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Oral Session
Viral diagnostics in the immunocompromised

Clinical evaluation of a fully automated PCR assay for the detection of CMV-DNA in plasma of immunosuppressed patients receiving solid organ and bone marrow transplantation

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Objectives. Cytomegalovirus (CMV) is responsible of the most common infection after transplantation, resulting in significant morbidity, graft loss, and adverse outcomes. Quantification of CMV load (CMV-DNA) is central to the management of the infection and quantitative real-time PCR assays are the first-line choice for monitoring active CMV infection. CMV-DNA results significantly differ across DNA extraction and PCR systems, but also according to the biological matrix tested. Plasma (PL) and whole-blood (WB) both provide prognostic and diagnostic information regarding CMV infection. The presence of free virus in PL has been reported to more accurately reflect the degree of viral replication than in WB and PL offers the chance of a much simpler biological matrix for sample processing and result standardization. Aim of the study was to evaluate performances of the fully automated COBAS® AmpliPrep/COBAS® TaqMan® CMV Test (CAP/CTM; Roche Molecular System, Branchburg, NJ, USA) calibrated against the first WHO CMV Standard, for the detection of CMV-DNA on sequential PL specimens from immunosuppressed patients. CAP/CTM results were compared with those obtained from a standard real-time PCR test (ELITe MGB-CMV, Elitech Group, Italy) integrated with the Qiasymphony DNA extraction (Qiagen Italia, Milan, Italy) routinely applied on WB from the same series of patients.

Methods. PL specimens (n=206) from 50 patients routinely tested on WB for CMV-DNA were retrospectively evaluated with CAP/CTM CMV. The first WHO International Standard for CMV DNA (09/162) and a 2012 QCMD external quality assessment panel were used to verify assay performances according to reference values.

Results. Correlation between WB and PL was very good ($r=0.957$, $p<0.0001$) with 81.6% concordant samples. CMV-DNA kinetics as detected in PL and WB from consecutive specimens within the same patient, showed a similar trend with a significant CMV-DNA decline at day 21 of antiviral therapy both in PL and WB. Viral load was constantly 1 Log lower in PL than in WB (mean quantitation difference between WB and PL: 1.1 ± 0.8 Log copies/mL). CAP/CTM correlation with the WHO Standard was excellent ($r=0.999$, $p<0.0001$) with 100% detection rate at 50 IU/mL, as was with QCMD panel ($r=0.989$, $p<0.0001$).

Conclusions. Quantification of CMV-DNA in PL with the CAP/CTM provided reliable results for monitoring CMV infection in immunosuppressed patients with a simple, rapid and standardized procedure as required for the early initiation of antiviral therapy and monitoring response to treatment. CMV-DNA was detected in lower amounts in PL than in WB; however, the good correlation between results obtained with CAP/CTM on WHO and QCMD Standards raises the question of whether the lower values observed in PL are also due to differences in assay standardization. At the moment, one specimen type should be used in serially monitoring patients at high risk of CMV infection.