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Journal of Human Virology & Retrovirology

Research Article

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Alternative cellular energy based therapy using enercel™ in advanced AIDS patients co-infected with tuberculosis and treated in Chernigov, Ukraine

Abstract

The therapeutic response of tuberculosis (TB) infected AIDS patients to the administration of Enercel®, a registered homeopathic product, was investigated. While all 11 patients in the study patients received anti-TB medication, only 2 patients received antiretroviral (ARV) drugs. The patients received daily Enercel® therapy administered by 4 routes (intravenous, sublingual, intranasal and intrabronchial). Eight of the 11 Enercel treated patients had TB positive sputum smears and the beginning of the study (baseline). The patients receiving Enercel plus ARV became sputum negative at 1 month and those that received Enercel without ARV were sputum negative at 2 months. Clinical and laboratory findings relating to HIV (virus load and CD4 cell counts) improved in all of the Enercel treated patients and especially in the 2 patients receiving combination therapy. The improvements far exceeded those in similar TB infected AIDS patients conventionally treated with ARV and anti-TB medication. Two such patients were included as controls in the present study. One of the control patients not receiving Enercel® had negative TB sputum at the start of the study but his sputum became TB positive during the study. The other control patient not receiving Enercel® died during the study; as did 6 previously evaluated patients not included in the trial. The benefits to the Enercel® treated patients also included a markedly improved quality of life (QOL). This preliminary study is presented to highlight a new, non-toxic approach to the therapy of AIDS patients. The proposed mechanism of action of Enercel® is briefly discussed.

Keywords: Enercel, AIDS, HIV, Tuberculosis, Homeopathy, Alternative cellular energy, KELEA, Activated water

Volume 2 Issue 6 - 2015

Valerij Dubrov,[1] Tatiana Dubrova,[1] David Christner,[2] Dariel Laurent,[2,3] W John Martin[3]

[1]Regional Antituberculosis Hospital, Ukraine
[2]World Health Advanced Technologies Ltd, USA
[3]Institute of Progressive Medicine, USA

Correspondence: W John Martin, Institute of Progressive Medicine, 1634 Spruce Street, South Pasadena CA, USA, Tel 626-616-2868, Email paudelsharmi@gmail.com

Received: September 09, 2015 | **Published:** September 28, 2015

Abbreviations: AIDS, Acquired Immune Deficiency Syndrome; HIV, Human Immunodeficiency Virus; ARV, Anti-Retroviral; QOL, Quality of Life; TB, Tuberculosis; ACE, Alternative Cellular Energy; KELEA, Kinetic Energy Limiting Electrostatic Attraction; GMP, Good Manufacturing Practice; ICE, Insufficiency of Cellular Energy

Introduction

The human immunodeficiency virus (HIV) can render the immune system incapable of effectively responding not only to HIV but to many other infectious agents.[1] Tuberculosis (TB) is among the more severe of the secondary infections occurring in HIV infected AIDS patients.[2-4] The effectiveness of antibiotic therapy for many pathogens; including TB is enhanced by an intact immune system.[5] Antibiotic therapy for TB is; therefore; relatively ineffective in AIDS patients.[2-4] Moreover; prolonged; ineffective standard antibiotic therapy in TB infected patients; has led to the emergence of new strains of TB bacilli that are resistant to the more commonly used anti-TB drugs.[6] TB caused by drug resistant bacilli is requiring the use of far more toxic antibiotics; against which the bacilli can also potentially acquire resistance. This process is leading to the eventual formation of TB bacilli for which there may no longer be effective antibiotics.[7]

Homeopathy has a long history as a treatment modality for a wide range of illnesses.[8-9] It involves the use of highly diluted solutions that apart from water and commonly a low concentration of ethanol, are essentially free of biochemically active components. Enercel has been classified by its manufacturer as a homeopathic product without any known adverse effects.[10] In combination with TB medications; it has been shown to improve both cure rates and time to sterilization in a study of newly-diagnosed TB patients in the Ukraine.[11] This paper reports on extremely promising findings with 4 months use of Enercel therapy in nine TB infected AIDS patients who were not receiving ARV during the study period. The findings were compared with the results of 3-months therapy in 2 patients who received both Enercel and ARV and in 2 patients in whom ARV therapy was provided without added Enercel. The study was conducted in the Regional Anti-tuberculosis Hospital; Chernigov; Ukraine with Institutional Review Board (IRB) approval.

Materials and methods

Patient selection and therapy groups

The HIV infected patients were recruited from within the inpatient population of Communal Medical and Preventive Institution; Regional Anti-tuberculosis Hospital; Chernigov; Ukraine. The eligibility requirements included being 18 to 65 year-old; with active pulmonary TB defined radiologically and/or by TB smear positive sputum. The patients' baseline CD4 count had to be below 500 cells/mm^3 with an HIV viral load of greater than 10,000 copies/ml. Hemoglobin levels >90 g/L; leukocytes >3.0x103 cells/ml and serum alanine aminotransferase [ALT] level <3x upper limit of normal were also required at enrollment. Dietary supplements other than multivitamins; minerals and protein supplements were not allowed during the study. Nineteen patients were evaluated; 6 of whom were not enrolled into the study because of various exclusion criteria (including continuing alcohol and/or drug abuse). These 6 patients died within the study time period; in spite of receiving anti-TB and ARV therapies. Of the

13 enrolled patients; 9 received Enercel with no added ARV therapy (numbered as patients 1 to 9); two patients (number 10 and 11) received Enercel plus ARV therapy. Two control patients who only received ARV as the anti-HIV therapy were also included in the study as representing conventionally treated TB infected AIDS patients. All 13 enrolled patients were maintained on standard anti-TB medication.

Enercel therapy

Eleven patients received each of 3 Enercel products registered in the Ukraine and manufactured per the Homeopathic Pharmacopoeia of the United States (HPUS) in GMP facilities. Enercel Plus was administered intravenously at a dose of 50ml twice a day for 1 month and then once a day for 2 months in the two patients also receiving ARV and for 3 months in the 9 patients not receiving ARV. Seven ml of Enercel Mist was administered via an Omron Compare NE-C29-E nebulizer once daily; with an additional two puffs per nostril 3 times daily throughout the patient study periods; along with 20 drops of Enercel Max administered sublingually twice daily.

ARV therapy

Regimens of three ARV were chosen for the 4 patient (2 receiving Enercel in addition to the ARV and 2 receiving ARV without added Enercel). The choices of ARV were determined for each patient by the Infectious Disease consultant and were not modified during the study.

Assessments

HIV

CD4 counts and HIV virus loads were determined in the hospital's licensed clinical laboratory at the beginning of the study (baseline) and monthly; thereafter; till the end of the study. The lowest detectable level of HIV is 40 copies per ml.

TB

Microscopic examination of sputum samples obtained from each patient by bronchoscopy was performed using established acid fast bacilli staining methods.

Quality of life (QOL)

This was a self-assessed level of overall incapacity/disability caused by the illness and reflected the perceived severity of the symptoms being experienced. The major symptoms assessed included: cough; energy; mood; weakness; appetite; fevers; night sweats; weight and ease of breathing. The patient's overall assessment of the impact of his disease on his QOL was made at the beginning and at the end of the study. It was recorded as a percentage within the range of 0% being free of symptoms and 100% being totally disabled by the illness.

Toxicity

Laboratory analysis included: hemoglobin; red blood cell count; total leukocytes with differential subsets; erythrocyte sedimentation rate; total bilirubin; ALT; and thymol turbidity test. In addition; the patients were questioned for toxicity and clinically monitored during the daily administration of Enercel.

Accuracy of data recording

Study data were entered into a computer using the program Epi-Info 2000. Representative information from the patient charts and case report forms were cross-checked with the entered information to ensure >99.5% accuracy of the entered data.

Results

Group 1: Enercel without ARV (9 patients)

The baseline and monthly thereafter HIV viral load values for the 9 patients; numbered 1 to 9; are shown in Table 1. Seven of the 9 patients had viral loads >100,000 copies per ml at the beginning of the study; with 2 patients having baseline viral loads below 100,000 copies per ml. With the exception of patient number 6; all of the patients with virus loads exceeding 100,000 at baseline attained virus loads values at 4 months of <100,000 copies per ml. Patient number 6 had a very high baseline reading of 2,674,129 copies. There were reductions in virus loads at the second and third months, yet an increase at month four. Despite this, the patient's CD4 count had clearly improved at the fourth month. Of the 2 patients with initial virus loads of <100,000; one had no detectable virus (<40 copies per ml) at 4 months. Excluding patient number 6 because of the exceptionally high baseline value; the average virus loads in the 8 patients at baseline and at 4 months were 204,559 and 63,529 copies per ml; respectively; a significant reduction.

Table 1 Laboratory parameters in the 9 patients receiving Enercel® without ARV

Patient	Month	CD4*	Viral Load**
Patient # 1			
	Baseline	60	130,811
	Month 1	74	60,666
	Month 2	93	34,212
	Month 3	106	55,399
	Month 4	100	10,957
Patient # 2			
	Baseline	66	397,187
	Month 1	87	233,581
	Month 2	98	60,666
	Month 3	108	60,243
	Month 4	111	45,241
Patient # 3			
	Baseline	358	41,603
	Month 1	544	44,926
	Month 2	405	96,872
	Month 3	458	63,262
	Month 4	404	21,879
Patient # 4			
	Baseline	61	294,136
	Month 1	151	227,145
	Month 2	127	96,872
	Month 3	132	ND***
	Month 4	139	10,290
Patient # 5			
	Baseline	481	177,879
	Month 1	503	121,986
	Month 2	651	47,841
	Month 3	633	30,809
	Month 4	532	17,931
Patient # 6			
	Baseline	233	2,674,129
	Month 1	252	ND
	Month 2	391	1,885,818
	Month 3	209	1,132,513
	Month 4	581	1,400,045
Patient # 7			
	Baseline	360	35,428

Citation: Dubrov V, Dubrova T, Christner D, et al. Alternative cellular energy based therapy using enercel™ in advanced AIDS patients co-infected with tuberculosis and treated in Chernigov, Ukraine. *J Hum Virol Retrovirol.* 2015;2(6):202–205. DOI: 10.15406/jhvrv.2015.02.00061

Table Continued...

Patient	Month	CD4*	Viral Load**
	Month 1	466	15,867
	Month 2	546	8,228
	Month 3	447	5,199
	Month 4	458	< 40
Patient #8			
	Baseline	345	181,619
	Month 1	263	207,628
	Month 2	287	100,016
	Month 3	370	67,605
	Month 4	388	73,204
Patient #9			
	Baseline	112	378,233
	Month 1	81	502,236
	Month 2	225	213,260
	Month 3	247	81,907
	Month 4	259	90,812

*Number of CD4 cells/mm^3

**HIV copies per ml

***Not done—because of too little blood to analyze

The baseline and monthly thereafter CD4 counts for all 9 patients are also shown in Table 1. Although there was considerable variability in individual patients; the trend was clearly towards an increasing CD4 value. All of the patients showed an increase of 40 or more CD4 cells; with patient number 6 having the highest increase of CD4 cells from 233 to 581. The average CD4 count of all of the patients at baseline was 231 cells/mm^3; rising to 330 cells/mm^3 at 4 months.

An example of improvement is provided by patient number 1. He had disseminated herpes simplex at enrollment with a CD4 count of 60 cells/mm^3 and a viral load 130,811 copies/ml. Within 10 days; his herpes infection resolved. At 4 months his CD4 count had risen to 100 cells/mm^3 and his viral load decreased to 10,957 copies/ml. Along with the other 8 patients his QOL had greatly improved. Using a self-assessed measure of the degree to which each patient considered himself to be totally disabled; the average evaluation at baseline in the 9 patients was 47.3%. It had dramatically dropped to 14.1% when again self-assessed at the end of the 4-month study. TB sputum smears were positive in 6 of the 9 patients at baseline—the diagnosis of TB was made on the basis of clinical and radiological findings in the other 3 patients. TB smears were negative by 2 months in each of the previously smear-positive patients receiving Enercel.

Group 2: Enercel with ARV (2 patients)

Two patients designated as patients 10 and 11; were included in this treatment group. Both achieved undetectable levels of HIV by 1 month of combined therapy; including one patient with an initial extremely high viral load of 5, 192, 532 copies per ml. (Table 2) His CD4 count rose from 338 cells/mm^3 at baseline to 788 cells/mm^3 at 3 months. His self-assessed percent disability fell from 39% to 6%; becoming essentially symptom free. The CD4 count in the second patient in this group rose from 87 cells/mm^3 at baseline to 338 cells/mm^3 at 3 months. His self-assessed disability fell from 44% at baseline to 18% at 3 months. The sputum smears of each patient were positive at the beginning of therapy and were negative at 1 month and; thereafter; to the end of the study.

Group 3: ARV only (2 patients)

One patient on ARV alone had no detectable HIV particles in the blood by 1 month; but his CD4 count did not significantly change over the 3 months (baseline 28 cells/mm^3 and 29 cells/mm^3 at 3 months). His sputum smear for TB; which was negative at baseline; became positive at 3 months. Moreover; only a modest lessening of his disability symptoms was recorded; decreasing from 51% to 43% during the study. The second patient on ARV alone also achieved an undetectable viral load; but; as with the other patient in this group; his CD4 count did not change significantly [140 cells/mm^3 at baseline and 152 cells/mm^3 at 2 months]. This patient developed a high fever and died at 2 ½ months.

Table 2 Laboratory Parameters in the 2 Patients Receiving Enercel® With ARV

Month	Patient #	CD4	Viral Load
Patient # 10			
	Baseline	87	630,073
	Month 1	352	750
	Month 2	318	64
	Month 3	338	<40
Patient #11			
	Baseline	459	5,192,532
	Month 1	438	<40
	Month 2	378	<40
	Month 3	788	<40

Number of CD4 cells/ mm^3

HIV copies per ml

Discussion

The data presented in this paper highlight the value of seeking therapies for infectious diseases outside of the conventional pharmaceutical and immunotherapy approaches.[10] A striking feature of certain proposed therapies is the apparent effectiveness against a wide range of both infectious and non-infectious illnesses. This is seen with Enercel in its benefits in suppressing TB and HIV; as shown in this paper. Enercel has also been reported as beneficial in treating children with diarrhea[11] and patients with amyotrophic lateral sclerosis (ALS).[12]

Access to primary care is limited among the patients at risk for HIV/TB co-infection in the Ukraine; including prisoners; poverty-stricken; alcoholic and intravenous drug users.[13] Therefore; these patients typically present with advanced TB and HIV disease; with greater than 50% mortality within a year in spite of medications. Although the medications can usually suppress HIV viral load and TB infection; immune reconstitution is rarely achieved. Because of the relative clinical ineffectiveness of ARV therapy in this patient population; the IRB approved and the patient volunteers agreed to the planned 4-month delay in beginning ARV in some of the participants so as to allow Enercel to be evaluated.

Using Enercel either alone (9 patients) or in combination with ARV (2 patients) proved to be clearly beneficial in the therapy of advanced AIDS patients. None of the 11 Enercel treated patients died during the 4-month study period. This contrasts with the deaths of the 6 ARV-treated patients who did not meet the study inclusion criteria and of 1 of the 2 study patients not receiving Enercel. Moreover; all of the Enercel treated patients; gained significant improvement in their QOL; far beyond that typically seen in conventionally treated advanced AIDS patients. It is especially noteworthy that no adverse effects occurred with Enercel administration in any of the treated patients. Additional studies are required to determine if the current protocol can be further optimized to achieve undetectable virus load and normalized CD4 cell counts in advanced AIDS patients. It is also important that Enercel be tested for its benefits in less severely ill HIV infected patients.

The 2 patients treated with Enercel plus ARV did better in terms of QOL, CD4 counts and TB negative sputum than the 1 surviving study patients who received ARV alone. A favorable comparison of the Enercel plus ARV therapy can reasonably be extended to other advanced AIDS patients only receiving ARV therapy. Thus, while it is premature to propose Enercel as an available substitute for ARV, it can presently be considered a potential useful adjunct to existing ARV therapy. It is important; therefore; to define the mode of action of Enercel and related homeopathic products.

The traditional view of homeopathy as providing symptom specific relief according to the Laws of Similar is not sustained by actual clinical experience.[14,15] A more informed view is that of diseases being manifestations of an insufficiency of cellular energy (ICE) in various regions of the body.[16] It has been suggested that products such as Enercel and various other forms of complementary alternative medicine (CAM) assist cellular functions through an alternative cellular energy (ACE) pathway; expressed as an enhanced dynamic (kinetic) activity of the body's fluids.[15-18] The increase in kinetic activity is attributed to a lessening of the intermolecular, electrostatic, hydrogen bonding between water molecules.[19,20] Specifically; it is proposed that the herbal, plant and mineral constituents of Enercel allow for the absorption of an environmental force termed KELEA (kinetic energy limiting electrostatic attraction). KELEA activated fluids; such as Enercel; are seemingly able to further increase the body's direct absorption of KELEA from the environment. This can potentially lead to additional and continuing enhancement of the body's ACE pathway.

A wide range of compounds added to fluids can attract KELEA from the environment and transfer energy into the fluid. If necessary; the activating compounds can then be removed from the activated fluid by zero-residue filtration or by progressive dilutions; as in homeopathy. Various electrical devices can similarly be used to activate fluids or to more directly activate the body's ACE pathway. Rather than requiring injections; it will be highly advantageous to develop protocols in which KELEA activated fluids are orally consumed. The successful use of Enercel as described in this paper provides an important impetus to proceed with studies on the possible benefits of KELEA activated drinking water in patients with AIDS and other illnesses.

Conclusion

Rather remarkable therapeutic benefits were observed in 9 severely ill, TB co-infected AIDS patients using Enercel as the sole anti-HIV agent. Enercel also increased the effectiveness of standard anti-TB and ARV therapies. Although categorized as homeopathy; Enercel and similar products are more likely able to provide therapeutic benefits through the alternative cellular energy (ACE) pathway. Further studies are required to better define the mechanism of action of Enercel and related products and to optimize their therapeutic use in AIDS and other illnesses.

Acknowledgments

None.

Conflicts of interest

None.

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