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Implementation of a Targeted Congenital Cytomegalovirus Newborn Screening Program in a Tertiary Care Center in Lombardy Region, Italy.

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Background: and Objective Congenital cytomegalovirus (cCMV) is the most common non-genetic cause of sensorineural hearing loss (SNHL). SNHL can be identified at birth by hearing screening, which is now performed universally in all Italian regions. Neonates with cCMV-induced SNHL may benefit from antiviral therapy. However, a legal mandate for hearing-targeted cCMV newborn screening has not been introduced in Lombardy region yet. Here we present the results of the targeted cCMV screening program at our tertiary care center in Lombardy region.
Methods: We developed a targeted cCMV screening protocol for neonates admitted to our low risk neonatal unit (LRNU). These neonates receive hearing screening by OAE within 48 hours after birth. A second OAE is performed at 10-12 days of life in those who fail the initial test. If hearing failure (HF) is confirmed, urine CMV DNA has to be assessed within 3 weeks of life; in addition, hearing evaluation by ABR is performed. Medical records of all neonates admitted to our LRNU June 1st (protocol implementation)-October 31st, 2018 were reviewed, and cases with confirmed HF were assessed.
Results: During the study period, 1,005 children were born and 934 (92.9%) were admitted to our LRNU. An abnormal first OAE was found in 114 (12.2%) newborns. HF was confirmed in 9/114 neonates, and all of them were assessed for CMV DNA in urine. Median age at testing was 16 days (10-19 days); all 9 urine samples were negative for CMV. ABR assessment confirmed HF in 2/9 neonates.
Conclusions: Our results suggest that successful implementation of a targeted cCMV newborn screening program in a tertiary care center is feasible, especially if added to the established universal hearing screening workflow. Thus, steps to foster development of a CMV screening program in other centers in Lombardy region have been currently undertaken.
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Clinical Utility of the QuantiFERON®-CMV Assay in Congenital Cytomegalovirus (cCMV) Infection

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Background: The QuantiFERON®-CMV assay evaluates CMV-specific CD8+ cell mediated immunity (CMI). We analysed QuantiFERON®-CMV results in relation to clinical and laboratory data in cCMV.
Methods: The QuantiFERON®-CMV was performed in subjects with cCMV within day 14th of life (T0) and during the second month of life (T1). At the same time-points, blood and urine viral load (VL) were evaluated. Maternal, clinical and laboratory data were collected and correlated with QuantiFERON®-CMV results. Based on IFN-γ responses, QuantiFERON®-CMV results are: reactive (detectable CMV-specific CMI); non-reactive (absent CMV-specific CMI); indeterminate (absence of any CMI).
Results: Twenty subjects were enrolled, 7/20 (35%) symptomatic and 13/20 (65%) asymptomatic. Median age was 11 days (range 4-14) at T0 and 42 days (range 28-60) at T1. All symptomatic infants had non-reactive/indeterminate QuantiFERON®-CMV results at both T0 and T1; among asymptomatic infants, 11/13 (85%) had a reactive result at T0 and 12/13 (92%) at T1 (P=0.005, P=0.003). The duration of maternal infection was comparable between subjects with reactive and non-reactive/indeterminate results (15 weeks, range 7-36, versus 27 weeks, range 9-30, P=0.33). Blood VL was not significantly different between subjects with reactive and subjects with non-reactive/indeterminate results at T0 (3.3 log, range 2.6-5.1 log, versus 4.1 log, range 2-5.9, P=0.35), but it reached significance at T1 (2 log, range 2-4.7, versus 3.2 log, range 2-4.7, P=0.03); the number of subjects with complete VL suppression at T1 was 8/12 (67%) versus 1/7 (14%, P=0.05). Urine VL overlapped between groups at both time-points (P>0.05). At a median follow-up of 36 months (range 3-72), none of the subjects with reactive results and/or blood VL suppression at T1 developed sequelae.
Conclusions: QuantiFERON®-CMV assay results correlated with clinical presentation of cCMV infection and blood VL suppression. The combined use of QuantiFERON®-CMV, maternal and virological data may help predicting a good outcome in cCMV infection.
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