

In Vivo Antiretroviral Effects of the *Medicinal Synthetic Aluminum-Magnesium Silicate*

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Received 23 April 2015; accepted 14 May 2015; published 19 May 2015

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Abstract

Viral loads (copies of RNA per ml of plasma) of HIV/AIDS patients, who volunteered for clinical trial of the *Medicinal synthetic Aluminum-magnesium silicate*, were assessed, before and after they were treated. The treatment lasted 4 weeks, 8 weeks and 12 weeks respectively. A patient who could not access approved laboratory for viral load test on time, continued the treatment for 24 weeks. Following treatment with the medicine, mean viral load of HIV/AIDS patients reduced (P < 0.05) from 18875.00 \pm 17059.18 to 327.50 \pm 226.84. Rates of the viral load reduction were: 86% after 4 weeks, 96% after 8 weeks and 99.71% after 12 weeks. Clinical signs complained of, by the patients during the treatment, included, fever, dermatitis, boils, joint pain, leg edema and sore throat. These clinical signs ceased when they were treated, so that the antiretroviral treatment was completed. The patient who was on the medication for 24 weeks had no adverse drug reaction.

Keywords

Clinical Trial, *Medicinal Synthetic Aluminum-Magnesium Silicate (Nanoparticles)*, Cure for HIV/AIDS

1. Introduction

Mechanisms by which antiviral medicines act are: inhibition of attachment of viruses to cells of their hosts, inhibition of virus-cell fusion, preventing viruses to un-coat and/or inhibiting reverse transcription of viral genomic RNAs [1].

Molecules of Aluminum-magnesium silicate (AMS) are composed of platelets which have negative electrical charges on their surfaces and the positive charges on their edges [2] and genomes of viruses are positively charged while viral phosphate components are negatively charged [1]. These charges on viral components make every virus to end up with either net positive electrical charges or net negative electrical charges. HIV and other

RNA viruses have net positive electrical charges [3].

AMS has been in use as medicine and in drug formulations for many decades, without report of toxicity [2]. Possession of both negative and positive electrically charged ends makes AMS a broad spectrum antiviral medicine, because, it uses surfaces of its molecular platelets to inhibit attachment of positively charged viruses to their hosts' cells and uses their edges to inhibit negatively charged viruses. When a significant number of particles of invading viruses adsorb onto the AMS molecules, instead of onto their hosts' cells, body immune responses are able to eliminate what is left of the viral infections [4].

Also, platelets of AMS molecules are only 0.96 nm thick [2]. So, it is made of *Nanoparticles* [5]. Small size of *Nanoparticles* makes it possible for them to pass physiological barriers. Therefore, AMS is able to reach viral particles in every organ and in every tissue of body of infected persons, to physically adsorb them out.

Adsorbing out HIV means that millions of new viral particles released from infected cells would be prevented from establishing their own foci of infection in more cells [6]. Thus, HIV would no longer be able to overwhelm the body immune system and the acquired immune-deficiency syndrome (AIDS) stage could be prevented. When AIDS is prevented, patients' immunity clears HIV particles that escape the virus-trapping action of the AMS-*Nanoparticles* [7].

Nigeria does not have deposits of AMS as a natural resource but it has, in abundance, deposits of Aluminum silicate and Magnesium silicate. These other two minerals have been purified and are being used as medicines in the country. Aluminum silicate and Magnesium silicate were therefore reacted [8] to get a synthetic form of AMS $\{Al_4(SiO_4)_3 + 3Mg_2SiO_4 \rightarrow 2Al_2Mg_3(SiO_4)_3\}$. Dextrose monohydrate, a simple sugar, was incorporated in the *medicinal synthetic* AMS (MSAMS), to carry its molecules, by active transport, across mucous membranes of stomachs and intestines [9] of treated patients, into blood, which carries them to all organs and tissues.

Studies have demonstrated that the MSAMS inhibits viruses of all the six viral families so far tested [8] [10]-[16] *in vitro*, (*Paramyxoviridae*, *Orthomyxoviridae*, *Birnarviridae*, *Parvorviridae*, *Avipoxviridae* and *Retroviridae*). *In vivo*, it has also been used to successfully treat animals that were experimentally challenged with viruses of *Paramyxoviridae*, *Birnarviridae* and *Parvoviridae* families [10] [13] [14].

Aluminum silicate and Magnesium silicate reacted to get the medicine, are very inexpensive minerals. So, the new medicine would be cheap and affordable by low income earners who are the people mostly affected by HIV/AIDS [7]. Since *in vitro* studies have demonstrated its antiretroviral effects [6] and literature has revealed that it is safe for use to treat both animals and human-beings, the medicine was patented by the Nigerian gov-ernment and was dispensed to HIV positive individuals who volunteered to try it, for cure of HIV/AIDS.

2. Materials and Methods

HIV/AIDS patients who requested to try the MSAMS (after it was patented) were made to read the articles titled "Assessment of antiretroviral effects of a synthetic Aluminum-magnesium silicate" [6] and "Antiretroviral effects of a medicinal synthetic Aluminum-magnesium silicate" [17]. Those who volunteered, by writing through Email, to treat themselves with the medicine were selected for the trial, on condition that they would submit results of viral load tests conducted on their plasma, before and after the treatment. Reports from five of such volunteers are presented in this article.

A formulation of the MSAMS and Ampicillin trihydrate (Antivirt $A^{\text{(B)}}$) and a formulation of the MSAMS alone (Antivirt $B^{\text{(B)}}$) were made [18]. All the patients were on oral medication with Antivirt $A^{\text{(B)}}$ for 1 week at dose rates of 50mg of the MSAMS/kg body weight and 7.5mg of Ampicillin trihydrate/kg body weight, daily. Thereafter, one of the patients was on Antivirt $B^{\text{(B)}}$ for 3 weeks at dose of 50 mg/kg, daily. Two patients were on Antivirt $B^{\text{(B)}}$ at same dosage for 7 weeks. A patient was on the Antivirt $B^{\text{(B)}}$ therapy for 11 weeks while another patient continued the Antivirt $B^{\text{(B)}}$ treatment for 23 weeks. Each of the patients also took 1 capsule of multi-B-vitamins, each day, throughout period of the treatment. Plasma of each of the patients was tested for viral load (HIV) before the treatment and after the treatment, by laboratories approved for the test by the Nigerian government.

Means of the viral loads, before treatment and after treatment, were compared for statistical difference by the *Students T test*.

3. Results

Clinical signs complained of by the HIV/AIDS patients during the period of treatment, included, fever, dermati-

tis, multiple boils, joint pain and edema of the legs. One patient had sore throat that was so serious that the antiretroviral medication had to be stopped but after treatment of the sore throat, the experimental treatment was completed, without further complaints. One of the patients who had fever was confirmed to be sick of malaria. Viral loads of the patients before treatment were 500/ml, 1000/ml, 4000/ml and 70,000/ml. One of the patients who tested for his viral load after one week on the treatment and repeated the test on completion of his four weeks treatment period, reported that the viral load increased from 500/ml to 1000/ml after one week on the treatment before reducing to 70/ml, after 4 weeks on the treatment. Generally, viral loads of the patients reduced to 70/ml, 40/ml, 1000/ml and 200/ml after their respective periods of treatment. Mean of the viral loads reduced significantly (P \leq 0.05), from 18,875.00 \pm 17059.18 to 327.50 \pm 226.84, following treatment with the MSAMS (**Table 1**). Rates of reduction of the viral loads were: 86% for the patient treated for a total of 4 weeks, 96% for one of the patients who were on the treatment for 8 weeks and 99.71% for the patient who was on the treatment for 12 weeks. The patient who was on the treatment for 24 weeks had no adverse drug reaction, despite the long period of treatment.

4. Discussion

HIV/AIDS pandemic has its biggest effects in Africa. The continent had highest number of new HIV/AIDS cases reported in 2012 [19]-[22]. World health organization [23], also reported that more than 95% of new cases of the disease, in the world, came from Africa, Asia and South America. Therefore, there was need for African scientists to join the global search for vaccines for the pandemic or for medicines that can cure the disease.

Studies on use of vaccines to control infectious bursa disease of chickens, have demonstrated that when live vaccines of viruses that destroy lymphocytes, are used to vaccinate animals, vaccine-induced AIDS often results [24] [25]. Also, use of live vaccines for HIV/AIDS could lead to spread of the infection, because, main mode of transmitting the infection is human to human, through sex. So, persons vaccinated with live HIV vaccine would transmit the virus to their sex partners and after many passages, the live vaccines can reactivate to virulent HIV. Immunity from inactivated vaccines and sub-unit vaccines lasts for short periods of time. So, it may not be convenient to use inactivated vaccines or sub-unit vaccines to control HIV/AIDS because that would require revaccinating people many times within a year [4]. It is therefore reasoned that the best thing to do, is to search for inexpensive medicines that can cure the disease, so that even low income earners can treat themselves instead of hiding their status which leads to uncontrolled spread of the infection, especially in Africa, Asia and South-America [23].

Lack of simple, *in vitro*, tests for titer of HIV in specimens made it difficult for scientists to test medicines suspected to have antiretroviral effects, *in vitro*, before clinical trials. So, most people who claimed invention of cures for HIV/AIDS were not able to scientifically explain mechanisms of actions of the medicines. Development of the passive hemagglutination test for HIV [26] made *in vitro* test of antiretroviral effects of the MSAMS, possible [6].

In the *in vitro* study of antiretroviral effects of the medicine, mean titer of HIV in plasma samples incubated with it, increased (P < 0.01) from 4.00 \pm 1.60 to 14.00 \pm 2.00, when the incubation was done only once. This suggests that the AMS-*Nanoparticles* destroyed infected cells and so released intracellular HIV particles before adsorbing them out, which reduced the titer (P < 0.05) from 14.00 \pm 2.00 to 6.50 \pm 1.50, when the incubation was repeated [17].

Patients/length of treatment	Before treatment	After treatment
1 (4 weeks)	500	70
2 (8 weeks)	1000	40
3 (8 weeks)	4000	1000
4 (12 weeks)	70,000	200
Mean	$18875.00 \pm 17,\!059$	327.50 ± 226.84

 Table 1. Viral loads (copies of RNA/ml of plasma) of HIV/AIDS patients treated with the Medicinal synthetic Aluminummagnesium silicate.
 Also, the MSAMS has been observed to enhance efficacy of Sulphadimidine, Chloroquine, Ampicillin and Piparazine stabilized with it [28]-[32]. So, it helps antimicrobials to maximally reduce loads of secondary infections in organs and tissues of treated patients.

So, properties of AMS-*Nanoparticles* responsible for the cure of HIV/AIDS observed in this clinical trial of the MSAMS include:

1) AMS-*Nanoparticles* use negative electrical charges on their surfaces to adsorb onto positive electrical charges on HIV to prevent adsorption of the virus onto its hosts' cells. Mechanism of action of the medicine is therefore, a physical effect which makes it safe for use in prolonged treatment.

2) As *Nanoparticles*, molecules of the medicine pass physiological barriers and so, reach HIV particles, in all organs and all tissues of infected persons.

3) *Nanoparticles* have selective affinity for abnormal cells [5] and traditional uses of AMS include to enhance disintegration of capsules, when swallowed [2]. So, AMS-*Nanoparticles* may destroy the abnormal cells they adsorb onto. By that action, the MSAMS is able to act both on extracellular viruses and on intracellular viruses.

4) As stabilizing agent [2], AMS enhances efficacy of antimicrobials against secondary infections. So, secondary infections that associate with HIV/AIDS are effectively treated.

5) It has been observed that when antimicrobials are stabilized with the MSAMS, their lower doses (75%) become more effective than their recommended doses. By use of lower doses of drugs for treatment, side effects of the drugs are minimized which allows immune systems of patients to function optimally. Enhancing immune responses of patients has already been reported to clear HIV infections [23].

That mean HIV load in plasma of patients, who participated in the clinical trial, reduced significantly (P < 0.05) from 18875.00 \pm 17059.18 to 327.50 \pm 226.84, suggests that the AMS-*Nanoparticles* adsorbed out HIV particles from the patients' organs and tissues.

Increase of viral load of one of the patients, from 500 copies of RNA per ml of plasma to 1000/copies per ml, agrees with the *in vitro* result in which the viral titer of plasma samples incubated with the MSAMS, also increased from a mean of 4.00 ± 1.60 to 14.00 ± 2.00 [6]. These initial increases observed in HIV titers of plasma specimens incubated with the MSAMS and in patients treated with it, support the suggestion that AMS-*Nanoparticles* destroy infected cells to bring out HIV particles that are within the cells. Most antiretroviral therapies (ARTs) in current use, fail to achieve permanent cure of HIV/AIDS because they have no effect on viruses that are within cells. So, ability of the MSAMS to act on both extracellular and intracellular HIV particles is an advantage over other ARTs.

Observation that the patient who was on the MSAMS for four weeks had only 86% reduction of the viral load whereas those who were on the medication for 8 weeks and 12 weeks had 96% reduction and 99.71% reduction, respectively, supports our suggestion that the medicine continuously mops out HIV particles from organs and tissues of treated patients. So, the longer the medication lasts, the more viral particles that could be mopped out.

Since a patient was on the medication for 24 weeks without adverse drug reaction, it means that the medicine is safe for the prolonged treatment which HIV/AIDS requires. Also, whereas the patient who experienced only 96% reduction in his viral load, had copies of RNA per ml of his plasma brought down to normal (50 or less) which means he was cured [7], the one who had the highest rate of reduction (99.71%) was not yet cured, because his viral load of 200 copies of RNA per ml of plasma was still above the normal maximum of 50 copies of RNA per ml of plasma, in healthy human-beings. This suggests that period of treatment required to cure a patient of HIV/AIDS with the MSAMS may depend on viral load of the patient before the treatment.

The patient who had 99.71% reduction of his viral load, started with a very high viral load of 70,000 copies of RNA per ml of plasma, before the treatment, whereas the one who was cured after 8 weeks medication had initial viral load of only 1000 copies of RNA per ml. Other factors that may affect length of time of medication with the MSAMS, before cure of HIV/AIDS could be achieved, may include level of immune response of individual patients. For that reason, supportive treatment with immune stimulants, such as multi-B-vitamins, is suggested.

Since rate of reduction of HIV load increased as length of time of the medication with the MSAMS increased and since the treatment could go on for 24 weeks without adverse drug reaction, it is suggested that viral load of each patient on the medication be monitored until it comes down to 50 copies of RNA or less, per ml of plasma.

That the MSAMS was taken every day for 24 weeks, without adverse drug reaction, supports the suggestion that its mechanism of action is a physical effect. Medicines that inhibit viruses or micro-organisms by biochemical effects would interfere with biochemistry of normal cells. So, the prolonged medication which treatment of

HIV/AIDS demands may not be safe with such medicines. Viruses and micro-organisms also mutate by changing their biochemical compositions in order to develop resistance against drugs. That means that the physical effect by which the MSAMS acts is another advantage it has over other ARTs. It may be difficult for HIV to develop resistance against it.

Affinity of *Nanoparticles* for abnormal cells [5] is not for virus-infected cells alone. So, if the AMS-*Nanaparticles* destroy bacteria-infected cells or parasite-infected cells, arrested bacterial infections or arrested parasitic infections could be reactivated. Since the medicine may not have effect against such reactivated infections, they could lead to bacteriamia or parasiteamia which would result to fever and other clinical signs. Such reactivation of arrested infections is suspected to be responsible for the fever, dermatitis, multiple boils, leg edema, sore throat and joint pain complained of, by patients who participated in the clinical trial.

Again, since the patient diagnosed of malaria and the one who had sore throat were able to continue with the antiretroviral treatment, after being treated of those inter-current diseases, it means that the problem of reactivation of arrested infections by the MSAMS would not hinder use of the medicine for cure of HIV/AIDS.

For a confirmed case of HIV/AIDS to have less than 50 copies of RNA per ml of plasma, following treatment with the new medicine means he was no longer HIV positive. Also, reduction of mean viral load of all the HIV/AIDS patients who participated in the clinical trial, from 18875.00 \pm 17059.18 to 327.50 \pm 226.84, is 98.26% reduction. Kaplan [27] reported that when treatments reduce loads of infectious agents by 95% or more, body immunity is able to eliminate what are left of the infections. What these results mean, is that the MSAMS cures HIV/AIDS, not just prolongation of lives of HIV-positive persons.

Aluminum silicate and Magnesium silicate, reacted to synthesize the MSAMS are inexpensive medicinal minerals that are abundant in Nigeria. So, the new antiretroviral medicine would be cheap, such that low income earners can afford treatment of HIV/AIDS without having to queue-up in designated centers for free ARTs. This will help in controlling the pandemic, because most patients of HIV/AIDS in Africa detest going to designated centers for treatment, because of stigmatization associated with the disease. These persons who reject governments' policy of dispensing free ARTs from designated centers, are responsible for spreading the infection which results to most of the new HIV cases reported from the developing countries [23]. If people can treat themselves of HIV/AIDS privately and get cured, rate of spread of the infection would reduce.

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