PUBLIC RELEASE: 20-NOV-1996

Group B Strep Vaccine Shows Promise In Clinical Studies

NIH/NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

A major step toward developing a vaccine to prevent infections with Group B streptococci bacteria, an important cause of infant disease and death, has been reported by researchers supported by the National Institute of Allergy and Infectious Diseases (NIAID). The study results appear in the Nov. 15, 1996, issue of The Journal of Clinical Investigation.

An experimental vaccine against one type of Group B strep stimulated strong immune responses in human volunteers. Later, in laboratory experiments, antibodies isolated from the volunteers neutralized the same type of Group B strep bacteria and prevented infection in newborn mice that were exposed to it.

"We are very excited about this important clinical finding," says Pamela McInnes, D.D.S., project officer for NIAID's Group B Streptococcal Initiative, a program begun in 1992 to develop a Group B strep vaccine. "This work provides the most promising evidence to date that we're getting closer to finding an effective vaccine."

Ten to 30 percent of all women are asymptomatic carriers of Group B strep, harboring the bacteria in their genital tracts. During childbirth, the bacteria is transmitted to approximately half of all infants born to these women. Nearly two of every 1,000 infants in the United States develop invasive infections, which can cause pneumonia, meningitis and other serious illnesses, usually within the first three months of life. Half of all infants who develop Group B strep meningitis experience long-term neurologic problems, including seizure disorders and mental retardation. About 10 percent of infected infants die.

"Studies have shown that babies who get Group B strep disease are born to women who lack antibodies to the bacteria," explains Dennis L. Kasper, M.D., lead author of the current study. "The good news, however, is that women who have antibodies to Group B strep pass those antibodies to their infants during pregnancy. Those antibodies protect the infants from infection after they are born."

For more than a decade, Dr. Kasper and his colleagues at Brigham and Women's Hospital in Boston have tried to develop a vaccine that would protect infants from Group B strep by stimulating the production of antibodies in pregnant women. Theoretically, the maternal immunity generated by such a vaccine would cross the placental membranes and protect the newborn for the first few months of its life, when most Group B strep disease occurs.

The Group B strep bacterium is enveloped in a complex sugar molecule called a polysaccharide capsule. Because it is known to play a key role in stimulating the production of antibodies to Group B strep, the capsule is a logical vaccine candidate. However, previous studies supported by NIAID found that immunization with the purified capsule molecule produced insufficient amounts of antibody in human volunteers. Those studies led Dr. Kasper and his colleagues to try to boost the vaccine's performance by chemically linking, or conjugating, the capsule to tetanus toxoid, a protein that has been used to increase the immune-stimulating properties of several other vaccines.

Media Contact

John Bowersox
jbowersox@flash.niaid.nih.gov
301-402-1663

@NIAIDNews

http://www.niaid.nih.gov

In the current study the researchers compared this so-called conjugate vaccine with its predecessor. Under the direction of Carol J. Baker, M.D., an NIAID-funded investigator at Baylor College of Medicine in Houston, 100 women of child-bearing age received either the conjugate vaccine, the pure polysaccharide vaccine or a placebo injection. The conjugate vaccine stimulated the production of much higher levels of antibody than did the pure polysaccharide vaccine. In addition, linking the capsule to the tetanus toxoid protein did not affect the function of the resulting antibodies--in test tube experiments, antibodies produced by either vaccine neutralized Group B strep equally well.

Dr. Kasper, Dr. Baker and their colleagues then injected pregnant mice with antibodies isolated from women immunized with the conjugate vaccine. Upon exposure to Group B strep bacteria, nearly three-fourths of the offspring born to these mice were protected from infection. Offspring born to mice that had been injected during pregnancy with human serum lacking Group B strep antibodies died after exposure to the bacteria.

"These findings demonstrate that the antibodies produced by the conjugate vaccine are able to cross the placental membrane and could confer protection against Group B strep to the fetus," says Dr. Kasper.

The vaccine used in the current study was a monovalent product--designed to protect against just one of the various types of Group B strep that cause disease in infants. Ultimately, a multivalent vaccine, providing protection against all types, will be needed. Acknowledging that much more work remains before a Group B strep vaccine reaches the marketplace, Dr. Kasper says that the conjugate vaccine developed by his group provides a blueprint for subsequent vaccines.

"We're definitely headed in the right direction," he says. "This is a prototype of what Group B strep vaccines will look like."

Prior to developing a multivalent vaccine, Dr. Kasper and his colleagues are constructing monovalent conjugate vaccines against other types of Group B strep and testing them in animals and humans. Preliminary results, he says, have been encouraging. A clinical trial using two monovalent vaccines in combination could begin within the next few months. Such studies, he explains, are necessary to ensure that the immune response to one type does not adversely affect the immune response to another.

NIAID, a component of the National Institutes of Health (NIH), conducts and supports research to prevent, diagnose and treat illnesses such as AIDS and other sexually transmitted diseases, tuberculosis, asthma and allergies. NIH is an agency of the Public Health Service, U.S. Department of Health and Human Services.

###

NIAID press releases, fact sheets and other materials are available on the Internet via the NIAID home page at http://www.niaid.nih.gov.