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Implementation and outcomes of a newborn screening protocol for congenital cytomegalovirus infection via saliva samples testing in a tertiary medical center

Statement of the Problem: Congenital CytomegaloVirus (cCMV) infection is the most common cause of non-genetic hearing loss in childhood, which might be underestimated due to the recognition of most infected newborns lacking clinical manifestations at birth. We conducted a prospective study of newborn screening for cCMV infection via testing CMV PCR in saliva.

Methodology & Theoretical Orientation: Neonates who admitted to our hospital in the period spanning from Mar 2018 to Dec 2019 were enrolled in this study. Dried saliva swabs were collected and investigated for CMV-DNA. Newborns with any of positive screening-results are referred to confirm the diagnosis using urine PCR or cultures. Newborns with confirmed cCMV infection were suggested for scheduled follow-up of auditory function and neurodevelopment evaluation for 2 years.

Findings: Of the 1684 newborns in northern Taiwan during study period, nine has positive results of saliva samples. Of positive cases, seven newborns were confirmed cCMV infection and one refused to further study. In 4 cases with discordant findings the discrepancy was due to false-negative (n = 3) or false-positive (n = 1) PCR results in saliva. PCR in saliva showed a positive predictive value of 77.8% compared to urine. The 3 false-negative cases had a significantly lower level of viral load in urine than the 7 cases with concordantly positive results had ($p < 0.0001$; Mann-Whitney test). The incidence of cCMV infection is 0.65%. Two cases with cCMV infection failed the hearing screening and had diagnosis of mild hearing impairment at 1-month-old. These cases with confirmed cCMV infection had auditory and neurodevelopmental evaluation at age of 12 and 24 months. All of these cases had reports of normal neurodevelopmental performance, except one of them had mild hearing impairment.

Conclusion & Significance: Saliva qPCR is a feasible approach for screening of congenital CMV infection. Newborn screening for asymptomatic cCMV infection might contribute to late-onset auditory and neurological sequelae monitoring and early intervention.

Audience Take Away Notes

- To implement a universal cCMV newborn screening using saliva samples and follow-up protocol
- The diagnosis of cCMV infection using saliva samples is a non-invasive and efficient method
- From the perspective of public health, this study provided information about the epidemiology and long-term outcomes of asymptomatic cCMV