Improving the effect of HIV drugs by the use of a vaccine

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A vaccine containing a protein necessary for virus replication can boost an HIV-infected patient's immune system, according to clinical research published in the open access journal *Retrovirology*. This boost can result in increased effectiveness of antiretroviral drugs.

When people are first diagnosed with HIV they are put on antiretroviral drugs, also known as highly active antiretroviral therapy (HAART). These drugs can stop the virus reproducing almost completely. When taking HAART, however, it is known that the virus can still replicate at low levels and accumulate in a latent form in what are called "reservoirs". These reservoirs, located throughout the body including the brain, bone marrow and genital tract, cannot be acted upon by HAART and can cause complications and deaths due to non-AIDS related diseases.

A vaccine was developed that targets the viral protein "Tat", which is produced early on in HIV infection. Tat has a key role in viral replication and progression of the disease by weakening the immune system. By designing a vaccine that included a small amount of the Tat protein, researchers were able to produce an immune response to prevent disease progression.

Lead researcher, Barbara Ensoli, said: "We prove for the first time that antiretroviral therapy may be intensified by a vaccine. These results open new scenarios to investigate, namely whether this vaccine may help with virus control where patients have low adherence to antiretroviral therapy, simplify treatment, and reduce transmission of the disease."

Researchers from the Italian National AIDS Center at Istituto Superiore di Sanità (Rome, Italy) conducted a Phase II clinical trial that injected 168 HIV-infected patients with the vaccine that contained either 7.5 micrograms or 30 micrograms of the Tat protein. For both doses, the participants received the vaccine once a month over the course of either three or five months. None of the participants had anti-Tat antibodies at the start of the trial and it was anticipated that the vaccine would induce them. The patients also continued on HAART treatment.

Patients were followed for three years (144 weeks). It was found that the vaccine induced production of anti-Tat antibodies. A significant growth of CD4+ T cells was also seen, which is a sign of the immune system's strength. There was also an increase in the T, B and other immune cells. The biggest response was seen amongst those who received the vaccine with 30 micrograms of Tat over the course of three months. These effects were found to persist for all the three years.

Those who received the vaccine also had a significant reduction in HIV "proviral" DNA load, which acts as an indicator of the latent form of the virus in reservoirs. This reduction was compared to a group of 79 patients receiving only HAART enrolled in a separate observational study, which acted as reference group for biomarkers of the disease. This is different from an internal control group.

The researchers see the results as very promising for the treatment of HIV in the future. However, they await the results of future efficacy studies, and of a phase II double-blinded trial of the vaccine with a control that has taken place in South Africa, to confirm their findings.

More information: HIV-1 Tat immunization restores immune homeostasis and attacks the HAART-resistant blood HIV DNA: results of a randomized phase II exploratory clinical trial, *Retrovirology* 2015, DOI: 10.1186/s12977-015-0151-y

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