Tissue-cultured smallpox vaccine appears promising

March 10 2009

Administration of a tissue-cultured smallpox vaccine showed signs of an effective vaccine response with no serious adverse events, according to a study in the March 11 issue of *JAMA*.

"The threat of smallpox bioterrorism has prompted reconsideration of the need for smallpox vaccination. Serious adverse events associated with first-generation vaccines such as the New York City Board of Health (Dryvax), Lister, and Ikeda strains have raised obstacles to vaccination campaigns in the United States," the authors write. They add that certain second-generation vaccines are also often accompanied by a high frequency of adverse events. "Developing a vaccine that is safer than first-generation vaccines yet highly immunogenic [producing immunity or an immune response] is crucial to constructing a prevention plan in the event of bioterrorist attack."

Tomoya Saito, M.D., Ph.D., of Keio University, Tokyo, and colleagues examined the clinical and immunological responses to the LC16m8 vaccine in adults who had been previously vaccinated (n = 1,692) and in those who had not (n = 1,529). LC16m8 is a live, attenuated (reduced in strength), tissue-cultured third-generation vaccine that was administered to more than 100,000 infants in Japan between 1973 and the beginning of 1976. The adults in this study, who are in the Japan Self-Defense Forces, received the LC16m8 vaccine between 2002 and 2005. Vaccinees were examined 10 to 14 days after vaccination to determine if they had developed a major skin reaction ("take"; a measure of immune response). The researchers monitored vaccinees for adverse events for

30 days after the vaccination.

The researchers found that administration of the vaccine was associated with high levels of seroconversion (development of antibodies) in adults who were not previously vaccinated and yielded an effective booster response in some previously vaccinated individuals. Seroconversion or an effective booster response among the individuals with take was elicited in 37 of 41 (90.2 percent) participants who had not been vaccinated before and in 93 of 155 (60.0 percent) previously vaccinated participants. The overall proportion of clinical take was significantly higher in primary vaccinees (1,443/1,529 [94.4 percent]) than in revaccinees (1,465/1,692 [86.6 percent]).

"Appropriate training in vaccination technique may help achieve a higher proportion of takes, because we observed a higher proportion of takes in later vaccination rounds," the authors write.

One case of allergic dermatitis and another of erythema multiforme (a rash), both of which were mild, were suspected to be caused by vaccination. No severe adverse events were observed.

"We demonstrated the immunogenicity of LC16m8 vaccine in vaccinia-naive adults by a single vaccination. LC16m8 vaccine also induces a good booster response in previously vaccinated individuals. Our study also offers supportive evidence for the safety of LC16m8 vaccine in adults; LC16m8 vaccine appears to be a viable alternative to first-, second- and other third-generation vaccines in a smallpox preparedness program," the researchers conclude.

Source: JAMA and Archives Journals (news : web)