1166. Detection of Cytomegalovirus (CMV) in Saliva of Congenitally Infected Neonates

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Background. Congenital cytomegalovirus (cCMV) infection is a significant, but potentially under-recognized health threat. Approximately 1 of 150 neonates in the US is born with cCMV infection, with 20% exhibiting long-term health problems due to infection. Both targeted CMV testing of newborns with failed hearing screens and universal CMV screening of all newborns have been proposed as approaches to identify infected newborns early in life. Congenital CMV infection can be diagnosed by testing a newborn's saliva, urine, or blood by CMV qPCR or culture. Dried blood spots for use in qPCR assays have been shown to be a minimally sensitive specimen. Of the three specimens that are recommended, only saliva is simple, noninvasive and easy to collect.

Methods. In this study, we have validated a real-time (TaqMan) PCR assay for use in testing saliva samples from neonates for the presence of CMV. In conjunction with compatible clinical findings, a CMV positive PCR result forms the basis for a clinical diagnosis. The assay was shown to be specific for CMV, with no cross-reactivity detected for other human herpesviruses or for other human viral pathogens. Since CMV shedding levels from cCMV cases are known to be above the analytical limit of detection for the assay, and samples are collected in a nonsterile environment in which incidental CMV shedding may be present from other neonatal or pediatric patients, the reporting cutoff for this assay was set at 1000 IU/mL. Following analytical validation of the assay, stored (-80°C) residual de-identified clinical saliva samples were tested. The comparator assay was CMV cell culture, and the clinical diagnosis was used to resolve discrepant results.

Results. A total of 9 saliva samples, collected at approx. 1 month of age (or earlier) were tested by both assays. Two samples were negative by both assays and 6 samples were positive by both assays. A single sample was positive by qPCR but negative by cell culture; the qPCR value for this sample was 15,100 IU/mL. This infant had two positive urine cultures, a positive saliva shell vial culture and was clinically confirmed to have cCMV infection.

Conclusion. This study suggests improved sensitivity of qPCR over CMV cell culture for identification of neonates congenitally infected with CMV.

Disclosures. **M. Wissel**, Viracor Eurofins Laboratories: Employee, Salary **S. Cravens**, Viracor Eurofins Laboratories: Employee, Salary **A. Berg**, Viracor Eurofins Laboratories: Employee, Salary **A. Widen**, Viracor Eurofins Laboratories: Employee, Salary **M. Altrich**, Viracor Eurofins Laboratories: Employee, Salary **S. Kleiboeker**, Viracor Eurofins Laboratories: Employee, Salary

1167. Cytomegalovirus Management in Adult Hematopoietic Stem Cell Transplant Patients with Pre-Engraftment Viremia: A Single-Center, Retrospective, Descriptive Study

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Background. Scant data exist regarding cytomegalovirus (CMV) viremia in hematopoietic stem cell transplant (HSCT) recipients during the pre-engraftment period. The goal of this study was to describe management of CMV in neutropenic adult HSCT patients at our institution, and to assess the possible impact of different quantitative CMV PCR tests (QPCRs).

Methods. Post-HSCT monitoring at this center includes weekly CMV QPCR from plasma. Three different QPCR assays were used sequentially during the study period (1/2010–12/2015): two with lower limits of quantification (LLOQ) of 300 and 100 copies/mL through 4/2013, and after that the FDA-approved assay with LLOQ of 137 IU/mL. Medical records of first-time HSCT patients were reviewed. Pre-/peri-engraftment CMV was defined as detectable CMV DNA with [ANC] < 1000 cells/mm^3. Information collected included demographics, donor/recipient CMV serostatus, conditioning regimen, CMV QPCR and ANC results, dates of CMV treatment, CMV disease within 100 days, and death within 6 months of HSCT. Data were analyzed with STATA v14.

Results. Of 1151 total HSCT, 76 patients had a positive CMV QPCR when ANC < 1000 cells/mm^3. CMV was first detected a median of 12 days (0–48) post-transplant, and was above LLOQ at a median of 28 days (0–49). 71/76 (93%) were treated at a median of 33 days post-transplant (range 4–105 days), most with valganciclovir (40) or ganciclovir (30); 1 received foscarnet initially. 5 patients with low-level viremia were monitored without treatment. At initiation of therapy, median CMV level was 1471 (range 159–22,900) copies or IU/mL and ANC was 1202 (range 28–9680) cells/mm^3. Median treatment duration was 34 days (range 9–392). Only 2 patients had possible tissue-invasive CMV disease.

Conclusion. Ganciclovir and valganciclovir were used to treat most pre- and peri-engraftment CMV viremia, despite potential bone marrow toxicity. The LLOQ of different CMV QPCR tests did not affect the viral threshold for starting treatment. The time between first CMV DNA detection (median day +12) and initiation of treatment (median day +33) suggests clinicians waited for CMV DNA and/or ANC to rise before treating. With this deferred-treatment approach, the proportion of patients with tissue-invasive disease remained low.

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1168. Quality Assessment of Cytomegalovirus PCR Testing at an Academic Tertiary Referral Hospital

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Background. Cytomegalovirus (CMV) Polymerase chain reaction (PCR) test is a valuable tool for diagnosis and therapeutic monitoring of CMV infection. Academic medical centers with a high volume of organ transplant and immunosuppressed patients often utilize CMV quantitative and qualitative PCR testing. CMV qualitative PCR typically does not alter clinical management, and positive CMV qualitative test often needs follow up quantitative test. Despite its lack of usefulness, CMV qualitative PCR is often over-ordered and may unnecessarily raise the cost of hospitalization. We evaluated utility of CMV PCR testing at a tertiary care medical center.

Methods. We reviewed CMV PCR testing done from June 2015-November 2016 at Hahnemann University Hospital in Philadelphia, PA. CMV qualitative test was performed at LabCorp and CMV quantitative test was done at Focus Labs. Data collected included demographics, length of stay, and immunosuppression. Selected patients had either CMV qualitative PCR positive without follow up quantitative PCR, or negative CMV qualitative PCR with unnecessary CMV quantitative PCR ordered.

Results. We evaluated 226 CMV PCR test results including 162 qualitative and 64 quantitative CMV PCR in 139 patients. 39 (28%) patients had superfluous CMV testing. Mean age was 52.6 years, 61% were male, 46% were African American. Mean length of stay was 24 days. A half (N = 19,49%) were immunocompromised. 28 (17.2%) results were positive for CMV qualitative PCR, 7 (25%) of whom follow up CMV quantitative PCR were not sent. Thirty-two patients had negative CMV qualitative testing yet had CMV quantitative PCR sent. Six had redundant CMV quantitative PCR tests within 7 days likely resulting from delayed result report from send out. After performing cost analysis, these unnecessary tests would have saved $3930.

Conclusion. In our cohort, significant unnecessary CMV testing resulted in increased health care cost and patient discomfort. Positive Qualitative CMV PCR without Quantitative testing impairs diagnosis and treatment follow up. Given complicated testing algorithm and limited value of CMV qualitative PCR testing in the adult population, we plan to simplify CMV testing to quantitative only and perform in house testing to shorten result time.

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1169. Comparison of Roche and Abbott Cytomegalovirus Quantitative PCR Assays in Allogeneic Hematopoetic Cell Transplant Recipients

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Background. Human Cytomegalovirus (CMV) infection is prevalent in patients undergoing transplantion (Tx) and carries significant morbidity and mortality. Quantification of CMV viremia has improved with the use of standardized international units and new commercial real time PCR assays. This study compares the current Roche cobas AmpliPrep/cobas TaqMan CMV test (TM assay) and Abbott Molecular RealTi*m*e CMV Investigational Use Only assay (ART assay) for quantification of CMV viremia in patients receiving allogeneic hematopoietic stem cell transplants (aHSCT).

Methods. Prospective CMV positive patients, planned for aHSCT, were consented prior to Tx and followed weekly up 12 weeks post-transplant (PT) and once ~3 months PT. Matched paired plasma samples were processed and analyzed per manufacturer instructions, Henry Ford clinical laboratory processed the samples using the TM assay and the McKinnon Research Laboratory processed the paired samples using the ART assay. Parametric and non-parametric analyses were conducted as appropriate.

Results. Fourteen patients enrolled, 1 patient withdrew after entering, 1 patient died after 9 weeks PT (primary disease). Patients received peripheral blood stem cells and 84.6% received myeloablative chemotherapy. In paired samples, quantifiable CMV by TM and ART assays was detected in 6 (5 treated) vs. 8 of 13 patients respectively. ART assay detected CMV in all patients with positive paired samples, 1 detected in an unpaired sample and in 2 patients missed by TM assay (P = 0.021). Assays also differed in samples with no detection, detectable and quantifiable CMV viremia, with more frequent detection in the ART assay (P = 0.009). Time to quantifiable viremia PT by TM and ART assays was a median of 5 vs. 3 weeks (P = 0.026). Bland-Altman plot shows higher viremia levels quantified using the ART assay (P = 0.023). After week 4 PT, ART assay results inversely correlated with platelets counts (P = 0.013). CMV viremia tended to persist 1.9 weeks longer using ART vs.. TM assay (P = 0.07).

Conclusion. CMV viremia was quantified earlier, at higher levels and persisted in patients with aHSCT using the ART assay compared with the TM assay. Further study is warranted to determine clinical impact of ART assay on the management of CMV viremia.