

Life Sciences of Washington Inc. HIV Case Studies therapy in the use of IB 100

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CURRENT CONCEPTS IN CYTOKINE RESEARCH

INTERFERON-Alpha and HIV/AIDS: A general and clinical retrospective
Victer Muhammad, Abdul Alim Muhammad and Frederick Johnson. Dec. 1998.

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Interferon alpha (IFN- α) is a naturally occurring protein found in the bodies of most animals including man. It belongs to a family of proteins known as cytokines (cyto-cell and kine-to move). The name cytokine was perhaps coined as a result of the inter- and intracellular activity possessed by this class of proteins. There are at least two other forms (types) of interferon that are beta and gamma. Having antiviral, antiinflammatory and immunomodulatory properties, interferon has been used in clinical management of hairy cell leukemia, condyloma acuminata and in AIDS associated Karposi's sarcoma (2-4).

Interferons are produced by the body and secreted in response to viral infections. Interferons have been produced in culture using leukocytes stimulated with Sendai Virus (1). Reportedly there is a large family of molecular species that constitute the IFN- α repertoire. These molecular species are more commonly known as sub-types and are reported to be as many as twenty (7).

There is much known about IFN- α and perhaps even more not as yet reported. IFN- α appears to possess a specificity for cell surface receptors. The antiviral effects of IFNs are generally associated with the induction of at least two enzymatic activities... one of which is responsible for degradation of viral and cellular RNAs

(5). Interferons, specifically alpha, have demonstrated interesting immunoregulatory properties including enhancement of phagocytotic activity by macrophages, improved lymphocyte cytotoxicity and enhanced leukocyte antigen expression. IFN- α has shown to be most effective in its antiviral activity. These and other actions are perhaps in response to the symbiotic relationship believed to exist when cells are stimulated by interferon.

Unlike most drugs and "medicines", IFN- α , which for our purposes is neither a drug or medicine, does not possess the many side affects commonly associated with those products. In our hands there have been only two reported "side affects" which are an increase in libido and an increase in appetite.

These are the same side affects reported by Koech et. al. in a similar study

(6). Although there are reported cases of flu-like symptoms and other problems associated with the use of IFN- α , to date these symptoms have all been associated with the administration of high concentrations (>1000 international units {iu} at one dosage and more importantly a recombinant (synthetic) version of IFN- α . Furthermore, most of the reported clinical uses of IFN-8 and other cytokines have been administered in bolus amounts of several million iu/cc and/or continuous flow of similar volumes and concentrations over a period of days.

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Those reports published on the clinical use of recombinant IFN- α (rIFN- α) in high doses do not parallel those found in our hands where we used Low Dose Intranasal Natural IFN α ® TM (LIN-IFN- α). This difference is perhaps due to the nature of the two products.

There are quite a number of pharmaceuticals available on the market from a recombinant source. Recombinant refers to the synthetic or synthesizing of DNA or protein material i.e. insulin, protein c and other biological materials via bacteria (e.coli) or biovats such as the mammary system of the mouse, rat, rabbit, sheep, goat and cow. The gene for the desired protein is introduced into the fertilized ovum of one or more of these animals and reimplanted in a surrogate pseudopregnant mother. Once the gene-injected embryos are carried to term and are delivered, they are then mated after reaching sexual maturity. After a successful pregnancy the transgenic females are milked where, if the transgene is successfully incorporated and expresses itself, then the protein can be extracted from the milk of the transgenic mammal.

The technology used to do this is quite impressive however, is not as novel as one might consider at first thought and there are perhaps drawbacks...especially when considering the synthetic production of multigene molecular biologicals such as cytokines.

In addition to its technological advancement, the recombinant versions of these proteins are often patentable thus allowing the holder of the patent the opportunity to reap unlimited riches. Inasmuch as most if not all of the aforementioned properties on INF-a and other cytokines are well established by the scientific community, one would think that IFN. Interferons and other cytokines have shown to be effective in the realm of treating viral, cancerous and tumor related malignancies.

Yet opinions toward cytokines in clinical therapy remain skeptical.

Interferon alpha was first used as an antiviral agent in cattle. In the late 1980's the use of IFN- α was begun in human antiviral HIV/AIDS research at the Kenyan Medical Research Institute (KMRI) by Dr. Davey Koech in Nairobi, Kenya (6). Dr. Koech et. al. have reported success in the use of IFN- α since that time in treating patients suffering from HIV/AIDS. Doctor Koech's clinical research may be found in its published form where it may be critiqued as well. Drs. A. Muhammad and Justice et. al. upon learning of Dr. Koech's claims traveled to Nairobi to determine the validity of Dr. Koech's findings.

The investigative team of A. Muhammad et. al. returned to the USA and reported that "the Low-dose Oral Interferon alpha was the closest therapy that they had seen to date to the Elea and reported the "the successfully treating HIV/AIDS". At this point (~1991) the method of application was lozenges containing< ui which were permitted to dissolve in the mouth before swallowing.

Muhammad and Justice found promising results giving low-dose interferon alpha by mouth which were quite similar to those reported by Koech (6). These results were fewer infections, weight gain, increased appetite, and improved quality of life.

However'in 1994 after several interruptions in the supply of the IFN- α lozenges we decided to seek our own supply and strategy for introducing the IFN- α .

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Victer Muhammad et. al. believed that receptors for the IFN- α were located in the mucosal membranes of the nose and throat. Armed with this information, Victer et. al. developed a solution containing $<10^6$ IU/ml IFN- α . A single 1-ml dropperful was to be dispersed into the nose of the viral infected individual every 24 hour. (IB 100).

This new method of application yielded astounding results and there were no reported differences between the use of the low-dose oral lozenges used by Koech et. al. and the LIN-IFN- α ™ form now used by Muhammad et. al. We have compiled some actual case studies from individuals given the LIN-IFN- α supplement to date:

Case #1 A 26 year old Black male originally diagnosed to be HIV+ June 1992. Patient's CD4 and CD8 counts were 958 each and patient reported night sweats, head aches, itching, body rashes and cold/flu-like symptoms. Patient was immediately placed on IFN- α lozenges taken once daily before bed. Patient reported an increase in energy, increase in appetite and a moderate increase in weight. After being on the therapy for some time patient reported that " It was a very trying year for me... I went through many trials and it affected the progress of my treatment. Being "hard-headed" was my problem... it was not the medicine[kemron)". During this time patient's CD4 count dropped to 717. Patient resumed the therapy in February 1994. In January patient was placed on Low-dose natural intranasal Interferon alpha and in July 1995 CD4 count was 1174. Patient HIV status was again tested and found to be seronegative for HIV on September 18, 1995. As of December 26, 1998 patient remains HIV(-).

Case #2 A 37 year old Black female diagnosed HIV+ August 1993 and began the IFN- α therapy in November 1993. During the first three years of therapy patient experienced "no health problems". Patient reported having two small children who frequently had colds or flu but was never contracted by patient. Patient reported that after being on therapy for a period of time and "feeling fine, I became sluggish about taking my medicine as instructed by my doctor". Patient's CD4 (T cell) count plummeted to ~ 120 and all clinical parameters were at an alarming state and remained that way for approximately 5 weeks. Patient became serious about their treatment regimen and CD4 count again rose and have remained stabilized in the upper 500's since. Patient reports as of December 21, 1998 that " I am feeling fine, doing well and taking my Interferon every day".

*NOTE. all patients began therapy with Low-dose natural intranasal Interferon as of January 1995. All patients included in this report are under Medical Doctor's supervision.

Case #3: ' A 25 year old Black male who tested HIV+ in 1987. Patient was started on IFN- α in 1991 and began a therapy of Low-dose natural intranasal Interferon in December 1995 where he maintains to date. Patient suffered from chronic respiratory infections and had a T cell count 350. After 6 weeks patient's T cell rose > 600 and reported an increase in appetite and libido (increase in libido common among male patients). Patient reported that whenever he was not taking the interferon therapy both appetite and libido decreased dramatically. Patient did not take therapy for 9 months at which time viral load rose to $> 250,000$ (measured at the National Institutes of Health (Aug. 1998]), however once regimen was resumed viral load fell to 2 165 (NIH (Nov. 1998]).

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Most patients (82%) who have, over the past 8 years, taken the low-dose oral or intranasal preparations of the natural interferon alpha have responded favorably. H.L. Aubrey, A.A. mad et. al. reported these findings first in the United States in 1991. Since that time these data have been consistently duplicated with some variation..

Perhaps the greatest difficulty and cause for variation has been in those patients who respond positively to the Interferon therapy and for reasons unapparent do not remain consistent in the treatment regimen. Furthermore there is a small percentile (s18%) who do not respond to the therapy and this requires further research. Nonetheless, few can boast of an 82% response to a treatment regimen.

We recommend that all HIV/AIDS patients should be on LIN IFN- α regardless of CD 4 count or viral load and it can be used in patients on triple therapy without loss of effectiveness. We suggest that LIN IFN- α improves the quality of life for HIV/AIDS patients by stabilizing and maintaining the immune system.

T= personal communication

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