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Standard heel-stick test ineffective at screening for CMV in newborns, UT Southwestern researchers find

DALLAS – May 4, 2010 – A national study involving a UT Southwestern Medical Center neonatologist and pediatric infectious diseases specialist suggests that a screening test routinely performed in newborns is not very good at identifying cytomegalovirus (CMV) infection, a leading cause of hearing loss in children.

The findings, published in the April 14 issue of the *Journal of the American Medical Association*, suggest that testing blood drawn from a newborn's heel has limited value in detecting CMV infection.

The heel-stick procedure involves pricking a newborn's heel and drawing a small amount of blood that is then absorbed onto a filter paper and dried. The dried blood is analyzed for several diseases including sickle cell disease. Because the procedure already is used to test for several metabolic and genetic disorders, researchers hoped it would be a good candidate for a universal screening program for CMV.

"Our findings tell us that if we rely on the standard heel-stick test to detect CMV, more than half of the babies who are infected will be missed," said Dr. Pablo Sanchez, professor of pediatrics at UT Southwestern and a co-author of the study. "The fact that this screening test is virtually ineffective has major public health implications because congenital CMV infection is the most common nongenetic cause of hearing loss in the United States."

Each year, 30,000 to 50,000 U.S. infants are born with CMV, the most common infection passed from a mother to her unborn child. Although only about 10 percent of infected babies have any clinically detectable abnormalities, half of those with clinical signs and 10 percent to 15 percent of those who appear well are at risk for developing hearing loss.

The study is part of a multicenter investigation seeking to find the most effective screening test for CMV infections in newborns and study the natural history of hearing loss among these babies. Currently, the only way to identify accurately a CMV infection is to culture a urine or saliva sample collected from the patient, a process unlikely to be widely adopted because it is labor-intensive and requires a tissue culture facility.

(MORE)

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Prior research has shown that dried blood spots can be used to identify CMV infection. Because no studies have compared it to the gold standard CMV rapid culture test, however, researchers have been unable to say whether the heel-stick method is effective at identifying all infected babies.

For the study, the researchers used a new molecular diagnostic technique, polymerase chain reaction (PCR), to analyze dried blood samples obtained using the heel-stick procedure from more than 20,000 infants born between March 2007 and May 2008 at seven medical institutions nationwide, including Parkland Memorial Hospital in Dallas. Parkland has one of the country's largest and busiest obstetrics services, with about 16,000 births a year. Attending physicians are faculty members of UT Southwestern's obstetrics and gynecology and pediatrics departments.

Of the more than 20,000 babies screened in this study, 92 were confirmed to have congenital CMV infection. The CMV rapid culture method identified all but one of those children.

In contrast, of the 11,422 children screened with a basic version of the diagnostic test of dried blood spots, only 17 out of 60 infected children were identified. Eleven out of 32 infected babies were identified in a group screened with a slightly more sensitive test.

The next step, Dr. Sanchez said, is to determine whether using the molecular technique to analyze saliva samples rather than blood spots is as effective as the CMV rapid culture test.

The project is part of the ongoing CMV and Hearing Multicenter Screening (CHIMES) Study. The other participating centers are the University of Alabama at Birmingham; Saint Peter's University Hospital in New Brunswick, N.J.; the University of Mississippi Medical Center in Jackson; the Carolinas Medical Center in Charlotte, N.C.; the University of Pittsburgh and the Children's Hospital of Pittsburgh; and the University of Cincinnati and Cincinnati Children's Hospital Medical Center.

The study was funded by the National Institute on Deafness and Other Communication Disorders, part of the National Institutes of Health.

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