

Abstract

Background:

Because the vaccine was not manufactured over 20 years ago in most countries, the potential for a bioterrorism using smallpox has led to an alarm whether current stocks of smallpox vaccine are enough.

Objective:

To evaluate the potential to increase the supply of smallpox vaccines by diluting the vaccinia virus of Lister strain in vaccination of vaccinia-naïve and previously vaccinated subjects.

Design and subjects:

A total of 219 enrolled subjects (97 vaccinia-naïve and 122 previously vaccinated) were enrolled from February 10 to October 31, 2003 in this prospective, single-blinded study. Vaccinia-naïve subjects (aged 20 to 23 years) were randomized to receive either undiluted or diluted (1:5, 1:10) smallpox vaccines, and previously vaccinated subjects (aged 24 to 65 years) were randomized to receive either undiluted or diluted (1:10, 1:30) smallpox vaccines.

Setting: a national university hospital

Measurements:

The main measure was the rate of clinical success of vaccination, defined as the presence of a vesicular or pustular lesion at the inoculum site following vaccination. The second measure was immunological success rate, including significant T cell or antibody responses to vaccinia virus after vaccination.

Results: Except two subjects who received 1:30 diluted vaccine, the vaccination of all of the vaccinia-naïve and previously vaccinated subjects, who received undiluted or diluted vaccines, was successful clinically. All enrolled subjects had significant vaccinia-specific T cell and antibody responses. No difference in response to vaccine in different age group. The diluted vaccines were not associated with decreased local reactions or adverse events when compared with undiluted vaccines. However, local reactions were more marked and most adverse events were more frequently observed in vaccinia-naïve subjects than observed in previously vaccinated subjects. No serious or life-threatening events were noted.

Conclusion:

With Lister strain of vaccinia virus, the smallpox vaccine can be safely used as 1:10 dilution in vaccinia-naïve subjects and 1:30 dilution in previously vaccinated subjects if viral titer $\geq 10^8$ and $10^{7.5}$ pfu/mL after dilution,

respectively.

Keywords: Bioterrorism ; Smallpox ; Vaccinia virus ; Lister strain