

Clinical Assessment of a Unani Formulation Safoof Jawahar Mohra in Clinical Sign and Symptoms of HIV/AIDS

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A controlled, randomized, single blind clinical trial was conducted in forty patients with HIV positive individuals of either sex between the age group of 15-50 years. The patients who were not taking anti retroviral treatment and whose CD4 count was above 550 cells/mm³ were included in the study. The control group, received placebo (starch capsules) orally, in the dose of 250 mg. twice a day; while the test group was treated with the Safoof Jawahar Mohra (SJM) at 250 mg. orally, twice a day. The duration of study was five months. The assessment of the disease in the control and test groups was monitored before treatment and every month up to 5 months, on the basis of sign and symptoms of HIV/AIDS. The scoring was done using standard scales.

The study revealed that the Unani poly pharmaceutical preparation Safoof Jawahar Mohra produced remarkable improvement in the sign and symptoms of HIV/AIDS individuals.

Keywords: Safoof Jawahar Mohra.

Introduction

HIV/AIDS pandemic is emerging as one of the most serious health problems of this century and the focus is shifting fast from developed nations to developing countries and to India (Rewari and Nag, 2004). AIDS was first recognized in the United States in the summer of 1981

(Fauci and Lane, 2005). The virus causing AIDS was independently identified by a team of French Scientists led by Luc Montagnier of Pasteur Institute; and American Scientists led by Robert C. Gello, of National Cancer Institute in 1983-1984 (Gao *et al.*, 1999; Sharp *et al.*, 1994). In 1983, Human Immunodeficiency Virus (HIV) was isolated from a patient with lymphadenopathy, and by 1984 it was demonstrated clearly to be the causative agent of AIDS (Fauci and Lane, 2005, De Clereq, 1995).

Globally 35.3 (32.2-38.) million people were living with HIV in 2012. Of these, approximately 16.8 million are women and 3.4 (3.1-3.7) million are less than 15 years old. There were about 1.6 (1.4-1.9) million deaths from AIDS in 2012 (Anonymous, 2013).

There has been extensive drug development research programs worldwide and few Antiretroviral drugs appeared to be effective. (ART) Antiretroviral drugs are found. However, due to severe side effects, search for safe therapeutics for AIDS is still remains active.

There are strong possibilities that some drugs of natural origin, derived from either from plants or minerals would be effective to modulate immunity to against HIV, at different levels of its replicative cycle. There are many Unani formulations composed of herbs and minerals and particularly gems, which are used as *Muqawwi-e-Aam* (general body tonic) for the purpose of improving functions of vital organs, increasing *Hararat-e-Ghareezi* (metabolic heat) and *Rooh* (vital energy or life force) and for boosting the immune systems. The Safoof Jawahar Mohra is one of such preparation, but it has not been scientifically evaluated for the above functions.

In the present study the Safoof Jawahar Mohra, containing plant and minerals origin drugs, was prepared according to the formula described in the National Formulary of Unani Medicine (Government of India); and considering its efficacy as general body tonic and vital organic tonic it was selected to conduct present clinical study.

Methodology

Preparation of the Test Drugs

The test drugs i.e. Safoof Jawahar Mohra (SJM) was prepared according to standard method described in the national formulary of Unani medicine (Government of India) (Anonymous, 1993) as described in the Table 1. The preparation procedures were performed in the Saidla (Pharmacy) Section of the Department of Ilmul Advia, Dr. MIJ Tibbia College and HARK Hospital, Mumbai.

The ingredients of the test formulation i.e. SJM were procured from authentic source. The quality assurance was conducted on the basis of description provided in the classical Unani literatures, as well as from the authorities approved for testing the identity and purity of plants, minerals, and animal origin sources.

TABLE 1
Formula of Safoof Jawahar Mohra (SJM)

S.No.	Ingredients	Scientific names	Quantity (g)
1.	Zehar Mohra	Serpent Stone	30
2.	Marwareed	Pearl	10
3.	Bussud	Red coral	10
4.	Kehroba	<i>Vateria indica</i>	10
5.	Lajward	<i>Lapis lazuli</i>	10
6.	Yaqoot	Ruby	10
7.	Yaqoot Kabood	Sapphire	10
8.	Yaqoot Asfar	Topaz	10
9.	Yashab Sabz	Green Jade	10
10.	Zamuurrad	Emerald	10
11.	Aqeeq Surkh	Red Agate	10
12.	Warq-e-Nuqra	Silver leaves	10
13.	Mastagi	<i>Pistacia lentiscus</i>	10
14.	Warq-e-Tila	Gold leaves	10
15.	Jadwar	<i>Delphinium denudatum</i>	10
16.	Narjeel Dariyae	<i>Lodoicea seychellarum</i>	5
17.	Arq-e-Gulab	Rose water	Q.S. (Approx. 700 ml.)

(Anonymous, 1993)

Clinical Trial Protocol

A controlled, randomized, single-blind clinical trial was conducted as per GCP guidelines, on the individuals with HIV positive cases. The patients were diagnosed through the serological test.

Sample Size and Randomization

A total 40 cases of HIV/ Positive were registered for clinical trial. The patients were randomly divided into two groups. In both controlled and test group (20 cases in each group).

Inclusion and Exclusion Criteria

Inclusion criteria was:

1. Male or female belonging to the age group of 15-50 years, suffering from AIDS.
2. The patients who were not taking anti-retroviral therapy and their CD4 count was above 550 cells/mm³.
3. The Informed Consent Form was given to each individual. The patients willingly accepting the treatment were included in the clinical trial.

Exclusion criteria:

1. The patients suffering from late symptomatic and advanced stage. The patients having diabetes, hypertension, cardiac disorders, renal disorders, severe psychiatric disorders and hepatitis.
2. The pregnant/lactating women and also children.

Subjects and Groups

As described above HIV positive individuals whose CD4 count was above 550 cells/ mm³ were included in this study were randomly grouped as 'Control' and 'Test'. The following schedule was adopted for study.

1. **Control Group:** Placebo (Capsule of 250 mg. containing starch) orally, twice a day.
2. **Test Group:** Safoof Jawahar Mohra (SJM) in the dose of 250 mg. capsule orally twice a day.

Duration of the Study

Total duration of the study on individual cases was five months including the assessment of the effects and the inference of the results. However, the follow-up of each individual was done after the completion of the study.

Assessment Criteria

The assessment of the treatment on the individuals suffering from HIV/AIDS was made on the basis of clinical sign and symptoms.

The complete history of the HIV/AIDS patients was recorded in the Case Report Form (CRF). The sign and symptoms in consideration included fever, headache, body ache, fatigue, arthralgia, pharyngitis, erythematous morbilliform eruptions, urticarial rash, anorexia, diarrhoea, nausea, vomiting and chronic weight loss.

The intensity of the signs and symptoms was graded and rated as: Mild (1), moderate (2), severe (3) and absent (0). The clinical sign and symptoms were recorded before the treatment (baseline phase) and every month, up to five months in the treatment phase.

The results were analyzed statistically using ANOVA and paired 't' test.

Adverse Drug Reactions

As the Safoof Jawahar Mohra (SJM) has been used as vital organs' and general body tonic in Unani System of Medicine, and since over hundreds of years it was found to be safe and with no reports regarding any side effects on any organ or system. Hence, it was used safely in a controlled dosage form. However, a close observation was made to check and record any early sign of adverse effects in the Case Report Form (CRF).

Analysis of Signs and Symptoms in Control Group

The statistical analysis of the signs and symptoms related to AIDS, using ANOVA test in the patients of HIV/AIDS, treated with the placebo showed that the mean scores of the manifestations were 45.00 ± 0.89 (mean \pm standard error) ($p > 0.10$) at the baseline phase (column A); 49.0 ± 0.95 ($p > 0.10$) at the Ist month (column B); 54.20 ± 1.33 ($p > 0.10$) at the IInd month (column C) 59.35 ± 1.44 ($p > 0.10$) at the IIIrd month

(column D) 62.40 ± 1.27 ($p > 0.10$) at the IVth month (column E) and 67.10 ± 1.09 ($p > 0.10$) at the Vth month (column F) of the treatment phase of clinical trial. The severity of the manifestations directly related to AIDS were gradually increased in the control group (placebo) within the total span of the clinical study.

Within Group Comparisons

The comparisons of the mean scores of the signs and symptoms of HIV Positive Individuals, at various stages of treatment were also made. It was observed that the scores of baseline phases of IInd, IIIrd, IVth and Vth month, Ist and IIIrd month, Ist and IVth month, Ist and Vth month, IInd and IVth month, IInd and Vth month, IIIrd and Vth month demonstrated significant differences ($p < 0.001$). The scores of Ist and IInd month, IInd and IIIrd month also showed significant differences ($p < 0.05$). While it was observed that there was no significant difference between the means scores of baseline phase of Ist, IInd and IVth month, IVth and Vth month of the treatment phase ($p > 0.05$).

Within Group Comparisons

The (ANOVA) analysis of the result of different stages of treatment of the HIV Positive individuals with the test drug, i.e. Safoof Jawahar Mohra, elaborated that the scores of the sign and symptoms at baseline phase (column A) was 47.90 ± 1.24 (mean \pm standard error) ($p > 0.10$); on Ist month (column B) it was 43.20 ± 1.06 ($p > 0.10$); at the end of IInd month (column C) it was 39.50 ± 0.98 ($p > 0.10$); on IIIrd month (column D) it was 35.65 ± 1.18 ($p > 0.10$) at IVth month (column E) it was 31.10 ± 1.09 ($p > 0.10$); and at the end of Vth month (column F) of the treatment phase the mean score was 28.15 ± 1.06 ($p > 0.10$). It is clear that the severity of sign and symptoms gradually declined in the test group with SJM within the total span of treatment.

Individual Signs and Symptoms of HIV positive Individuals – (Inter Group Comparisons)

The inter-group comparisons of each individuals were made through the paired 't' test at each stage of the treatment i.e. baseline phase and at the end of every month up to Vth month in the control and test groups.

TABLE 2
Individual Sign and Symptoms Directly of HIV Positive (Inter Group Comparisons)

Mf	Baseline Phase		Phase Treatment Phase (Months)														
			I			II			III			IV			V		
	C	T	C	T	C	T	C	T	C	T	C	T	C	T	C	T	
1.	2.55±0.14	2.95±0.05	2.50±0.14	2.65±0.11	2.65±0.11	2.30±0.13	2.70±0.13	1.85±0.13	2.45±0.21	1.70±0.15	2.75±0.22	1.25±0.16					
	P=0.0165		P=0.4528			P=0.0493			P=0.0002			P=0.0055			P<0.0001		
2.	1.90±0.23	2.55±0.18	2.35±0.20	2.20±0.20	2.10±0.23	2.05±0.21	2.60±0.15	1.90±0.91	2.46±0.18	1.70±0.19	2.60±0.18	1.40±0.18					
	P=0.0497		P=0.6142			P=0.8743			P=0.0093			P=0.0148			P=0.007		
3.	2.20±0.26	2.30±0.21	1.90±0.29	2.20±0.19	2.35±0.25	2.15±0.18	2.45±0.23	2.05±0.18	2.35±0.27	1.86±0.21	2.65±0.22	1.55±0.18					
	P=0.7547		P=0.3900			P=0.5508			P=0.2258			P=0.1799			P=0.0020		
4.	1.75±0.28	2.30±0.19	1.70±0.29	2.05±0.18	2.06±0.30	2.10±0.18	2.05±0.30	1.85±0.21	2.30±0.27	1.70±0.21	2.60±0.27	1.55±0.21					
	P=0.1570		P=0.3087			P=0.9020			P=0.6239			P=0.1372			P=0.0138		

Contid.....

Mf	Phase Treatment Phase (Months)														
	Baseline Phase		I		II		III		IV		V				
	C	T	C	T	C	T	C	T	C	T	C	T			
5.	2.35±0.17	2.15±0.22	2.10±0.22	2.00±0.21	2.20±0.24	1.85±0.18	2.25±0.24	1.90±0.18	2.40±0.23	1.86±0.23	2.46±0.25	1.60±0.18			
	P=0.5068		P=0.7607		P=0.2856		P=0.3087		P=0.0938		P=0.0253				
6.	1.60±0.31	2.10±0.19	1.55±0.31	2.05±0.18	1.50±0.31	2.00±0.19	1.80±0.26	1.90±0.20	2.05±0.29	1.70±0.21	2.50±0.31	1.65±0.21			
	P=0.0967		P=0.0761		P=0.1351		P=0.7481		P=0.2465		P=0.0226				
7.	2.30±0.26	2.15±0.21	2.30±0.27	1.70±0.21	2.620±0.29	1.70±0.16	2.45±0.21	1.70±0.18	2.15±0.29	1.50±0.19	2.25±0.30	1.35±0.15			
	P=0.6513		P=0.0486		P=0.0761		P=0.0039		P=0.0237		P=0.0046				
8.	0.90±0.23	1.90±0.29	1.60±0.30	1.45±0.25	1.70±0.29	1.40±0.23	1.90±0.28	1.20±0.24	1.95±0.28	0.95±0.22	2.15±0.27	0.80±0.17			
	P=0.0125		P=0.7157		P=0.4528		P=0.0845		P=0.0125		P=0.0007				

Mf=Manifestations, 1=Fever, 2=Headache, 3=Malaise, 4=Body ache, 5=Fatigue, 6=Anorexia, 7=Arthralgia, 8=Chronic Weight Loss

1. FEVER

The inter group comparisons of the severity of fever demonstrated that: At the baseline phase the scores of the control group was 2.55 ± 0.14 , while it was 2.95 ± 0.05 in the test group. The two tailed p value is 0.0165 which is considered highly significant.

At the Ist month the scores of the control group was 2.50 ± 0.14 , while it was 2.65 ± 0.11 in the test group. The two tailed p value is 0.4528 and is non-significant.

At the IInd month the scores of the control group was 2.65 ± 0.11 , while it was 2.30 ± 0.13 in the test group. The two tailed p value is 0.0493 which is considered highly significant.

At the IIIrd month the scores of the control group was 2.70 ± 0.13 , while it was 1.85 ± 0.13 in the test group. The two tailed p value is 0.0002 which is considered highly significant.

At the IVth month the scores of the control group was 2.45 ± 0.21 , while it was 1.70 ± 0.15 in the test group. The two tailed p value is 0.0055 that is considered highly significant.

At the Vth month the scores of the control group was 2.75 ± 0.22 , while it was 1.25 ± 0.16 in the test group. The two tailed is $p < 0.0001$ that is considered highly significant (Fig. 1).

2. HEADACHE

The inter group comparisons of the severity of headache showed that: At the baseline phase the scores of the control group was 1.90 ± 0.23 , while it was 2.55 ± 0.18 in the test group. The two tailed p value is 0.0497 which is highly significant.

At the Ist month the scores of the control group was 2.35 ± 0.20 , while it was 2.20 ± 0.20 in the test group. The two tailed p value is 0.6142 which is non-significant.

At the IInd month the scores of the control group was 2.10 ± 0.23 , while it was 2.05 ± 0.21 in the test group. The two tailed p value is 0.8743 which is non-significant.

At the IIIrd month the scores of the control group was 2.60 ± 0.15 , while it was 1.90 ± 0.91 in the test group. The two tailed p value is 0.0093 which is highly significant.

At the IVth month the scores of the control group was 2.46 ± 0.18 , while it was 1.70 ± 0.19 in the test group. The two tailed p value is 0.0148 that is highly significant.

At the Vth month the scores of the control group was 2.60 ± 0.18 , while it was 1.40 ± 0.18 in the test group. The two tailed p value is 0.007 that is highly significant (Fig. 2).

3. MALAISE

The inter group comparisons of the severity of malaise at the baseline phase the scores of the control group was 2.20 ± 0.26 , while it was 2.30 ± 0.21 in the test group. The two tailed p value is 0.7547 which is considered non-significant.

At the Ist month the scores of the control group was 1.90 ± 0.29 , while it was 2.20 ± 0.19 in the test group. The two tailed p value is 0.3900 which is considered non-significant.

At the IInd month the scores of the control group was 2.35 ± 0.25 , while it was 2.15 ± 0.18 in the test group. The two tailed p value is 0.5508 which is considered non-significant.

At the IIIrd month the scores of the control group was 2.45 ± 0.23 , while it was 2.05 ± 0.18 in the test group. The two tailed p value is 0.2258 which is considered non-significant.

At the IVth month the scores of the control group was 2.35 ± 0.27 , while it was 1.86 ± 0.21 in the test group. The two tailed p value is 0.1799 that is considered non-significant.

However, at the Vth month the scores of the control group was 2.65 ± 0.22 , while it was 1.55 ± 0.18 in the test group. The two tailed is p value is 0.0020 that is considered highly significant (Fig. 3).

4. BODY ACHE

The inter group comparisons of the severity of body ache at the baseline phase the scores of the control group was 1.75 ± 0.28 , while it was 2.30 ± 0.19 in the test group. The two tailed p value is 0.1570 which is considered non-significant.

At the Ist month the scores of the control group was 1.70 ± 0.29 , while it was 2.05 ± 0.19 in the test group. The two tailed p value is 0.3087 which is considered non-significant.

At the IInd month the scores of the control group was 2.06 ± 0.30 , while it was 2.10 ± 0.18 in the test group. The two tailed p value is 0.9020 which is considered non-significant.

At the IIIrd month the scores of the control group was 2.05 ± 0.30 , while it was 1.85 ± 0.21 in the test group. The two tailed p value is 0.6239 which is considered non-significant.

At the IVth month the scores of the control group was 2.30 ± 0.27 , while it was 1.70 ± 0.21 in the test group. The two tailed p value is 0.1372 that is considered non-significant.

However, the inter group comparisons of the severity of body ache

at the Vth month the scores of the control group was 2.60 ± 0.27 , while it was 1.55 ± 0.21 in the test group. The two tailed is p value is 0.0138 which is significant (Fig. 4).

5. FATIGUE

The inter group comparisons of the severity of fatigue at the baseline phase the scores of the control group was 2.35 ± 0.17 , while it was 2.15 ± 0.22 in the test group. The two tailed p value is 0.5068 which is considered non-significant.

At the Ist month the scores of the control group was 2.10 ± 0.22 , while it was 2.00 ± 0.21 in the test group. The two tailed p value is 0.7607 which is considered non-significant.

At the IInd month the scores of the control group was 2.20 ± 0.24 , while it was 1.85 ± 0.18 in the test group. The two tailed p value is 0.2856 which is considered non-significant.

At the IIIrd month the scores of the control group was 2.25 ± 0.24 , while it was 1.90 ± 0.18 in the test group. The two tailed p value is 0.3087 which is considered non-significant.

At the IVth month the scores of the control group was 2.40 ± 0.23 , while it was 1.86 ± 0.20 in the test group. The two tailed p value is 0.0938 that is considered non-significant.

However, the inter group comparisons of the severity of Fatigue at the Vth month the scores of the control group was 2.45 ± 0.25 , while it was 1.60 ± 0.18 in the test group. The two tailed is p value is 0.0253 that is considered highly significant (Fig. 5).

6. ARTHRALGIA

The inter group comparisons of the severity of arthralgia at the baseline phase the scores of the control group was 1.60 ± 0.31 , while it was 2.10 ± 0.19 in the test group. The two tailed p value is 0.0967 which is considered non-significant.

At the Ist month the scores of the control group was 1.55 ± 0.31 , while it was 2.05 ± 0.18 in the test group. The two tailed p value is 0.0761 which is considered non-significant.

At the IInd month the scores of the control group was 1.50 ± 0.31 , while it was 2.00 ± 0.19 in the test group. The two tailed p value is 0.1351 which is considered non-significant.

At the IIIrd month the scores of the control group was 1.80 ± 0.26 , while it was 1.90 ± 0.20 in the test group. The two tailed p value is 0.7481 which is considered non-significant.

At the IVth month the scores of the control group was 2.05 ± 0.29 , while it was 1.70 ± 0.21 in the test group. The two tailed p value is 0.2465 that is considered non-significant.

However, the inter group comparisons of the severity of arthralgia at the Vth month the scores of the control group was 2.50 ± 0.31 , while it was 1.65 ± 0.20 in the test group. The two tailed p value is 0.0226 that is considered highly significant (Fig. 6).

7. ANOREXIA

The inter group comparisons of the severity of anorexia at the baseline phase the scores of the control group was 2.30 ± 0.26 , while it was 2.15 ± 0.21 in the test group. The two tailed p value is 0.6513 which is considered non-significant.

At the Ist month the scores of the control group was 2.30 ± 0.27 , while it was 1.70 ± 0.21 in the test group. The two tailed p value is 0.0486 which is considered highly significant.

At the IInd month the scores of the control group was 2.20 ± 0.29 , while it was 1.70 ± 0.16 in the test group. The two tailed p value is 0.0761 which is considered non-significant.

At the IIIrd month the scores of the control group was 2.45 ± 0.21 , while it was 1.70 ± 0.18 in the test group. The two tailed p value is 0.0039 that is considered highly significant.

At the IVth month the scores of the control group was 2.15 ± 0.29 , while it was 1.50 ± 0.19 in the test group. The two tailed p value is 0.0237 that is considered highly significant.

At the Vth month the scores of the control group was 2.25 ± 0.30 , while it was 1.35 ± 0.15 in the test group. The two tailed p is 0.0046 that is considered highly significant (Fig. 7).

8. CHRONIC WEIGHT LOSS

The inter group comparisons of the severity of chronic weight loss at the baseline phase the scores of the control group was 0.90 ± 0.23 , while it was 1.90 ± 0.29 in the test group. The two tailed p value is 0.0125 which is considered highly significant.

At the Ist month the scores of the control group was 1.60 ± 0.30 , while it was 1.45 ± 0.25 in the test group. The two tailed p value is 0.7157 which is considered non-significant.

At the IInd month the scores of the control group was 1.70 ± 0.29 , while it was 1.40 ± 0.23 in the test group. The two tailed p value is 0.4528 which is considered non-significant.

At the IIIrd month the scores of the control group was 1.90 ± 0.28 , while it was 1.20 ± 0.24 in the test group. The two tailed p value is 0.0845 which is considered non- significant.

Where as, at the IVth month the scores of the control group was 1.95 ± 0.28 , while it was 0.95 ± 0.22 in the test group. The two tailed p value is 0.0125 that is significant. The inter group comparisons of the severity of chroic weight loss at the Vth month the scores of the control group was 2.15 ± 0.27 , while it was 0.800 ± 0.17 in the test group. The two tailed p is 0.0007 that is considered highly significant (Fig. 8).

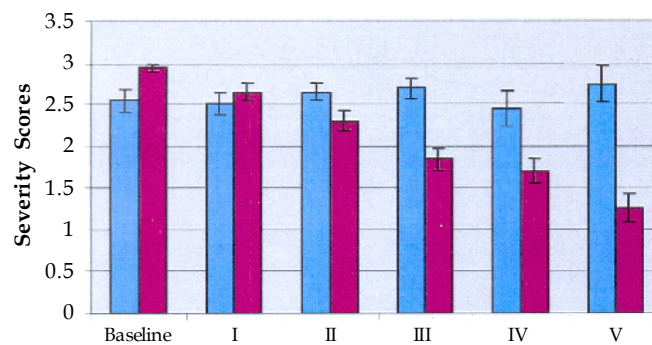
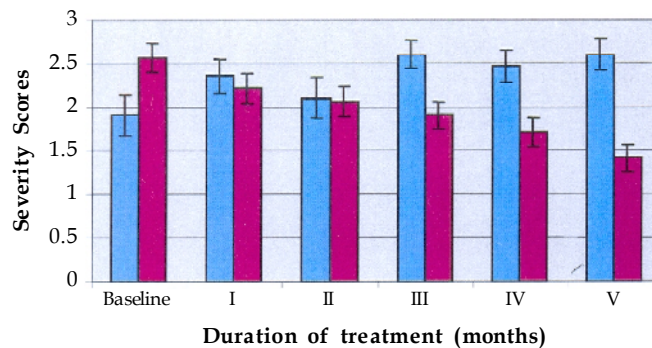
Fig. 1**Fig. 2**

Fig. 3

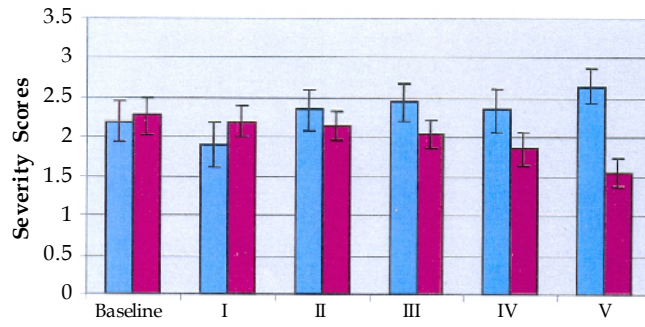


Fig. 4

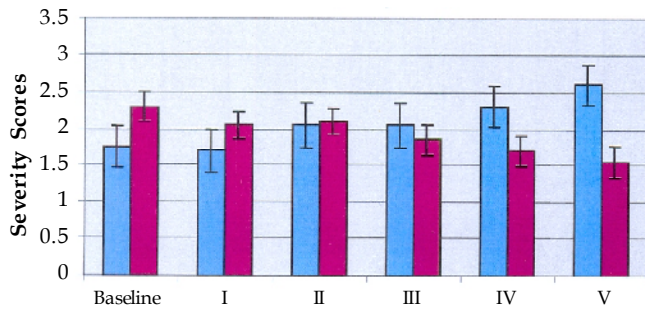


Fig. 5

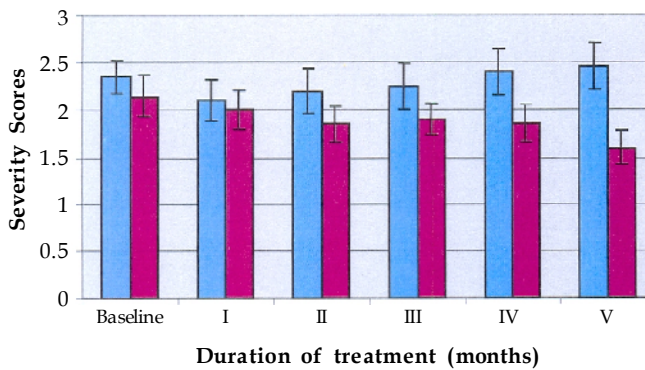


Fig. 6

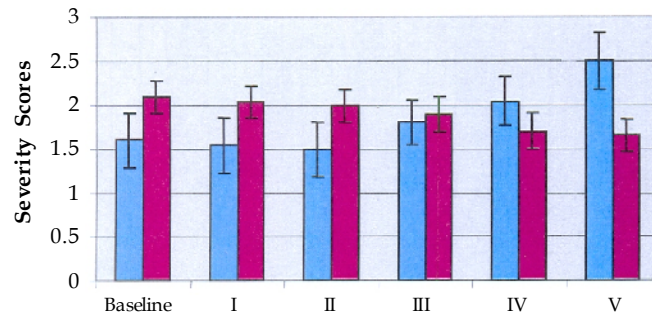


Fig. 7

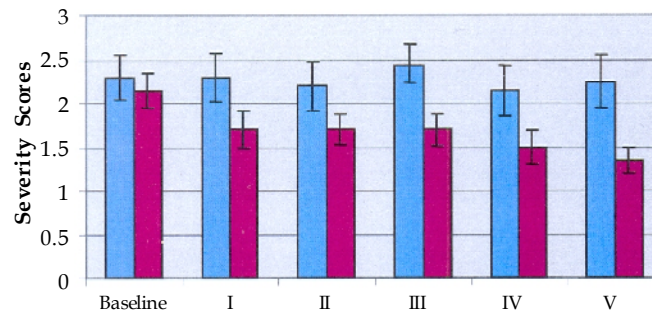
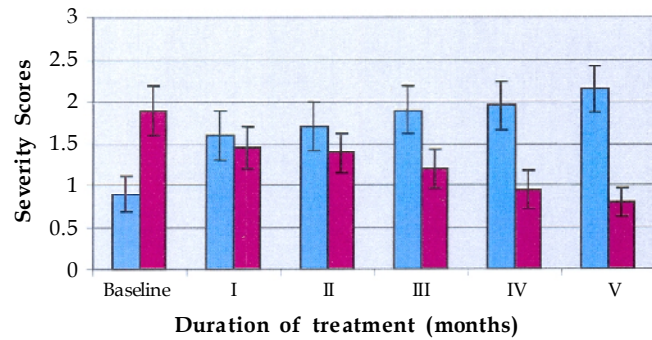


Fig. 8



Control group = ■ and Treated group = ■

Discussion

Analysis of Signs and Symptoms

The statistical analysis of the severity of the sign and symptoms to the HIV positive in the control and treated groups included in the clinical trial were subjected to the ANOVA and paired 't' test. The scores were recorded at baseline phase and at each month of the treatment phase up to 5 months.

The ANOVA was performed with the severity scores of the sign and symptoms in control and test groups. The comparisons within the control group at various stages of treatment demonstrated that the scores of baseline phase and IInd and IIIrd month, IVth month, baseline phase and Vth month, Ist month and IIIrd month, Ist month and IVth month, Ist month and Vth month, IInd month and IVth month, IInd month and Vth month, IIIrd month and Vth showed significant differences. The scores of Ist month and IInd month, IInd month and IIIrd month also showed significant differences. While it was observed that there was no significant difference between the means scores of baseline phase and Ist, IInd, IVth and Vth month of the treatment phase.

The comparisons of the mean scores of sign and symptoms within the test group showed that the corresponding scores of baseline phase and IInd and IIIrd month, and IVth month and Vth month; Ist month and IIIrd month, IVth month and Vth month; IInd and IVth month, IInd and Vth month; IIIrd and Vth month, showed highly significant differences. The mean scores of the baseline phase and Ist, IIIrd and IVth months also showed significant differences. While the differences between the scores of Ist and IInd month; IInd and IIIrd month; IVth month and Vth month were non-significant.

The inter group comparisons of mean scores of the sign and symptoms in control and test groups in the baseline and treatment phase were done by the paired 't' test.

The results of the baseline phase and Ist, IInd, IIIrd, IVth and Vth months of the treatment phase showed that the mean scores of the manifestations directly related to AIDS/signs and symptoms were significantly different in the control and test groups. The severity of the manifestations directly related to AIDS/signs and symptoms were markedly increased in the control group treated with the placebo; while the severity of these manifestations gradually and significantly reduced in the test group which was treated with the test drug, i.e. SJM. Apparently, the SJM has direct effects on the AIDS because the severity of the signs and symptoms were reduced significantly.

It seems that the blending of these drugs has created a unique

mode of action, by which the SJM was effective. Considering the actions and therapeutic uses of the ingredients of SJM, in many ways these are useful. Some of their main actions and uses, which are described in the Unani literature, are given below:

The Zehar Mohra (Serpent stone) is described as vital organ tonic, exhilarant, antidote to poisons, protects *quwa* (faculties) and *arwah* (vital force), purifier and detoxicant of body humours and strengthens the muscles. It is used in diarrhoea, vomiting, phobia, anxiety, poisoning, inflammations etc. The Marwareed (Pearl) is exhilarant, enhances body faculties and vital force, tonic for vital organs, stimulant, anti-depressant etc. It is used in weakness of stomach, liver, kidney, heart and brain; heart diseases, mania, impurities of blood etc.

The Bussud (Red Coral) is described as astringent, desiccant, exhilarant, nervine and heart tonic etc. It is useful in mania, palpitation, weakness of stomach, anorexia, haemorrhage, intestinal ulcers, headache, vomiting etc. The Kehrubia (*Vateria indica*) is described as alexipharmic, tonic, carminative, resolvent, stomachic, exhilarant, cardiac and liver tonic, styptic, astringent etc. It is useful in palpitation, haemoptysis, diarrhoea, haemetemesis, nasal ulcers, wounds, weakness of stomach and kidneys; dysentery, abdominal cramps, burning micturition, diarrhoea, jaundice, tuberculosis, skin eruptions etc.

The Larjward (*Lapis lazuli*) is described as blood purifier, diuretic, exhilarant general body tonic, analgesic, resolvent, cleanses body humours, evacuates thick humours, controls *ufoonat* (infections) etc. It is also useful in palpitation, eye ulcers, illusion, phobia, grief, anxiety, *saudavi* ailments, mania etc. The Yaqoot Surkh (Ruby) is described as heart and brain tonic, exhilarant, blood purifier, enhances and protects *hararat-e-ghareezi* (body energy) etc. It is useful in weak functions of vital organs, depression, palpitation, nausea, tuberculosis and effects of poisons etc.

The Yaqoot Kabood (Sapphire) is described as exhilarant, general body tonic, brain tonic, antidote of poisons etc. It is useful in palpitation, illusion, poisoning, cough and impurities of blood etc. The Yaqoot Asfar (Topaz) is described as exhilarant, brain and heart tonic, anodyne, aphrodisiac, protective actions for body, enhances and protects *harara-e-ghareezi* (innate heat or energy) etc. It is useful in blood, effects of poisons, weak digestion, mania, palpitations, tuberculosis, poisoning etc.

The Yashab Sabz (Green Jade) is described as tonic for heart, brain and stomach etc. It is useful in internal ulcers, dysentery, illusion, palpitations etc. The Zamurrad (Emerald) is described as exhilarant, vital organ tonic, stomachic, liver tonic, enhances *hararat-e-ghareezi* (body energy) and *rooh* (vital force) etc. It is useful in pneumonia, mania, palpitation, jaundice, effect of poison, grief, depression, anxiety, weak function of brain, heart, stomach, liver, kidney etc.

The Aqeeq Surkh (Red Agate) is described as cardiac tonic, aphrodisiac etc. It is used in palpitation, obstructions of liver and spleen, weakness of vital organs, heart diseases etc. The Warq-e-Nuqra (silver leaves) is described as tonic, stimulant, aphrodisiac, general body tonic, exhilarant; tonic to heart, brain, liver and stomach; protects quwwat-e-haiwani (vital faculty) etc. It is used in diseases of heart and brain, chest affections, irritable condition of the stomach and intestines, chronic diarrhea, cough, weakness of nerves etc. The Mastagi (*Pistacia lentiscus*) is described as attenuant, resolvent, vital organ tonic, stomachic, liver tonic, carminative, general body tonic, appetizer etc. It is used in intestinal ulcers, haemoptasis, inflammation, hepatitis, gastritis, diarrhoea, excess of phlegm, weak functions of stomach, amnesia, cough etc.

The Warq-e-Tila (gold leaves) is described in Unani literature as general body tonic, exhilarant, tonic for heart and brain, purifier of body humours, anti-depressant, improves *hararat-e-ghareezi*, liver tonic etc. It is useful in palpitation, anxiety, chronic headache, cough, weight loss, tuberculosis, weakness of heart, phobias, emaciation, anorexia, weak digestion, weak function of liver, dysentery; and it is a good protective agent for general health etc. The Jadwar (*Delphinium denudatum*) is described in Unani literature as appetizer, stomachic, theriac, *dafe-ufoonat* (antiseptic), *musakkin* (mild sedative) etc. It is useful in epidemic diseases, catarrh and coryza, lymphadenitis, cardiac weakness, palpitation, brain diseases, blood diseases, general debility etc.

The Narjeel Daryae (*Lodoicea seychellarum*) is described in Unani literature as general tonic, enhances *hararat-e-ghareezi*, antidote to poisons, protects body faculties, removes waste and toxic humours, removes the effects of poisons from the deep tissues and also protects body faculties etc. It is useful in diarrhoea, brain diseases, poisoning, paralysis, facial palsy, arthralgia etc. The Rose (*Rosa damascena*) is described in Unani literature as general body tonic, anti-inflammatory, brain and heart tonic etc. It is useful in palpitation, abdominal cramps, pain in liver and spleen, headache etc.

The SJM contains many useful ingredients and described above and a combined effect of some of their actions may have relevance and effectiveness in controlling the severity of AIDS and improving general health and quality of life of the patients. The actions appear to be general body tonic, vital organs tonic, exhilarant, anti depressant, nerve and brain tonic, *musakkin* (mild sedative), resolvent, stomachic, protector of general health, liver tonic; antidote to poisons or alexipharmic or theriac; blood purifier; cleansing, purifying or detoxicating actions on body humours; remover of waste and toxic humours; remover of effects of poisons from deep tissues; evacuator of the thick humours; controls *ufoonat* (infection); enhancing or protecting actions on *quwa* (body

faculties), *hararat-e-ghareezi* (energy) and *arwah* (vital force) etc. According to Unani philosophy, these actions have multiple benefits for the human body, which require further research and validation. But certainly, these actions are giving some indications of the possible effectiveness of the test drug, SJM regarding its benefits in the treatment of patients suffering form AIDS.

The ingredients of SJM are variably useful in different manifestations and diseases, which have direct relevance with the clinical manifestations directly or indirectly related to AIDS. The diseases in which the ingredients of SJM are described to be useful are, viz. diarrhoea, dysentery, vomiting, weakness of heart, brain and liver, weak digestion, anorexia, intestinal ulcers, haemoptysis, tuberculosis, abdominal cramps, headache, jaundice, skin eruptions, poisoning, internal ulcers, cough, pneumonia, catarrh, coryza, arthralgia, liver pain, facial palsy, paralysis, brain diseases, lymphadenitis, anxiety, phobias, impurities of blood , weight loss, general debility, weakness of muscles, haemetemesis etc.

Due to the usefulness of the ingredients of SJM in the above described ailments, this formulation may also be effective for symptomatic relief in the clinical manifestations/signs and symptoms of HIV/AIDS, and improving general health of the AIDS patients. Furthermore, the clinical study, SJM did not produce any adverse effects on any individuals during entire span of trial. Therefore, the present study reveals that this formulation is also clinically safe in the treatment of various sign and symptoms of HIV/AIDS individuals.

Conclusion

Therefore it is finally concluded that the Safoof Jawahar Mohra appeared as an effective remedy in reducing the severity of various sign and symptoms and hence this formulation may be used as a supportive therapy in the treatment of AIDS. However, further studies with the investigations particularly CD4 count and viral load are also required to evaluate direct effect of the SJM in improving the immunity and suppressing the viraemia in the AIDS patients.

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