

EFFICACY STUDIES ON EFFECT OF COMPLEMENTARY ALTERNATIVE MEDICINAL FORMULATION ON BIOMARKERS AND IMMUNE FUNCTIONING OF HIV/AIDS PATIENTS

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ABSTRACT

AIDS (Acquired immune deficiency Syndrome) is characterised by infection with HIV (Human immune deficiency virus) which leads to collapse of immune system. Although highly active antiretroviral therapy (HAART) has contributed significantly to lowering morbidity and mortality from AIDS, antiretroviral drugs do not fully restore the immune system and patients often fail multi-drug treatment. Hence there is a need for alternative /complementary medicine (CAM) that can restore an immune system ravaged by HIV/AIDS. The present study was undertaken to study the efficacy of Ayurvedic formulation MIRACLETM, made from extracts of *Swertia Chirayita*, and other plants like *Asparagus racemosus*, *Picrorhiza kurroa*, and Vitamin E Composition in HIV/AIDS infected male adults unresponsive to HAART.

KEYWORDS: *Swertia Chirayita*, *Asparagus racemosus*, *Picrorhiza kurroa*, Complementary alternative medicine (CAM).

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INTRODUCTION

AIDS (Acquired immune deficiency Syndrome) is characterised by infection with HIV (Human immune deficiency virus) which leads to collapse of immune system. Although highly active antiretroviral therapy (HAART) has contributed significantly to lowering morbidity and mortality from AIDS, antiretroviral drugs do not fully restore the immune system and patients often fail multi-drug treatment. Hence there is a need for alternative /complementary medicine (CAM) that can restore an immune system ravaged by HIV/AIDS. To address this need, investigators have formed multidisciplinary collaboration to evaluate and demonstrate utility of natural immune –based modulators in ethnically diverse patients with HIV/AIDS. The long – term goal of this study is to develop a CAM therapy to facilitate immune reconstitution and HIV eradication following cessation of antiretroviral treatment or concurrent with continued antiretroviral treatment. It is based on the premise of a widespread deficiency of GSH (Glutathione)¹, vital lymphocyte function, in patients

with HIV/AIDS. Research has shown that increase of oxidative stress in HIV/AIDS patients with reduced levels of GSH and also ESR has shown as prominent marker for progression of disease². ESR (Erythrocyte sedimentation rate) is very high in patients with HIV/AIDS³.

The present study was undertaken to study the efficacy of Ayurvedic formulation MIRACLETM, made from extracts of *Swertia Chirayita*, and other plants like *Asparagus racemosus*, *Picrorhiza kurroa*, and Vitamin E Composition in HIV/AIDS infected male adults unresponsive to HAART (i.e. those with persistent CD4+ (Cluster of differentiation)Count > 50 cells/mm³, viral load > 5000 copies /cc) and HIV-negative controls.

MATERIALS AND METHODS

Study Population

The population consisted of 30 subjects divided into three groups was selected. HIV infected patients 10 cases (n=10) males, AIDS patients 10 cases (n=10) males and equal number of age sex matched control subjects (n=10) were investigated randomly. All patients were subjected

to detailed history taking and clinical examinations. Informed consent of the patients was taken before testing. All the subjects were treated for 30 days with MIRACLE™ along with their regular HAART.

Biochemical Investigation

Total haemoglobin, Neutrophils %, lymphocyte % were determined by fully automated haematology analyzer (Beckmann coulter Germany). ESR was determined by Wintrobe's tube for first hour. CD4, CD8, CD3 were determined by BD FACS machine.

Estimation of GSH

Serum reduced GSH was analyzed with the KIT from Northwest Life science specialities, LLC LOT No: 7100 on micro plate reader and calculated.^{1,3}

RESULTS AND DISCUSSION

The HIV –seropositive group consisted of 10 male individuals with symptomatic or asymptomatic HIV infection (mean CD4 Cell count 310 cells/mm³). HIV-seropositive AIDS group consisted of 10 male individuals (mean CD4 cell count 110 cells/mm³). Both the groups were receiving Combinational antiretroviral therapy. The control group was composed of 10 healthy, seronegative individuals from local workers and hospital staff. Control subjects had no acute or chronic illness and were not taking any medications or nutritional supplements. From **Table 1** and **Fig.1** the mean haemoglobin levels, mean neutrophil %, mean lymphocyte % count has increased in HIV/AIDS patients significantly after treating with MIRACLE™ for a period of 30 days. There was significant decrease of ESR mm/hr in all HIV/AIDS patients. GSH Levels has increased markedly in HIV/AIDS subjects which indicates there decrease of oxidative stress which helps lymphocyte activation. The control group also had shown good response to MIRACLE™ (CAM) with marginal response to the treatment. From **Table 2** and **Fig 2** it is clear that there was significant elevation of CD4, CD8 and CD3 T-Lymphocyte subsets before and after the treatment of HIV/AIDS subjects.

Human monocyte derived macrophages are involved in a variety of pathological vents in HIV infection the hallmark of which is immunodeficiency with progressive CD4 T lymphocyte depletion³. Even if the exact cause of this loss of CD4 T cells is unknown, the most widely accepted hypothesis is that HIV primes the cell to apoptotic cell death⁵. Oxidative stress might be one of the reasons as increased oxidative stress depletes GSH levels and promotes apoptotic cell death^{5,6}. Haematological abnormalities are among the most common complications of infection with HIV^{4,5}. The observed dramatic reduction in GSH plasma levels of

HIV seropositive patients compared to AIDS patients in which GSH levels are drastically lowered⁷⁻¹⁰ indicating severity of progression of disease is shown in Fig-1. Rapid elevation of ESR has also been observed during disease progression in HIV/AIDS^{11,12}. There were significant correlation between depleted GSH Levels, elevated ESR and decreased CD 4 levels. Research has shown elevated GSH levels decreases apoptotic cell death⁴. *Swertia Chirayita*, *Picrorhiza kurroa* and *Asparagus racemosus* has proven immunoadjuvant properties and antioxidant properties¹³⁻¹⁹. Complementary alternative medicine has got better answer to increase the GSH levels and to prevent apoptotic cell death in HIV/AIDS patients. There was significant increase of Plasma GSH levels in both HIV/AIDS groups where control group has shown moderate plasma GSH elevation after the 30 days treatment with CAM named MIRACLE™. All HIV/AIDS group of subjects has shown decreased ESR values and increased haemoglobin levels comparatively after the treatment. Increase in Neutrophil %, lymphocyte % and elevation of CD 4 T lymphocytes along with elevated GSH levels has been observed in both HIV, AIDS subjects after treatment.

CONCLUSION

This study showed that during progression of disease in HIV to AIDS there was significantly decrease in plasma GSH levels and high ESR values which comparatively has shown decrease in haemoglobin levels. It also highlights the importance of GSH concentration which directly reflecting the immune activity in HIV/AIDS patients. The study has proven the efficacy of Complementary alternative medicine MIRACLE™ has shown promising elevation of plasma GSH levels and comparatively decreased the T Lymphocytes apoptotic cell death .after the treatment ESR has been decreased in both HIV/AIDS subjects comparatively elevating CD 4 cell population.

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Table 1

PARAMETRE	CONTROL SUBJECTS		HIV INFECTION		AIDS PATIENTS	
	INITIAL	FINAL	INITIAL	FINAL	INITIAL	FINAL
Hb gm/dl	14.36	14.86	12.02	13.3	9.8	10.8
Neutrophil%	49.7	58.2	43.0	48.4	48.5	50.6
Lymphocyte %	31.6	33.9	34.5	42.4	48.5	50.6
ESR mm/hr	10.3	10.1	63.6	20.5	105.6	31.7
GSH mg/dl	50.9	54.3	36.2	52.1	19.6	36.0

Table 2

PARAMETRE	HIV PATIENTS		AIDS PATIENTS	
	INITIAL	FINAL	INITIAL	FINAL
CD4 cells/mm3	310	450	110	320
CD8 cells/mm3	105	625	125	565
CD3 cells/mm3	1180	1700	250	1225

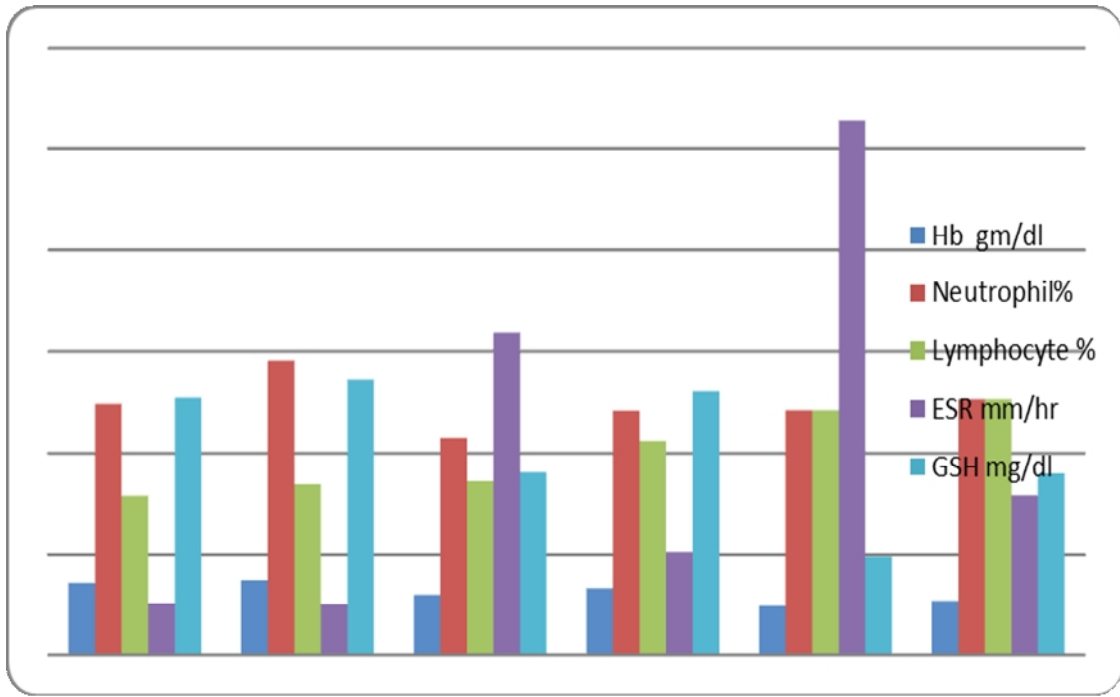


Fig.1 : Control subjects with biochemical parameters before and after treatment has shown marginal response of immune activation compared with HIV Seropositive groups and AIDS groups.HIV Seropositive groups has shown significant response to treatment when compared to AIDS group .AIDS subjects has also shown marked response to treatment with significant immune activation.

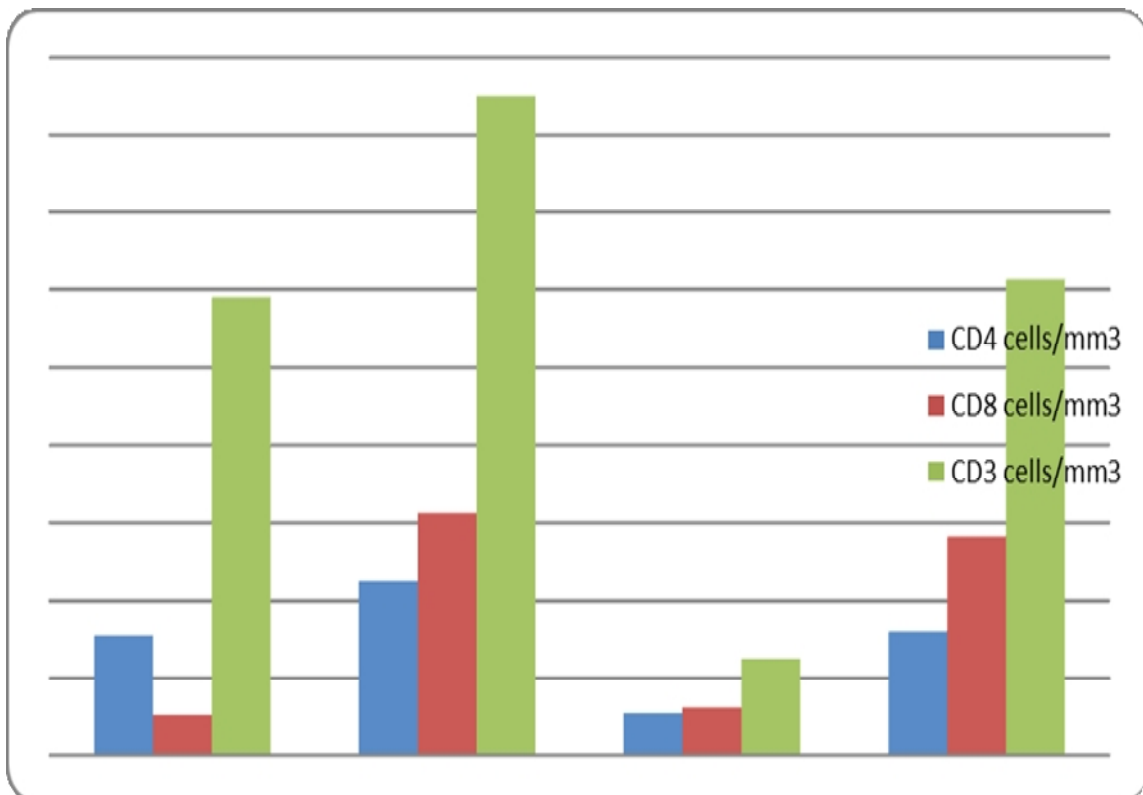


Fig. 2: Significant elevation of CD 4, CD8 AND CD3 Lymphocytes has been observed in both HIV/AIDS groups after treatment

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