.99$).

### Conclusions

The ECLIA is a sensitive and useful method for routine TDM of everolimus.

Table1. Characteristic of blood concentration measurement system on everolimus

Zoom image