Significant reduction of HIV loads in the sera of patients treated with VANHIVAX

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ABSTRACT

VANHIVAX, a prototype vaccine against the HIV, was tested in the first instance, as auto-vaccines in HIV infected persons who had not received any anti-retroviral drugs. The vaccines provoked significant falls in the viral counts in the patients' sera and when fully developed, could provide effective immunotherapy for early cases of HIV infections.

Key words: VANHIVAX, auto-vaccines, falls in viral counts in HIV patients

RESUME

VANHIVAX est un prototype de vaccin contre le VIH. Il a été testé, en phase initiale, sous forme d'autovaccin chez des patients porteurs de VIH mais ne recevant pas d'anti-rétroviraux; ce qui a entraîné une forte réduction de la charge virale dans le sérum des sujets témoins. Par conséquent, le vaccin pourrait, s'il est entièrement développé, s'avérer une immunothérapie efficace pour les cas d'infection récente.

Mots clés: VANHIVAX, auto-vacines, forte réduction de la charge virale dans les malades de VIH.

Introduction

We have prepared a proto-type vaccine against the HIV called VANHIVAX. To demonstrate its effectiveness as a vaccine, we decided to test it, in the first instance, as auto-vaccines in HIV infected persons. The scientific basis for such auto-vaccines and for testing them had previously been described (1.). A preliminary report on testing the auto-vaccines (2) showed that they induced improvements in the general clinical status of the patients treated, increased body weights and CD4+ or T4 counts. Changes in the viral counts in the sera of the patients were not, however, recorded; there had been no facilities for doing viral counts.

The principal interest of the present paper is to report on changes in the viral counts of patients receiving VANHIVAX or auto-vaccines alone with no retroviral drug treatment whatsoever. Antibiotics, anti-malarial and other non-retroviral drugs were, however, administered when this was indicated.

Patients and treatment

A new set of 10 patients (table 1), for a short term study, were selected for auto-vaccines on the basis of a confirmed positive serology for HIV, an intact immune system as shown by their CD4+ with a CDC classification of A1. There were 5 males and 5 females and their ages varied from 24 to 62 years. The auto-vaccines were given as simple subcutaneous injections. In the first 2 patients, the vaccines were given on two separate occasions 5 and 4 days apart respectively. Each of the other 8 patients received a single dose of the auto-vaccine. Centre Pasteur du Cameroun, an independent public health and reference laboratory carried out the viral HIV_1 and the CD4+ counts

In an earlier and longer-term study (see Fig.2), 20 patients, 9 men and 11 women, were randomly selected with ages that ranged between 22 and 56 years. Viral counts were available for them and they received auto-vaccines on more than one occasion over a period of several months. Auto-vaccines were sometimes administered as simple subcutaneous injections only but were frequently cultured for several hours *in vitro* with washed peripheral leucocytes of the persons concerned in a medium free from host sera and then administered (2).

Results

Table 1, the short term study, shows changes in the viral count 3 – 4 weeks after one dose of auto-vaccine (cases No 1 and 2 received 2 doses each). The viral counts before and after auto-vaccines, the absolute and the percentage falls in the viral counts are given in columns 3, 4, 5 and 6 respectively. The falls in viral counts varied between 128 110 (5.1 log 10)/ml or 91% in case No. 1 and 4163 (3.6 log 10)/ml or 6% in case No. 7 respectively. It was greatest in the 2 patients who received auto-vaccines on two occasions

	INITIAL	INITIAL T4	VIRAL COUNT BEFORE AUTO-VACCIME	VIRAL COUNT AFTER AUTO-VACCINE	ABSOLUTE FALL IN VIRAL COUNT AFTER 3 - 4 WEEKS	PERCENTAGE FALL IN VIRAL COUNT
			Copies/ml	Copies/ml	Copies/ml	
1	NA	567	140 362 (5.1 $\log_{10}$)	12 152 (4.1 $\log_{10}$)	128 110 (5.1 $\log_{10}$) *	91%
2	FE	408	166 476 (5.2 $\log_{10}$)	41 157 (4.6 $\log_{10}$) ⊕	125 319 (5.1 $\log_{10}$) *	75%
3	CH	433	220 860 (5.0 $\log_{10}$)	147 073 (5.2 $\log_{10}$)	80 787 (4.9 $\log_{10}$)	36%
4	FM	505	46 416 (4.7 $\log_{10}$)	28 194 (4.5 $\log_{10}$)	18 222 (4.3 $\log_{10}$)	39.3%
5	SM	390	13 358 (4.1$\log_{10}$)	4 047 (3.6 $\log_{10}$)	9 301 (4.0 $\log_{10}$)	69.6%
6	BD	667	6 524 (3.8 $\log_{10}$)	1 098 (3.0$\log_{10}$)	5 426 (3.7 $\log_{10}$)	86.2%
7	CD	387	69 192 (4.8 $\log_{10}$)	65 029 (4.8 $\log_{10}$)	4 163 (3.6 $\log_{10}$)	6%
8	NNG	364	13 056 (4.1 $\log_{10}$)	4 517 (3.6 $\log_{10}$)	8 739 (3.9 $\log_{10}$)	66.93%
9	LG	739	3 073 (3.5 $\log_{10}$)	1 800 (3.3 $\log_{10}$)	1 273 (3.1 $\log_{10}$)	41.4%
10	AD	554	2 714 (3.4 $\log_{10}$)	1 563 (3.2 $\log_{10}$)	1 151 (3.1 $\log_{10}$)	42%

* Received 2 doses of vaccines

⊕ Viral count 4 weeks after auto-vaccine

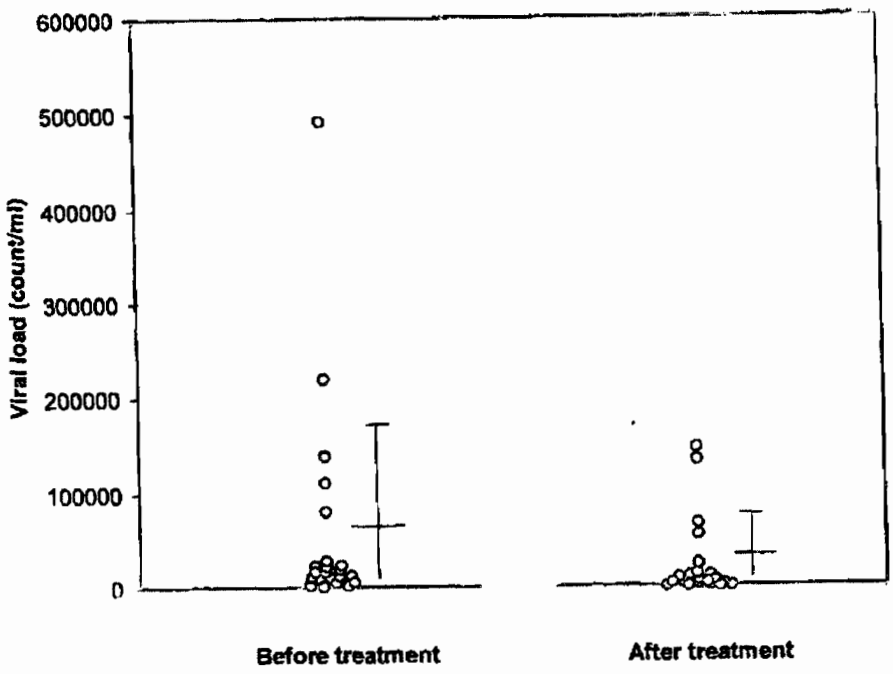

Fig. 2: Change in the viral load in 20 randomly selected patients receiving HIV auto-vaccines

Comment: Although the patients in this short-term study were few, the falls in the viral counts in individual patients ***were significant*** because they were well above the 0.7 log10 considered as normal variation by Centre Pasteur du Cameroun. In addition, these patients showed a distinct improvement in their general clinical status (not recorded).

Fig. 2 is a histogram of the viral counts in the 20 randomly selected patients in whom the diagnosis of HIV had been confirmed and who received several auto-vaccines over a period of months. The differences in viral counts before and after treatment were significant ($P = 0.01$). In 3 patients in the group (not shown), the viral count had fallen from 17,607 (4.2 log10), 29,568 (4.5 Log10) and 2,569 (3.4 Log10) to below 50 copies/ml (1.7 log10) respectively, the limit for counting viral particles in the Centre Pasteur du Cameroun.

Discussion

The above preliminary results (tables 1 and Fig. 2) show clearly that in HIV infected persons with functional immune systems, auto-vaccines ***alone*** have provoked immune responses that cause significant fall in the viral counts in the sera of the persons concerned. The importance of the very marked fall in viral counts in the first 2 patients who had received 2 auto-vaccines 4 and 5 days apart respectively remains to be determined.

The total numbers of viral particles destroyed at the level of the whole body in each patient in the two groups must have been enormous! In 3 patients in Fig 2 the count was down to below 50 copies/ml. What this means for the long-term future of these 3 patients and indeed for the other patients in whom significant falls has been achieved remains to be determined. The viral destruction, the rise in the T4 count, the gain in body weights in some cases and an improvement in the general clinical status of the patients constitutes evidence of the positive effects of the auto-vaccines in these patients.

The natural time course of viraemia in AIDS patients in Cameroon is unavailable; the technique for viral count is relatively recent and few persons are seen early in their infections. The course of the viraemia in European and North American AIDS patients shows in "progressors" and 'non-progressors", that significant falls in the viral counts occurred naturally but only at the start (in the first 3 months) of the infection. Thereafter, there is a steady rise in the counts, which terminates in death. In contrast, all the patients reported above were well past the initial period of 9 to 12 weeks of their infections. The fall in the viral counts observed in the above patients could therefore be ascribed to the action of the auto-vaccines alone.

.The exact nature of the immune responses responsible for these changes in the body also remains to be determined. This notwithstanding, these preliminary results strongly suggest that VANHIVAX has therapeutic properties for the HIV patient and when fully developed could effectively contribute to the immunotherapy of early cases of HIV infections.

As regards a preventive vaccine for the HIV, we believe that vaccines prepared on the same basis as VANHIVAX should provoke, in healthy uninfected persons, immune responses that are as strong and even stronger than those observed in patients with compromised immune systems. Moreover, the relatively small amounts of viruses involved in ***natural infections***, as compared to the large amounts that have been destroyed in the patients reported here, should present no problems to a healthy vaccinated person with an intact immune system. Such vaccines should, in principle, provide full protection against infections with the corresponding viral strains. Studies are under way for confirming these results and for testing in normal uninfected volunteers preventive vaccines prepared on the same basis as VANHIVAX and this prior experience with VANHIVAX should contribute positively to and enhance the testing of such a preventive vaccine.

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DEO OMNIS GLORIA.

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