Improvements in Quality of Life for HIV/AIDS Patients Using Hyperimmune Egg — The TASO Study

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Introduction

Management of HIV/AIDS and its long list of associated opportunistic infections has been the subject of textbooks and numerous scientific articles. While no cure for HIV infection presently exists, the introduction of ARVs and novel therapies for opportunistic infections have brought some improvements in care. But a major problem for HIV patients on the African continent, where the HIV epidemic is worst, is the almost total unavailability of antiretroviral drugs (ARVs). A UNAIDS Commission reports that 99.9% of the 30 million HIV/AIDS patients in Africa have no present access to ARVs. Nor is that percentage likely to change as the disease continues to spread rapidly throughout the continent. The complex issues of triple-drug ARV use, growing incidence of resistance, expensive infrastructure required to administer and monitor ARV s and the high levels of toxicity associated with ARV use are additional barriers to adoption of these drugs. [6,7,8] Improvements in quality of life should be a primary goal in the management of any disease, and can be elusive for HIV/AIDS patients.

The Aids Support Organization (TASO) of Uganda provides outpatient medical and counseling care for HIV positive patients who have illness or opportunistic infections. This usually comes in the form of antibiotic, anti-fungal, anti-tuberculosis, anti-pyretic, and anti-diarrhea medications and will often include nutrition counseling and other "quality of life" services. It does not supply or manage ARV therapy. TASO has recently become interested in a new and novel approach to management of our patients, namely, a food supplement scientifically designed to provide broad-based immune support to key body functions. The product, Immune 26*, is not a drug, nor does it function like a drug. Rather, it is dried hyperimmune egg from laying hens that have been vaccinated with 26 or more human pathogens. This produces eggs rich in antibodies and numerous other immune co-factors that act against intestinal pathogens and provide anti-inflammatory activity when the product is consumed[9]. This product is supported by twenty years of research studies and currently carries over 100 United States and international patents. The product purportedly:

- Balances and supports the immune system
- Helps maintain cardiovascular function and a healthy circulatory system
- Helps maintain digestive tract health
- Helps modulate inflammatory responses
- Helps maintain flexible and healthy joints
- Helps increase energy levels
- Helps to enhance a sense of well-being

The American FDA and the Uganda National Drug Authority (NDA) both consider this hyperimmune egg product (Immune 26*) to be a food supplement.

Since all infectious diseases are known to put stress on the immune system and HIV specifically attacks and destroys immune function, it seemed reasonable to test a scientifically credible immune-enhancing supplement.

Methods and Study Design

To assess the efficacy of the hyperimmune egg powder to improve quality of life, a small pilot study of ten(10) patients was first employed. After a four-week review, results were sufficiently impressive that the study group was expanded by forty (40) additional patients, in two groups of twenty. The initial group of ten names had been picked randomly from a bowl containing thirty names of symptomatic patients willing to participate. This group (Group A) was followed for eight weeks. The second group consisted of twenty names picked randomly from a bowl containing the names of fifty symptomatic patients willing to participate. This group (Group B) was followed for six weeks. The third group consisted of the twenty sickest patients seen that clinic day out of fifty patients seen that day. This group (Group C) was followed for four weeks.

Only known HIV positive patients with symptomatic illness participated. None of the patients were now or ever had been on antiretroviral drugs. All participants were counseled and their consent obtained. All patients came from peri-urban, very-low income areas. They were required to pay the standard office visit fee of 500 Ugandan shillings(28 cents U.S.) There was no charge for the hyperimmune egg food supplement.

The study was an open-label study without placebo controls. But to decrease placebo effects, patients were told only that the product was being tested to see of it would be "of help" or "of no help" in their situation. Since most patients had participated in several previous studies testing various vitamin, mineral, herbal, and food supplement products where results were insignificant, there was little reason for them to expect more from this product. The study extended from June through September, 2002.

To assess whether the hyperimmune egg product "helped" or "didn't help", a three-page, multi-systems, signs-and-symptoms evaluation was done on each clinic visit. All patients were seen and evaluated only by the author (Dr. Kizito) of this paper .

Each study participant was instructed to take three capsules of product three times daily. Each capsule contained 0.5 gm, making the total daily dose 4.5 gm of product, equivalent to one third of an egg.

Laboratory studies were done on each participant at the beginning of the study and at the conclusion of the study for each of the three groups. The tests included hemoglobin, white blood cell count and differential, urinalysis, erythrocyte sedimentation rate (ESR), and CD4 T-lymphocyte cell count. Each participant was weighed at the beginning and at the end of the study. All lab studies were done at the same on-site laboratory and by the same technician.

Results

Of the fifty patients initially recruited, thirty-one (15, 10, 6) continued in the study to completion. Evaluation of "drop outs" showed that a major reason was inability to pay for transportation to and from the clinic among those who lived furthest away or were poorest. Results are shown below for the three study groups.

Table 1 - Changes in the occurrence of common signs and symptoms presenting initially and after four weeks use of hyperimmune egg (Group C)

Presenting sign or symptom	Initial (N=15)	Four Week (N=15)	% with symptom	% with symptom improved
Anorexia	7	0	47 %	100 %
Fever	5	1	33 %	80 %
Fatigue	9	1	60 %	89 %
Poor Sleep	7	2	47 %	71 %
Bone or Joint Pain	8	3	53 %	63 %
Dizziness	6	4	40 %	33 %
Abdominal Pain	9	3	60 %	67 %
Cough	10	8	67 %	20 %
Chest Pain	6	3	40 %	50 %
Headache	9	5	60 %	44 %
Diarrhea	3	0	20 %	100 %
Night Sweats	5	2	33 %	60 %
Dyspnea	9	2	60 %	78 %

Table 1.1 - Changes in laboratory results after four weeks of administration of hyperimmune egg (Group C)

Lab Test	Improved	Worsened	Unchanged
Hemoglobin	27 %	53 %	20 %
ESR	27 %	73 %	---
CD4	20 %	73 %	7 %
Weight	40 %	47 %	13 %

Table 2 - Changes in the occurrence of common signs and symptoms presenting initially and after six weeks use of hyperimmune egg (Group B)

Presenting sign or symptom	Initial (N=10)	Six Week (N=10)	% with symptom	% with symptom improved
Anorexia	5	0	50 %	100 %
Fever	2	1	20 %	50 %
Fatigue	5	1	50 %	80 %
Poor Sleep	3	1	30 %	67 %
Bone or Joint Pain	5	3	53 %	63 %
Dizziness	6	1	60 %	83 %
Abdominal Pain	4	1	40 %	83 %
Cough	7	5	70 %	29 %
Chest Pain	5	5	50 %	0 %
Headache	8	4	80 %	50 %
Diarrhea	4	0	40 %	100 %
Night Sweats	2	2	20 %	0 %
Dyspnea	5	1	50 %	80 %
Memory Loss	5	0	50 %	100 %

Table 2.1 - Changes in laboratory results after six weeks of administration of hyperimmune egg (Group B)

Lab Test	Improved	Worsened	Unchanged
Hemoglobin	30 %	50 %	20 %
ESR	30 %	60 %	10 %
CD4	10 %	60 %	30 %
Weight	50 %	30 %	20 %

Table 3 - Changes in the occurrence of common signs and symptoms presenting initially and after eight weeks use of hyperimmune egg (Group A)

Presenting sign or symptom	Initial (N=6)	Eight Week (N=6)	% with symptom	% with symptom improved
Anorexia	2	0	33 %	100 %
Fever	1	0	17 %	100 %
Fatigue	1	0	17 %	100 %
Poor Sleep	1	0	17 %	100 %
Bone or Joint Pain	1	0	17 %	100 %
Dizziness	0	0	0 %	--
Abdominal Pain	2	1	33 %	50 %
Cough	2	2	33 %	0 %
Chest Pain	2	1	33 %	50 %
Headache	4	2	67 %	50 %
Diarrhea	0	0	0 %	--
Night Sweats	0	0	0 %	-- %
Dyspnea	2	1	33 %	50 %
Memory Loss	3	0	50 %	100 %

Table 3.1 - Changes in laboratory results after eight weeks of administration of hyperimmune egg (Group A)

Lab Test	Improved	Worsened	Unchanged
Hemoglobin	33 %	50 %	17 %
ESR	83 %	0 %	17 %
CD4	33 %	50 %	17 %
Weight	100 %	0 %	--

Table 4 - Summary of changes in the occurrence of common signs and symptoms for all three study groups

Presenting sign or symptom	Initial (N=31)	Final (N=31)	% with symptom	% with symptom improved
Anorexia	14	0	45 %	100 %
Fever	8	1	26 %	88 %
Fatigue	15	1	49 %	93 %
Poor Sleep	11	3	36 %	73 %
Bone or Joint Pain	14	6	45 %	57 %
Dizziness	12	5	39 %	58 %
Abdominal Pain	15	6	48 %	60 %
Cough	19	15	61 %	21%
Chest Pain	13	9	42 %	31 %
Headache	21	11	68 %	48 %
Diarrhea	8	1	23 %	88 %
Night Sweats	7	4	23 %	43 %
Dyspnea	16	4	52 %	75 %
Memory Loss	6	0	19 %	100 %

Results are shown on Table 1, Table 2, and Table 3 for Group C, Group B, and Group A respectively. Table 4 represents the combined summary of all three groups.

Observations can be made as follows:

1. Signs and symptoms associated with gastrointestinal function showed substantial improvement (see Table 4): anorexia was 100% improved, abdominal pain 60% improved, and diarrhea 88% improved.
2. Symptoms relating to CNS-brain function also showed substantial improvement (see Table 4): short-term memory loss was 100% improved, dizziness 58% improved, headache 48% improved, and definitely feeling better (N=27 of 31) 87% improved.
3. Constitutional systemic parameters also showed high levels of improvement (see Table 4): fever 88% improved, fatigue 91% improved, poor sleep 73% improved, definitely feeling better 87%.

4. Less responsive were cough – 21% improved and chest pain – 31% improved. This was probably a reflection of those with active tuberculosis – a chronic disease slower to respond to usual treatment programs.
5. Of those with dyspnea, 75% improved. This could reflect improved cardiac function, decreased pulmonary inflammation, or a general increase in strength.
6. Weight gain showed progression in the three groups over time: four weeks (Table 1.1) 40% improved, six weeks (Table 2.1) 50% improved, and eight weeks (Table 3.1) 100% improved.
7. Erythrocyte Sedimentation Rate (ESR) also showed progressive improvement over time: 27% at four weeks, 30% at six weeks, and 83% at eight weeks. This probably reflects a decreasing level of systemic illness and inflammation with longer use of Immune 26.
8. Interestingly, CD4 counts improved in a number of clients in each group, suggesting a strengthening of immune function. One wonders if giving Immune 26 longer or in larger amounts would produce greater gains in CD4 counts.

In our TASO study, each participant had come to the clinic because they were ill and "didn't feel well." Of the 31 total participants all but four stated they were "much improved," or "definitely better" by the end of the study. Though this is a subjective response, it is significant because of how enthusiastically it was expressed by most.

In the four week Group (C):

J.B. – age 40 female stated, "this gives me a lot of energy and good appetite, and my fevers are gone."

J.N. – age 36 female, "I can now do work around the house, and the swelling in my feet has gone."

F.N. – age 22 male, noted he was "quite strong now and have a good appetite."

H.M. – age 42 female said she was "improved and can cultivate my land now ... very high appetite."

J.T. – 43 year old woman is "smiling because of this food ... much gain in energy ... could hardly walk, and had paralysis, now can walk three kilometers with strength in my muscles."

In the six week Group (B):

L.A. – 30 year old female "appetite is improved and there's less bone pain."

F.K. – 48 year old male "much improvement and now very good appetite."

A.K. – 40 year old female "No more fevers or headaches. I have more strength and less fatigue."

S.N. – 28 year old female "this stuff has improved my strength and I feel good." In the eight week Group (A):

D.M. – 43 year old male "I'm greatly improved on the supplement."

P.N. – 45 year old female "this product is very helpful, felt better in one week."

M.N. – 43 year old female "Felt much improved in two weeks." At the end of eight weeks, "I'm doing real well and have now a good appetite."

Discussion:

Infectious diseases are the number one cause of death worldwide[1]. And nowhere is this more true than on the African continent. Ancient diseases like leprosy, polio, cholera and bubonic plague are still ever present. And emerging African killer viruses like Ebola, Crimean-Congo fever, Rift Valley fever, Lassa fever, and O'nyong-nyong fever make headlines regularly[2].

Human acquired immune deficiency syndrome (HIV/AIDS) is now believed to have arisen from animal primates in sub-Saharan Africa[3]. And Africa remains the primary reservoir for this disease. A UNAIDS report estimates that 70% of the worlds 40 million HIV-infected people live in Africa, and that 2 million die annually. Current estimates range from 6.2% prevalence in Uganda to 32% in Zimbabwe and 38% in Botswana[5]. Health management for these large, infected populations represents a major unsolved problem for all African countries. Quality of life remains marginal for millions.

TASO Uganda LTD is a local NGO (non-government organization) founded in 1987 and today is the largest organized national response to the HIV/AIDS epidemic in Uganda. TASO has seven major provincial centers and a dozen additional outreach sites where trained personnel provide support services and medical care on an outpatient basis[4]. The TASO mission is "to improve quality of life for persons affected by HIV."

HIV/AIDS poses some unique challenges for the African continent. Anti-retroviral drugs are unlikely to be a helpful answer in the foreseeable future. Their inability to cure, high costs to administer, high rates of resistance, and unacceptable levels of toxicity[7] make them unsuitable for Africa's immediate needs. And despite pressures by international organizations and pharmaceutical companies to encourage greater ARV use by Africa, it is difficult to envision their effective use here. Even in developed countries with sophisticated clinical and laboratory infrastructures the limitations of ARVs are being recognized[7].

"We need something else in addition to anti-retrovirals; otherwise we are not going to move forward in this field," says Dr. José Gatell, Co-Chair of the 2002 Barcelona International AIDS Conference. "We need to treat the immune system," he says. "With anti-retroviral therapy, we have reached the roof."[6]

TASO does not administer ARVs; our focus is on management of the multiple opportunistic infections seen in our AIDS clients. Hyperimmune egg, being a food supplement with reported unique abilities to support immune function, seemed to fit TASO interests. Arkion Life Sciences, whose scientists developed this product state clearly that the product is not intended to treat or cure any classified diseases. Rather, by supporting body systems and functions, it may improve quality of life – a TASO goal.

Our focused HIV/AIDS population seemed ideal for evaluating this product inasmuch as our clients demonstrate well recognized structure-function problems. These include gastrointestinal malfunction, cerebral dementias, musclulo-skeletal weakness and wasting, and constitutional systemic symptoms[8]. Interestingly, failures in all these systems tend to parallel failures in immune functions, as roughly evidenced by falling CD4 lymphocyte counts. The TASO patient evaluation forms were designed to test these structures and their functions through the signs and symptoms usually associated with them. The study demonstrated impressive improvements in gastrointestinal function, CNS-brain function, constitutional systemic parameters, body weight and muscle strength, and Erythrocyte Sedimentation Rates. Eight-seven percent (87%) of patients said they were "definitely improved" at the end of the study.

While TASO and the world await a *cure* for HIV, or a vaccine to *prevent* it, the use of a non-toxic, immune-enhancing food supplement to improve quality of life has substantial appeal.

Conclusion:

The purpose of this TASO Study was to test whether hyperimmune egg would or would not improve quality of life for a sick HIV/AIDS population. The product demonstrated an impressive overall ability to improve signs and symptoms (i.e. quality of life) and with no apparent toxicity or undesirable side effects. These results suggest that hyperimmune egg could play an important role in African countries looking for a scientifically sound, non-toxic, easy-to-administer food supplement that demonstrates an impressive ability to improve quality of life. Because it can safely be administered by nurses in small village health stations, it is well suited to present realities in Africa. The TASO experience further suggests that reductions in expensive hospital care might be achievable with hyperimmune egg.

Dr. Francis Kizito received his Bachelor of Medicine and Bachelor of Surgery Degrees from Makerere University School of Medicine and has been with TASO since October 1998. He is presently Chief Medical Officer and oversees the medical support services for the seven major TASO Centers throughout Uganda.

*Unlike scientific articles evaluating a generic drug, I have explicitly recognized this hyperimmune egg product by brand name (Immune 26). This is important here since, unlike drugs which are almost always single chemical compounds, hyperimmune egg contains scores of antibodies, immune-modulating co-factors, and nutritional substances that could vary widely from different producers, depending on vaccinating antigens, feed given the chickens, and production techniques. Consistent with scientific correctness, it is important to note that this study only evaluated Immune 26.

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