

## CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF SHIVAGUTIKA IN PATIENTS WITH H.I.V

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### ABSTRACT

HIV-AIDS is the most dreaded challenge that the today's medical world is facing! An estimation reveals approximately 15 million children have been orphaned worldwide by HIV-AIDS. Shockingly, around 1800 children under-15 age-group are added to the newly infected figure, mainly by mother to child transmission. HIV is akin to the description of *Rajyakshma* characterized by involvement of multiple *Srotas* and presenting with diarrhea, cough, and fever and similar other symptoms. Needless to say this points towards plethora of clinical infections of Aids. Also the literature elaborates many of the radical cures for this serious sickness which include oral medication and are claimed to be very effective. At this juncture exploring effective treatment for this dreadful disease is the need of the day.

The specific observation confirms the *shivagutika* as enhancing the *vyadhikshamtva* more to add this best response to *shivagutika* in comparison to ART is found to be superior. Further the reduction in Hb%, the complication of hepatitis; gastritis developed in treated with ART proves the supremacy of *shivagutika* is the treatment. More than anything the definite significant increase in cd4 count confirms the efficacy of *shivagutika* in *Rajyakshma*/ HIV infection. From this observation it can be definitely said that *shivagutika* can be prescribed as an effective treatment in *Rajyakshma* / HIV infection.

**Key words:** HIV, *Rajyakshama*, *Shivagutika*

### INTRODUCTION

A comprehensive overview of how and why HIV grows and spreads when made, it reveals that HIV primarily targets the individual's immune system, compromising the body's ability to fight the diseases or disorders of any and all kinds; thereby paving the way for untold opportunistic infections. Socially speaking, the very word

HIV/AIDS has painfully created a social stigma amongst the unaware and uneducated Indian society making the lives of our HIV positive brethren more hopeless than ever. This is owing to the lack of awareness about the facts and truths about HIV; merely being HIV positive doesn't necessarily is/leads to full blown AIDS! AIDS thrives because of

lack of knowledge of how actually it spreads and how well it can be prevented and controlled. As we have embarked the celebration of World AIDS Day on Dec. 1st of this year, today, let's proceed with the word that Prevention is better than Cure (when cure in AIDS is a rare and bare possibility). Clear cut knowledge, Good Nutrition, Proper Medical Care and Optimistic Approach is the need of the hour.

On the other hand the clinical presentation of HIV is akin to the description of Rajayakshma characterized by involvement of multiple srotas (Multisystem) and presenting with diarrhea, cough, fever and similar other symptoms. Needless to say this points towards plethora of clinical infections of Aids. Also the literature elaborates many of the radical cures for this serious sickness which include oral medication and are claimed to be very effective. At this juncture exploring effective treatment for this dreadful disease is the need of the day.

Involvement of *Pranavaha srotas* (respiratory System), *Annavaha srotas* (Gastrointestinal Tract), *Purisavahasrotas* (Excretory), *Rasavaha srotas* and *Raktavaha Srotas* (Hematological) characterizes the disease *Rajayakshma*<sup>1</sup> (Multisystem involved Disease). *Visamasana janaya*, *sahasajanya*, *vegadharana janya* and *Ksayaja* are the different clinical varieties of the same. The defective *Vyadhiksamatva* (Defective Immunity) is invariable in the pathogenesis of this disease. *Trirurpi*, *Sadrupi* and *Ekadasarupi Rajayakshma* are the different progressive syndrome presentation indicating the occurrence of horde of diseases. The illness is typically chronic and tends to debilitate the physique. *Sodhana* (Expulsion of morbid factor through natural root), *Samana* (Cure morbid factor with effective medicine with oral medicine), *Brmhana* (Nourish to

Musculo-Skeletal System) and *Ra-sayana* (Immunity enhancer) form the crux of the treatment of *Rajayakshma*.

Thus exclusive remedies should be explored to uproot the disease or else the potent medicines for effective control over this dreadful disease. *Shivagutika* is a *Shamana* (oral medicine) treatment, administered orally for a long duration is said to be very effective in combating the multiple system involvement of this disease.

## **MATERIALS AND METHODS**

### **Aims and objectives of the study**

To evaluate the therapeutic effect of *Shivagutika*<sup>3</sup> in patients suffering from 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 SDM. Ayurveda hospital, Udupi Karnataka, India from -1.9.2008 to 5.10.2009

**Design of Study:** This is a single blind comparative clinical study with pre test and post test design

**Duration of Study:** 6 months

**Diagnostic criteria:** Patients presenting with symptoms of *Rajayakshma* like *Kshaya* (Emaciation), *Kasa* (Cough), *Swasa* (Breathlessness), *Jvara* (Fever) etc, Elisa + ve

### **Inclusion Criteria:**

- Patients of either sex fulfilling the diagnostic criteria
- Patients between the age group of 16 to 70 years.
- HIV patients with cd4+ cell count 200.

### **Exclusion Criteria**

- Patients suffering from AIDS complex of group III and IV According to WHO criteria.
- CD4+ cell count 200
- Patients of age 16 years and 70 years.

**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.

Table No1 Performance scale 4

Performance Scale	Criteria
1	Asymptomatic with normal activity
2	Symptomatic but normal activity
3	Bed-ridden < 50% of day during the last month
4	Bed-ridden >= 50% of day during the last month

### Investigations

Routine hematological investigations that include Hb% (Sahli's), Total leukocyte count, differential count, ESR (Westegren's Method), Random blood sugar, ELISA TEST (HIV1 and HIV2), Western Blot method (Thyrocare), Cd4+ cell count (Freedom foundation).

### Intervention

All the recruited patients were admitted in the SDM Ayurveda hospital. Severity of the illness/symptoms was recorded as per the assessment criteria. The patients were randomly categorized into two groups consisting of 20 patients each

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

### Karnofsky Performance Scale Index

Table No2 WHO Criteria of Performance scale Cd

TEST NAME	Male	Female	UNITS
Absolute CD3+ T lymphocytes count	617-2485	898-2786	Cells per/microlitre
CD4+ T Helper cells percentage of CD3	20-45	20-45	%
Absolute CD4 + T helper cells count	337-1090	424-1050	Cells per/microlitre
CD8% of CD3	30-60	30-60	%
Absolute CD8 count	174-1240	255-1353	Cells per/microlitre
CD4/CD8 Ratio	0.61-2.68	0.95-2.40	

### BMI Ratio

The body mass index calculated on the formula weight in kg divided by height in meter square. The details of the different

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

### Criteria for assessment:

#### Subjective parameters

The subjective parameters that included were *Kasa, Swasa, Angamarda* assessed by adapting Visual analogue scale.

#### Objective parameters:

**Jwara:** The symptom fever was assessed with the due consideration of intensity, frequency, severity of rigors

**Body weight-** The body weight was calculated before treatment and also in monthly follow up of the patient

symptoms including subjective and objective parameters of assessment present in the patients were taken initially and during every follow up. The statistical significance

of the Results obtained following the treatment was analyzed by adapting the paired t test in each group.

## RESULTS

Table No3 Effect of Shivagutika and ART on the symptom Kasa

Kasa	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
Shwasa	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
Jwara	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
Krishangata	SG	6.550 (±0.240)	1.700 (±0.147)	4.850	1.089	±0.369	19.909	<0.001
	ART	7.450(±.246)	4.200(±.196)	3.250	1.650	±.369	8.867	<0.001
Lymphadenopathy	SG	1.85(±0.549)	0.7 (±.219)	1.150	1.663	±0.495	3.192	<0.006
	ART	2.2(±.671)	1.35(±.406)	0.8	1.268	±0.284	2.998	<0.007
Body weight	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
BMI	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
Karnofsky Performance Scale	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
Hb%	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
ESR	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
TLC	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
CD4 Count	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

## DISCUSSION

The disease *Rajyakshma* is known by different names as *Kshaya*, *Rogaraat*, *Shosha* and so on. *Rajyakshma* is composed of two words viz. *Raja* and *Yakshma*. The word *Raja* is derived from *Dhatu 'Raj'* meaning 'Deeptau' which means the person who rules. Plurality of etiology causes multiple manifestation of *Rajyakshma*. The plural

etiology factor falls under unique 4 categories, they are *Shoshaja nidana*, *Vishamashana*, *Vegasandharana*, *Dhatukshayaja nidana*.

The clinical presentation of *Rajyakshma* is never the same. The *Rajyakshma* contracted by way of sexual relation or by the other means also exhibit the

similar nature of multiple clinical presentations. The multiple clinical presentations are described as *Triroopi Rajayakshma*, *Shadroopi Rajayakshma*, *Ekadashiroopi Rajayakshma* and so on. Person suffering from *Rajayakshma* may have any of the above said clinical presentation or intermediary between any of clinical presentation as *Saptharoorpi Rajayakshma*, *Astharoorpi Rajayakshma* *Dasharoorpi Rajayakshma* and so on.

The eventuality of clinical presentation of *Rajayakshma* depends upon the interaction between *Vyadhikasmavta* and etiological factors. The different etiological factors tend to reduce the *Vyadhikshamvta* ultimately manifests as the disease *Rajayakshma*. This unique pathogenesis of interaction between host immune mechanism and the pathogenesis holds good for both *Rajayakshma* as well as HIV infection/AIDS.

The etiological factors causing morbidity of *Dosha*, morbid *Dosha* in turn circulating in the body gets localized in different parts. Finally leading to the different symptoms related to *Sandhi*, *Pranavaha*, *Annavahasrotas* and so on. It's worth mentioning here that clinical manifestation and severity of illness may vary from patient to patient and is dependent upon the *Vyadhik-*

#### **MODE OF ACTION OF THE DRUG SHIVAGUTIKA**

Among the different oral medications *Shivagutika* is unique in its category as it is capable of showing *Shaman*, *Bramhana*, and *Rasayana* effect. Simultaneously *Rajayakshma* is characterized by the depletion of body aliments. The body became lean and this person becomes emaciation this counte-

*shamatva* interacting with virulence of etiological factors. Akin to this HIV infection/AIDS may be present with the multiple clinical manifestations, probably related to opportunistic infection or otherwise.

The treatment of disorders of *Rajayakshma* should consist of such operations as to give rise to the concordance of *Dhatus*. Treatment is given with the objective of ensuring that no discordance will arise in the *Dhatus* and there is continuance of their concordance. In *Rajayakshma* there is vitiation of *Doshas* that ultimately leads to depletion of *Dhatus*. Therefore, the prime aim of management of *Rajayakshma* is concordance of *Doshas* and *Dhatus*. The possibility of *Shodhana* in a patient suffering from HIV/AIDS adapting the principle of *Shodhana* treatment of *Ayurveda*; it can be argued that the HIV/AIDS is an illness of *Bahudosavastha*, and *Shodhana* is essential. With the due consideration of the physical strength *Mrudu Shodhana* may be adapted further, exclusive remedies should be explored to uproot the disease or else the potent medicines for effective control over this dreadful disease. *Sivagutika* is a *Shamana* treatment/*Rasayana*, administered orally for a long duration is said to be very effective in combating the multiple system involvement of this disease.

ract that effect. The *Shivagutika* contains *Brahamana* drugs like *Shatavari*, *Vidari*, *Drasksha*, *Godugdha*, *Jeevanthi* and so on. The present study shows the improvement in the body weight of patient following the treatment of *Shivagutika* affirms its *Brahmana* effects.

One of the factors related to the depletion of the body aliments and emaciation is

*Angnimandhya*. *Agnimandhya* exhibits the progressive biotransformation of body alimments from *rasa* to *sukra dhatu*. This pathogenesis includes both *Jataragnimandhaya* and *Dhatvagnimandhaya*, this *Angnimandhaya* is best treated by *Shivagutika* and the formulation contains many *Deepana*, *Pachana* drugs like *Pippali*, *Marchia*, *Nagara*, *Gajapippali* etc. once again improvement in ability to consume food followed by the increasing the weight, patient treated with *Shivagutika* proves the effect.

Symptoms related to *Pranavaha Srotas* are common in *Rajayakshma*. It includes *Kasa*, *Swasha*, *Prathisaya*, *Peenasa*, *Parshvashoola* and so on, *Shivagutika* is a unique combination having drugs to counteract the symptoms also the drugs like *Talsipatra*, *Puksharamoola*, *Pippali*, *Kantakari*, *Brathi* etc. The reduction of *Kasa* from 5.85 to 2.050 by the drug *Shivagutika* confirms this effect.

*Atisara* is another commonest symptom of *Rajayakshma*. Medicines like *Musta*, *Kutaja* controls the same. The *Atisara* which was seen among the patients treated with *Shivagutika* and complete remission is seen. Contrary to this the patient of *Rajayakshma* also develops constipation. Drugs like *Danti*, *Triphala* are effective in maintain the *Anulomana* of the *Vata*.

*Jwara* is considered as invariable symptoms of *Rajayakshma* *Shivagutika* as drug to counteract *Jwara* also like *Musta*, *Patola*, *Katuki*, *Agnimantha* this evidence in present study shows that *Jwara* by reduction from 6.850 to 1.850 by the effect of *Shivagutika* confirms the efficacy in relation to *Jwara*. The drugs are also having action on *Kusta*,

*Cahrdhi*, *Angamardha*, *Kristhangata*, and so on.

More than anything the definite significant increase in CD4 count confirms the efficacy of *Shivagutika* in *Rajayakshma*/HIV infection. From this observation it can be definitely said that *Shivagutika* can be prescribed as an effective treatment in *Rajayakshma* / HIV infection. This study is carried out in stage I and II of HIV infection with a single dose per day regimen. Therefore there is ample of 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.

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## CONCLUSION

- The etiology of *Rajayakshma* mediates through *Dhatu Kshaya* and consequently reduces the *Vyadhikshamtva*.
- *Sahasa*, *Vishamasna*, *Vegasandharana* and *Dhatukshaya* are the unique categories of etiology of *Rajayakshma* and the patient may have the causes from any or all the categories.
- Etiological factor rendering impaired *Vyadhikshamtva* increases the risk of diseases hence the plethora of manifestation, multitude of the disease and plurality of complication marks the illness *Rajayakshma*.
- Intimate contact, sexual relation takes a major role in transmission of the disease.
- The etiology, the pathology, the clinical symptoms, complication and final outcome of disease is similar to tuberculosis and identical to HIV Infection/AIDS.

- *Shivagutika* is effective in controlling the clinical manifestation of *Rajayakshma* AIDS/HIV infection.
- *Shivagutika* as definite *Brahmana* effect increase in body weight and BMI.
- *Shivagutika* is effective in recuperating the depleted *Dhatu*, increase in Hb% is one among the evidences for the same.
- The important in CD4 count affirms the therapeutic benefit of *Shivagutika* in HIV infection/AIDS beyond the doubt.

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