

# Co-intervention of an Immune Modulator - SIVA Herbal Drops versus Treatment Outcome

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## Abstract

S.I.V.A herbal drops are a poly herbal preparation in drops formulation. It is indicated in the immune modulating benefit. The *in vitro* studies have established its activity of boosting phagocytosis based immunity. In the present study the immune boosting efficacy of S.I.V.A herbal drops in infectious disease conditions was evaluated in the human subjects in Apollo Wellness Plus Centre and Apollo Children's Hospital between 2009-2010.

The study is planned in three different treatment regimens.

1. S.I.V.A herbal drops + Dr. JRK's 777 oil in Psoriasis
2. Co-intervention of SIVA in the treatment outcome of antibiotic treatment
3. Co-intervention of SIVA in the treatment outcome of antifungal therapy

In all the clinical evaluations, inclusion of S.I.V.A herbal drops in the regular treatment regimen has given greater improvement in clinical condition compared to standalone therapy. Complete details are discussed in the present paper.

## Introduction

SIVA herbal drops are a polyherbal proprietary Siddha drug which has been proven abundantly through several scientific studies for its immune modulation property and improving the phagocytic ability of macrophages, the primary immune surveillance cells in human circulation and fluid tissue [1-4].

However, whether the immune modulation of phagocytes especially when the host is under infection would influence the treatment outcome significantly or such immune modification will work only during pre-infection stage, we have not yet evaluated conclusively in human subjects [5].

Further the immune modulators influencing the treatment outcome may vary greatly from adult to children and also with reference to the type of infection such as bacterial, viral, fungal, parasitic etc., or the autoimmune disorders [6].

In order to answer the impending question about the role of immunomodulator in predicting the treatment outcome with mainline treatment, a human based study was planned in Apollo Wellness Plus Centre and Apollo Children's Hospital between 2009-2010.

The treatment intervention of SIVA herbal drops was adopted along with conventional antifungal therapy and antibiotic therapy in fungal and bacterial infection. Alongside, the treatment intervention of SIVA + topical Dr. JRK's 777 oil, a well proven single herb based Siddha drug for Psoriasis was also taken up. Details are presented in this paper.

## Materials and Methods

Apollo Wellness Plus Centre is specialized in providing various wellness associated services such as massage therapy, physiotherapy, speech therapy, YOGA, meditation etc. The

dermatologists of the hospital conducted the trial by keeping the above center as nodal body to co-ordinate and guide the trial.

A total of 20 patients with fungal infection of the skin both tinea infection, candidiasis and pityriasis were included in the trial.

Similarly, 20 patients with Psoriasis where the extent and severity remain comparable between tall patients were included in the trial.

Twenty children with fever, cold and headache with proven bacterial etiology were also included in the trial.

All necessary formalities as required by the regulatory agencies on any study on human subjects were followed by the center. However, the drugs tested were herbal Siddha recipes and have been in the market for several years, the trial protocol was prepared and followed in a bit lucid and casual manner.

The clinicians who conducted the trial had followed strict ethics both in diagnosis and treatment and only difference was that SIVA was also given to one set of the patients to understand whether SIVA intervention could offer any positive impact in the treatment outcome.

Similarly, the Psoriatic patients were treated with Dr. JRK's 777 oil for a period of 3 months and in one group, SIVA drops were also included with the above objectives in mind.

The duration of the trial for fungal and bacterial treatment was 35 days. Apollo's Children's Hospital conducted the study in pediatric patients. All patients participated in the trial were above 15 years of age, the socio-economic status was low and the parents had given consent in writing in standard consent form.

## Results

The 10 patients with Psoriasis when treated with Dr. JRK's 777 oil alone only 5/10 showed some improvement which was as low as 20% on day 30.

When SIVA intervention was adopted in other group of 10 patients who were treated with topical Dr. JRK's 777 oil, 9/10 patients showed 60% improvement in symptoms of Psoriasis just in 20 days of therapy.

Both clinicians and patients rated the treatment outcome of SIVA intervention to be excellent whereas the standalone therapy with Dr. JRK's 777 oil did not evoke such feedback (Table 1).

**Table 1:** Co-intervention of SIVA in the treatment outcome of Dr. JRK's 777 oil in Psoriasis.

Treatment details	No. of patients	Degree of response in %/number of patients/duration in days		
		Clinical outcome	Overall Clinicians response	Overall Patient's feedback
Dr JRK' 777 oil	10	20/5/30	Promising	No effective
Dr JRK's 777 oil + SIVA drops	10	60/9/20	Excellent	Excellent

SIVA intervention has significantly shortened the treatment time by 50% from the duration of standalone conventional antibiotic and antipyretic drug treatment (Table 2). Overall

feedback of both clinicians and patients were also excellent when SIVA was co-administered.

**Table 2:** Co-intervention of SIVA in the treatment outcome of antibiotic treatment.

Treatment details	No. of patients	Number of patients with near complete relief /duration in days		
		Clinical outcome	Overall Clinicians response	Overall Patient's feedback
Antibiotics + antipyretic	10	10/15	Good	Good
Antibiotics + antipyretic + SIVA	10	10/7	Excellent	Excellent

SIVA intervention has significantly shortened the treatment time of fungal infections and increased the positive treatment response significantly. As against 26 days required to achieve near complete fading of tinea corporis with topical clotrimazole and oral grieseofulvin, SIVA co-intervention has shortened the treatment time to 11 days.

The treatment outcome due to SIVA intervention was extremely positive in both pityriasis versicolor and in candidiasis as well (Table 3). Both clinicians and patients also stated SIVA intervention has brought a remarkable improvement in the treatment.

**Table 3:** Co-intervention of SIVA in the treatment outcome of antifungal therapy.

Treatment details	Diagnosis	No. of patients	Patients with near complete cure /duration in days		
			Clinical outcome	Overall Clinicians response	Overall Patient's feedback
Topical clotrimazole + oral grieseofulvin	Tinea corporis	5	5/26	Good	Good
Topical clotrimazole + oral fluconazole	Tinea versicolor	1	1/36	Good	Good
Topical clotrimazole + oral Itraconazole	Candidiasis	4	4/18	Good	Good
Topical clotrimazole + oral grieseofulvin + SIVA	Tinea corporis	3	3/11	Excellent	Excellent
Topical clotrimazole + oral fluconazole + SIVA	Tinea versicolor	2	2/20	Excellent	Excellent
Topical clotrimazole + oral Itraconazole + SIVA	Candidiasis	5	5/12	Excellent	Excellent

## Discussion

Although the role of immunomodulators are widely appreciated in treating several diseases but how far and what extent such intervention would influence the treatment outcome with conventional therapy remains mystery and warrants a proper study. In strict sense, immunomodulators at best can only strengthen the innate immune defense offered predominantly by phagocytes in circulation and fluid tissue.

The question that remains enigmatic is whether phagocytes would ever respond to immunomodulations especially when the host suffers from a disease. Phagocyte mediated immunity at best can only offer the much needed protection to the host from the infectious agents and also may help the host to recover fast post treatment [8-10].

During active infection, the role of boosting the phagocyte mediated immunity whether would influence the treatment outcome have not been studied in detail. Only such study alone may give us solid footing to authenticate the role of immunomodulators in shortening the treatment time, reducing the drug dosage and the sufferings of the host.

SIVA herbal drops are a polyherbal proprietary siddha drug. All the herbs used in the formulation have vast legacy in AYUSH and the ancient scholars who researched all of them to offer elixir to human life and also have described the medicinal values of the herbs used in SIVA herbal drops so proficiently.

At laboratory level, we had already established the efficacy of the formulation in increasing the phagocytic ability of the phagocytes and also such ability of the macrophages even under hypoxic condition. Most of the other laboratory level studies that we had conducted on SIVA herbal drops have

also proved beyond any reasonable doubt about the immune boosting effect of SIVA herbal drops.

In the present investigation that was conducted by Apollo Wellness Plus Centre and Apollo Children's Hospital have established undoubtedly the role of SIVA herbal drops in the treatment outcome of conventional therapy in the case of fungal and bacterial infections and Psoriasis.

In the case of fungal and bacterial infections, SIVA herbal drops co-intervention has reduced the treatment time, reduced the suffering and would offer high quality of life much faster. We do not want to interpret the above findings or suggest based on the above possibility that SIVA may reduce the drug dosage used in conventional allopathic drug therapy if SIVA herbal drops intervention is adopted.

The phagocytes although may fight the pathogen effectively but the phagocytes also perform many other functions which are beyond the armamentarium of pathogen or virulence.

We believe that SIVA may reduce the virulence of the pathogen by making them highly susceptible to both antibiotic/antifungal attack and also from immunity driven attack. Therefore, the use of SIVA herbal drops in the treatment of all infectious conditions may reduce the emergence of drug resistant microbes. The above is only our possible hypothesis which we have evolved from the findings of the present study.

Until now it is largely assumed that immunomodulators may support and protect the health of the healthy and may have only limited role in disease condition [7]. Vitamins, minerals and other health supplements are traditionally prescribed to the patients' only post therapy or during convalescent period to increase the recovery and restore health.

We are the first to establish that immunomodulators can come handy also in the treatment of infectious diseases. Interestingly all fungal infections such as tinea corporis, tinea versicolor and candidiasis responded very well to SIVA intervention. The role of SIVA in shortening the treatment time in the case of fungal infections assumes special significance because most of the azole antifungal agents are hepatotoxic and also may produce many other side effects. Therefore, the drug load and treatment time shortening with the help of an immunomodulator SIVA has enormous medical advantage at global level in treating several infectious diseases.

Similarly, role of the immune modulators in the treatment of Psoriasis was also established in the present investigation. Instead of going for globally approved conventional antipsoriatic drug, we have used Dr. JRK's 777 oil to treat psoriasis in our present study. SIVA co-administration has dramatically influenced the treatment outcome. The duration of therapy was quite short and also Psoriasis is not a curable disease. Therefore, we postulate the findings more due to greater absorption of the herbal drugs into the system than due to any other reason. Dr. JRK's 777 oil is a single herb preparation and when such preparation is applied topically along with oral polyherbal SIVA, the bio-burden of the phytoactives is expected to increase and thus the treatment response became excellent.

The treatment outcome with reference to the treatment of Psoriasis, we limit to the effect due to the differences between monotherapy versus combination therapy than due to any great alteration in the immune system.

Our findings clearly show that Siddha system of healing practices is quite scientific and proof based and is also as effective as allopathic system of medicine. The study findings clearly foretell to the entire medical fraternity that inclusion of SIVA herbal drops both in the treatment of active infectious and non-infectious diseases and also to protect and promote the health of the healthy is essential, urgent and imminent. With the help of SIVA herbal drops, we can deal most of the medical problems of infectious and non-infectious origin.

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