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A COMPARITIVE CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF *SHIVAGUTIKA* IN PATIENTS WITH H.I.V (HUMAN IMMUNO DEFICIENCY VIRUS) INFECTION

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ABSTRACT

Objective: To evaluate the therapeutic effect of *Shivagutika* in patients suffering from HIV Infection/ *Rajayakshma*. **Design of Study:** A comparative clinical study with Pre-test & Post- test design. **Setting:** SDM Hospital of Ayurveda, Udupi, Karnataka. **Sample Selection:** 40 Patients suffering from HIV Infection of either sex were selected for the study. **Intervention:** The patients were randomly categorized into two groups as *Shivagutika* group and ART group consisting of 20 patients each. *Shivagutika* group- 20 patients were treated orally with *Shivagutika* in a dose of 12 grams OD, (30 minutes before breakfast) along with 100 ml of milk for 6 months. ART group- 20 patients were treated with ART for six months. **Main Outcome Measures:** Percentage changes in the Subjective and Objective Criterias including Karnofsky Performance Scale Index, Visual Analogue scale and performance scale following the intervention. **Results:** Among the criteria's selected for the evaluation like Cough, Dyspnea, Fever, Body weight, Hb%, ESR and CD4 count were statistically analyzed with paired 't' test and the outcome was statistically highly significant as $P<0.001$. One way *Anova* test carried showed marked significant results in patients administered with *Shivagutika*. The severity of illness showed marked remission. The better improvement observed in *Shivagutika* group was statistically significant. Following medication with *Shivagutika* the value of CD4 count was 567 in comparison to initial value of 391. In the ART group the initial value of 417.6 increased to 447.6 following treatment. The improvement in CD4 count affirms the therapeutic benefit of *shivagutika* in HIV infection /AIDS.

Keywords: *Rajayakshma, Shivagutika*

INTRODUCTION

HIV-AIDS (Human Immuno Deficiency Virus-Auto Immune deficiency syndrome) is one of the most dreaded challenges that today's medical world is facing. An estimation reveals approx-

imately 15 million children have been orphaned worldwide by HIV-AIDS[1]. Shockingly, around 1800 children under the age of 5 are added to the newly infected figure, mainly by mother to child transmission. HIV primarily targets the individual's immune system compromising the body's ability to fight the diseases of all kinds. Hence it paves the way for untold opportunistic infections. A social stigma has been unnecessarily created owing to the ignorance about the facts and truths of HIV. Good nutrition, proper medical care and optimistic approach is the need of the hour instead. The clinical presentation of AIDS is akin to the description of *Rajayakshma* characterized by involvement of multiple *srotas* (channels)and presenting with diarrhea, cough, fever and similar other symptoms. Literature has referred to the radical cure for this serious sickness which includes oral medication and are claimed to be very effective. Involvement of *pranavahasrotas, annavahasrotas, purisavahasrotas, rasavaha* and *raktavahasrotas* characterizes the disease Rajayakshma[2]. *Visamashanajanya* (Diet induced), *sahasajanya* (Activity induced), ve*gadharanajanya* (Faulty lifestyle) and *kshayajanya* (Debility induced) are the different clinical varieties of thesame[3]. The defective *vyadhiksamatva* (Immunity) is invariable in the *samprapti* of this disease. *Trirupi, shadrupi and ekadasharupirajayakshma* are the different syndrome presentations indicating the occurrence of the disease[4]. The illness is typically chronic and tends to debilitate the patient. *Shodhana* (Elimination), *shamana* (Eliviation), *brumhana* (Nourishing) and *rasayana* (Rejuvenation) forms the basis of the treatment of Rajayaksma[5].*Shivagutikaashamana* treatment, administered orally for a long duration is said to be very effective in combating the multiple system involvement of this disease[6].

Methodology

Aims and objectives of the study

To evaluate the therapeutic effect of *Shivagutika* in patients of HIV infection.

Source of data: The study was conducted on 40 patients of suffering from H.I.V infection confirmed by Western blot technique from IPD and OPD of S.D.M. Ayurveda hospital, Udupi, Karnataka

Design of study: This is a comparative clinical study with pretest and posttest design

Duration of study: 6 months

Diagnostic criteria: Patients having Elisa +ve with or without symptoms of *Rajayaksma* like *kshaya* (Loss of weight), *kasa* (Cough), *swasa* (Dypsnea) and *jvara* (Fever)were taken for the study.

Inclusion Criteria

1. Patients of either sex fulfilling the diagnostic criteria of *Rajayakshma*
2. Patients between the age group of 16 to 70 years.
3. HIV patients with CD4+ cell count ≥ 200.

Exclusion Criteria

1. Patients suffering from AIDS complex of group III and IV according to WHO criteria[7]

Criteria for assessment: 40 patients with confirmed diagnosis of *Rajayakshma*/HIV infection fulfilling the diagnostic, inclusion, exclusion criteria were recruited for the study. The recruited patient's were informed about the clinical study and their written consent was taken for the same. The statistical significance of the results obtained following the treatment was analyzed by adapting the paired t test in each group. The results of the two groups were compared and its statistical significance was analyzed unpaired t test. The details of the different symptoms including subjective and objective parameters of assessment present in the patients were taken initially and during every follow up.

Subjective parameters: The subjective parameters *kasa, shwasa, angamarda* were assessed by

adapting Visual analogue scale as depicted in Annexure:

Intervention: All the recruited patients were admitted in the SDM Ayurveda hospital Udupi and the severity of the illness/symptoms was recorded as per the assessment criteria. The patients were randomly categorized using the permuted block randomization method, into two groups consisting of 20 patients each.

Test group- In this group the 20 patients were treated orally with *shivagutik*a in a dose of 12 grams O.D., (30 minutes before morning food) along with 100 ml of milk for 6 months

Control group- In this the 20 patients were given with ART(Anti Retro Viral treatment) Stavudine 30mg**,** Lamivudine 150mgfromCipla Company in combination with LAMIVIR S twice daily for six months.

Investigations: Routine hematological investigations included Hb% (Sahli's), Total leukocyte count, Differential count, ESR (Westegren's Method), Random blood sugar. ELISA TEST (HIV1 and HIV2), Western Blot method (Thyrocare) and CD4+ cell count (Freedom foundation)

Results

All the forty patients taken for the study were assessed before and after treatment to know the favorable response of the regimen. Following medication with *Shivagutika* the change in the mean symptom score of *kasa* was 2.05 from the initial score of 5.8, score of *swasha* was 2.15 from the initial score of 6.2, score of *jwara* to1.85 from the initial score of 6.85, symptom score of *prathishyaya* was 1.15from the initial score of 5.2, symptom score of body weight was 57.95 from the initial score of 53.25, BMI was 23.01 increased from the initial score of 20.063, score of Karnofsky Performance Scale Index was 84 from the initial score of 59, symptom score of Hb% was 11.8 from the initial score of 10.55, mean value of ESR was 39.2 from the initial score of 88, score of TLC was 5767 which came down to 5645.5, value of CD4 count was567 in comparison to initial value of 391

In the ART group the initial mean symptom *kasa* score of 6.4reduced to 4.2, *shwasa* score of 6.5reduced to 4.15 following treatment, *jwara* score of 7.05reduced to 4.0, *pratishyaya* reduced from 5.6 to 3.75, body weight score of 50.5 increased to 52, value of BMI was 20.395 and it increased to20.515, Karnofsky Performance Scale Index score of 63 increased to 72.5, Hb% score of 10.395 increased to 10.515, ESR score of 88.1reduced to77.421, score of TLC before treatment was 5405 which changed to 5645.5, CD4 value of417.6 increased to 447.6

All the details are shown in the tables below. The effect of *Shivagutika* on the other symptoms like *shirashula, krishangata, angamarda* and *atisara* was also cured. The drug also acted on symptoms like *asyapaka, agnimandya, medhrapaka* which were seen in some patients.

Statistical analysis using paired t test showed significant results in all parameters within the groups after the administration of *Shivagutika* and ART except in Hb% in ART group and reduction in TLC in *Shivagutika* group. The statistical analysis between the groups using unpaired t showed significant results in all parameters except in weight, BMI and TLC.

DISCUSSION

Varied causative factors, variety of pathogenesis, plethora of clinical symptoms forms the unique nature of *Rajayakshma*. Depletion of body elements reduces the *vyadhikshamstva* and increases the risk of suffering from the diseases. The judicious usage of *shodhana, shamana, bruhmana* and *rasayana* improves the possibility of improvement as well as remission.

Among the different oral medications *Shivagutika* is unique as it is capable of showing *shamana, bramhana*, and *rasayana* effect simultaneously. The *Shivagutika* contains drugs like *shatavari, vidari, drasksha, godugdha, jeevanthi* hav-

ing *bruhmana* thus shows the improvement in the body weight. One of the factors responsible for the depletion of the body elements and emaciation is *agnimandya*. This disease includes both *jataragnimandya* and *dhatvagnimandya*. This *angnimandya* is tackled as the formulation contains many *deepana, pachana* drugs like *pippali, maricha, nagara, gajapippali* etc. Symptoms related to *pranavahasrotas* are seen in *rajayakshma* including *kasa, swasha, prathishyaya, peenasa, parshvashoola* and so on. *Shivagutika* contains drugs like *talisapatra, puksharamoola, pippali. Kantakari, brahati* etc. to counter act all these symptoms. *Atisara* is another symptom of *Rajayakshma* which is tackled by*mustaandkutaja*. Also patients of *Rajayakshma* develop constipation and drugs like *danti, triphala* are effective in maintaining the *anulomana* of the *vata. Shivagutika* contains drugs to counteract *jwara* such as *musta, patola, katuki* and *agnimantha*. The drugs also act on *kushta, chardi, angamarda*. When the patients were treated with *Shivagutika* the incidence of sufferings decreased and the course of illness has reduced a lot. This confirms that *Shivagutika* has enhancing effect on *vyadhikshamtva.* Further the reduction in Hb%, the complication of hepatitis and gastritis developed in ART group proves the supremacy of *Shivagutika*. Moreover the definite significant increase in CD4 count confirms the efficacy of *Shivagutika* in *Rajayakshma*/HIV infection. These observations prove that *Shivagutika* can be prescribed as an effective treatment in *Rajayakshma* / HIV infection. This clinical study was carriedout in stage I and II of HIV infection with a single dose per day regimen. Therefore there is ample continued scope of continuation of study in the other stages of HIV infection and also in increased dosage for the better response of *Rajayakshma*/ HIV infection in Stage III and IV.

CONCLUSION

Response to *Shivagutika* in comparison to ART is found to be superior in all the parameters. The specific observations confirm that *Shivagutika* has enhancing effect on *vyadhikshamtva* observing the CD4 count. Further the reduction in Hb%, the complication of hepatitis, gastritis developed in ART group proves the supremacy of *Shivagutika*. Hence it can be said that *Shivagutika* can beprescribed as an effective treatment in *Rajayakshma* / HIV infection.

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Tables and Illustrations

Table 1: Effect of treatments on severity of *kasa* in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	5.850 (.±0.638)	2.050 (±0.303)	3.800	1.852	±0.414	9.174	<0.001
ART	6.500(±0.564)	4.200(±0.395)	2.300	0.979	±0.219	-10.510	<0.001

Effect of treatments during the course of treatment on severity of kasa in SG and ART groups

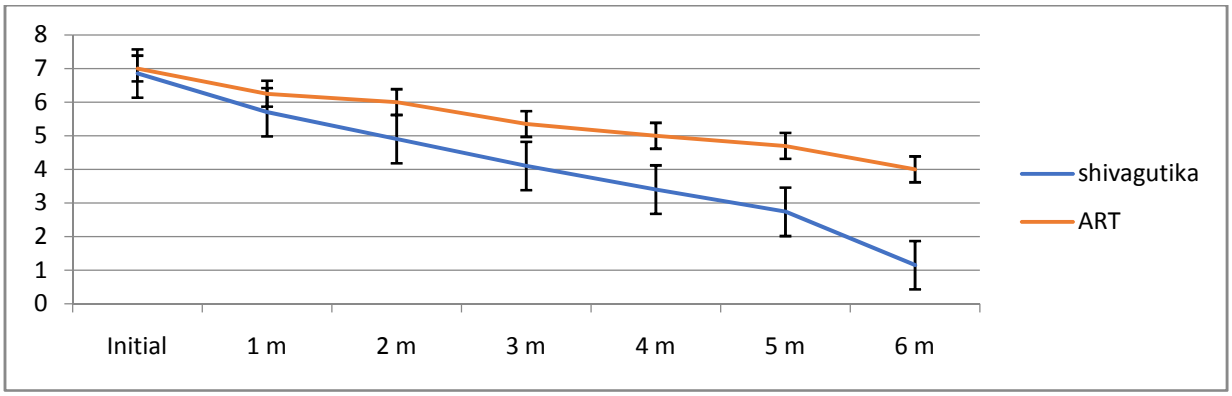

Table 2: Effect of treatments on severity of swasha in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	6.200(±0.639)	2.150(±0.357)	4.050	2.212	±0.495	-8.189	<0.001
ART	6.500(±0.550)	4.150(±0.412)	2.350	1.268	±0.284	8.288	<0.001

Effect of treatments during the course of treatment on severity of *shwasa* in SG and ART groups

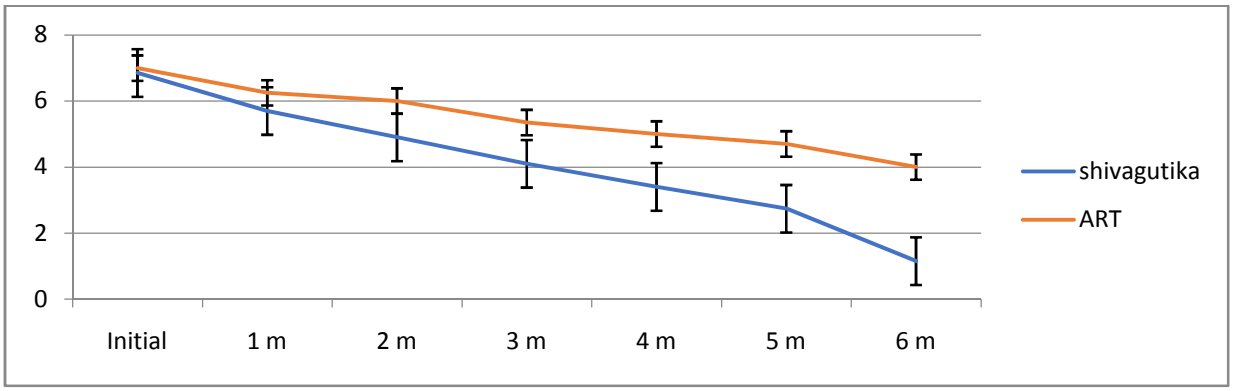

Table 3: Effect of treatments on severity of *jwara* in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	6.850 (±2.293)	1.850(±.182)	5.050	1.356	±0.299	-16.716	<0.001
ART	7.050(±2.596)	4.000(±1.391)	3.050	1.356	±.303	10.057	<0.001

Effect of treatments during the course of treatment on severity of *jwara* in SG and ART groups

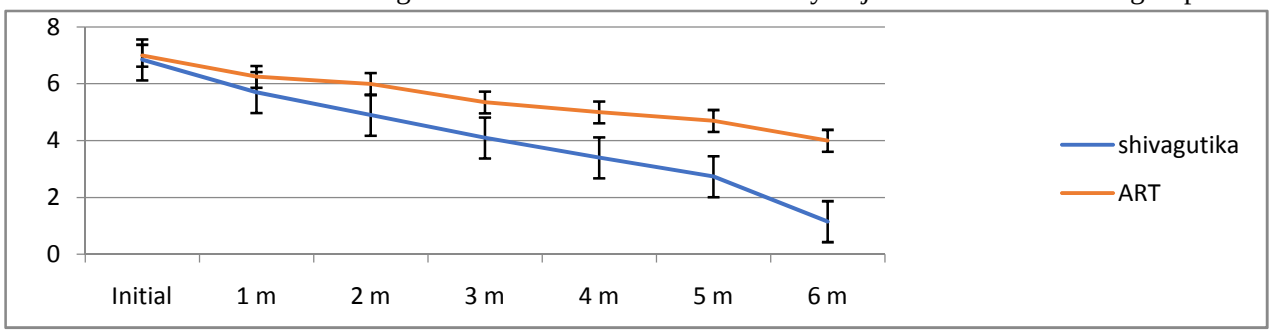

Table 4: Effect of treatments on severity of *prathishyaya* in SG and ART group

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	5.200 (±0.560)	1.150(±.150)	4.050	1.986	±0.444	-9.119	<0.001
ART	5.600(±.694)	3.750(±.502)	1.850	1.226	±.274	-6.749	<0.001

`Effect of treatments during the course of treatment on severity of *prathishyaya* in SG and ART groups

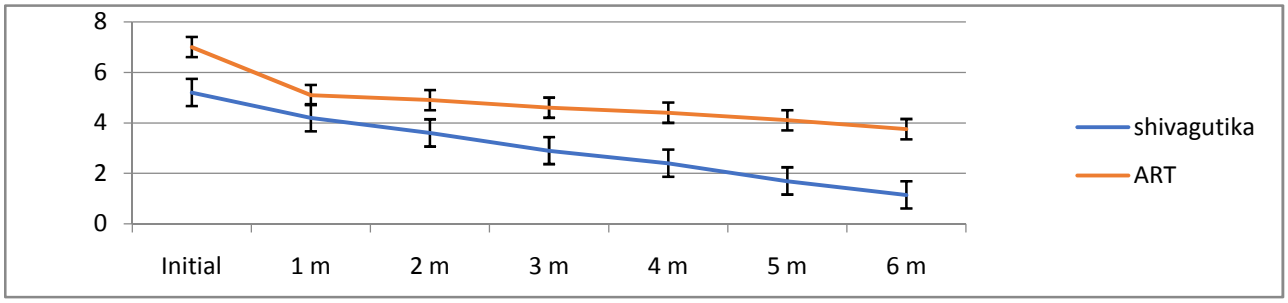

Table 5: Effect of treatments on body weight in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	53.250 (±2.224)	57.950 (±2.229)	4.7	1.229	±0.275	-17.102	<0.001
ART	50.5(±2.623)	52(±2.511)	1.5	±.795	.177	-8.441	<0.001

Effect of treatments during the course of treatment on body weight

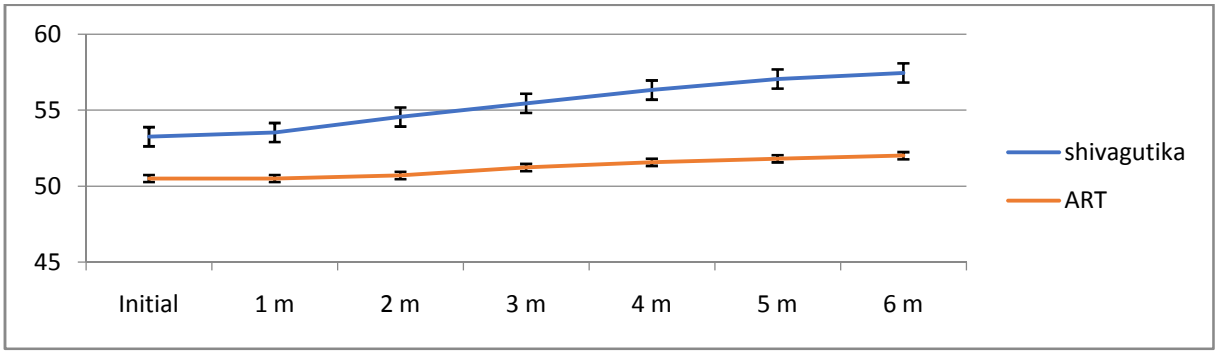

Table 6: Effect of treatments on BMI in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	21.063 (±0.887)	23.011 (±0.907)	1.948	0.620	±0.139	-14.045	<0.001
ART	20.395(±.399)	20.515(±.410)	0.120	0.679	±.152	-0.791	<0.001

Table 7: Effect of treatments on Karnofsky Performance Scale Index in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	59 (±1.762)	84 (±1.522)	25	8.272	±1.871	-13.516	<0.001
ART	63 (±1.638)	72.5(±1.428)	9.5	7.592	±1.629	-5.592	<0.001

Table 8: Effect of treatments on Hb% in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	10.55 (0.454)	11.80 (0.373)	1.285	0.699	0.156	-8.22	<0.001
ART	10.395 (1.785)	10.515(1.835)	.120	0.679	0.152	-0.791	0.439

Table 9: Effect of treatments on severity of ESR in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	88.1 (±4.664)	39.2 (±4.354)	48.9	13.042	±2.916	16.78	<0.001
ART	88.158(±5.571)	77.421(±5.591)	10.471	7.723	±1.771	6.068	<0.001

Table 10: Effect of treatments on TLC in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	5767 (±396.298)	5645.5 (±401.01)	105	1383.3	±309.5	-0.346	0.737
ART	5405(±326.321)	5645.5(±336.67)	240	991.181	±2222.63	-1.085	0.0291

Table 11: Effect of treatments on severity of CD4 count in SG and ART groups

Group	Mean (SE±)		Difference in mean	Paired T test			
	BT	AT		S.D	S.E	't'	P
SG	391(±23.545)	567 (±38.762)	175	133.850	±29.93	-5.867	<0.001
ART	417.650(±127.2)	447.650(±336.67)	29	26.20	±5.841	-5.051	<0.001

Table 12: Between group comparison in all parameters

Parameter	t value	P Value	Parameter	t value	P Value
Kasa	36.567	< 0.001	KPSI	30.366	< 0.001
Shwasa	21.367	< 0.001	Hb%	5.711	0.021
Jwara	36.567	< 0.001	ESR	31.884	0.001
Pratishyaya	96.902	< 0.001	TLC	0.188	0.0667
Body weight	3.14	0.083	CD 4	6.445	< 0.001
BMI	0.845	0.364			

Grading and scales

Table 13: Visual analogue scale

Symptoms	Visual analogue scale	Remarks
Kasa	1 2 3 4 5 6 7 8 9 10	
Swasha	1 2 3 4 5 6 7 8 9 10	
Pratishyaya	1 2 3 4 5 6 7 8 9 10	

Objective parameters: *Jvara*: The symptom fever was assessed with due consideration of intensity, frequency, severity of chills and rigors as mentioned below.

(I) Intensity of Fever (^{0}F)

0 -Normal - <99°F
1 -99° - 100°F
2 -100.2° - 102°F
3 -102.2° - 104°F

II) Frequency of fever:

0 -No fever
1 -Fever occurring once in 2 month
2 -Fever occurring once in 1 Month
3 -Fever occurring once a fortnight
4 -Fever occurring weekly once
5 -Constant persistent fever

(III) Chills and rigors:

0-No Chills and rigors
1-Mild
2-Moderate
3-Severe

Severity of the fever was calculated by summing up of the scores of the above said three details of the fever. Thus the severity of the fever ranges between 0 to 11

Table 14: Karnofsky Performance Scale Index

General Category Description	Specific Criteria	Index
Able to carry out normal activities; no special care required	Normal; no evidence of disease and no physical complaints	100
	Able to carry on normal activities but has minor signs or symptoms of disease	90
	Normal activity with effort; some signs or symptoms of disease	80
Unable to work; able to live at home and care for most personal needs; varying amounts of assistance needed	Unable to carry on normal activities or to work, but able to care for self	70
	Requires occasional assistance from others but able to care for most needs	60
	Requires considerable assistance from others and frequent medical care	50
Unable to care for self; requires institutional or hospital care or equivalent; disease may be rapidly progressing	Disabled; requires special care and assistance	40

	Severely disabled; death not imminent; stay in hospital indicated	30
	Very sick; necessary to be in hospital; active supportive treatment necessary	20
	Moribund	10
	Dead	0

Body weight: The body weight is calculated before treatment and also during monthly follow up for 6 months of the patient

BMI ratio: The body mass index is calculated on the formula weight in kg divided by height in meter square. The weight of the patient is recorded and height of the patient is converted in to meter square and then BMI is calculated.

Clinical stages: The clinical stages adapted for the diagnostic, inclusion, exclusion criteria were taken from the staging system for patients with HIV infection and disease developed by World Health Organization[7]-

Clinical Stage 1 -Asymptomatic or persistent generalized lymphadenopathy:

One or more of the following

(1) Asymptomatic, performance scale 1

2) Persistent generalized lymphadenopathy (PGL), maintaining normal activities

Clinical Stage 2 - Early or mild disease:

One or more of the following

(1) Weight loss < 10% of usual body weight

(2) Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilitis)

(3) Herpes zoster within the last 5 years

(4) Recurrent upper respiratory tract infections such as sinusitis

(5) Performance scale 2

Clinical Stage 3 -Intermediate or moderate disease:

One or more of the following

(1) Weight loss > 10% of body weight

(2) Unexplained chronic diarrhea for > 1 month

(3) Unexplained prolonged fever (intermittent or constant), > 1 month

(4) Oral candidiasis (thrush)

(5) Oral hairy leukoplakia

(6) Pulmonary tuberculosis within the past year

(7) Severe bacterial infection such as pneumonia or pyomyositis

(8) Performance scale 3

Clinical Stage 4 - Late or severe disease, essentially equivalent to AIDS:

One or more of the following

1. HIV wasting syndrome as defined by the CDC: weight loss > 10% of body weight plus either unexplained chronic diarrhea > 1 month or chronic weakness with unexplained, prolonged fever > 1 month
2. Pneumocystis carinii pneumonia
3. Toxoplasmosis of the brain
4. Cryptosporidiosis with diarrhea > 1 month
5. Cryptococcosis, extra pulmonary
6. Cytomegalovirus disease of an organ other than liver, spleen or lymph node
7. Herpes simplex virus infection, mucocutaneous> 1 month, or visceral of any duration
8. Progressive multifocal leukoencephalopathy
9. Any disseminated endemic mycosis such as histoplasmosis or coccidioidomycosis
10. Candidiasis of the esophagus, trachea, bronchi or lungs
11. Atypical mycobacteriosis, disseminated
12. Non-typhoid Salmonella septicemia
13. Extrapulmonary tuberculosis
14. Malignant lymphoma
15. Kaposis sarcoma

16. HIV encephalitis as defined by the CDC: clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that can explain the findings

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Conflict Of Interest: None Declared

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