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Perspective

Significance of Virosomes Targeting HIV-1 in Rhesus Macaques

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DESCRIPTION

Chinese-origin Rhesus Macaques (RMs) were previously protected against vaginal SHIVSF162P3 challenges by a virosomal vaccination that induces systemic/mucosal anti-HIV-1 gp41 IgG/IgA. Here, we used intramuscular priming/intranasal boosting (n=12/group) to evaluate its effectiveness in RMs of Indian ancestry. Group L combined virosome-rgp41+virosome-P1, Group M got placebo virosomes, and Group K received virosome-P1-peptide alone (harbouring the Membrane Proximal External Area). No neutralizing antibodies were produced after vaccination although plasma binding was. After the seventh SHIV challenge, only one animal from Group L was chronically infected compared to six controls.

IgG phenotypes and effector functions were examined in plasmas and sera; the former revealed that protection in Group L was substantially correlated with enhanced binding to FcR2/3(A/B) at various time points, as did some IgG measures. Vaginal washes revealed low-level anti-gp41 IgGs and IgAs, reflecting a 1- to 5-fold excess over the gp41 content of the SHIV inoculum, which may help to explain why protection was lost once the challenge-virus dose was increased. During the first seven Simian-Human Immunodeficiency Virus (SHIV) challenges in Indian-origin RMs, virosomal gp41-vaccine effectiveness was demonstrated when the SHIV inoculum had at least 100 times more HIV RNA than acutely infected men's semen.

The cooperation between systemically administered IgG1 and mucosally applied dimeric IgA2 monoclonal antibodies, which as single-agents provided no/low protection-but when combined, prevented mucosal SHIV transmission in all passively immunized RMs, is a parallel to the vaccine protection provided by virosome-induced IgG and IgA. Almost 40 years ago, the first instances of the undiagnosed acquired immunodeficiency syndrome in young people-later known as AIDS-were documented, and the causal culprit, HIV-1, was identified in 1983. HIV has killed 32.7 million people and infected 75.7 million people since the AIDS pandemic began (UNAIDS). Including sexual and neonatal transmission incidents, mucosal exposures cause around 90% of all new HIV infections.

The major infection foci for HIV infection are generated in the vaginal and rectal tissues during sexual transmission. From these foci, the virus travels to the intestines and other host organs. CCR5 is almost always the coreceptor used by newly transmitted HIV strains (R5 strains), and they can be challenging to neutralise (tier 2 strains). Typically, a newly infected person initially has a single dominant strain, the so-called transmitted founder virus. Even if the source person carries numerous HIV quasi-species, this is still the case. There is no safe and effective vaccine against HIV/AIDS despite the best efforts of numerous organizations.

With the exception of the RV144 study, which demonstrated a 31.2% decrease in the risk of HIV infection among vaccination recipients as compared to those who received a placebo, many Phase 3 clinical studies revealed a lack of effectiveness. In studies conducted in Non-Human Primate (NHP) models or people, the majority of vaccination techniques using HIV envelope immunogens concentrated on gp120, gp140, or gp160 and did not involve evaluations of mucosal immune responses. Studies of the Robert-Guroff team, which examined the delivery of vaccine antigens to the mucosa via intratracheal or intranasal routes, are notable outliers. Additionally, when administering subunit vaccines, only one parenteral route or occasionally one mucosal administration has been used; combination mucosal and Intramuscular (IM) vaccinations, as was the case with virosomal vaccines, are far less common.

For maximum protection of various mucosal entry points, some have hypothesized that a successful HIV/AIDS vaccine must be able to elicit both systemic and mucosal immune protection. Yet, it is difficult to induce robust immune responses in a variety of nearby and distant mucosal tissues as well as in the systemic compartment because of the segmented mucosal and systemic immune systems. Traditional parenteral vaccination by the Intramuscular (IM) or Subcutaneous (SC) methods can cause circulating B and T cells, although they usually stay mostly in the periphery. In order to generate both systemic and mucosal anti-HIV immunity, the idea of an HIV vaccine vaccination regimen combining the traditional intramuscular immunization route with mucosal boosting *via* the Intranasal (IN) route was developed.

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Unadjuvanted influenza virus-based virosomes displaying HIV gp41 antigens were used to test this significantly different vaccination approach. Chinese-origin Rhesus Macaques (RMs) were used to measure the vaccine's effects on systemic and mucosal Antibody (Ab) responses after intravaginal Simian-Human Immunodeficiency Virus (SHIV) challenges were given to the RMs. The highly conserved Env regions seen in numerous HIV clades and strains served as the source of the gp41 antigens. These virosomes are lipid-based, *in vitro*-reconstituted influenza virus particles that lack nucleic acids and are therefore not contagious. To create virosome-P1, one population of virosomes was put together to exhibit Peptide 1 (P1), an expanded form of the Membrane Proximal External Region (MPER) of HIV gp41, on its surface. A different population of virosomes was shown to include recombinant, shortened gp41 (virosome-rgp41), which is missing the immunodominant region that includes the KLIC motif and other domains similar to human host proteins. The combination vaccination formulation known as MYM-V201 consists of virosomes-P1 and rgp41. The intrarectal route required the least amount of virus, whereas the intravaginal route required eight times more virus to cause chronic systemic infection in naive animals. Adult animals required the greatest viral doses when challenged orally. Given that the quick breakdown of protective defences at the start of Challenge Phase II suggested that the vaccine-induced Ab responses looked to be limited, it would be interesting to look at the gp41 vaccine's effectiveness.